

## Systematisk opsporing med struktureret protokol versus Ingen struktureret protokol for Dysfagi

### Review information

#### Authors

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Citation example: TDHaMA. Systematisk opsporing med struktureret protokol versus Ingen struktureret protokol for Dysfagi. Cochrane Database of Systematic Reviews [Year]. Issue [Issue].

### Characteristics of studies

#### Characteristics of included studies

##### Hinchey 2005

<b>Methods</b>	<p><b>Study design:</b> Cluster randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b> YES</p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● Age (<i>sd/interquartile range</i>): 68.7 (15)</li> <li>● Males %: 50</li> <li>● Mild, NIHSS 0-8 %: 70</li> <li>● Moderate, NIHSS 9-16 %: 18</li> <li>● Severe, NIHSS &gt; 17, %: 12.5</li> <li>● Pneumonia, %: 2.4</li> <li>● Time from onset of symptoms to ASU (<i>min.</i>):</li> </ul> <p>Ingen systematisk opsporing (control)</p> <ul style="list-style-type: none"> <li>● Age (<i>sd/interquartile range</i>): 71.3 (14)</li> <li>● Males %: 50</li> <li>● Mild, NIHSS 0-8 %: 69</li> <li>● Moderate, NIHSS 9-16 %: 16</li> <li>● Severe, NIHSS &gt; 17, %: 14</li> <li>● Pneumonia, %: 5.3</li> <li>● Time from onset of symptoms to ASU (<i>min.</i>):</li> </ul> <p><b>Included criteria:</b> Included in the study were all patients 18 years of age who were discharged with a diagnosis of acute ischemic stroke. The target population consists of all acute ischemic stroke patients under the care of neurologists either as consulting or attending physicians.</p> <p><b>Excluded criteria:</b> The inclusion and exclusion criteria for the dysphagia screening indicator are: number of patients screened for dysphagia before food and drink/number of patients excluding in-hospital transfers. Optional data included in-hospital complications such as pneumonia and stroke severity on admission as measured by the NIHSS. Five sites did not collect data on in-hospital complications or stroke severity, and we excluded their data from the outcome assessment part of the project.</p>
<b>Interventions</b>	<p><b>Intervention Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● Procedure: A formal screen was defined as a check sheet listing a process by which the patient is progressively assessed for previous risk factors of aspiration and current increased risk on the basis of clinical findings. All formal screens recommended nothing by mouth (NPO) status and further evaluation by a speech-language pathologist (or similarly trained professional) if any of these abnormalities existed and did not allow for participation in a water challenge. If the patient passed the initial portion of the screen, it</li> </ul>

	<p>was followed by a waterchallenge and observed. All screening tools described various abnormal consequences that could be observed.</p> <p>Ingen systematisk opsporing (control)</p> <ul style="list-style-type: none"> <li>● Procedure: Informal Protocol at Site</li> </ul> <p><b>Nutritional status</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Continuous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Severity dysphagia</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Continuous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Quality of life</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Continuous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Mortality</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Dichotomous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Aspiration pneumonia</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Dichotomous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Length of stay (LOS)</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Dichotomous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Readmissions</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Dichotomous Outcome</li> <li>● Measure names: [Final value]</li> </ul> <p><b>Length of hospital stay</b></p> <ul style="list-style-type: none"> <li>● Outcome type: Continuous Outcome</li> <li>● Measure names: [Final value]</li> <li>● Unit of measure: Days</li> <li>● Direction: Lower is better</li> </ul>
<p><b>Identification</b></p>	<p><b>Sponsorship source:</b> J.A.H. is supported by National Institutes of Health grant K23NS021663. This work was also partially supported by funding from the American Academy of Neurology, the American Stroke Association, and Boehringer Ingelheim Pharmaceuticals, Inc.</p> <p><b>Country:</b> USA</p> <p><b>Setting:</b> 15 healthcare institutions with a variety of practice settings.</p> <p><b>Comments:</b> Comment to setting: Three hospitals had 200 acute beds, 6 had 200 to 400 acute beds, and 6 had 400 acute beds. Other site characteristics included 4 urban academic hospitals, 2 academic affiliated community hospitals, and 9 community hospitals. A dedicated stroke unit was present in 73% (11 of 15) of hospitals. 93% (14 of 15) had stroke teams, and 100% had stroke pathways.</p> <p><b>Authors name:</b> Hinchey et al, 2005</p> <p><b>Institution:</b> Department of Neurology (J.A.H.), Saint Elizabeth's Medical Center, Boston,</p> <p><b>Email:</b> Jhinchey@tufts-nemc.org</p> <p><b>Address:</b> Tufts-New England Medical Center, Institute for Clinical Research and Health Policy Studies, 750 Washington St, Box 63, Boston, MA 02111.</p>
<p><b>Notes</b></p>	<p><b>Identifications:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b> Nkr <i>Dystagi</i> This study is limited in that the design was not specific for a randomized controlled trial of dysphagia screening protocols versus no protocols and was done as a</p>

secondary analysis	<p><b>Baseline characteristics:</b></p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b></p> <p>Nkr <i>Dystagi</i> OBS LOS is reported in median. Variability measures are not given</p> <p><b>Dichotomous outcomes:</b></p> <p><i>Elisabeth Ginnerup-Nielsen</i> Pneumoni er omtalt som pneumoni og ikke som aspirationspneumoni???</p> <p>Nkr <i>Dystagi</i> OBS LOS is reported as median</p> <p><b>Adverse outcomes:</b></p>
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## Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Comment: Citat: This is part of a group-randomized, controlled, multicenter trial. Citat: This study is limited in that the design was not specific for a randomized controlled trial of dysphagia screening protocols versus no protocols and was done as a secondary analysis.
Allocation concealment (selection bias)	High risk	Comment: Nothing described. As randomization is not done correctly this item also receives high risk
Blinding of participants and personnel (performance bias)	Unclear risk	Comment: Is not reported explicitly. The study was conducted using in-hospital data that were prospectively collected between December 2001 and January 31, 2003, as part of the Stroke Practice Improvement Network (SPIN) registry. This is part of a group-randomized, controlled, multicenter trial assessing the efficacy of a multimodal intervention aimed at increasing the adherence rates of 4 primary, in-hospital ischemic stroke process of care indicators
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Nothing described. I don't think outcome assessors are blinded. Outcome (pneumonia) is objective and difficult to "cheat with". citat: The definition of pneumonia includes either the clinical finding of rales or dullness to percussion and 1 of the following: purulent sputum, or isolation of the organism, or chest radiograph showing evidence of an infiltrate/consolidation/cavitation or pleural effusion and 1 of the following: purulent sputum or isolation of the agent or antibody evidence of an agent
Incomplete outcome data (attrition bias)	High risk	Comment: Dropouts not described
Selective reporting (reporting bias)	High risk	Comment: One or more reported primary outcomes were not pre-specified. Death, npo, los.
Other bias	High risk	Comment: Had extreme baseline imbalance for age and race.

## Middleton, 2011

Methods	<p><b>Study design:</b> Cluster randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b> YES</p>
Participants	<p><b>Baseline Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● Males %: 60</li> <li>● Mild, NIHSS 0-8 %:</li> <li>● Moderate, NIHSS 9-16 %:</li> <li>● Severe, NIHSS &gt; 17, %:</li> <li>● Pneumonia, %:</li> <li>● Age (sd/interquartile range)/sd:</li> </ul> <p>Ingen systematisk opsporing (control)</p>

	<ul style="list-style-type: none"> <li>● Males %: 60</li> <li>● Mild, NIHSS 0-8 %:</li> <li>● Moderate, NIHSS 9-16 %:</li> <li>● Severe, NIHSS &gt; 17, %:</li> <li>● Pneumonia, %:</li> <li>● Age (sd/interquartile range)/sd:</li> </ul> <p><b>Included criteria:</b> Patients were eligible if they spoke English, were aged 18 years or older, had a diagnosis of ischaemic stroke or intracerebral haemorrhage, and presented within 48 h. of onset of symptoms to a participating ASU.</p> <p><b>Excluded criteria:</b> Patients were excluded if they did not have a telephone or were admitted for palliative care.</p>
<p><b>Interventions</b></p>	<p><b>Intervention Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● <i>Procedure:</i> Fever, sugar, swallowing (FeSS) intervention protocol. As a part of the protocol, patients were screened with the ASSIST tool by either a nurse who passed the competency test or a speech pathologist within 24 h of admission to ASU; the result of the screening was clearly documented in the patient's medical record by use of a sticker. ● Patients who failed the swallowing screening were referred to a speech pathologist for a swallowing assessment. The swallowing assessment included three elements, namely, assessment of level of consciousness, cranial nerve assessment, and water swallow test.</li> </ul> <p>Ingen systematisk opsporing (control)</p> <ul style="list-style-type: none"> <li>● <i>Procedure:</i> ASUs in the control group received only an abridged version of existing guidelines</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Severity dysphagia</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Quality of life</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> <li>● <b>Range:</b> 0-100</li> <li>● <b>Unit of measure:</b> SF-36 Physical health</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Mortality</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> <li>● <b>Direction:</b> Lower is better</li> </ul> <p><i>Aspiration pneumonia</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Length of stay (LOS)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Readmissions</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Nutritional status</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Quality of life_mental</i></p>

	<ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Range:</b> 0-100</li> <li>● <b>Unit of measure:</b> SF-36 Mental health</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Length of hospital stay</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Unit of measure:</b> days</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul>
<p><b>Identification</b></p>	<p><b>Sponsorship source:</b> National Health &amp; Medical Research Council ID 353803, St Vincent's Clinic Foundation, the CurranFoundation, Australian Diabetes Society-Servier, the College of Nursing, and Australian Catholic University.</p> <p><b>Country:</b> Australia</p> <p><b>Setting:</b> Acute Stroke Units</p> <p><b>Comments:</b> No comments</p> <p><b>Authors name:</b> Middleton et al, 2011</p> <p><b>Institution:</b> Nursing Research Institute, St Vincent's &amp; Mater Health Sydney and School of Nursing (NSW &amp; ACT), Australian Catholic University, NSW, Australia</p> <p><b>Email:</b> sandy.middleton@acu.edu.au</p> <p><b>Address:</b> Prof Sandy Middleton, NursingResearch Institute, St Vincent'sHospital, Darlinghurst,NSW 2010, Australia</p>
<p><b>Notes</b></p>	<p><b>Identifications:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b>  <i>Elisabeth Ginnerup-Nielsen</i> Age: &lt;65 control: 137/498 (28%) Intervention: 195/625 (31%)65-74 control: 130/498 (26%) Intervention: 150/625 (24%)75-84 control: 158/498 (32%) Intervention: 181/625 (29%) ≥ 85 control 73/498 (15%) Intervention: 99/625 (16%)Los Angeles Motor scale: 0 (mild stroke) control: 203/493 (41%) 262/622 (42%) ≥ 1 (more severe stroke) control: 290/493 (59%) 360/622 (58%)</p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b>  <i>Elisabeth Ginnerup-Nielsen</i> Follow-up done at 3 months</p> <p><b>Dichotomous outcomes:</b></p> <p><b>Adverse outcomes:</b></p>

## Risk of bias table

	Authors' judgement	Support for judgement
Bias	Low risk	
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	Comment: De-identified stratification details were provided to an independent statistician who used random number generating software to randomise withinstrata with allocation concealed until provided to theProject Officer (SD) who assigned ASUs to their groups.

Blinding of participants and personnel (performance bias)	Low risk	Comment: Citat: Patients were masked to ASU group allocation but clinicians delivering our intervention were not. For the outcomes quality of life this is a problem. Less for length of stay. Patients were masked to ASU group allocation but clinicians delivering our intervention were not. Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias
Blinding of outcome assessment (detection bias)	Low risk	Comment: An independent organisation was contracted to conduct computer assisted telephone interviews with patients. Research assistants who undertook the computer-assisted telephone interviews and the medical record audits were masked to trial aims, design, and group allocation; the trial statistician was masked to group allocation. Blinded retrospective medical record audits were undertaken using data documented prospectively.
Incomplete outcome data (attrition bias)	Low risk	Comment: ITT but unclear how. Analysis has been done on 558/626 in the intervention group and 451/500 pts in the control group. 117 (10%) patients were lost to follow-up or withdrew. Equal both groups. We used intention-to-treat analysis for all outcomes.
Selective reporting (reporting bias)	Low risk	Comment: All outcomes from protocol seem reported
Other bias	Low risk	

## Osborne 2006

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● Males %: 36.4</li> <li>● Age (sd/interquartile range)/sd: 77.31</li> <li>● Surgery type Elective: 40.9</li> <li>● Surgery type Emergency: 51.9</li> <li>● Comorb. Respiratory: 31.8</li> <li>● Comorb. Stroke: 4.5</li> <li>● Comorb. Cardiac: 18.2</li> <li>● Comorb. Hypertension: 36.4</li> <li>● Comorb. Periph. vascular disease: 18.2</li> <li>● Comorb. DM: 13.6</li> <li>● Sedation: 81.8</li> </ul> <p>Ingen systematisk opsporing (control)</p> <ul style="list-style-type: none"> <li>● Males %: 26.9</li> <li>● Age (sd/interquartile range)/sd: 75.64</li> <li>● Surgery type Elective: 50</li> <li>● Surgery type Emergency: 50</li> <li>● Comorb. Respiratory: 30.8</li> <li>● Comorb. Stroke: 15.4</li> <li>● Comorb. Cardiac: 34.6</li> <li>● Comorb. Hypertension: 46.2</li> <li>● Comorb. Periph. vascular disease: 15.4</li> <li>● Comorb. DM: 30.8</li> <li>● Sedation: 80.1</li> </ul>
<b>Included criteria:</b>	Patients admitted to the facility for orthopedic surgery who required a stay of at least one night in the hospital; were undergoing either elective, subacute, or emergency orthopedic surgery; and were admitted to the orthopedic surgery ward from the postanesthesia care unit (PACU) postoperatively.

	<p><b>Excluded criteria:</b> younger than 65 years old, unable to give informed consent, presented with documented preexisting swallowing conditions (eg, dysphagia), or were unable to swallow due to the nature of specific intraoperative interventions or postoperative procedures or complications (eg, fractured jaw surgery).</p> <p><b>Intervention Characteristics</b> Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● <i>Procedure:</i> The participants were assessed in as upright position as possible. The same pulse oximeter was used for all patients to assess SaO<sub>2</sub>. An SaO<sub>2</sub> reading was recorded (ie, the pretest reading). The participant then was given 10 mL of tapwater to drink while swallowing was observed. An SaO<sub>2</sub> reading was recorded within two minutes (ie, the posttest reading). This procedure was conducted a total of three times, and all SaO<sub>2</sub>. A positive sip test result was recorded if the posttest reading was at least 2% less than the pretest reading in all three sip tests (ie, desaturation of 2%). If 2% desaturation did not occur in all three sip tests, a negative sip test result was recorded.</li> <li>● <i>Duration:</i> For participants assigned to the experimental group, the sip test was conducted preoperatively when possible and then within the initial six hours of the postoperative period on the postoperative ward. A series of three sip tests were conducted as described.</li> </ul> <p>Ingen systematisk opsporing (control)</p> <ul style="list-style-type: none"> <li>● <i>Procedure:</i> postoperative care based on current practice</li> <li>● <i>Duration:</i></li> </ul> <p><b>Outcomes</b></p> <p><i>Severity dysphagia</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Quality of life</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Mortality</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Dichotomous Outcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Aspiration pneumonia</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Dichotomous Outcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Length of stay (LOS)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Dichotomous Outcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Readmissions</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Dichotomous Outcome</li> <li>● <b>Measure names:</b> ["Final value longest follow-up"]</li> </ul> <p><i>Nutritional status</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Quality of life_mental</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul> <p><i>Length of hospital stay</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Measure names:</b> ["Final value Longest follow-up"]</li> </ul>
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<b>Identification</b>	<p><b>Sponsorship source:</b> AORN, The Canberra Hospital Salaried Specialist Fund, The Canberra Hospital Auxiliary, and the ACT Nurses Registration Board.</p> <p><b>Country:</b> Australia</p> <p><b>Setting:</b> Orthopedic surgery hospital ward</p> <p><b>Comments:</b> Email contacts not reported in publication, but retrieved through the Queensland University</p> <p><b>Authors name:</b> Osborne S, Gardner G, Gardner A, Franklin A, Franklin S, Tuohy E, Fisher A</p> <p><b>Institution:</b> Queensland University of Technology, School of Nursing, Kelvin Grove, Brisbane, Queensland.</p> <p><b>Email:</b> s.osborne@qut.edu.au</p> <p><b>Address:</b> Kelvin Grove, Brisbane, Queensland, Australia.</p>
<b>Notes</b>	<p><b>Identifications:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b> Nkr <i>Dystagi</i> SD or range for age mean not reported in the paper</p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b></p> <p><b>Dichotomous outcomes:</b> <i>Elisabeth Ginnerup-Nielsen</i> OBS Aspiration pneumonia in this study = pneumonia and pneumonitis</p> <p><b>Adverse outcomes:</b></p>

## Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: A block randomization process was used
Allocation concealment (selection bias)	Low risk	Comment: Consecutive numbers were randomly selected in blocks of 20 numbers and placed in consecutively numbered opaque envelopes.
Blinding of participants and personnel (performance bias)	Low risk	Comment: Either participants or key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others unlikely to introduce bias.
Blinding of outcome assessment (detection bias)	Low risk	Comment: For objective pneumonia outcome probably not relevant
Incomplete outcome data (attrition bias)	Low risk	Comment: 32 to 26 in control group, 27 to 22 in intervention group. No intention to treat.
Selective reporting (reporting bias)	Unclear risk	Comment: There were no positive postoperative sip tests or trials of fluid recorded on the data collection sheets and thus, no outcome measure of aspiration risk. Therefore the authors performed subgroup analysis that were not pre-specified. The primary outcome (aspiration pneumonia) of interest in the study are reported only as percentages - however, it is possible to enter in meta-analysis
Other bias	Low risk	Comment: The study appears to be free of other sources of bias

## vanderMeulen 2014

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>Systematisk opsporing (Intervention)</p> <ul style="list-style-type: none"> <li>● Males %: 62 (70)</li> <li>● Age (sd/interquartile range)/sd: 60.1 (10)</li> </ul>



- Tumor site hypopharynx: 11 (13)
- Tumor site Larynx: 20 (23)
- Tumor site Oral cavity: 41 (47)
- Tumor site oropharynx: 16 (18)
- Tumor site unknown: 0
- Tumor stage I-II: 51 (58)
- Tumor stage III-IV: 37 (42)
- Tumor stage unknown: 0
- Surgery: 22 (25)
- Radiotherapy: 25 (28)
- RT/CH: 12 (14)
- Combination: 29 (33)

#### Ingen systematisk opsporing (control)

- Males %: 64 (70)
- Age (sd/interquartile range)/sd: 60.7 (10)
- Tumor site hypopharynx: 7 (8)
- Tumor site Larynx: 22 (24)
- Tumor site Oral cavity: 44 (19)
- Tumor site oropharynx: 17 (48)
- Tumor site unknown: 1 (1)
- Tumor stage I-II: 54 (59)
- Tumor stage III-IV: 36 (40)
- Tumor stage unknown: 1 (1)
- Surgery: 29 (32)
- Radiotherapy: 24 (26)
- RT/CH: 12 (13)
- Combination: 26 (29)

**Included criteria:** Primary diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx, treatment with curative intent, ability to complete questionnaires in Dutch and ability to participate in the intervention

**Excluded criteria:** Patients were excluded if they had a previous or concomitant malignancy and/or were being treated for depression, diagnosed according to Diagnostic and Statistical Manual of Mental Disorders criteria (American Psychiatric Association, 2000), as stated in their medical record

#### Interventions

##### Intervention Characteristics

##### Systematisk opsporing (Intervention)

- *Procedure:* Six components (evaluating current mental status with the Hospital Anxiety and Depression Scale (HADS); discussing current problems; systematically asking about physical problems and functioning in six relevant life domains; providing the Adjustment to Fear, Threat or Expectation of Recurrence (AFTER) intervention,) of which the Patients were then systematically asked about physical problems related to HNC, such as mastication, swallowing, shoulder function, sense of taste or smell, breathing, restrictions in speech, pain and fatigue.
- *Duration:* Patients received a maximum of six counselling sessions of 45-60 min every 2 months over a period of 1 year, starting 6 weeks after the completion of cancer treatment. The counselling session was always combined with the patient's bimonthly medical check-up at the outpatient clinic

##### Ingen systematisk opsporing (control)

- *Procedure:* Care as usual was provided bimonthly by HNC specialists and was primarily aimed at the treatment of complications and the detection of recurrences or second primary tumours. Patients were examined, their physical history was reviewed, and ancillary tests were arranged as necessary. If the patient had psychosocial problems, the HNC specialist could refer the patient to psychological aftercare.
- *Duration:* 10-minute medical follow-up visit

<p><b>Outcomes</b></p>	<p><i>Mortality</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value 18 month follow-up"]</li> </ul> <p><i>Aspiration pneumonia</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value 18 month follow-up"]</li> </ul> <p><i>Length of stay (LOS)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value 18 month follow-up"]</li> </ul> <p><i>Readmissions</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Measure names:</b> ["Final value 18 month follow-up"]</li> </ul> <p><i>Severity dysphagia_ EORTC-H&amp;N35_Swallowing</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Follow-up 18 month"]</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> EORTC-H&amp;N35_Swallowing</li> <li>● <b>Unit of measure:</b> Ordinal</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Quality of life_ EORTC-H&amp;N35_Social eating</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Follow-up 18 month"]</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> EORTC-H&amp;N35_Social eating</li> <li>● <b>Unit of measure:</b> Ordinal</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Quality of life_Global</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Measure names:</b> ["Follow-up 18 month"]</li> <li>● <b>Reporting:</b> Not reported</li> <li>● <b>Scale:</b> EORTC_C30_Global</li> <li>● <b>Unit of measure:</b> Ordinal</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul>
<p><b>Identification</b></p>	<p><b>Sponsorship source:</b> The research was funded through a grant from the Dutch CancerSociety.</p> <p><b>Country:</b> The Netherlands</p> <p><b>Setting:</b> Outpatient oral maxillofacial and the otorhinolaryngology clinics of a Dutch university hospital</p> <p><b>Comments:</b></p> <p><b>Authors name:</b> van der Meulen IC, May AM, de Leeuw JR, Koole R, Oosterom M2, Hordijk GJ, Ros WJ</p> <p><b>Institution:</b> Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht</p> <p><b>Email:</b> i.c.vandermeulen@umcutrecht.nl</p> <p><b>Address:</b> Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Street 6.131, PO Box: 85500, 3508GAUtrecht, The Netherlands</p>

<p><b>Notes</b></p> <p><b>Identifications:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b></p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b></p> <p><i>Nkr Dysfagi</i> obs. use qo-global for quality of life</p> <p><b>Dichotomous outcomes:</b></p> <p><i>Nkr Dysfagi</i> No estimates for these outcomes. Mortality reported for 24 month follow-up and not at 18 month</p> <p><b>Adverse outcomes:</b></p>	
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## Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "After informed consent and the completion of cancer treatment, participants were randomised to the intervention or control group, using a web-based computer programme with an open block procedure stratified for sex and tumour stage."
Allocation concealment (selection bias)	Unclear risk	Comment: It is unclear how the persons who allocated the participants were blinded (they used a open block procedure) - Participants were randomised to the intervention or control group, using a web-based computer programme with an open block procedure stratified for sex and tumour stage. All researchers were blinded to the block sizes.
Blinding of participants and personnel (performance bias)	Unclear risk	Comment: It is unclear how the authors ensured this item - "For the duration of the study, participants were not informed which treatment they received". The patients must have read the information form before the written consent, and in here it must be explained what interventions are given. Therefore, the patients must have known what they got.
Blinding of outcome assessment (detection bias)	Low risk	Comment: All outcome data were collected by an independent researcher.
Incomplete outcome data (attrition bias)	Unclear risk	Comment: Citat: Of the participants who completed the assessment at 12 months, 49% hadreceived >5 counselling sessions; at 18 months the proportion was91% and at 24 months 95%. Two patients, one at 18 and one at 24months, received an additional seventh counselling session. - Still unclear how many dropped out of the control group? Did many drop out before first follow-up measurement?
Selective reporting (reporting bias)	Low risk	Comment: the published reports include all expected outcomes, including those that were pre-specified. All relevant estimates are given
Other bias	Low risk	Comment: The study appears to be free of other sources of bias. Adequate power for the analysis

## Footnotes

## References to studies

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**Other references****Additional references****Other published versions of this review****Classification pending references****Data and analyses****1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control)**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Severity dysphagia	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.2 Quality of life_mental	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.3 QOL_mental 2	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.4 Quality of life (physical functioning)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.5 qol physical - 2	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.6 Length of hospital stay	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.7 Length of hospital stay - 2	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.7.1 New Subgroup	1	1086	Mean Difference (IV, Fixed, 95% CI)	-2.40 [-3.80, -1.00]
1.8 Mortality	1		Risk Ratio (IV, Fixed, 95% CI)	Subtotals only
1.9 Aspiration pneumonia	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.10 Aspiration pneumonia - 2	1	1086	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.32, 1.47]
1.11 Aspiration pneumonia - 3	1	48	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.61, 2.30]

**Figures****Figure 1 (Analysis 1.1)**

Study or Subgroup	Systematisk opsporing (Intervention)		Ingen systematisk opsporing (control)		Total	Weight	Mean Difference		Risk of Bias					
	Mean	SD	Mean	SD			IV, Fixed, 95% CI	IV, Fixed, 95% CI		A	B	C	D	E
vanderMeulen 2014	18.3	28.14249456	21.2	26.71029764	88	91	-2.90	[-10.94, 5.14]	●	?	?	?	?	?

Favours Systematisk opsporing (intervention) Favours Ingen systematisk opsporing (control)

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.1 Severity dysphagia.

Figure 2 (Analysis 1.4)

Study or Subgroup	Systematisk opsporing (Intervention)		Ingen systematisk opsporing (control)		Total	Weight	Mean Difference		Risk of Bias					
	Mean	SD	Mean	SD			IV, Fixed, 95% CI	IV, Fixed, 95% CI		A	B	C	D	E
Middleton, 2011	45.6	10.2	42.5	10.5	558	451	3.10	[1.81, 4.39]	●	●	●	●	●	●

Ingen systematisk opspori Systematisk opsporing

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.4 Quality of life (physical functioning).

Figure 3 (Analysis 1.2)

Study or Subgroup	Systematisk opsporing (Intervention)		Ingen systematisk opsporing (control)		Total	Weight	Mean Difference		Risk of Bias					
	Mean	SD	Mean	SD			IV, Fixed, 95% CI	IV, Fixed, 95% CI		A	B	C	D	E
Middleton, 2011	49.5	10.9	49.4	10.6	558	451	0.10	[-1.23, 1.43]	●	●	●	●	●	●

Ingen systematisk opspori Systematisk opsporing

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.2 Quality of life\_mental.



Figure 4 (Analysis 1.6)

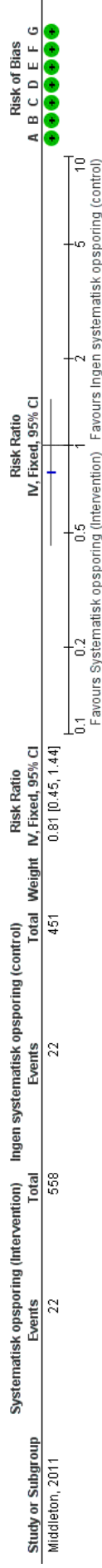


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.6 Length of hospital stay.

Figure 5 (Analysis 1.8)



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.8 Mortality.

Figure 6 (Analysis 1.9)



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Systematisk opsporing (Intervention) vs Ingen systematisk opsporing (control), outcome: 1.9 Aspiration pneumonia.