

A study in four European countries to examine the importance of sensory attributes of oral nutritional supplements on preference and likelihood of compliance

Tahsin Gökçem ÖZÇAĞLI¹, Janet STELLING², Julia STANFORD²

Department of ¹Nutrition, Abbott Pharmaceuticals, İstanbul

Department of ²Nutrition, Abbott Pharmaceuticals, Maidenhead, United Kingdom

Background/Aims: A study designed to examine the importance of the sensory attributes of oral nutritional supplements on preference and likelihood of compliance. **Materials and Methods:** Independent individuals ≥ 50 years not currently receiving oral nutritional supplements were recruited to a two-stage, single-blind, randomised, preference study, conducted in four European countries. Stage 1 consisted of a 5-day trial period during which two units of commonly prescribed oral nutritional supplements were administered, with a different oral nutritional supplement being consumed each day. In Stage 2, all participants consumed two units daily of one oral nutritional supplement for five days and two units daily of a second oral nutritional supplement for a further five days. Using standardised hedonic scales, participants reported their perceptions of each oral nutritional supplement for a range of sensory attributes, and estimated how many units of each oral nutritional supplement they could consume. **Results:** One thousand seven hundred seventy one individuals completed the study. The overall opinion of each oral nutritional supplement was strongly correlated with taste ($r=0.91$; $p<0.0001$), while unit volume demonstrated a weak relationship ($r=0.29$; $p<0.0001$). One oral nutritional supplement (Reformulated Ensure Plus) was preferred overall, scoring significantly higher for taste ($p<0.05$) and oral sensation ($p<0.05$) than other oral nutritional supplements. **Conclusions:** This study contributes to the understanding of how sensory attributes, particularly taste and oral sensation, influence preference and compliance to oral nutritional supplements.

Key words: Oral nutritional supplements, taste, sensory attributes, oral sensation, SUSTAIN, compliance

Oral beslenme destek ürünlerine özgü duyusal niteliklerin tercih ve uyum açısından önemini dört Avrupa ülkesi genelinde değerlendirmeye yönelik bir çalışma

Giriş ve Amaç: Oral beslenme destek ürünleri özgü duyusal niteliklerin tercih ve uyum açısından önemini değerlendirmek. **Gereç ve Yöntem:** İki aşamalı, tek-kör randomize tasarımlı bu tercih belirleme çalışmasına dört Avrupa ülkesinden, halihazırda oral beslenme destek ürünleri kullanmayan 50 yaş ve üzeri serbest yaşayan bireyler dahil edildi. İlk aşamada, katılımcılara 5 günlük bir deneme periyodu boyunca her biri günde iki ünite ve her gün bir başka marka olmak üzere yaygın olarak reçetelendirilmekte olan oral beslenme destek ürünlerini örnekleri verildi. İkinci aşamada katılımcılar günde iki ünite olmak üzere ilk 5 gün bir oral beslenme destek ürünü, takip eden ikinci 5 gün ise başka bir oral beslenme destek ürününe örneği kullandı. Katılımcıların, çeşitli duysal özellikler bağlamında, her bir oral beslenme destek ürünleri örneğine özgü alguları ve her örneken kaç ünite tüketebildikleri kaydedildi. **Bulgular:** Toplam 1771 kişi çalışmaya tamamladı. Oral beslenme destek ürünlerilarındaki genel görüşlerin tat ile güclü ($r=0.91$; $p<0.0001$), birim hacim ile ise zayıf ($r=0.29$; $p<0.0001$) korelasyon gösterdiği görüldü. Kullanılan oral beslenme destek ünitelerinden biri (reformülé Ensure Plus) diğerlerine göre daha çok tercih edildiği ve tat ($p<0.05$) ve ağızda bıraktığı his ($p<0.05$) açısından daha yüksek skorlarla ilişkili olduğu görüldü. **Sonuçlar:** Bu çalışma oral beslenme destek ünitelerine özgü duysal niteliklerin, başta tat ve ağızda bıraktıkları his olmak üzere tercih ve uyuma olan etkilerinin anlaşılmasına katkıda bulunmaktadır.

Anahtar kelimeler: Oral beslenme destek ürünleri, tat, duysal özellikler, ağızda-his, SUSTAIN, uyum

Address for correspondence: Tahsin Gökçem ÖZÇAĞLI
 Abbott Nutrition, Abbott Labb. Saray Mah. Dr. Adnan Büyükdeleniz
 Cad. No: 2 Akkom Ofis Park Kelif Plaza 3. Blok Ümraniye,
 İstanbul, Turkey
 E-mail: tahsin.ozcagli@abbott.com

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INTRODUCTION

Undernutrition is considered to be a multifactorial disorder caused by metabolic effects of underlying disease, reduced nutritional intake, and additional factors that might increase the general risk of developing nutritional deficits such as age, therapeutic interventions, educational level, and/or low socioeconomic status of the patient (1,2).

Oral nutritional supplements (ONS) are accepted as an integral part of the medical management of malnutrition in both hospitals and the community. Studies have shown that in malnourished patients, ONS can improve overall nutritional intake, increase body weight and functional outcomes, and reduce morbidity and mortality (3-5).

Notably, despite its high prevalence, undernutrition is seldom identified by clinicians (2), and as with all areas of medical management, patient compliance is necessary to improve clinical outcomes. For ONS to be effective in the management of malnutrition, patients need to consume the amount they are prescribed for the recommended period of time. However, the evidence highlights challenges in compliance in both the community and hospital settings (6,7).

Factors which impact ONS compliance include environmental factors, such as whether supplements are administered in hospital or at home (8), and specific patient needs including personal preferences (9). It has been reported that taste fatigue may occur when ONS are consumed regularly over a prolonged period (8). The sensory attributes which affect ONS palatability, including taste and oral sensation, are important considerations (8-10) for improving compliance and clinical outcomes. To date, the impact of ONS palatability on likelihood of compliance with recommended intake has not been widely studied. SUSTAIN (Study to improve Understanding of Sensory factors and Taste And their Impact on compliance with oral Nutritional supplements) is a two-stage preference study designed to investigate the relationship between the sensory attributes of ONS routinely prescribed in clinical practice and likelihood of compliance.

MATERIALS and METHODS

Study participants

In this preference study, independent individuals aged ≥ 50 years were randomly recruited in the United Kingdom (UK), Czech Republic (CZ), Spain (E) and the Netherlands (NL). Recruitment was

conducted through a combination of street interviews and door-to-door enquiries, using a screening interview to determine suitability. Individuals aged 50–59 years, 60–75 years, and ≥ 75 years were selected since these age groups are representative of the population most commonly prescribed ONS. A 50:50 male to female ratio was targeted in each country to limit sex bias. For inclusion in the study, participants were required to live independently. Participants were excluded if they had any dietary restrictions relating to a medical condition, were already taking ONS, or were identified during the screening interview as being unable to take either of the flavours to be tested in the study. Interviews for this preference study were conducted by an independent research company. For preference studies, ethical approval is not required, however the study was conducted in accordance with all relevant guidelines (British Healthcare Business Intelligence Association (BHBIA) and EU Pharmaceutical Market Research Association (EphMRA) (11,12). Informed consent was obtained from all study participants.

Study design

In this two-stage, single-blind preference study, participants were randomised to receive one of two ONS flavours (either strawberry or vanilla). To reflect routine clinical practice, participants were required to consume two units of each ONS daily (one in the morning and one in the afternoon/evening, between meals). Participants were instructed to refrigerate the unlabelled product and pour it into a glass prior to consumption.

Stage 1 of the study was conducted in the UK. Two units of ONS were taken daily for five consecutive days. A different ONS was consumed each day, namely: Reformulated Ensure Plus (1A), Abbott Nutrition; Ensure Plus (1B), Abbott Nutrition; Fortisip (1C), Nutricia Advanced Medical Nutrition; Fortisip Compact (1D), Nutricia Advanced Medical Nutrition; and Ensure TwoCal (1E), Abbott Nutrition. The order was rotated to avoid bias.

In Stage 2 of the study, which was conducted in the UK, CZ, E and NL, all participants took ONS 2A (Reformulated Ensure Plus; Abbott Nutrition), for one 5-day trial period and were randomised to receive a different ONS for another 5-day period. The order was rotated to avoid bias, and each participant acted as his own control. Comparators were selected from the most routinely prescribed ONS in each country, namely: Ensure Plus (2B), Abbott Nutrition; Fortisip Compact (2C), Nutricia

Advanced Medical Nutrition; Fortisip (2D), Nutricia Advanced Medical Nutrition; Clinutren 1.5 (2E), Nestlé Healthcare Nutrition; and Fresubin Energy (2F), Fresenius Kabi.

Outcome measures

In both stages, participants completed a self-administered questionnaire each day after consuming the ONS. Using standardised hedonic scales (13,14), participants rated the ONS using a 5-point scale for a range of sensory attributes: sweetness (5=much too sweet; 1=not nearly sweet enough), thickness (5=much too thick; 1=much too thin), strength of flavour (5=much too strong; 1=much too weak), fruitiness/vanilla (5=much too fruity; 1=not nearly fruity enough) and aftertaste (5=very pleasant; 1=not at all pleasant). Taste, oral sensation, aroma, and appearance were rated using a 9-point scale (1=extremely disliked; 9=extremely liked). The reliability, validity, and discriminative ability of the standardised hedonic scale have been proven in food acceptance tests (13,14). At the end of the study period, a face-to-face interview was carried out to establish overall preference. Participants were asked to gauge how long they could consume each ONS for, and the average number of ONS units they would be able to consume per day in order to estimate short-term compliance.

Statistical analysis

For both Stages 1 and 2, combined flavour data (strawberry and vanilla) are presented. Significant differences between the mean scores for sensory aspect opinions and overall preference of ONS were determined at the 95% level of confidence using t-tests. Sweetness, thickness, strength of flavour, fruitiness/vanilla, and oral coating are expressed as the percentage of respondents giving a score on each standardised hedonic scale that indicated that the attribute was “about right”. For aftertaste, the results are presented as the percentage of participants rating each ONS as very or fairly pleasant. Likelihood of compliance in the short-term is expressed as the average number of ONS units participants estimated they could consume per day. In Stage 2, Pearson’s correlation analysis was conducted to determine the relationship between product attributes and the estimated time participants were prepared to take ONS. Pearson’s correlation analysis was also conducted to determine relationships between ONS taste perception and other product attributes.

RESULTS

Demographics

A total of 174 individuals (85 male, 89 female) were recruited in Stage 1 of the study, and 1597 (751 male, 846 female) in Stage 2 (Table 1).

Sensory attributes

Stage 1

Mean scores [standard deviation] for taste were significantly higher for ONS 1A compared with ONS 1B to 1E (6,3 [2,0] vs. 5,5 [2,2], 5,8 [2,1], 5,4 [2,2], 5,7 [2,2], respectively; $p<0,05$). Similarly, mean scores [standard deviation] for oral sensation were significantly higher for ONS 1A compared with ONS 1B to 1E (6,0 [2,0] vs. 5,4 [2,2], 5,5 [2,0], 4,8 [2,3], 5,1 [2,2] respectively; $p < 0.05$). The greatest proportion of participants reported that the sweetness, thickness, strength of flavour, fruitiness/vanilla flavour, and oral coating of ONS 1A was “about right”. A total of 53% of participants found that ONS 1A left either a very or fairly pleasant aftertaste compared with 39%, 39%, 33% and 38% for 1B to 1E, respectively ($p<0,05$).

Stage 2

Combined data from the four European countries included in the study demonstrate that ONS 2A was rated highest for participants’ overall opinion of taste and oral sensation compared with ONS 2B to 2F (Figure 1; $p<0,05$). The ratings on a 9-point scale for aroma and appearance of ONS 2A were significantly higher than all other ONS. On a scale of 1–5, ONS 2A had a significantly higher mean score [standard deviation] for aftertaste compared with all other ONS (3,4 [1,0], 3,2 [1,0], 3,2 [1,1], 3,1 [1,0], 3,2 [1,0] and 2,9 [0,9], respectively; $p<0,05$).

Table 1. Participant demographics

	Stage 1	Stage 2
Total participants (n)	174	1597 ^b
Male (n)	85	751
Female (n)	89	846
50–59 y (n)	68 ^a	639
60–75 y (n)	70 ^a	623
≥ 76 y (n)	34 ^a	335
Tested strawberry flavour (%)	51	50
Tested vanilla flavour (%)	49	50

^aTwo respondents declined to provide their age

^bUK, n=392; CZ, n=400; E, n=406; NL, n=399

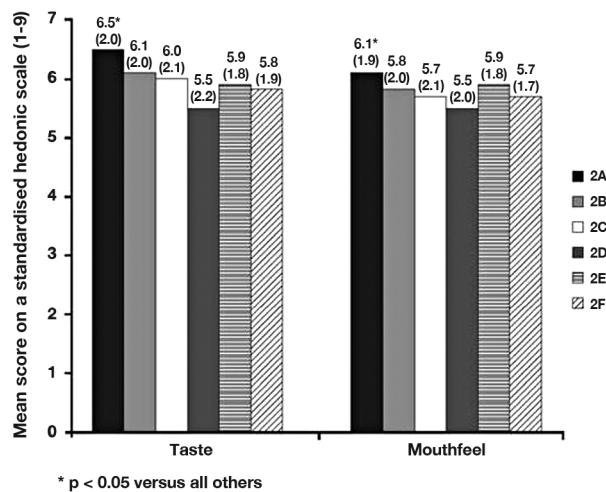


Figure 1. Mean overall scores for taste and oral sensation (Stage 2). Overall scores (standard deviations) for taste and oral sensation on a 9-point scale: 1=extremely disliked; 9=extremely liked 2A=Reformulated Ensure Plus; 2B=Ensure Plus; 2C=Fortisip Compact; 2D=Fortisip; 2E=Clinutren 1.5; 2F=Fresubin Energy

Likelihood of compliance

Stage 1

The average number of units (standard deviation) that respondents estimated they could consume, in one day, was highest for ONS 1A, at 2.2 (1.2) units per day compared with 1.9 (1.0), 2.1 (1.1), 1.9 (1.1) and 1.9 (1.0) units for ONS 1B to 1E, respectively. The estimated consumption per day was significantly higher for ONS 1A and 1C compared with ONS 1B to 1E ($p<0.05$).

Stage 2

Participants estimated they would be likely to consume an average (standard deviation) of 2.2 (1.2), 2.0 (1.0), 2.1 (1.2), 2.0 (1.3), 1.5 (0.7) and 2.2 (1.4) units of ONS 2A to 2F, respectively. ONS 2A scored significantly higher when compared with ONS 2B to 2E ($p<0.05$).

Analysis of the relationship between the estimated length of time that participants were likely to consume two units of ONS and product attributes that may affect likely compliance highlighted a range of correlations from $r=0.47$ for taste ($p<0.0001$) to $r=0.23$ for volume ($p<0.0001$) and $r=0.22$ for thickness ($p<0.0001$), where volume and thickness accounted for only 5% each of the overall variance (versus 22% for taste) (Figure 2). The overall opinion of ONS was strongly correlated with taste ($r=0.91$; $p<0.0001$), which accounted for 83% of variance in overall. Other product characteristics relating strongly to taste included the

oral sensation, aroma, appearance, and aftertaste (Figure 3). Volume demonstrated a weak relationship with taste ($r=0.29$, $p<0.0001$); only 8% of the variance was accounted for by volume (Figure 3).

DISCUSSION

Poor compliance with ONS has previously been reported for a variety of reasons, ranging from poor administration of the supplements to lack of education for healthcare providers and patients on the value of ONS, as well as the palatability and volume of the supplements (8,15-17). This large two-stage study investigated the relationship between

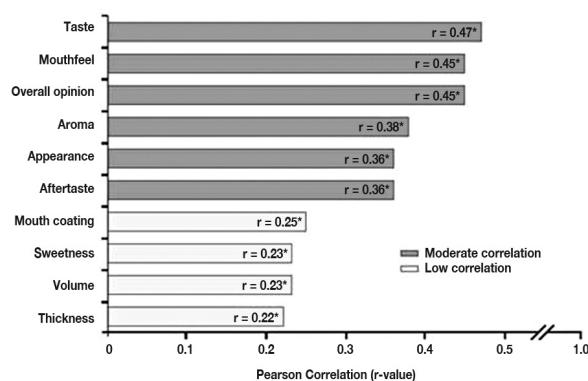


Figure 2. Pearson correlation analysis between the estimated length of time participants were prepared to take of two units of ONS daily and product attributes

^a p < 0.0001 for the correlation between the length of time participants estimated they were likely to consume two units daily and product attributes

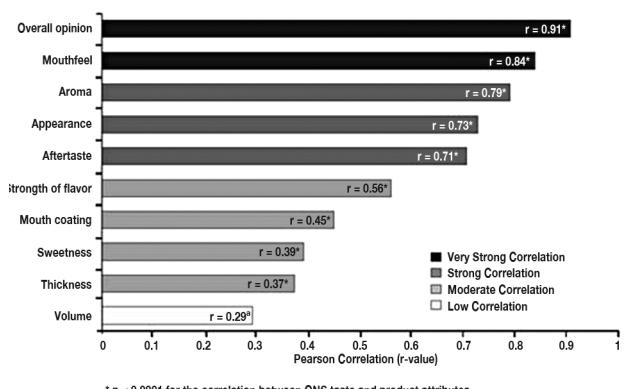


Figure 3. Pearson correlation analysis between ONS taste and product attributes

^a p < 0.0001 for the correlation between ONS taste and product attributes

the sensory attributes of ONS that are routinely prescribed in clinical practice and the likelihood of compliance. Analysis of taste preference was subdivided into key elements that included oral sensation, aftertaste, aroma, sweetness, and thickness. In this European study, identical ONS were not used in all countries. To represent usual clinical practice the ONS tested were those most routinely prescribed in each country, meaning that in some instances, ONS of different energy densities and volumes were tested. The preferred ONS from Stage 1 was used as a comparator in Stage 2 of the study. Independent of energy density and volume, the results from SUSTAIN demonstrate that key sensory attributes of ONS, including taste and oral sensation, are most closely related to the likelihood of compliance in independent individuals.

Of the 3 million people in the UK with, or at risk of, malnutrition, approximately 93% are estimated to live in the community. Malnutrition can affect all age groups; however risk increases with age due to comorbidities, which can be chronic and progressive (18). The European Nutrition for Health Alliance (19) reported that malnutrition affects 10% of the population aged over 65 years and significantly increases with age. Likewise, in a past study concerning nutritional risk of hospitalized patients in Turkey, nutritional risk was reported to increase with age from 9.3% for those patients under 60 to 25% for those over 60 (2).

The present study was conducted with over 1700 independent individuals aged 50 years, with more than 15% of participants over 75 years of age. Although health status was not assessed, it is probable that due to the normal ageing process, some participants had underlying health problems and comorbidities contributing to increased risk of malnutrition. Naughton *et al.* (20) report that as many as 85% of adults aged over 70 years receive regular medication (3 or more drug items) to treat chronic conditions associated with ageing.

The consumption of a food or drink is linked to sensory experience. Those experiences that are deemed pleasurable are most likely to be pursued, and those with negative associations avoided (8). The perceived palatability of a food relates to sensory aspects including taste, flavour, oral sensation, aroma, and appearance. A preference for sensory attributes ultimately leads to acceptability, but this can be influenced by other factors such as the environment where the food is served, memories of pleasant or unpleasant experiences with

that food, age, mood, and health status (8,21). One study has demonstrated the importance of the sensory attributes of foods on the likelihood of consumption, and food flavour has been specified as one of the main influencers of choice among older adults (8). Further, it has been reported that taste fatigue may occur following prolonged consumption of ONS (22).

In SUSTAIN, taste was identified as the key determinant of the overall opinion of any particular ONS, reinforcing the importance of this characteristic for preference and acceptance. Furthermore we identified oral sensation as accounting for 71% of the overall variance for taste preference. Volume had a very weak relationship with likely compliance and taste preference. It is clear that taste and sensory preference play an important role in likely compliance in independent individuals. However, further research is needed in patients, since previous studies have reported that the sensory aspects of ONS are important considerations for patient preference, compliance, and thus long-term consumption (9,10,15,23).

As assessed by the NRS-2002, the percent of patients nutritionally at-risk on hospital admission was reported to range from 20 to 39.9% in Denmark (24,25), 39.0% in Beijing (26), 51.0% in Baltimore (26), 24.5% in Turkey (2) and 32.6% in a recent multinational study comprised of 12 countries in Europe (27).

Although the percent of patients with malnutrition at hospital admission was reported to range from 13% to 100% in relation to heterogeneity of the patient populations from various specialities, regions and departments (27), only a minority of inpatients at risk for malnutrition were reported to actually receive appropriate nutrition during hospitalization, with sufficient nutritional support available only for 14.7 to 25% of at-risk patients (24,25,27). Hence, the results from SUSTAIN and previous studies should be considered in the context of the nutritional management strategy for each patient.

The crucial role of physician awareness was emphasized in published reports, with an increase in physician recognition of malnutrition from 12.5% to 100% after training (28), as well as the possibility of learning assessment easily via a short training program (29).

Additionally, in a previous study concerning nutritional risk of hospitalized patients in Turkey, ro-

oughly two-thirds of the nutritionists were determined to be familiar with the NRS-2002 in the training meeting prior to the study, while those not familiar with the NRS-2002 were reported to be able to implement the screening tool independently after 3 h of training (2).

Based on the consistently reported association between physician training and accurate nutritional assessment (28), it seems reasonable to anticipate the positive influence of both patient and caregiver-directed education on therapeutic success via better patient compliance. In this context, the National Institute for Health and Clinical Excellence (NICE) recommends that all patients and their caregivers should be educated prior to discharge into the community, to ensure they understand how to take their ONS and why ONS forms an important part of treatment. Training should also be provided to any community staff involved in the care of patients receiving ONS (3). Such education may help overcome potential psychological and practical barriers and improve compliance with nutritional advice.

The major limitation of the present study is the

lack of long-term follow up given that variations in hedonic scales as well as compliance are likely over the course of time. Additionally, while no clinical end-points have been included in the present study, due to our goal of measuring palatability and acceptance on the ability to comply, rather than measuring efficacy; future research on palatability and ability to comply on clinical outcome would be warranted. In conclusion, the results from SUSTAIN demonstrate that taste and oral sensation are the sensory attributes of ONS that have the greatest influence on preference. Furthermore, the ONS rated highest for taste and oral sensation (Reformulated Ensure Plus) was also the product that participants stated they would be most likely to consume more of and for a longer duration. Further research is warranted to substantiate these findings within a patient population. Providing ONS that meet patients' needs in terms of taste and sensory preferences, in addition to education regarding the role of nutritional supplements as a key part of treatment, may help to achieve nutritional goals and hence improve clinical outcomes.

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