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Should food or supplements be used in the community for the treatment of disease-related malnutrition?

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Strategies are needed for community-based treatment of disease-related malnutrition (DRM), which is a common debilitating condition that in the UK is estimated to cost $>£7 \times 10^9$ annually. Whilst dietary fortification and counselling are often used as a first-line treatment for malnutrition, the numbers of dietitians available to undertake and oversee such practices are currently insufficient to address the extent of DRM in primary care. Although dietary fortification and counselling can improve nutritional (primarily energy) intake, the evidence base for this practice is weak and it needs addressing with well-designed trials that assess clinically-relevant outcome measures and costs. Liquid oral nutritional supplements (ONS) are increasingly used in the community, often in combination with dietary counselling. The larger evidence base of trials that have assessed ONS suggests that nutritional intake and some functional outcomes can be improved in some patient groups in the community. Although meta-analysis indicates significant reductions in mortality (odds ratio 0.59 (95% CI 0.48, 0.72), n 3258) and complication rates (odds ratio 0.41 (95% CI 0.31, 0.53), n 1710) with ONS *v.* routine care, few of these studies are community based. Thus, the impact of ONS on clinical outcome, healthcare use and costs requires further assessment. Similarly, the clinical and cost efficacy of other strategies (e.g. sensory enhancement, music, behavioural therapy), alone or in combination with other treatments, requires greater investigation in order to meet the challenge of treating DRM more effectively and cheaply in the future.

Malnutrition: Supplements: Dietetic counselling: Food fortification: Primary care

Rationale for treatment: the problem of disease-related malnutrition

Effective treatment for disease-related malnutrition (DRM) is still needed despite the medical advances of the 20th and 21st centuries. Whilst healthcare policies and resources are increasingly focused on the problem of overnutrition and obesity in Western societies, the substantial and costly burden of DRM and its treatment is sometimes overlooked. With an increasingly ageing population and pressure on healthcare resources, a greater proportion of sick and debilitated individuals are cared for outside the hospital

environment, i.e. at home or in nursing or residential homes. Many studies, including national surveys, highlight the extent of malnutrition across populations, in the elderly and in different patient groups (patients with cancer, patients with renal disease and patients who have had surgery). Estimates suggest that the prevalence of malnutrition ranges from 5 to 23% of the patients visiting their general practitioner (GP), about 26% of the patients receiving district nursing care and $\leq 100\%$ of patients in nursing homes (depending on methods of identification and clinical condition; Stratton *et al.* 2003; King *et al.* 2004).

Abbreviations: DRM, disease-related malnutrition; GP, general practitioner; ONS, oral nutritional supplements; RCT, randomised controlled trials.
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Analysis of the National Diet and Nutrition Survey of people aged >65 years (n 1355) gives some insight into the extent of DRM in the elderly in the UK and its impact on individuals and their use of health care. Of older individuals 14% have been identified as at risk of malnutrition using 'Malnutrition Universal Screening Tool' type criteria (Elia, 2003). The prevalence of malnutrition increases with age (18% of those aged >85 years) and is almost twofold greater in individuals in institutions (Stratton *et al.* 2002). Also noteworthy is the geographic variation in the prevalence of malnutrition in the elderly across England, with the highest prevalence being found in those living in the north of England (north 19.4%, central 12.3%, south 11.2%, $P=0.002$ for trend; Stratton & Elia, 2005; Elia & Stratton, 2005). The proportion of malnourished (medium and high risk of malnutrition) elderly patients who are admitted to hospital or visit their GP is greater than that for elderly patients at low risk of malnutrition. Similarly, the malnourished elderly individual has a greater number of hospital admissions and GP visits. In addition to the impact on the quality of life of individuals, there are also cost implications of the increased healthcare utilisation associated with malnutrition. Recent economic estimates (Elia *et al.* 2005) have put the annual expenditure on DRM for the UK at $\pounds 7.4 \times 10^9$, approximately 50% of which is spent in community settings and includes the use of home artificial nutritional support, which continues to grow (Jones *et al.* 2005).

In addition to the increased costs and healthcare use associated with DRM, there are many physical and psychological consequences of DRM that also adversely affect recovery from disease and injury. Consequently, it is not surprising that many national and international organisations have recommended that routine screening should be in place in different healthcare settings, including community settings, so that DRM is promptly identified and treated (Table 1). Furthermore, a system of screening that has continuity between both community and hospital settings has recently been advocated by the Malnutrition Advisory Group of the British Association for Parenteral and Enteral Nutrition, with the launch of the 'Malnutrition Universal Screening Tool' (Elia, 2003; Stratton *et al.* 2004).

Following the identification of patients at risk of malnutrition by screening, there is a need to implement evidence-based treatments. The question arises as to what is the most appropriate and effective treatment of malnutrition for the community patient. It is clear that most cases of DRM primarily develop as a result of a deficit in energy intake associated with diseases or injury (as opposed to excessive or elevated energy expenditure; Elia *et al.* 2000; Stratton *et al.* 2003), and there are multiple causes that range from anorexia, poor dentition and the loss of taste and smell to nausea and vomiting and the physical inability to purchase, prepare and eat sufficient food. There may be other inter-related social and psychological factors, including depression, social isolation and poverty. Effective treatment strategies must result in a maximal increase in nutrient intake despite these problems. Artificial feeding, used alone or in addition to

food, can be a valuable life-saving method of preventing or treating malnutrition in the community patient. In the UK the use of home enteral tube feeding continues to rise (estimates suggest that at the end of 2003 the point prevalence was 25 000), and approximately 600 patients receive intravenous feeding at home each year (Jones *et al.* 2005). However, many individuals with malnutrition or at risk of developing malnutrition do not require artificial feeding and can be managed using oral feeding. Strategies commonly used, individually or in combination, include dietary fortification and counselling and oral nutritional supplements (ONS). There are also other strategies to increase oral nutritional intake, including sensory enhancement of foods, use of music and resistance training or exercise, that may also aid the treatment of DRM, particularly in long-term care settings. The evidence base for these strategies will be considered briefly.

Treatment strategies for disease-related malnutrition

Dietary (food) fortification

The *Manual of Dietetic Practice* (Thomas, 2001) recommends that 'If a patient is able to eat a normal diet, but in quantities insufficient to meet requirements, fortification of the diet should be considered ... to maximise the energy and/or nitrogen content of the diet', which suggests that dietary fortification, typically overseen by dietitians, is often used as the first-line treatment of DRM. The primary aim of this treatment is to increase energy and protein dietary intakes. Dietary fortification can include 'fortifying' foods to increase their energy and, to a lesser extent, protein density. This strategy involves adding or increasing the use of energy- and protein-rich food ingredients in the diet, including oil, cream, butter, milk, cheese, sugar and skimmed-milk powder. These ingredients can change the sensory properties of foods, which may or may not be desirable for individual patients. Alternatively, commercial energy or protein supplements (modular), available on prescription, can be added to the diet. These products include both powders and liquids supplying energy primarily as glucose polymers (e.g. Polycal (Nutricia Ltd, Towbridge, Wilts., UK), Vitajoule (VitaFlo Ltd, Paisley, Renfrewshire, UK), Polycose (Abbot Laboratories Ltd, Maidenhead, Berks., UK) and Maxijul (SHS International, Liverpool, UK)) and/or as a lipid emulsion (e.g. Calogen (SHS International) and Duocal (SHS International)). Protein supplements (e.g. Promod (Abbot Laboratories Ltd), Protifar (Nutricia Ltd) and Vitapro (VitaFlo Ltd)) and combined protein and energy supplements (e.g. Pro-cal; VitaFlo Ltd) can also be used.

Very few randomised controlled trials (RCT) have addressed the impact of dietary fortification *per se* on the clinical outcome of malnourished patients in the community in the developed world. Trials in institutions (including hospitals) have indicated the ability of dietary fortification, using food items (e.g. cream) and glucose polymers, to increase energy intakes (Odlund-Olin *et al.* 1998; Barton *et al.* 2000) but not protein intakes. Although these trials have suggested that dietary fortification is a low-cost option, they have not assessed the effects on

Table 1. Recommendations for nutritional screening in the community*

Source	Reference	Recommendations
Report on the malnutrition universal screening tool (MUST)	Elia (2003)	The report, produced by the Malnutrition Advisory Group of the British Association for Parenteral and Enteral Nutrition (BAPEN), recommends nutritional screening of various patient groups in different care settings. It provides the evidence base for the MUST. The report has seals of support from BAPEN, British Dietetic Association, Royal College of Nursing, and Registered Nursing Home Association. MUST is also supported by the Royal College of Physicians (London)
European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines for nutritional screening	Kondrup <i>et al.</i> (2003)	The ESPEN Educational and Clinical Practice Committee recommends that all patients admitted to hospital or other institutions should be screened, and that the screening process must be linked to defined courses of action
Report of a working party of the Royal College of Physicians	Royal College of Physicians (2002)	The report emphasises the doctor's responsibility in preventing and managing nutritional problems, as part of an integrated, multidisciplinary programme that begins with nutritional screening
American Society for Parenteral and Enteral Nutrition guidelines	American Society for Parenteral and Enteral Nutrition (2002)	The practice guidelines recommend nutrition screening as part of the initial evaluation of all patients, including those in community care settings and periodic nutrition re-screening
Report on standards for care homes for older individuals	Department of Health (2000)	The report provides minimum national standards for care homes, as part of the Care Standards Act 2000 (UK Parliament, 2000). The report recommends that nutritional risk screening in care homes should be undertaken on admission, and subsequently on a periodic basis. It also recommends that the findings should be recorded, and appropriate action implemented
The National Service Framework (NSF) for older individuals	Department of Health (2001 <i>b</i>)	The report recommends that routine nutritional screening should be undertaken and appropriate action plans implemented. It refers to Essence of Care 10 (Department of Health, 2001 <i>a</i>) for more specific standards on nutritional screening. The report also advocates a single integrated assessment framework rather than multiple independent assessment procedures. The Single Assessment Process for Older People (Department of Health, 2003) provides recommendations for implementing a single assessment process with a scale and depth according to needs, so that assessments converge in an effective way without duplication
National nutritional audit of elderly individuals in long-term care	Walker & Higginson (2001)	The report recommends that high priority should be given to decrease the high prevalence of malnutrition in long-term care facilities. It recommends that all residents should be screened for risk of malnutrition within 1 week of admission and at monthly intervals thereafter
Guidelines for the detection and management of malnutrition	Elia (2000)	The Malnutrition Advisory Group of the BAPEN report on the high prevalence of unrecognised and untreated malnutrition and produce a screening tool linked to a care plan to combat the problem in the community
King's Fund report	Lennard-Jones (1992)	The report, which has helped raise the profile of clinical nutrition in the UK during the last decade, concludes that the full benefits of nutritional treatment will only be realised when the assessment of every patient's status has become routine

*Based on the 'MUST' report (Elia, 2003).

patient recovery. Furthermore, the intakes of many micronutrients may not be improved by such a strategy, and yet elderly and malnourished patients are often deficient in vitamins and trace elements (Finch *et al.* 1998; Elia & Stratton, 2004). Detection and treatment of any micronutrient deficiencies is an important consideration in the management of DRM.

The use of food fortification may be an attractive option for the patient with anorexia, if the quantity and volume of food consumed does not increase. However, changing the energy density or the macronutrient composition of the diet may influence hunger, satiety and total food intake (Stubbs *et al.* 1996, 1998), but few studies have assessed

this outcome in the clinical setting. There may also be practical difficulties if patients are physically (e.g. disability, fatigue) or mentally unable or unwilling to modify their diet at home without help, thus reducing compliance.

Dietary fortification using snacks

Additional food items may also be recommended or given, such as snacks, cakes and puddings, either in addition to the current diet or to replace less-energy-dense items. The impact of such strategies on clinical outcome has not been addressed in many, if any, well-designed RCT. The addition of food snacks to the diet of elderly patients in

nursing homes has been shown to facilitate 30% increases in energy intakes (Turic *et al.* 1999), while in free-living elderly subjects it has been found that the provision of fortified nutrient-dense foods increases the intakes of some vitamins (vitamins A, C, D and E, and B-vitamins) and corrects some deficiencies (riboflavin, vitamin B₁₂, vitamin D) but does not increase energy intakes (de Jong *et al.* 1999). Functional and clinical outcomes were not assessed in these trials. In children with cystic fibrosis additional food snacks (i.e. milk shakes and puddings) can elevate energy intakes (by 1.9 MJ (445 kcal) daily) but are not associated with changes in function (respiratory and skeletal muscle strength and growth; Hanning *et al.* 1993). The use of additional food items in the treatment of malnutrition may be less effective in patients with severe anorexia, who may be unable to increase their food intake and in whom snacks may then replace their usual dietary intake. For free-living patients there are also cost considerations and issues of purchase, preparation and storage. Any physical difficulties with eating (chewing, swallowing) may also reduce the efficacy of this strategy.

Dietary counselling

In the treatment of DRM dietary counselling, usually by a state-registered dietitian, typically aims to maximise dietary intake, particularly energy and protein intakes. Advice on dietary fortification may be given in addition to encouragement to eat and advice on food choice, food preparation and how to overcome anorexia or specific difficulties with eating, perhaps as a result of side effects or symptoms associated with a disease or its treatment. Additional nutritional support, including oral supplements and artificial nutrition, may be prescribed. The effectiveness of dietetic counselling will depend on many factors that relate to the counsellor, the methods of counselling that are used, the content and form of the advice given and the patient. There have been few studies of the impact of dietary counselling (including the effectiveness of different methods of counselling and the advice given) in the treatment of DRM in the developed world. Very few trials have shown that dietary counselling can improve food intake and nutritional status (body weight) in the treatment of malnutrition in Western society (Stratton *et al.* 2003). Most trials do not mention who did the counselling, what form the counselling took (written diet sheets, oral instructions) or the patients' compliance or understanding of the advice.

The impact of dietary counselling on patients' outcome has been generally overlooked in research. One preliminary report of a RCT involving fifty outpatients with chronic obstructive pulmonary disease has found that tailored dietary advice from a dietitian and food fortification (using skimmed-milk powder) leads to weight gain and improvements in activity and dyspnoea scores compared with a control group. No changes in muscle strength or healthcare use at 6 months follow-up were recorded but longer-term results are awaited (Weekes *et al.* 2004). Other preliminary reports of RCT have also suggested that dietary counselling may have clinical benefits in the treatment of patients with cancer undergoing radiotherapy (Ravasco *et al.* 2003).

Further research is needed to address the clinical efficacy of dietetic counselling in the community setting and its relative efficacy compared with other treatments for DRM (Baldwin & Parsons, 2004). A dietitian's role can also involve the prescription of ONS (often alongside counselling and other strategies), the efficacy of which will be discussed.

Oral nutritional supplements

ONS are typically multinutrient (macro- and micro-nutrients) liquid feeds (and occasionally puddings or bars), either prescribed by the GP or purchased by the patient. There have been many more trials of ONS than of other community nutrition support strategies, although in many trials ONS are given alongside dietary counselling. The most recent systematic review of studies of ONS in community-based patients has identified 108 trials (forty-four RCT) undertaken in patients with a variety of conditions (including chronic obstructive pulmonary disease, Crohn's disease, cystic fibrosis, elderly with various conditions, HIV, liver disease, cancer and renal disease; Stratton *et al.* 2003). Community-based RCT of ONS (typically 1.05–2.52 MJ (250–600 kcal)/d given for 2 weeks–>2 years) have suggested a number of improvements in clinically-relevant outcomes (Table 2). Although there are currently insufficient trials from the community setting alone, a combined meta-analysis of trials in both hospital and community settings has indicated a significant reduction in mortality (twenty-six RCT, *n* 3258; odds ratio 0.59 (95% CI 0.48, 0.72)) and complication rates (twenty-seven RCT, *n* 1710; odds ratio 0.41 (95% CI 0.31, 0.53); Stratton *et al.* 2003). The impact of ONS on outcome may be associated with the minimal effect that liquid supplements appear to have on appetite and voluntary food intake, i.e. increasing total energy and nutrient intake. ONS have little suppressive effect on food intake, with an average of 68% of the energy being additive to food intake (Fig. 1). They appear to be most effective in studies in which the mean BMI of patients is <20 kg/m² (with 80%

Table 2. Summary of important functional and clinical outcome improvements following oral nutritional supplementation in community patients from randomised controlled trials*

Patient group	Functional and clinical outcome
Cancer	Immunological benefits
Chronic obstructive pulmonary disease	Respiratory muscle function Hand-grip strength Walking distances
Elderly with various conditions	Reduced no. of falls Increased activities of daily living Muscle power
HIV and AIDS	Cognitive function
Liver disease	Lower incidence of severe infections Lower frequency of hospitalisation
Osteoarthritis	Increased activities of daily living† Improved osteoarthritis index†

*Based on Stratton *et al.* (2003).

†Nutritional supplement also containing IgG (90 mg).

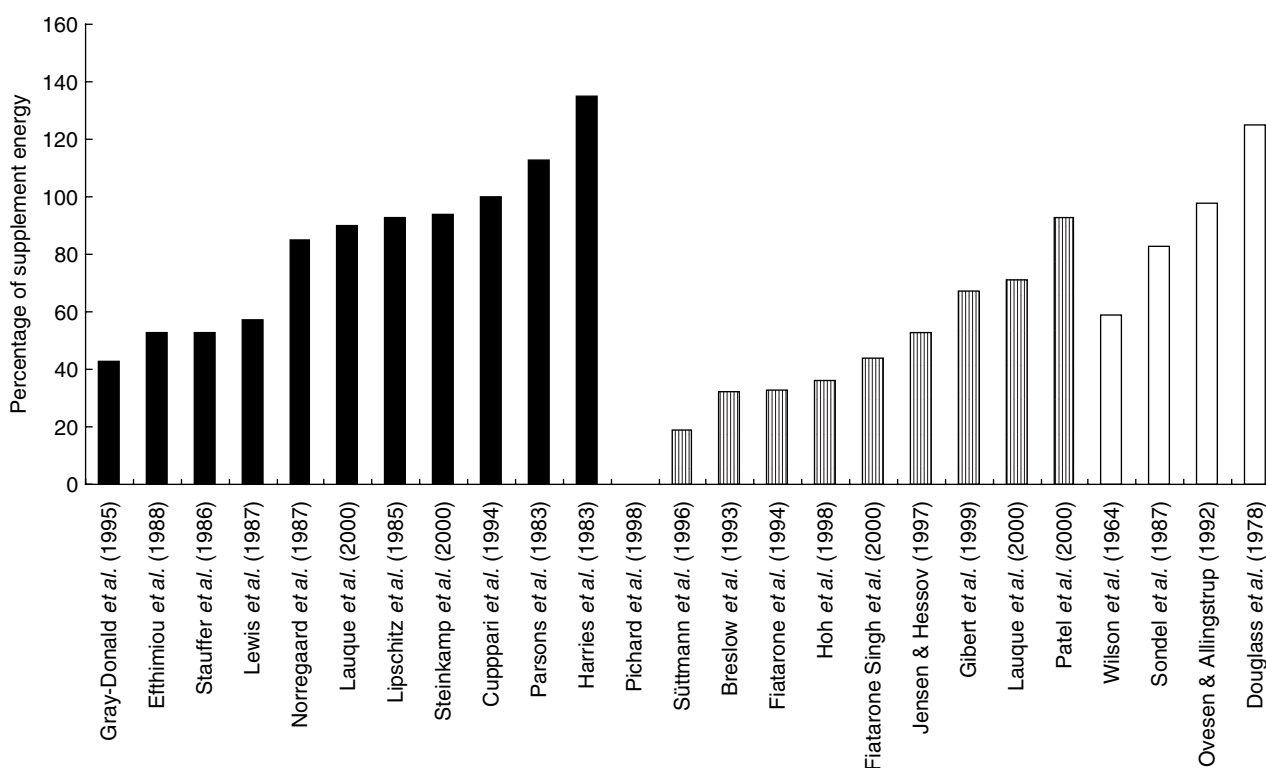


Fig. 1. Increment in total energy intake as a percentage of the supplement energy consumed in community studies (■), BMI <20 kg/m²; (▨), BMI >20 kg/m²; (□), BMI unknown (From Stratton *et al.* 2003).

of the ONS energy being additive compared with 45% in those with a BMI >20 kg/m²). This finding suggests that liquid ONS may be a good strategy for the treatment of the malnourished (underweight and/or weight-losing) patient, including the anorexic patient (epidemiological studies also suggest that the consumption of energy-rich liquids effectively increases dietary intake and so contributes to the rise in obesity; St-Onge *et al.* 2003; Bray, 2004). The efficacy of ONS may be limited if compliance is poor, which can be an issue with long-term supplementation of the chronically-sick patient in the community. Thus, a more-energy-dense supplement taken as small doses or as a 'medication' as opposed to 'food' may aid compliance. Varied flavours and a choice of different supplement types and consistencies may also help. In some patient groups the combination of ONS with physical activity programmes (resistance training) may facilitate improvements in intake (e.g. in the elderly; Fiatarone *et al.* 1994; Bonnefoy *et al.* 2003; Bunout *et al.* 2004).

It is unclear how increases in nutritional intake from ONS improve outcome. It could be that increases in weight and muscle mass associated with supplementation can aid recovery. A meta-analysis of percentage weight change data from thirteen RCT (*n* 509) has suggested that ONS has a significant effect on body-weight gain compared with routine care (no supplementation) in community patients (effect size 0.51 (95% CI 0.30, 0.71), with significant heterogeneity between studies; Stratton *et al.* 2003). However, community-based studies assessing function in elderly patients and those with chronic obstructive pulmonary disease have shown that functional benefits

occur when weight gain with supplementation is >2 kg (Fig. 2). As with increases in nutrient intake, community-based studies have shown that increases in weight and function are more likely in patients who are underweight (mean BMI <20 kg/m²; Stratton *et al.* 2003). Alternatively, outcome may be improved independently of changes in body structure. The provision of a mix of nutrients, including micronutrients, may correct a deficiency or alter immune function and outcome with short- and long-term supplementation. The mechanisms of action of ONS have yet to be elucidated and should be considered as part of further intervention trials.

There is little information about the effect of ONS on healthcare utilisation in the community. One longitudinal cohort study in France (Arnaud-Battandier *et al.* 2004) has compared the healthcare costs of two groups of malnourished elderly patients cared for by physicians with either rare or frequent prescribing of nutritional supplements. The adjusted costs per patient (hospital care, nursing care and other medical care) were found to be significantly lower in the group frequently prescribed ONS (−€723 (90% CI −€1444, −€43)). Another RCT of 8 weeks of ONS in malnourished elderly people after hospital discharge has prospectively examined the impact of supplementation on healthcare utilisation (costs of hospital admissions, prescriptions and GP and outpatient visits; Edington *et al.* 2004). Analysis of patient diaries shows no significant effects of supplementation, but analysis of GP records shows a reduction in hospital costs (£2704 per patient; *P*<0.001) in the control group alone (£327 per patient; for a review, see Elia *et al.* 2005).

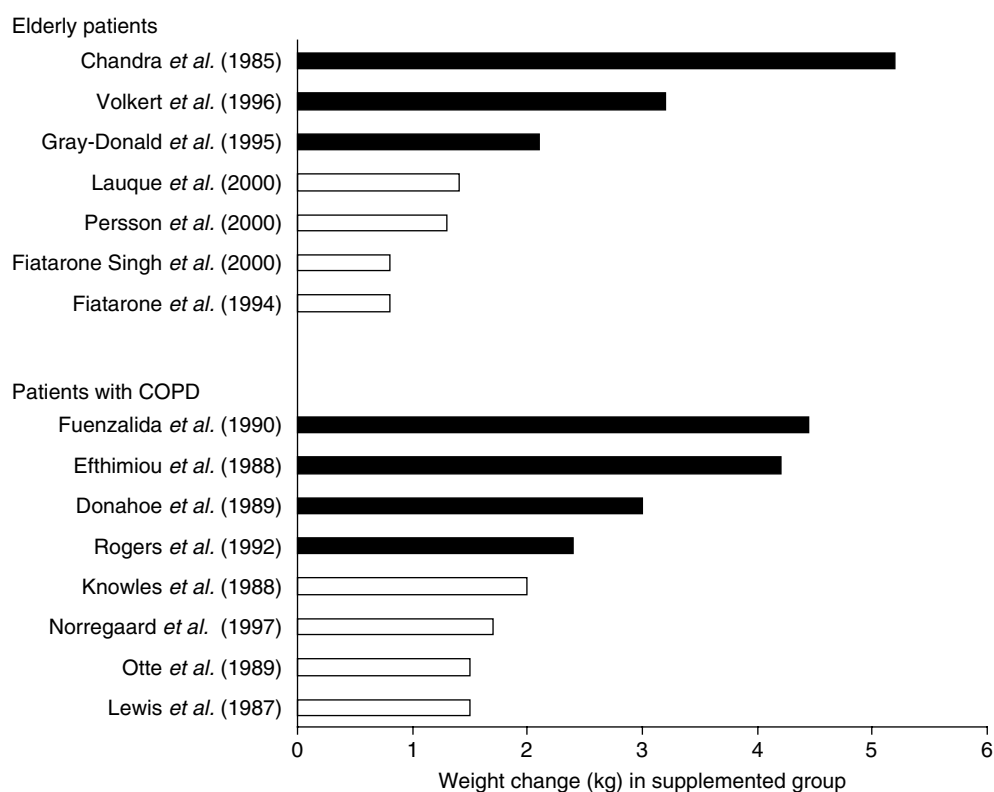


Fig. 2. Relationship between functional benefits and weight change with oral nutritional supplementation in elderly patients (BMI $<20\text{ kg/m}^2$ and $>20\text{ kg/m}^2$) and patients with chronic obstructive pulmonary disease (COPD; BMI $<20\text{ kg/m}^2$) (■), Functional benefits; (□), no functional benefits (From Stratton *et al.* 2003).

Other strategies to increase oral intake, e.g. dietary flavour and odour enhancement, environmental changes (including music) and behavioural therapy, have been reported in the literature and will be discussed. However, very few of these strategies are used clinically, possibly because of practicality and cost issues and also because more evidence of their effects is needed.

Dietary flavour and odour enhancement

Flavour enhancement of nutrient-dense foods (using roast beef, ham, natural bacon, prime beef, maple and cheese flavours) has been shown to increase food consumption in elderly patients in a residential home over a 3-week period (Schiffman & Warwick, 1993). Furthermore, improvements in immune function (total lymphocyte count and total B- and total T-cell counts) and grip strength accompany the intake of these flavour-enhanced foods. This strategy may be particularly effective in the elderly, who experience age- and disease-related changes in taste and odour sensations (Schiffman, 1983).

Environmental changes (including music)

For individuals living in institutions the ways in which food is provided and the environment associated with dining may be important in maximising patients' dietary intakes. Case & Gilbert (1997) have summarised the dining expectations of residents of long-term care facilities. The

strategies that have been considered include: providing a pleasant atmosphere for dining (e.g. use of tablecloths); having staff in the dining room to help with eating; providing meals that are social occasions for all residents. An interesting study by Elmstahl *et al.* (1987), found that redecorating a dining room in 1940s style (changing furniture, fabrics, paintings, china) and allowing patients to help themselves to or be served food at mealtimes over a period of 16 weeks increased their energy and protein intakes (by 25%) and the intakes and status of some micronutrients. The positive effects on the food intake of elderly demented patients of playing lively music have also been reported (Ragneskog *et al.* 1996). It was found that when pop music or 1920–30s tunes are played during mealtimes patients eat more dessert, staff serve more food and the patients are less irritable, anxious and depressed than when no music is played.

Behavioural therapy

Child behaviour management training may assist parents in helping their child meet their energy (and other nutrient) requirements (Stark *et al.* 1990, 1996).

Summary

DRM is a common and debilitating condition that in the UK alone is estimated to cost $>£7 \times 10^9$ /year, and there is

a need for effective strategies for its treatment in the community. In order to identify those patients requiring treatment regular screening for malnutrition is recommended followed by an evidence-based care plan for treatment. There is little evidence to support the consensus that dietary (food) fortification should be used as the first treatment of malnutrition in preference to liquid ONS. Whilst dietary fortification and counselling are often the initial method of choice for treating malnutrition, the numbers of dietitians available to undertake and oversee such practices are currently insufficient to address the extent of DRM in primary care. The evidence base for this practice is also weak and needs addressing with well-designed trials that assess clinically-relevant outcome measures and costs. However, there is a larger evidence base of assessment trials that suggests that nutritional intake and some functional outcomes can be improved with ONS, but the impact on clinical outcome and healthcare use and costs requires further assessment. Similarly, the clinical and cost efficacy of other strategies (e.g. sensory enhancement, music and behavioural therapy), alone or in combination with other treatments, requires greater investigation in order to meet the challenge of treating DRM more effectively and cheaply in the future.

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