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# Predictors for reporting of dietary assessment methods in food-based randomized controlled trials over a ten-year period

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# Predictors for reporting of dietary assessment methods in food-based randomized controlled trials over a ten-year period

## **Abstract**

The importance of monitoring dietary intake within a randomized controlled trial becomes vital to justification of the study outcomes when the study is food-based. A systematic literature review was conducted to determine how dietary assessment methods used to monitor dietary intake are reported and whether assisted technologies are used in conducting such assessments. OVID and ScienceDirect databases 2000-2010 were searched for food-based, parallel, randomized controlled trials conducted with humans using the search terms "clinical trial," "diet\$ intervention" AND "diet\$ assessment," "diet\$ method\$," "intake," "diet history," "food record," "food frequency questionnaire," "FFQ," "food diary," "24-hour recall." A total of 1364 abstracts were reviewed and 243 studies identified. The size of the study and country of origin appear to be the two most common predictors of reporting both the dietary assessment method and details of the form of assessment. The journal in which the study is published has no impact. Information technology use may increase in the future allowing other methods and forms of dietary assessment to be used efficiently.

## **Disciplines**

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## **Publication Details**

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# Predictors for Reporting of Dietary Assessment Methods in Food-based Randomized Controlled Trials over a Ten-year Period

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*The importance of monitoring dietary intake within a randomized controlled trial becomes vital to justification of the study outcomes when the study is food-based. A systematic literature review was conducted to determine how dietary assessment methods used to monitor dietary intake are reported and whether assisted technologies are used in conducting such assessments. OVID and ScienceDirect databases 2000–2010 were searched for food-based, parallel, randomized controlled trials conducted with humans using the search terms “clinical trial,” “diet\$ intervention” AND “diet\$ assessment,” “diet\$ method\$,” “intake,” “diet history,” “food record,” “food frequency questionnaire,” “FFQ,” “food diary,” “24-hour recall.” A total of 1364 abstracts were reviewed and 243 studies identified. The size of the study and country of origin appear to be the two most common predictors of reporting both the dietary assessment method and details of the form of assessment. The journal in which the study is published has no impact. Information technology use may increase in the future allowing other methods and forms of dietary assessment to be used efficiently.*

**Keywords** Dietary assessment, randomized controlled trials, food

## INTRODUCTION

While growing numbers of dietary trials can be found in the scientific literature, little is reported on the associated dietary assessment methods per se, nor the details for conducting these dietary assessment methods. Many scientific journals now demand greater detail on dietary methodology in intervention trials, but little is published in the literature on reference standards for describing these methods.

Randomized controlled trials (RCTs) provide the highest level of evidence for effects of test substances (including foods and diets) and are often associated with testing effects of pharmacological agents. RCTs require tightly controlled procedures, generally comparing outcomes of a placebo with an active form. The duration of the trial can depend on the substance being tested. When

the test variable is food-based, the nature of the test variable makes control more difficult (Blumberg et al., 2010; Jacobs et al., 2012).

Food-based RCTs are limited in their ability to blind participants to the test variable and require monitoring of a number of lifestyle related factors that inherently impinge upon eating behaviors and dietary patterns. Influences such as personal preferences for food, cultural background of participants, form of the variable being tested, and the background diet of the participants to be included in the trial may all effect the outcomes (Jacobs et al., 2012) Food-based RCTs commonly employ a wash-in phase where the dietary intake of participants is standardized in an attempt to limit the variability of the participant’s diets prior to exposure to the test variable. Although this approach cannot remove all of the variability between participants it does provide a useful approach.

Wash-in phases are, however, difficult to standardize in a free living setting so another approach is to monitor dietary intake at baseline prior to commencement of the trial’s intervention and continue to monitor this regularly throughout the trial. This ensures that participants who make drastic changes to their intake can be accounted for in the analysis of the study outcomes (Jacobs et al., 2012)

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Monitoring of food intake during a food-based RCT does not necessarily require additional personnel to obtain such data, but rather may be automated in an approach to streamline the data collected as well as improve overall efficiencies. The use of telephones and/or computers are two approaches that may assist with self-administered or interviewer-administered data capture during the monitoring process (Probst and Tap-sell, 2005). The question of whether or not studies do actually monitor dietary intake when running a food-based RCT has yet to be addressed as are the influences on reporting of such data when the study outcomes are published.

The aim of this systematic literature review was to answer the question: How are dietary assessment methods reported in the food-based dietary trials literature and how often is technology used to assist in the data capture? It was hypothesized that studies published in nutrition and dietetic journals would include a greater level of detail than those in food science and other health related and nonhealth scientific publications and there would be a decrease in the reported use of computer-assisted technologies with increased age of the study.

### **SEARCH STRATEGY**

A review of the databases Medline, PreMedline, PsychINFO, Cochrane, ERIC, Cynahl, and ScienceDirect databases was conducted to identify food-based, parallel, RCTs. The search terms included: "clinical trial," "diet\$ intervention" AND "diet\$ assessment," "diet\$ method\$," "intake," "diet history," "food record," "food frequency questionnaire," "FFQ," "food diary," "24-hour recall." The search was restricted to a 10-year period (2000-2010) and limited to Clinical trials (all), adults, and English language only publications. The outcomes from each of the databases were exported to EndNote referencing software and duplicate references removed.

### **LITERATURE SCREENING- INCLUDED AND EXCLUDED STUDIES**

Literature screening was conducted by two independent reviewers. Abstracts of all remaining publications were reviewed iteratively to determine their ability to meet the a priori criteria for inclusion and exclusion. Studies relating to drug testing, pharmacokinetic studies, vitamin or mineral supplements, enteral or parenteral nutrition, animal or cellular studies, and behavioral and/or educational interventions were excluded as were those following a clustered or pseudo-randomized controlled and cross-over trial designs. Meal-replacement studies were included.

### **DATA EXTRACTION**

Full text publications of all the included studies were obtained and a tabular summary created noting the publishing

journal, year of publication, country in which the study was conducted, approach of the RCT design, duration of the trial, participants included, type of dietary assessment method used or reported, and the number of and time points at which dietary assessments were applied. The use of technology to assist with assessment (assessment form), reference food composition database used for analysis of the dietary data and software used in the analysis were also summarized. Any factors that were not addressed were documented as not reported. Where a study referred to a parent study that was not obtained using the above search strategy, the parent publication was sourced from the reference list and details combined with the study found from the database search. Similarly, where substudies stemming from the same parent study were found, all were combined together.

### **STATISTICAL ANALYSIS**

The summary table was coded and transferred into SPSS for Windows (version 19, IBM, 2010). Data for type of journal (nutrition/dietetic vs. non-nutrition/dietetic determined by inclusion of the term nutrition or dietetic in the journal title), country of study, size of the study ( $\geq 100$  participants vs.  $< 100$  participants), dietary assessment method (food record, 24-hour recall, food frequency questionnaire, diet history, and other) and dietary assessment form (computerized, telephone based, and paper based) were categorically analyzed while the duration of the study was converted to a consistent timeframe (months) and the number of times dietary assessments were reported within a study were summated. The most common time points at which dietary assessments were reported was calculated as a proportion of the total study for each time point. For example a 12-week study with assessments at week 0, 6, and 12 were recorded as 0, 0.5, and 1.0. This allowed for a comparison across multiple studies of varying lengths. Only the first named dietary assessment method was included in the analysis for consistency. Where multiple publications resulted from the same study, these were referred to as a single study count. Chi-square and Fishers exact analyses were calculated for categorical variables to determine significant relationships between factors while multivariate logistic regression was used to determine influential variables for reporting of dietary assessment and reporting of assessment form overall. A particular focus was placed upon the country of the study and age of the study to determine predictors for reporting dietary assessment method use in an RCT and predictors of not reporting data.

### **RESULTS**

A total of 5359 studies were retrieved from the initial search, a total of 1364 abstracts were reviewed and 350 studies identified for the review. A further 107 studies were excluded after obtaining the full text articles leaving 243 studies. Parent publications were sought from the reference lists of 29 studies.

Of the included publications, 49.2% were from a nutrition and/or dietetic journal and the most common time period for the publications was 2004 (20.1%) with the majority (38.8%) conducted in North America followed by Europe (36.7%). The approach of the RCTs was highly varied ranging from those focused on a specific food item to those trialing a test diet. Tables 1 and 2 display the detail of each of the studies (by size of the study) that did report a dietary assessment method. In total 50 studies (20.6%) did not report the dietary assessment method used (Janatuinen et al., 1995; Sacks et al., 1995; Conlin et al., 2000; Fan et al., 2000; Kauwell et al., 2000; Knopp et al., 2000; Vuksan et al., 2000; Gregory et al., 2001; Lietz et al., 2001; Moore et al., 2001; Svetkey et al., 2001; Vollmer et al., 2001; Janatuinen et al., 2002; Pijls et al., 2002; Shankar et al., 2002; Vicennati et al., 2002; Allison et al., 2003; Berg et al., 2003; Engstrom et al., 2003; Facchini et al., 2003; Gluck and Gebbers, 2003; Hadley et al., 2003; Hoyt et al., 2003; Khan et al., 2003; Upritchard et al., 2003; Vozzo et al., 2003; Wolfe et al., 2003; Xiao et al., 2003; Writing group of the PREMIER Collaborative Research Group, 2003; Chen et al., 2004; Maubach et al., 2004; McGuire et al., 2004; Miyashita et al., 2004; Parra et al., 2004; Sagara et al., 2004; Westerterp-Plantenga et al., 2004; Davey Smith et al., 2005; Svetkey et al., 2004; Derouiche et al., 2005; Lejeune et al., 2005; Pieterse et al., 2005; Shankar et al., 2005; Benito et al., 2006; Karantonis et al., 2006; Han-Geurts et al., 2007; Cheskin et al., 2008; Due et al., 2008; Feng et al., 2008; Sathiaraj et al., 2008; Fernandez-Rivas et al., 2009).

The food record/food diary method was the most commonly reported dietary assessment technique (52.9%) applied, with a three-day duration the most common reference time-frame. Following this, the food-frequency questionnaire (14.8%) and 24-hour recall (7.8%) comprised the three most common forms of dietary assessment, though overall, 18.9% of food-based RCTs failed to report any dietary assessment methods. Similarly, 87.3% of studies also failed to report the manner in which the assessment was conducted while 5.3% reported it being telephone based.

(Keyserling et al., 1999, Kris-Etherton et al., 2002; Pierce et al., 2002; Ammerman et al., 2003, Appel et al., 2003; Maskarinec et al., 2003; Acharya et al., 2004, Malaveille et al., 2004, Rock et al., 2004b, Rock et al., 2004a, Vincent et al., 2004, Gann et al., 2005; Barnard et al., 2006, Chlebowski et al., 2006, Segovia-Siapco et al., 2007, Turner-McGrievy et al., 2008; Barnard et al., 2009, Gold et al., 2009, Hoy et al., 2009), 4.9% paper based (Djuric et al., 1999b; Campbell et al., 2000, Glasgow and Toobert, 2000, Forli et al., 2001a, Forli et al., 2001b, Djuric et al., 2002a, De Mendonca et al., 2003, Djuric et al., 2003, Nydahl et al., 2003, Sondergaard et al., 2003, Hays et al., 2004, Wu et al., 2005, Marfella et al., 2006, Hawkes et al., 2009) and 2.5% computerised. (Berrino et al., 2001, Heath et al., 2001, Schatzkin et al., 2000a, Kaaks et al., 2003, He et al., 2004, Hudson et al., 2006, Greenberg et al., 2009). Although this review assessed the first reported form of dietary assessment, 28 (11.5%) studies did report use of two or

more forms of assessment (Ash et al., 2003, Ashfield-Watt et al., 2003, Barnard et al., 2009, Barnard et al., 2006, Brinkworth et al., 2004, Chee et al., 2003, Cifuentes et al., 2004, Cline et al., 2000, Conceicao de Oliveira et al., 2003, Davis et al., 2009, Dawson-Hughes et al., 2004, Dragsted et al., 2004, Fard et al., 2004, Gann et al., 2005, Gillen et al., 2005, Hudson et al., 2006, Schatzkin et al., 2000a, Maki et al., 2002, Malaveille et al., 2004, Manios et al., 2006, Manios et al., 2009, Maskarinec et al., 2004a, Maskarinec et al., 2005, Maskarinec et al., 2004b, Moller et al., 2003, Morgan and Clayshulte, 2000, Murphy et al., 2007, Natri et al., 2005, Ramel et al., 2008, Rotily et al., 2000, Spiller et al., 2003, Turner-McGrievy et al., 2008, Vincent et al., 2004, Wilkinson et al., 2005, Xinying et al., 2004) with no consistent patterns identified for the methods selected. A significant positive relationship was seen between the reporting of assessment method and reporting the manner of assessment  $G = 11.378$  ( $p = 0.002$ ) while no relationship was seen for the type of journal (nutrition/dietetic vs. other) in which the study was published and reporting of dietary assessment method  $\chi^2 2.758$  ( $p = 0.097$ ) or dietary assessment form  $\chi^2 1.121$  ( $p = 0.290$ ).

Time points calculated as a proportion of the overall study length indicated that the commencement of the study was the most commonly used time point (57.5%,  $n = 61$ ) for dietary assessment. The second assessment was more likely to be at the midpoint of the study (32.3%,  $n = 32$ ) (Armstrong et al., 2000, Donaghue et al., 2000, Riddell et al., 2000, Sebedio et al., 2000, Smith-Warner et al., 2000, Davidson et al., 2001, Maki et al., 2002, McGavin et al., 2001, Leslie et al., 2002, Shah et al., 2002, Chee et al., 2003, Drummond et al., 2003, Hendriks et al., 2003, Moeller et al., 2003, Sondergaard et al., 2003, Mori et al., 2004, Dyerberg et al., 2004, He et al., 2004, Bhargava et al., 2004, Maskarinec et al., 2004a, Maskarinec et al., 2004b, Shah et al., 2004, Sloth et al., 2004, Tapsell et al., 2004, Waller et al., 2004, Hermansen et al., 2005, Barnard et al., 2006, Chen et al., 2006, Iyer et al., 2006, Marfella et al., 2006, Ashley et al., 2007, Murphy et al., 2007, Turner-McGrievy et al., 2008, Barnard et al., 2009, Davis et al., 2009) with 25 studies completing their dietary assessments in only two periods of assessment of which only 11 included the endpoint of the study as the final time point. (Barr et al., 2000, Conceicao de Oliveira et al., 2003, Erlund et al., 2003, Griffin et al., 2006, Haub et al., 2005, Pins et al., 2002, Scholtz et al., 2004, Spiller et al., 2003, Takatsuka et al., 2000, Thompson et al., 2005b, Wilkinson et al., 2005) The third and fourth time points were the most common times for a final assessment with 41.3% ( $n = 31$ ) (Ammerman et al., 2003, Keyserling et al., 1999, Armstrong et al., 2000, Sebedio et al., 2000, Barnard et al., 2009, Barnard et al., 2006, Bhargava et al., 2004, Chee et al., 2003, Davidson et al., 2001, Davis et al., 2009, Djuric et al., 2003, Djuric et al., 2004, Djuric et al., 1999a, Donaghue et al., 2000, Drummond et al., 2003, Dyerberg et al., 2004, Haub et al., 2002, He et al., 2004, Hermansen et al., 2005, Iyer et al., 2006, Jacobs et al., 2002, Alberts et al., 2000, Maki et al., 2002, McGavin et al., 2001, Moeller

**Table 1** Studies with <100 participants

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Mamo et al., 2005)	European Journal of Clinical Nutrition	Australia	6 wks	<i>N</i> = 20	3-d WFR ( <i>t</i> = NR)
(Donaghue et al., 2000)	Diabetes Research & Clinical Practice	Australia	12 wks	<i>N</i> = 23	4-d FR ( <i>t</i> = 0, 6, 12 wks)
(Heilbronn et al., 2002)	Journal of the American College of Nutrition	Australia	12 wks	<i>N</i> = 45	3-d FR ( <i>t</i> = every 2 wks)
(Ash et al., 2003)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	Australia	12 wks (18 mo F/Up)	<i>N</i> = 51	24-HR (NR); FFQ ( <i>t</i> = 12 wks)
(Gillen et al., 2005)	Journal of the American Dietetic Association	Australia	6 mo	<i>N</i> = 55	3-d WFR; dietitian admin. FFQ ( <i>t</i> = NR)
(Farnsworth et al., 2003)	American Journal of Clinical Nutrition	Australia	16 wks	<i>N</i> = 57	Daily 3-d WFR
(Tapsell et al., 2004)	Diabetes Care	Australia	6 mo	<i>N</i> = 58	3-d FR ( <i>t</i> = 0, 3, 6 mo)
(Brinkworth et al., 2004)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	Australia	68 wks	<i>N</i> = 58	Daily diet checklist ( <i>t</i> = 0–16 wks); FFQ ( <i>t</i> = 3, 6, 9, 12 wks)
(Cox et al., 2003, Cox et al., 2004)	Metabolism: Clinical & Experimental; American Journal of Clinical Nutrition	Australia	16 wks	<i>N</i> = 60	3-d FR ( <i>t</i> = every 2 wks)
(Howes et al., 2000)	Atherosclerosis	Australia	14 wks	<i>N</i> = 66	7-day FR ( <i>t</i> = NR)
(Fenech et al., 2005)	British Journal of Nutrition	Australia	16 wks	<i>N</i> = 68	Daily FR
(Mori et al., 2004)	Journal of Hypertension	Australia	16 wks	<i>N</i> = 69	3-d WFR ( <i>t</i> = 1/mo)
(Murphy et al., 2007)	British Journal of Nutrition	Australia	6 mo	<i>N</i> = 86	DH; 3-d WFR ( <i>t</i> = 0, 3, 6 mo)
(Noakes et al., 2004)	Journal of Nutrition	Australia	6 mo	<i>N</i> = 97	3-d WFR ( <i>t</i> = 4-wk intervals)
(Feiten et al., 2005)	European Journal of Clinical Nutrition	Brazil	4 mo	<i>N</i> = 24	3-d FR ( <i>t</i> = NR)
(de Oliveira et al., 2008)	Appetite	Brazil	10 wks	<i>N</i> = 49	3-d FR ( <i>t</i> = NR)
(De Mendonca et al., 2003)	Journal of Renal Nutrition	Brazil	3 days	<i>N</i> = 70	3-d FR ( <i>t</i> = NR)
(Wolever and Mehling, 2002, Wolever et al., 2003)	British Journal of Nutrition; American Journal of Clinical Nutrition	Canada	4 mo	<i>N</i> = 35	2 × 3-d FR ( <i>t</i> = 0, 1, 2, 3, 4 mo)
(Thompson et al., 2005b)	Clinical Cancer Research	Canada	1 mo	<i>N</i> = 32	3-d FR ( <i>t</i> = 0, before surgery)
(Tsihlias et al., 2000)	American Journal of Clinical Nutrition	Canada	6 mo	<i>N</i> = 91	3-d FR, ( <i>t</i> = 2 × 0 mo and 4 × during the study)
(Henriksen et al., 2003)	Acta Anaesthesiologica Scandinavica	Denmark	1 d (2 mo F/Up)	<i>N</i> = 48	FR ( <i>t</i> = NR)
(Due et al., 2004)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	Denmark	6 mo + 6–12 mo diet counsel, 24 mo F/Up	<i>N</i> = 50	7-d FR ( <i>t</i> = 0, 7.5, 9, 12 mo)
(Dragsted et al., 2004)	American Journal of Clinical Nutrition	Denmark	25 d	<i>N</i> = 43	Validated FFQ; 4-d WFR ( <i>t</i> = NR)
(Moller et al., 2003)	Cancer Epidemiology, Biomarkers & Prevention	Denmark	24 days	<i>N</i> = 43	FFQ; 4-d WFR ( <i>t</i> = NR)
(Sloth et al., 2004)	Cancer Epidemiology, Biomarkers & Prevention	Denmark	10 wks	<i>N</i> = 45	7-d WFR ( <i>t</i> = prior to, 5, 10 wks)
(Vasilaras et al., 2004)	European Journal of Clinical Nutrition	Denmark	6 mo	<i>N</i> = 46	7-d WFR ( <i>t</i> = 23 wks)
(Haulrik et al., 2002)	American Journal of Clinical Nutrition	Denmark	6 mo	<i>N</i> = 65	7-d WFR ( <i>t</i> = 0, 14 d)
(Skov et al., 2002)	Obesity Research	Denmark	6 mo	<i>N</i> = 65	7-d WFR ( <i>t</i> = NR)
(Dyerberg et al., 2004)	European Journal of Clinical Nutrition	Denmark	8 wks (12 wks F/Up)	<i>N</i> = 79	4-d WFR ( <i>t</i> = prior to, 4, 8 wks)
(Hermansen et al., 2005)	European Journal of Clinical Nutrition	Denmark	24 wks	<i>N</i> = 89	3-d WFR ( <i>t</i> = 0, 12, 24 wks)
(Natri et al., 2005)	European Journal of Clinical Nutrition	Finland	7 wks	<i>N</i> = 29	4-d FR ( <i>t</i> = recruit); 3 × 24HR ( <i>t</i> = during study)
(Erlund et al., 2003)	European Journal of Clinical Nutrition	Finland	8 wks	<i>N</i> = 40	3-d FR ( <i>t</i> = 0, 8 wks)
(Marniemi et al., 2000)	Nutrition Metabolism & Cardiovascular Diseases	Finland	8 wks	<i>N</i> = 60	3-d FR ( <i>t</i> = prior to, 7 wks)
(Karvonen et al., 2002)	Metabolism: Clinical & Experimental	Finland	6 wks	<i>N</i> = 68	4d FR ( <i>t</i> = NR)
(Tikkanen et al., 2001)	American Journal of Cardiology	Finland	15 wks	<i>N</i> = 78	3-d FR ( <i>t</i> = 0, 5, 10, 15 wks)
(Malaveille et al., 2004)	Mutation Research	France	8 wks	<i>N</i> = 90	FFQ ( <i>t</i> = 0wks); 24HR dietary diary ( <i>t</i> = NR)

(Continued on next page)

**Table 1** Studies with <100 participants (*Continued*)

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Rotily et al., 2000)	Kidney International	France	4 mo	<i>N</i> = 96	Semi-quantitative FFQ; 7-d FR ( <i>t</i> = 0, 4 mos)
(Kaaks et al., 2003)	European Journal of Clinical Nutrition	France	5 mo	<i>N</i> = 99	24HR; FFQ ( <i>t</i> = 24 × Intervention, 10 × control)
(Koebnick et al., 2004)	European Journal of Clinical Nutrition	Germany	4 wks	<i>N</i> = 32	7-d FR ( <i>t</i> = NR)
(Ditschuneit et al., 2002)	European Journal of Clinical Nutrition	Germany	51 mo	<i>N</i> = 73	7-d FR ( <i>t</i> = 0–2, monthly first 27 mo)
(Manios et al., 2006)	Maturitas	Greece	5 mo	<i>N</i> = 82	24HR; 3-d WFR ( <i>t</i> = NR)
(Azadbakht et al., 2008)	Diabetes Care	Iran	4 yrs	<i>N</i> = 41	3-d FR ( <i>t</i> = 3 monthly)
(Ferrara et al., 2006)	European Journal of Clinical Nutrition	Italy	6 mo	<i>N</i> = 15	7-d FR ( <i>t</i> = NR)
(Giacco et al., 2000)	Diabetes Care	Italy	6 mo	<i>N</i> = 63	7-d FR ( <i>t</i> = monthly)
(Meloni et al., 2002)	Journal of Renal Nutrition	Italy	12 mo	<i>N</i> = 69	3-d diet questionnaire ( <i>t</i> = NR)
(Doi et al., 2001)	Asia Pacific Journal of Clinical Nutrition	Japan	12 wks	<i>N</i> = 17	FR ( <i>t</i> = for 12 wks)
(Nagata et al., 2001)	Cancer Epidemiology, Biomarkers & Prevention	Japan	8 wks	<i>N</i> = 35	7-d FR ( <i>t</i> = prior to, 7 wks)
(Takatsuka et al., 2000)	Preventive Medicine	Japan	3 mo	<i>N</i> = 52	9-d FR ( <i>t</i> = first, third menstrual cycles)
(Tuekpe et al., 2006)	Hypertension Research - Clinical & Experimental	Japan	14 days	<i>N</i> = 56	FR ( <i>t</i> = NR)
(Katsuyama et al., 2004)	Journal of Nutritional Science & Vitaminology	Japan	1 yr	<i>N</i> = 73 women	FFQ ( <i>t</i> = NR)
(Maeda et al., 2005)	Diabetes, Obesity & Metabolism	Japan	16 wks	<i>N</i> = 76	Daily FR ( <i>t</i> = NR)
(Kasai et al., 2003)	Asia Pacific Journal of Clinical Nutrition	Japan	12 wks	<i>N</i> = 82	FR for 12 wks
(Armstrong et al., 2000, Sebedio et al., 2000)	Thrombosis Research; European Journal of Clinical Nutrition	Multicentre	6 wks	<i>N</i> = 88	4-d WFR ( <i>t</i> = 0, 6, 12 wks)
(Vermunt et al., 2001)	British Journal of Nutrition	Multicentre	12 wks	<i>N</i> = 88	4-d FR ( <i>t</i> = prior to, 5, 11wks)
(Riddell et al., 2000)	American Journal of Clinical Nutrition	New Zealand	12 wks	<i>N</i> = 65	4-d FR ( <i>t</i> = recruitment, 6, 12 wks)
(Heath et al., 2001)	Journal of the American College of Nutrition	New Zealand	16 wks	<i>N</i> = 75	FFQ ( <i>t</i> = recruitment, 4,8, 16 wks)
(McGavin et al., 2001)	European Journal of Clinical Nutrition	New Zealand	8 wks	<i>N</i> = 82	4-d EFR ( <i>t</i> = 0, 4, 8 wks)
(Seierstad et al., 2005)	European Journal of Clinical Investigation	Norway	6 wks	<i>N</i> = 60	FFQ ( <i>t</i> = NR)
(Forli et al., 2001a, Forli et al., 2001b)	Annals of Nutrition & Metabolism; Respiration	Norway	5 yrs	<i>N</i> = 71	7-d FR; dietitian reviewed ( <i>t</i> = NR)
(Hussain et al., 2004)	Food & Nutrition Bulletin	Pakistan	3 mo	<i>N</i> = 80	24HR 1 wk apart ( <i>t</i> = NR)
(Scholtz et al., 2004)	Thrombosis Research	South Africa	8 wks	<i>N</i> = 59	24HR ( <i>t</i> = 0, 8 wks)
(Morales et al., 2003)	American Journal of Kidney Diseases	Spain	5 mo	<i>N</i> = 30	3-d FR ( <i>t</i> = NR)
(Abete et al., 2008)	Journal of Human Nutrition & Dietetics	Spain	8 wks	<i>N</i> = 32	3-d WFR ( <i>t</i> = –1, 7 wks)
(Rodriguez-Rodriguez et al., 2007)	Annals of Nutrition & Metabolism	Spain	6 wks	<i>N</i> = 57	3-d FR ( <i>t</i> = NR)
(Palacios et al., 2005)	Menopause	Spain	6 mo	<i>N</i> = 80	FR ( <i>t</i> = NR)
(Dahlman et al., 2005)	American Journal of Clinical Nutrition	Sweden	10 wks	<i>N</i> = 40	3-d WFR ( <i>t</i> = prior to, 10 wks); 1-d WFR ( <i>t</i> = 2, 5, 7 wks)
(Hafstrom et al., 2001)	Rheumatology	Sweden	1 yr	<i>N</i> = 66	FR
(Cohn et al., 2004)	European Journal of Nutrition	Switzerland	22 d	<i>N</i> = 18	Nutritional FR ( <i>t</i> = NR)
(Golay et al., 2000)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	Switzerland	6 wks	<i>N</i> = 54	1-d FR ( <i>t</i> = weekly)
(Chen et al., 2006)	Nutrition & Cancer	Taiwan	12 wks	<i>N</i> = 26	3-d 24HR ( <i>t</i> = 4 weekly)
(Auvichayapat et al., 2008)	Physiology & Behavior	Thailand	12 wks	<i>N</i> = 60	Daily FR
(Hursel et al., 2009)	American Journal of Clinical Nutrition	The Netherlands	4 mo	<i>N</i> = 80	Food history questionnaire
(Drummond et al., 2003)	Journal of Human Nutrition & Dietetics	UK	8 wks	<i>N</i> = 25	7-d FR ( <i>t</i> = 0 wks); 4-d FR ( <i>t</i> = 4, 8 wks)
(Green et al., 2005)	Psychoneuroendocrinology	UK	8 wks	<i>N</i> = 56	3-d EFR ( <i>t</i> = NR)
(Wallace et al., 2000)	Annals of Nutrition & Metabolism	UK	4 wks	<i>N</i> = 25	FR ( <i>t</i> = NR)
(Rees et al., 2005)	Journal of the Royal Society for the Promotion of Health	UK	8–12 wks	<i>N</i> = 28	7-d FR( <i>t</i> = NR)

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**Table 1** Studies with <100 participants (*Continued*)

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Nydahl et al., 2003)	Public Health Nutrition	UK	24 wks	$N = 51$	7-d FR ( $t = \text{NR}$ )
(Wilkinson et al., 2005)	Atherosclerosis	UK	12 wks	$N = 57$	7-d FR ( $t = 1, 12$ wks); 3-d FR ( $t = 6$ wks)
(West and De Looy, 2001)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	UK	8 wks	$N = 95$	2-d FR ( $t = 0, 2, 4, 8$ wks)
(Hawkes et al., 2009)	Journal of Trace Elements in Medicine & Biology	USA	48 wks	$N = 42$	3-d FR ( $t = 2 \times$ run in, 24, 48 wks)
(Miller et al., 2002)	Hypertension	USA	9 wks	$N = 44$	Daily FR
(Redman et al., 2009)	PLoS ONE	USA	6 mo	$N = 48$	Self-reported FR ( $t = \text{NR}$ )
(Fitzgibbon et al., 2005)	Preventive Medicine	USA	20 wks	$N = 64$	FFQ ( $t = \text{NR}$ )
(Brodsky et al., 2004b, Brodsky et al., 2004a)	Metabolism: Clinical & Experimental; Journal of Nutrition	USA	4 wks	$N = 14$	3-d FR ( $t = \text{NR}$ )
(Shah et al., 2002, Shah et al., 2004)	Journal of Rheumatology	USA	12 wks	$N = 17$	3-d FR ( $t = 0, 6, 12$ wks)
(Morgan and Clayshulte, 2000)	Journal of the American Dietetic Association	USA	8 wks	$N = 19$	FFQ; 3-d FR ( $t = 0, 2, 4, 6, 8$ wks)
(Wells et al., 2003)	Journal of the American Dietetic Association	USA	14 wks	$N = 21$	3-d FR ( $t = 0, 5, 12$ wks)
(Haub et al., 2002, Haub et al., 2005)	American Journal of Clinical Nutrition; Metabolism: Clinical & Experimental	USA	15 wks	$N = 21$	3-d FR ( $t = 0, 1, 3, 12, 15$ wks)
(Cornier et al., 2005)	Obesity Research	USA	16 wks	$N = 21$	3-d FR ( $t = \text{NR}$ )
(Ebbeling et al., 2005)	American Journal of Clinical Nutrition	USA	12 mo	$N = 23$	7-d FR ( $t = 0, 3, 6, 12$ mo)
(Campbell et al., 2000)	Nutrition & Cancer	USA	3 menstrual cycles	$N = 25$	3-d FR ( $t = \text{NR}$ )
(Castaneda et al., 2001)	Annals of Internal Medicine	USA	12 wks	$N = 26$	3-d assisted FR; meetings with dietitian ( $t = \text{NR}$ )
(Ricci et al., 2001)	American Journal of Clinical Nutrition	USA	6 mo	$N = 27$	24HR ( $t = 0$ , during study)
(Nickols-Richardson et al., 2005)	Journal of the American Dietetic Association	USA	6 wks	$N = 28$	4-d FR ( $t = 0, 1, 2, 4, 6$ wks)
(Zemel et al., 2004)	Obesity Research	USA	24 wks	$N = 32$	Daily FR
(Dawson-Hughes et al., 2004)	Journal of Clinical Endocrinology & Metabolism	USA	9 wks	$N = 33$	FFQ ( $t =$ screening visit, 9 wks); FR
(Hays et al., 2004)	Archives of Internal Medicine	USA	14 wks	$N = 34$	FR ( $t = \text{NR}$ )
(Spiller et al., 2003)	Journal of the American College of Nutrition	USA	4 wks	$N = 38$	FFQ ( $t =$ weekly); 4-d FR ( $t = -1, 4$ wks)
(Demling and DeSanti, 2000)	Annals of Nutrition & Metabolism	USA	12 wks	$N = 38$	Nutrient intake form ( $t =$ daily)
(Li et al., 2008)	European Journal of Clinical Nutrition	USA	4 yrs	$N = 40$	FFQ ( $t = 3, 6, 12, 18, 24, 30, 36, 42, 48$ mo)
(Kien et al., 2005)	American Journal of Clinical Nutrition	USA	8 wks	$N = 43$	FR ( $t = \text{NR}$ )
(Van Berge-Landry et al., 2004)	Annals of Human Biology	USA	1 mo	$N = 48$	FR ( $t = \text{NR}$ )
(Jen et al., 2004)	Obesity Research	USA	1 yr	$N = 48$	3-d FR ( $t = 1$ wk prior to 0, 3, 6, 12 mo)
(Brehm et al., 2003, Brehm et al., 2005)	Journal of Clinical Endocrinology & Metabolism	USA	6 mo	$N = 53$	3-d FR ( $t = 1, 2, 3, 4, 5, 6, 7, 8$ wks)
(Wu et al., 2005)	American Journal of Clinical Nutrition	USA	8 wks	$N = 57$	3-d FR ( $t = \text{NR}$ )
(Barnard et al., 2005, Barnard et al., 2004, Turner-McGrievy et al., 2004)	Journal of Cardiopulmonary Rehabilitation; American Journal of Medicine; Nutrition	USA	14 wks	$N = 59$	3-d WFR ( $t =$ prior to, 0, 14 wks)
(Waller et al., 2004)	Journal of the American College of Nutrition	USA	4 wks	$N = 62$	3-d FR ( $t = 0, 2, 4$ wks)
(Zemel et al., 2005)	Obesity Research	USA	52 wks	$N = 63$	FR ( $t = 0$ )
(Cline et al., 2000)	Aviation Space & Environmental Medicine	USA	11 d	$N = 63$	WFR; daily dietary log cards ( $t = \text{NR}$ )
(Thompson et al., 2005a)	Journal of Agricultural & Food Chemistry	USA	14 days	$N = 64$	FR ( $t = \text{NR}$ )

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**Table 1** Studies with <100 participants (*Continued*)

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Moeller et al., 2003)	Menopause	USA	24 wks	<i>N</i> = 69	5-d FR ( <i>t</i> = 0, 12, 24 wks)
(Swain et al., 2002)	American Journal of Clinical Nutrition	USA	24 wks	<i>N</i> = 69	5-d FR ( <i>t</i> = 0, 2, 24 wks)
(Cifuentes et al., 2004)	American Journal of Clinical Nutrition	USA	6 wks	<i>N</i> = 73	FFQ; 3-d FR ( <i>t</i> = NR)
(Jensen et al., 2002)	American Journal of Clinical Nutrition	USA	3 yr	<i>N</i> = 83	4-d FR ( <i>t</i> = 0, 1, 2, 3 yrs)
(Davidson et al., 2001)	Journal of the American College of Nutrition	USA	8 wks	<i>N</i> = 84	3-d FR ( <i>t</i> = 0, 4, 8 wks)
(Djuric et al., 2002a)	Journal of the American College of Nutrition	USA	12 wks	<i>N</i> = 86	Daily FR
(Segovia-Siapco et al., 2007)	Public Health Nutrition	USA	6 mo	<i>N</i> = 87	Minimum 6 × 24HR ( <i>t</i> = NR)
(Pins et al., 2002)	Journal of Family Practice	USA	12 wks	<i>N</i> = 88	3-d FR ( <i>t</i> = 0, 12 wks)
(Anderson et al., 2005)	Journal of the American College of Nutrition	USA	12 wks	<i>N</i> = 90	Lifestyle diary ( <i>t</i> = 2, 4, 6, 8, 10, 12 wks)
(Barnard et al., 2009, Barnard et al., 2006)	Diabetes Care; Nutrition	USA	22 wks	<i>N</i> = 93	3-d WFR ( <i>t</i> = 0, 11, 22 wks); 24HR ( <i>t</i> = 4, 8, 13, 20 wks)
(Ashley et al., 2007)	Nutrition Journal	USA	12 mo	<i>N</i> = 96	3-d FR ( <i>t</i> = 0, 6, 12 mo)
(Turner-McGrievy et al., 2008)	Journal of the American Dietetic Association	USA	22 wks	<i>N</i> = 99	3-d WFR ( <i>t</i> = prior to, 0, 11, 22); 24HR ( <i>t</i> = 4, 8, 13, 20 wks)

NR: Not reported, mo: month, wk, week, yr, year; F/Up: Follow up, FR: Food record, WFR: Weighed food record, EFR: Estimated food record, 24HR: 24-hour recall, FFQ: Food frequency questionnaire, 25 studies (not shown in table) did not report an assessment method (Janatuinen et al., 1995, Sacks et al., 1995, Conlin et al., 2000, Fan et al., 2000, Vuksan et al., 2000, Kauwell et al., 2000, Knopp et al., 2000, Gregory et al., 2001, Moore et al., 2001, Lietz et al., 2001, Svetkey et al., 2001, Vollmer et al., 2001, Janatuinen et al., 2002, Pijls et al., 2002, Shankar et al., 2002, Vicennati et al., 2002, Vozzo et al., 2003, Khan et al., 2003, Engstrom et al., 2003, Hadley et al., 2003, Xiao et al., 2003, Allison et al., 2003, Wolfe et al., 2003, Berg et al., 2003, Facchini et al., 2003, Gluck and Gebbers, 2003, Hoyt et al., 2003, Writing group of the PREMIER Collaborative Research Group, 2003, Uprichard et al., 2003, Westerterp-Plantenga et al., 2004, Svetkey et al., 2004, Miyashita et al., 2004, Parra et al., 2004, Sagara et al., 2004, Maubach et al., 2004, Chen et al., 2004, Davey Smith et al., 2005, Derouiche et al., 2005, McGuire et al., 2004, Pieterse et al., 2005, Shankar et al., 2005, Lejeune et al., 2005, Benito et al., 2006, Karantonis et al., 2006, Han-Geurts et al., 2007, Feng et al., 2008, Cheskin et al., 2008, Due et al., 2008, Sathiaraj et al., 2008, Fernandez-Rivas et al., 2009).

et al., 2003, Murphy et al., 2007, Riddell et al., 2000, Shah et al., 2002, Shah et al., 2004, Sloth et al., 2004, Swain et al., 2002, Tapsell et al., 2004, Turner-McGrievy et al., 2008, Van Horn et al., 2001, Leslie et al., 2002) and 40.5% (*n* = 17) (Chen et al., 2006, Due et al., 2004, Ebbeling et al., 2005, Greenberg et al., 2009, Hawkes et al., 2009, Heath et al., 2001, Hendriks et al., 2003, Jen et al., 2004, Jensen et al., 2002, Ma et al., 2005, Metz et al., 2000, Mori et al., 2004, Rolls et al., 2005, Smith-Warner et al., 2000, Sondergaard et al., 2003, West and De Looy, 2001) of studies, respectively opting for this approach. By the third time point, the midpoint of the study was still noted by 21.3% (*n* = 16) studies (Giacco et al., 2000, Golay et al., 2000, Metz et al., 2000, Morgan and Clayshulte, 2000, Heath et al., 2001, West and De Looy, 2001, Jen et al., 2004, Noakes et al., 2004; Anderson et al., 2005, Dahlman et al., 2005, Ebbeling et al., 2005, Noakes et al., 2005, Rolls et al., 2005, Teegarden et al., 2005, Greenberg et al., 2009, Hawkes et al., 2009) though by the fourth time point only 4.8% (*n* = 2) of studies (Wolever and Mehling, 2002, Cox et al., 2003, Wolever et al., 2003, Cox et al., 2004) were using the midpoint for assessment. This is suspected to be due to the variability of the study durations and designs with studies containing four or more assessments having many differing patterns for data capture.

The size of the studies conducted (by participant number) varied in line with the approach being used (Morgan and Clayshulte, 2000, Women's Health Initiative Study, 2004). As the

approaches included such variability as the testing of single diet shakes (Allison et al., 2003) through to the impact of entire meal-based diet plans (Moore et al., 2001), it is suspected that this alongside resource availability, country of origin, and outcome variables impacted upon the size of the study though this was not statistically determined. The size of the study did, however, strongly relate to the choice of dietary assessment method  $G = 25.406$  ( $p = 0.0005$ ) and region of the study  $\chi^2 12.188$  ( $p = 0.032$ ) when considering only the United States against all other regions. This same regional comparison again displayed a significant relationship  $\chi^2 6.595$  ( $p = 0.010$ ) when analyzed for reporting of the manner of delivery of dietary assessment method in the study. When this relationship was tested as a model, a larger study size was found to be 1.493 times more likely to not report the assessment form than a smaller study size ( $p = 0.003$ , CI 0.764–2.841) and a study conducted in the United States was 1.110 times more likely to report the assessment method than one conducted in other countries ( $p = 0.003$ , CI 0.562–2.193).

Overall, there was a limited use of information technology for the conduct of the dietary assessment itself. It appeared that this is due to the primary focus of most papers related to primary outcomes of the studies rather than the dietary detail. Although it was hypothesized that newer studies would utilize technology for dietary assessment more so than older ones, this was not found to be the case  $\chi^2 0.487$  ( $p = 0.485$ ). Writers of the publications also appeared to have assumed that the

**Table 2** Studies with >100 participants

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Noakes et al., 2005)	American Journal of Clinical Nutrition	Australia	12 wks	<i>N</i> = 100	3-d WFR ( <i>t</i> = 2, 4, 6, 8, 10, 12 wks)
(Rae et al., 2000)	Australian & New Zealand Journal of Obstetrics & Gynaecology	Australia	NR	<i>N</i> = 125	3× 3-d FR ( <i>t</i> = NR)
(Xinying et al., 2004)	Asia Pacific Journal of Clinical Nutrition	Australia	1 mo	<i>N</i> = 159	2× 3-d WFR ( <i>t</i> = NR); semi quantitative FFQ ( <i>t</i> = 1 mo)
(Burke et al., 2005)	Journal of Hypertension	Australia	4 mo; 1 yr F/Up	<i>N</i> = 241	7-d retrospective diaries for alcohol intake
(Conceicao de Oliveira et al., 2003)	Nutrition	Brazil	12 wks	<i>N</i> = 411	FFQ; 3-d FR ( <i>t</i> = 3, 12 wks)
(Liu et al., 2009)	Asia Pacific Journal of Clinical Nutrition	China	8 wks	<i>N</i> = 112	Daily FR
(Sondergaard et al., 2003)	American Heart Journal	Denmark	12 mo	<i>N</i> = 131	4-d FR ( <i>t</i> = 3, 6, 9, 12 mo)
(Vincent et al., 2004)	Public Health Nutrition	France	4 yrs	<i>N</i> = 212	3-d recall questionnaire; 2–3 24HR ( <i>t</i> = 0–3 mo)
(Ditschuneit and Flechtner-Mors, 2001)	Obesity Research	Germany	4 yrs	<i>N</i> = 100	7-d FR ( <i>t</i> = monthly)
(Manios et al., 2009)	Journal of Human Nutrition & Dietetics	Greece	5 mo	<i>N</i> = 101	24HR; 3-d WFR ( <i>t</i> = NR)
(Ramel et al., 2008)	Diabetologia	Iceland	8 wks	<i>N</i> = 324	FFQ; 2-d WFR ( <i>t</i> = prior to, 6 wks)
(Fard et al., 2004)	Indian Journal of Pediatrics	Iran	1 yr	<i>N</i> = 180	4-d FR; dietary questionnaire ( <i>t</i> = NR)
(Shahar et al., 2007)	Diabetes Care	Israel	6 mo	<i>N</i> = 259	FFQ ( <i>t</i> = NR)
(Greenberg et al., 2009)	Journal of the American College of Nutrition	Israel	2 yrs	<i>N</i> = 322	FFQ ( <i>t</i> = 0, 6, 12, 24 mo)
(Esposito et al., 2004a)	JAMA	Italy	3 yrs	<i>N</i> = 110	3-d FR ( <i>t</i> = NR)
(Carruba et al., 2006)	Nutrition & Cancer	Italy	6 mo	<i>N</i> = 106	FFQ ( <i>t</i> = NR)
(Marfella et al., 2006)	Diabetic Medicine	Italy	1 yr	<i>N</i> = 115	4-d FR ( <i>t</i> = 3, 6, 9, 12 mo)
(Esposito et al., 2003)	JAMA	Italy	3 yrs	<i>N</i> = 120	3-d FR ( <i>t</i> = NR)
(Meloni et al., 2004)	Journal of Renal Nutrition	Italy	1 yr	<i>N</i> = 169	3-d diet questionnaire ( <i>t</i> = monthly)
(Esposito et al., 2004b)	JAMA	Italy	2 yrs	<i>N</i> = 180	3-d FR ( <i>t</i> = NR)
(Berrino et al., 2001)	Cancer Epidemiology, Biomarkers & Prevention	Italy	18 wks	<i>N</i> = 312	FFQ; 24HR ( <i>t</i> = 24× intervention, 10× control)
(Chee et al., 2003)	Osteoporosis International	Malaysia	2 yrs	<i>N</i> = 200	3-d FR; FFQ ( <i>t</i> = 0, 12, 24 mo)
(Andersson et al., 2002, Vessby et al., 2001)	American Journal of Clinical Nutrition; Diabetologia	Multicenter	3 mo	<i>N</i> = 162	3-d WFR ( <i>t</i> = NR)
(Appel et al., 2001, Appel et al., 1995)	Archives of Internal Medicine; Annals of Epidemiology	Multicenter	36 mo	<i>N</i> = 639	24HR ( <i>t</i> = -1 wk, 0, 9, 12, 18, 24, 30, 36 mo)
(Swinburn et al., 2001)	Diabetes Care	New Zealand	5 yr (F/Up)	<i>N</i> = 103	3-d FR ( <i>t</i> = prior to, 1 yr)
(Hjerkinn et al., 2004, Hjermann et al., 1981)	Journal of Internal Medicine; The Lancet	Norway	5 yrs	<i>N</i> = 104	Food questionnaire ( <i>t</i> = NR)
(Helland et al., 2001)	Pediatrics	Norway	12 mo	<i>N</i> = 590	Self-administered FFQ ( <i>t</i> = 18, 35 wks)
(Fito et al., 2007, Estruch et al., 2006) <sup>78:246</sup>	Archives of Internal Medicine; Ann Intern Med			<i>N</i> = 372	FFQ ( <i>t</i> = NR)
	Asia Pacific Journal of Clinical Nutrition	The Netherlands	11 wks	<i>N</i> = 105	Dietitian interview ( <i>t</i> = 2–3 weekly)
(Pijls et al., 2000)	European Journal of Clinical Nutrition	The Netherlands	12 mo	<i>N</i> = 125	FFQ ( <i>t</i> = NR)
(Hendriks et al., 2003)	European Journal of Clinical Nutrition	The Netherlands	1 yr	<i>N</i> = 185	FFQ ( <i>t</i> = 3, 6, 9, 12 mo)
(Bemelmans et al., 2004, Bemelmans et al., 2002, Bemelmans et al., 2000)	European Journal of Clinical Nutrition; American Journal of Clinical Nutrition	The Netherlands	104 wks	<i>N</i> = 282	Semi-quantitative FFQ ( <i>t</i> = NR)
(Saris et al., 2000)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	The Netherlands	6 mo	<i>N</i> = 398	3-d/7-d WFR ( <i>t</i> = 0, 1, 2, 4, 6 mo)
(Leslie et al., 2002)	International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity	UK	24 wks	<i>N</i> = 122	FFQ ( <i>t</i> = 0, 12, 24)
(Ashfield-Watt et al., 2003)	European Journal of Clinical Nutrition	UK	4 mo	<i>N</i> = 135	Screening DH, cereal intake ( <i>t</i> = 0); 2-wk folate diary ( <i>t</i> = 0, 2, 4 mo); Semi-quantitative FFQ ( <i>t</i> = NR)

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**Table 2** Studies with >100 participants (*Continued*)

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Kew et al., 2003)	American Journal of Clinical Nutrition	UK	6 mo	<i>N</i> = 150	FFQ ( <i>t</i> = NR)
(Burdge et al., 2003, Finnegan et al., 2003)	British Journal of Nutrition; American Journal of Clinical Nutrition	UK	6 mo	<i>N</i> = 150	FFQ ( <i>t</i> = 0, 5 mo)
(Harrison et al., 2004)	Nutrition Metabolism & Cardiovascular Diseases	UK	5 wks	<i>N</i> = 213	Daily FR ( <i>t</i> = NR)
(Griffin et al., 2006)	American Journal of Clinical Nutrition	UK	6 mo	<i>N</i> = 258	7-d WFR ( <i>t</i> = 0, 6 mo)
(Jacobs et al., 2002, Alberts et al., 2000)	Journal of the National Cancer Institute; New England Journal of Medicine	USA	3 yrs	<i>N</i> = 1,304	FFQ ( <i>t</i> = 0, 1, 3 yrs)
(Hall et al., 2003)	Ethnicity & Disease	USA	18 mo	<i>N</i> = 2,208	FFQ ( <i>t</i> = 0, 6 mo)
(Maskarinec et al., 2004b)	Journal of Nutrition	USA	2 yrs	<i>N</i> = 220	FFQ ( <i>t</i> = 0, 12 mo); 7 × 24HR ( <i>t</i> = random)
(Djuric et al., 2004, Djuric et al., 1999a, Djuric et al., 2003)	Biomarkers; Nutrition & Cancer; Nutrition	USA	12 wks	<i>N</i> = 104	4-d FR ( <i>t</i> = 1, 2, 3 mo)
(Davis et al., 2009)	Diabetes Care	USA	1 yr	<i>N</i> = 105	Daily FR; Interviewer 24HR (0, 6, 12 mo)
(Mattes, 2002)	Journal of the American College of Nutrition	USA	6 wks	<i>N</i> = 109	FR ( <i>t</i> = NR)
(He et al., 2004)	Journal of Hypertension	USA	12 wks	<i>N</i> = 110	24HR ( <i>t</i> = 0, 6, termination)
(Djuric et al., 2002b)	Nutrition & Cancer	USA	12 mo	<i>N</i> = 122	5 × 4-d FR ( <i>t</i> = NR)
(Wadden et al., 2004)	American Journal of Clinical Nutrition	USA	65 wks	<i>N</i> = 123	Daily FR
(Van Horn et al., 2001)	Journal of the American Dietetic Association	USA	9 wks	<i>N</i> = 127	3-d FR ( <i>t</i> = 0, 3, 9 wks)
(Iyer et al., 2006)	International Journal of Obesity	USA	8 wks	<i>N</i> = 129	3-d FR ( <i>t</i> = 0, 4, 8 wks)
(Maki et al., 2002)	American Journal of Clinical Nutrition	USA	24 wks	<i>N</i> = 131	3-d FR; study product diaries ( <i>t</i> = 0, 12, 24 wks)
(Teegarden et al., 2005)	Journal of Clinical Endocrinology & Metabolism	USA	1 yr	<i>N</i> = 135	3-d FR ( <i>t</i> = 0, 3, 6, 9, 12 mo)
(Kris-Etherton et al., 2002)	Journal of the American Dietetic Association	USA	7 wks	<i>N</i> = 150	24HR ( <i>t</i> = NR)
(Gann et al., 2005)	Journal of the American Dietetic Association	USA	15 mo	<i>N</i> = 154	3 × 24HR ( <i>t</i> = random); FFQ ( <i>t</i> = 0, cycle 12)
(Ma et al., 2005)	Journal of the American College of Nutrition	USA	5 wks	<i>N</i> = 159	3 × 7-d FR ( <i>t</i> = prior to, 0, 5 wks)
(Maskarinec et al., 2005)	British Journal of Nutrition	USA	2 yrs	<i>N</i> = 196	FFQ ( <i>t</i> = 0); 7 × 24HR ( <i>t</i> = random)
(Chlebowski et al., 2006)	Journal of the National Cancer Institute	USA	60 mo	<i>N</i> = 2,437	Daily FR, fat intake
(Hoy et al., 2009)	Journal of the American Dietetic Association	USA	5 yrs	<i>N</i> = 2,437	24HR ( <i>t</i> = 0, 3 mo, 2, 3, 4, 5 yrs)
(Gold et al., 2009, John P. Pierce, 2002) <sup>209210</sup>	Journal of Clinical Oncology; Controlled Clinical Trials	USA	4 yrs	<i>N</i> = 2,967	4 × 24HR ( <i>t</i> = random over 3-wk period)
(Rolls et al., 2005)	Obesity Research	USA	12 mo	<i>N</i> = 200	3-d FR ( <i>t</i> = 1, 2, 6, 12 mo)
(Smith-Warner et al., 2000)	Cancer Epidemiology, Biomarkers & Prevention	USA	1 yr	<i>N</i> = 202	3-d FR ( <i>t</i> = 3, 6, 9, 12 mo)
(Barr et al., 2000)	Journal of the American Dietetic Association	USA	12 wks	<i>N</i> = 204	3-d FR ( <i>t</i> = 8, 12 wks)
(Maskarinec et al., 2004a, Acharya et al., 2004, Maskarinec et al., 2003)	Cancer Epidemiology, Biomarkers & Prevention; Journal of Human Nutrition & Dietetics; Journal of the American Dietetic Association	USA	2 yrs	<i>N</i> = 220	FFQ ( <i>t</i> = 0, 12 mo); 7 × 24HR ( <i>t</i> = random)
(Fitzgibbon et al., 2003)	Preventive Medicine	USA	8 mo	<i>N</i> = 256	3 × Interviewer 24HR ( <i>t</i> = NR)
(Metz et al., 2000)	Archives of Internal Medicine	USA	1 yr	<i>N</i> = 302	4-d FR ( <i>t</i> = 0, 12, 26, 52)
(Glasgow and Toobert, 2000)	Medical Care	USA	6 mo	<i>N</i> = 320	FFQ ( <i>t</i> = NR)
(Harsha et al., 2004)	Hypertension	USA	90 d	<i>N</i> = 390	Daily FR
(Hudson et al., 2006, Schatzkin et al., 2000a)	Journal of the American College of Nutrition; New England Journal of Medicine	USA	1 yr	<i>N</i> = 399	FFQ; 4-d FR ( <i>t</i> = NR)
(Sacks et al., 2001)	New England Journal of Medicine	USA	30 d	<i>N</i> = 412	Daily FR

(Continued on next page)

**Table 2** Studies with >100 participants (*Continued*)

Study	Journal	Location	Duration (as reported)	Population	Dietary assessment method (time point)
(Ammerman et al., 2003, Keyserling et al., 1999)	Preventive Medicine; Public Health Nursing	USA	12 mo	<i>N</i> = 468	FFQ ( <i>t</i> = 0, 3, 12 mo), dietary risk assessment, optional for control group
(Women's Health Initiative Study, 2004)	Journal of the American Dietetic Association	USA	5 yrs	<i>N</i> = 48,836	FFQ ( <i>t</i> = screening, 1 yr)
(Flood et al., 2008, Schatzkin et al., 2000b)	European Journal of Clinical Nutrition; New England Journal of Medgenmed	USA	4 yrs	<i>N</i> = 750	Self-reported dietary practice
(Appel et al., 2003)	Journal of the American Medical Association	USA	6 mo	<i>N</i> = 810	24HR ( <i>t</i> = 0, 6 mo, 1 random); Alcohol questionnaire
(Bhargava et al., 2004)	Preventive Medicine	USA	12 mo	<i>N</i> = 866	FFQ ( <i>t</i> = 0, 6, 12 mo)
(Hoa et al., 2005)	Food & Nutrition Bulletin	Vietnam	16 wks	<i>N</i> = 168	3 × 24HR ( <i>t</i> = 0)

NR: Not reported, mo: month, wk, week, yr, year: F/Up: Follow up, FR: Food record, WFR: Weighed food record, EFR: Estimated food record, 24HR: 24-hour recall, FFQ: Food frequency questionnaire, 25 studies (not shown in table) did not report an assessment method (Sacks et al., 1995, Conlin et al., 2000, Knopp et al., 2000, Svetkey et al., 2001, Vollmer et al., 2001, Pijls et al., 2002, Allison et al., 2003, Berg et al., 2003, Facchini et al., 2003, Gluck and Gebbers, 2003, Hadley et al., 2003, Hoyt et al., 2003, Upritchard et al., 2003, Writing group of the PREMIER Collaborative Research Group, 2003, Chen et al., 2004, Svetkey et al., 2004, McGuire et al., 2004, Westertep-Plantenga et al., 2004, Lejeune et al., 2005, Davey Smith et al., 2005, Benito et al., 2006, Han-Geurts et al., 2007, Cheskin et al., 2008, Due et al., 2008, Sathiaraj et al., 2008).

assessments were conducted in hardcopy form unless it was otherwise stated. The use of technology was primarily reported for analysis of nutrient data though again this feature was not consistently reported nor was the reporting of the food composition database used for analysis. A total of *n* = 144 (59.3%) of studies mentioned either a software package and/or food composition data table used for analysis of the dietary data. Dietary analysis software used to determine the nutrient intakes was high specific to the country in which the study was conducted.

## DISCUSSION

Reporting of dietary assessment methods appears to be a detail that is often forgotten or not considered during the publication of food-based RCTs. This does not appear to be influenced by the type of journal in which the publications appear, despite the assumption that those with a nutrition and dietetic focus would require greater detail to be included.

The inconsistent reporting for dietary assessment methods is of concern given the importance of food and nutrient patterns on a range of lifestyle related diseases and their risk factors. Monitoring of total, saturated and unsaturated fat intakes, for example, is important when addressing outcomes related to cardiovascular health (Hooper et al., 2011) and similarly, awareness of foods containing varying levels of salts should be considered when addressing hypertension (He et al., 2004). If the background diet is not adequately monitored or controlled, the reported outcomes of the study may be strongly biased by nature of the variability of the food and health platform (Paschos et al., 2004). Such monitoring does not need to be overly onerous to the study researchers nor its participants but should at least capture the minimum food/nutrient data related to the area of interest.

The regular use of the food record methods to measure actual rather than usual dietary intake may not capture foods

eaten intermittently, though on the contrary, is not as resource heavy for a study to use by comparison to other methods. Studies utilizing food record methods were most likely to require a 3-day time period of recording a factor which is strongly associated with respondent burden as the period of recording increases (Rebro et al., 1998). The detail relating to which days were required, for example, weekday vs. weekend was often defined while the use of the type of food record, namely, weighed or estimated appeared arbitrarily. The bias related to the use of weighed food records, often considered gold standard for dietary assessment (Arab et al., 2011), has been related to the gender of the participants while the level of education does not have as great an influence upon their completion (Sudo et al., 2010). Intake is often modified during the period of recording resulting in under reporting of dietary intake (Thompson and Subar, 2008). The reporting of the 24-hour recall method also lacked sufficient detail and this may impact upon the reported nutrient outcomes of the study. This method of dietary assessment may be self-administered or interviewer administered each of which has its own inherent bias. Underreporting of calories consumed is commonly seen with this method of assessment and has been related to both gender, primarily females, and weight status, primarily overweight (Probst et al., 2009). The bias related to the administration method, interviewer or self-administered, also has further impact upon the detail obtained from the participants (Black and Cole, 2001) though repeated use can help to create a picture of usual intake of the participants. Similarly, the FFQ method may also be administered by the above means but can also vary significantly in the number of food items or food groups included with nested food groups appearing to be better suited to this method (Thompson et al., 2002). The number of food groups overall and the portion size associated with them is also likely to influence not only the duration of the assessment itself and in turn the quality of the responses given with

findings showing that foods which have a higher degree of between person variation better probed for by portion size by comparison to the traditional frequency of consumption focussed approach (Kim and Youl Choi, 2002).

The time points at which a dietary assessment method was employed in a study also varied with the overall design of the trial. Proportionate analysis allowed us to capture the most common time point, namely, the commencement of the study. Such data capture helps to create a baseline or reference of dietary intake prior to intervening. This may create detail about the participants' usual intake or their compliance with a suggested wash-in dietary approach and be referred to for comparison later in the study. Similarly, the detail about when the dietary assessment method(s) were conducted in the food-based RCT was often omitted from the publications. More than half (53.5%) of the studies captured in this review failed to report such detail.

The terminology employed when referring to the dietary assessment methodology is also largely inconsistent. Our review sought to classify the different methods reported into commonly used terminology. The use of a food diary for example was analyzed with food records given the approach similarity between the two methods. Similarly, an interview with a dietitian was assumed to be a diet history interview although it could also have been an interviewer administered 24-hour recall. This approach was only recorded as the first mentioned assessment method for three of the total studies. It is assumed that the limited use of this method was due to its resource intensive nature both for data capture and analysis and the range of external influences that may affect the intake that is resultantly reported. It is however a useful tool to obtaining information about participants' usual dietary intake following a meal-based approach rather than a food-based approach seen in other assessment methods (Thompson and Subar, 2008).

Despite the expansion of technology within society generally, the reported use of technology was limited in relation to food-based RCTs. Although it was predicted that more recent studies would be more likely to utilize technology, no consistent patterns were identified. Further to this, the range of technological platforms utilized was not as broad as expected. Use of cellular/mobile or smartphone-based interventions for automated collection of the dietary data (Daugherty et al., 2012) were not captured in this review despite their growing presence in society overall. Traditional use of either of these technologies, that is, for verbal person-to-person communication would have been captured as telephone-based trials; however, this detail was also not presented in the studies identified. It is suspected that given the time period of the studies captured in this review a growing use of portable technologies including cellular/mobile (Six et al., 2010) or smart phones (Long et al., 2010) may be seen in food-based RCTs beyond 2010 drawing on the various functionalities including short message service (Anhoj and Moidrup, 2005), voice recording (Rollo et al., 2011), and photographic image capture (Boushey et al., 2009)

as validity and acceptance of such methods grows amongst both researchers and their participants. Information technology use in food-based RCTs is expected to increase in the future allowing automation of dietary analysis and also allowing other forms of assessment to be used efficiently. A true snapshot of the use of technology in these trials was not possible due to the varied detail that is actually included in such study publication overall.

In the studies reviewed, technology was primarily reported for analysis of nutrient data. Dietary analysis software used to determine for nutrient intakes was seen to be country specific. The inclusion of technology for this process of RCT implementation is likely to be due to the shift in food composition data worldwide. A high proportion of food composition data is now contained in computerized and online databases allowing updates to be made as required (Probst, 2011, Probst and Tapsell, 2005). The shift to such forms of nutrient data also resulted in an expansion of the number of software companies producing analysis packages. Use of technology for such purposes has been common practice for a greater time period than was addressed in this review (Adelman et al., 1983, Bachman, 2003) again indicating that the level of detail reported in food-based RCTs may need further consideration.

## CONCLUSION

This review has demonstrated that there does not appear to be a standard approach to reporting on dietary methodology in food-based RCTs. The main influential variables found were the country in which the study was conducted and the number of participants included in the study overall. These outcomes may have been affected by the skewed proportion of studies conducted in the United States of America by comparison to other countries worldwide. Overall, the importance of reporting dietary intake in a food-based RCT should be encouraged to allow for a level of consistency in appraising the value of such studies. It is also noted that nutrition or dietetic experts may not always be employed for a study and, therefore, such detail may be omitted from the final publication. Similarly the word and page limits set by the different journals often push the authors to prioritize the data that is to be presented though in the instance where multiple publications have resulted from the one study at least one should include this vital information. Consistent requirements between journals for particular types of studies would be ideal; however, due to the variability of the test variables identified in this review alone, it is unlikely that this would be feasible.

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