Quality of development and reporting of dietetic intervention studies in primary care: a systematic review of randomised controlled trials

Background High-quality research methodologies and clear reporting of studies are essential to facilitate confidence in research findings. The aim of this study was to conduct an in-depth examination of the methodological quality and reporting of studies included in a recent systematic review of dietitians' effectiveness at providing individualised nutrition care to adult patients.

Methods The methodological quality and reporting of 27 Randomised Controlled Trials (RCTs) were appraised using the UK Medical Research Council (MRC) Guidelines for complex interventions and the CONSORT checklist for reporting RCTs. A quality appraisal checklist was developed for each guideline/assessment tool to evaluate the extent to which each study met the designated criteria. Excerpts from studies that best addressed criteria were collated to provide exemplary accounts of how criteria may be achieved in future studies.

Results None of the reviewed studies met more than half of the MRC guidance criteria, indicating there is clear room for improvement in reporting the methodological underpinnings of these studies. Similarly, no studies met all criteria of the CONSORT checklist, suggesting there is also room for improvement in the design and reporting of studies in this field.

Conclusions Dietitians, researchers and journal editors are encouraged to use the results and exemplary accounts from this review to identify key aspects of studies that could be improved in future research. Improving future research will enhance the quality of the evidence-base that investigates the outcomes of dietary interventions involving dietitians.

Keywords: nutritionist, workforce, manpower, nutrition therapy, diet therapy, outpatients, research, reporting, manuscript, study design.

Introduction

Dietary behaviour change is the first-line approach to optimal management of chronic diseases such as obesity, cardiovascular disease and type 2 diabetes mellitus ([1]). Facilitating individuals to make sustained changes to their dietary behaviours is widely recognised as challenging ([2, 3]). It is therefore not surprising that dietary behaviour change interventions usually demonstrate limited long-term success ([3]). Dietary interventions are regarded as "complex" due to the range of possible outcomes, variability in target population and multifaceted nature of intervention components ([4]). As a result, the design, implementation and evaluation of dietary behaviour change interventions require special attention.

Dietitians are members of the primary health workforce specifically trained in facilitating dietary behaviour change by providing nutrition care ([5]). In this context, nutrition care involves assessing an individual's nutritional status, diagnosing any nutrition-related problems, counselling on dietary behaviour change and monitoring and evaluating changes over time ([5]). Evidence about the effectiveness of dietitian consultations has the potential to inform health policy and commissioning for dietetic services, thereby impacting patient access to nutrition care.

The methodological quality of many primary health care interventions have been assessed as less than rigorous ([8-11]). Two commonly cited reasons for low methodological quality are the levels of research expertise of practitioners ([12]); and an increasing prevalence of complex interventions, such as those targeting dietary behaviour change, requiring advanced skills in methodological design ([4]). Education and training organisations have recognised that primary health care practitioners and researchers would benefit from greater support to enhance the methodological design and reporting of interventions ([12]).

Our recent systematic review of the effectiveness of dietitian consultations with adult patients in the primary health care setting was the first synthesis of this evidence base ([6]). The review only included studies that used a randomised controlled trial (RCT) design to ensure the highest quality evidence was appraised ([6]). The variability in results and risk of bias limits confidence that can be placed in the findings of the studies and subsequently reduces the ability to advocate for dietetic care for patients. Therefore, there is a crucial need for future studies investigating the effectiveness of dietitian consultations to utilise high-quality methods to inform appropriate advocacy and primary health care policy decisions related to dietetic services.

To support enhanced methodological design and reporting of dietetic interventions, the aim of this study was to conduct an in-depth examination of the methodological quality and reporting of studies included in the recent systematic review of effectiveness of dietitians providing individualised nutrition care to adult patients in the primary health care setting. This information is needed in order to improve study design and reporting of future studies to strengthen the quality of the evidence base for effectiveness of dietetic consultations.

Methods

Overview

This study revisited the studies included in a recent systematic review of dietitians providing nutrition care to adult patients in the primary health care setting ([6]). In the review, the Cochrane Risk of Bias tool was used to conduct the quality assessment of the individual studies ([7]). The critical appraisal in the current study further examines the methodological design and reporting of each study using structured assessment tools.

Details of the search strategy and selection process used in the systematic review have been previously published ([6]). Briefly, the literature search was conducted in ProQuest Family Health, Scopus, PubMed Central, Medline, the Cumulative Index to Nursing and Allied Health Literature and Cochrane databases. All studies with at least one search term in the title or abstract from each of the following three categories were included for consideration: (1) *patient* OR *client* OR *client-centred* OR *participant* OR *adult* AND (2) *dietitian* OR *dietetic* AND (3) *consult** OR *referral* OR *practice* OR *counselling* OR *interview* OR *advice* OR *outpatient* OR *clinic*. Study selection was limited to systematic reviews and studies using an RCT design. Cross-matching reference lists and forward citation searching were conducted to identify additional studies for consideration. Studies were selected using defined eligibility criteria outlined in **Table 1**. Studies needed to include a baseline and follow up measure of at least one outcome of anthropometric, clinical or dietary intake measures. Articles were limited to adults and those published in the English language. No date restriction was applied. The original search was conducted in September 2015. The search was repeated in October 2017 to identify any further studies that met the eligibility criteria (n=1).

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Critical Appraisal

For the present study, the methodological quality of the 27 eligible studies were assessed using (i) the UK Medical Research Council (MRC) Guidance on complex interventions ([4]); and (ii) the CONSORT Guidelines for reporting randomised interventions ([39]).

The UK MRC Guidance on complex interventions aims to assist researchers with the development, design, evaluation and implementation of complex interventions ([4]). These guidelines describe four main stages (each with three sub-stages) that should be followed

when developing complex interventions: 1) Development; 2) Feasibility and piloting; 3) Evaluation; and 4) Implementation. The MRC Guidance was used as the basis for a 12-item checklist developed by the research team to appraise how well published studies were designed.

The CONSORT statement is a 25-item checklist (with 12 embedded sub-items) that provides standardised and evidence-based recommendations for reporting randomised trials ([39]). The 25-item appraisal checklist was adapted by allocating scores to items considered relevant to all studies. Sub-items of the CONSORT statement that did not apply to the evidence under investigation (e.g. changes to methods after trial commencement and trial stopping guidelines) were appraised but not scored.

Both checklists were pilot tested by four members of the research team (LM, LB, LR and LW) by independently completing each checklist for six studies. Responses were compared and discussed as a team to ensure consistent interpretation. Two research team members then appraised all studies independently, with discrepancies resolved by the whole team. Where studies referenced a feasibility study, pilot study or logic model, these were retrieved to inform the review. Assessment data from all included articles were then double extracted using an electronic spreadsheet developed for the purpose of the quality appraisal.

Assessment

All studies were assessed according to the following standards: ‘completely’ met the item criterion; ‘partially’ met the item criterion; or ‘no evidence’ of meeting the item criterion. The numbers of studies meeting each criterion were collated and tallied. Individual studies were sorted from highest to lowest quality according to the number of criteria met, partially

met or not met. Where fewer than 50% of studies partially or fully met an item criterion (indicated in tables by an *), an excerpt from a study that fully met the criterion was provided as an exemplary account of how to fully meet the item criterion.

Results

Twenty-seven RCTs met the eligibility criteria and were included in the review, as shown in **Figure 1** ([13-38]).

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Of the 27 RCTs reviewed, 18 showed at least some statistically significant differences in dietary, anthropometric or clinical outcomes between intervention and comparator groups ([6]). Significant improvements favouring the intervention compared with control groups were found for the following management areas: glycaemic control (four out of four studies), dietary change (four out of four studies), anthropometry (four out of seven studies), cholesterol (two out of eight studies), triglycerides (one out of five), and blood pressure (zero out of three) studies ([6]). The inconsistency in results for outcome measures warranted further investigation.

Table 2 provides an overview of the quality assessment of each study reviewed. None of the reviewed studies fully met all criteria for either checklist. The top ranking studies for each checklist were published after the year 2012 ([34, 38]) and the lowest ranking studies were published prior to the year 1995 ([26, 33]). Despite more recent studies generally ranking higher for the CONSORT checklist, this was not evident for the MRC Guidance.

INSERT TABLE TWO ABOUT HERE

MRC Quality of Study Development

Table 3 provides the results of the quality appraisal of trial development and testing conducted using the MRC Guidance for complex interventions. The highest ranked study completely met six of the 12 criteria ([34]). Most studies (18 of the 27 studies reviewed) completely met two or fewer criteria. Most studies (n=19, 73%) did not identify relevant evidence to justify their intervention and nearly all (n=24, 92%) failed to provide any evidence of using a theory to guide intervention development. Although many studies completely or partially measured the effectiveness of the intervention (n=25, 93%), many failed to estimate expected recruitment or retention (n=25, 93%) or assess cost-effectiveness of the intervention (n=23, 88%). For nine of the 12 criteria, more than 50% of reviewed studies provided no evidence of meeting the criteria at all (indicated with an *).

INSERT TABLE THREE ABOUT HERE

Table 4 provides exemplar excerpts from those studies that were highly ranked on the MRC criteria, suggesting well-developed intervention trial development and testing.

INSERT TABLE FOUR ABOUT HERE

CONSORT Quality of Reporting

Table 5 provides the results of the quality appraisal of RCT reporting conducted using the CONSORT checklist. The highest ranked study completely met 24 of the 28 criteria ([38]). Twelve of the 27 studies reviewed completely met 10 or fewer criteria. Nearly all studies

provided a structured summary (n=25, 93%), described eligibility criteria for participants (n=23, 85%), and detailed the setting where data were collected (n=19, 70%). Many studies partially fulfilled some criteria, such as describing the intervention (n=12, 44%), defining outcome measures (n=18, 67%) and displaying results with effect sizes (n=14, 52%). However, few studies completely described the trial design (n=5, 19%), the method used to generate random allocation sequence (n=6, 22%), mechanism used to implement the random allocation sequence (n=2, 7%), and blinding of participants (n=3, 11%). For 10 of the 28 criteria, more than 50% of reviewed studies provided no evidence of meeting the criteria at all (indicated with an *).

INSERT TABLE FIVE ABOUT HERE

Table 6 provides exemplar excerpts from studies that were highly ranked and met the CONSORT criteria, suggesting they are well reported trials.

INSERT TABLE SIX ABOUT HERE

Discussion

This review is the first examination of the methodological quality and reporting of studies investigating the effectiveness of dietitians providing individualised nutrition care in the primary care setting. None of the reviewed studies met more than half of the MRC guidance criteria, indicating there is clear room for improvement in reporting the methodological underpinnings of dietetic intervention studies. Similarly, none of the studies met all criteria of the CONSORT checklist, suggesting there is also a need for improvement in the design and reporting of RCTs in this field. This review has outlined the suboptimal quality of studies

investigating the effectiveness of dietitians, which may help to explain why the findings of these studies can be variable ([6]).

The MRC Guidance on complex interventions was first introduced in 2000 to assist researchers with the development, evaluation and implementation of complex interventions, such as those targeting dietary behaviour change ([4]). Within these guidelines, it is postulated that rigorous development, feasibility and pilot testing of interventions are essential to ensure the outcomes of an intervention occur as predicted ([4]). Given that key aspects of development, feasibility and pilot testing were lacking in all reviewed studies, interventions involving a dietitian either lack the planning required for successful study execution or have not prioritised its reporting. Researchers are recommended to invest greater efforts in the development and pilot testing of future studies investigating the effectiveness of dietitians to produce more consistent, trustworthy findings as well as reporting all aspects of development in publications. Greater efforts in pilot testing will also assist with refining the design of the study, ensuring acceptability of the intervention and calculating a required sample size for a subsequent trial that tests the effectiveness of the intervention.

The CONSORT checklist was implemented in 2001 to aid authors in transparent reporting of trials, as well as to assist journals in consistent, high standard critical appraisal of studies being considered for publication ([39]). Each item in the checklist is clear and succinct, including detailed examples of sentences that appropriately meet the requirements of reporting ([39]). Given the widespread uptake of the CONSORT checklist since its dissemination, it is not surprising that newer studies were generally ranked higher than older studies. However, it is surprising that studies published after 2001 still demonstrated suboptimal reporting. A notable challenge of using CONSORT for dietary interventions is the

individually-tailored nature of dietetic counselling which prohibits detailed information about the content of the intervention given to all participants. Authors, peer reviewers and journal editors are encouraged to align manuscripts with the CONSORT checklist to ensure the achievement of high quality reporting of dietary interventions.

The MRC Guidance and CONSORT documents contain some criteria that are not often published in health journals. It is therefore possible that some tasks such as identifying theory, modelling processes and outcomes and assessing cost-effectiveness may have been undertaken, but not published. However, without evidence of these tasks, it is unclear whether variability in study findings are a result of different approaches to intervention development and execution that are not reported, or due to other reasons warranting further investigation. While researchers no doubt are mindful that articles cannot exceed the permitted word length of journals, foundational information still needs to be communicated. Strategies to communicate this information might include publishing separate manuscripts that articulate the development and piloting of interventions, or disseminating information through databases of interventions or trial registries.

This review provides exemplar excerpts from manuscripts to assist future researchers in enhancing the methodological quality and reporting of studies investigating the effectiveness of dietitians providing individualised nutrition care. Exemplar excerpts were not available for five criteria, suggesting there are priority areas in the body of evidence requiring improvement. These areas are: (i) modelling processes and outcomes of interventions, (ii) testing the feasibility of intervention procedures, and (iii) estimating recruitment/retention of the study sample, which are all part of study protocol development and research planning; (iv) monitoring outcomes over time, which requires a plan for following participants into the

251 future; and (v) identifying where the full trial protocol can be accessed, which requires
252 registration of the study. These areas should be considered when educating dietitians about
253 intervention research and emphasised in scientific conference presentations.
254
255 This review has notable strengths and limitations. This is the first time the methodological
256 quality and reporting of studies investigating the effectiveness of dietitians has been
257 examined. Despite RCT designs being considered as gold standard for investigating clinical
258 effectiveness, it's possible that the complex nature of dietetic interventions prohibited
259 comprehensive design and reporting. Regardless, the findings provide useful
260 recommendations for future research that can enhance the confidence that can be placed in
261 the findings of studies assessing the effectiveness of dietitians (**Box 1** provides key
262 recommendations). Greater confidence in findings will increase the ability to advocate for
263 dietetic care for patients based on synthesised evidence. The MRC and CONSORT checklists
264 were independently completed by two researchers, minimising risk of error in data extraction.
265 Furthermore, all available supporting materials (such as pilot publications) were accessed to
266 inform the critical appraisal of each study. Despite these strengths, it is important to
267 acknowledge that seven of the 26 reviewed studies were published before the year 2000, and
268 therefore would not have had access to the MRC Guidance or CONSORT documents. It is
269 possible that the checklists may not fully appraise all aspects of methodological quality and
270 reporting given they are subject to regular review over time. There is also the possibility of
271 publication bias, where developmental research work or non-significant findings tend not to
272 be published ([40, 41]). Therefore, despite a rigorous approach to identifying relevant studies, the
273 reviewed studies may not represent all work that has been conducted in this area of research.
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277 This study revisited the 26 studies included in a recent systematic review of dietitians
278 providing nutrition care to adult patients in the primary health care setting ([6]). There is clear
279 room for improvement in the methodological quality and reporting of studies investigating
280 the effectiveness of dietitians, which may explain variability in study outcomes. This review
281 has highlighted key areas for improvement for dietitians, researchers and journal editors in
282 order to strengthen future study design and the evidence base in the field. High quality
283 studies will increase confidence in dietary interventions that involve dietitians.

284

285 *Transparency Declaration:* The lead author affirms that this manuscript is an honest,
286 accurate, and transparent account of the study being reported. The reporting of this work is
287 compliant with PRISMA guidelines. The lead author affirms that no important aspects of the
288 study have been omitted.

289

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