Ensure® PLUS STRENGTH

Ensure Plus Strength
Clinical Compendium

Food for Special Medical Purposes. Use under medical supervision.

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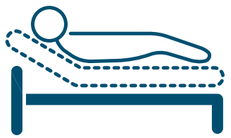
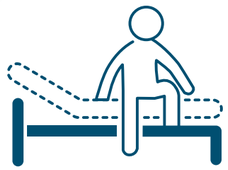
A REVIEW OF THE CLINICAL EVIDENCE ACROSS THE CONTINUUM OF CARE

HOSPITAL



- Cornejo-Pareja I, *et al.* 2021
- Deutz NE, *et al.* 2016
- Deutz NE, *et al.* 2021
- Ekinci O, *et al.* 2016
- Espina S, *et al.* 2021
- Loman BR, *et al.* 2019
- López-Rodríguez-Arias F, *et al.* 2021
- Matheson EM, *et al.* 2021
- Ritch CR, *et al.* 2019

REHABILITATION



- Malafarina V, *et al.* 2017
- Olveira C, *et al.* 2020
- Olveira G, *et al.* 2016

AGED CARE FACILITIES

- De Luis DA, *et al.* 2018
- Zana S, *et al.* 2021

COMMUNITY

- Berton L, *et al.* 2015
- Cramer JT, *et al.* 2016
- De Luis DA, *et al.* 2015
- De Luis DA, *et al.* 2018
- Peng LN, *et al.* 2021
- Pereira SL, *et al.* 2022
- Standley RA, *et al.* 2020

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A REVIEW OF THE CLINICAL EVIDENCE WITH DIFFERENT INTERVENTIONS

1 BOTTLE PER DAY

- Berton L, *et al.* 2015
- Olveira C, *et al.* 2020
- Olveira G, *et al.* 2016
- Zana S, *et al.* 2021

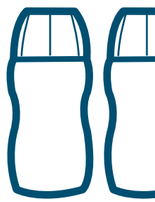
WITH EXERCISE

- Berton L, *et al.* 2015
- Cornejo-Pareja I, *et al.* 2021
- López-Rodríguez-Arias F, *et al.* 2021
- Olveira C, *et al.* 2020
- Olveira G, *et al.* 2016
- Zana S, *et al.* 2021

PREHABILITATION

- López-Rodríguez-Arias F, *et al.* 2021
- Ritch CR, *et al.* 2019

VS STANDARD/HIGH PROTEIN ONS



- Cornejo-Pareja I, *et al.* 2021
- Cramer JT, *et al.* 2016
- Espina S, *et al.* 2021
- Pereira SL, *et al.* 2022
- Standley RA, *et al.* 2020

ONS, oral nutritional supplement.

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A REVIEW OF THE CLINICAL EVIDENCE IN DIFFERENT MEDICAL CONDITIONS

CARDIOVASCULAR
(Congestive Heart Failure, Acute Myocardial Infarction)

Deutz NE, *et al.* 2016
Loman BR, *et al.* 2019
Matheson EM, *et al.* 2021

RESPIRATORY
(COPD, Bronchiectasis)

Deutz NE, *et al.* 2016
Deutz NE, *et al.* 2021
Loman BR, et al. 2019
Matheson EM, *et al.* 2021
Olveira C, *et al.* 2020
Olveira G, *et al.* 2016
Zana S, et al. 2021

ONCOLOGY
(Including surgery)

Cornejo-Pareja I, *et al.* 2021
López-Rodríguez-Arias F, *et al.* 2021
Ritch CR, *et al.* 2019

HIP FRACTURES
(Surgery and Rehabilitation)

Ekinci O, *et al.* 2016
Malafarina V, *et al.* 2017

LIVER
(Liver disease, Cirrhosis)

Espina S, et al. 2021

PRE-FRAIL

Peng LN, *et al.* 2021

UNDERNUTRITION

Cornejo-Pareja I, *et al.* 2021
Cramer JT, *et al.* 2016
De Luis DA, *et al.* 2015
De Luis DA, *et al.* 2018
Pereira SL, *et al.* 2022

HEALTHY

Berton L, *et al.* 2015
Standley RA, *et al.* 2020

COPD, chronic obstructive pulmonary disease.

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CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

READMISSION AND MORTALITY IN MALNOURISHED, OLDER, HOSPITALIZED ADULTS TREATED WITH A SPECIALIZED ORAL NUTRITIONAL SUPPLEMENT: A RANDOMIZED CLINICAL TRIAL

Deutz NE *et al. Clin Nutr* 2016;35(1):18–26

Study:

- The NOURISH study: a randomised, placebo-controlled, double-blind study
- Designed to evaluate the impact of a high protein ONS with HMB, vitamins and minerals (intervention ONS) on mortality and nonelective hospital readmission rates, compared with a placebo
- Patients were randomly assigned to one of two groups: standard of care plus either a high protein ONS with HMB (intervention ONS; n = 313) or a placebo supplement* (n = 309), 2 servings/day from within 3 days of hospital admission and up to 90 days post-discharge

Participants:

- 622 older (≥65 years), malnourished cardiopulmonary patients (with CHF, AMI, COPD or pneumonia) were included in the analysis

Results:

- 90-day mortality was significantly reduced by 50% in patients receiving the intervention ONS compared with those receiving the placebo (4.8% vs 9.7%; $p = 0.018$)
- In addition, patients receiving the intervention ONS had improved odds of achieving a better SGA nutritional class after 90 days ($p = 0.009$), increased body weight at day 30 ($p = 0.035$) and serum vitamin D concentration at days 30 and 60 ($p = 0.035$ and $p = 0.008$, respectively), compared with patients receiving the placebo

Conclusion:

Combined with standard of care, a high protein ONS with HMB has been shown to significantly decrease 90-day mortality rates by 50% in older, malnourished patients hospitalised for CHF, AMI, pneumonia or COPD, compared with a placebo supplement

Read the full study online

*Placebo contained 48kcal, 12g carbohydrate, 10mg Vitamin C

NOURISH, Nutritional effect On Unplanned ReadmIssion and Survival in Hospitalised patients; ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; CHF, congestive heart failure; AMI, acute myocardial infarction; COPD, chronic obstructive pulmonary disease; SGA, Subjective Global Assessment.

CARE CONTINUUM × | INTERVENTIONS × | MEDICAL CONDITIONS ×

REDUCED MORTALITY RISK IN MALNOURISHED HOSPITALIZED OLDER ADULT PATIENTS WITH COPD TREATED WITH A SPECIALIZED ORAL NUTRITIONAL SUPPLEMENT: SUB-GROUP ANALYSIS OF THE NOURISH STUDY

Deutz NE, *et al. Clin Nutr* 2021;40(3):1388–1395

Study:

- A post-hoc, sub-group analysis of the NOURISH study
- Examined the effect of a high protein ONS with HMB, vitamins and minerals (intervention ONS) on malnourished, hospitalised older adults with COPD and aimed to identify predictors of outcomes

Participants:

- The COPD subgroup (n = 214) included hospitalised, malnourished (based on SGA), older adults (≥65 years), with an admission diagnosis of COPD, who received standard of care plus 2 servings/day of either a high protein ONS with HMB (intervention ONS; n = 109) or placebo* supplement (n = 105)

Results:

- The 30, 60 and 90-day mortality risk was found to be ~71% lower in the intervention group compared to those who had the placebo (p = 0.0395, 0.0193, 0.0113, respectively)
- In addition, nutritional supplementation with the intervention ONS resulted in significant improvements in handgrip strength (HGS) from discharge to day 30 (+1.56 kg vs -0.34 kg, p = 0.0413); body weight from baseline to discharge ($p < 0.05$); and blood nutritional biomarker concentrations, including haemoglobin and serum concentrations of calcium and vitamin D

Conclusion:

In malnourished, hospitalised patients with COPD, supplementation with a high protein ONS with HMB was associated with a significant reduction in mortality risk by ~71%, and improved HGS, body weight and nutritional biomarkers within a 90-day period after hospital discharge

Read the full study online

*Placebo contained 48kcal, 12g carbohydrate, 10mg Vitamin C. NOURISH, Nutritional effect On Unplanned Readmission and Survival in Hospitalised patients; ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; COPD, chronic obstructive pulmonary disease; SGA, Subjective Global Assessment; HGS, handgrip strength.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

PERIOPERATIVE ORAL NUTRITION SUPPLEMENTATION REDUCES PREVALENCE OF SARCOPENIA FOLLOWING RADICAL CYSTECTOMY: RESULTS OF A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Ritch CR *et al. J Urol* 2019;201(3):470–477

Study:

- Prospective, randomised, controlled study
- The study was designed to investigate the effects of a HMB-enriched ONS on body composition and clinical outcomes following radical cystectomy

Participants:

- 61 patients (median patient age of 68 years) who had undergone radical cystectomy were randomised to receive either Ensure Clinical Strength with HMB (ONS; n = 31) or a multivitamin multimineral supplement (MVI; n = 30), twice daily during an 8-week perioperative period

Results:

- Patients in the ONS group lost significantly less muscle mass (-3.2 vs -5 cm^2/m^2, $p = 0.01$); compared with the MVI group
- The proportion of patients with sarcopenia did not change in the ONS group but increased by 20% in the MVI group ($p = 0.01$)
- The proportion of patients with sarcopenic obesity decreased by 33.3% in the ONS group compared with the MVI group where it increased by 16.7% ($p = 0.01$)
- The ONS group had a lower rate of overall and major (Clavien grade 3 or greater) complications (48% vs 67% and 19% vs 25%, respectively) and a lower readmission rate (7% vs 17%) but the differences did not reach statistical significance

Conclusion:

Patients who undergo radical cystectomy after consuming an ONS enriched with HMB perioperatively have a reduced prevalence of sarcopenia and may also experience fewer and less severe complications and readmissions

Read the full study online

HMB, beta-hydroxy beta-methylbutyrate; ONS, oral nutritional supplement; MVI, multivitamin multimineral supplement.

CARE CONTINUUM × | INTERVENTIONS × | MEDICAL CONDITIONS ×

EFFECTIVENESS OF NUTRITIONAL SUPPLEMENTATION ON SARCOPENIA AND RECOVERY IN HIP FRACTURE PATIENTS. A MULTI-CENTRE RANDOMIZED TRIAL

Malafarina V *et al. Maturitas* 2017;101:42–50

Study:

- Multi-centre, randomised open label study
- The aim was to assess whether Ensure Plus Advance with HMB improves muscle mass and nutritional markers in elderly patients with a hip fracture

Participants:

- 92 older patients (≥65 years) with hip fractures admitted to rehabilitation facilities were included in the analysis. The patients were randomly assigned to receive a standard diet* either with no ONS (control group; n = 43) or with Ensure Plus Advance (intervention group; n = 49). The intervention was not blinded

Results:

- Weight and muscle mass (aLM) were stable in the intervention group, whilst these parameters decreased from admission to discharge in the control group, with a significant difference between groups ($p < 0.001$ and $p = 0.02$, respectively)
- Three factors predicted Δ-aLM: 1)ONS, 2) previous BI score, and 3) previous FAC score
- In the intervention group, total protein and vitamin D blood concentrations were significantly higher upon discharge than in the control group ($p = 0.007$ and $p < 0.001$, respectively)

Conclusion:

Ensure Plus Advance has been shown to improve muscle mass and prevent the onset of sarcopenia in elderly patients with hip fractures

Read the full study online

*Standard diet provided 1500 kcal, 87.4 g protein a day

HMB, beta-hydroxy beta-methylbutyrate; ONS, oral nutritional supplement; aLM, appendicular lean mass; Δ-aLM, aLM upon discharge minus aLM on admission; BI score, Barthel Index score (measures performance in activities of daily living); FAC score, Functional Ambulation Category score (determined by a functional walking test).

ORAL SUPPLEMENT ENRICHED IN HMB COMBINED WITH PULMONARY REHABILITATION IMPROVES BODY COMPOSITION AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH BRONCHIECTASIS (PROSPECTIVE, RANDOMISED STUDY)

Olveira G *et al. Clin Nutr* 2016;35(5):1015–1022

Study:

- Single centre, randomised controlled study with a parallel treatment design
- The goal was to assess the effect of PR for 12 weeks in normally-nourished patients with non-cystic-fibrosis bronchiectasis (NCFB), and compare it with the effect of PR plus a hyperproteic ONS enriched with HMB on body composition, muscle strength, quality of life and serum biomarkers

Participants:

- 30 normally nourished patients aged <65 years with BMI over 18.5 kg/m^2 or >65 years with BMI over 20 kg/m^2) with NCFB receiving either PR* alone (PR; n = 15) or PR plus ONS† (PRONS; n = 15)

Results:

- In the PRONS group there were significant increases in BMD, mean and maximum HGS, body composition, QOL and prealbumin from baseline at 12 and 24 weeks, and FFM and FFM index at 12 weeks
- In the PR group only mean HGS and prealbumin were significantly increased at 12 and 24 weeks

Conclusion:

The addition of Ensure Plus Advance^ with HMB (1 serve/day) to PR could improve body composition, BMD, muscle strength and QOL in normally-nourished bronchiectasis patients

Read the full study online

*PR: Exercise program of three 60 minute sessions per week.
†PRONS: PR plus Ensure Plus Advance^ with HMB (1 serving/day).
^Ensure Plus Advance is known as Ensure Plus Strength in Australia.
HMB, beta-hydroxy beta-methylbutyrate; PR, pulmonary rehabilitation; NCFB, non-cystic-fibrosis bronchiectasis; ONS, oral nutritional supplement; BMI, body mass index; BMD, bone mineral density; HGS, hand grip strength; QOL, quality of life; FFM, fat free mass.

CARE CONTINUUM ✕ | INTERVENTIONS ✕ | MEDICAL CONDITIONS ✕

EFFECT OF CALCIUM β-HYDROXY-β-METHYLBUTYRATE (CaHMB), VITAMIN D, AND PROTEIN SUPPLEMENTATION ON POSTOPERATIVE IMMOBILIZATION IN MALNOURISHED OLDER ADULT PATIENTS WITH HIP FRACTURE: A RANDOMIZED CONTROLLED STUDY

Ekinci O *et al. Nutr Clin Pract* 2016;31(6):829–835

Study:

- Randomised, controlled trial
- The goal was to investigate the effects of a specialised high protein ONS enriched with HMB on wound healing, mobilisation time and muscle strength in older female patients following surgery for a hip fracture

Participants:

- 62 older female patients (≥65 years) with hip fractures admitted to orthopaedic clinics were included in the analysis, and were randomly assigned to receive either standard postoperative nutrition* alone (control group; n = 30) or combined with a high protein ONS enriched with HMB (intervention group; n = 32), twice daily for 30 days

Results:

Compared with the control group, the intervention group had:

- Significantly more patients that were mobile on days 15 and 30 (26/32 of patients in the intervention group were mobile on days 15 and 30 compared with 8/30 of patients in the control group ($p = 0.001$))
- Significantly greater muscle strength on day 30 ($p = 0.026$)
- Significantly shorter wound-healing period ($p < 0.05$)

Conclusion:

Nutrition support of elderly hip fracture patients, with a specialised high protein ONS enriched with HMB, led to accelerated wound healing after orthopaedic surgery, reduced immobilisation period, and increased muscle strength. It also reduced duration of bed rest and related complications after orthopaedic surgery

Read the full study online

*Postoperative nutrition included 3 meals, providing 1900 kcal and 76 g protein a day
ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate.

CARE CONTINUUM × | INTERVENTIONS × | MEDICAL CONDITIONS ×

IMPACTS OF HIGH-PROTEIN ORAL NUTRITIONAL SUPPLEMENTS AMONG MALNOURISHED MEN AND WOMEN WITH SARCOPENIA: A MULTICENTER, RANDOMIZED, DOUBLE-BLINDED, CONTROLLED TRIAL

Cramer JT *et al. J Am Med Dir Assoc* 2016;17(11):1044–1055.

Study:

- A multicentre, randomised, double-blinded, controlled clinical trial
- Designed to evaluate two different high-quality ONS: Ensure Plus (a standard ONS) and Ensure Plus Advance* (a specialised high protein ONS enriched with HMB)

Participants:

- 330 older patients (≥65 years) with malnutrition and sarcopenia assigned to receive either Ensure Plus (control ONS, 14 g protein; 147 IU Vitamin D_3; n = 165) or Ensure Plus Advance* (experimental ONS, 20 g protein; 499 IU vitamin D_3; 1.5 g CaHMB; n = 165), twice daily for 24 weeks

Results:

- Both groups significantly increased leg strength, muscle quality, grip strength and gait speed from baseline, with no treatment differences
- Participants with mild-moderate sarcopenia and normal grip strength who received the experimental ONS showed significant improvement in leg strength and muscle quality from baseline to 12 weeks as compared with the control ONS ($p = 0.032$ and $p = 0.027$ respectively)

Conclusion:

ONS improved strength outcomes in malnourished older adults with sarcopenia. In those with mild-moderate sarcopenia, but not severe sarcopenia, consumption of Ensure Plus Advance* improved leg muscle strength and muscle quality compared with Ensure Plus

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia
ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

EFFECT OF ORAL BETA-HYDROXY-BETA-METHYLBUTYRATE (HMB) SUPPLEMENTATION ON PHYSICAL PERFORMANCE IN HEALTHY OLD WOMEN OVER 65 YEARS: AN OPEN LABEL RANDOMIZED CONTROLLED TRIAL

Berton L, *et al. PLoS One* 2015;10(11):e0141757.

Study:

- A parallel-group, randomised, controlled, open-label trial
- The aim was to evaluate whether 1 serving of a high protein ONS with HMB (Ensure Plus Advance*) could improve physical performance and muscle strength in a group of community dwelling women

Participants:

- 65 healthy older female patients (≥65 years) who regularly attended a twice-weekly mild fitness program completed the study. Participants were randomly assigned to receive either 1 bottle per day of Ensure Plus Advance* with HMB (intervention group; n = 32) or no treatment or placebo (control group; n = 33) for 8 weeks

Results:

After 8 weeks:

- There were no significant differences between the groups' SPPB, hand grip strength or DXA parameters
- The intervention group scored significantly better than the control group for PT isokinetic flexion ($p = 0.03$) and extension ($p = 0.03$); PT isometric strength ($p = 0.02$); 6 minute walking test ($p = 0.04$), hand grip endurance ($p = 0.02$), and muscle density assessed with pQCT

Conclusion:

1 daily bottle of Ensure Plus Advance* combined with a mild fitness program twice a week, for 8 weeks, had no significant effects on SPPB, but did significantly improve several muscle strength and physical performance parameters in healthy older women

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia

ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; SPPB, Short Physical Performance Battery; DXA, dual-energy X-ray absorptiometry; PT, peak torque; PQCT, peripheral quantitative computerised tomography.

EFFECT ON QUALITY OF LIFE AND HANDGRIP STRENGTH BY DYNAMOMETRY OF AN ENTERAL SPECIFIC SUPLEMENTS WITH BETA-HYDROXY-BETA-METHYLBUTYRATE AND VITAMIN D IN ELDERLY PATIENTS

De Luis DA *et al. Nutr Hosp* 2015;32(1):202–207

Study:

- Open-label, 12-week study
- The aim was to study the effect of 2 bottles per day of a high protein ONS with HMB (Ensure Plus Advance*) on various parameters, including strength and quality of life in older patients vs baseline

Participants:

- 35 older patients (≥65 years) with recent weight loss (>5% in the previous 3 months)

Results:

Compared with baseline, after 3 months:

- All patients had significant improvements in prealbumin and vitamin D3 levels ($p < 0.05$)
- All patients significantly increased their consumption of calories, carbohydrates, protein, fat and vitamin D from baseline
- Patients who experienced >3.4% weight gain had significant improvements in hand grip strength and the physical and general health domains of the SF-36 quality of life score ($p < 0.05$)
- Patients who experienced >3.4% weight gain consumed Ensure Plus Advance* at a higher volumetric rate than those who experienced <3.4% weight gain (1.86 + 0.82 vs 1.25 + 0.78 units/day)

Conclusion:

Elderly patients with previous weight loss and a high consumption of Ensure Plus Advance* experienced a significant improvement in anthropometric and biochemical parameters, hand grip strength and quality of life

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia
ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; SF-36, short form-36.

CARE CONTINUUM × | INTERVENTIONS × | MEDICAL CONDITIONS ×

ADNUT STUDY: EFFECTIVENESS OF A HIGH CALORIE AND PROTEIN ORAL NUTRITIONAL SUPPLEMENT WITH β-HYDROXY-β-METHYLBUTYRATE IN AN OLDER MALNOURISHED POPULATION IN USUAL CLINICAL PRACTICE

De Luis DA *et al. Eur Geriatr Med* 2018;9(6):809–817

Study:

- Observational, prospective, 12-week, open-label, multicentre study
- The aim was to evaluate the effectiveness of twice daily consumption of a high protein ONS with HMB, Ensure Plus Advance*, on nutritional status, activities of daily living and quality of life (QoL) in older malnourished patients

Participants:

- 148 older patients (>65 years) who were malnourished or at nutritional risk (NRS† ≥3) were included in the analysis. Participants were living either in a nursing home or in the community receiving outpatient care, and were included in an ONS plan of Ensure Plus Advance* twice daily per standard of care

Results:

After Ensure Plus Advance* intervention:

- Weight increased significantly at 6 and 12 weeks compared with baseline ($p < 0.001$)
- Activities of daily living (Katz index^), and QoL (EQ-5D scoring) were both significantly improved at 6 and 12 weeks compared with baseline ($p < 0.001$)
- NRS-2002 score decreased significantly at 6 and 12 weeks ($p < 0.001$ and $p = 0.002$, respectively)
- No association was observed between patients with baseline BMI ≤ 20 kg/m^2 vs BMI > 20 kg/m^2 and weight loss, NRS, Katz index or EQ-5D ($p > 0.05$), indicating that nutritional, functional and QoL improvements were independent of baseline BMI values

Conclusion:

The results suggest that administration of Ensure Plus Advance* improves nutritional status and may lead to a significant improvement in patients' activities of daily living and QoL, independent of baseline BMI

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*Ensure Plus Advance is known as Ensure Plus Strength in Australia

†Where a score of 0 = no nutritional risk, 1 = mild nutritional risk, 2 = moderate nutritional risk and 3 = severe nutritional risk

^Katz index was used to assess individual's ability to perform 6 activities of daily living including feeding, toileting, bathing, dressing, continence, and transferring (0 = complete dependence to 6 = independence)

ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; QoL, quality of life; NRS, Nutrition Risk Score; EQ-5D, EuroQol-5 Dimension; BMI, body mass index.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

SPECIALIZED ORAL NUTRITIONAL SUPPLEMENT (ONS) IMPROVES HANDGRIP STRENGTH IN HOSPITALIZED, MALNOURISHED OLDER PATIENTS WITH CARDIOVASCULAR AND PULMONARY DISEASE: A RANDOMIZED CLINICAL TRIAL

Matheson EM *et al. Clin Nutr* 2021;40(3):844-849

Study:

- A post-hoc analysis of the NOURISH study
- The goal was to examine the effect of a high protein ONS with HMB (intervention ONS) on hand grip strength (HGS) and its relationship to nutritional status and ADL in elderly, malnourished, hospitalised adults who were participants in the NOURISH trial

Paticipants:

- The NOURISH study included 652 older patients (≥65 years) with malnutrition, hospitalised for cardiovascular and pulmonary events who received standard of care plus 2 servings/day of either a high protein ONS with HMB (intervention ONS; n = 328) or a placebo supplement* (n = 324), from within 3 days of hospital admission and up to 90 days post-discharge
- The evaluable group included 54 participants who were compliant (study product intake of at least 50%) with the feeding protocol to within 42 days post-discharge

Results:

- Patients in the intervention group had significant improvements in HGS vs the placebo* group ($p = 0.043$)
- At day 90, there was a significant positive association between HGS and nutritional status. Of those patients with increased HGS from discharge, 49% had improved nutritional status vs 31% with unchanged or decreased HGS ($p = 0.003$)

Conclusion:

Intervention ONS provided during hospitalisation and up to 90 days post-discharge improves HGS in malnourished older adults following cardiovascular and pulmonary events and may contribute to improvement in patients' overall recovery

Read the full study online

*Placebo: 48kcal, 12g carbohydrate, 10mg Vitamin C

NOURISH, Nutritional effect On Unplanned ReadmIssion and Survival in Hospitalised patients; ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; HGS, hand grip strength; ADL, activities of daily living

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

ORAL NUTRITIONAL SUPPLEMENT WITH β-HYDROXY-β-METHYLBUTYRATE (HMB) IMPROVES NUTRITION, PHYSICAL PERFORMANCE AND AMELIORATES INTRAMUSCULAR ADIPOSITY IN PRE-FRAIL OLDER ADULTS: A RANDOMIZED CONTROLLED TRIAL

Peng LN *et al. J Nutr Health Aging* 2021; 25(6):767–773

Study:

- 12-week, open-label, parallel group, randomised controlled trial
- The goal was to evaluate the effect of high protein ONS with HMB on muscle mass, muscle strength, physical performance and intramuscular adiposity among community-dwelling pre-frail older persons

Participants:

- 62 pre-frail community-dwelling participants (mean patient age of 71.1 ± 3.8 years) without active or uncontrolled conditions, disability or dementia completed the study
- Participants were randomly assigned to receive either 2 servings per day of a high protein ONS enriched with HMB, Ensure Plus Advance* (intervention group; n = 29) or professional nutritional counselling for sufficient protein intake (control group; n = 33) for 12 weeks

Results:

- At the 12-week mark, the intervention group showed significant improvements in mid-thigh muscle mass† ($p = 0.045$), serum levels of vitamin D ($p = 0.002$), body weight ($p = 0.005$) and BMI ($p = 0.019$) compared to the control group
- The IMAT-to-CSA ratio, which evaluates intramuscular adiposity,^ was reduced in the intervention group ($p = 0.06$).
  The chair stand test# SPPB score was significantly improved in the intervention group ($p = 0.026$)

Conclusion:

12-week supplementation with 2 daily servings of a high protein ONS enriched with HMB (Ensure Plus Advance*) significantly increased muscle mass, as well as nutritional status and physical performance, and ameliorated the intramuscular adiposity of pre-frail older persons

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*Ensure Plus Advance is known as Ensure Plus Strength in Australia
†Muscle mass was calculated using the cross-sectional area of muscle at the mid-thigh of the dominant leg using MRI
^IMAT was analysed using MRI
#Chair stand test records how fast a patient can stand up from a chair and sit back down 5 times, one after another
ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; BMI, body mass index; IMAT, intramuscular adipose tissue; CSA, cross-sectional area; SPPB, short physical performance battery; MRI, magnetic resonance imaging.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

SPECIALIZED HIGH-PROTEIN ORAL NUTRITION SUPPLEMENT IMPROVES HOME NUTRIENT INTAKE OF MALNOURISHED OLDER ADULTS WITHOUT DECREASING USUAL FOOD INTAKE

Loman BR, *et al. JPEN J Parenter Enteral Nutr* 2019;43(6):794–802

Study:

- Analysis of a subset of patients from the NOURISH study
- The goal was to evaluate the impact of a high-protein ONS with HMB on nutrient intake post discharge of older adults hospitalised with CHF, AMI, pneumonia or COPD

Participants:

- 30 older patients hospitalised with CHF, AMI, pneumonia or COPD who received standard of care plus 2 servings/day of either a high protein ONS with HMB (S-ONS; n = 14) or a placebo supplement* (n = 16) as part of the NOURISH study, completed 24-hour dietary recalls conducted on 3 randomly selected days during the weeks of 30, 60, and 90 days post discharge. Nutrient intake was estimated using Nutrition Data System for Research software. Adequate energy and protein intake were defined as 30 kcal/kg/d and 1.2 g/kg/d, respectively. DRIs were used for other nutrients

Results:

- In the S-ONS group, 50% and 71% of participants met their energy and protein goals respectively at 90 days (compared with 29% and 36% in the placebo group)
- In the S-ONS group, 100% of participants met their DRIs for carbohydrate, iron, phosphorus, copper, selenium, thiamin, and riboflavin at all time points, all of which were consumed at higher amounts vs placebo

Conclusion:

Two daily servings of a high protein ONS enriched with HMB over 3 months increases intake of numerous nutrients without decreasing nutrient intake from food in older malnourished adults post hospital discharge

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*Placebo supplement: 48 kcal, 12 g carbohydrate, 10 mg Vitamin C

NOURISH, Nutritional effect On Unplanned ReadmIssion and Survival in Hospitalised patients; ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate; CHF, congestive heart failure; AMI, acute myocardial infarction; COPD, chronic obstructive pulmonary disease; DRIs, Dietary Reference Intakes.

CARE CONTINUUM ✕ | INTERVENTIONS ✕ | MEDICAL CONDITIONS ✕

OXIDATIVE AND INFLAMMATORY EFFECTS OF PULMONARY REHABILITATION IN PATIENTS WITH BRONCHIECTASIS. A PROSPECTIVE, RANDOMIZED STUDY

Olveira C, *et al. Nutr Hosp* 2020;37(1):6–13

Study:

- Open, randomised controlled trial
- The goal was to evaluate the effect of PR in non-cystic-fibrosis bronchiectasis (NCFB) patients, and to compare it with the effect of PR and ONS with HMB on serum inflammatory and oxidative biomarkers

Participants:

- 30 normally nourished participants (mean patient age of 56.1 ± 13 years) with NCFB were assigned to a 12 week program of either PR alone (n = 15) or PR+ONS (n = 15)
- PR = Exercise program of 60 minute sessions, 3 times a week; ONS = Ensure Plus Advance* with HMB taken at least 60 minutes before each exercise session

Results:

- The PR+ONS group showed significantly lower neutrophil levels at 6 months than at baseline (p = 0.01)
- Neutrophil levels were the only blood cells that showed statistically different fold-change percentages according to ONS intake status, being positive in the PR group but negative in the PR+ONS group (p = 0.01)

Conclusion:

Results suggest a possible beneficial effect of Ensure Plus Advance* with HMB on the reduction of neutrophil levels, a systemic inflammatory biomarker, in NCFB patients

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia

PR, pulmonary rehabilitation; NCFB, non-cystic-fibrosis bronchiectasis; ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate.

MULTICOMPONENT REHABILITATION AFTER COVID-19 FOR NURSING HOME RESIDENTS

Zana S, *et al. J Am Med Dir Assoc* 2021;22(7):1358–1360

Study:

- Single arm exploratory study
- The goal was to evaluate the effect of 1 daily serving of a multicomponent nutritional supplement containing 1.5 g of CaHMB together with a physical rehabilitation program on the recovery of nursing home residents previously affected by COVID-19

Participants:

- 28 nursing home residents previously affected by COVID-19 (mean patient age of 87.8 ± 7.3 years), within 3 days from the naso-pharingeal swab testing negative to COVID-19, participated in a physical rehabilitation program (at least 3 days a week) and received 1 daily serving of an ONS containing 1.5 g CaHMB for 30 days

Results:

- At the 30-day mark, the residents significantly improved in mean Barthel Index*, in terms of activities of daily living ($p < 0.001$), mobility ($p < 0.001$), and total score ($p < 0.001$) from baseline
- The risk of pressure sores** was significantly reduced at 30 days compared with baseline ($p < 0.001$)
- Compliance was high with 85% of participants consuming the supplementation every day

Conclusion:

1 daily serving of an ONS containing 1.5 g CaHMB and physical rehabilitation were able to significantly improve disability and reduce the risk of pressure sores in nursing home residents previously affected by COVID-19

Read the full study online

*The presence of disability was assessed using the Barthel Index and its 2 main domains, that is, Barthel activities of daily living and mobility.
**The risk of pressure scores was assessed using the Exton-Smith scale.
CaHMB, calcium beta-hydroxy beta-methylbutyrate; ONS, oral nutritional supplement.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

SKELETAL MUSCLE ENERGETICS AND MITOCHONDRIAL FUNCTION ARE IMPAIRED FOLLOWING 10 DAYS OF BED REST IN OLDER ADULTS

Standley RA, *et al. J Gerontol A Biol Sci Med Sci* 2020;75(9):1744–1753

Study:

- Prospective, randomised, double-blinded, placebo-controlled trial
- The goal was to evaluate the effects of bed rest on mitochondrial energetics in muscle from older adults, and to examine the effect of HMB supplementation on mitochondrial energetics

Participants:

- 20 older adults before and after a 10-day bed rest, who consumed 2 servings per day of an ONS either with 3.0 g/d HMB (HMB, n = 11) or without HMB (CON, n = 9), were included in the analysis

Results:

- At the 10-day mark, there was a significant down-regulation of ribosome, oxidative metabolism and mitochondrial gene transcripts following bed rest in the CON group. Alterations to these gene transcripts were significantly blunted in the HMB group

Conclusion:

10 days of bed rest in older adults causes a significant deterioration in mitochondrial energetics, while some of these negative effects may be attenuated by an ONS containing HMB.

Read the full study online

HMB, beta-hydroxy beta-methylbutyrate; ONS, oral nutritional supplement; CON, control.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

BIOMARKER CHANGES IN RESPONSE TO A 12-WEEK SUPPLEMENTATION OF AN ORAL NUTRITIONAL SUPPLEMENT ENRICHED WITH PROTEIN, VITAMIN D AND HMB IN MALNOURISHED COMMUNITY DWELLING OLDER ADULTS WITH SARCOPENIA

Pereira SL, *et al. Nutrients* 2022;14(6):1196

Study:

- Analysis of serum biomarkers from a subset of participants of a previous randomised, double-blinded, controlled trial
- The goal was to determine if the intervention ONS containing HMB (Ensure Plus Advance*) modulated additional biomarkers beyond those modulated by a standard ONS without HMB (Ensure Plus) among older patients with malnutrition and sarcopenia

Participants:

- 193 older patients (median age 77 years, 61.1% females) with or at risk for malnutrition and with sarcopenia who were receiving 2 servings per day of either the standard control ONS (n = 103) or intervention ONS (n = 90), and who had fasted blood samples collected at baseline and 12 weeks post-intervention

Results:

- At the 12-week mark, 16 biomarkers significantly changed in response to both standard control and intervention ONS, including nutritional and metabolic markers
- 13 biomarkers significantly changed in response to intervention ONS but not standard control ONS. Increases in immunoglobulins, myoglobin, total protein, vitamin E and magnesium were observed with the intervention ONS. Inflammation-related ferritin and osteopontin decreased, while soluble receptors for cytokines increased, suggesting decreased inflammation. Sex hormone-binding globulin associated with sarcopenia also decreased with intervention ONS

Conclusion:

Biomarkers reflective of multiple biological systems were impacted by nutritional intervention in sarcopenic older adults. Additional biomarker changes were observed in response to Ensure Plus Advance* containing HMB that possibly link to improvements in skeletal muscle health.

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia
ONS, oral nutritional supplement; HMB, beta-hydroxy beta-methylbutyrate.

CARE CONTINUUM ✕ | INTERVENTIONS ✕ | MEDICAL CONDITIONS ✕

AMINO ACID PROFILE IN MALNOURISHED PATIENTS WITH LIVER CIRRHOSIS AND ITS MODIFICATION WITH ORAL NUTRITIONAL SUPPLEMENTS: IMPLICATIONS ON MINIMAL HEPATIC ENCEPHALOPATHY

Espina S, *et al. Nutrients* 2021;13(11):3764

Study:

- Post hoc analysis of a 12-week, double-blind, randomised controlled trial
- The goal was to identify a metabolic signature of minimal hepatic encephalopathy (MHE) in malnourished cirrhotic patients and evaluate its modification with ONS enriched with HMB

Participants:

- 43 patients with cirrhosis and malnutrition (median patient age of 64.4 years) who received two servings per day of either an ONS enriched with HMB, Ensure Plus Strength (HMB group, n = 22), or a high protein ONS, Ensure Plus High Protein (HP, no HMB group, n = 21), for 12 weeks

Results:

- From baseline to 12 weeks, HMB treatment reduced the MHE prevalence from 38% to 21% ($p = 0.16$) vs no reduction in the HP group (19% to 21%, $p = 1$).
- MHE was associated with a reduced total plasma amino acid concentration, a reduced BCAA and Fischer's ratio, and an increased Gln/Glu ratio
- Compared with the HP group, HMB-enriched ONS led to a larger increase in Val (35% vs. 13%, $p = 0.055$), Leu (27% vs. 1%, $p = 0.035$), Phe (36% vs. 0%, $p = 0.057$), Trp (35% vs. 11%, $p = 0.066$) and BCAA fasting plasma levels (25% vs. 3%, $p = 0.046$)
- Both groups increased Fischer's ratio (BCAA/AAA) ($p = 0.013$) without differences between treatments, although an upward trend was observed in the HMB group

Conclusion:

MHE events were nearly halved in individuals with cirrhosis and malnutrition supplemented with HMB-enriched ONS after 12 weeks of treatment. Furthermore, HMB-enriched ONS increased Fischer's ratio by increasing BCAA levels in a greater proportion than AAA levels, without varying Gln or ammonia plasma levels, a protective amino acid profile that can help prevent MHE.

Read the full study online

MHE, minimal hepatic encephalopathy; ONS, oral nutritional supplement ; HMB, beta-hydroxy beta-methylbutyrate; HP, high protein; BCAA, branched chain amino acids; Gln/Glu ratio, Glutamine-to-glutamate ratio; AAA, aromatic amino acids.

CARE CONTINUUM × | INTERVENTIONS × | MEDICAL CONDITIONS ×

EFFECT OF AN ORAL NUTRITIONAL SUPPLEMENT WITH β-HYDROXY-β-METHYLBUTYRATE AND VITAMIN D ON MORPHOFUNCTIONAL ASPECTS, BODY COMPOSITION, AND PHASE ANGLE IN MALNOURISHED PATIENTS

Cornejo-Pareja I, *et al. Nutrients* 2021;13(12):4355

Study:

- Retrospective analysis of a hospital database
- The goal was to evaluate the effect of Ensure Plus Advance* with HMB on nutritional status, body weight, and muscle-related parameters in adult patients with or at risk of malnutrition under standard of care, majority being cancer patients

Participants:

- 283 adult patients with or at risk of malnutrition under standard of care, 63% being cancer patients (mean patient age 60.9) were included in the analysis
- Patients received exercise and dietary counselling combined with either Ensure Plus Advance* (n = 240) or standard ONS† (n = 43), twice daily for up to 6 months

Results for entire cohort:

- Over 65% of patients took more than 75% of the recommended dose of 2 serves/day
- Nutritional status, body weight and BMI significantly improved from baseline in both groups
- In the Ensure Plus Advance* group, fat-free mass significantly increased from baseline by 1.3 kg ($p < 0.05$), but did not significantly increase in the standard ONS group
- Estimated increase in handgrip strength was higher in patients receiving Ensure Plus Advance* compared with those receiving standard ONS (6.2 kg vs 4.7 kg), but the difference did not reach statistical significance
- Inflammatory marker CRP/prealbumin ratio significantly decreased from baseline in the Ensure Plus Advance* group ($p < 0.05$) but not in the standard ONS group, which points to a higher anti-inflammatory effect vs standard ONS group

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia
†Standard ONS contained 206-320 kcal, 10.7-20 g protein, 7.8-13 g fat, 25.5-37.7 g carbohydrates
HMB, beta-hydroxy beta-methylbutyrate; ONS, oral nutritional supplement; BMI, body mass index; CRP, C Reactive Protein.

Results for subgroup tested by PhA (n = 43):

Parameters obtained by BIVA, including phase angle (PhA) and body cell mass (BCM), were measured in a subgroup of 43 patients (Ensure Plus Advance*; n = 31; standard ONS† n = 12):

- PhA^ increased by 0.95 degrees only in the Ensure Plus Advance* group (vs -0.36 for standard ONS). An increase of one degree in PhA has been associated with higher survival rates in different conditions such as advanced cancer and ICU
- BCM# increased by 2.98 kg from baseline only in the Ensure Plus Advance group (vs -0.6 kg for standard ONS)

Results for subgroup of oncology patients receiving Ensure Plus Advance* (n = 155):

In a subgroup of cancer patients (n = 155) with or at risk of malnutrition, receiving Ensure Plus Advance* at 2 serves/day combined with dietary counselling and exercise recommendations for 3-6 months:

- Nutritional status was improved from baseline where 100% of patients were considered 'malnourished or at risk of malnutrition' vs after the program where 70% of patients were considered 'well-nourished'
- HGS significantly increased by 6.9 kg (37%) ($p < 0.05$)
- Body weight increased more than 3 kg (5%) ($p < 0.05$)
- BMI increased by 1.2 units (5%) ($p < 0.05$)
- FFM increased by 1.0 kg (2%) ($p < 0.05$)
- Inflammatory markers (CRP and CRP/prealbumin ratio) significantly decreased by 56% ($p < 0.05$)

Conclusion:

A program including dietary and strength exercise counselling together with the use of ONS is beneficial to support nutritional, clinical, and functional outcomes, especially those related to improved muscle health in adult patients with or at risk of malnutrition. Ensure Plus Advance* showed greater improvements in HGS, FFM and anti-inflammatory effects

*Ensure Plus Advance is known as Ensure Plus Strength in Australia
†Standard ONS group received: 206-320 kcal, 10.7-20 g protein, 7.8-13 g fat, 25.5-37.7 g carbohydrates
^PhA, measured by BIVA, is a good predictor of muscle abnormalities and function with a good diagnostic accuracy for detecting low muscle mass in cancer patients
#BCM, measured by BIA and height data, is an indicator of muscle mass and is not affected by hydration status

PhA, Phase Angle; BIVA, Bioelectrical Impedance Vector Analysis; BCM, Body Cell Mass; ONS, oral nutritional supplement; BIA, Bioelectrical Impedance Analysis; ICU, intensive care unit; HGS, Handgrip Strength; BMI, Body Mass Index; FFM, Fat Free Mass; CRP, C Reactive Protein.

CARE CONTINUUM | INTERVENTIONS | MEDICAL CONDITIONS

EFFECT OF HOME-BASED PREHABILITATION IN AN ENHANCED RECOVERY AFTER SURGERY PROGRAM FOR PATIENTS UNDERGOING COLORECTAL CANCER SURGERY DURING THE COVID-19 PANDEMIC

López-Rodríguez-Arias F, *et al. Support Care Cancer* 2021;29(12):7785–7791

Study:

- A prospective, randomised controlled study
- The goal was to evaluate the effect of home-based prehabilitation (PH), including ONS, on body composition, post-operative complications and hospital stay in patients undergoing oncological colorectal surgery

Participants:

- 20 patients (median patient age of 66 years) undergoing elective surgery for colorectal cancer during COVID-19 lockdown
- Participants were randomly allocated into two study groups: Prehabilitation (ERAS plus PH) (n = 10) vs Standard Care (ERAS without PH) (n = 10). PH was performed at home for 30 days before the surgery and the first 30 days after hospital discharge and included physical exercise, relaxation exercises, and nutritional supplementation with Ensure Plus Advance* containing HMB

Results:

- PH reduced hospital stay (4.8 vs 7.2 days, $p = 0.052$) and postoperative complications (20% vs 50%, $p = 0.16$) compared with the standard care group
- 45 days after surgery, the loss of lean mass was lesser in the PH group compared with the standard care group (1.7% vs 7.1%, $p = 0.17$)
- These differences in lean mass were attenuated at 90 days, however, the standard care group had increased fat mass while the PH group had decreased fat mass (+8.72% vs -8.16%)

Conclusion:

Home-based PH (including Ensure Plus Advance*) has been shown to be effective in attenuating loss of lean mass in the early postoperative period and decreasing fat mass in the late postoperative period. In addition, its inclusion in ERAS protocols has reduced length of hospital stay and postoperative complications

Read the full study online

*Ensure Plus Advance is known as Ensure Plus Strength in Australia

PH, prehabilitation; ONS, oral nutritional supplement; ERAS, Enhanced Recovery After Surgery; HMB, beta-hydroxy beta-methylbutyrate.