NKR 35 - PICO 3 - Instrumentel undersøgelse suppleret med klinisk undersøgelse for dysfagi

Review information

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Characteristics of studies

Characteristics of included studies

Kjaersgaard 2014

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention (FEES) ● *Age, median year (range)*: 59 (18-76) ● *Men, n (%)*: 41 (72) ● *Injury to admission, median days (range)*: 35 (10 - 2845) ● *Cerebral infarction, n*: 25 ● *Brainstem infarction, n*: 2 ● *Haemorrhage, n*: 9 ● *Subarachnoid haemorrhage, n*: 3

	● *Traumatic brain injury, n*: 8 ● *Anoxia, n*: 5 ● *Other neurological conditions*: 5 ● *FIM eating, level 1*: 41 ● *FIM mobility, level 1*: 49 Control (CBE) ● *Age, median year (range)*: 61 (30-78) ● *Men, n (%)*: 38 (61) ● *Injury to admission, median days (range)*: 36 (10 - 447) ● *Cerebral infarction, n*: 23 ● *Brainstem infarction, n*: 1 ● *Haemorrhage, n*: 12 ● *Subarachnoid haemorrhage, n*: 7 ● *Traumatic brain injury, n*: 11 ● *Anoxia, n*: 6 ● *Other neurological conditions*: 2 ● *FIM eating, level 1*: 43 ● *FIM mobility, level 1*: 54 **Included criteria:** - Adults > 18 years of age- Patients with acquired brain injury (stroke, subarachnoid haemorrhage, traumatic braininjury and anoxia – and with other neurological).- Need of feeding tube or modified consistencies of food or liquid- Stable vital functions and informed or surrogate consent. **Excluded criteria:** - Full oral intake at admission without the need for feeding tube.- Modified texture of food and liquids, - Previously known dysphagia - Cancer diagnosis - Pneumonia at admission, - Tracheostomy tube at admission, - Under 18 years of age
Interventions	**Intervention Characteristics** Intervention (FEES) ● *Procedure*: The patient was positioned in an upright position with a straight spine, the pelvis forward and the neck in a flexed position. The patient’s nose and mouth were cleared of saliva. The endoscope (Ø3.7 mm flexible fibreoptic rhinolaryn-goscope 11101rp1, Karl Storz, Tüttlingen, Germany) was passed through the patient’s nostril and moved forward along the floor of the nose through the velopharyngeal port. The tip of the endoscope was advanced into the hypopharynx.23 The examining team observed, via colour video monitor: changes in the anatomy of the larynx and pharynx; timing and eliciting of physiologic movements of the bolus (pureed food, liquid (water, mineral water,

	milk), solid food) through the pharynx; the ability to protect the airways; the management of saliva (dyed to enhance visibility); spontaneous swallows; the capability to clear the bolus during deglutition; resi-due of material in the hypopharynx; and timing of bolus flow and laryngeal closure. Recording was performed with the Telepack Pal 20043020 and stored by Aida Control 20096020 (Karl Storz, Tüttlingen, Germany). The examination lasted an average of 30 minutes. In cases where the patient could not cooperate and/or saliva was pooling with penetration or aspiration, no oral intake was initiated Control (CBE) ● *Procedure*: All patients admitted received standard clinical assessment of oral functions from the treating occupational therapist within 24 hours of admission. The aim was to assess the prerequisites for swallow-ing saliva and initiation of oral intake with visual and tactile assessment. Before the assessment, the patient was positioned in an upright position with a straight spine, the pelvis forward and the neck in a flexed position. The visual assessment of the oral cavity was performed with a flashlight and a spatula to inspect the oral structures, both at rest and in movement. In the tactile assessment, the occupa-tional therapist applied, via a gloved finger, a struc-tured stimulation with tactile, rhythmic strokes of the gums and cheeks with jaw control grip. It was repeated three times at each quarter of the mouth then a three-step touch along the tongue and lastly a firm touch at the alveolar ridge. In the tactile assessment, the focus was on the responses to oral sensation and tone. In both visual and tactile assess-ment, whether the patient swallowed saliva sponta-neously, frequency of swallowing and the ability to protect the airway was observed. In the study chart, the occupational therapist had to evaluate the fol-lowing seven criteria, based on selected assessment component in the Facial-Oral Tract Therapy approach:Was the patient:1)awake and conscious and/or could he or she respond to verbal address?2)able to sit upright and with some control of his or her head?Did the patient have:3)some oral transport of saliva?4)spontaneous or facilitated swallowing of saliva?5)coughing following swallowing of saliva?6)gurgling breath sounds following swallowing of saliva?7)difficulties in breathing following swallowing of saliva?To initiate oral intake, YES was required in the four first criteria and NO in the subsequent three.
Outcomes	*Aspiration pnuemonia* ● **Outcome type**: DichotomousOutcome ● **Measure names**: ["End of intervention"] ● **Reporting**: Partially reported ● **Scale**: Pneumonia yes/no ● **Direction**: Lower is better ● **Data value**: Change from baseline ● **Notes**: Incidence of pneumonia during the study period is reported and not as endpoint as stated in the outcome for

	NKR. *Dropouts* ● **Outcome type**: DichotomousOutcome ● **Measure names**: ["End of intervention"] ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Length of stay (LOS) (Median n days, range)* ● **Outcome type**: ContinuousOutcome ● **Measure names**: ["End of intervention"] ● **Reporting**: Fully reported ● **Scale**: Counts ● **Unit of measure**: Ratio ● **Direction**: Lower is better ● **Data value**: Endpoint *Initiation of oral intake (median n days, range)* ● **Outcome type**: ContinuousOutcome ● **Measure names**: ["End of intervention"] ● **Scale**: Counts ● **Unit of measure**: Ratio ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** University of Southern Denmark and the Danish Association of Occupational Therapist **Country:** Denmark **Setting:** Hammel Neurorehabilitation and Research Centre **Comments:** No comments **Authors name:** Annette Kjaersgaard,, Lars Hedemann Nielsen & Bengt H Sjölund, 2013 **Institution:** Hammel Neurorehabilitation and Research Centre **Email:** annette.kjaersgaard@hammel.rm.dk **Address:** Voldbyvej 15, Hammel, DK-8340, Denmark

Notes	**Identifications:** **Participants:** *Nkr Dysfagi* **Study design:** *Nkr Dysfagi* **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Karin Bak AksglæDe* I kolonnen "mean" er angivet median og "range" i parentes. Enhed: dageDen kan ikke gemme alle tallene ;-)range intervention 4-245 range kontrol 16-156 *Nkr Dysfagi* See notes for the specific outcomesLOS Reported in median (range). Intervention 78 (4-245); Control 65 (16-156)Initiation of oral intake: intervention: 42 (10.00 - 2,888.00) control: 41 (11-447) **Dichotomous outcomes:** **Adverse outcomes:** *Karin Bak AksglæDe* No adverse events reported

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: RCT med to grupper der begge består af patienter der er repræsentative ud fra "P" kriterierne, men som kun indeholder 1 af de nævnte P-grupper. Patienterne er indrulleret konsekutivt.. Antal ptt. i hver gruppe er tilfredsstilende og der er ingen sign. forskel mellem grupperne. The study was designed as a prospective randomizedcontrolled trial. The basis of the power calculationwas the estimated risk of aspiration17,18 duringneurorehabilitation, since it was not possible to findany specific data regarding aspiration pneumonia. Itwas assumed that there is a 20% higher risk of aspirationpneumonia in the group assessed using FacialOralTract Therapy than in the group using FibreopticEndoscopic Evaluation of Swallowing. With a significancelevel of 5% and a strength of 80%, thesample size was calculated by a power calculus,showing that each group had to include 59 subjectsfor rejection of the null hypothesis. The study wastherefore designed to include 118 subjects.

Allocation concealment (selection bias)	Low risk	Comment: Randomiseringsprocessen er velbeskrevet og udført således et det er tilfældigt om den pågældende pt. kommer i. kontrol- eller interventionsgruppen. Der er anvendt en computer styret metode.An administrator (not involved inthe study) had produced blocks of opaque sequentiallynumbered sealed envelopes containing the randomizationinformation (Facial-Oral Tract Therapy(control group) or Fibreoptic Endoscopic Evaluationof Swallowing (intervention group)) from an independentlycomputer-generated, randomization list,produced by a hospital pharmacy. The randomizationwas performed in blocks of 20. The patients or the relatives and the patients' general practitioner or medical public health officer received the oral and written information about the study from the treatingoccupational therapist within 24–48 hours. Having two leading staff members were responsible for the allocation of patients by opening the next sealedenvelope and using the information therein.
Blinding of participants and personnel (performance bias)	Low risk	Comment: Da det ikke er muligt at "skjule" interventions-undersøgelsen i interventionsgruppen er der tale om "single-blinding", hvilket formentlig ikke har den store betydning da outcome er baseret på objektive data. The primary outcome for this study was pneumoniadiagnosed according to the international definitionused in our centre29 as:● fever (>38°C);● leukocytosis with neutrophilia or leukopaeniaor increase in C-reactive protein; and● appearance of new infiltrative changes onchest radiograph plus detection of at least one ofthe following clinical findings: cough; expectoration;dyspnoea and pain, synchronous to respiration; tachypnoea; attenuation and/orcrepitation at lung auscultation.
Blinding of outcome assessment (detection bias)	Low risk	Comment: The authors reports that the main outcome (pneumonia) was diagnosed according to international definition's and criteria, and that the diagnosis was made by the treating physician. The recording of the data for the purpose of this study was performed before the randomisation code was known.Koden brydes først efter at alle patienter er inkluderet og efter at 1. og 2. forfatter har gennemset journalerne.This diagnosis was made by the treating physicianson a special study chart during the whole length ofstay at our centre, and retrieved from the patients'medical records for this study. After the inclusion ofall patients and before breaking the code, the firstand second author double-checked all medicalrecords for patients receiving antibiotics and results of the chest radiographs.
Incomplete outcome data (attrition bias)	High risk	Comment: Otte ud af 12 patienter med pneumoni i interventionsgruppen er droppet ud. Set i relation til hele gruppen svarer det til 14%, set i forhold til antallet af patienter i gruppen med positivt outcome svarer det til 2/3. Six patients in the intervention group but none inthe control group developed pneumonia before initiationof oral intake and had to be excluded from

		furtheranalysis. The remaining 10 patients (4 controls/6interventions) developed aspiration pneumonia 3–49 days after initiation of oral intake. Of those 10patients, 5 developed aspiration pneumonia3–10 days (1 control/4 interventions) after initiationof oral intake and 5 patients after 32–49days (3 controls/2 interventions). Unfortunately, 2intervention patients did not have new infiltrativechanges on chest radiography and 1 control patientwas not evaluated by chest radiography in spite ofclinical signs of pneumonia. They therefore had tobe excluded. Thus, 7 patients remained for analysis.Of these, 3 of the 62 patients were initiated havingbeen assessed by Facial-Oral Tract Therapy and 4 ofthe 57 patients having been assessed by Fibreoptic
Selective reporting (reporting bias)	Unclear risk	Comment: The authors report that other data regarding initiation of oral intake, time to recovery of total oral intake an other influencing data were analysed in a separate study (not published). However, these data are reported in table 3.Det primære outcome var "aspirationspneumoni". Ingen urapportede outcomes.
Other bias	High risk	Comment: Observationsperioden for outcome er ikke i overensstemmelse med outcome i PICO spørgsmålet.Stor "range" mht. "Injury to admission neurohabilitation (10-2845 dage). Uklart hvad der menes med : (from text): "Patients were transferred from acute departments inother hospitals within 2–4 weeks after injury."Ikke beskrevet om rtg. thorax er set og beskrevet af en speciallæge i radiologi eller om det er "treating physicians".Ikke oplyst hvilken grad af peroral ernæring der er tale om, f.eks. terapeutisk spisning + sondemad, kun supplerende sondemad, kompensatoriske foranstaltninger, fuld peroral ernæring.Udelukkende patienter med "acquried brain damage".Incidensen af aspirationspneumonier var lav medførende risiko for en type 2 fejl.

Footnotes

References to studies

Included studies

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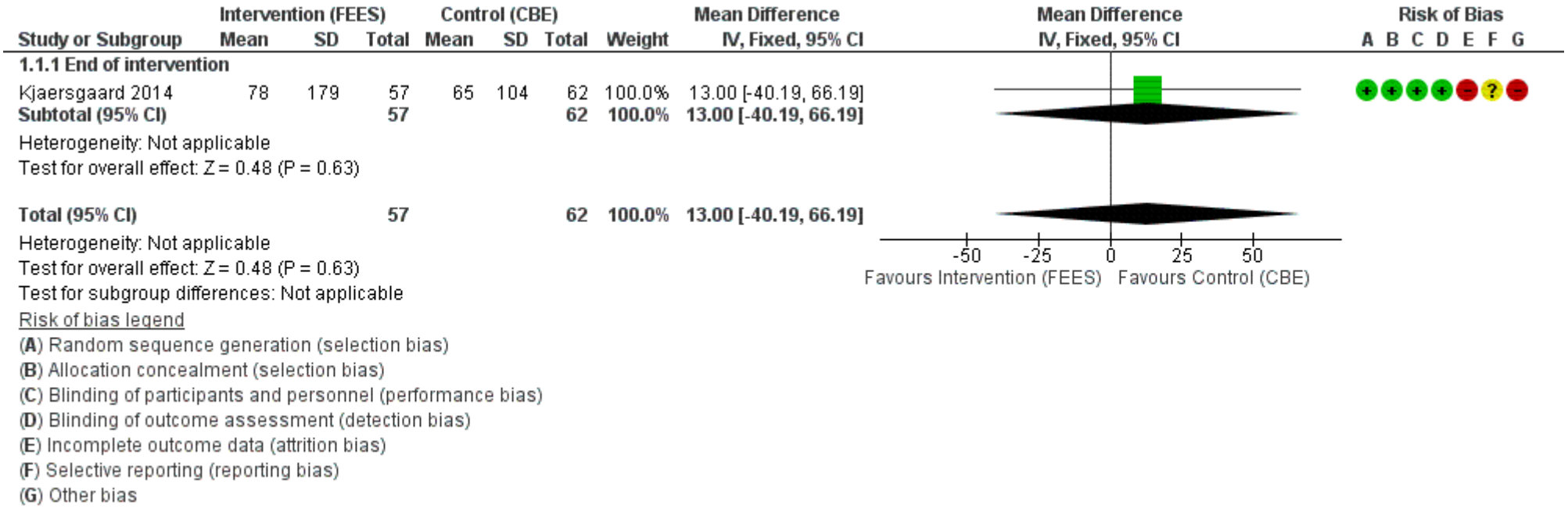
Data and analyses

1 Intervention (FEES) vs Control (CBE)

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Length of stay (LOS) - days	1	119	Mean Difference (IV, Fixed, 95% CI)	13.00 [-40.19, 66.19]
1.1.1 End of intervention	1	119	Mean Difference (IV, Fixed, 95% CI)	13.00 [-40.19, 66.19]
1.2 Initiation of oral intake - days	1	119	Mean Difference (IV, Fixed, 95% CI)	1.00 [-536.27, 538.27]
1.2.1 End of intervention	1	119	Mean Difference (IV, Fixed, 95% CI)	1.00 [-536.27, 538.27]
1.3 Aspiration pnuemonia	1	119	Risk Ratio (IV, Fixed, 95% CI)	3.26 [1.12, 9.54]
1.3.1 End of intervention	1	119	Risk Ratio (IV, Fixed, 95% CI)	3.26 [1.12, 9.54]

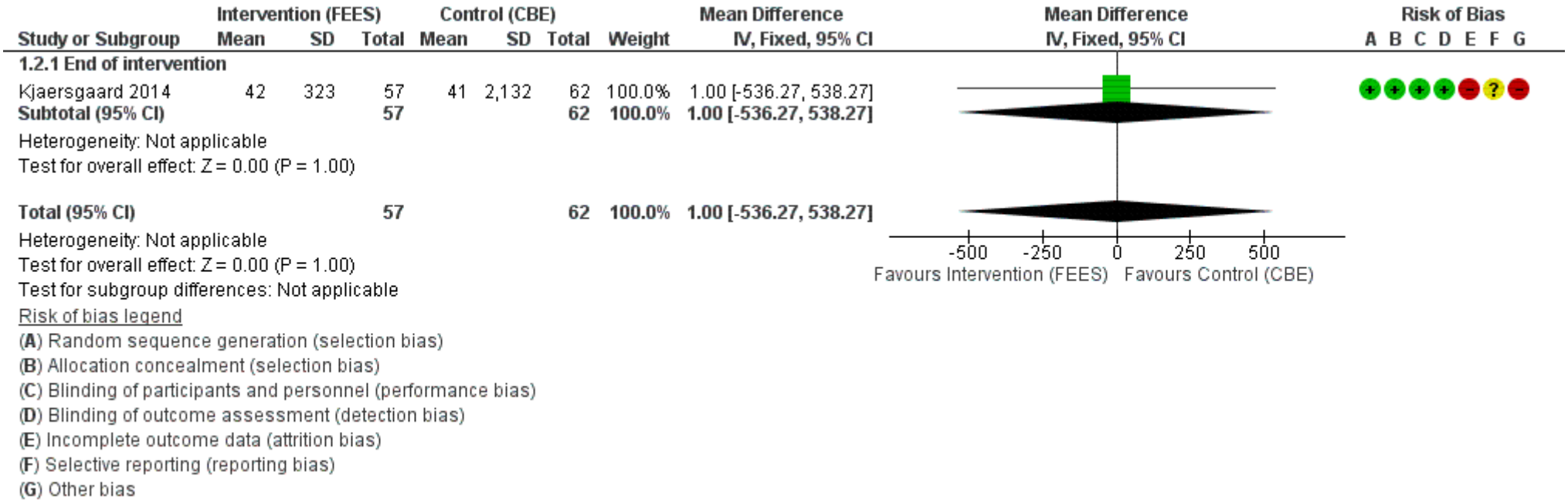
Figures

Figure 1 (Analysis 1.1)



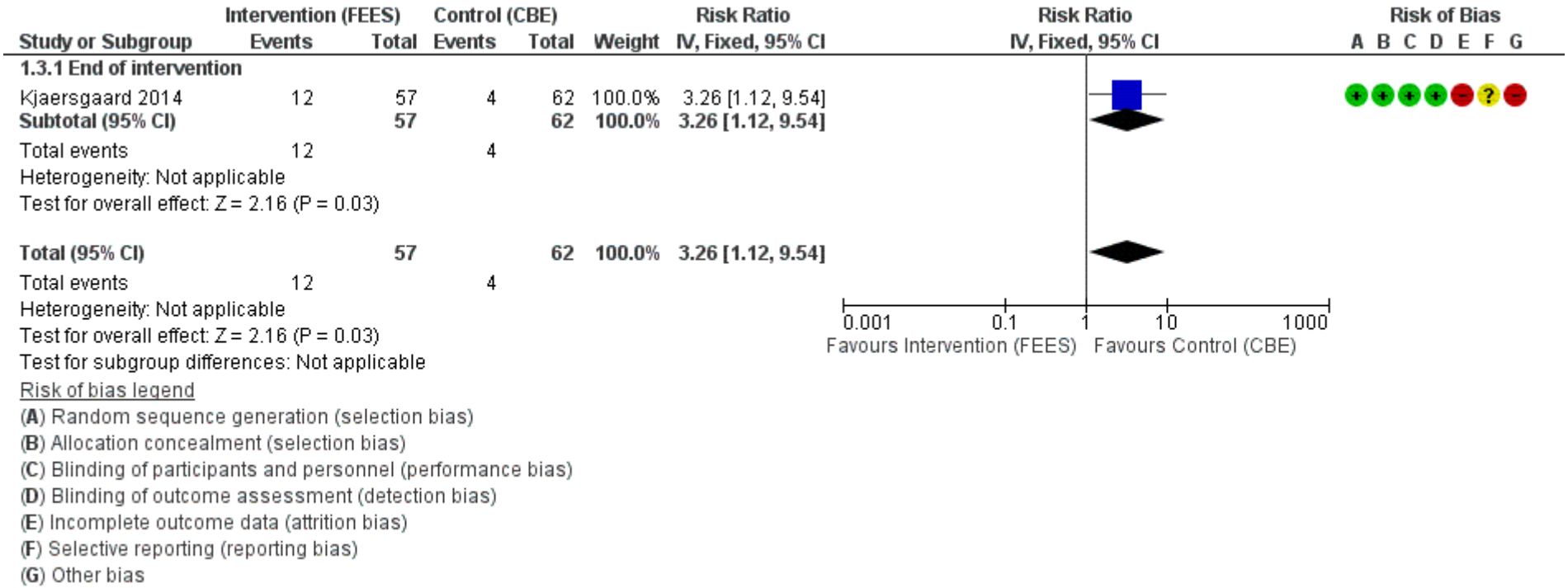
Forest plot of comparison: 1 Intervention (FEES) vs Control (CBE), outcome: 1.1 Length of stay (LOS) - days.

Figure 2 (Analysis 1.2)



Forest plot of comparison: 1 Intervention (FEES) vs Control (CBE), outcome: 1.2 Initiation of oral intake - days.

Figure 3 (Analysis 1.3)



Forest plot of comparison: 1 Intervention (FEES) vs Control (CBE), outcome: 1.3 Aspiration pnuemonia.