

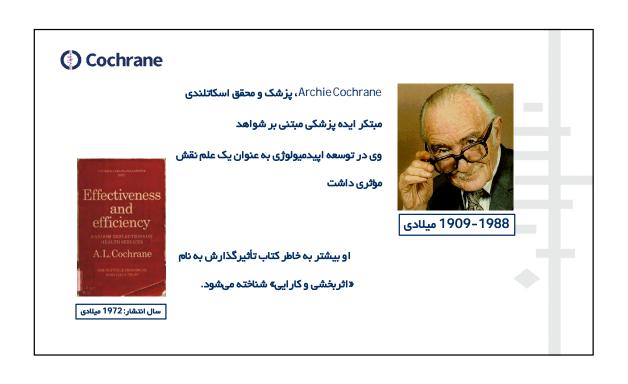






77 نفر از 19 کشور دنیا در سال 1993 میلادی در کلکیوم کاکرین شرکت کردند و ایده راهاندازی شبکه همکاریهای کاکرین (Cochrane Collaboration) در این سمینار شکل گرفت.







## شبکه جهانی کاکرین

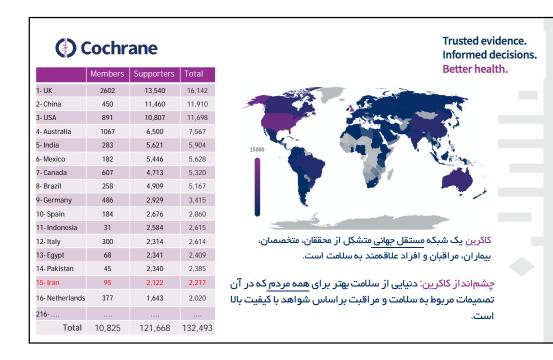
هیچ مکان یا دفتری تحت عنوان «کاکرین» وجود ندارد.

شبکه جهانی اعضا و حامیان ما با یکدیگر همکاری میکنند تا به اهداف راهبردی خـود دسـت یابنـد و معمولاً بر اساس علایق، تخصص و/یا موقعیت جغرافیایی وابسته به یک یا چند گروه کاکرین هستند.

- اعضای کاکرین (Cochrane Members): مشارکتکنندگانی که عضویت دریافت کردهاند (تا یان سال 2023: 10،825 غفر)
- حامیان کاکرین (Cochrane Supporters): شبکه جهانی دارندگان پروفایل (Account) در کاکرین که مشارکت فعال دارند (تا پایان سال 2023: 121،668 نفر)



تعداد كل اعضا و حاميان كاكرين تا پايان سال 2023: 132،493 نفر









### 10 اصل کاری کاکرین

- Collaboration) ممكارى -1
- 2- بنا شحه بر پایه شور و شوق افراد (Building on the enthusiasm of individuals)
  - (Avoiding duplication of effort) اجتناب از تکرار تلاش 3
    - 4- بەحداقل رساندن سوگیری (Minimizing bias)
      - 5- بەروزبودن (Keeping up-to-date)
    - 6- تلاش برای مرتبطبودن (Striving for relevance)
      - 7 گسترش دسترسی (Promoting access)
        - 8- اطمینان از کیفیت (Ensuring quality)
          - 9- تداوم (Continuity)
  - 10 امكان مشاركت گسترده (Enablingwide participation)

# () Cochrane

# مهمترین محصول کاکرین

کتابخانه کاکرین (Cochrane Library) مشتمل بر چندین پایگاه اطلاعاتی از جمله کتابخانه کاکرین (Cochrane Database of Systematic Reviews یا CDSR کے مرورهای سیستماتیک کاکرین ادر آن منتشر میشود، مهمترین محصول کاکرین است.

تا كنون ٩،193 مرور كاكرين در 37 دستهبندي موضوعي منتشر شده است.

742

ر اهنمای بالینی در سال 2022 منتشر شده که حداقل به یک مرور کاکرین ارجاع داده است. 8/4 Impact Factor CDSR دیتابیس 83،897 مجموع استنادات به مرورهای کاکرین در سال 2022

**343** سرور کاکرین جدید

مرور کاکرین جدید یا به روز شده و 250 پروتکل در سال 2022 منتشر شد.

6

**Cochrane Database** 

of Systematic Reviews

11 OUT OF 167

9.880



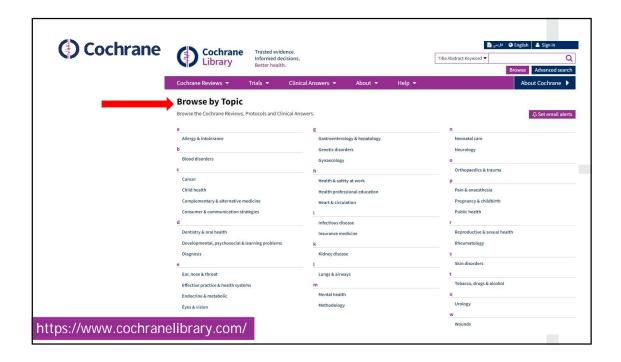
All Cochrane Reviews are published in the Cochrane Database of Systematic Reviews (launched in 1995) in The Cochrane Library, an online platform, cochrane library.com

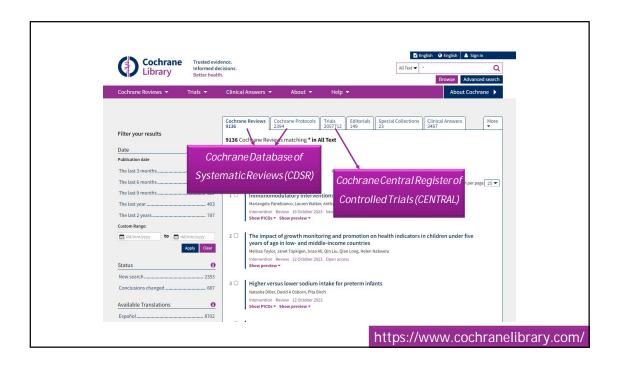
Cochrane Library includes three databases:

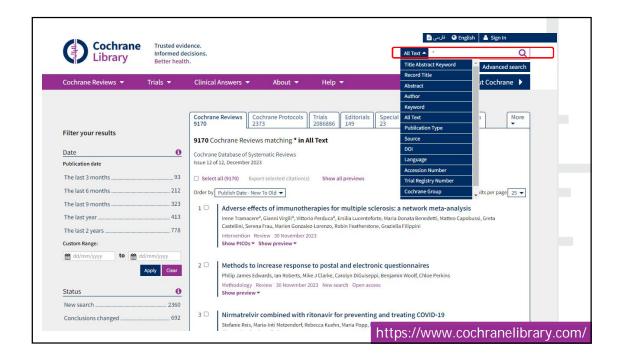
- 1. Cochrane Database of Systematic Reviews (Cochrane Reviews)
- 2. Cochrane Central Register of Controlled Trials (Clinical Trials)
- 3. Cochrane Clinical Answers

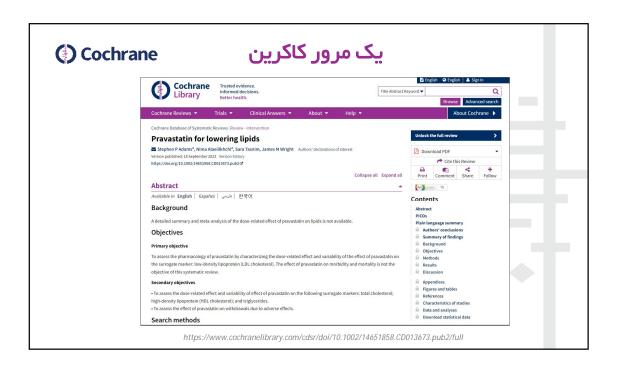


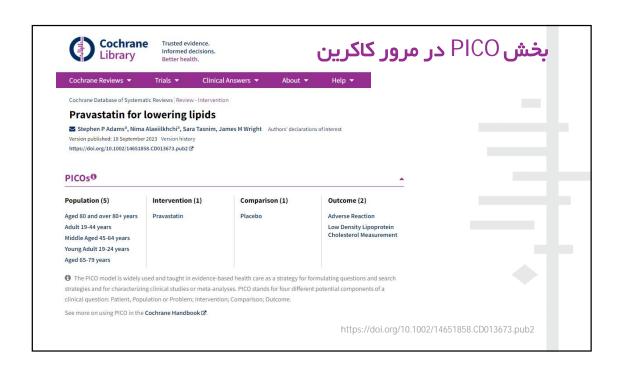




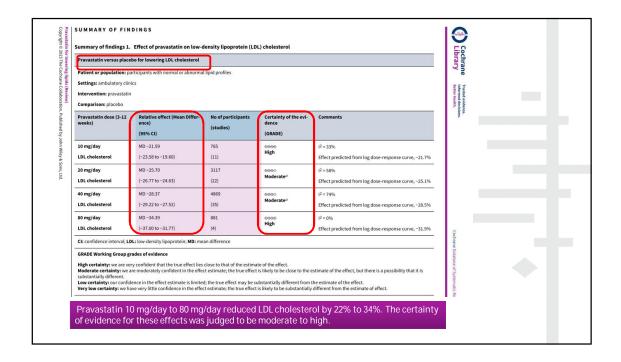
























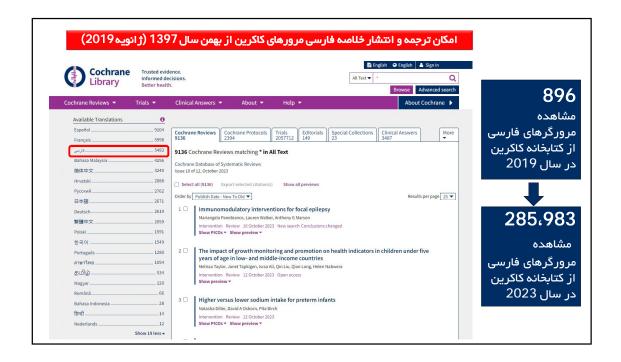
### گروههای جغرافیایی <mark>کاکرین</mark> در 53 کشور

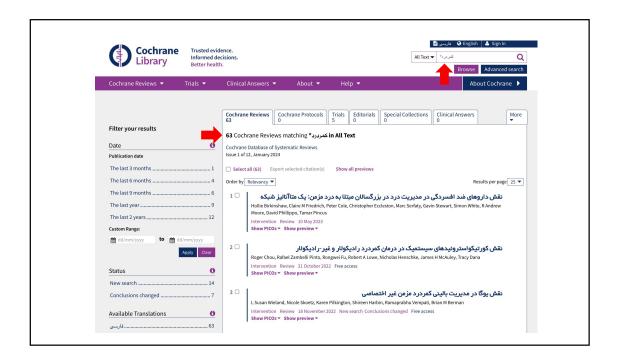
کاکرین <mark>ایران</mark> تنها شعبه کاکرین در خاورمیانه و کشورهای همسایه

 کاکرین کانادا كاكرين پرتغال (6 مركز يا مركز وابسته) كاكرين اتريش كاكرين آرژانتين (8 مركز/مركز وابسته) كاكرين كانادا فرانكوفن کاکرین پرو (2 مرکزیا مرکز وابسته) کاکرین کرہ جنوبی کاکرین تایوان (2 مرکز/مرکز وابسته) كاكرين اسپانيا (5 مركز/مركز وابسته) كاكرين تايلند كاكرين استراليا کاکرین کرواسی كاكرين كلمبيا (9 مركز/مركز وابسته) کاکرین جمهوری چک كاكرين اكوادور كاكرين كنيا کاکرین جمهوری دومینیکن كاكرين آلمان کاکرین آفریقای جنوبی (2 مرکز/مرکز وابسته) 🗖 كاكرين لهستان کاکرین چین (9 مرکز/مرکز وابسته) کاکرین مالزی کاکرین دانمارک كاكرين آمريكا (16 مركز/مركز وابسته) کاکرین آمریکای جنوبی كاكرين مجارستان کاکرین روسیه کاکرین مکزیک (10 مرکز/مرکز وابسته) كاكرين روماني کاکرین آمریکای مرکزی **کاکرین هند** (10 مرکز/مرکز وابسته) کاکرین ژاپن كاكرين اندونزي كاكرين نروژ كاكرين سوئيس كاكرين ايتاليا (5 مركز/مركز وابسته) كاكرين نيجريه كاكرين سوئد کاکرین ایران کاکرین سنگاپور كاكرين ايرلند كاكرين نيوزلند كاكرين هلند کاکرین شیلی (6 مرکز/مرکز وابسته) کاکرین برزیل (6 مرکزیا مرکز وابسته) کاکرین هنگکنگ كاكرين بلژيک كاكرين فرانسه كاكرين يونان كاكرين فنلاند کاکرین بوسنی و هرزوگوین كاكرين كامرون کاکرین پار اگوئہ















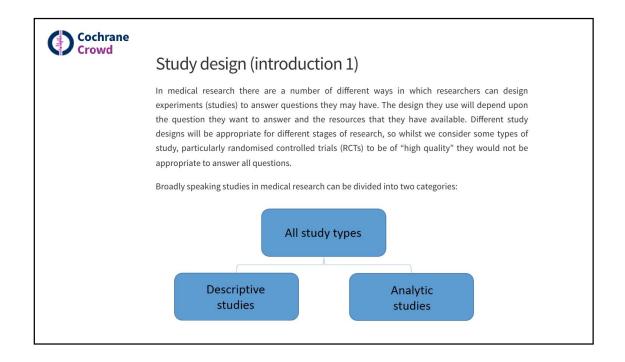


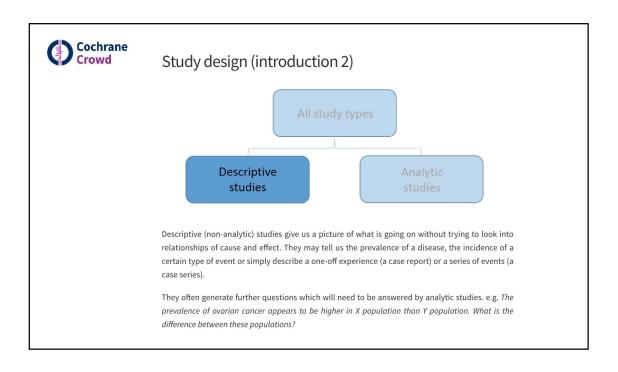


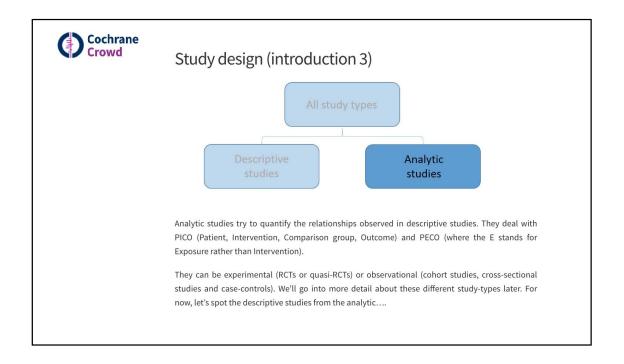














## Management of aneurysmal subarachnoid hemorrhage: A national survey of current practice

Objectives: The Royal College of Physicians and American Heart Association/American Stroke Association published recommendations in 2012 for the management of aneurysmal subarachnoid hemorrhage (aSAH). This was followed by recommendations included in the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report published in November 2013. The aim of this study was to assess how many of these recommendations were being followed across the UK and Ireland 6 months after publication of the latest recommendations, and to compare current practice with the NCEPOD data collected in 2011. Methods: We formulated a survey composed of 19 questions regarding the management of aSAH, and conducted a telephone interview with the neurosurgical registrars on call. Results: 22 out of 30 centers aimed to treat ruptured aneurysms by coiling or clipping within 48 h from ictus, yet only 15 units offered regular weekend interventional neuroradiological treatment. In 9 units, all aSAH patients were routinely discussed in a multidisciplinary meeting. Conclusions: At 6 months following publication of the NCEPOD report we found that in the majority of neurosurgical units, most of the key recommendations were being met. However, in the remainder there was variability in clinical practice.

Is this study an analytic study or a descriptive one?

1 Descriptive study

2 Analytic study



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Is this study an analytic study or a descriptive one?

### We agree!

This is a descriptive study. It's a survey and gives us a general picture of how well the guidelines in the treatment of this condition are adhered to. It doesn't attempt to quantify the relationship between the two factors. The data described are factual and there is an analysis to present the data in a manageable way. We can't attempt to draw conclusions about cause and effect from descriptive studies, but we can use them to create a hypothesis which can be tested with an analytic study.

Descriptive study

Analytic study



#### Myxolipoma of the renal capsule: A case report

INTRODUCTION Although lipomas are the most common mesenchymal tumors of the human body, primary intrarenal lipomas are quite rare. In this report we present a case of benign mesenchymal tumor with lipomatous and myxoid components. PRESENTATION OF CASE A sixty one years old male patient was admitted to our outpatient clinic for a general control since he had a right radical nephrectomy operation due to renal cell carcinoma (RCC) eight years ago and he did not have any urological control for last 3 years. However the urinary ultrasound revealed a mass lesion on left kidney and then on axial contrast-enhanced computed tomography (CT) scan, there were two masses on the left kidney. In the magnetic resonance imaging (MRI), the tumor on cortex was depicted as a homogeneous low-signal intensity on the T1-weighted pulse sequence and as a heterogeneous high-signal intensity on the T2-weighted pulse sequence. In pathological evaluation, the biopsy material of the cortical mass was a tumoral lesion containing lipomatous and mixoid areas without atypia, mitosis or necrosis which was diagnosed as myxolipoma, DISCUSSION Myxolipoma, an uncommon type of lipoma, is a benign tumor composed mainly of fat cells with myxoid (mucus-like) components. In our case, the tumor was composed of mature adipocytes together with areas rich in mucoid substances and there were no malignant features including lipoblasts, mitosis or abundant capillary network. CONCLUSION Herein we present a case of a fatty tumor originating from the renal capsule with the histologic diagnosis of myxolipoma. To the best of our knowledge, myxolipoma, a very rare form of lipoma, is not reported in kidney, in the literature before. Copyright © 2014 The Authors. Published by Elsevier Ltd.

Is this study an analytic study or a descriptive one?

1 Descriptive study

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NORMAL STROMA

FIBROBLASTS

BLOOP VESSELS

MYXOID STROMA

BLUE / PNEPLE

APPEARANCE



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Is this study an analytic study or a descriptive one?

#### We agree!

This is a descriptive study. Case reports describe an interpret and individual case, usually in narrative format. They may examine a unique set of symptoms that cannot be explained by known disea syndromes; an important variation of a disease of condition; unexpected events or progression in a disease that may help us to learn more; or a case where a patient has two or more unrelated diseases or disorders. Case reports are not considered to be rigorous evidence in medical research as they deal with one patient, so conclusions may not be generalizable. Case reports are really important to help generate new ideas and hypotheses which should be tested in analytic studies.

Descriptive study

Analytic study



# Environmental and school influences on physical activity in South Asian children from low socio-economic backgrounds: A qualitative study

South Asian (SA) children are less active but have enhanced metabolic risk factors. Physical activity (PA) is a modifiable risk factor for metabolic disease. Evidence suggests that environmental factors 1 and socio-economic status influence PA behaviour. The purpose of this study was to understand PA environments, barriers and facilitators of PA in deprived environments for children from SA backgrounds. Focus groups were conducted with 5 groups of children aged 7-9 years (n = 33; male =  $\frac{2}{3}$ 16, female = 17; SA = 17, White = 8 and Black = 8) from two schools in deprived wards of Coventry, England. Thematic analysis was used to identify key themes and subthemes across all transcripts. From the results, emergent themes included school and home environment, outdoor activity, equipment, weather, parental constraints and safety. Ethnic differences were apparent for sources of beliefs and knowledge and religious practice as constraints for PA. The findings suggest that school provides a good foundation for PA attitude, knowledge and behaviour, especially for SA children. To increase PA, multi-component interventions are needed, which focus on changing the home environment (i.e. junk food and media time), encouraging outdoors activity, changing perceptions of safety and weather conditions, which provide parental constraints for children. Interventions also need to be considerate to religious practices that might constrain time. Copyright © The Author(s) 2013.

Does this study generate a hypothesis or test a hypothesis?

Generates hypothesis

Tests hypothesis



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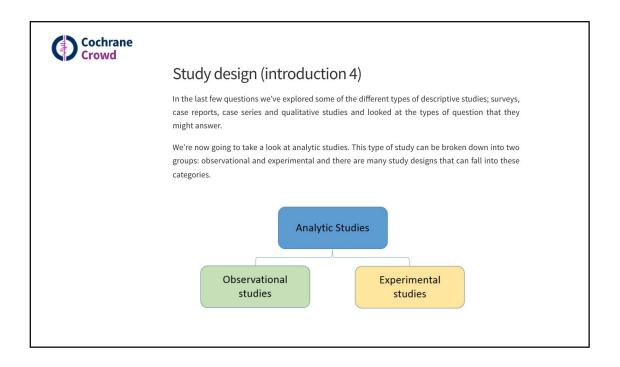
Does this study generate a hypothesis or test a hypothesis?

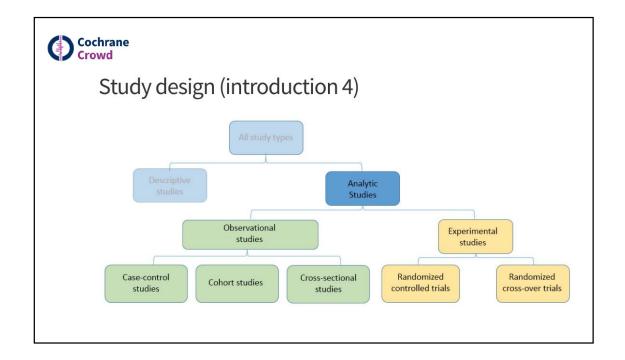
### We agree!

This is a qualitative study. The researchers have a general theory that physical activity might not be equal amongst children from all backgrounds and have conducted focus groups to demonstrate that this is the case. They can now generate a hypothesis about the specific difference(s) between the groups affecting this, and possible interventions and they can test this using an analytic study.

Generates hypothesis

Tests hypothesis







## High-flow nasal cannula oxygen therapy versus noninvasive ventilation versus in immunocompromised patients with acute respiratory failure

BACKGROUND: Acute respiratory failure is the main cause of admission to intensive care unit in immunocompromised patients. In this subset of patients, the beneficial effects of noninvasive ventilation (NIV) as compared to standard oxygen remain debated. High-flow nasal cannula oxygen therapy (HFNC) is an alternative to standard oxygen or NIV, and its use in hypoxemic patients has been growing. Therefore, we aimed to compare outcomes of immunocompromised patients treated using HFNC alone or NIV as a first-line therapy for acute respiratory failure in an observational cohort study over an 8-year period. Patients with acute-on-chronic respiratory failure, those treated with standard oxygen alone or needing immediate intubation, and those with a do-not-intubate order were excluded. RESULTS: Among the 115 patients analyzed, 60 (52 %) were treated with HFNC alone and 55 (48 %) with NIV as first-line therapy with 30 patients (55 %) receiving HFNC and 25 patients (45 %) standard oxygen between NIV sessions. The rates of intubation and 28-day mortality were higher in patients treated with NIV than with HFNC (55 vs. 35 %, p = 0.04, and 40 vs. 20 %, p = 0.02 log-rank test, respectively). Using propensity score-matched analysis, NIV was associated with mortality. Using multivariate analysis, NIV was independently associated with intubation and mortality. CONCLUSIONS:Based on this observational cohort study including immunocompromised patients admitted to intensive care unit for acute respiratory failure, intubation and mortality rates could be lower in patients treated with HFNC alone than with NIV. The use of NIV remained independently associated with poor outcomes.

Is this study experimental or oberservational?

Experimental

2 Observational



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Is this study experimental or oberservational?

### We agree!

This is an observational study. It's looking at a cohort and gives us an insight into the relationship between one factor of their treatment and the patient outcome. It trie to quantify the extent of the cause and effect and examines different variables to see whether recommending one or another intervention might be appropriate, either overall or for a specific subset of the group. The researchers don't have control over allocation of patients to the two groups, so they must be aware of bias that might make one treatment appear to be more successful. For instance, are the patients who are given one of the treatment options sicker in the first place?

Experimental

Observationa



#### Ticagrelor versus aspirin in acute stroke or transient ischemic attack

BACKGROUND Ticagrelor may be a more effective antiplatelet therapy than aspirin for the prevention of recurrent stroke and cardiovascular events in patients with acute cerebral ischemia. METHODS We conducted an international double-blind, controlled trial in 674 centers in 33 countries, in which 13.199 patients with a nonsevere ischemic stroke or high-risk transient ischemic attack who had not received intravenous or intraarterial thrombolysis and were not considered to have had a cardioembolic stroke were randomly assigned within 24 hours after symptom onset, in a 1:1 ratio, to receive either ticagrelor (180 mg loading dose on day 1 followed by 90 mg twice daily for days 2 through 90) or aspirin (300 mg on day 1 followed by 100 mg daily for days 2 through 90). The primary end point was the time to the occurrence of stroke, mvocardial infarction, or death within 90 days. RESULTS During the 90 days of treatment, a primary end-point event occurred in 442 of the 6589 patients (6.7%) treated with ticagrelor, versus 497 of the 6610 patients (7.5%) treated with aspirin (hazard ratio, 0.89; 95% confidence interval [CI], 0.78 to 1.01; P = 0.07). Ischemic stroke occurred in 385 patients (5.8%) treated with ticagrelor and in 441 patients (6.7%) treated with aspirin (hazard ratio, 0.87; 95% CI, 0.76 to 1.00). Major bleeding occurred in 0.5% of patients treated with ticagrelor and in 0.6% of patients treated with aspirin, intracranial hemorrhage in 0.2% and 0.3%, respectively, and fatal bleeding in 0.1% and 0.1%. CONCLUSIONS In our trial involving patients with acute ischemic stroke or transient ischemic attack, ticagrelor was not found to be superior to aspirin in reducing the rate of stroke, myocardial infarction, or death at 90 days. (Funded by AstraZeneca; ClinicalTrials.gov number, NCT01994720.). © Copyright 2016 Massachusetts Medical Society. All rights reserved.

Is this study experimental or oberservational?

1 Experimental

2 Observational



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Is this study experimental or

### We agree!

This is a randomized controlled trial. That means that the reseachers took a group of patients with a condition or group of similar conditions and assigned which treatment they should receive in a randomized way. In this case, patients received either Ticagrelor or Aspirin to reduce the chance of them having a stroke, myocardial infarction or dying within 90 days after symptom onset and treatment. They could then examine any difference in outcome between the two groups to see which drug was more effective. Randomized trials are always experimental because the researchers are determining an aspect of the patients' care rather than just measuring the outcome of the normal course of action

Experimental

Observational



### Tai Chi and meditation-plus-exercise benefit neural substrates of executive function: A cross-sectional, controlled study

Background: We report the first controlled study of Tai Chi effects on the P300 event-related potential, a neuroelectric index of human executive function. Tai Chi is a form of exercise and moving meditation. Exercise and meditation have been associated with enhanced executive function. This cross-sectional, controlled study utilized the P300 event-related potential (ERP) to compare executive network neural function between self-selected long-term Tai Chi, meditation, aerobic fitness, and sedentary groups. We hypothesized that because Tai Chi requires moderate aerobic and mental exertion, this group would show similar or better executive neural function compared to meditation and aerobic exercise groups. We predicted all health training groups would outperform sedentary controls. Methods: Fifty-four volunteers (Tai Chi, n=10; meditation, n=16; aerobic exercise, n=16; sedentary, n=12) were tested with the Rockport 1-mile walk (estimated VO2 Max), a well-validated measure of aerobic capacity, and an ecologically valid visuospatial, randomized, alternating runs Task Switch test during dense-array electroencephalographic (EEG) recording. Results: Only Tai Chi and meditation plus exercise groups demonstrated larger P3b ERP switch trial amplitudes compared to sedentary controls. Conclusions: Our results suggest long-term Tai Chi practice, and meditation plus exercise may benefit the neural substrates of executive function. Copyright © 2014 by De Gruyter.

Is this study a randomised controlled trial (RCT)? RCT

Not an RCT



### Tai Chi and meditation-plus-exercise benefit neural substrates of executive function: A cross-sectional, controlled study

Background: We report the first controlled study of Tai Chi effects on the P300 event-related potential, a neuroelectric index of human executive function. Tai Chi is a form of exercise and moving meditation. Exercise and meditation have been associated with enhanced executive function. This cross-sectional, controlled study utilized the P300 event-related potential (ERP) to compare executive network neural function between self-selected long-term Tai Chi, meditation, aerobic fitness, and sedentary groups. We hypothesized that because Tai Chi requires moderate aerobic and mental exertion, this group would show similar or better executive neural function compared to meditation and aerobic exercise groups. We predicted all health training groups would outperform sedentary controls. Methods: Fifty-four volunteers (Tai Chi, n=10; meditation, n=16; aerobic exercise, n=16; sedentary, n=12) were tested with the Rockport 1-mile walk (estimated VO2 Max), a well-validated measure of aerobic capacity, and an ecologically valid visuo $spatial, randomized, alternating \ runs \ Task \ Switch \ test \ during \ dense-array \ electroence phalographic$ (EEG) recording. Results: Only Tai Chi and meditation plus exercise groups demonstrated larger P3b ERP switch trial amplitudes compared to sedentary controls. Conclusions: Our results suggest long-term Tai Chi practice, and meditation plus exercise may benefit the neural substrates of executive function. Copyright © 2014 by De Gruyter.

#### We agree!

This is a cross-sectional study. It's looking at a cohort of people who practise Tai Chi to ee whether their executive function is better than a cohort who don't practise Tai Chi. In order to help us to decide whether the benefit comes from Tai Chi specifically, o general physical activity, or meditation, the researchers have includede 3 control groups: 'meditation without physical activity' "aerobic exercise without meditation", and "no exercise". Looking at the executive function scores of these different control groups in relation to each other and the "Tai Chi" group allows us to see which, if any, aspects of Tai Chi may be beneficial. The groups all practised their respective exercise types prior to the study so it's observational. A randomized trial in this area might be follow the participants for enough time for the exercise to take effect.



#### Seven-year efficacy of RTS, S/AS01 malaria vaccine among young african children

BACKGROUND The candidate malaria vaccine RTS, S/ASO1 is being evaluated in order to inform a decision regarding its inclusion in routine vaccination schedules. METHODS: We conducted 7 years of follow-up in children who had been randomly assigned, at 5 to 17 months of age, to receive three doses of either the RTS, S/ASO1 vaccine or a rabies (control) vaccine. The end point was clinical malaria (temperature of >37.5degreeC and infection with Plasmodium falciparum of>2500 parasites per cubic millimeter). In an analysis that was not prespecified, the malaria exposure of each child was estimated with the use of information on the prevalence of malaria among residents within a 1-km radius of the child's home. Vaccine efficacy was defined as 1 minus the hazard ratio or the incidence-rate ratio, multiplied by 100, in the RTS, S/AS01 group versus the control group. RESULTS: Over 7 years of follow-up, we identified 1002 episodes of clinical malaria among 223 children randomly assigned to the RTS, S/AS01 group and 992 episodes among 224 children randomly assigned to the control group. The vaccine efficacy, as assessed by negative binomial regression, was 4.4% (95% confidence interval [CI], -17.0 to 21.9; P = 0.66) in the intentionto-treat analysis and 7.0% (95% CL -14.5 to 24.6; P = 0.52) in the per-protocol analysis. Vaccine efficacy waned over time (P = 0.006 for the interaction between vaccination and time), including negative efficacy during the fifth year among children with higher-than-average exposure to malaria parasites (intention-to-treat analysis: -43.5%; 95% CI, -100.3 to -2.8 [P = 0.03]; per-protocol analysis: -56.8%; 95% CI, -118.7 to -12.3 [P = 0.008]). CONCLUSIONS: A three-dose vaccination with RTS, S/AS01 was initially protective against clinical malaria, but this result was offset by rebound in later years in areas with higher than-average exposure to malaria parasites. Copyright © 2016 Massachusetts Medical Society.

Is this study a randomised controlled trial (RCT)?

Not an RCT



### Seven-year efficacy of RTS, S/AS01 malaria vaccine among young african children

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Is this study a randomised controlled trial (RCT)?

### We agree!

In a randomized study, the reseachers allocate participants to one treatment group or another in a randomized way. In this casea vaccine against malaria and a vaccine against rabies. Having a control group is important because it allows you to compare values for the two groups. The control group can receive another treatment, often treatment-as-usual, so we can see if a new option is more effective. Sometimes they receive a placebo which is usually an inactive intervention. In this case, administering a rabies vaccine wouldn't be expected to prevent malaria, so the rabies vaccine acts as the control.

RCT

Not an RC



## Background radiation and childhood leukemia: A nationwide register-based case-control study

High doses of ionizing radiation are an established cause of childhood leukemia. However, substantial uncertainty remains about the effect of low doses of radiation, including background radiation and potential differences between genetic subgroups of leukemia have rarely been explored. We investigated the effect of the background gamma radiation on childhood leukemia using a nationwide register-based case-control study. For each of the 1.093 cases, three age- and gender matched controls were selected (N = 3,279). Conditional logistic regression analyses were adjusted for confounding by Down syndrome, birth weight (large for gestational age), and maternal smoking. Complete residential histories and previously collected survey data of the background gamma radiation in Finland were used to assess the exposure of the study subjects to indoor and outdoor gamma radiation. Overall, background gamma radiation showed a non-significant association with the OR of childhood leukemia (OR 1.01, 95% CI 0.97, 1.05 for 10 nSv/h increase in average equivalent dose rate to red bone marrow). In subgroup analyses, age group 2-<ars displayed a larger effect (OR 1.27, 95% CI 1.01, 1.60 for 1 mSv increase in equivalent cumulative dose to red bone marrow). Suggestive difference in OR by genetic subtype was found. Our results provide further support to the notion that low doses of ionizing radiation increase the risk for childhood leukemia, particularly at age 2-<rs. Our findings suggest a larger effect of radiation on leukemia with high hyperpdiploidy than other subgroups, but this result requires further confirmation. Copyright © 2016 UICC

Is this study a randomised controlled trial (RCT)?

RCT

Not an RCT



### Background radiation and childhood leukemia: A nationwide register-based case-control study

High doses of ionizing radiation are an established cause of childhood leukemia. However, substantial uncertainty remains about the effect of low doses of radiation, including background radiation and potential differences between genetic subgroups of leukemia have rarely been explored. We investigated the effect of the background gamma radiation on childhood leukemia using a nationwide register-based case-control study. For each of the 1,093 cases, three age- and gender matched controls were selected (N = 3,279). Conditional logistic regression analyses were adjusted for confounding by Down syndrome, birth weight (large for gestational age), and maternal smoking. Complete residential histories and previously collected survey data of the background gamma radiation in Finland were used to assess the exposure of the study subjects to indoor and outdoor gamma radiation. Overall, background gamma radiation showed a non-significant association with the OR of childhood leukemia (OR 1.01, 95% CI 0.97, 1.05 for 10 nSv/h increase in average equivalent dose rate to red bone marrow). In subgroup analyses, age group 2-<ars displayed a larger effect (OR 1.27, 95% CI 1.01, 1.60 for 1 mSv increase in equivalent cumulative dose to red bone marrow). Suggestive difference in OR by genetic subtype was found. Our results provide further support to the notion that low doses of ionizing radiation increase the risk for childhood leukemia, particularly at age 2-<rs. Our findings suggest a larger effect of radiation on leukemia with high hyperpdiploidy than other subgroups, but this result requires further confirmation. Copyright © 2016 UICC

Is this study a randomised controlled trial (RCT)?

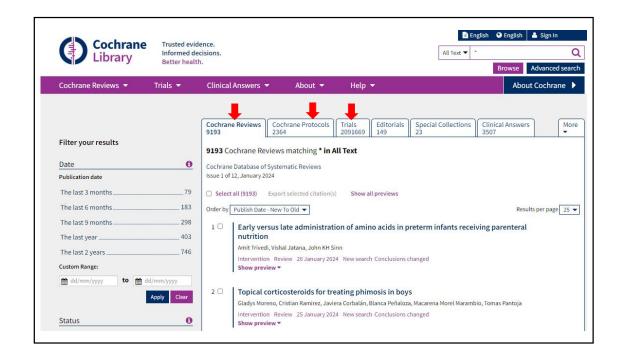
### We agree!

This is looking at exposure as a cause of disease and the study design is case-control. In this case, the study looks at the difference in childhood exposure to background radiation in participants with and without leukemia. A significant difference in the levels of background radiation between the groups may indicate a causative relationship between the two factors.

RCT

Not an RCT

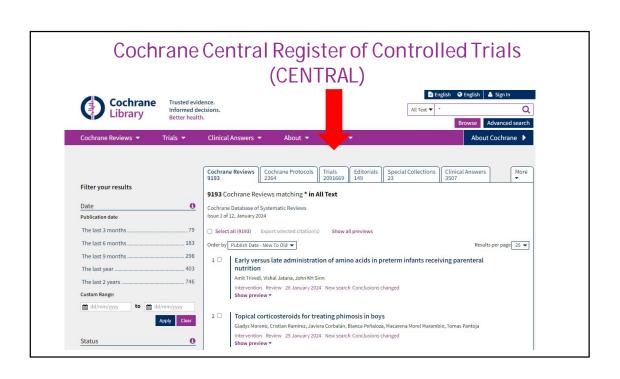






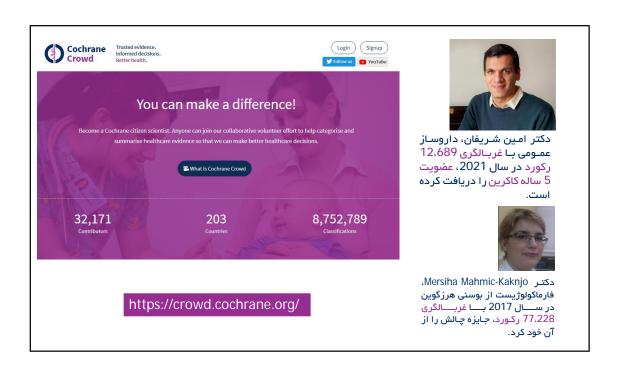
Pubmed and Embase as well as CINAHL, ClinicalTrials.gov and

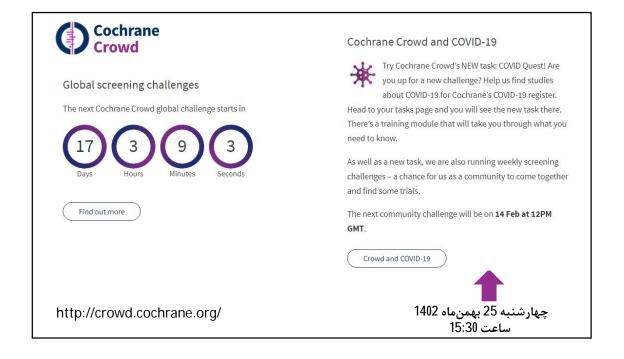
WHO's international Clinical Trials Registry Platform)

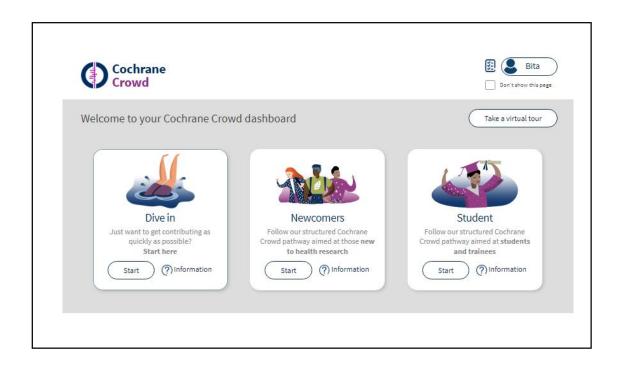


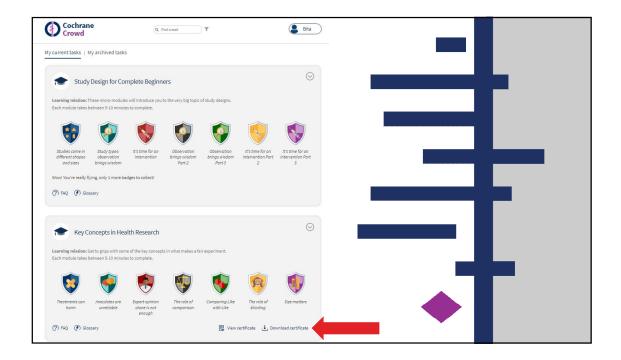














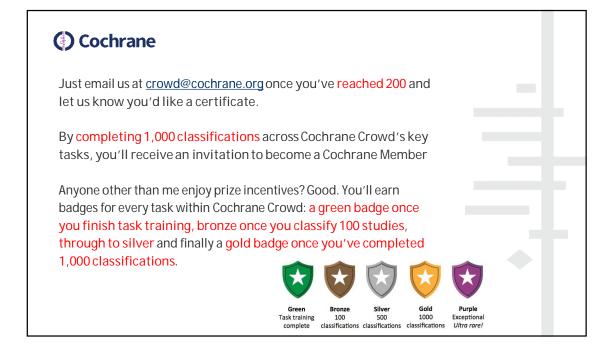


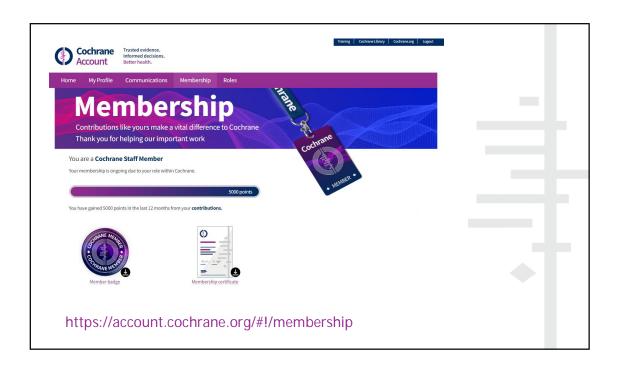
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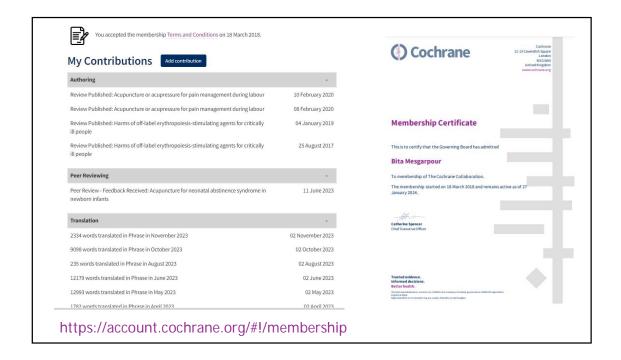






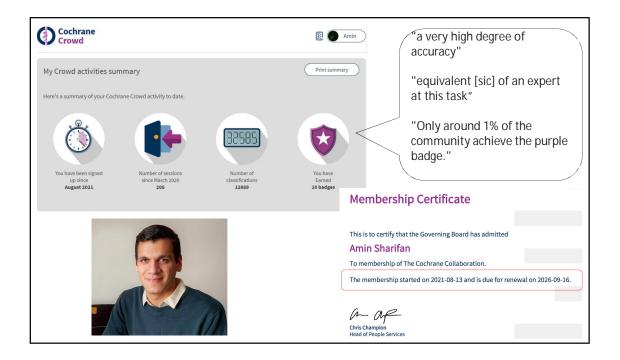














### Randomised controlled trial in human subjects

کار آزمایی کنترل شده تصادفی در آزمودنی انسانی

Sometimes this kind of trial is called a randomised trial or an RCT.



### Comparative trial where randomisation is not described

#### کار آزمایی مقایسهای که در آن تصادفیسازی توصیف نشده است

You will sometimes come across records where there is a lack of detail regarding whether the participants were randomised. It might say something like: "patients were allocated into the experimental and control arms". It's impossible to know if they were randomly allocated. In these cases, it is best to play it safe, and classify the record as RCT/q-RCT (or Unsure).



#### To be classified RCT/q-RCT

#### Quasi-randomised trial in human subjects

#### کار آزمایی شبه تصادفی در آزمودنی انسانی

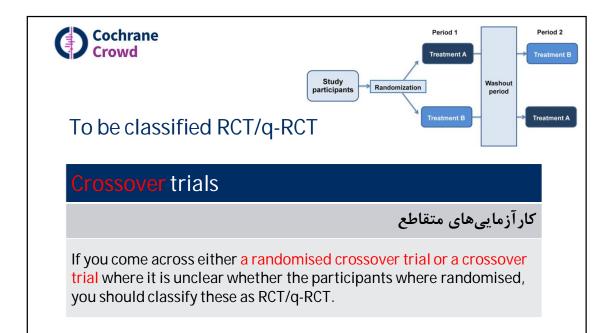
Sometimes the form of randomisation used is not truly random. For example, treatment may have been allocated by date of birth or day of the week. These are what we think of as quasi-randomised trials (q-RCTs).



#### **Cluster** randomised controlled trial

#### کار آزمایی کنترل شده تصادفی خوشهای

This is where groups, rather than individuals, are randomised. For example, the four hospitals in a city could be randomised to a new protocol for Accident and Emergency (two hospitals to try the new protocol and two to carry on as normal).

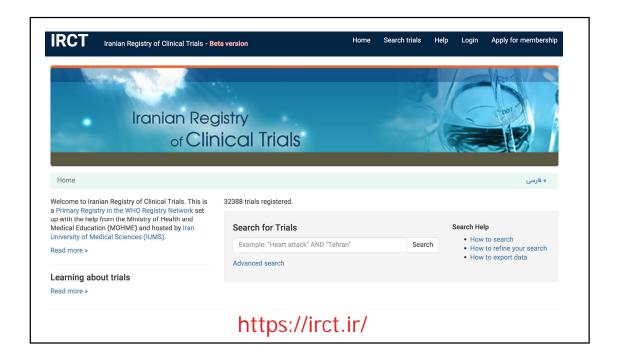




#### Protocol to a randomised controlled trial

پروتکل یک کار آزمایی کنترلشده تصادفی

This is a record that describes a planned randomised controlled trial. We'd like these to be captured as it is very useful to know what RCTs are being planned.





#### Interim results of a randomised controlled trial

نتایج موقت یک کار آزمایی کنترلشده تصادفی

Often seen on conference records. This is where a record that describes the results of an on-going randomised trial is eligible.

#### Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial



Published Online November 11, 2021 https://doi.org/10.1016/ S0140-6736(21)02000-6

\*All members listed in apper (pp 2-5)

Raches Ella, Siddarth Reddy, William Blackwelder, Varsha Potdar, Pragya Yadav, Vamshi Sarangi, Vinay K Aileni, Suman Kanungo, Sanjay Rai, Prabhakar Reddy, Savita Verma, Chandramani Singh, Sagar Redkar, Satyajit Mohapatra, Anil Pandey, Pajaniwel Ranganadin, Raghavendra Gumashta, Manish Multani, Shameem Mohammad, Parul Bhatt, Laxmi Kumari, Gajanan Sapkal, Nivedita Gupta, Priya Abraham, Samiran Panda, Sai Prasad, Balram Bhargava, Krishna Ella, Krishna Mohan Vadrevu, on behalf of the COVAXIN Study Group

Summary
Background We report the clinical efficacy against COVID-19 infection of BBV152, a whole virion inactivated SARS-CoV-2 vaccine formulated with a toll-like receptor 7/8 agonist molecule adsorbed to alum (Algel-IMDG) in

Methods We did a randomised, double-blind, placebo-controlled, multicentre, phase 3 clinical trial in 25 Indian hospitals or medical clinics to evaluate the efficacy, safety, and immunological lot consistency of BBV152. Adults (age 2.18 years) who were healthy or had stable chronic medical conditions (not an immunocompromising condition or requiring treatment with immunosuppressive therapy) were randomised 1:1 with a computer-generated randomisation scheme (stratified for the presence or absence of chronic conditions) to receive two intramuscular doses of vaccine or placebo administered 4 weeks apart. Participants, investigators, study coordinators, study-related personnel, the sponsor, and nurses who administered the vaccines were masked to tratement group allocation; an unmasked contract research organisation and a masked expert adjudication panel assessed outcomes. The primary outcome was the efficacy of the BBV152 vaccine in preventing a first occurrence of laboratory-confirmed (RT-PCR-positive) symptomatic COVID-19 (any severity), occurring at least 14 days after the second dose in the per-protocol population. We also assessed safety and reactogenicity throughout the duration of the study in all participants who had received at least one dose of vaccine or placebo. This report contains interim results (data cutoff May 17, 2021) regarding immunogenicity and safety outcomes (captured on days 0 to 56) and efficacy results with a median of 99 days for the study population. The trial was registered on the Indian Clinical Trials Registry India. CTRI/2020/11/028976, and ClinicalTrials.gov. NCT04641481 (active, not recruiting). India, CTRI/2020/11/028976, and ClinicalTrials.gov, NCT04641481 (active, not recruiting).

The Lancet Journal

DOI: https://doi.org/10.1016/S0140-6736(21)02000-

Hyderabad, India (R Ella MBB S Reddy MSc, V Sarangi BSc, V K Aileni PhD, S Prasad MBA, K Ella PhD, K M Vadrevu PhD);



#### Follow-up study to a randomised controlled trial

We would like these to be classified as RCT/q-RCT. They can yield very important information about the longer-term effects of a treatment.



#### To be classified RCT/q-RCT

## Post-hoc analysis of a randomised controlled trial

#### تحلیلهای بیشتر یک کارآزمایی کنترلشده تصادفی

Where an analysis has been done on a randomised controlled trial that is in addition to the originally planned analysis. These are to be classified as RCT/q-RCT as they can provide useful information about the RCT, both its methods and its results.



### Sub-group analysis of a randomised controlled trial

#### تحلیلهای زیرگروهی یک کارآزمایی کنترلشده تصادفی

Very similar to the post-hoc analyses, sub-group analyses of randomised controlled trials can have useful information in them.







# Randomised controlled trial on part of the human body

#### کارآزمایی کنترلشده تصادفی بر روی بخشی از بدن انسان

For example a trial where one eye of a patient receives the experimental treatment and the other eye does not. Often these studies don't say whether they randomly chose which part of the body would get the experimental treatment. Don't worry too much about that, just classify it as RCT/q-RCT.







## Erratum, corrections, letters and replies to a randomised controlled trial

اصلاح، نامه و پاسخ به یک کار آزمایی کنترلشده تصادفی

All of these, if they relate to an RCT or q-RCT should be kept in. They can provide useful additional information about the trial.

<u>Diabetes Care.</u> 2021 Jun; 44(6): 1454. Published online 2021 Apr 23. doi: 10.2337/dc21-er06 PMCID: PMC8247519 PMID: 33893165

Erratum. Clinical Translation of Cardiovascular Outcome Trials in Type 2 Diabetes: Is There More or Is There Less Than Meets the Eye? Diabetes Care 2021;44:641–646

Ele Ferrannini and Julio Rosenstock

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This corrects the article "Clinical Translation of Cardiovascular Outcome Trials in Type 2 Diabetes: Is There More or Is There Less Than Meets the Eye?" on page 641.

In the reference list of this article, reference 7 was incorrect and is replaced as follows:

7. Buse JB, Garg SK, Rosenstock J, et al. Sotagliflozin in combination with optimized insulin therapy in adults with type 1 diabetes: the North American inTandem1 study. Diabetes Care 2018;41:1970–1980

In addition, in Table 1 the incidence rates in the placebo arm (IR $_{Plb}$ ) and change in absolute risk ( $\Delta$ IR) presented for the LEADER trial have been corrected, and Figure 2 has been revised using the corrected data.

The authors apologize for the errors. The online version of the article (https://doi.org/10.2337/dc20-0913) has been corrected to include the new reference and the revised figure and table.



#### Retractions to a randomised controlled trial

بازپسگیری یک کار آزمایی کنترلشده تصادفی

Retraction notices to randomised controlled trials should be classified as RCT/q-RCT. We want to know if any trials have been retracted.

<u>J Midlife Health.</u> 2020 Oct-Dec; 11(4): 264. Published online 2021 Jan 21. doi: <u>10.4103/0976-7800.307580</u> PMCID: PMC7978052 PMID: <u>33767570</u>

#### Retraction: Office Cervicoscopy versus Stationary Colposcopy in Suspicious Cervix: A Randomized Controlled Trial

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This retracts the article "Office Cervicoscopy versus Stationary Colposcopy in Suspicious Cervix: A Randomized Controlled Trial" in volume 10 on page 115.

The original article titled "Office cervicoscopy versus stationary colposcopy in suspicious cervix: A randomized controlled trial" published in Journal of Mid-life Health, on pages 115-122. Issue 3, Volume 10, 2019. [11] is being retracted because the same article was published later with title "Office cervicoscopy versus stationary colposcopy in cases with suspicious cervix: a randomized controlled trial" in Journal of Current Medical Research and Practice, on pages 355-361, Issue 3, Volume 4, 2019. [2] It was brought to the attention of JMH's editorial board that there is substantial overlap of content in article published later in ICMBP

Plagiarism, fabrication, unethical or redundant publication violates the editorial policy of Journal of Midlife Health, which follows best practice guidelines given by the International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE) mentioned on the Information for Authors and as codified in the signed statements made by the authors regarding the copyright of their work.

This article has been retracted on request of the Editors-in-Chief and editorial board of the journal.

Editors-in-Chief:

Meeta Meeta, Vishal Tandon

Journal of Mid-life Health



#### Theses that include a randomised controlled trial

پایاننامهای که شامل یک کارآزمایی کنترلشده تصادفی باشد

You are unlikely to come across many records like this but if you do, you can classify it as RCT/q-RCT.



#### To be classified RCT/q-RCT

Cost-effectiveness analyses that are based on data from a randomised controlled trial

تحلیلهای هزینه - اثربخشی که مبتنی بر دادههای یک کار آزمایی کنترلشده تصادفی باشد

Classify these evaluations as RCT/q-RCT.



#### Randomised trials related to medical education

Trials that aim to assess an intervention or interventions that have outcomes related to medical education should be classified as RCT/q-RCT.



#### To be classified RCT/q-RCT

#### Randomised trials related to medical costs

کار آزماییهای تصادفی مرتبط با هزینههای پزشکی

If the trial has medical related costs as an outcome, it should be classified as RCT/q-RCT.



#### Randomised trials in healthy people

کار آزماییهای تصادفی شده در افراد سالم

If the trial has some healthcare aspect to it but it is in healthy people you should classify this as RCT/q-RCT.



#### To be classified RCT/q-RCT

### Pooled analyses of randomised controlled trials

تحلیلهای ترکیبی کار آزماییهای تصادفی شده

A pooled analysis is very similar to a meta-analysis but we currently want pooled analyses of randomised controlled trials classified as RCT/q-RCT. Pooled analysis that do not include any RCTs can be rejected.



# Randomised controlled trial in non-human subjects

کار آزماییهای کنترل شده تصادفی در آزمودنیهای غیرانسانی

Animal studies are to be rejected.



#### To be classified Reject

#### Open-label extension studies

مطالعات توسعهای با برچسب باز

These are trials often carried out on some or all of the participants from a randomised controlled trial. These are not the same as follow-up studies. An open-label extension study is a new study, and not a randomised one so it can be rejected.



#### Randomised controlled trial in cadavers

کار آزماییهای کنترل شده بر روی اجساد

Randomised studies performed on dead bodies are out and this includes studies on specific parts of cadavers.



#### To be classified Reject

Randomised controlled trial on extracted human parts

کار آزماییهای کنترل شده تصادفی بر روی بخشی از بدن که جدا شده

Extracted parts are not eligible. For example, a randomised trial on extracted teeth is to be rejected.



#### Randomised controlled trial in vitro

کار آزماییهای کنترل شده تصادفی در in vitro

A randomised trial performed on components of an organism isolated from their usual biological surrounding is not eligible.



#### To be classified Reject

#### Non-randomised controlled trials

كارآزماييهاي كنترل شده غيرتصادفي

If a record explicitly states that a trial was non-randomised then it's out. Sometimes it's hard to tell whether a trial was randomised in some way or not. If you are not sure, select Unsure.



### Systematic review or literature review

مرورهای سیستماتیک یا مرور متون

All systematic reviews are to be rejected (great though they are, they don't belong in CENTRAL).



#### To be classified Reject

#### Meta-analysis or network meta-analysis

متاآناليز يا متاآناليز شبكهاي

All meta-analyses are to be rejected.



### Overview of a number of randomised controlled trials

مرور اجمالی تعدادی از کار آزماییهای کنترل شده تصادفی

Similar to a review or systematic review, an overview seeks to summarise the available evidence. Overviews should be rejected.



#### To be classified Reject

### Case-control study

مطالعه مورد- شاهدی

Where some of the participants were 'cases' (those with the disease of interest) and some are 'controls' (often healthy, age-matched participants). Likely to come across quite a few of these. Might describe them as a 'controlled study'.



#### Observational study

مطالعه مشاهدهای

For example longitudinal cohort studies or cross-sectional studies. Observational studies differ from experimental studies in that the researchers are observing and recording rather than testing a new treatment or intervention.



#### To be classified Reject

Methodological study of a randomised controlled trial

مطالعه متدولوژیک یک کار آزمایی کنترل شده تصادفی

You are likely to come across a few of these – they are not reporting a specific trial so they are not eligible.

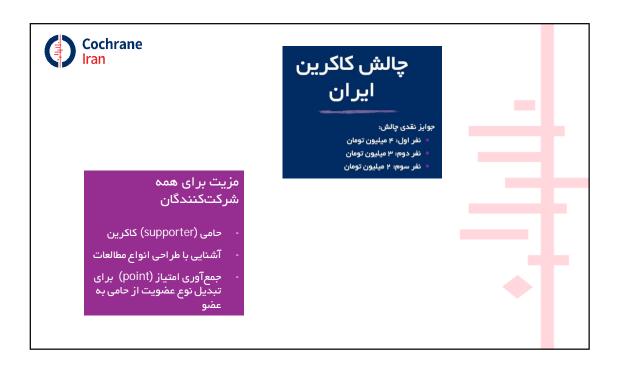


# Randomised controlled trials that are not related to healthcare

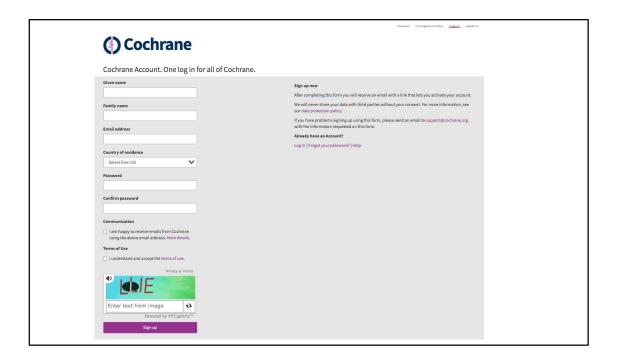
کار آزماییهای کنترل شده تصادفی که مربوط به سلامت نیستند

Such as a trial looking at the effect of different reward structures for teaching young children.









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