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Online-Only Supplement:

**Early oral protein-containing diets following elective
lower gastrointestinal tract surgery in adults:
A meta-analysis of randomized controlled trials.**

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16 Dec 2020

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PubMed, Embase and CNKI search terms

PubMed search terms:

The MEDLINE subject heading terms used to identify the nutritional support literature included:

nutrition therapy [MeSH terms] or nutritional support [MeSH terms] or nutrition phenomena [MeSH terms] or nutrition processes [MeSH terms] or nutrition disorders [MeSH terms] or nutrition assessment [MeSH terms]

These nutrition related terms were crossed with MEDLINE terms to restrict the results to RCTs conducted in patients undergoing large bowel surgery:

("lower gastrointestinal tract"[MeSH Terms] OR ("lower"[All Fields] AND "gastrointestinal"[All Fields] AND "tract"[All Fields]) OR "lower gastrointestinal tract"[All Fields]) OR ("intestine, large"[MeSH Terms] OR ("intestine"[All Fields] AND "large"[All Fields]) OR "large intestine"[All Fields] OR ("large"[All Fields] AND "bowel"[All Fields]) OR "large bowel"[All Fields]) OR ("colectomy"[MeSH Terms] OR "colectomy"[All Fields]) OR (("colostomy"[MeSH Terms] OR "colostomy"[All Fields]) AND colorectal[All Fields]) OR ("colon"[MeSH Terms] OR "colon"[All Fields]) OR ("administration, rectal"[MeSH Terms] OR ("administration"[All Fields] AND "rectal"[All Fields]) OR "rectal administration"[All Fields] OR "rectal"[All Fields]) OR ("rectum"[MeSH Terms] OR "rectum"[All Fields])

AND

("surgery"[Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgery"[All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields]) OR ("surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgical"[All Fields]) OR operat\$[All Fields] OR postoperati\$[all]

AND broad MeSH terms to identify RCTs:

((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])

Embase search terms:

The EMTREE terms used to identify the nutritional support literature included:

diet therapy/ or nutritional support/ or nutritional disorder/ or nutritional assessment/ or nutritional deficiency/ or feeding behaviour/ or nutritional status/ or overnutrition/

These nutrition related terms were crossed with EMTREE terms to restrict the results to RCTs conducted in large bowel surgery patients:

(random or clinical trial or randomised or randomized or randomized controlled trial or randomised controlled trial).mp

AND

(surgery or surgical or operat\$ or post-operat\$ or postoperat\$).tw

AND

(lower gastrointestinal or large bowel or colectomy or colostomy or colorectal or colon or rectal or rectum).tw

China National Knowledge Infrastructure search terms:

The CNKI subject heading terms used to identify the nutritional support literature included:

营养生理学现象 or 营养疗法 or 营养支持 or 营养状况 or 营养评价 or 肠道营养 or 营养需要 or 胃肠外营养 or 胃肠外营养, 全 or 营养价值

AND

结肠切除术 or 直肠结肠切除术, 重建性 or 结肠造口术

AND

随机分配 or 随机对照试验 or 临床试验

eTable 1: RCTs excluded after detailed review.

Study	Patient population	Protocol specified early nutrition intervention	Reasons for exclusion
Boelens ¹ 2014	Major rectal surgery	POD 1: on the day of surgery (day 0), 8 hours after ending the surgical procedure, enteral nutrition (Nutrison Protein Plus Multi Fibre, Nutricia) was started at 500 mL/24 hours. The next day (day 1 postoperative), at 8 o'clock in the morning, the continuous infusion was increased to 1 L/24 hours; on day 2, the infusion was increased to 2 L/24 hours. Early EN compared to early PN (Kabiven Central with Dipeptiven, Fresenius Kabi) . PN protocol same as EN protocol above.	Mortality not explicitly reported. Both groups received early protein.
Behrns ² 2000	Elective intestinal surgery.	Clear liquid diet commenced on POD 2.	No early protein.
Binderow ³ 1994	Elective laparotomy with either a colonic or ileal resection.	Regular solid food on morning of POD 1.	Mortality not explicitly reported.
Cao ⁴ 2009	Postoperative colorectal cancer.	POD 1: Began 5% Glucose 500ml; POD 2: Enteral nutrition (Peptison, NUTRICIA) 500ml and 5% Glucose injection 500ml; POD 3: Peptison 500ml to 1500ml on the third POD, progressed to Peptison 100ml/h on the fourth to seventh POD.	No early protein.
Chatterjee ⁵ 2012	Gastrointestinal anastomosis and uncomplicated simple biliary-enteric anastomosis (choledochoduodenostomy) on an emergency or elective basis.	"Oral liquids" (25ml/hr) were started within 24 hours of operation in group A with clamping the NGT.	Early protein <i>possible</i> , but not explicit in protocol. 'Oral liquids' protein content not described.
Chen ⁶ 2015	Surgery for colorectal cancer.	Water was started on POD 1, water and a small amount of EN was taken repeatedly on POD 2. 1L of EN was taken repeatedly on POD 3 followed by a small amount of liquid food.	No early protein. Mortality not explicitly reported.
Chen ⁷ 2010	Surgery for colorectal cancer.	Liquid diet was began within 24 hours after surgery, and then gradually continued to solid diet.	Mortality not explicitly reported.
Da Fonseca ⁸ 2011	Colorectal resections.	'Oral liquid diet' commenced on POD 1.	Early protein <i>possible</i> , but not explicit in protocol. 'Oral liquid diet' protein content not described.

Dag ⁹ 2011	Colorectal surgery	Postoperative oral feeding commencing approximately 12 hours after the operation with a “fluid diet”.	Early protein <i>possible</i> , but not explicit in protocol. ‘Fluid diet’ protein content not described.
Delaney ¹⁰ 2003	Patients scheduled for elective segmental intestinal or rectal resection by laparotomy.	On Postoperative Day (POD) 1, patients were encouraged to walk at least one circuit of the nursing floor (approximately 60 meters) up to five times, to sit out of bed between walks, and to do regular incentive spirometry. They were allowed noncarbonated liquids <i>ad libitum</i> and were offered solid food that evening if tolerating oral fluids.	Mortality not explicitly reported.
El Nakeeb ¹¹ 2009	Elective colonic anastomosis.	Patients began fluids on the first postoperative day and advanced to a regular diet within the next 24–48 h, as tolerated (indicated by an absence of vomiting or abdominal distension).	Early protein <i>possible</i> , but not explicit in protocol. ‘Fluids’ protein content not described.
Feo ¹² 2004	Colorectal resection.	Patients were ‘ allowed to drink ’ the day after the operation, eat a soft diet the following day regardless of the passage of flatus, and were then advanced to solid food as tolerated.	Early protein <i>possible</i> , but not explicit in protocol. ‘Fluids’ protein content not described.
Han ¹³ 2012	Surgery for colorectal cancer.	Liquid diet was begun within 6-8 hours.	Mortality not explicitly reported.
Han-Geurts ¹⁴ 2001	Elective abdominal surgery including open colonic surgery and transabdominal central vascular reconstruction procedures.	Patients were assigned to a patient-controlled (PC) diet after surgery of a fixed regimen (FR). Patients in the PC group chose when to start an oral diet. There was no motivation to start early. Patients in the FR group started water on POD 0 and 1. On POD 2 a ‘liquid diet’ was commenced. Liquid diet was defined as water, tea, coffee, lemonade.	No early protein.
Han-Geurts ¹⁵ 2007	Elective open colorectal or abdominal vascular surgery.	Patients were assigned to a conventional dietary regimen or a diet of their own choice. There was no motivation to start early. Patients in the conventional diet group started water on POD 0 and 1. POD 2 and 3, they continued with a ‘liquid diet’ defined as water, tea, coffee and lemonade.	No early protein.
Hartsell ¹⁶ 1997	Elective colorectal surgery.	Commence ‘ liquid diet ’ on POD 1, advance to regular diet when they consumed 1L in 24 h.	Early protein <i>possible</i> , but not explicit in protocol. Protein content of ‘liquid diet’ not described.
He ¹⁷ 2016	Elective resection for colorectal carcinoma.	Water was begun on POD 1, followed by 500ml of enteral nutrition on POD 2.	No early protein. Mortality not explicitly reported.

Hoover ¹⁸ 2000	Extensive esophageal, gastroduodenal, biliary or pancreatic procedures.	Immediate post-op elemental diet via jejunostomy catheter vs. IV glucose.	Not lower GI tract surgery. Mortality not explicitly reported.
Kemen ¹⁹ 1995	Upper GI malignancies.	On POD 1, patients were randomized to receive either the arginine, RNA, and omega-3 fatty acids supplemented diet or an isocaloric and isonitrogenous placebo diet.	Not lower GI tract surgery. Both groups received early protein.
Lee ²⁰ 2011	Laparoscopic colon surgery.	Patients were allowed to take water (less than 1 L) immediately after the operation. They progressed to semifluid diet on POD 1 and commenced a regular diet in 2 days after surgery.	Early protein <i>possible</i> , but not explicit in protocol. Protein content of 'semifluid diet' not described.
Li ²¹ 2006	Postoperative colorectal cancer	POD 1: Began 5% Glucose 500ml through jejunostomy tube ; POD 2: Enteral Nutrition (Peptison, NUTRICIA) 1500ml to 2000ml and continued until POD 7.	No early protein.
Lidder ²² 2013	Colorectal surgery.	Pre-op carbohydrate and Post-op protein drink (factorial design). In the postoperative period patients were given polymeric nutritional supplement drink or placebo (600 ml/day) from the period immediately after their operation until discharge. Patients in the supplement group consumed Fortifresh (Numico, Zoetermeer, the Netherlands). All patients received "free fluids permitted immediately after surgery and a light diet as tolerated by the patient."	Both groups received early protein. This trial compares 'standard' early protein (light diet from POD 1) to 'standard' early protein (light diet from POD 1) <i>plus</i> protein supplement drink.
Lucha ²³ 2005	Elective open GI surgery. Over half procedures were lower GI.	Early management consisted of bowel rest for 8 hours after completion of surgery followed by a regular diet . Traditional management consisted of bowel rest until the passage of flatus, followed by 24 hours of clear liquids and advancement to a regular diet.	Mortality not explicitly reported.
MacFie ²⁴ 2000	Majority colorectal (94%)	Pre-op carbohydrate and Post-op protein drink (factorial design). On POD 1, patients were randomized to normal diet or normal diet plus protein supplement drink (Fortisip, Nutricia Ltd., Towbridge, Wiltshire, UK).	Both groups received early protein. This trial compares 'normal' early protein (normal diet from POD 1) to 'normal' early protein (normal diet from POD 1) <i>plus</i> protein supplement drink.

Nematihonar ²⁵ 2018	Colorectal anastomosis.	Early feeding after surgery was initiated by filtrate liquids within 24 h after surgery. Over the next 24 h, the liquid diet was replaced by a normal diet in case tolerance was desirable.	Early protein <i>possible</i> , but not explicit in protocol. Protein content of 'filtrate liquids' not described. Normal diet introduced later than 24 h after surgery.
Nessim ²⁶ 1999	Patients without stoma who underwent anorectal reconstructive surgery.	Study intervention (bowel confinement) patients received a clear liquid diet with loperamide 4 mg by mouth three times per day for three days, with codeine phosphate 30 mg by mouth four times per day for three postoperative days after the operation. Patients in the regular diet group began a regular diet on the day of surgery.	Mortality not explicitly reported.
Reissman ²⁷ 1995	Elective colorectal surgery with bowel resection.	Patients in the early feeding group began a clear liquid diet on the first postoperative day and advanced to a regular diet within the next 24 to 48 hours, as tolerated (absence of vomiting or abdominal distention). Control group received NPO until resolution of ileus.	No early protein.
Pragatheeswarane ²⁸ 2014	Elective open bowel surgery.	Clear liquid diet started at the 24 hour mark after surgery. Full fluid diet offered within 48 h and solid diet over next 24 h.	No early protein.
Qu ²⁹ 2011	Surgery for colorectal cancer.	Water was began within 2 hours of surgery and then a small amount of enteral nutrition was began after 2 hours, with total amount less than 600ml.	Mortality not explicitly reported.
Ren ³⁰ 2014	Surgery for colorectal cancer.	Water was began on POD 1, followed by water and 500ml of enteral nutrition on POD 2.	Mortality not explicitly reported. No early protein.
Ryan ³¹ 1981	Elective colectomy.	Early postoperative jejunal feeding (n=9) of elemental diet (Vivonex HN, 42 g/L protein) compared to intravenous isotonic glucose (n=7).	Mortality not explicitly reported.
Sagar ³² 1979	Major GI surgery. (>70% lower GI tract surgery)	Starting POD 1, for the first 24 hours elemental solution (Flexical) was infused at half strength solution at 25 ml/hour. Thereafter, undiluted Flexical was infused at 25 ml/hour on the second postoperative day, 50 ml/hour on the third postoperative day, and 100 ml/hour on the fourth and fifth days. Conventional patients received NPO for two days.	Mortality not explicitly reported.
Sharma ³³ 2013	Colorectal surgery.	Standard Hospital Diet includes free fluids allowed immediately postoperatively with a standard diet offered to all the patients from day 1. Patients were randomized to Standard Hospital Diet or Standard Hospital Diet plus protein drink supplements (Pro-Cal).	Both groups received early protein. This trial compares 'normal' early protein (standard hospital diet from POD 1) to 'normal' early protein (standard hospital diet from POD 1) <i>plus</i> protein supplement drink.

Schroeder ³⁴ 1991	Bowel resection. (>90% received lower GI tract procedures.)	On arrival back at the ward from the recovery room, the patient was assessed and immediate nasojejunal infusion with full-strength Osmolite (Ross Laboratories) at 50 mL/h via a continuous infusion pump was commenced. The control group received 5% dextrose plus oral fluids and food recommenced at the discretion of the clinical team, usually depended on the presence of bowel sounds and passage of flatus.	Mortality not explicitly reported.
Smedley ³⁵ 2004	Lower GI tract surgery.	Pre-op carbohydrate and Post-op protein drink (factorial design). Protocol does not prescribe early normal diet or early protein drink intake. All patients received standard postoperative care with commencement of free fluids and reintroduction of normal diet without interference by the study team or protocol. Patients randomized to standard diet plus supplement were encouraged to drink Fortisip (Nutricia) ad libitum in small, frequent quantities between meals.	No early protein.
Soliani ³⁶ 2001	Major surgery of the abdomen and pelvis.	Compares early PN vs. early EN vs. early immunoenhanced EN. No differences in time to receiving protein between groups (ePN, eEN and eEIN).	All three groups received early protein.
Wang ³⁷ 2015	Postoperative colorectal cancer.	Water was began on POD 1, followed by water and 500ml of enteral nutrition on POD 2	Mortality not explicitly reported. No early protein.
Wang ³⁸ 2013	Postoperative colorectal cancer.	POD 1: Began small amount of water orally ; POD 2: progressed to Enteral Nutrition (Jevity, Abbott) 500 ml and water; POD 3: EN 1000 ml and Liquid diet on the third POD (Jevity, Abbott) 1000 ml , added Liquid diet on the fourth, and continued on the fifth POD .	No early protein.
Wu ³⁹ 2007	Malnourished patients undergoing elective GI cancer surgery (65% had gastrectomy, 35% had colon or rectal surgery)	Randomized to three groups: Commenced on POD 1, compares 1) control (5% and 10% glucose IV and later normal diet) vs. 2) early EN vs. 3) early PN.	Mortality not explicitly reported for colorectal surgery patients.
Wu ⁴⁰ 1996	Gastrointestinal disease surgery.	Randomized to three groups: Commenced on POD 1, compares 1) control (5% and 10% glucose IV and later normal diet) vs. 2) early EN vs. 3) early PN.	Mortality not explicitly reported. Abstract only.
Wu ⁴¹ 2000	Gastrointestinal disease surgery.	Randomized to three groups: Commenced on POD 1, compares 1) control (5% and 10% glucose IV and later normal diet) vs. 2) early EN vs. 3) early PN.	Mortality not explicitly reported. Abstract only.

Wu ⁴² 2012	Postoperative colorectal cancer	Started within 24 h of surgery: 500mls of protein drink (Ensure, Abbott) . POD 2: 1000 mls of protein drink; POD 3: 1500 mls of protein drink, continued until POD 7. Compared to Parenteral Nutrition (glucose, amino acids and lipids) until POD 7. PN was commenced within 24 h of completion of surgery.	Both groups received early protein.
Xu ⁴³ 2012	Postoperative colorectal cancer	Water was began within 6 hours after surgery, enteral nutrition was started on POD 1.	Mortality not explicitly reported.
Yang ⁴⁴ 2013	Postoperative colorectal cancer	Oral intake of 30ml to 50ml Ensure (US Abbott) 6 to 12 hours post-surgery at 1- to 2-hours intervals. Progressed to 100ml to 200ml Ensure at 2- to 3- hours intervals on POD 2. POD 3 to 4; started with liquid diet and gradually changed to a regular diet .	Mortality not explicitly reported.
Zhou ⁴⁵ 2006	Colorectostomy.	Early feeding patients were provided immediately water and gradually to a liquid fiberless diet after one day, and a semi-liquid fiber diet after three days. Control patients commenced nutrition after passage of flatus.	Mortality not explicitly reported. Early protein <i>possible</i> , but not explicit in protocol. Protein content of 'liquid fiberless diet' not described.

CNKI: Identified by searching China National Knowledge Infrastructure, **EN:** enteral nutrition, **PN:** refers to a parenteral nutrition solution containing protein.

eFigure 1. Risk of bias summary figure.

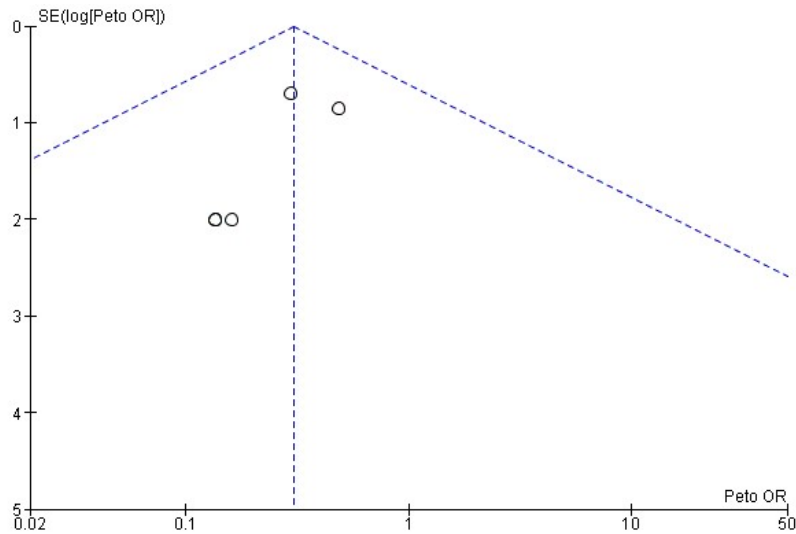
Study	Allocation concealment	Use of any form of blinding	Incomplete outcome data (loss to follow-up exceeds 10%)	Sequence generation*	Reporting bias**
Beier-Holgersen 1996	●	●	●	●	●
Carr 1996	●	●	●	●	●
Lau 2014	●	●	●	●	●
Minig 2009	●	●	●	●	●
Mulrooney 2005	●	●	●	●	●
Ortiz 1996	●	●	●	●	●
Shen 2013	●	●	●	●	●
Stewart 1998	●	●	●	●	●

- Low risk of bias
- Unclear risk of bias
- High risk of bias

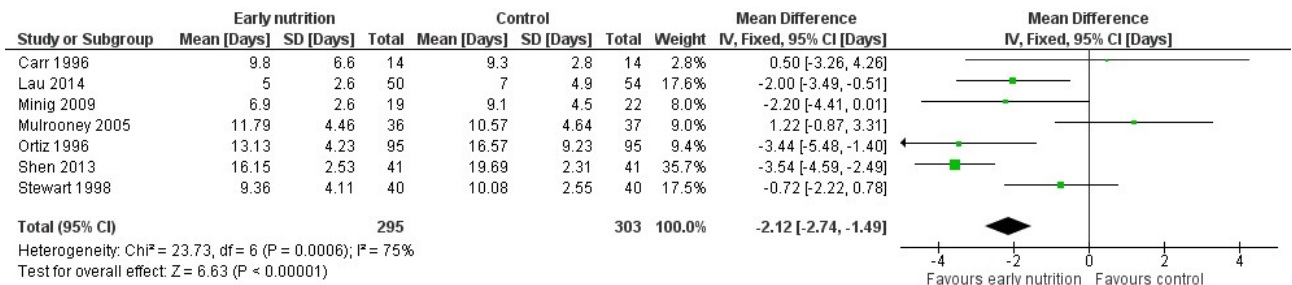
* Complete reporting of Sequence generation procedures helps improve confidence the study is not at high risk of selection bias and should be interpreted in context of Allocation concealment.

** Selective reporting is best interpreted in the context of an a priori published study Protocol. No studies reported publicly available a priori published Protocols.

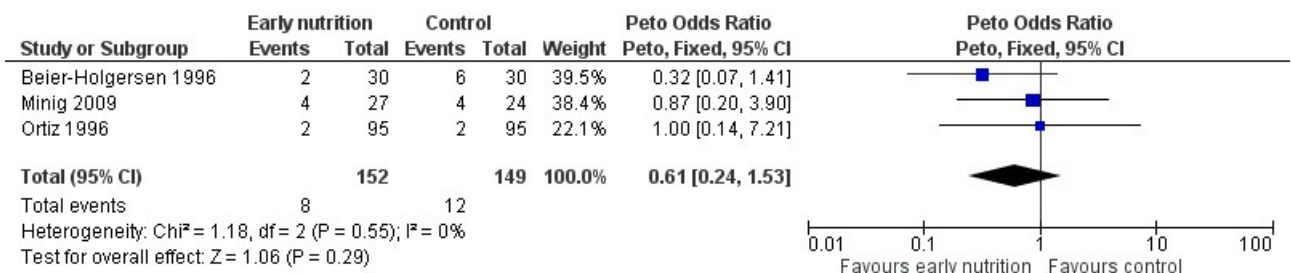
eFigure 2. Funnel plot for publication bias. Primary outcome (mortality).



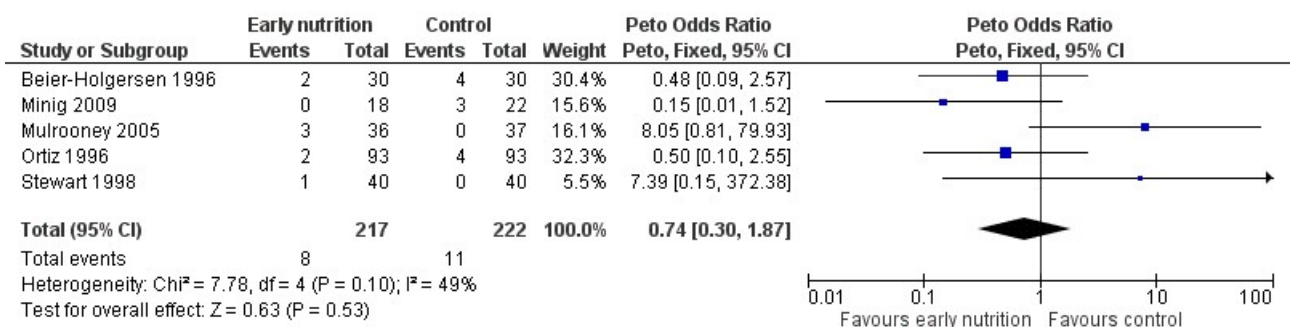
eFigure 3: Duration of hospital stay



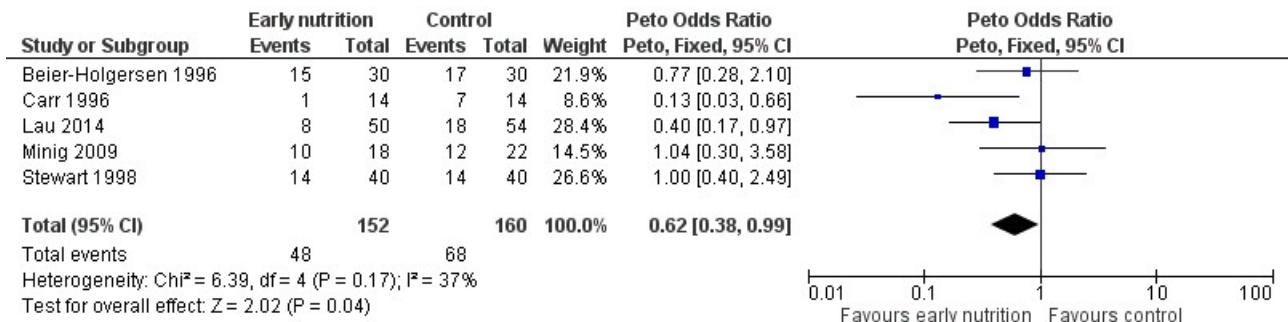
eFigure 4: Need for ICU admission



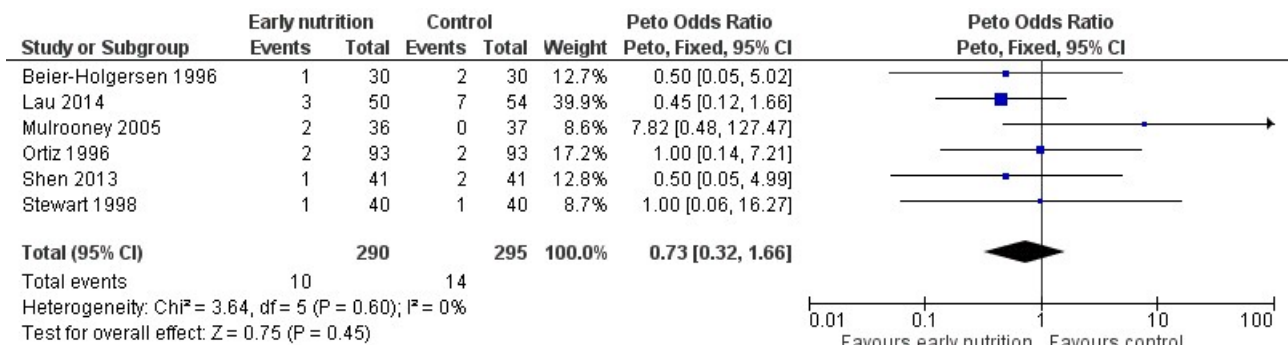
eFigure 5: Anastomotic leak/dehiscence



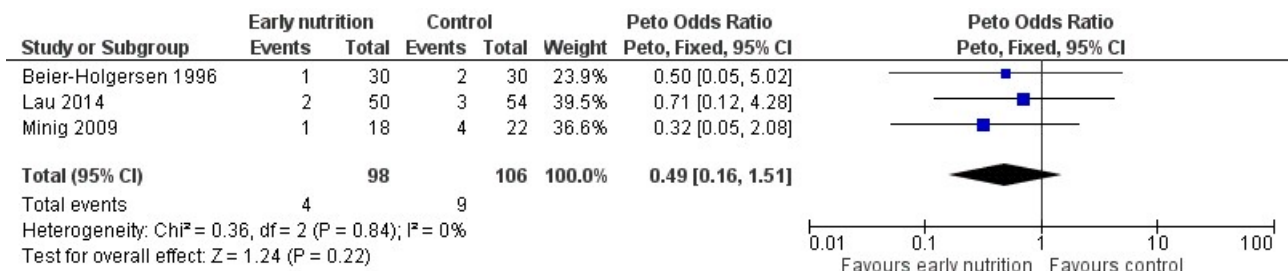
eFigure 6: Postoperative nausea and vomiting



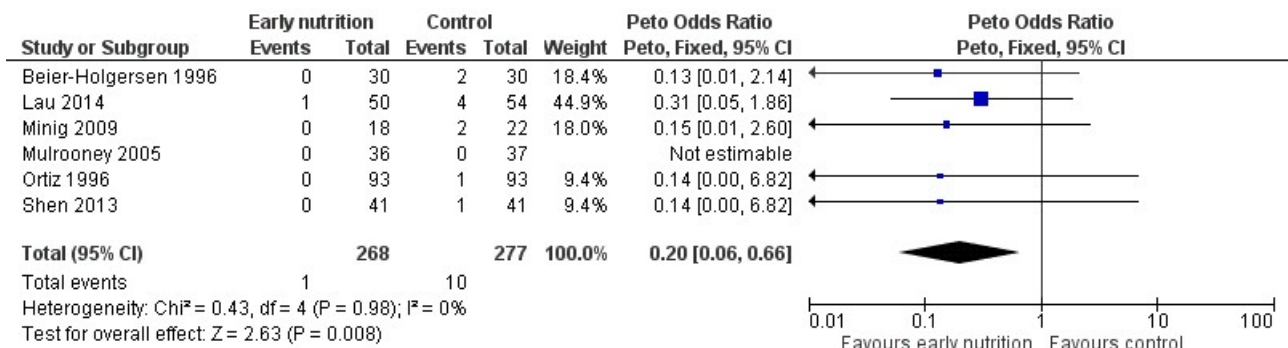
eFigure 7: Pneumonia



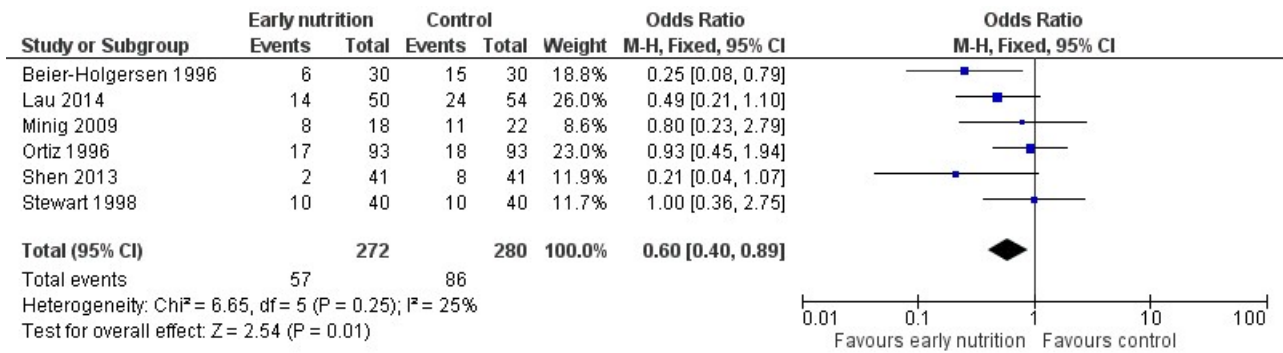
eFigure 8: Need for re-operation



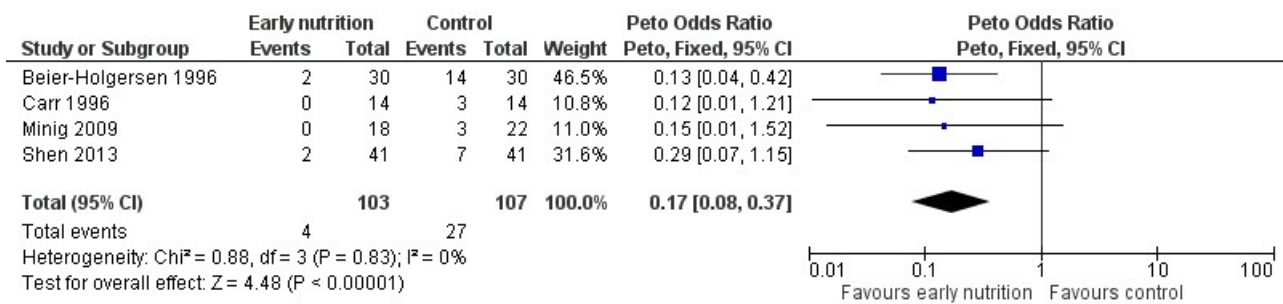
eFigure 9: Number of patients with intra-abdominal abscess/peritonitis



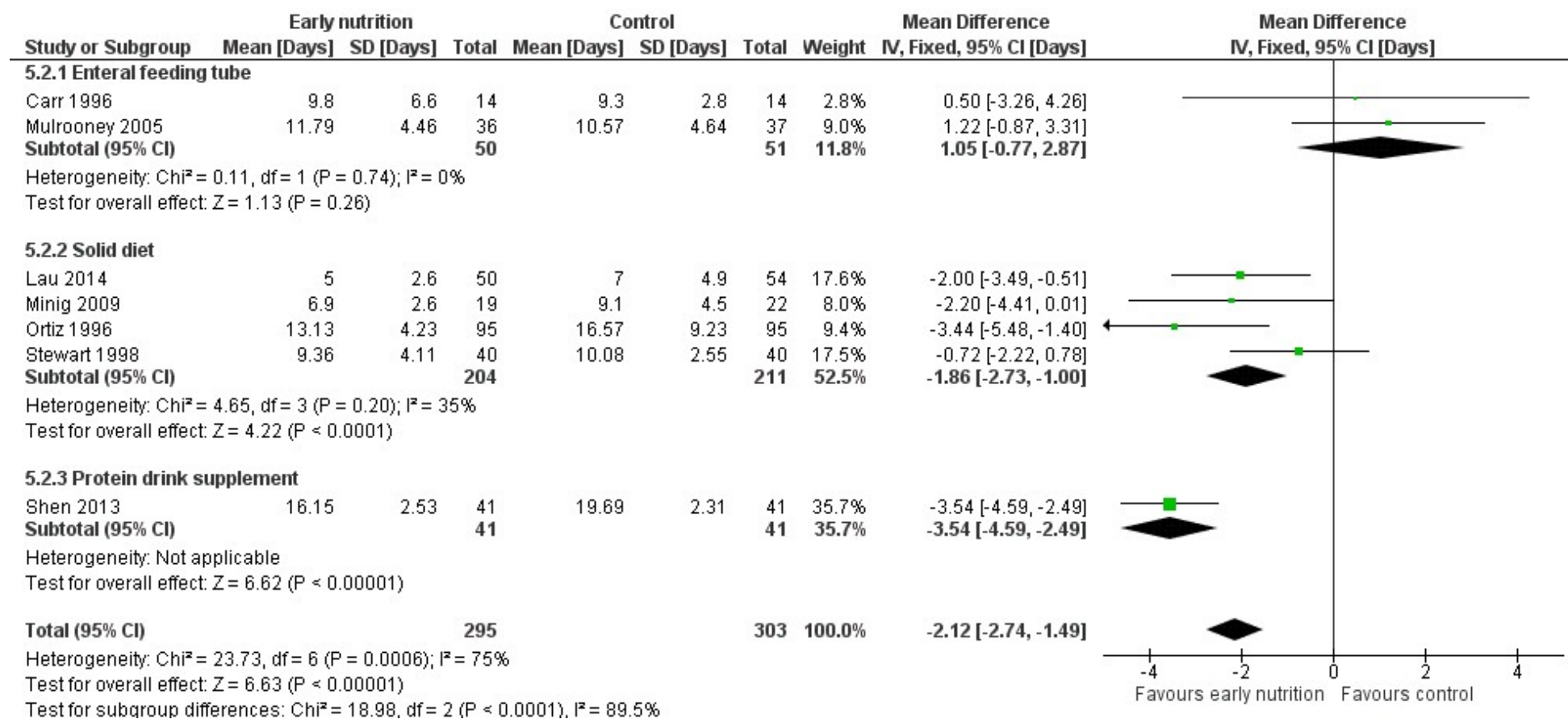
eFigure 10: Number of patients with serious post-operative complications



eFigure 11: Number of patients with a post-operative infection



eFigure 12: Stratified analysis of duration of hospital stay



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