Development of a Core Outcome Set for nutritional intervention studies in older adults with malnutrition and those at risk

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Background: Malnutrition (i.e., protein-energy malnutrition) in older adults is associated with significant complications and increased mortality, highlighting the need for effective treatments. Many randomized controlled trials (RCTs) testing the effectiveness of nutritional interventions for the treatment of malnutrition showed mixed results and there is a need for meta-analyses. However, evidence synthesis is hampered by the wide variety of outcomes and assessment methods in RCTs. This project, led by EuGMS Special Interest Group Nutrition, aims to develop a Core Outcome Set (COS) for nutritional intervention studies in older adults with malnutrition and those at risk.

Methods: The project consists of five phases: 1) a scoping review (completed) to identify frequently used outcomes in published RCTs and select additional patient-reported outcome measures (PROMs). Patient and Public Involvement (PPI) representatives have been involved to provide feedback on the proposed list of outcomes resulting from the review and PROMs; 2) a modified Delphi Survey whereby experienced researchers and health care professionals working in the field of malnutrition in older adults will be invited to rate the importance of the proposed outcomes; 3) a consensus meeting to discuss and agree what critical outcomes need to be
included in the COS; 4) a systematic review to determine how each COS outcome should be measured and a second consensus meeting; 5) a dissemination and implementation phase.

Conclusions: The result of this project will be a COS that should be included in any RCT testing the effectiveness of interventions to tackle malnutrition in older people as a minimum. This COS will facilitate comparison of RCT results, will promote efficient use of research resources and might reduce bias in measurement of the outcome and publication bias. Ultimately, the COS will support clinical decision making by identifying the most effective approaches for treating and preventing malnutrition in older adults.