Help doctors search the medical literature: outcomes

Annotation Instructions

We are interested in finding all phrases that describe **outcomes** in a clinical trial.

Outcomes describe what is measured in people taking part in a trial, to find out if their treatment has worked. In clinical trials, the researchers compare outcomes for two or more groups of patients, each of whom receive a different treatment.

Outcomes can be physical measurements of patients (*blood pressure, weight*), the score on a medical test or questionnaire (*Autism Diagnostic Observation Schedule assessment, Quality of Life Scales*), or positive or negative events in the patient groups (*quit smoking, improved social communication; deaths, stroke, number of caries, number of hospital readmissions*). Often there are multiple outcomes; you should mark the description of all of them.

Outcomes may be described in general terms (*quality of life*), or sometimes by naming the specific score or measurement tool which was used (*the Quality of Life Scale*). Some outcomes are only described generally. For example, a medical treatment may be described simply as *preventive*, without a description of how the researchers verified that claim. Similarly, a treatment may be described as *improving quality of life*, without specific details of how this was measured. Mark such general description, as well as any information that describe the specifics of what was measured.

Mark the description of what outcomes were measured. Do NOT annotate the text reporting numbers or results, or their interpretation. For instance, if the outcome is *quit smoking* this should be highlighted, but the number of people who quit smoking at the end of the trial in different groups should not be. Similarly abstracts often report if certain treatment improved, reduced or was beneficial for some outcome of interest. We do not want to mark these evaluations, only the description of what was measured and how it was measured.

Occasionally abstracts will report adverse reactions. Mark these as outcomes.

Text in titles **should** be marked if it contains description of an outcome, as in *Garlic lowers blood pressure*.

Some medical papers have structured abstracts that have an explicitly marked section called OUTCOMES. These usually describe the outcomes that were measured, followed by reports of the actual values of the measurements in the following section of the abstract. Again, you would annotate only the former.

Read the text and highlight all phrases that describe the outcomes. Mark **the longest contiguous texts** that include such descriptions. An outcome may be referenced or described more than once in an abstract; **all such occurrences should be marked**. It may be helpful to read the entire text once and only after that mark the text snippets describing the outcomes measured in the study.

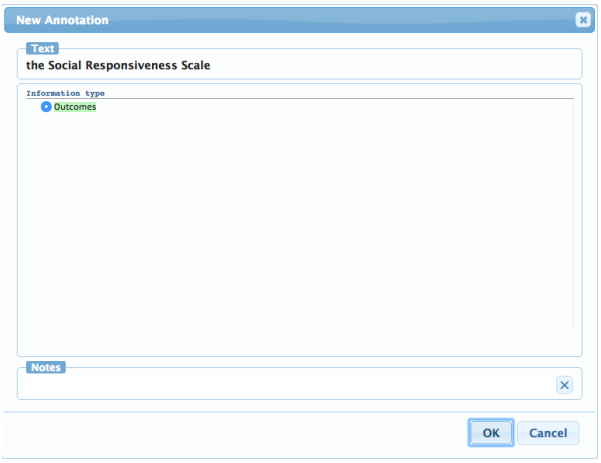

Figure 1: Markup dialog window. A "delete" button will appear for a span already marked.

To mark a portion of the text, highlight the text. A menu will appear. At the top, in "Text" you will see the selected text. The "Information type" section has the "Outcomes" tag. At the bottom, there is a "Notes" section where you can leave comments about this particular mark-up. Select "Ok" at the bottom right to finalize the mark-up.

If you wish to delete a mark-up section, double click on the existing label, then select "Delete" at the bottom right.

A highlighted span should look like Figure 2.

Figure 2: A highlighted span.

Below are some example annotations:

> ***Effects of 12 weeks' treatment with a proton pump inhibitor on insulin secretion, glucose metabolism and markers of cardiovascular risk in patients with type 2 diabetes: a randomised double-blind prospective placebo-controlled study.***
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> *AIMS/HYPOTHESIS:*
> *Recent studies suggest that proton pump inhibitor treatment may increase insulin secretion and improve glucose metabolism in type 2 diabetes. In a randomised double-blind prospective placebo-controlled 2 × 2 factorial study, we examined the effect of esomeprazole on insulin secretion, HbA(1c) and cardiovascular risk factors in type 2 diabetes.*
> *METHODS:*
> *Forty-one patients with type 2 diabetes using dietary control or oral glucose-lowering treatment were randomised to receive add-on esomeprazole 40 mg (n = 20) or placebo (n = 21) for 12 weeks. Randomisation was carried out prior to inclusion on the basis of a computer-generated random-number list. The allocation sequence was concealed in sealed envelopes from the researcher enrolling and assessing participants. The study was undertaken at Steno Diabetes Center, Gentofte, Denmark. The primary outcome was change in AUC for insulin levels during a meal test. Secondary outcomes were the levels of HbA(1c) and biochemical markers of cardiovascular risk, including lipids, coagulation factors, inflammation markers, markers of endothelial function and 24 h ambulatory BP measurements.*
> *RESULTS:*
> *Forty-one participants were analysed. In the esomeprazole-treated group the AUC for insulin did not change (before vs after treatment: 28,049 ± 17,659 vs 27,270 ± 32,004 pmol/l × min (p = 0.838). In the placebo group AUC for insulin decreased from 27,392 ± 14,348 pmol/l × min to 22,938 ± 11,936 pmol/l × min (p = 0.002). Esomeprazole treatment (n = 20) caused a ninefold increase in the AUC for gastrin. HbA(1c) increased from 7.0 ± 0.6% (53 ± 5 mmol/mol) to 7.3 ± 0.8% (56 ± 6 mmol/mol) in the esomeprazole-treated group and from 7.0 ± 0.6% (53 ± 5 mmol/mol) to 7.4 ± 0.8% (57 ± 6 mmol/mol) in the placebo group (n = 21) (p for difference in change >0.05). Except for BP, there were no differences between the groups in the markers of cardiovascular risk (p > 0.05). Monitoring of 24 h ambulatory BP showed a significant decrease in daytime systolic BP, daytime diastolic BP and 24 h diastolic BP in the placebo group (p < 0.05). No change in BP was seen in the patients treated with esomeprazole.*
> *CONCLUSIONS/INTERPRETATION:*
> *Treatment with esomeprazole over 12 weeks did not improve insulin secretion, glycaemic control or cardiovascular disease biomarkers in patients with type 2 diabetes.*
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> ***Safety, Feasibility, and Efficacy of Vagus Nerve Stimulation Paired With Upper-Limb Rehabilitation After Ischemic Stroke***
>
> *BACKGROUND AND PURPOSE:*
> *Recent animal studies demonstrate that vagus nerve stimulation (VNS) paired with movement induces movement-specific plasticity in motor cortex and improves forelimb function after stroke. We conducted a randomized controlled clinical pilot study of VNS paired with rehabilitation on upper-limb function after ischemic*

stroke.
METHODS:
Twenty-one participants with ischemic stroke >6 months before and moderate to severe upper-limb impairment were randomized to VNS plus rehabilitation or rehabilitation alone. Rehabilitation consisted of three 2-hour sessions per week for 6 weeks, each involving >400 movement trials. In the VNS group, movements were paired with 0.5-second VNS. The primary objective was to assess safety and feasibility. Secondary end points included change in upper-limb measures (including the Fugl-Meyer Assessment-Upper Extremity).
RESULTS:
Nine participants were randomized to VNS plus rehabilitation and 11 to rehabilitation alone. There were no serious adverse device effects. One patient had transient vocal cord palsy and dysphagia after implantation. Five had minor adverse device effects including nausea and taste disturbance on the evening of therapy. In the intention-to-treat analysis, the change in Fugl-Meyer Assessment-Upper Extremity scores was not significantly different (between-group difference, 5.7 points; 95% confidence interval, -0.4 to 11.8). In the per-protocol analysis, there was a significant difference in change in Fugl-Meyer Assessment-Upper Extremity score (between-group difference, 6.5 points; 95% confidence interval, 0.4 to 12.6).
CONCLUSIONS:
This study suggests that VNS paired with rehabilitation is feasible and has not raised safety concerns. Additional studies of VNS in adults with chronic stroke will now be performed.

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Risperidone in children with autism and serious behavioral problems

BACKGROUND:
Atypical antipsychotic agents, which block postsynaptic dopamine and serotonin receptors, have advantages over traditional antipsychotic medications in the treatment of adults with schizophrenia and may be beneficial in children with autistic disorder who have serious behavioral disturbances. However, data on the safety and efficacy of atypical antipsychotic agents in children are limited.
METHODS:
We conducted a multisite, randomized, double-blind trial of risperidone as compared with placebo for the treatment of autistic disorder accompanied by severe tantrums, aggression, or self-injurious behavior in children 5 to 17 years old. The primary outcome measures were the score on the Irritability subscale of the Aberrant Behavior Checklist and the rating on the Clinical Global Impressions - Improvement (CGI-I) scale at eight weeks.
RESULTS:
A total of 101 children (82 boys and 19 girls; mean [+/-SD] age, 8.8+/-2.7 years) were randomly assigned to receive risperidone (49 children) or placebo (52). Treatment with risperidone for eight weeks (dose range, 0.5 to 3.5 mg per day) resulted in a 56.9 percent reduction in the Irritability score, as compared with a 14.1 percent decrease in the placebo group (P<0.001). The rate of a positive response, defined as at least a 25 percent decrease in the Irritability score and a rating of much improved or very much improved on the CGI-I scale, was 69 percent in the risperidone group (34 of 49 children had a positive response) and 12 percent in the placebo group (6 of 52, P<0.001). Risperidone therapy was associated with an average weight gain of 2.7+/-2.9 kg, as compared with 0.8+/-2.2 kg with placebo (P<0.001). Increased appetite, fatigue, drowsiness, dizziness, and drooling were more common in the risperidone group than in the placebo group (P<0.05 for each comparison). In two thirds of the children with a positive response to risperidone at eight weeks (23 of 34), the benefit was maintained at six months.
CONCLUSIONS:
Risperidone was used for the treatment of tantrums, aggression, or self-injurious behavior in children with autistic disorder. The short period of this trial limits inferences about adverse effects such as tardive dyskinesia.

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Video-feedback Intervention to promote Positive Parenting adapted to Autism (VIPP-AUTI): A randomized controlled trial

In a randomized controlled trial, we evaluated the early intervention program Video-feedback Intervention to promote Positive Parenting adapted to Autism (VIPP-AUTI) with 78 primary caregivers and their child (16-61 months) with Autism Spectrum Disorder. VIPP-AUTI is a brief attachment-based intervention program, focusing on improving parent-child interaction and reducing the child's individual Autism Spectrum Disorder-related symptomatology in five home visits. VIPP-AUTI, as compared with usual care, demonstrated efficacy in reducing parental intrusiveness. Moreover, parents who received VIPP-AUTI showed increased feelings of self-efficacy in child rearing. No significant group differences were found on other aspects of parent-child interaction or on child play behavior. At 3-months follow-up, intervention effects were found on child-initiated joint attention skills, not mediated by intervention effects on parenting. Implementation of VIPP-AUTI in clinical practice is facilitated by the use of a detailed manual and a relatively brief training of interveners.

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Results of the Randomized Danish Lung Cancer Screening Trial with Focus on High-Risk Profiling

RATIONALE:
As of April 2015, participants in the Danish Lung Cancer Screening Trial had been followed for at least 5 years since their last screening.
OBJECTIVES:
Mortality, causes of death, and lung cancer findings are reported to explore the effect of computed tomography (CT) screening.
METHODS:
A total of 4,104 participants aged 50-70 years at the time of inclusion and with a minimum 20 pack-years of smoking were randomized to have five annual low-dose CT scans (study group) or no screening (control group).
MEASUREMENTS AND MAIN RESULTS:
Follow-up information regarding date and cause of death, lung cancer diagnosis, cancer stage, and histology was obtained from national registries. No differences between the two groups in lung cancer mortality (hazard ratio, 1.03; 95% confidence interval, 0.66-1.6; P = 0.888) or all-cause mortality (hazard ratio, 1.02; 95% confidence interval, 0.82-1.27; P = 0.867) were observed. More cancers were found in the screening group than in the no-screening group (100 vs. 53, respectively; P < 0.001), particularly adenocarcinomas (58 vs. 18, respectively; P < 0.001). More early-stage cancers (stages I and II, 54 vs. 10, respectively; P < 0.001) and stage IIIa cancers (15 vs. 3, respectively; P = 0.009) were found in the screening group than in the control group. Stage IV cancers were nonsignificantly more frequent in the control group than in the screening group (32 vs. 23, respectively; P = 0.278). For the highest-stage cancers (T4N3M1, 21 vs. 8, respectively; P = 0.025), this difference was statistically significant, indicating an absolute stage shift. Older participants, those with chronic obstructive pulmonary disease, and those with more than 35 pack-years of smoking had a significantly increased risk of death due to lung cancer, with nonsignificantly fewer deaths in the screening group.
CONCLUSIONS:
No statistically significant effects of CT screening on lung cancer mortality were found, but the results of post hoc high-risk subgroup analyses showed nonsignificant trends that seem to be in good agreement with the results of the National Lung Screening Trial.

Navigation Instructions

Figure 3: Navigation bar.

Each HIT consists of three short texts to annotate. For qualification you will mark one text. Use the left and right arrows at the top bar to navigate through the articles. When you are finished with all texts, press the "right" arrow again and a "submit" button will appear, shown in Figure 3. There you will see a code unique for the HIT you just completed. **Do NOT refresh or zoom the annotation page** (this will cause your annotations to be lost). **Make sure to leave the Mechanical Turk window open as you complete the annotation.** When you are finished, you will return to the Mechanical Turk page to paste the code into the box.

In the annotation page you can always view these instructions again by clicking on the "help" button at the upper right corner of the navigation bar.