

PERSPECTIVE



Optimal use of oral nutritional supplements (ONS) in medical nutrition therapy: ONS consensus report from KEPAN

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Medical nutrition therapy is one of the core components of the patient management, although its implication is still limited in daily practice globally. Clinicians are in need of guidance that will ease the application of medical nutrition therapy. The first treatment choice in medical nutrition therapy is the use of oral nutritional supplements (ONS) after or concomitant with dietary interventions. The pre and post-graduate curriculum for medical nutrition therapy is limited in most regions, worldwide. A report that is short, clear, and having clear-cut recommendations that will guide the primary healthcare professionals in indications, choice, practical application, follow-up, and stopping ONS would facilitate the application and success of medical nutrition therapy. KEPAN is the Clinical Enteral and Parenteral Nutrition Society of Turkey and is an active member of the European Society for Clinical Nutrition and Metabolism (ESPEN). In this study, we present the KEPAN ONS consensus report on optimal ONS use in medical nutrition therapy as outlined by works of academicians experienced in clinical application of ONS (eight working group academicians and 19 expert group academicians). This report provides 22 clear-cut recommendations in a question-answer format. We believe that this report could have a significant impact in the ideal use of ONS in the context of medical nutrition therapy when clinicians manage everyday patients.

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INTRODUCTION

Malnutrition (MN) is a prevalent problem worldwide [1–3]. The prognosis of patients and compliance to treatment become worse in its presence [4]; however, early recognition and management of MN is well-known to mitigate morbidity and mortality [5]. Hence, medical nutrition therapy is considered a critical component of medical treatment, and all the patients must be evaluated for nutritional status and the need for medical nutrition therapy (MNT) [1]. It is noteworthy that the clinical application of medical nutrition therapy is still limited, falling short of the desired targets [6]. Therefore, there is a need for interventions that aim to increase recognition of the utmost importance, need of nutritional evaluation and those that are directed to ease application of ideal medical nutrition therapy in clinical practice in the patients that are identified at MN or malnutrition risk (MNR).

The European Society for Clinical Nutrition and Metabolism (ESPEN) facilitates education on medical nutrition therapy via online and onsite education programs and onsite accredited courses within the Life Long Learning Program (LLL), which involves a variety of countries worldwide, including Turkey [1, 7, 8]. These onsite accredited courses have been held in Turkey beginning from 2009 and have been viewed with great

interest and were hugely successful. These courses are held two times a year, and the feedback from these courses are motivating and helpful for the tutors. Thus far, 22 live onsite courses and two live online courses have been held. The last two courses were held online because of the coronavirus disease 2019 pandemic.

The guidelines and consensus reports in the management of diseases guide and help the clinicians practice evidence-based, updated management. In MNT, after or concomitant with dietary interventions; oral, enteral, and/or parenteral nutritional supplementations are required. A report that is short, clear, and having clear-cut recommendations that will guide the primary healthcare professionals in indications, choice, practical application, follow-up, and stopping oral nutritional supplements (ONS) would facilitate the application and success of MNT. In this regard, KEPAN took the liberty of studying and practically guiding three reports: on use of “oral nutritional supplements”, “enteral nutrition”, and “parenteral nutrition”.

For each consensus report, a working group has been created composed of academicians belonging to a variety of specialties, who are experienced and involved in the application of clinical nutrition. The working group members include physicians and dieticians, and some of them also include nurses and pharmacists

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as well with representation of a variety of different departments in medical nutrition. Each consensus work had a study leader. The group of academicians that comprises all the working group members of these three reports makes up the “KEPAN extended consensus report group: The expert group.” The current chair of KEPAN society, who is a general surgery specialist member (OA), functions as the chair of the KEPAN extended consensus report group. This report presents the work and results of the first consensus report of the KEPAN initiative, the “Oral nutritional supplements (ONS) in medical nutrition therapy: KEPAN ONS consensus report.”

METHODS

The working group of the ONS consensus report was comprised of eight academicians, including the following specialists: Two from internal medicine-geriatrics (GB, MH), one from radiation oncology (MA), one from neurology (LG), two dietitians (DHB, NK), one from general surgery (YO), and one from intensive care (HS). One of the internal medicine specialists (GB) was selected as the group leader. The expert group comprised 19 academicians (five from general surgery, four from critical care, three from internal medicine, one from neurology, one oncology physician, two dietitians, two pharmacists, and one nurse) who were experienced in clinical nutrition. All the participants filled the International Committee of Medical Journal Editors (ICMJE) conflict of interest forms.

In Phase 1, three consensus leaders and KEPAN extended consensus report group chair conducted a face-to-face meeting and determined the subject and questions of each consensus report in June 2019. The content was aimed to include the questions and subjects confronted in clinical nutrition practice. The group reached a complete consensus on the content of each consensus report. In this meeting, 22 questions/subjects were designated for ONS consensus report (Box 1).

In Phase 2, the group leader (GB) sent the report via email to a minimum of two group members after considering their specialty and experience in clinical practice. All the members were asked to constitute a “recommendation” and a “comment” for each question/subject that they were responsible. The content was asked to be created via a review of the meta-analysis, systematic review, and randomized controlled studies published in English in the EMBASE, PubMed, and Cochrane databases. When these publications were insufficient or absent, observational studies (prospective or retrospective) were considered. International nutritional guideline reports were also considered whenever needed. The major keyword was “oral nutrition(al) supplements,” and this keyword was co-used with the corresponding question/subject title, for example, diabetes, dysphagia, and aspiration. The group members sent the study summaries of all the studies they considered when constituting the recommendations and comments. The summary of these studies included the title, year, authors, and results in case they needed to be re-considered during the construction of consensus. All recommendations were stated as follows: (i) Should be performed (strong recommendation), (ii) Can be performed (moderate recommendation), and (iii) Inadequate evidence (expression of no firm opinion).

In Phase 3, the specific group members responsible for the specific questions/subjects evaluated the corresponding recommendations and comments together with the specified group for that question/subject.

In Phase 4, we planned to present all the questions/subjects to the ONS consensus working group in a face-to-face meeting and reach a consensus report. However, because of the COVID-19 pandemic at this stage, we conducted an online meeting instead of a face-to-face one.

In Phase 5, a total of 22 questions/subjects and recommendations was sent to the ONS working group plus the expert group

Box 1. Topics (Questions) in KEPAN ONS consensus report

1. In which situations should the use of ONS be considered?
2. How should ONS be stored? How long should the opened products be consumed?
3. How many times a day and at what times of the day should ONS be used?
4. How should problems with taste and flavor be managed in the use of ONS?
5. How and how often should patients using ONS be monitored for nutritional adequacy?
6. When should these products be discontinued in patients using ONS?
7. Should routine vitamin or trace element supplementation be given to patients using ONS?
8. Which patients should be planned for ONS at discharge?
9. How should the use of ONS be managed in diabetic patients?
10. What are the points to be considered when using an ONS in patients with concomitant diseases?
11. What are the points to be considered when using ONS in patients with chronic kidney disease?
12. What are the points to be considered when using ONS in patients with chronic liver disease?
13. What are the points that should be considered when using ONS in patients with chronic heart failure?
14. What are the points to be considered when using ONS in patients with chronic obstructive pulmonary disease?
15. What are the points to be considered when using ONS in patients with neurological disease?
16. What are the points to be considered when using ONS in patients with pressure sores?
17. What are the points to be considered in the use of ONS in patients with suspected swallowing disorder?
18. In which situations and how should thickening products be used?
19. Are there differences in the use of ONS in older individuals who need nutritional therapy?
20. What is the role of special products in the use of ONS in patients with cancer?
21. Should the use of ONS be recommended to older patients undergoing surgical treatment for hip fracture?
22. What are the common problems in using ONS? How should they be managed?

ONS: Oral nutritional supplements

KEPAN: The Clinical Enteral and Parenteral Nutrition Society of Turkey, an active member of the European Society for Clinical Nutrition and Metabolism (ESPEN)

members via email. We used the modified Delphi consensus methodology. Delphi is a method of eliciting and refining group judgments [9] and is designed to facilitate structured group communications with a view to reaching a consensus in expert opinions in the face of complex problems, expensive endeavors, and uncertain outcomes and has been used in similar studies with success [10–13]. We used the SurveyMonkey® software as an established computerized process to achieve consensus via conducting Delphi rounds online. During the Delphi rounds, we asked each member (Delphi panelists) to indicate to what extent they agreed or disagreed with each recommendation for the questions/subjects, considering the available evidence and their own experience. We used a Likert scale to assess agreement on the recommendation, scored as follows: 1 = strongly agree; 2 = agree; 3 = neither agree nor disagree; 4 = disagree; and 5 = strongly disagree. The panelists were provided the opportunity to comment on each recommendation and add suggestions to the recommendations by referring to literature data. We calculated the median and interquartile range values for each recommendation in each iteration of the Delphi round. Criteria with median value of 1 or 2 and 75th centile value of 1 or 2 were accepted. Accepted criteria were included in the final consensus report. Criteria with median value >2 were rejected and removed. Criteria with median value 1 or 2 but 75th centile value >2 were reserved to be assessed in the next round. Henceforward, neither rejected nor accepted criteria composed the content of the next Delphi round to be re-considered by the panelists. The suggestions that were provided by the Delphi panelists were evaluated by the ONS consensus report group leader (GB) and chair (OA),

and the recommendations were modified provided that those suggestions were according to the current evidence. We provided the scores, 75th centile values, and the comments of the panelists related to those recommendations. Subsequently, we proceeded to the next Delphi round, once again inviting the panelists to score for agreement and comment on each criterion. Panelists re-scored the criteria using the Likert scale in the next Delphi rounds considering the prior scoring values related to those reserved recommendations. This approach was applied to reject, accept, or reserve the criteria for the next Delphi rounds. On the basis of this outlined concept, we planned to go on with the Delphi rounds until a consensus was reached for rejection or acceptance of each recommendation.

We planned the ONS consensus report to be completed in 13 months beginning from the first phase.

RESULTS

We started the study in July 2019 and completed in July 2021, a 24-month period owing to the emergence of COVID-19 pandemic during the study period. Phase 2 was completed in April 2020, and we were able to start phase 3 in September 2020 and complete it in February 2021. After the face-to-face meeting in the first phase, the two subsequent phases were conducted online. The fourth phase, which was originally planned as a face-to-face meeting including the ONS consensus report working group members, was held online and completed in May 2021. The fifth and last phase of the study comprising the Delphi rounds was performed between May and June 2021 (Fig. 1).

The first round of Delphi study resulted in acceptance of 21 recommendations (95.4%). One recommendation was reserved for the next Delphi round. None of the criteria were rejected. The question, for which consensus was not accomplished, was question/subject 6 (*-When should these products be discontinued in patients using ONS?*) and had a median score of 4.75 and 75th percentile score of 3. This recommendation was re-evaluated in the second round, and consensus was reached for this recommendation as well. The final report was sent to all 28 panelists and was approved without any revision suggestions.

The ONS consensus report is composed of 22 questions/subjects and their recommendations and commentaries (Appendix). Each *Question* is followed by its summary *Recommendation* and detailed *Commentary*. Each *Question/Recommendation/Commentary* has its own reference list. The report consists of 362 references in total.

DISCUSSION

The first step in clinical nutrition therapy, after or concomitant with dietary regulations, is the use of ONS [1]. The ONS group comprises slightly more than 50% of the consumed nutritional products, including ONS, enteral products, and parenteral products, in the market [14, 15]. The education curriculum in college, medical faculties, and residency, including those on use of ONS, is still inadequate [16]. In the market, there are a variety of ONS that can be used in nutritional intervention [17]. Although this is an opportunity to use more ideal products for different clinical problems, it also causes a confusion on which product to

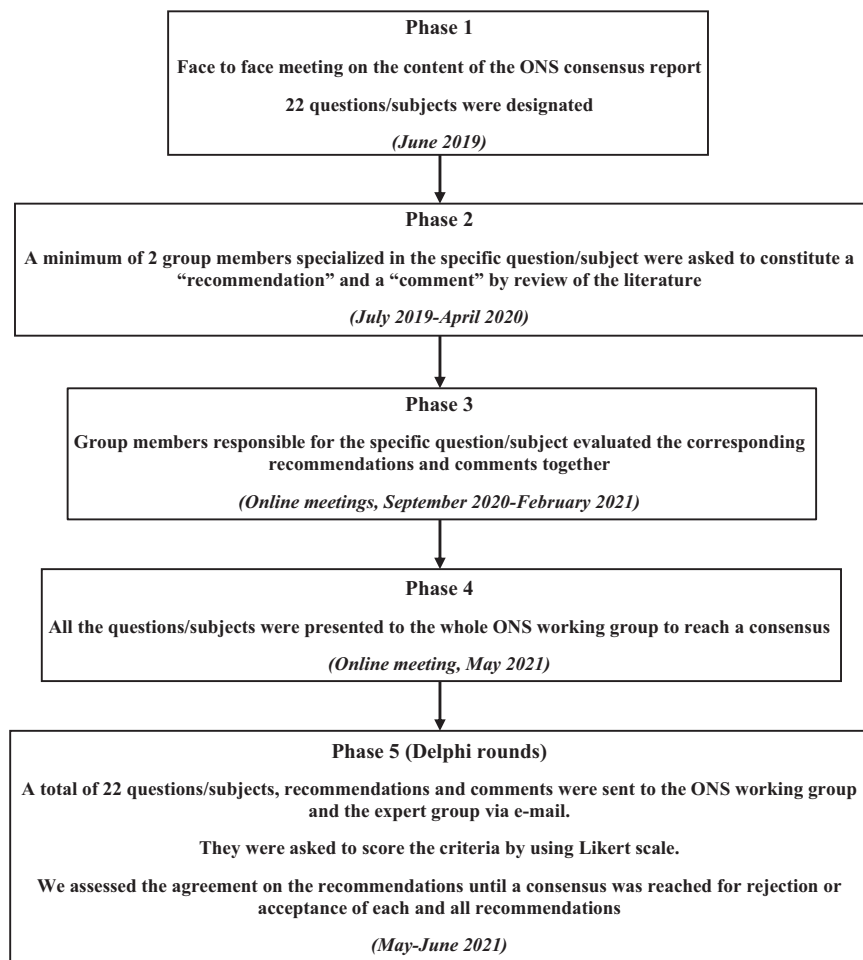


Fig. 1 Flow chart of the different stages of the study protocol. ONS oral nutritional supplements.

choose. In daily clinical practice, practical recommendations on ONS indication, choice, application, follow-up, and cessation in indicated patients (ready for use by physicians, nurses, and dieticians) would facilitate ideal implementation of clinical nutrition therapy. This need formed the crux of this study.

In this consensus report, we included indications for commencement of ONS as a part of clinical nutrition therapy, its storage and usage instructions, the problems frequently confronted during implementation of ONS products and their management strategies, follow-up recommendations, cessation instructions, and ONS choice and management in common diseases (diabetes mellitus, chronic renal disease, chronic liver disease, congestive heart failure, chronic obstructive pulmonary disease, neurological diseases, and cancer) and in specific common syndromes, such as pressure sores and dysphagia and in older adults suffering from hip fracture.

The recommendations were constructed through extensive literature review by the clinically experienced academicians. Each recommendation was constructed using a study of at least two independent academicians. After a consensus was reached in the question/subject specific group, the recommendations were fully reviewed by the eight ONS working members plus group leader and the chair of the consensus with review of the corresponding references. After the consensus in this group, a Delphi study was conducted with contribution of a total of 27 clinically experienced academicians (eight working group and 19 expert group academicians) over the country and eventually reached its final version after approval of all of the working and extended group members.

This study had its limitations and strengths. After the first physical meeting between the consensus chair and three group leaders, the subsequent physical meetings that was planned within the ONS consensus working group could not be conducted owing to the emerging COVID-19 pandemic. All the processes were performed via online meetings and email communications. In addition, the evaluations were performed by an extended group, and these factors caused the study to be completed at a later date than originally planned. However, in the fifth phase, a Delphi consensus study was performed. The Delphi methodology has the features of anonymity, iteration, and feedback and signifies conventional emphasis on the consensus of experts. This approach with anonymous presentation of scores and suggestions of the Delphi panelists precluded possible expression limitations that could be encountered in time-limited physical meetings. This last point contributed to the neutrality of the consensus report. The study was performed by an absolute collaboration between the disciplines involved in clinical nutrition therapy. KEPAN's stature in clinical nutrition, academic background, and uniting organization ability empowered the study with representation and contributions from all the professional groups involved in nutritional care. Nevertheless, the recommendations relied on the studies published so far, and therefore, should not be regarded as absolute statements. In parallel with scientific progress, the content needs to be changed and updated.

CONCLUSION

This consensus report has been constructed for use of healthcare professionals involved in nutritional care in primary care settings. The report was developed by a multidisciplinary, clinically experienced expert academician group involving all the collaborators of clinical nutrition. Healthcare professionals are referred to the cited references in case they seek detailed information. In addition to the consensus recommendations, in the management of other health problems, clinicians should consider their clinical experience and patient/caregiver values with shared decision making practice. We believe that these consensus recommendations will be beneficial and easy-to-use in implementation of clinical nutrition therapy and hope that this study will contribute to a widespread and successful use of clinical nutrition therapy when indicated.

DATA AVAILABILITY

Data sharing is not applicable to this paper as no new data were created or analyzed in this study.

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AUTHOR CONTRIBUTIONS

GB: Conceptualization, Methodology, Investigation, Formal analysis, Writing- Original draft preparation; Writing- Reviewing and Editing. MA: Investigation, Delphi panelist; LG: Investigation, Delphi panelist; MH: Investigation, Delphi panelist; DHB: Investigation, Delphi panelist; NK: Investigation, Delphi panelist; YO: Investigation, Delphi

panelist; HS: Investigation, Delphi panelist; OA: Conceptualization, Methodology, Investigation, Writing- Reviewing and Editing, Supervision; the Extended Group for KEPAN ONS Consensus Report: Delphi panelists.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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