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CLINICAL PRACTICE

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Effectiveness of diet, psychological, and exercise therapies for the management of bile acid diarrhoea in adults: A systematic review

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Abstract

Background: Bile acid diarrhoea (BAD) causes chronic diarrhoea and is primarily treated pharmacologically. This systematic review aimed to evaluate the effectiveness of non-pharmacological therapies for evidence-based management of BAD in adults.

Methods: A systematic review of the medical literature was performed from 1975 to 13 July 2021 to identify studies on diet, psychological, and exercise therapies that met diagnostic criteria for BAD in adults with diarrhoea. Effectiveness was judged by responder or improvement in diarrhoea at study endpoint according to each study's definition of diarrhoea. Therapeutic effect on abdominal pain and flatulence was also measured. Risk of bias was assessed using the Risk Of Bias In Non-Randomised Studies of Interventions tool. A narrative review was conducted using 'Synthesis Without Meta-analysis' guidance. Certainty of the evidence was assessed using Grading of Recommendations Assessment, Development, and Evaluation.

Results: Eight prospective cohort studies were identified on diet therapies from 2 weeks to over 2 years involving 192 patients. No psychological or exercise therapies were found. Carbohydrate modification (one study, $n = 2$) in primary BAD, and dietary fat intake reductions (five studies, $n = 181$) and an exclusive elemental diet therapy (two studies, $n = 9$) in secondary BAD, showed beneficial directions of effect on diarrhoea, abdominal pain, and flatulence. Risks of bias for each study and across studies for each therapy type were serious. Certainty of the evidence was very low for all outcomes.

Conclusions: No conclusions could be drawn on the effectiveness of diet, psychological, or exercise therapies on diarrhoea, abdominal pain, and flatulence for the management of BAD in adults. High-quality randomised controlled trials are needed.

KEYWORDS

bile acid diarrhoea, bile acid malabsorption, diet, exercise, psychotherapy, systematic review

Key points

- We do not know whether non-pharmacological therapies can improve diarrhoeal symptoms in adults with bile acid diarrhoea.
- Available data from cohort studies outlined in this systematic review found that: (i) in primary bile acid diarrhoea, lactose and/or sorbitol and fructose intake reductions provided very low-certainty evidence of a beneficial effect after optimisation with colestyramine; (ii) in secondary bile acid diarrhoea,

dietary fat intake reduction and exclusive oral nutritional supplementation with elemental formula provided very low-certainty evidence of beneficial effects as sole treatment or after optimisation with bile acid sequestrants; and (iii) there was no evidence on psychological or exercise therapies.
- We need high-quality studies to evaluate the acceptability, feasibility, and effectiveness of diet, psychological, and exercise therapies adjunctive or separate to medication for the management of BAD in adults.

INTRODUCTION

Bile acid diarrhoea (BAD) is a chronic gastrointestinal disorder of bile acid-induced diarrhoea as a result of dyshomeostasis of enterohepatic bile acid recycling, the symptoms of which usually improve by bile acid sequestrant administration.[1,2] The cause of primary BAD (also known as Type 2 BAD)[3] is often idiopathic[4] and BAD was indirectly estimated to affect at least one in 100 of the Western adult population.[5] Secondary BAD, comprising Types 1 and 3,[3] is secondary to inadequate reabsorption of bile acids as a result of disease states affecting the ileum or another organ, respectively.[6] The prevalence is unclear and uncertainties include lack of data on incidence comparisons between countries because of limited screening.[6]

Meal ingestion prompts the ejection of conjugated bile acids that constitute two-thirds of the weight of aqueous bile[7] from the gallbladder into the duodenum. Bile acids are amphiphilic, enteroendocrine hormones that are essential for the mixed micellar solubilisation and absorption of ingested dietary fats, as well as fat-soluble vitamins A, D_2, E, and K, along the small intestine.[8] To complete one enterohepatic cycle, unused bile acids are actively absorbed in the ileum by the apical sodium bile acid transporter and transported back to the liver via portal venous blood, incurring 5% loss of conjugated bile acids to the colon daily.[9] A negative feedback system[10] enables replacement of this loss via further hepatic bile acid synthesis.

In primary BAD, hepatic bile acid synthesis is excessive.[11] Deficiency in serum fibroblast growth factor 19 produced by ileal enterocytes is hypothesised as causative, leading to ileal absorptive capacity saturation, increased colonic spillover, and diarrhoea.[12] Fibroblast growth factor 19 is low during fasting in healthy adults,[13] whereas in primary BAD, fibroblast growth factor 19 was found to fail to increase to inhibit hepatic bile acid synthesis in response to meal ingestion.[12] Excessive prosecretory bile acids in the colon induce watery diarrhoea following their bacterial deconjugation and dihydroxylation.[14,15] After cholecystectomy, during both fasting and post-prandially, negative feedback inhibition becomes continuous to maintain cycling balance with reductions in conjugated bile acid pool sizes and circulation rate increases.[16] After ileal resection of the last 100 cm of the ileum, malabsorption of both conjugated bile acids and dietary fats has been shown to cause steatorrhoea.[17,18]

Treatment effectiveness requires establishing an accurate diagnosis, which is challenging as a result of low-quality evidence supporting specific diagnostic tests and varying availability.[19,20] Approximately 30% of adults with primary BAD have been previously diagnosed with diarrhoea-predominant irritable bowel syndrome,[21,22] although BAD and irritable bowel syndrome may co-exist.[23–25] ^{75}Selenium homocholic acid conjugated with taurine (SeHCAT) testing is the current 'gold standard' method to diagnose BAD[6] but is based on treatment response from low-quality evidence.[26] The test involves ingestion of a capsule containing a radiolabelled bile acid analogue, SeHCAT, to calculate the percentage of bile acid retained in the body after seven days and whether diarrhoea is a result of excessive faecal excretion of bile acids. Severe, moderate, and mild BAD are < 5%, < 10%, and < 15% retention of SeHCAT, respectively.[21] Recent observational data using this test showed that primary BAD is also a painful disorder according to Rome IV criteria (abdominal pain frequency at least once a week). From a cohort of 184 patients presenting in secondary care with diarrhoea-predominant irritable bowel syndrome (76%) or chronic diarrhoea of presumed functional origin (24%), 53 out of 70 (76%) of the patients diagnosed with BAD also had abdominal pain.[27] From data collected via an online survey, abdominal pain (recorded as always, mostly, or fairly often) was present in 77% of 91 respondents with a self-reported diagnosis of BAD from a BAD support group in the UK of over 1300 members.[28]

Although there is an integrated healthcare approach of medication, diet, and behavioural interventions for irritable bowel syndrome,[29] treatment for BAD is limited to life-long bile acid sequestrants or alternative anti-diarrhoeal drugs.[19] Medication side effects include poor tolerance,[30-32] constipation, abdominal pain, nausea, and bloating.[33-37] The proportion of adults successfully treated pharmacologically was estimated to be 70% (range 63%–100%), as determined from a systematic review performed in 2013, totalling 1223 patients from 18 studies.[38] However, despite medication optimisation, symptoms may persist.[28,30] In a Danish retrospective survey, unaltered or worsened diarrhoea was identified amongst 235 out of 377 (64%) respondents.[30] These data were collected over 13 years in BAD

diagnosed by SeHCAT. In the online UK cross-sectional survey, 33% reported persisting diarrhoea, 46% reported abdominal pain, 60% reported flatulence, 71% reported extreme tiredness, and 55% reported reduced activity/exercise levels amongst other symptoms (recorded as always, mostly, or fairly often).[28] Dietary modifications including low-fat, gluten-free, low-carbohydrate, lactose-free, and wheat-free diets were also self-reported, although effectiveness on diarrhoea or individual symptoms was not explored. Clinical practice guidelines developed by an international group of gastroenterologists[19] reported that 'low-fat dietary interventions can improve gastrointestinal symptoms for some patients'. This was based on evidence from one cohort study[39] but had no documented appraisal and no dietary recommendations for clinical practice or research. In a systematic review of the management of chronic diarrhoea as a result of BAD,[38] no diet studies were included and one was excluded.[40] An investigation of the effectiveness of non-pharmacological treatments has not been undertaken to date. Therefore, there is a need to identify all non-pharmacological interventions and to critically appraise benefits and harms on diarrhoeal symptoms in BAD. The presemt study aimed to evaluate the effectiveness of diet, psychological, and exercise therapies on diarrhoea, abdominal pain, and flatulence in adults with BAD by performing a systematic review.

METHODS

The methods for performing this systematic review were specified in a protocol following Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) for Protocols standards,[41] registered with the International Prospective Register of Systematic Reviews (CRD42020188328). The PRISMA 2020 Checklist[42] was followed in the reporting of this review.

Eligibility criteria

The inclusion and exclusion criteria for the review are specified in Table 1. Studies were included if they examined the effect on diarrhoea of diet, psychological, or exercise therapies in adults (≥ 16 years) with BAD and diarrhoea. The PICO framework[43] was used to structure reporting and includes on study design and reporting of the study. We intended to include all study designs from 1975 onwards in humans, excluding single cases. This was because findings from a prior systematic review

TABLE 1 Inclusion and exclusion criteria for eligible studies

PICO	Inclusion criteria	Exclusion criteria
	Adults with BAD aged ≥ 16 years and with diarrhoea	Adults with BAD aged ≥ 16 years and with no reporting of diarrhoea prior to undertaking the intervention
Participants	Diagnosis of BAD determined via any of these tests: SeHCAT, serum C4, faecal BA excretion ≥ 48 h collection,[14]C-glycocholate stool test	BAD diagnosed by: faecal BA excretion collection < 48 h, diarrhoea defined by faecal weight or BAS trial
	In Type 1 BAD: a reported method to diagnose BAD was not required	Pregnancy; other medication or food that could influence GI symptoms or motility: metformin; alcohol abuse; other serious morbidities such as active Crohn's disease, microscopic colitis, liver disease, AIDs/HIV, depression
	Diarrhoea: as defined or described by study authors or according to the Bristol Stool Form Scale Types 6 or 7	
Intervention	A therapy, as induction or adjunct treatment for BAD	
	Induction treatment was defined as a therapy without the use of BAD medication (colestyramine, colesevelam, colestipol or anti-diarrhoeals)	
	Adjunct treatment was defined as a therapy undertaken after BAD medication had been optimised	
Comparator	A placebo, another therapy, or no treatment	
Outcomes	Diarrhoea: Number/proportion of observed responders or the reported change using a clear scoring system at study endpoint	Diarrhoea: No reporting by responder or change in diarrhoea at study endpoint
Study design	RCT, prospective and retrospective cohort and case series	Single case
Study reporting	No language restrictions	Studies reported as an abstract or letter

Abbreviations: BA, bile acid; BAD, bile acid diarrhoea; BAS, bile acid sequestrant; BSFS, Bristol Stool Form Scale; C4, 7α-Hydroxy-4-cholesten-3-one[14]; C-glycocholate; GI, gastrointestinal; RCT, randomised controlled trial; SeHCAT, [75]selenium homocholic acid taurine.

showed low-quality evidence consisting of only one randomised controlled trial (RCT) out of 28 studies examining pharmacotherapies, and did not identify or include two cohort studies on diet.[44,45] Additionally, diarrhoea was variably defined and often vaguely described across these studies. Therefore, we included studies in which it was clear from patient or clinician-reported description that participants had diarrhoea at study start, and an outcome on diarrhoea was reported at study endpoint. In this review, diarrhoea relating to stool consistency was defined according to the validated Bristol Stool Form Scale (BSFS) as stool form Types 6 or 7.[46,47] BAD diagnostic tests used in clinical practice and research are described elsewhere.[48–51] In this review, aside from SeHCAT, three tests were included. The serum C4 test measures fasting serum 7a-hydroxy-4-cholesten-3-one (C4), a direct measure of hepatic bile acid synthesis. Faecal bile acid excretion measures total bile acids from stool collected during the last 48 h of dietary modification to a daily fat intake of 100 g for four days. The ^{14}C-glycocholate stool test (no longer used) measured bile salt excretion via the activity of ^{14}C-labelled cholic acid in a faecal collection, from when an intravenous saline infusion was started, to 24 h later when carmine red was given orally as a faecal marker to show collection endpoint.[52] An amendment was made to the protocol to include studies in patients with diarrhoea who had had ileal resections or ileal disease in the absence of a test to diagnose BAD because of high certainty (97%) of Type 1 BAD.[36,53]

Information sources, search strategy, and study selection

Cochrane Central Register of Controlled Trials, Embase and MEDLINE through Ovid, and Web of Science were searched from 1975 to 13 July 2021. ClinicalTrials.gov and the EU Clinical Trials Register were checked for ongoing trials or supplementary data for potentially eligible studies. For each search strategy and the development process used, see Supporting information, S1 and S2. Literature search strategies were developed using medical subject headings and free-text headings. Studies on therapies were identified using diet, including relevant terms relating to fats, carbohydrates including fibre, and protein; psychotherapy including behaviour change; and exercise including yoga. The theme of BAD was then combined with the set operator AND each therapy theme to identify studies. Backward citation searching was conducted in systematic reviews in BAD[19,38,54] prior to this review and in the included studies on 15 July 2021.

One investigator performed the electronic literature search. The results were uploaded to an EndNote management program (X9; Clarivate), where duplicates were removed. Each title and abstract was screened by two investigators. First, one investigator identified all potentially eligible studies and then a second investigator screened all excluded titles and abstracts to verify exclusion and check retrieved studies against the eligibility criteria. If any titles and abstracts did not provide adequate detail to determine eligibility then full-text articles were assessed. Two investigators independently screened full-text articles for inclusion.

Data collection process and data items

Data extraction was undertaken by one investigator, into an Excel spreadsheet (Microsoft Corp.). Extracted data on participant numbers and outcomes were triple checked to minimise mistakes and data selection bias, and all other items were checked twice. Data entries were then checked against each study by a second investigator. We involved a third investigator to resolve disagreement through consensus. We collected data on:

- author, year of publication
- study design, country of origin, number of centres, diagnostic tool used to diagnose BAD, BAD subtype, BAD severity category
- participants: number with diarrhoea; number with diarrhoea who completed the therapy: sex, age, body weight, body mass index
- intervention: description including food and nutrient intakes, duration, behaviour change theory or behaviour change techniques, induction or adjunct to BAD medication including dose, use of other medication, tolerance and adherence rates to the intervention with any reported definitions and target rates, using a clear scoring scale
- primary outcome, diarrhoea: patient or clinician-reported definition or description, any measurement tools used, target outcome, stool consistencies and frequencies at baseline and study endpoint, number of responders at study endpoint
- secondary outcomes: abdominal pain and flatulence: the measurement tool used, number of participants at baseline and study endpoint, number of responders at study endpoint; adverse effects: the number of clinically relevant reported side or adverse effects, regardless of causality, including constipation (BSFS Types 1 and 2).

Where the mean ± SD could not be collected, median values and interquartile ranges were extracted.

Risk of bias in individual studies and across studies for each therapy

One investigator assessed risk of bias in each included study using the Cochrane 'Risk Of Bias In Non-Randomised

Studies Of Interventions' (ROBINS-I) tool).[55] After considering Stage I, a hypothetical pragmatic RCT, the seven domains were addressed: Pre-intervention: confounding, selection of participants; At intervention: classification of intervention; Post-intervention: deviation from intended intervention, missing data, selection of the reported result. The ROBINS-I Guidance (2016) was used to judge risk of bias for each domain (low; moderate; serious; critical; no information). Judgements and justifications were tabulated to support discussion with a second investigator to reach consensus agreement on judgement of risk of bias for each domain and overall in each study and then across studies for each therapy.

Summary measures

We anticipated that performing any meta-analyses would not be possible as a result of few studies reporting specific dietary interventions with available data. A narrative synthesis of the results was conducted by one investigator using the Synthesis Without Meta-analysis guideline to guide on reporting and presentation.[56] Presentation of the data was prioritised: primary before secondary BAD, type of diet therapy (whole food-first approach before artificial nutrition treatment), and outcomes on diarrhoea (first, by stool consistency and frequency, then by stool consistency, and, lastly, by stool frequency, with measurement by responder before change in the scoring scale). Outcomes on diarrhoea in all but one study[39] lacked adequate statistical analyses to estimate effect; therefore, effect was reported as a positive or negative direction using vote counting.[57] The method of vote counting compares the number of observed direction of effects showing 'benefit' to the number showing 'harm' for a particular outcome to give evidence of effect across studies. A positive/negative direction of effect (benefit/harm) was defined as a patient or clinician-reported positive/negative response or improvement/worsening in an outcome being assessed.

Certainty assessment

Certainty of the evidence for each therapy on outcomes was judged using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system[58] (see Supporting information, S3). Quality determinants along with risk of bias and direction of effect across studies are presented as a summary of findings with a comments and evidence statement field to aid interpretation and footnotes for explanations. Confidence was assessed as 'low' because all study designs were non-randomised.

RESULTS

Study selection

Searches using all four databases generated, for diet, psychological, and exercise therapies, a total of 2671, 46, and 54 citations, respectively. The PRISMA 2020 flow diagram is shown in Figure 1. From two clinical trial registries, four records of studies were identified, with one an ongoing RCT in secondary BAD (dietary fat intake reduction). Eight full-text articles were retrieved and backward citation searching of these studies identified one additional study.[59] No RCTs were identified. One retrospective study did not meet the inclusion criteria because outcome data on diarrhoea could not be extracted for 123 out of 143 patients who undertook dietary intervention.[60] Eight studies of diet therapies were included in this review. No studies were identified that examined psychological or exercise therapies.

Study characteristics

All eight included studies were prospective, single-arm, cohort studies in single centres from the hospital setting,[39,44,45,59,61–64] although one study also included patients from a primary care centre.[62] In two studies the samples were inpatients.[59,64] The studies totalled 288 adults, and study sample size ranged from two to 114 participants out of a total of 192 analysed who undertook diet therapy as sole treatment or adjunct to bile acid sequestrants. No data on any psychological or exercise therapies were found within these dietary studies. The study characteristics are shown in Table 1.

Intervention

Intervention descriptions are shown in Table 2. In primary BAD, a 'malabsorbed sugar-free diet' was administered depending on the results of hydrogen breath testing using standardised challenges of 20 g of lactose and 20 g of fructose plus 3.5 g of sorbitol in one study.[61] The carbohydrate modification consisted of either a lactose-free diet or reductions in sorbitol and fructose in excess of glucose, or both, as described elsewhere.[65,66] However, the carbohydrate modification the two participants with moderate or severe BAD undertook is unclear. Nutritional intakes were not measured and no nutritional data were reported.

In secondary BAD, five studies were on fat intake reduction in cancer survivors from four European centres.[39,44,45,62,63] All included patients with severe BAD, although severity was not measured in one study conducted before SeHCAT was used to diagnose BAD.[45] The two studies with the largest sample populations included patients with mild and borderline severity

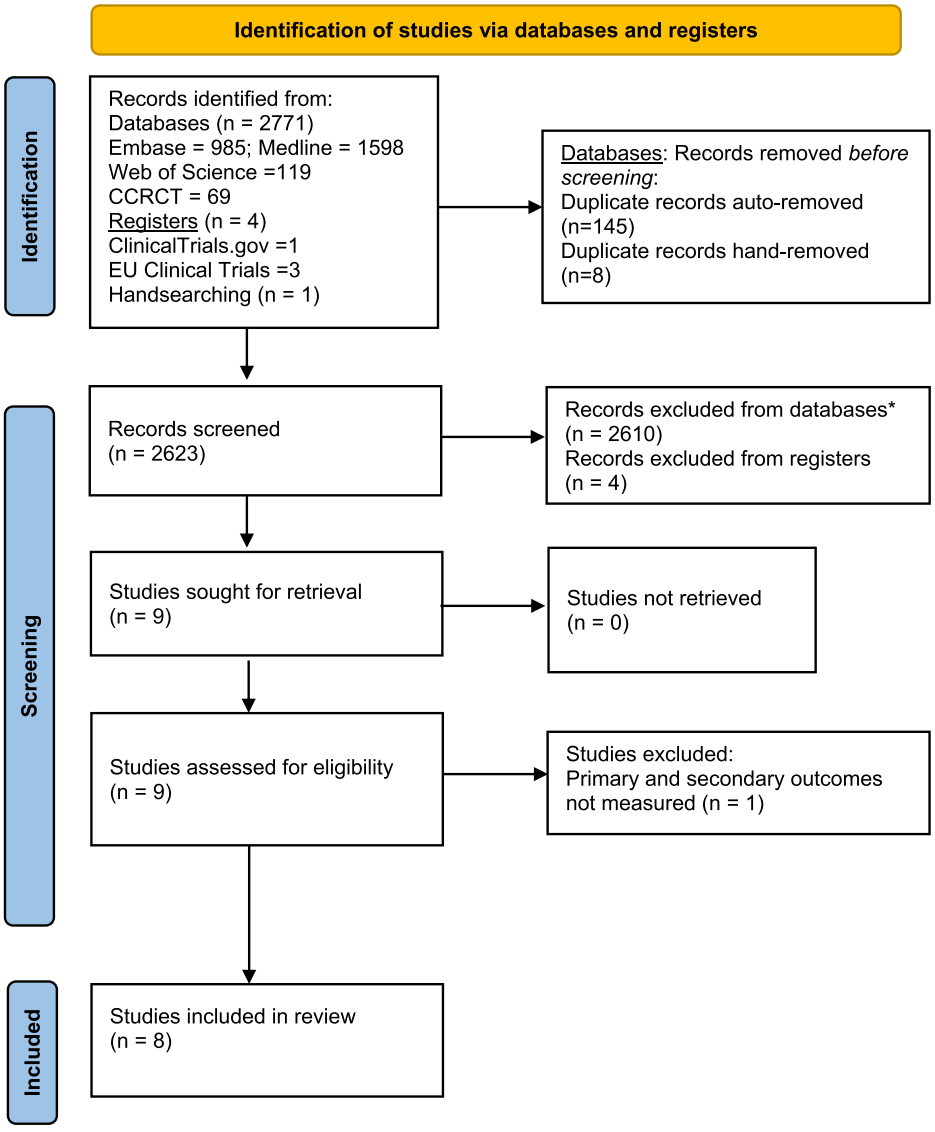

FIGURE 1 Flow diagram of systematic review (PRISMA 2020).

defined by SeHCAT.[39,62] Quantified dietary intervention targets were defined in three studies in two ways. In one study, the target fat intake was 40 g day^{-1}.[45] In two studies, '20% of total energy' was used,[39,62] although how the fat intake target was calculated was not stated. In the other two studies, the interventions of 'low-fat'[63] and 'reduced-fat' [44] were not described or quantified. One study described what 'low-fat' consisted of by food group and preparation methods.[45] One out of these five studies provided quantitative nutritional data.[39] Fat and fibre intakes only were measured from 7-day food diaries analysed using an electronic nutritional analysis programme (Dietplan6; ForestField Software Ltd).[39] Baseline (habitual) dietary fat intake was a mean of 62.3 g day^{-1} (median 58.9 g, range 34.5–100.8). Intake decreased to a mean of 42.2 g day^{-1}, ranging widely (median 39.1 g, range 24.5–80.8) ($p < 0.01$). Mean dietary fibre intake did not change from a habitual low quantity of 14.8 g^{-1} day (median 13.8 g, range 10–32) at baseline to 14.4 g (median 13.6 g, range 4.4–34.7) at follow up. However, how dietary fibre was defined was not stated. It may have be an underestimation if measurement was for non-starch polysaccharides only. In one study, seven-day food diaries and dietary recall data were collected but no nutrient intakes were reported.[62] Nutritional supplementation (Forceval, Alliance; and Calcichew-D3 Forte, Takeda) was reported to be prescribed in severe and moderate BAD in one study.[39] Two years later in the same centre, in the study published in 2017, Forceval only was reported to be prescribed after checking nutritional adequacy of trace elements and fat soluble vitamins.[62]

TABLE 2 Study characteristics of included studies.

First study author Year	Country Study design	Diagnostic tool used to diagnose BAD	Type of BAD % patients, BAD severity category	Number of patients with diarrhoea (% female)	Number that completed diet therapy (% female)	Age, years mean (SD) range	Body weight, kg Baseline mean (SD), range /Endpoint mean (SD), range	BMI, kg/m^2 Baseline mean (SD), range /Endpoint mean (SD), range
Carbohydrate intake modification: reduction in lactose and/or fructose and sorbitol								
Fernandez-Banares 2007	Spain Cohort, prospective	SeHCAT[a]	Primary 100% severe to moderate (<11%)	2 (–)	2 (–)	–	–	–
Fat intake reduction								
Bosaeus 1979	Sweden Cohort, prospective	^{14}C stool test	Secondary[b] –	9 (100)	9 (100)	58 (7.6) 48–75	–	–
Danielsson 1991	Sweden Cohort, prospective	SeHCAT[c]	Secondary[b] 100% severe	4 (100)	4 (100)	–	–	–
Jackson 2017	England Cohort, prospective	SeHCAT[a]	Secondary[d] 29% severe 17% moderate (0%–5%) 25% mild (10%–15%) 28% borderline (>15% to 20%)	188 (–)	114 (57)	Median: 64 (IQR: 55–71) 23–86	Median: 77 (IQR: 64–90) 39–127 /–	Median: 27 (IQR: 23–31) 16–45 /–
Larsen 2019	Denmark Cohort, prospective	SeHCAT[a]	Secondary[e] 100% severe to mild (0% to ≤15%)	14 (–)	14 (–)	–	–	–
Watson 2015	England Cohort, prospective	SeHCAT[a]	Secondary[f] 50% severe 17% moderate (0%–5%) 25% mild (10%–15%) 8% borderline (>15% to 20%)	62 (–)	40 (50)	61 (12) 22–90	71.2 (18.3) 32.7–109.3 /–	25.5 (5.2) 12.8–38.1 /–
Exclusive elemental (Vivonex)								
Nelson 1977	Scotland Cohort, prospective	Clinician judgment	Secondary[g] –	6 (–)	6 (–)	–	–	–
Russell 1979	Scotland Cohort, prospective	Clinician judgment	Secondary[h] –	3 (–)	3 (–)	–	– (stable)	–

Abbreviations: BAD, bile acid diarrhoea; BMI, body mass index; IQR, interquartile range; SD, standard deviation, SeHCAT, ^{75}selenium homocholic acid taurine; WBR, whole body retention.
[a]SeHCAT measured by 7-day whole body retention.
[b]Cancer survivors, gynaecological post radiation treatment.
[c]SeHCAT measured daily for up to 72 h to calculate the biological half-life of SeHCAT to determine diagnosis of BAD: severe, <40 h.
[d]Cancer survivors, 51 (84%) with small intestinal bacterial overgrowth, 21 (34%) with pancreatic insufficiency.
[e]Cancer survivors, colon and pelvic organ.
[f]Four cancer survivors, 13 (33%) with small intestinal bacterial overgrowth, five (13%) with pancreatic insufficiency.
[g]Ileal resections: four Crohn's disease, one carcinoma of the caecum, one mesenteric thrombosis.
[h]Crohn's disease: 'extensive damage to the terminal ileum' (no resections).

In secondary BAD, for hospitalised ileal patients, two studies reported on an exclusive elemental diet given orally (Vivonex; Eaton Laboratories).[59,64] Key treatment purpose was to provide short-term bowel rest by reducing stool volume, feacal bile acid excretion, and stool frequency at the same time as ensuring nutritional intake adequacy in patients at risk of fat malabsorption in bile acid malabsorption. Prescribed as an orange-flavoured powder mixed with tap water, data sources showed its nutrient composition as: fat, 1.4%[67] or 0.43 g per sachet (as safflower oil)[64]; carbohydrate, 90.5% (glucose and oligosaccharides)[67]; mixed amino acids, 8.1%.[67] Both studies reported on nutritional intake, as assessed by the number of sachets used per day[64] or as the energy intake range per day over the study period,[59] although procedures to verify either were not described. Energy intakes were clinician-reported as less than the energy intake aim for each study (12,552 kJ day^{-1}): a mean of 10,251 kJ day^{-1} (4.9 sachets day^{-1}, range 3–6) for up to 15 days in one study[64] and 10,460 to 12,552 kJ day^{-1} for 2–3 weeks in the other.[59]

No studies reported on behaviour change theory or use of behaviour change techniques to improve dietary adherence or clinical outcomes.

Delivery of the interventions by a dietitian was reported in four studies but without reference to specialist expertise in gastroenterology.[39,45,62,63] Missed reporting of dietitian-delivery is likely in all others,[44,59,61,64] including dietetic monitoring in the two inpatient studies.[59,64] Planned dietetic follow up was 6–8 weeks in two studies[39,62] and not stated in any others. Study endpoints varied within each study. In the carbohydrate modification study, the duration was at least 12 months.[61] Across studies investigating fat intake, the reduction duration ranged from 2 weeks[63] to after 2 years.[44] Patients undertook the exclusive elemental diet therapy for 8–21 days, specified in one study as dependent on each patient's treatment effect for which 2–3 weeks sufficed.[59]

In primary, moderate to severe BAD, bile acid sequestrants were offered before diet therapy.[61] In secondary BAD, two out of five studies also used them before fat intake reduction.[44,63] In one study, colestyramine was used after dietary intervention for persisting diarrhoea.[45] In two studies, a SeHCAT screening algorithm stratified treatment according to BAD severity defined by SeHCAT. This mild to borderline BAD to fat intake reduction was offered before colesevelam. For moderate BAD severity, patient choice was offered, whereas, for severe BAD, the dose of colesevelam was optimised first.

The use of other medication in the investigation of carbohydrate modification was not reported.[61] In secondary BAD, the study design permitted the use of other anti-diarrhoeals in three studies,[59,62,63] and was not reported in the other four.[39,44,45,64] Use of laxatives was reported in two out of the seven studies.[62,63] In studies of fat intake reduction, antibiotics reported because of the severity of their BAD were given to all patients before initiating dietary change in one study[44] and for prior coexisting small intestinal bacterial overgrowth in three studies in unclear proportions of patients.[39,62,63]

Tolerance to the intervention was not defined or measured in any of the studies.

An adherence rate target was given in one study.[39] A high rate of 90% was achieved in 28 out of 40 (70%) patients obtained from patient-recorded 7-day food diaries completed before the intervention and again prior to study endpoint analysed electronically (Dietplan6). In another study, necessary adherence to a fat intake of 40 g day^{-1} to control diarrhoea was verified via fat intake re-challenge.[45] 'Palatability problems' were noted with the exclusive elemental diet therapy in one study,[59] but, as an adherence marker, the proportion who maintained body weight was unclear. No definitions or data on adherence were reported in any of the other studies on carbohydrate modification,[61] fat intake reduction,[44,62,63] and exclusive elemental diet therapy.[64]

Outcomes

Diarrhoea

Diarrhoea was defined by stool consistency in five of eight studies, as measured at baseline via patient self-reporting using the BSFS[47] in two studies.[62,63] However, outcomes using this validated tool were reported in only one study.[62] Normalisation of stool consistency by the proportion of responders at study endpoint was clinician-reported in one study,[45] whereas improvement without further quantification was clinician-reported in three studies.[59,61,63]

Three studies reported on changes in stool frequency without accounting for improvements in loose stool consistencies to measure response to therapy.[39,44,64] In one study, an unvalidated, verbally administered 11-point numerical rating scale, NRS-10 (0, no symptoms to 10, severe symptom affecting daily life)[68] was used to measure frequency.[39] In one study, the number of bowel movements per week was reported having measured stool frequency by using patient-reported daily counting on a diary card.[44] In another study, frequency was reported per day, but how this was measured was not reported.[64] In the three studies that reported on both stool consistencies and frequencies,[61-63] a normal frequency was described as ≤ 3[63] or ≤ 2[61] bowel movements day^{-1}.

The effects of diet therapies on diarrhoea are shown in Table 3. In all studies, vote counting was positive, indicating that all three diet therapies provided a beneficial direction of effect on diarrhoea.

Abdominal pain and flatulence

Two out of five studies on fat intake reduction from the same centre measured abdominal pain and

TABLE 3 Diet therapy characteristics and outcomes of included studies: diarrhoea

First study author Year	Intervention Description Duration	Induction or adjunct to BAS BAS used, dose prescribed	Definition of diarrhoea used Measurement tools used	Diarrhoea description/Measurement Baseline	Diarrhoea description/Measurement Endpoint	Evidence of an effect (%) Vote count: Positive/Negative
Carbohydrate intake modification						
Outcome by stool consistency and frequency, responder (%)						
Fernandez-Banares 2007	Lactose-free and/or reduced fructose plus sorbitol intakes[a] Other components: undefined 12 months	Adjunct COL started at 8 g/day, 2–12 g/day	Three loose or liquid bowel movements/day for ≥4 weeks and a stool weight >200 g/day Aim after 12 months: 2 or fewer formed or semi-formed stools/day and no clinical relapse at >12 months PR	Loose or liquid	–	Improved: 'good response' in 2/2 patients (100), unquantified --- Positive **Vote count: 1/0**
Fat intake reduction						
Outcome by stool consistency and frequency, responder (%)						
Larsen 2019	Low-fat: undefined Other dietary components: undefined 2–4 weeks	Induction and adjunct COL, COV, COS	Loose stools, BSFS types 6 and 7 Frequent, >3 movements per day BSFS PR	–	–	Improved bowel function in 14/14 patients (100), unquantified --- Positive
Jackson 2017	Low-fat: 20% total daily energy, all types of dietary fat Other dietary components: personalized, undefined 4–12 weeks	Induction and adjunct COV[b]	BSFS type 6 or 7 even intermittently Modified GSRS, BSFS PR	T7: 47% = 51/114 T6: 53% = 61/114 ≥7×/day: 37% = 42/114 ≥4–6×/day: 42% = 48/114	Reduction in proportion[c] by: Consistency: T7, 40% T6, 17% Frequency: ≥7×/day: 32% ≥4–6×/day: 30%	Improved in no. of patients by Consistency: 20/51 (39) 10/61 (16) Frequency: 13/42 (31) 14/48 (29) --- Positive
Outcome by stool consistency, responder (%)						
Bosaeus 1979	Low-fat: 40g/day Defined by food items and preparation methods 3–6 months	Induction	Watery CR	Watery	Formed	Normalized in 8/9 (88) patients Unchanged in 1/9 (12) patients (cholecystectomized) until COL added to the low-fat diet Watery diarrhoea returned in all 9 patients when fat intake was temporarily increased --- Positive

(Continues)

TABLE 3 (Continued)

First study author Year	Intervention Description Duration	Induction or adjunct to BAS BAS used, dose prescribed	Definition of diarrhoea used Measurement tools used	Diarrhoea description/Measurement Baseline	Diarrhoea description/Measurement Endpoint	Evidence of an effect (%) Vote count: Positive/Negative
Outcome by stool frequency, responder (%)						
Danielsson 1991	Low-fat: undefined Other dietary components: undefined 2 years	Adjunct[d] COL, 4–8 g/day	Severe chronic or intermittent diarrhoea interfering with daily activities 7-day symptom and stool frequency diary card PR	Stool frequency per day[e]: 7.4, 5.7, 4, 3.4	Stool frequency per day[e]: 5.1, 5.0, 2.6, 2	Normalized in 2/4 (50) patients Improved in 4/4 (100) patients, unquantified --- Positive
Outcome by change in stool frequency, scoring scale						
Watson 2015	Low-fat: 20% total energy from fat Other dietary components: tailored, undefined 7.9 weeks (3–20)	Induction or adjunct COV[b]	– Bowel frequency, NRS-10 PR	Median score, 8/10	Median score, 5/10	Improved by median score, 3/10 (37.5), $p < 0.01$ --- Positive **Vote count: 5/0**
Exclusive elemental						
By stool consistency, responder (%)						
Russell 1979	Vivonex Up to 6 sachets/day given orally Water allowed 2–3 weeks	Induction	Watery, unformed CR	Watery, unformed	Less watery and better formed	Improved in 3/3 (100) patients, unquantified --- Positive
By stool frequency, responder (%)						
Nelson 1977	Vivonex only Up to 6 sachets/day given orally[f] 8–15 days	Induction	Urgent, watery CR	2–10×/day	0–7×/day	Normalized in 2/6 (33) patients Improved in 6/6 (100) patients, unquantified --- Positive **Vote count: 2/0**

Abbreviations: BAS, bile acid sequestrant; BSFS, Bristol Stool Form Scale; COL, colestyramine; COS, colestipol; COV, colesevelam; CR, clinician-reported; GSRS, Gastrointestinal Symptoms Rating Scale; NRS-10, Numeric Rating Scale-10; PMH, past medical history; PR, patient-reported.

[a]Data on sorbitol, fructose, and glucose in Fernandez-Bañares 66 (pp. 829–830, Appendix A).

[b]An algorithm based on bile acid diarrhoea severity determined by SeHCAT was used to determine medication treatment before starting diet therapy.

[c]Data extracted from spider diagram, in Jackson *et al.* 62 (figs. 2 and 3, p. 416).

[d]Given metronidazole and doxycycline for 7–10 days before starting BAS.

[e]Stool frequency data in Danielsson *et al.* 44 (fig. 6, p. 1185) was given per week, not per day and therefore divided by 7. Patient 7 did not have a high stool frequency: excluded from analysis.

[f]One patient may have been fed via a nasogastric tube.

flatulence but in different ways.[39,62] In one study, to measure proportions of responders, the validated Gastrointestinal Symptom Rating Scale[69] was modified from a seven-point rating scale to two outcome categories of 'frequent and causes major changes in life' or 'never or occasional'.[62] In the other study, NRS-10[68] was used to measure patient-reported symptom change.[39]

Abdominal pain improved, as measured by responder[62] and by reduction in NSR-10 score.[39] For flatulence, there was an improvement according to NSR-10 scoring in one study[39] and a trend for improvement by responder in the other.[62] Both therapies were given positive vote counts for each symptom. The data are provided in the Supporting information (Table S1).

Adverse effects

Adverse effects were not reported in any studies.

Risk of bias and certainty of the evidence

Overall risk of bias for each included study was judged to be serious (see Supporting information, Table S2). Risk of bias justification of assessments across studies for each therapy using the ROBINS-I tool is provided in the Supporting information (Table S3). Certainty of the evidence using GRADE was assessed as very low quality for each outcome (Table 4). Very low-quality evidence was in particular a result of limitations of study design, impresicion due to very small population sizes, and inconsistency in the definition of diarrhoea and its measurement across studies.

DISCUSSION

This first systematic review of studies of diet, psychological, and exercise therapies meeting diagnostic criteria for BAD in adults with diarrhoea identified eight prospective cohort studies from Denmark, Spain, Sweden, and the UK, published between 1977 and 2019. No RCTs were identified. None investigated psychological or exercise therapies. Three types of diet therapy showed beneficial directions of effect on diarrhoea, abdominal pain, and flatulence. Data on any adverse effects were lacking. From very low-quality evidence, no conclusions can be drawn on the effectiveness of diet, psychological, or exercise therapies on diarrhoea, abdominal pain, and flatulence for the management of BAD in adults. Therefore, no recommendations for clinical and dietetic practice can be made.

In primary BAD, the beneficial effect on diarrhoea of removing lactose, sorbitol and fructose after optimisation with colestyramine[61] is suggestive of co-existing diarrhoea-predominant irritable bowel syndrome with underpinning gastrointestinal hypersensitivity,[70] rather than defective carbohydrate malabsorption.[71] Hydrogen breath testing using 20 g of the test carbohydrate is not adequately diagnostic for either lactose or fructose intolerance,[72] indicating that, in the study published by Fernandez-Banares in 2007,[61] there was inadequate rationale for dietary exclusion of either carbohydrate. Indeed, lactose is well tolerated at a dose of 12 g, as shown in a randomised, double-blind, cross-over study amongst adults with lactose malabsorption who were otherwise healthy, given as 240 ml of of cow's milk (2% fat) twice daily for 7 days.[73] This demonstrates the importance of food challenge to verify benefit on diarrhoea, which was not reported even though the study duration was 12 months. Diarrhoea and symptoms including abdominal pain and flatulence may present in susceptible individuals when carbohydrates are poorly absorbed in the small intestine and ferment in the large intestine in healthy adults,[74,75] as well as in gastrointestinal disorders.[76] From accumulated evidence on these carbohydrates, a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs)[77-79] evolved, with efficacy on global symptoms in irritable bowel syndrome supported by the findings of a network meta-analysis.[80] Compared to the limited data on sorbitol and fructose contents in foods used in this study,[61] our current knowledge on FODMAP composition of foods across food groups is far greater.[81-84] This suggests that a superior version of the carbohydrate modification therapy is the low FODMAP dietary intervention and that the intervention in this study did not truly treat diarrhoea as a result of BAD.[61]

Perhaps surprisingly, there is a paucity of evidence demonstrating diarrhoea induction as a result of dietary components. Food transit through the small intestine may be important to the rate of bile salt absorption, a faster ileocolonic inflow increasing potential for colonic spillover and diarrhoea. Physical aspects such as food ingestion timing, food particle size, and osmotic actions were not considered factors reported in the study design of the interventions of the included studies. For example, coarse wheat bran (15 g) but not fine psyllium (Fybogel, 7 g) significantly accelerates small intestinal transit compared to control (cooked pudding rice, 25 g) in healthy volunteers.[85] In the large intestine, absorptive capacity of water is enhanced by short-chain fatty acids derived from non-digestible carbohydrates,[86] although excess (e.g., when given as lactulose) leads to osmotic diarrhoea once absorptive capacity is reached.[87] It might be speculated that amylase-resistant starches, found in cooked and cooled rice and used in oral-rehydration solution for acute diarrhoea,[88] could potentially increase net colonic absorption of fluid in BAD and reduce faecal flow rate. Dietary fibre intakes are often unnecessarily low amongst people with diarrhoeal disorders and diseases,[89,90] as evidenced in one study[39] in this review.

TABLE 4 GRADE Summary of findings on diet therapies

What is the effectiveness of diet therapies on diarrhoea, abdominal pain, and flatulence?				
Patients or population: adults with bile acid diarrhoea and chronic diarrhoea				
Interventions: Carbohydrate intake modification, fat intake reduction optimised on medication; exclusive elemental (Vivonex)				
Setting: Hospital outpatients for carbohydrate intake modification, fat intake reduction; inpatients for exclusive elemental				
Outcome	**Direction of effect**	**Number of participants**	**Certainty of the evidence**	**Comments**
	ROB across studies	**(studies)**	**GRADE**	
Carbohydrate intake modification on diarrhoea	Positive Serious	2 (1 cohort study)	⊕◯◯◯ Very Low[a,b,c]	Data in primary BAD only. Long-term evaluation made (one study, clinician-reported) but in two patients only. No validated tool used to assess diarrhoea
Fat intake reduction on diarrhoea	Positive Serious	181 (5 cohort studies)	⊕◯◯◯ Very Low[a,d,b,c]	Data in secondary BAD, cancer survivors only. Large sample size (one study). Data on sex, age and weight/BMI (two studies). Validated method used to assess diarrhoea (two studies). Longer-term evaluation made (one study, patient-reported). Long-term evaluation made (one study, clinician-reported)
Exclusive elemental diet therapy on diarrhoea	Positive Serious	9 (2 cohort studies)	⊕◯◯◯ Very Low[a,b,c]	Data in secondary BAD, Type 1 BAD/BAM only. No validated tool used to assess diarrhoea
Fat intake reduction on abdominal pain	Positive Serious	122 (2 cohort studies)	⊕◯◯◯ Very Low[a,d,b]	Data in secondary BAD, cancer survivors only. No validated tool used to assess abdominal pain
Fat intake reduction on flatulence	Positive Serious	122 (2 cohort studies)	⊕◯◯◯ Very Low[a,d,b]	Data in secondary BAD, cancer survivors only. No validated tool used to assess flatulence
Adverse effects	- Serious	192 (8 cohort studies)	⊕◯◯◯ Very Low[e]	Laxatives: allowed (2 studies), unclear (6 studies). Anti-diarrhoeals: allowed (3 studies), unclear (5 studies)

Abbreviations: BAD, bile acid diarrhoea; BAM, bile acid malabsorption; BMI, body mass index; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; ROB, risk of bias.

[a]Inconsistency: narrative synthesis conducted, no estimates of the therapy effect possible.

[b]Indirectness: diarrhoea or abdominal pain or flatulence was measured differently across studies, unvalidated tools were used.

[c]Imprecision: population samples were too small to generate precise results.

[d]Inconsistency: differing end-points across studies to measure therapy effect.

[e]No studies reported on adverse effects.

However, BAD and diarrhoea-predominant irritable bowel syndrome exhibit dysbiosis and, in comparison, reduced bacterial diversity was shown in BAD.[24] Although the exclusive elemental diet therapy was designed for short-term use, our current understanding supports inclusion of carbohydrate substrates as an important variable to modulate the colonic microbiota[91] via their physicochemical properties.[89] Psyllium, for example, appears to be safe in the long-term treatment of BAD based on patient-reported survey data.[30] Containing arabinoxylan, it is a viscous fibre and recommended as a food supplement to treat symptoms of irritable bowel syndrome.[92] Viscous fibres also include alginates, beta-glucans, and pectins[89] found naturally in seaweed, oats, and chickpea husks. Interestingly, in a synthetic form, hydroxypropyl cellulose (European 463, used as a food thickener) was mistakenly used as the inactive comparator against colestyramine in an RCT in primary BAD and rapidly reduced the number of watery stools.[93] New insight into understanding the mechanisms of action that improve bowel habit may lie with microbiome-manipulation therapies.[94]

In the management of secondary BAD, fat intake reduction was found to have a beneficial effect on diarrhoea, abdominal pain, and flatulence in cancer survivors at 2 weeks and up to 2 years as induction treatment in borderline to moderate BAD or adjunct to BAS. Fat intakes ranged from 25 to 81 g day^{-1}, likely reflecting the broad variation in body weight and low and very high body mass indices.[39] However, none of the studies described behaviour change techniques used to support dietary adherence and internal validity, nor any underpinning behaviour change theories to potentially improve intervention effectiveness.[95] Psychological factors that hinder or aid adherence to fat intake reductions in this patient population are as yet unknown.

The strongest stimulators for bile acid release are fatty acids with a chain length of at least 12 carbons,[96] indicating that intake per day is not a suitable outcome measure. In lean, healthy adults, as little as 1.5 g fat (Intralipid) stimulated one-quarter of the gallbladder bile volume to be ejected,[97] whereas 25 g was found to expel 85% over 75 min.[98] The exclusive elemental diet therapy provided less than 0.5 g of fat per sachet. However, inadequate gallbladder volume evacuation (e.g., when 'nil by mouth' or in very low calorie dieting) initiates gallbladder dysmotility and stasis, which is reversible but can precipitate to gallstones.[99] This is relevant in primary BAD because obesity management may be a treatment option to consider.[27] One study conducted in obese, weight-reducing adults showed protection against biliary sludge when the fat intake was 12.2 g day^{-1} compared to 3 g day^{-1}.[100] This suggests that, when managing bile salt output, lower and upper thresholds of fat intake may be applicable. To prevent gallbladder stasis, 10 g per meal, irrespective of the level of obesity, has been proposed.[101] In studies of fat intake reduction excluding those for body weight reduction, fat intake was calculated based on a proportion of an individual's energy intake,[102–105] However, when considering that bile acids are recycled four to 12 times daily[106] with 0.2 to 0.6 g day^{-1} lost into the colon,[11] we hypothesise that, for further research studies, the quantity of fat intake per eating session rather than per day is appropriate for BAD. Furthermore, with bile acid pool doubling in primary BAD,[11] data are lacking to justify any differences in fat intake goal by age, weight, height or body mass index.[107]

Protein but not starch,[108] coffee (regular and decaffeinated),[109] and colestyramine taken with a meal[110] also stimulate gallbladder bile acid excretion. The amino acids in the exclusive elemental diet therapy have been proposed as the reason why gallbladder contractions were no different compared to 60 ml of corn oil in 300 ml of water consumed within 5 min, although the small study was in healthy adults.[67] This further indicates complexity in the role of macronutrients and other dietary components when considering the entire enterohepatic pathway and also that dietary intervention in primary BAD may be different from that in secondary BAD.

Caution should be exercised when interpreting these findings for multiple reasons. The small number of studies, although prospective, included no RCTs and no control groups. Five of the eight studies had very small sample sizes of less than 10 patients,[44,45,59,61,64] whereas 59% of the total of 192 patients analysed were from one study.[62] The findings cannot be generalised to outside of Europe, and data are lacking from outside of hospital settings.

Demographic data on sex, age, and body mass index were missing in primary BAD and in secondary BAD in those who were not cancer survivors, particularly after cholecystectomy, which may be an under-recognised group. Data from a multicentre survey conducted in 38 UK hospitals (1036 patients) showed the mean ± SD age was 50 ± 17 years across all BAD subtypes.[111] In a cross-sectional study conducted in a single-centre hospital in 70 patients with primary BAD, the mean ± SD age was very similar, at 48 ± 15 years.[27] The older ages of the patients in the studies of fat intake reduction[39,45,62] may have implications for aids used to support dietary adherence that were not reported on in any of the studies, such as digital technology. The inclusion of low body weights was a major confounder for two studies of fat intake reduction. For these patients, relief of diarrhoeal symptoms may not have been a priority compared to other important goals such health-related quality of life.[112] Indeed, fat intake reduction to a very low level may have been an inappropriate treatment goal for those with a body mass index of less than 18.5 kg m^{-2}, an indicator of undernutrition as defined by the World Health Organisation's weight classification system.

Searches were conducted to include as many studies as possible because non-pharmacological therapies have

not been previously systematically reviewed. The broad inclusion criteria allowed inconsistency in definitions for the diagnosis of BAD. However, this was unavoidable as a result of the availability and advancement of valid, accurate tests over the last 50 years. Historically, diarrhoea has been variably and poorly defined, and, by accepting all author definitions in the eligibility criteria, no studies were rejected. Had the definition of diarrhoea been restricted to stool consistency, defined using the BSFS or descriptively, then three out of the eight studies would have been excluded. Eligibility criteria also allowed reporting of outcomes on diarrhoea, abdominal pain, and flatulence, which were variably measured with variable duration to study endpoint and without statistical analysis in six of the eight studies.

A further limitation in this review process is that the screening of records and data collection were not independently conducted by at least two investigators. Although records and data were checked by another investigator, this is not compatible with best practice to reduce risk of error. In our opinion, it is unlikely that these results would have altered had we employed independent review by two investigators.

On the basis of the lack of evidence, no conclusions could be drawn on the effectiveness of diet, psychological, or exercise therapies for the management of BAD. High-quality RCTs in diet and as yet unexplored therapies compared to usual care are needed, which assess their acceptability, feasibility, and effectiveness in treating symptoms of BAD. Because BAD is a lifelong condition and therapies may be adjunctive to medication, any study design should carefully consider optimal treatment adherence by incorporating behaviour change techniques underpinned by behaviour change theory.[97] The outcome measures most important to people with BAD should be prioritised and, if possible, validated methods should be used to assess them. Prioritisation should be given to studies in primary BAD that could have the greatest positive impact on those living with this often debilitating condition.

AUTHOR CONTRIBUTIONS

Yvonne A. McKenzie was responsible for the conception, protocol development, literature searches and screening, data collection, qualitative data synthesis, and writing of the manuscript. Active contributions were made by: Jana Sremanakova on literature screening, data extraction review, and qualitative data synthesis review; Sorrel Burden on protocol development, data extraction review, critical review of all drafts; Chris Todd on study design. All authors critically reviewed its content and approved the final version submitted for publication.

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This article is dedicated to Juanita Rothman (1925–2019).

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

ETHICS STATEMENT

Not applicable.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study reported. The reporting of this work is compliant with the PRISMA 2020 statement and Checklist. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from this study as planned were explained.

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SUPPORTING INFORMATION

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

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Evaluating augmented reality for 'real life' teaching of food portion concepts

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Abstract

Background: Estimation of food portions is a vital skill for dietitians, which is developed during formal nutrition training. Skill development is often accomplished by training with food portion estimation tools. These tools can vary in design but evaluations often reveal them to be limited in their effectiveness and generally impractical for everyday use. The aim of this study was to develop and evaluate an augmented reality (AR) tool for the estimation food portions.

Methods: An online, quasi-experimental, randomised pre-test post-test study was conducted to evaluate the effectiveness of three food portion tools with nutrition students. These tools consisted of an online, AR, and an infographic tool (control). Students tested 10 different food images and were asked to estimate food portion sizes with and without assistance of a portion tool to determine absolute error, relative error, and overall improvement in estimation.

Results: A total of 33 participants enrolled in the study with 26 (72.0%) completing the study. The mean absolute error was lowest in the online group (53.0%), followed by AR (59.5%) and control (64.0%). Relative error scores revealed higher accuracy for the AR group (45.5%) followed by online (43.5%), and control group (29.0%). Overall improvement in estimation was highest in the AR group (+12.2%) followed by the online (+11.6%) tool with a decrease seen for the infographic (−1.7%) tool.

Conclusions: The use of technology, notably AR technology, may provide some advantage when training nutrition students in food portion estimation, although further investigation is advised.

KEYWORDS

augmented reality, dietetics and nutrition training, food portion estimation, nutrition education

Key points

- Augmented reality technology may be useful in improving food portion estimation skills.
- The type and shape of food may increase the overall difficulty when estimating portion sizes.
- Number of years spent studying nutrition and dietetics may influence estimation accuracy.

INTRODUCTION

The portion sizes of prepackaged and restaurant meals have steadily increased over time, which can lead to an increased energy intake of as much as 35% per meal.[1–4] This can present a challenge to dietitians as they are often required to monitor their client's food intakes, and exposure to these larger portions can alter their perception of serving sizes. Although there are many methods that can assist a dietitian in helping clients to manage food intake, one of the primary techniques used is known as portion control.[5,6] To assist with this, it is important that dietitians are well trained in identifying portion sizes.

Portion control techniques are used by dietitians to advise and educate clients on selecting appropriate food portions at their meals.[7,8] This may be used for those who are underweight or malnourished and to assist with weight loss. The overall effectiveness of this dietetic skill relies on a specific subset of visual and spatial skills generally taught under the nomenclature of food portion estimation.

The fundamentals of food portion estimation include the ability to identify correctly the weight and volume of a wide range of foods by visual observation through the conceptualisation of food shapes.[9] Dietitians build on these skills during their formal education with the assistance of various food portion tools. These tools may include food image atlases, digital food models, food replica models, or training with different hand shapes to build the visual, conceptual, and memory skills that are required.[9–11] In studies which have assessed the effectiveness of these tools to increase food portion estimation accuracy, results have shown varying levels of success, with participants averaging 50–60% accuracy after training.[12,13] Increased difficulty is also reported when estimating amorphous foods such as cereal or pasta because of their irregular shapes.[14] Furthermore, many food portion tools have been perceived to be inaccessible or lacking in practicality as a result of their high costs or low portability.[13,15] Despite this, developments in technology have allowed for highly portable and visually engaging tools to be produced utilising virtual technologies such as augmented reality (AR).

The use of AR technology has become more common in recent years because of the ubiquitous natureof smartphone and tablet devices.[16] Recent studies have shown that these devices can be integrated successfully with AR technologies to create 'new' educational tools, which have been shown to significantly improve learning outcomes.[17–19] As the technology continues to improve, it brings with it the possibility for increased learning efficiency, portability, and accessibility, all of which can be used to create new and improved food portion tools. Furthermore, results from a recent survey indicate that dietitians tend to have a positive attitude towards the use of technology in their practice.[20] The aim of this study was, therefore, to develop and evaluate a new AR portion tool for nutrition students and to compare the accuracy of estimation against two other portion tools.

METHODS

Study design and recruitment

To assess the accuracy of the estimation food portions a quasi-experimental randomised pre-test, post-test study design was implemented (Figure 1). The study consisted of an online survey with questions designed to assess participant accuracy at baseline and following an intervention. The intervention contained a brief refresh of food portion estimation and provided access to a food portion tool. Participants were able to familiarise themselves with their assigned tool before reassessing their accuracy immediately after the intervention. All participants were randomised into either a control group or one of two technology groups. The technology groups included an AR tool and an online tool, while the control group received an infographic instructing them how to estimate food portions with different hand shapes. Images of hand shapes were determined to be an appropriate control as they are an accepted non-technology-based tool used in food portion estimation.[21] The control group also helped to account for confounding variables that are commonly seen in repeated measures studies such as history, maturation, and return to median.[22]

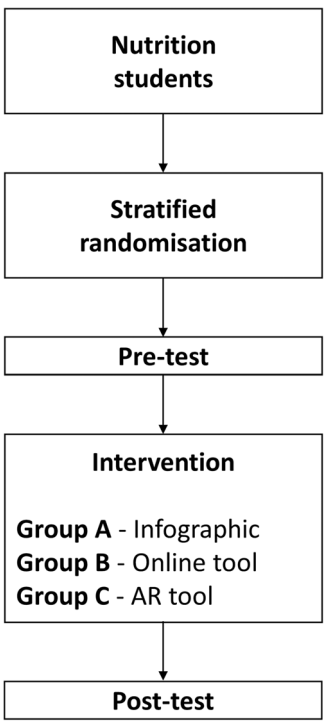

FIGURE 1 Conceptual framework of study design.

Students undertaking a nutrition degree at the University of Wollongong, attending the spring session of 2019, were recruited because of their relevance to the research topic. Recruitment occurred across all year levels. Stratified randomisation was used to ensure that an even number of male and female students across each year level were included in all arms. An a priori calculation was used to determine that a sample size of 21 students were needed per study arm (63 total) to ensure a power level of 80%. The researcher, independent of the dietetic teaching faculty, gave a brief presentation at lectures of nutrition subjects during the spring (second) session, during weeks 1–5 of 13, to inform the students about the study and encourage their participation. Students that wished to participate in the study were required to contact the researcher. Randomisation occurred after a cut-off period at the end of week 5 once all applicants had been screened, with the study commencing at week 6. Ethics approval for the study was granted by the University of Wollongong Human Research Ethics Committee (2016/022).

Online survey

An online survey was created using Survey Monkey (SurveyMonkeyInc., San Mateo, California, USA, www.surveymonkey.com). This consisted of 20 questions spread across two sections (post- and pre-test). Minor changes to the survey were implemented depending on how each group received access to their food portion tool. The access sections consisted of either a downloadable image, weblink, or a quick response (QR) code. Questions were designed to capture estimation accuracy, with an approximate completion time of 15–20 min. The survey underwent three iterations of validation (face, content, and construct) before a final version was disseminated for the study. This was to ensure that all questions and food images were free of confusion and easy to understand.

Portion estimation

Participants were asked to estimate the weight (in grams) of 10 different food images. The images (Table 1) consisted of two foods from each of the five food groups, with both solid and amorphous foods represented. Food images were sourced from a validated food image atlas with known portion sizes listed for each food.[23] The food image atlas was developed as part of a previous research project and, thus, participants had no access to or knowledge of the tool. Questions were ordered to ensure that each image contained a different food group from that of the previous question. The ordering of questions remained identical in both the pre- and post-test survey sections for consistency between the groups. Participants were also provided with a scale of the plate and bowl sizes presented in each image as a point of reference (Figure 2).

TABLE 1 Foods used in the portion estimation surveys (pre and post).

No.	Food image	Food group	True weight (g)	Display item
1	Cereal/cornflakes	Grains/cereals	30	Bowl
2	Green beans	Vegetables	140	Plate
3	Steak	Meat/poultry	130	Plate
4	Apple	Fruit	143	Plate
5	Cheese, sliced	Dairy	45	Plate
6	Cauliflower	Vegetables	132	Plate
7	Yogurt	Dairy	260	Bowl
8	Bananas, sliced	Fruit	157	Plate
9	Rice	Grains/cereals	190	Bowl
10	Fish	Meat/poultry	200	Plate

Note: Reference; Plate = 26 cm diameter, Bowl = 17.5 cm diameter.

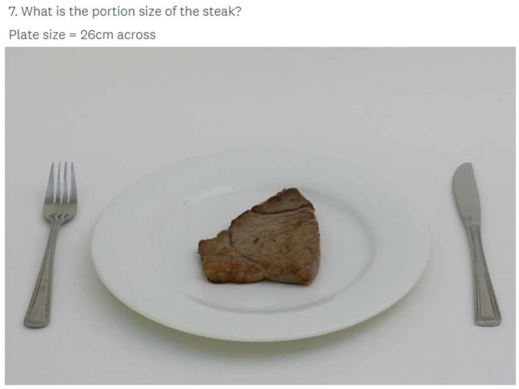

FIGURE 2 Example screenshot from online survey (steak).

Image quality

The original image quality for each food item had a dimension of 3504 × 2336 pixels and an average file size of 4.8 MB. Images were hosted on Google Drive (https://drive.google.com/drive/my-drive), where they were converted to 740 × 493 pixels to ensure that the survey images would load with speed whilst maintaining their clarity.

Food portion tools

Three food portion tools were examined. Each tool used a different type of technology ranging from a simple infographic to an interactive smartphone app.

Infographic

The infographic contained six sections instructing the participants how to estimate food portions using different hand shapes (Table 2). The graphic was embedded in the survey with a download link so that the participants could access the tool in the post-test. Images of different hand shapes (cupped, palm, fist) were used to convey a typical serving size along with the corresponding portion size. The infographic was created in line with the Australian Guide to Healthy Eating[24] to allow for calculation of the portion sizes displayed in the graphic.

Online tool

The online tool was designed as an interactive, web-based tool. Upon accessing the tool through a web browser, participants were shown a menu screen prompting them to select a food item. Once a food item was selected, an image of the food was loaded along with a list of options for interacting with the food. Participants had the ability to increase or decrease the portion sizes of each food and select three viewing angles. There was also an option to display the portion size of each food and compare each portion size to a reference image (tennis ball) which was shown to scale next to the selected food portion, providing additional visual assistance (Figure 3). A list of all the food types, portion sizes and plate sizes used can be seen in Table 3.

TABLE 2 List of food portion information included in the infographic tool (control group).

Hand shape = 1 serving	Food section	Portion information for One serving
Palm	Meat: beef, pork, lamb	65 g
Palm	Meat: chicken	80 g
Flat hand	Meat: fish	100 g
Cupped hand	Vegetables: nonstarchy	75 g
Cupped hand	Vegetables: starchy	75 g
Cupped hand	Grains/cereals: cereal	30 g
Cupped hand	Grains/cereals: rice	100 g
Cupped hand	Grains/cereals: pasta	50 g
Fist	Dairy: milk	250 ml
Fist	Dairy: yoghurt	200 g
Thumbs (×2)	Dairy: cheese	40 g
Fist	Fruit: berries, apples, apricots	150 g

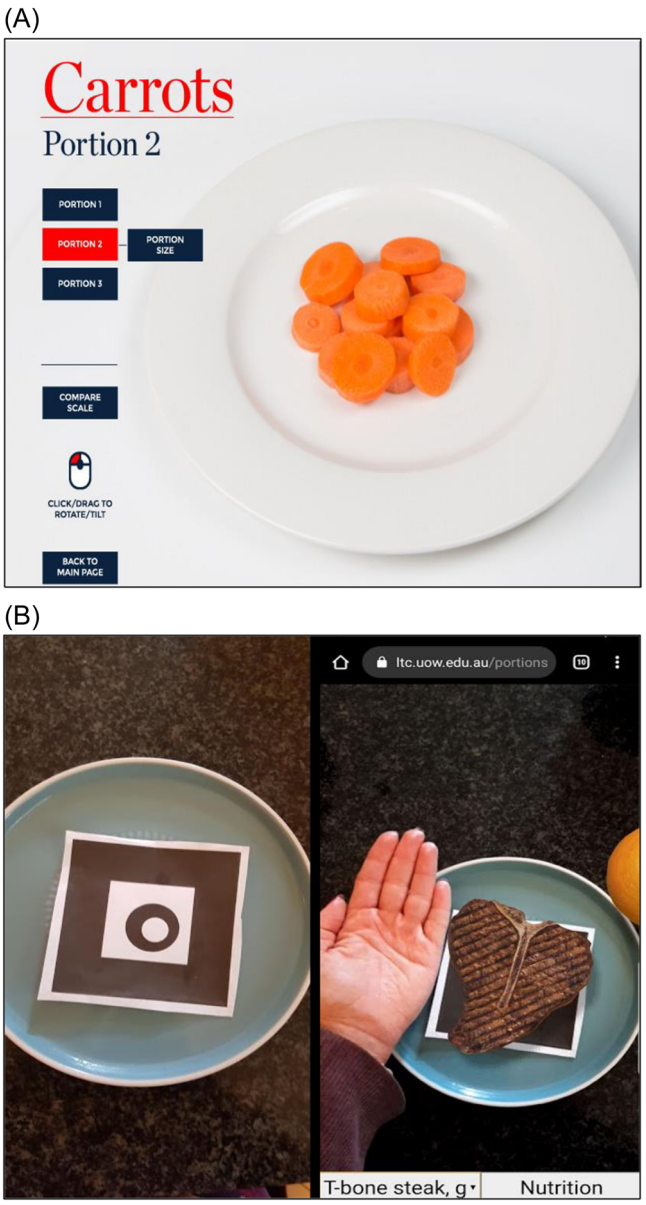

FIGURE 3 Example screenshots from two food portion tools. (a) Online tool, (b) augmented reality tool.

AR tool

The AR tool was designed to work as an app on the participants' smartphone device. To access the app, participants were given a QR code to scan with their smartphone. Participants were also required to download and print a fiducial marker. The fiducial marker consisted of a specialised printed pattern on 10 cm × 10 cm piece of paper, which, when scanned by the participants phone camera, would activate the mobile app. Brief instructions on how to use the app were provided in the survey.

The tool allowed participants to view virtual images of food overlayed onto real world environments on their

TABLE 3 List of foods and portion sizes available in online tool.

Food image	Food group	Portion sizes	Display item
Scotch fillet	Meat	71, 123, 176 g	Plate
Chicken (diced)	Meat	40, 80, 160, 200 g	Plate
Muesli (no milk)	Cereal/grains	30, 60, 90, 100 g	Bowl
Rice (white, long grain)	Cereal/grains	45, 90, 135, 220 g	Bowl
Milk (full fat, cow)	Dairy	100, 200, 250 ml	Glass
Cheese (tasty, pre-sliced)	Dairy	20,37,73,107 g	Plate
Banana (with peel)	Fruit	93, 165, 253 g	Plate
Apple (slices)	Fruit	37, 75, 150 g	Plate
Peas (baby)	Vegetables	13, 37, 75, 150 g	Plate
Carrots (slices)	Vegetables	37, 75, 150 g	Plate

Note: Reference; plate = 26 cm diameter; bowl = 17.5 cm diameter; glass = 6 cm diameter by 14 cm height.

TABLE 4 List of foods included in the AR app.

Food group	Food image	Portion sizes
Meat	Steak (T-bone, grilled)	180 g
Dairy	Cheese (gouda, wedge)	100 g
Grains/cereals	Rice (white)	120 g
Vegetables	Broccoli (small head of)	250 g
Fruit	Banana (medium)	98 g
Fruit	Apple (red delicious, medium)	164 g
Miscellaneous	Coffee (black, takeaway cup)	281 ml

smartphone screen at a 1:1 scale. Participants had the ability to zoom and rotate around the virtual image in the x, y and z planes by moving their smartphones around the fiducial marker.

Participants could use their hands as a point of reference on the screen if needed (Figure 3) and had the option to select from seven different food types. One portion for each food was available, with at least one food item from each food group represented (Table 4).

The AR tool was created as part of a collaborate program by University of Wollongong Learning and Teaching Centre. This was programmed as a smartphone app using javascriptlibraries (a-frame, ar.js, javascript edition 2019) run on either Android or iOS devices. Three-dimensional food model images were purchased from the turbosquid, sketchfab, and cgtrader websites.[25–32] Food models were edited in Blender software[33] before being exported to the app. The total number of foods available was lower than the other tools owing to limited resources availability at the time. Portion sizes of the images were determined by visual inspection and nutrient data was calculated using FoodWorks software (Xyris software Australia Pty Ltd) using the AUSNUT 2011–13 food composition database.[34] The fiducial marker wascreated with the Blender software AR tool kit.[33]

Data collection and analysis

The survey data was extracted from Survey Monkey and imported into an XLS file for data management and analysis (Microsoft Excel, 2019, version 16.0.6742.2048). The estimation accuracy for pre- and post-test results were calculated using: *accuracy* = (estimation − true weight)/(true weight) × 100, providing the total level of error expressed as a percentage. Improvement in the estimation accuracy was calculated as the difference between the post-estimation error and pre-estimation error scores. The measured level of relative error was found to vary between studies, and so this study used an amalgamation of relative error rates used by studies with a similar a design.[35,36] This consisted of estimates within ±50% and ±25%[35–37] of the true weight. All data were statistically analysed using SPSS software (IBM Corp, Released 2012, SPSS Statistics for Windows, Version 21.0). Normality was assessed with a Shapiro–Wilk test. Where data met assumptions of the Levene test for homogeneity of variances, a one-way analysis of variance (ANOVA) was conducted with a post-hoc Bonferroni adjustment. All non-parametric data was assessed with a Kruskal–Wallis one-way ANOVA.

RESULTS

Participants

There were 33 participants recruited (11 in each group) and of these, 78.7% (n = 28) attempted the survey, with 72.7% (n = 26) completing both the pre- and post-test sections of the study. The final totals consisted of eight, ten, and eight participants in the control, online, and AR groups, respectively. Participants were predominately female (88% n = 23) ranging from 18 to 24 years with a mean of 2.2 (SD 0.89) years of study. Owing to the number of withdrawals in the study (n = 6), the spread of participants per group varied.

Absolute error

Analysis with a one-way ANOVA (pre-test) revealed that there were no significant differences in the pre-test estimation scores for the intervention and control

groups, signifying that the mean level of accuracy at the pre-test was similar across all groups. The average error rates were 64%, 59%, and 53% for the control, AR, and online groups, respectively. Further analysis with a one-way ANOVA (post-test) revealed a significant difference in the absolute error rate between the groups for certain food types. These were, steak (p = 0.037), and fish (p = 0.013) for the AR group, with green beans (p = 0.018) and rice (p = 0.017) for the online group, when compared with the control group. No significant differences were found for the absolute error when adjusting for participant year level, age, or gender. The average absolute estimation error percentages for each food item and group can be seen in Table 5.

TABLE 5 Average estimation error (absolute) of foods by intervention group and year level.

Average estimation error per food item by experiment group (%)			
Food	**Control (n = 8)**	**Online (n = 10)**	**AR (n = 8)**
Cereal	152.0	226.6	233.3
Beans	50.8	14.6	40.5
Steak	33.3	25.4	21.8
Apple	45.5	29.6	10.9
Cheese	48.1	38.8	114.8
Cauliflower	54.9	49.3	31.4
Yogurt	45.5	25.0	24.3
Bananas (sliced)	71.6	61.8	55.4
Rice	65.2	15.8	31.5
Fish	65.7	43.1	31.0
Mean error	64.1	52.9	59.5
Average estimation error per food item by year level (%)			
Food	**First year (n = 7)**	**Second year (n = 4)**	**Third year (n = 15)**
Cereal	245.1	272.7	196.8
Beans	48.5	51.8	27.7
Steak	43.7	40.9	25.2
Apple	40.5	57.8	23.4
Cheese	56.3	60.9	54.3
Cauliflower	56.4	48.2	45.3
Yogurt	34.4	36.3	32.1
Bananas (sliced)	73.9	44.5	58.2
Rice	39.7	38.8	26.8
Fish	47.5	36.9	34.7
Mean error	68.6	68.9	52.5

Relative error

Relative error refers to the percentage of estimations that fell within ±50% and ±25% of the true weight of food. The mean scores were similar across all groups at the pre-test with one-way ANOVA showing no significant differences. The post-test scores revealed that 45.5% and 43.5% of estimations fell within the test ranges for the AR and online groups, respectively, while the control group recorded 28.9% of all estimations within the relative error margins (Figure 4). When adjusting for participant year level, accuracy was seen to increase by year level, with 28.0%, 30.0%, and 49.5% of scores within assigned error margins for first, second, and third year, respectively.

Improvement of estimation accuracy

Improvements in the accuracy of estimation varied between the intervention and control groups. Positive scores were recorded in the AR and online groups with a +12.2% and +11.6% increase, respectively. This contrasted with the control group, which recorded a negative improvement rate of −1.7% (Figure 5). When investigated by year level, the mean improvement was found to vary. Participants in second year recorded the greatest improvement at 35%, followed by third year at 3.5%, while first year participants recorded a negative improvement of −1.5% irrespective of group.

DISCUSSION

This study compared three different portion tools for the estimation accuracy outcomes of nutrition students. Participants in the AR and online tool groups had a greater overall accuracy in estimating food portions when compared with the control group.

Food portion estimation studies are known to contain highly variable outcomes when assessing the accuracy of estimation as the estimations can be either over or under the true weight of a food.[38] In this study, relative error measurement was used to account for this variability, taking all estimations into consideration. Overall, the AR group was shown to have the highest level of accuracy when assessing relative error with 2% greater accuracy than the online group and 16.6% greater accuracy than the control group. These results partly align with similar studies,[35,36] which found a greater level of estimation accuracy when using an AR technology. However, the level of accuracy reported in these studies was substantially higher. The results from this study may have been affected by a number of factors, such as the wider variety of portion sizes and types of foods used, and the use of food images for making the estimations as

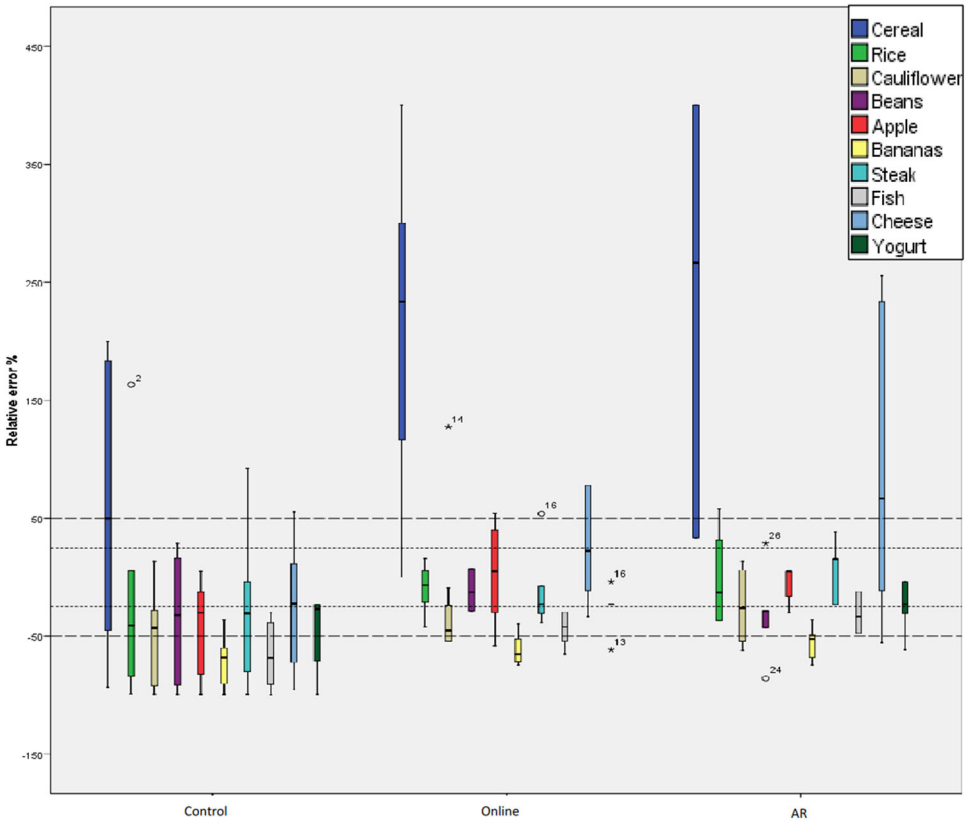

FIGURE 4 Relative error levels between study groups showing 0%, ±25%, and ±50% error.

opposed to estimating with 'real' food portions in person.

Participants were required to make estimations against images of food instead of real foods, which is less common in evaluation studies. Estimating from images instead of from real foods could increase the difficulty, as some studies have found mixed results when using this technique.[13,39,40] Furthermore, participants also estimated a wider range of foods at varying portion sizes, whereas comparative studies either required participants to estimate a single serving of one food group[33] or to make estimations on only one food type.[34] In addition, the shape and size of the food being estimated is known to have an impact on the overall accuracy, with previous studies revealing that smaller, irregular shaped foods can produce higher rates of error.[10,14,40,41] This trend was generally observed when assessing the average error rates for foods across groups, however, the level of error between amorphous and solid foods was shown to vary, especially in the AR group. The level of variability seen in the AR group was somewhat comparable to two previous studies,[35,37] which also found mixed results across different food types when using an AR food portion tool. Overall, difficulty with certain foods was shown to have a significant impact on accuracy of the results. This was especially apparent for breakfast cereal, which had an average error rate of +268.5% across each tool and was the most over-estimated food type. The high level of error may have been resulted from the complexity of cereal as it consists of small irregular shapes with multiple units, which have been found to increase difficulty with estimation of food portions.[38,42] This may also explain the high error for banana slices (62.9%) but did not account for the high error rate seen for cheese, which was only observed in the AR group at 114.8%. It is possible that the image used for cheese in the AR tool (wedge) was not suitable for training when compared with more common images, such as cheese slices.

The improvement in accuracy between the pre-test and post-test scores was highest in the AR group followed by the online group, while the control group showed decreased accuracy. The improvements could not be directly compared with other food portion estimation studies as they had either not assessed or had not used the same food portion technology. However, when comparing against food portion estimation studies using older technologies,[15,43,44] both the AR and online groups showed greater improvement (by an average of 7.8%). This may be due to both technologies providing an enhanced level of visual information when compared with older methods, such as the use of hand shapes. These outcomes suggest that the AR and online tools may be more effective for improving accuracy with short-term training.

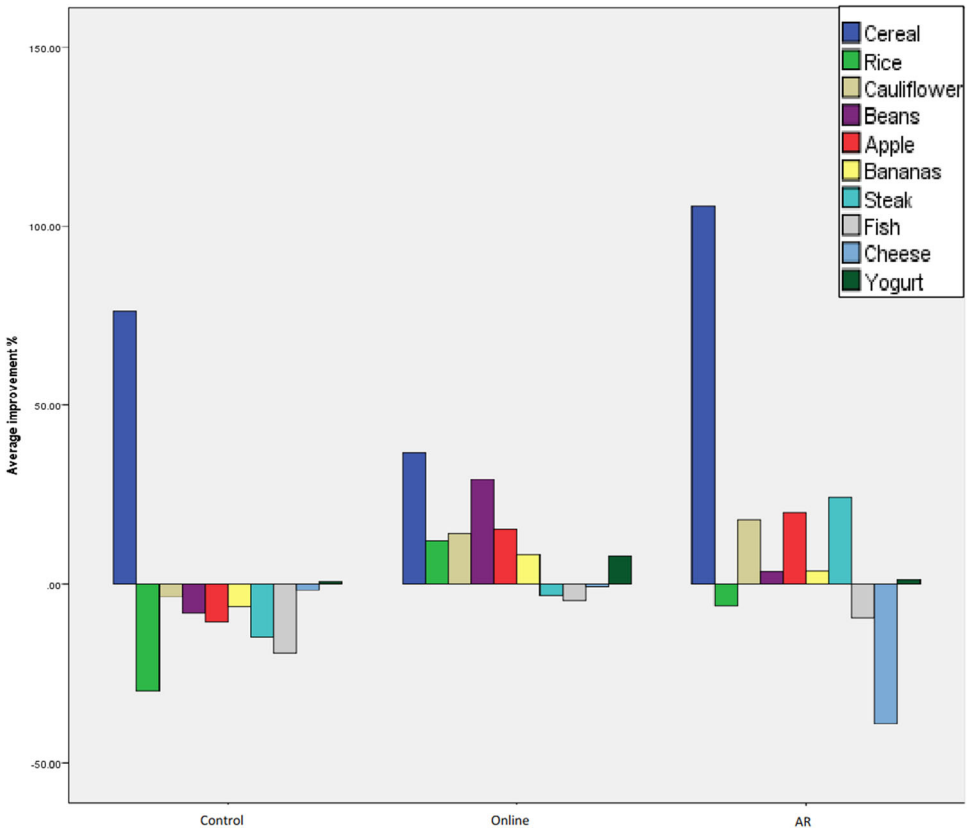

FIGURE 5 The overall level of improvement in each food type between groups as a percentage.

The spread of participants was noted as an important confounding variable at the beginning of the study and care was taken to ensure an even distribution of first, second, and third year participants into each study group using stratified randomisation. This was to account for any differences in learning experience. When controlling for accuracy outcomes by subject year, there was a noticeable difference in overall performance between participants and year of study. First-year participants had the lowest scores while second-year participants recorded the highest ratings across all domains, followed by the third-year participants with moderate improvements. The variation in first-year participants may have resulted from an overall lack of experience and exposure to portion estimation techniques while the differences between second and third year may have resulted from the low sample size in second-year participants. Despite the low sample size, study groups were relatively even, with the exception of the AR group, which did not contain second-year participants owing to dropout. Furthermore, the distribution of first-year participants was relatively even across the groups, suggesting that the overall accuracywas not significantly impacted by the participants' year of study.

There were several limitations noted when assessing the outcomes. First, the sample size affected the overall power and strength of results and the use of food images may have increased the difficulty by comparison with the use of real foods. The study was also conducted in the participants' own time, which meant that it was not possible to know if other tools were used by the participants, although the similar pre-test scores indicate that this may not have been the case. In addition, the type of food images used across three tools differed as it was not possible to use the same images owing to formatting restrictions. This meant that it was possible that some images may have been more effective than others regardless of the tool used. The AR tool also lacked functionality, such as portion scaling and a larger selection of food items, which may be added in future versions of the app. Lastly, this study did not assess the effectiveness of the AR tool in patient populations which would require further investigation.

CONCLUSION

This study investigated the accuracy of three different food portion tools. The findings suggest that both the AR and online tools may provide a more effective method for the training of student food portion estimation skills when compared with the use of traditional hand shapes. The AR and online tools were generally comparable in all areas of evaluation.

Continued development of the technologies may be beneficial for improving food portion estimation skills in nutrition students and further evaluation is recommended.

AUTHOR CONTRIBUTIONS

Ioannis Mellos: conceptualization (equal); data curation (lead); formal analysis (lead); investigation (lead); methodology (lead); project administration (lead); resources (supporting); software (equal); validation (equal); visualization (lead); writing–original draft preparation (lead); writing–review & editing (lead). **Yasmine Probst:** conceptualization (equal); data curation (supporting); formal analysis (supporting); investigation (supporting); methodology (supporting); project administration (supporting); resources (lead); software (equal); supervision (lead); validation (supporting); visualization (supporting); writing–original draft preparation (supporting); writing–review and editing (supporting).

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CONFLICTS OF INTEREST

The authors have declared no conlficts of interest.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported. This research involved the use of an online survey with ethics approval. The lead author confirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

ETHICS STATEMENT

University of Wollongong Human Research Ethics Committee, approval number 2016/022.

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The nutritional quality of food parcels provided by food banks and the effectiveness of food banks at reducing food insecurity in developed countries: a mixed-method systematic review

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Abstract

Background: Research indicates that food parcels provided by food banks are nutritionally poor. Food insecurity and the use of food banks are both rising, with detrimental effects on the dietary intake and health of users. This mixed-method systematic review aims to investigate the current nutritional adequacy of pre-packaged food parcels and whether using food banks reduces the food insecurity and improves the dietary intake of their users.

Methods: A mixed-method systematic literature review, restricted to articles published from 2015, was conducted using eight electronic databases, four grey literature databases and eight relevant websites. Quantitative findings, investigating the nutritional quality of food parcels and/or their impact on dietary intake or food insecurity, were presented narratively. Qualitative findings reporting the views of food bank users regarding food from food banks underwent thematic synthesis. These independent syntheses were integrated using configurative analysis and presented narratively.

Results: Of 2189 articles, 11 quantitative and 10 qualitative were included. Food parcels were inconsistent at meeting nutritional requirements and often failed to meet individual needs, including cultural and health preferences. Using food banks improved food security and dietary quality of users, allowing otherwise unachievable access to food. However, food insecurity remained, and is explained by limited food variety, quality and choice. The mixed-method findings support interventions to ensure consistent, adequate nutrition at food banks, including catering for individual needs.

Conclusions: Food banks are a lifeline for those severely food insecure. However when used alone, food banks struggle to eliminate the heightened food insecurity of their users. Efforts to improve the nutritional quality of food parcels could improve the experiences and diet-related outcomes of those requiring food banks.

KEYWORDS

food assistance, food parcel, food security, food bank, nutrition

Key points

- The nutritional quality of food parcels is inconsistent, and is often poor compared with national nutritional recommendations. This can be

explained by the limited quantity and variety of food options as well as a lack of nutritional guidelines at food banks.
- Food banks struggle to meet individual health, social, and cultural dietary needs in socially acceptable ways. Positive outcomes from diabetes-specific food parcels highlight the advantages of tailoring parcels to meet individual needs and preferences.
- Food banks are a lifeline, which improve dietary intake and food security in times of crisis. However, as a sole intervention, food banks do not eliminate the heightened food insecurity and poor diets of food bank users.

INTRODUCTION

Food insecurity is a state which is defined as the limited or uncertain access to nutritionally adequate, safe foods, in a socially acceptable way.[1] Food insecurity can be mild, moderate or severe, ranging from worrying about accessing food to experiencing days without eating.[2] Economic need drives food insecurity, thus incidence is highest among households at the bottom of the income distribution table.[2–4] Food insecurity has been rising over the past decade across high-income countries.[5] In Canada, the USA, and the UK, 10.5%, 12.7%, and 14% of households experience food insecurity, respectively.[6–8] Such countries have experienced unprecedented levels of food insecurity during the COVID-19 pandemic, owing to reduced food access and economic crises.[9–12] This trend is predicted to continue; thus the world is not on track to meet the UN Sustainable Development Goal of diminishing hunger by 2030.[13,14]

Social-security policies, including welfare benefits, intend to ensure basic standards of living are met, but they are inadequate to eradicate food insecurity.[15–17] Therefore, charity-run food services such as soup kitchens, community-based meal provision, and food banks have been increasingly used, with the aim of minimising food insecurity.[18,19] Food banks have been established in the USA and Canada for decades and they are now common across high-income countries, including the UK, Australia and Germany.[20–23] Food banks are either warehouses collecting and distributing food to charities or smaller charitable organisations serving clients directly.[20,24] The latter will be the focus of this review, and these typically operate by providing households with prepackaged food parcels without charge.[19,21] Measures of key performance indices for food banks are nonmonetary (i.e. efficiency and effectiveness) as they are nonprofit organisations. Food bank efficiency is defined as the total allocated amount (in terms of weight) of food items distributed by a food bank. However, the effectiveness of a food bank is defined by how well the nutritional needs of users are met by the service provided by that food bank.[25]

Food bank use is greatest among unemployed, lone-parent and single-person households, and those suffering ill-health.[2,26] Individuals using food banks are predominantly severely food insecure, hence they represent a small proportion of food insecure populations.[2,27,28] For example, 3% of the Canadian population is severely food insecure, a figure rising to 66% among food bank users.[28] In the UK, 14% of households experience food insecurity, yet only 2.5% use food banks.[2,6] Similarly, among a sample of low-income families in Canada, only 23% of those suffering food insecurity used a food bank.[4] These figures are unsurprising as food banks are not the only intervention for food insecurity; in addition, referrals are often not received and stigma discourages use.[4,29,30]

Corresponding with rising food insecurity, food bank use has been increasing.[2,31] In the UK, USA, and Canada, this is driven by recession, austerity and welfare reforms, particularly benefit sanctions and delays.[2,12,14,30] COVID-19 saw an exacerbated demand for food banks, including an increase of 33% in the UK from 2020 to 2021, resulting in 2 537 198 parcels being distributed.[32] This is significantly greater than typical annual rises, with 37% of use attributed to COVID-19.[2] Europe, Canada, the USA, and Australia also report unforeseen demand from consequences related to the COVID-19 pandemic.[33–36]

A high-quality diet can be defined as aligning with national dietary recommendations, including the UK 'Eatwell Guide' and the 'MyPlate' in the USA.[37,38] Food insecurity is associated with poor dietary intake, including low fruit and vegetable (FV) and micronutrient consumption,[39,40] as well as undernutrition and obesity.[41,42] The latter relationship is supported by reliance on inexpensive, nutrient-poor, energy-dense food.[41] Rising food costs, increasing price gaps between healthy and unhealthy foods, and reduced access to nutrient-dense food in deprived areas further hinders dietary quality.[43–46] Individuals who use food banks have inadequate energy, FV, dairy, and meat intake compared with national recommendations.[47–49] In addition, their dietary quality is worse than the general population.[50] This is unsurprising, as for example, the poorest UK decile require 74% of their disposable income to follow the 'Eatwell Guide' dietary recommendations.[51] Moreover, in the USA, food-insecure food bank users have a poorer knowledge of nutrition, which negatively influences dietary choices compared with those that of the food secure.[47]

Food insecurity influences health-inequalities, with heart disease, diabetes, anaemia, and poor mental health more prevalent among the food insecure.[52–56] This is

reflected in food bank users: in the UK, 83% suffer ill-health, and in the USA, rates of obesity, diabetes, and heart disease are greater than in the general populations.[2,55] Food insecurity, ill-health and food bank use is cyclical, with poor nutrition influencing chronic disease and ill-health driving use.[29] This is exacerbated when donated food is unsuitable for some health conditions and healthcare professionals struggle to support patients with food insecurity.[56,57] Economic disparities and an overwhelmed healthcare system due to the COVID-19 pandemic means ill-health is projected to worsen for those with food insecurity.[58]

Food provided by food banks can provide over half of their clients' total dietary intake.[59] Previous systematic reviews investigating the nutritional quality of food bank parcels found variance across studies.[48,60] However, parcels are often insufficient in dairy, meat, FV, and micronutrients (e.g. calcium, iron, and vitamins A and C).[48,60] These reviews were published in 2016 and are limited to the USA, Australia, and Canada.[60] Since 2016, studies in Europe have investigated the nutritional quality of food bank parcels.[61,62] Qualitative research similarly suggests that food banks inadequately meet dietary needs, with food that is of poor quality, disliked, and culturally inappropriate.[4,23,63–65] Despite food banks being considered an emergency source of food, their chronic and multiple use is reported, suggesting their contribution to dietary intake is long-term.[15,66,67] Annually, 43–50% of UK food bank users receive multiple parcels and in Canada, 65% of parcels are supplied to repeat clients.[2,31,68]

Despite the rising use of food banks, qualitative research indicates that they are inadequate to address food insecurity.[16,48] In addition, quantitative studies investigating whether food banks reduce food insecurity have conflicting results.[30,47,69] Considering dietary intake, improvements in energy and nutrient intake are seen following food bank use, yet overall dietary quality may remain poor.[59,70] There is recognised need for further research investigating the efficacy of food banks, including a synthesis of these studies.[15] This systematic review aims to provide an update on the nutritional quality of food parcels and their effectiveness at improving food security, building on reviews published in 2016.[48,60] This review is limited to high-income countries and the objectives were to (a) investigate the nutritional quality of food parcels compared with adult nutritional requirements and (b) investigate the effectiveness of food banks at improving the food security and dietary intake of food bank users.

METHODOLOGY

This systematic review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[71,72] The Joanna Briggs Institute (JBI) methodology for mixed-method systematic reviews was followed[73] and the review protocol was registered a priori with PROSPERO (CRD42021269065).

Eligibility criteria

The terms food 'banks', 'pantries', and 'shelves' describe charitable food parcel provision. In this review, the term 'food bank' refers to charitable organisations providing prepackaged food parcels directly to eligible clients without charge.

The eligibility criteria is outlined in Table S1. Quantitative and qualitative studies available in English were considered. A mixed-method approach allows greater insight, with personal perspective and experience investigated in the context of objective findings.[74] To update the previous systemic reviews, articles included were published from 2015 onwards.[48,60]

The population of interest was adults receiving prepackaged food parcels from food banks in high-income countries as defined by the World Bank.[75] While food banks are present globally, operational characteristics in low-income countries often differ.[76] Therefore, with limited similarities, studies from low-income countries were excluded. Articles solely investigating food parcel provision to children were also excluded, as different nutritional requirements from those of adults would make comparison between studies difficult.[77]

Quantitative studies either, (a) measured the nutritional quality of food parcels provided by food banks, compared to national dietary recommendations, and/or (b) evaluated the impact or association of food banks on the food security and/or dietary intake of food bank users. Qualitative studies investigated both research objectives, exploring the views/perceptions of users regarding food bank food. With differences in aims and operations, interventions providing only preprepared meals, such as soup kitchens, subsidiary programmes, or client-choice food banks were excluded.[15,18,78] Articles were excluded if food parcel items were listed without indication of quantity, as this does not allow nutritional assessment. If food security or dietary intake were measured, yet not related to food bank use, articles were excluded as this does not explore their effectiveness. Unlike Simmet et al., excluding interventions <6 months, no temporal restrictions were placed on intervention studies.[60] Although precluding long-term outcomes, temporal restrictions could exclude beneficial approaches for improving food banks.

Search

On 15 June 2021, systematic title and abstract literature searches were conducted by reviewer 1 (L.O.) to simultaneously retrieve qualitative and quantitative

TABLE 1 The grey literature sources searched for grey literature to include in the review

Grey literature databases	Organisational websites
OpenGrey (System for Information on Grey Literature in Europe)	The Trussell Trust
The Grey Literature Report	The Food Foundation
Health Management Information centre (HMIC) (Ovid)	The Independent Food Aid Network (IFAN)Feeding America
Social Care Online (SCO)	European Food Bank Federation
	Food Banks Canada
	Food Bank Australia
	The Global Food Banking Network

studies. Eight databases were used: ASSIA (ProQuest), CINAHL (EBSCOhost), Cochrane Central Register of Controlled Trials (Cochrane Library), EMBASE (Ovid), MEDLINE (EBSCOhost), PubMed, PsycINFO (EBSCOhost), Scopus. A scoping search identified relevant grey literature.[79] With public health research abundant in grey literature, and to prevent omission of appropriate data, grey literature databases and relevant websites were searched on 17 June 202180 (Table 1).

There was initially a limited search of MEDLINE, including analysis of free-text keywords in titles/abstracts and medical subject headings (MesH). The search strategy was adapted to include the identified keywords and MesH. The following free-text keywords were used in the search strategies: 'food bank', 'food bank', 'food pantry', 'food shelves', 'food parcel', 'diet', 'nutrition', 'food security', 'food insecurity'. MEDLINE, PubMed, CINAHL, and Cochrane searches used the subject heading 'food assistance'. Searches were filtered to English articles published from 2015 onwards. Tables S2 and S3 document the search strategies.

Study selection

Stage 1: All search results were exported to 'EndNote20', and duplicates were removed. Two reviewers (L.O., C.P.) independently screened the results by title and abstract, and articles were excluded if they did not meet the inclusion criteria.

Stage 2: Full texts included in Stage 1 were reviewed for inclusion by reviewer 1 (L.O.) and 20% were independently assessed by reviewer 2 (C.P.). Full texts that did not meet the inclusion criteria were excluded (Figure 1).

The reference lists of full texts meeting the eligibility criteria were searched by reviewer 1 (L.O.). Any uncertainties during study selection were resolved through consensus between the reviewers.

Data extraction

A standardised data extraction form was used to ensure that the data extracted from the included studies was consistent. The following information was gathered: study characteristics (authors, year, location, study design, sample size), population characteristics, methodology, outcomes, and key findings. By comparison with the eligibility criteria, studies were organised into quantitative and qualitative, and data was arranged in Microsoft Excel spreadsheets (Tables 2–4).

Assessment of methodological quality

The methodological quality of the included studies was assessed using standardised critical appraisal tools from JBI, which were specific for the study design of each article.[81–83] The scores are based upon the possibility of risk of bias in the methodology, conduct, and analysis. 'Yes' represents a score of 1. The following maximum scores show the highest quality: RCT, 13; quasi-experimental, 9; cross-sectional, 9; and qualitative, 10. Uncertainties were agreed through discussion between reviewers. Methodological quality is reported, but this did not influence inclusion.

Quantitative data synthesis

The outcomes extracted from quantitative studies were, (i) the nutritional quality of food parcels: overall quality, food groups, energy and nutrients; and (ii) the effect and/or association of food bank use on the food security or dietary intake of food bank users. Heterogeneity of study designs, methodology and outcomes precluded meta-analysis; therefore, common outcomes were narratively synthesised.

Qualitative data synthesis

Qualitative data underwent meta-synthesis, involving generating themes that captured the views from food bank users regarding whether food banks meet their nutritional needs. Analysis followed steps adapted from thematic synthesis: (1) line-by-line coding; (2) developing descriptive themes; (3) generating analytical themes.[97]

Mixed-method data synthesis

A convergent segregated approach was followed for mixed-method data synthesis.[73] This included integration of quantitative and qualitative data, linking complementary

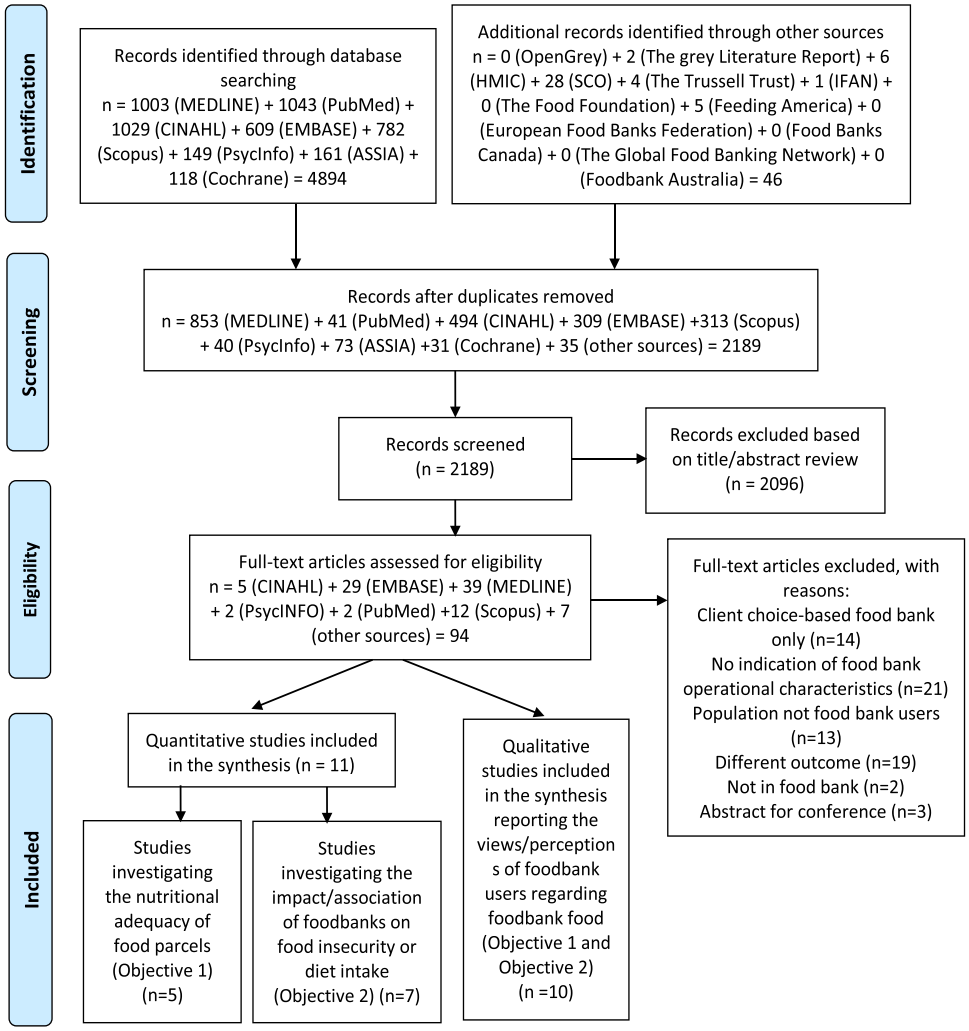

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart outlining the study selection process for inclusion in the mixed-method systematic review[71]

findings using configurative analysis. Mixed-method synthesis was presented narratively and relevant outcomes, limitations, and recommendations were discussed.

RESULTS

Figure 1 details the study selection process. After removing duplicates, a total of 2189 records were identified. Following title and abstract screening, the full texts of 93 articles were reviewed for inclusion. No additional studies were identified through reference searching. Twenty-one studies met the inclusion criteria, including 11 quantitative studies,[59,61,62,79,81–87] and 10 qualitative studies.[57,63–65,88–93]

Quantitative study characteristics

Of 11 quantitative studies published from 2016 to 2020, three were randomised-controlled trials (RCTs)[84,86,87]; two were pre–post studies,[81,83] and six were cross-sectional studies[61,62,82,85,59,79]. Six studies were conducted in the USA,[59,84,85,87,89,91] two in England,[61,79] two in the Netherlands,[62,86] and one in Israel[82] (Tables 2–3).

Five studies investigated the nutritional adequacy of 563 food parcels, from 45 food banks (Table 2). All five studies compared mean nutritive values with national guidelines, controlled by household size, and four controlled analysis by intended days of parcel use, ranging 2–9 days.[61,62,82] One pre–post study, evaluating an intervention to improve parcel quality, analysed up to 2000 kcals from parcels.[81] Outcomes varied: all five reported energy and macronutrients; four reported micronutrients[61,79,81,82]; three reported food groups[62,81,82]; and one reported nutritional quality.[82] Three studies calculated the days parcels provided sufficient energy or nutrients,[61,62,79] andone study also assessed the percentage of parcels meeting household requirements[82] (Table 2).

Seven studies explored the effect of food banks on food insecurity or diet (Table 3). All seven studies

TABLE 2 The characteristics and findings of the five quantitative studies that were included in the systematic review and investigated the nutritional adequacy of food parcels provided by food banks (objective 1)

Study characteristics					Methodology		Outcomes			
Citation	**Location**	**Study design**	**Sample size**	**Population**	**Aim/intervention**	**Data collection and analysis**	**Food parcel**	**Diet**	**Other**	**Key findings**
Fallaize et al. (2020)[61]	England, Oxfordshire Food banks (prepackaged)	Cross-sectional	Food banks: *n* = 10 Food parcels: *n* = 11	NA	To investigate the nutritional adequacy of single-adult food parcels	Food bank manager questionnaire. Researchers collect contents and input into dietplan7 Controlled for recommended days of parcel use (4–9), mean nutritive values compared with UK adult DRVs *t*-test	Nutrients and energy: E, F, Sf, Uf, P, C, S, Fi, Sa, Na, K, Ca, Mg, Po, Fe, Cu, Zn, Se, I, Va, Vd, Th, Ni, Vb6, Fo, Vb12, Vc	NA	Days food parcels could provide sufficient energy Independent foodbanks compared to Trussell Trust foodbanks	Nutrients and energy: mean weighted F met DRV and E, P, C, S, Fi and Sa significantly exceeded DRVs ($p < 0.05$); providing 138%, 220%, 170%, 277%, 238%, and 180% DRVs, respectively. Carbohydrates provided greatest percentage of energy per parcel (62.2%) significantly exceeding DRV (50%, $p < 0.001$). All micronutrients significantly exceeded DRVS ($p < 0.05$), other than selenium meeting DRV, and Vd and Va, meeting 25% and 27% of DRVs, respectively Ideal days: food parcels provided adequate energy beyond recommended days, ranging 4–9 days Independent vs. Trussell Trust: no differences in nutritional quality, other than mean Vd and Cu, where significantly less of these nutrients was provided in Trussell Trust parcels ($p < 0.05$)
Hughes and Prayogo (2018)[79]	England, London Food banks (prepackaged)	Cross-sectional	Food banks: *n* = 5 Food parcels: *n* = 71	NA	Nutritional analysis of single-adult food parcels	Photographs of food parcel contents, data inputted into dietplan7 Controlled for recommended days of parcel use (3), mean nutritive values compared with UK adult RNIs	Nutrients and energy: E, P, C, F, S, Sf, tf, Sa, Na, K, Ca, Mg, Fe, Cu, Zn, Se, I, Va, Vc, Ve, Th, Ri, Ni, Vb6, Vb12, Fo	NA	Ideal number of days food parcels could provide sufficient energy and nutrients Impact of removing items on sugar content	Nutrients and energy: Parcels exceeded 100% of RNIs for E, P, C, S, Sa, minerals, trace elements and all vitamins, other than Vd and Ve, which were below 100% of RNIs. Fat was also below nutritional recommendations Ideal days: parcels could provide sufficient P for 6 days and E for 5 days; however, nutrients (Fe, Vc, Vd, Ve, and Fo) would be below recommendations Removing items: removing sugar, jam and preserves, biscuits, or apple juice, reduced S by over 10%

(Continues)

TABLE 2 (Continued)

Study characteristics					Methodology		Outcomes			
Citation	**Location**	**Study design**	**Sample size**	**Population**	**Aim/intervention**	**Data collection and analysis**	**Food parcel**	**Diet**	**Other**	**Key findings**
Long et al. (2019)[81]	USA, Northwest Arkansas Food pantries (prepackaged)	Pre–post	Food banks: n = 3 Food parcels: n = 123 (pre), n = 172 (post) Food bank users: n = 123 (pre), n = 172 (post)	Age (years): ≥18 Female: pre (99, 80.4%), post (109, 63.4%)	Evaluate an intervention aiming to improve the nutritional quality of food parcels Intervention: food donation lists and informing donors, educational material for food bank users, discussing healthy foods	Foodbank user surveys; audit of food parcel items at baseline and 1 year Mean nutritive values of parcels per-household and per person Parcels controlled for maximum 2000 kcals of food and compared with US adult DRVs χ^2; t-test	Nutrients and energy: E, P, Na, C, Fi, S, F, Sf, Tf, Ch Food groups: Fresh fruit and vegetable servings	NA	NA	Nutrients and energy: from pre- to post-intervention, no nutrients changed per person. Mean E per household significantly increased (20,256.38 [SD 16,301.03] vs. 25,108.46 [SD 19,099.66], p = 0.009), but no significant change per person Up to 2000 kcals, mean food parcels exceeded P, C, Na, and Fi DRVs and were below F, Sf and Ch DRVs (both pre- and post-intervention) Food groups: from pre- to post-intervention, mean fruit and vegetable servings per person significantly increased (0.22 [SD 1.38] vs. 3.33 [SD 7.69], p < 0.001). Pre-intervention, fruit and vegetable servings were 99% apples; however, post-intervention, servings included strawberries (29.0%), tomatoes (13.6%), onions (13.5%), apples (10.6%), and others (33.2%)
Neter et al. (2016)[62]	Netherlands Food banks (prepackaged)	Cross-sectional	Food banks: n = 11 Food parcels: n = 96	NA	To assess the nutritional quality of food bank parcels	Standard scoring form – food items coded using Dutch food composition table code using measures, weights and Codes guide Controlled for recommended days of parcel use (2.5) and the intended number of users. Mean nutritive values compared with Dutch healthy diet nutritional guidelines and Dutch food composition table of food groups	Nutrients and energy: E, C, P, F, Uf, Fi Food groups: fruit, vegetable, fish. Dutch food composition food groups	NA	Ideal number of days that food parcels could provide sufficient energy, nutrients, fish, fruit, and vegetables for one adult	Nutrients and energy: mean E, P, and Sf exceeded nutritional guidelines and C met nutritional guidelines Food groups: mean fruit and fish were below, whereas vegetable content exceeded guidelines. Food (percentage of parcels including): bread and vegetables (100); pastry and cookies (96); nuts, seeds and snacks (95); sugar, candy, sweet filling, sweet sauces (90); milk, milk products (82); fats, oils and savoury sauces (78); fruits (76); meat, meat products and poultry (75); grains, flour, rice (69);

TABLE 2 (Continued)

Study characteristics				Population	Methodology		Outcomes			Key findings
Citation	Location	Study design	Sample size		Aim/intervention	Data collection and analysis	Food parcel	Diet	Other	
										potatoes (69); combined dish (55); cheese (52); soup (34); fish (27); soya and vegetarian (25); eggs (21); savoury fillings (17); legumes (8) Median amount (g) and IQR in parcels: bread (256 [156–398]); milk (358 [91–724]); meat (124 [6–228]); bread (256 [156–398]); vegetables (247 [168–455]); potatoes (143 [0–245]); fish (0 [0–22]); soya and vegetarian (0 [0–1]); eggs, legumes (0) Ideal days: Nutrient (days could last): E (4.4–6.2); P (6.4–11.3); C (3.1–7.8), Fi (3.1–1.4); F (3.7–10.5); fish (1.7); fruit (1.2), vegetables (3.7)
Philip et al. (2018)[82]	Israel Food pantries (prepackaged)	Cross-sectional	Food banks: n = 16 Food parcels: n = 90 Food bank users: n = 105	Mean age (SD): 52.1 (14.5) Female: 81 (77.1%)	To assess the nutritional quality of food parcels and the association between food parcel quality and their users dietary quality and food security	Telephone survey with food bank users; staff-reported food parcel items Based on weekly parcel provision and controlled for household size, age and gender. Mean nutritive values compared to weekly USA RDAs and energy and portions recommended by the National Nutrition Security CouncilUnivariate analysis; χ^2 test; t-test; one-way ANOVA	Nutrients and energy: E, P, Fi, Ca, Fe, Mg, Va, Ve, Vd, Vc, Th, Ri, Ni, pa, vb6, Fo, and Vb12 Nutritional quality: HPS; NDS Food groups: fruit and vegetable portions	FFQ for HPS and NDS	Percentage of parcels meeting weekly household RDAs	Food parcel nutrition (objective 1): nutrients and energy: mean parcels provided 29.6% E, 54.9% P, 49.9% Fi recommendations; 1.1%, 11.1%, 11.1% of parcels met household E, P, Fi requirements, respectively. Mean parcels exceeded Va, Ri, Fo, and Vb12 recommendations, but were insufficient in Ca, Fe, Ve, Vd, Th, Ni, Pa, and Vb6. No parcels met weekly household Vd and Ca requirements Nutritional quality: Mean parcel HPS and NDS were 20 (SD 20.3) and 0.3 (SD 0.3), respectively. Mean parcels provided 36.4% of recommended total portions and 14.4% of parcels met household portion guidelines Food groups: Mean parcels provided 87% of recommended fruit and vegetable portions, with 25%

(Continues)

TABLE 2 (Continued)

Study characteristics					Methodology		Outcomes			
Citation	**Location**	**Study design**	**Sample size**	**Population**	**Aim/intervention**	**Data collection and analysis**	**Food parcel**	**Diet**	**Other**	**Key findings**
										of parcels meeting fruit and vegetable portions Food bank effectiveness (objective 2): dietary quality: food parcel nutritional quality (HPS) positively correlated with diet quality (NDS), both before and after adjusting for gender, marital status and country of birth (Standardized: $\beta = 0.22$, $p = 0.03$. Overall model: $R^2 = 0.18$, $F = 4.65$, $p < 0.01$)

Note: Dutch food composition groups: bread, non-alcoholic beverages, vegetables, pastry and cookies, nuts, seeds and snacks, sugar, candy, sweet filling and sweet sauces, fruits, meat and poultry, grains, flour and rice, potatoes, cheese, combined dish, cheese, soup, fish, soya and vegetarian products, eggs, savoury filling, legumes.[61] HPS: adherence to "Basic Healthy Food Basket Guidelines" established by the Government of Israel's National Nutritional Security Council and Ministry of Health. These guidelines define adequate portion sizes for each of five healthy food groups (whole grains, fruits, vegetables, protein-rich foods, fats and oils) and the recommended daily portions according to RR age and sex. HPS is a food-based score. Division of total healthy portions by total energy is meant to account for unhealthy foods in the diet so the HPS score increases as healthy portions in the diet increases but decreases with increasing total energy intake. The higher the score the higher the quality of food or diet.[82] NDS: degree to which the diet achieves the RDA for macronutrients and micronutrients, divided by the overall energy density of the food. A score of 1 indicates a food or diet that provides 100% of the RDA at the required energy intake; a score <1 indicates some degree of deficiency, and a score higher than 1 indicates possible excess.[82] Nutrient and energy outcomes key: E (energy), P (protein), C (carbohydrate), F (fat), Sf (saturated fat), Uf (unsaturated fat), Tf (trans fat), Ch (cholesterol), Fi (fibre), S (sugar), Sa (salt), K (potassium), Na (sodium) Ca (calcium), Fe (iron), Mg (magnesium), Po (phosphorus), I (iodine), Zn (zinc), Cu (copper), Se (selenium), Va (vitamin A), Ve (vitamin E), Vd (vitamin D), Vc (vitamin C), Vk (vitamin K), Th (Thiamine), Ri (Riboflavin), Ni (niacin), Ma (manganese), pa (pantothenic acid), vb6 (vitamin B6), Fo (folate), Vb12 (vitamin B12), FV (fruit and vegetables).

Abbreviations: DRV, dietary reference value; HPS, healthy portions score; IQR, interquartile range; NA, not applicable for the study or this systematic review; NDS, nutrient density score; RDA, recommended daily allowance; RNI, reference nutrient intake; SD, standard deviation.

TABLE 3 The characteristics and findings of the seven quantitative studies that were included in the systematic review which investigated the impact or association of food banks on the food insecurity or diet intake of food bank users (objective 2)

Study characteristics					Methodology		Outcomes				
Citation	**Location**	**Study design**	**Sample size**	**Population**	**Aims/intervention**	**Data collection and analysis**	**Food parcel**	**Food security**	**Diet**	**Other**	**Key findings**
Cheyne et al. (2020)[83]	USA, Oakland, California Food pantries (pre-packaged)	Pre–post	Food banks: n = 12 Food bank users: n = 192	Mean age (SD): 48.5 (12.7) years Female: 174 (90.6%) Condition: food bank user with prediabetes	To assess effectiveness of food bank-based intervention at improving food insecurity, diet intake and diabetes risk Intervention: monthly food parcels, text-based health promotion education; engagement messages	Participants completed survey at baseline and at 6 months χ^2test; t-test; Fisher exact tests	NA	USDA 6-item	Food groups: FRESH foods survey	Physical activity, general health, BMI, engagement in the intervention	Food security: after 6 months, percentage of participants reporting food insecurity decreased from 68.8% to 62.5% (Pearson χ^2 = 72.6, p < 0.001). Food groups: from pre–post, frequency of consumption of fruits and vegetables, whole grains, green salad, potatoes, nonfried vegetables, and cooked beans significantly increased, whereas consumption of sweetened drinks, fried potatoes, candy/chocolate, cookies and cakes significantly decreased ($p \leq 0.05$). Other: minutes of physical activity per week increased 95.6–145.1 (paired t-test = 4.05, p < 0.001). Percentage reporting health status as poor or fair declined 73.9–60.1% (Fisher exact = 39.19, p < 0.001). Mean BMI (32.4 kg/m^2) did not change
Ferrer et al. (2019)[84]	USA Food bank (prepackaged)	RCT	Food banks: n = 1 Food bank users: n = 58 (29 control, 29 intervention)	Age (mean): 34–72 (54) years Female: 36 (62%) Condition: HbA1c >9% and food insecure	To assess whether a food bank–primary care collaboration improves food security and diabetes control Intervention: 2× weekly provision of fresh and canned food parcels; nutrition education conducted by a	Outcome measurement at baseline and at 6 months Kernel density plots	NA	NA	Dietary quality: STC-Diet	HbA1c, BMI	Dietary quality: mean STC-Diet increased by 2.47 points (21-point scale) in intervention (95% CI = 1.42–3.52; Cohen's d = 1.10, p < 0.001). No significant difference in the STC-Diet in the controls. Other: mean baseline BMI and HbA1c were 32 kg/m^2 and 11%, respectively. Both decreased more in the intervention group, but differences were only significant for the outcome HbA1c, which decreased

(Continues)

TABLE 3 (Continued)

Study characteristics					Methodology		Outcomes				
Citation	Location	Study design	Sample size	Population	Aims/intervention	Data collection and analysis	Food parcel	Food security	Diet	Other	Key findings
					dietitian; health worker visits						−3.09% (95% CI = −4.04 to −2.13; Cohen's d = −0.516, p = 0.012)
Liu et al. (2019)[85]	USA,Indiana Food pantries (pre-packaged and client choice)	Cross-sectional	Food banks: n = 27 Food bank users: n = 270	Mean age (SEM): 45.7 (0.9) years Female: 149 (67%)	To determine the associations between food bank use and food security status with BMI, diet quality and chronic disease	Food bank user survey, interviewer assisted 24-h diet recall χ^2 test; least-squares means; logistic regression	NA	USDA 18-item	Dietary quality: ASA24-2014 for HEI-2010 total and compo-nent scores	Frequency food bank use (> once a month; < once a month), BMI, self-reported chronic disease; BMI; chronic disease	Dietary quality: visiting food banks > once a month showed significantly greater HEI-2010 total (44.1 [SD 3.9] vs. 38.9 [SD 3.7], p = 0.03), and greater protein component score (4.7 [SD 0.4] vs. 4.3 [SD 0.4], p = 0.05), compared with visiting foodbanks < once a month). Food security was not associated with HEI-2010
Mousa and Freeland-Graves (2019)[59]	USA, Central Texas Food pantries (pre-packaged)	Cross-sectional	Food banks: n = 10 Food bank users: n = 112	Mean age (SD): 50.91 (1.17) Female: 75 (67%)	To assess impact of 2× monthly food parcels on the total nutrient intake of foodbank users	Interview; FFQ to measure past months nutrient and food intake Daily nutrient intake of base diet, food parcel and total diet estimated. Percentage of nutrients and food groups in total diet and from food parcels. Compared with USA adult DRIs and 'Choose MyPlate' t-tests	NA	NA	Nutrients and energy: E, C, P, F, Sf, Uf, Tf, Ch, Fi, S, Va, Vd, Ve, Vk, Vc, Th, Ri, Ni, Vb6, Fo, Vb12, Ca, Po, Mg, Fe, Zn, Cu, Ma, Se, Na, and K Food groups: 'choose MyPlate'	Weight and monthly value ($) of food parcel items (per person and household)	Nutrients and energy: base diets were below DRIs for C, Fi, F and all vitamins and minerals, except Vb12 and Na, which exceeded DRIs. After food parcels, total daily diet exceeded DRIs of E, P, F, Ch, Th, Ri, Ni, Vb6, Fo, Po Vb12, Zn, Cu, Ma, Se, and Na. After food parcels, significant increases in: E, C, P, F, Ch, Fi, S, Va, Vk, Vc, Ni, Fo, Vb12, Ca, Po, Mg, Fe, Zn Se Na, and K (p < 0.05) Food parcels provided >40% of DRI for: macronutrients, E, Fi, Vc, Ri, Vb6, Vb12, Fe, Zn, Na, Po, Cu, and Se Food groups: food parcels provided >50% of whole grains, fruit, vegetable, dairy, protein, and meat portions, contributing significantly to total diet ($p \leq 0.05$). Total diets lacked whole grains and dairy

TABLE 3 (Continued)

Study characteristics					Methodology		Outcomes				
Citation	Location	Study design	Sample size	Population	Aims/intervention	Data collection and analysis	Food parcel	Food security	Diet	Other	Key findings
Neter et al. (2020)[86]	Netherlands Food banks (pre-packaged)	RCT	Food banks: $n = 3$ Food bank users: $n = 163$ (56 control, 28 − snacks, 25 + FV, 54 − snacks + FV)	Mean age (SD): 45.1 (10.8) years Female: 111 (68.1%)	To assess if improving the diet quality of food parcels positively impacts diet intake Intervention: crossover RCT of 10 possible sequences. Weekly provision of food parcels (control parcel,[a] −snacks, +FV, −snacks +FV) in two consecutive 4-week periods	Baseline socio-demographic questionnaire and 24-h diet recall using USDA MPM at baseline, 4 weeks (T1) and 8 weeks (T2) Multi-level linear regression analysis	NA	NA	Nutrients and energy: E, P, F, Sf, S, Fi, Vc, Na, and KFood groups: fruit and vegeta-bles; grains, flour, rice; nuts, seeds, and snacks; pastry and cookies; pulses; sugar, candy, sweet filling, and sweet sauces	NA	Nutrients and energy: In +FV and −snacks + FV, mean daily C, S, fi were significantly higher, whereas F was significantly lower, compared with controls ($p < 0.05$). In −snacks + FV, mean daily Vc and K were significantly higher compared with controls and −snacks ($p < 0.05$). Food groups: mean daily intake of fruit was significantly greater in + FV and −snacks + FV interventions compared with controls. Intake of vegetables was significantly higher in −snacks + FV compared with controls Intake of pulses was significantly higher in −snacks than controls and −snacks + FV ($p < 0.05$)
Philip et al. (2018)[82]	Israel Food pantries (pre-packaged)	Cross-sectional	Food banks: $n = 16$ Food parcels: $n = 90$ Food bank users: $n = 105$	Mean age (SD): 52.1 (14.5) years Female: 81 (77.1%)	To assess the nutritional quality of food parcels and the association between food parcel quality and their users' dietary quality	Telephone survey with food bank users; staff-reported food parcel items Based on weekly parcel provision and controlled for household size, age and gender. Compared with USA RDAs Univariate analysis; χ^2 test; t-test; one-way ANOVA	Nutrients: E, P, Fi, Ca, Fe, Mg, Va, Ve, Vd, Vc, Th, Ri, Ni, pa, vb6, Fo, and Vb12. Nutritional quality: HPS; NDS Food groups: fruits and vege-tables	NA	Dietary quality: FFQ to devise HPS; NDS	Percentage of parcels meeting weekly household dietary require-ments	Food parcel nutrition (objective 1): nutrients and energy: mean parcels provided 29.6% E, 54.9% P, and 49.9% Fi recommendations. 1.1%, 11.1%, 11.1% of parcels met household E, P, and Fi requirements, respectively. Mean parcels exceeded Va, Ri, Fo, and Vb12 recommendations, but were insufficient in Ca, Fe, Ve, Vd, Th, Ni, Pa, and Vb6. No parcels met weekly household Vd and Ca requirements Nutritional quality: mean parcel HPS and NDS were 20 (SD 20.3) and 0.3 (SD 0.3),

(Continues)

TABLE 3 (Continued)

Study characteristics					Methodology		Outcomes				
Citation	Location	Study design	Sample size	Population	Aims/intervention	Data collection and analysis	Food parcel	Food security	Diet	Other	Key findings
											respectively. Mean parcels provided 36.4% of recommended total portions and 14.4% of parcels met household portion guidelines Food groups: mean parcels provided 87% of recommended fruit and vegetable portions, with 25% of parcels meeting fruit and vegetable portions Food bank effectiveness (objective 2): dietary quality: food parcel nutritional quality (HPS) positively correlated with diet quality (NDS), both before and after adjusting for gender, marital status, and country of birth (Standardized: $\beta = 0.22$, $p = 0.03$. Overall model $R^2 = 0.18$, $F = 4.65$, $p < 0.01$)
Seligman et al. (2018)[87]	USA Food pantries (pre-packaged)	RCT	Food banks: $n = 27$ Food bank users: $n = 568$ (285 intervention, 285 control)	Mean age (±SD): 55 (±11.4) years Female: 384 (68.3%) Condition: food bank user with HbA1c ≥7.5%	To investigate the effectiveness of a foodbank-based diabetes intervention Intervention: diabetes self-management education; 2× monthly food parcels Randomised into intervention or waitlist control	Participant survey and HbA1c at baseline and 6 months χ^2test; *t*-test; Wilcoxon rank sums test	NA	USDA 6-item	Food groups: fruit, vegetable, and sugar intake (California health interview survey)	Food instability; HbA1c; self-management; satisfaction	Food insecurity: at baseline, 75.5% of participants were food insecure. Intervention participants had significant improvements in food security compared with controls (60% vs. 69.4%, RR = 0.85, 95% CI = 0.73, 0.98, $p = 0.03$) Food groups: intervention participants had significant increase in fruit and vegetable servings compared with controls (4.2 vs. 3.9, RD = 0.34; 95% CI = 0.34, 0.34, $p = 0.04$). No significant differences in sugar intake Other: food instability significantly decreased in interventions, compared

TABLE 3 (Continued)

Study characteristics					Methodology		Outcomes				
Citation	Location	Study design	Sample size	Population	Aims/intervention	Data collection and analysis	Food parcel	Food security	Diet	Other	Key findings
											with controls (54.9% vs. 70.2%, RD = 0.34; 95% CI = 0.34, 0.34, p = 0.01). No other outcomes differed; 80% preferred the food parcel compared with usual food offered

Note: Choose MyPlate: developed by USDA to determine serving size equivalents for food groups (vegetables, fruits, refined and whole grains, milk and dairy products, beans and meat, and empty calories (solid fats, added sugars and alcohol).[59] HEI-2010: higher scores indicate better diet quality. HEI-2010 total score is the sum of 12 component scores.[85] HPS: adherence to "Basic Healthy Food Basket Guidelines" established by the Government of Israel's National Nutritional Security Council and Ministry of Health. These guidelines define adequate portion sizes for each of five healthy food groups (whole grains, fruits, vegetables, protein-rich foods, fats and oils) and the recommended daily portions according to RR age and sex. HPS is a food-based score. Division of total healthy portions by total energy is meant to account for unhealthy foods in the diet so HPS score increases as healthy portions in the diet increases but decreases with increasing total energy intake. The higher the score the higher the quality of food or diet.[82] NDS: degree to which the diet achieves the RDA for macronutrients and micronutrients, divided by the overall energy density of the food. A score of 1 indicates a food or diet that provides 100% of the RDA at the required energy intake; a score <1 indicates some degree of deficiency, and a score higher than 1 indicates possible excess.[82] Nutrient and energy outcomes key: E (energy), P (protein), C (carbohydrate), F (fat), Sf (saturated fat), Uf (unsaturated fat), Tf (trans fat), Ch (cholesterol), Fi (fibre), S (sugar), Sa (salt), K (potassium), Na (sodium) Ca (calcium), Fe (iron), Mg (magnesium), Po (phosphorus), I (iodine), Zn (zinc), Cu (copper), Se (selenium), Va (vitamin A), Ve (vitamin E), Vd (vitamin D), Vc (vitamin C), Vk (vitamin K), Th (Thiamine), Ri (Riboflavin), Ni (niacin), Ma (manganese), pa (pantothenic acid), vb6 (vitamin B6), Fo (folate), Vb12 (vitamin B12), FV (fruit and vegetables). STC-Diet: 7-item diet assessment for intake of: fruit/vegetables, fast food, chicken/fish/beans, chips/crackers, soda, sweets, and butter. Items are scored 1–3 and a higher score indicates better diet quality.[84] USDA MPM: developed for collecting interviewer-administered 24-h recalls and includes multiple passes through the 24-h of the previous day, during which respondents receive cues to help them remember and describe foods and drinks they consumed. Interviewers also asked participants whether the recall day was a normal day regarding dietary intake (yes/no) and a portion size photo booklet assisted in portion-size estimation of foods and drink consumed.[86] USDA 6-item: questions are about the food eaten in your household in the last 12 months.[83]

Abbreviations: ASA24-2014, automated self-administered 24-h recall version 2014[85]; BMI, body mass index; CI, confidence interval; DRI, dietary reference intake; HEI-2010, Healthy Eating Index-2010; HPS, healthy portions score; NA, not applicable for the study or this systematic review; NDS, nutrient density score; RD, risk difference; RDA, recommended daily allowance; RCT, randomised controlled trial; RR, relative risk; SEM, standard error of the mean; SD, standard deviation; STC-Diet, starting the conversion-Diet; USDA MPM, USDA five-step multiple-pass method (MPM); USDA 6-item, the United States Department of agriculture 6-item questionnaire for food security.

[a]Control parcel (standard food bank specific food parcel with additional non-food items [e.g. personal care products, blanket]). −Snacks (standard food bank specific food parcel in which unhealthy snacks [e.g. chocolate, cookies, potato chips]) were replaced by staple foods (e.g. pasta, rice), with additional non-food items (e.g. personal care products, blanket), +FV (standard food bank specific food parcel plus recommended daily amount of fruit [2] and vegetables [200 g] for all household members for 7 days), −snacks + FV (standard food bank specific food parcel in which unhealthy snacks [e.g. chocolate, cookies, potato chips]) were replaced by staple foods (e.g. pasta, rice) plus the recommended daily amount of fruit (2) and vegetables (200 g) for all household members for 7 days.[86]

TABLE 4 Characteristics of the 10 qualitative studies included in the mixed-method systematic review

Study characteristics				Methodology	
Citation	**Location (country, area, foodbank)**	**Sample size**	**Population**	**Aim/phenomena of interest**	**Method of data collection**
Douglas et al. (2020)[57]	Scotland Food bank (pre-packaged) and food pantry (client choice)	Foodbank: *n* = 1 Foodbank users: *n* = 20	Age range (mean): 23–83 (53) years Female: 9 (45%): 6 food bank, 3 food pantry Inclusion: physical or mental health condition/s	What challenges face food insecure people affected by a long-term health condition as far as their self-care/management practices are concerned; what issues they encountered in disclosing and discussing the experience of managing their health condition with a third party such as a health care professional; and what sort of support they would wish from a health care professional	Semi-structured interviews
Douglas et al. (2015)[63]	Scotland Food bank (pre-packaged)	Foodbank: *n* = 1 Foodbank users: *n* = 7	Age range: 25–50 years Female: 2 (28.6%)	Factors that caused individuals to seek food aid from the food bank; strategies food bank clients use to try to reduce or mitigate household food insecurity; what they thought of the food they received from the food bank; and how they were incorporating it in their diets	Participant observation and semi-structured interviews
Enns et al. (2020)[88]	Canada, Ottawa Food banks (pre-packaged and client choice)	Food banks: *n* = 11 (8 prepackaged; 3 client choice) Food bank users: *n* = 29	Age range (mean): 21–67 (45) years Female: 13 (44.8%)	To explore experiences of food insecurity and accessing food banks over time and investigate the perceived impact of food banks on the participants' lives	Semi-structured interviews at baseline and 6 months
Garthwaite et al. (2015)[64]	England, Stockton-on-Tees Food bank (prepackaged)	Food bank: *n* = 1 Food bank users: *n* = 42	Age range: 18–60 years Female: 20 (47.6%)	To examine the relationship between ill health and food insecurity among food bank users in the UK	Participant observation and semi-structured interviews
Greenthal et al. (2019)[89]	USA Food pantry (prepackaged)	Foodbank: *n* = 1 Foodbank users: *n* = 30	Age category (*n*): <50 (7), 50–66 (16), >65 (7) years Female: 20 (67%) Inclusion: hospital patients used food pantry at least once	To identify strengths and opportunities for improvement in programme functioning and common aspects of patients' experiences at a hospital-based food bank	Semi-structured interviews
Hardcastle and Caraher (2021)[90]	Australia, Perth Food bank (pre-packaged)	Foodbank: *n* = 1 Foodbank users: *n* = 33	Mean age (SD): 44.12 (13.74) Female: 25 (76%)	To investigate the perceptions of food received by users attending a food bank, and, to better understand household food choices	Semi-structured interviews
Lee et al. (2020)[91]	Canada, Food bank (prepackaged)	Food bank: *n* = 1 Foodbank users: *n* = 9	Age range: ≥18 years Female: 4 (44.4%) Inclusion: students used university food bank at least once in past year	To summarise the experience of food insecurity among students attending a Canadian university food bank who were caring for children	Semi-structured interviews

TABLE 4 (Continued)

Study characteristics			Methodology		
Citation	Location (country, area, foodbank)	Sample size	Population	Aim/phenomena of interest	Method of data collection
McKay et al. (2018)[92]	Australia, Melbourne Food bank (prepackaged)	Foodbank: n = 1 Foodbank users: n = 70	Age category (n): <30 (29), 31–40 (24), 41–50 (11), ≥50 (6) years Female: 18 (25.7%) Inclusion: asylum seekers used a food bank at least twice in past year, but no longer	To explore the experiences of asylum seekers who were entitled to use a foodbank but who had ceased attending the service, to understand why they were not using the charity, and to investigate their food-related experiences	Telephone interviews closed and open-ended questions
Neter et al. (2020)[65]	Netherlands Food banks (prepackaged)	Foodbank: n = 7 Food bank users: n = 44	Age range: 20–64 years Female: 22 (50%)	To gain insight in Dutch foodbank recipients' perception on the content of the food parcels, their dietary intake and how the parcels contribute to their overall dietary intake	Semi-structured focus groups of 2–6 people
Remley et al. (2019)[93]	USA Food pantries (prepackaged)	Foodbank: not reported. Foodbank users: n = 612	Age category (%): 18–34 (18.8%), 35–54 (37%), ≥55 (44.2%) years Female: 435 (71.1%)	To determine whether clients self-reporting chronic health conditions in their households have unique perceptions about food banks and their ability to meet needs	Survey of closed and open-ended questions

investigated the impact or association of food banks on the diets of 1513 users across 96 food banks (Table 3). One study also included client-choice food banks in addition to pre-packaged parcels.[85] Dietary outcomes varied: four studies reported food groups;[59,83,86,87] two reported energy and nutrients;[59,86] and two assessed dietary quality.[84,85] Three studies evaluated the impact of 6-month food bank based diabetes interventions, including monthly or twice monthly food parcel provision, on food bank users with diabetes or prediabetes.[83,84,87] One study evaluated an 8-week intervention focused on improving the nutritional quality of food parcels.[86] Two studies investigated the impact of food banks on the food security of 760 food bank users across 39 food banks[83,87] (Table 3). One of these studies was a pre–post design[83] and the other study was a RCT.[87] Both studies were food bank-based diabetes interventions.[83,87]

Qualitative study characteristics

Of 10 qualitative studies published from 2015 to 2021, three were conducted in the UK[57,63,64]; two in the USA,[89,93] two in Canada[88,91]; two in Australia[90,92]; and one the Netherlands.[65] The sample size ranged from 7 to 612, totalling 896 participants (63.4% female) (Table 4). One study recruited participants suffering health conditions,[57] another focused on Australian asylum seekers,[92] one explored a hospital-based food bank,[89] and two studies included client-choice food banks in addition to prepackaged parcels.[57,88]

Five studies investigated users' perceptions regarding food bank food.[63,65,90,92,93] The remaining five studies investigated food bank users experiences, which included views on the food provided.[57,64,88,89,91] Methodologies varied: one study administered a survey,[93] one used focus groups,[65] one used telephone interviews,[98] and seven used semistructured interviews,[57,63,64,88–91] of which two included participant observation[63,64] (Table 4).

Methodological quality

Results from the methodological quality assessment of the quantitative and qualitative studies included are presented below.

Quantitative studies

All three RCTs scored 7/13 using the JBI Critical Appraisal Checklist for RCTs (Table 5). The nature of the interventions meant blinding was challenging. Two studies did not describe losses at follow up or measure food bank use in controls[84,87] and one did not detail randomisation[86] (Table S4). Both quasi-experimental studies scored 4/9 using the JBI Critical Appraisal Checklist for Quasi-Experimental Studies (Table 5). Quality was limited by self-reported

TABLE 5 Critical appraisal results for the 10 quantitative studies included

JBI Critical Appraisal Checklist for Randomised Controlled Trials						
Citation	**Ferrer et al. (2019)[84]**		**Neter et al. (2020)[86]**		**Seligman et al. (2018)[87]**	
Overall score	7	7	7			
JBI Critical Appraisal Checklist for Quasi-Experimental Studies (nonrandomised experimental studies)						
Citation	Cheyne et al. (2020)[83]				Long et al. (2019)[81]	
Overall score	4				4	
JBI Critical Appraisal Checklist for Analytical Cross-Sectional Studies						
Citation	Philip et al. (2018)[82]	Fallaize et al. (2020)[61]	Hughes and Prayogo (2018)[79]	Liu et al. (2019)[85]	Mousa and Freeland-Graves (2018)[59]	Neter et al. (2016)[62]
Overall score	6	7	4	8	4	7

Note: Higher scores demonstrate higher quality, with maximum scores of: RCT, 13; quasi-experimental, 9; and cross-sectional, 9.[95,96]
Abbreviations: JBI, Joanna Briggs Institute; RCT, randomised-controlled trial.

outcomes, not considering additional exposures, and the precluded pre–post designs controls [81,83] (Table S4).

Scores of the six cross-sectional studies ranged from 4 to 8 using the JBI Critical Appraisal Checklist for Analytical Cross-Sectional Studies (Table 5). Five studies used standardised methods to assess outcomes, excluding Hughes and Prayogo's study where the inclusion criteria and methodology lacked detail[79] (Table S4). One study did not identify and consider confounders.[59] Another study was limited by self-reported exposure.[82]

Qualitative studies

The 10 qualitative studies were deemed as good quality, with congruity between the methodology, analysis, and interpretation. Scores ranged from 7 to 10 the JBI Critical Appraisal Checklist for Qualitative Research (Table 6). All studies used thematic analysis, reporting verbatim quotes. The lower scores were explained by the philosophical premises being unstated and researcher influence being unaddressed[89,92] (Table S4).

Quantitative findings

Below is a narrative summary of the data from the 11 quantitative studies that were included. The findings are presented based on common outcomes for each objective of this systematic review.

Nutritional quality of food parcels

The quantitative findings of the first objective of this review, to investigate the nutritional quality of food parcels compared with adult nutritional requirements, are presented below.

Nutritional quality

The one study investigating the overall nutritional quality of food parcels reported a mean Nutrient Density Score of 0.3 (SD 0.3). A score below 1 indicates a relative deficiency in macronutrients and micronutrients.[82]

Food groups

Three studies assessed FV content[62,81,82] (Table 2). One study found that a mean number parcels provided 87% of recommended FV portions, with 25% of parcels meeting requirements.[82] In the pre–post study, mean FV servings per person were 3.33 (SD 7.690), increasing significantly from 0.22 (SD 1.38, $p < 0.001$).[81] Preintervention, 99.9% of FV servings were apples; postintervention, parcels also included strawberries, tomatoes, onions, and other FV.[81] These were considered separately by Neter et al. (2016), who found mean weighted fruit was below (97 g [SD: 1441 g]), whereas vegetables exceeded (295 g [SD: 2700 g]) guidelines. Moreover, FVs were adequate for 1.2 and 3.7 days, respectively.[62]

Neter et al. (2016) investigated other foods, including mean weight of fish, which was below guidelines (23 g [SD: 640 g]), and lasted 1.7 days.[62] The most prevalent foods were bread, vegetables, pastries, and cookies, whereas vegetarian products, eggs, and legumes were least prevalent (Table 2).

Energy

Of five studies reporting energy, requirements were exceeded in four.[61,62,79,81] In contrast, Philip et al. (2018) found that a mean of parcels met 29.6% of recommendations, with 1.1% meeting requirements.[82] Considering ideal days of use, energy was sufficient beyond recommended, ranging from 4–9 (recommended 3–5),[61] 4.4–6.2 (recommended 2.5),[62] and 4–5

TABLE 6 Critical appraisal results for the 10 included qualitative studies

Citation	*JBI Critical Appraisal Checklist for Qualitative Research*										
	Le et al. (2020)[58]	Douglas et al. (2015)[63]	Enns et al. (2020)[88]	Garthwaite et al. (2015)[64]	Greenthal et al. (2019)[89]	Hardcastle and Caraher (2021)[90]	Lee et al. (2018)[91]	McKay et al. (2018)[92]	Neter et al. (2020)[65]	Remley et al. (2019)[93]
Overall score	10	10	8	10	7	10	8	7	10	8

Note: Higher scores demonstrate higher quality, with a maximum score of 10.[81]
Abbreviation: JBI, Joanna Briggs Institute.

(recommended 3).[79] The pre–post study saw no changes in mean energy per person ($p = 0.44$).[81]

Nutrients

Four of the studies reporting macronutrient content found protein and carbohydrates met or exceeded recommendations[61,62,79,81]; however, one study found that parcels were below requirements.[82] When calculating ideal days of parcel use, protein was sufficient for 6–11.3 days, although other nutrient deficiencies were present [62,79] (Table 2). One study revealed that carbohydrates contributed the greatest proportion energy in the parcels (62.2% [SD: 5]), which is significantly greater than recommended (50%, $p < 0.001$).[61] In the two studies reporting sugar content, recommendations were exceeded.[61,79] Fat content varied across studies (Table 2).

Of the four studies reporting mean micronutrient content, parcels generally exceeded or met recommendations,[61,79,81,82] however this included salt and sodium exceeding requirements in the three studies reporting these.[61,79,81] In contrast, vitamin D was insufficient in the three studies assessing this,[61,79,82] and insufficiencies, including vitamin E, vitamin A, calcium, and iron, were found across other studies (Table 2). Philip et al. (2018) found that no parcels met calcium or vitamin D requirements.[82] Nutrient content did not change in the pre–post study design.[81]

Effectiveness of food banks on food insecurity

The quantitative findings of the second objective of this review, to investigate the effectiveness of food banks at improving the food insecurity and dietary intake of food bank users, are presented below.

Food insecurity

Studies investigating the impact of food banks on insecurity found improvements at 6 months.[83,87] In the pre–post study, food insecurity significantly decreased from 68.8 to 62.5% (Pearson $\chi^2 = 72.6$, $p < 0.001$).[83] In the RCT, 74.5% of participants were food insecure at baseline, with food insecurity significantly decreased in interventions, compared with controls (60% vs. 69.4%, 0.85 [0.73, 0.98] [RR (95% CIs)], $p = 0.03$).[87]

Dietary intake

The included articles that investigated the effectiveness of food banks at improving dietary intake of food bank users are presented as findings from the cross-sectional and intervention studies.

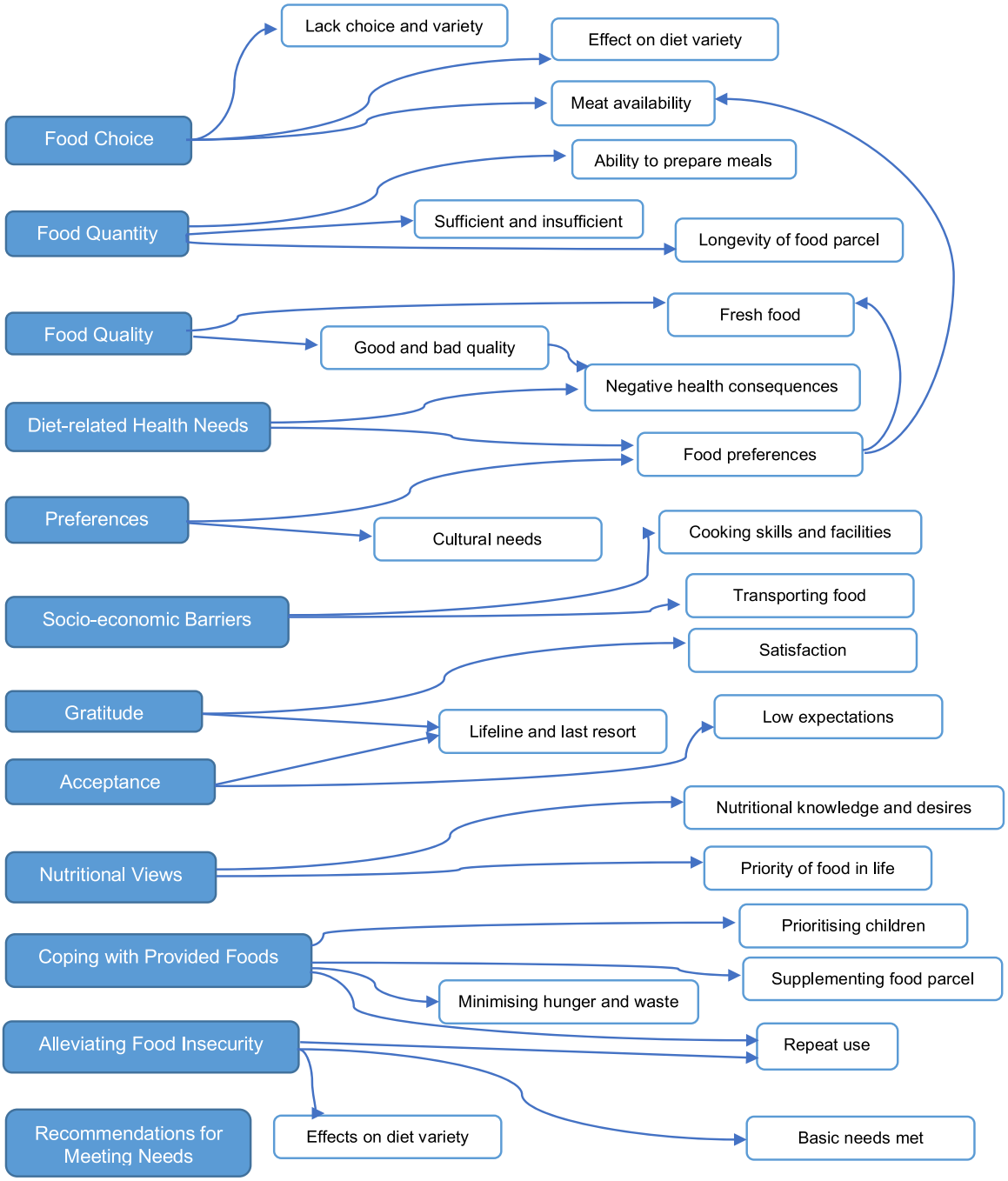

FIGURE 2 The 12 descriptive themes (blue) and codes derived by line-by-line coding of the 10 qualitative studies included in the systematic review. The themes and codes are reflective of the views of food bank clients regarding whether food banks meet their nutritional needs

Cross-sectional studies

Food parcel quality and dietary quality were positively correlated (standardised β = 0.22, p = 0.03)[82]; also, visiting food banks over once-per-month was associated with significantly higher dietary quality scores, compared with visiting under once-per-month (4.1 [SD: 3.8] vs. 38.9 [SD: 3.7], p = 0.03).[85] Mousa and Freeland-Graves (2019) found over 40% of nutrient and food group intake was attributed to food parcels, allowing insufficiencies to meet recommendations.[59] However, intake exceeded energy and fat yet lacked whole grains and dairy.[59]

Intervention studies

Improving the nutritional quality of food parcels by adding FV and removing nutrient-poor snacks significantly improved FV, vitamin C, and potassium

TABLE 7 The five analytical themes that were inferred from the 12 descriptive themes, including practice recommendations and illustrations

	Analytical themes
1	Limited food options, particularly fresh foods and meat; and inadequate quantity to make meals and for families, limits food parcels ability to meet their users' nutritional requirements. Increasing food variety is recommended
	'*Not a lot of meat options, lacking in fresh produce and dairy*' (Remley et al., 2019)
	'*The problem is the food isn't worth it. We aren't interested in those foods. Food offered is not enough quantity or type of food they we interested in, for example canned food are not appropriate*' (Mckay et al., 2018)
	'*We have to live from the parcel with five people, that is impossible. It is very meagre*'; '*Not all ingredients are always there for a complete meal*' (Neter et al., 2020)
	'*There have been times when the fridge and cupboards were pretty bare despite going to the food bank*' (Lee et al., 2020)
2	Food bank users recognise healthy eating; however, it is not prioritised, thus gratitude for food, regardless of its nutritional value, is apparent. Implementing consistent nutritional guidelines at food banks is advised
	'*I know enough about that, what I should be eating but you can't always manage to do it*' (Garthwaite et al., 2015)
	'*The choices available are what they are and I must accept and choose what is available*'; '*You don't get a ton of choices, but hunger makes any choice great*' (Remley et al., 2019)
	'*Well, in this crisis, I think that you just have to accept what you eat…you can't change anything*' (Neter et al., 2020)
3	Prepackaged food parcels prevent the food from meeting health, cultural and social dietary needs. Therefore, providing choice for individual preferences is essential for mitigating food insecurity
	'*I found some foods that I didn't really use because I am Hindu and we didn't eat beef and sometimes like canned food or the noodles or whatever they have beef flavours…*' (Lee et al., 2020)
	'*Since I became diabetic I can't eat 90% of the stuff they have there so it's not been that much help to me. The stuff they give out, I can't have*' (Enns et al., 2020)
	'*At the beginning we received sweet food, salty food. But I had to ask for a letter for them, about this item. No salted food, no sweet food*' (Greenthal et al., 2019)
	'*Well they give ya a lot of rice and they give ya a lot of vegetables… but if you're homeless like me it is not necessarily easy to cook those types of food*' (Douglas et al., 2015)
	'*They said how to cook it but I still ain't know how to do that and I said nope, I ain't doin' it*' (Greenthal et al., 2019)
4	Food banks are a lifeline; however, reports of out-of-date food and food bank users still acquiring socially-unacceptable strategies to reduce hunger (e.g. prioritising children, skipping meals), indicates absence of food security. Ensuring safe food, of sufficient quantity, is crucial
	'*So coming [to the food bank] by the end of the month is a key part of general surviving*' (Enns et al., 2020)
	'*It is there when we need it. At least we are not starving to death*' (Remley et al., 2019)
	'*Sometimes, the food, it's nearly expired which is scary*' (MacKay et al., 2018)
	'*I eat the least so I can spare food for the rest of my family*' (Greenthal et al., 2018)
	'*I feed my children first. If they are finished, I collect their leftovers in a Tupperware*' (Neter et al., 2020)
5	Food parcels can increase dietary quantity and/or quality. However, foodbanks are insufficient for alleviating hunger, particularly for repeat and multiple-person household users
	'*The content of the food parcel influences my dietary intake for 100%, because I completely rely on the food parcel*' (Neter et al., 2020)
	'*Times… when you just see yourself right on "E" [referring to 'empty'] or close to "E", you come in here twice a month and it lifts you right back up to where you need to be*' (Greenthal et al., 2019)
	'*It still isn't enough what [the food bank] gives you but you know I've got to make it last*' (Enns et al., 2020)
	'*If I am lucky less than two days… the amount that teenage boys eat, you can probably imagine*' (Hardcastle and Caraher, 2021)

intake.[86] Food bank based diabetes interventions also improved dietary intake.[83,84,87] Servings of FV significantly increased in interventions compared with controls (4.2 vs. 3.9, 0.34 [0.34–0.34] [RD (95% CIs)], $p = 0.04$).[87] Cheyne et al. (2020) similarly found FV consumption increased significantly postintervention (2.83 vs. 3.20, $p < 0.001$).[83] Assessing dietary quality, a significant improvement was seen in interventions (1.42–2.52 [95% CI] Cohen's $d = 1.10$, $p < 0.001$) compared with no change in controls.[84]

TABLE 8 A summary of the integrated mixed-method synthesis of the independent quantitative and qualitative study findings

Synthesised qualitative findings	Textual description of quantitative findings	Mixed-method synthesis with recommendations
1. Limited food options, particularly fresh foods and meat, and inadequate quantity to make meals and for families, limits food parcels ability to meet their users' nutritional requirements. Increasing food variety is recommended 2. Food bank users recognise healthy eating; however, it is not prioritised, thus gratitude for food, regardless of its nutritional value, is apparent. Implementing consistent nutritional guidelines at food banks is advised	Whether food parcels meet national nutritional requirements for nutrients and food groups is inconsistent. However, food parcels do typically exceed energy, carbohydrate, sugar, and salt recommendations, yet are often insufficient in fruit, vegetables and various micronutrients, including vitamin D, calcium and iron. An intervention aiming to improve food parcel nutrition increased fruit and vegetable variety	Nutritionally inadequate food parcels can be explained by the charitable nature of food banks, often limiting the variety and quantity of food options. Improving the nutritional quality of food parcels should focus on increasing food variety, such as increasing meat, fruit and vegetable content, along with implementing nutritional guidelines, to allow consistency
3. Pre-packaged parcels prevent food meeting health, cultural and social dietary needs. Therefore, providing choice for individual preferences is essential for mitigating food insecurity 4. Foodbanks are a lifeline; however, reports of out-of-date food and users still acquiring socially-unacceptable strategies to reduce hunger (e.g. prioritising children, missing meals, multiple food banks), indicates absence of food security. Ensuring safe food, of sufficient quantity, is crucial	Participation in food bank based diabetes interventions, including prepackaged parcels significantly improved the food insecurity status and dietary quality of food bank users with diabetes. However, the incidence of food insecurity was still greater than in the general populations	Food banks struggle to meet individual dietary needs and in socially acceptable ways, thus allowing food security is limited. Positive outcomes from diabetes-specific food parcels, and health-related dietary needs often unmet by food banks, supports benefit of tailoring food parcels to meet individual preferences
5. Food parcels can increase dietary quantity and/or quality. However, food banks are insufficient for alleviating hunger, particularly for repeat and multiple-person household users	Despite food parcels contributing significantly to users diets and improving the nutritional quality of parcels having been shown to positively influence diet intake, overall dietary quality often remains insufficient	As a sole intervention, food banks do not eliminate the heightened food insecurity and poor diets of food bank users. Continuing effort to reduce diet-related inequalities of food bank users is required, particularly among repeat and multiple-person household users

Qualitative synthesis

The qualitative findings were coded into 12 descriptive themes (Figure 2). Table S5 provides details of the descriptive themes with illustrations. Five analytical themes, including recommendations, were then inferred based on the two objectives of this review (Table 7).

Mixed-method synthesis

Based on the two objectives of this review, integrating the quantitative and qualitative findings explored whether they supported or contradicted each other. Furthermore, recommendations for practice and policy were devised (Table 8).

Whether parcels were nutritionally adequate varied across and within the quantitative and qualitative studies (Table 2; Figure 2). Cases of nutritional insufficiency were explained by qualitative reports of limited food quantity and variety.[63,88,90,91] The findings that sugar and salt exceeded requirements and FV were often insufficient,[62,63,79,81] were similarly reported qualitatively.[89,93] An absence of meat was reported in seven qualitative studies,[63–65,90–93] yet the one quantitative study investigating this outcome found 75% of parcels contained meat.[62] Despite energy exceeding requirements (Table 2), parcels were inadequate for meals and large families.[64,90,93] Any discrepancies between the findings are explained by the comparison with national guidelines in quantitative studies, whereas the qualitative studies reported the opinions and experiences of food bank users.

Intervention studies showed food banks reduce food insecurity in individuals.[83,87] Nevertheless, an inability to eliminate food insecurity was evident.[83] These findings were supported qualitatively as food banks allowed otherwise unachievable access to food.[63,90,93] However, cultural, social, and health-related dietary needs were often unmet, which is explained by a limited choice of food.[57,65,90,91] In addition, expired food was common, yet food security requires being able to acquire safe food.[64,65,88,92]

Aligning with qualitative findings that food banks are a lifeline for basic dietary needs,[88] quantitative studies

revealed that the use of food banks use associated with improved dietary quality (Table 4). The positive dietary outcomes from diabetes-specific interventions and after improving the nutritional quality of food parcels were unsurprising.[84,87,93] This is because traditional food parcels were often inadequate at meeting personal preferences.[63,88,89,93] Despite using food parcels, dietary quality often remained inadequate.[59,82] This was demonstrated qualitatively, as when using food banks, strategies to minimise hunger were still acquired[57,89,91] (Table 7).

The mixed-method integration indicates benefit in improving the nutritional quality of food parcels, including implementing guidelines for consistency, increasing food variety, and tailoring food parcels to individual needs (Table 8).

DISCUSSION

This review has indicated that food parcels provided by food banks can reduce food insecurity and improve the dietary intake of their users by enabling access to food. However, food banks alone are limited in solving food insecurity and wider diet-related inequalities. This review updates the evidence regarding the nutritional adequacy of food parcels and the mixed-method findings support implementing policy to improve the nutritional quality of food parcels for them to meet individual dietary needs.

The first objective was to investigate whether food parcels adequately meet the nutritional requirements of food bank users. Aligning with findings from previous systematic reviews, our findings suggested that the nutritional content of food parcel varied across and within studies. In addition, nutritional inadequacies, which were the same as previous reviews, included iron, calcium, and FV.[48,60] Heterogeneity between the study designs, methodology, and outcomes similarly precluded meta-analysis; thus, the results were presented narratively, and generalisation of findings is limited. This systematic review provides an expanded synthesis to previous reviews by including studies conducted in Europe and a study analysing overall nutritional quality.[61,62,79,82] In addition, the qualitative studies explored whether food parcels met personal dietary needs and, similar to previous research, the findings suggested nutritional insufficiencies.[23]

The second objective was to investigate whether food banks improve the food security and dietary intake of food bank users, as there was previously no quantitative synthesis assessing this.[19] Although the findings indicated that using food parcels can improve food security and dietary quality, the prevalence of food insecurity remained higher than in general populations.[83,87] Moreover, the qualitative findings align with previous research in that the charitable food supply limits the variety, quantity, and choice of food at food banks, indicating that food insecurity persisted.[48] It is understood that the charitable nature of food banks is a key barrier to providing adequate nutrition.[98] This includes reliance on donations, insufficient food storage, a lack of nutritional guidance, and minimal links to fresh food distributors, which all hinder food quality.[98,99]

Parcels consistently exceeded energy requirements,[61,62,79,81] contradicting qualitative reports of there being an insufficient quantity of food, particularly for families.[65,90] Based on energy content, food parcels lasted beyond recommended number of days, yet nutrients available in these were inadequate.[62,79] This, in addition to sugar and salt exceeding recommendations, indicates that food parcels provide energy-dense and nutrient-poor food. This is concerning as nutritionally poor diets and risk of obesity are greater among food bank users, and multiple-child families are over-represented at food banks.[2,50] Given that purchasing additional food is often unaffordable, exacerbated by rising food prices, acquiring food for health is challenging for those relying on food banks.[43] Inadequate vitamin D was reported in three studies.[61,79,82] Vitamin D insufficiency is common in the general population; thus, vitamin D supplementation is recommended over winter months.[100] Whether food bank users follow this guidance is unknown. Minimal provision of meat was consistent across the qualitative studies.[63–65,90–93] In addition to not meeting personal preferences, this is worrying as food bank users' diets are known to lack meat and the prevalence of anaemia, most commonly caused by haem–iron deficiency, is greater when food insecure.[49,54,101]

This systematic review expands on previous reviews by showing that food bank based diabetes interventions positively influenced diet intake and food insecurity. However, findings from these studies are not generalisable to all food bank users and despite improving, health-related outcomes (for example HbA1c levels), did not always reach significance.[83,84,87] The multiple-component interventions make distinguishing the effect of the food parcels challenging, however the diabetes-specific parcels were preferred by participants.[87] Inclusion of diabetes-specific studies in this review was relevant, with food parcels often inadequate for health-related dietary needs, including diabetes.[88] The incidence of diabetes is also higher among food bank users.[55] To minimise the cyclical effects of food insecurity, poor diet and ill-health, tailoring food parcels to health-related dietary needs is indicated.

Findings from this systematic review demonstrate a benefit in improving the nutritional quality of food parcels. For example, Long et al.'s pre–post study,[81] which included implementing food donation lists at food banks, showed significant increases in FV servings and food variety. Moreover, higher quality food parcels positively influenced diet intake.[82,86] The qualitative studies also revealed that food bank users were appreciative when parcels included fresh produce.[63,90,93] Supporting these findings from this review, a 'no soda, no candy' donation policy was successfully introduced in food banks in New

York, which minimised the provision of these nutrient-poor items.[102] Collaboration of food banks with fresh-food distributors also allows provision of otherwise unaffordable items to food bank users.[60,98] Therefore, the current evidence supports interventions aiming to improve the variety and quality of food at food banks, particularly FV.

To enable food security, personal dietary needs, which were consistently unmet qualitatively, can be argued as important to meeting national nutritional guidelines.[103] Despite acceptance and powerlessness towards inclusion of prepackaged parcels, food bank users desired more choice to meet their preferences.[57,93] Although out of the scope of this review, client-choice food banks are becoming increasingly popular and are shown to improve self-efficacy, which is associated with reduced food insecurity.[78] Reflecting findings from previous research,[23] food parcels were also culturally inappropriate.[90,91] Food banks commonly recommend items to include in each food parcel.[104] Findings from this review support updating these recommendations and incorporating cultural needs.

The nature of food banks means that surplus or outdated food may be offered.[105] In this review, provision of expired food was frequently reported in qualitative studies.[64,65,88,92] Encouraging food bank clients to use resources, such as the 'FoodKeeper App', which is a phone application to educate around food quality and storage, may be beneficial.[106] The FoodKeeper App has shown to increase willingness to eat outdated foods that are still safe to consume.[107] Nevertheless, consuming outdated foods could be deemed unsafe and socially unacceptable (stigma attached), preventing food security.[2] Food provided was also often unsuitable for the cooking facilities and skills of food banks users.[63] Previous research suggests that food bank users with poor cooking facilities and nutrition knowledge use food parcel food suboptimally, limiting dietary quality.[47,48,99] Therefore, these findings support benefits of food bank-based cooking and nutrition education interventions, which have been shown to improve the dietary quality, nutrition knowledge, cooking skills and food insecurity of food bank users.[108]

Strengths and limitations

This systematic review provided a needed update to the evidence base regarding the nutritional quality of food bank parcels, but also expanded this by including additional countries, investigating the effectiveness of food banks, and exploring personal views regarding food bank food. Aspects of food insecurity can be subjective, hence the mixed-method approach, combining quantitative data assessing the nutritional quality and effectiveness of food parcels, with the views of food bank users, was of great value, particularly for guiding public health recommendations.[73,74] The objectives, eligibility criteria, search strategy, and analysis were clearly stated and unlike previous reviews,[60] there were no time constraints on intervention studies. This was to ensure that all relevant evidence was captured. Including articles published from 2015 onwards ensured that there was no gap in the evidence between this review and the two previous reviews it was updating.[48,60] Research in public health, including food banks and food insecurity, is abundant in grey literature.[80] Therefore, searching for eligible studies in grey literature databases and relevant organisational websites prevented omission of relevant data.

We acknowledge a number of limitations. The focus on prepackaged food parcels meant that 12 articles were excluded from this review becaause the operational characteristics of the food banks were unstated. This included a cross-sectional study, which found food donations provided by food banks significantly improve the diet quality and reduce the probability of food insecurity of adult food bank clients in the USA.[47] This potentially limited the inclusion of relevant evidence, with only two studies investigating the impact of food banks on food insecurity.[83,87] In addition, different dietary recommendations between high-income countries means that international comparisons of nutritional quality are challenging.[62,77]

The included studies which investigated the nutritional quality of food parcels assumed how long the food parcels lasted. However, the discrepancy between the nutritional content and the ideal length of use suggests inaccurate comparisons with nutritional guidelines.[61,62,79] This could explain the study conflictingly reporting inadequate energy, protein and carbohydrate.[82] Of the four intervention studies investigating the effectiveness of food banks, three studies were restricted to diabetes and the USA, limiting translation to general populations and other countries.[83,84,87] Moreover, the intervention studies being 8 weeks and 6 months long prevented investigation of lasting outcomes, limiting relevance for long-term food bank users.[66] Only three RCTs, all moderate in methodological quality, explored the effectiveness of food banks, limiting the validity of the findings.[84,86,87]

Recommendations for policy and practice

This systematic review revealed that food parcels significantly contribute to dietary intake and are repeatedly used by individuals.[59,89] This supports the evidence concerning chronic food bank use.[66] In addition to nutritionally poor food parcels, these findings emphasise the importance of encouraging societal action to reduce inequalities to facilitate national and international goals of eradicating food insecurity and the need for food banks.[13,14,109] Food banks do not solve the wider causes of food insecurity and there is an argument that they take this responsibility away from governments.[110] However,

without policies to ensure sufficient income for adequate standards of living, combined with the economic crises related to COVID-19, the incidence of poverty, food insecurity and food bank use are predicted to continue rising.[14,58,111]

Although nutritional guidance at food banks is currently nonmandatory and limited by availability of donations, food banks that do follow nutritional recommendations are shown to have greater food variety.[112] Volunteers also support introducing nutritional guidance at food banks.[113] With food parcels variable at meeting nutritional guidelines and individual needs, this review supports implementing food bank-based nutritional guidelines, allowing a sufficient and consistent quality of food. The findings also encourage interventions to improve the variety of food at food banks, in particular by increasing fresh produce and health condition-specific parcels. In practice, guidelines and interventions should consider individual needs and preferences to promote food security and minimise diet-related inequalities as well as try to reduce stigma attached to food bank use.[52] As established in some food banks, collaboration with dietitians and qualified nutritionists could ensure parcels are nutritionally adequate.[99]

Recommendations for research

Further RCTs investigating the impact of food banks on food insecurity among general populations, rather than diabetes-specific, and in countries beyond the USA, will strengthen the evidence base. Only one quantitative study investigated the adequacy of food groups beyond FV, thus additional research exploring this outcome would support increased incorporation into parcels. Food bank use is prevalent and rising among children, hence investigating and reviewing the nutritional adequacy of food parcels for children is required. Cultural preferences and social-security programmes are country specific, which prevents generalisation of findings;[15] therefore, synthesis by country could strengthen the policy recommendations.

CONCLUSIONS

This comprehensive systematic review has updated evidence on the nutritional adequacy of food parcels provided by food banks and the effectiveness of food banks in terms of reducing food insecurity. The evidence highlights that food banks are a lifeline, particularly for those who are severely food insecure. However, it reinforces evidence that pre-prepared food parcels struggle to meet the nutritional needs of their users. With inadequate social-security driving food insecurity and food bank use, approaches to reduce the broader inequalities that these populations suffer is crucial. The mixed-method findings support implementing policy to ensure adequate nutrition at food banks, including increasing food variety, choice and safety. Additionally, interventions that improve the suitability of food for individual needs and maintain the dignity of the user are supported. Therefore, these efforts could improve the experiences, food insecurity and health of those requiring food banks.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

ETHICS STATEMENT

This review used only published sources of data. Ethical review by a Research Ethics Committee was not required.

AUTHOR CONTRIBUTIONS

Lucy Oldroyd, Fatemeh Eskandari and Amelia A. Lake contributed to developing the PROSPERO protocol. Lucy Oldroyd was the first reviewer and Charlotte Pratt was the second reviewer. Lucy Oldroyd conducted data analysis and led the writing of the manuscript. Amelia A. Lake and Fatemeh Eskandari provided supervision and support throughout the research project. All authors have commented on drafts of the manuscript.

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PEER REVIEW

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with PRISMA guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained. This study is registered with PROSPERO (registration number CRD42021269065).

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SUPPORTING INFORMATION

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Resting energy expenditure of a diverse group of South African men and women

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Abstract

Background: In South Africa, overweight/obesity is a public health concern, disproportionally affecting Black females. A contributory role of a lower resting energy expenditure (REE) is suggested for African Americans. The present study assessed the REE of Black and White South African adults aiming to better understand the underlying predictors to overweight/obesity and transform this into locally appropriate recommendations.

Methods: In 328 (63% female; 39% Black) healthy South African adults, REE was measured with indirect calorimetry and body composition with multi-frequency bioelectrical impedance analysis. The REE was estimated with 30 sets of published equations. Black–White differences in REE, as measured and adjusted (analysis of covariance), were determined with quantile regression. Reliability/agreement of estimated (against measured) REE was determined with intra-class correlations (ICCs) and Bland–Altman analysis. A new equation was developed by median regression followed by preliminary validation.

Results: Measured REE (adjusted for age along with fat-free mass [FFM], FFM index, FFM plus fat mass, FFM index plus fat mass index) in White subjects was significantly higher ($p < 0.001$) than in Black subjects for men and women alike, regardless of obesity class. None of the sets of estimation equations had good agreement with measured REE for Black, White, male and female subjects simultaneously. A new estimation equation, based on whole-body variables, had good reliability (ICC = 0.79) and agreement (mean difference: 27 kJ) and presents practical opportunities for groups at the local grass-roots level.

Conclusions: The REE in Black South African adults is lower than in White adults. Tailored REE equations may improve REE estimation of racially/ethnically diverse South African groups and contribute to improved obesity management.

KEYWORDS

body composition, estimation equations, indirect calorimetry, obesity, race/ethnicity, resting energy expenditure

Key points

- A lower resting energy expenditure (REE) may partially explain the disproportionate prevalence of overweight/obesity among Black South African females. The present study assessed the REE of Black and White

South African men and women to improve the understanding of the underlying predictors to overweight/obesity and to transform this into locally appropriate recommendations.

- The REE, when adjusted for age along with body composition variables, of Black subjects were significantly lower than in White subjects for both males and females alike. This may indicate the need for population-specific prediction equations to calculate REE in resource-limited settings where access to REE measurements are limited.
- As a secondary objective, the reliability/agreement between measured REE and estimation equations, typically used in local settings to calculate REE, was determined. Informed by the outcome, a new population-specific equation was developed followed by preliminary validation for application at the local grass-roots level.

INTRODUCTION

The importance of knowing the energy expenditure of individuals or groups is universally acknowledged in health and nutrition care[1,2] and in research.[3–5] Among the components of total energy expenditure, resting energy expenditure (REE) constitutes the largest fraction.[3,6] REE, in turn, is related to various predictors, including age, sex, genetics, body size, body composition or a recent energy imbalance.[3,6,7]

South Africa, a low- to middle-income country with diverse races/ethnicities, is burdened by a disproportionately high prevalence of overweight (26.5%) or obesity (40.9%) among African Black women.[8] Simultaneously, it is possible that the high prevalence of stunting in childhood (27% of children under 5 years[8]) may track into adult shortness, again especially among the Black population. In this context, all predictors of energy balance, including REE and factors related to it, should be studied as objectively as possible to direct tailored obesity management, keeping in mind resource limitations in those settings where this problem is most prevalent. International studies (e.g., among African Americans) suggested race/ethnicity differences in REE[9] mainly among women. This was confirmed by some previous local work limited to women being overweight,[10] whereas another South African group[11] disagreed. The question arises whether race/ethnicity differences in REE, if they exist, are sex-specific.

The present study aimed to determine whether Black and White South African adults differed in terms of measured REE (within sex), unadjusted and adjusted for relevant predictors, including anthropometry, body composition and age. Body composition was conceptualised in terms of fat-free mass (FFM), fat-free mass index (FFMI), fat mass (FM) and fat mass index (FMI). Informed by the outcome of the aforementioned, a secondary objective was to determine whether selected estimation equations of REE could differentiate between the measured REE in Black and White adult males and females, that is, the reliability/agreement[12] of the equations. Lastly, we developed and preliminarily validated an equation for South African practice. This referred to a whole-body estimation equation[13] for application at grass-roots (i.e., clinical and community level) in a resource-limited setting, where the overweight/obesity challenges are most prevalent. Race/ethnicity referred to a self-reported classification as Black or White. The REE was taken to reflect basal energy expenditure plus diet-induced thermogenesis.[14]

METHODS

In this cross-sectional study, we conveniently recruited anthropometrically diverse Black and White adults via printed notices posted in hospital tearooms, electronic invitations to local recreational sport clubs (such as runners and volleyball players), and word of mouth invitations to staff and students in the Faculty of Health Sciences at the Univesrity of Pretoria. Self-reported illness, including acute infections and chronic disease, medications known to be related to energy expenditure, implantable electronic devices, and self-reported weight change exceeding 5 kg in the past 6 months, acted as exclusion criteria. Comparison of Black and White subjects with respect to REE, for both females and males, was considered for sample size calculation. In a post-hoc analysis, it was determined that the power of the study was in excess of 90% when using a two-sided two-group Student's paired t test at $p < 0.05$ (sample size and power determination in Stata, version 14; StataCorp).

REE and bioelectrical impedance analysis data were collected in a thermo-neutral (22–25°C) secluded venue at the Faculty of Health Sciences. In preparation for the assessment, participants were requested to be fasted, consuming water only for ≥5 h (self-reported energy intake [by means of a short questionnaire] before this fasting period did not exceed 1200 kJ and assessments were completed during the morning) and abstain from alcohol, smoking, stimulants and exercise for at least

4 h.[1,2] The REE was measured with indirect, open-circuit calorimetry (Quark RMR; Cosmed). The device has evidence of reliability and accuracy.[15] For the assessment of body composition, multifrequency bioelectrical impedance analysis (Quadscan 4000; Bodystat) was used. Weight and height were measured with a digital scale (Sensa 804; Seca) and a stadiometer (Seca), respectively. The standardised protocol followed for measurement of REE including pretesting of the metabolic cart, achieving and identifying steady state, body composition and anthropometry has been described previously.[10] All measurements were taken by trained dietitians. The Quadscan 4000 outputs were used to attain measures for FFM, FM and percentage body fat (%BF). Equipment was fully serviced prior to the study and daily calibration/verification was performed in accordance with the manufacturers' instructions.

Raw data were entered into Excel (Microsoft Corp.), where basic calculations, including estimations of REE, were done (the REE estimation equations typically used in clinical and local settings were selected). Twenty sets of equations are based on whole-body parameters, and 10 include body composition data. For calculating body mass index (BMI), FMI and FFMI, respectively, body mass, FM and FFM (all three in kg), were divided by height in metres squared. Obesity class was a dichotomous variable, with obesity defined as BMI ≥ 30 kg m^{-2} based on the World Health Organization (WHO) classification. Energy conversion from kcal to kJ was done through multiplication by 4.2.

Stata, version 14 (StataCorp) was used for statistical analyses. Continuous variables were summarised by race/ethnicity and sex reporting the linear estimated means (predictive margins), including a 95% confidence interval (CI). For REE outcome variables, a quantile regression model with bootstrap estimates race/ethnicity by sex was employed with covariates (five models for REE adjusted for age plus (a) FFM, (b) FFMI, (c) FFM plus FM, (d) FFMI plus FMI and (e) height, respectively). The combinations for these models were guided by factors influencing REE of race/ethnic groups and the findings of our previous research.[10] Reliability/agreement of REE estimations was conceptualised in accordance with 'GRRAS' guidelines.[12] For every equation, variability was calculated using intraclass correlation (ICC) and Bland–Altman (BA) analysis estimates and their 95% CI through one-way analysis of variance for measured REE within the four sex/ethnicity by race subgroups. Informed by the work of Nunnally,[16] ICC was classified as: 0 ≤ ICC ≤ 0.4 = poor; 0.4 < ICC ≤ 0.75 = moderate; 0.75 < ICC ≤ 0.9 = good; ICC > 0.9 = excellent. Similar to previous studies,[6,17] estimation accuracy was defined as a percentage difference between estimated and measured REE of < 10. As a result of the skewed distribution of measured REE, median regression (based on the whole-body variables weight and height plus sex, race/ethnicity and age) was used for developing a local estimation equation. Based on easier application at clinical (grass-roots) level in a low- to middle-income country and a higher ICC, this approach was deemed superior to when logarithmically transformed data were regressed against the whole-body variables. Reliability/agreement between REE as measured and estimated with the new equation was again determined with ICC and the BA method. A leave-one-out preliminary-validation was employed: for each case, the median regression for estimating REE was fitted to the data set after omitting that particular case. $p < 0.05$ was considered statistically significant.

The study was approved by the University of Pretoria's Faculty of Health Sciences Research Ethics Committee and all participants were required to provide their written informed consent.

RESULTS

Description of sample

For the final sample of 328 subjects, a complete and credible dataset was available (Table 1). The data from 10 subjects were excluded from the original group of 338 (for five subjects, the self-reported race/ethnicity was

TABLE 1 Sex, race/ethnicity and obesity class distribution of sample ($N = 328$).

	Race/ethnicity								
	Black				White				
Sex	Healthy weight,[a] *n* (%)	Over-weight,[b] *n* (%)	Obesity,[c] *n* (%)	Total, *n* (%)	Healthy weight,[a] *n* (%)	Over-weight,[b] *n* (%)	Obesity,[c] *n* (%)	Total, *n* (%)	Total *n* (%)
F	31 (9.4)	12 (3.7)	39 (11.9)	82 (25.0)	77 (23.5)	20 (6.1)	29 (8.8)	126 (38.4)	208 (63.4)
M	11 (3.4)	29 (8.8)	7 (2.1)	47 (14.3)	27 (8.2)	40 (12.3)	6 (1.8)	73 (22.3)	120 (36.6)
Total	42 (12.8)	41 (12.5)	46 (14.0)	129 (39.3)	104 (31.7)	60 (18.4)	35 (10.6)	199 (60.7)	328 (100.0)

Abbreviations: BMI, body mass index; F, female; M, male.

[a]BMI < 25 kg m^{-2}.

[b]BMI 25–29.9 kg m^{-2}.

[c]BMI ≥ 30 kg m^{-2}.

TABLE 2 Anthropometry and body composition of sample ($N = 328$).

		Black ($n = 129$)			White ($n = 199$)			Race/ethnicity difference, p value[b]
		Mean	SD	95% CI[a]	Mean	SD	95% CI[a]	
Age (years)	F	32.1	11.7	(29.7–34.5)	30.5	11.7	(28.6–32.4)	0.312
	M	38.9	8.3	(35.8–42.1)	36.8	10.2	(34.2–39.3)	0.291
Weight (kg)	F	77.0	21.0	(73.0–80.9)	70.6	20.1	(67.4–73.8)	0.014
	M	81.0	15.2	(75.8–86.2)	84.4	11.8	(80.2–88.6)	0.322
Height (m)	F	1.6	0.1	(1.6–1.6)	1.7	0.1	(1.7–1.7)	<0.001
	M	1.7	0.1	(1.7–1.8)	1.8	0.1	(1.7–1.8)	<0.001
BMI (kg m^{-2})	F	29.7	8.1	(28.3–31.1)	25.6	7.5	(24.4–26.7)	<0.001
	M	27.0	4.5	(25.1–28.9)	25.8	3.1	(24.3–27.3)	0.326
FFM (kg)	F	46.9	7.0	(45.2–48.5)	47.9	6.6	(46.6–49.2)	0.347
	M	61.4	8.4	(59.2–63.5)	66.8	9.0	(65.0–68.5)	<0.001
FFMI (kg m^{-2})	F	18.0	2.3	(17.5–18.5)	17.3	2.2	(16.9–17.7)	0.025
	M	20.5	2.2	(19.8–21.1)	20.4	2.3	(19.9–20.9)	0.91
FM (kg)	F	30.1	15.3	(27.4–32.9)	22.6	14.8	(20.4–24.8)	<0.001
	M	19.7	8.2	(16.0–23.3)	16.8	6.0	(13.9–19.7)	0.233
FMI (kg m^{-2})	F	11.7	6.0	(10.7–12.7)	8.2	5.5	(7.4–9.1)	<0.001
	M	6.6	2.6	(5.2–7.9)	5.1	1.8	(4.1–6.2)	0.113
%BF	F	36.8	9.8	(35.0–38.7)	29.6	9.6	(28.1–31.1)	<0.001
	M	23.8	6.1	(21.4–26.2)	19.3	5.1	(17.4–21.2)	0.004

Abbreviations: BMI, body mass index; CI, confidence interval; F, female; FFM, fat-free mass; FFMI, fat-free mass index; FM, fat mass; FMI, fat mass index; M, male; %BF, percentage body fat.

[a]95% Confidence interval around the mean.

[b]Welch two-sample t test.

neither Black nor White and, for one Black and four White males, the measured REE was not credible as determined by outlier analysis [box and whiskers plot; data not shown]). The anthropometric and body composition characteristics of the final sample are summarised in Table 2.

Table 2 shows that Black females had a significantly higher weight, BMI, FFMI, FM, FMI and %BF but a lower height, than White females. In the case of males, the height and FFM of Black subjects were significantly lower, while %BF was higher than in White males.

Measured REE of Black versus White adults

Table 3 shows that the unadjusted (measured) REE of White males was significantly higher than that of the Black counterparts ($p < 0.001$). This difference was not found among women. However, when adjusted for age along with FFMI alone or FFMI plus FMI, the difference between the race/ethnicity groups was highly significant for males and females alike. Age together with FFM or height as covariate resulted in a statistically significant difference between the two race/ethnicity groups in males only. Age with FFM and FM together as covariates resulted in a statistically significant difference between the two race/ethnicity groups in females only. In all comparisons (i.e., unadjusted and adjusted, females and males), the percentage difference in REE was negative, indicating higher REE in White compared to Black subjects. The values ranged from just over 2% (unadjusted REE of females) to approximately 14% (males adjusted for FFMI plus FMI).

Table 4 shows that the unadjusted REE of Black and White subjects differed significantly regardless of sex and obesity class. The percentage difference was larger for the subjects with obesity

Estimated versus measured REE

In Table 5, the reliability/agreement in terms of ICC and BA mean difference of 30 sets of equations estimating REE is displayed for males and females, Black and White subjects as subgroups (see Supporting information, Table S1 with REE estimation equations and Table S2

TABLE 3 Median of measured REE (kJ day^{-1}) of Black and White adults ($N = 328$).

REE			Black		White		Race/ethnicity difference	
			Median	95% CI[a]	Median	95% CI[a]	%[b]	*p* value[c]
Unadjusted		F	6085	(5668–6502)	6224	(5960–6488)	−2.2	0.557
		M	7325	(7049–7601)	8216	(7854–8578)	−10.8	<0.001
Adjusted for age plus:	FFM	F	6272	(6080–6464)	6384	(6238–6531)	−1.8	0.313
		M	7495	(7245–7745)	8001	(7692–8310)	−6.3	0.019
	FFMI	F	6034	(5792–6276)	6527	(6361–6693)	−7.6	<0.001
		M	7147	(6824–7470)	8060	(7662–8457)	−11.3	<0.001
	FFM plus FM	F	6062	(5881–6243)	6626	(6462–6791)	−8.5	<0.001
		M	7458	(7075–7842)	7987	(7595–8378)	−6.6	0.082
	FFMI plus FMI	F	5974	(5718–6230)	6601	(6393–6810)	−9.5	<0.001
		M	7063	(6717–7410)	8220	(7810–8630)	−14.1	<0.001
	Height (m)	F	6103	(5830–6376)	6345	(6055–6634)	−3.8	0.257
		M	7596	(7264–7929)	8151	(7769–8531)	−6.8	0.024

Abbreviations: CI, confidence interval; F, female; FFM, fat-free mass; FFMI, fat-free mass index; FM, fat mass; FMI, fat mass index; M, male; REE, resting energy expenditure.

[a]95% Confidence interval around the median.

[b]([Black – White]/White) × 100.

[c]Welch two-sample *t* test.

TABLE 4 Mean measured REE (kJ day^{-1}) of Black and White subjects who are obese and non-obese ($N = 328$).

Sex		Black		White		Race/ethnicity difference			
						Nonobese		Obese	
		Nonobese	Obese	Nonobese	Obese	%[a]	*p* value[b]	%[a]	*p* value[b]
F	n	43	39	97	29	−8.9	0.0013	−13.8	0.0001
	REE	5454	7047	5990	8182				
	95% CI[c]	(5200–5708)	6721–7373)	(5804–6175)	(7719–8645)				
M	n	40	7	67	6	−10.8	0.0019	−16.8	0.0247
	REE	7097	7545	7960	9078				
	95% CI[c]	(6773–7421)	(6984–8107)	(7589–8331)	7583–10574)				

Abbreviations: CI, confidence interval; F, female; M, male; REE, resting energy expenditure.

[a]([Black – White]/White) × 100.

[b]Welch two-sample *t* test.

[c]95% Confidence interval around the mean.

with references for REE estimation equations). Regardless of the model (i.e., whole-body anthropometry or body composition), the reliability of the sets of equations varied from 'consistently poor' (ICC ≤ 0.4 across subgroups) for four sets of equations, or 'consistently moderate' (0.4 < ICC < 0.75) for two sets, to 'mixed' (two different classifications of reliability across the subgroups) and 'very mixed' (three different classifications for the four subgroups) for each of 13 sets. No set of equations performed 'consistently good' (ICC > 0.75 for all four subgroups). In fact, no single equation had an ICC ≥ 0.75 (i.e., good reliability) for men, regardless of race/ethnicity. On the other hand, four equations (De Lorenzo; Johnstone; Lazzer; WHO [age]) were classified as 'good' for females across the two race/ethnicity groups. However, for all of these, the reliability classification for the two male subgroups differed, resulting in a 'very mixed' reliability of these equations across the subgroups. In ten cases, 'good' reliability between an estimation equation and measured REE was

TABLE 5 Reliability/agreement of estimated REE[a] of Black and White adults by sex

Model	Sets of estimation equations:Author, alphabetically(see Supporting information, Tables S1 and S2) (REE unit)	Sex	Black				White				Race/ethnicity difference	
					Bland–Altman analysis				Bland–Altman analysis			
			Mean REE (kJ) (95% CI)[b]	ICC(95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	Mean REE (kJ) (95% CI)[b]	ICC (95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	%[c]	*p* value[d]
Whole body	Bernstein (kcal)	F	5275 (5127–5423)	0.34 (0.14–0.53)	962 (793–1130)	(−574 to 2498)	5086 (4966–5205)	0.09 (0.00–0.26)	1433 (1270–1596)	(−420 to 3286)	3.7	0.051
		M	5899 (5703–6094)	0.03 (0.00–0.32)	1293 (1033–1554)	(−479 to 3066)	6441 (6284–6598)	0.00 (0.00–0.23)	1642 (1327–1957)	(−1100 to 4346)	−8.4	<0.001
	Black (MJ)	F	6247 (6093–6401)	0.70 (0.60–0.81)	−36 (−206 to 135)	(−1600 to 1517)	6132 (6007–6256)	0.62 (0.51–0.73)	362 (206–519)	(−1400 to 2138)	1.9	0.252
		M	7290 (7086–7493)	0.54 (0.33–0.74)	−125 (−369 to 118)	(−1800 to 1532)	7689 (7526–7853)	0.34 (0.13–0.54)	363 (50–675)	(−2300 to 3040)	−5.2	0.003
	BMI (kcal)	F	6416 (6266–6566)	0.71 (0.60–0.82)	−204 (−372 to −36)	(−1700 to 1327)	5972 (5851–6093)	0.56 (0.45–0.68)	522 (360–684)	(−1300;2362)	7.4	<0.001
		M	7523 (7324–7721)	0.29 (0.03–0.55)	−359 (−622 to −95)	(−2200 to 1438)	7439 (7280–7598)	0.17 (0.00–0.39)	613 (287–939)	(−2200 to 3404)	1.1	0.519
	De Lorenzo (kJ)	F	6513 (6326–6700)	0.79 (0.71–0.87)	−301 (−442 to −160)	(−1600 to 983)	6326 (6174–6476)	0.77 (0.70–0.84)	169 (34–303)	(−1400 to 1692)	3.0	0.126
		M	7500 (7253–7747)	0.48 (0.26–0.70)	−336 (−602 to −69)	(−2200 to 1481)	7894 (7695–8092)	0.40 (0.21 0.59)	159 (−152 to 469)	(−2500 to 2818)	−5.0	0.015
	Harris–Benedict, 1919 (kcal)	F	6435 (6262–6607)	0.74 (0.64–0.84)	−223 (−376 to 68)	(−1600 to 1193)	6251 (6112–6390)	0.68 (0.58–0.77)	243 (94–393)	(−1500;1941)	2.9	0.103
		M	7453 (7225–7680)	0.50 (0.28–0.71)	−289 (−565 to −13)	(−2200 to 1592)	7870 (7688–8053)	0.42 (0.23–0.61)	182 (−128 to 492)	(−2500 to 2839)	−5.3	0.005
	Harris–Benedict, 1984 (kcal)	F	6478 (6311–6646)	0.72 (0.62–0.82)	−267 (−424 to −110)	(−1700 to 1163)	6328 (6192–6463)	0.68 (0.59–0.78)	167 (16–317)	(−1500 to 1872)	2.4	0.170
		M	7452 (7231–7673)	0.50 (0.28–0.71)	−288 (−560 to −16)	(−2100 to 1563)	7848 (7670–8025)	0.41 (0.21–0.60)	204 (−106 to 515)	(−2500 to 2864)	−5.0	0.006
	Henry (W, H, A–MJ)	F	6085 (5919–6252)	0.75 (0.66–0.85)	126 (−30–283)	(−1300 to 1551)	6006 (5872–6141)	0.66 (0.56–0.76)	488 (347–629)	(−1100 to 2089)	1.3	0.467
		M	7212 (6992–7432)	0.53 (0.32–0.74)	−48 (−305 to 209)	(−1800 to 1701)	7622 (7446–7799)	0.33 (0.12–0.53)	430 (114–745)	(−2300 to 3134)	−5.4	0.004
	Henry (W, A–MJ)	F	6208 (6021–6395)	0.80 (0.72–0.88)	3 (−144 to 150)	(−1300 to 1342)	5977 (5826–6128)	0.70 (0,61–0,79)	517 (385–649)	(−977 to 2011)	3.9	0.059
		M	7302 (7054–7549)	0.50 (0.28–0.71)	−137 (−414 to 140)	(−2000 to 1749)	7589 (7390–7787)	0.34 (0.14–0.55)	464 (151–776)	(−2200 to 3141)	−3.8	0.075
	Huang *et al.* (kcal)	F	5979 (5809–6148)	0.81 (0.74–0.89)	233 (98–367)	(−992 to 1457)	5803 (5666–5940)	0.63 (0.52–0.73)	691 (560–823)	(−801 to 2184)	3.0	0.113
		M	7447 (7224–7671)	0.46 (0.23–0.69)	−283 (−533 to −33)	(−2000 to 1420)	7731 (7551–7910)	0.29 (0.08–0.50)	321 (4–639)	(−2400 to 3041)	−3.7	0.053
	Korth (kJ)	F	6491 (6319–6663)	0.73 (0.63–0.83)	−280 (−440 to −119)	(−1700 to 1182)	6438 (6300–6577)	0.72 (0.64–0.81)	56 (−90–202)	(−1600 to 1713)	0.8	0.636
		M	8049 (7822–8275)	0.22 (0.00–0.49)	−885 (−1100 to −634)	(−2600 to 820)	8501 (8320–8683)	0.32 (0.11–0.52)	−449 (−764 to −134)	(−3100 to 2251)	−5.3	0.002
	Lazzer (MJ)	F	6388 (6193–6583)	0.83 (0.76–0.90)	−176 (−313 to −39)	(−1400 to 1070)	6308 (6150–6465)	0.79 (0.72–0.85)	187 (58–316)	(−1300 to 1651)	1.3	0.528
		M	7557 (7300–7814)	0.48 (0.26–0.70)	−393 (−657 to −129)	(−2200 to 1406)	8123 (7917–8330)	0.39 (0.20–0.59)	−71 (−389 to 247)	(−2800 to 2653)	−7.0	0.001
	Livingston and Kohlstadt (kcal)	F	6133 (5990–6275)	0.73 (0.62–0.83)	79 (−82–240)	(−1400 to 1544)	5916 (5802–6031)	0.55 (0.43–0.67)	578 (422–733)	(−1200 to 2340)	3.7	0.021
		M	7215 (7027–7403)	0.49 (0.28–0.72)	−51 (−299 to 197)	(−1700 to 1641)	7429 (7278–7580)	0.25 (0.03–0.46)	623 (311–935)	(−2100 to 3299)	−2.9	0.082

(Continues)

TABLE 5 (Continued)

Model	Sets of estimation equations:Author, alphabetically(see Supporting information, Tables S1 and S2) (REE unit)	Sex	Black				White				Race/ethnicity difference	
					Bland–Altman analysis				Bland–Altman analysis			
			Mean REE (kJ) (95% CI)[b]	ICC(95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	Mean REE (kJ) (95% CI)[b]	ICC (95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	%[c]	*p* value[d]
	Mifflin-St Jeor *et al.* (kcal)	F	6058 (5892–6224)	0.75 (0.66–0.85)	153 (−5–311)	(−1300 to 1592)	5959 (5825–6093)	0.63 (0.52–0.73)	535 (389–682)	(−1100 to 2197)	1.7	0.359
		M	7086 (6867–7305)	0.52 (0.31–0.73)	78 (−171 to 328)	(−1600 to 1777)	7472 (7297–7648)	0.28 (0.07–0.49)	580 (267–893)	(−2100 to 3263)	−5.2	0.007
	Müller (W, A–MJ)	F	7077 (6875–7278)	0.65 (0.52–0.78)	−865 (−988 to 743)	(−2000 to 252)	6755 (6592–6917)	0.82 (0.76–0.88)	−260 (−381 to −140)	(−1600 to 1107)	4.8	0.015
		M	8374 (8108–8640)	0.00 (0.00–0.29)	−1200 (−1500 to −943)	(−3000 to 606)	8501 (8287–8714)	0.22 (0.00–0.44)	−449 (−778 to −119)	(−3300 to 2374)	−1.5	0.465
	Müller (BMI–MJ)	F	7278 (7054–7503)	0.57 (0.42–0.71)	−1100 (−1200 to −932)	(−2300 to 158)	6979 (6798–7160)	0.77 (0.71–0.85)	−485 (−607 to −363)	(−1900 to 897)	4.3	0.042
		M	8573 (8277–8869)	0.00 (0.00–0.29)	−1400 (−1700 to −1100)	(−3500 to 633)	8682 (8444–8920)	0.21 (0.00–0.43)	−630 (−959 to −300)	(−3500 to 2195)	−1.3	0.573
	Owen *et al.* (kcal)	F	5634 (5504–5763)	0.59 (0.45–0.73)	578 (421–734)	(−849 to 2004)	5443 (5338–5547)	0.32 (0.16–0.48)	1051 (897–1206)	(−705 to 2808)	3.5	0.024
		M	7128 (6957–7299)	0.46 (0.23–0.68)	36 (−218 to 290)	(−1700 to 1767)	7272 (7135–7409)	0.15 (0.00–0.37)	780 (460–1101)	(−2000 to 3529)	−2.0	0.198
	Schofield (WHO) (kcal)	F	6322 (6141–6504)	0.75 (0.66–0.85)	−111 (−275 to 53)	(−1600 to 1382)	6125 (5979–6272)	0.73 (0.64–0.81)	369 (231–506)	(−1200 to 1931)	3.2	0.097
		M	7550 (7311–7790)	0.43 (0.19–0.66)	−386 (−649 to −123)	(−2200 to 1405)	7824 (7632–8016)	0.34 (0.14–0.55)	228 (−87–544)	(−2500 to 2934)	−3.5	0.081
	Schofield (W, H, A–kcal)	F	6277 (6100–6454)	0.77 (0.68–0.86)	−66 (−223 to 92)	(−1500 to 1366)	6111 (5968–6254)	0.72 (0.64–0.81)	387 (251–524)	(−1200 to 1927)	2.7	0.152
		M	7551 (7318–7785)	0.43 (0.20–0.67)	−387 (−647 to −127)	(−2200 to 1384)	7826 (7639–8014)	0.35 (0.15–0.55)	226 (−87–539)	(−2500 to 2911)	−3.5	0.072
	WHO/FAO (W, A–kcal)	F	6804 (6562–7047)	0.79 0.71–0.87)	−593 (−723 to −462)	(−1800 to 594)	6411 (6216–6607)	0.87 (0.83–0.91)	83 (−33–199)	(−1200 to 1397)	6.1	0.014
		M	7051 (6731–7371)	0.49 (0.27–0.71)	113 (−170 to 396)	(−1800 to 2041)	7258 (7001–7515)	0.23 (0.01–0.45)	794 (477–1111)	(−1900 to 3510)	−2.9	0.322
	WHO/FAO (W, H, A–kcal)	F	6360 (6181–6539)	0.78 (0.70–0.87)	−148 (−299 to 3)	(−1500 to 1229)	6179 (6035–6323)	0.75 (0.68–0.83)	315 (183–447)	(−1200 to 1811)	2.9	0.123
		M	7498 (7262–7735)	0.45 (0.23–0.68)	−334 (−591 to −77)	(−2100 to 1417)	7787 (7597–7976)	0.35 (0.15–0.55)	266 (−47–578)	(−2400 to 2947)	−3.7	0.062
Body composition	Bernstein (body composition–kcal)	F	4976 (4819–5134)	0.25 (0.05–0.46)	1235 (1075–1395)	(−219 to 2689)	4950 (4823–5077)	0.12 (0.00–0.29)	1544 (1396–1692)	(−134 to 3222)	0.5	0.798
		M	5922 (5714–6130)	0.04 (0.00–0.32)	1242 (999–1486)	(−415 to 2900)	6320 (6153–6486)	0.00 (0.00–0.23)	1733 (1411–2055)	(−1000 to 4491)	−6.3	0.004
	Cunningham (body composition–kcal)	F	5778 (5630–5927)	0.57 (0.42–0.72)	433 (254–612)	(−1200 to 2064)	5870 (5750–5989)	0.49 (0.35–0.62)	625 (462–787)	(−1200 to 2465)	−1.6	0.347
		M	7088 (6892–7283)	0.57 (0.38–0.77)	77 (−162 to 315)	(−1500 to 1700)	7573 (7416–7730)	0.30 (0.09–0.51)	479 (152–806)	(−2300 to 3283)	−6.4	<0.001
	Huang *et al.* (body composition–kcal)	F	5925 (5746–6103)	0.81 (0.74–0.89)	287 (156–418)	(−903 to 1477)	5700 (5556–5844)	0.60 (0.49–0.71)	794 (667–922)	(−651 to 2240)	3.9	0.055
		M	7250 (7014–7485)	0.51 (0.30–0.72)	−86 (−339 to 168)	(−1800 to 1642)	7470 (7281–7659)	0.26 (0.05–0.48)	582 (263–902)	(−2200 to 3320)	−2.9	0.153
	Johnstone *et al.* (body composition–kJ)	F	6401 (6195–6607)	0.82 (0.75–0.89)	−190 (−329 to −50)	(−1500 to 1080)	6274 (6108–6440)	0.80 (0.73–0.86)	220 (95–346)	(−1200 to 1643)	2.0	0.345
		M	7295 (7022–7567)	0.55 (0.35–0.75)	−130 (−399 to 138)	(−2000 to 1699)	7717 (7498–7935)	0.39 (0.19–0.58)	336 (12–659)	(−2400 to 3112)	−5.5	0.018

TABLE 5 (Continued)

Model	Sets of estimation equations:Author, alphabetically(see Supporting information, Tables S1 and S2) (REE unit)	Sex	Black				White				Race/ethnicity difference	
					Bland–Altman analysis				Bland–Altman analysis			
			Mean REE (kJ) (95% CI)[b]	ICC(95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	Mean REE (kJ) (95% CI)[b]	ICC (95% CI)[b]	Mean difference (kJ) (95% CI)[b]	Limits of agreement (95% CI)[b]	%[c]	*p* value[d]
	Korth (body composition–kJ)	F	6298 (6120–6475)	0.71 (0.60–0.81)	−86 (−256 to 84)	(−1600 to 1464)	6407 (6264–6550)	0.69 (0.59–0.78)	87 (−64–239)	(−1600 to 1803)	−1.7	0.347
		M	7865 (7631–8100)	0.40 (0.15–0.64)	−701 (−953 to −448)	(−2400 to 1019)	8447 (8258–8635)	0.35 (0.15–0.56)	−394 (−728 to −61)	(−3300 to 2464)	−6.9	<0.001
	Lazzer (body composition–MJ)	F	6095 (5872–6318)	0.88 (0.83–0.93)	117 (−5–239)	(−994 to 1227)	5816 (5636–5996)	0.72 (0.64–0.81)	678 (563–792)	(−622 to 1978)	4.8	0.057
		M	3000 (2705–3295)	0.00 (0.00–0.29)	4164 (3882–4446)	(2245–6083)	3338 (3102–3575)	0.00 (0.00–0.23)	4714 (4393–5035)	(1962–7466)	−10.1	0.079
	Mifflin-St Jeor et al. (body composition–kcal)	F	5586 (5451–5721)	0.45 (0.28–0.63)	626 (441–810)	(−1100 to 2304)	5669 (5560–5778)	0.36 (0.21–0.51)	825 (657–993)	(−1100 to 2728)	−1.5	0.347
		M	6780 (6601–6959)	0.48 (0.26–0.70)	384 (150–619)	(−1200 to 1981)	7223 (7080–7366)	0.19 (0.00–0.41)	829 (504–1155)	(−2000 to 3621)	−6.1	<0.001
	Müller (body composition–MJ)	F	7021 (6833–7209)	0.65 (0.53–0.78)	−809 (−932 to 687)	(−1900 to 305)	6751 (6600–6903)	0.81 (0.74–0.87)	−257 (−379 to −135)	(−1600 to 1123)	4.0	0.029
		M	8300 (8052–8548)	0.02 (0.00–0.31)	−1100 (−1400 to −877)	(−2900 to 629)	8439 (8240–8639)	0.24 (0.02–0.46)	−387 (−717 to −57)	(−3200 to 2442)	−1.7	0.390
	Müller (body composition & BMI–MJ)	F	7014 (6785–7243)	0.61 (0.48–0.75)	−803 (−966 to −639)	(−2300 to 683)	6774 (6590–6959)	0.74 (0.66–0.82)	−280 (−427 to −133)	(−1900 to 1384)	3.5	0.109
		M	7343 (7041–7645)	0.30 (0.04–0.56)	−179 (−534 to 196)	(−2700 to 2375)	7635 (7392–7877)	0.04 (0.00–0.27)	418 (12–823)	(−3100 to 3894)	−3.8	0.139
	Owen *et al.* (body composition–kcal)	F	5256 (5111–5400)	0.29 (0.09–0.48)	956 (771–1140)	(−722 to 2634)	5339 (5223–5455)	0.20 (0.04–0.37)	1155 (988–1323)	(−748 to 3058)	−1.6	0.377
		M	6933 (6742–7123)	0.55 (0.35–0.75)	231 (−9–472)	(−1400 to 1867)	7434 (7281–7587)	0.28 (0.07–0.49)	618 (290–946)	(−2200 to 3429)	−6.7	<0.001

Abbreviations: A, age in years; BMI, body mass index; CI, confidence interval; F, female; H, height (m); h, height (cm); ICC, intra-class correlation; M, male; REE, resting energy expenditure; kJ = kcal × 4.2; W, weight (kg)

[a]Compared to measured, unadjusted REE.

[b]95% Confidence interval around the mean.

[c]([Black −White]/White) × 100.

[d]Welch two-sample *t* test.

noted in Black subgroups, whilst this was the case for seven White subgroups. Similarly, the table shows considerable variability in terms of agreement (based on mean differences and limits of agreement in the BA analyses) between estimated and measured REE within the race/ethnicity groups and sexes.

In almost all cases, the race/ethnicity difference in the estimation of REE, when expressed as a percentage, was below 10. Among the women, the percentage difference between the race/ethnicity group tended to be positive. Conversely, the percentage difference in estimated REE between Black and White men tended to be negative and larger than the corresponding value for women. The latter concurs with the observation that 14 of all the equations identified a statistically significant ($p < 0.05$) difference in estimated REE between Black and White males. Seven other equations indicated a significant race/ethnicity difference in REE for females. Eight equations identify the race/ethnicity difference in either males or females.

Local estimation equation

The following estimation equation emerged from our data:

[a] Sex: 1 if male; 0 if female.

[b] Race/ethnicity: 1 if Black; 0 if White.

[c] Sex-race/ethnicity interaction: 1 if male and Black; 0 if otherwise.

[d] Age in years.

[e] Weight (kg).

[f] Height (m).

The validation of the equation resulted in an ICC = 0.79 (95% CI = 0.75–0.83; R^2 = 89.7%).

A BA comparison (Figure 1) of the average measured REE (kJ day^{-1}) of the sample and the local estimation equation for REE (kJ day^{-1}) of South African adults resulted in a mean difference of −27 (95% CI = −123 to 69) with limits of agreement ranging between −1800 and 1731 kJ.

Figures 2 and 3 illustrate the BA comparison of the average measured REE (kJ day^{-1}) of the sample and the two estimation equations (Harris–Benedict and WHO [age-based]) generally used to calculate the for REE (kJ day^{-1}) of South African adults (the mean difference with limits of agreement are indicated in Table 5).

DISCUSSION

Self-report of energy intake and physical activity are fraught with challenges,[18] particularly among people with obesity. As a result, the international trend is towards objectively measured energy expenditure when determining energy (im)balance or energy requirements.[5] In this respect, the measurement of REE, for example with indirect calorimetry, is usually recommended, rather than estimation.[1,2,5,6,14] In resource-limited settings such as South Africa, the availability and affordability of the equipment for measuring REE and body composition are considerable challenges. Hence, reliance on estimation equations based on the whole-body level remains the pillar, especially in clinical and community settings. Furthermore, Landes *et al.*[19] doubt the impact of indirect calorimetry on patient outcome.

The REE, as measured and when adjusted for age together with various anthropometric and body composition indices of Black and White males, differed statistically significantly ($p \leq 0.001$) and the mean difference was deemed clinically meaningful (>10%). The absence of a statistically significant difference in measured REE between Black and White females may be related to the differences in their body composition because, when corrected for (Table 3), in most cases the difference became highly significant ($p < 0.001$). When

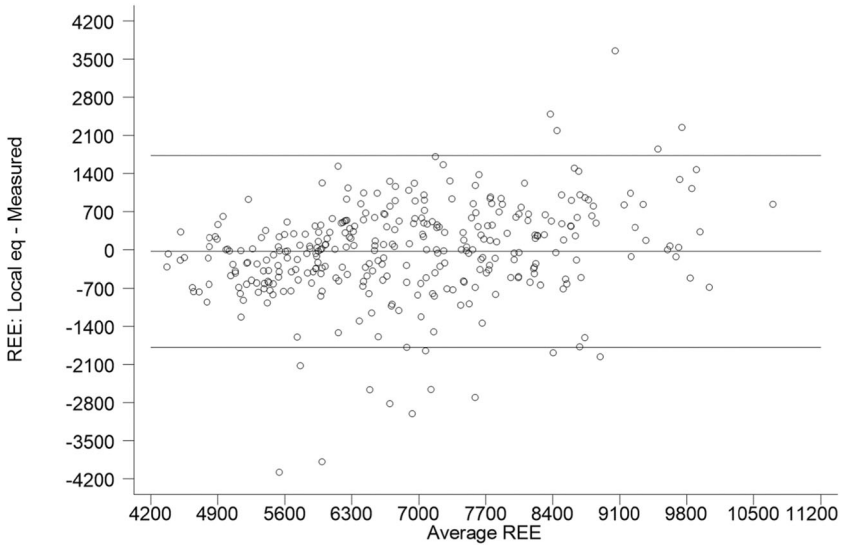

FIGURE 1 Bland–Altman analysis of measured resting energy expenditure (REE) (kJ day^{-1}) of the sample and local estimation equation for REE (kJ day^{-1}) of South African adults

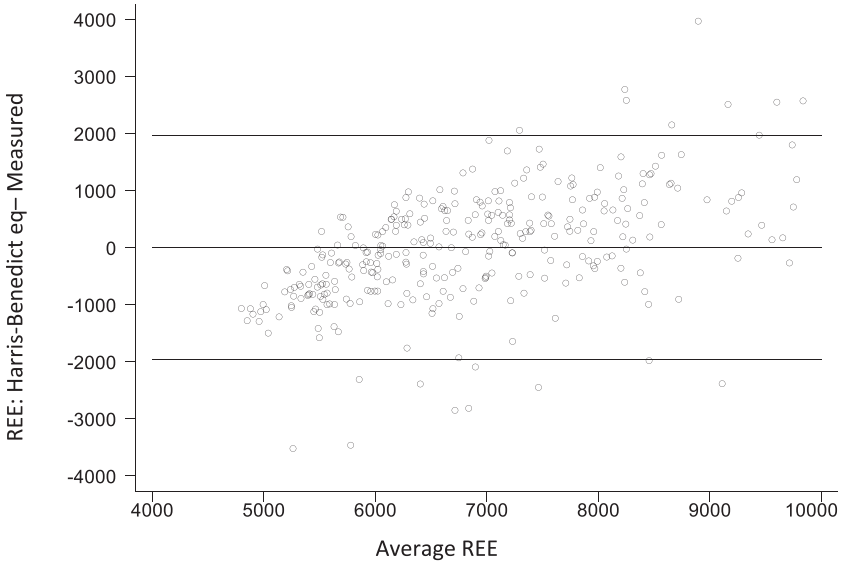

FIGURE 2 Bland–Altman analysis of measured resting energy expenditure (REE) (kJ day^{-1}) of the sample and Harris-Benedict estimation equation for REE (kJ day^{-1}) of South African adults

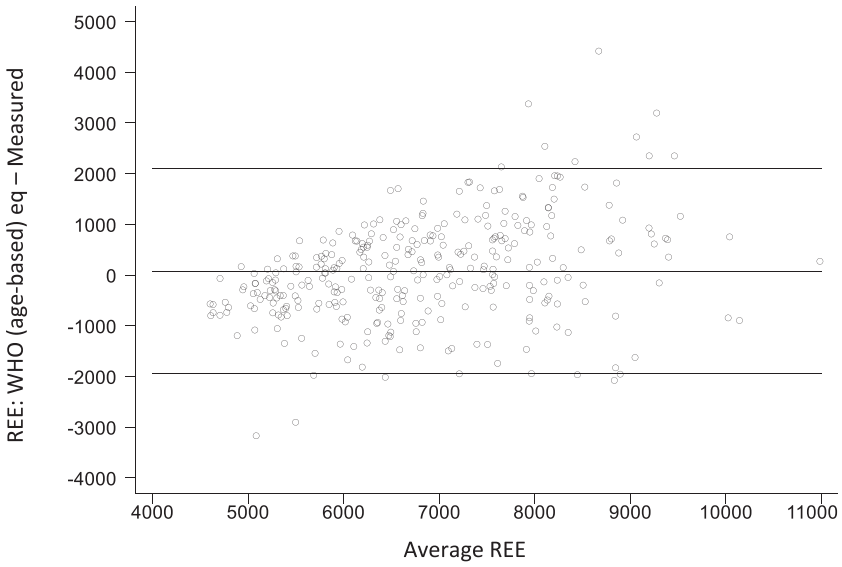

FIGURE 3 Bland–Altman analysis of measured resting energy expenditure (REE) (kJ day^{-1}) of the sample and WHO (age-based) estimation equation for REE (kJ day^{-1}) of South African adults

adjusted for FFM, differences in the REE remained relatively unchanged. However, when adjusted for FFMI, the REE of Black females was significantly ($p < 0.001$) lower than of White females. It could therefore be argued that, despite their shorter stature, the higher FFM per unit of height in Black women may have contributed to their measured REE. In addition, Black females had a significantly higher FM ($p < 0.001$) than White counterparts. Even though FM is less metabolically active than FFM,[5] it contributed to their measured REE, hence the increase in REE differences when adjusted for FFM + FM and FFMI + FMI. Shook *et al.*[20] have reported similar findings. Their percentage difference, when translated to a mean absolute difference in unadjusted REE (282 and 985 kJ for females and males, respectively), is smaller than the range of 150–300 kcal (630−1260 kJ) reported by Amen-Ra *et al.*[21] when REE was adjusted for common confounders including body fat.

The race/ethnicity difference in measured REE was apparent irrespective of the subjects' obesity class and sex (Table 4), expanding the findings of Olivier *et al.*[10] beyond females. Our data do, however, suggest that the magnitude of the difference is larger among subjects with obesity. The critical review of Heymsfield *et al.*[22] aimed to unravel the significant race/ethnicity differences in the relationship between BMI and adiposity. Race/ethnic groups may vary in body shape and composition at a constant BMI. The lower fat percentage in Black than White subjects may therefore partly explain their lower REE and the bigger difference in the group with obesity noted in our study. Heymsfield *et al.*[22] further reported that differentiating between the environmental versus inherited effects on body shape and composition remains

a challenge. However, a cross-sectional study in adults does not take into consideration different environmental exposures earlier in life. The South African history of socio-economic disparities along race/ethnicity and, for example, the shorter statures among the Black subjects in our study (Table 2), suggest that the 'nature–nurture' interplay, including persisting effects of early malnutrition,[23] requires more disentanglement. As mentioned in the Introduction, overweight/obesity and childhood stunting are both public health concerns in the country. In addition to biology, genetic and behavioural factors are an inherent part of an integrated approach to the aetiology of obesity.[24]

Many equations for predicting REE have been developed and evaluated.[25–29] These equations may be based on the whole body, tissue-organ, cellular and molecular level,[13] or for specific populations, defined by health status or otherwise.[1,30,31] Heymsfield *et al.*[31] have argued that equations that are based on the tissue-organ model are more likely to agree with measured REE as the proportion of 'active protoplasmic mass', and not just FFM, significantly affects REE.[3,5] Such an emerging approach would only be useful for developing countries if the equipment to assess it is more affordable and feasible than indirect calorimetry. The development of indirect calorimetry devices that are accurate, easy to use and affordable (by standards of industrialised countries) is underway.[14]

In the meantime, countries such as South Africa have to rely on estimation equations, despite the documented limitations of using equations in populations dissimilar to those from which the equations were derived.[1] In this regard, ethnicity is one of the variables singled out in the performance of the Harris–Benedict equation,[32] which is commonly used in South Africa. The equations analysed in our study were either on the whole-body anthropometry and/or the body composition level (Table 5) and were tested in apparently healthy adults. Contrary to expectation, equations on the body composition level did not necessarily outperform those based on whole-body variables only. Similarly, the performance did not follow a race/ethnicity pattern for males or females alike. Broadly speaking, for women, the estimations of REE were higher for the Black women, whereas, for men, the estimations tended to be higher for the White subjects. Nonetheless, for women, regardless of race/ethnicity the agreement between measured REE and the prediction thereof was good for the equations from WHO (age-based), Lazzer (whole body), de Lorenzo and Johnstone (FFM-based). Of these, only the WHO equation is commonly used in South Africa across sexes and race/ethnic groups. It follows that no single equation can be recommended for Black and White adults (females and males), particularly not on the individual nor clinical level. The conflicting findings previously reported in respect of prediction accuracy of estimation equations are thus also reflected in our study. Hasson *et al.*[26] previously reported that the accuracy of four REE equations (Harris–Benedict, Mifflin-St Jeor, Owen, and WHO/Food and Agriculture Organization/United Nations University) varied 'dramatically' when their data set was stratified by sex, BMI, age and race/ethnicity. Anjos *et al.*[25] also noted that the equations they investigated in Brazilian adults did not perform satisfactorily across sexes and age categories.

The purpose and target group for which an estimation equation is to be used are important considerations. No individual equations showed *excellent* reliability (when compared with measured REE) for any subgroup. Furthermore, *good* reliability was not achieved in all four sub-groups for any set of equations. If required for research (i.e., groups of people), some of the individual equations may be considered for certain subgroups. If the equations are the basis for energy prescriptions for individuals, then considerable error should be anticipated. In over half of the equations, the difference in the measured, unadjusted REE between Black and White males was reflected. Because the unadjusted REE did not differ significantly between Black and White women, it was not surprising that only three equations (albeit different to those for males) pointed out a race/ethnicity difference.

Frankenfield[17] and Landes *et al.*[19] have noted better prediction accuracy of equations among adults with healthy BMI, suggesting obesity-class-specific prediction equations, as was done by Müller *et al.*[33] and Orozco-Ruiz *et al.*[29] Which weight (e.g., actual, ideal or adjusted) to use remains, however, an unresolved issue.[1] Our data do, however, show that the % difference between Black and White subjects was larger for those with obesity.

The present study must be interpreted with some caution. Not all predictors of REE were objectively controlled for. We attempted to describe physical activity of our subjects by using the International Physical Activity Questionnaire (IPAQ)[34] but abandoned this because of challenges expressed by our participants. To some extent, this supports the reservations related to self-reports of the components of energy balance.[18] The study by Shook *et al.*,[20] however, highlighted cardiorespiratory fitness as partly explaining race/ethnicity differences among Black and White women in America. Self-report of diabetes and HIV were exclusion criteria in our study but cannot be completely ruled out because if the high prevalence of undiagnosed morbidity and/or sensitivity related to disclosure. Martin *et al.*[35] considered diabetes, especially when uncontrolled,[36] in addition to race as important when predicting REE. Even though Ashcraft and Frankenfield[15] identified the Quark RMR as an accurate and reliable instrument, the perfect measurement of REE is still debated.[1,7,37] In addition, the prediction and comparability of body composition data across studies and different body composition models/methods poses challenges, particularly in racially diverse, resource-limited settings.[21,38,39]

To our knowledge, this is the first study in (South) Africa that includes such a population and sample size objectively measuring REE. We took into account sex, age, body composition and height when determining race/ethnicity differences in measured REE. Similarly, the large number of estimation equations that were analysed and the development and preliminary validation of a new equation for groups of (South) Africans in a resource-limited setting are unique. Expanding the investigation to other race/ethnicities and formal cross-validation of the equation in a different study group are recommended. Anthanont and Jensen[40] found that adults with low, compared to those with high, basal metabolic rates did not gain more weight, thereby concurring with the earlier review of Luke *et al.*,[41] who argued that increased weight gain among Black individuals is unlikely to be related to lower REE. Nonetheless, Amen-Ra *et al.*[21] and at least the move towards personalised nutrition in clinical settings[1] suggest accounting for related factors, including race/ethnicity, when considering an energy prescription for the management of obesity. It is hoped that our new equation will serve this purpose. In research and public health, resource-limited settings, awareness of race/ethnicity differences in REE may pave the way for purposefully integrated investigation of the role of lifelong nutrition and environmental versus genetic factors in this regard. The recently reported genomic diversity of Black South Africans[42] adds to the research challenge ahead.

CONCLUSIONS

Black South African adults have lower measured REE than their White counterparts, irrespective of obesity class and sex. When adjusted for age and body composition variables, these differences increased for males and females. General non-population-specific equations did not perform well in estimating the measured REE for Black and White adults (females and males). Considering local resource limitations to measure REE, a new estimation equation relying on whole-body parameters shows promise to more accurately estimate energy requirements of the diverse South African population.

AUTHOR CONTRIBUTIONS

Adeline Pretorius collected data, contributed to data analysis, interpreted the data and completed the writing of the manuscript. Monique Piderit collected data and contributed to data analysis and interpretation. Piet Becker performed the statistical analysis of the data. Friede Wenhold designed the study, interpreted the data and drafted the manuscript. All authors read and approved the final version of the manuscript submitted for publication.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

TRANSPARENT PEER REVIEW

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

DATA AVAILABILITY STATEMENT

The datasets used and analysed during the current study are deposited in the University of Pretoria Research Data Storage Repository and are available from the corresponding author/institution upon reasonable request.

ETHICAL STATEMENT

The study was approved by the University of Pretoria, Faculty of Health Sciences Research Ethics Committee (Certificate: 263/2014). Written informed consent was obtained. No incentives were offered, yet transport costs to the assessment venue were paid on request. Each participant received a personalised printed summary of his/her anthropometric status and a risk warning or recommendation/referral, where applicable.

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SUPPORTING INFORMATION

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

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CLINICAL PRACTICE

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Medical nutrition therapy for gestational diabetes mellitus in Australia: What has changed in 10 years and how does current practice compare with best practice?

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Abstract

Background: The present study aimed to report Australian dietetic practice regarding management of gestational diabetes mellitus (GDM) and to make comparisons with the findings from a 2009 survey of dietitians and with the Academy of Nutrition and Dietetics Evidence-Based Nutrition Practice Guidelines (NPG).

Methods: Cross-sectional surveys were conducted in 2019 and 2009 of dietitians providing medical nutrition therapy (MNT) to women with GDM in Australia. The present study compares responses on demographics, dietetic assessment and interventions, and guideline use in 2019 vs. 2009.

Results: In total, 149 dietitians (2019) and 220 (2009) met survey inclusion criteria. In both surveys >60% of respondents reported dietary interventions aiming for >45% energy from carbohydrate, 15%–25% energy from protein and 15%–30% energy from fat. Many variations in MNT found in 2009 continued to be evident in 2019, including the percentage of energy from carbohydrate aimed for (30%–65% in 2019 vs. 20%–75% in 2009) and the wide range in the recommended minimum daily carbohydrate intake (40–220 and 60–300 g). Few dietitians reported aiming for the NPG minimum of 175 g of carbohydrate daily in both surveys (32% in 2019 vs. 26% in 2009). There were, however, some significant increases in MNT consistent with NPG recommendations in 2019 vs. 2009, including the minimum frequency of visits provided (49%, $n = 61$ vs. 33%, $n = 69$; $p < 0.001$) and provision of gestational weight gain advice (59%, $n = 95$ vs. 40%, $n = 195$; $p < 0.05$).

Conclusions: Although many dietitians continue to provide MNT consistent with existing NPG, there is a need to support greater uptake, especially for recommendations regarding carbohydrate intake.

KEYWORDS

gestational diabetes, guidelines, medical nutrition therapy

Key points

- Consistencies continue a decade later in broad education topics covered for gestational diabetes mellitus.
- Variations in dietetic practice remain, especially regarding carbohydrate recommendations and frequency of review visits.

- Adherence to some Nutrition Practice Guidelines (NPG) (2016) recommendations remain low, especially regarding minimum carbohydrate intake.
- Adherence to NPG recommendations increased for the minimum frequency of visits provided and provision of gestational weight gain advice.
- There is a need to further increase medical nutrition therapy consistent with existing NPG, especially for recommendations regarding carbohydrate intake.

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as diabetes diagnosed in the second or third trimester of pregnancy, without overt diabetes prior to gestation.[1] GDM increases the risk of a number of adverse outcomes, including caesarean delivery, large for gestational age infants, and neonatal hypoglycaemia.[2] Medical nutrition therapy (MNT) is recognised as first-line therapy in GDM management.[3] Evidence-based MNT has been shown to improve clinical outcomes in diabetes.[4,5] The Academy of Nutrition and Dietetics (A.N.D) first published evidence-based nutrition practice guidelines (NPG) for GDM in the USA in 2008.[6] Evaluation of implementation of these guidelines compared to usual MNT found less insulin use, and significantly lower follow-up glycated haemoglobin in non-diabetes specific clinics when NPG-based MNT was followed.[7] To our knowledge, the USA guidelines[8] are the only nutrition-specific published evidence-based guidelines for GDM that have been informed by a systematic review of scientific evidence. The 18 recommendations in this guideline are based on conclusion statements from the systematic review. Guideline recommendations are provided for the nutrition assessment process, frequency and duration of MNT visits, calorie prescription, macronutrient requirements, vitamin and mineral supplementation, meal and snack frequency, sweeteners and alcohol intake, nutrition monitoring, and evaluation.[3] The guideline advises that all women with GDM are referred to a dietitian for individualised MNT that includes initial education (group or individual for 60–90 min) followed by at least two individual review visits (30–45 min duration). Guideline recommendations also include provision of individualised calorie prescriptions (based on the Institute of Medicine maternal weight gain guidelines) and adequate macronutrients to support pregnancy (minimum of 175 g carbohydrate, 71 or 1.1 g protein kg^{-1} body weight).[3] The recommendations also advise that the amounts, types and distribution of carbohydrate be individualised according to blood glucose levels, physical activity and medications. Currently, Australian guidelines do not exist, and it is unknown whether the A.N.D NPGs are followed. Morrison *et al.*[9] conducted a national dietetic survey in 2009 highlighting variations in MNT, and also found that dietetic practice frequently did not align with the NPG.[6]

Subsequent to the first Australian GDM dietetic practice survey in 2009,[9] the World Health Organization diagnosis and classification of hyperglycaemia in pregnancy guidelines have been published[10] and widely implemented.[11] This has resulted in a substantial increase in GDM diagnosis and clinical populations,[11] with increased clinical workloads of up to 200%.[12] Furthermore, in 2016, the A.N.D NPG were updated.[8] This included changes to carbohydrate intake recommendations from a target of < 45% total energy intake in 2009[6] to 36%–65% in 2016.[8] MNT remains first-line therapy for women with GDM.[3] Given the recent changes in GDM diagnosis, clinical workload and the NPG, it is unclear how MNT for GDM is currently defined and implemented in Australia. Considering this evidence gap, a national survey of dietitians who provide MNT to women with GDM was updated and redistributed. The primary aim was to survey Australian dietitians on current dietetic practice in GDM management. Secondary aims were to identify changes in MNT for GDM subsequent to 2009 and to compare current MNT provided in Australia with the NPGs.

METHODS

Cross-sectional surveys of dietitians who provided MNT to women with GDM in Australia were conducted from March to June 2009, and from October to November 2018. A further recruitment round was conducted from June to July 2019 to increase the number of respondents, with results from 2018 and 2019 being pooled. Inclusion criteria were dietitians who worked in Australia and currently provided dietary advice to women with GDM. Survey invitations were sent electronically to all financial members of Dietitians Australia (DA) via the weekly newsletter. Email alerts with a survey link were also sent to those registered with the following DA national interest groups: Diabetes, Private Practice, and Paediatric and Maternal Interest Groups from October to November 2018. To increase the number and range of respondents, members of Dietitian Connection (https://dietitianconnection.com) were also invited to participate from June to July 2019 via their weekly newsletter and Facebook posts. The survey link was also posted on the

following Facebook groups: Dietitians in Private Practice and Australian Independent Dietitians-Nutritionists Group. The researchers had no direct contact details of participants.

The 2019 and 2009 surveys were 63-item and 55-item questionnaires, respectively, and included multiple-choice, open-ended questions and Likert scale responses. The present study reports findings from 30 questions asked in both 2019 and 2009 on demographics (10 items), dietetic assessment and GDM interventions (15 items), and practice guidelines and recommendations used (five items). The present study also includes findings from six additional questions on dietetic assessment and GDM interventions in the 2019 survey that were necessary to enable comparison of current MNT with the current NPG. All questions on macronutrient targets (including questions regarding recommended grams and percentage of total energy), carbohydrate frequency and timing, and fibre amounts were free-text responses. Responses from the current survey were analysed and compared with the 2009 survey results.

The first survey page contained the Participant Information statement. The survey was completed anonymously. As a result of the voluntary nature of the survey and the indirect contact between researchers and participants, participation in the online survey was taken as implied consent. This study was approved by the University of Newcastle Ethics Committee, (Approval Reference Number: H-2017-0388) and distribution of the survey was approved by DA and Dietitian Connection.

The survey was administered via the Qualtrics XM Platform, version October 2018 to November 2020 (https://www.qualtrics.com).

Macronutrient content of diets recommended by survey participants were categorised according to the American Diabetes Association criteria.[13] High, low, and very low carbohydrate diets were defined as >45%, 26%–45%, and <26% energy from carbohydrate respectively. High protein intakes was defined as >25% and moderate protein as <25% energy. High, low fat and very low-fat diets were defined as >30%, 10%–30%, and <10% total energy from fat.[13]

Data were compared using an independent samples *t*-test or chi-squared Fisher's exact test to assess differences between categorical variables, whereas analysis of variance was used to assess differences in continuous variables. Data analysis was conducted using Qualtric XM and QuickCals (https://www.graphpad.com/quickcalcs) (accessed July 2020). All survey responses were included in the analyses, including those by participants who did not complete the entire survey.

RESULTS

Of 152 dietitians who commenced the survey in 2019, 149 respondents met the inclusion criteria compared to 220 respondents in 2009. In total, 94 (63%) completed the survey in 2019, whereas 190 (86%) completed the survey in 2009. Table 1 summarises the demographics of survey responders in 2019 and 2009 and includes a comparison of completers vs. non-completers of the current survey.

As is evident from Figure 1, there continued to be consistency in key components of nutrition education provided by dietitians to women with GDM in 2019 compared to in 2009 (Figure 1).

Figure 1 also suggests a trend away from broad dietary advice to more targeted dietary advice, predominantly focusing on macronutrients (especially carbohydrate), weight gain, and physical activity. In 2019, consistent with the 2009 survey, more than 60% dietitians reported providing dietary advice aiming for macronutrient targets that align with a high carbohydrate (>45% energy), moderate protein (15%–25% energy), moderate fat (15%–30% energy) diet[13] with a high fibre content of 28 ± 4 g day^{-1} (mean ± SD). Furthermore, in 2019, most dietitians advised distributing carbohydrate over three main meals containing 30–45 g of carbohydrate, with multiple snacks (most commonly two to three) containing 15–30 g. Despite these consistencies, significant variations in macronutrient targets (by per cent energy), minimum and maximum carbohydrate targets (in g), and glycaemic index advice were reported by respondents in both 2019 and 2009 (Table 2).

When the 2019 survey participants were asked what the recommended carbohydrate amounts were based on (not asked in 2009), the most common responses were clinical experience (51.3%, $n = 78$), balance of good health for pregnancy (36.6%, $n = 51$), energy requirements (25%, $n = 38$), desired maternal weight gain (21.7%, $n = 33$), and lastly clinical guidelines for diabetes (19.1%, $n = 29$), with more than one answer allowed. When asked to specify the clinical guidelines used, a number were mentioned ($n = 26$), including local and state-wide guidelines. The most common GDM NPG specified by respondents in 2019 was the A.N.D NPG[8] ($n = 7/87$, 8.0%).

Figure 2 reports on common teaching tools used in education on carbohydrate distribution. In the category of 'other', the most common teaching tool reported was the use of household measures such as metric cups to explain recommended serve sizes. In both surveys, approximately one-third of dietitians reported that they would routinely teach carbohydrate portions or exchanges (counting intake in 10- or 15-g increments) to all women with GDM (33%, $n = 34$ vs. 35%, $n = 77$ in 2019 and 2009; $p = 0.80$). In both surveys, at least half of dietitians reported that they would teach carbohydrate portions or exchanges as appropriate according to clinical judgement, dependent on language skills and level of education, although significantly fewer chose this response in 2019 compared to in 2009 (50%, $n = 51$ vs. 62%, $n = 122$; $p < 0.05$).

Table 3 reports findings from both surveys compared to some of the key recommendations in NPG. Alignment

TABLE 1 Demographics of respondents

Percentage (*n*) respondents	2019 survey responders *n* = /149 (%) [A]	2019 survey completers *n* = /94 (%) [B]	2009 survey (*n* = /220) (%) [C]
Type of geographical location			
Metropolitan	93 (63)	60 (64)	121 (55)
Regional	30 (20)	20 (21)	62 (28)
Rural/remote	24 (16)	14 (15)	37 (16.5)
Other	1 (1)	0	1 (0.5)
Employment location			
Victoria	42 (28)	24 (25)	52 (24)
New South Wales	40 (27)	27 (28)	66 (30)
Queensland	31 (21)	22 (23)	44 (20)
Western Australia	18 (12)	9 (10)	32 (14.5)
South Australia	6 (4)	2 (2)	21 (9.5)*
Australian Capital Territory	5 (3)	4 (4)	1 (0.5)*
Northern Territory	5 (3)	4 (4)	1 (0.5)*
Tasmania	2 (1)	2 (2)	3 (1)
Employment sector (a)			
Public hospital	82 (55)	58 (44)*	115 (52)
Private practice	33 (22)	11 (8)	56 (26)
Community health centre	31 (20)	23 (18)	58 (26)
Specialist diabetes service/centre	20 (13)	17 (13)	28 (13)
Antenatal/obstetric Service	12 (8)	11 (8)	NA
Other	19 (13)	2 (2)**	25 (11)
Primary area of practice (a)			
Diabetes	59 (40)	43 (46)	127 (58)***
General clinical	37 (25)	21 (22)	101 (46)****
Community nutrition	26 (17)	12 (13)	53 (24)
Antenatal	16 (11)	11 (12)	30 (14)
Other	11 (7)	7 (7)	29 (13)
Years of diabetes experience			
Greater than 10 years	51 (34)	38 (41)	66 (30)
5–10 years	31 (21)	17 (18)	53(24)
1–5 years	51 (34)	31 (33)	79 (36)
Less than 1 year	16 (11)	8 (8)	22 (10)

Percentage (*n*) respondents	2019 survey responders *n* = /149 (%) [A]	2019 survey completers *n* = /94 (%) [B]	2009 survey (*n* = /220) (%) [C]
Professional membership	*n* = 149	*n* = 94	*n* = 220
Member of DA	145 (97)	90 (96)	213 (97)
APD	147 (99)	92 (98)	209 (95)
DA Diabetes Interest Group member	84 (65)	56 (60)	148 (69)*
Credentialed diabetes educators	16 (24)	17(18)	20 (9)

Abbreviations: APD, Accredited Practising Dietitian; DA, Dietitians Australia.

(a) Could choose more than one option.

[A] is the reference group, for [B] versus [A], and [C] versus [A].

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$.

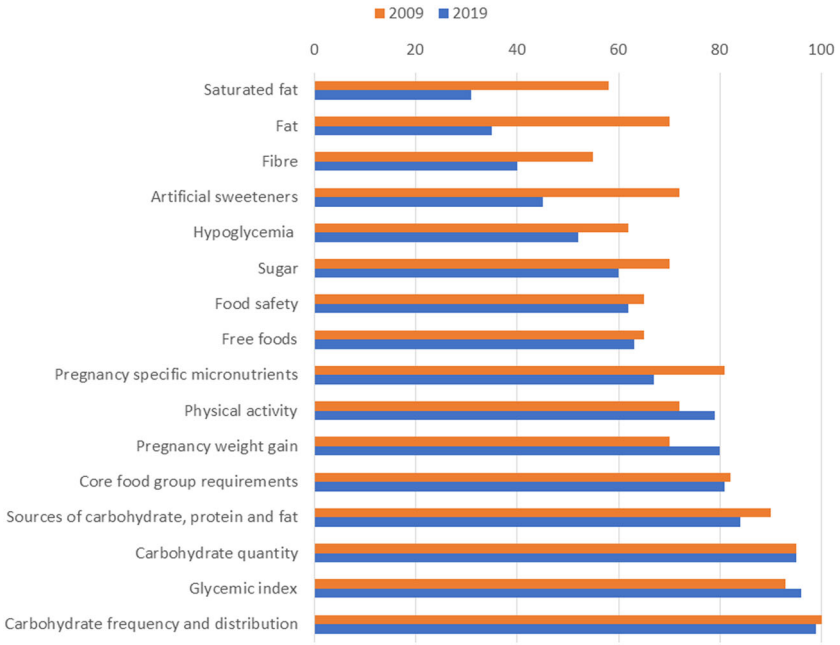

FIGURE 1 Topics covered in dietetic education with clients with gestational diabetes mellitus.

to specific NPG recommendations within the NPG ranged widely from 32% to 100% of respondents in 2019 vs. 13% to 98% in 2009. Alignment was highest for recommendations regarding dietary fibre intake and glycaemic index in both surveys. Concurrently, alignment remained low in both surveys for the recommendation to aim for a minimum carbohydrate intake of 175 g day^{-1}. Despite low numbers of dietitians in both surveys recommending a minimum carbohydrate intake of 175 g day^{-1} in line with NPG (Table 3), 96% ($n = 80$) of respondents in the 2019 survey recommended a percentage of total energy from carbohydrate that was in line with the NPG (36%–65%). By contrast, a minority of dietitians in the 2009 survey ($n = 7$, 7%) reported aiming for a carbohydrate target recommended in the 2008 USA NPG of <45% of total energy from carbohydrate. However, there were significant increases in NPG alignment in 2019 for some areas, including frequency of visits, provision of maternal weight gain advice, and routine weighing of women at clinic visits.

Most respondents rated their confidence in providing dietary advice to women with GDM, using a four-point Likert scale, as confident or very confident (86%, $n = 88$ vs. 83%, $n = 163$ in 2019 and 2009; $p = 0.62$).

DISCUSSION

The present study describes current MNT for GDM provided by dietitians in Australia. The findings were compared with the previous 2009 survey by Morrison *et al.*[9] and with the Academy of Nutrition and Dietetics Nutrition Practice Guidelines.[8] As found in 2009,

TABLE 2 Macronutrient targets aimed for in dietetic interventions [a]

Recommendation[a]	2019 survey *n* (%) (range)	2009 survey *n* (%)
Carbohydrate (% energy)		
Percentage of energy target (range)	30–65	20–75
High carbohydrate diet (>45% energy)	51 (62)	54 (50)
Low carbohydrate diet (<45% energy)	20 (24)***	7 (7)
Inclusive of low and high carbohydrate diets (26%–65%)	11 (13)***	45 (42)
Inclusive of low and very low carbohydrate (<26%–45%)	0	2 (2)
Very low carbohydrate diet (<26% energy)	0	0
Fibre per day (g) (mean ± SD) (range)	28 ± 4 (10–40)[b]	29 ± 4 (15–45)
Carbohydrate, g (% respondents) (range)		
Minimum carbohydrate intake per day (g)	149 ± 34 (40–220)	145 ± 36 (60–300)
Maximum carbohydrate intake per day (g)	213 ± 36 (150–280)	NA
Breakfast, 30–45 g	58/87 (67) (10–60)	NA
Lunch and dinner, 30–45 g	54/87 (62) (0–60)	NA
Snacks, 15–30 g	60/87 (69) (0–30)	NA
Glycaemic index advice	*n* = 103	*n* = 195
Choose low GI where possible	24 (23)	38 (20)
At least 1 low GI CHO at each meal & snack	23 (22)****	85 (44)
Include at least 1 low GI CHO at each meal	18 (18)	44 (23)
Avoid high GI foods	19 (18)*	14 (7)
All carbohydrate food should be low GI	19 (18)***	11 (6)
Protein	*n* = 75	*n* = 91
Percentage of energy target (range)	15–40	10–40
High protein diet (>25% energy)	17 (23)	10 (11)
Moderate protein diet (15%–25% energy)	49 (65)	59 (65)
Range (low and moderate protein diets, 10%–25%)	8 (11)	22 (24)
Range (moderate to high, 15%–40% energy)	0	13 (14)
Fat	*n* = 76	*n* = 98
Percentage of energy target (range)	10–40	7–45
High fat diet (>30% energy)	7 (9)	4 (4)
Moderate fat diet (15%–30% energy)	56 (74)	60 (61)
Low fat diet (<15%)	0	5 (5)
Range encompassing low and moderate fat diets (7%–30%)	0	6 (6)
Range encompassing moderate and high fat diets (20%–40%)	13 (17)	19 (19)

Recommendation[a]	2019 survey *n* (%) (range)	2009 survey *n* (%)
Saturated fat	*n* = 64	*n* = 73
Percentage of energy target (range)	2–15	5–15
Low saturated fat (≤10% energy)	62 (97)	68 (93)

Abbreviations: a, as defined by Evert et al.[13]; b, the minimum of the range was used for respondents who provided an answer as a range versus single figure. The mean was not significantly different to when the maximum of the range was used; NA, question not asked.

2019 versus 2009 for each recommendation; CHO, carbohydrate; GI, glycaemic index.

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$.

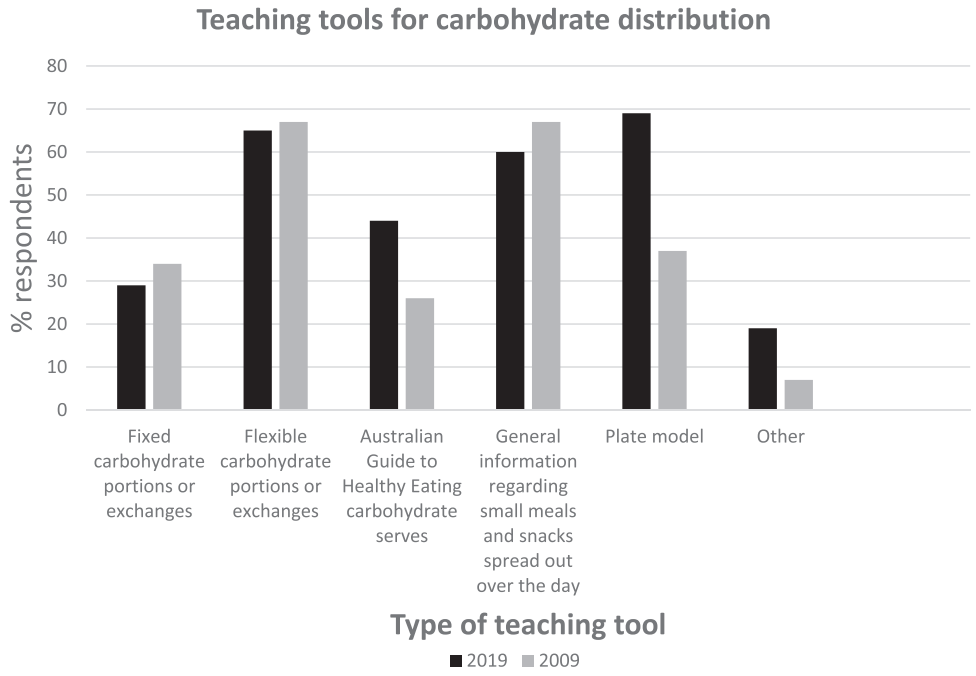

FIGURE 2 Teaching tools used in education regarding carbohydrate distribution (% respondents).

consistencies continue a decade later in broad education topics covered for women with GDM, including core food groups, food sources of macronutrients, carbohydrate intake (frequency, distribution, quantity and glycaemic index), and pregnancy weight gain. Variations remained for interventions provided by dietitians, especially in relation to carbohydrate recommendations (mean and range of minimum and maximum daily intake recommended, and percentage of total energy) and frequency of review appointments. There was also variable alignment to the 2016 NPG depending on the recommendations. Adherence remained low for some recommendations, especially regarding minimum carbohydrate intake. Low carbohydrate diets have gained popularity in many countries as evidenced by much media attention and research activity.[14–16] This may have impacted on dietetic practice and consequently the responses in this survey. However, little is known about how dietetic practice is influenced by popular trends in nutrition. More research is needed in this area. Furthermore, although not specific to GDM, a recent Cochrane Systematic review has confirmed that the efficacy of low carbohydrate diets is not superior to carbohydrate-balanced diets for glycaemic control and weight management in type 2 diabetes.[17] Adherence to the NPG recommendation on total percentage energy from carbohydrate is easier to achieve in the revised NPG. This is supported by the high adherence rate found in the 2019 survey. This is likely a result of the wide range in the recommendations within the updated guidelines (36%–65%)[3] compared to the 2008 NPG recommendations of <45% of total energy. Given the wide range in recommended percent energy from carbohydrate, an important consideration for dietitians is the safety concerns related to lower carbohydrate diets and higher risk of micronutrient inadequacies, particularly in thiamine, folate, calcium, and iodine, because they are found in

TABLE 3 Comparison of medical nutrition therapy to evidence-based nutrition practice guidelines (AND, 2016)

Recommendation	2019 survey Number of respondents *n* (%)	2009 survey Number of respondents *n* (%)
MNT		
All women with GDM referred to a dietitian	107/129 (83)	168/218 (77)
Visit frequency of 1 initial[e#], and 1 or more reviews[a]	109/125 (87)***	144/209 (69)
Visit frequency of 1 initial and 2 or more reviews[b]	61/125 (49)***	69/209 (33)
Visit frequency of 1 initial, and 1 review	48/125 (38)	75/209 (36)
Provides maternal weight gain advice	61/103 (59)*	77/195 (40)
Gestational weight gain advice according to IOM[c]	77/83 (93)****	13/97 (13)
Macronutrients		
Carbohydrate ≥175 g day^{-1}	36/112 (32)	26/108 (26)
Fibre ≥28 g day^{-1}	75/112 (67)	88/119 (74)
Provides advice regarding glycaemic index	103/103 (100)	192/195(98)
Advises smaller meals, and multiple snacks	82/109 (75)	NA
Micronutrients		
Provides dietary advice on pregnancy-specific micronutrients	75/112 (67)*	178/220 (81)
Nutrition monitoring and evaluation	*n* = 136	*n* = 209
Checks progress including: SMBG, food intake, appetite, and weight changes [d]	109/125 (87)***	144 (69)
Routine weighing by service reported	70/95 (74)*	116/195 (60)

Abbreviations: A.N.D, Academy of Nutrition and Dietetics; GDM, gestational diabetes mellitus; IOM, Institute of Medicine; MNT, medical nutrition therapy; NA, question not asked; SMBG, self-monitored blood glucose.

[a]*n* = 11 respondents in the 2019 survey did not provide an average number of visits per patient with GDM (and so were excluded from analysis), but instead indicated that it depended on individual factors such as patients' blood glucose levels, weeks of gestation, inadequate weight gain, and dietary over-restriction.

[b]Best practice according to AND guidelines, 2016.

[c]Institute of Medicine Maternal weight gain guidelines (2009).

[d]Number (%) respondents indicating at least one review is provided to each woman with GDM where nutrition monitoring and evaluation could have occurred.

[#]Either group or individual visit.

2019 versus 2009 for each recommendation.

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$, 2019 versus 2009 for each recommendation.

carbohydrate rich foods such as breads, cereals, milk, and yoghurt.[18,19] Maternal diets already commonly fail to meet micronutrient requirements.[20,21] Restriction of these nutrient dense carbohydrate rich foods may further increase the risk of such deficiencies.[22] Inclusion of adequate amounts of nutrient dense, fibre rich sources of carbohydrate may need more reinforcement in MNT for GDM.

There was a significant increase in the number of dietitians providing the number of visits consistent with NPG recommendations between 2009 and 2019, although more than half reported a frequency less than that recommended. The greatest improvements in NPG adherence were for recommendations related to maternal weight gain advice and monitoring.

Consistent with our findings, two other similar surveys[23,24] also found significant variation in clinical practice among dietitians. In the current survey, the variations in advice given to women with GDM were particularly evident in MNT regarding carbohydrate intake. This is of concern given that carbohydrate intake is a central focus of MNT for GDM. It is possible that the variations in clinical practice found in this survey simply reflect clinical experience and individualised patient-centred MNT focusing on addressing the individual needs in the context of social, cultural and personal preferences. The NPG clearly stipulate that MNT for women with GDM needs to be individualised, with the aims of achieving and maintaining glycaemic targets and appropriate weight gain,

at the same time as meeting the nutritional requirements of pregnancy. Adjusting MNT according to individual requirements would result in variations in practice. The wide range in percentage energy from carbohydrate recommended in the updated NPG also allows scope for evidence-based variations in practice.[8] Dietitians have the challenge of providing individualised care in the context of navigating the limitations in dietetic staffing and in the current evidence to guide practice in this clinical area.[25]

However, although, individualisation of MNT may explain the variations in MNT found in these surveys, it is not possible to determine this because of the survey design. Dietitians were asked to state what MNT they usually advise and not how advice differs between individuals. For example, dietitians were asked 'What amounts of carbohydrate do you usually recommend?'[3] It is also possible that the limited MNT review visits reported limits individualisation of MNT as a result of limited opportunities for adjusted MNT according to ongoing evaluation of appetite, dietary intake, weight, and glycaemic control. Future research in this area may benefit from alternative methodology because it was not possible to explore the reasons for the apparent deviations from best practice found in this survey given the anonymous structured survey design. Qualitative research such as open- ended questions and face to face interviews may be warranted.

Many changes have occurred in the clinical management of GDM in the 10 years between surveys, which likely impacted on MNT provided to women with GDM. These include an increase in universal screening and a change in the diagnostic criteria, and an increase in those diagnosed before 24 weeks.[10–12] All these factors have resulted in an increase in the total number of women with GDM[26] and also appear to have resulted in an increase in the number of women who may have milder degrees of GDM.[27,28] Consequently, more women are managed with MNT alone, in which dietitians play a pivotal role. These changes in the clinical landscape suggest an opportunity to explore new models of care such as dietitian led GDM clinics.

There are likely to be many barriers to the uptake of the NPG in Australia. Identifying these barriers is the first step in developing tailored implementation strategies.[29-32] Lack of dietetic staffing has been reported as one of the greatest barriers to GDM guideline implementation in several studies given the frequency of visits recommended (one initial visit and two or more reviews).[33–35] Given the rising rates of GDM globally and concurrent increases in clinical workload, this is not surprising.[11,12] However, despite these challenges, several Australian studies have developed models of care aimed at increasing provision of evidence-based MNT for GDM.[36–38] These studies successfully increased the proportion of women with GDM receiving the frequency of MNT consistent with NPG recommendations in their services. Although dietetic staffing was increased in these services, additional strategies included staff training, development of clinical pathways, audit and feedback processes, and identification of profession specific clinical champions. These findings suggest that a multi-pronged approach could increase effectiveness. Such an approach could be considered by other GDM services.

A lack of familiarity with, and consequently utilisation of, clinical guidelines is another commonly reported barrier to clinical guideline implementation.[31] The lack of utilisation is evident in the finding that only 19% of respondents reported using any clinical guideline to guide their carbohydrate intake recommendations. The lack of familiarity with the NPGs in particular is evident in that only 8% of respondents in the 2019 survey reported use of this guideline to guide their practice. Similarly, the low number of respondents recommending the minimum carbohydrate intake of 175 g day^{-1} in line with these guidelines also suggests a lack of familiarity with these guidelines. Given the NPGs are American, they may require local endorsement and adaptation to the Australian context, as well as training to increase awareness and subsequent implementation. Targeted professional development opportunities are clearly needed to increase familiarisation and implementation of the NPG.

Another commonly reported barrier to guideline implementation is the lack of credibility of the evidence.[30,31] In GDM, MNT has been clearly shown to reduce blood glucose levels, medication use, macrosomia, and infant birthweight.[39] Although the NPG are based on the best available evidence at that time, there are still substantial inconsistencies within the body of evidence.[3] Furthermore, there is a lack of evidence on the most optimal, sustainable, and acceptable MNT for GDM management.[40] Because respondents were not asked to report on their level of confidence in the current evidence to guide practice, this potential barrier could not be confirmed. However, these guidelines, based on a rigorous systematic review, are the best available evidence at the time of writing.[3] Given the time and resources required to develop evidence-based guidelines, the development of Australian specific guidelines would be difficult to justify. Strategies to increase implementation of and confidence in the NPGs appear to be the best next steps, including adaptation to the Australian context.

The present study has several strengths. Both surveys were widely distributed via a range of online platforms, including DA, Dietitian Connect and Facebook groups. Furthermore, through use of many of the same survey questions, this study uniquely captured dietetic practice in GDM at two time-points that were 10 years apart.

A significant limitation of the present study was the substantial drop-out rate in the 2019 survey, with only 63% of respondents completing it, perhaps as a result of the length of the survey. It is therefore unknown whether these findings are truly representative of all dietetic practice in GDM in Australia. An additional limitation is that it was not possible to assess responses according to employment sectors, and primary areas of practice where dietitians worked in more than one sector/area because

more than one response could be selected. A further limitation is that it was not possible to calculate a response rate because the number of dietitians providing dietary advice to women with GDM in Australia is not known (personal communication, Dietitians Australia).

However, many findings from the 2019 survey are similar to findings by Morrison *et al.*[9] Furthermore, respondents from both surveys were from a range of geographical locations and employment sectors, including representation from public and private, generalist, and specialist services, and had varying years of diabetes experience. Of note, there were no significant differences in the demographics of completers versus noncompleters in the 2019 survey.

In conclusion, variations in approaches to MNT provided by dietitians for women with GDM in Australia observed in 2009 continue to be seen 10 years later. This is despite updated NPGs. Although these variations may reflect individualisation of MNT, there are likely multiple barriers to MNT best practice in GDM. Strategies to address barriers to implementation of NPG need urgent consideration, including increasing staffing and provision of targeted training opportunities. Such strategies should be prioritised given the rising rates of GDM both in Australia and globally and also because of evidence of the vital role of MNT in optimising maternal and neonatal outcomes in GDM pregnancies.

AUTHOR CONTRIBUTIONS

Melinda Morrison and Clare E. Collins were responsible for the conception and design of the original 2009 survey. Robyn A. Barnes, Melinda Morrison, Lesley MacDonald-Wicks, Clare E. Collins, Carmel E. Smart, Jeff R. Flack, and Glynis P. Ross were responsible for adaption of the original survey for the 2019 survey. Robyn A. Barnes and Melinda Morrison were responsible for data analysis for the 2019 and 2009 surveys, respectively. Robyn A. Barnes, Melinda Morrison, Lesley MacDonald-Wicks, Clare E. Collins, Carmel E. Smart, Jeff R. Flack, and Glynis P. Ross were responsible for interpretation of the data. Robyn A. Barnes was responsible for writing and editing the manuscript. Melinda Morrison, Lesley MacDonald-Wicks, Clare E. Collins, Carmel E. Smart, Jeff R. Flack, and Glynis P. Ross were responsible for critical revision of the manuscript. Supervision was provided by Lesley MacDonald-Wicks, Clare E. Collins, Carmel E. Smart, Jeff R. Flack, and Glynis P. Ross. All authors approved the final version of the manuscript submitted for publication.

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

ETHICS STATEMENT

This study was approved by the University's Human Research Ethics Committee, Approval Reference Number: H-2017-0388.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The lead author affirms 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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Prevalence of hospital-acquired malnutrition and modifiable determinants of nutritional deterioration during inpatient admissions: A systematic review of the evidence

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Abstract

Background: Malnutrition affects between 20% and 50% of hospital inpatients on admission, with further declines expected during hospitalisation. This review summarises the existing literature on hospital-acquired malnutrition that examines the magnitude of nutritional deterioration amongst adult inpatients and identifies preventable barriers to optimising nutrition support during episodes of care.

Methods: A systematic review was conducted to answer the question: Among adult hospital inpatients, the presence of which modifiable factors contribute to hospital-acquired malnutrition? A database search was conducted between the 24 April and 30 June 2020 using CINAHL, MEDLINE, Scopus and PubMed databases according to a protocol registered with PROSPERO (CD42020182728). In addition, issues of the 10 top clinical nutrition journals published during the period of from 1 April 2015 to 30 March 2020 were hand-searched.

Results: Fifteen articles were eligible for inclusion from a total of 5944 retrieved abstracts. A narrative synthesis of evidence was completed because of the high level of heterogeneity in methodologies. Nutritional deterioration is common among previously well-nourished and nutritionally compromised patients, with studies reporting that 10%–65% of patients experienced nutritional decline. Frequently reported barriers were meal-time interruptions, meal dissatisfaction, procedure-related fasting, effects of illness or treatment, chewing difficulties, poor appetite and malnutrition as a low clinical priority.

Conclusions: The findings of this review support the need for routine nutritional risk screening throughout each hospital admission with hospital-acquired malnutrition affecting up to 65% of inpatients. Clear establishment of the roles and responsibilities of each member within multidisciplinary healthcare teams in the provision of nutrition care and cost–benefit analyses are recommended to demonstrate the effectiveness of changes to models of care.

KEYWORDS

inpatients, malnutrition, nutrition assessment, nutritional status

Key points

- Among adult hospital inpatients, the presence of which modifiable factors contribute to hospital-acquired malnutrition?
- Nutritional deterioration was identified in 10%–65%of patients from 15 eligible studies, with barriers to nutritional adequacy frequently reported on both the institution and patient levels.
- There is a need for routine nutritional risk screening throughout each hospital admission, shared responsibility for nutrition care across the broader multidisciplinary healthcare team, and greater emphasis to be placed on patient satisfaction with hospital meal services.

INTRODUCTION

Malnutrition affects between 20% and 50% of hospital inpatients.[1–3] If untreated, a further two-thirds of patients admitted with malnutrition will experience a decline during the course of their admission, whereas one-third of well-nourished patients may become malnourished.[4] Malnutrition in hospital may be precipitated by iatrogenic factors, barriers to intake and complex physiological and metabolic alterations accompanying the acute inflammatory response that disrupt normal nutrient utilisation and promote catabolism and/or hypermetabolism.[5–7] In some cases of disease-related malnutrition, nutrition support alone may be inadequate to prevent further nutritional decline despite energy provision corresponding with measured energy expenditures.[5,8]

Hospital malnutrition is a predictor of increased length of stay, impaired wound healing, increased risk of infections and complications, and increased morbidity and mortality.[1,4] Thus, malnourished patients have more substantial care needs with a greater reliance on hospital resources resulting in higher healthcare costs.[1,3,4,6–13] This has led to the integration of nutrition screening into hospital admission protocols. However, whether nutrition screening is required to be undertaken at all, as well as the timeframe in which it is to be completed, is at the discretion of the regional healthcare governing body. In New South Wales (NSW), nutrition screening using a validated tool is a requirement for all hospitals. It is recommended to be undertaken within the first 24 h and weekly thereafter during an acute admission or following a change in a patient's clinical condition.[14] Despite this, routine nutrition screening using validated tools is not always performed and, often, nutrition intervention is more reactive rather than proactive.[15] Ongoing nutrition screens may be disregarded because of competing clinical priorities, which remains a primary challenge to circumventing persistently high rates of hospital-acquired malnutrition.[16] Although malnutrition in hospitalised patients has been thoroughly studied in the past, the evidence examining the magnitude of malnutrition acquired during hospital stays, and institution-level factors that contribute to worsening of nutritional status during admission is less concrete. Taking a proactive approach to combatting hospital-acquired malnutrition necessitates that system-level barriers are clearly identified to develop targeted solutions.

Documentation in medical records does not typically delineate cases of hospital-acquired malnutrition from cases of community-acquired malnutrition, in which patients present with pre-existing malnutrition on admission. The former can be further categorised based on preventable and non-preventable aetiologies. Preventable hospital-acquired malnutrition may or may not be accompanied by injury or inflammation with consequent increases in nutritional requirements, where nutritional requirements have not been met. Non-preventable hospital-acquired malnutrition refers to malnutrition in the presence of injury or inflammation, where nutritional status remains compromised despite adequate nutritional intake.[8] The Australian Commission on Safety and Quality in Health Care recognises malnutrition as one of 16 Hospital-Acquired Complications (HACs), defined as nosocomial conditions for which the clinical risk may be mitigated through appropriate preventive strategies. In July 2018, a new Risk Adjustment Model was implemented by the Independent Hospital Pricing Authority (IHPA). Under this model, hospitals receive financial penalties to reimbursements when HACs, including hospital-acquired malnutrition, are coded.[17] The financial burden associated with caring for patients with hospital-acquired malnutrition and the additional onus now placed on Australian hospitals under the IHPA model creates strong incentive to identify and address causes of preventable hospital-acquired malnutrition.

Studies examining modifiable determinants of hospital-acquired malnutrition are limited. In one study, 76% of malnourished patients experienced at least one institution-level care gap including poor dietitian–physician communication, inappropriate nil-by-mouth (NBM) orders or inaccurate dietetic discharge instructions.[18] NBM is often prescribed inappropriately as a result of updated clinical practice guidelines not being widely adopted.[19,20] Evidence suggests a strong association between any care-related gap and increased length of hospital stay.[19–23] However, the generalisability of these studies is limited because of a

reliance on single-centre data and having been conducted prior to full implementation of the pricing model. Preventable components may also extend beyond these predetermined classifications, and more precisely identifying these shortcomings will enable the development of protocols to mitigate preventable causes.

Recommendations have been made for the establishment of targeted interventions addressing barriers related to food service, mealtime and nutrition care, which include the need for a multidisciplinary team approach and institutional culture that prioritises nutrition more broadly within the context of clinical care. However, specific nutrition care responsibilities of each member of the team have yet to be established.[15] Identifying existing shortcomings is a critical first step to promoting changes in practice through evidence-based education of administrators on the direct benefit of enhanced food service and care-related processes to patient outcomes and subsequent costs of patient care.

This systematic literature review summarises the existing literature on hospital-acquired malnutrition that examines the magnitude of nutritional deterioration amongst adult inpatients and identifies preventable barriers to optimising nutrition support during episodes of care. For the purpose of this review, hospital-acquired malnutrition is defined as any decline in nutritional status during the course of hospitalisation. The PEO exploratory research question being addressed was: Among adult hospital inpatients (Population), the presence of which modifiable factors (Exposure) contribute to hospital-acquired malnutrition (Outcome)?

METHODS

The systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 5 July 2020 (CD42020182728). The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines were followed[24] and a protocol of the review methods was established prior to undertaking the review.

Search strategy and selection

A pilot search was conducted in PubMed to identify key search terms and to guide the development of the search strategy. Once complete, a literature search was conducted between the 24 April and 30 June 2020. Search terms can be found in the Supporting information (Figure S1). Four electronic databases were searched (CINAHL, MEDLINE, Scopus and PubMed). In addition, all issues of ten top journals in clinical nutrition published during the period from 1 April 2015 to 30 March 2020 were reviewed to ensure that all recent relevant articles were identified (for details, see Supporting information, Figure S2). Search results were exported to EndNote X20 reference management tool (Clarivate Analytics). All titles, abstracts and full-text articles were screened by a single investigator (AC). A second reviewer (KC) was consulted if there was uncertainty as to whether an article met the inclusion criteria once full-text articles were retrieved. A narrative synthesis of evidence was completed due to the high level of heterogeneity in methodologies.

Inclusion and exclusion criteria

Study designs eligible for inclusion were randomised-controlled trials, cross-sectional, cohort or case–control studies. This criterion was established to include a broader range of study designs given the more recent shift in research investigations from measuring inpatient malnutrition at a single time point to evaluating patient progression overtime. Consequently, the investigators anticipated drawing from a smaller pool of eligible studies, thus necessitating a broader inclusion criterion to avoid excluding relevant findings. Studies examined adult (≥18 years) male or female inpatients (acute care, sub-acute or rehabilitation). Included studies measured nutritional status on at least two separate occasions, on admission (or shortly thereafter) and again at a specified time that was sufficiently long to observe a clinically relevant change in nutritional status (>7 days) or just prior to discharge. Only full-texts available in English were included. Studies examining famine, pre-existing malnutrition or those conducted in paediatric or pregnant patients, or community-dwelling, outpatients and nursing home residents were excluded.

Quality assessment

Using the Academy of Nutrition and Dietetics (AND) Risk of Bias Tool, the methodological quality of each study was assessed by a single investigator (AC) based on the following quality checklist domains: study relevance, research questions, subject selection, group comparability, withdrawals handling, blinding, interventions/exposure, outcomes, analyses, conclusion support and likelihood of bias. A second investigator (KC) was consulted if there was any uncertainty. Studies were assigned a quality rating of positive, negative or neutral. The AND Quality Criteria Checklist was selected as it has been designed to assess the methodological quality for non-specific research topics within nutrition and dietetics and is applicable across a range of study designs, including cross-sectional and cohort studies. The Evidence Analysis Manual allows researchers to adapt the assessment to the specific study design by assigning more weight to questions and domains that are specifically relevant to the

study design in question.[25] All relevant articles were assigned a level of evidence based on the National Health and Medical Research Council (NHMRC) criteria, which provides a ranking of the quality of evidence based on the strength and precision of research methods used, the ability to control for bias and to establish cause and effect relationships in humans. Levels of evidence range from highest, Level I, assigned to secondary, preappraised or filtered studies, to lowest, Level IV, assigned to case series, post-test or post-test and pretest.[26]

Data extraction

Key data from selected articles were summarised and tabulated by one reviewer (AC) according to authors, year and country of publication, study design, number of participants, clinical setting, median participant age, nutritional assessment tool and timing, results of nutritional assessment and determinants of malnutrition. *p* values are reported where available.

RESULTS

Search results

The search strategy identified 5944 titles from the databases and a further 73 titles from hand-searching of top journals, resulting in 6017 articles. After 863 duplicates were removed, 5154 titles were screened and 4865 titles were further excluded. Abstracts of 289 articles underwent further screening, leading to retrieval of 34 full-text articles, of which 15 were eligible for inclusion. A PRISMA flowchart is provided in Figure 1. A full list of full-text articles that were excluded is available in the Supporting information (Figure S3).

Study characteristics

Table 1 summarises key characteristics and findings of the included studies. All but one study was observational in design,[27–40] with the remaining study being quasi experimental.[41] Eight studies were prospective cohorts,[27,33,34,36–39,41] four were prospective cross-sectional studies,[29,32,35,40] one was a retrospective cohort study[31] and one was a sequential explanatory mixed-methods study.[30] Four reported on factors associated with deteriorating nutritional status.[28,30,31,36] Studies were conducted across several countries with representation from both low-middle and high-income countries across Africa, Asia, Europe, North America and Oceania.[27–41]

Description of assessment methods

All studies evaluated nutritional status or risk on at least two occasions over the course of the admission.

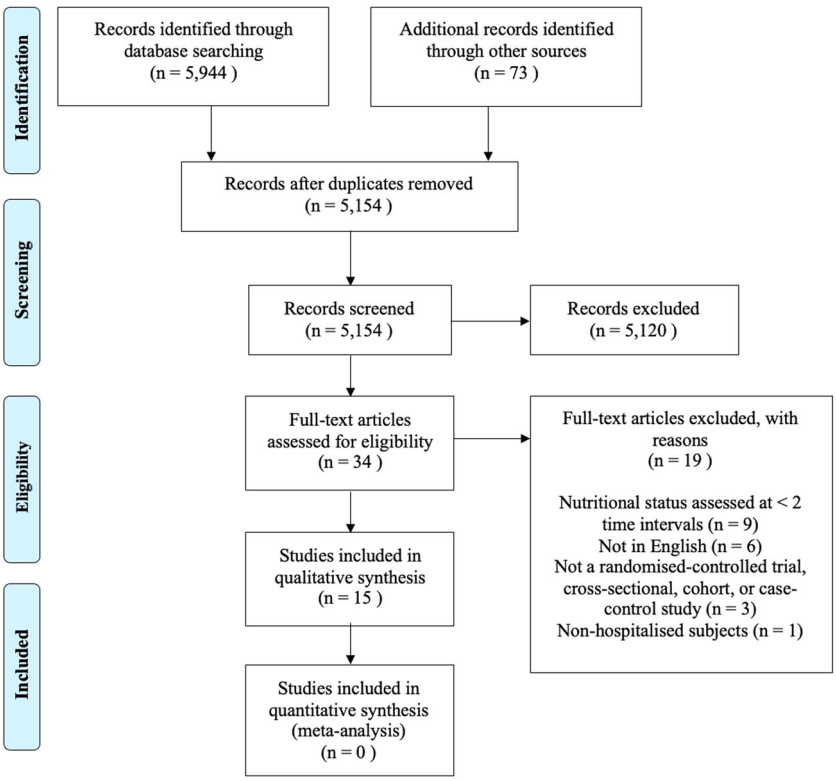

FIGURE 1 Summary of search and selection process according to the Preferred Reporting Items for Systematic Review and Meta-Analyses Flowchart (PRISMA).

TABLE 1 Study characteristics and outcomes

Authors, year (country)	Study design	NHMRC[a] level of evidence	*n*	Clinical setting	Median age (years)	Assessment tool (intervals)	Prevalence of hospital-acquired malnutrition	Barriers
Abahuje *et al.* (2020) (Rwanda)[27]	Single-centre prospective cohort	II[a]	279	Acute care surgery	38	AND/ASPEN[b] (admission, weekly) SGA[c] (admission)	Week 1: 41% malnourished. Week 2: 37% malnourished. Week 3: 50% malnourished. Week 4: 43% malnourished.	Not described
Allard *et al.* (2015) (Canada)[28]	Multicentre prospective cohort	II[a]	424	Medical and surgical	68	SGA[c] (admission, discharge)	19.6% deteriorated, 17.4% improved, 63.0% remained stable.	Dissatisfaction with meal quality and illness-related effects in medical patients ($p < 0.01$).
Álvarez-Hernández *et al.* (2012) (Spain)[29]	Multicentre prospective cross-sectional	IV[a]	1707	Inpatients	63	NRS-2002[d] (within 48 h of admission, discharge or day 28 if length of stay > 28 days)	118/1225 (9.6%) well-nourished on admission became malnourished. 252/351 (72%) malnourished on admission remained malnourished. 99/351 (28.2%) malnourished on admission improved.	Not described
Bell *et al.* (2012) (Australia)[30]	Single-centre sequential explanatory mixed-methods	III-2[a]	44	Orthogeriatric hip fracture patients	81.7	AND/ASPEN[b] (admission, discharge)	23/44 (52.2%) malnourished at baseline 28/44 (63.6%) malnourished on discharge 9/44 (20.5%) deteriorated	Patient-perceived: mealtime interruptions (43.1%), poor appetite (36.2%) Clinician-perceived: Patients do not recognise malnutrition as a problem, low clinical priority amongst clinicians.

(Continues)

TABLE 1 (Continued)

Authors, year (country)	Study design	NHMRC[a] level of evidence	*n*	Clinical setting	Median age (years)	Assessment tool (intervals)	Prevalence of hospital-acquired malnutrition	Barriers
Cheng *et al.* (2019) (Australia)[31]	Single-centre retrospective cohort	III-2[a]	15419	Inpatients	59	SGA[c] (undefined)	23/15419 (0.1%) with hospital-acquired malnutrition 23/419 (5.5%) cases of malnutrition acquired in hospital	Poor appetite (4/23, 25%), meal dissatisfaction (3/23, 19%), operation-related fasting (3/23, 19%)
Collins *et al.* (2016) (Australia)[32]	Single-centre prospective cross-sectional	IV[a]	248	Sub-acute (rehabilitation, geriatric)	80	MNA[e] (within 72 h of admission, discharge)	62.0% stable, 10.3% deteriorated, 27.7% improved.	Not described
Diendéré *et al.* (2017) (Burkina Faso)[33]	Single-centre prospective cohort	II[a]	222	CVA	60.5	BMI < 18.5 kg m^{-2}(days 0, 8, 14)	25.2% (95% confidence interval = 19.7–31.5) malnourished at baseline 29.4% (95% confidence interval = 23.2–36.3) malnourished on day 8 31.0% (95% confidence interval = 24.4–38.2) malnourished on day 14	Not described
Haffsteinsdóttir *et al.* (2010) (the Netherlands)[34]	Single-centre prospective cohort	II[a]	196	Neurology, neurosurgery	68	MNA[e] (days 0, 10)	Admission: 34% at risk, 7% malnourished, 59% well-nourished. Day 10: 57% at risk, 22% malnourished, 21% well-nourished.	Not described

TABLE 1 (Continued)

Authors, year (country)	Study design	NHMRC[a] level of evidence	*n*	Clinical setting	Median age (years)	Assessment tool (intervals)	Prevalence of hospital-acquired malnutrition	Barriers
Hosseini *et al.* (2006) (Iran)[35]	Single-centre prospective cross-sectional	IV[a]	156	Inpatients	43	BMI[f] (admission, discharge)	Admission: 9 (5.8%) malnourished, 1 (0.6%) severely malnourished. Discharge: 17 (10.9%) malnourished, 2 severely malnourished (1.3%)	Not described
Incalzi *et al.* (1996) (Italy)[36]	Single-centre prospective cohort	II[a]	286	General medicine, geriatric	79	MUAC (admission, weekly, discharge)	27% deteriorated	Group with poor intake: rate of poor appetite greater ($p = 0.001$), referred to dietitian no more frequently than those with fair (40%–70%) and good (> 70%) intakes ($p = 0.49$, $p = 0.76$, respectively)
McWhirter *et al.* (1994) (Scotland)[37]	Single-centre prospective cohort	II[a]	500	General surgery, general medicine, respiratory medicine, orthopaedic surgery, medicine for elderly	Not reported	BMI and TSF or MUAC[g] (admission, discharge)	16/112 deteriorated.	Not described
Mosselman, *et al.* (2013) (the Netherlands)[38]	Single-centre prospective cohort	II[a]	73	Acute stroke	65	MNA[e] (days 0, 10)	15/23 (65%) deteriorated	Not described
Patel *et al.* (2008) (UK)[39]	Single-centre prospective cohort	II[a]	100	Elderly acute inpatients	82	Demiquet or mindex[h] (admission, discharge or 4 weeks if length of stay > 4 weeks)	3/100 well-nourished on admission deteriorated.	Not described

(Continues)

TABLE 1 (Continued)

Authors, year (country)	Study design	NHMRC[a] level of evidence	*n*	Clinical setting	Median age (years)	Assessment tool (intervals)	Prevalence of hospital-acquired malnutrition	Barriers
Planas *et al.* (2016) (Spain)[40]	Sub-analysis of multicentre prospective cross-sectional	IV[a]	401	Oncology	65	NRS-2002[d] (within 48 h of admission, discharge or day 28 if length of stay > 28 days)	Admission: 136/401 (33.9%) malnourished. Discharge: 135/371 (36.4%) malnourished.	Not described
Ramos-Martínez *et al.* (2016) (Spain)[41]	Single-centre quasi experimental	III-2[a]	133	Onco-haematology	Positive MST at follow-up (63.4) Negative MST at follow-up (63.2)	MST[i] (day 1, weekly)	28/133 (21%) well-nourished at baseline became malnourished *$p < 0.05$	Not described

[a]National Health and Medical Research Council (NHMRC) levels of evidence and grades for recommendations.[42]

[b]Academy of Nutrition and Dietetics (AND)/American Society for Parenteral and Enteral Nutrition (ASPEN) diagnostic criteria require two of six characteristics to be present for a malnutrition diagnosis (i.e., insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, localised or generalised fluid accumulation and diminished functional status based on hand grip strength). Malnutrition is categorised as moderate or severe in the context of acute or chronic illness or injury, or social and environmental circumstances.[43]

[c]Subjective Global Assessment (SGA) categorises patients as well-nourished (SGA A), mild-moderate malnutrition (SGA B) or severe malnutrition (SGA C).[44]

[d]NRS scores three parameters from 0 to 3. A total score greater than three indicates nutritional risk.[44]

[e]Mini Nutritional Assessment (MNA) classifies patients at no nutritional risk (12–14 points), at risk of malnutrition (8–11 points) or malnourished (0–7 points).[44]

[f]Body mass index (BMI) < 18.5 kg m^{-2} (malnourished), BMI < 16.0 kg m^{-2} (severely malnourished).[34]

[g]BMI < 20 and triceps skinfold (TSF) or mid-upper arm circumference (MUAC) below 15th centile (mildly undernourished), BMI < 18 and TSF or MUAC below 5th centile (moderately undernourished), BMI < 16 and TSF or MUAC below 5th centile (severely undernourished).[44]

[h]Demiquet is the weight divided by the square of the demispan in centimetres. Mindex is weight divided by height in metres.[38]

[i]Malnutrition Screening Tool (MST) classifies nutritional risk based on numerical scores of 0 (low risk), 1 (medium risk) and 2 or higher (high risk).[45]

This included an assessment or screening on admission as a baseline measure of nutritional status with follow-ups either at a predetermined time or just prior to discharge. Methods to assess changes in nutritional status were heterogeneous across studies and included the Malnutrition Screening Tool (MST)[41,46] ($n = 1$), the AND/American Society for Parenteral and Enteral Nutrition (ASPEN) criteria[27,30] ($n = 2$), the Subjective Global Assessment (SGA)[28,31] ($n = 2$), the Mini Nutritional Assessment (MNA)[32,34,38] ($n = 3$) and the Nutrition Risk Screening 2002 tool (NRS-2002)[29,40] ($n = 2$), whereas the remaining five studies used either a single or a combination of two anthropometric parameters such as body mass index (BMI), mid-upper arm circumference (MUAC), triceps skinfolds (TSF) and weight.[33,35–37,39]

Participant characteristics

Mean participant age ranged from 38 to 82 years[27–36,38–41] and one study did not report age.[37] Clinical specialities varied considerably across studies; 53% ($n = 8$) of studies included patients across two or more clinical areas,[28,29,31,32,35–37,39] and the remaining seven studies recruited only patients from a single clinical specialty or ward.[27,30,33,34,38,40,41]

Quality assessment

Using the AND Risk of Bias Tool, seven and eight studies were respectively assigned positive and neutral quality ratings, with details of individual studies' quality assessments outlined in the Supporting information (Table S1). According to the NHMRC levels of evidence criteria, eight studies were assessed as Level II evidence, three studies were assessed as Level III-2 evidence and the remaining four studies were assessed as Level IV evidence.

Nutritional deterioration

The prevalence of nutritional deterioration was reported to range from 2% to 65% of patients across studies.[27–41] Studies that examined inpatients indiscriminately tended to have lower rates of decline compared to studies that focused on only one or two clinical areas or wards. Nutritional decline amongst more diverse patient cohorts ranged from 5.5% to 20.9%.[29,31,35,37] Amongst studies that included patients from only one or two clinical areas, sub-acute rehab and geriatric patients had the most favourable outcomes with 62.0% remaining nutritionally stable, whereas only 10.3% declined, and 27.7% had improved since their baseline assessments.[32] Neurology and stroke patients experienced the highest rates of nutritional deterioration ranging from 38% to 65% when malnutrition was assessed using a validated screening tool.[34,38] Notably, on admission, 91% of acute stroke patients were well-nourished and no patients were malnourished.[38] When stroke patients were assessed using BMI as an indicator of malnutrition, rates of deterioration dropped to 5.8%.[33] General medicine and surgery patients showed considerable heterogeneity in rates of deterioration across studies, ranging from 2% to 27%.[27,28,36] In a Canadian study, 37% of medical and surgical patients experienced a change in nutritional status from admission to discharge; 19.6% of patients across all SGA categories at baseline had deteriorated, whereas 17.0% showed an improvement in nutritional status.[28] Similarly, 3%–27% of acute geriatric patients were observed to decline.[30,36,39] Amongst oncology and onco-haematology patients, 2.5%–21.0%, respectively, deteriorated.[40,41]

Barriers to nutrition support

Four studies reported on factors associated with decline in nutritional status.[28,30,31,36] On the institutional level, poor meal quality (taste, appearance and aroma) and satisfaction with the food service was reported by patients from all studies.[28,30,31,36] Forty-three per cent of orthogeriatric hip fracture patients reported meal-time interruptions as the most common barrier to intake.[30] NBM orders and procedure-related fasting were also frequently reported by Australian inpatients across specialties.[30,31] Clinicians reported that nutrition being a low clinical priority amongst other healthcare personnel was a major barrier to optimising patient nutrition care.[30] On the patient level, effects of illness and treatment were consistently reported as barriers across all studies.[28,30,31,36] Notably, poor appetite was the most common complaint, affecting 25%–55.5% of patients.[30,31,36] Italian inpatients meeting less than 40% of their prescribed nutritional requirements reported poor appetite significantly more compared to those with greater nutritional intakes.[36] In Canadian medical patients, loss of appetite was significantly associated with nutritional deterioration ($p < 0.01$).[28] Additional symptoms reported to inhibit intake included drowsiness, memory, constipation and pain.[28,30] Chewing and swallowing difficulties were similarly a common complaint affecting intake, particularly in older cohorts.[30,36] Clinicians perceived that a lack of awareness of malnutrition as a problem by patients was a predominant barrier to meeting nutritional requirements.[30] When the preventable nature of hospital-acquired malnutrition was examined, Cheng *et al.*[31] found that only two of 16 Australian inpatients could be classified as having non-preventable hospital-acquired malnutrition because of metabolic derangements that resulted in nutritional needs exceeding the patients'

metabolic capacity, despite the provision of adequate nutritional support.

DISCUSSION

This systematic review characterised the change in nutritional status of hospital inpatients during episodes of care and identified the modifiable determinants associated with nutritional decline. A deeper understanding of the preventable factors associated with hospital-acquired malnutrition will inform opportunities to guide the development of appropriate preventive strategies and adoption of protocols that target identified institution-level gaps in practice. Consequently, this may result in both improved patient outcomes and cost-effectiveness of inpatient care.

This review demonstrated that nutritional compromise is not only an effect of pre-existing factors, but also generally worsens during inpatient admissions, with hospital-acquired malnutrition affecting up to 65% of patients, thus supporting the need for repeated nutrition screening and assessment during the course of hospital stay. Barriers to optimising nutritional status at the institutional level were identified by four of the studies reviewed and included poor meal quality and satisfaction, mealtime interruptions, NBM orders and procedure-related fasting, and low clinical priority amongst both clinical staff and patients. Patient-level barriers frequently reported included effects of treatment and illness, most notably poor appetite.[28,30,31,36] In another study, patients who acquired malnutrition during the course of their stay responded positively to oral nutrition supplements, parenteral nutrition (PN) and dietary modifications[41] which suggests that mitigation is possible with appropriate preventive strategies.

Although all studies reported and compared nutritional status on at least two separate occasions to determine the level and direction of nutritional evolution, only one study reported the true rate of hospital-acquired malnutrition,[31] as defined by a deterioration in nutritional status during the course of the admission. As a result of differences in analyses and reporting methods, it is difficult to define the true prevalence of hospital-acquired malnutrition; however, 2%–65% of patients experienced nutritional deterioration in the included studies.[27–41]

All studies demonstrated some level of nutritional deterioration of inpatients over time; however, few studies delineated patients who were malnourished at baseline and improved from those that were previously well-nourished or malnourished and who saw further declines, likely underestimating the true prevalence of hospital-acquired malnutrition. Other studies only followed patients who presented as well-nourished on admission,[31,39] thus overlooking the two-thirds of patients already malnourished on admission, who are at risk of deteriorating over the course of their hospitalisation.[4]

Only one study was retrospective in design, which may have contributed to the lower rates of hospital-acquired malnutrition identified in this study compared to the studies that observed patients prospectively. Because prospective studies reflect ideal research conditions, this may have resulted in more effective identification of hospital-acquired malnutrition; however it is not necessarily reflective of usual care.[47]

Heterogeneity in the methods used to assess nutritional evolution limited comparability between studies. Many studies could only classify patients into two categories of either well-nourished or malnourished,[33,35,36,39] which prevents identification of further nutritional deterioration among already malnourished patients. Moreover, only some studies relied on validated tools to diagnose malnutrition. Tools should be validated for the population in which they are to be used to ensure that they will appropriately detect malnutrition and trigger intervention.[16] Three studies used BMI[33,35,37] as a measure of nutritional status, and a fourth study used a modified BMI score.[39] BMI is often a useful component of more comprehensive nutritional assessments; however, based on current cut-off points, BMI alone is not adequately sensitive to identify malnourished hospitalised patients.[48] This is because BMI cannot delineate between body fat and fat-free mass, particularly relevant to the sarcopaenic population,[49] nor accommodate changes in fluid resulting from oedema and/or ascites, thereby masking weight loss.[50] Notably, the lowest rates of deterioration were reported by studies that relied on BMI or demiquet/mindex exclusively as a measure of nutritional status,[33,35,39] suggesting that BMI or similar measures in isolation may not be adequately sensitive to detect clinically relevant nutritional decline in hospitalised patients, which is consistent with findings from prior research.[47] Three studies reported on scores using the NRS-2002 and MST[29,40,46] nutritional risk screening tools, which are not appropriate for use in diagnosing malnutrition,[48] whereas the remaining seven studies relied on validated assessment tools such as the AND/ASPEN diagnostic criteria, MNA and SGA.[27,28,30–32,34,38]

Future research evaluating the prevalence of hospital-acquired malnutrition should emphasise accurate assessment of malnutrition using validated assessment tools, rather than screening tools or discrete parameters associated with nutritional status. Furthermore, relying on tools that stratify patients based on the severity of malnutrition provides greater insight into the true rate of hospital-acquired malnutrition as patients who are already malnourished on admission are not overlooked when clinically relevant deterioration occurs. Although the current review was not limited to include only studies that followed the progression of individual patients from admission to discharge, but rather included studies that compared different cohorts of patients on admission

versus on discharge, future research that follows individual patients overtime will enable researchers to delineate patients who were malnourished at baseline and improved, from those who declined during the episode of care to establish a true prevalence of hospital-acquired malnutrition.

Despite the use of many different criteria to assess hospital-acquired malnutrition, it commonly occurs globally in countries across Africa, Asia, Europe, North America and Oceania. Although clinical practice guidelines for medical nutrition therapy and monitoring do not differ considerably between nations, disparities in resource availability will impact on the capacity for nutrition care practices to be implemented. For example, patient food services are a standard of Australian hospitals and must adhere to state-level policies for safety and nutritional adequacy.[14] At the opposite end of the spectrum, a study of acute surgical patients in Rwanda identified that meals were not provided by the hospital and that patients are expected to be fed by family members or caregivers. PN supplies are also limited as a result of insufficient financial resources in healthcare systems.[27] Hospital food services and access to nutrition support supplies are an integral component of nutrition care, and these discrepancies in resources are likely to influence the rate of nutritional decline during inpatient admissions. Furthermore, despite greater financial capacities and funding within healthcare systems of developed countries, routine nutritional screening using validated tools is not always performed, and often nutrition intervention is more reactive rather than proactive.[15,16] A recent study of patients with hospital acquired malnutrition admitted to Australian public hospitals identified that while nutrition screening was routinely undertaken shortly after admission for almost all patients ($n = 207/208$), only one-third were screened on a weekly basis thereafter. Furthermore, patients with extended lengths of stay were less frequently screened relative to those who had shorter admissions.[51]

Although all studies evaluated patients' nutritional evolution over the course of hospital admissions, only four described barriers to optimising nutritional status.[28,30,31,36] Furthermore, only one study delineated cases of preventable hospital-acquired malnutrition that may have been mitigated with timely and appropriate intervention from non-preventable cases.[31] In a 2020 retrospective study, Woodward et al found that the odds of developing hospital-acquired malnutrition increased by 0.6% for each subsequent day of admission; however, whether this is an effect of the hospitalisation or an effect of the illness remains unclear.[47] Given this gap in our understanding of the specific elements of care that when overlooked or are undervalued have direct repercussions on patients' nutritional status, this presents an important area for future investigations.

Amongst the studies that evaluated barriers to nutritional intake, patients consistently report institutional level barriers including mealtime interruptions, meal dissatisfaction and procedure-related fasting. Poor appetite, feeling sick and pain on the patient level were common complaints as primary inhibitors to food intake in hospital.[28,30,31,36] These findings are consistent with those of a recent study in which 85% of patients with hospital-acquired malnutrition were found to have nutrition impact symptoms and protein and energy intakes less than 80% of prescribed requirements for longer than 2 weeks.[51] Where oral intake is negatively affected by condition- or treatment-related symptoms, as is often the case in hospitalised patients,[52] and particularly oncological patients undergoing chemotherapy or radiation therapy, it may be argued that appropriate pharmacological management of symptoms may result in optimised intakes. Lack of provision thereof can be considered to be a modifiable and preventable cause of malnutrition. For example, patients experiencing pain, or nausea and vomiting are often prescribed analgesics and antiemetics, respectively, on an 'as needed' basis for symptom relief. However, medications charted as such may not be offered unless the patient complains or requests the medication directly. As a result of the busy nature of hospital wards, patients often feel uncomfortable making requests to nursing staff because they fear being a burden and interfering with nurses' abilities to complete other tasks that are perceived to be of higher importance.[53,54,55]

Over 40% of patients in Canadian hospitals reported having been interrupted by staff at mealtimes. When meals were missed, almost 70% of patients were not provided with additional food.[56] Protected mealtimes have been adopted by some hospitals; however, the results of studies examining the efficacy of these interventions have been inconsistent.[57,58] Patient meal satisfaction remains low,[56] although some studies have seen improvements in oral intake with greater attention to the quality and personalisation of the food service. Australian inpatients' energy and protein intake improved significantly with the implementation of a room service foodservice model in which patients order a meal at a time suitable to them, with meal delivery occurring within 45 min.[59] A bedside menu ordering system similarly showed improvements in patient intake.[60] Both studies demonstrated reductions in plate waste and food costs.[59,60] Patient food services directly impact on nutritional status and should prioritise flexibility within the system to better meet patient needs.[15] The importance of hospital food service quality may not be recognised at times of budget cuts; however, the cost-savings associated with shorter lengths of stay and reduced rates of complications, which are affected by nutritional status, remain a reminder that overall healthcare costs may be reduced with greater patient meal satisfaction.[1,3,4,6–13]

Where nutritional requirements cannot be met orally despite appropriate mitigation strategies, delays to initiating artificial nutrition support, when indicated,

should be avoided to prevent further nutritional deterioration and delayed convalescence.[61,62,63] Despite it being widely accepted that early initiation of nutrition support remains imperative to preventing nutritional decline, recent findings indicate that more than half of patients with hospital-acquired malnutrition did not receive nutrition support.[51] Dietitians consistently report a lack of autonomy concerning the initiation and discontinuation of nutritional support, preventing timely intervention as a result of the resistance met by medical officers and the time spent discussing the appropriateness of such interventions.[15] However, although this route of feeding promotes improved intake, ethical concerns in relation to artificial nutrition support warrant consideration for the patient's quality of life because oral feeding is an intrinsically social activity. Further, artificial nutrition support may inappropriately prolong death in terminally ill patients and voluntary refusal of nutrition during palliation should be respected.[62]

Two major barriers identified by clinicians were a lack of clinical priority amongst clinicians and limited understanding of malnutrition as a problem amongst patients.[30] On the patient level, almost all malnourished hip fracture patients failed to recognise their poor nutritional status. Severely inadequate energy and protein intake, in combination with neuropeptide, hormonal and metabolic effects of cachexia, a common physiological feature amongst hip fracture patients, were presumed to contribute to nutritional decline.[30] At the institutional level, nutrition as a low clinical priority has been identified as a concern for some time, with dietetics personnel reporting that limited autonomy and credibility to perform their respective roles within a multidisciplinary team may contribute to low acknowledgement of nutrition as an important part of medical care amongst non-dietetics professionals.[15] This may partly be a consequence of limited provision of formal nutrition education by medical schools.[64] Although a consensus exists amongst nursing staff regarding the high level of importance of patient nutrition, a lack of clarity regarding nurses' involvement and responsibilities, limited flexibility in food services and the absence of nutrition protocols disincline nursing involvement in nutrition care. Additionally, staffing and time constraints result in competing clinical priorities because treating the acute medical condition is perceived to have a higher level of importance.[65–69] This makes relying on nursing staff to obtain and record key nutritional information, such as weights and food chart data very challenging. When data used to inform nutrition screening and assessments are unavailable because of staffing constraints, patients are at a greater risk of not being identified for nutritional intervention.[15] Recio-Saucedo *et al.*[66] found that compliance with policies that mandate nutritional screening within 24 h of admission in the UK is positively associated with nurse staffing levels. These findings are consistent with earlier research suggesting that patient care suffers during periods of inadequate staffing.[67] This association was weakened by higher levels of healthcare assistant staffing which suggests a potential approach to address such staffing challenges by enabling nursing staff to direct their time to other patient-related activities.[61] Nurses consistently self-report that nutrition-related responsibilities are likely to be neglected when staffing constraints produce competing priorities,[67] indicating that strategies to address hospital-acquired malnutrition must be practical when considering the responsibilities of the broader multidisciplinary team rather than nutrition and dietetics personnel only. In the absence of patient information including weights, establishing a malnutrition diagnosis and consequent intervention is likely to be delayed. Obtaining patient weights is well-documented as a challenge in the clinical setting and when requested by ward dietitians, most patients were not weighed within 24 h. Furthermore, this delay in establishing a diagnosis of malnutrition may prevent timely advocacy for supplemental feeding. This may partly explain why less than one-third of patients with hospital-acquired malnutrition had documented recommendations for initiation of nutrition support by dietitians.[51]

Although the preventable nature of hospital-acquired malnutrition remains unclear, prior research has suggested that up to 95% of hospital-acquired malnutrition is preventable with appropriate mitigation strategies.[51] Additional practices have been suggested to address iatrogenic malnutrition through enhanced hospital nutrition care practices. To shift the paradigm of nutrition care, institutions must adopt a culture where nutrition is valued by all members of the multidisciplinary team and administrators, and where all members understand how nutrition care influences patients' broader clinical outcomes and the financial implications of hospital malnutrition.[4] The Alliance to Advance Patient Nutrition (The Alliance) has made three recommendations to achieve this: (1) educating clinicians on how to recognise and treat malnutrition and discussing this as part of ward rounds; (2) considering malnutrition as part of the patient's medical diagnosis and intervention as a fundamental element of medical care; and (3) cultivating an understanding of the cost savings associated with optimising patient nutrition care amongst administrators, ongoing cost–benefit analyses and revision of budgets to facilitate appropriate preventive strategies.[4] Furthermore, it is recommended to redefine the roles of members within the multidisciplinary team in the provision of nutrition care. Non-dietetics professionals from the multidisciplinary team may be assigned a greater level of responsibility in the detection and management of malnutrition by understanding nutrition risk factors and allowing nursing staff autonomy with implementing low risk nutrition care activities.[4,68–71] For example, initiating food and fluid charts, previously

established enteral nutrition (EN) orders in the interim when awaiting dietetics reviews, and obtaining patient weights when malnutrition is suspected. Allowing dietitians a greater level of autonomy with nutrition care activities such as ordering privileges for therapeutic diets, prescribing oral nutrition supplements or enteral nutrition regimens, and requesting serology can eliminate delays in waiting for physician sign-off.[4] Hospitals must implement formal policies and procedures that mandate initial malnutrition screening using tools validated for use by non-dietetic professionals.[4] Although this is a requirement in all NSW hospitals, rescreening of patients throughout episodes of care is not required and is often not completed despite it being well-documented that early identification of malnutrition and timely intervention improves patient outcomes.[14,16] Given that one-third of well-nourished patients are expected to become malnourished, and two-thirds of patients who present as malnourished on admission are expected to deteriorate,[4] hospitals seeking to mitigate the consequences of hospital-acquired malnutrition must establish policies that ensure regular rescreening of patients using simple validated tools, including establishment of individual roles and responsibilities within multidisciplinary teams.[4,16,68,71] Once the presence of malnutrition is identified, strategies to mitigate further deterioration must be implemented promptly. The Alliance recommends ensuring malnourished or at-risk patients are fed within 24 h, making every effort to ensure all EN or PN is administered as prescribed, promoting supportive meal environments, flagging when meal consumption is poor, adopting procedures to ensure meal provision when meals are missed, and avoiding NBM orders and holds on EN prior to procedures when practical.[4] Additionally, clear documentation of nutrition interventions is necessary to enhance communication within the multidisciplinary team, including adopting standardised policies for electronic medical record automatic triggers related to nutritional status. Inclusion of nutrition care plans in discharge summaries enhances continuity of care when patients are transferred to sub-acute facilities. Further, patients, families and their carers should receive nutrition education and a comprehensive postdischarge care plan which clearly outlines information regarding follow-up appointments, instructions for nutrition care postdischarge and any recommendations for vitamins, minerals, or oral nutrition supplements.[4]

There are a number of limitations to the findings of this review. First, in some studies, the researchers were unable to follow-up with all patients and were subsequently excluded from analyses.[27,34,37,38] This was a result of having been discharged prior to the predetermined follow-up time intervals or because of death or transfers to other hospitals. However, whether or not the patients that were lost to follow-up differed significantly in baseline characteristics from those with complete datasets was not reported. Second, because malnutrition has yet to be clearly defined and a gold standard to be established for detecting malnutrition, significant heterogeneity exists between the methods of assessment used in the included studies. Ten of the 15 studies used validated tools,[27–32,34,38,40,41]; however, three relied on screening tools.[29,40,41] The remaining seven studies used three different nutritional assessment tools (MNA, SGA and AND/ASPEN).[27,28,30–32,34,38]

Articles retrieved through individual review of journal issues were limited to a 5-year search period because of the resource-intensive nature of hand-searching; thus, it is possible that relevant articles published prior to this search period were not identified. Limiting search periods is a known limitation to systematic reviews because it may omit relevant research. However, hospital-acquired malnutrition is a relatively new focus in the literature, whereas research conducted prior to this period primarily examined all hospital malnutrition, irrespective of whether acquired prior to or during hospitalisations. Furthermore, utilising a broader study design inclusion criterion contributed to greater heterogeneity amongst the included studies. Heterogeneity of future reviews and the strength of their results may be enhanced by focusing on studies with prospective or retrospective cohort designs. The reliance on a single investigator for conducting the search, screening, extraction and risk of bias assessment is acknowledged as a weakness of this review because there is greater potential for the introduction of systematic and random errors in the absence of double-screening.

In conclusion, this review highlighted that nutritional deterioration is common among previously well-nourished and nutritionally compromised patients during hospital admissions. Often, this is a result of preventable barriers to optimal nutrition care that are present at the institutional level. Future research is necessary to determine which strategies are the most effective in preventing or reversing hospital-acquired malnutrition to optimise patient outcomes. There is a need for institutional nutrition care policies and protocols that outline mandatory monitoring of nutritional status of inpatients at regular intervals to ensure that nutritional risk screening is an ongoing process. Quality improvement initiatives that emphasise patient meal satisfaction are essential to promote optimal intake. Cost–benefit analyses are required to demonstrate the effectiveness of changes to models of care on patient lengths of stay and complications associated with poor nutritional status. Clear establishment of the roles and responsibilities of each member within multidisciplinary healthcare teams in the provision of nutrition care is pivotal to ensuring accountability and mitigating the negative outcomes associated with nutritional decline during hospitalisations.

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AUTHOR CONTRIBUTIONS

Alyssa R. Cass designed the review with support from Karen E. Charlton. Alyssa R. Cass carried out the searches, screened titles, abstracts and full-text articles against the inclusion criteria in consultation with Karen E. Charlton. Both authors contributed to the interpretation of the results and writing of the manuscript. All authors are in agreement with the manuscript and declare that this review has not been published elsewhere.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with PRISMA guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned (PROSPERO: CD42020182728) have been explained.

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SUPPORTING INFORMATION

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

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Knowledge, perceptions and behaviours regarding dietary management of adults living with phenylketonuria

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Abstract

Background: Lifelong dietary treatment remains the mainstay for many with phenylketonuria (PKU); however, adherence is known to reduce with age. It remains unclear whether knowledge and perceptions of the PKU diet amongst adults with PKU influence dietary behaviours.

Methods: A nationwide questionnaire survey was performed to investigate the knowledge and perceptions, and associated diet behaviours of adults with PKU in the UK. The survey was sent to adults with PKU under the care of the host hospital and members of the National Society of PKU.

Results: One hundred and thirty-seven respondents ($n = 78$ females, 56.9%) completed the survey with a mean age of 34 years and 4 months (16–65 years). Sixty (43.8%) respondents had always followed a PKU diet, 39 (28.5%) returned to diet and 35 (25.5%) were off diet. Overall mean ± SD knowledge score was 75.2% ± 13.4%, with significantly higher scores for knowledge of PKU (80.7% ± 16.2%) compared to knowledge specifically of the PKU diet (72.6% ± 14.5%, $p < 0.001$). Knowledge was associated with dietary adherence. Respondents who always followed a PKU diet had similar knowledge to those who returned to diet, whereas respondents off diet had significantly lower scores. Perception of the diet was not a predictor of dietary adherence, with the exception of whether patients had concerns for their long-term health when on diet or felt well when not following a diet.

Conclusions: The present study highlights the importance of ongoing dietetic input in building knowledge and skills for dietary management. Further research is needed to understand the motivators and beliefs that influence dietary adherence.

KEYWORDS

adults, dietary behaviours, dietary management, knowledge, perceptions, phenylketonuria

Key points

- Lifelong dietary treatment remains the mainstay for many with phenylketonuria (PKU); however, adherence is known to reduce with age.
- The present study aimed to determine whether knowledge and perceptions of the PKU diet amongst adults with PKU influence dietary behaviours.

Radha Ramachandran and Kevin Whelan contributed equally to this work.

- Knowledge of PKU and the PKU diet was associated with dietary adherence, highlighting the importance of ongoing dietetic input in building knowledge and skills for dietary management.
- Perception of the diet was not a predictor of dietary adherence.
- Further research is needed to understand the motivators and beliefs that influence dietary adherence.

INTRODUCTION

Phenylketonuria (PKU; OMIM 261600) is a rare inherited metabolic disorder of protein metabolism with a prevalence of 1:10,000 births in Europe. Dietary management involves the restriction of phenylalanine through a low protein diet, supplemented with specialist phenylalanine free or low phenylalanine protein substitutes providing all remaining amino acids and specialist low protein foods to ensure adequate energy and variety in the diet. All these dietary components are essential to the management of PKU. However, many find the diet challenging, and adherence has been shown to reduce with age, as revealed in a large UK-based survey where only 57% of adults with PKU reported following a low phenylalanine diet.[1] Current consensus advocates treatment for life[2]; therefore, understanding the factors that influence dietary behaviours and removing barriers to improve dietary adherence will improve patient outcomes.

The knowledge, attitude, behaviour theoretical model of health education suggests that behaviour (e.g., adherence to diet) is influenced by knowledge (e.g., knowledge of diet) and attitudes (e.g., perceptions of diet). Within PKU, studies have explored patients' and caregivers' knowledge of PKU and its dietary management, with some studies investigating the association of knowledge with adherence (behaviour) to the diet.[1,3–8] However, evidence for knowledge as a predictor for metabolic control remains equivocal.

A questionnaire survey in 62 people with PKU and 161 caregivers, as well as another survey in 32 people with PKU, did not show associations between knowledge and adherence,[3,4] whereas a study in 29 patients and 16 caregivers reported no association between perceived knowledge and adherence, but found perceived barriers to treatment to impact phenylalanine levels.[7] Moreover, a study in 218 people with PKU, including 45 aged ≥ 20 years, and 110 caregivers, found no correlation between knowledge and attitudes.[6] By contrast, a survey in 46 caregivers and another in 144 caregivers of children with PKU reported their knowledge of PKU and its dietary management to correlate with their children's blood phenylalanine concentrations.[5,8] However, the findings only reached statistical significance for young children whose carers had higher knowledge scores[5] and for knowledge specific to PKU exchanges.[8] A study in 183 adults with PKU reported dietary behaviours, but provided no insight into whether behaviours were influenced by knowledge and attitudes.[9] A common theme for all studies was the lack of comprehensive assessment of attitudes/perceptions of PKU dietary management, as well as a limited focus on the perceptions and knowledge specifically regarding the role of protein substitutes in the diet. Furthermore, majority of studies were conducted in caregivers, children, and/or younger adults with PKU, with no studies specially focussed on investigating the association of knowledge and perceptions on dietary adherence in adults with PKU.

Following a low phenylalanine diet requires an understanding of dietary sources of phenylalanine, determining protein content of foods and regular consumption of protein substitutes, all of which require consideration when investigating both knowledge and perceptions of the dietary management of PKU. Studies have investigated factors that influence adherence to the PKU diet[1,6,7,10,11]; however, to our knowledge, no studies to date have specifically investigated whether perceptions of the PKU diet are associated with dietary adherence.

It remains unclear whether knowledge and perceptions of both protein restriction and protein supplementation in the PKU diet amongst adults with PKU influence dietary behaviours. The present study aimed to investigate the knowledge and perceptions and behaviours of adults with PKU across the UK, regarding numerous dietary aspects of PKU management and the factors associated with these. This will help to inform the direction of clinical care and future research to optimise supporting people with PKU to follow a diet for life.

METHODS

A nationwide questionnaire survey was performed regarding the knowledge and perceptions of dietary management, and diet behaviours of adults with PKU in the UK.

Participants

Two approaches were adopted to optimise recruitment to increase representation and statistical power. First, all patients with PKU attending the Adult Inherited Metabolic Disorder Service at St Thomas' Hospital,

London, were sent an email with information and an electronic link to the survey, and patients attending routine outpatient clinic appointments were also provided with the survey information. Second, to ensure opportunities for adults with PKU from across the UK to participate, the survey was advertised by the National Society of Phenylketonuria (NSPKU), shared with all members via email and newsletter and advertised on their patient organisation website and social media platforms. The PKU Research Patient Advisory Group at the host hospital aided the advertisement of the survey on social media.

The inclusion criteria were patients: ≥16 years of age; able to complete the online survey independently; currently residing in the UK, diagnosed with PKU on newborn screening; and having been on a PKU diet for a period of their life. Potential participants were excluded if they resided outside of the UK or were <16 years of age. Eligibility was determined by participant self-report at the start of the questionnaire survey.

Questionnaire design

This questionnaire consisted of four sections: (i) knowledge of PKU and the PKU diet; (ii) perception of the PKU diet; (iii) dietary behaviours and metabolic control; and (iv) demographics. The knowledge section consisted of 25 multichoice questions; eight on knowledge of PKU and 17 specific to PKU dietary management, including four questions adapted from a questionnaire by Bekhof *et al.*[3] Each multiple-choice knowledge question was scored as correct, incorrect or participants selected 'don't know'. The perception section consisted of 25 attitude statements relating to the PKU diet, protein substitutes and the impact of the PKU diet on health and physical ability, developed by the research team, and was rated using a five-point Likert scale (strongly agree to strongly disagree), in addition to two questions relating to their perceived importance of research on PKU and diet. The dietary behaviours and metabolic control section for respondents currently following a PKU diet, consisted of nine questions regarding current and historical dietary behaviours, including providing information on prescribed dietary regimen, current PKU exchanges, protein substitutes taken, frequency of phenylalanine monitoring, blood phenylalanine target and last recorded phenylalanine level. The dietary behaviours section for respondents who were currently off diet, consisted of three questions to determine the time since last on a PKU diet, current dietary patterns and frequency of consuming high protein foods. The demographics section consisted of questions relating to sex, age, ethnicity, marital status, education and employment status. The questionnaire was piloted with two adults with PKU from the patient panel at the host hospital to test readability, length and clarity.

The questionnaire survey was hosted on an online platform and open for three months between May and August 2021. Five email reminders were sent to patients at the host hospital and advertisements for the survey were reposted multiple times by NSPKU to its members.

Ethical approval

The study was given favourable ethical opinion by the South West—Central Bristol Research Ethics Committee (REC reference 21/SW/0062; IRAS project ID 291736) and received approval by the Health Research Authority and Health and Care Research Wales. Participant consent was obtained at the start of the online survey. Only respondents who provided consent and completed the full survey were included in the study.

Statistical analysis

Descriptive statistics were used to report questionnaire responses for continuous data (mean ± SD) and categorical data (*n*, %). Age categories of ≤30 years and >30 years were selected to define two district phases of life that may impact dietary self-efficacy, and gave sufficiently large numbers in both groups to enable statistical comparison. Perceptions were collapsed into nominal variables as follows: agree ('strongly agree', 'agree'); neutral; and disagree ('strongly disagree', 'disagree'). Paired sample *t* tests were used to compare the dietary regimens advised to participants with that taken by participants, and in comparing knowledge of PKU and of the PKU diet. Associations between knowledge, dietary behaviours and participant characteristics were analysed using Pearson's correlation coefficient for continuous variables, unpaired *t* test for binary variables and one-way analysis of variance for polychotomous variables with Bonferroni post-hoc correction. Associations between perceptions, dietary behaviours and participant characteristics were analysed using a chi-squared or Fisher's exact test, as appropriate. All analyses were conducted using SPSS, version 27.0 (IBM Corp.).

RESULTS

Participant characteristics

One hundred and eighty-nine respondents started the online survey. Nine did not meet eligibility criteria. Of the 180 eligible participants, 43 only partially completed the survey, and were therefore excluded from the analysis. In total, 137 respondents completed the full survey and were included in the study.

Table 1 describes the demographic characteristics of the respondents. Fifty-seven (41.6%) were male, 78 (56.9%) female and 2 two 1.5%) abstained from specifying their sex. Mean age was 34 years and 4 months (range 16–65 years). Majority were of white ethnicity (97.1%). In terms of formal qualifications, 73 (53.3%) had no university qualifications and 64 (46.7%) had university qualifications. One hundred and three (75.2%) respondents were in full or part-time employment.

Dietary behaviours and metabolic control

Of the 137 respondents, 60 (43.8%) reported following a PKU diet as recommended by their healthcare provider all of their life, 39 (28.5%) had returned to a PKU diet after a period off diet, three (2.2%) returned to a PKU diet specifically for pre-conception or pregnancy and 35 (25.5%) were not currently on a PKU diet.

Table 2 outlines the dietary behaviours of participants currently following a PKU diet. The prescribed number of PKU exchanges ranged from 2 to 45 (100–2250 mg of phenylalanine) per day (mean ± SD: 11.8 ± 7.4); however, the number of actual PKU exchanges consumed per day was higher at 12.5 ± SD 8.1 ($p = 0.003$). The majority of participants (44; 43.1%) had been prescribed between 5.5 and 10 exchanges (275–500 mg of phenylalanine). Two respondents reported to be advised to consume 45 exchanges per day (2250 mg of phenylalanine). Both reported to be 'on a PKU diet' and that their previous phenylalanine concentrations to be within target range. Given the number of exchanges advised, these respondents would likely have a mild PKU as they have a significant protein tolerance. Of the 85 participants who provided data on their PKU exchange regimen, nine (10.6%) reported consuming fewer exchanges than advised, 47 (55.3%) were consuming exchanges as advised and 29 (34.1%) were consuming more than advised.

Most respondents (60; 58.8%) were advised to have protein substitutes three times daily. The number of protein substitutes actually taken by respondents (mean ± SD: 3.1 ± 1.1 per day) was significantly lower than the number prescribed (3.3 ± 0.9 per day) ($p = 0.002$). Sixteen (16.5%) were having less protein substitute than advised, 77 (79.4%) were having protein substitutes as advised and 4 (4.1%) were having more than advised. Sixty-four (68.7%) participants reported not having all supplements, over a third of participants reported not having some or all of their protein substitutes at least once a week, and 5.9% of participants did not have at least one protein substitute daily.

The majority of participants were aiming for a blood phenylalanine of 120–600 $\mu molL^{-1}$ (54; 52.9%) or below 700 $\mu mol\ L^{-1}$ (16; 15.7%) and 14 (13.7%) did not know their blood phenylalanine target. The most recent

TABLE 1 Respondent characteristics

Subject characteristics ($n = 137$)	n (%)
Sex	
Male	57 (41.6)
Female	78 (56.9)
Rather not say	2 (1.5)
Age (years)	
Mean (SD)	34 years and 4 months (10 years and 3 months)
Range	16–65
Age categories	
≤30 years	55 (40.1)
>30 years	82 (59.9)
Ethnicity	
White	133 (97.1)
Asian or Asian British	1 (0.7)
Other ethnic group	1 (0.7)
Rather not say	2 (1.5)
Marital status	
Single	51 (37.2)
Married/civil partnership	53 (38.7)
Co-habiting	21 (15.3)
Separated/divorced	5 (3.6)
Other[a]	7 (5.1)
Education level	
No university education	73 (53.3)
No formal qualifications	4 (2.9)
School level qualifications	22 (16.1)
Vocational qualifications	20 (14.6)
Advanced School level qualifications	22 (16.1)
Other[b]	5 (3.6)
University education	64 (46.7)
Bachelor's degree (e.g., BSc, BA)	47 (34.3)
Postgraduate degree (e.g., MSc, MA, PhD)	17 (12.4)
Employment status	
Employed (full-time or part-time)	103 (75.2)
Not currently employed	34 (24.8)

[a]The category of 'Other' included the following: engaged, in a relationship and not living together and would rather not say.

[b]The category of 'Other' included the following: Higher level teaching assistant status, Certificate of Higher Education, language interpreter and would rather not say.

TABLE 2 Dietary behaviours of respondents currently following a diet for phenylketonuria (PKU) ($n = 102$)

Number of PKU exchanges advised per day[a]	
Mean ± SD	11.8 ± 7.4
Minimum – Maximum	2–45
Exchanges categories, *n* (%)	
≤5 exchanges	12 (11.8)
>5–10	44 (43.1)
>10–15	23 (22.5)
>15–20	10 (9.8)
More than 20 exchanges	7 (6.9)
Don't know	6 (5.9)
Number of PKU exchanges taken per day[a]	
Mean ± SD	12.5 ± 8.1
Minimum – Maximum	2–45
Exchanges categories, *n* (%)	
≤5 exchanges	10 (9.8)
>5–10	34 (33.3)
>10–15	20 (19.6)
>15–20	12 (11.8)
More than 20 exchanges	8 (7.8)
Don't know	18 (17.6)
Exchanges taken vs. advised, *n* (%)	($n = 85$)
Fewer than advised	9 (10.6)
As advised	47 (55.3)
More than advised	29 (34.1)
Frequency of protein substitute advised per day, *n* (%)	
Once a day	1 (1.0)
Twice a day	8 (7.8)
Three times a day	60 (58.8)
Four or more times a day	26 (25.5)
Don't know	2 (2.0)
Other	5 (4.9)
Frequency of protein substitute taken per day, *n* (%)	
Once a day	5 (4.9)
Twice a day	14 (13.7)
Three times a day	49 (48.0)
Four or more times a day	23 (22.5)
Don't know	0 (0.0)
Other	11 (10.8)
Protein substitute taken vs. advised, *n* (%)	($n = 97$)
Fewer than advised	16 (16.5)
As advised	77 (79.4)
More than advised	4 (4.1)
Frequency of missing some/all protein substitute, *n* (%)	
Every day	6 (5.9)
Two to four times a week	18 (17.6)
Once a week	19 (18.6)
Once a fortnight	5 (4.9)
Less than once a fortnight	16 (15.7)
I never miss taking my protein substitute	38 (37.3)
Blood phenylalanine target level advised, *n* (%)	
Less than 300 μmol L^{-1}	3 (2.9)
Between 120 and 360 μmol L^{-1}	9 (8.8)
Between 120 and 600 μmol L^{-1}	54 (52.9)
Less than 700 μmol L^{-1}	16 (15.7)
Less than 1000 μmol L^{-1}	4 (3.9)
I don't have a blood phenylalanine target	2 (2.0)
Don't know	14 (13.7)
Last reported blood phenylalanine level, *n* (%)	
Phenylalanine ≤ 600 μmol L^{-1}	52 (51.0)
Less than 120 μmol L^{-1}	0 (0)
Between 120 and 360 μmol L^{-1}	17 (16.7)
Between 360 and 600 μmol L^{-1}	35 (34.3)
Phenylalanine> 600 μmol L^{-1}	40 (39.2)
Between 600 and 1000 μmol L^{-1}	30 (29.4)
More than 1000 μmol L^{-1}	10 (9.8)
Don't know	10 (9.8)

[a]If range of exchanges reported, value included in analysis was midpoint of the range.

phenylalanine level was reported to be <600 μmol L^{-1} by 52 (51%) and >600 μmol L^{-1} by 40 (39.2%) respondents.

Of the 35 respondents currently not following a PKU diet, 23 (65.7%) were following an unrestricted diet, 8 (22.9%) a vegetarian diet, 1 (2.9%) on a vegan diet, and 2 (5.7%) a low protein diet (but not taking any protein substitutes). Over half (18, 51.4%) had been off a PKU diet for more than 10 years.

Knowledge of PKU and the PKU diet

Table 3 outlines the knowledge questions included in the survey, of which Q1–Q8 related to knowledge of PKU

TABLE 3 Respondents' knowledge of phenylketonuria (PKU) and its dietary management

Questions		Correct, *n* (%)	Incorrect, *n* (%)	Don't know, *n* (%)
Knowledge of PKU				
Q1	What is the cause of PKU?	133 (97.1)	4 (2.9)	0 (0.0)
Q2	What is the recommended blood phenylalanine level for an adult with PKU in the UK?	97 (70.8)	28 (20.4)	12 (8.8)
Q3	What makes blood phenylalanine levels go high?	132 (96.4)	4 (2.9)	1 (0.7)
Q4	What makes blood phenylalanine levels go too low?	113 (82.5)	17 (12.4)	7 (5.1)
Q5	Blood phenylalanine level is high. What might your dietitian or doctor recommend?	122 (89.1)	12 (8.8)	3 (2.2)
Q6	What will happen to blood phenylalanine level when you fast for 2 days?	71 (51.8)	36 (26.3)	30 (21.9)
Q7	To keep blood phenylalanine level in target range, it is important to do what with your diet?	123 (89.8)	10 (7.3)	4 (2.9)
Q8	Compared to an adult without PKU, an adult with PKU needs how much exercise to keep healthy?	93 (67.9)	28 (20.4)	16 (11.7)
Knowledge of the PKU diet				
Q9	What is protein?	131 (95.6)	2 (1.5)	4 (2.9)
Q10	What is phenylalanine?	132 (96.4)	0 (0.0)	5 (3.6)
Q11	When on a PKU diet, the diet should provide how much total protein compared to someone without PKU	2 (1.5)	129 (94.2)	6 (4.4)
Q12	When on a PKU diet, an adult with PKU needs how much energy/calories compared to someone without PKU	85 (62)	40 (29.2)	12 (8.8)
Q13	On a PKU diet, where should most of your protein come from?	132 (96.4)	3 (2.2)	2 (1.5)
Q14	What will happen if someone with PKU is following a low protein diet and not taking their protein substitute daily?	105 (76.6)	24 (17.5)	8 (5.8)
Q15	Why is it necessary to take protein substitutes?	125 (91.2)	6 (4.4)	6 (4.4)
Q16	What is the most important reason for taking your protein substitutes spaced out over the day?	92 (67.2)	41 (29.9)	4 (2.9)
Q17	In general, how much protein is there in one PKU exchange?	111 (81)	8 (5.8)	18 (13.1)
Q18	How many PKU exchanges are in 120 g of broccoli?	56 (40.9)	44 (32.1)	37 (27)
Q19	How many PKU exchanges are in 100 g of tomatoes?	100 (73)	12 (8.8)	25 (18.2)
Q20	How many PKU exchanges are in 180 g of French fries (chips)?	58 (42.3)	37 (27)	42 (30.7)
Q21	What is an exchange-free food?	83 (60.6)	51 (37.2)	3 (2.2)
Q22	Which product has the most protein per 100 g? (data extraction from food label provided)	128 (93.4)	8 (5.8)	1 (0.7)
Q23	Which product has the most energy/calories per 100 g? (data extraction from food label provided)	133 (97.1)	2 (1.5)	2 (1.5)
Q24	How much protein would you have if you ate a 25 g pack of Product A? (data extraction from food label provided)	128 (93.4)	3 (2.2)	6 (4.4)
Q25	How much of Product B can you have for one PKU exchange? (data extraction and calculation from food label provided)	91 (66.4)	12 (8.8)	34 (24.8)

and Q9–Q25 related to knowledge about the PKU diet. The mean ± SD number of correct answers (total knowledge score) was 18.8 ± 3.4 out of 25 (range 5–24), which is 75.2% ± 13.4%. The mean ± SD number of correct answers for knowledge of PKU (PKU knowledge score) was 6.5 ± 1.3 out of 8 (range 1–8), and the mean ± SD number of correct answers for knowledge of the PKU diet (PKU diet knowledge score) was 12.4 ± 2.5 out of 17 (range 4–17). This resulted in a higher mean PKU knowledge score (80.7% ± 16.2%) than PKU diet knowledge score (72.6% ± 14.5%) ($p < 0.001$).

The majority of questions relating to knowledge of PKU were scored correctly by over 70% of participants (Table 3). By contrast, correct responses relating to knowledge of the PKU diet were more varied. For the question relating to total protein requirements from protein substitutes and PKU exchanges when on a PKU diet (Q11), only two (1.5%) correctly reported needing more than the general population, whereas more than three-quarters correctly identified the role of protein substitutes in the diet (Q13–Q15). When considering questions related to knowledge of the PKU exchanges in common foods (Q18–Q20), the proportion of participants answering correctly varied from 42.3% to 73%.

Four questions required interpretation of two food package labels (Q22–Q25). Respondents scored highly for questions requiring only data extraction from the food label (>90% correct); however, when required to do calculations using data, 91 (66.4%) provided the correct answer and 34 (24.8%) responded 'don't know'.

Knowledge, dietary behaviours and respondent characteristics

Table 4 reports the associations between knowledge scores, PKU dietary behaviours and respondent characteristics. No associations were found between knowledge scores (total knowledge, PKU knowledge, PKU diet knowledge) and sex, age, marital status and employment status. Having a university education was associated with significantly higher knowledge scores compared to those with no university education.

There were significant associations between knowledge scores (total knowledge, PKU knowledge, PKU diet knowledge) and whether a respondent always followed a PKU diet, had returned to diet or was currently off diet. Post-hoc analysis showed significantly lower correct scores amongst those who are currently off diet (mean ± SD total knowledge score 69.1% ± 15.4%) compared to those who have always followed their recommended PKU diet (78.0% ± 12.0%, $p = 0.005$). No significant differences were found in knowledge scores of respondents who have returned to a PKU diet (mean ± SD total knowledge score 76.3% ± 12.3%) and those who have always followed a PKU diet (78.0% ± 12.0%, $p = 1.00$). Knowledge scores of respondents who have returned to a PKU diet were higher than those who were off diet, but findings only reach statistical significance for PKU diet knowledge scores (74.4% ± 12.4% vs. 66.2% ± 15.7%, $p = 0.039$).

No associations were found between knowledge scores and either the number of PKU exchanges (advised or taken) or the number of protein substitutes (advised or taken). PKU diet knowledge scores were higher in those consuming more exchanges than advised compared to those consuming fewer than advised. Knowledge scores were not associated with taking less, more or same protein substitute than advised.

A trend towards lower knowledge scores in those with higher phenylalanine levels (>1000 μmol L^{-1}) was observed, but this association was not significant ($p = 0.096$). For respondents who were currently off diet, there was no significant association between knowledges scores and years since discontinuing a PKU diet.

Perception of the PKU diet

Table 5 outlines respondents' perceptions of the PKU diet. Majority agreed that when following a PKU diet, the diet will keep them well (114; 87%), of whom 56/60 (93.3%) had always followed a PKU diet, 37/42 (88.1%) had returned to diet and 21/35 (60.0%) were 'off diet'. Therefore, more than half of participants who were off diet also believed that being on a PKU diet will keep them well.

Greater variability in respondents' perceptions, with responses distributed across the agree, neutral and disagree, were seen for statements relating to the PKU diet's fat content, provision of adequate protein to keep healthy and to build muscle including during exercise, and impact on long-term health. Furthermore, perception varied for how someone felt when not on the PKU diet (Table 5).

Perception of the PKU diet, dietary behaviours and respondent characteristics

The majority of participants' perceptions of the PKU diet were not associated with dietary behaviours, and no associations were found between perceptions and participant characteristics (data not shown). Table 6 outlines perceptions and dietary behaviours found to be associated. Participants' perceptions of the following statements were found to be significantly associated with whether they always followed a PKU diet, returned to diet or were currently off diet: 'when on a PKU diet, I get concerned about my long-term health', 'I feel that the diet will keep me well' and 'I feel well when I am not on the PKU diet'.

Of the participants currently following a PKU diet, 61 (86%) remained concerned about their long-term health when on diet, whereas 29 (70.7%) did not have concerns for their long-term health. Of the 35 participants currently off diet, 19 (63.3%) felt well when not on the diet and 9 (13.2%) did not feel well off diet.

A participant's perception of whether the PKU diet provides adequate protein when exercising was associated with adherence to prescribed PKU exchanges, whereas those who 'disagreed' were predominately taking more exchanges than advised (Table 6).

Of note, perceptions of the following statements were not associated with adherence to PKU exchanges or

TABLE 4 Associations between knowledge, dietary behaviours and respondent characteristics

	n	Total knowledge score (%), mean ± SD	*p* value	PKU knowledge score (%), mean ± SD	*p* value	PKU diet knowledge score (%), mean ± SD	*p* value
Sex							
Male	57	75.0 ± 14.7	0.894	80.7 (16.5	0.981	72.4 ± 15.6	0.866
Female	78	75.3 ± 12.6		80.8 ± 16.1		72.8 ± 13.9	
Age							
≤30 years	55	72.7 ± 15.4	0.076	78.4 ± 16.9	0.184	70.1 ± 16.5	0.087
>30 years	82	76.9 ± 11.8		82.2 ± 15.6		74.4 ± 12.9	
Marital status							
Single	51	72.5 ± 13.6	0.114	78.4 ± 15.0	0.380	69.8 ± 14.9	0.094
Married/civil partnership	53	78.3 ± 13.8		84.0 ± 17.1		75.7 ± 14.6	
Co-habiting	21	76.6 ± 11.6		80.4 ± 16.1		74.8 ± 12.2	
Separated/divorced	5	66.4 ± 6.1		77.5 ± 10.5		61.2 ± 10.7	
Other	7	73.1 ± 14.4		75.0 ± 20.4		72.3 ± 15.5	
Education level							
No university education	73	71.6 ± 14.1	< 0.001	76.5 ± 18.2	0.001	69.3 ± 15.1	0.004
University education	64	79.3 ± 11.4		85.4 ± 12.1		76.5 ± 12.9	
Employment status							
Employed (full time or part-time)	103	75.8 ± 13.0	0.339	81.8 ± 15.8	0.152	73.0 ± 14.1	0.582
Not currently employed	34	73.3 ± 14.8		77.2 ± 17.0		71.5 ± 16.1	
PKU diet pattern							
Always been on diet	60	78.0 ± 12.0[a]	0.006	84.0 ± 12.8[a]	0.042	75.2 ± 14.3[a]	0.009
Returned to diet	42	76.3 ± 12.3[a,b]		80.4 ± 16.6[a,b]		74.4 ± 12.4[a]	
Off diet	35	69.1 ± 15.4[b]		75.4 ± 19.5[b]		66.2 ± 15.7[b]	
PKU exchanges advised	96	PCC = 0.054	0.601	PCC = 0.107	0.300	PCC = 0.016	0.875
PKU exchanges consumed	84	PCC = 0.101	0.359	PCC = 0.097	0.381	PCC = 0.82	0.457
PKU exchanges adherence							
Fewer than advised	9	74.2 ± 16.0	0.106	86.1 ± 13.2	0.673	68.6 ± 20.4[a]	0.035
As advised	47	77.8 ± 11.3		83.2 ± 14.3		75.2 ± 12.5[a,b]	

(Continues)

TABLE 4 (Continued)

	n	Total knowledge score (%), mean ± SD	*p* value	PKU knowledge score (%), mean ± SD	*p* value	PKU diet knowledge score (%), mean ± SD	*p* value
More than advised	29	82.1 ± 8.0		85.8 ± 12.0		80.3 ± 8.2[b]	
Protein substitute advised	98	PCC = −0.029	0.780	PCC = −0.072	0.480	PCC = −0.001	0.988
Protein substitute consumed	98	PCC = 0.103	0.313	PCC = 0.026	0.801	PCC = 0.121	0.236
Protein substitute adherence							
Fewer than advised	16	72.3 ± 17.3	0.088	78.1 ± 22.1	0.125	69.5 ± 17.9	0.156
As advised	77	79.2 ± 10.3		84.6 ± 11.5		76.6 ± 12.3	
More than advised	4	74.0 ± 13.7		75.0 ± 17.7		73.5 ± 15.6	
Last reported phenylalanine level							
Between 120 and 360 μmol/L	17	80.0 ± 9.9	0.096	86.0 ± 12.4	0.061	77.2 ± 11.9	0.199
Between 360 and 600 μmol L^{-1}	35	78.5 ± 12.2		85.7 ± 11.8		75.1 ± 14.9	
Between 600 and 1000 μmol L^{-1}	30	79.6 ± 11.4		82.9 ± 14.1		78.0 ± 12.4	
More than 1000 μmol L^{-1}	10	69.2 ± 15.2		72.5 ± 21.9		67.7 ± 13.7	
Years since discontinuing diet							
Less than 3 years ago	12	73.3 ± 10.1	0.409	79.2 ± 11.1	0.626	70.6 ± 12.8	0.397
3–10 years ago	5	71.2 ± 15.9		77.5 ± 16.3		68.2 ± 16.4	
More than 10 years ago	18	65.8 ± 17.9		72.2 ± 24.5		62.7 ± 17.1	

Note: *p* values comparing two groups are the result of independent *t* tests (two groups). *p* values comparing three groups are the result of an analysis of variance, when a statistically significant difference was identified across the three groups, comparisons were made between two groups using a Bonferroni post hoc correction, in which case values that do not share a common superscript letter are statistically significantly different.

Abbreviations: PCC, Pearson's correlation co-efficient and *p* value or the association; PKU, phenylketonuria.

TABLE 5 Respondents' perceptions of the phenylketonuria (PKU) diet

	Don't know, *n* (%)[b]	Valid response, *N* =	Responses, *n* (% of *N*)				
			Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
The PKU diet I am recommended to follow:							
Is healthy	8 (5.8)	129	35 (27.1)	57 (44.2)	18 (14.0)	12 (9.3)	7 (5.4)
Gives me all the vitamins and minerals I need	5 (3.6)	132	49 (37.1)	66 (50.0)	5 (3.8)	11 (8.3)	1 (0.8)
Gives me all the energy/calories I need	5 (3.6)	132	29 (22.0)	72 (54.5)	15 (11.4)	12 (9.1)	4 (3.0)
Gives my body enough protein	5 (3.6)	132	31 (23.5)	84 (63.6)	13 (9.8)	3 (2.3)	1 (0.8)
Is higher in sugar compared to the diet for the general population	14 (10.2)	123	32 (26.0)	48 (39.0)	25 (20.3)	15 (12.2)	3 (2.4)
Is higher in carbohydrates compared to the diet for the general population	15 (10.9)	122	38 (31.1)	55 (45.1)	16 (13.1)	10 (8.2)	3 (2.5)
Is higher in fats compared to the diet for the general population	15 (10.9)	122	14 (11.5)	36 (29.5)	39 (32.0)	31 (25.4)	2 (1.6)
Is higher in fruits and vegetables compared to the diet for the general population	9 (6.6)	128	47 (36.7)	60 (46.9)	14 (10.9)	6 (4.7)	1 (0.8)
When I am following my recommended PKU diet:							
My protein substitutes need to be taken daily	3 (2.2)	134	102 (76.1)	28 (20.9)	3 (2.2)	0 (0.0)	1 (0.7)
Taking my protein substitutes daily is not as important as following a low protein diet for PKU	5 (3.6)	132	1 (0.8)	8 (6.1)	15 (11.4)	54 (40.9)	54 (40.9)
I don't understand why I need to take protein substitutes	3 (2.2)	134	1 (0.7)	3 (2.2)	9 (6.7)	36 (26.9)	85 (63.4)
The number of protein substitutes I have been recommended to take a day was right for me	11 (8.0)	126	22 (1.5)	73 (57.9)	17 (13.5)	11 (8.7)	3 (2.4)
I get concerned that the amount of protein substitutes that I have been recommended to take is too many	6 (4.4)	131	3 (2.3)	3 (2.3)	23 (17.6)	64 (48.9)	38 (29.0)
I get concerned that the amount of protein substitutes that I have been recommended to take is too few	7 (5.1)	130	7 (5.4)	12 (9.2)	19 (14.6)	63 (48.5)	29 (22.3)
Taking my protein substitutes, I feel confident that I am getting enough protein	8 (5.8)	129	27 (20.9)	76 (58.9)	14 (10.9)	9 (7.0)	3 (2.3)
My protein substitutes help to improve my blood phenylalanine levels	9 (6.6)	128	41 (32.0)	64 (50.0)	20 (15.6)	2 (1.6)	1 (0.8)
When I am following my recommended PKU diet:							
I feel that the diet will keep me well	6 (4.4)	131	35 (26.7)	79 (60.3)	9 (6.9)	5 (3.8)	3 (2.3)
I get concerned about not having enough protein to keep healthy	4 (2.9)	133	6 (4.5)	21 (15.8)	22 (16.5)	58 (43.6)	26 (19.5)
I get concerned about not having enough protein to build muscle	6 (4.4)	131	17 (13.0)	27 (20.6)	22 (16.8)	46 (35.1)	19 (14.5)

(Continues)

TABLE 5 (Continued)

	Don't know, *n* (%)[b]	Valid response, *N* =	Responses, *n* (% of *N*)				
			Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
I get concerned about my long-term health	4 (2.9)	133	36 (27.1)	35 (26.3)	21 (15.8)	30 (22.6)	11 (8.3)
I feel well when I am not on the PKU diet	19 (13.9)	118	10 (8.5)	20 (16.9)	20 (16.9)	25 (21.2)	43 (36.4)
When someone with PKU exercises:							
The PKU diet will give them all the vitamins and minerals they need	16 (11.7)	121	22 (18.2)	63 (52.1)	20 (16.5)	15 (12.4)	1 (0.8)
The PKU diet will give them all the protein they need	15 (10.9)	122	20 (16.4)	54 (44.3)	18 (14.8)	24 (19.7)	6 (4.9)
The PKU diet will give them all the carbohydrates they need	19 (13.9)	118	29 (24.6)	66 (55.9)	18 (15.3)	5 (4.2)	0 (0.0)
The PKU diet will give them all the energy/calories they need	18 (13.1)	119	21 (17.6)	62 (52.1)	14 (11.8)	20 (16.8)	2 (1.7)

[b]% of responses out of the total responses ($n = 137$). These responses are excluded from the data analysis.

protein substitutes: 'when on a PKU diet, I get concerned about not having enough protein to keep healthy' and 'when on a PKU diet, I get concerned about not having enough protein to build muscle'.

Importance of research in the dietary management and health of adults with PKU

The survey included questions to understand how important two research areas were for adults with PKU. Research to understand the impact of different amounts, frequency and/or types of protein substitutes on muscle and general health was seen as extremely or very important by majority of respondents (104; 75.9%). Research to understand how protein substitutes can be tailored (amount, frequency and/or type) to match personal muscle and personal activity levels was also seen as extremely or very important by majority of respondents (99; 72.3%).

DISCUSSION

This is the first nationwide study investigating both knowledge and perceptions of PKU and its dietary management, and the associations with dietary behaviours in a large cohort of adults with PKU.

Overall, respondents demonstrated good knowledge of both PKU in general and the PKU diet; however, knowledge of the former was greater than knowledge of the latter. Incorrect or 'don't know' responses were more frequent in questions related to PKU exchanges of common foods, a finding shown in previous studies,[3,6,8] and the question requiring data extraction and calculations from food labels. Retention of knowledge regarding PKU exchanges, as well as the ability to determine PKU exchanges from food labels, requires cognitive skills such as memory, attention and information processing. Deficits in cognitive functioning have been reported, even amongst those adhering to their phenylalanine restricted diet.[12] This present study highlights that even patients currently on a PKU diet, and likely in regular contact with dietitians, may experience some cognitive dysfunction that impacts label reading and diet recall and they may benefit from more structured refresher education sessions at regular intervals.

Respondent characteristics were not predictors of knowledge, with the exception of having a university education, which inevitably may be associated with improved knowledge acquisition and utilisation. As expected, those who have always followed a PKU diet had greater knowledge of PKU and its dietary management. Interestingly, no difference in knowledge was found between participants who have returned to diet and those who have always followed a diet, demonstrating that either (i) adults returning to diet can gain

TABLE 6 Associations between perceptions of the Phenylketonuria (PKU) diet, dietary behaviours and respondent characteristics

	Agree, *n* (%)	Neutral, *n* (%)	Disagree, *n* (%)	*p* value
When on a PKU diet, I get concerned about my long-term health				
PKU diet pattern				
Always on diet	31 (43.7)	10 (47.6)	19 (46.3)	0.009
Returned to diet	30 (42.3)	2 (9.5)	10 (24.4)	
Off diet	10 (14.1)	9 (42.9)	12 (29.3)	
Protein substitute adherence				
Taking fewer than advised	11 (19.6)	4 (33.3)	1 (3.4)	0.049
Taking as advised	43 (76.8)	7 (58.3)	27 (93.1)	
Taking more than advised	2 (3.6)	1 (8.3)	1 (3.4)	
I feel well when I am not on the PKU diet				
PKU diet pattern				
Always on diet	4 (13.3)	6 (30.0)	35 (51.5)	< 0.001
Returned to diet	7 (23.3)	11 (55.0)	24 (35.3)	
Off diet	19 (63.3)	3 (15.0)	9 (13.2)	
I feel that the diet will keep me well				
PKU diet pattern				
Always on diet	56 (49.1)	1 (11.1)	2 (25.0)	0.011
Returned to diet	37 (32.5)	2 (22.2)	3 (37.5)	
Off diet	21 (18.4)	6 (66.7)	3 (37.5)	
When someone with PKU exercises, the PKU diet will give them all the protein they need				
PKU exchange adherence				
Consuming fewer than advised	6 (13.0)	3 (27.3)	0 (0.0)	0.014
Consuming as advised	27 (58.7)	7 (63.6)	8 (40.0)	
Consuming more than advised	13 (28.3)	1 (9.1)	12 (60.0)	

equivalent levels of knowledge to those who have always been on diet or (ii) that higher knowledge of PKU and diet was associated with the decision to return to diet. Participants who had returned to diet, had greater knowledge of the PKU diet than participants off diet. It is unclear whether knowledge was the catalyst to returning to diet or whether as part of the return to diet, participants received increased education and training on the PKU diet.

Knowledge did not predict adherence to using protein substitutes or consuming PKU exchanges as advised. Although not significant, lower knowledge scores were associated with poorer metabolic control, findings which have been reported when considering caregivers' knowledge and their children's metabolic control.[5,8]

To support dietary adherence for adults with PKU, establishing an individual's baseline knowledge of PKU and the PKU diet is important to identify their further education and training needs. Routine clinic appointments may not allow adequate time for assessment of knowledge and provision of further training and education, and therefore establishing additional clinics dedicated to enhancing knowledge of PKU and the dietary management may be warranted. Written resources are typically provided with dietary management information[4]; however, with consideration for different learning styles, training sessions could be extended to include short educational videos, use of mobile applications and hands on practical sessions such as working through mathematic calculations to determine PKU exchanges using different food labels.

The majority of participants shared the perception that the PKU diet will keep them well, a positive perception that was also shown in a previous study where majority of adults with PKU reported to feel better when on a PKU diet.[9] However, participants in the present study shared similar perceptions of the PKU diet whether

they were currently off diet, had a period off the PKU diet or always followed a PKU diet. In this regard, 21 (60.0%) participants off diet shared the belief that following a PKU diet will keep them well. Given this significant number, further research to assess barriers to being on diet and evaluate methods to overcome these barriers is important.

Perceptions of the PKU diet did not appear to predict dietary behaviours, with the exception of a participant's perception of whether they have concerns for their long-term health when on a PKU diet and whether they feel well when not following a PKU diet. Lifelong treatment is recommended as the long-term health outcomes of high phenylalanine levels is currently unknown.[2] However, even amongst participants who have always followed a diet, concerns remain about their long-term health. This highlights the importance of further research in adults and older adults with PKU into understanding the long-term neurocognitive, physical and functional outcomes. Although the long-term outcomes are unknown, for many participants, feeling well when on the PKU diet will be the motivator for remaining on diet. This was shown in the current study where participants who disagreed with the statement regarding feeling well when not following a PKU diet were predominately on diet; however, 13.2% of participants who were off diet also disagreed with this statement, demonstrating the complexities of factors influencing adherence to a PKU diet.

Disagreeing that the PKU diet provides all the protein needed to exercise was associated with taking more exchanges than advised. Limited research has focused on the impact of exercise on protein requirements in PKU, and the present study has highlighted concerns that exist amongst adults with PKU. Furthermore, research to understand how protein substitutes can be tailored to match body composition and physical activity levels was ranked by majority of respondents as extremely or very important. Further research is needed to explore how these factors influence dietary requirements in adults with PKU.

Study strengths and limitations

The strengths of the present study include the recruitment method leading to one of the largest ever samples of adults with PKU, and from across the whole of the UK, together with the novel use of a comprehensive assessment for perceptions of the PKU diet. Moreover, including participants both on and off a PKU diet allowed insight to be gained on the influence of knowledge and perceptions on dietary adherence. However, a higher proportion of participants were currently following a PKU diet compared to reports in previous UK based studies,[1,4] despite adherence to protein substitutes being similar[1,4]; meanwhile, a high proportion of respondents had university education (46.7%) compared to the general UK population (27% with level 4 or above).[13] Therefore, selection bias might have encouraged more knowledgeable patients to participate and thus the knowledge of the general PKU population may indeed be lower than measured here. It should be noted that knowledge about PKU and the diet may encompass more than the 25 questions included in the questionnaire; however, the questionnaire used had the advantage of including questions on the different aspects of dietary management.

CONCLUSIONS

It is well established that adherence to a PKU diet reduces with age, and therefore gaining an understanding of the factors that influence dietary adherence is essential to removing barriers to improving dietary management and patient outcomes for adults with PKU. The present study found knowledge to be associated with dietary adherence. Ongoing dietetic input is needed to further enhance knowledge of the PKU diet and in developing skills to determine and calculate PKU exchanges of foods, which are essential tools for successful dietary management. It is of interest that participants shared similar perceptions of the diet, despite their history with adherence to their PKU diet, an area that requires further research to understand the motivators and beliefs that influence dietary adherence.

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AUTHOR CONTRIBUTIONS

Sarah J. Firman, Radha Ramachandran and Kevin Whelan were involved in the conceptualisation and design of the questionnaire survey. Sarah J. Firman led on recruitment and data analysis, with support from Kevin Whelan who provided supervision. The original draft was prepared by Sarah J. Firman. Radha Ramachandran and Kevin Whelan provided critical revision of the draft. Sarah J. Firman, Radha Ramachandran and Kevin Whelan revised and approved the final version of the manuscript submitted for publication.

CONFLICTS OF INTEREST

Sarah J. Firman has received funding to attend conferences and study days from Nutricia, Vitaflo International and Dr Schär UK Ltd, as well as consulting fees from Vitaflo International and Meta Healthcare Ltd. Kevin Whelan is in receipt of research funding from Danone and has acted as a consultant for Danone.

ETHICAL STATEMENT

The study was given favourable ethical opinion by the South West—Central Bristol Research Ethics Committee (REC reference 21/SW/0062; IRAS project ID 291736) and received approval by the Health Research Authority and Health and Care Research Wales.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with STROBE guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained (REC reference 21/SW/0062; IRAS project ID 291736).

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Characterising body composition and bone health in transgender individuals receiving gender-affirming hormone therapy

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Abstract

Background: Gender-affirming hormone therapy (GAHT) is prescribed to produce secondary sex characteristics aligning external anatomy with gender identity to mitigate gender dysphoria. Transgender women are generally treated with oestrogens and anti-androgens, whereas transgender men are treated with testosterone. The objective of this narrative review was to characterise the influence of GAHT on body composition and bone health in the transgender population to help address weight concerns and chronic disease risk.

Methods: Studies were extracted from PubMed and Scopus and limited to only those utilising imaging technologies for precise adipose tissue, lean mass, and bone mineral density (BMD) quantification.

Results: Although methodologies differed across the 20 investigations that qualified for inclusion, clear relationships emerged. Specifically, among transgender women, most studies supported associations between oestrogen therapy and decreases in lean mass and increases in both, fat mass and body mass index (BMI). Within transgender men, all studies reported associations between testosterone therapy and increases in lean mass, and although not as consistent, increases in BMI and decreases in fat mass. No consistent changes in BMD noted for either group.

Conclusions: Additional research is needed to appropriately assess and evaluate the implications of these body composition changes over time (beyond 1 year) in larger, more diverse groups across all BMI categories. Future studies should also seek to evaluate nutrient intake, energy expenditure and other important lifestyle habits to diminish health disparities within this vulnerable population. Policies are needed to help integrate registered dietitians into the routine care of transgender individuals.

KEYWORDS

adipose tissue, body composition, hormone replacement therapy, lean mass, narrative review, transgender persons

Key points

- Among transgender women, most studies support associations between oestrogen therapy and decreases in lean mass, increases in fat mass, increases in body mass index (BMI) and no changes in bone mineral density (BMD).

- Among transgender men, most studies support associations between testosterone therapy and increases in lean mass, decreases in fat mass, increases in BMI and no changes in BMD.
- There is an urgency to evaluate and adapt hospital, clinic and insurance policies supporting improved integration of registered dietitians into the routine care of transgender patients, especially for those undergoing gender-affirming hormone therapy and gender-affirming surgeries.

INTRODUCTION

Transgender is an umbrella term for people whose gender identity and/or expression is different from cultural expectations based on their sex assigned at birth.[1] By contrast, cisgender is a term for people whose gender identity aligns with cultural expectations based on their sex assigned at birth.[1] Over one million adults identify as transgender in the USA.[2] However, only a few national population-based surveys collect information regarding gender identity. As a result, many transgender individuals go unreported or are not accurately captured during the data collection process; thus, current approximations likely underestimate this visibly growing population. Gender-affirming hormone therapy (GAHT) is prescribed to produce secondary sex characteristics aligning external anatomy with gender identity to mitigate gender dysphoria, comprising the psychological distress transgender individuals experience because of incongruence. The initiation of GAHT is significantly and positively associated with improvements in emotional well-being, social functioning and quality of life.[3,4] Transgender women are generally treated with oestrogens and anti-androgens, whereas transgender men are treated with testosterone. The long-term physiological impacts of GAHT are not well studied.

Over the past 30 years, clinicians have been trained to calculate body mass index (BMI) routinely, using a BMI $\geq 30\,kg\ m^{-2}$ to indicate the presence of obesity.[5] Currently, 42.4% of the US population has obesity; a condition disproportionately affecting the transgender community.[6–10] Theoretically, BMI aligns linearly with total adiposity; however, BMI is considered a crude measure of body composition because it fails to differentiate between lean and adipose compartments. Precise tools to quantify body composition are becoming more readily available and can easily distinguish these tissues, relaying important information concerning total and regional adiposity (abdominal vs. gluteal), as well as lean mass.[11] Determining the influence of feminising and masculinising hormone therapies on body composition in the transgender population is essential for appropriately addressing weight concerns before and after GAHT and to evaluate eligibility for surgical treatments. Cruz *et al.*[12] demonstrated simple metrics, such as body weight, cannot detect favourable improvements after attempting lifestyle changes in nearly one-third of people whose body weight remains the same and in one-third of people who gain weight. Clinicians must start to look beyond crude measures of obesity to more precisely assess future chronic disease risk, specifically cardiovascular disease (CVD) or hormonally-derived cancers. Therefore, the objective of this narrative review was to characterise the patterns of body composition changes occurring in persons receiving GAHT focusing on investigations employing imaging technologies for precise adipose tissue and lean mass quantification. This information will inform future research pertaining to weight concerns and body composition changes in the transgender community, aiding in achieving health equity and more precise chronic disease risk stratification.

METHODS

A literature search was conducted in PubMed and Scopus (February 2022) to include studies from 1997 to 2022. This timeframe parallels the expansion and wider availability of body composition imaging technologies, predominantly dual energy X-ray absorptiometry (DXA). PubMed and Scopus were selected because of their extensive coverage of biomedical sciences literature. Scopus includes social, physical and life sciences journals in addition to health sciences. The concepts of gender-affirming hormone therapy, transgender, body composition and imaging were searched in each database utilising the appropriate keywords and controlled vocabulary, when available. The texts of the searches are presented in Supporting information (Table S1). The results were filtered to include studies published in the English language and human participants. Abstracts were further reviewed excluding studies stating a cross-sectional design or lacking body composition parameters prior to initiating GAHT. Studies were required to include adult participants (> 18 years of age), a quantifiable measure of body composition applying imaging methodologies, specifically DXA or magnetic resonance imaging (MRI) and have > 1 year of follow-up. The use of bioelectrical impedance analyses (BIA) was accepted if complementary to MRI or DXA imaging. Figure 1 depicts the article selection process. No ethical approval was required for the conduct of this work.

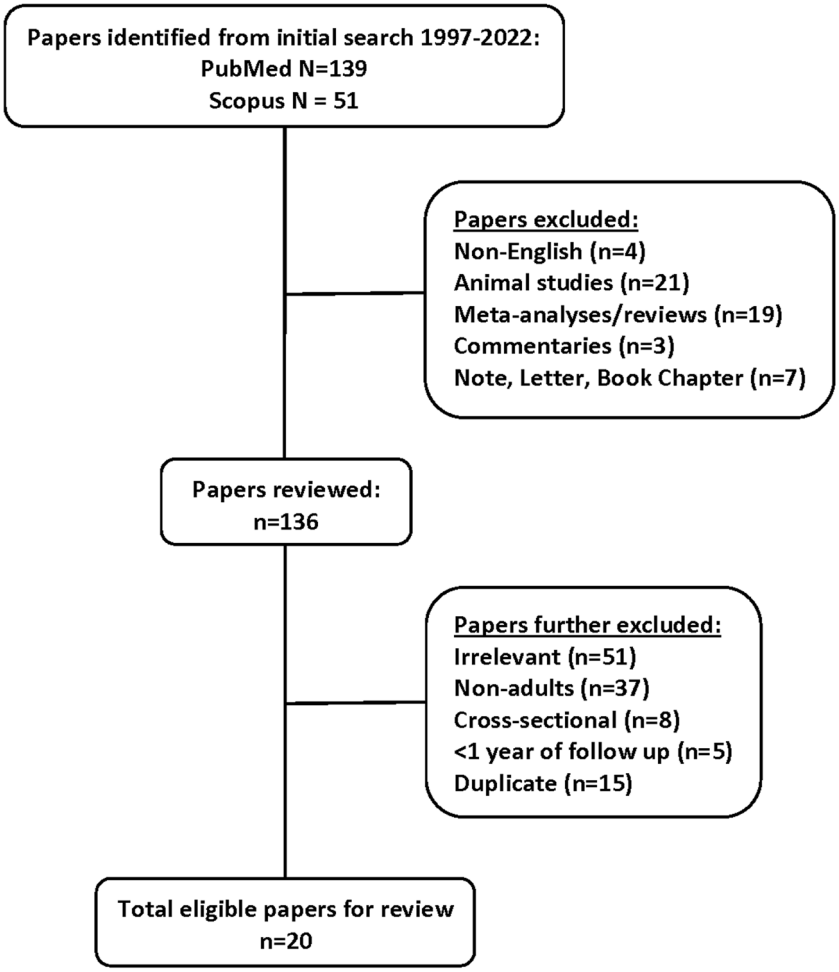

FIGURE 1 Methodology depicting the article selection process to assess body composition in transgender individuals following gender affirming hormone therapy

RESULTS

In total, 20 studies met all inclusion criteria; 14 used DXA,[13–26] three used MRI,[27–29] and three used a combination of MRI and BIA.[30–32] Collectively, 1099 participants (586 transgender men and 513 transgender women) were represented. The majority of studies reviewed were prospective cohorts, apart from two retrospective investigations[13,24] and one randomised controlled trial.[23] Three studies included cisgender controls[14,15,25] and one study included cisgender reference values.[17] All of the investigations were conducted in European countries (five studies in the Netherlands, one study in the Netherlands and Belgium, four studies in Belgium, one study in Belgium and Norway, five studies in Italy, one study in Sweden, one study in Spain, one study in Norway and one study in Germany.) In general, the follow-up period was 1 year, although a few studies included data for 2–5 years after GAHT initiation.

Variations in feminising and masculinising hormone therapy were noted across studies. Transgender women were most frequently treated with 100 μg of ethinyl oestradiol daily or 4 mg of oestradiol valerate daily in combination with 50–100 mg of cyproterone acetate daily. Transgender men were most frequently treated with intramuscular injections of 250 mg of testosterone undecanoate every 12 weeks or 250 mg of testosterone esters every 2 weeks. Summary findings for transgender women and transgender men are presented in Tables 1 and 2, respectively.

Despite differences in methodologies and treatments, obvious relationships are appreciated across investigations. Specifically, among transgender women, clear collective associations between oestrogen therapy and decreases in lean mass,[14–19,24,26,27,29,31] concomitant increases fat mass[14,17,18,29] and BMI[15,16,24,27,31] were observed. Within transgender men, testosterone therapy was associated with increases in lean mass in every study (except two investigations not measuring lean mass[30,32] and with increases in BMI.[13,16,19,20,22,25,30–32] Eleven studies also demonstrated associations between testosterone treatment and decreases in fat mass[16–20,22,23,25,27,29,30], specifically subcutaneous fat.[28,31,32] In most of the studies, no changes in bone mineral density were noted. One study assessed energy intake, reporting no changes among transgender men but decreased energy intake among transgender women.[31] Five studies assessed physical activity,[15,16,18,25,29] noting no significant changes over time. Overall,

TABLE 1 Studies evaluating body composition in transgender women following gender affirming hormone therapy

Article	Country/year	Study design	Treatment	*N*	Lean mass	Fat mass	WHR	BMI	Method	Duration
Gava *et al.*[24]	Italy 2016	Retrospective	1–2 mg transdermal oestradiol with 50 mg oral cyproterone acetate daily or 3.75 mg leuprolide (IM) monthly	40	↓ (NS)	↑	↔	↑ (NS)	DXA	1 year
Haraldsen *et al.*[14]	Norway 2007	Prospective	50 μg ethinyl oestradiol daily for 3 months then 100 μg daily	12	↓	↑	–	–	DXA	1 year
Van Caenegem *et al.*[15]	Belgium 2015	Prospective	< 45 years old: 4 mg oral oestradiol valerate daily with 50 mg oral cyproterone acetate daily > 45 years old: 100 μg transdermal 17β-oestradiol every 24 h with 50 mg oral cyproterone acetate daily	49	↓	↑	↓	↑	DXA	2 years
Wiik *et al.*[29]	Sweden 2020	Prospective	Transdermal oestradiol gel 1–2 mg daily or patch 100–200 μg every 24 h, 4–8 mg oral oestradiol daily or 80 mg oestradiol (IM) every 2–4 weeks	11	↓ (NS)	↑	–	–	MRI	1 year
Elbers *et al.*[31]	The Netherlands 1999	Prospective	100 μg ethinyl oestradiol with 100 mg cyproterone acetate daily	20	↓	↑	↔	↑	MRI and BIA	1 year
Giltay *et al.*[27]	The Netherlands 1998	Prospective	100 μg ethinyl oestradiol daily with 100 mg cyproterone acetate daily	18	↓ (NS)	↑	↑	↑	MRI	1 year
Elbers *et al.*[30]	The Netherlands 1997	Prospective	100 μg ethinyl oestradiol daily with 100 mg cyproterone acetate daily	17	–	↑	–	↑	MRI and BIA	1 year
Elbers *et al.*[32]	The Netherlands 2003	Prospective	100 μg ethinyl oestradiol daily with 100 mg cyproterone acetate daily	20	–	↑	–	↑	MRI and BIA	1 year
Auer *et al.*[16]	Belgium 2016	Prospective	< 45 years old: 50 mg oral cyproterone acetate with 4 mg oral oestradiol valerate daily > 45 years old: 50 mg cyproterone acetate daily with 100 μg transdermal 17β-oestradiol patch every 24 h	20	↓	↑	↔	↑ (NS)	DXA	1 year
Klaver *et al.*[17]	The Netherlands and Belgium 2018	Prospective	50 mg cyproterone acetate daily with 4 mg oral oestradiol valerate daily or 100 μg transdermal oestradiol patch every 24 h twice weekly	179	↓	↑	↓	–	DXA	1 year
Auer *et al.*[18]	Belgium 2018	Prospective	< 45 years old: 50 mg cyproterone acetate daily with 2 mg oestradiol valerate twice daily > 45 years old: 50 mg cyproterone acetate daily and a 100 mg transdermal 17β-oestradiol patch every 24 h	24	↓	↑	↓	↔	DXA	1 year
Wierckx *et al.*[19]	Belgium and Norway 2014	Prospective	< 45 years old: 50 mg cyproterone acetate daily with 4 mg oestradiol valerate daily > 45 years old: 50 mg cyproterone acetate daily with 100 μg transdermal 17β-oestradiol every 24 h	53	↓	↑	↓	↔	DXA	1 year
Gava *et al.*[26]	Italy 2020	Prospective	50 mg oral cyproterone acetate or 3.75 mg leuprolide acetate (IM) with 1 or 2 mg transdermal oestradiol or oral oestradiol valerate daily	50	↓ (NS)	↑ (NS)	↔	↑ (NS)	DXA	5 years

Abbreviations: BIA, bioelectrical impedance analyses; BMI, body mass index; DXA, dual energy X-ray absorptiometry; IM, intramuscular; MRI, magnetic resonance imaging; NS, not significant; WHR, waist-to-hip ratio.

TABLE 2 Studies evaluating body composition in transgender men following gender affirming hormone therapy

Article	Country/year	Study design	Treatment	*N*	Lean mass	Fat mass	WHR	BMI	Method	Duration
Gava *et al.*[13]	Italy 2018	Retrospective	1000 mg testosterone undecanoate (IM) at Weeks 0 and 6 then every 12–16 weeks or 250 mg testosterone enanthate (IM) every 3–4 weeks	50	↑	↔	↑ (NS)	↑ (NS)	DXA	5 years
Haraldsen *et al.*[14]	Norway 2007	Prospective	250 mg testosterone enanthate (IM) every 3 weeks	21	↑	↑ (NS)	–	–	DXA	1 year
Van Caenegem *et al.*[25]	Belgium 2015	Prospective	1000 mg testosterone undecanoate (IM) every 12 weeks	23	↑	↓	↔	↑ (NS)	DXA	1 year
Wiik *et al.*[29]	Sweden 2020	Prospective	1000 mg testosterone undecanoate (IM) at weeks 0 and 6 then every 10 weeks with GnRH analogue (IM) every 3 months	12	↑	↓	-	-	MRI	1 year
Elbers *et al.*[31]	The Netherlands 1999	Prospective	250 mg testosterone esters (IM) every 2 weeks	17	↑	↑ VAT ↓ SAT	↑	↑	MRI and BIA	1 year
Giltay *et al.*[27]	The Netherlands 1998	Prospective	250 mg testosterone esters (IM) every 2 weeks	15	↑	↓	↑	↔	MRI	1 year
Elbers *et al.*[30]	The Netherlands 1997	Prospective	250 mg testosterone esters (IM) every 2 weeks	15	–	↓	–	↑	MRI and BIA	1 year
Elbers *et al.*[32]	The Netherlands 2003	Prospective	250 mg testosterone ester (IM) every 2 weeks	17	–	↑ VAT ↓ SAT	–	↑	MRI and BIA	1 year
Auer *et al.*[16]	Belgium 2016	Prospective	1000 mg testosterone undecanoate every 3 months	20	↑	↓ (NS)	↔	↑ (NS)	DXA	1 year
Klaver *et al.*[17]	The Netherlands and Belgium 2018	Prospective	50 mg testosterone gel daily, 1000 mg testosterone undecanoate (IM) every 12 weeks or 250 mg testosterone esters (IM) every 2 weeks	162	↑	↓	↑	–	DXA	1 year
Auer *et al.*[18]	Belgium 2018	Prospective	1000 mg testosterone undecanoate every 3 months	45	↑	↓	↔	↔	DXA	1 year
Wierckx *et al.*[19]	Belgium and Norway 2014	Prospective	1000 mg testosterone undecanoate (IM) at weeks 0, 6 then every 3 months	53	↑	↓	↑	↑	DXA	1 year
Elbers *et al.*[28]	The Netherlands 1997	Prospective	Preovariectomy: 250 mg testosterone esters (IM) every 2 weeks Postovariectomy: 250 mg testosterone esters (IM) every 3 weeks Two participants switched to 160 mg oral testosterone undecanoate daily	10	↑	↑ VAT ↓ SAT (NS)	–	–	MRI	3 years
Aranda *et al.*[20]	Spain 2019	Prospective	1000 mg testosterone undecanoate (IM) every 2–3 months Two participants received 50 mg transdermal testosterone daily	20	↑	↓ NS	–	↑ (NS)	DXA	1 year
Mueller *et al.*[21]	Germany 2010	Prospective	1000 mg testosterone undecanoate (IM) every 12 weeks	45	↑	↔	–	↔	DXA	2 years

(Continues)

TABLE 2 (Continued)

Article	Country/year	Study design	Treatment	*N*	Lean mass	Fat mass	WHR	BMI	Method	Duration
Pelusi *et al.*[22]	Italy 2014	Prospective	100 mg testosterone esters (IM) every 10 days, 50 mg testosterone gel daily or 1000 mg testosterone undecanoate (IM) at weeks 0 and 6 then every 12 weeks	45	↑	↓	↔	↑	DXA	1 year
Gava *et al.*[23]	Italy 2021	Randomised controlled trial	1000 mg testosterone undecanoate (IM) at weeks 0, 6, 18, 30, 42 with oral placebo or 5 mg 5a-reductase inhibitor dutasteride daily	16	↑	↓ (NS)	↔	↔	DXA	1 year

Abbreviations: BIA, bioelectrical impedance analyses; BMI, body mass index; DXA, dual energy x-ray absorptiometry; GnRH, gonadotropin-releasing hormone; IM, intramuscular; MRI, magnetic resonance imaging; NS, not significant; SAT, subcutaneous adipose tissue; VAT, visceral adipose tissue, WHR, waist hip ratio.

transgender and cisgender men were significantly more active in sports than transgender women.[15,18] However, transgender men experienced a significant decrease in work and overall physical activity after 1 year of GAHT.[18]

Fat distribution

Excessive adiposity is presumed to predict health and chronic disease, where the health risks of obesity are considered to be dependent upon specific adipose tissue compartments. Traditionally, the waist-to-hip ratio (WHR) is considered a surrogate marker of abdominal to gynoid adiposity. This simple anthropometric measure can predict risk of myocardial infarction in the general population.[33] In transgender women, several studies reported decreases in WHR as a result of an increase in gynoid pattern of fat distribution.[15,17–19] Yet, for studies enrolling transgender men, we found a WHR increase[13,17,19,27,31] likely because of an increase in android pattern of fat distribution and reduced hip circumference. In general, fat mass decreased in transgender men and increased in transgender women, where transgender men displayed a tendency to gain visceral adiposity and lose subcutaneous adiposity. These observations correlate with what is expected of identified gender, reaffirming that GAHT is an important determinant of regional changes in adiposity. This has clinical significance because visceral adipose tissue is associated with early mortality, whereas subcutaneous adiposity is considered to serve as an energy reservoir of triglycerides for padding and protection.[34,35] Although looking beyond BMI and body weight by focusing on body composition provides greater insights into the proportion of lean and fat mass in transgender individuals, additional efforts are needed to better decipher the clinical implications of these changes on health outcomes. This review provides a needed framing for such investigations.

Lean mass

Overall, transgender men gained lean mass, whereas transgender women lost lean mass. This change is representative of the secondary sex characteristics resulting from GAHT administration. When transgender individuals transition after puberty, hormone therapy has little effect on height because of the permanent closure of bone plates, as well as genetic factors. However, in general, individuals assigned male at birth are typically taller than those assigned female at birth. On average, studies included in this review show transgender women were approximately 178 cm in height, whereas transgender men were 165 cm in height. Thus, when clinicians apply the standard BMI metrics, transgender men are at high risk of obesity misclassification because of a higher lean mass

relative to shorter stature. This phenomenon is parallel to BMI misclassifications frequently observed in athletes.[36] Recent national survey data indicate that 66% of transgender men have 'overweight' or 'obesity'; however, these numbers may not be accurate. For example, in the study by Wierckx *et al.*,[19] BMI significantly increased in transgender men from 'normal' to 'overweight', even though lean mass significantly increased, and fat mass significantly decreased. The present study underscores the importance of measuring body composition in transgender individuals.

DISCUSSION

The origins of obesity are multifactorial, yet clearly influenced by environment, lifestyle habits and genetics. Based on the results of this review, the potential contribution of GAHT as an etiologic factor of obesity and societal factors impacted after GAHT warrants consideration. Transgender women appear to be exceptionally at risk following GAHT due to observed increases in body weight, specifically fat mass. In general, transgender people with obesity are at increased risk for CVD and body dissatisfaction,[37] and likely obesity-related cancers. The study by Martinson *et al.*[8] reported that 26% of the transgender sample had obesity compared to just 18% of the cisgender sample. Furthermore, despite being highly motivated, the efficacy of a self-monitored weight management program did not significantly decrease average BMI and transgender patients remained ineligible for gender-affirming surgeries because of elevated BMI. Obesity can exclude transgender individuals from gender-affirming surgeries that effectively treat gender dysphoria, improve overall wellbeing and quality of life, and have the potential to be lifesaving.[38] Identifying methods to combat or address obesity are critical to improving the overall health of this population. Such actions are consistent with the Healthy People 2030 goals to reduce the proportion of adults with obesity and increase the proportion of healthcare visits pertaining to weight loss, nutrition or physical activity counselling.[39,40]

Role of registered dietitians and other clinicians

Registered dietitians have an important role in the management of transgender patients and possess a unique skillset to contribute to improved care. First, they should be encouraged to collaborate with surgeons to improve screening and treatment, similar to that of a Registered Dietitian on the bariatric team.[41] Second, registered dietitians can work with patients directly, providing evidence-based weight loss strategies to set realistic expectations, improve body composition and image, and support favourable surgical outcomes. Unfortunately, transgender individuals report high levels of mistreatment when seeking health care and when accessing gender-affirming treatments;[38] thus, registered dietitians and other clinicians need to focus on inclusivity to broaden their reach and impact in this visibly growing community. Although most transgender adults largely identify as white, data from the Behavior Risk Factor Surveillance System shows that the proportion of transgender adults who are Black or Latinx/e are higher than that of the general population.[2] This is concerning because these individuals reflect two marginalized identities (gender and race),[42] widening the gap on health disparities and obesity-related conditions. Implementing educational resources to reduce stigma in all communities is important with respect to providing culturally competent, equitable care to the transgender population. Third, in healthcare settings, intake forms should include gender identity and pronouns. Transgender individuals are unique in what language they use to describe themselves. Rather than assuming pronouns and language used to describe their anatomy, health professionals should ask what language best affirms transgender patients.

Applying and adapting gender-specific equations

Registered dietitians are encouraged to use a variety of techniques to conduct a comprehensive nutrition assessment; however, many of the tools we apply in daily clinical practice are based on assumptions of the cisgender population. For example, the Durnin–Womersley formula to calculate percentage body fat considers gender, using the sum of four skinfold thicknesses. BMI-for-age percentile growth charts, waist circumference cut-points and energy calculations, specifically Mifflin St-Jeor Method, Ireton-Jones and Harris Benedict, are all gender based. Furthermore, dietary recommendations for total energy, fibre, calcium, vitamin D, potassium and iron levels are also stipulated applying a male or female context. These are a small sample of the many calculations registered dietitians and other health professional utilise to create nutrition care plans, yet they may not be transferable to the transgender population. Linsenmeyer *et al.*[43] discussed potential approaches on how to navigate nutrition assessments with transgender patients. It is recommended clinicians use values aligned with a patient's gender identity after being on GAHT for 1 year or use the estimated energy requirement equation and calculate needs for both sexes to provide a transgender patient with the range of the difference between both sexes. The findings from our review also support the adaption and routine implementation of body composition assessment to help gauge the effectiveness of GAHT. Ultrasonography is a low cost, portable, non-invasive and widely available body composition tool that does not expose patients to radiation and can easily be adapted in the clinical setting with training.[44] Regardless of the approach

taken, transgender patients will need to be closely monitored to make appropriate adjustments in their treatment plan, considering body composition changes over time.

Address previous shortcomings to support advancement

As with any research area, there are inherent limitations that merit mentioning and offer novel opportunities for improvement and progress. First, almost all study participants in this review were relatively young, non-Hispanic white, non-obese and recruited from the Netherlands, Belgium and other European countries. Therefore, these findings are not representative of the global population and greatly limit generalisability. Better efforts are needed going forward to include and investigate the impact of GAHT on a more diverse, representative transgender population.[42] Second, the average study duration was approximately 1 year. GAHT produces maximum effects after 2–5 years of initiation.[45] This short time of observation impacts a comprehensive appreciation of body composition changes and future chronic disease risk. It also greatly impedes the ability to observe meaningful changes on bone architecture. Third, based on the relatively small sample sizes across studies, the probability of committing a type 2 error cannot be ruled out and may be reflected in several of the non-significant findings (Tables 1 and 2). Larger, adequately powered studies of longer duration are needed to overcome these shortcomings. Fourth, all but one study was a randomised controlled trial. The predominance of observational study designs diminishes the ability to make causal inferences; however, the precision of imaging techniques, relative uniformity in treatment regimens and follow-up period of at least 1 year elevate the overall quality of evidence depicted in this review. Finally, language is ever evolving in the transgender community. Transgender is an overarching term encompassing many genders beyond the traditional gender binary. As humans evolve, language evolves to describe the complexity of gender. Studies including transgender participants may be difficult to find in research databases given that there is no standardised language. If language is standardised in future research, periodic reevaluation is required to best reflect and represent the transgender population in this field. Some studies have incorrectly referred to transgender women as men and transgender men as women.[14,24]

CONCLUSIONS

Overall, the findings of this review support body composition changes for individuals receiving GAHT are gender-affirming and align secondary sex characteristics with gender identity. The impact on GAHT on bone health appears minimal; however, the relatively short period of observation precludes definitive conclusions. Additional research is needed to appropriately assess and evaluate the implications of these body composition changes over time (beyond 1 year) in larger, more diverse groups across all BMI categories. Future studies should also seek to evaluate nutrient intake, energy expenditure and other important lifestyle habits to diminish the health disparities and adverse health outcomes within this vulnerable population. Hospital, clinic and insurance policies require immediate evaluation and adaptation to help integrate registered dietitians into the routine care of transgender patients, especially for those undergoing GAHT and gender-affirming surgeries.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

AUTHOR CONTRIBUTIONS

Ky Ford, Elizabeth Huggins and Patricia Sheean contributed to the conceptual design, interpretation and drafting of the manuscript. Ky Ford, Elizabeth Huggins and Patricia Sheean have read and approve the final version of this manuscript submitted for publication.

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SUPPORTING INFORMATION

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

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Carbohydrate quantity is more closely associated with glycaemic control than weight in pregnant women with type 1 diabetes: Insights from the Diabetes and Pre-eclampsia Intervention Trial (DAPIT)

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Abstract

Background: The present study aimed to explore the relationships between carbohydrate intake, body mass index (BMI) and glycaemic control (HbA1c) in pregnant women with type 1 diabetes mellitus (T1DM)

Methods: Secondary analysis of data was undertaken to assess dietary intake in a cohort of women who participated in a randomised controlled trial (RCT) of antioxidant supplementation to prevent preeclampsia (DAPIT[10]). Study-specific peripheral venous blood samples were obtained for HbA1c at 26 and 34 weeks. Diet was collected using a validated semiquantitative food frequency questionnaire at 26–28 weeks of gestation which assessed dietary intake over 2 weeks. Mean daily average nutrient intakes were analysed using Q Builder nutritional software and SPSS, version 25.

Results: Dietary data were available for 547 pregnant women (72% of cohort) aged 29 years (95% confidence interval [CI] = 28.9–29.9) with average diabetes duration 11.8 years (95% confidence interval = 11.1–12.6). Average body mass index (BMI) (<16 weeks of gestation) was 26.7 kg/m^2 (95% CI = 26.3 −27, range 18.8–45.6 kg/m^2); 43% ($n = 234$) were overweight (BMI = 25.0−29.9 kg/m^2) and 20% ($n = 112$) were obese (BMI ≥ 30 kg/m^2). Differences in HbA1c and carbohydrate quantity and quality were found when adjusted for age and insulin dose. No differences between BMI group were observed for total carbohydrate and glycaemic control; however, differences were noted in fibre and glycaemic index.

Conclusions: Average quantity of dietary carbohydrate influenced HbA1c when adjusted for insulin dose however, BMI had less impact. More research is required on the relationship between carbohydrate consumption and glycaemic control in pregnancy.

KEYWORDS

body weight, carbohydrate, dietary assessment, pregnancy, Type 1 diabetes

Key points

- A positive association between glycaemic control (HbA1c) and higher quantity of carbohydrate (>264 g of carbohydrate) consumed in late pregnancy (mean gestational age 27.9 weeks) ($p = 0.002$) was shown in the present study.

- Sixty-three percent of women were classified as overweight or obese in early pregnancy, and almost 70% gained above the Institute of Medicine recommendations for optimal gestational weight gain. However, no association between body mass index or gestational weight gain and glycaemic control was found.
- This present study suggests that monitoring quantity and type of carbohydrate consumed (and matching insulin doses) may have an impact on glycaemic control and is more closely associated than weight.

INTRODUCTION

The prevalence of maternal overweight and obesity is rapidly increasing with 28% and 17%, respectively, reported in the general obstetric UK population.[1] However, the prevalence is reported to be higher in women with diabetes[2] although there are limited data available for comparison. One study in Swedish women with type 1 diabetes mellitus (T1DM) reported approximately 50% overweight and obese (35% and 18%, respectively) before pregnancy[3] and, more recently, a study in a subgroup of CONCEPTT[4] reported an average body mass index (BMI) of 26.2 kg/m². High maternal prepregnancy BMI in T1DM is strongly associated with elevated risk of adverse pregnancy outcome and, in addition TIDM in combination with overweight and obesity constitutes to a higher risk than either condition alone.[3] Therefore, BMI is an important risk factor for adverse pregnancy outcomes in T1DM.[3]

Optimising glycaemic control by glucose monitoring, insulin adjustment and appropriate dietary intake is a well-established goal in pregnancy. Weight gain is a common problem with intensive insulin regimens and has significant metabolic effects outside pregnancy including the development of an atherogenic lipid profile, increased blood pressure and abdominal obesity[5,6] and cardiovascular risk with long-term weight retention postpartum.[7] In addition, excessive gestational weight gain is an independent risk factor for adverse pregnancy outcomes in the general obstetric population[8] and a major contributor to excessive foetal growth in women with diabetes independent of glycaemic control,[9,10] with 65% of pregnant women with T1DM reported to have gained more weight than recommended.[11] Therefore, optimising weight gain during pregnancy reduces the risks of short- and long-term maternal and neonatal outcomes.[8]

Carbohydrate is the main dietary determinant influencing postprandial hyperglycaemia and it is well recognised that the amount, as well as the type, of carbohydrate in meals influences the glycaemic response.[12] The role of low carbohydrate diets in the management of T1DM is unclear and existing evidence from a recent systematic review was inconclusive at providing guidance for their use in non-pregnant women with T1DM.[13] In pregnancy, American Diabetes Association guidance for women with diabetes recommends a moderate carbohydrate diet of 175 g daily to ensure sufficient glucose for both mother and foetus.[8] The present study aimed to enhance the evidence base in this area by exploring the relationships between BMI, carbohydrate intake and glycaemic control in pregnant women with T1DM.

METHODS

In total, 547 (72%) pregnant women with T1DM were included in this secondary analysis of data obtained from participants in the Diabetes and Pre-eclampsia Intervention Trial (DAPIT; $n = 761$ participants) and in whom dietary data were available. DAPIT was a multicentre randomised double-blind placebo-controlled trial to investigate the use of antioxidants (vitamins C and E) for prevention of preeclampsia in pregnant women with T1DM.[14] Details of the methodology have been described previously.[14,15] In brief, eligible women with T1DM were recruited from 25 joint antenatal-metabolic clinics in Northern Ireland, Scotland and Northwest England between 2003 and 2008 where they received usual routine care throughout the DAPIT trial. Women were enrolled to the study between 8 and 22 weeks of gestation and where additional study data was collected as outlined in the study protocol.[14,15] Data were collected at baseline (booking: mean [SD] gestation 8.7 [2.675] weeks and 95% by week 15). Study specific peripheral venous blood samples were obtained for HbA1c at 26 weeks (mean [SD] gestation 26.3 [1.59] weeks) and 34 weeks (mean [SD] gestation 34.2 [1.21] weeks) and stored immediately at −70°C until analysis. HbA1c was measured by spectrophotometry using an automated ILab600 biochemical analyser. As a National Glycohemoglobin Standardisation Programme and International Federation for Clinical Chemistry certified method, the values reported were aligned with the Diabetes Control and Complications Trial system with intra- and inter-assay coefficients coefficients of variation values <2%. Blood glucose profiles were recorded by participants and provided to researchers from study diary readings. Early pregnancy BMI (kg/m^2) was calculated from a measured weight recorded <16 weeks of gestation. Women were categorised using the World Health Organization classification: underweight (BMI ≤ 18.5 kg/m^2); normal weight (BMI = 18.5–24.99 kg/m^2); overweight (BMI = 25.0–29.99 kg/m^2); obese class I (BMI = 30–34.99 kg/m^2):

obese class II (BMI = 35.0–39.99 kg/m^2): obese class III (BMI ≥ 40 kg/m^2). Gestational weight gain was then calculated only for participants who had accurate measured weights at all time-points ($n = 249$). This was achieved by calculating the total amount of weight gained (from week 13 to last weight measurement) and dividing by the number of weeks of gestation to give kg/week^1. Informed consent was given by all subjects who participated in the present study and ethical approval was obtained and the West Midlands Multicentre Ethics Research Committee provided ethical approval for DAPIT[14] (MREC 02/7/016).

Dietary evaluation

Pregnant women completed a validated semiquantitative food frequency questionnaire (FFQ) between 26 and 28 weeks of gestation (mean [SD] gestation 27.9 [1.56] weeks). The FFQ included 72 quantitative and qualitative questions of which 48 focused on frequency of consumption of cereals, meats, poultry and fish, fats and oils, sweet foods, fruits and vegetables and drinks. Researchers trained by a specialist diabetic dietitian instructed women to record their usual intake of foods consumed close to 26 weeks of gestation over a 2-week period using a standardised protocol. Questions were also asked regarding frequency of meals and supplements taken. Portion sizes when not specified in the FFQ were estimated based on standard UK portion sizes. Dietary questionnaires were returned to the study dietitian for checking, assessment and analysis. Mean average nutrient intakes of each participant were calculated from the FFQ using the nutritional software package Q-Builder (Questionnaire Design System, version 2.0; Tinuviel Software) where the frequency of consumption of foods was converted into foods and weights which generated a mean average daily nutrient intake. Estimated energy intakes calculated from the FFQ were validated against those obtained from a 7-day weighed food record ($n = 68$), which showed significant positive correlations for nutrients (range for nutrients $r = 0.14$–0.72; Bronte unpublished 2012). Under-reporting of energy intake (EI) was determined by calculating basal metabolic rate (BMR) using published equations based on age, prepregnancy weight and height.[16] Using the Goldberg method, the levels of under-reporting were predicted, using the ratio of energy intake (EI reported) to estimated BMR (BMR estimated).[17] A ratio of ≤ 1.2 may indicate under-reporting and a ratio of ≤ 0.9 is a sign of definite under-reporting.[17] Subjects were divided into three groups 'definite under-reporters' if EI:BMR ratio was ≤ 0.9; 'potential under-reporters' if ratio was > 0.9 to ≤ 1.2 and 'normal reporters' > 1.2.[18] Analysis was run both with and without definite under-reporters.

Statistical analysis

Differences between groups were assessed using analysis of covariance, adjusted for age, on log-transformed data where appropriate. Geometric means were back transformed from natural logs. Associations between nutrient intake and glycaemic control were analysed using Pearson's correlation coefficients (r) on log-transformed data and adjusted for age, BMI and insulin/kg^1/day^1. Determinants of poor glycaemic control were identified using binary logistic regression. $p < 0.05$ was considered statistically significant. A test for tend in means was carried out. All data was analysed using SPSS, version 25.0 (IBM Corp.).

RESULTS

Table 1 shows maternal characteristics of participants ($n = 547$ 72%) included in this secondary analysis, according to BMI category. No significant differences were found between those participants who were included (dietary information available) in the analysis: (mean [SD] [$n = 547$] with BMI = 27.5 [4.6] kg/m^2) and those excluded (no dietary information available) ($n = 214$) with BMI = 27.2 (4.8) kg/m^2 ($p = 0.49$). Subjects were almost exclusively Caucasian (98%) with a mean age of 29.4 years (95% confidence interval [CI] = 28.9–29.9) and average diabetes duration of 11.8 years (95% CI = 11.1–12.6). At booking, mean (SD) gestation was 8.71 (2.675) weeks, mean HbA1c (International Federation of Clinical Chemistry and Laboratory Medicine [IFCC]) was 59.6 mmol/mol^1 (95% CI = 58.4–60.8) (mean HbA1c = 7.7%; 95% CI = 7.5–7.8) and average BMI was 26.7 kg/m^2 (95% CI = 26.3−27.00, range 18.8–45.6 kg/m^2); 0% of patients were classed as underweight, 37% ($n = 201$) were classed as normal weight, 43% ($n = 234$) were classed as overweight and 20% ($n = 112$) were classed as obese. Of those categorised as obese, 14% ($n = 75$) were classed as obese Class I, 5% ($n = 29$) were classed as obese Class II and 1% ($n = 8$) were classed as obese Class III.

Women who were obese were significantly older ($p < 0.005$) compared to normal weight women, although no differences were observed between duration of diabetes, glycaemic control and units of insulin/kg^1/day^1 at booking. No women were receiving insulin using an insulin pump at the time of the study. Obese women gained significantly less weight during pregnancy (0.41 kg/week^1) compared to healthy weight women (0.52 kg/week^1) ($p < 0.040$).

Dietary data were available for 72% ($n = 547$) of participants in the DAPIT[14] study at mean (SD) gestational age of 27.9 (1.56) weeks, and no differences in BMI were observed between those women who completed dietary assessment (BMI 27.5 [4.6] kg/m^2) ($n = 547$) and those who did not (BMI 27.2 [4.8] kg/m^2) ($n = 214$) ($p = 0.49$).

TABLE 1 Maternal characteristics of pregnant women with type 1 diabetes mellitus by prepregnancy body mass index (BMI)

	BMI					
	N	All Mean (95% CI)	Healthy (18.5–24.99 kg/m^2) *n* = 201 Mean (95% CI)	Overweight (25.0–29.99 kg/m^2) *n* = 234 Mean (95% CI)	Obese (30.0+ kg/m^2) *n* = 112 Mean (95% CI)	*p* value
Age at booking (years)	547	29.4 (28.9–29.9)	28.6 (27.8–29.4)[a]	29.5 (28.8–30.2)[ab]	30.7 (29.7–31.8)[b]	0.005*
Duration of diabetes (years)	547	11.8 (11.1–12.6)	10.8 (9.6–12.1)	12.9 (11.8–14.0)	11.6 (10.0–13.4)	0.082
Weight (<16 weeks) (kg)	547	71.5 (70.5–72.5)	61.8 (61.0–62.6)[a]	73.0 (72.2–73.8)[b]	88.7 (86.4–91.0)[c]	<0.0001*
Height (m)	547	163.7 (163.1–164.3)	164.8 (163.8–165.7)[a]	163.6 (162.8–164.4)[ab]	161.8 (160.3–163.4)[b]	0.001*
BMI (<16 weeks) (kg/m^2)	534	26.7 (26.3–27.0)	22.8 (22.5–23.0)[a]	27.3 (27.1–27.5)[b]	33.9 (33.3–34.5)[c]	<.0001*
HbA1c (<13 weeks) (%)	531	7.7 (7.5–7.8)	7.7 (7.5–7.9)	7.7 (7.6–7.9)	7.4 (7.2–7.6)	0.171
IFCC (<13 weeks) (mmol/mol^1)	531	59.6 (58.4–60.8)	59.9 (57.7–62.1)	60.6 (58.8–62.5)	57.1 (54.8–59.5)	0.178
Insulin (26 weeks) (units/kg^1/day^1)	461	0.91 (0.88–0.93)	0.86 (0.82–0.91)	0.92 (0.88–0.96)	0.94 (0.87–1.01)	0.059
Gestation at delivery (weeks)	547	36.7 (36.5–36.9)	36.6 (36.3–36.9)	36.8 (36.5–37.0)	36.6 (36.2–37.0)	0.774
Weight gain (kg/week^1)	249	0.50 (0.47–0.53)	0.52 (0.47–0.57)[ab]	0.51 (0.47–0.55)[a]	0.41 (0.32–0.51)[b]	0.040*
Cholesterol (mmol/L^1)	502	4.82 (4.74–4.90)	4.68 (4.56–4.81)	4.91 (4.79–5.03)	4.91 (4.71–5.11)	0.059
Vitamin C (mmol/L^1)	483	38.8 (36.5–41.2)	40.4 (36.7–44.5)	39.7 (36.0–43.8)	34.0 (30.1–38.3)	0.114

Notes: Blood cholesterol and vitamin C randomisation visit; mean (SD) 14 (3.36) weeks of gestation. Gestational weight gain was calculated only for participants with accurate weights at all time-points ($n = 249$). CI, confidence interval.

[a,b,c]Mean values within a row with different superscript letters indicate a significant difference between groups.

*Significant difference between variable mean between BMI category by ANCOVA analysis with adjustment for age ($p < 0.05$).

Average daily energy intake was 6.892 MJ (95% CI = 6.737–7.050) for the group as a whole (Table 2). Daily average intakes for most nutrients did not differ between BMI categories, although exceptions were fibre, where the overweight (15.7 g) and obese (15.5 g) groups had significantly lower intakes than normal weight women (17 g) ($p = 0.013$). Overall, the diets of the cohort comprised, on average, approximately 55% carbohydrate, 30% fat and 18% protein of total energy, although no differences were observed between BMI groups (Table 2). No differences across the three BMI categories of normal weight, overweight or obese were observed for blood glucose profile at 26 weeks (Table 3) and likewise at all visits.

Under reporting of energy intake was observed (EI:BMR) in the overweight and obese groups with significantly greater under reporting in both groups ($p < 0.0001$) as shown in Table 2. When the 'definite' under-reporters (EI:BMR < 0.9) (20.3% of sample) were excluded from the analysis, mean energy intake increased to 7.158 MJ; however, no significant differences between BMI groups were observed for energy and macronutrient intake.

No relationship was seen between average nutrient intake which was assessed at 26–28 weeks of gestation and glycaemic control (HbA1c mmol/mol^1) at that time. However, differences were observed between energy (kJ) ($p < 0.041$), carbohydrate (g) ($p < 0.023$), fibre (g) (0.047) and glycaemic load ($p < 0.016$) when adjusted for age, BMI and insulin dose (insulin/kg) (Table 4). Linear regression showed that total carbohydrate intake, energy and glycaemic load were strongly correlated ($r > 0.8$); energy and glycaemic load were therefore omitted from the regression model. Carbohydrate was the strongest predictor of glycaemic control (>48 mmol/mol^1) at this time with the highest quintile of carbohydrate (>264 g/day^1) being the strongest predictor ($p = 0.002$) of higher HbA1c (Table 4). Duration of diabetes was a significant determinant ($p = 0.012$); however, BMI and age were not found to be significant determinants.

DISCUSSION

In the present study, a secondary analysis of data collected as part of the DAPIT examined the relationships between glycaemic control, BMI and carbohydrate intakes in pregnant women with T1DM, which showed a positive association between HbA1c and quantity of carbohydrate consumed in late pregnancy (mean [SD] gestational age of 27.9 [1.56] weeks), but no relationship was observed between glycaemic control and BMI.

Positive associations between the quantity of carbohydrate intake and glycaemic control have been previously reported in both pregnant and non-pregnant women with type 1 diabetes.[19] The present current study showed that the quantity of carbohydrate consumed in late pregnancy (approximately 26–28 weeks) showed a positive association

TABLE 2 Nutrient intake of cohort at an average 26 weeks of gestation split by prepregnancy body mass index (BMI) categories

	BMI				
	All ($n = 547$)	Healthy (18.5–24.99 kg/m^2) ($n = 201$)	Overweight (25.0–29.99 kg/m^2) ($n = 234$)	Obese (30.0+ kg/m^2) ($n = 112$)	p value
Energy (kJ)	6892 (6737–7050)	7064 (6788–7351)	6815 (6598–7040)	6751 (6409–7112)	0.377
Carbohydrate (g)	225 (220–230)	226 (219–236)	224 (217–231)	221 (210–232)	0.787
Sugars total (g)	79.3 (76.9–81.7)	79.3 (75.3–83.5)	80.3 (76.8–84.0)	77.1 (71.7–82.8)	0.563
% Energy CHO	55.1 (54.6–55.6)	54.6 (53.8–55.5)	55.4 (54.6–56.2)	55.2 (54.0–56.3)	0.398
% Energy fat	29.5 (29.0–30.0)	30.1 (29.3–30.9)	29.0 (28.2–29.8)	29.6 (28.6–30.8)	0.201
% Energy protein	17.9 (17.7–18.2)	17.9 (17.5–18.3)	18.1 (17.7–18.5)	17.7 (17.1–18.2)	0.343
Fibre Englyst (g)	16.1 (15.6–16.6)	17.0 (16.2–17.8)^a	15.7 (15.0–16.4)^b	15.5 (14.4–16.7)^b	0.013*
Iron (mg)	10.7 (10.5–11.0)	11.4 (10.9–11.9)^a	10.4 (10.1–10.8)^b	10.4 (9.8–11.0)^b	0.002*
Vitamin D (μg)	2.4 (2.3–2.6)	2.7 (2.5–3.0)^a	2.2 (2.0–2.5)^b	2.2 (2.0–2.5)^b	0.003*
Vitamin C (mg)	108 (103–113)	109 (101–118)	109 (101–117)	106 (95–118)	0.727
Glycaemic load	124 (121–127)	126 (121–131)	122 (118–127)	122 (116–129)	0.671
Glycaemic index	55.2 ± 3.4	55.5 ± 3.1^a	54.7 ± 3.5^b	55.4 ± 3.4^{ab}	0.029*
EI:BMR ratio	0.82 (0.80–0.84)	0.88 (0.85–0.92)^a	0.80 (0.78–0.83)^b	0.75 (0.71–0.79)^b	< 0.0001*

^{a,b}Mean values within a row with different superscript letters indicate a significant difference between groups.

Abbreviations: BMR, basal metabolic rate; CHO, carbohyrdrate; EI, energy intake.

*Significant difference between variable mean between BMI category by analysis of covariance, adjusted for age ($p < 0.05$).

TABLE 3 Blood glucose profile at 26 weeks of gestation by body mass index (BMI) categories

		BMI			
	N	Healthy (18.5–24.99 kg/m^2)	Overweight (25.0–29.99 kg/m^2)	Obese (30+ kg/m^2)	p value
Fasting glucose (mmol/L)	481	5.8 (5.5–6.1)	5.8 (5.5–6.1)	5.9 (5.5–6.4)	0.886
Glucose 1 h postbreakfast (mmol/L)	358	7.1 (6.5–7.7)	7.3 (6.8–7.8)	7.2 (6.5–8.0)	0.886
Glucose prelunch (mmol/L)	476	5.6 (5.3–6.0)	5.8 (5.5–6.2)	5.9 (5.4–6.4)	0.511
Glucose 1 h postlunch (mmol/L)	346	6.8 (6.2–7.4)	6.6 (6.2–7.1)	6.7 (6.0–7.4)	0.901
Glucose predinner (mmol/L)	470	5.8 (5.5–6.2)	5.7 (5.4–6.0)	5.6 (5.2–6.1)	0.947
Glucose 1 h postdinner (mmol/L)	340	6.7 (6.1–7.2)	7.2 (6.7–7.7)	6.7 (6.2–7.3)	0.253
Glucose presupper (mmol/L)	412	6.1 (5.7–6.5)	6.2 (5.8–6.6)	5.8 (5.3–6.3)	0.458
Glucose 1 h postsupper (mmol/L)	219	7.0 (6.4–7.6)	6.7 (6.1–7.4)	6.9 (6.1–7.7)	0.731

*Significant difference between variable mean between BMI category by analysis of covariance, adjusted for age ($p < 0.05$).

between HbA1c and that a higher quantity of carbohydrate (> 264 g of carbohydrate) was positively associated with HbA1c ($p = 0.002$). However, because dietary intake was assessed at only one time point, no conclusion can be drawn about other stages of pregnancy, although a previous study in early pregnancy (64 days) showed that a lower amount of carbohydrate was associated with better glycaemic control.[19] However, it must be noted that the American Diabetes Association recommends a minimum intake of 175 g of carbohydrate daily.[8]

Approximately 96% of women in the present study reported an average carbohydrate intake > 175 g/day^1, which is recommended to provide sufficient supplementation of glucose to the mother and foetus for fetal growth and brain development.[8] Average carbohydrate intakes observed in the present study were 55% of total energy (range 35–73%) with an average intake of 225 g/day^1 (95% CI = 220–230 g/day^1, which is classed as 'high' carbohydrate (> 55% total energy intake) [13,20] and is similar to the 56% reported in a subgroup of CONCEPPT trial[4] and also a

		OR	95% CI	*p*
Age		0.419	(0.132–1.331)	0.140
Duration (years)		0.688	(0.514–.921)	0.012*
BMI	Healthy (18.5–24.99 kg/m^2)	Ref	–	–
	Overweight (25.0–29.99 kg/m^2)	1.213	(0.758–1.942)	0.421
	Obese (30.0+ kg/m^2)	1.076	(0.615–1.885)	0.797
Carbohydrate intake	< 191.3 g	Ref	–	–
	191.4–225.1 g	2.194	(1.188–4.052)	0.012*
	225.2–264.0 g	2.022	(1.130–3.620)	0.018*
	> 264.1 g	2.510	(1.385–4.547)	0.002*

TABLE 4 Determinants of poor glycaemic control (HbA1c IFCC 48 mmol/mol^1 ≥ 6.5%)

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio.

*Binary logistic regression ($p < 0.05$). Patients were categorised into quartiles according to their carbohydrate intake.

review[21] that reported the range 45%–64%; therefore, evidence on the minimum amount of carbohydrate that is safe in the management of T1DM and also the type of carbohydrate and the relationship with glycaemic control and pregnancy outcome is required.[21]

Carbohydrate counting is an integral component of modern dietary management; however, at the time of the present study, women were not routinely educated on insulin adjustment. All women were on multiple daily injections with less flexibility, although all had good awareness of carbohydrate and the effect on glycaemia. Evidence from one study showed that women using carbohydrate counting had lower HbA1c,[19] and it is now recommended that carbohydrate counting and insulin dose adjusting is an effective strategy for optimising blood glucose control,[12] although no optimal amount of carbohydrate is suggested.[12]

In addition to the quantity of carbohydrate, the quality has also been shown to be an important determinant of postprandial glycaemic response.[22] Small positive differences in glycaemic control were shown in the present study between fibre intake and glycaemic load when adjusted for age, BMI and insulin dose. Average fibre intake was 16 g/day^1, which is below the recommended (12–24 g/day^1 Englyst method); therefore, those women with T1DM should be encouraged to achieve the UK recommended (30 g AOAC method/23–24 g Englyst) because evidence suggests that diets high in fibre may be beneficial for those with T1DM.[12]

It is well known that obesity is associated with increased insulin resistance and decreased insulin sensitivity[23] and women may therefore have poorer control in early pregnancy than women with normal or slightly elevated BMI.[3] In the present study, 63% ($n = 346$) of women were overweight or obese in early pregnancy (<16 weeks of gestation); however, no relationships between BMI and glycaemic control were noted from measurements recorded routinely before pregnancy (HbA1c 6 months prior to pregnancy, $p = 0.934$) or in early pregnancy (HbA1c at booking, $p = 0.171$) were shown. Likewise, no significant differences in glycaemic control at 26 weeks of gestation across the normal, overweight or obese groups in terms of fasting glucose, 1 h postprandial or premeal glucose levels were found.

The present study shows a higher prevalence of overweight and obesity in early pregnancy than that found in a study by Persson *et al.*,[3] which reported 53% in pregnant women with type 1 diabetes compared to reported rates of 45%[1] and 41%[24] in the general obstetric non-diabetic population. It is recommended that pregnant women with diabetes who have a prepregnancy BMI of > 27 kg/m² be given weight reduction advice prior to pregnancy.[12] However in the DAPIT study, over one-third of women (39%) considered their pregnancy unplanned[25] and, additionally, the proportion of women who reported receiving prepregnancy counselling was significantly lower among those with unplanned pregnancies.[24] Therefore, although there was no relationship found between unplanned pregnancy and BMI in the present study, it is nevertheless recommended that all women with T1DM receive advice about pregnancy planning[26] and this should also include weight management dietary advice.[12]

Associations between obesity in T1DM women and aggravated insulin resistance leading to the requirement for increased insulin doses to maintain optimal glycemic control have been reported[11] and it is recognised that weight gain with intensive insulin regimens increase BMI by 5 kg/m^2 in nonpregnant women.[27] However, the present study did not show any association between dose of insulin (unit/kg^1/day^1), BMI or gestational weight gain and glycaemic control. Almost 70% (of 249 women with data available) gained above the recommendations for optimal gestational weight gain relative to prepregnancy BMI,[8] which is higher than that in a similar study of T1DM that reported 54%[10] (of 115 women). In the

present study, obese women were shown to gain significantly less weight (0.41 kg/week^{1}) than normal weight women (0.52 kg/week^{1}) ($p = 0.040$) between 13 and 36 weeks of gestation, which is consistent with another study[28] reporting that weight gain decreased with increasing prepregnancy BMI. Given that improved glycaemic control is required to reduce the risk of adverse pregnancy outcomes and that weight management plays a central role in achieving optimal control, a combination of lifestyle interventions and modern insulin treatments and adjustment that are associated with less weight gain should be promoted. HbA1c does not reliably reflect changes in mean blood glucose in pregnancy; however, higher levels may still be useful as a marker of poor glycaemic control.

No difference in dietary energy intake was observed in relation to glycaemic control, regardless of BMI. Average daily energy intake was 6.892 MJ (95% CI = 6.737–7.050) for the group as a whole, although, when under-reporters (20%) were removed, this increased to 7.158 ± 1.879 MJ, which is broadly similar to those in a general obstetric population (non-diabetic), such as in Sheffield[29] (7.8 MJ), Bristol[30] (7.7 MJ) and Ireland[18] (8.0 MJ), but slightly higher than in a similar study in pregnant women with T1DM (6.99 MJ).[4]

The present study has a number of strengths. This secondary analysis of data collected from women with type 1 diabetes who participated in the DAPIT[14] study characterise nutrient intakes at the same time as including accurate BMI measurements and gestational weight gain in a large cohort of UK pregnant women ($n = 547$) exclusively with T1DM. The present study used BMI data on women who had an early BMI weight <16 weeks of gestation to ensure consistency and comparability. This is unlike other studies in pregnant women that have used recalled antenatal weight measurements, which has the potential for bias by misclassifying women. The present study relied on self-reported dietary data, which was collected using a validated semiquantitative FFQ at one time point (26–28 weeks of gestation), using estimated portion sizes; therefore, as with all dietary surveys, recording food intake has limitations and may limit generalisation of results. Likewise, the results may not be truly representative of pregnant women with T1DM in the UK because participants were recruited to an RCT study and only women who correctly completed food records were included.

In conclusion, the present study showed that a lower amount of carbohydrate consumed was positively associated with lower HbA1c regardless of BMI, gestational weight gain, insulin dose or energy intake. Therefore, the present study suggests that monitoring quantity and type of carbohydrate consumed (and matching insulin doses) may have an impact on glycaemic control and be an important strategy for optimising glycaemic control. No association between BMI or gestational weight gain and glycaemic control was found; however, 63% of women were overweight and obese in early pregnancy and almost 70% gained above the recommendations for optimal gestational weight gain. Accordingly, routine monitoring of weight at set time points during pregnancy may be justified.

AUTHOR CONTRIBUTIONS

Alison J. Hill wrote the manuscript. D. R. McCance and I. S. Young designed and promoted the study. I. S. Young sought ethics approval. V. A. Holmes coordinated all aspects of the trial and managed the data. C. C. Patterson provided statistical advice and analysed the data. All authors helped to prepare the final report.

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CONFLICTS OF INTEREST

AJH has received speaker honoraria. DRM and ISY have received speaker honoraria and have participated in advisory boards. CCP and VH declare that they have no conflicts of interest.

ETHICS STATEMENT

DAPIT study was given a favourable ethical opinion by West Midlands Multicentre Ethics Research Committee (MREC 02/7/016).

PEER REVIEW

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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 (the author will delete as appropriate). The lead author affirms 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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