Clinical Nutrition xxx (2017) 1–11

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: http://www.elsevier.com/locate/clnu

Review

Incomplete descriptions of oral nutritional supplement interventions in reports of randomised controlled trials

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ARTICLE INFO

Article history:
Received 1 December 2016
Accepted 21 March 2017

Keywords:
Oral nutritional supplements
Reporting quality
Malnutrition

SUMMARY

Background & aims: The effects of oral nutritional supplements (ONS) have been evaluated in several clinical trials and more studies have been requested. To facilitate replication, support accurate evaluations of research results and avoid research waste, high quality reporting of interventions in clinical trials is needed. The aim of this study is to assess the quality of reporting of interventions in publications describing randomised controlled trials of ONS in populations with malnutrition or at nutritional risk.
Methods: The PubMed database was searched for articles describing ONS trials published between January 2002 and December 2015. The quality of intervention descriptions was evaluated using the Template for Intervention Description and Replication (TIDieR) checklist and guide, which contains twelve items. Articles published before and after 2011 were compared.
Results: Of 76 articles identified, only 3% reported all TIDieR items in sufficient detail. The most frequently missing elements were descriptions of the intervention procedures (e.g. how the ONS were to be taken and if participants were given a choice of flavours), which were adequately presented in only 26% of the articles. Less than half of the articles included a description of the intervention provider and sufficient information about the location(s) for the intervention. Information about adherence and mode of delivery was reported in 60–65% of the articles. Most frequently reported, in >70% of the articles, were items regarding the brief name of the intervention, the rationale for the intervention and the materials used (i.e. information about the specific ONS product(s) administered). The reporting quality for two of the items (materials and provider) was higher in articles published after 2011.
Conclusions: The quality of reporting of ONS interventions was found to be poor. The descriptions mostly lacked information about intervention procedures, provider and location(s). A moderately higher reporting quality was observed in articles published after 2011. These findings imply that an improvement in the descriptions of ONS interventions is required in future clinical trials of malnutrition treatment.

1. Introduction

Oral nutritional supplements (ONS) are multi-nutrient products (ready-made liquid, pudding or powder to be mixed with fluids) used to increase the energy and nutrient intakes of patients with malnutrition and those at nutritional risk [1]. ONS have been shown to be clinically effective [2–4], and the use of ONS to treat disease-related malnutrition is endorsed in several international guidelines [3,5–7]. However, the use of ONS has also been questioned due to low adherence [8,9], and a lack of beneficial results for some patient groups [10]. In order to establish confident evidence-based guidelines regarding treatment with ONS, further randomised controlled trials (RCT) are frequently requested. Conducting clinical trials is expensive and time consuming. In order to avoid research waste, the knowledge obtained from completed clinical trials of interventions should be communicated in well-described reports [11,12].

When a clinician or a researcher wants to replicate, evaluate or extend the findings from a RCT, an adequate description of the intervention is of great importance [11]. If researchers cannot

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http://dx.doi.org/10.1016/j.clnu.2017.03.024
0261-5614/

replicate trials and clinicians cannot use the interventions, the goals of improving evidence-based treatment and providing beneficial interventions for the patients become less attainable. A study of reporting quality in 137 non-pharmacological interventions found that only 39% were adequately described [13]. In line with this result, descriptions of physiotherapy interventions were recently evaluated as being typically incomplete [14]. The reporting quality of interventions in published trials within the field of nutrition support has, to our knowledge, not been systematically studied. However, review authors investigating the effect of dietary advice with or without ONS have commented on the pronounced absence of reporting of the nature, intensity and content of nutrition support interventions in clinical trials [15]. Inadequate reporting of adherence to ONS can be anticipated since, in a systematic review of compliance to ONS, a large number of studies (n = 174/288) had to be excluded due to inadequate reporting of that specific aspect [16].

In 2014, the Template for Intervention Description and Replication (TIDieR) checklist and guide was published, which emphasises the importance of complete reporting of RCT interventions in order to enable their replication [11]. The checklist is an extension of item 5 of the CONSORT 2010 (Consolidation Standards of Reporting Trials) statement [17] and item 11 of the SPIRIT 2013 (Standard Protocol Items: Recommendations for Interventional Trials) statement [18], which are documents providing guidance for the description of clinical trials and protocols of clinical trials. Intervention duration, dose or intensity, mode of delivery, essential processes, monitoring and adherence are all key features of the TIDieR checklist developed to support authors in their descriptions of RCTs [11].

Information about an ONS intervention, which is followed by either high or low adherence and/or clinical benefit, offers guidance to clinicians and researchers. This is why high quality reporting of ONS trials is of great importance. The implications of good quality reporting of ONS trials is evident in a systematic review of compliance to ONS, where lower compliance was demonstrated in surveys of usage (61%) when compared to clinical trials (77–79%) [16]. The review authors discuss the possible occurrence of a "trial effect", where trial conditions might promote increased knowledge of the disease or condition, more encouragement from healthcare staff and extra visits. The surveys of ONS usage included in the review were all conducted in hospitals or nursing homes [16]. In a survey of ONS usage in an Irish community setting, 46% of the study participants stated that they did not consume the prescribed amount of ONS on most days of the week [19]. The large difference between adherence to ONS in clinical trials and in surveys of usage implies that elements of the ONS interventions in clinical trials might be of importance for achieving high adherence to ONS prescriptions in clinical practice. However, a prerequisite for being able to identify these important elements in a successful trial is adequate reporting.

No previous studies that we are aware of have examined the quality of reporting of interventions with ONS or which elements are most frequently missing. The aim of this study is to assess the quality of reporting of interventions in publications describing randomised controlled trials of ONS in populations with malnutrition or at risk of malnutrition.

2. Materials and methods

2.1. Search strategy

The PubMed database was searched to identify randomised controlled trials of ONS in individuals with malnutrition or at nutritional risk. The search strategy was intended to capture terms relating to (i) malnutrition or risk of malnutrition (ii) ONS and (iii) randomised controlled trials. The search was conducted in January 2016 with a publication year restriction applied (2002–2015); the complete search strategy is presented in Appendix 1. The second revision of the CONSORT statement was published in April 2001 [20] and item 4 states that trial reports should include "*Precise details of the interventions intended for each group and how and when they were actually administered*" (p. 659). This was more specific than in the previous version (CONSORT 1996) which stated that "*Planned intervention and their timing*" were to be described [21] (p. 638). January 2002 was therefore chosen as the starting point for the search in this study, since authors of trial reports would then have had eight months to follow the new RCT reporting guidelines.

2.2. Eligibility criteria

Criteria for inclusion of published articles were: (i) RCTs where all of the participants in one of the intervention arms or control group received multi-nutrient ONS (≥2 macronutrients and added micronutrients) alone or in combination with other intervention elements; (ii) a study population with malnutrition or risk of malnutrition (referring to undernutrition and not obesity). Since there is no international consensus regarding the definition of the terms malnutrition and risk of malnutrition, articles were included if the participants were described as being at nutritional risk by the trial authors or if the authors of the article judged them to be at nutritional risk due to their clinical condition or treatment. In borderline populations, the article was included rather than excluded since this study examines reporting and not outcome. Further inclusion criteria were (iii) a study population consisting of participants aged ≥ 18 years; (iv) duration of intervention ≥ 28 days; (v) any type of comparator; (vi) published between 01/01/2002 and 31/12/2015; (vii) published in English; (viii) any type of publication status (e.g. published in print, electronically published only); and (ix) any type of outcome measure. The exclusion criteria were: (i) combined interventions using ONS and enteral or parenteral nutrition and (ii) contexts where impaired nutritional status is caused by food safety issues and/or lack of food rather than a disease or condition.

2.3. Assessment of reporting quality

Reporting quality was assessed using the Template for Intervention Description and Replication (TIDieR) checklist, which contains twelve items [11] that are presented in Table 1. The completeness of reporting of the trials was assessed for each of the twelve items of the TIDieR checklist and rated as either "YES" or "NO". For items 9 and 10 the option "Not applicable" could be selected for articles where no indication of any tailoring or modification procedure was apparent. When trials contained descriptions of more than one ONS intervention arm, they were rated together. Consequently, an item was rated as "YES" only if the reporting of the intervention in all arms using ONS was complete. Interventions or parts of interventions other than ONS, e.g. physical activity, dietary advice or pharmaceuticals, or the treatment received by the control group (when the control group did not use ONS), were not evaluated.

A manual was developed (see Appendix 2) with the aim of facilitating the use of the TIDieR checklist and a guide to evaluate the reporting of ONS interventions. The manual was developed by all four authors who are all qualified clinical dietitians. The development of the manual comprised several steps. In step (i) a first training session (MN, AA and ELb) was held where one article was reviewed using only the original TIDieR checklist and guide. During this session a first proposal of the content of the manual was

Please cite this article in press as: Liljeberg E, et al., Incomplete descriptions of oral nutritional supplement interventions in reports of randomised controlled trials, Clinical Nutrition (2017), http://dx.doi.org/10.1016/j.clnu.2017.03.024