

## Supplementary Online Content

Chen T, Li C, Qin R, et al. Comparison of clinical trial changes in primary outcome and reported intervention effect size between trial registration and publication. *JAMA Netw Open.* 2019;2(7):e197242. doi:10.1001/jamanetworkopen.2019.7242

**eTable 1.** Search History in PubMed

**eTable 2.** Search History in EMBASE via Ovid After Excluding Medline Journals

**eTable 3.** Number of Hits by Year

**eTable 4.** List of Included Randomized Clinical Trials With Classification and Type of Primary Outcome Change

**eReferences.**

This supplementary material has been provided by the authors to give readers additional information about their work.

## 1. Electronic search strategies

We performed electronic search at both PubMed and EMBASE on 23 Jan 2016. The search history is listed in eTable 1 and eTable 2.

**eTable 1.** Search History in PubMed

| Search    | Query   | Items found   | Time     |
|-----------|---|---------------|----------|
| <u>#3</u> | Search (((((((Registries/standards [MESH Terms]) OR registration) OR registry) OR Clinicaltrials.gov) OR ICTRP) OR ISRCTN)) AND (((((((randomized controlled trial [pt]) OR controlled clinical trial [pt]) OR randomized [tiab]) OR placebo [tiab]) OR clinical trials as topic [mesh: noexp]) OR randomly [tiab]) OR trial [ti])) NOT ((animals [mh] NOT humans [mh])) Filters: Publication date from 2011/01/01 to 2015/12/31; English | <u>28810</u>  | 15:43:18 |
| <u>#2</u> | Search (((((((randomized controlled trial [pt]) OR controlled clinical trial [pt]) OR randomized [tiab]) OR placebo [tiab]) OR clinical trials as topic [mesh: noexp]) OR randomly [tiab]) OR trial [ti])) NOT ((animals [mh] NOT humans [mh]))   | <u>930151</u> | 15:42:21 |
| <u>#1</u> | Search (((((((Registries/standards [MESH Terms]) OR registration) OR registry) OR Clinicaltrials.gov) OR ICTRP) OR ISRCTN   | <u>197732</u> | 15:40:43 |

**eTable 2.** Search History in EMBASE via Ovid After Excluding Medline Journals

| Search | Query   | Results |
|--------|---|---------|
| 1      | (random\$ or placebo\$ or single blind\$ or double blind\$ or triple blind\$).ti,ab.  | 1160063 |
| 2      | (animal\$ not human\$).sh,hw.   | 3970214 |
| 3      | (book or conference paper or editorial or letter or review).pt. not exp randomized controlled trial/                                    | 4295441 |
| 4      | (random sampl\$ or random digit\$ or random effect\$ or random survey or random regression).ti,ab. not exp randomized controlled trial/ | 68833   |
| 5      | 1 not (2 or 3 or 4)   | 892573  |
| 6      | (registry or clinicaltrials gov or ictrp or isrctn or registration).tw.   | 166894  |
| 7      | 5 and 6   | 22816   |
| 8      | limit 7 to (english language and exclude medline journals and yr="2011 - 2015")   | 939     |

## 2. Method

In total, there are 29,749 hits (see below).

**eTable 3.** Number of Hits by Year

| Year    | Number of hits |
|---------|----------------|
| 2011    | 5088           |
| 2012    | 5998           |
| 2013    | 7104           |
| 2014    | 7784           |
| 2015    | 3775           |
| Overall | 29749          |

Each item was assigned a number according to the order of appearance in PubMed/Embase by year. A computer-generated random sequence was then created within each year, and then ranked.

Since no similar study had been performed before and there was no standard way to calculate the sample size, we reviewed the sample size for previous studies regarding the association between study quality and treatment effect size and found that most of them included 150 to 310 studies.<sup>1,2 3,4</sup> Therefore, if the first 5% items selected included more than 300 eligible papers, we would not select another 5%.

## 3. Article listing

**eTable 4.** List of Included Randomized Clinical Trials With Classification and Type of Primary Outcome Change

| First author                        | year of publication | Journal           | Title   | Classification | type of changes |
|-------------------------------------|---------------------|-------------------|---|----------------|-----------------|
| F. Cognetti <sup>5</sup>            | 2013                | Gynecol Oncol     | A Phase II, randomized, double-blind study of zibotentan (ZD4054) in combination with carboplatin/paclitaxel versus placebo in combination with carboplatin/paclitaxel in patients with advanced ovarian cancer sensitive to platinum-based chemotherapy (AGO-OVAR 2.14). | no             |                 |
| Arianne C. Lim <sup>6</sup>         | 2011                | Obstet Gynecol    | 17 $\alpha$ -hydroxyprogesterone caproate for the prevention of adverse neonatal outcome in multiple pregnancies: a randomized controlled trial.  | no             |                 |
| Christoph C Lees <sup>7</sup>       | 2015                | Lancet            | 2 year neurodevelopmental and intermediate perinatal outcomes in infants with very preterm fetal growth restriction (TRUFFLE): a randomised trial.  | yes            | new outcome     |
| Tia Ngandu <sup>8</sup>             | 2015                | Lancet            | A 2 year multidomain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial.  | yes            | omission        |
| Jinhyun Kim <sup>9</sup>            | 2013                | J Korean Med Sci  | A clinical trial and extension study of infliximab in Korean patients with active rheumatoid arthritis despite methotrexate treatment.  | no             |                 |
| Brett E. Skolnick <sup>10</sup>     | 2014                | N Engl J Med      | A clinical trial of progesterone for severe traumatic brain injury.   | no             |                 |
| Thomas C. Keyserling <sup>11</sup>  | 2014                | JAMA Intern Med   | A comparison of live counseling with a web-based lifestyle and medication intervention to reduce coronary heart disease risk: a randomized clinical trial.  | no             |                 |
| Jens Cosedis Nielsen <sup>12</sup>  | 2011                | Eur Heart J       | A comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome.  | no             |                 |
| Juan-Osvaldo Talavera <sup>13</sup> | 2013                | Curr Med Res Opin | A double-blind, double-dummy, randomized, placebo-controlled trial to evaluate the effect of statin therapy on triglyceride levels in Mexican hypertriglyceridemic patients.  | no             |                 |

|  |      |                          |   |     |             |
|--|------|--------------------------|---|-----|-------------|
| Anthony Yuen<br>Bun Teoh <sup>14</sup> | 2012 | Ann Surg                 | A double-blinded randomized controlled trial of laparoendoscopic single-site access versus conventional 3-port appendectomy.  | no  |             |
| Marta Ramon-<br>Krauel <sup>15</sup>   | 2013 | Child Obes               | A low-glycemic-load versus low-fat diet in the treatment of fatty liver in obese children.  | no  |             |
| Hanik K.Yoo <sup>16</sup>              | 2013 | J Clin Psychiatry        | A multicenter, randomized, double-blind, placebo-controlled study of aripiprazole in children and adolescents with Tourette's disorder.   | no  |             |
| Pierre Quartier <sup>17</sup>          | 2011 | Ann Rheum Dis            | A multicentre, randomised, double-blind, placebo-controlled trial with the interleukin-1 receptor antagonist anakinra in patients with systemic-onset juvenile idiopathic arthritis (ANAJIS trial).   | yes | new outcome |
| Dennis G. Maki <sup>18</sup>           | 2011 | Crit Care Med            | A novel antimicrobial and antithrombotic lock solution for hemodialysis catheters: a multi-center, controlled, randomized trial.  | no  |             |
| Andrew C. Chen <sup>19</sup>           | 2015 | N Engl J Med             | A Phase 3 Randomized Trial of Nicotinamide for Skin-Cancer Chemoprevention.   | yes | new outcome |
| Rachelle S.<br>Doody <sup>20</sup>     | 2013 | N Engl J Med             | A phase 3 trial of semagacestat for treatment of Alzheimer's disease.   | no  |             |
| Kiran Nanchahal <sup>21</sup>          | 2012 | BMJ Open                 | A pragmatic randomised controlled trial in primary care of the Camden Weight Loss (CAMWEL) programme.   | yes | omission    |
| Michael G. Sarr <sup>22</sup>          | 2014 | Surgery                  | A prospective, randomized, multicenter trial of Surgisis Gold, a biologic prosthetic, as a sublay reinforcement of the fascial closure after open bariatric surgery.  | no  |             |
| Ranjit Lall <sup>23</sup>              | 2015 | Health Technol<br>Assess | A randomised controlled trial and cost-effectiveness analysis of high-frequency oscillatory ventilation against conventional artificial ventilation for adults with acute respiratory distress syndrome. The OSCAR (OSCillation in ARDS) study. | no  |             |

|   |      |                          |   |     |              |
|---|------|--------------------------|---|-----|--------------|
| Lesley M Roberts <sup>24</sup>          | 2013 | BMC Gastroenterol        | A randomised controlled trial of a probiotic 'functional food' in the management of irritable bowel syndrome.   | no  |              |
| Ramachandran Venkitaraman <sup>25</sup> | 2015 | Eur Urol                 | A randomised phase 2 trial of dexamethasone versus prednisolone in castration-resistant prostate cancer.  | no  |              |
| Bruce E Sands <sup>26</sup>             | 2013 | Gut                      | A randomised, double-blind, sham-controlled study of granulocyte/monocyte apheresis for moderate to severe Crohn's disease.   | yes | new outcome  |
| Thomas Yeoh <sup>27</sup>               | 2011 | Heart Lung Circ          | A randomised, placebo-controlled trial of carvedilol in early familial dilated cardiomyopathy.  | yes | omission     |
| Hawk Kim <sup>28</sup>                  | 2012 | Ann Hematol              | A randomized comparison of cyclophosphamide vs. reduced dose cyclophosphamide plus fludarabine for allogeneic hematopoietic cell transplantation in patients with aplastic anemia and hypoplastic myelodysplastic syndrome. | yes | new outcome  |
| Neil Stollman <sup>29</sup>             | 2013 | J Clin Gastroenterol     | A randomized controlled study of mesalamine after acute diverticulitis: results of the DIVA trial.  | yes | time changes |
| Angelo E. Volandes <sup>30</sup>        | 2012 | J Palliat Med            | A randomized controlled trial of a goals-of-care video for elderly patients admitted to skilled nursing facilities.   | no  |              |
| Mark D Farrar <sup>31</sup>             | 2015 | Am J Clin Nutr           | A randomized controlled trial of green tea catechins in protection against ultraviolet radiation-induced cutaneous inflammation.  | no  |              |
| Kieran J. Phelan <sup>32</sup>          | 2011 | Arch Pediatr Adolesc Med | A randomized controlled trial of home injury hazard reduction: the HOME injury study.   | yes | new outcome  |
| Sagar V. Parkh <sup>33</sup>            | 2012 | J Clin Psychiatry        | A randomized controlled trial of psychoeducation or cognitive-behavioral therapy in bipolar disorder: a Canadian Network for Mood and Anxiety treatments (CANMAT) study [CME].  | yes | omission     |

|                                   |      |                                    |   |     |             |
|-----------------------------------|------|------------------------------------|---|-----|-------------|
| Paul Y. Takahashi <sup>34</sup>   | 2012 | Arch Intern Med                    | A randomized controlled trial of telemonitoring in older adults with multiple health issues to prevent hospitalizations and emergency department visits.  | yes | omission    |
| Corrine I. Voils <sup>35</sup>    | 2013 | Prev Med                           | A randomized controlled trial to evaluate the effectiveness of CouPLES: a spouse-assisted lifestyle change intervention to improve low-density lipoprotein cholesterol.   | no  |             |
| Myriam Harfterkamp <sup>36</sup>  | 2012 | J Am Acad Child Adolesc Psychiatry | A randomized double-blind study of atomoxetine versus placebo for attention-deficit/hyperactivity disorder symptoms in children with autism spectrum disorder.  | no  |             |
| C. H. Smorenburg <sup>37</sup>    | 2014 | Ann Oncol                          | A randomized phase III study comparing pegylated liposomal doxorubicin with capecitabine as first-line chemotherapy in elderly patients with metastatic breast cancer: results of the OMEGA study of the Dutch Breast Cancer Research Group BOOG. | no  |             |
| George Van Buren II <sup>38</sup> | 2014 | Ann Surg                           | A randomized prospective multicenter trial of pancreaticoduodenectomy with and without routine intraperitoneal drainage.  | no  |             |
| Angelo Naselli <sup>39</sup>      | 2012 | European Urology, Supplements      | A randomized prospective trial to assess impact of TUR performed in narrow band imaging modality on non muscle invasive bladder cancer recurrence.  | no  |             |
| Charles W. Lynde <sup>40</sup>    | 2012 | J Dermatolog Treat                 | A randomized study comparing the combination of nbUVB and etanercept to etanercept monotherapy in patients with psoriasis who do not exhibit an excellent response after 12 weeks of etanercept.  | no  |             |
| Andrea O. Rossetti <sup>41</sup>  | 2011 | Neurocrit Care                     | A randomized trial for the treatment of refractory status epilepticus.  | no  |             |
| Massimo Imazio <sup>42</sup>      | 2013 | N Engl J Med                       | A randomized trial of colchicine for acute pericarditis.  | yes | new outcome |
| Tina M. Slusher <sup>43</sup>     | 2015 | N Engl J Med                       | A Randomized Trial of Phototherapy with Filtered Sunlight in African Neonates.  | yes | new outcome |



|                                     |      |                           |   |     |              |
|-------------------------------------|------|---------------------------|---|-----|--------------|
| N. Low, A. Bavdekar <sup>44</sup>   | 2015 | N Engl J Med              | A randomized, controlled trial of an aerosolized vaccine against measles.   | no  |              |
| David A. Berntsen <sup>45</sup>     | 2012 | Invest Ophthalmol Vis Sci | A randomized trial using progressive addition lenses to evaluate theories of myopia progression in children with a high lag of accommodation.   | no  |              |
| Hideaki Katagiri <sup>46</sup>      | 2013 | BMC Psychiatry            | A randomized, double-blind, placebo-controlled study of rapid-acting intramuscular olanzapine in Japanese patients for schizophrenia with acute agitation.  | no  |              |
| J. L. C. Borges <sup>47</sup>       | 2011 | Diabetes Obes Metab       | A randomized, parallel group, double-blind, multicentre study comparing the efficacy and safety of Avandamet (rosiglitazone/metformin) and metformin on long-term glycaemic control and bone mineral density after 80 weeks of treatment in drug-naïve type 2 diabetes mellitus patients. | no  |              |
| Katy E. Mitchell <sup>48</sup>      | 2014 | Eur Respir J              | A self-management programme for COPD: a randomised controlled trial.  | no  |              |
| J. Tan <sup>49</sup>                | 2014 | Br J Dermatol             | A treatment for severe nodular acne: a randomized investigator-blinded, controlled, noninferiority trial comparing fixed-dose adapalene/benzoyl peroxide plus doxycycline vs. oral isotretinoin.  | no  |              |
| Philip Mease <sup>50</sup>          | 2011 | Arthritis Rheum           | Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial.   | yes | new times    |
| Kamran Siddiqi <sup>51</sup>        | 2013 | Ann Intern Med            | Action to stop smoking in suspected tuberculosis (ASSIST) in Pakistan: a cluster randomized, controlled trial.  | yes | omission     |
| Willem Pieter Brouwer <sup>52</sup> | 2015 | Hepatology                | Adding pegylated interferon to entecavir for hepatitis B e antigen-positive chronic hepatitis B: A multicenter randomized trial (ARES study).   | no  |              |
| Lotte M. Kruidenier <sup>53</sup>   | 2011 | J Vasc Interv Radiol      | Additional supervised exercise therapy after a percutaneous vascular intervention for peripheral arterial disease: a randomized clinical trial.   | yes | time changes |

|                                     |      |                       |   |     |              |
|-------------------------------------|------|-----------------------|---|-----|--------------|
| Johan Vansteenkiste <sup>54</sup>   | 2013 | J Clin Oncol          | Adjuvant MAGE-A3 immunotherapy in resected non-small-cell lung cancer: phase II randomized study results.   | yes | new outcome  |
| Jordi Bruix <sup>55</sup>           | 2015 | Lancet Oncol          | Adjuvant sorafenib for hepatocellular carcinoma after resection or ablation (STORM): a phase 3, randomised, double-blind, placebo-controlled trial.   | no  |              |
| JM Watson <sup>56</sup>             | 2013 | Health Technol Assess | AESOPS: a randomised controlled trial of the clinical effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care.           | no  |              |
| Graziella Badin Aliti <sup>57</sup> | 2013 | JAMA Intern Med       | Aggressive fluid and sodium restriction in acute decompensated heart failure: a randomized clinical trial.  | yes | time changes |
| P Higgins <sup>58</sup>             | 2014 | Heart                 | Allopurinol reduces brachial and central blood pressure, and carotid intima-media thickness progression after ischaemic stroke and transient ischaemic attack: a randomised controlled trial.                     | no  |              |
| C. Parker <sup>59</sup>             | 2013 | N Engl J Med          | Alpha emitter radium-223 and survival in metastatic prostate cancer.  | no  |              |
| John J.V. McMurray <sup>60</sup>    | 2014 | N Engl J Med          | Angiotensin-neprilysin inhibition versus enalapril in heart failure.  | no  |              |
| Stuart J. Connolly <sup>61</sup>    | 2011 | N Engl J Med          | Apixaban in patients with atrial fibrillation.  | no  |              |
| Richard K Burt <sup>62</sup>        | 2011 | Lancet                | Autologous non-myeloablative haemopoietic stem-cell transplantation compared with pulse cyclophosphamide once per month for systemic sclerosis (ASSIST): an open-label, randomised phase 2 trial.                 | yes | omission     |
| Takahiko Kojima <sup>63</sup>       | 2011 | Circ J                | Azelnidipine and amlodipine anti-coronary atherosclerosis trial in hypertensive patients undergoing coronary intervention by serial volumetric intravascular ultrasound analysis in Juntendo University (ALPS-J). | no  |              |

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|---------------------------------|------|---------------------------|---|-----|--------------|
| Richard K. Albert <sup>64</sup> | 2011 | N Engl J Med              | Azithromycin for prevention of exacerbations of COPD.   | no  |              |
| Alberto Papi <sup>65</sup>      | 2013 | Lancet Respir Med         | Beclometasone-formoterol as maintenance and reliever treatment in patients with asthma: a double-blind, randomised controlled trial.  | no  |              |
| Nicola A. Hanania <sup>66</sup> | 2012 | Respir Med                | Benefits of adding fluticasone propionate/salmeterol to tiotropium in moderate to severe COPD.  | no  |              |
| J. E. Foley <sup>67</sup>       | 2011 | Diabetologia              | Beta cell function following 1 year vildagliptin or placebo treatment and after 12 week washout in drug-naive patients with type 2 diabetes and mild hyperglycaemia: a randomised controlled trial. | no  |              |
| Mabrouk M. Elgadi <sup>68</sup> | 2011 | Drugs R D                 | Boosted tipranavir versus darunavir in treatment-experienced patients: observational data from the randomized POTENT trial.   | no  |              |
| Tamera J. Corte <sup>69</sup>   | 2014 | Am J Respir Crit Care Med | Bosentan in pulmonary hypertension associated with fibrotic idiopathic interstitial pneumonia.  | no  |              |
| i.c.Lawrance <sup>70</sup>      | 2011 | Endoscopy                 | Bowel cleansing for colonoscopy: prospective randomized assessment of efficacy and of induced mucosal abnormality with three preparation agents.  | yes | new outcome  |
| Robert E. Coleman <sup>71</sup> | 2011 | N Engl J Med              | Breast-cancer adjuvant therapy with zoledronic acid.  | no  |              |
| Ian H Kunkler <sup>72</sup>     | 2015 | Lancet Oncol              | Breast-conserving surgery with or without irradiation in women aged 65 years or older with early breast cancer (PRIME II): a randomised controlled trial.   | no  |              |
| Nusrat Husain <sup>73</sup>     | 2014 | Br J Psychiatry           | Brief psychological intervention after self-harm: randomised controlled trial from Pakistan.  | yes | time changes |

|                                  |      |                     |   |     |              |
|----------------------------------|------|---------------------|---|-----|--------------|
| H. Gelderblom <sup>74</sup>      | 2014 | Eur J Cancer        | Brostallicin versus doxorubicin as first-line chemotherapy in patients with advanced or metastatic soft tissue sarcoma: an European Organisation for Research and Treatment of Cancer Soft Tissue and Bone Sarcoma Group randomised phase II and pharmacogenetic study. | no  |              |
| Woon Geon Shin <sup>75</sup>     | 2012 | Gastrointest Endosc | Can rebamipide and proton pump inhibitor combination therapy promote the healing of endoscopic submucosal dissection-induced ulcers? A randomized, prospective, multicenter study.  | yes | time changes |
| Jithin Yohannan <sup>76</sup>    | 2013 | JAMA Ophthalmol     | Can we stop mass drug administration prior to 3 annual rounds in communities with low prevalence of trachoma?: PRET Ziada trial results.  | yes | time changes |
| Harriette R. Mogul <sup>77</sup> | 2014 | PLoS One            | Carbohydrate modified diet & insulin sensitizers reduce body weight & modulate metabolic syndrome measures in EMPOWIR (enhance the metabolic profile of women with insulin resistance): a randomized trial of normoglycemic women with midlife weight gain.             | yes | omission     |
| Elisabeth Quoix <sup>78</sup>    | 2011 | Lancet              | Carboplatin and weekly paclitaxel doublet chemotherapy compared with monotherapy in elderly patients with advanced non-small-cell lung cancer: IFCT-0501 randomised, phase 3 trial.   | no  |              |
| Nicholas A Zwar <sup>79</sup>    | 2012 | Med J Aust          | Care of patients with a diagnosis of chronic obstructive pulmonary disease: a cluster randomised controlled trial.  | yes | omission     |
| JA Costa <sup>80</sup>           | 2013 | Spinal Cord         | Catheter length preference in wheelchair-using men who perform routine clean intermittent catheterization.  | no  |              |
| Nicholas D James <sup>81</sup>   | 2012 | Lancet Oncol        | Celecoxib plus hormone therapy versus hormone therapy alone for hormone-sensitive prostate cancer: first results from the STAMPEDE multiarm, multistage, randomised controlled trial.   | no  |              |
| I.-J. Wang <sup>82</sup>         | 2015 | Clin Exp Allergy    | Children with atopic dermatitis show clinical improvement after Lactobacillus exposure.   | yes | omission     |
| Rebecca J Kean <sup>83</sup>     | 2015 | Am J Clin Nutr      | Chronic consumption of flavanone-rich orange juice is associated with cognitive benefits: an 8-wk, randomized, double-blind, placebo-controlled trial in healthy older adults.  | yes | omission     |

|                                     |      |                          |   |     |   |
|-------------------------------------|------|--------------------------|---|-----|---|
| Paul L.P. Brand <sup>84</sup>       | 2011 | Respir Med               | Ciclesonide in wheezy preschool children with a positive asthma predictive index or atopy.  | yes | new outcome                                   |
| Dermot Ryan <sup>85</sup>           | 2012 | BMJ                      | Clinical and cost effectiveness of mobile phone supported self monitoring of asthma: multicentre randomised controlled trial.   | no  |   |
| David L. Wessel <sup>86</sup>       | 2013 | N Engl J Med             | Clopidogrel in infants with systemic-to-pulmonary-artery shunts.  | yes | new outcome                                   |
| Anne Forster <sup>87</sup>          | 2015 | Stroke                   | Cluster Randomized Controlled Trial: Clinical and Cost-Effectiveness of a System of Longer-Term Stroke Care.  | no  |   |
| Thomas K Houston <sup>88</sup>      | 2013 | BMC Oral Health          | Cluster-randomized trial of a web-assisted tobacco quality improvement intervention of subsequent patient tobacco product use: a National Dental PBRN study.                            | yes | secondary to primary                          |
| Jeffrey J Wood <sup>89</sup>        | 2015 | Behav Ther               | Cognitive behavioral therapy for early adolescents with autism spectrum disorders and clinical anxiety: a randomized, controlled trial.   | no  |   |
| Josep M Ramon <sup>90</sup>         | 2014 | BMC Med                  | Combining varenicline and nicotine patches: a randomized controlled trial study in smoking cessation.   | no  |   |
| Charlotte Gry Harmsen <sup>91</sup> | 2014 | Br J Gen Pract           | Communicating risk using absolute risk reduction or prolongation of life formats: cluster-randomised trial in general practice.   | yes | registry to primary but reported as secondary |
| Brian I Rini <sup>92</sup>          | 2011 | Lancet                   | Comparative effectiveness of axitinib versus sorafenib in advanced renal cell carcinoma (AXIS): a randomised phase 3 trial.   | no  |   |
| M. R. OSTOVANEH <sup>93</sup>       | 2014 | Neurogastroenterol Motil | Comparing omeprazole with fluoxetine for treatment of patients with heartburn and normal endoscopy who failed once daily proton pump inhibitors: double-blind placebo-controlled trial. | yes | secondary to primary                          |

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|---|------|---------------------------|---|-----|--------------|
| Ensieh Shahrokh<br>Tehranejad <sup>94</sup> | 2012 | J Assist Reprod<br>Genet  | Comparison of cabergoline and intravenous albumin in the prevention of ovarian hyperstimulation syndrome: a randomized clinical trial.  | yes | omission     |
| T.J. Hilton <sup>95</sup>                   | 2013 | J Dent Res                | Comparison of CaOH with MTA for direct pulp capping: a PBRN randomized clinical trial.  | no  |              |
| Richard P. Allen <sup>96</sup>              | 2014 | N Engl J Med              | Comparison of pregabalin with pramipexole for restless legs syndrome.   | yes | time changes |
| Heng Zhang <sup>97</sup>                    | 2015 | Arthritis Res Ther        | Comparison of two hyaluronic acid formulations for safety and efficacy (CHASE) study in knee osteoarthritis: a multicenter, randomized, double-blind, 26-week non-inferiority trial comparing Durolane to Artz.   | no  |              |
| Anders Prestmo <sup>98</sup>                | 2015 | Lancet                    | Comprehensive geriatric care for patients with hip fractures: a prospective, randomised, controlled trial.  | yes | omission     |
| Romana<br>Dmitrovic <sup>99</sup>           | 2012 | Obstet Gynecol            | Continuous compared with cyclic oral contraceptives for the treatment of primary dysmenorrhea: a randomized controlled trial.   | no  |              |
| Rony Carlos<br>Preti <sup>100</sup>         | 2013 | Br J Ophthalmol           | Contrast sensitivity evaluation in high risk proliferative diabetic retinopathy treated with panretinal photocoagulation associated or not with intravitreal bevacizumab injections: a randomised clinical trial. | no  |              |
| Gareth J.<br>Morgan <sup>101</sup>          | 2011 | Blood                     | Cyclophosphamide, thalidomide, and dexamethasone (CTD) as initial therapy for patients with multiple myeloma unsuitable for autologous transplantation.   | no  |              |
| Benedikt<br>Huttner <sup>102</sup>          | 2013 | J Antimicrob<br>Chemother | Decolonization of intestinal carriage of extended-spectrum $\beta$ -lactamase-producing Enterobacteriaceae with oral colistin and neomycin: a randomized, double-blind, placebo-controlled trial.                 | no  |              |
| Timothy P.<br>Hughes <sup>103</sup>         | 2014 | Blood                     | Deep molecular responses achieved in patients with CML-CP who are switched to nilotinib after long-term imatinib.   | no  |              |

|   |      |                              |   |     |                      |
|---|------|------------------------------|---|-----|----------------------|
| Selim Corbacioglu <sup>104</sup>        | 2012 | Lancet                       | Defibrotide for prophylaxis of hepatic veno-occlusive disease in paediatric haemopoietic stem-cell transplantation: an open-label, phase 3, randomised controlled trial.                    | yes | omission             |
| Chung-Hua Hsu <sup>105</sup>            | 2011 | Altern Med Rev               | Does supplementation with green tea extract improve insulin resistance in obese type 2 diabetics? A randomized, double-blind, and placebo-controlled clinical trial.                        | no  |                      |
| Carmen A. Prieto-Jimenez <sup>106</sup> | 2011 | J Pediatr Gastroenterol Nutr | Double-blind randomized trial of quadruple sequential Helicobacter pylori eradication therapy in asymptomatic infected children in El Paso, Texas.  | yes | secondary to primary |
| Irina Mezhebovsky <sup>107</sup>        | 2013 | Int J Geriatr Psychiatry     | Double-blind, randomized study of extended release quetiapine fumarate (quetiapine XR) monotherapy in older patients with generalized anxiety disorder.                                     | no  |                      |
| Ian Judson <sup>108</sup>               | 2014 | Lancet Oncol                 | Doxorubicin alone versus intensified doxorubicin plus ifosfamide for first-line treatment of advanced or metastatic soft-tissue sarcoma: a randomised controlled phase 3 trial.             | no  |                      |
| Jean-Louis Trouillet <sup>109</sup>     | 2011 | Ann Intern Med               | Early percutaneous tracheotomy versus prolonged intubation of mechanically ventilated patients after cardiac surgery: a randomized trial.   | no  |                      |
| Martin L. Blakely <sup>110</sup>        | 2011 | Arch Surg                    | Early vs interval appendectomy for children with perforated appendicitis.   | no  |                      |
| Robert P. Giugliano <sup>111</sup>      | 2013 | N Engl J Med                 | Edoxaban versus warfarin in patients with atrial fibrillation.  | no  |                      |
| Kenneth D. Coburn <sup>112</sup>        | 2012 | PLoS Med                     | Effect of a community-based nursing intervention on mortality in chronically ill older adults: a randomized controlled trial.   | no  |                      |
| Simon J Griffin <sup>113</sup>          | 2011 | Lancet                       | Effect of early intensive multifactorial therapy on 5-year cardiovascular outcomes in individuals with type 2 diabetes detected by screening (ADDITION-Europe): a cluster-randomised trial. | no  |                      |

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|--|------|--|--|-----|----------------------|
| Rehana A Salam <sup>114</sup>          | 2015 | Arch Dis Child Fetal Neonatal Ed                 | Effect of emollient therapy on clinical outcomes in preterm neonates in Pakistan: a randomised controlled trial.   | no  |                      |
| Kalathil K. Sureshkumar <sup>115</sup> | 2012 | Clin J Am Soc Nephrol                            | Effect of high-dose erythropoietin on graft function after kidney transplantation: a randomized, double-blind clinical trial.  | no  |                      |
| Sophie Boisson <sup>116</sup>          | 2013 | PLoS Med   | Effect of household-based drinking water chlorination on diarrhoea among children under five in Orissa, India: a double-blind randomised placebo-controlled trial.                               | no  |                      |
| Nele Devoogdt <sup>117</sup>           | 2011 | BMJ  | Effect of manual lymph drainage in addition to guidelines and exercise therapy on arm lymphoedema related to breast cancer: randomised controlled trial.   | no  |                      |
| Jean Reigner <sup>118</sup>            | 2013 | JAMA   | Effect of not monitoring residual gastric volume on risk of ventilator-associated pneumonia in adults receiving mechanical ventilation and early enteral feeding: a randomized controlled trial. | no  |                      |
| Marian Wiegersma <sup>119</sup>        | 2014 | BMJ  | Effect of pelvic floor muscle training compared with watchful waiting in older women with symptomatic mild pelvic organ prolapse: randomised controlled trial in primary care.                   | yes | omission             |
| Margaret M. Redfield <sup>120</sup>    | 2013 | JAMA   | Effect of phosphodiesterase-5 inhibition on exercise capacity and clinical status in heart failure with preserved ejection fraction: a randomized clinical trial.                                | no  |                      |
| Kim L. Bennell <sup>121</sup>          | 2014 | JAMA   | Effect of physical therapy on pain and function in patients with hip osteoarthritis: a randomized clinical trial.  | yes | omission             |
| Maryam Eftekhari <sup>122</sup>        | 2013 | International Journal of Fertility and Sterility | Effect of progesterone supplementation on natural frozen-thawed embryo transfer cycles: A randomized controlled trial.   | yes | secondary to primary |
| Harsha Thirumurthy <sup>123</sup>      | 2014 | JAMA   | Effect of providing conditional economic compensation on uptake of voluntary medical male circumcision in Kenya: a randomized clinical trial.  | no  |                      |



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| Sayeed Ikramuiddin <sup>124</sup>      | 2014 | JAMA              | Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial.  | no  |          |
| Miles D. Witham <sup>125</sup>         | 2013 | Atherosclerosis   | Effect of short-term vitamin D supplementation on markers of vascular health in South Asian women living in the UK--a randomised controlled trial.   | no  |          |
| Germer-Michael Pinggera <sup>126</sup> | 2014 | Urology           | Effect of tadalafil once daily on prostate blood flow and perfusion in men with lower urinary tract symptoms secondary to benign prostatic hyperplasia: a randomized, double-blind, multicenter, placebo-controlled trial. | no  |          |
| Stephen J. Nicholls <sup>127</sup>     | 2011 | N Engl J Med      | Effect of two intensive statin regimens on progression of coronary disease.  | no  |          |
| Mihai Gheorghide <sup>128</sup>        | 2015 | JAMA              | Effect of Vericiguat, a Soluble Guanylate Cyclase Stimulator, on Natriuretic Peptide Levels in Patients With Worsening Chronic Heart Failure and Reduced Ejection Fraction: The SOCRATES-REDUCED Randomized Trial.         | no  |          |
| Theresa M. Marteau <sup>129</sup>      | 2012 | PLoS One          | Effect on adherence to nicotine replacement therapy of informing smokers their dose is determined by their genotype: a randomised controlled trial.  | no  |          |
| Brian Yoshio Laing <sup>130</sup>      | 2014 | Ann Intern Med    | Effectiveness of a smartphone application for weight loss compared with usual care in overweight primary care patients: a randomized, controlled trial.  | no  |          |
| Jennifer K. Coffeng <sup>131</sup>     | 2014 | PLoS One          | Effectiveness of a worksite social & physical environment intervention on need for recovery, physical activity and relaxation; results of a randomized controlled trial.   | yes | omission |
| Alan N. Barkun <sup>132</sup>          | 2013 | CMAJ              | Effectiveness of disseminating consensus management recommendations for ulcer bleeding: a cluster randomized trial.  | no  |          |
| Philipp Zanger <sup>133</sup>          | 2013 | Lancet Infect Dis | Effectiveness of rifaximin in prevention of diarrhoea in individuals travelling to south and southeast Asia: a randomised, double-blind, placebo-controlled, phase 3 trial.  | no  |          |

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|-----------------------------------|------|-------------------|---|-----|----------------------|
| Ronald I. Shorr <sup>134</sup>    | 2012 | Ann Intern Med    | Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial.   | no  |                      |
| Beatriz Grinsztejn <sup>135</sup> | 2014 | Lancet Infect Dis | Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial.  | yes | new outcome          |
| Chris T. Bolliger <sup>136</sup>  | 2011 | Clin Ther         | Effects of varenicline in adult smokers: a multinational, 24-week, randomized, double-blind, placebo-controlled study.  | no  |                      |
| Joachim Sieper <sup>137</sup>     | 2013 | Ann Rheum Dis     | Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis: results of a randomised placebo-controlled trial (ABILITY-1).  | no  |                      |
| Jun Ishigooka <sup>138</sup>      | 2015 | Schizophr Res     | Efficacy and safety of aripiprazole once-monthly in Asian patients with schizophrenia: a multicenter, randomized, double-blind, non-inferiority study versus oral aripiprazole.   | no  |                      |
| S. Whittaker <sup>139</sup>       | 2012 | Br J Dermatol     | Efficacy and safety of bexarotene combined with psoralen-ultraviolet A (PUVA) compared with PUVA treatment alone in stage IB-IIA mycosis fungoides: final results from the EORTC Cutaneous Lymphoma Task Force phase III randomized clinical trial (NCT00056056). | yes | secondary to primary |
| José A. Vazquez <sup>140</sup>    | 2012 | Curr Med Res Opin | Efficacy and safety of ceftazidime-avibactam versus imipenem-cilastatin in the treatment of complicated urinary tract infections, including acute pyelonephritis, in hospitalized adults: results of a prospective, investigator-blinded, randomized study.       | no  |                      |
| Xavier Girerd <sup>141</sup>      | 2011 | Blood Press Suppl | Efficacy and safety of early versus late titration of fixed-dose irbesartan/hydrochlorothiazide: ACTUAL study.  | no  |                      |
| Ashley Woodcock <sup>142</sup>    | 2013 | Chest             | Efficacy and safety of fluticasone furoate/vilanterol compared with fluticasone propionate/salmeterol combination in adult and adolescent patients with persistent asthma: a randomized trial.  | no  |                      |
| J Sieper <sup>143</sup>           | 2014 | Ann Rheum Dis     | Efficacy and safety of infliximab plus naproxen versus naproxen alone in patients with early, active axial spondyloarthritis: results from the double-blind, placebo-controlled INFAST study, Part 1.   | no  |                      |

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|------------------------------------|------|--------------------------|--|-----|-------------|
| Roland Buhl <sup>144</sup>         | 2015 | Thorax                   | Efficacy and safety of once-daily QVA149 compared with the free combination of once-daily tiotropium plus twice-daily formoterol in patients with moderate-to-severe COPD (QUANTIFY): a randomised, non-inferiority study.   | yes | new outcome |
| Vivian Fonseca <sup>145</sup>      | 2013 | J Diabetes Complications | Efficacy and safety of sitagliptin added to ongoing metformin and pioglitazone combination therapy in a randomized, placebo-controlled, 26-week trial in patients with type 2 diabetes.  | no  |             |
| Johann Altenberger <sup>146</sup>  | 2014 | Eur J Heart Fail         | Efficacy and safety of the pulsed infusions of levosimendan in outpatients with advanced heart failure (LevoRep) study: a multicentre randomized trial.  | no  |             |
| Paul W. Jones <sup>147</sup>       | 2012 | Eur Respir J             | Efficacy and safety of twice-daily acclidinium bromide in COPD patients: the ATTAIN study.   | yes | omission    |
| B. Charbonnel <sup>148</sup>       | 2013 | Diabetologia             | Efficacy and safety over 26 weeks of an oral treatment strategy including sitagliptin compared with an injectable treatment strategy with liraglutide in patients with type 2 diabetes mellitus inadequately controlled on metformin: a randomised clinical trial. | no  |             |
| Rainard Fuhr <sup>149</sup>        | 2012 | Chest                    | Efficacy of acclidinium bromide 400 $\hat{I}$ g twice daily compared with placebo and tiotropium in patients with moderate to severe COPD.   | no  |             |
| Taciana Duque Braga <sup>150</sup> | 2011 | Am J Clin Nutr           | Efficacy of Bifidobacterium breve and Lactobacillus casei oral supplementation on necrotizing enterocolitis in very-low-birth-weight preterm infants: a double-blind, randomized, controlled trial   | no  |             |
| A.S. Papas <sup>151</sup>          | 2012 | J Dent Res               | Efficacy of chlorhexidine varnish for the prevention of adult caries: a randomized trial.  | no  |             |
| P Noel Barrett <sup>152</sup>      | 2011 | Lancet                   | Efficacy, safety, and immunogenicity of a Vero-cell-culture-derived trivalent influenza vaccine: a multicentre, double-blind, randomised, placebo-controlled trial.  | yes | omission    |
| T.M. Beer <sup>153</sup>           | 2014 | N Engl J Med             | Enzalutamide in metastatic prostate cancer before chemotherapy.  | no  |             |

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|---------------------------------------|------|------------------------------|---|-----|-------------|
| Philippe Jouve <sup>154</sup>         | 2013 | Anesthesiology               | Epidural versus continuous preperitoneal analgesia during fast-track open colorectal surgery: a randomized controlled trial.  | no  |             |
| W. SONGPRAKUN <sup>155</sup>          | 2012 | J Psychiatr Ment Health Nurs | Evaluation of a cognitive behavioural self-help manual for reducing depression: a randomized controlled trial.  | yes | omission    |
| Gaurang R Shah <sup>156</sup>         | 2012 | BMC Complement Altern Med    | Evaluation of a multi-herb supplement for erectile dysfunction: a randomized double-blind, placebo-controlled study.  | no  |             |
| Jeffrey Kaine <sup>157</sup>          | 2012 | Ann Rheum Dis                | Evaluation of abatacept administered subcutaneously in adults with active rheumatoid arthritis: impact of withdrawal and reintroduction on immunogenicity, efficacy and safety (phase IIb ALLOW study). | yes | omission    |
| Eric S. Orwoll <sup>158</sup>         | 2014 | J Clin Invest                | Evaluation of teriparatide treatment in adults with osteogenesis imperfecta.  | yes | new outcome |
| Alice D. Domar <sup>159</sup>         | 2015 | Fertil Steril                | Exploratory randomized trial on the effect of a brief psychological intervention on emotions, quality of life, discontinuation, and pregnancy rates in in vitro fertilization patients.                 | no  |             |
| D.L. Morton <sup>160</sup>            | 2014 | N Engl J Med                 | Final trial report of sentinel-node biopsy versus nodal observation in melanoma.  | yes | new outcome |
| Sanne K Poulsen <sup>161</sup>        | 2014 | Am J Clin Nutr               | Health effect of the New Nordic Diet in adults with increased waist circumference: a 6-mo randomized controlled trial.  | yes | omission    |
| Prabaharan Chellamuthu <sup>162</sup> | 2014 | Epilepsy Res                 | High dose (4 mg/kg/day) versus usual dose (2 mg/kg/day) oral prednisolone for treatment of infantile spasms: an open-label, randomized controlled trial.  | no  |             |
| Pierre Asfar <sup>163</sup>           | 2014 | N Engl J Med                 | High versus low blood-pressure target in patients with septic shock.  | no  |             |

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| Naoyoshi Nagata <sup>164</sup>       | 2015 | Ann Surg                     | High-dose barium impaction therapy for the recurrence of colonic diverticular bleeding: a randomized controlled trial.   | no  |              |
| S. Tiplady <sup>165</sup>            | 2013 | Hum Reprod                   | Home ovulation tests and stress in women trying to conceive: a randomized controlled trial.  | yes | omission     |
| Michael Teut <sup>166</sup>          | 2013 | Trials                       | Homeopathic drug proving of <i>Okoubaka aubrevillei</i> : a randomised placebo-controlled trial.   | no  |              |
| Clifton O Bingham III <sup>167</sup> | 2015 | Ann Rheum Dis                | Humoral immune response to vaccines in patients with rheumatoid arthritis treated with tocilizumab: results of a randomised controlled trial (VISARA).   | no  |              |
| Jörg Hausleiter <sup>168</sup>       | 2012 | JACC Cardiovasc Imaging      | Image quality and radiation exposure with prospectively ECG-triggered axial scanning for coronary CT angiography: the multicenter, multivendor, randomized PROTECTION-III study.   | no  |              |
| Feng-Cai Zhu <sup>169</sup>          | 2013 | Lancet                       | Immunogenicity and safety of an enterovirus 71 vaccine in healthy Chinese children and infants: a randomised, double-blind, placebo-controlled phase 2 clinical trial.   | yes | time changes |
| Peter Nash <sup>170</sup>            | 2013 | Arthritis Care Res (Hoboken) | Immunogenicity, safety, and efficacy of abatacept administered subcutaneously with or without background methotrexate in patients with rheumatoid arthritis: results from a phase III, international, multicenter, parallel-arm, open-label study. | no  |              |
| Howman, Andrew <sup>171</sup>        | 2013 | Lancet                       | Immunosuppression for progressive membranous nephropathy: a UK randomised controlled trial.  | no  |              |
| Romain Dugravier <sup>172</sup>      | 2013 | PLoS One                     | Impact of a manualized multifocal perinatal home-visiting program using psychologists on postnatal depression: the CAPEDP randomized controlled trial.   | yes | omission     |
| Annie Y S Lau <sup>173</sup>         | 2012 | J Am Med Inform Assoc        | Impact of a web-based personally controlled health management system on influenza vaccination and health services utilization rates: a randomized controlled trial.  | no  |              |

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|----------------------------------|------|-----------------------------|--|-----|--------------|
| Stephen M. Cohn <sup>174</sup>   | 2011 | World J Surg                | Impact of low-dose vasopressin on trauma outcome: prospective randomized study.  | yes | omission     |
| Swagata Ganguly <sup>175</sup>   | 2013 | Antimicrob Agents Chemother | In vivo therapeutic efficacy of chloroquine alone or in combination with primaquine against vivax malaria in Kolkata, West Bengal, India, and polymorphism in pvm-dr1 and pvcrt-o genes.   | yes | omission     |
| Timothy S. Walsh <sup>176</sup>  | 2015 | JAMA Intern Med             | Increased Hospital-Based Physical Rehabilitation and Information Provision After Intensive Care Unit Discharge: The RECOVER Randomized Clinical Trial.   | no  |              |
| Peter Hajek <sup>177</sup>       | 2015 | JAMA Intern Med             | Increasing varenicline dose in smokers who do not respond to the standard dosage: a randomized clinical trial.   | yes | time changes |
| Bruno Mourvillier <sup>178</sup> | 2013 | JAMA                        | Induced hypothermia in severe bacterial meningitis: a randomized clinical trial.   | no  |              |
| Jacqueline Detert <sup>179</sup> | 2013 | Ann Rheum Dis               | Induction therapy with adalimumab plus methotrexate for 24 weeks followed by methotrexate monotherapy up to week 48 versus methotrexate therapy alone for DMARD-naïve patients with early rheumatoid arthritis: HIT HARD, an investigator-initiated study. | no  |              |
| R. Ratner <sup>180</sup>         | 2011 | Diabetes Obes Metab         | Influence of preprandial vs. postprandial insulin glulisine on weight and glycaemic control in patients initiating basal-bolus regimen for type 2 diabetes: a multicenter, randomized, parallel, open-label study (NCT00135096).                           | no  |              |
| D. Bilton <sup>181</sup>         | 2011 | Eur Respir J                | Inhaled dry powder mannitol in cystic fibrosis: an efficacy and safety study.  | no  |              |
| Gwyneth Vance <sup>182</sup>     | 2014 | Health Policy Plan          | Integrating family planning messages into immunization services: a cluster-randomized trial in Ghana and Zambia.   | no  |              |
| Holger Thiele <sup>183</sup>     | 2012 | Lancet                      | Intracoronary versus intravenous bolus abciximab during primary percutaneous coronary intervention in patients with acute ST-elevation myocardial infarction: a randomised trial.  | no  |              |

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|-------------------------------------|------|-----------------------------|---|-----|--------------|
| J. Curtis Nickel <sup>184</sup>     | 2012 | J Urol                      | Investigation of a Ca <sup>2+</sup> channel $\alpha_2\delta_1$ ligand for the treatment of interstitial cystitis: results of a randomized, double-blind, placebo controlled phase II trial. | no  |              |
| F. Stephen Hodj <sup>185</sup>      | 2014 | JAMA                        | Ipilimumab plus sargramostim vs ipilimumab alone for treatment of metastatic melanoma: a randomized clinical trial.   | no  |              |
| Claire Harrison <sup>186</sup>      | 2012 | N Engl J Med                | JAK inhibition with ruxolitinib versus best available therapy for myelofibrosis.  | no  |              |
| Judith L. Kristeller <sup>187</sup> | 2013 | Pharmacotherapy             | Lack of effectiveness of sodium bicarbonate in preventing kidney injury in patients undergoing cardiac surgery: a randomized controlled trial.  | no  |              |
| Janet T. Holbrook <sup>188</sup>    | 2012 | JAMA                        | Lansoprazole for children with poorly controlled asthma: a randomized controlled trial.   | no  |              |
| Jean-Paul Galmiche <sup>189</sup>   | 2011 | JAMA                        | Laparoscopic antireflux surgery vs esomeprazole treatment for chronic GERD: the LOTUS randomized clinical trial.  | no  |              |
| Gavin J. Murphy <sup>190</sup>      | 2015 | N Engl J Med                | Liberal or restrictive transfusion after cardiac surgery.   | yes | new outcome  |
| Jeffrey L. Carson <sup>191</sup>    | 2011 | N Engl J Med                | Liberal or restrictive transfusion in high-risk patients after hip surgery.   | yes | new outcome  |
| N. Østerås <sup>192</sup>           | 2014 | Osteoarthritis<br>Cartilage | Limited effects of exercises in people with hand osteoarthritis: results from a randomized controlled trial.  | yes | time changes |
| Martin Fassnacht <sup>193</sup>     | 2015 | Lancet Oncol                | Linsitinib (OSI-906) versus placebo for patients with locally advanced or metastatic adrenocortical carcinoma: a double-blind, randomised, phase 3 study.                                   | no  |              |

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| Tom Van Herpe <sup>194</sup>       | 2013 | Diabetes Care             | LOGIC-insulin algorithm-guided versus nurse-directed blood glucose control during critical illness: the LOGIC-1 single-center, randomized, controlled clinical trial.  | no  |                      |
| Jean-Louis Pepin <sup>195</sup>    | 2014 | Chest                     | Long-acting bronchodilators and arterial stiffness in patients with COPD: a comparison of fluticasone furoate/vilanterol with tiotropium.  | no  |                      |
| Kenneth L. Subotnik <sup>196</sup> | 2015 | JAMA Psychiatry           | Long-Acting Injectable Risperidone for Relapse Prevention and Control of Breakthrough Symptoms After a Recent First Episode of Schizophrenia. A Randomized Clinical Trial.   | yes | secondary to primary |
| Moira L. Aitken <sup>197</sup>     | 2012 | Am J Respir Crit Care Med | Long-term inhaled dry powder mannitol in cystic fibrosis: an international randomized study.   | no  |                      |
| Roland Tubiana <sup>198</sup>      | 2013 | Clin Infect Dis           | Lopinavir/ritonavir monotherapy as a nucleoside analogue-sparing strategy to prevent HIV-1 mother-to-child transmission: the ANRS 135 PRIMEVA phase 2/3 randomized trial.  | no  |                      |
| JamesM. Chamberlain <sup>199</sup> | 2014 | JAMA                      | Lorazepam vs diazepam for pediatric status epilepticus: a randomized clinical trial.   | no  |                      |
| Timothy A. Brighton <sup>200</sup> | 2012 | N Engl J Med              | Low-dose aspirin for preventing recurrent venous thromboembolism.  | yes | new outcome          |
| Hong H. Chen <sup>201</sup>        | 2013 | JAMA                      | Low-dose dopamine or low-dose nesiritide in acute heart failure with renal dysfunction: the ROSE acute heart failure randomized trial.   | no  |                      |
| Frank Buttgereit <sup>202</sup>    | 2013 | Ann Rheum Dis             | Low-dose prednisone chronotherapy for rheumatoid arthritis: a randomised clinical trial (CAPRA-2).   | no  |                      |
| Joseph Gligorov <sup>203</sup>     | 2014 | Lancet Oncol              | Maintenance capecitabine and bevacizumab versus bevacizumab alone after initial first-line bevacizumab and docetaxel for patients with HER2-negative metastatic breast cancer (IMELDA): a randomised, open-label, phase 3 trial. | no  |                      |



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| Roger Stupp <sup>204</sup>            | 2015 | JAMA                       | Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial.  | no  |             |
| Martine Vercelletto <sup>205</sup>    | 2011 | J Alzheimers Dis           | Memantine in behavioral variant frontotemporal dementia: negative results.   | no  |             |
| Amitabh Chak <sup>206</sup>           | 2015 | Clin Gastroenterol Hepatol | Metformin does not reduce markers of cell proliferation in esophageal tissues of patients with Barrett's esophagus.  | no  |             |
| Axel Finckh <sup>207</sup>            | 2014 | Arthritis Res Ther         | Methotrexate in chronic-recurrent calcium pyrophosphate deposition disease: no significant effect in a randomized crossover trial.   | yes | omission    |
| Kate Hallsworth <sup>208</sup>        | 2015 | Clin Sci (Lond)            | Modified high-intensity interval training reduces liver fat and improves cardiac function in non-alcoholic fatty liver disease: a randomized controlled trial.   | yes | new outcome |
| Luis Ostrosky-Zeichner <sup>209</sup> | 2014 | Clin Infect Dis            | MSG-01: A randomized, double-blind, placebo-controlled trial of caspofungin prophylaxis followed by preemptive therapy for invasive candidiasis in high-risk adults in the critical care setting.            | no  |             |
| Carol E. Smith <sup>210</sup>         | 2014 | Heart Rhythm               | New image processing and noise reduction technology allows reduction of radiation exposure in complex electrophysiologic interventions while maintaining optimal image quality: a randomized clinical trial. | yes | new outcome |
| Lukas R.C.Dekker <sup>211</sup>       | 2013 | Gastroenterology           | No difference between high-fructose and high-glucose diets on liver triacylglycerol or biochemistry in healthy overweight men.   | no  |             |
| Alice K. Jacobs <sup>212</sup>        | 2013 | N Engl J Med               | Nonemergency PCI at hospitals with or without on-site cardiac surgery.   | no  |             |
| Jean-Christian Borel <sup>213</sup>   | 2012 | Chest                      | Noninvasive ventilation in mild obesity hypoventilation syndrome: a randomized controlled trial.   | no  |             |

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|-------------------------------------|------|----------------------------|---|-----|----------|
| Jan van Lunzen <sup>214</sup>       | 2012 | Lancet Infect Dis          | Once daily dolutegravir (S/GSK1349572) in combination therapy in antiretroviral-naive adults with HIV: planned interim 48 week results from SPRING-1, a dose-ranging, randomised, phase 2b trial.   | yes | omission |
| WILLIAM J. SANDBORN <sup>215</sup>  | 2012 | Gastroenterology           | Once-daily budesonide MMX <sup>®</sup> extended-release tablets induce remission in patients with mild to moderate ulcerative colitis: results from the CORE I study.   | no  |          |
| Nobuya Inagaki <sup>216</sup>       | 2015 | Lancet Diabetes Endocrinol | Once-weekly trelagliptin versus daily alogliptin in Japanese patients with type 2 diabetes: a randomised, double-blind, phase 3, non-inferiority study.   | no  |          |
| Heikki Joensuu <sup>217</sup>       | 2012 | JAMA                       | One vs three years of adjuvant imatinib for operable gastrointestinal stromal tumor: a randomized trial.  | no  |          |
| Tom Adriaenssens <sup>218</sup>     | 2014 | EuroIntervention           | Optical coherence tomography study of healing characteristics of paclitaxel-eluting balloons vs. everolimus-eluting stents for in-stent restenosis: the SEDUCE (Safety and Efficacy of a Drug eluting balloon in Coronary artery rEstenosis) randomised clinical trial. | yes | omission |
| Ambrose Agweyu <sup>219</sup>       | 2015 | Clin Infect Dis            | Oral amoxicillin versus benzyl penicillin for severe pneumonia among kenyan children: a pragmatic randomized controlled noninferiority trial.   | no  |          |
| Shirley S.L. Leung <sup>220</sup>   | 2011 | J Public Health (Oxf)      | Outcome of a postnatal depression screening programme using the Edinburgh Postnatal Depression Scale: a randomized controlled trial.  | yes | omission |
| Yong Sang Hong <sup>221</sup>       | 2014 | Lancet Oncol               | Oxaliplatin, fluorouracil, and leucovorin versus fluorouracil and leucovorin as adjuvant chemotherapy for locally advanced rectal cancer after preoperative chemoradiotherapy (ADORE): an open-label, multicentre, phase 2, randomised controlled trial.                | no  |          |
| Monique van Nielen <sup>222</sup>   | 2014 | J Nutr                     | Partly replacing meat protein with soy protein alters insulin resistance and blood lipids in postmenopausal women with abdominal obesity.   | no  |          |
| Sara Bristol Calvert <sup>223</sup> | 2012 | Am Heart J                 | Patient-focused intervention to improve long-term adherence to evidence-based medications: a randomized trial.  | no  |          |

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| Peter A Calabresi <sup>224</sup>            | 2014 | Lancet Neurol           | Pegylated interferon $\beta$ -1a for relapsing-remitting multiple sclerosis (ADVANCE): a randomised, phase 3, double-blind study.   | no  |              |
| Chen-Hua Liu <sup>225</sup>                 | 2013 | Ann Intern Med          | Pegylated interferon- $\beta$ 2a with or without low-dose ribavirin for treatment-naive patients with hepatitis C virus genotype 1 receiving hemodialysis: a randomized trial.  | yes | time changes |
| Jacqueline A. French <sup>226</sup>         | 2015 | Neurology               | Perampanel for tonic-clonic seizures in idiopathic generalized epilepsy A randomized trial.   | no  |              |
| LCDR Thomas Q. Gallagher <sup>227</sup>     | 2012 | JAMA                    | Perioperative dexamethasone administration and risk of bleeding following tonsillectomy in children: a randomized controlled trial.   | no  |              |
| Neena Duggal <sup>228</sup>                 | 2013 | Obstet Gynecol          | Perioperative oxygen supplementation and surgical site infection after cesarean delivery: a randomized trial.   | yes | new outcome  |
| Raffaele Marfella <sup>229</sup>            | 2012 | J Clin Endocrinol Metab | Peri-procedural tight glycemic control during early percutaneous coronary intervention is associated with a lower rate of in-stent restenosis in patients with acute ST-elevation myocardial infarction.  | no  |              |
| A. Ruzsa <sup>230</sup>                     | 2014 | Invest New Drugs        | Phase 2, open-label, 1:1 randomized controlled trial exploring the efficacy of EMD 1201081 in combination with cetuximab in second-line cetuximab-naïve patients with recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN). | no  |              |
| Andreas Pfu <sup>tzner</sup> <sup>231</sup> | 2011 | Diabetes Technol Ther   | PIOfix-study: effects of pioglitazone/metformin fixed combination in comparison with a combination of metformin with glimepiride on diabetic dyslipidemia.  | no  |              |
| Ping-Yen Liu <sup>232</sup>                 | 2013 | PLoS One                | Pitavastatin and Atorvastatin double-blind randomized comparative study among high-risk patients, including those with Type 2 diabetes mellitus, in Taiwan (PAPAGO-T Study).  | no  |              |
| Michelle A. O. Kinney <sup>233</sup>        | 2012 | Pain Pract              | Preoperative gabapentin for acute post-thoracotomy analgesia: a randomized, double-blinded, active placebo-controlled study.  | no  |              |

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| James M Scheiman <sup>234</sup>        | 2011 | Heart  | Prevention of peptic ulcers with esomeprazole in patients at risk of ulcer development treated with low-dose acetylsalicylic acid: a randomised, controlled trial (OBERON).  | no  |             |
| Ian T. Meredith <sup>235</sup>         | 2012 | J Am Coll Cardiol  | Primary endpoint results of the EVOLVE trial: a randomized evaluation of a novel bioabsorbable polymer-coated, everolimus-eluting coronary stent.  | no  |             |
| Ralph G. Zinner <sup>236</sup>         | 2015 | J Thorac Oncol   | PRONOUNCE: randomized, open-label, phase III study of first-line pemetrexed + carboplatin followed by maintenance pemetrexed versus paclitaxel + carboplatin + bevacizumab followed by maintenance bevacizumab in patients with advanced nonsquamous non-small-cell lung cancer. | no  |             |
| Kyoung Heo <sup>237</sup>              | 2014 | J Korean Med Sci   | Pro+E1092 prophylactic effect of erythropoietin injection to prevent acute mountain sickness: an open-label randomized controlled trial.   | yes | omission    |
| Mario A. Rojas <sup>238</sup>          | 2012 | Pediatrics   | Prophylactic probiotics to prevent death and nosocomial infection in preterm infants.  | no  |             |
| Roman Prymula <sup>239</sup>           | 2014 | Lancet   | Protection against varicella with two doses of combined measles-mumps-rubella-varicella vaccine versus one dose of monovalent varicella vaccine: a multicentre, observer-blind, randomised, controlled trial.  | yes | omission    |
| Tim R H Read <sup>240</sup>            | 2013 | BMJ  | Provision of rapid HIV tests within a health service and frequency of HIV testing among men who have sex with men: randomised controlled trial.  | no  |             |
| Diego Galace de Freitas <sup>241</sup> | 2014 | Arch Phys Med Rehabil  | Pulsed electromagnetic field and exercises in patients with shoulder impingement syndrome: a randomized, double-blind, placebo-controlled clinical trial.  | yes | new outcome |
| Gilda Kianimehr <sup>242</sup>         | 2014 | Daru : journal of Faculty of Pharmacy, Tehran University of Medical Sciences | Raloxifene adjunctive therapy for postmenopausal women suffering from chronic schizophrenia: a randomized double-blind and placebo controlled trial.   | no  |             |
| J.J. De Waele <sup>243</sup>           | 2013 | Int J Antimicrob Agents  | Randomised clinical trial of moxifloxacin versus ertapenem in complicated intra-abdominal infections: results of the PROMISE study.  | no  |             |

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|---------------------------------------|------|------------------|---|-----|-------------|
| Niels R. Holm <sup>244</sup>          | 2014 | EuroIntervention | Randomised comparison of manual compression and FemoSeal <sup>®</sup> , a vascular closure device for closure after femoral artery access coronary angiography: the CLOSure dEVICES Used in everyday Practice (CLOSE-UP) study.                   | no  |             |
| Sharon E Cox <sup>245</sup>           | 2013 | BMJ Open         | Randomised controlled trial of weekly chloroquine to re-establish normal erythron iron flux and haemoglobin recovery in postmalarial anaemia.   | no  |             |
| Paramdeep Singh Bilkhu <sup>246</sup> | 2014 | Br J Ophthalmol  | Randomised masked clinical trial of the MGDRx EyeBag for the treatment of meibomian gland dysfunction-related evaporative dry eye.  | yes | new outcome |
| J Souglakos <sup>247</sup>            | 2012 | Br J Cancer      | Randomised phase-II trial of CAPIRI (capecitabine, irinotecan) plus bevacizumab vs FOLFIRI (folinic acid, 5-fluorouracil, irinotecan) plus bevacizumab as first-line treatment of patients with unresectable/metastatic colorectal cancer (mCRC). | yes | new outcome |
| Patricia Echeverri <sup>248</sup>     | 2014 | PLoS One         | Randomised study to assess the efficacy and safety of once-daily etravirine-based regimen as a switching strategy in HIV-infected patients receiving a protease inhibitor-containing regimen. Etraswitch study.                                   | no  |             |
| A. M. Wolthuis <sup>249</sup>         | 2015 | Br J Surg        | Randomized clinical trial of laparoscopic colectomy with or without natural-orifice specimen extraction.  | no  |             |
| L. S. Sorensen <sup>250</sup>         | 2013 | Br J Surg        | Randomized clinical trial of perioperative omega-3 fatty acid supplements in elective colorectal cancer surgery.  | no  |             |
| Ning Liu <sup>251</sup>               | 2014 | Stroke           | Randomized controlled trial of early rehabilitation after intracerebral hemorrhage stroke: difference in outcomes within 6 months of stroke.  | no  |             |
| Yi-Hsiang Huang <sup>252</sup>        | 2013 | J Clin Oncol     | Randomized controlled trial of entecavir prophylaxis for rituximab-associated hepatitis B virus reactivation in patients with lymphoma and resolved hepatitis B.  | no  |             |
| P. T. McCollum <sup>253</sup>         | 2011 | Br J Surg        | Randomized phase II clinical trial of avotermin versus placebo for scar improvement.  | yes | omission    |

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|---|------|-----------------------------|---|-----|-------------|
| Chigusa Morizane <sup>254</sup>         | 2013 | Cancer Sci                  | Randomized phase II study of gemcitabine plus S-1 versus S-1 in advanced biliary tract cancer: a Japan Clinical Oncology Group trial (JCOG 0805).   | no  |             |
| Robert D Reid <sup>255</sup>            | 2011 | Eur J Prev Cardiol          | Randomized trial of an internet-based computer-tailored expert system for physical activity in patients with heart disease.   | yes | omission    |
| Jean-Pierre Bronowicki <sup>256</sup>   | 2014 | J Hepatol                   | Randomized trial of asunaprevir plus peginterferon alfa and ribavirin for previously untreated genotype 1 or 4 chronic hepatitis C.   | no  |             |
| Nathalie Bocquet <sup>257</sup>         | 2012 | Pediatrics                  | Randomized trial of oral versus sequential IV/oral antibiotic for acute pyelonephritis in children.   | no  |             |
| K. Steindorf <sup>258</sup>             | 2014 | Ann Oncol                   | Randomized, controlled trial of resistance training in breast cancer patients receiving adjuvant radiotherapy: results on cancer-related fatigue and quality of life.   | no  |             |
| Peter V. Draganov <sup>259</sup>        | 2012 | Gastrointest Endosc         | Randomized, controlled trial of standard, large-capacity versus jumbo biopsy forceps for polypectomy of small, sessile, colorectal polyps.  | no  |             |
| David Oldach <sup>260</sup>             | 2013 | Antimicrob Agents Chemother | Randomized, double-blind, multicenter phase 2 study comparing the efficacy and safety of oral solithromycin (CEM-101) to those of oral levofloxacin in the treatment of patients with community-acquired bacterial pneumonia.             | no  |             |
| Martin Bornhäuser <sup>261</sup>        | 2012 | Lancet Oncol                | Reduced-intensity conditioning versus standard conditioning before allogeneic haemopoietic cell transplantation in patients with acute myeloid leukaemia in first complete remission: a prospective, open-label randomised phase 3 trial. | no  |             |
| Kristina Dupont Hougaard <sup>262</sup> | 2014 | Stroke                      | Remote ischemic preconditioning as an adjunct therapy to thrombolysis in patients with acute ischemic stroke: a randomized trial.   | yes | new outcome |
| Timo Vesikari <sup>263</sup>            | 2011 | Clin Vaccine Immunol        | Results from a randomized clinical trial of coadministration of RotaTeq, a pentavalent rotavirus vaccine, and NeisVac-C, a meningococcal serogroup C conjugate vaccine.   | no  |             |

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|---|------|-------------------------------|---|-----|----------|
| Cheryl L. Rock <sup>264</sup>             | 2015 | J Clin Oncol                  | Results of the Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) Trial: A Behavioral Weight Loss Intervention in Overweight or Obese Breast Cancer Survivors.   | no  |          |
| Sanne M. van der Made <sup>265</sup>      | 2015 | PLoS One                      | Resveratrol does not influence metabolic risk markers related to cardiovascular health in overweight and slightly obese subjects: a randomized, placebo-controlled crossover trial.   | no  |          |
| Te-Fa Chiu <sup>266</sup>                 | 2013 | BMC Complement Altern Med     | Rhodiola crenulata extract for prevention of acute mountain sickness: a randomized, double-blind, placebo-controlled, crossover trial.  | no  |          |
| Timothy Iveson <sup>267</sup>             | 2014 | Lancet Oncol                  | Rilotumumab in combination with epirubicin, cisplatin, and capecitabine as first-line treatment for gastric or oesophagogastric junction adenocarcinoma: an open-label, dose de-escalation phase 1b study and a double-blind, randomised phase 2 study. | no  |          |
| Jolien E J Boesten <sup>268</sup>         | 2012 | Fam Pract                     | Rimonabant improves obesity but not the overall cardiovascular risk and quality of life; results from CARDIO-REDUSE (CArdiometabolic Risk reDuctiOn by Rimonabant: the Effectiveness in Daily practice and its USE).                                    | yes | omission |
| Hossein-Ardeschir Ghofrani <sup>269</sup> | 2013 | N Engl J Med                  | Riociguat for the treatment of chronic thromboembolic pulmonary hypertension.   | no  |          |
| L. Guillevin <sup>270</sup>               | 2014 | N Engl J Med                  | Rituximab versus azathioprine for maintenance in ANCA-associated vasculitis.  | no  |          |
| David Devos <sup>271</sup>                | 2013 | J Neurol Neurosurg Psychiatry | Rivastigmine in apathetic but dementia and depression-free patients with Parkinson's disease: a double-blind, placebo-controlled, randomised clinical trial.  | no  |          |
| Lorenzo Capussotti <sup>272</sup>         | 2012 | J Gastrointest Surg           | Routine anterior approach during right hepatectomy: results of a prospective randomised controlled trial.   | no  |          |
| J M Munster <sup>273</sup>                | 2013 | Euro Surveill                 | Routine screening for <i>Coxiella burnetii</i> infection during pregnancy: a clustered randomised controlled trial during an outbreak, the Netherlands, 2010.   | no  |          |

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|---------------------------------|------|--|--|-----|--------------|
| J. McCready <sup>274</sup>      | 2014 | Europace                                       | Safety and efficacy of multipolar pulmonary vein ablation catheter vs. irrigated radiofrequency ablation for paroxysmal atrial fibrillation: a randomized multicentre trial.   | yes | omission     |
| W. Rigby <sup>275</sup>         | 2012 | Arthritis Rheum                                | Safety and efficacy of ocrelizumab in patients with rheumatoid arthritis and an inadequate response to methotrexate: results of a forty-eight-week randomized, double-blind, placebo-controlled, parallel-group phase III trial.                                       | no  |              |
| GE Gray <sup>276</sup>          | 2011 | Lancet Infect Dis                              | Safety and efficacy of the HVTN 503/Phambili study of a clade-B-based HIV-1 vaccine in South Africa: a double-blind, randomised, placebo-controlled test-of-concept phase 2b study.  | no  |              |
| Mario Siebler <sup>277</sup>    | 2011 | Stroke   | Safety of Tirofiban in acute Ischemic Stroke: the SaTIS trial.   | no  |              |
| Olivier Sitbon <sup>278</sup>   | 2015 | N Engl J Med                                   | Selexipag for the Treatment of Pulmonary Arterial Hypertension.  | no  |              |
| Manna Zhang <sup>279</sup>      | 2015 | J Clin Endocrinol Metab                        | Sequential Versus Continual Purified Urinary FSH/hCG in Men With Idiopathic Hypogonadotropic Hypogonadism.   | no  |              |
| Rachel Jenkins <sup>280</sup>   | 2013 | International Journal of Mental Health Systems | Short structured general mental health in service training programme in Kenya improves patient health and social outcomes but not detection of mental health problems - a pragmatic cluster randomised controlled trial.   | yes | new outcomes |
| Arkaitz Imaz <sup>281</sup>     | 2013 | Antivir Ther                                   | Short-term and long-term clinical and immunological consequences of stopping antiretroviral therapy in HIV-infected patients with preserved immune function.   | yes | new outcome  |
| James W Denham <sup>282</sup>   | 2014 | Lancet Oncol                                   | Short-term androgen suppression and radiotherapy versus intermediate-term androgen suppression and radiotherapy, with or without zoledronic acid, in men with locally advanced prostate cancer (TROG 03.04 RADAR): an open-label, randomised, phase 3 factorial trial. | yes | omission     |
| Mads J. Andersen <sup>283</sup> | 2013 | Circulation                                    | Sildenafil and diastolic dysfunction after acute myocardial infarction in patients with preserved ejection fraction: the Sildenafil and Diastolic Dysfunction After Acute Myocardial Infarction (SIDAMI) trial.  | yes | omission     |



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|----------------------------------|------|------------------------------|--|-----|--------------|
| Seung Tae Kim <sup>284</sup>     | 2014 | Eur J Cancer                 | Simvastatin plus capecitabine-cisplatin versus placebo plus capecitabine-cisplatin in patients with previously untreated advanced gastric cancer: a double-blind randomised phase 3 study. | no  |              |
| S. Friman <sup>285</sup>         | 2011 | Am J Transplant              | Sostrastaurin, a novel small molecule inhibiting protein-kinase C: randomized phase II study in renal transplant recipients.   | no  |              |
| Ian M Gralnek <sup>286</sup>     | 2014 | Lancet Oncol                 | Standard forward-viewing colonoscopy versus full-spectrum endoscopy: an international, multicentre, randomised, tandem colonoscopy trial.  | yes | new outcome  |
| Ashlesha Patel <sup>287</sup>    | 2014 | Vaccine                      | Staying on track: a cluster randomized controlled trial of automated reminders aimed at increasing human papillomavirus vaccine completion.  | yes | time changes |
| Edoardo Camenzind <sup>288</sup> | 2012 | Lancet                       | Stent thrombosis and major clinical events at 3 years after zotarolimus-eluting or sirolimus-eluting coronary stent implantation: a randomised, multicentre, open-label, controlled trial. | no  |              |
| ALAN KIVITZ <sup>289</sup>       | 2014 | Arthritis Care Res (Hoboken) | Subcutaneous tocilizumab versus placebo in combination with disease-modifying antirheumatic drugs in patients with rheumatoid arthritis.   | no  |              |
| P.K. Smith <sup>290</sup>        | 2014 | N Engl J Med                 | Surgical treatment of moderate ischemic mitral regurgitation.  | no  |              |
| A. Dhanya Mackeen <sup>291</sup> | 2014 | Obstet Gynecol               | Suture compared with staple skin closure after cesarean delivery: a randomized controlled trial.   | yes | new outcome  |
| Gonzague Jourdain <sup>292</sup> | 2013 | PLoS Med                     | Switching HIV treatment in adults based on CD4 count versus viral load monitoring: a randomized, non-inferiority trial in Thailand.  | no  |              |
| Yong-Chul Kim <sup>293</sup>     | 2013 | PLoS One                     | Tacrolimus decreases albuminuria in patients with IgA nephropathy and normal blood pressure: a double-blind randomized controlled trial of efficacy of tacrolimus on IgA nephropathy.      | no  |              |

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|------------------------------------|------|------------------------|---|-----|--------------|
| David Biondi <sup>294</sup>        | 2013 | Pain Physician         | Tapentadol immediate release versus oxycodone immediate release for treatment of acute low back pain.   | yes | time changes |
| Lisanne M Verweij <sup>295</sup>   | 2012 | Occup Environ Med      | The application of an occupational health guideline reduces sedentary behaviour and increases fruit intake at work: results from an RCT.                          | yes | omission     |
| George Ou <sup>296</sup>           | 2014 | Gastrointest Endosc    | The effect of chewing gum on small-bowel transit time in capsule endoscopy: a prospective, randomized trial.  | no  |              |
| Ilsoon Son <sup>297</sup>          | 2014 | ScientificWorldJournal | The effect of sufentanil administration on remifentanil-based anaesthesia during laparoscopic gynaecological surgery: a double-blind randomized controlled trial. | yes | omission     |
| Brian R Leaker <sup>298</sup>      | 2014 | BMC Pulm Med           | The effect of the novel phosphodiesterase-4 inhibitor MEM 1414 on the allergen induced responses in mild asthma.  | yes | new outcome  |
| Julie Kinley <sup>299</sup>        | 2014 | Palliat Med            | The effect of using high facilitation when implementing the Gold Standards Framework in Care Homes programme: a cluster randomised controlled trial.              | no  |              |
| James A. Blumenthal <sup>300</sup> | 2014 | Psychosom Med          | The effects of a telehealth coping skills intervention on outcomes in chronic obstructive pulmonary disease: primary results from the INSPIRE-II study.           | no  |              |
| Eun Bong Lee <sup>301</sup>        | 2014 | N Engl J Med           | Tofacitinib versus methotrexate in rheumatoid arthritis.  | yes | omission     |
| Silvio Danese <sup>302</sup>       | 2015 | Gut                    | Tralokinumab for moderate-to-severe UC: a randomised, double-blind, placebo-controlled, phase IIa study.  | no  |              |
| BW Prick <sup>303</sup>            | 2014 | BJOG                   | Transfusion policy after severe postpartum haemorrhage: a randomised non-inferiority trial.   | no  |              |

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|--|------|---------------------|---|-----|--------------|
| W. Jack Rejeski <sup>304</sup>         | 2011 | Arch Intern Med     | Translating weight loss and physical activity programs into the community to preserve mobility in older, obese adults in poor cardiovascular health.  | yes | new outcome  |
| Maggie C Walter <sup>305</sup>         | 2013 | Orphanet J Rare Dis | Treatment of dysferlinopathy with deflazacort: a double-blind, placebo-controlled clinical trial.   | no  |              |
| Ploenchan Chetchotisakd <sup>306</sup> | 2014 | Lancet              | Trimethoprim-sulfamethoxazole versus trimethoprim-sulfamethoxazole plus doxycycline as oral eradication treatment for melioidosis (MERTH): a multicentre, double-blind, non-inferiority, randomised controlled trial. | yes | omission     |
| Marieke L Duiverman <sup>307</sup>     | 2011 | Respir Res          | Two-year home-based nocturnal noninvasive ventilation added to rehabilitation in chronic obstructive pulmonary disease patients: a randomized controlled trial.   | no  |              |
| Lucy C Chappell <sup>308</sup>         | 2012 | BMJ                 | Ursodeoxycholic acid versus placebo, and early term delivery versus expectant management, in women with intrahepatic cholestasis of pregnancy: semifactorial randomised clinical trial.                               | no  |              |
| John B. Buse <sup>309</sup>            | 2011 | Ann Intern Med      | Use of twice-daily exenatide in Basal insulin-treated patients with type 2 diabetes: a randomized, controlled trial.  | no  |              |
| Tae Joon Yi <sup>310</sup>             | 2014 | J Infect Dis        | Valacyclovir therapy does not reverse herpes-associated alterations in cervical immunology: a randomized, placebo-controlled crossover trial.   | yes | time changes |
| Michael Larsen <sup>311</sup>          | 2012 | Ophthalmology       | Verteporfin plus ranibizumab for choroidal neovascularization in age-related macular degeneration: twelve-month MONT BLANC study results.   | no  |              |
| Tzu-Chieh Yu <sup>312</sup>            | 2013 | Ann Surg            | Warm, humidified carbon dioxide gas insufflation for laparoscopic appendectomy in children: a double-blinded randomized controlled trial.   | yes | omission     |
| Marco Valgimigli <sup>313</sup>        | 2015 | J Am Coll Cardiol   | Zotarolimus-eluting versus bare-metal stents in uncertain drug-eluting stent candidates.  | no  |              |

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|--------------------------------------|------|--|--|-----|----------|
| John G.F. Cleland <sup>314</sup>     | 2011 | Eur J Heart Fail                                 | The Heart Failure Revascularisation Trial (HEART).   | no  |          |
| Fa'bio Coelho Guarany <sup>315</sup> | 2013 | PLoS One   | A double-blind, randomised, crossover trial of two botulinum toxin type a in patients with spasticity.   | no  |          |
| N. Blanch <sup>316</sup>             | 2014 | Nutr Metab Cardiovasc Dis                        | Effect of high potassium diet on endothelial function.   | no  |          |
| Kevin C. Maki <sup>317</sup>         | 2011 | J Cardiovasc Pharmacol                           | Effects of prescription omega-3-acid ethyl esters on fasting lipid profile in subjects with primary hypercholesterolemia.  | yes | omission |
| Ari Shechter <sup>318</sup>          | 2013 | Am J Clin Nutr                                   | Experimental sleep curtailment causes wake-dependent increases in 24-h energy expenditure as measured by whole-room indirect calorimetry.  | yes | omission |
| Elizabeth A Green <sup>319</sup>     | 2014 | Cardiovasc Ther                                  | Melatonin reduces tachycardia in postural tachycardia syndrome: a randomized, crossover trial.   | no  |          |
| Helen Vlassara <sup>320</sup>        | 2012 | Clin J Am Soc Nephrol                            | Effects of sevelamer on HbA1c, inflammation, and advanced glycation end products in diabetic kidney disease.   | yes | omission |
| A.Nadjarzadeh <sup>321</sup>         | 2011 | J Endocrinol Invest                              | Coenzyme Q10 improves seminal oxidative defense but does not affect on semen parameters in idiopathic oligoasthenoteratozoospermia: a randomized double-blind, placebo controlled trial. | yes | omission |
| Nasrin Saharkhiz <sup>322</sup>      | 2014 | International Journal of Fertility and Sterility | Comparison between conventional blind embryo transfer and embryo transfer based on previously measured uterine length.   | yes | omission |
| Mads Buhl <sup>323</sup>             | 2013 | J Clin Endocrinol Metab                          | Direct effects of locally administered lipopolysaccharide on glucose, lipid, and protein metabolism in the placebo-controlled, bilaterally infused human leg.                            | yes | omission |

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|---|------|---|--|-----|-------------|
| Morten Petersen <sup>324</sup>                      | 2012 | Clin Exp Pharmacol<br>Physiol               | Effect of the Arg389Gly $\beta_2$ -adrenoceptor polymorphism on plasma renin activity and heart rate, and the genotype-dependent response to metoprolol treatment.                               | yes | omission    |
| Deok Man Hong <sup>325</sup>                        | 2012 | Circ J                                      | Effects of remote ischemic preconditioning with postconditioning in patients undergoing off-pump coronary artery bypass surgery--randomized controlled trial.                                    | no  |             |
| Ellen L. Poleshuck <sup>326</sup>                   | 2014 | J Psychosom Res                             | Randomized controlled trial of interpersonal psychotherapy versus enhanced treatment as usual for women with co-occurring depression and pelvic pain.  | no  |             |
| Kamalesh J. Ramaiya <sup>327</sup>                  | 2013 | Ophthalmic Surg<br>Lasers Imaging<br>Retina | Ranibizumab versus photodynamic therapy for presumed ocular histoplasmosis syndrome.   | no  |             |
| Sarajini Maria Dos Remedios Monteiro <sup>328</sup> | 2014 | Prev Med                                    | Results of a randomized controlled trial to promote physical activity behaviours in mothers with young children.   | yes | omission    |
| Marc-Dennan Tensil <sup>329</sup>                   | 2013 | J Med Internet Res                          | Two fully automated web-based interventions for risky alcohol use: randomized controlled trial.  | yes | omission    |
| Eva Van Braeckel <sup>330</sup>                     | 2011 | Clin Infect Dis                             | An adjuvanted polyprotein HIV-1 vaccine induces polyfunctional cross-reactive CD4+ T cell responses in seronegative volunteers   | yes | omission    |
| R Landewé <sup>331</sup>                            | 2013 | Ann Rheum Dis                               | Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. | no  |             |
| BRUCE E. SANDS <sup>332</sup>                       | 2012 | Gastroenterology                            | Basiliximab does not increase efficacy of corticosteroids in patients with steroid-refractory ulcerative colitis.  | yes | new outcome |
| Banny S. Wong <sup>333</sup>                        | 2011 | Am J Gastroenterol                          | Effects of A3309, an ileal bile acid transporter inhibitor, on colonic transit and symptoms in females with functional constipation.   | no  |             |

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|---|------|---------------------------|--|-----|-------------|
| Otilia-Constantina Rogoveanu <sup>334</sup> | 2015 | Biol Trace Elem Res       | Effects of Calcium Fructoborate on Levels of C-Reactive Protein, Total Cholesterol, Low-Density Lipoprotein, Triglycerides, IL-1 $\beta$ , IL-6, and MCP-1: a Double-blind, Placebo-controlled Clinical Study. | yes | omission    |
| Edward M. Kerwin <sup>335</sup>             | 2012 | COPD                      | Efficacy and safety of a 12-week treatment with twice-daily acclidinium bromide in COPD patients (ACCORD COPD I).  | no  |             |
| Vik Khullar <sup>336</sup>                  | 2013 | Eur Urol                  | Efficacy and tolerability of mirabegron, a $\beta$ (3)-adrenoceptor agonist, in patients with overactive bladder: results from a randomised European-Australian phase 3 trial.                                 | no  |             |
| PING-I HSU <sup>337</sup>                   | 2011 | Gastroenterology          | Esomeprazole with clopidogrel reduces peptic ulcer recurrence, compared with clopidogrel alone, in patients with atherosclerosis.  | no  |             |
| Julian M. Somers <sup>338</sup>             | 2013 | PLoS One                  | Housing first reduces re-offending among formerly homeless adults with mental disorders: results of a randomized controlled trial.   | yes | new outcome |
| L.A. Ferrara <sup>339</sup>                 | 2015 | Nutr Metab Cardiovasc Dis | Low-lipid diet reduces frequency and severity of acute migraine attacks.   | yes | omission    |
| Michael A Roussel <sup>340</sup>            | 2012 | Am J Clin Nutr            | Beef in an Optimal Lean Diet study: effects on lipids, lipoproteins, and apolipoproteins.  | yes | omission    |
| T. R. Andersen <sup>341</sup>               | 2014 | Scand J Med Sci Sports    | Effect of football or strength training on functional ability and physical performance in untrained old men.   | yes | omission    |
| Adrienne Birnbaum <sup>342</sup>            | 2012 | Acad Emerg Med            | Efficacy of patient-controlled analgesia for patients with acute abdominal pain in the emergency department: a randomized trial.   | yes | omission    |
| Allison E. Aiello <sup>343</sup>            | 2012 | PLoS One                  | Facemasks, hand hygiene, and influenza among young adults: a randomized intervention trial.  | yes | new outcome |

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|---|------|-----------------------------|---|-----|--------------|
| Patricia M. Flynn <sup>344</sup>        | 2011 | J Acquir Immune Defic Syndr | Hepatitis B vaccination in HIV-infected youth: a randomized trial of three regimens.  | no  |              |
| Lindy Clemson <sup>345</sup>            | 2012 | BMJ                         | Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): randomised parallel trial.  | no  |              |
| André Robidoux <sup>346</sup>           | 2013 | Lancet Oncol                | Lapatinib as a component of neoadjuvant therapy for HER2-positive operable breast cancer (NSABP protocol B-41): an open-label, randomised phase 3 trial.  | no  |              |
| Joachim von Pawel <sup>347</sup>        | 2014 | Clin Lung Cancer            | Phase II trial of mapatumumab, a fully human agonist monoclonal antibody to tumor necrosis factor-related apoptosis-inducing ligand receptor 1 (TRAIL-R1), in combination with paclitaxel and carboplatin in patients with advanced non-small-cell lung cancer. | no  |              |
| Tanya Simuni <sup>348</sup>             | 2015 | Lancet Neurol               | Pioglitazone in early Parkinson's disease: a phase 2, multicentre, double-blind, randomised trial.  | no  |              |
| Tonine Bartelmaos <sup>349</sup>        | 2013 | Transfusion                 | Plasma transfusion in liver transplantation: a randomized, double-blind, multicenter clinical comparison of three virally secured plasmas.  | no  |              |
| Masunori Matsuzaki <sup>350</sup>       | 2011 | J Hypertens                 | Prevention of cardiovascular events with calcium channel blocker-based combination therapies in patients with hypertension: a randomized controlled trial.  | no  |              |
| Michael J Yelland <sup>351</sup>        | 2011 | Br J Sports Med             | Prolotherapy injections and eccentric loading exercises for painful Achilles tendinosis: a randomised trial.  | yes | time changes |
| Deborah S. Hasin <sup>352</sup>         | 2013 | Addiction                   | Reducing heavy drinking in HIV primary care: a randomized trial of brief intervention, with and without technological enhancement.  | yes | omission     |
| Veerachai Watanaveeradej <sup>353</sup> | 2014 | Am J Trop Med Hyg           | Safety and immunogenicity of a rederived, live-attenuated dengue virus vaccine in healthy adults living in Thailand: a randomized trial.  | yes | omission     |

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|----------------------------------|------|---------------------------|---|-----|----------|
| Jacques p. Barber <sup>354</sup> | 2012 | J Clin Psychiatry         | Short-term dynamic psychotherapy versus pharmacotherapy for major depressive disorder: a randomized, placebo-controlled trial.  | yes | omission |
| Paul Emery <sup>355</sup>        | 2014 | N Engl J Med              | Sustained remission with etanercept tapering in early rheumatoid arthritis.   | no  |          |
| Sylvie Négrier <sup>356</sup>    | 2011 | Lancet Oncol              | Temsirolimus and bevacizumab, or sunitinib, or interferon alfa and bevacizumab for patients with advanced renal cell carcinoma (TORAVA): a randomised phase 2 trial.  | no  |          |
| Mitsuru Adachi <sup>357</sup>    | 2012 | J Asthma                  | The efficacy and tolerability of intravenous montelukast in acute asthma exacerbations in Japanese patients.  | no  |          |
| Mary Kay Koenig <sup>358</sup>   | 2012 | Drugs R D                 | Topical rapamycin therapy to alleviate the cutaneous manifestations of tuberous sclerosis complex: a double-blind, randomized, controlled trial to evaluate the safety and efficacy of topically applied rapamycin. | yes | omission |
| Jacques Donnez <sup>359</sup>    | 2012 | N Engl J Med              | Ulipristal acetate versus leuprolide acetate for uterine fibroids.  | no  |          |
| Kishore M. Gadde <sup>360</sup>  | 2012 | Arch Intern Med           | Zonisamide for weight reduction in obese adults: a 1-year randomized controlled trial.  | no  |          |
| Donald A. Mahler <sup>361</sup>  | 2014 | Eur Respir J              | Dual bronchodilation with QVA149 reduces patient-reported dyspnoea in COPD: the BLAZE study.  | no  |          |
| Paul L.Jacobsen <sup>362</sup>   | 2015 | J Clin Psychiatry         | A randomized, double-blind, placebo-controlled study of the efficacy and safety of 2 doses of vortioxetine in adults with major depressive disorder.  | no  |          |
| Chuan-Mo Lee <sup>363</sup>      | 2014 | J Interferon Cytokine Res | A double-blind randomized controlled study to evaluate the efficacy of low-dose oral interferon-alpha in preventing hepatitis C relapse.  | no  |          |



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|--|------|------------------------------|---|-----|-------------|
| Richard D. Blondell <sup>364</sup>     | 2011 | J Addict Dis                 | A randomized trial of two behavioral interventions to improve outcomes following inpatient detoxification for alcohol dependence.   | no  |             |
| Christian Torp-Pedersen <sup>365</sup> | 2011 | Circ Arrhythm Electrophysiol | A randomized, placebo-controlled study of vernakalant (oral) for the prevention of atrial fibrillation recurrence after cardioversion.  | no  |             |
| Lori A. Bateman <sup>366</sup>         | 2011 | Am J Cardiol                 | Comparison of aerobic versus resistance exercise training effects on metabolic syndrome (from the Studies of a Targeted Risk Reduction Intervention Through Defined Exercise - STRRIDE-AT/RT).  | yes | omission    |
| Richard D. Blondell <sup>367</sup>     | 2011 | Respir Med                   | Contrasting breathing retraining and helium-oxygen during pulmonary rehabilitation in COPD: a randomized clinical trial.  | no  |             |
| Michal G Ison <sup>368</sup>           | 2012 | Antivir Ther                 | Efficacy and safety of oral oseltamivir for influenza prophylaxis in transplant recipients.   | no  |             |
| William C. Cushman <sup>369</sup>      | 2012 | Hypertension                 | Azilsartan medoxomil plus chlorthalidone reduces blood pressure more effectively than olmesartan plus hydrochlorothiazide in stage 2 systolic hypertension.   | no  |             |
| Christopher W Teshima <sup>370</sup>   | 2014 | World J Gastroenterol        | Magnetic imaging-assisted colonoscopy vs conventional colonoscopy: a randomized controlled trial.   | yes | new outcome |
| N. Galiè <sup>371</sup>                | 2015 | N Engl J Med                 | Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension.   | no  |             |
| Ragaa Mansour <sup>372</sup>           | 2011 | Fertil Steril                | Intrauterine injection of human chorionic gonadotropin before embryo transfer significantly improves the implantation and pregnancy rates in in vitro fertilization/intracytoplasmic sperm injection: a prospective randomized study. | no  |             |
| Guoqing Qian <sup>373</sup>            | 2012 | PLoS One                     | Mitigation of oxidative damage by green tea polyphenols and Tai Chi exercise in postmenopausal women with osteopenia.   | yes | new outcome |

|                                     |      |                          |  |     |             |
|-------------------------------------|------|--------------------------|--|-----|-------------|
| Kevin Patrick <sup>374</sup>        | 2013 | J Diabetes Sci Technol   | Outcomes of a 12-month technology-based intervention to promote weight loss in adolescents at risk for type 2 diabetes.  | no  |             |
| Norman A Constantine <sup>375</sup> | 2015 | BMC Public Health        | Short-term effects of a rights-based sexuality education curriculum for high-school students: a cluster-randomized trial.  | yes | omission    |
| Tia M Rains <sup>376</sup>          | 2015 | Nutr J                   | A randomized, controlled, crossover trial to assess the acute appetitive and metabolic effects of sausage and egg-based convenience breakfast meals in overweight premenopausal women. | no  |             |
| Benjamin Speich <sup>377</sup>      | 2012 | PLoS Negl Trop Dis       | Efficacy and safety of nitazoxanide, albendazole, and nitazoxanide-albendazole against <i>Trichuris trichiura</i> infection: a randomized controlled trial.                            | yes | omission    |
| Krysia Dziedzic <sup>378</sup>      | 2015 | Ann Rheum Dis            | Self-management approaches for osteoarthritis in the hand: a 2 <sup>Å</sup> –2 factorial randomised trial.   | no  |             |
| George Du Toit <sup>379</sup>       | 2015 | N Engl J Med             | Randomized trial of peanut consumption in infants at risk for peanut allergy.  | no  |             |
| Michael P. Diamond <sup>380</sup>   | 2014 | Journal of Endometriosis | Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist: Results from a phase 2, randomized controlled study.  | yes | time change |
| Said A. Ibrahim <sup>381</sup>      | 2013 | Arthritis Rheum          | Willingness and access to joint replacement among African American patients with knee osteoarthritis: a randomized, controlled intervention.   | no  |             |
| Michael W. Fried <sup>382</sup>     | 2013 | Hepatology               | Once-daily simeprevir (TMC435) with pegylated interferon and ribavirin in treatment-na <sup>Å</sup> ve genotype 1 hepatitis C: the randomized PILLAR study.                            | yes | new outcome |
| R. L. Dobbins <sup>383</sup>        | 2013 | Diabetes Obes Metab      | GSK256073, a selective agonist of G-protein coupled receptor 109A (GPR109A) reduces serum glucose in subjects with type 2 diabetes mellitus.   | no  |             |

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|-------------------------------------|------|-------------------------|--|-----|-------------|
| Jeanne M. Marrazzo <sup>384</sup>   | 2015 | N Engl J Med            | Tenofovir-based preexposure prophylaxis for HIV infection among African women.   | no  |             |
| Fernando J. Martinez <sup>385</sup> | 2013 | Respir Med              | Fluticasone furoate/vilanterol (100/25; 200/25 $\hat{1}$ / <sub>4</sub> g) improves lung function in COPD: a randomised trial.   | no  |             |
| Gemma Chiva-Blanch <sup>386</sup>   | 2013 | Clin Nutr               | Effects of red wine polyphenols and alcohol on glucose metabolism and the lipid profile: a randomized clinical trial.  | yes | omission    |
| Joseph E. Donnelly <sup>387</sup>   | 2013 | Obesity (Silver Spring) | Aerobic exercise alone results in clinically significant weight loss for men and women: midwest exercise trial 2.  | yes | new outcome |
| Harold E. Bays <sup>388</sup>       | 2013 | Am J Cardiol            | Efficacy and safety of ezetimibe added to atorvastatin versus atorvastatin uptitration or switching to rosuvastatin in patients with primary hypercholesterolemia.                         | no  |             |
| A. P. Sykes <sup>389</sup>          | 2016 | Diabetes Obes Metab     | Randomized efficacy and safety trial of once-daily remogliflozin etabonate for the treatment of type 2 diabetes.   | no  |             |
| H. Asita de Silva <sup>390</sup>    | 2011 | PLoS Med                | Low-dose adrenaline, promethazine, and hydrocortisone in the prevention of acute adverse reactions to antivenom following snakebite: a randomised, double-blind, placebo-controlled trial. | yes | new outcome |
| Jeffrey T. Kullgren <sup>391</sup>  | 2014 | Ann Intern Med          | Financial incentives for completion of fecal occult blood tests among veterans: a 2-stage, pragmatic, cluster, randomized, controlled trial.   | no  |             |
| Rakesh Lodha <sup>392</sup>         | 2014 | Am J Clin Nutr          | Effect of micronutrient supplementation on treatment outcomes in children with intrathoracic tuberculosis: a randomized controlled trial.  | no  |             |
| Rakesh Lodha <sup>393</sup>         | 2014 | Eur J Anaesthesiol      | Low-dose neostigmine to antagonise shallow atracurium neuromuscular block during inhalational anaesthesia: A randomised controlled trial.  | no  |             |

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