Effective Health Care Program

Comparative Effectiveness Review
Number 94

# Interventions for Feeding and Nutrition in Cerebral Palsy

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*Comparative Effectiveness Review*

**Number 94**

# Interventions for Feeding and Nutrition in Cerebral Palsy

**Prepared for:**
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

**Contract No. 290-2007-10065-I**

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**AHRQ Publication No. 13-EHC015-EF**
**March 2013**

This report is based on research conducted by the Vanderbilt Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10065-I). The findings and conclusions in this document are those of the author(s), who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

**Suggested citation:** Ferluga ED, Archer KR, Sathe NA, Krishnaswami S, Klint A, Lindegren ML, McPheeters ML. Interventions for Feeding and Nutrition in Cerebral Palsy. Comparative Effectiveness Review No. 94. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I) AHRQ Publication No. 13-EHC015-EF. Rockville, MD: Agency for Healthcare Research and Quality. March 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

# Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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## Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project:

Mr. Jeffrey Seroogy and Ms. Katie Worley assisted with managing the review, including handling day-to-day logistics and participating in screening studies.

Dr. Christopher Fonnesbeck provided a statistical review of studies included in the review to determine the potential for meta-analyses.

Dr. Steven R. Couch provided valuable insight into the care of and clinical decision making for individuals with cerebral palsy.

Ms. Rachel Walden and Mr. Zachary Fox, library scientists for the review, created comprehensive searches, and assisted with screening of abstracts and full text studies. We appreciate their thoughtful input across the project's stages.

Ms. Sharana Jones and Mr. Ross Brown provided helpful assistance in locating articles and preparing materials for meetings.

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# Interventions for Feeding and Nutrition in Cerebral Palsy

## Structured Abstract

**Objectives:** The Vanderbilt Evidence-based Practice Center examined the effects of available interventions for feeding and nutrition problems that have been evaluated in individuals with cerebral palsy (CP).

**Data sources.** MEDLINE® via the PubMed® interface, PsycINFO® (psychology and psychiatry literature), the Educational Resources Information Clearinghouse℠, OTSeeker, REHABDATA, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL®) database. Additional studies were identified from reference lists and technical experts.

**Review methods.** We reviewed studies providing effectiveness data for feeding interventions in populations of any age with CP. We included studies focused on nonsurgical and surgical interventions for feeding and nutrition difficulties. Nonsurgical interventions included positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training. Surgical interventions included gastrostomy or jejunostomy tubes and fundoplication. We assessed both intermediate/surrogate and patient-centered/health outcomes.

**Results.** Fifteen articles (comprising 13 unique studies) met our inclusion criteria. One good quality systematic review on behavioral interventions for feeding issues in individuals with cerebral palsy was published in 2011 and is updated with one additional study on caregiver education in this review. The existing review included 21 studies with conflicting results related to the effects of sensorimotor interventions on short-term improvements in feeding. Eleven studies (nine case series) of surgical interventions met our inclusion criteria. These studies included 309 children. In all nine studies of gastrostomy (with or without fundoplication), gastrostomy-fed children gained weight. Baseline weight z-scores ranged from −3.56 to −0.39; followup z-scores ranged from −2.63 to −0.33, relative to typically developing populations. Two studies assessed fundoplication for reflux: in one RCT both Nissen fundoplication and vertical gastric plication reduced reflux (reduction in symptoms of 57% and 43%, respectively), while in one case series, reflux recurred within 12-months postfundoplication in 30 percent of children. The highest rates of reported harms in any study were minor site infection (59%), formation of granulation tissue (42%), gastric leakage, recurrent reflux (30%), and aspiration and pneumonia (29%). Even though the reported death rates ranged from 7 percent to 29 percent, the underlying cause of death was most likely not due to the surgical treatment.

**Conclusions.** Evidence for behavioral interventions for feeding disorders in CP consists of mostly small, short-term, pre-post studies, with strength of evidence ranging from insufficient to moderate. Some studies suggest that interventions such as oral appliances may enhance oral sensorimotor skills, but there is a clear need for rigorous, comparative studies. Evidence for surgical interventions is insufficient to low. All studies to date demonstrate significant weight gain with gastrostomy. Results for other growth measures are mixed, and substantial numbers of children remained underweight, although given a lack of appropriate reference standards for the CP population, these results should be interpreted cautiously. Longer term, comprehensive case

series are needed, as are prospective cohort studies. More research is needed to understand potential harms in the context of benefits and potential risks of not treating.

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# Executive Summary

## Background

Cerebral palsy (CP) is a "group of disorders of the development of movement and posture, causing activity limitation, that is attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder."[1] This group of syndromes ranges in severity and is the result of a variety of etiologies occurring in the prenatal, perinatal, or postnatal period. Though the disorder is nonprogressive, the clinical manifestations may change over time as the brain develops, with other neurologic impairments frequently co-occurring.[1,2]

More than 100,000 children are estimated to be affected with CP in the United States. Due to advances in supportive medical care, approximately 90 percent of children with CP survive into adulthood, resulting in an additional estimated 400,000 adults living with CP in the United States.[3-8] Lifetime costs are estimated to be nearly $1 million per person.[9]

## Classification and Spectrum of Disorder

CP includes a spectrum of disorders of movement, posture, and coordination with heterogeneous etiologies. The diversity of the clinical features is reflected in multiple classification systems that include reference to type of motor dysfunction, body parts affected, severity, and functional abilities. Further classification is by severity level (mild, moderate, severe), and gross motor function, which reflects the functional capabilities of the affected.[10,11] Developed in the late 1990s, the Gross Motor Function Classification System (GMFCS) outlines a standardized system for classifying motor function based on constructs of disability and functional limitation.[12] The GMFCS includes levels that reflect abilities ranging from walking without limitations (level I) to severe head and trunk control limitations requiring extensive use of assisted technology, physical assistance, and a wheelchair (level V). Table A summarizes criteria used in widely accepted classification systems.

**Table A. CP classification systems used and understood by qualified medical practitioners***

| Severity Level | Topographical Distribution | Motor Function | Gross Motor Function Classification System |
|---|---|---|---|
| • **Mild:** Child can move without assistance; his or her daily activities are not limited.<br>• **Moderate:** Child will need braces, medications, and adaptive technology to accomplish daily activities.<br>• **Severe:** Child will require a wheelchair and will have significant challenges in accomplishing daily activities.<br>• **No CP:** Child has CP signs, but the disorder was acquired after completion of brain development and is therefore classified under the incident that caused the CP, such as traumatic brain injury or encephalopathy.<br>CP is often classified by severity level as mild, moderate, severe, or no CP. These are broad generalizations that lack a specific set of criteria. Even when doctors agree on the level of severity, the classification provides little specific information, especially when compared with the GMFCS. Still, this method is common and offers a simple method of communicating the scope of impairment, which can be useful when accuracy is not necessary. | • **Monoplegia/monoparesis** means only one limb is affected. It is believed this may be a form of hemiplegia/hemiparesis where one limb is significantly impaired.<br>• **Diplegia/diparesis** usually indicates the legs are affected more than the arms; primarily affects the lower body.<br>• **Hemiplegia/hemiparesis** indicates the arm and leg on one side of the body is affected.<br>• **Paraplegia/paraparesis** means the lower half of the body, including both legs, are affected.<br>• **Triplegia/triparesis** indicates three limbs are affected. This could be both arms and a leg, or both legs and an arm. Or, it could refer to one upper and one lower extremity and the face.<br>• **Double hemiplegia/double hemiparesis** indicates all four limbs are involved, but one side of the body is more affected than the other.<br>• **Tetraplegia/tetraparesis** indicates that all four limbs are involved, but three limbs are more affected than the fourth.<br>• **Quadriplegia/quadriparesis** means that all four limbs are involved.<br>• **Pentaplegia/pentaparesis** means all four limbs are involved, with neck and head paralysis often accompanied by eating and breathing complications. | • **Spastic:** Implies increased muscle tone. Muscles continually contract, making limbs stiff, rigid, and resistant to flexing or relaxing. Reflexes can be exaggerated, while movements tend to be jerky and awkward. Arms and legs often affected. Tongue, mouth, and pharynx can be affected, as well, impairing speech, eating, breathing, and swallowing. Spastic CP is hypertonic and accounts for 70% to 80% of CP cases. The injury to the brain occurs in the pyramidal tract and is referred to as upper motor neuron damage.<br>• **Nonspastic:** Decreased and/or fluctuating muscle tone. Multiple forms of nonspastic CP are each characterized by particular impairments; one main characteristic is involuntary movement, can be slow or fast, often repetitive, and sometimes rhythmic. Planned movements can exaggerate the effect (known as intention tremors). Stress can also worsen the involuntary movements, whereas sleeping often eliminates them. An injury in the brain outside the pyramidal tract causes nonspastic CP. Due to the location of the injury, mental impairment and seizures are less likely. Nonspastic CP is divided into two groups, ataxic and dyskinetic. Together they make up 20% of CP cases. Broken down, dyskinetic makes up 15% of all CP cases, and ataxic comprises 5%. | The GMFCS uses head control, movement transition, walking, and gross motor skills such as running, jumping, and navigating inclined or uneven surfaces to define a child's accomplishment level. The goal is to present an idea of how self-sufficient a child can be at home, at school, and at outdoor and indoor venues.<br>• **GMFCS Level I:** Walks without limitations.<br>• **GMFCS Level II:** Walks with limitations. Limitations include walking long distances and balancing, but not as able as Level I to run or jump; may require use of mobility devices when first learning to walk, usually prior to age 4; and may rely on wheeled mobility equipment when outside of home for traveling long distances.<br>• **GMFCS Level III:** Walks with adaptive equipment assistance. Requires hand-held mobility assistance to walk indoors, while utilizing wheeled mobility outdoors, in the community and at school; can sit on own or with limited external support; and has some independence in standing transfers.<br>• **GMFCS Level IV:** Self-mobility with use of powered mobility assistance. Usually supported when sitting; self-mobility is limited; and likely to be transported in manual wheelchair or powered mobility.<br>• **GMFCS Level V:** Severe head and trunk control limitations. Requires extensive use of assisted technology and physical assistance; and transported in a manual wheelchair, unless self-mobility can be achieved by learning to operate a powered wheelchair. |

 For more information about types and forms of cerebral palsy please visit MyChild™ at /cerebralpalsy.org/about-cerebral-palsy/types/.

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The epidemiologic Oxford Feeding Study reported significant correlations between severity of motor impairment and feeding problems including choking, underweight, prolonged feeding times, vomiting, and need for gastrostomy feeding (p values typically <0.005).[13] Although CP is a motor disorder, many children and adults with CP are affected by other developmental disabilities, including intellectual disability, impaired vision and hearing, language and behavioral disorders, and epilepsy.[11,14,15] Survival and quality of life vary across the spectrum of CP, but both are associated with severity and functional disabilities, as well as comorbid conditions.[15]

## Feeding Difficulties and Interventions

Individuals with CP frequently have feeding and swallowing problems that may lead to poor nutritional status, growth failure, chronic aspiration, esophagitis, and respiratory infections. Across the cerebral palsy spectrum, poor nutritional status is caused by distinct pathways ranging from inadequate intake, oral dysphagia, oral-pharyngeal dysphagia, gastroesophageal reflux, chronic aspiration, and behavioral etiologies. Some patients with oral-pharyngeal dysphagia and gastroesophageal reflux (GER), particularly those with severe CP, are also at risk for recurrent aspiration, which can lead to chronic pulmonary disease. Patients with feeding difficulties range from those with self-feeding skills to populations with severe disability (GMFCS V) who require extensive use of assisted technology and are dependent on others to feed them. Caregiver burden is a significant concern as the feeding process may require considerable time and may be associated with stress and caregiver fatigue[16]; stress and fatigue may in turn affect the feeding process.[17] A number of feeding and oral-motor intervention strategies have been developed to address difficulties with sucking, chewing, swallowing, and improve oral-motor skills. Strategies include oral sensorimotor management, positioning, oral appliances, food thickeners, specialized formulas, and neuromuscular stimulation. These interventions address different aspects of feeding difficulties, reflecting the range in specific problems associated with feeding and nutrition in CP. Sensorimotor techniques seek to strengthen oral-motor control and counteract abnormal tone and reflexes to improve oral feedings, and typically require months of daily application. Positioning techniques address poor postural alignment and control that exacerbates swallowing difficulties, and include stabilizing the neck and trunk. Positioning interventions are individualized and often guided by video-fluoroscopy to optimize swallowing. Oral appliances have been used to stabilize the jaw, improve sucking, tongue coordination, lip control, and chewing. Multiple approaches may be used in children with growth failure. For children with moderate to severe aspiration or malnutrition related to oral-pharyngeal dysphagia and GER, surgical interventions with gastrostomy (tube feeding directly into the stomach) or jejunostomy tubes (tube feeding into the middle portion of the small intestine, the jejunum) and antireflux procedures are often deemed necessary to improve nutritional status and reduce risk of chronic aspiration.[16,18]

No uniform decision pathway exists for deciding when a child should move from oral feeding to enteral tube feedings, but there is general consensus.[19] If oral calorie intake is insufficient to maintain growth, there is increased risk or occurrence of aspiration into the lungs, or the level of work necessary to maintain adequate caloric intake orally by the individual and the caregiver is excessive, then a medical provider may recommend enteral tube feedings (see Glossary). The method of tube feeding is based on the likely time span needed for tube supplementation, the availability of an experienced surgeon, and specific symptoms of the child. For example, a child may be considered too medically fragile for surgery, so a nasal tube may be

used for a time, which may be advanced beyond the stomach into the jejunum to reduce gastroesophageal reflux, then later replaced with a surgically placed tube. A gastric fundoplication may be included to reduce GER, if needed in the judgment of the surgeon.

## Clinical Uncertainties

The goal for management of CP is to improve the quality of life for both the child and family, through interventions that maximize independence in activities of daily living, mobility, and nutrition. Guidelines have been published by the American Academy of Neurology on the use of pharmacologic treatment of spasticity in children and adolescents with CP.[20] However, there is a limited evidence base for the majority of interventions in CP, including those that address nutrition and growth.[21] Despite a range of potential feeding interventions for patients with CP, synthesis is lacking on the efficacy, safety, and applicability of these interventions. Limited information is available on the impact on health outcomes, including quality of life. Existing reviews are limited in scope, and clinicians and families will benefit from consolidation of data for making clinical decisions.

Goals of treatment and measures of effectiveness may differ by type of CP (spastic or nonspastic), location of motor involvement (e.g., diplegia, quadriplegia), functional status, including ability to walk or sit, and degree of head and trunk control. Comorbid conditions, particularly intellectual disability (related to ability to monitor and maintain appropriate nutrient intake) as well as concurrent medications that potentially have gastrointestinal side effects may influence treatment outcomes. Different feeding interventions may perform differently across the spectrum of CP. For example, oral-motor interventions may be highly effective in populations with oral dysphagia with malnutrition. However, these same interventions could have less value in less mobile populations that are experiencing pharyngeal dysphagia with aspiration. Gastrostomy feeding may reduce aspiration during swallowing, but does not address aspiration of oral secretions, and could exacerbate GER.[22-24] Additional interventions, such as positioning and caloric supplementation may still be needed. To examine the overall effectiveness of interventions intended to improve feeding and nutrition outcomes in CP, adequate characterization of the patient populations is essential. Additionally, the need for management into later life has increased, and the optimal interventions for adults with feeding difficulties are unknown.[8,25]

Potential harms associated with feeding interventions include surgical complications, new or worsening GER, risk of aspiration, and mortality. Gastrostomy has been associated with excess weight gain.[26] The impact of antireflux procedures in addition to gastrostomy is relatively unknown. Finally, there is a need to understand the potential impact of feeding interventions on families and caregivers as substantial caregiver time and training may be required.

### Objectives

The goal of this review is to examine the effects of available interventions for feeding and nutrition problems that have been evaluated in individuals with CP.

### Population

We included studies whose populations included at least 80 percent of participants with CP. We did not require any specific diagnostic information or approach.

## Interventions

Studies assessed interventions falling into the broad categories of nonsurgical interventions, including behavioral approaches (positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training) and nutritional interventions (food thickeners, caloric supplementation with formulas, vitamin supplementation, and altering food consistency) and surgical interventions (gastrostomy tube [g-tube], percutaneous endoscopic gastrostomy [PEG], jejunostomy, and fundoplication). Studies may have used combinations of approaches (e.g., behavioral plus nutritional interventions).

## Comparators

Comparators included other nonsurgical approaches or no intervention compared with behavioral interventions or nutritional interventions (Key Questions 1a, 2a), oral feeding or nutritional and behavioral interventions compared with tube feeding (Key Question 3a), oral feeding compared with g-tube with fundoplication (Key Question 3b), and jejunostomy tube compared with fundoplication (Key Question 3c).

## Outcomes

Intermediate outcomes included changes in growth status, including height, weight, skinfold status, limb length, and energy expenditure; improvements in swallowing; and need for surgical or nutritional intervention. Patient-centered and health outcomes included mortality, hospitalizations, days of antibiotics for aspiration, quality of life, patient and family satisfaction and stress, feeding time, physical and mental health of caregiver, and reflux episodes. We also assessed the harms of interventions, defined by the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care program as all possible adverse consequences of an intervention, including adverse events (Figure A).[27]

# Key Questions

We have synthesized evidence in the published literature to address these Key Questions:

**Key Question 1a.** When compared with other nonsurgical interventions or no intervention, how effective are behavioral interventions, including positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training, for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life in individuals with CP and feeding difficulties?

**Key Question 1b.** Is the effectiveness of behavioral interventions modified by age, race, severity, functional status (e.g., GMFCS level), or initial nutritional status?

**Key Question 2a.** When compared with other nonsurgical interventions (e.g., positioning, oral appliances or stimulation) or no intervention, how effective are nutritional interventions (food thickeners, caloric supplementation with formulas, vitamin supplementation, and altering food consistency [e.g., pureeing]) for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life in individuals with CP and feeding difficulties?

**Key Question 2b.** Is the effectiveness of nutritional interventions modified by age, race, severity, functional status (e.g., GMFCS level), or initial nutritional status?

**Key Question 3a.** What is the comparative effectiveness of tube feeding when compared with oral feeding or with nutritional and behavioral interventions in individuals with CP who present with feeding difficulties, including malnourishment, failure to thrive, aspiration, and excessive caregiver burden?

**Key Question 3b.** Among individuals with CP and feeding difficulties *with significant reflux*, what is the effectiveness of g-tube placement with fundoplication versus oral feeding for reducing reflux and for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life?

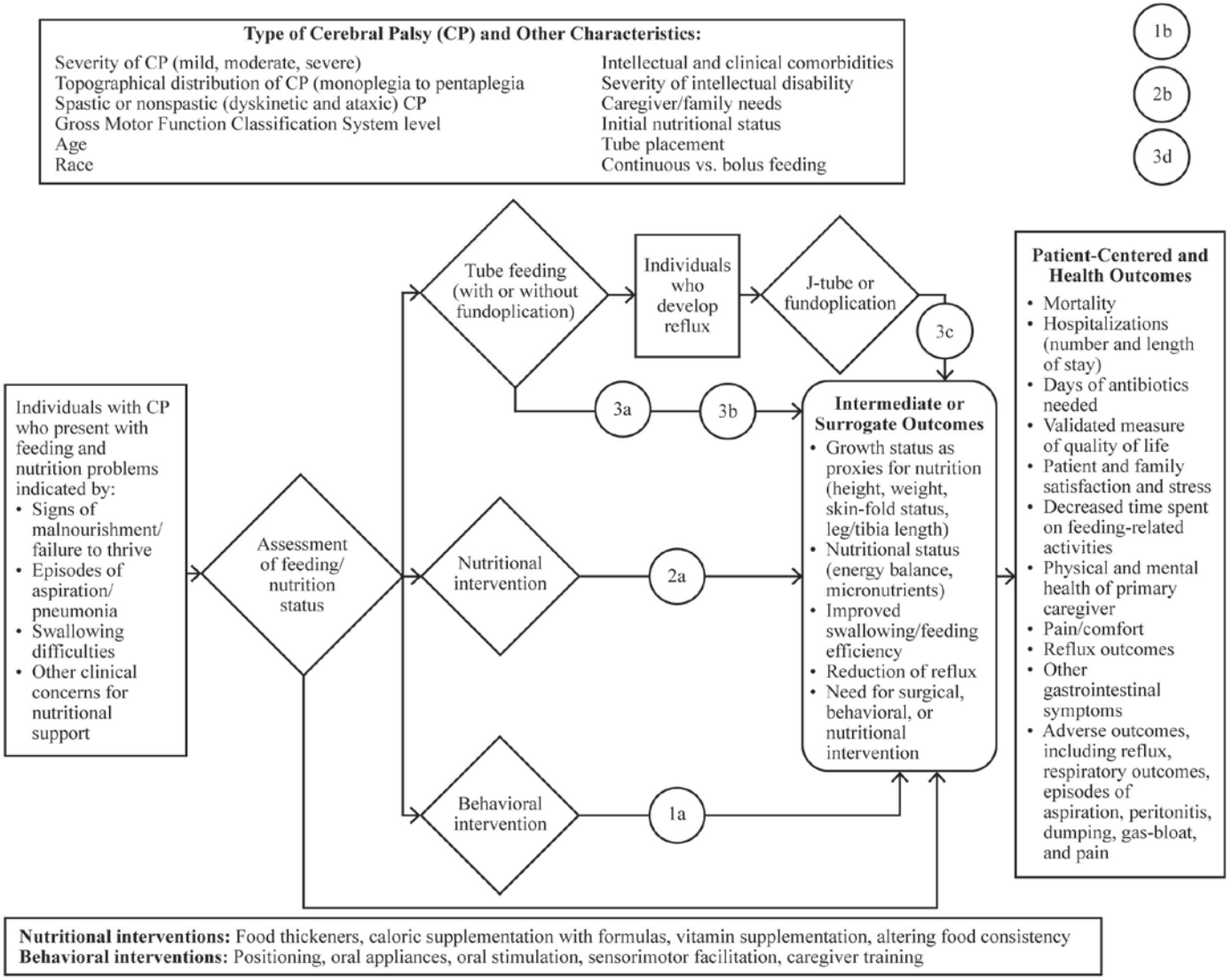
**Key Question 3c.** Among individuals *who develop reflux after gastrostomy*, what is the comparative effectiveness of j-tube versus fundoplication for reducing reflux in the short term and achieving improvements in nutritional state/growth, health outcomes, health care/resource utilization, and quality of life?

**Key Question 3d.** Is the effectiveness of tube feeding modified by tube placement, age, race, severity, functional status (e.g., GMFCS level), initial nutritional status, or continuous versus bolus feeding?

## Analytic Framework

The analytic framework (Figure A) outlines the path of care for individuals with CP and feeding difficulties. There may be multiple indications among this population, including signs of malnourishment or failure to thrive, episodes of aspiration or pneumonia, swallowing difficulties, or other clinical concerns for nutritional support. Individuals typically undergo a feeding and nutrition assessment, which could be followed by a behavioral (Key Question 1a) or nutritional (Key Question 2a) feeding intervention or a combination of such approaches, or the placement of a tube for feeding (Key Questions 3a-c). Individuals with reflux may undergo tube placement with fundoplication to help alleviate reflux (Key Question 3b). Individuals without pre-existing reflux who undergo a tube placement may develop reflux following the procedure[22-24] and require additional treatment via a jejunostomy tube or fundoplication (Key Question 3c). Possible intermediate or surrogate outcomes resulting from these interventions can include a change in growth status, improved swallowing, or various adverse effects. At this point on the pathway, individuals with CP may undergo another feeding and nutrition assessment followed by an alternative intervention. Patient-centered and health outcomes following the intermediate outcomes can include mortality, incidences of hospitalizations, antibiotic use, quality of life, patient and family satisfaction and stress, changes in time spent on feeding activities, physical and mental health of the primary caregiver, pain or comfort, and various adverse effects. Certain factors may influence the pathway at all stages and can include the type and severity of CP, age, race, intellectual and clinical comorbidities, severity of intellectual disability, and caregiver or family needs (Key Questions 1b, 2b, and 3d specifically address potential modifiers of treatment effectiveness). Numbers in circles within the diagram indicate the placement of Key Questions in relation to the treatment process.

**Figure A. Analytic framework**




Note: Numbers in circles represent Key Questions.

# Methods

## Input From Stakeholders

The topic for this report was nominated in a public process. We drafted the initial Key Questions and analytic framework and refined them with input from key informants with expertise in child health and development, pediatric gastroenterology, occupational therapy, and neurodevelopment and developmental disabilities. After review from AHRQ, the questions and framework were posted to a public Web site. The public was invited to comment on these questions.

After reviewing the public commentary, we drafted final Key Questions and submitted them to AHRQ for review. During the topic development phase we identified a recent, rigorously conducted systematic review addressing behavioral feeding interventions.[16] We thus structured the part of the review relevant to behavioral interventions as an update to the previous review. We convened a Technical Expert Panel (TEP) to provide input during the project on issues such as setting inclusion/exclusion criteria and assessing study quality. We identified key informants and TEP members through scanning recent research related to CP, reviewing stakeholders in an AHRQ-funded research exploration forum on CP,[28] and through discussions with our AHRQ Task Order Officer (TOO). All candidates were approved by the TOO after disclosure and review of potential conflicts of interest.

## Data Sources and Selection

### Data Sources

We searched key databases including studies related to surgical and nonsurgical interventions for promoting feeding and nutrition in individuals with CP: the MEDLINE® via the PubMed® interface, PsycINFO® (psychology and psychiatry database), the Cumulative Index of Nursing and Allied Health Literature (CINAHL®), OTSeeker, REHABDATA, and the Education Resources Information Clearinghouse (ERIC℠). The appendixes of the full report include a description of the databases' content and breadth of coverage. Our search strategies used a combination of subject heading terms appropriate for each database and keywords relevant to CP and nutrition (e.g., cerebral palsy, enteral feeding). We also manually searched the reference lists of included studies and of recent systematic and narrative reviews and also invited TEP members to suggest potential citations.

### Inclusion and Exclusion Criteria

We included all study designs except single case reports provided that studies reported on an intervention aimed at feeding/nutrition in individuals with CP. We excluded studies that:

- Were not original research
- Did not report information pertinent to the Key Questions
- Did not address treatment modalities aimed at outcomes of interest
- Did not include aggregate data (i.e., included only individual data for each participant) or data presented only in graphics/figures
- Were single case reports

- Were not published in English
- Were published before 1980.

### Screening of Studies

Two reviewers separately evaluated each abstract. If one reviewer concluded that the article could be eligible, we retained it. Two reviewers independently read the full text of each included article to determine eligibility, with disagreements resolved via third-party adjudication.

## Data Extraction and Quality Assessment

### Data Extraction

A team member with methodologic expertise entered information into the evidence tables. After initial data extraction, a second team member edited entries for accuracy, completeness, and consistency.

### Quality Assessment

Two reviewers independently assessed quality using quality assessment tools appropriate for the study design (Cochrane Risk of Bias tool for RCTs,[29] Newcastle-Ottawa scale for cohort studies,[30] a tool adapted from AHRQ Effective Health Care Program guidance for case series,[31] and the AMSTAR tool for systematic reviews[32]). The reliability and other characteristics of the Cochrane Risk of Bias tool, Newcastle scale, and AMSTAR have been previously assessed with positive ratings overall.[33-38] We resolved differences though discussion, review of the publications, and consensus with the team. We rated studies as good, fair, or poor quality and retained poor studies as part of the evidence base discussed in this review. More information about our quality assessment methods is in the full report, and Table B describes the quality ratings.

**Table B. Description of study quality levels**

| Quality Level | Description |
|---|---|
| Good | Good studies are considered to have the least bias and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to treatments; has a low dropout rate; and uses appropriate means to prevent bias; measure outcomes; analyze and report results. |
| Fair | Fair studies are susceptible to some bias, but probably not sufficient to invalidate the results. A study may be missing information, making it difficult to assess limitations and potential problems. As the "fair quality" category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid. |
| Poor | Poor studies are subject to significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions. |

# Data Synthesis and Analysis

## Evidence Synthesis

### Prior Systematic Reviews

When we identified published, high-quality systematic reviews addressing a Key Question that were largely up to date and relevant, we intended to cite and summarize these reviews as evidence and not extract data from the primary studies. One review met these criteria.[16] We provide a summary of the methods of this review and overall findings in line with guidance in Using Existing Systematic Reviews to Replace de novo Processes in Conducting Comparative Effectiveness Reviews.[39]

### Primary Research

For interventions not covered in existing systematic reviews, we extracted and synthesized data from primary studies meeting our criteria. The small number of the studies, the weak study designs and the heterogeneity in outcomes made a meta-analysis both inappropriate and unnecessary.

## Strength of the Evidence

### Prior Systematic Reviews

We used the included systematic review on behavioral interventions[16] to assess strength of evidence for the literature included in the prior review, translating the assessment used in that review (see full report, Table 5) into levels used in the EPC program.

### Primary Research

We also assessed the strength of the body of literature for surgical studies included in the current review. The assessment of the literature is done by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and it can be regarded as insufficient, low, moderate, or high.

Methods for applying strength of evidence assessments are established in the AHRQ EHC Series Paper 5: Grading the Strength of a Body of Evidence When Comparing Medical Interventions[40] and are based on consideration of four domains: risk of bias, consistency in direction of the effect, directness in measuring intended outcomes, and precision of effect. Strength of evidence is assessed separately for major outcomes.

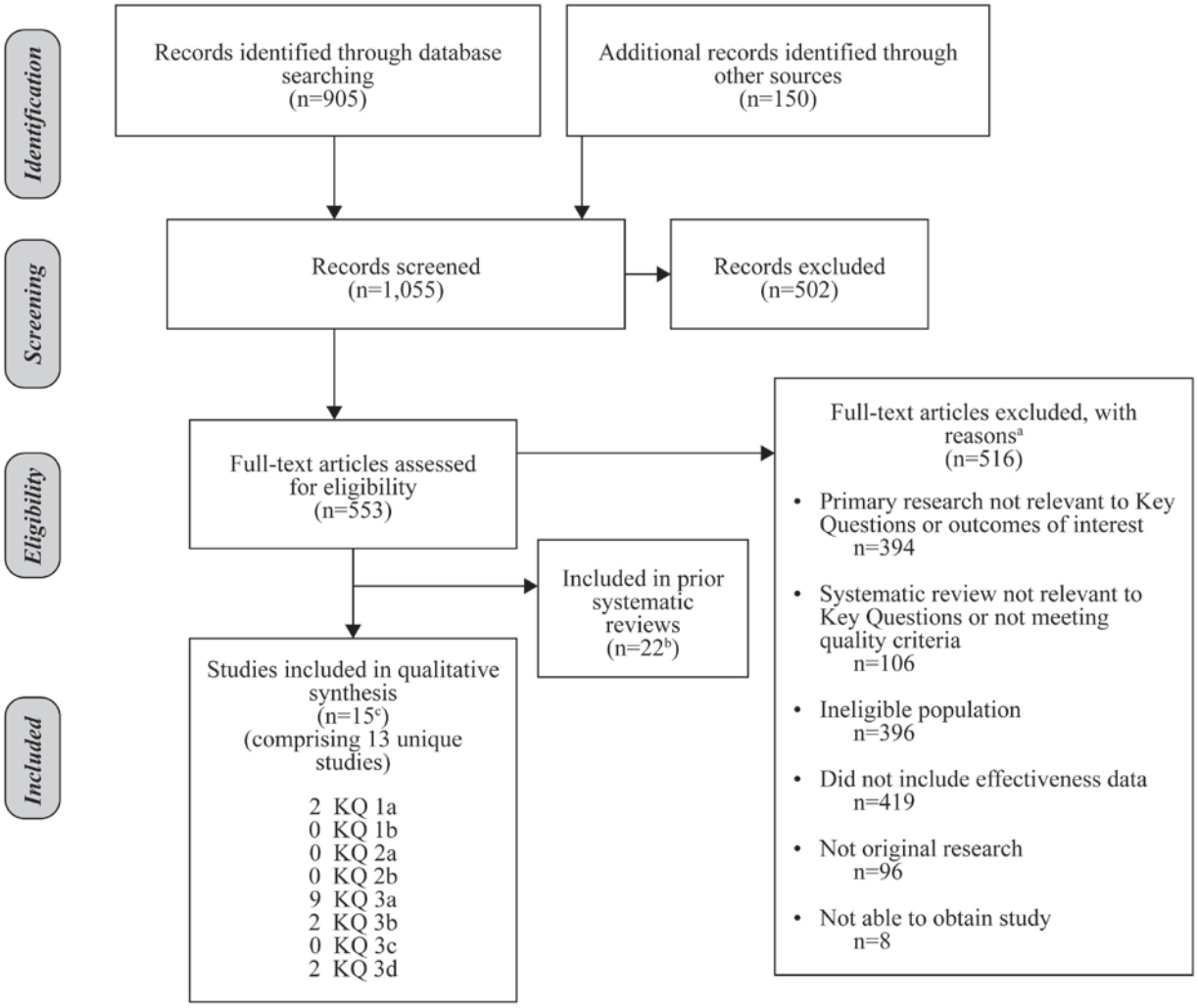
# Results

## Article Selection

Of the entire group of 1,055 citations, 553 articles required full-text review (Figure B). Of the 553 full-text articles reviewed, 15 articles (comprising 13 unique studies) met our inclusion criteria. This figure includes 12 unique primary research studies (reported in 14 publications) described in this comparative effectiveness review and one systematic review meeting our

inclusion criteria. As indicated in Figure B, we were unable to obtain the full text of eight studies. Seven of these appeared from their abstracts to be narrative reviews, and one report, which may contain primary data, focuses on upper limb movement in CP. Thus, we do not feel that any of these papers would change our conclusions.

**Figure B. Disposition of studies identified for this review**




CER = comparative effectiveness review; KQ = Key Question; n = number
[a]Numbers do not tally as studies could be excluded for multiple reasons.
[b]This number includes one study (Gisel 1994[41]) not explicitly referenced in the Snider review; the Snider review cites a later Gisel paper[42] reporting on the same population.
[c]This figure includes 12 unique primary research studies (reported in 14 publications) described in the current CER and one systematic review meeting our screening criteria.

# Summary of Findings by Key Question

## Key Questions 1a-b. Effectiveness of Behavioral Interventions

Two studies assessing behavioral interventions met our criteria: one was a good quality systematic review.[16] The primary literature updating the review consisted of one case series.[43] The systematic review, published in 2011 by Snider and colleagues, included 21 studies (5 RCTs), most with no more than 20 subjects, assessing interventions including sensorimotor approaches, positioning, oral appliances, altering food consistency, and feeding interventions, and largely addressing the outcomes of feeding efficiency and safety; overall, the review concluded that the evidence base was generally of poor quality that limited conclusions about effectiveness for all of the interventions.[16] Effects of sensorimotor interventions were inconsistent, with one good quality study finding no effect, and smaller, less rigorous studies demonstrating improvements in efficiency and safety during feeding. A set of small case series of positioning found consistently positive effects, including reductions in food leakage and aspiration, but a larger, more rigorous study has yet to be conducted. One comparative study of the role of altering food consistency suggested that feeding could be made safer and more efficient by pureeing food. Oral appliances were associated with enhanced oral sensorimotor skills, but with only 2 RCTs, one of which was good, more research is needed. No effect of these appliances was seen on safety. Two small case series reported improvements in feeding efficiency, oral-motor behaviors and independence through the use of feeding devices. The small, short-term case series of a caregiver intervention[43] reported some improvements in oral-motor behaviors, caregiver stress, and number of chest infections, but it does not change the conclusions laid out in the prior review.

No studies were designed or powered to directly assess modifiers of the effectiveness of behavioral interventions (Key Question 1b). One study reported in the Snider review provides data separately for children with and without a history of aspiration.[44,45] The study, reported in two publications rated as fair quality on the PEDro scale, reported improved eating efficiency and safety when eating pureed food for aspirating children after sensorimotor intervention, but no effect among those who did not aspirate.

## Key Questions 2a-b. Effectiveness and Modifiers of Nutritional Interventions

No studies met criteria to address this question although pureed food was used in conjunction with positioning and sensorimotor interventions described in the review by Snider and colleagues.[16]

## Key Question 3a. Effectiveness of Tube Feeding for Feeding Difficulties

The primary literature included six case series focused on assessing clinical outcomes after gastrostomy,[46-53] one fair quality cohort study on the potential for overfeeding with gastrostomy that also included effectiveness data,[54] and one case series regarding the potential for gastrostomy to result in gastroesophageal reflux (GER).[55] Harms were also addressed in one case series assessing the effects of a low energy feed on the potential for overfeeding.[26]

Evidence for the effectiveness of tube feeding (either g-tube or j-tube) comes from six case series and one prospective cohort study and one case series, designed to study the potential for overfeeding. All six case series assessing gastrostomy focused on severely impaired children and

all reported significant increases in weight after gastrostomy, over six to 20 months. The most comprehensive case series[50-52] reported improvements on all weight and growth related outcomes (weight, head growth, linear growth, arm circumference and skinfold thickness), including closing the gap significantly with a normally developing reference population, and significantly more than would have been expected without intervention. Followup continued to 12 months postsurgery, with data available on 46 of the initial 57 children, and 6 unavailable due to loss to followup. The three other case series with growth data also reported significant pre-post increases in weight, but data on other measures were unreported or inconsistent. One case series also assessed health care utilization as a proxy for overall health and found the number of hospitalizations significantly reduced over the year following gastrostomy.[52]

Two studies reported on QOL measures; in one,[51] parental QOL improved significantly overall as rated on the SF-36 II, in tandem with decreases in feeding time. In the other, 98 percent of parents expected that their child's QOL (measured using a study-created tool based on questions from the validated CHQ-PF50 scale and a visual analog scale) would improve with gastrostomy, but did not report that to be the case.[47]

The studies included in this review were fairly short term and constrained by the requirement that they provide data both before and after surgery. Thus, harms of gastrostomy were limited to those in the fairly short term, and larger, retrospective studies that do report on harms data were excluded. Harms associated with tube feeding include surgical harms, infection, increased rates of reflux requiring further treatment, and potential overfeeding. Overall, rates of peritonitis were low, ranging from 2 to 5 percent, one study reported minor site infections at 59 percent and leakage at 30 percent. Deaths ranged from 7 to 29 percent, but were considered not to be related to gastrostomy in all studies. Mortality is high along individuals with CP, and it is impossible to know whether the observed deaths were causally related to treatment or to the course of the condition.

Three studies were specifically intended to analyze harms of tube feeding: one on the potential for tube feeding to induce reflux[55] and two others on potential to overfeed.[26,54] Two studies found positive associations with the harmful outcome of interest (overfeeding or reflux).[54,55] One study assessing the effects of a low energy feed, which increased weight without increasing fat mass, suggests that such formulas may have the potential to reduce the risk of overfeeding.[26] The clinical importance of these and other harms, relative to the potential danger of not intervening is unclear and likely must be assessed in the context of each individual patient and family. Clearly, surgical interventions can lead to increased weight gain; the degree to which harms outweigh those benefits likely depends on the starting point of the individual, family stressors, and the degree to which harms can be mitigated using appropriate feed and other approaches—an area that warrants continued research.

The frequent report of GER that develops after gastrostomy may be balanced by study investigators' observations that it is frequently managed medically. In terms of overfeeding, the two studies on this subject demonstrate that tube fed children may be at risk for obesity without careful attention to the content and quantity of their food products.

## Key Question 3b. Effectiveness of Tube Placement With Fundoplication for Reducing Reflux

No studies directly compared the use of g-tube with fundoplication to oral feeding for the treatment of reflux. One RCT including children with diplegic spastic or tetraplegic spastic CP compared two forms of plication (fundoplication versus vertical gastric plication),[56] and in one

case series children with mixed and spastic forms of CP undergoing gastrostomy plus Nissen fundoplication showed improvements in reflux symptoms and weight gain but not episodes of pneumonia;[57] 30 percent of participants had recurrent reflux within 12 months of surgery. In the RCT, GER improved in both groups, with the Nissen fundoplication group having a significant decrease in the total number of reflux episodes, percentage of acidic pH, and longer reflux episodes, and the vertical gastric plication group showing a significant change in the pH measurement parameters.

Major complications were experienced by 14.3 percent of the children in each arm of the RCT, and minor harms included aspiration, urinary tract infection and pneumonia.[56] In the case series early complications (within one week of fundoplication) included pneumothorax, stomach ulcers, and cellulitis, all in patients undergoing laparoscopic fundoplication. Late complications (i.e., more than one week postfundoplication) included bloating, diarrhea (dumping syndrome), and intestinal obstruction; these events were all reported in individuals undergoing open fundoplication.

### Key Question 3c. Effectiveness of J-tube Compared With Fundoplication

We did not identify any studies addressing this Key Question.

### Key Question 3d. Modifiers of the Effectiveness of Surgical Interventions

We sought potential modifiers (age, race, severity, functional status, initial nutritional status, and continuous vs. bolus feeding) considered as important by our technical experts. Few studies addressed modifiers of effects of surgical interventions. Subanalyses were conducted in two case series[46,48] to assess the degree to which age and type of procedure modified outcomes. In the first, children were divided into age bands of <2, 2 to 4, 5 to 7, 8 to 11 and 12 to 18. No age group included more than five children. Weight increased in all groups except ages 5 to 7, although this group had significant increases in triceps skinfold measurement. The very small size of each group, however, precludes any conclusion about age as a modifier.

The other retrospective case series of 57 individuals[48] reported that the highest proportion of individuals reaching weight for height were in the groups that had surgery before age 2, had had their gastrostomy for at least 2 years or had fundoplication. One study assessing outcomes by the presence of fundoplication suggested that use of antibiotics and respiratory hospitalizations did not differ by whether the child had a fundoplication. The decision about whether or not to use fundoplication, was made clinically and not for research purposes.[52] One series evaluating the g-tube with fundoplication found no difference in outcomes associated with laparoscopic versus open approach.[57] The intent of the study was not to compare the two approaches; rather, the clinical team changed their approach during the course of the study.

## Discussion

Feeding and nutrition problems are common among children with CP and have significant health implications. Some patients with oral-pharyngeal dysphagia and GER, particularly those with severe CP, are also at risk for recurrent aspiration which can lead to chronic pulmonary disease. Patients with feeding difficulties range from those with self-feeding skills to populations with severe disability (GMFCS V) who require extensive use of assisted technology and are

dependent on others to feed them. Indeed, chronic pulmonary disease related to aspiration is a leading cause of death among patients with severe CP.[58-61]

Ultimately, few data exist to guide care. Our analysis of the behavioral literature consists of a summary of a good quality systematic review published in 2011, updated with one new case series evaluating a caregiver training program that is not manualized (documented in a manual so that it can be replicated). The surgical literature consists of a total of 11 studies meeting our criteria; studies were largely case series. One prospective cohort study focused primarily on harms.

Across all interventions, the study populations are almost exclusively children with severe CP; when it is assessed populations generally meet criteria for level IV or V of the GMFCS. Although study populations are generally assessed on overall severity (e.g., GMFCS) and weight, the use of other measures for growth and nutrition, and explicit characterization of the feeding challenges in the study population is lacking. Surgical outcomes data are available for fewer than 300 children, and only one cohort study provides comparative data comparing surgical with oral interventions for any population of CP. Of note, those studies that do provide data on weight gain do so against reference populations of typically developing children. These are likely not appropriate reference standards; improvement in z-scores among children with CP may very well be clinically meaningful even if these children do not approach weight standards for the reference group.

## Key Findings and Strength of the Evidence

We used the included systematic review on behavioral interventions to assess strength of evidence, translating the assessment used in that review into levels used in the EPC program. Behavioral studies included in the prior review[16] were small, typically short-term, and typically conducted using pre-post designs subject to bias. The authors of the systematic review used a modified Sackett approach to assess the strength of the body of evidence (see Table 5 in the full report). We have translated those assessments into EPC program equivalents in Table C.

Strength of evidence for behavioral interventions ranges from low to moderate. The moderate rating for the positive effects of oral appliances on sensorimotor outcomes is based on one good and one fair quality RCT and additional supporting studies of varying designs. Effects on eating efficiency and swallowing were not consistent, and the small sample sizes suggest imprecision. The low strength of evidence for positive effects of positioning, altering food consistency, and feeding devices on all outcomes is due to the lack of RCTs and generally small sample sizes. Studies typically reported some positive effects on mealtime length and eating efficiency; however, rigorously conducted studies are lacking. The strength of the evidence for the effects of oral sensorimotor interventions and oral appliance on feeding safety and efficiency is insufficient based on a paucity of rigorous studies.

Longer term studies are lacking across all interventions; thus, the durability of effects is not clear. Studies also did not consistently assess harms, though aspiration and swallowing difficulties, which may be related to the underlying condition as well as the intervention, are reported in some. Overall, more data on greater numbers of participants, including adults as well as children, are needed to understand the effectiveness of behavioral approaches.

**Table C. Strength of the evidence for behavioral interventions assessed in Snider review[16]**

| Intervention | Outcome(s) | Level of Evidence (Sackett) | EPC Equivalent Strength of Evidence (Direction of Effect) |
|---|---|---|---|
| Oral sensorimotor interventions | Increased feeding safety and efficiency | 4 (conflicting) | **Insufficient** Inconsistent evidence and a paucity of comparative studies. Poor quality studies had positive results; whereas those with more rigor showed no effect, but may have been underpowered. |
| Positioning | Increased feeding safety and efficiency | 2b (limited) | **Low** No RCTs, but positive results consistently observed in other study designs. Studies were small, and therefore imprecise. |
| Altering food consistency | Increased feeding safety and efficiency | 2b (limited) | **Low** One experimental study that was of adequate size showed some positive effects on increasing feeding safety and efficiency. |
| Oral appliances | Enhanced oral sensorimotor skills | 1b (moderate) | **Moderate** One good RCT, one fair RCT, and additional supporting studies of varying designs. Better quality studies showed positive effects, but effects were not entirely consistent; small sample sizes suggest imprecision and rigorous studies should be replicated. |
| Oral appliances | Increased feeding safety and efficiency, generalized postural control | 5 (no good evidence) | **Insufficient** Only studies of poor quality were available to assess feeding efficiency and generalized postural control. |
| Feeding devices | Increased feeding efficiency | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |
| Feeding devices | Enhanced oral-motor behaviors | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |
| Feeding devices | Increased independence | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |

EPC = Evidence-based Practice Center; RCT = randomized controlled trial

We also assessed strength of evidence for six primary outcomes associated with feeding tubes in comparison with oral feeding, and for feeding tubes with fundoplication to address reflux: changes in growth outcomes; respiratory outcomes, including reflux; quality of life; long term morbidity and mortality; and harms (Tables D–E). We found the evidence to be insufficient to low for all outcomes. The low strength of evidence for the effects of gastrostomy on increasing growth measures, including weight, is based on a clearly significant effect measured in five case series and one prospective cohort study and in a small number of children. Additional data are needed on greater numbers of children to better quantify expected effects, particularly in subgroups by severity and age, and to better understand the implications of observed harms. Long-term effects are unknown as data on mortality are short term only. Nonetheless, it is clear that, in children with significant feeding difficulties, most of whom

present significantly underweight, tube feeding leads to weight gain. Evidence is currently insufficient to assess whether and to what degree fundoplication is effective specifically to treat children with CP who present with significant reflux.

**Table D. Outcome, strength of evidence domains, and strength of evidence for feeding tubes (KQ3a)**

| Outcome | Study Type (Number Reporting Outcome) | Domains Pertaining to Strength of Evidence (SOE) | | | | SOE (Direction of Effect) |
|---|---|---|---|---|---|---|
| | | Risk of Bias | Consistency | Directness | Precision | |
| **Growth measures (weight, height, skinfold)**[26,46-50,53,54] | Case series (7) Prospective cohort (1) | High | Consistent | Direct | NR | Low (Increase in growth measures) |
| **Respiratory outcomes**[26,52] | Case series (2) | High | NA | Direct | NR | Insufficient |
| **Parental quality of life**[51] | Case series (1) | High | NA | Direct | NR | Insufficient |
| **Child quality of life**[47] | Case series (1) | High | NA | Indirect | NR | Insufficient |
| **Long term morbidity and mortality** | None | | | | | Insufficient |
| **Harms**[26,46-48,51,54,55] | Case series (6) Prospective cohort (1) | High | Consistent | Direct | NR | Low (Increased potential for overfeeding and reflux) |

KQ = Key Question; NA = not applicable; NR = not reported

**Table E. Outcome, strength of evidence domains, and strength of evidence for fundoplication (KQ3b)**

| Outcome | Study Type (Number Reporting Outcome) | Domains Pertaining to Strength of Evidence (SOE) | | | | SOE |
|---|---|---|---|---|---|---|
| | | Risk of Bias | Consistency | Directness | Precision | |
| **Growth measures (weight, height, skinfold)**[57] | Case series (1) | High | NA | Direct | NR | Insufficient |
| **Reflux outcomes**[56,57] | RCT (1); Case series (1) | High | Inconsistent | Direct | NR | Insufficient |
| **Quality of life** | None | | | | | Insufficient |
| **Long term morbidity and mortality** | None | | | | | Insufficient |
| **Harms**[56,57] | RCT (1); Case series (1) | High | Consistent | Direct | NR | Insufficient |

KQ = Key Question; NA = not applicable; NR = not reported; RCT = randomized controlled trial

# Applicability of the Evidence

## Applicability of Studies of Behavioral Interventions

Studies of behavioral interventions to date have been limited in scope and focus on a limited selection of outcomes of interest. Studies typically provided limited data on health outcomes including hospitalizations, antibiotic use, patient and family satisfaction and quality of life, measures of family stress, and pain/comfort. In addition to the recent systematic review from

Snider and colleagues, we located one case series based in the home among child-caregiver pairs in Bangladesh. The study focused on caregiver training related to diet, food consistency, appropriate utensils, and postural and physical support for positioning and feeding. Evidence from this study is likely primarily applicable to younger children who are able to eat at least some foods orally. The approach studied may not closely match interventions available in practice as it was conducted in the home setting, which is likely highly variable, and was not well described. Thus, individuals wishing to infer the potential results of clinical practice based on the available research need to assess carefully the degree to which the study methods matched those available and used in practice. Ultimately, the effectiveness of behavioral interventions within and outside of this limited sample and setting is currently unknown.

### Applicability of Studies of Surgical Interventions

All of the studies of surgical interventions focused, appropriately, on severely impaired individuals, generally GMFCS levels of IV or V. Those studies that provided data to characterize the participants indicated that children in the studies had experienced substantial lack of growth for up to 12 months prior to intervention. Participants were followed for 6 months to over a year, and studies assessed outcomes of interest to clinicians and caregivers of individuals with CP, including changes in measures of growth, hospitalizations, and chest infections. The two studies of fundoplication for reflux similarly included children, but their level of functional impairment was not clearly described. Studies were not designed to assess subsets of individuals as defined by types of feeding disorders or specific surgical intervention.

## Future Research

The study of feeding and nutritional interventions for individuals with cerebral palsy is a nascent field, but certainly one that is growing. Rigorous, comparative studies of behavioral and nutritional interventions need to be conducted; good RCTs are largely missing from the literature. Nonetheless, current research is available to provide potential directions for study. For example, studies of sensorimotor interventions currently provide conflicting evidence and more rigorous evidence is needed to answer the open question of whether they can be effective at improving outcomes. Studies of positioning are also warranted. Studies should also compare behavioral interventions with one another, with extensive characterization of the participants to better understand what works for which patients. Foundational research is needed to establish the most appropriate, patient-centered outcomes that are important to families of individuals with CP. The degree to which improved changes are considered target outcomes by families is not well established. It is also not clear whether short-term outcomes translate to longer term health outcomes. We note that there is a complete lack of studies designed or powered to identify modifiers of effectiveness of the behavioral interventions.

The ethics of conducting comparative surgical studies or studies of nutritional interventions in the absence of appropriate comparison groups may preclude rigorous comparative designs. Case series can be conducted in ways that move them closer to providing effectiveness data; in addition, well-developed registries may provide a source of data for observational study designs. Of particular importance is the need to conduct large enough studies to fully characterize both participants and interventions so that the question of whether treatment approaches are better for individuals who, for example, aspirate or do not aspirate, can be answered. Patients with cerebral palsy are heterogeneous in many ways, including severity and comorbid conditions; rigorous subgroup analyses are needed to obtain data for targeting treatment. Furthermore, they and their

families already experience substantial burden in terms of health care and other stressors. Recruitment and retention is likely to be a challenge, and may be a reason for the relatively poor evidence base to date.

In both types of interventions, data are absent on the role of feeding interventions for adults with CP. In addition to the interventions included in this review, it is necessary to consider the nutritional makeup (energy composition) of the food products themselves. Prospective, comparative studies should be carefully conducted to determine what type of nutrition is appropriate for obtaining positive health outcomes without inducing excessive weight gain.

Considerable uncertainty remains concerning harms over both the short and long term. Harms associated with feeding interventions have not been thoroughly reviewed in prior systematic reviews, and observational studies continue to raise questions about the risks and benefits of surgical interventions for children with severe CP and feeding difficulties.

## Implications for Clinical and Policy Decisionmaking

The effectiveness of feeding and nutrition interventions for individuals with cerebral palsy remains largely unknown, with strength of evidence not exceeding moderate for any intervention. Nonetheless, clinical decisionmakers can use this review to understand what interventions are available, what outcomes have been seen, and, to some degree, to balance potential harms. When a child has a severe feeding disorder, is unable to consume adequate nutrition, and is affected by frequent aspiration and pneumonias, the health outcomes can be dire. Understandably, treatment decisions must be made, even with inadequate evidence. Parents and providers contemplating gastrostomy can use the review to help understand potential effects on their quality of life and that of the child, potential harms that may occur, and potential tradeoffs related to social functioning. They should do so in light of the severity and other issues facing the individual child and family. Of note, nonclinical considerations may include family stress and pressures related to providing optimal care for the individual child. Stressors associated with caring for a severely disabled child and the potential impact of feeding interventions on the relationship with the child should not be underestimated and may play into decisionmaking along with the limited clinical evidence available. Ideally, this review will help policymakers and researchers understand what types of studies are essential to lead to more informed clinical decisionmaking.

# Conclusions

Evidence for behavioral interventions for feeding disorders in cerebral palsy ranges from insufficient to moderate. Some studies suggest that sensorimotor interventions such as oral appliances (moderate strength of evidence) and positioning (low strength of evidence) may be beneficial, but there is a clear need for rigorous, comparative studies. Evidence for surgical interventions is insufficient to low. All studies to date demonstrate significant weight gain with gastrostomy. Results for other growth measures are mixed, and substantial numbers of children remained underweight, although given a lack of appropriate reference standards for the CP population, these results should be interpreted cautiously. Considerable uncertainty remains concerning harms over both the short and long term. Harms with gastrostomy can be common, and include overfeeding, site infection, stomach ulcer, and reflux. Mortality rates range from 7 to 29 percent. Longer-term, comprehensive case series are needed to understand potential harms in the context of benefits and potential risk of not treating.

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## Glossary

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| **Bolus feeding** | Method of delivering enteral feedings using a limited amount of nutritional product administered through a tube into the stomach over a span of 15–30 minutes several times per day; not usually recommended for persons with a jejunostomy tube as the intestine cannot hold the same volume that the stomach can.[1] |
| **Castillo-Morales Device** | Oral device including removable plates positioned on the upper jaw and including stimulatory elements to promote normal tongue and lip movements. |
| **Continuous feeding** | Method of delivering nourishment that involves the drip of formula by gravity or assisted by a pump in an ongoing manner over a specified number of hours into a gastrostomy, jejunostomy, or gastrojejunal tube.[1] |
| **Endoscopy** | Procedure in which an instrument containing a camera is inserted into the gastrointestinal tract to visualize organs. This procedure is one of the methods used in the percutaneous placement of gastrostomy, jejunostomy, or gastrojejunal tubes.[1] |
| **Enteral feeding tube** | Feeding device placed into the stomach or jejunum (middle section of the small intestine) through which formula, fluids, and/or medication are given to a person as an alternative to oral feeding.[1] |
| **Fundoplication/ Nissen Fundoplication** | Surgical procedure performed for the management of GERD. During the Nissen fundoplication, the upper part of the stomach is wrapped around the lower esophageal sphincter (the ring of muscle at the bottom of the esophagus that acts like a valve between the esophagus and stomach) to strengthen the sphincter and prevent acid reflux. The Nissen fundoplication may be performed using a laparoscope, an instrument that is inserted through tiny incisions in the abdomen, and uses small instruments to hold a camera to look at the abdomen and pelvis, which is less invasive and promotes faster recovery but requires more technical skill.[2,3] |
| **Gastroesophageal reflux (GER)** | Occurs when stomach contents reflux, or back up, into the esophagus (tube that connects the mouth to the stomach) during or after a meal. GER occurs when the lower esophageal sphincter opens spontaneously, for varying periods of time, or does not close properly and stomach contents rise up into the esophagus. GER is also called acid reflux or acid regurgitation, because digestive juices—called acids—rise up with the food. When refluxed stomach acid touches the lining of the esophagus it may cause a burning sensation in the chest or throat (heartburn or acid indigestion).[2] |

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| **Gastroesophageal reflux disease (GERD)** | More serious form of gastroesophageal reflux (GER); when acid reflux occurs, food or fluid may rise into the back of the mouth and could then fall down into the lungs, causing respiratory symptoms. Some degree of GER is considered normal, but persistent reflux that occurs more than twice a week or causes symptoms is considered GERD, and it can eventually lead to more serious health problems.[2] |
| **Gastrojejunal (G/J-tube)** | Type of tube for nutritional support that is inserted into the jejunum (the middle section of the small intestine) through an established gastrostomy. It is also referred to as a G/J-tube or transgastric tube.[1] This uses a double lumened tube with 2 ports or openings. The G tube opening empties into the stomach and can be used for medication and the J-(jejunum) tube opening which empties into the small intestine can be used for feedings and water.[4] |
| **Gastrostomy** | Surgical procedure that creates an artificial opening in the stomach for the insertion of a feeding tube.[5] |
| **Gastrostomy tube (G-tube) insertion** | Placement of a feeding tube through the skin and the stomach wall, directly into the stomach (also called a G-tube). This tube helps with feeding and releases air from the stomach.[6] |
| **Innsbruck Sensorimotor Activator and Regulator (ISMAR)** | Oral appliance designed to provide stability for the jaw to develop lip closure and tongue mobility, improving eating and drinking skills.[7] |
| **Jejunostomy (J-tube)** | Surgically placing a feeding tube through the abdominal wall directly into a part of the small intestine called the jejunum. The feeding tube bypasses the stomach and delivers a special liquid food with nutrients directly into the jejunum.[2] |
| **Nasogastric tube (NG-tube)** | Tube is inserted through the nose or mouth, down the esophagus, and into the stomach.[6] Typically used for short term.[4] |
| **Percutaneous endoscopic gastrostomy (PEG) tube insertion** | Gastrostomy tubes can be placed under endoscopic guidance, using a much smaller incision (percutaneous endoscopic gastrostomy tube placement, or PEG). An endoscope is passed into the mouth, down the esophagus, and into the stomach. The surgeon can then see the stomach wall through which the PEG tube will pass. Under direct visualization with the endoscope, a PEG tube passes through the skin of the abdomen, through a very small incision, and into the stomach. A balloon is then blown up on the end of the tube, holding in place. PEG gastrostomy tubes avoid the need for general anesthesia and a large incision.[6] |
| **Percutaneous endoscopic jejunostomy** | A type of J-tube placement for nutritional support that occurs with the aid of endoscopy to visualize the jejunum so that a tube can be threaded through a small opening made in the abdominal wall into the jejunum. It is also known as a PEJ tube.[1] |

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# Introduction

## Background

Cerebral palsy (CP) is a "group of disorders of the development of movement and posture, causing activity limitation, that is attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder."[1] This group of syndromes ranges in severity and is the result of a variety of etiologies occurring in the prenatal, perinatal or postnatal period. Though the disorder is nonprogressive, the clinical manifestations may change over time as the brain develops, with other neurologic impairments frequently co-occurring.[1,2]

CP is the most common cause of motor disability in children. Prevalence estimates in the United States over the past 20 years have been approximately 2–4 cases per 1,000 children under the age of 18, with spastic CP being the most common subtype.[3-11] More than 100,000 children are estimated to be affected in the United States. Due to advances in supportive medical care, approximately 90 percent of children with CP survive into adulthood, resulting in an additional estimated 400,000 adults living with CP in the United States.[12-17] Lifetime costs are estimated to be nearly $1 million per person.[18]

## Classification and Spectrum of Disorder

CP includes a spectrum of disorders of movement, posture, and coordination with heterogeneous etiologies. The diversity of the clinical features is reflected in multiple classification systems that include reference to type of motor dysfunction, body parts affected, severity, and functional abilities (see Table 1).

Of note, when classifying on motor function, spastic CP accounts for 70 to 80 percent of all cases of CP, with dyskinetic accounting for 10 to 15 percent and ataxic 15 percent, though combinations of clinical manifestations are common. Further classification is by severity level (mild, moderate, severe), and gross motor function, which reflects the functional capabilities of the affected.[19,20] Developed in the late-1990s, the Gross Motor Function Classification System (GMFCS) outlines a standardized system for classifying motor function based on constructs of disability and functional limitation.[21] GMFCS includes levels that reflect abilities ranging from walking without limitations (level I) to severe head and trunk control limitations requiring extensive use of assisted technology, physical assistance, and wheelchair (level V).

The epidemiologic Oxford Feeding Study reported significant correlations between severity of motor impairment and feeding problems including choking, underweight, prolong feeding times, vomiting, and need for gastrostomy feeding (p values typically $<0.005$).[22] Although CP is a motor disorder, many children and adults with CP are affected by other developmental disabilities, including intellectual disability, impaired vision and hearing, language and behavioral disorders, and epilepsy. Population-based studies have reported the proportion of children with CP who have intellectual disability ranges from 31 to 65 percent and 20 to 46 percent for epilepsy of children with CP.[20,23,24] Intellectual disability varies with subtype of CP and level of impairment.[13,24-26] Survival and quality of life vary across the spectrum of CP, but are associated with severity and functional disabilities, as well as comorbid conditions.[24]

**Table 1. CP classification systems used and understood by qualified medical practitioners***

| Severity Level | Topographical Distribution | Motor Function | Gross Motor Function Classification System |
|---|---|---|---|
| • **Mild:** Child can move without assistance; his or her daily activities are not limited.<br>• **Moderate:** Child will need braces, medications, and adaptive technology to accomplish daily activities.<br>• **Severe:** Child will require a wheelchair and will have significant challenges in accomplishing daily activities.<br>• **No CP:** Child has CP signs, but the disorder was acquired after completion of brain development and is therefore classified under the incident that caused the CP, such as traumatic brain injury or encephalopathy.<br>CP is often classified by severity level as mild, moderate, severe, or no CP. These are broad generalizations that lack a specific set of criteria. Even when doctors agree on the level of severity, the classification provides little specific information, especially when compared to the GMFCS. Still, this method is common and offers a simple method of communicating the scope of impairment, which can be useful when accuracy is not necessary. | • **Monoplegia/monoparesis** means only one limb is affected. It is believed this may be a form of hemiplegia/hemiparesis where one limb is significantly impaired.<br>• **Diplegia/diparesis** usually indicates the legs are affected more than the arms; primarily affects the lower body.<br>• **Hemiplegia/hemiparesis** indicates the arm and leg on one side of the body is affected.<br>• **Paraplegia/paraparesis** means the lower half of the body, including both legs, are affected.<br>• **Triplegia/triparesis** indicates three limbs are affected. This could be both arms and a leg, or both legs and an arm. Or, it could refer to one upper and one lower extremity and the face.<br>• **Double hemiplegia/double hemiparesis** indicates all four limbs are involved, but one side of the body is more affected than the other.<br>• **Tetraplegia/tetraparesis** indicates that all four limbs are involved, but three limbs are more affected than the fourth.<br>• **Quadriplegia/quadriparesis** means that all four limbs are involved.<br>• **Pentaplegia/pentaparesis** means all four limbs are involved, with neck and head paralysis often accompanied by eating and breathing complications. | • **Spastic:** Implies increased muscle tone. Muscles continually contract, making limbs stiff, rigid, and resistant to flexing or relaxing. Reflexes can be exaggerated, while movements tend to be jerky and awkward. Arms and legs often affected. Tongue, mouth, and pharynx can be affected, as well, impairing speech, eating, breathing, and swallowing. Spastic CP is hypertonic and accounts for 70% to 80% of CP cases. The injury to the brain occurs in the pyramidal tract and is referred to as upper motor neuron damage.<br>• **Nonspastic:** Decreased and/or fluctuating muscle tone. Multiple forms of nonspastic CP are each characterized by particular impairments; one main characteristic is involuntary movement, can be slow or fast, often repetitive, and sometimes rhythmic. Planned movements can exaggerate the effect (known as intention tremors). Stress can also worsen the involuntary movements, whereas sleeping often eliminates them. An injury in the brain outside the pyramidal tract causes nonspastic CP. Due to the location of the injury, mental impairment and seizures are less likely. Nonspastic CP is divided into two groups, ataxic and dyskinetic. Together they make up 20% of CP cases. Broken down, dyskinetic makes up 15% of all CP cases, and ataxic comprises 5%. | The GMFCS uses head control, movement transition, walking, and gross motor skills such as running, jumping, and navigating inclined or uneven surfaces to define a child's accomplishment level. The goal is to present an idea of how self-sufficient a child can be at home, at school, and at outdoor and indoor venues.<br>• **GMFCS Level I:** Walks without limitations.<br>• **GMFCS Level II:** Walks with limitations. Limitations include walking long distances and balancing, but not as able as Level I to run or jump; may require use of mobility devices when first learning to walk, usually prior to age 4; and may rely on wheeled mobility equipment when outside of home for traveling long distances.<br>• **GMFCS Level III:** Walks with adaptive equipment assistance. Requires hand-held mobility assistance to walk indoors, while utilizing wheeled mobility outdoors, in the community and at school; can sit on own or with limited external support; and has some independence in standing transfers.<br>• **GMFCS Level IV:** Self-mobility with use of powered mobility assistance. Usually supported when sitting; self-mobility is limited; and likely to be transported in manual wheelchair or powered mobility.<br>• **GMFCS Level V:** Severe head and trunk control limitations. Requires extensive use of assisted technology and physical assistance; and transported in a manual wheelchair, unless self-mobility can be achieved by learning to operate a powered wheelchair. |

## Feeding Difficulties and Interventions

Individuals with CP frequently have feeding and swallowing problems that may lead to poor nutritional status, growth failure, chronic aspiration, esophagitis, and respiratory infections. Across the cerebral palsy spectrum, poor nutritional status is caused by distinct pathways ranging from inadequate intake, oral dysphagia, oral-pharyngeal dysphagia, gastroesophageal reflux (GER), chronic aspiration, and behavioral etiologies. Some patients with oral-pharyngeal dysphagia and GER, particularly those with severe CP, are also at risk for recurrent aspiration which can lead to chronic pulmonary disease. Patients with feeding difficulties range from those with self-feeding skills to populations with severe disability (GMFCS V) who require extensive use of assisted technology and are dependent on others to feed them. Chronic pulmonary disease related to aspiration is a leading cause of death among patients with severe CP.[27-30]

Data suggest that during the first year of life, 57 percent of children with CP have sucking problems, 38 percent have swallowing problems, 80 percent have been fed nonorally on at least one occasion, and more that 90 percent have clinically significant oral motor dysfunction.[31] More severe motor impairment is associated with greater difficulty with swallowing.[32] Among children with spastic quadriplegia, one third has been reported to require assisted feeding.[33] Individuals with severe functional limitations (GMFCS level IV or V) commonly need assisted feeding. Caregiver burden is also a significant concern, as the feeding process may require considerable time and may be associated with stress and caregiver fatigue[34]; stress and fatigue may in turn affect the feeding process.[35]

A number of feeding and oral-motor intervention strategies have been developed to address difficulties with sucking, chewing, swallowing, and improve oral-motor skills, including oral sensorimotor management, positioning, oral appliances, food thickeners, specialized formulas, and neuromuscular stimulation. These interventions address different aspects of feeding difficulties, reflecting the range in specific problems associated with feeding and nutrition in CP. Sensorimotor techniques seek to strengthen oral-motor control and counteract abnormal tone and reflexes to improve oral feedings, and typically require months of daily application. Positioning techniques address poor postural alignment and control that exacerbates swallowing difficulties, and include stabilizing the neck and trunk. Positioning interventions are individualized and often guided by video-fluoroscopy to optimize swallowing. Oral appliances have been used to stabilize the jaw, improve sucking, tongue coordination, lip control, and chewing. Multiple approaches may be used in children with growth failure, including sensorimotor stimulation, positioning, food thickeners, and caloric supplementation. For children with moderate to severe aspiration or malnutrition related to oral-pharyngeal dysphagia and GER, surgical interventions with gastrostomy (tube feeding directly into the stomach) or jejunostomy tubes (tube feeding into the middle portion of the small intestine, the jejunum) and antireflux procedures may be necessary to improve nutritional status and reduce risk of chronic aspiration.[34,36]

No uniform decision pathway for deciding when a child should move from oral feeding to enteral tube feedings exists, but there is general consensus.[37] If oral calorie intake is insufficient to maintain growth, there is increased risk or occurrence of aspiration into the lungs, or the level of work necessary to maintain adequate caloric intake orally by the individual and the caregiver is excessive, then a medical provider may recommend enteral tube feedings (see Glossary). The method of tube feeding is based on the likely time span needed for tube supplementation, the availability of an experienced surgeon, and specific symptoms of the child. For example, a child may be considered too medically fragile for surgery, so a nasal tube may be

used for a time, which may be advanced beyond the stomach into the jejunum to reduce gastroesophageal reflux, and then later replaced with a surgically placed tube. A gastric fundoplication may be included to reduce GER, if needed in the judgment of the surgeon.

## Clinical Uncertainties

The goal for management of CP is to improve the quality of life for both the child and family, through interventions that maximize independence in activities of daily living, mobility, and nutrition. Guidelines have been published by the American Academy of Neurology on the use of pharmacologic treatment of spasticity in children and adolescents with CP.[38] However, there is a limited evidence-base for the majority of interventions in CP, including those that address nutrition and growth.[39] Despite a range of potential feeding interventions for patients with CP, synthesis is lacking on the efficacy, safety and applicability of these interventions. Limited information is available on the impact on health outcomes, including quality of life. Existing reviews are limited in scope, and clinicians and families will benefit from consolidation of data for making clinical decisions.

Goals of treatment and measures of effectiveness may differ by type of CP (spastic or nonspastic), location of motor involvement (e.g., diplegia, quadriplegia), functional status, including ability to walk or sit, and degree of head and trunk control. Comorbid conditions, particularly intellectual disability (related to ability to monitor and maintain appropriate nutrient intake) as well as concurrent medications that potentially have gastrointestinal side effects may influence treatment outcomes. Different feeding interventions may perform differently across the spectrum of CP. For example, oral-motor interventions may be highly effective in populations with oral dysphagia with malnutrition. However, these same interventions could have less value in less mobile populations that are experiencing pharyngeal dysphagia with aspiration. Gastrostomy feeding may reduce aspiration during swallowing, but does not address aspiration of oral secretions, and could exacerbate GER. Additional interventions, such as positioning and caloric supplementation may still be needed. To examine the overall effectiveness of interventions intended to improve feeding and nutrition outcomes in CP, adequate characterization of the patient populations is essential. Additionally, the need for management into later life has increased, and the optimal interventions for adults with feeding difficulties are unknown.[17,40]

Potential harms associated with feeding interventions include surgical complications, new or worsening GER, risk of aspiration, and mortality. Gastrostomy feeding has been associated with excess weight gain.[41] The impact of antireflux procedures in addition to gastrostomy is relatively unknown. Finally, there is a need to understand the potential impact of feeding interventions on families and caregivers as substantial caregiver time and training may be required.

## Importance of This Review

Families of children with cerebral palsy face significant challenges in providing the best care for their children. The known high rates of morbidity, including aspiration and pneumonia, associated with feeding difficulties, cause substantial stress and have significant health implications. Collecting what data exist in one location, and assessing the studies objectively, will provide families and clinicians with an overview of potential interventions and what they might expect with them.

## Scope and Key Questions

The scope of this review encompassed feeding and nutrition interventions for individuals of all ages with cerebral palsy. We attempted to answer the following Key Questions:

**Key Question 1a.** When compared with other nonsurgical interventions or no intervention, how effective are behavioral interventions, including positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training, for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life in individuals with CP and feeding difficulties?

**Key Question 1b**. Is the effectiveness of behavioral interventions modified by age, race, severity, functional status (e.g., GMFCS level), or initial nutritional status?

**Key Question 2a.** When compared with other nonsurgical interventions or no intervention, how effective are nutritional interventions (food thickeners, caloric supplementation with formulas, vitamin supplementation, and altering food consistency [e.g., pureeing]) for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life in individuals with CP and feeding difficulties?

**Key Question 2b.** Is the effectiveness of nutritional interventions modified by age, race, severity, functional status (e.g., GMFCS level), or initial nutritional status?

**Key Question 3a.** What is the comparative effectiveness of tube feeding when compared with oral feeding or with nutritional and behavioral interventions in individuals with CP who present with feeding difficulties, including malnourishment, failure to thrive, aspiration, and excessive caregiver burden?

**Key Question 3b.** Among individuals with CP and feeding difficulties with significant reflux, what is the effectiveness of g-tube placement with fundoplication versus oral feeding for reducing reflux and for improving nutritional state/growth, health outcomes, health care/resource utilization, and quality of life?

**Key Question 3c.** Among individuals who develop reflux after gastrostomy, what is the comparative effectiveness of j-tube versus fundoplication for reducing reflux in the short term and achieving improvements in nutritional state/growth, health outcomes, health care/resource utilization, and quality of life?

**Key Question 3d.** Is the effectiveness of tube feeding modified by tube placement, age, race, severity, functional status (e.g., GMFCS level), initial nutritional status, or continuous versus bolus feeding?

## Organization of This Report

The Methods section describes our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and our method for extraction of data into evidence

tables and compiling evidence. We also describe our approach to grading of the quality of the literature and to evaluating the strength of the body of evidence.

The Results section presents the findings of the evidence report, including data from prior systematic reviews of high quality and findings from primary studies not included in those reviews synthesized by Key Question and outcomes reported. We report the number and type of studies identified, and we differentiate between total numbers of publications and unique studies. The final section of the report discusses key findings and expands on methodologic considerations relevant to each Key Question. We also outline the current state of the literature and challenges for future research in feeding and nutrition interventions for individuals with CP.

The appendixes are as follows—

- Appendix A. Search Strategies
- Appendix B. Data Extraction Forms
- Appendix C. Evidence Table
- Appendix D. Tools Used to Assess the Quality of the Literature
- Appendix E. Quality of the Literature
- Appendix F. Excluded Studies.

We also include a list of abbreviations and acronyms at the end of the report.

## Uses of This Report

We anticipate that the report will be of value to clinicians who treat individuals with CP, including pediatricians, occupational and physical therapists, speech and language pathologists, nurses, nutritionists, and other health professionals who provide care for individuals with CP. The report itself is not a guideline. It is a review of evidence that other groups and individuals can use in developing guidelines or treatment decisions, but we assume that those decisions would be made with other considerations as well, including an individual's diagnosis, severity of CP, concomitant conditions, and familial context.

In addition, this review will be of use to the National Institutes of Health, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration–all of which have offices or bureaus devoted to developmental issues. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of therapeutic options for the management feeding- and nutrition-related difficulties in CP. It will be of interest to individuals affected by CP and their families because of the significant personal costs associated with it and the recurring need for individuals with CP, their families, and their health care providers to make the best possible decisions among numerous options.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to understand best approaches to interventions for feeding and nutrition in CP.

# Methods

## Topic Development and Refinement

The topic for this report was nominated in a public process. We drafted the initial Key Questions and analytic framework and refined them with input from key informants with expertise in child health and development, pediatric gastroenterology, occupational therapy, neurodevelopment, and developmental disabilities. After review from the Agency for Healthcare Research and Quality (AHRQ), the questions and framework were posted to a public Web site. The public was invited to comment on these questions.

After reviewing the public commentary, we drafted final Key Questions and submitted them to AHRQ for review. During the topic development phase we identified a recent, rigorously conducted systematic review addressing behavioral feeding interventions.[34] We thus structured the part of the review relevant to behavioral interventions as an update to the previous reviews. We developed a protocol for the review that was also posted to the AHRQ Effective Health Care web site.[42]

We identified technical experts on the topic of feeding and nutrition in cerebral palsy (CP) to provide assistance during the project. Technical Expert Panel (TEP) members represented the clinical and research communities from a range of perspectives and were invited to participate based on our commitment to engaging a range of experts who could help solidify the decisional dilemmas facing individuals and families with CP. They included both researchers and clinicians with expertise in behavioral, medical, surgical, and allied health approaches. We identified TEP members through scanning recent research related to CP, reviewing stakeholders in an AHRQ-funded research exploration forum on CP,[43] and through discussions with our AHRQ Task Order Officer (TOO). All candidates were approved by the TOO after disclosure and review of potential conflicts of interest.

The TEP contributed to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included seven members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and Key Questions at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria;
- Ensure that relevant outcomes and studies were addressed.

## Role of the AHRQ Task Order Officer

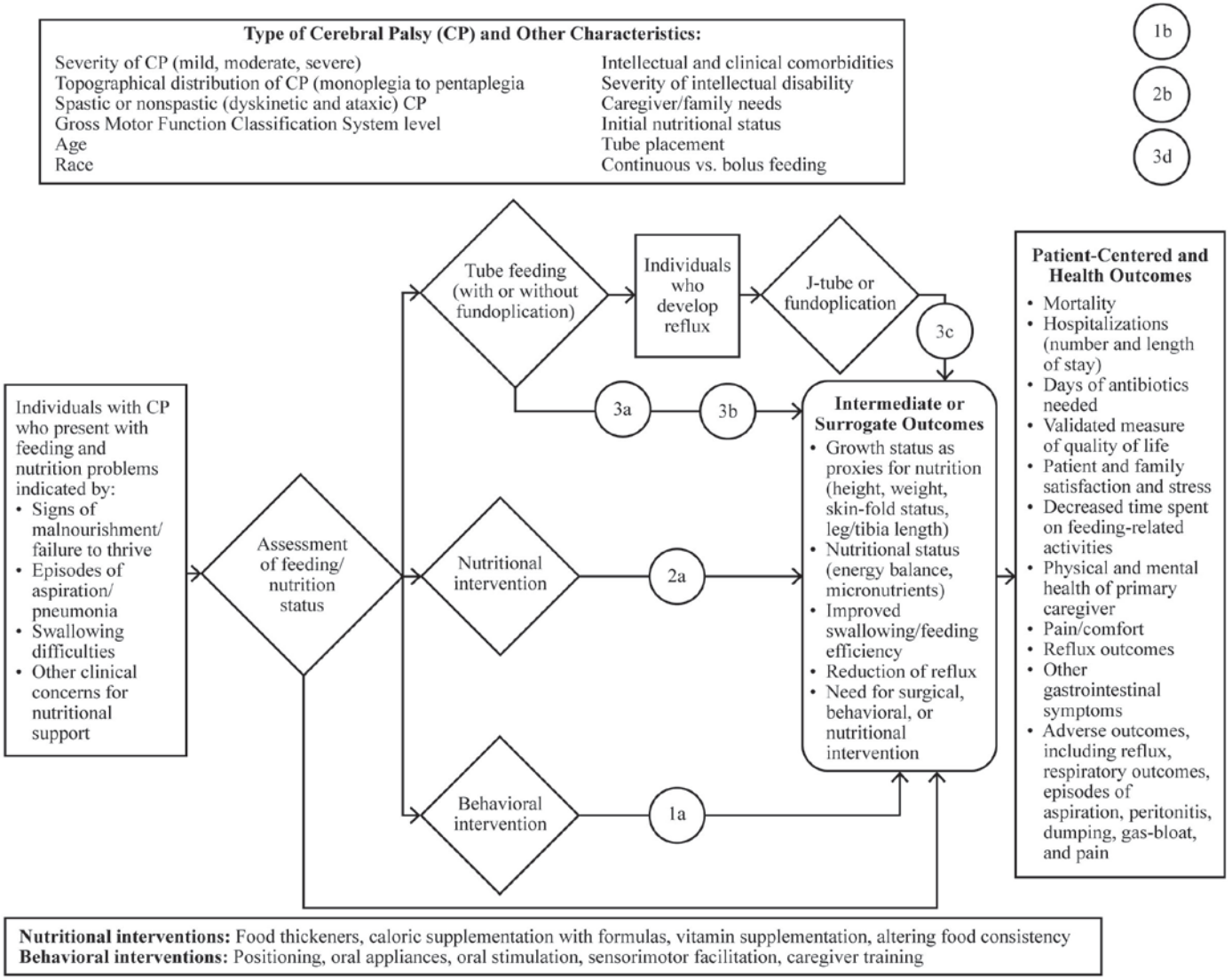
The TOO was responsible for overseeing all aspects of this project. The TOO helped to develop a common understanding among all parties involved in the project, resolved questions and ambiguities, and addressed our queries regarding the scope and processes of the project. The TOO reviewed the report for consistency, clarity, and to ensure that it conforms to AHRQ standards.

## Analytic Framework

The analytic framework (Figure 1) outlines the path of care for individuals with CP and feeding difficulties; numbers in circles on the diagram represent Key Questions. The framework illustrates multiple indications of disrupted nutrition among this population, including signs of malnourishment or failure to thrive, episodes of aspiration or pneumonia, swallowing difficulties, or other clinical concerns for nutritional support. Individuals typically undergo a feeding and nutrition assessment, which could be followed by a behavioral (Key Question 1a) or nutritional (Key Question 2a) feeding intervention or a combination of such approaches, or the placement of a tube for feeding (Key Questions 3a–c). Individuals with reflux may undergo tube placement with fundoplication to help alleviate reflux (Key Question 3b). Individuals without pre-existing reflux who undergo a tube placement may develop reflux following the procedure[44-46] and require additional treatment via a jejunostomy tube or fundoplication (Key Question 3c). Possible intermediate or surrogate outcomes resulting from these interventions can include a change in growth status, improved swallowing, or various adverse effects. At this point on the pathway, individuals with CP may undergo another feeding and nutrition assessment followed by an alternative intervention. Patient-centered and health outcomes following intermediate outcomes can include mortality, incidences of hospitalizations, antibiotic use, quality of life, patient and family satisfaction and stress, changes in time spent on feeding activities, physical and mental health of the primary caregiver, pain or comfort, and various adverse effects.

Certain factors may influence the pathway at all stages and can include the type and severity of CP, age, race, intellectual and clinical comorbidities, severity of intellectual disability, and caregiver or family needs (Key Questions 1b, 2b, 3d specifically address potential modifiers of treatment effectiveness). Numbers in circles within the diagram indicate the placement of Key Questions in relation to the treatment process.

**Figure 1. Analytic framework**




Note: Numbers in circles represent Key Questions.

# Literature Search Strategy

## Search Strategy

### Databases

A librarian employed search strategies provided in Appendix A to retrieve research on feeding and nutrition interventions in CP. All strategies were peer reviewed by a second librarian. Our primary literature search employed six databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), the Educational Resources Information Clearinghouse, OTSeeker, REHABDATA, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database; see Appendix A for a description of database content. Our search strategies used a combination of subject heading terms appropriate for each database and key words relevant to CP and nutrition (e.g., cerebral palsy, enteral feeding). We also conducted a secondary search on the broader topic of neurologic impairment and surgical feeding interventions to capture research potentially including individuals with CP. We limited searches to literature published since 1980 to ensure that interventions used currently would be represented.

We also manually searched the reference lists of included studies and of recent narrative and systematic reviews and meta-analyses addressing CP and feeding and nutrition issues. We invited TEP members to provide additional citations.

### Prior Systematic Reviews

We identified systematic reviews retrieved by the searches for primary literature as well as through a search of the Cochrane Database of Systematic Reviews using the search terms cerebral palsy, feeding, and nutrition. We also searched MEDLINE via PubMed using our MEDLINE strategy for primary research but limited to the review or meta-analysis publication types (Appendix A).

### Grey Literature and Regulatory Information

To ensure that we captured relevant research that may not yet be published in biomedical journals, we located conference abstracts presented at annual meetings of the American Academy of Cerebral Palsy and Developmental Medicine and the American Academy of Physical Medicine and Rehabilitation (as available) from 2009 to 2012. We selected these associations in consultation with our clinical experts who felt that they would capture relevant presentations.

An expert librarian also searched for information on the VitalStim device as it is approved by the U.S. Food and Drug Administration to promote swallowing in individuals with swallowing difficulties in resources including the websites of the Food and Drug Administration and Health Canada. We also gave manufacturers of the device an opportunity to provide additional information, with a comment period of June 6 to July 19, 2012.

### Search Terms

Controlled vocabulary terms served as the foundation of our search in each database (e.g., MEDLINE vocabulary terms including cerebral palsy, gastrostomy), complemented by additional keyword phrases (e.g., CP, tube feeding). We also limited searches to items published

in English and from 1980 to the present. Our TEP felt that most CP research of relevance to the review topic is published in English.

Our searches were done between March and July 2012. Appendix A provides search terms and the yield from each database. We imported all citations into an electronic database.

## Inclusion and Exclusion Criteria

We developed criteria for inclusion and exclusion in consultation with the TEP (Table 2). Studies needed to include individuals of any age with CP and feeding difficulties and had to include at least two individuals (i.e., single case reports were excluded; multiple baseline studies with only one participant—regardless of the number of data points—were excluded). For studies with populations including individuals with CP and other conditions, we retained the study if we could infer that at least 80 percent of the study participants had CP or if we could isolate data on those participants with CP. Comparators included other nonsurgical approaches for the behavioral interventions (Key Questions 1–3a), oral feeding, intervention or pre-intervention data (Key Question 3b) or jejunostomy tube, fundoplication or pre-intervention data (Key Question 3c). Behavioral studies had to include an active comparator; surgical studies could be pre-post design (case series) in which individuals served as their own comparators.

We assessed both intermediate/surrogate and patient-centered/health outcomes. We considered intermediate outcomes as those that occur directly as a result of the intervention and that may also have longer term implications for the ultimate, functional outcomes that are the long-term goal of therapies. Outcomes assessed include:

- Intermediate or surrogate outcomes
    - Growth status as proxies for nutrition (height including leg length or tibia length, weight, skin fold status, energy expenditure)
    - Nutritional status (measures of energy balance, micronutrient scores)
    - Improved swallowing (including feeding efficiency score)
    - Need for surgical or nutritional intervention
- Patient-centered and health outcomes
    - Mortality
    - Hospitalizations
    - Days of antibiotics for aspiration needed
    - Validated measures of quality of life
    - Patient and family satisfaction and stress
    - Decreased parent/caregiver time spent on feeding-related activities
    - Physical and mental health of primary caregiver
    - Reflux outcomes (episodes of reflux, duration).

We also assessed the harms of interventions, defined by the AHRQ Effective Health Care program as the totality of adverse consequences of an intervention.[47] Harms may include:

- Adverse effects related to surgical procedures (e.g., feeding tube migration or dislodgement, interference with pulmonary toilet)
- Need for further surgery
- Gastrointestinal bleeding or ulceration
- Peritonitis
- Episodes of aspiration or acute respiratory problems
- Pain/comfort

- Other gastrointestinal symptoms (e.g., constipation, retching, dumping, gas-bloat syndrome, secondary GER)
- Reduction in and negative influences on quality of life.

We included studies with any length of followup and in any setting (clinic, home, etc.).

**Table 2. Inclusion and exclusion criteria**

| Category | Criteria |
|---|---|
| Study population | Individuals with CP and feeding or nutrition difficulties, at least 80% of population with CP in studies that include mixed populations |
| Time period | 1980–present |
| Publication languages | English only |
| Admissible evidence (study design and other criteria) | <u>Admissible designs</u><br>• Controlled trials, observational studies including prospective and retrospective cohort studies, prospective and retrospective case series providing data from before and after intervention, and systematic reviews<br><u>Other criteria</u><br>• Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results<br>• Patient populations must include individuals with CP (at least 80% for studies with mixed populations not reporting data separately for individuals with CP) and feeding or nutrition difficulties<br>• Studies must address one or more of the following:<br>o Nonsurgical interventions<br>o Behavioral interventions (including positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training)<br>o Nutritional interventions (food thickeners, caloric supplementation with formulas, supplementation with vitamins and minerals, and altering food consistency)<br>o Tube feeding<br>o Oral feeding<br>o Surgical interventions (G-tube, J-tube, fundoplication)<br>o Modifiers of nonsurgical intervention effectiveness (age, race, severity, functional status)<br>o Modifiers of tube feeding effectiveness (tube placement, age, race, severity, functional status, initial nutritional status, or continuous vs. bolus feeding)<br>o Baseline and outcome data (including harms) related to interventions for feeding difficulties<br>• Studies must include extractable data on relevant outcomes, including data presented in text or tables (vs. solely in figures)<br>• Studies must provide aggregate data vs. data for each individual participant |

CP = cerebral palsy; G-tube = gastrostomy tube; J-tube = jejunostomy tube

## Language

We focused the review on studies published in English. In the opinion of our content experts, most research on feeding and nutrition interventions in CP is published in English regardless of the native language of the investigators or country of publication. We reviewed the English abstracts of the non-English literature retrieved by our MEDLINE search to assess whether we had missed any relevant studies and verified that we had not.

# Study Selection

## Screening of Studies

Once we identified articles through the electronic database searches, review articles, and bibliographies, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated each abstract for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it for full text assessment.

Two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a third-party adjudicator. One reviewer also separately assessed the abstracts of review articles identified by our database searches for relevance to the comparative effectiveness review topic (See form in Appendix B). The group of abstract and full text reviewers included expert clinicians and health services researchers.

# Data Extraction and Data Management

The staff members and clinical experts who conducted this review jointly developed the evidence table, which was used to summarize data from the studies. We modeled the table on that used in a recent systematic review of feeding interventions for CP[34] and designed the table to include issues of study design, descriptions of the study populations (for applicability), description of the intervention, and baseline and outcome data on constructs of interest.

One team member initially entered information into the evidence table. Another member of the team also independently reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The full research team met during the article extraction period and discussed issues related to data extraction (e.g., optimal level of detail in the description of the intervention, determining key population characteristic such as GMFCS level to include). In addition to outcomes related to intervention effectiveness, we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence table is presented in Appendix C. Studies are presented in the evidence table alphabetically by the last name of the first author within each year. When possible to identify, analyses resulting from the same study were grouped into a single evidence table.

# Quality (Risk of Bias) Assessment of Individual Studies

We assessed quality using separate tools as appropriate by study design. The detailed tools used to assess quality are in Appendix D and include the Cochrane Risk of Bias tool for randomized controlled trials (RCTs),[48] the Newcastle-Ottawa scale for cohort studies,[49] a tool adapted from AHRQ's Effective Health Care program guidance for case series,[50] and the AMSTAR tool for systematic reviews.[51] The reliability and other characteristics of the Cochrane Risk of Bias tool, Newcastle scale, and AMSTAR have been previously assessed with positive ratings overall.[52-57]

Two reviewers independently assessed quality for each study, with final decisions made via discussion to reach consensus or by third party adjudication by a senior methodologist as needed.

We describe the individual quality components below and report individual quality assessments for each study in Appendix E.

## Determining Quality Levels

We used targeted sets of questions to assess randomized trials, case series, and cohort studies and systematic reviews. Appendix D includes the individual questions used to assess each study type, and Appendix E lists scores for each question for each study. Three quality levels were possible: good, fair, and poor (Table 3).

- We required that RCTs receive a positive score (i.e., low risk of bias for RCTs) on all of the questions used to assess quality to receive a rating of good. RCTs had to receive at least five positive scores to receive a rating of fair, and studies with ≤ four positive ratings were considered poor quality. We considered a rating of "unclear" as a positive rating as long as the consensus of the investigators assessing quality was that study outcomes were not likely to be biased by the factor.
- We required that cohort studies receive positive scores (stars) on all elements to receive a rating of good, ≤ 2 negative ratings for fair, and > 2 negative scores for a rating of poor quality.
- Case series, or pre-post studies, have inherently high risk of bias. Nonetheless, prospective case series that enroll participants consecutively and control for potentially confounding factors may provide more evidence to support comparative studies. We assessed case series using questions identified in the AHRQ Effective Health Care program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[47] but did not assign a quality level for these studies as it would be inappropriate to assess them on the same scale as prospective cohort and RCT designs. Rather, the elements on which they were scored and the results are presented in Appendix E.
- We used the approach recommended in the AHRQ guidance on use of prior reviews in systematic reviews to assess systematic reviews identified through the literature search, with the expectation that we would only consider updating a review that was of good quality.[58] Other reviews might be used to provide context or as a source of references but not to provide data for our review. We required that systematic reviews receive no more than two negative scores and receive positive scores on questions related to quality assessment, search of the literature, and appropriate synthesis to receive a rating of good. Reviews had to receive three or fewer negative scores and a positive score on quality assessment for a rating of fair; reviews with four or more negative scores were considered poor quality. We conducted an audit of papers included in good quality reviews to assess the quality of individual studies and determine that our assessments would match those of the review author before accepting their data and summarizing the review.

**Table 3. Description of study quality levels for individual studies**

| Quality Level | Description |
|---|---|
| Good | Good studies are considered to have the least bias and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to treatments; has a low dropout rate; and uses appropriate means to prevent bias; measure outcomes; analyze and report results. |
| Fair | Fair studies are susceptible to some bias, but probably not sufficient to invalidate the results. A study may be missing information, making it difficult to assess limitations and potential problems. As the "fair quality" category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid. |
| Poor | Poor studies are subject to significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions. |

## Data Synthesis

When we identified published, high-quality systematic review addressing a Key Question that was largely up to date and relevant, we intended to cite and summarize these reviews as evidence and not extract data from the primary studies. Of note, only one review met these criteria. We provide a summary of the methods of this review and overall findings in line with guidance in the Using Existing Systematic Reviews to Replace de novo Processes in Conducting Comparative Effectiveness Reviews chapter of the AHRQ Effective Health Care Program Methods Guide.[58]

For interventions not covered in existing systematic reviews or to update existing reviews, we extracted and synthesized data from primary studies meeting our criteria. We considered the possibility of conducting a meta-analysis, but the small number of the studies, the study designs and the heterogeneity in outcomes made a meta-analysis both inappropriate and unnecessary.

## Strength of the Body of Evidence for Each Key Question

The assessment of the literature is done by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and it can be regarded as insufficient, low, moderate, or high. Strength of evidence describes the adequacy of the current research, both in terms of quantity and quality, as well as the degree to which the entire body of current research provides a consistent and precise estimate of effect. Interventions that have demonstrated benefit in a small number of studies but have not yet been replicated using the most rigorous study designs will therefore have insufficient or low strength of evidence to describe the body of research. Future research may find that the intervention is either effective or ineffective.

Methods for applying strength of evidence assessments are established in the "Grading the Strength of a Body of Evidence When Comparing Medical Interventions" chapter of the Methods Guide[59] and are based on consideration of four domains: risk of bias, consistency in direction of the effect, directness in measuring intended outcomes, and precision of effect (Table 4). Strength of evidence is assessed separately for major intervention-outcome pairs.

**Table 4. Domains used to assess strength of evidence[a]**

| Domain | Explanation |
|---|---|
| Risk of bias | Degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through two main elements:<br>• Study design (e.g., RCTs or observational studies).<br>• Aggregate quality of the studies under consideration.<br>Information for this determination comes from the rating of quality (good/fair/poor) done for individual studies. |
| Consistency | Degree to which reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements:<br>• Effect sizes have the same sign (that is, are on the same side of ''no effect'').<br>• The range of effect sizes is narrow. |
| Directness | Relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Evidence is indirect if:<br>• It uses intermediate or surrogate outcomes instead of ultimate health outcomes. In this case, one body of evidence links the intervention to intermediate outcomes and another body of evidence links the intermediate to most important (health or ultimate) outcomes.<br>• It uses two or more bodies of evidence to compare interventions A and B, e.g., studies of A vs. placebo and B vs. placebo, or studies of A vs. C and B vs. C but not A vs. B.<br>Indirectness always implies that more than one body of evidence is required to link interventions to the most important health outcomes. Directness may be contingent on the outcomes of interest. |
| Precision | Precision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately). If a meta-analysis was performed, this will be the confidence interval around the summary effect size. |

RCTs = randomized controlled trials
[a]Excerpted from Owens et al., 2010[59]

Once we had established the maximum strength of evidence possible based upon these criteria, we assessed the number of studies and range of study designs for a given intervention-outcome pair, and downgraded the rating when the cumulative evidence was not sufficient to justify the higher rating. The possible grades were—

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

# Prior Systematic Reviews

One prior systematic review met all of our criteria and was used in its entirety in our review.[34] That review had used a modified Sackett approach to strength of evidence (Table 5).

**Table 5. Levels of evidence (adapted from Sackett) used in Snider review[34]**

| Level | Description |
|---|---|
| 1a (strong) | Well-designed meta-analysis, or 2 or more "high-quality" RCT's (PEDro score ≥ 6) showing similar findings. |
| 1b (moderate) | 1 RCT of "high-quality" (PEDro score ≥ 6). |
| 2a (limited) | At least 1 "fair-quality" RCT (PEDro score = 4–5). |
| 2b (limited) | At least 1 "poor-quality" RCT (PEDro score < 4) or well-designed nonexperimental study (nonrandomized controlled trial, quasi-experimental studies, cohort studies with multiple baselines, single subject series with multiple baselines, etc.). |
| 3 (consensus) | Agreement by an expert panel or a group of professionals in the field or a number of pre–post studies, all with similar results. |
| 4 (conflict) | Conflicting evidence of 2 or more equally well-designed studies. |
| 5 (no evidence) | No well-designed studies—only case studies/case descriptions, or cohort studies/single-subject series with no multiple baselines. |

PEDro = Physiotherapy Evidence Database; RCT = randomized controlled trial

We translated this approach (as described in the Discussion) into equivalent strength of evidence grades.

## Applicability

Finally, it is important to consider the ability of the outcomes observed to apply both to other populations and to other settings (especially for those interventions that take place within a clinical/treatment setting but are hoped to change behavior overall). Our assessment of applicability included determining the population, intervention, comparator, outcomes and setting in each study and developing an overview of these elements for each intervention category.

## Peer Review and Public Commentary

Researchers and clinicians with expertise in the area and individuals representing stakeholder communities were invited to provide external peer review of this report; AHRQ personnel and an associate editor also provided comments. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment (August 7 to September 3, 2012). We addressed all reviewer comments, revising the text as appropriate, and documented changes and revisions to the report in a disposition of comments report that will be made available 3 months after AHRQ posts the final evidence report on the AHRQ Web site.

# Results

In this section we present findings for each Key Question, beginning with an overview of the content of the literature addressing interventions for feeding and nutrition in individuals with cerebral palsy (CP) meeting our criteria, including the range of study designs used, approaches assessed and participants included. The detailed analysis of the literature provides further discussion and analysis.

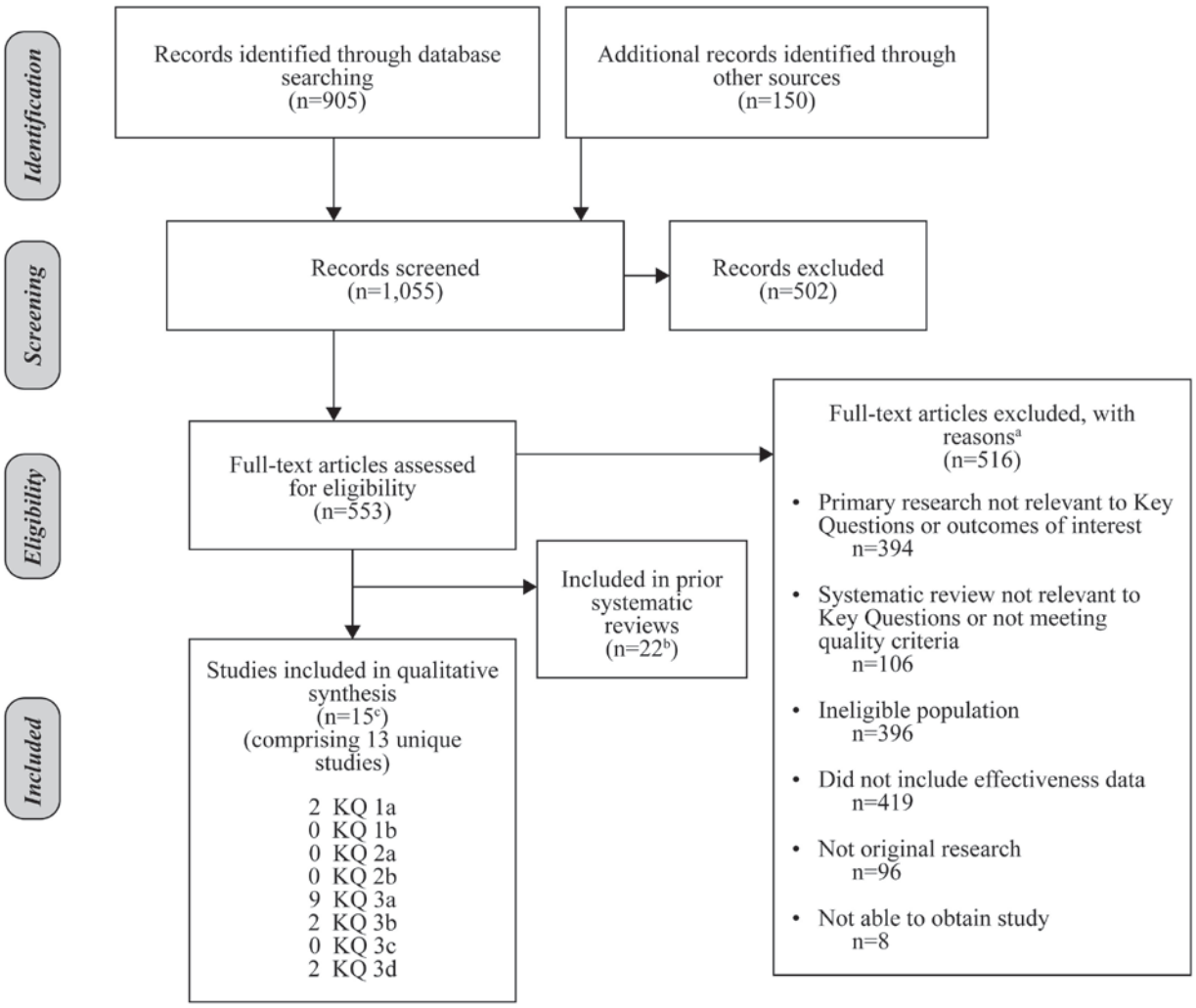
Studies also are described in summary tables in the relevant section of text. For further information on quality scores for each study, see Appendix E.

## Results of Literature Searches and Description of Included Studies

### Article Selection

We conducted a broad search to identify any titles or abstracts that might include relevant data for the review. Of the entire group of 1,055 titles and abstracts, we reviewed the full text of 553 because they either appeared to meet criteria or did not provide enough information in the abstract to determine definitively that they should be excluded (Figure 2). Of the 546 full text articles reviewed, 15 articles (comprising 13 unique studies) met our inclusion criteria. This figure includes 12 unique primary research studies (reported in 14 publications) described in this comparative effectiveness review and one systematic review meeting our inclusion criteria. Reasons for article exclusion are listed in Appendix F. As indicated in Figure 2, we were unable to obtain the full text of eight studies. Seven of these appeared from their abstracts to be narrative reviews, and one report, which may contain primary data, focuses on upper limb movement in CP. Thus, we do not feel that any of these papers would change our conclusions.

**Figure 2. Disposition of studies identified for this review**




CER = comparative effectiveness review; KQ = Key Question; n = number
[a]Numbers do not tally as studies could be excluded for multiple reasons.
[b]This number includes one study (Gisel 1994[60]) not explicitly referenced in the Snider review; the Snider review cites a later Gisel paper[61] reporting on the same population.
[c]This figure includes 12 unique primary research studies (reported in 14 publications) described in the current CER and one systematic review meeting our screening criteria.

Table 6 summarizes characteristics of the primary literature meeting our criteria and not addressed in prior systematic reviews summarized here. The majority of studies were case series.

**Table 6. Overview of primary literature addressing feeding and nutrition interventions in CP**

| Characteristic | RCTs | Prospective Cohort Studies | Prospective Case Series | Retrospective Case Series | Total Literature |
|---|---|---|---|---|---|
| Total number of studies: | 1 | 1 | 8 | 2 | 12 |
| ***Intervention Category*** | | | | | |
| Behavioral | 0 | 0 | 1 | 0 | 1 |
| Surgical | 1 | 1 | 7 | 2 | 11 |
| ***Duration of Followup*** | | | | | |
| <1 month | 1 | 0 | 0 | 0 | 1 |
| >1 to ≤3 months | 0 | 0 | 0 | 0 | 0 |
| >3 to ≤6 months | 0 | 0 | 3 | 0 | 3 |
| >6 to ≤12 months | 0 | 1 | 3 | 0 | 4 |
| >12 months | 0 | 0 | 2 | 2 | 4 |
| ***Study Population*** | | | | | |
| United States | 0 | 0 | 0 | 2 | 2 |
| Europe | 0 | 1 | 3 | 0 | 4 |
| Other | 1 | 0 | 5 | 0 | 6 |
| **Total number of participants with CP** | 14 | 40 | 201 | 76 | 331 |

CP = cerebral palsy; RCTs = randomized controlled trials

Key Question 1a. Compared with other nonsurgical interventions or no intervention, how effective are behavioral interventions, including positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training, for improving nutritional state/growth, health outcomes and health care/resource utilization, and quality of life in individuals with cerebral palsy and feeding difficulties?

# Key Points

- One recent, good quality,[34] systematic review was available. The primary literature updating the review consisted of one case series.[66]
- The systematic review assessed interventions including sensorimotor approaches, positioning, oral appliances, altering food consistency, and feeding interventions and largely addressed the outcomes of feeding efficiency and safety; overall, the review concluded that the evidence base was generally of poor quality that limited conclusions about effectiveness for all of the interventions. Strength of evidence (confidence in the estimate of effect) for these interventions across outcomes therefore ranged from insufficient to low.
- The small, short-term case series of a caregiver intervention[66] reported some pre- to post-intervention improvements in oral-motor behaviors (increase in number of children able to perform some self-feeding from 0 to 6), caregiver stress (18 indicated feeling very stressed pre-intervention to 2 post), and number of chest infections (15 pre-intervention vs. 6 post), but it does not change the conclusions laid out in the prior review.

# Overview of the Literature

We identified two studies addressing behavioral interventions for feeding in CP: one good quality systematic review[34] and one case series.[66]The good quality systematic review, published in 2011, included 21 studies of behavioral interventions including sensorimotor interventions, positioning, food consistency, feeding devices, and oral appliances.[34] The primary literature consisted of one home-based prospective case series assessing a caregiver training program implemented in Bangladesh and providing data on 22 child-caregiver pairs.[66] Outcomes examined included measures of growth and feeding skills, caregiver stress, and time spent feeding at 6 months after training.

# Detailed Analysis

## Summary of Relevant Prior Systematic Reviews

The good quality systematic review,[34] conducted by Snider and colleagues, focused on whether regular application of feeding interventions improves feeding efficiency and safety and results in enhanced weight gain in children with CP. We assessed the review as good quality as it reported search procedures, assessed and reported quality of studies, and appropriately synthesized results. The review investigators searched 12 electronic databases including MEDLINE, PsycINFO, CINAHL, ERIC, and HealthStar. After analysis, 21 studies (two case reports, four case series, one single-subject ABA design, six experimental, six quasi-experimental, one prospective matched pairs, and one RCT) were included in the review. Most (13 of 21) studies would have met inclusion criteria for our review as well; those that did not were either case reports, published prior to 1980, or did not address interventions of interest. Included studies were assessed as oral sensorimotor facilitation ("techniques specific to the enhancement of oral-motor control aim[ing] to decrease or increase tone and inhibit abnormal reflexes that interfere with safe feeding"[34]), food consistency, positioning, oral appliances, or adaptive equipment. Some studies assessed more than one intervention (e.g., electric feeder + positioning,[67] oral device + motor-sensory therapy[68] or positioning,[69] feeding skills + positioning,[70] oral-motor exercises + attention and parent training,[71] and oral-motor skills + thermal stimulation + dietary modification[72]), with results presented in the aggregate. Methodological quality was assessed using the Physiotherapy Evidence Database rating scale (PEDro). A PEDro score of 9–10 points is considered to be of excellent quality, a score of 6–8 points is good, 4–5 points is fair and a score below 4 points is of poor quality. A total of 414 participants aged 1.6 to 17 years were included in the reviewed studies. Severity, type of CP, nutrition status and feeding skills varied among participants. We summarize key findings of the studies included in the review below:

## Sensorimotor Interventions

Six studies of sensorimotor interventions were included.[61,71-75] All were small, with the largest study including 35 children.[61] This study was of good quality (PEDro score of 6) and found no effect of the sensorimotor treatment on a range of outcomes, including eating time, clearing time, textures consumed, or weight gain. The remaining studies all were smaller and of poorer quality and results were mixed. Two studies by the same group as that above appear to provide data on overlapping patients and provided data separately for children with and without a history of aspiration.[74,75] The papers were rated as fair quality, and reported improved eating efficiency and safety of the sensorimotor intervention when eating pureed food for aspirating

children, but no effect among those who did not aspirate. They reported no change in weight or skinfold measures. In a case series of eight children with spastic diplegia, sensorimotor treatment provided four times per day was associated with increased efficiency of chewing and swallowing skills, caloric consumption, and gains in height and weight.[71] Treatment was provided for up to six weeks, with outcomes measured over the course of a year. A case series with six severe cases of CP reported improved efficiency and speed of swallowing when using a thermal modality.[72] When individuals continued receiving thermal stimulation, frequency of aspiration and recurrence of upper respiratory tract infections were reduced. Overall, evidence was low for improved feeding efficiency and safety outcomes as to the effectiveness of a sensorimotor treatment when compared with no intervention at all as the one good RCT found no effect, and those studies that did report positive effects were of poorer quality.

## Positioning

Four studies of positioning[70,76-78] were included in the Snider review, none of which was a comparative study; thus all studies had a high risk of bias. The largest included 24 participants evaluated before and after use of a thoracic-lumbar-sacral orthosis kept within a nonrigid frame.[78] Participants demonstrated increased tolerance of varied textures at meals, shorter feeding times, improved mouth opening, less food leakage and a decrease in tongue protrusion, but the study did not include a comparison group. In one study with five participants, videofluoroscopy was used to visualize the effectiveness of feeding in a 30 percent reclined position.[77] In this position, participants who had received food puree mixed with barium powder had decreased aspiration. Two participants showed a decrease in oral leakage and ability to consume purees improved. Another case series using videofluoroscopy reported that the best reclining position depended on the phase of feeding in which problems occurred.[76] Given the poor quality of the studies and lack of comparative data, Snider concluded that there may be limited evidence that positioning is effective in reducing episodes of aspiration and decreasing mealtime but there is insufficient evidence to draw conclusions.

## Altering Food Consistency

The one study on altering food consistency[79] in the Snider review would not have met criteria for inclusion in our review on the basis that the study provided no pre-post data and did not include an untreated or differently treated comparison group.

## Oral Appliances

Eight studies of oral appliances were included in the Snider review.[68,69,80-85] A series of studies with overlapping participants assessed the effectiveness of Innsbruck Sensorimotor Activator and Regulator (ISMAR) therapy, which is the use of the ISMAR appliance to stabilize the jaw and promote improved swallowing and lip control.[69,83,84] One RCT in which 20 participants were randomized either to 12 months of ISMAR, or 6 months of standard rehabilitation followed by 12 months of ISMAR. Oral-motor skills improved during the stabilization (initial) period in each group, but not in the control period during which standard rehabilitation took place. No significant improvements in weight or feeding skills (*our primary outcomes*) could be attributed to the treatment; rather these physical changes occurred equally in the two groups and were thus associated with maturation. Two papers[69,84] report on participants randomized to immediate versus delayed treatment, followed by cessation of use by one group while the other continued use. The goal was to determine the degree to which improvements

continued in the group that ceased use of the ISMAR device. At this point in time, no significant differences were observed, suggesting that maturation accounted for improvements in the second year.

Two other studies without comparison groups examined the use of the ISMAR and other oral appliances and effects on oral sensorimotor functions. A small study with seven subjects reported improvements in lip seal, nasal breathing, transport of saliva and speech articulation.[68] A study with 71 subjects reported no improvements in drooling, tongue position, coordination of tongue movement, lip position, or mouth posture.[81] Two case series reported positive results with lip control and closure, deglutition skills, and chewing skills after using an oral appliance; followup occurred after the 18[th85] or sixth month[68] of using a device. A case study showed that following one year of ISMAR therapy improvements in feeding skills, swallow, and efficiency eating different textures were observed.[82] A change in facial expression and improvements in ambulation and upper extremity functions were noted. Harms noted in the studies include worsening of isolated oral functions (leading to discontinuation of the device in 5 participants)[81] and discomfort associated with the device.[85] Overall, although individual studies report improvements in typically short term outcomes associated with oral appliances, there is limited evidence to suggest that they are associated with the health outcomes of interest in our review.

## Feeding Devices

Two studies analyzed effectiveness of an electric feeder in 20 participants (17 with CP) using a pre-post design.[67,86] Neither demonstrated positive effects in outcomes of interest for our review and improvements in components of oral-motor behaviors were not observed at followup. Electric feeding devices were not included in our review. Table 7 outlines key findings as summarized in the review's evidence table.[34]

**Table 7. Key findings summarized in Snider et al.[34] systematic review***

| | Author, Year<br>Study Design | Intervention | CP Type/Severity<br>Participants<br>Age Range | Key Findings |
|---|---|---|---|---|
| **Oral sensorimotor facilitation** | *Helfrich-Miller et al., 1986[72]<br>**Case series** | Dietary modification, oral program during feeding, thermal stimulation | Severe CP<br>n=6<br>10–13 years | • Improvements in swallowing efficiency and speed<br>• Reductions in aspirations and incidence of upper respiratory tract infections for those remaining on thermal stimulations program |
| | Ganz 1987[73]<br>**Single-subject ABA design** | Neuromotor and sensory facilitation | Severe CP<br>n=1<br>8 years | • Decreased tongue thrust and positive changes in tongue and jaw movements<br>• Poorer elevation of tongue with jaw separation for liquids and solids |
| | *Gisel et al., 1995[74]<br>**Prospective cohort study comparing outcomes in aspirators and nonaspirators[a]** | Tailored sensorimotor treatment with emphasis on tongue lateralization, lip control, chewing | Moderate to severe motor impairment<br>n=27<br>2–10 years | • Limited change in eating efficiency in non aspirators; improvements with purees in aspirating group but declines with solids<br>• Rank in weight- and skin fold-or-age measurements maintained<br>• Eating efficiency may be related to severity of eating impairment |
| | *Gisel et al., 1996[75]<br>**Prospective cohort study comparing outcomes in aspirators and nonaspirators[a]** | Tailored sensorimotor treatment with emphasis on tongue lateralization, lip control, chewing | Moderate to severe motor impairment<br>n=27<br>2–10 years | • Significant improvements in spoon feeding, chewing (lateralization of the tongue), and swallowing<br>• No significant changes in rotary chewing or drinking skills<br>• No catch-up growth reported |
| | *Gisel et al., 1996[61]<br>**RCT** | Tailored sensorimotor treatment with emphasis on tongue lateralization, lip control, chewing | Moderate to severe motor impairment<br>n=35<br>4.3–13.3 years | • Eating time of standard food textures did not decrease significantly<br>• No significant changes in clearing time or ability to advance to more solid foods between groups<br>• No differences between groups regarding weight gain |
| | *Clawson et al., 2007[71]<br>**Case series** | Beckman oral-motor exercise, parent training | Spastic diplegia<br>n=8<br>1.6–4.7 years | • Chewing and swallowing improved<br>• Number of calories increased (less need for supplementation)<br>• Height and weight gain<br>• Improvements in caregiver ability to feed |
| **Food consistency** | Croft et al., 1992[79]<br>**Prospective cohort study** | Mashed vs. nonmashed food | Hemiplegia, athetoid, spastic quadriplegia plus athetoid<br>n=67<br>3–18 years | • Children without speech took significantly longer to eat nonmashed than mashed food<br>• Children with CP more likely to cough or choke while eating more solid foods |

**Table 7. Key findings summarized in Snider et al.[34] systematic review* (continued)**

| | Author, Year<br>Study Design | Intervention | CP Type/Severity<br>Participants<br>Age Range | Key Findings |
|---|---|---|---|---|
| **Positioning** | Banerdt et al., 1978[70]<br>**Case report** | Self-feeding skills program, positioning | Spastic CP<br>n=1<br>2.5 years | • Number of independent responses from the child increased throughout treatment. New self feeding behaviors at 5 months followup |
| | Morton et al., 1993[76]<br>**Case series** | Feeding assessment with videofluoroscopy, positioning recommendations | Majority CP with malnourishment<br>n=14<br>4–16 years | • Children with difficulties mainly in oral phase fed best in the reclined position<br>• Children with difficulties mainly in pharyngeal phase fed best in the erect position<br>• Parents found seating recommendations helpful<br>• No changes in weight gain reported |
| | *Larnert et al., 1995[77]<br>**Case series** | Positioning | Tetraplegia with dystonia (aspiration, recurrent pneumonia)<br>n=5<br>3–10 years | • Aspiration decreased for all participants in reclined position with neck flexed<br>• Oral leak diminished in 2 children<br>• Retention of puree improved in 1 child |
| | *Vekerdy et al., 2007[78]<br>**Case series** | Thoracic-lumbar-sacral orthosis | CP, nonambulatory<br>n=24<br>1.7–11.2 years | • Improvement in meal textures tolerated<br>• Decreases in feeding time<br>• Improvements in mouth opening, food leakage, tongue protrusion |
| **Oral appliance** | Haberfellner et al.,1977[80]<br>**Case series** | Oral appliance (oral shield, vestibular pads) | Mixed forms of spasticity, athetosis, and /or ataxia<br>n=9<br>6–12 years | • Sensibility, lip seal, saliva transport, and nasal breathing improved<br>• Speech articulation improved |
| | *Fischer-Brandies et al.,1987[81]<br>**Case series** | Oral appliance (upper palate plates), physical therapy | CP, majority spastic diplegia, majority severe dysfunction<br>n=71<br>4–14 years | • Improvements in spontaneous tongue position and coordination of tongue movement, food intake, speech development and drooling in at least half of participants<br>• Treatment discontinued in 5 children due to lack of improvement<br>• Unclear if positive effects due to physical therapy or appliance |

**Table 7. Key findings summarized in Snider et al.[34] systematic review* (continued)**

| | Author, Year<br>Study Design | Intervention | CP Type/Severity<br>Participants<br>Age Range | Key Findings |
|---|---|---|---|---|
| **Oral appliance (continued)** | Gisel et al., 1999[82]<br>**Case report** | ISMAR | Moderate spastic quadriplegia<br>n=1<br>2 years, 10 months | • Improved functional feeding skills and visible aspects of the swallow<br>• Improved eating efficiency of three standard textures<br>• Catch-up of weight during treatment phase, improvements in ambulation and upper extremity function<br>• Child became able to self-feed |
| | *Gisel, et al., 2000[b69]<br>**RCT** | ISMAR | Tetraparesis with moderate motor impairment<br>n=20<br>4–13 years | • Improvement in sitting postural control and upper extremity control<br>• Improvements in jaw stabilization and oral-motor control<br>• Improvement in oral posture but not tongue position in half of participants |
| | *Gisel et al., 2001[b83]<br>**RCT** | ISMAR | Tetraparesis with moderate motor impairment<br>n=17<br>6–15 years | • ISMAR tolerated without complications<br>• No significant differences in 7 domains of functional feeding or weight gain 18–24 month followup<br>• Maturation equally effective as ISMAR therapy after the first year of use |
| | *Haberfellner et al., 2001[b84]<br>**RCT** | ISMAR | Tetraparesis with moderate motor impairment<br>n=20<br>4.2–13.1 years | • Improvements in oral-motor and chewing skills |
| | *Johnson et al., 2004[85]<br>**Case series** | ISMAR | CP, majority with moderate to sever dysphagia<br>n=18<br>4–13 years | • Clinically important and statistically significant changes in chewing, cup drinking, straw drinking, and swallowing at various points of study |
| | *Gerek et al., 2005[68]<br>**Case series** | Castillo-Morales device | CP, majority with moderate to severe dysphagia<br>n=7<br>8–17 years | • Changes noted in deglutition skills with higher consistency in food intake, decreased risk of aspiration, better saliva control<br>Parental satisfaction with treatment results |

**Table 7. Key findings summarized in Snider et al.[34] systematic review* (continued)**

| | Author, Year<br>Study Design | Intervention | CP Type/Severity<br>Participants<br>Age Range | Key Findings |
|---|---|---|---|---|
| **Adapted equipment** | Pinnington et al., 1999[c86]<br>**ABA within-subjects design** | Electric feeder (Handy 1 Robotic Aid to Eating) | Majority CP, moderate-very severe motor disorder<br>n=16<br>7–17 years | • Food intake and weight gain maintained using feeder<br>• Eating efficiency reduced; energy and protein intake unchanged using feeder |
| | Pinnington et al., 2000[c67]<br>**ABA within-subjects design** | Electric feeder (Handy 1 Robotic Aid to Eating) | Majority CP, moderate-very severe motor disorder<br>n=16<br>7–17 years | • Improvements in oral-motor behaviors using feeder but not always sustained<br>• Children with more limited speech appeared to have greater benefit |

CP = cerebral palsy; ISMAR = Innsbruck Sensorimotor Activator and Regulator; n = number; RCT = randomized controlled trial
*Study meets inclusion criteria for current comparative effectiveness review.
[a]Same study population.
[b]Same study population.
[c]Same study population.

## Summary of Primary Research

In updating the Snider review described above, we identified one case series addressing caregiver training.[66] The study was conducted in child-caregiver pairs who received in-home training and support in Dhaka, Bangladesh (Table 8). All of the children had moderate to severe CP, assessed as levels III to IV on the Gross Motor Function Classification System (GMFCS). Thirty-seven pairs were enrolled in the study, but only 22 completed it. Pairs received advice and completed a baseline assessment during an initial home session and then participated in four to six sessions focused on improving dietary intake and ease and efficiency of feeding, including introduction of a high calorie diet, adaptation of food consistency, use of appropriate utensils and provision of appropriate postural and physical support. The intervention was delivered over 2.5 months and evaluated 4 to 6 months after completion.

Children had significantly fewer episodes of chest-related illness after 3 months (15 vs. 6, p=0.005), had improved mean weight-for-age z-scores (−4.83 vs. −4.07, p=0.02), mean mid-upper-arm circumference (14.75 cm vs. 15.46 cm, p=0.02 and 0.001), and fluid intake during meals (173.7 ml vs. 300.2 ml, p<0.01) 4 to 6 months after the end of intervention. Observed child feeding skills and affect also improved, with a significant decrease in child fussiness and food refusal and improvement in general mood and child feeding skills (p<0.05). At baseline, nine children always refused food, no children were involved in self-feeding, and six were observed munching or chewing. At 4 to 6 months after the caregiver training, only one child was observed refusing food and six and eight children were involved in self-feeding and demonstrated munching or chewing, respectively. The authors also reported a significant improvement in caregiver self-reported stress and reduction in mealtime length (p=0.005).

Similarly, a study with a parent training component[71] reviewed by Snider et al.[34] reported an increase in parents' feeding effectiveness, but as noted, these studies are of high risk of bias (typically pre-post design) and report high attrition.

**Table 8. Key outcomes of studies assessing behavioral interventions**

| Author, Year<br>Country<br>Groups, Number of Participants (Enrollment/Final) | Age (mean years ± SD)<br><br>CP Severity, n (%) | Key Outcomes |
|---|---|---|
| Adams et al., 2011[66]<br>Bangladesh<br><br>**G1:** Caregiver training (4 to 6 sessions over 2.5 months), 37/22 | **Age:** 3.11 ± 2.3<br><br>**Severity (GMFCS):**<br>Level III: 3 (14)<br>Level IV: 3 (14)<br>Level V: 16 (72)<br>(moderate to severe) | • Significant improvement in chest health (frequency of illness) (p=0.005), nutritional status (mean weight-for-age z-scores and mid-upper-arm circumference) (p=0.02 and 0.001), and fluid intake during meals (p<0.01) at 4 to 6 months after end of intervention.<br>• Significant improvement in child observed fussiness, food refusal and general mood (p<0.01) and feeding skills (p<0.05) at 4 to 6 months after end of intervention.<br>• Significant decrease in caregiver self-reported stress (p<0.001) and perceived reduction in mealtime length (p=0.005). |

CP = cerebral palsy; G = group; GMFCS = Gross Motor Function Classification System; SD = standard deviation

### Key Question 1b. Is the effectiveness of behavioral interventions modified by age, race, severity, functional status (e.g. GMFCS level), or initial nutritional status?

No studies were designed or powered to directly assess this question. Of note, the studies focused on children with moderate or severe CP and provided little detail that might allow for stratification by severity or functional status. One study reported in the Snider review provides data separately for children with and without a history of aspiration.[74,75] The study, reported in two publications rated as fair quality on the PEDro scale, reported improved eating efficiency and safety when eating pureed food for aspirating children after sensorimotor intervention, but no effect among those who did not aspirate.

### Key Question 2a. Compared with other nonsurgical interventions or no intervention, how effective are nutritional interventions (food thickeners, caloric supplementation with formulas, vitamin supplementation, and altering food consistency (e.g. pureeing)), for improving nutritional state/ growth, health outcomes and health care/resource utilization, and quality of life in individuals with cerebral palsy and feeding difficulties?

No studies met criteria to address this question although pureed food was used in conjunction with positioning and sensorimotor interventions described in the review by Snider and colleagues.[34]

### Key Question 2b. Is the effectiveness of nutritional interventions modified by age, race, severity, functional status (e.g. GMFCS level), or initial nutritional status?

No studies met criteria to address this question.

### Key Question 3a. What is the comparative effectiveness of tube feeding compared with oral feeding or to nutritional and behavioral interventions in individuals with cerebral palsy who present with feeding difficulties, including malnourishment, failure to thrive, aspiration and excessive caregiver burden?

## Key Points

- The primary literature included six case series (described in eight publications) focused on assessing clinical outcomes after gastrostomy,[87-94] one fair quality cohort study on the potential for overfeeding with gastrostomy that also included effectiveness data,[95] one prospective case series assessing the potential for overfeeding using a low energy feed following gastrostomy,[41] and one case series regarding the potential for gastrostomy to result in gastroesophageal reflux (GER).[96] These latter three studies were considered harms studies.
- Case series included <60 participants each and reported improvements in weight gain, most measures of caregiver satisfaction, and hospitalizations due to chest infections.

- Harms included reflux, tube migration or blockage, stoma ulcers, gastric leakage, peritonitis, pneumonia, and gastrointestinal complications.
- The prospective cohort focused on potential overfeeding compared orally fed and gastrostomy-fed children and reported no significant differences between tube-fed and orally fed groups in normalized weight and skinfold z-scores, energy expenditure, resting metabolic rate, fat mass index, or fat-free mass index, but both groups had higher body fat content than a reference population of age- and sex-matched typically developing children.
- The case series assessing a low energy feed reported weight gain without a corresponding increase in fat mass.
- The strength of the evidence was low for measures of growth and harms of gastrotomy and insufficient for all other outcomes (respiratory outcomes including reflux, quality of life, long term morbidity and mortality).

# Overview of the Literature

The fair quality cohort study included 40 children with spastic quadriplegic CP from a tertiary feeding clinic. Children either had gastrostomy (n=22) or were able to eat orally (n=18) and were evaluated using growth measures and energy expenditure.[95] Case series,[41,87-94,96] were conducted in the United Kingdom, Canada, Brazil, Australia, and the United States and assessed gastrostomy with and without fundoplication in young children. Outcomes evaluated included measures of growth, quality of life, respiratory events, episodes of GER, and harms. Across studies, followup typically occurred 6 to 12 months after surgery, with one study following patients for up to 41 months[91] and another for a median of 55 days.[96]

# Detailed Analysis

## Effectiveness Data

Effectiveness data for gastrostomy come from one prospective cohort study,[95] four prospective,[87-89,92-94] and two retrospective case series[90,91] (Table 9). The prospective cohort study was intended to assess potential harms of treatment and is therefore discussed in detail in that section, below. The one multicenter, prospective case series provides the most detailed outcomes data available.[92-94] This study includes data collected systematically prior to the intervention, establishes primary outcomes a priori, controls for age and sex in reporting results, and uses standards for typically developing children as a comparison in z-score analyses. The study (reported in three publications[92-94]) included 57 children (age range: 5 months–17 years, median: 4 years) with CP and severe motor difficulties (75% with spastic quadriplegia, 93% unable to feed independently, 77% with global developmental delay) undergoing gastrostomy (percutaneous endoscopic gastrostomy [PEG] in 53 children and open gastrostomy in 4). Eighteen children with significant reflux (determined by a reflux index > 10% as proposed by Sullivan 1999[97]) had fundoplication performed at the same time as gastrostomy. The majority of children (n=53/57) had severe CP, assessed to be equivalent to level V GMFCS, with 95 percent unable to walk independently. All had substantial oral-motor impairment and feeding difficulty. None of the children had experienced adequate (not defined) weight gain for at least 12 months prior to surgery. Some had experienced no weight gain at all. Outcome measures included changes in body weight and skinfold measurement; dietary intake; general health (measured by infections requiring hospitalization or antibiotics); harms, including respiratory morbidity; and

quality of life for caregivers (measured using the validated Short-Form 36, version II [SF-36][98]). Although there was no active comparison group in this study, standards for typically developing children were used as a reference.

Participants improved on all measures of growth. Median weight z-scores (relative to standards for typically developing children of the same age and sex) increased from −3 at baseline to −1.6 at 12 months post-gastrostomy, and the proportion of children more than 2 standard deviations below the mean decreased from 2/3 to under half at 12 months. Linear growth (lower leg length, median baseline z-score −1.31 vs. −0.44 at followup) and head circumference (median baseline z-score among those with 12 month data available 0.15 vs. 0.52 at followup) measures improved significantly at followup as did arm circumference (median baseline z-score −0.14 vs. 0.58 at followup) and skinfold z-scores (median baseline z-score −1.71 vs. −0.59 at followup). Thus, improvements were observed and were statistically significant for every measure of growth (p values ranging from <0.0001 to 0.004).

Energy intake as measured by 3-day dietary records maintained by caregivers increased, and the proportion of children experiencing at least one infection requiring hospitalization decreased from 26 to 7 percent (p=0.021). A separate analysis of chest infections showed a significant decrease in the mean number of infections requiring antibiotics from baseline to 12 month followup (mean at baseline=1.8 [SD=2.7], mean at followup=0.9 [SD=1.7], p=0.07) and in hospitalizations for chest infection (mean at baseline=0.5 [SD=1.0], mean at followup=0.09 [SD=0.4], p=0.04).[94]

An Australian prospective case series including 21 children with quadriplegic CP (median age=8 years 5 months, all GMFCS level V) similarly reported significant increases in weight (median baseline weight in kg=15.4, followup=23.3, p<0.05) and height (median baseline height in cm=105.4, followup=118.3, p<0.05) after a median 19.4 months of gastrostomy tube feeding.[87] Standard deviation scores for weight, but not height, also increased significantly (p<0.05). Body fat percentage increased from a median 10.7 percent at baseline to 16.3 percent at followup (p<0.05). Another prospective case series conducted in Brazil included 16 children (mean age 6.5 years) with CP and dysphagia or recurrent aspiration undergoing PEG tube placement; the study also included 4 children with swallowing dysfunction but not CP.[88] Children were followed for a mean of 5.9 months (range: 2–10 months). Weight, but not height or skinfold, z-scores significantly increased from baseline across all participants (data presented graphically only).

A retrospective case series conducted in the United States assessed growth in gastrostomy-fed children with CP between the ages of 9 months and 23 years (mean=10.7 years). At the time of data collection, most participants had severe motor dysfunction, and over 70 percent had signs of GER.[90] No data are provided on the proportion that had GER prior to surgery and it is not possible to assess whether surgery ameliorated or created cases of GER. Fifty-six percent (n=32) of participants had Nissen fundoplication as well as gastrostomy, suggesting that at least half had substantial reflux prior to surgery; two of these later required jejunostomy after failed fundoplication. Baseline and followup data were available for 35 participants; among these, roughly 70 percent remained below the 5$^{th}$ percentile for height and weight post-gastrostomy. Roughly half (46%) attained appropriate weight for height standards, 21 percent were overweight, and 33 percent were underweight. In subgroup analyses, at least 50 percent of children with gastrostomy before age 2; those with gastrostomy for more than 2 years; and those with fundoplications reached appropriate weight for height. Caution should be used, however, in interpreting these data as reference standards in the literature are often for typically developing

children and not an appropriate comparison for individuals with CP. Caregivers generally reported satisfaction with gastrostomy and noted increased ease of feeding and improvements in child affect.

An additional retrospective case series evaluated outcomes for 19 children with CP (mean age: 60.4 months) and reported increases in growth overall (baseline mean weight/length z-scores: −2.71, followup: −1.18).[91] Two studies assessed quality of life. One, the Sullivan case series, assessed quality of life (QOL) of *caregivers* using the SF-36 and interviews with caregivers of these 57 children.[93] Participants completed the questionnaire prior to their child's gastrostomy and at 6 and 12 months post-placement; roughly 35 individuals completed the 12-month followup. Baseline scores on all measures were lower than those for the population norm at baseline. By 12 months, scores had improved on all measures and improved significantly (p values <0.01) on the domains of Role limitations—emotional (baseline: 68.06 ± 31.05, followup: 73.54 ± 27.27), Energy/vitality (baseline: 41.59 ± 23.58, followup: 51.56 ± 22.46), and on the Mental Component summary (baseline: 40.10 ± 15.60, followup: 46.37 ± 11.84). Caregivers reported declines in feeding time from baseline (median: 2.5 hours/day) to 12 month followup (1 hour/day) and greater ease in medication administration. Caregiver concern/worry over their child's nutritional state also lessened post-gastrostomy, with 15 percent indicating concern at 12-month followup compared with 78 percent at baseline. While SF-36 scores improved overall, not all participants reported positive changes; scores on social functioning declined post-gastrostomy for one in four caregivers, and scores for 13 of 39 respondents were lower for the Energy/vitality domain.

The other study assessing QOL was also prospective, but focused on parental perception of *the child's* quality of life. In this series, 50 children underwent gastrostomy, 42 of whom had static neurologic disorders, presumably CP (overall median age: 591 days).[89] Investigators used a 10 cm visual analog scale (VAS) to assess parental perception of the child's life and health, an unvalidated questionnaire adapted from the CHQ-PF50 to assess QOL, and collected anthropometric data at baseline and 12 months post-gastrostomy. The study also documented harms. Most parents (98%) expected QOL to improve for their children prior to gastrostomy; however, parent-rated VAS QOL scores did not differ between baseline and followup. Ratings on questions related to global health, impact on activities, and impact on feeding improved at 6 months, but improvements were not sustained at the final, 12-month followup. Ratings on questions related to impact on parental time and medications improved significantly at 12 months ($p \leq 0.05$), and ratings on bodily pain, mental health, health perceptions, and parental impact on emotions and respite care did not change. Weight for age z-scores increased significantly at 12 months ($p < 0.01$) though height did not change significantly. Triceps skinfold measurements were increased or maintained.

**Table 9. Summary of key outcomes of studies of surgical interventions reporting effectiveness data**

| Author, Year<br>Country<br>Groups, Number of Participants, N Enrollment/N Final | Age<br><br>CP Severity/Type, N (%) | Key Outcomes |
|---|---|---|
| Arrowsmith et al., 2010[87]<br>Australia<br><br>G1: Gastrostomy, 21/21 | **Age:** 8 years, 5 months (median)<br><br>**Severity (GMFCS):**<br>Level V: 21 (100) | • Median gastrostomy feeding time=19.4 months, range=7.7-29.9 months; median followup=20.6 months, range 11.3-34.4 months<br>• Significant increase in weight, height, body fat at followup ($p<0.05$) with mean body weight increase of approximately 50%<br>• Significant increase in weight standard deviation (-4.8 at baseline, -3.0 at followup, $p<0.05$) |
| Mahant et al., 2009[89]<br>Canada<br><br>G1: Gastrostomy or gastrojejunostomy tube feeding, 50/43 | **Age:** 591 days (median, range: 20–5663 days)<br><br>**Severity (among those with static neurologic disorder, GMFCS):**<br>Level V: 29 (69)<br>Level IV: 6 (14)<br>Level III: 5 (11) | • 42/50 participants had static neurological disorder; study assessed parent-reported child QOL and anthropometric changes<br>• Improvements from baseline to 6 months (including activities, parental time, feeding) but not sustained<br>• Improvement in medications sustained at 12 months<br>• No impact on pain, mental health, health perceptions, parental impact on emotions and respite care<br>• Overall significant increase in weight for age (baseline z-score -2.8 vs. -1.8 at followup, $p<0.01$) but not height (baseline -2.1 vs. -2.0 at followup)<br>• At 12 months 87% of parents felt that tube insertion improved the health of their child<br>• 3 deaths |

**Table 9. Summary of key outcomes of studies of surgical interventions reporting effectiveness data (continued)**

| Author, Year<br>Country<br>Groups, Number of Participants, N Enrollment/N Final | Age<br><br>CP Severity/Type, N (%) | Key Outcomes |
|---|---|---|
| Sullivan et al., 2004, 2005, 2006[92-94]<br>United Kingdom<br><br>**G1**:Gastrostomy (PEG=53, laparoscopic gastrostomy=2, open gastrostomy=2), 57/46 | **Age:** 4.32 years (median)<br><br>**Type:**<br>Spastic quadriplegic: 43<br>Mixed CP: 6<br>Hemiplegic:3<br>Undiagnosed: 3<br>Ataxia: 1<br>Extrapyramidal disorder: 1 | • Significant positive change in median z-scores for weight (-3 at baseline vs. -1.6 followup), head circumference (0.15 at baseline vs. 0.52 at followup), lower leg length (-1.21 at baseline vs. -0.44), arm circumference (-0,14 at baseline vs. 0.58 at followup), and skin fold measurements (-1.71 at baseline vs. -0.59 at followup) after 12 months, p values ranging from <0.0001 to 0.004<br>• Hospitalizations due to infection dropped from 26% at baseline to 7% at 12 months post-gastrostomy, p=0.021; number of infections requiring antibiotics did not change<br>• Significant decrease in both hospitalizations(mean # at baseline=0.5, at followup=0.09, p=0.04) and antibiotics for chest infections (mean # at baseline=1.8, at followup=0.0, p=0.07) after tube placement; no difference in hospitalization or antibiotics for chest infection in patients who had fundoplication<br>• 4/57 participants died, 1 prior to insertion of g-tube<br>• Significant improvement on caregiver-rated measures of social function (mean change 13.51, 95%CI 1.55 to 25.48; p=0.028), mental health (9.88, 95%CI 2.03 to 17.72; p=0.015), energy (9.94, 95%CI 2.29 to 17.58; p=0.012), general health perception (6.35, 95%CI 0.15 to 12.56; p=0.045), and mental component summary (7.06, 95%CI 0.90 to 13.22; p=0.026); no change in pain.<br>• At baseline, caregivers had lower QOL due to physical problems, emotional problems, social functioning, mental health, and energy compared with the general public. At the end of 12 months, these had normalized except for emotional problems<br>• Post gastrostomy, caregivers reported decreased feeding times and decreased overall concern about nutritional status and increased ease of medication administration |
| Brant et al., 1999[88]<br>Brazil<br><br>**G1:** PEG, 16/16 | **Age:** 6.5 years (mean)<br><br>**Type:**<br>Tetraparesis: 16 | • Weight z-scores increased significantly from baseline in all participants; height and skinfold did not change significantly (data only reported graphically)<br>• Harms included leakage, granulation tissue, ostomy infection, pneumonia, pneumoperitoneum<br>• 3 participants died |

**Table 9. Summary of key outcomes of studies of surgical interventions reporting effectiveness data (continued)**

| Author, Year<br>Country<br>Groups, Number of Participants, N Enrollment/N Final | Age<br><br>CP Severity/Type, N (%) | Key Outcomes |
|---|---|---|
| Rempel et al., 1988[90]<br>United States<br><br>**G1:** Gastrostomy with and without fundoplication, 57/57 | **Age:** 10.7 (range: 9 months–23 years)<br><br>**Severity:**<br>No useful motor activity/dependent for all needs: 49<br>Moderate to severe involvement/dependent for most needs: 8 | • Over 70% of participants symptomatic for GER; 32 had Nissen fundoplication plus gastrostomy<br>• Most participants gained weight; roughly half attained appropriate height for weight standards, 21% were overweight, 33% were underweight<br>• 8/57 died after gastrostomy; 5 deaths occurred within 1 year of placement |
| Shapiro et al., 1986[91]<br>United States<br><br>**G1**: Gastrostomy, 19/19 | **Age:** 60.4 months<br><br>**Severity:**<br>All were profoundly handicapped, 17/19 had oral-motor dysfunction | • Significant improvement in weight (3 participants >10$^{th}$ percentile weight for length ratio preoperatively vs. 11 postoperatively, p<0.10) more than length; growth improved in most overall with children moving on average 1.5 standard deviations closer to 50$^{th}$ percentile for children of similar ages<br>• 2 children required subsequent fundoplication |

CP = cerebral palsy; G = group; GER = gastroesophageal reflux; GMFCS = Gross Motor Function Classification System; PEG = percutaneous endoscopic gastrostomy; QOL = quality of life

## Harms Data

Three studies were focused specifically on potential harms of gastrostomy; two were related to the potential to overfeed,[41,95] and one on the potential to induce GER post-gastrostomy[96] (Table 10).

A fair quality prospective cohort study included 40 consecutive children (median age: 8 years 6 months, range: 1–18 years) at a tertiary feeding clinic for children with neurological impairment in the United Kingdom.[95] Given the reduced energy requirements of quadriplegic children with CP, it is conceivable that they might be overfed, which would be indicated by an imbalance in body composition (i.e., excessive fat mass to fat-free mass) and this was the focus of this study. Investigators also used a reference population of normally developing children for comparison. Twenty-two children were gastrostomy fed (approximately 2/3 also underwent preoperative nasogastric tube feeding prior to gastrostomy), and 18 were fed orally. Investigators took anthropometric (weight, skinfold, height), body composition, and energy expenditure measurements at baseline and after 12 months (median duration of tube feeding: 12 months, range: 4–60 months). As expected, children in the orally fed group had lower (less severe) GMFCS scores, lower weight, higher fat-free mass index, and lower skinfold thickness (p=0.01) z-scores than the gastrostomy group at baseline. Children in the gastrostomy group had lower energy expenditure (p=0.04) and resting metabolic rates and higher fat mass index (p=0.02) than the orally fed group at baseline.

At followup, the gastrostomy group had greater fat mass than the orally fed group, and had lower fat-free mass, but the differences were not statistically significant. Compared with data from the reference population, both CP groups had higher body fat content and lower fat-free content, with the gastrostomy group having greater fat mass relative to the reference population

than the orally fed participants. The investigators note that results may be confounded by preoperative nasogastric tube feeding in the gastrostomy group and ongoing nutritional therapy (caloric supplementation and/or enteral feeds) in the orally fed participants, and the degree to which gastrostomy may be associated with poor outcomes from overfeeding remains unclear.[95]

One case series similarly addressing the potential for overfeeding assessed the use of a low-energy feed on weight, body fat, and other anthropometric measures (assessed using a doubly labeled water method); micronutrient status; and general health in 14 gastrostomy-fed children (median age=2 years).[41] Participants had severe disability: all had spastic quadriplegic CP, a GMFCS level of V (n=13) or IV (n=1), and weight between 8 and 30kg at baseline (median=12.1 kg). All participants were solely tube-fed, and seven of 14 had undergone fundoplication in addition to gastrostomy. Six month followup data were available for eight of the 14 participants; three participants died of respiratory infections in the study period.

Participants' weight, mid-upper arm circumference, and lower leg length increased significantly over the 6-month feeding period. Fat mass and body fat percentage increased, but not significantly (fat mass at baseline=3.1 kg, at followup=5.0; body fat percentage at baseline=28.3, at followup=32.5). Fat mass was not significantly different from that of a reference group of children without disability, though these data should be interpreted with caution given the limited comparability of the two groups. Micronutrient levels were largely within normal limits both prior to and after gastrostomy feeding, with levels of zinc, coper, vitamin B1 and chromium elevated beyond recommended ranges at followup. Fiber intake remained below recommended levels, and bowel movement frequency was generally unchanged over the study period. Chest infections requiring antibiotics decreased in half of participants at followup; 25 percent had no chest infections pre- or post-gastrostomy.

In one case series, investigators used impedance monitoring to assess episodes of GER pre- and post-PEG in children with CP (n=9) and Down syndrome (n=1) and normal reflux indices.[96] The intent of the study was to assess the degree to which tube feeding increased rates of GER. Participants' median age was 4.9 years (range: 0.5–16.8 years), and six were taking gastric pH/motility medications. The number of reflux events increased significantly post-PEG (183 at baseline to 355 post-PEG, p=0.047), with the percentage of events reaching the pharyngeal space increasing from 56 percent pre-procedure to 82 percent. The number of nonacidic events at followup was 182, while 173 were acidic. The proportion of reflux events that were acidic dropped from 85 percent prior to PEG to 51 percent after PEG. Weight increased over time (median weight gain: 2.53 kg, range: 0.8–7.24 kg), but the study was not designed to clearly ascertain the degree to which weight gain was associated with the PEG, and no comparisons were made to any reference group.

**Table 10. Summary of surgical papers focused on harms**

| Author, Year<br>Country<br>Groups, N<br>Enrollment/N Final | Age (Median Years)<br><br>CP Severity/Type, N | Key Outcomes |
|---|---|---|
| Thompson et al., 2011[96]<br>United Kingdom<br><br>**G1:** Neurologically impaired with feeding difficulty treated with PEG, 10/10 | **Age:** 4.9<br><br>**Severity:**<br>NR | • 9/10 participants had CP; 183 total GER events recorded pre-PEG (median =17.50); 355 events recorded post-PEG (median=39.50)<br>• GER episodes measured with combined intraluminal pH and multiple intraluminal impedance monitoring pre- and post-gastrostomy<br>• Significant increase in both acidic and nonacidic reflux events post-PEG, with majority nonacidic<br>• Percent of the events reaching highest impedance channel was 56% pre-PEG and 82% post-PEG |
| Vernon-Roberts et al. 2010[41]<br>United Kingdom<br><br>**G1:** Gastrostomy tube with or without fundoplication+low energy, high fiber enteral feed, 14/8 | **Age:** 2<br><br>**Severity (GMFCS):**<br>Level V: 13<br>Level IV:1 | • Significant increases in weight 6th month study period (p=0.012) without a change in fat mass<br>• Increase in muscle mass without increase fat stores<br>• No significant change in micronutrient status or fiber intake<br>• 50% decrease in chest infections requiring antibiotics<br>• 3 deaths during study period from respiratory infections related to CP |
| Sullivan et al., 2006[95]<br>United Kingdom<br><br>**G1:** Gastrostomy tube, 22/14<br>**G2:** Orally fed, 18/11 | **Age:**<br>G1: 9.0 (range: 1.3–14.6 )<br>G2: 8.0 (range: 1.3–18.9 )<br><br>**Severity (GMFCS):**<br>**G1:**<br>Level V: 19<br>Level IV: 2<br>**G2:**<br>Level V:11<br>Level IV: 4<br>Level I: 1 | • Gastrostomy-fed children had greater fat mass and less fat-free mass than orally fed children with CP (differences not significant)<br>• Both groups had higher fat content and lower lean muscle mass than reference population of normally developing children<br>• Number with GER not reported |

CP = cerebral palsy; G = group; GER = gastroesophageal reflux; GMFCS = Gross Motor Function Classification System; N = number; NR = not reported; PEG = percutaneous endoscopic gastrostomy

Table 11 outlines harms included in other surgical studies. In the Sullivan case series,[92-94] four of 57 children died during the study period, which the investigators note is comparable with death rates reported in other studies of tube-fed children. Importantly, given the observed decreases in hospitalizations and no change in antibiotic use, gastrostomy did not appear to increase respiratory morbidity.[94] No child in this study developed reflux that could not be managed medically. Three children died during the course of the quality of life study[93]; the authors note that deaths were due to the children's underlying condition rather than the gastrostomy. In the Brazilian case series,[88] three participants died of causes thought to be unrelated to gastrostomy. In one retrospective case series, 23 percent of all participants had major complications including gastrointestinal bleeding (n=5), peritonitis (n=3), bowel obstruction (n=3), tube migration (n=2), wound dehiscence (n=1). Rates of harms did not differ among subgroups. Eight children died after gastrostomy, with 5 deaths occurring within 1 year of placement.[90]

Overall, rates of peritonitis were low, ranging from 2 to 5 percent, one study reported minor site infections at 59 percent and leakage at 30 percent. Deaths ranged from 6 to 15 percent, but were considered not to be related to gastrostomy in all studies. Mortality is high among individuals with CP, and it is impossible to know whether the observed deaths were causally related to treatment or to the course of the condition.

**Table 11. Harms reported in case series assessing effectiveness of feeding interventions in CP**

| Author, Year<br>Study Design<br>Number of Participants | Harm/Adverse Event | N (%) |
|---|---|---|
| Mahant et al., 2009[89]<br>Prospective case series<br>n=50 | Peritonitis | 1 (2) |
| | Gastroesophageal reflux disease | 4 (8) |
| | Deaths[a] | 3 (6) |
| | Tube removal during study | 4 (8) |
| Sullivan et al., 2004, 2005, 2006[92-94]<br>Prospective case series<br>n=57 | Serious post-surgical complications (gastric leakage, peritonitis, skin erythema, excoriation and ulceration) | 1 (2) |
| | Minor site infection | 27/46 (59) |
| | Granulation tissue | 20/48 (42) |
| | Leakage | 14/46( 30) |
| | Tube blockages | 9/47 (19) |
| | Tube migration | 3/46 (7) |
| | Child pulled tube out | 2/46 (4) |
| | Peritonitis | 1/46 (2) |
| | Deaths (1 occurred prior to gastrostomy placement) | 4/57 (7) |
| Brant et al., 1999[88]<br>Prospective case series<br>n=20 (16 with CP) | Deaths[a] | 3 (15) |
| | Granulation[b] | 7 (35) |
| | Ostomy infection | 7 (35) |
| | Pneumoperitoneum | 1 (5) |
| | Pneumonia | 3 (15) |
| Rempel et al., 1988[90]<br>Retrospective case series<br>n=57 | Deaths[a] | 8 (14) |
| | Gastrointestinal bleeding and ulceration | 5 (9) |
| | Peritonitis | 3 (5) |
| | Bowel obstruction | 3 (5) |
| | Tube migration | 2 (4) |
| | Wound dehiscence | 1 (2) |

CP = cerebral palsy; N = number; PEG = percutaneous endoscopic gastrostomy
[a]Deaths thought to be unrelated to study treatment; in Rempel et al.[90] 5/8 deaths occurred within 1 year of surgery.
[b]Study reports both 7/20 and 10/20 participants with granulation--not clear which number is accurate.

Key Question 3b. Among individuals with cerebral palsy and feeding difficulties *with significant reflux*, what is the effectiveness of g-tube placement with fundoplication versus oral feeding for reducing reflux and for improving nutritional state/ growth, health outcomes and health care/resource utilization, and quality of life?

## Key Points

- One fair quality RCT,[99] and one case series[100] addressed surgical interventions in individuals with CP and reflux.
- Reflux in participants undergoing either Nissen fundoplication or vertical gastric plication improved; the mean number of episodes decreased from 11.28 at baseline to 2.9 at followup in the Nissen group versus 6.35 at baseline and 4.40 at followup in the vertical plication group.
- In a case series, children undergoing gastrostomy plus Nissen fundoplication showed improvements in reflux symptoms and weight gain but not episodes of pneumonia; 30 percent of participants had recurrent reflux post-surgery.
- Harms included valve migration, gastrointestinal bleeding, peritonitis, pneumonia, and gastrointestinal symptoms.

## Overview of the Literature

One RCT[99] and one case series[100] addressed surgical intervention in individuals with CP and reflux. A good quality, Cochrane review attempted to study efficacy of fundoplication versus post-operative medication to control GER in CP but identified no studies meeting inclusion criteria.[63] The review is therefore not summarized further.

The fair quality RCT, conducted in Brazil, randomized 14 children (age range: 4–147 months) to either fundoplication or gastric plication and evaluated changes in episodes of GER.[99] Followup lasted for an average of 5.2 months. One case series,[100] conducted in China, included 20 children (ages ranging from 3.9 to 14.4 years at surgery) and assessed gastrostomy with Nissen fundoplication; nine participants underwent an open procedure while the rest were laparoscopic. Outcomes evaluated included measures of growth, episodes of GER, and harms over a median of 3.5 years of followup.[100]

## Detailed Analysis

### Effectiveness Data

No studies directly compared the use of g-tube with fundoplication to oral feeding. One fair quality RCT compared Nissen fundoplication (in which the upper part of the stomach is wrapped around the lower esophagus to create a one-way valve) with vertical gastric plication (in which the esophagus is lengthened) at two hospitals in Brazil.[99] GERD was established in the participants based on esophageal pH. Both groups had clinically significant improvement in reflux symptoms. The Nissen fundoplication group had a statistically significant decrease in the total number of reflux episodes ($p=0.012$), percentage of pH ($p=0.002$), and composite of pH parameters ($p<0.001$), whereas the vertical gastric plication group had a significant decrease in

pH parameters (p=0.041) and percentage (p=0.042). There was no difference between the groups in the length of the procedure or hospitalization.

In one prospective case series, reflux and pH monitoring were reported to be improved after gastrostomy plus Nissen fundoplication, regardless of laparoscopic versus open approach (baseline median reflux index=5.7% vs. 0.15%, p=0.009).[100] Within one year after surgery, 30 percent of the patients had a relapse in reflux symptoms but were responsive to medical intervention. Table 12 summarizes key outcomes of these studies.

**Table 12. Summary of key outcomes of studies of surgical interventions in individuals with CP and significant reflux**

| Author, Year<br>Country<br>Groups, Number of Participants (Enrollment/Final) | Age<br><br>CP Type | Key Outcomes |
|---|---|---|
| Durante et al., 2007[99]<br>Brazil<br><br>**G1:** Nissen fundoplication, 7/7<br>**G2:** Vertical gastric plication, 7/7 | **Age:** 67.8 months (overall mean, range: 4–147 months)<br><br>**Type:**<br>**G1:**<br>Diplegic spastic: 2<br>Tetraplegic spastic: 5<br>**G2:**<br>Diplegic spastic: 2<br>Tetraplegic spastic: 5 | • 2 children in G1 also underwent gastrostomy and 2 underwent gastrostomy and tracheostomy; 2 in G2 underwent gastrostomy.<br>• Significant reduction in parameters related to GERD in both groups (p≤0.006).<br>• 42.8% of G1 and 57.1% of G2 participants asymptomatic throughout followup period.<br>• All esophageal pH measurements except number of reflux episodes >5 minutes improved significantly in G1; total # of reflux episodes, number episodes >5 minutes, and longer reflux episodes did not improve significantly in G2.<br>• Length of stay and duration and surgery were not significantly different between groups. |
| Cheung et al., 2006[100]<br>China<br><br>**G1:** Nissen fundoplication plus gastrostomy, 20/20 | **Age:** 8.5 ± 3.5 (mean years ± SD)<br><br>**Type:**<br>Mixed: 5<br>Spastic: 13<br>Hypotonic: 1<br>Dystonic: 1 | • Participants were residents at rehabilitation center for individuals with severe neurological impairment and undergone nasogastric feeding for minimum 12 months prior to surgery; all had GER for at least 3 months and were taking antireflux medications; 9 had open surgery, 11 laparoscopic.<br>• Median reflux index decreased significantly post-surgery (p=0.009) and median longest reflux, median # of reflux episodes >5 minutes improved; weight increased from mean 17.4 kg at baseline to 22.8 kg at median followup of 3.5 years.<br>• 6/20 (30%) of participants had recurrent reflux post-surgery.<br>• Improvements in vomiting and gastrointestinal bleeding indices sustained at 4 years post-surgery; pneumonia index not significantly affected. |

CP = cerebral palsy; G = group; GER = gastroesophageal reflux; GERD = gastroesophageal reflux disease; SD = standard deviation; UTI = urinary tract infection

## Harms Data

The RCT comparing Nissen fundoplication with vertical gastric plication reported a rate of major complications (valve migration, hernia) of 14.3 percent in both the Nissen and vertical plication groups. Other harms reported are listed in Table 13; two participants died during the study (one in each group, considered unrelated to surgery).[99] In the case series early complications (within one week of fundoplication) included pneumothorax, stoma ulcers, and cellulitis, all in patients undergoing laparoscopic fundoplication. Late complications (i.e., more

than one week post-fundoplication) included bloating, diarrhea (dumping syndrome), and intestinal obstruction; these events were all reported in individuals undergoing open fundoplication.[100]

**Table 13. Harms reported in primary research studies of surgical interventions in individuals with CP and significant reflux**

| Study<br>Study Design<br>Number of Participants | Harm/Adverse Event | N (%) |
|---|---|---|
| Durante et al., 2007[99]<br>RCT<br>n=14 | Valve migration | 1 (14) |
| | Paraesophageal hernia | 1 (14) |
| | Aspiration of contrast into tracheobronchial tree | 2 (29) |
| | Urinary tract infection | 1 (14) |
| | Pneumonia | 2 (29) |
| | Deaths[a] | 2 (29) |
| Cheung et al., 2006[100]<br>Prospective case series<br>n=20 | Recurrent gastroesophageal reflux postoperatively | 6 (30) |
| | Pneumothorax | 1 (5) |
| | Stoma ulcers | 6 (30) |
| | Air bloating and diarrhea | 1 (5) |
| | Intestinal obstruction | 1 (5) |
| | Deaths[a] | 4 (20) |

CP = cerebral palsy; N = number; RCT = randomized controlled trial
[a]Deaths thought to be unrelated to study treatment.

## Key Question 3c. Among individuals who develop reflux following gastrostomy, what is the comparative effectiveness of j-tube versus fundoplication for reducing reflux in the short term and achieving improvements in nutritional state/ growth, health outcomes and health care/resource utilization, and quality of life?

We did not identify any studies addressing this Key Question.

## Key Question 3d. Is the effectiveness of tube feeding modified by tube placement, age, race, severity, functional status (e.g. GMFCS level), initial nutritional status, or continuous v bolus feeding?

Sub-analyses were conducted in two case series[88,90] to assess the degree to which age and type of procedure modified outcomes. In the first, children were divided into age bands of <2, 2 to 4, 5 to 7, 8 to 11 and 12 to 18. No age group included more than five children. Weight increased in all groups except ages 5 to 7, although this group had significant increases in triceps skinfold measurement. The very small size of each group, however, precludes any conclusion about age as a modifier. The other, retrospective case series of 57 individuals[90] reported that the highest proportion of individuals reaching weight for height were in the groups that had surgery before age 2, had had their gastrostomy for at least 2 years or had fundoplication. The group of children who had their gastrostomies earliest in life also had the smallest proportion remaining at less than the 5$^{th}$ percentile of weight for height. Because this is a retrospective study, however, it is likely that the groups represent patient populations that presented with differing levels of severity or indication; thus the comparisons are likely confounded by indication. One study

assessed outcomes by the presence of fundoplication.[94] This analysis suggested that use of antibiotics and respiratory hospitalizations did not differ by whether the child had a fundoplication. The decision about whether or not to use fundoplication, was made clinically and not for research purposes.

One series evaluating the g-tube with fundoplication found no difference in outcomes associated with laparoscopic versus open approach.[100] The intent of the study was not to compare the two approaches; rather, the clinical team changed their approach during the course of the study.

# Grey Literature

## Regulatory Information

The manufacturer of the VitalStim device, DJO, noted that no controlled studies have been conducted on the use of VitalStim specifically to treat dysphagia and provided a summary of evidence related to neuromuscular electrical stimulation in general. None of the studies included in the summary appeared to include individuals with CP. We did not identify effectiveness or safety information in other resources including the U.S. Food and Drug Administration web site.

## Conference Abstracts

We located conference abstracts from 2009–2012 from the annual meetings of the American Academy of Cerebral Palsy and Developmental Medicine and the American Academy of Physical Medicine and Rehabilitation. Abstracts from 2012 for the American Academy of Physical Medicine and Rehabilitation meeting were not available as the annual meeting had not taken place at the time of this review's conduct.

We did not identify any poster or presentation abstracts of relevance to the current review among those available. Some presentations assessed elements that may modify growth (e.g., GMFCS status) or used registries to evaluate prevalence of feeding problems, but we did not identify any abstracts assessing *interventions* for feeding or nutritional status.

# Discussion

## Key Findings and Strength of Evidence

### State of the Literature

Feeding and nutrition problems are common among children with cerebral palsy (CP), and have significant health implications. Some patients with oral-pharyngeal dysphagia and gastroesophageal reflux (GER), particularly those with severe CP, are also at risk for recurrent aspiration which can lead to chronic pulmonary disease. Patients with feeding difficulties range from those with self-feeding skills to populations with severe disability (i.e., Gross Motor Function Classification System [GMFCS] V) who require extensive use of assisted technology and are dependent on others to feed them. Indeed, chronic pulmonary disease related to aspiration is a leading cause of death among patients with severe CP.[27-30]

This review is intended to gather together what data exist to support families and clinicians in making decisions about caring for children with CP as these decisions pertain to addressing problems with feeding and nutrition. It may also point the way forward to a future research agenda. Clinicians have available to them both behavioral and surgical treatments, which may be offered in sequence depending on the severity of the feeding issues, the effectiveness of initial treatment approaches, or new conditions brought on by prior treatment in the case of reflux that develops as a result of gastrostomy.

Ultimately, very few data exist to guide care. Our analysis of the behavioral literature consists of a summary of a good quality systematic review published in 2011, updated with one new case series evaluating a caregiver training program that is not manualized (documented in a manual so that it can be replicated). The surgical literature consists of a total of eleven studies meeting our criteria; studies are largely case series. One prospective cohort study was focused primarily on harms.

Across all interventions, the study populations are almost exclusively children with severe CP; when it is assessed, populations generally meet criteria for level IV or V of the GMFCS. Although study populations are generally assessed on overall severity (e.g., GMFCS) and weight, the use of other measures for growth and nutrition, and explicit characterization of the feeding challenges in the study population is lacking. Surgical outcomes data are available for fewer than 200 children and only one cohort study provides comparative data comparing surgical with oral interventions for any population of CP. Of note, those studies that do provide data on weight gain do so against reference populations of typically developing children. These are likely not appropriate reference standards; improvement in z-scores among children with CP may very well be clinically meaningful even if these children do not approach weight standards for the reference group.

Cerebral palsy is a group of conditions with wide variation in their expression thus it is difficult to assess whether outcomes observed in these studies represent likely, population-level effects. Furthermore, none of the studies providing effectiveness data was comparative. Interventions that address feeding and nutrition are often combined (e.g., positioning with pureed food, gastrostomy tube with fundoplication and supplementation, etc.), making it difficult to determine the independent effect of each.

# Summary of Outcomes

## Behavioral Interventions

We concur with the assessment of the author of the included systematic review that data on the effectiveness of sensorimotor interventions ( "techniques specific to the enhancement of oral-motor control aim[ing] to decrease or increase tone and inhibit abnormal reflexes that interfere with safe feeding"[34]) are conflicting, with the highest quality study (a good randomized controlled trial [RCT] of oral appliances) demonstrating no effect on feeding efficiency, but a fair quality RCT reporting positive outcomes in the subset of children with a history of aspiration using pureed foods. Other noncomparative studies demonstrated improvements in feeding skills, but these were poorly conducted case series.

No good quality studies were identified on the role of positioning to improve efficiency and safety measures, including reducing leakage and decreasing feeding time as well as reductions in choking. Despite the high risk of bias associated with the study designs, however, results were consistent that identifying an optimal position for the head and neck may help with feeding outcomes with individual studies reporting improvements in aspiration, feeding skills, feeding time, or food leakage

One study of limited quality reported that children with CP without speech, had better outcomes when eating mashed rather than solid food. Evidence for the benefit of oral appliances is mixed, with some studies reporting positive results in very short term outcomes, but few studies reporting on the outcomes of interest for our review. A fair quality study that included longer term data found no benefit of the appliances for feeding skills or weight gain beyond natural maturation of the children. Overall, there are few studies of any particular behavioral modality and those that have been conducted are small and lack rigor.

## Surgical Interventions

We conducted a de novo review of the surgical literature. Data were available for two of the four surgical Key Questions—namely, Key Questions 3a and 3b.

The first question for which data were available was on the effectiveness of tube feeding versus oral feeding for children with CP without significant reflux. Evidence for the effectiveness of tube feeding (either g-tube or j-tube) comes from six case series[87-94] and one prospective cohort study,[95] designed to study the potential for overfeeding, and described below. All six case series focused on severely impaired children, and all reported significant increases in weight after gastrostomy, over six to more than 12 months. The most comprehensive case series reported improvements on all weight and growth related outcomes (weight, head growth, linear growth, arm circumference and skinfold thickness), including closing the gap significantly with a normally developing reference population, and significantly more than would have been expected without intervention. Followup continued to 12 months post surgery, with data available on 46 of the initial 57 children, and 6 unavailable due to loss to followup. The five other case series with growth data also reported significant pre-post increases in weight, but data on other measures were unreported or inconsistent. One case series also assessed health care utilization as a proxy for overall health and found the number of hospitalizations significantly reduced over the year following gastrostomy.[94]

Two studies that reported on quality of life (QOL) measures[89,93] in one, parental QOL improved significantly, in tandem with decreases in feeding time, after gastrostomy. In the other,

most parents (98%) expected that their child's QOL would improve with gastrostomy, but did not report that to be the case after surgery.

No studies directly compared the use of g-tube with fundoplication with oral feeding for the treatment of reflux. One RCT compared two forms of plication (fundoplication versus vertical gastric plication),[99] and in one case series children undergoing gastrostomy plus Nissen fundoplication showed improvements in reflux symptoms and weight gain but not episodes of pneumonia; 30 percent of participants had recurrent reflux post-surgery. In the RCT, the Nissen fundoplication group had a greater decrease in the total number of reflux episodes, percentage of pH, and longer reflux episodes, whereas the vertical gastric plication group showed only a change in the pH percentage.

Harms associated with tube feeding and reported in the comparative literature include surgical harms, infection, increased rates of reflux requiring further treatment, and potential overfeeding. The harms reported with gastrostomy are not significant. Overall, rates of peritonitis were low, ranging from 2 to 5 percent, but one study reported minor site infections at 59 percent and leakage at 30 percent. In the studies focused on fundoplication, major complications were experienced by 14.3 percent of the children in each arm of the RCT, and minor harms included aspiration, urinary tract infection and pneumonia. In the case series early complications (within one week of fundoplication) included pneumothorax, stoma ulcers, and cellulitis, all in patients undergoing laparoscopic fundoplication. Late complications (i.e., more than one week post-fundoplication) included bloating, diarrhea (dumping syndrome), and intestinal obstruction; these events were all reported in individuals undergoing open fundoplication.[100]

Prior, retrospective studies, have suggested that gastrostomy may be associated with higher than expected rates of mortality. In the surgical studies included in this review, reported death rates ranged from 7 to 29 percent, with varying follow up times. The investigators report that these rates are comparable with those in other studies of feeding tubes, but there are no data to suggest whether these are reduced relative to what would have occurred absent treatment. In one study that did not meet our inclusion criteria, 2 of 15 patients with cerebral palsy and no gastrostomy died, relative to 17 of 47 with gastrostomy. This was a retrospective review of cases, however, so any comparison would likely be confounded by indication, as only children with severe feeding and growth problems are typically treated surgically.[101] In another retrospective study that did not meet our inclusion criteria, survival rates after gastrostomy or jejunostomy were 83 percent after 2 years and 75 percent after 7 years.[102] It is unclear what these apparently high rates of mortality mean relative to expected mortality, and to families facing the reality of a severely undernourished or growth deficient child.

Three studies were specifically intended to analyze harms of tube feeding: one on the potential for tube feeding to induce reflux[96] and two on the potential to overfeed.[41,95] Two found positive associations with the harmful outcome(overfeeding or reflux).[95,96] The clinical importance of these and other harms, relative to the potential danger of not intervening is unclear and likely must be assessed in the context of each individual patient and family. Clearly, surgical interventions can lead to increased weight gain; the degree to which harms outweigh those benefits likely depends on the starting point of the individual, family stressors, and the degree to which harms can be mitigated using appropriate feed and other approaches – an area that warrants continued research.

The frequent report of GER that develops after gastrostomy may be balanced by the study investigators' observations that it is frequently managed medically. In terms of overfeeding, one

study on this subject demonstrates that tube fed children may be at risk for obesity without careful attention to the content and quantity of their food products; one study assessing the effects of a low energy feed, which increased weight without increasing fat mass, suggests that such formulas may have the potential to reduce the risk of overfeeding.[41]

No studies directly compared the use of g-tube with fundoplication with oral feeding for the treatment of reflux. One RCT compared two forms of plication (fundoplication versus vertical gastric plication),[99] and in one case series children undergoing gastrostomy plus Nissen fundoplication showed improvements in reflux symptoms and weight gain but not episodes of pneumonia; [100] 30 percent of participants had recurrent reflux post-surgery. In the RCT, the Nissen fundoplication group had a greater decrease in the total number of reflux episodes, percentage of pH, and longer reflux episodes, whereas the vertical gastric plication group showed only a change in the pH percentage. Major complications were experienced by 14.3 percent of the children in each arm of the RCT, and minor harms included aspiration, urinary tract infection and pneumonia. In the case series early complications (within one week of fundoplication) included pneumothorax, stoma ulcers, and cellulitis, all in patients undergoing laparoscopic fundoplication. Late complications (i.e., more than one week post-fundoplication) included bloating, diarrhea (dumping syndrome), and intestinal obstruction; these events were all reported in individuals undergoing open fundoplication.[100]

# Strength of the Evidence for Effectiveness of Therapies

## Overview

We used the included systematic review on behavioral interventions to assess strength of evidence, translating the assessment used in that review into levels used in the EPC program. Behavioral studies including in the prior review[34] were small, typically short-term, and typically conducted using pre-post designs subject to bias. The author of the systematic review used a modified Sackett approach (Table 5) to assess the strength of the body of evidence. We have translated those assessments into EPC program equivalents in Table 14.

Strength of evidence for behavioral interventions ranges from low to moderate. The moderate rating for the positive effects of oral appliances on sensorimotor outcomes is based on one good and one fair quality RCT and additional supporting studies of varying designs. Effects on eating efficiency and swallowing were not consistent, and the small sample sizes suggest imprecision. The low strength of evidence for beneficial effects of positioning, altering food consistency, and feeding devices on all outcomes is due to the lack of RCTs and generally small sample sizes. Studies typically reported some positive effects on mealtime length and eating efficiency; however, rigorously conducted studies are lacking. The strength of the evidence for the effects of oral sensorimotor interventions and oral appliance on feeding safety and efficiency is insufficient based on a paucity of rigorous studies.

Longer term studies are lacking across all interventions; thus, the durability of effects is not clear. Studies also did not consistently assess harms, though aspiration and swallowing difficulties, which may be related to the underlying condition as well as the intervention, are reported in some. Overall, more data on greater numbers of participants, including adults as well as children, are needed to understand the effectiveness of behavioral approaches.

**Table 14. Strength of the evidence for behavioral interventions assessed in Snider review[34]**

| Intervention | Outcome(s) | Level of Evidence (Sackett) | EPC Equivalent Strength of Evidence |
|---|---|---|---|
| Oral sensorimotor interventions | Increased feeding safety and efficiency | 4 (conflicting ) | **Insufficient** Inconsistent evidence and a paucity of comparative studies. Poor quality studies had positive results; whereas those with more rigor showed no effect, but may have been underpowered. |
| Positioning | Increased feeding safety and efficiency | 2b (limited) | **Low** No RCTs, but positive results consistently observed in other study designs. Studies were small, and therefore imprecise. |
| Altering food consistency | Increased feeding safety and efficiency | 2b (limited) | **Low** One experimental study that was of adequate size showed some positive effects on increasing feeding safety and efficiency. |
| Oral appliances | Enhanced oral sensorimotor skills | 1b (moderate) | **Moderate** One good RCT, one fair RCT and additional supporting studies of varying designs. Better quality studies showed positive effects, but effects were not entirely consistent; small sample sizes suggest imprecision and rigorous studies should be replicated. |
| Oral appliances | Increased feeding safety and efficiency, generalized postural control | 5 (no good evidence) | **Insufficient** Only studies of poor quality were available to assess feeding efficiency and generalized postural control. |
| Feeding devices | Increased feeding efficiency | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |
| Feeding devices | Enhanced oral-motor behaviors | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |
| Feeding devices | Increased independence | 2b (limited) | **Low** Consistently positive results in two non-RCTs of small sample sizes. |

EPC = Evidence-based Practice Center; RCT = randomized controlled trial

We also assessed strength of evidence for six primary outcomes associated with feeding tubes in comparison with oral feeding, and for feeding tubes with fundoplication to address reflux: changes in growth outcomes, respiratory outcomes including reflux, quality of life, long term morbidity and mortality, and harms. We found the evidence to be insufficient to low for all outcomes (Tables 15–16).

The low strength of evidence for the effects of gastrostomy on increasing growth measures, including weight, is based on a clearly significant effect measured in five case series and one prospective cohort study and in a small number of children. Additional data are needed on greater numbers of children to better quantify expected effects, particularly in subgroups by severity and age, and to better understand the implications of observed harms. Long term effects are unknown as data on mortality are short term only. Nonetheless, it is clear that, in children

with significant feeding difficulties, most of whom present significantly underweight, tube feeding leads to weight gain. Evidence is currently insufficient to assess whether and to what degree fundoplication is effective specifically to treat children with CP who present with significant reflux.

**Table 15. Outcome, strength of evidence domains, and strength of evidence for feeding tubes (KQ3a)**

| Outcome | Study Type (Number Reporting Outcome) | Domains Pertaining to Strength of Evidence (SOE) | | | | SOE (Direction of Effect) |
|---|---|---|---|---|---|---|
| | | Risk of Bias | Consistency | Directness | Precision | |
| **Growth measures (weight, height, skinfold)**[41,87-92,95] | Case series (7) Prospective cohort (1) | High | Consistent | Direct | NR | Low (Increase in growth measures) |
| **Respiratory outcomes**[41,94] | Case series (2) | High | NA | Direct | NR | Insufficient |
| **Parental quality of life**[93] | Case series (1) | High | NA | Direct | NR | Insufficient |
| **Child quality of life**[89] | Case series (1) | High | NA | Indirect | NR | Insufficient |
| **Long term morbidity and mortality** | None | | | | | Insufficient |
| **Harms**[41,88-90,93,95,96] | Case series (6) Prospective cohort (1) | High | Consistent | Direct | NR | Low (Increased potential for overfeeding and reflux) |

KQ = Key Question; NA = not applicable; NR = not reported

**Table 16. Outcome, strength of evidence domains, and strength of evidence for fundoplication (KQ3b)**

| Outcome | Study Type (Number Reporting Outcome) | Domains Pertaining to Strength of Evidence (SOE) | | | | SOE |
|---|---|---|---|---|---|---|
| | | Risk of Bias | Consistency | Directness | Precision | |
| **Growth measures (weight, height, skinfold)**[100] | Case series (1) | High | NA | Direct | NR | Insufficient |
| **Reflux outcomes**[99,100] | RCT[a] (1); Case series (1) | High | Inconsistent | Direct | NR | Insufficient |
| **Quality of life** | None | | | | | Insufficient |
| **Long term morbidity and mortality** | None | | | | | Insufficient |
| **Harms** [99,100] | RCT (1); Case series (1) | High | Consistent | Direct | NR | Insufficient |

KQ = Key Question; NA = not applicable; NR = not reported; RCT = randomized controlled trial
[a]This study compared Nissen fundoplication with vertical gastric plication.

# Findings in Relationship to What Is Already Known

The findings from this review for both surgical and nonsurgical interventions are consistent with both prior systematic reviews and relevant clinical practice reviews, as there is little robust evidence about the effectiveness of either behavioral or surgical interventions for children with feeding difficulties and CP. As a result, there are no definitive clinical guidelines for physicians

due to this uncertainty and it is difficult for parents to make an informed decision about the risks and benefits of these interventions, particularly surgical interventions. Findings from this review and all prior systematic reviews call for well-designed randomized controlled trials of both medical management and surgical interventions to assess for short and long term outcomes, including harms, for both children and adults.

Our findings support the conclusions of the prior systematic review on behavioral interventions, including oral sensorimotor, oral appliances, and positioning. Furthermore, due to the recentness and completeness of that review, our review identified only one additional study, a case series. The case series, at high risk of bias, addressed caregiver training.

Regarding surgical interventions (gastrostomy), our review found no randomized trials or high quality observational studies comparing gastrostomy with oral feeding for patients with CP and feeding difficulty. Only five case studies and one retrospective cohort study informed this question. Our findings are consistent with the prior 2004 Cochrane systematic review which also found no randomized clinical trials comparing g-tube with oral feeding for patients with CP and feeding difficulties, and another systematic review which included observational studies, found severe methodologic limitations to the studies, and therefore insufficient evidence regarding the effects of gastrostomy compared with oral feeding.

Harms associated with feeding interventions have not been thoroughly reviewed in prior systematic reviews, and observational studies continue to raise questions about the risks and benefits of surgical interventions for children with severe CP and feeding difficulties. This review continues to find limited data on harms.

# Applicability

## Applicability of Studies of Behavioral Interventions

Studies of behavioral interventions to date have been limited in scope and focus on a limited selection of outcomes of interest. Studies typically provided limited data on heath outcomes including hospitalizations, antibiotic use, patient and family satisfaction and quality of life, measures of family stress, pain/comfort. In addition to the recent systematic review from Snider and colleagues, we located one case series based in the home among child-caregivers pairs in Bangladesh and assess applicability in Table 17. The study focused on caregiver training related to diet, food consistency, appropriate utensils, and postural and physical support for positioning and feeding. Evidence from this study is likely primarily applicable to younger children who are able to eat at least some foods orally. The approach studied may not closely match interventions available in practice as it was conducted in the home setting, which is likely highly variable, and was not well-described. Thus, individuals wishing to infer the potential results of clinical practice based on the available research need to assess carefully the degree to which the study methods matched those available and used in practice. Ultimately, the effectiveness of behavioral interventions within and outside of this limited sample and setting is currently unknown.

**Table 17. Applicability of studies of behavioral interventions**

| Domain | Description of Applicability of Evidence |
|---|---|
| Population | Children (mean age 3 years, 11 months) with moderate to severe motor impairment; child-caregiver dyads. Children were able to eat orally. |
| Intervention | Interventions included caregiver training comprising education on diet, food consistency, appropriate utensils, and postural and physical support for positioning and feeding. Caregivers received 4–6 training sessions with final followup approximately 6 months after training. |
| Comparators | NA |
| Outcomes | Outcomes assessed included weight gain, triceps and subscapular skinfold measures, as well as chest health, overall mood, feeding skills and affect during feeding. Caregiver outcomes were self-reported stress and time spent feeding. Assessments occurred at baseline and at 6 months after intervention. |
| Setting | Setting was the home in Bangladesh. |

NA = not applicable

# Applicability of Studies of Surgical Interventions

All of the studies of surgical interventions focused, appropriately, on severely impaired individuals, generally GMFCS levels of IV or V (Table 18). Those studies that provided data to characterize the participants indicated that children in the studies had experienced substantial lack of growth, for up to 12 months prior to intervention. Participants were followed for 6 months to over a year. Studies assessed outcomes of interest to clinicians and caregivers of individuals with CP including changes in measures of growth, hospitalizations, and chest infections. The two studies of fundoplication for reflux similarly included children, but their level of functional impairment was not clearly described. Studies were not designed to assess subsets of individuals as defined by types of feeding disorders or specific surgical intervention.

**Table 18. Applicability of studies of surgical interventions**

| Study Type | Domain | Description of Applicability of Evidence |
|---|---|---|
| **Studies Including Individuals Without Significant Presurgical Reflux** | Population | Studies included children between the ages of roughly 5 months to 18 years with typically severe motor impairment (majority with GMFCS levels of IV or V) and oral-motor dysfunction; one study assessed caregiver stress (children of caregivers were median age 4 years with GMFCS level IV or V; caregivers were typically mothers [77%]). |
| | Intervention | Intervention included placement of a gastrostomy tube (gastrostomy, gastrojejunostomy, PEG, gastrostomy plus fundoplication). Participants were typically followed for 6 to 12 months post-surgery. |
| | Comparators | The comparator in one cohort study was oral feeding. |
| | Outcomes | Outcomes assessed included measures of growth (weight, height, leg length, skinfold thickness), fat mass/fat-free mass, micronutrient status, episodes of GER, chest infections, hospitalizations, QOL (child and caregiver), caregiver stress/satisfaction, feeding time, energy expenditure, harms, and mortality. |
| | Setting | Settings included specialist feeding clinics and children's hospitals in Canada, Brazil, the United Kingdom, Australia, and the United States. |
| **Studies Including Individuals With Presurgical Reflux** | Population | Children (age range: 3 months–13 years) with largely mixed or spastic CP and GERD. |
| | Intervention | One RCT and one case series assessed Nissen fundoplication (with gastrostomy in the majority of cases); procedures were both open and laparoscopic. |
| | Comparators | The RCT compared Nissen fundoplication with vertical gastric plication. |
| | Outcomes | Outcomes assessed included reflux episodes (#, duration, and pH), weight, length of stay, surgical duration, respiratory symptoms, harms, and mortality. |
| | Setting | Patients were recruited from hospitals in Brazil and China. |

CP = cerebral palsy; GER = gastroesophageal reflux; PEG = percutaneous endoscopic gastrostomy; RCT = randomized controlled trial

## Implications for Clinical and Policy Decisionmaking

The effectiveness of feeding and nutrition interventions for individuals with cerebral palsy remains largely unknown with strength of evidence not exceeding moderate for any intervention. Nonetheless, clinical decision makers can use this review to understand what interventions are available, what outcomes have been seen, and to some degree, to balance potential harms. When a child has a severe feeding disorder and is unable to consume adequate nutrition and is affected by frequent aspiration and pneumonias, the health outcomes can be dire. Understandably, treatment decisions must be made, even with inadequate evidence. Parents and providers contemplating gastrostomy can use the review to help understand potential effects on their quality of life and that of the child, potential harms that may occur, and potential tradeoffs related to social functioning. They should do so in light of the severity and other issues facing the individual child and family. Of note, nonclinical considerations may include family stress and pressures related to providing optimal care for the individual child. Stressors associated with caring for a severely disabled child and the potential impact of feeding interventions on the relationship with the child should not be underestimated and may play into decisionmaking along with the limited clinical evidence available. Ideally, this review will help policymakers and researchers understand what types of studies are essential to lead to more informed clinical decisionmaking.

## Limitations of the Comparative Review Process

This review was focused on identifying and assessing effectiveness literature. As such, we used stringent requirements for the presence of appropriate comparison groups for the behavioral and nutrition literature and for pre-post data for the surgical literature. Thus, we excluded some literature lacking pre-intervention data that may have provided some information, although it is unclear that these studies would have contributed to an assessment of effectiveness. In addition, we required that at least 80 percent of the population have cerebral palsy. It is possible that some literature on populations with feeding disorders for reasons other than cerebral palsy may have included data that would be relevant. However, it is not clinically straightforward to determine which individuals or groups with feeding disorders are similar enough in etiology and presentation that their data would be appropriate for our population of interest.

## Limitations of the Evidence Base

Behavioral studies are uniformly small, and usually underpowered to demonstrate clinical effectiveness. Outcomes tended to be short-term feeding skills (e.g., drooling, chewing), and followup was typically less than 6 months post-intervention. The presence of one good systematic review provides a comprehensive overview of the state of the literature. Across the board, rigorous, comparative (ideally RCTs) studies should be done of behavioral interventions. While RCTs are best for establishing causal inference, it is likely that they may not be optimal study designs for all questions that are important in this field of study. In particular, eliminating the confounding effect of potential mediators and moderators could result in not fully understanding the complexity in the natural history and appropriate treatment of feeding challenges. A range of study designs will be necessary to address the breadth of important questions currently unanswered.

The most significant challenge in this body of surgical literature is the lack of comparative data and, absent direct comparisons, lack of understanding of the natural history of feeding

disorders among children with CP that might be useful in weighing the risks associated with surgery against potential benefits. The field generally considers comparative studies to be unethical, in part because no nonsurgical approaches to care have been clearly shown to be effective to serve as comparison treatments. Children presenting for surgical intervention are generally (as shown in all studies) substantially underweight and demonstrate additional deficiencies in nutrition. To delay treatment is ethically challenging. Denying or delaying nutritional treatments including food thickeners or special formulas similarly poses ethical challenges. Larger, well characterized series may be the only reasonable solution to obtaining good outcomes data. It is possible that a registry could be useful to capture detailed data on patients in addition to consistent outcomes data. Adequately capturing patient characteristics, including type of CP and functional level, is imperative for increasing our understanding of the risks and benefits of therapeutic approaches.

Another fundamental problem with the current studies is that they are relatively small; it is not possible to assess effectiveness of treatment approaches in subsets of individuals characterized by severity, specific feeding challenges, presence of reflux and type of procedure. Additionally, multiple interventions may be frequently used in these populations, particularly those with severe CP. Certainly, additional or continued multicenter series are needed. The studies included in this review were fairly short term and constrained by the requirement that they provide data both before and after surgery. Thus, harms were typically limited to those that occurred within a year of surgery; followup in surgical studies ranged widely from roughly two months[96] to over 18 years in one study.[90] Retrospective studies not meeting the criteria for inclusion in this review have been used to suggest that tube feeding is associated with increased mortality. One of the studies included in this review[94] was intended to prospectively address this question; this work should be continued and extended. Additional prospective data with potential confounders clearly characterized is necessary to better understand whether the mortality rates observed in these studies are due to the surgery or the cerebral palsy and associated respiratory disease.

## Research Gaps and Areas for Future Research

The study of feeding and nutritional interventions for individuals with cerebral palsy is a nascent field, but certainly one that is growing. Rigorous, comparative studies of behavioral interventions need to be conducted; good RCTs are largely missing from the literature. Nonetheless, current research is available to provide potential directions for study. For example, studies of sensorimotor interventions currently provide conflicting evidence and more rigorous evidence is needed to answer the open question as to whether they can be effective at improving outcomes. Studies of positioning are also warranted. Studies should also compare each of the behavioral interventions with one another, with extensive characterization of the participants to better understand what works for which patients. Research should also investigate promising approaches used in other populations with similar impairments for potential applicability to individuals with CP. Similarly, research should address nutritional interventions such as food thickeners or vitamin supplementation.

Foundational research is needed to establish the most appropriate, patient-centered outcomes that are important to families of individuals with CP. Along these lines, qualitative and mixed methods approaches may be useful for understanding the experiences, preferences, needs, and strengths of families and caregivers. The degree to which improved changes are considered target outcomes by families is not well established. It is also not clear whether short-term

outcomes translate to longer term health outcomes. We note that there is a complete lack of studies designed or powered to identify modifiers of effectiveness of the behavioral interventions.

As noted above, the ethics of conducting comparative surgical studies or studies of nutritional interventions in the absence of appropriate comparison groups may preclude rigorous comparative designs. Case series can be conducted in ways that move them closer to providing effectiveness data; in addition, well developed registries may provide a source of data for observational study designs. Of particular importance is the need to conduct large enough studies to fully characterize both participants and interventions so that the question of whether treatment approaches are better for individuals who, for example aspirate or do not aspirate, can be answered. Patients with cerebral palsy are heterogeneous in many ways, including severity and comorbid conditions; rigorous subgroup analyses are needed to obtain data for targeting treatment. Furthermore, they and their families already experience substantial burden in terms of healthcare and other stressors. Recruitment and retention is likely to be a challenge, and may be a reason for the relatively poor evidence base to date.

In all types of interventions, data are absent on the role of feeding interventions for adults with CP. In addition the interventions included in this review, the importance of the nutritional make-up (energy composition) of the food products themselves are necessary. Prospective, comparative studies should be carefully conducted to determine what type of nutrition is appropriate for obtaining positive health outcomes without inducing excessive weight gain.

Considerable uncertainty remains concerning harms over both the short and long term. Harms associated with feeding interventions have not been thoroughly reviewed in prior systematic reviews, and observational studies continue to raise questions about the risks or benefits of surgical interventions for children with severe CP and feeding difficulties.

## Conclusions

Evidence for behavioral interventions for feeding disorders in cerebral palsy is insufficient to moderate. Some studies suggest that interventions such as oral appliances (moderate strength of evidence for effects on oral sensorimotor skills) may be beneficial, but there is a clear need for rigorous, comparative studies. Evidence for surgical interventions also is insufficient to low. All studies to date demonstrate significant weight gain with gastrostomy. Results for other growth measures are mixed, and substantial numbers of children remained underweight, although given a lack of appropriate reference standards for the CP population, these results should be interpreted cautiously. Considerable uncertainty remains concerning harms over both the short and long term. Harms with gastrostomy can be common, and include overfeeding, site infection, stomach ulcer, and reflux. Mortality rates range from 7 to 29 percent. Longer term, comprehensive case series are needed to understand potential harms in the context of benefits and potential risks of not treating.

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# Acronyms/Abbreviations/Symbols

| | |
|---|---|
| AHRQ | Agency for Healthcare Research and Quality |
| AMSTAR | Assessment of Multiple Systematic Reviews |
| CER | Comparative Effectiveness Review |
| CINAHL® | Cumulative Index of Nursing and Allied Health Literature |
| CP | Cerebral palsy |
| EHC | Effective Health Care |
| ERIC[sm] | Educational Resources Information Center |
| GER | Gastroesophageal reflux |
| GERD | Gastroesophageal reflux disease |
| GJ-Tube | Gastrojejunal tube |
| GMFCS | Gross Motor Function Classification System |
| G-Tube | Gastrostomy tube |
| HealthSTAR | Health Services Technology, Administration and Research |
| ISMAR | Innsbruck Sensorimotor Activator and Regulator |
| J-Tube | Jejunostomy tube |
| KI | Key informant |
| MEDLINE® | Medical Literature Analysis and Retrieval System |
| PEDro | Physiotherapy Evidence Database |
| PEG | Percutaneous endoscopic gastrostomy |
| QOL | Quality of life |
| RCT | Randomized controlled trial |
| SD | Standard deviation |
| SOE | Strength of evidence |
| SQCP | Spastic quadriplegic cerebral palsy |
| TEP | Technical Expert Panel |
| TOO | Task Order Officer |
| VAS | Visual Analog Scale |

# Glossary

| | |
|---|---|
| **Bolus feeding** | Method of delivering enteral feedings using a limited amount of nutritional product administered through a tube into the stomach over a span of 15–30 minutes several times per day; not usually recommended for persons with a jejunostomy tube as the intestine cannot hold the same volume that the stomach can.[1] |
| **Castillo-Morales Device** | Oral device including removable plates positioned on the upper jaw and including stimulatory elements to promote normal tongue and lip movements. |
| **Continuous feeding** | Method of delivering nourishment that involves the drip of formula by gravity or assisted by a pump in an ongoing manner over a specified number of hours into a gastrostomy, jejunostomy, or gastrojejunal tube.[1] |
| **Endoscopy** | Procedure in which an instrument containing a camera is inserted into the gastrointestinal tract to visualize organs. This procedure is one of the methods used in the percutaneous placement of gastrostomy, jejunostomy, or gastrojejunal tubes.[1] |
| **Enteral feeding tube** | Feeding device placed into the stomach or jejunum (middle section of the small intestine) through which formula, fluids, and/or medication are given to a person as an alternative to oral feeding.[1] |
| **Fundoplication/ Nissen Fundoplication** | Surgical procedure performed for the management of GERD. During the Nissen fundoplication, the upper part of the stomach is wrapped around the lower esophageal sphincter (the ring of muscle at the bottom of the esophagus that acts like a valve between the esophagus and stomach) to strengthen the sphincter and prevent acid reflux. The Nissen fundoplication may be performed using a laparoscope, an instrument that is inserted through tiny incisions in the abdomen, and uses small instruments to hold a camera to look at the abdomen and pelvis, which is less invasive and promotes faster recovery but requires more technical skill.[2,3] |
| **Gastroesophageal reflux (GER)** | Occurs when stomach contents reflux, or back up, into the esophagus (tube that connects the mouth to the stomach) during or after a meal. GER occurs when the lower esophageal sphincter opens spontaneously, for varying periods of time, or does not close properly and stomach contents rise up into the esophagus. GER is also called acid reflux or acid regurgitation, because digestive juices—called acids—rise up with the food. When refluxed stomach acid touches the lining of the esophagus it may cause a burning sensation in the chest or throat (heartburn or acid indigestion).[2] |

| | |
|---|---|
| **Gastroesophageal reflux disease (GERD)** | More serious form of gastroesophageal reflux (GER); when acid reflux occurs, food or fluid may rise into the back of the mouth and could then fall down into the lungs, causing respiratory symptoms. Some degree of GER is considered normal, but persistent reflux that occurs more than twice a week or causes symptoms is considered GERD, and it can eventually lead to more serious health problems.[2] |
| **Gastrojejunal (G/J-tube)** | Type of tube for nutritional support that is inserted into the jejunum (the middle section of the small intestine) through an established gastrostomy. It is also referred to as a G/J-tube or transgastric tube.[1] This uses a double lumened tube with 2 ports or openings. The G tube opening empties into the stomach and can be used for medication and the J-(jejunum) tube opening which empties into the small intestine can be used for feedings and water.[4] |
| **Gastrostomy** | Surgical procedure that creates an artificial opening in the stomach for the insertion of a feeding tube.[5] |
| **Gastrostomy tube (G-tube) insertion** | Placement of a feeding tube through the skin and the stomach wall, directly into the stomach (also called a G-tube). This tube helps with feeding and releases air from the stomach.[6] |
| **Innsbruck Sensorimotor Activator and Regulator (ISMAR)** | Oral appliance designed to provide stability for the jaw to develop lip closure and tongue mobility , improving eating and drinking skills.[7] |
| **Jejunostomy (J-tube)** | Surgically placing a feeding tube through the abdominal wall directly into a part of the small intestine called the jejunum. The feeding tube bypasses the stomach and delivers a special liquid food with nutrients directly into the jejunum.[2] |
| **Nasogastric tube (NG-tube)** | Tube is inserted through the nose or mouth, down the esophagus, and into the stomach.[6] Typically used for short term.[4] |
| **Percutaneous endoscopic gastrostomy (PEG) tube insertion** | Gastrostomy tubes can be placed under endoscopic guidance, using a much smaller incision (percutaneous endoscopic gastrostomy tube placement, or PEG). An endoscope is passed into the mouth, down the esophagus, and into the stomach. The surgeon can then see the stomach wall through which the PEG tube will pass. Under direct visualization with the endoscope, a PEG tube passes through the skin of the abdomen, through a very small incision, and into the stomach. A balloon is then blown up on the end of the tube, holding in place. PEG gastrostomy tubes avoid the need for general anesthesia and a large incision.[6] |
| **Percutaneous endoscopic jejunostomy** | A type of J-tube placement for nutritional support that occurs with the aid of endoscopy to visualize the jejunum so that a tube can be threaded through a small opening made in the abdominal wall into the jejunum. It is also known as a PEJ tube.[1] |

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# Appendix A. Search Strategies

*Last updated July 16, 2012*

**Table A-1. PubMed search strategies (pubmed.gov interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | "Neurologic Manifestations"[Mesh:NoExp] OR "Neuromuscular Manifestations"[mh] OR (neurologic*[tiab] AND (impairment*[tiab] OR impaired[tiab] OR problem*[tiab] OR deficit*[tiab])) | 91,378 |
| **#2** | ("Surgical Procedures, Operative"[MeSH] OR surgery[tiab] OR gastrostomy[tiab] OR "gastrostomy"[MeSH] OR "PEG tube"[tiab] OR "tube feeding"[tiab] OR "tube fed"[tiab] OR "tube-fed"[tiab] OR "G-tube"[tiab] OR "G tube"[tiab] OR "J-tube"[tiab] OR "J tube"[tiab] OR "gj tube"[tiab] OR "g-j tube"[tiab] OR "gastrostomy-jejunostomy tube"[tiab] OR "Jejunostomy"[Mesh] OR jejunostomy[tiab] OR gastrojejunostomy[tiab] OR "nasogastric tube"[tiab] OR "ng tube"[tiab] OR "nasogastric feeding"[tiab] OR "Enteral Nutrition"[mesh] OR "enteral feeding"[tiab] OR "enteral nutrition"[tiab] OR "Fundoplication"[mesh] OR fundoplication[tiab] OR antireflux[tiab] OR "Gastroesophageal Reflux/surgery"[Mesh] OR (reflux[tiab] AND (surgery[tiab] OR surgical[tiab])) | 2,500,978 |
| **#3** | ("Nutritional Support"[MeSH] OR "Nutritional Status"[MeSH] OR Eating[MeSH] OR "Deglutition disorders"[MeSH] OR feeding[tiab] OR nutrition[tiab] OR nutritional[tiab] OR eating[tiab] OR "Energy Intake"[mesh] OR "Feeding Behavior"[MH]) | 464,9000 |
| **#4** | #1 AND #2 AND #3 AND english[la] | 732 |
| **#5** | #3 AND editorial[pt] | 0 |
| **#6** | #3 AND letter[pt] | 4 |
| **#7** | #3 AND comment[pt] | 3 |
| **#8** | #3 AND case reports[pt] | 143 |
| **#9** | #3 AND review[pt] | 96 |
| **#10** | #3 AND news[pt] | 0 |
| **#11** | #3 AND guideline[pt] | 1 |
| **#12** | #3 AND practice guideline[pt] | 1 |
| **#13** | #3 AND historical article[pt] | 0 |
| **#14** | #3 AND jsubsetk | 0 |
| **#15** | #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 | 230 |
| **#16** | #4 NOT #15 | 502 |
| **#17** | #16 AND ("1980"[PDAT] : "3000"[PDAT]) [limits to 1980 to present] | 477 |
| | [10 new items since May 2012 search] | |

Key: [mh] medical subject heading; [sh] subheading; [tiab] keyword in title or abstract; [la] language; [pt] publication type; jsubsetk consumer health subset; [PDAT] publication date.

* numbers may not add up as some records are indexed in multiple publication types.

*Last updated July 16, 2012*

**Table A-2. PubMed search strategies (pubmed.gov interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | ("Cerebral Palsy/drug therapy"[MeSH] OR "Cerebral Palsy/surgery"[MeSH] OR "Cerebral Palsy/diet therapy"[MeSH] OR "Cerebral Palsy/therapy"[MeSH]) OR (("cerebral palsy"[MeSH] OR "cerebral palsy"[tiab]) AND ("Surgical Procedures, Operative"[MeSH] OR surgery[tiab] OR "Drug Therapy"[MeSH] OR "drug"[tiab] OR "pharmacotherapy"[tiab] OR gastrostomy[tiab] OR "gastrostomy"[MeSH] OR "PEG tube"[tiab] OR "tube feeding"[tiab] OR "tube fed"[tiab] OR "tube-fed"[tiab] OR "G-tube"[tiab] OR "G tube"[tiab] OR "J-tube"[tiab] OR "J tube"[tiab] OR "gj tube"[tiab] OR "g-j tube"[tiab] OR "gastrostomy-jejunostomy tube"[tiab] OR "Jejunostomy"[Mesh] OR jejunostomy[tiab] OR gastrojejunostomy[tiab] OR "nasogastric tube"[tiab] OR "ng tube"[tiab] OR "nasogastric feeding"[tiab] OR "Enteral Nutrition"[mesh] OR "enteral feeding"[tiab] OR "enteral nutrition"[tiab] OR "Orthodontic Appliances"[MeSH] OR "intraoral appliance"[tiab] OR "intraoral appliances"[tiab] OR "oral appliance"[tiab] OR "oral appliances"[tiab] OR sensorimotor[tiab] OR "Feedback, Sensory"[mesh] OR "Posture"[mesh] OR posture[tiab] OR positioning[tiab] OR position[tiab] OR "Patient Positioning"[mesh] OR "Food, Fortified"[mesh] OR "Food, Formulated"[mesh] OR "Food Additives"[mesh] OR ((food[tiab] OR "Food"[mesh]) AND (handling[tiab] OR thickness[tiab] OR thickener*[tiab] OR consistency[tiab] OR additive[tiab] OR texture*[tiab] OR composition[tiab] OR presentation[tiab] OR preparation[tiab])) OR "ThickenUp"[tiab] OR "Thick-It"[tiab] OR SimplyThick[tiab] OR "Thick and Easy"[tiab] OR "feeding device"[tiab] OR "feeding devices"[tiab] OR "Self-Help Devices"[mesh] OR "Occupational Therapy"[mesh] OR "occupational therapy"[tiab] OR "Behavior Therapy"[mesh] OR "behavior therapy"[mesh] OR "behavioral therapy"[tiab] OR "Fundoplication"[mesh] OR fundoplication[tiab] OR antireflux[tiab] OR "Gastroesophageal Reflux/surgery"[Mesh] OR (reflux[tiab] AND (surgery[tiab] OR surgical[tiab])) OR "Family Therapy"[mesh] OR "family therapy"[tiab] OR (("Parenting"[mesh] OR parent*[tiab] OR family[tiab] OR caregiver*[tiab] OR Caregivers[mesh]) AND (behavior*[tiab] OR therapy[tiab] OR intervention*[tiab])))) | 8,232 |
| **#2** | ("Nutritional Support"[MeSH] OR "Nutritional Status"[MeSH] OR Eating[MeSH] OR "Deglutition disorders"[MeSH] OR feeding[tiab] OR nutrition[tiab] OR nutritional[tiab] OR eating[tiab] OR "Energy Intake"[mesh] OR "Feeding Behavior"[MH]) | 464,900 |
| **#3** | #1 AND #2 AND english[la] | 363 |
| **#4** | #3 AND editorial[pt] | 2 |
| **#5** | #3 AND letter[pt] | 2 |
| **#6** | #3 AND comment[pt] | 7 |
| **#7** | #3 AND case reports[pt] | 56 |
| **#8** | #3 AND review[pt] | 49 |
| **#9** | #3 AND news[pt] | 1 |
| **#10** | #3 AND guideline[pt] | 1 |
| **#11** | #3 AND practice guideline[pt] | 0 |
| **#12** | #3 AND meta-analysis[pt] | 1 |
| **#13** | #3 AND historical article[pt] | 1 |
| **#14** | #3 AND jsubsetk | 0 |
| **#15** | #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 | 111 |
| **#16** | #3 NOT #15 | 252 |
| **#17** | #16 AND ("1980"[PDAT] : "3000"[PDAT]) [limits to 1980 to present] | 230 |
| | [8 new since March 2012 search] | |

Key: [mh] medical subject heading; [sh] subheading; [tiab] keyword in title or abstract; [la] language; [pt] publication type; jsubsetk consumer health subset; [PDAT] publication date.
* numbers may not add up as some records are indexed in multiple publication types.

*Last updated July 17, 2012*

**Table A-3. REHABDATA search strategies (http://www.naric.com/research/rehab/ interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | Exact Phrase: cerebral palsy + At Least One of: eating food feeding nutrition nutritional – limited to 1980-2012 | 47 |
| **#2** | Hand-limited to exclude items that are clearly books or from non-research periodicals, and hits from prior to 1980 | 25 |
| | [6 new items since March 2012 search] | |

Used the advanced search interface for REHABDATA;
http://www.naric.com/research/rehab/results.cfm?search=2&type=advanced&all=&exact=cerebral%20palsy&any=eating%20food%20feeding%20nutrition%20nutritional%20&omit=&fld1=Title&txt1=&op1=AND&fld2=Title&txt2=&op2=AND&fld3=Title&txt3=&op3=AND&fld4=Title&txt4=&dte1=1980&dte2=&available=0&online=0

*Last updated July 16, 2012*

**Table A-4. CINAHL search strategies (EBSCOhost interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | (MH “Cerebral Palsy/DT/SU/DH/TH OR ((MH “Cerebral Palsy” OR TX “Cerebral Palsy”) AND ((MH "Surgery, Operative+" OR TX “Surgery” OR MH “Drug Therapy+” OR TX “Drug” OR TX “Pharmacotherapy” OR TX “Gastrostomy” OR MH “Gastrostomy” OR MH “Gastrojejunostomy Tubes+” OR TX “PEG tube" OR TX “tube feeding” OR TX "tube fed" OR TX "tube-fed" OR TX “G-tube" OR TX “G tube" OR TX “J-tube" OR TX “J tube” OR TX "gj tube" OR TX "g-j tube" OR TX "gastrostomy-jejunostomy tube" OR MH “Jejunostomy” OR TX “jejunostomy” OR TX “gastrojejunostomy” OR TX "nasogastric tube" OR TX "ng tube" OR TX “nasogastric feeding”) OR (MH "Enteral Nutrition" OR TX "enteral feeding" OR TX “enteral nutrition”) OR (MH “Orthodontic Appliances” OR TX “intraoral appliance” OR TX “intraoral appliances” OR TX “oral appliance” OR TX “oral appliances”) OR (TX “sensorimotor” OR TX “Sensory feedback” OR MH “Feedback” OR MH “Posture+” OR TX “posture” OR TX “positioning” OR TX “position” OR MH “Patient Positioning+”) OR MH “Food Additives” OR MH “Food, Formulated” OR MH “Food, Fortified” OR ((TX “food” OR MH “Food+”) AND (TX “handling” OR TX “thickness” OR thickener* OR TX “consistency” OR TX “additive*” OR TX “texture*” OR TX “composition” OR TX “presentation” OR preparation*)) OR TX “ThickenUP” OR TX “Thick-IT” OR TX “SimplyThick” OR TX “Thick and Easy” OR TX “feeding device” OR TX “feeding devices” OR TX “Self-Help Devices” OR MH “Assistive Technology Devices+” OR MH “Occupational Therapy+” OR TX “occupational therapy” OR MH “Behavior Modification+” OR MH “Behavior Therapy+” OR TX “behavior therapy” OR TX “behavioral therapy” OR TX “Fundoplication” OR MH “Gastric Fundus/SU” OR TX “antireflux” OR MH “Gastroesophageal Reflux/SU” OR (TX “reflux” AND (TX “surgery” OR TX “surgical”)) OR MH “Family Therapy” OR TX “family therapy” OR ((MH “Parenting” OR parent* OR TX “family” OR MH "Caregivers" OR TX “caregiver*”) AND (TX “behavior*” OR TX “therapy” OR TX “intervention*”))))) | 2,549 |
| **#2** | (MH "Nutritional Support+" OR MH "Home Nutritional Support" OR MH "Nutritional Status" OR MH "Nutrition (Iowa NOC) (Non-Cinch)+" OR MH "Eating" OR MH "Deglutition disorders" OR TX "feeding" OR TX "nutrition" OR TX "nutritional" OR TX "eating" OR MH "Energy Intake" OR MH "Eating Behavior" OR TX "Feeding behavior") | 139,244 |
| **#3** | S1 AND S2 AND LA "English" | 208 |
| **#4** | S3 AND PT "editorial" | 0 |
| **#5** | S3 AND PT "letter" | 0 |
| **#6** | S3 AND PT "commentary" | 6 |
| **#7** | S3 AND PT "case study" | 20 |
| **#8** | S3 AND PT "review" | 18 |
| **#9** | S3 AND PT "practice guidelines" | 1 |
| **#10** | S3 AND PT "meta analysis" | 0 |
| **#11** | S3 AND PT "historical material" | 0 |
| **#12** | S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 | 45 |
| **#13** | S3 NOT S12<br>• Excluding MEDLINE | 163<br>71 |
| **#14** | Published Date from: 19800101-30001231; [limits 1980-present] | 71 |
| | [0 new items since March 2012 search] | |

Key: MH CINAHL Subject Headings; + Explode Search Term; TX All Text; LA Language; PT Publication Type
* numbers may not add up as some records are indexed in multiple publication types.

*Last updated July 17, 2012*

**Table A-5. ERIC search strategies (eric.ed.gov interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | (Keywords:cerebral and Keywords:palsy) | 1,244 |
| **#2** | (Keywords:eating OR Keywords:feeding OR Keywords:nutrition OR Keywords:food OR Keywords:nutritional) | 21,718 |
| **#3** | ((Keywords:cerebral and Keywords:palsy) and (Keywords:eating OR Keywords:feeding OR Keywords:nutrition OR Keywords:food OR Keywords:nutritional)) and (Publication Type:"Journal Articles"), Publication Date:1980-2012 | 21 |
| | [5 new items since March 2012 search] | |

Key: [mh] medical subject heading; [sh] subheading; [tiab] keyword in title or abstract; [la] language; [pt] publication type; jsubsetk consumer health subset; [dp] publication date.
* numbers may not add up as some records are indexed in multiple publication types.

*Last updated July 17, 2012*

**Table A-6. OTseeker search strategies (www.otseeker.com interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | "cerebral palsy" AND (eating OR feeding OR nutrition OR nutritional OR food) AND Year Published: 1980 - | 5 |
| | [0 new items since March 2012 search] | |

**Table A-7. PsycINFO search strategies (ProQuest CSA Illumina interface)**

| Search terms | | Search results |
|---|---|---|
| **#1** | ((KW="cerebral palsy") AND (KW="surgery" OR KW="drug therapy" OR KW="Drug" OR KW="Pharmacotherapy" OR KW="gastrostomy" OR KW="Gastrojejunostomy" OR KW="Gastrojejunostomy tube" OR KW="PEG Tube" OR KW="tube feeding" OR KW="tube fed" OR KW="G tube" OR KW="G-Tube" OR KW="J tube" OR KW="J-Tube" OR KW="GJ Tube" OR KW="G-J Tube" OR KW="Gastrostomy-jejunostomy tube" OR KW="Jejunostomy" OR KW="nasogastric tube" OR KW="ng tube" OR KW="nasogastric feeding" OR KW="orthodontic appliance*" OR KW="intraoral appliance*" OR KW="oral appliance*" OR KW="sensorimotor" OR KW="Sensory Feedback" OR KW="Feedback" OR KW="Posture" OR KW="Positioning" OR KW="Position*" OR (KW="Food" AND (KW="handling" OR KW="Thickness" OR KW="thickener*" OR KW="Consistency" OR KW="Additive*" OR KW="Texture*" OR KW="Composition*" OR KW="Presentation" OR KW="Preparation*")) OR KW="Food Additive" OR KW ="Food Additives" OR KW="Feeding device" OR KW="Feeding devices" OR KW="Self-help device*" OR KW="Assistive Technology Devices" OR KW="Assistive Technology" OR KW="Assistive Devices" OR KW="Occupational Therapy" OR KW="Behavioral Therapy" OR KW="Behavior Therapy" OR KW="Behavior Modification" OR KW="Behavior" OR KW="Fundoplication" OR KW="Gastric Fundus" OR KW="Antireflux" OR (KW="Reflux" AND (KW="Surgery OR KW="Surgical")) OR KW="Family Therapy" OR KW="Family counseling" OR KW="Psychotherapeutic Counseling" OR KW=”Parent Training” OR ((KW="Family OR KW="Parent*" OR KW=”Caregivers” OR KW=caregiver) AND (KW="Behavior" OR KW="Therapy" OR KW="Intervention*")))) | 1,159 |
| **#2** | KW="Nutrition" OR KW="Eating" OR KW="Feeding" OR KW="Intake" OR KW="Nutritional" OR KW="Eating Behavior" OR KW="Feeding Behavior" OR KW="food" OR KW="Food Intake" | 110,030 |
| **#3** | #1 AND #2 AND "English" | 80 |
| **#4** | #3 AND<br>• Limited to Journals | 70 |
| **#5** | #4 limited to 1980 to 2012 | 62 |

Key: KW Keyword

**Table A-8. Description of Databases**

| Database | Description |
|---|---|
| **PubMed** | The database comprises of citations and abstracts from the fields of biomedicine and health. It coverage includes life sciences, behavioral sciences, chemical sciences, and bioengineering from MEDLINE, life science journals, and online books with over 21 million citations. PubMed was developed by the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM). |
| **REHABDATA** | Database for disability and rehabilitation research. Content includes physical, mental, and psychiatric disabilities, independent living, vocational rehabilitation, special education, and assistive technology. Document categories include reports, studies, and papers funded by the National Institute on Disability and Rehabilitation Research, rehabilitation-related articles, and published books. The database indexes over 70,000 documents from 1956 to present. REHABDATA is produced by the National Rehabilitation Information Center. |
| **CINAHL (Cumulative Index to Nursing and Allied Health Literature** | The cumulative index to nursing and allied health literature (CINAHL) indexes literature from the fields of nursing and allied health. The database includes health care books, nursing dissertations, conference proceedings, standards of practice, and book chapters. CINAHL provides indexing for more than 3,000 journals from 1981 to present. |
| **ERIC (Education Resources Information Center)** | Database compiled of records including journal articles, books, research syntheses, conference papers, technical reports, policy papers, and other education-related materials with more than 1.4 million bibliographic records. ERIC is sponsored by the Institute of Education Sciences (IES) of the U.S. Department of Education. |
| **OTseeker (Occupational Therapy Systematic Evaluation of Evidence)** | Database contains abstracts of systematic reviews and randomized controlled trials relevant to occupational therapy with over 8,500 articles in its database. OTseeker was developed by a team of occupational therapists from the University of Queensland School of Health and Rehabilitation Sciences and the University of Sydney, Australia. |
| **PsycINFO** | Abstracting and indexing database with records from peer-reviewed journals, books, and dissertations in behavioral sciences and mental health. Professional coverage of related disciplines including psychology, medicine, law, social work, neuroscience, business, and nursing. PsycINFO holds more than 3 million records and 2,500 journals, with coverage from 1597-present (comprehensive coverage 1880-present), and is produced by the American Psychological Association (APA). |

# Appendix B. Data Extraction Forms

## Feeding and Nutrition Interventions in Cerebral Palsy
**Abstract Review Form**

First Author, Year: _____

Reference#: _____ Abstractor Initials: __ __ __

| Primary Inclusion/Exclusion Criteria | | | |
|---|---|---|---|
| 1. Original research or systematic review<br>(Exclude editorials, commentaries, letters to editor, etc.) | Yes | No | Cannot Determine |
| 2. Study includes relevant population<br>• Individuals with cerebral palsy (all ages and severity) | Yes | No | Cannot Determine |
| 3. Study includes an evaluation of the effectiveness of feeding or nutrition intervention(s) in individuals with CP<br>• Surgical (gastrostomy using j-tube or g-tube, fundoplication)<br>• Food thickeners, caloric supplementation with formulas, vitamin supplementation, altering food consistency<br>• Positioning, oral appliances, oral stimulation, sensorimotor facilitation, caregiver training, other behavioral interventions | Yes | No | Cannot Determine |
| 4. Study published in English | Yes | No | Cannot Determine |

**Retain for:**

_____**BACKGROUND/DISCUSSION**

_____**REVIEW OF REFERENCES**

_____**OTHER**_____

**COMMENTS:**

# Feeding and Nutrition Interventions in Cerebral Palsy

**Full Text Review Form**

First Author, Year: _____

Reference#: _____ Abstractor Initials: __ __ __

| **Primary Inclusion/Exclusion Criteria** | | |
|---|---|---|
| 5. Is the study original research or a systematic review?<br>(Exclude editorials, commentaries, letters to editor, etc.) | Yes | No |
| 6. Is the study published in English? | Yes | No |
| 7. Does the study assess the correct population?<br>• Individuals with cerebral palsy and feeding difficulties | Yes | No |
| 8. Is this a study of the effectiveness of at least one of the following?<br>• behavioral interventions, including positioning, oral appliances, oral stimulation, sensorimotor facilitation, and caregiver training, compared to other nonsurgical interventions or no intervention<br>• nutritional interventions (food thickeners, caloric supplementation with formulas, vitamin supplementation, and altering food consistency (e.g. pureeing)) compared to other nonsurgical interventions or no intervention<br>• tube feeding compared to oral feeding or to nutritional and behavioral interventions<br>• g-tube placement with fundoplication versus oral feeding for reducing reflux<br>• j-tube versus fundoplication for reducing reflux in the short term and achieving improvements in nutritional state, growth, health and health care, and quality of life | Yes | No |
| 9. Does the study provide data before and after the intervention? | Yes | No |
| 10. Does the study include harms of an intervention related to feeding/nutrition in CP? | Yes | No |

## Relevance Review Form for Previous Systematic Reviews

First Author, Year: _____ Reference ID #: _____ Reviewer Initials: ___ ___ ___

| **PICOTS** | Comments |
|---|---|
| Includes appropriate **population**? | |
| Addresses target **interventions**? | |
| Includes studies with **comparators** (treatment approach to no treatment, placebo, or comparative interventions/combinations of interventions)? | |
| Addresses target **outcomes** (including adverse effects/harms)? | |
| Addresses target **timing**? | |
| Includes studies in target **setting**? | |
| **Other** | |
| Study types specified? (circle applicable: RCT, controlled trials, observational studies (retrospective/prospective cohort studies, case-control, case series), individual case studies, other: _____) | |
| Includes studies with appropriate N of subjects? (specify N: _____) | |
| Includes studies in English only? | |
| When was the literature search conducted (specify timeframe:_____) | |
| **Recommendation:** | |

# Appendix C. Evidence Table

**Table C-1. Evidence table—Interventions for feeding and nutrition in cerebral palsy**

| Author, Year<br>Study Design | Subjects<br>Sample Size<br>Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| **RCT** | | | | |
| Durante et al., 2007 [1]<br><br>RCT | Spastic CP with GERD symptoms<br><br>**CP type:**<br>Tetraplegic: n=10<br>Diplegic: n=4<br><br>**N=**14<br><br>**Age:** 4 months-147 months | **Groups:**<br>• Nissen fundoplication (n=7)<br>• Vertical gastric plication (n=7)<br>• Clinical assessment preoperative and 30, 90 and 180 days postoperative<br>• Average length of follow-up=5.2 months | • Clinical criteria associated with GERD symptoms (vomiting, retching, etc.)<br>• Esophageal pH<br>• Intra- and post-operative complications<br>• Length of hospital stay<br>• Mortality | • Participants in both groups improved significantly on composite score of 15 parameters associated with GERD from pre- to post-surgery (p=0.001 in Nissen group and p=0.006 in gastric plication group); 42.8% Nissen and 57.1% gastric plication participants asymptomatic throughout postoperative period<br>• All post-operative pH measurements except number of reflux episodes lasting for > 5 minutes significantly different from baseline (p≤0.04) in Nissen group<br>• No significant difference for total number of reflux episodes, episodes lasting for >5 minutes and longer reflux episodes in gastric plication group<br>• No significant difference between groups in length of hospital stay<br>• 2 deaths (28.6%) reported (one in each group), unrelated to surgical procedure<br>• No intra-operative complications reported, 1 Nissen participant had valve migration<br>• Harms in gastric plication group (n):<br>UTI (1)<br>Pneumonia (2)<br>Paraesophageal hernia (1) |
| **Cohort Study** | | | | |
| Sullivan et al., 2006 [2]<br><br>Prospective cohort<br><br>**Note:** see related studies by Sullivan et al.[3-5] | Children with spastic quadriplegic CP seen at tertiary feeding clinic<br><br>**Gross Motor Function Classification System Level:**<br>II: n=1 (oral feeding | • Gastrostomy (n=22)<br>• Oral feeding (n=18) | • Energy balance<br>• Body composition | • No significant differences in weight, triceps skinfold z scores, total energy expenditure, resting metabolic rate, fat mass index, fat free mass index between groups after gastrostomy<br>• Gastrostomy group had less fat-free mass on average (3.74kg/m$^2$ [95% CI 2.19-5.28]) than reference population of children without disability<br>• Compared with reference population, both gastrostomy (2.42kg/m$^2$ [95% CI 1.43-2.69]) and orally fed (1.15kg/m$^2$ [-0.18 to 2.78]) children had higher body-fat |

| Author, Year Study Design | Subjects Sample Size Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | group)<br>IV: n=6 (2 in gastrostomy and 4 in oral feeding groups)<br>V: n=30 (19 in gastrostomy, 11 in oral feeding groups)<br>Values NR for 3 participants<br><br>**N=**40<br><br>**Age:** 1 year 4 months-18 years 11 months | | | content and lower fat-free content |
| **Case Series** | | | | |
| Adams et al., 2011 [6]<br><br>Prospective case series | Moderate-severe CP with feeding difficulties<br><br>**CP type:**<br>Spastic: 77%<br>Hypotonic: 14%<br>Athetoid: 4.5%<br>Mixed: 4.5%<br><br>**N=**37 child-caregiver pairs (22 completed)<br><br>**Age:** 1-11 years | • Caregiver training and support sessions; training included educational content and supervised feeding; 8 training groups | • Chest –related illnesses<br>• Nutritional status (weight for age, mid-upper-arm-circumference)<br>• Child affect during feeding (discomfort/ distress) reported in carer reports<br>• Caregiver stress determined by self-reporting questionnaire 20 questions (SRQ20) anxiety scale<br>• Time spent feeding | • Significant improvements in chest health (p=0.005) and nutritional status (p=0.02)<br>• Child affect during feeding marginally significant (p=0.059)<br>• Marked reduction in caregiver stress with regard to feeding (p<0.001) with a significant reduction in mealtime length (p<0.001) |
| Thomson et al., 2011 [7]<br><br>Prospective case series | CP with severe feeding difficulties requiring long-term nutritional support<br><br>**N=**10 (9 with CP, 1 with Down's | • PEG placement with GER monitored using combined pH/impedance procedure; impedance conducted 1-79 days before and 12-384 days after PEG placement | • Total number of GER events(non-acid and acid events)<br>• pH and reflux index<br>• Nutritional improvement | • Total GER episodes post-PEG=355 (pre-PEG=183)<br>• Total number of distal acid reflux events significantly increased post-PEG placement (pre-PEG total 27, post-PEG total 173, p = 0.028)<br>• Mean distal pH decreased by 1.1 units (p=0.05); average proximal pH was lower post-PEG (p=0.058)<br>• Distal reflux index also significantly increased post-PEG |

| Author, Year<br>Study Design | Subjects<br>Sample Size<br>Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | syndrome—all data reported in aggregate)<br><br>**Age:** median 4.9 years (range: 0.5-16.8 years) | | | (pre-PEG 0.25 (0-2), post-PEG 2.95 (0-40)), p=0.03<br>• Median weight gain of 2.53 kg (range 0.8-7.24 kg) post-PEG |
| Arrowsmith et al., 2010[8]<br><br>Prospective case series | Children with spastic quadriplegic CP, all GMFCS level V<br><br>**N=**21<br><br>**Age:** median 8 years 5 months (range: 6 years 9 months-11 years 10 months) | • Gastrostomy tube feeding for median 19.4 months (range: 7.7-29.9 months) | • Weight<br>• Height<br>• Body fat<br>• Total body protein and bone mineralization | • Improved nutritional status with a significant increase in body weight, percent body fat and height but no alteration in height standard deviation score, median (interquartile range):<br><br>Weight, kg:<br>Baseline: 15.4 (12.0 to 20.5)<br>Followup:23.3 (16.6 to 25.9), p<0.05<br><br>Weight SD:<br>Baseline:-4.8 (-6.7 to -3.1)<br>Followup: -3.0 (-5.2 to -1.7) p<0.05<br><br>Height, cm, n=14:<br>Baseline: 105.4 (99.3 to 121.5)<br>Followup:118.3 (114.2 to 127.9) , p<0.05<br><br>Height SD, n=14:<br>Baseline: -3.9 (-4.7 to -2.0)<br>Followup: -3.5 (-4.2 to -1.7), p=ns |

| Author, Year Study Design | Subjects Sample Size Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| Vernon-Roberts et al., 2010[9]<br><br>Prospective case series | Children with severe spastic quadriplegic CP and significant feeding difficulties<br><br>**N=**14 (6-month followup data on 8 participants)<br><br>**Age:** median=2 years (range: 10 months-11 years) | • Low-energy, micronutrient complete, high fiber enteral feed via gastrostomy tube (0.75kcal/ml of energy concentration); assessments performed before gastrostomy insertion and after 6 months | • Growth (weight, arm lengths, skinfold thickness)<br>• Body composition (fat mass, fat percentage, fat-free mass)<br>• Nutritional intake (Micronutrient status)<br>• Respiratory (number of chest infections requiring either antibiotics/hospitalization)<br>• Gastrointestinal symptoms (frequency of bowel movements) | • Significant increase (baseline vs. 6 month) in median weight (difference in medians=1.9 (95%CI: 0.9 to 3)), mid-upper arm circumference (difference in medians=1.5 (95%CI: 0.4 to 3.5)), and lower leg length (difference in medians= 1.6 (95%CI: 0.4 to 4)). Non-significant increase in upper arm-length, triceps & subscapular skinfold thickness<br>• Fat-mass index was significantly higher than reference values after 6 months (difference in medians =1.2 (95%CI: 0.2-3.2, p=0.043), though neither FMI nor fat free mass index were different from baseline; increase in weight not associated with a corresponding increase in body fat mass or body fat percentage<br>• Serum/plasma concentrations of micronutrients were within normal range before and after intervention<br>• 25% had no respiratory infections at anytime; number of chest infections requiring antibiotics decreased in 50% of participants after 6 months<br>• 75% (n=6) had no change in bowel frequency from baseline to 6 months; decreased use of laxatives after 6 months in 25% of subjects |
| Mahant et al., 2009 [10]<br><br>Prospective case series | Children with severe neurological impairment including CP and progressive neurological disorder (n=50)<br><br>**N=**50 (N with CP=42, 43 total participants completed study, all data reported in aggregate)<br><br>**Age:** median age at tube insertion=591 days | • Image guided gastrostomy or gastrojejunostomy tube feeding; participants followed for 12 months | • Quality of life (10cm double-anchored visual analogue scale [VAS] with 10 representing maximal QOL)<br>• Global health-related quality of life (HRQOL) questionnaire-based measure<br>• Nutrition (anthropometric data including weight, height, length and tricep skinfold thickness was assessed)<br>• Parental satisfaction regarding child's health<br>• Harms | • No significant change in QOL related scores over time; no significant difference in scores between any 2 time points<br>• Significant improvement in global health from baseline to 6 months (2.5 vs. 3.0, p<0.01) but not sustained at 12 months<br>• Weight for age improved significantly over time (p<0.01), but no significant change in height for age scores; 6/13 (46%) had an increase in triceps percentile scores > 5$^{th}$ centile for age<br>• 29/31 (97%) maintained their triceps skinfold thickness >5$^{th}$ percentile for age<br>• At 12 months, 36/43 (84%) of parents felt that the tube insertions improved child's health with regards to feeding and administration of medications<br>• 98% of parents pre-surgery felt that gastrostomy would improve QOL<br>• Harms (n):<br>Peritonitis (1) |

| Author, Year<br>Study Design | Subjects<br>Sample Size<br>Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | | | | Deaths (3, not due to procedure) |
| Cheung et al., 2006 [11]<br><br>Prospective case series | Children with severe neurological impairment and CP and gastroesophageal reflux who were institutionalized in a regional medical center<br><br>**N=**20<br><br>**Age:** mean age at surgery=8.5±3.5 years | • Nissen fundoplication: open procedure (n=9), laparoscopic (n=11)<br>• Children monitored for 1.3 to 5.7 years after surgery | • Incidence of vomiting, GI bleeding, and pneumonia<br>• Surgical complications<br>• Mortality | • Incidence of vomiting and GI bleeding significantly decreased following surgery (P<0.001 and P=0.001, respectively)<br>• No difference between the preoperative and postoperative incidence of pneumonia (P=0.973)<br>• Median reflux index was reduced from 5.7% to 0.15% (p=0.009) after surgery but 6 patients overall had recurrent gastroesophageal reflux<br>• Mean body weight =17.4 kg (SD, 4.7 kg) at baseline and 22.8 kg (SD, 4.4 kg) at the end of follow-up (p<0.05)<br>• Harms (n):<br>Mild dumping syndrome (1, open procedure)<br>Episode of intestinal obstruction (1, open procedure)<br>Stoma ulcers (6, laparoscopic procedure)<br>Deaths (4 deaths, 1.9 to 5.0 years following surgery due to respiratory disease, mortality rate: 20%) |
| Sullivan et al., 2004 [3-5]<br><br>Prospective case series<br><br>**Note:** see related study by Sullivan et al.[2] | Children with spastic CP<br><br>**CP type:**<br>Quadriplegic: n=43<br>Hemiplegic: n=3<br>Ataxic: n=1<br>Mixed: n=6<br>Extrapyramidal: n=1<br>Undiagnosed neurological impairment: n=3<br><br>**N=**57 (46 at 12 month followup)<br><br>**Age:** 5 months to 17 years (range)<br>Median age of caregiver:<br>Mother: 30 years, father: 34 years. | • Gastrostomy (53 PEG, 2 laparoscopic, 2 open procedures); children followed up 6 and 12 months after tube insertion | • Quality of life of caregivers (Short Form-36 Version II generic indicator of health status questionnaire)<br>• Feeding time for caregivers<br>• Ease of drug administration<br>• Concern over child's nutritional status survey of carers<br>• Growth/anthropometry<br>• Nutritional intake<br>• General health<br>• Respiratory morbidity (chest infections, antibiotics, hospitalization)<br>• Gastroesophageal | **QOL:**<br>• Mean improvement in scores in all domains of the SF-36 II except pain from baseline to 12 month followup<br>• Significant improvements at 12 months related to social functioning (mean change 13.51, 95%CI 1.55 to 25.48; p=0.028), mental health (9.88, 95%CI 2.03 to 17.72; p=0.015), energy/ vitality (9.94, 95%CI 2.29 to 17.58; p=0.012), general health perception (6.35, 95%CI 0.15 to 12.56; p=0.045), and MCS (7.06, 95%CI 0.90 to 13.22; p=0.026)<br>• QOL of the carers not significantly different from that of the general population at 12 months<br>• Significant reduction in feeding time spent by caregivers (p<0.0001, median time at baseline=2.5 hours and 1 hour at 12 month followup)<br>• 90% reported ease of drug administration at 12 months vs. 5% at baseline<br>• Caregiver concern about child's nutritional status reduced from 78% to 25% (p<0.0001) after gastrostomy<br>**Growth:**<br>• Significant increase in weight from baseline (p<0.0001); |

| Author, Year Study Design | Subjects Sample Size Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | Main care giver was mother (90%) | | reflux<br>• Harms<br>• Mortality | median weight z score increased from –3 before gastrostomy placement to -1.6 at 12 months<br>• Lower leg length z score increased in 75% when compared to general population<br>• Significant increase in mid-upper-arm circumference (p<0.0001), triceps and subscapular skinfold thicknesses over 12 months<br>**General Health:**<br>• Infection requiring hospitalization reduced from 26% (11/43) at baseline to 7% (3/43) at 12 months (p=0.021); infection requiring antibiotics remained constant at 40%<br>• Mean number of chest infections requiring antibiotics at baseline=1.8, at 12 months=0.9 (p=0.07)<br>• Hospital admissions for chest infections fell significantly from 0.5 to 0.09 (p=0.04)<br>• Harms: complications reported by 2-59% of parents after 12 months ranged from peritonitis to minor site infection; 1 report of gastric leakage with peritonitis and ulceration<br>• Mortality: 4/57 died during the study |
| Brant et al., 1999 [12]<br><br>Prospective case series | Children with tetraparetic CP<br><br>**N**=16 /20 had CP<br><br>**Age:** 8 months-15 years | • Enteral feeding with age-specfic nutritional formula via PEG; monthly followup (mean duration follow-up=5.9 months) | • Weight<br>• Height<br>• Skinfold thickness (examination of triceps) | • 19 patients were under the 25th percentile for weight; 17 were under the 25th percentile for height. All had statistically significant increase in weight (p < 0.01), height (p < 0.01), mid-arm area, weight/age ratio (p< 0.01), and weight/height ratio (p < 0.01)<br>• Benefits differed by age:<br><2years: Significant improvement in weight (p=0.02), weight/height ratio did not reach statistical significance<br>2-4 years: Increase in weight and mid-arm muscle area (p=0.04) but not in height. No improvement with triceps skinfold<br>5-7 years: Change in Triceps skinfold reached statistical significance after PEG (p=0.01). weight though improved , it was not significant<br>8-11 years: Improvement in weight, but not height Weight/height ratio was significant (p=0.02)<br>12-18 years: Weight (p<0.01) & mid-arm area (p=0.02) improved but not height or weight/height ratio<br>• **Harms (n):** |

| Author, Year<br>Study Design | Subjects<br>Sample Size<br>Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | | | | Formation of granulation tissue at the stoma (7)<br>Stomal infection (4)<br>GER pneumonia (3)<br>Pneumoperitoneum (1) |
| Rempel et al., 1988[13]<br><br>Retrospective case series | Children with severe CP, largely spastic quadriparesis<br><br>**N=**57<br><br>**Age**: 9 months to 23.3 years (mean=10.7 years) | Gastrostomy | • GER symptoms<br>• Growth (plotted by height & weight measurements, by age, by Nissen procedures on National Center for Health Statistics growth charts)<br>• Caregiver satisfaction<br>• Harms<br>• Mortality | • 72% had GER symptoms and/or aspiration at baseline; GER confirmed in 77% of symptomatic children, aspiration was confirmed in 37%<br>• Among 35 participants with baseline and followup data, >90% were <5$^{th}$ percentile for height & weight at baseline. 80% were underweight for height; following gastrostomy, 33% were still underweight for height and 21% became overweight for height. Majority remained at < 5$^{th}$ percentile for height by weight<br>• Overall, 8 children (23%) showed improvement in height curve, 24(69%) in their weight curve and 25 (71%) in weight for height<br>• Growth by Age: 50% achieved appropriate weight for height among those with gastrostomies established before 2 years of age ; 55% attained appropriate weight for height among those with gastrostomies for > 2 years<br>• Growth by Nissen procedure: 50% achieved appropriate weight for height among those with fundoplications<br>• Care givers expressed satisfaction with treatment (no data reported)<br>• Harms (n):<br>GI bleeding & ulceration (5)<br>Peritonitis & bowel obstruction (3)<br>Tube migration (2)<br>Wound dehiscence (1)<br>Deaths (8, 5 within 1 year of tube placement) |
| Shapiro et al., 1986 [14]<br><br>Retrospective case series | Children with CP and severe neurological handicaps<br><br>**N=**19 | • Gastrostomy following aspiration or severe reflux or repeated dehydration or malnutrition; minimum 6 months postoperative followup | • GERD symptoms<br>• Growth measures | • Persistent vomiting at follow-up (n=5); feed independently after gastrostomy (n=1)<br>• Overall growth improved in most cases; 11/19 children attained the target weight/length ratio<br>• Mean Weight/ length z score at baseline= -2.71, at followup= -1.18<br>• On average, children moved 1.5 standard deviations |

| Author, Year<br>Study Design | Subjects<br>Sample Size<br>Age Range | Intervention and Methodology | Outcome Measures/Variables | Main Findings/Analysis |
|---|---|---|---|---|
| | **Age:** 5-168 months (mean: 60.4 months) | | | closer to the 50th percentile for age<br>• 6/19 increased weight/length ratio; 3 participants were at >10th percentile at baseline and 11 at followup ($p<0.01$), 7 were at >25th percentile at followup<br>• 3 participants showed declines in weight/length ratio<br>• Gender not related to length outcomes; 3 of the youngest and 3 oldest participants showed linear growth deceleration |

CI=confidence interval; CP=cerebral palsy; GER=gastroesophageal reflux; GERD=gastroesophageal reflux disease; GMFCS=Gross Motor Function Classification System; HRQOL=health-related quality of life; N=number; NR=not reported; PEG=percutaneous endoscopic gastrostomy; QOL=quality of life; RCT=randomized controlled trial; SD=standard deviation; UTI=urinary tract infection

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# Appendix D. Tools Used To Assess the Quality of the Literature

## Newcastle-Ottawa Quality Assessment Form for Cohort Studies

Note: A study can be given a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

**REFID:**_____ **Reviewer:**_____

**Selection**

1) Representativeness of the exposed cohort

   a) Truly representative ***(one star)***
   b) Somewhat representative ***(one star)***
   c) Selected group
   d) No description of the derivation of the cohort

2) Selection of the non-exposed cohort

   a) Drawn from the same community as the exposed cohort ***(one star)***
   b) Drawn from a different source
   c) No description of the derivation of the non exposed cohort

3) Ascertainment of exposure

   a) Secure record (e.g., surgical record) ***(one star)***
   b) Structured interview ***(one star)***
   c) Written self report
   d) No description
   e) Other

4) Demonstration that outcome of interest was not present at start of study

   a) Yes ***(one star)***
   b) No

**Comparability**

1) Comparability of cohorts on the basis of the design or analysis controlled for confounders

   a) The study controls for age ***(one star)***
   b) Study controls for other factors (list) _____***(one star)***
   c) Cohorts are not comparable on the basis of the design or analysis controlled for confounders

**Outcome**

1) Assessment of outcome

   a) Independent blind assessment ***(one star)***
   b) Record linkage ***(one star)***
   c) Self report
   d) No description
   e) Other

2) Was follow-up long enough for outcomes to occur

   a) Yes ***(one star)***
   b) No

Indicate the median duration of follow-up and a brief rationale for the assessment above:_____

3) Adequacy of follow-up of cohorts

a) Complete follow up- all subject accounted for ***(one star)***
b) Subjects lost to follow up unlikely to introduce bias- number lost less than or equal to 20% or description of those lost suggested no different from those followed. ***(one star)***
c) Follow up rate greater than 80% and no description of those lost
d) No statement

## Minimum Criteria to Assess Risk of Bias in Case Series[a]

| Risk of Bias | Criterion | YES | NO | NA | NR | COMMENTS |
|---|---|---|---|---|---|---|
| Selection bias and confounding | 1. Were the important confounding and modifying variables taken into account in the design and analysis? | | | | | |
| Performance bias | 2. Was any impact from a concurrent intervention or an unintended exposure that might bias results ruled out by the researchers? | | | | | |
| | 3. Did variation from the study protocol compromise the conclusions of the study? | | | | | |
| Attrition bias | 4. Was there a high rate of differential or overall attrition? | | | | | |
| | 5. Did attrition result in a difference in group characteristics between baseline and follow-up? | | | | | |
| Detection bias | 6. Were the outcome assessors blinded to the intervention or exposure status of participants? | | | | | |
| | 7a. Are the inclusion/exclusion criteria measured using valid and reliable measures? | | | | | |
| | 7b. Were the measures implemented consistently across all study participants? | | | | | |
| | 8a. Are interventions/exposures assessed using valid and reliable measures? | | | | | |
| | 8b. Were the interventions implemented consistently across all study participants? | | | | | |
| | 9a. Are primary outcomes assessed using valid and reliable measures? List outcome.<br><br>Outcome 1:_____ | | | | | |
| | Outcome 2:<br>_____ | | | | | |
| | Outcome 3:<br>_____ | | | | | |
| | Outcome 4:_____ | | | | | |
| | Outcome 5:_____ | | | | | |
| | Outcome 6:<br>_____ | | | | | |

| Risk of Bias | Criterion | YES | NO | NA | NR | COMMENTS |
|---|---|---|---|---|---|---|
| | 9b. Was outcome assessment implemented consistently across all study participants? | | | | | |
| | 10a. Are confounding variables assessed using valid and reliable measures? | | | | | |
| | 10b. Was assessment of confounding variables implemented consistently across all study participants? | | | | | |
| | 11. Did the study account for secular trends and regression to the mean? | | | | | |
| Reporting bias | 12a. Are the potential outcomes pre-specified by the researchers? | | | | | |
| | 12b. Are harms pre-specified by the researchers? | | | | | |
| | 13. Are all pre-specified outcomes reported? | | | | | |

[a] Adapted from Viswanathan M, Ansari MT, Berkman ND, Chang S, Hartling L, McPheeters ML, Santaguida PL, Shamliyan T, Singh K, Tsertsvadze A, Treadwell JR. Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions. Effective Health Care Program Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Agency for Healthcare Research and Quality Methods Guide for Comparative Effectiveness Reviews. March 2012. AHRQ Publication No. 12-EHC047-EF. www.effectivehealthcare.ahrq.gov/

# Cochrane Collaboration modified tool for assessing risk of bias for RCTs, PART I

*Use this form to assess risk of bias for randomized controlled trials*.

Bias is assessed as a judgment (high, low, or unclear) for individual elements from five domains of bias (selection, performance, attrition, reporting, and other).

Risk of selection, reporting, and other bias are assessed in the **Quality Assessment Form Part I.** Risk of performance, detection, and attrition bias are assessed using the **Quality Assessment Form Part II.**

Using the guidance provided at the end of this form, select either "high", "low" or "unclear" for each judgment. When complete, proceed to **Part II of the Quality Assessment Form**

**REF ID:**

| ***Domain*** | ***Description*** | ***High risk of bias*** | ***Low risk of bias*** | ***Unclear risk of bias*** | ***Reviewer Assessment*** |
|---|---|---|---|---|---|
| *Selection bias*<br><br>***Random sequence generation*** | Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.<br><br>**Reviewer Comments:** | Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence. | Random sequence generation method should produce comparable groups | Not described in sufficient detail | **Judgment: Random sequence generation**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |
| *Selection bias*<br><br>***Allocation concealment*** | Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment.<br><br>**Reviewer Comments:** | Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment. | Intervention allocations likely could not have been foreseen in advance of, or during, enrollment | Not described in sufficient detail | **Judgment: Allocation concealment**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |
| ***Domain*** | ***Description*** | ***High risk of bias*** | ***Low risk of bias*** | ***Unclear risk of bias*** | ***Reviewer Assessment*** |
| *Reporting Bias* | State how the possibility of selective | Reporting bias due to | Selective outcome | Insufficient information to | **Judgment: Selective** |

| | | | | | |
|---|---|---|---|---|---|
| ***Selective reporting*** | outcome reporting was examined by the authors and what was found.<br><br>**Reviewer Comments:** | selective outcome reporting. | reporting bias not detected | permit judgment of 'Low risk' or 'High risk'.<br><br>(*It is likely that the majority of studies will fall into this category.)* | **reporting**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |
| *Other bias*<br><br>***Other sources of bias*** | Any important concerns about bias not addressed above. If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry.<br><br>**Reviewer Comments:** | Bias due to problems not covered elsewhere in the table. | No other bias detected | There may be a risk of bias, but there is either:<br>Insufficient information to assess whether an important risk of bias exists; or<br>Insufficient rationale or evidence that an identified problem will introduce bias. | **Judgment: Other sources of bias**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |

## Cochrane Collaboration modified tool for assessing risk of bias for RCTs, PART II

*Use this form to assess risk of bias for randomized controlled trials.*

Bias is assessed as a judgment (high, low, or unclear) for individual elements from five domains of bias (selection, performance, attrition, reporting, and other).

Risk of selection, reporting, and other bias are assessed in the **Quality Assessment Form Part I.** Risk of performance, detection, and attrition bias are assessed using the **Quality Assessment Form Part II.**

Using the guidance provided at the end of this form, select either "high", "low" or "unclear" for each judgment.

Risk of bias for the domains in the Form Part II will be assessed for each main or class of outcomes. Please indicate the specific outcome and complete the assessment for each.

**REF ID:**

**Outcome(s):**

| *Domain* | *Description* | *High risk of bias* | *Low risk of bias* | *Unclear risk of bias* | *Reviewer Assessment* |
|---|---|---|---|---|---|
| *Performance bias*<br><br>***Blinding (participants and personnel)*** | Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.<br><br>**Reviewer Comments:** | Performance bias due to knowledge of the allocated interventions by participants and personnel during the study. | Blinding was likely effective. | Not described in sufficient detail | **Judgment: Blinding (participants and personnel)**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |
| *Detection bias*<br><br>***Blinding (outcome assessment)*** | Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.<br><br>**Reviewer Comments:** | Detection bias due to knowledge of the allocated interventions by outcome assessors. | Blinding was likely effective. | Not described in sufficient detail | **Judgment: Blinding (outcome assessment)**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |

| *Domain* | *Description* | *High risk of bias* | *Low risk of bias* | *Unclear risk of bias* | *Reviewer Assessment* |
|---|---|---|---|---|---|
| *Attrition bias*<br><br>***Incomplete outcome data*** | Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported.<br><br>**Reviewer Comments:** | Attrition bias due to amount, nature or handling of incomplete outcome data. | Handling of incomplete outcome data was complete and unlikely to have produced bias | Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided) | **Judgment: Incomplete outcome data**<br><br>□ **High**<br>□ **Low**<br>□ **Unclear** |

## Quality Assessment Form for Systematic Reviews (AMSTAR)

| | |
|---|---|
| 1. Was *a priori* design provided? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 2. Was there duplicate study selection and data extraction? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 3. Was a comprehensive literature search performed? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 5. Was a list of studies (included and excluded) provided? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 6. Were the characteristics of the included studies provided? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 7. Was the scientific quality of the included studies assessed and documented? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 9. Were the methods used to combine the findings of studies appropriate? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 10. Was the likelihood of publication bias assessed? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |
| 11. Was the conflict of interest included? | □ Yes □ No<br>□ Can't answer<br>□ Not applicable |

# Appendix E. Quality of the Literature

**Table E-1. Quality assessment of randomized controlled trials**

| Author, Year | Sequence Generation | Allocation Concealment | Selective Reporting | Other Bias | Blinding of Participants/ Personnel | Blinding of Outcome Assessment | Incomplete Outcome Data | Quality Rating |
|---|---|---|---|---|---|---|---|---|
| Durante 2007[1] | Low | Low | Low | Unclear | High | Unclear | Low | Fair |

Low=low risk of bias; High=high risk of bias

**Table E-2. Quality assessment of cohort studies**

| Domain | Selection | | | | Comparability | Outcome | | | Quality Rating |
|---|---|---|---|---|---|---|---|---|---|
| Author, Year | Representativeness of exposed cohort | Selection of non-exposed cohort | Ascertainment of exposure | Outcome of interest not present at start of study | Comparability of cohorts | Assessment of outcome | Duration of follow-up | Adequacy of follow-up of cohorts | |
| Sullivan 2006[2] | - | + | + | + | + | + | + | - | Fair |

**Table E-3. Quality assessment of systematic reviews**

| Domain | A priori design | Duplicate study selection/ extraction | Comprehensive literature search | Status of publication as exclusion criterion | Included and excluded studies provided | Characteristics of included studies provided | Quality assessed | Quality used appropriately | Synthesis methods appropriate | Publication bias assessed | Conflict of interest stated | Rating |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Author, Year** | | | | | | | | | | | | |
| Snider, 2011[3] | + | NR | + | - | + | + | + | + | + | - | + | Good |

NA=not applicable; NR=not reported/can't answer +=yes, -=no,

**Table E-4. Quality assessment of case series**

| Domain | Selection bias & confounding | Performance bias | | Attrition bias | | Detection bias | | | | | | | | | | Reporting bias | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Author, Year** | Confounding and modifying variables considered | Impact of concurrent interventions ruled out | Variation compromised conclusions | High rate of attrition | Attrition resulted in group differences | Outcome assessors blinded | Inclusion/exclusion assessed with valid & reliable measures | Measures consistent across all study participants | Interventions measured with valid & reliable measures | Interventions consistent across all study participants | Outcomes assessed with valid & reliable measures | Outcome assessment consistent across all study participants | Confounders assessed with valid & reliable measures | Confounding variables consistent across all study participants | Accounted for secular trends & regression to mean | Outcomes pre-specified | Harms pre-specified | Pre-specified outcomes reported |
| Adams, 2011[4] | Yes | No | No | Yes | NR | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| Thomson, 2011[5] | No | Yes | No | No | NA | No | No | Yes | Yes | Yes | Yes | Yes | No | No | No | Yes | No | Yes |
| Arrowsmith, 2010[6] | No | No | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | NA | NA | No | Yes | No | Yes |
| Vernon-Roberts 2010[7] | No | Yes | Yes | No | Yes | No | No | Yes | Yes | Yes | Yes | Yes | No | No | No | Yes | No | Yes |
| Mahant 2009[8] | Yes | No | No | Yes | NR | No | No | Yes | Yes | No | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| Cheung, 2006[9] | No | No | No | No | NA | No | Yes | Yes | Yes | Yes | Yes | Yes | No | No | No | Yes | Yes | Yes |
| Sullivan, 2004[10-12] | Yes | No | No | Yes | NR | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| Brant, 1999[13] | Yes | No | Yes | No | NA | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| Rempel, 1988[14] | Yes | No | NR | Yes | NR | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| Shapiro, 1986[15] | Yes | No | No | No | NA | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | No | Yes |

NA=not applicable, NR=not rated

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# Appendix F. Excluded Studies

**Reasons for exclusion**

X-1 Not original research
X-2 Not published in English
X-3 Population does not include at least 80% individuals with CP
X-4 Does not address interventions of interest
X-5 Does not include effectiveness data
X-9 Study not obtainable
X-10 Systematic review not relevant to current CER or not of good quality
X-11 Conference abstract or other ineligible publication

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