Preoperative low-energy diets for patients with body mass index >30kg/m² undergoing non-bariatric surgery: A pilot feasibility randomized clinical trial (RCT) and a systematic review and meta-analysis of efficacy data

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1 Background

- Obesity (BMI ≥30 kg/m) increases intraoperative difficulty and postoperative complications.
- Preoperative low-energy diets (LEDs) are standard in bariatric surgery for preoperative weight loss.
- Evidence in non-bariatric surgery is limited and of low quality.

Evidence Gaps:

- **No adequate RCT** evaluating LED before major non-bariatric surgery
- **Feasibility of trial unknown**

Objective: To determine the feasibility of a multi-centered RCT evaluating preoperative LED diets in patients with BMI ≥30 kg/m² undergoing major non-bariatric surgery.

2 Methods

Study Design

- Multicenter, 1:1 parallel pilot RCT (Canada, 4 sites)
- Registered on CTO: NCT03935451

- **Blinding**
  - Surgeon
  - Outcome assessor
  - Statistician

Patients older than 18 years of age with BMI≥ 30 kg/m2 undergoing elective non-bariatric surgery.

- Recruitment required≥ 3 weeks before surgery

Intervention:

- *LED group*
  - 3-week 920kca/day total diet replacement with Medimeal®
  - 4 meal replacements every/day
  - Up to 2 cups of non-starchy vegetables daily + zero-cal fluids
- *Control*
  - Standard preoperative care

Outcomes

1. Feasibility outcomes: recruitment rate, randomization percentage, adherence, f/u completion.
2. Clinical outcomes: Pre-op weight change, waist circumference, grip strength, 30-day morbidity.

Statistical Analysis

- Descriptive analyses with 95% confidence intervals
- Random-effects meta-analysis (DerSimonian–Laird) reporting risk ratios (RR) with 95% CI and I^2

3 Conclusions

Randomization:
373 patients screened → **91 randomized**

LED Group: n=45 **Control Group:** n=46

Feasibility Outcomes :

- Recruitment Rate: 9.4 patients/month (below target)
- Follow-up completion: 89% (below 90% threshold) (89%, 95%CI 80.7-94.6%)
- LED adherence: 81.7% (met feasibility criteria) (95%CI 74.1-89.3%)

∴ Yellow-light (57.3% of eligible patients consented)
(95%CI 51.4-63.1%)

Clinical Outcomes:

- LED Group
  - Lost significantly more weight (mean difference of 4.6kg) (95% CI 3.5–5.6 kg)
  - Waist circumference decreased by 3.6cm more than in the control group
  - Grip strength preserved

Meta-Analysis Results:

RCTs included (n=5)
Pooled analysis demonstrated an 18% relative risk reduction in 30-day postoperative morbidity, favouring LEDs.
(RR 0.82, 95% CI 0.52–1.28; I^2=0%)

4 Conclusions

VLE diets in non-bariatric surgery patients were **safe, well-tolerated, and produced meaningful short-term weight loss** without grip strength loss.

RCT results showed potential **reduction of postoperative morbidity**.

Although recruitment and follow-up targets were unmet, adherence was acceptable, and feasibility may improve with more sites and protocol adjustments.

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