

*e-table 5***Ethical and practical limitations in the design and implementation of randomised controlled trials to establish effectiveness of nutrition interventions****need large numbers of patients and multicentre trials to provide sufficient power**

- aetiology of undernutrition is complex and multifactorial
- patient groups extremely heterogeneous
- clinical course and severity of disease/surgery are major confounders
- variation in treatment/procedures between study sites

effect most likely to be seen in undernourished

- although under 'usual care' many cases unrecognised and untreated, once identified cannot withhold intervention
- placebo enteral/parenteral feeding unethical
- blinding impossible
- consent to 'no treatment' difficult

individual requirements may not be met and effect diluted

- current methods of estimation of energy requirements will theoretically underestimate need for 50% of individuals
- need to individualise nutrition support prescription adds complexity
- too little nutrition support given for too short a period of time
- compliance with oral supplements notoriously poor, volumes frequently inadequate, delivery unreliable
- prescribed enteral intakes often not met, feeding frequently interrupted

outcomes rarely include quality of life

trials very expensive, funding most likely from companies marketing formulae, therefore independence of data could be questioned