# **PICOS as identified by SCIBERT(multilabel, trained on structured PubMed abstracts)**

Source: *The New England Journal of Medicine*, Hajek P, *et al.*[13](https://www.ncbi.nlm.nih.gov/books/NBK545388/) A randomized trial of e-cigarettes versus nicotine-replacement therapy, Vol. 380, pp. 629–37.

## Method: With probability threshold of 95%

Line 18: This was a pragmatic RCT conducted between 2015 and 2018 in three sites in England that provide local SSSs.

Line 38: Recruitment and delivery of the interventions took place at the Health and Lifestyle Research Unit at Queen Mary University of London (QMUL), which is commissioned to deliver the SSS for the local boroughs of Tower Hamlets and the City of London, and the Leicester and East Sussex SSSs.

## Method: With probability threshold of 65%

Line 17: Overview of trial design

Line 18: This was a pragmatic RCT conducted between 2015 and 2018 in three sites in England that provide local SSSs.

Line 37: Setting

Line 38: Recruitment and delivery of the interventions took place at the Health and Lifestyle Research Unit at Queen Mary University of London (QMUL), which is commissioned to deliver the SSS for the local boroughs of Tower Hamlets and the City of London, and the Leicester and East Sussex SSSs.

Line 117: This was set up and hosted by the Barts Clinical Trials Unit (CTU).

Line 144: Randomisation

Line 145: Randomisation (1 : 1 in permuted blocks of 20) was undertaken using a web-based application, set up by the Barts CTU, and was stratified by trial site.

Line 175: carried out sensitivity analyses using multiple imputations via chained equation and excluding cases with missing outcomes.

Line 492: Economic analysis

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## P: With probability threshold of 95%

Line 29: Participants were included if they were aged ≥ 18 years, were current smokers who wanted to quit smoking and were able to read/write/understand English.

Line 30: Participants were excluded if they were pregnant or breastfeeding, had a strong preference for or against using NRT or e-cigarettes in their quit attempt, were currently enrolled in other interventional research or were currently using NRT or e-cigarettes.

Line 173: included participants lost to follow-up (i.e.

Line 302: The sample comprised mostly middle-aged smokers who started to smoke at a median age of 16 years and tried various smoking cessation aids before joining the trial.

Line 420: The trial sample comprised participants who are typical of clientele of UK SSSs: middle-aged smokers unable to quit smoking unaided, including some 40% in receipt of free prescriptions (a marker of illness or social disadvantage), with high baseline CO readings, who have tried a range of stop smoking aids before.

## P: With probability threshold of 90%

Line 29: Participants were included if they were aged ≥ 18 years, were current smokers who wanted to quit smoking and were able to read/write/understand English.

Line 30: Participants were excluded if they were pregnant or breastfeeding, had a strong preference for or against using NRT or e-cigarettes in their quit attempt, were currently enrolled in other interventional research or were currently using NRT or e-cigarettes.

Line 173: included participants lost to follow-up (i.e.

Line 179: Participants who moved to an untraceable address and whose telephone number(s) and e-mail address were no longer in use were excluded from the sample from the point that notification was received that they were no longer living at the address and their telephone number(s)/e-mail address were no longer in use, as per the Russell Standard.

Line 187: If outcome data at previous follow-up points were missing but no data were available to contradict claims of sustained abstinence, the participants who reported smoking no more than five cigarettes in total since 2 weeks post TQD at the 52-week follow-up and whose self-report was validated by a CO reading of < 8 p.p.m.

Line 192: including only participants who attended at least one treatment session, namely only those who engaged in treatment

Line 193: excluding participants who used the unassigned trial product for 5 consecutive days or more

Line 237: Three members of the panel were current e-cigarette users.

Line 302: The sample comprised mostly middle-aged smokers who started to smoke at a median age of 16 years and tried various smoking cessation aids before joining the trial.

Line 420: The trial sample comprised participants who are typical of clientele of UK SSSs: middle-aged smokers unable to quit smoking unaided, including some 40% in receipt of free prescriptions (a marker of illness or social disadvantage), with high baseline CO readings, who have tried a range of stop smoking aids before.

## 

## O: Probability threshold 95%:

Line 100: Fagerström Test for Cigarette Dependence (FTCD) score16

Line 101: score on the Mood and Physical Symptoms Scale, which measures severity of urges to smoke and other tobacco withdrawal symptoms17

Line 102: self-reported smoking status

Line 106: e-cigarette/NRT use and ratings of helpfulness in refraining from smoking cigarettes (from 1 = not at all helpful to 5 = extremely helpful) and satisfaction and how good it tasted in comparison with usual cigarettes (much less than normal cigarettes = 1, a little less = 2, the same = 3, a little more = 4, much more than normal cigarettes = 5)

Line 108: additional economic evaluation measures: EuroQoL-5 Dimensions, five-level version (EQ-5D-5L), score at baseline and at 6 and 12 months;18 smoking cessation service and health service use at baseline and during the preceding period at 6 and 12 months.

Line 109: Adverse reactions

Line 113: The following were evaluated at each session: nausea, throat/mouth irritation, sleep disturbances, dizziness, headache and four indicators of respiratory health: shortness of breath, cough, wheezing and phlegm.

Line 166: a summary measure of the outcome by treatment group, for example mean [standard deviation (SD)] for continuous outcomes and number (%) for binary outcomes

Line 181: Primary outcome

Line 183: a self-report of smoking no more than five cigarettes since 2 weeks post TQD), validated by a CO reading of < 8 p.p.m.

Line 197: Secondary outcomes

Line 205: Outcome Definition

Line 206: CO-validated sustained abstinence between 26 and 52 weeks post TQD Reporting no more than five cigarettes smoked between weeks 26 and 52, accompanied by a CO reading of < 8 p.p.m.

Line 209: CO-validated sustained abstinence at 4 weeks post TQD Reporting not a single puff in the previous 2 weeks at Q + 4 follow-up, accompanied by a CO reading of < 8 p.p.m.

Line 211: Sustained abstinence at 26 weeks post TQD Reporting no more than five cigarettes smoked since 2 weeks post TQD at Q + 24

Line 212: 7-day point prevalence at 4 weeks post TQD Reporting not a single puff in the previous 7 days

Line 213: 7-day point prevalence at 26 weeks post TQD Reporting not a single puff in the previous 7 days

Line 214: 7-day point prevalence at 52 weeks post TQD Reporting not a single puff in the previous 7 days

Line 219: Tobacco withdrawal symptoms at 1 and 4 weeks

Line 221: Treatment ratings (satisfaction, taste, helpfulness, reasons for stopping product use)

Line 225: Adverse reactions

Line 228: Changes in respiratory symptoms

Line 303: Abstinence rates

Line 308: TABLE 4 Sustained CO-validated abstinence rates at each time point and 52-week CO-validated smoking reduction

Line 325: TABLE 6 Seven-day smoking abstinence at each follow-up

Line 331: Attendance and adherence

Line 372: Urges to smoke

Line 389: Adverse reactions

Line 403: TABLE 20 Baseline and 12-month respiratory symptoms

Line 441: Product use at 1 year

Line 450: Product adherence and attractiveness

## I: With probability threshold of 95%

Line 10: Participants had access to cartridge-based e-cigarettes in both trial arms, but one arm was also given stop smoking medications.

Line 19: Eligible smokers seeking help to quit were randomised (1 : 1) to receive a NRT of their choice (a single NRT product or product combinations) plus usual care (weekly behavioural support provided by the SSS) or e-cigarettes plus usual care.

Line 20: Participants attended weekly sessions at their SSS, as per standard practice, and were followed up by telephone at 6 and 12 months.

Line 25: leaflets distributed to local households) was added.

Line 33: SSSs included information about the study in their advertising (typically posters, leaflets, digital media, local papers, through general practices, mail-outs to previous attenders and in local radio/newspaper interviews).

Line 34: Leaflets advertising the trial were also delivered to local households.

Line 48: Identical multisession behavioural support was provided to both trial arms.

Line 49: The exact procedures differed slightly between trial sites, but they followed the same treatment approach (withdrawal-oriented therapy14) that involves face-to-face support sessions with CO monitoring, which usually begins 1 or 2 weeks prior to the target quit date (TQD).

Line 50: Clients attended sessions weekly, typically for 4 weeks post TQD.

Line 58: Nicotine replacement therapy arm

Line 59: Participants were advised about the NRT products available at the baseline session.

Line 60: They chose their preferred NRT, as per usual practice, and were also provided with an option to use NRT combinations (normally the patch and one of the oral products) as per usual practice.

Line 62: A letter of recommendation (LOR) to supply NRT was issued on a fortnightly basis for up to 12 weeks at the London SSS, which service users exchange at a pharmacy in return for the NRT.

Line 64: East Sussex and Leicester service users receive direct supply of NRT free of charge, for up to 12 weeks.

Line 66: At sites that used LORs, all participants were given a LOR at their baseline session (as per standard practice).

Line 67: They were instructed to collect the NRT and bring it to their TQD session.

Line 69: Participants randomised to the e-cigarette condition, swapped their NRT for an e-cigarette starter pack (see E-cigarette arm).

Line 70: For sites that provided NRT directly, participants were provided with their NRT or e-cigarette during the TQD session following randomisation.

Line 71: For all sites, instructions on NRT use were provided as per routine clinic support.

Line 72: At the completion of the trial treatment period, participants could request further supplies of NRT in line with the SSS standard practice.

Line 73: Participants in the NRT arm were free to switch to other forms of NRT; this was recorded at every contact point.

Line 74: E-cigarette arm

Line 75: As noted in the previous section, participants in the e-cigarette group who attended a site using LORs were given a NRT LOR at their baseline session and were asked to collect the NRT and bring it to their TQD session.

Line 76: Participants who were then randomised to e-cigarettes at the TQD swapped their NRT for the e-cigarette starter kit.

Line 77: Participants randomised to the e-cigarette arm who attended a site that did not use LORs were provided with their e-cigarette starter kit at the TQD session.

Line 78: A starter pack was given to initiate e-cigarette use and demonstrate refillable e-cigarette products.

Line 79: Participants were expected to source their own e-liquid and were also encouraged to purchase a different device if the provided one did not suit their needs.

Line 80: To start the participants on using the e-cigarette, we provided a Conformité Européenne (CE)-marked refillable e-cigarette with 2 or 3 weeks’ supply (1 × 30-ml bottle) of e-liquid.

Line 81: The e-liquid was labelled as 18 mg/ml of nicotine, the most commonly used nicotine content at the time.15 The e-cigarette used was ‘One Kit’, an Aspire® (Shenzhen Eigate Technology Co. Ltd, Shenzhen, China) device with a 2.1-Ω resistance atomiser coil and a 650-mAh battery, branded by the UK Ecig Store (London, UK).

Line 86: The One Kit 2016 was purchased for £13 with the following accessories: an atomiser five pack (£3.75), a UK adapter (£2.99) and a spare battery (£7.50).

Line 88: The e-liquid used was 30 ml of Tobacco Royale flavour, purchased from the UK Ecig Store for £2.99.

Line 89: Verbal and written guidance was given about how to use the e-cigarette.

Line 91: Participants were instructed to obtain further supplies of e-liquid themselves and advised on how to do this via the internet or local vape shops.

Line 92: They were encouraged to try different strengths and flavours of e-liquids if they did not like the supplied one.

Line 93: Participants who did not manage to source their own supplies of e-liquid were provided with one additional supply on request (1 × 10-ml bottle), but this was not proactively offered.

Line 240: The DMEC and the TSC convened every 6–12 months.

Line 424: They were also encouraged to buy a different e-cigarette model if needed.

Line 429: Nicotine replacement therapy was provided under generous conditions that are probably optimal for treatment efficacy.

Line 430: The medication was provided free of charge, apart from the prescription charge applicable at one trial site.

Line 432: NRT use was also supervised by SSS clinicians trained in guiding clients and optimising NRT use.

Line 434: At the SSSs that provide NRT on LOR, participants in both groups had to collect NRT from a pharmacy, and the e-cigarette group exchanged this for an e-cigarette at randomisation.

Line 463: E-cigarette and nicotine replacement therapy products used

Line 464: The starter pack consisted of a refillable (tank) e-cigarette.

## I: With probability threshold of 95%

Line 20: Participants attended weekly sessions at their SSS, as per standard practice, and were followed up by telephone at 6 and 12 months.

Line 25: leaflets distributed to local households) was added.

Line 34: Leaflets advertising the trial were also delivered to local households.

Line 48: Identical multisession behavioural support was provided to both trial arms.

Line 67: They were instructed to collect the NRT and bring it to their TQD session.

Line 69: Participants randomised to the e-cigarette condition, swapped their NRT for an e-cigarette starter pack (see E-cigarette arm).

Line 71: For all sites, instructions on NRT use were provided as per routine clinic support.

Line 78: A starter pack was given to initiate e-cigarette use and demonstrate refillable e-cigarette products.

Line 80: To start the participants on using the e-cigarette, we provided a Conformité Européenne (CE)-marked refillable e-cigarette with 2 or 3 weeks’ supply (1 × 30-ml bottle) of e-liquid.

Line 89: Verbal and written guidance was given about how to use the e-cigarette.

Line 91: Participants were instructed to obtain further supplies of e-liquid themselves and advised on how to do this via the internet or local vape shops.

Line 93: Participants who did not manage to source their own supplies of e-liquid were provided with one additional supply on request (1 × 10-ml bottle), but this was not proactively offered.

Line 240: The DMEC and the TSC convened every 6–12 months.

Line 424: They were also encouraged to buy a different e-cigarette model if needed.

Line 432: NRT use was also supervised by SSS clinicians trained in guiding clients and optimising NRT use.

## 

# Trial 2: Clinical comparative effectiveness of acupuncture versus manual therapy treatment of lateral epicondylitis: feasibility randomized clinical trial

## M (60%):

Line 4: This pilot trial took place in an outpatient interdisciplinary institute of sports medicine and rehabilitation in Oslo, Norway.

Line 40: Trial design and setting

Line 41: To prepare for a full-scale trial, a feasibility RCT was conducted in a private, interdisciplinary outpatient health care setting (NIMI) in Oslo, Norway.

Line 42: The design is a three-armed RCT [19].

Line 44: The Regional Committees for Medical Research Ethics in South East Norway (Rek Sør-Øst B) (ref.

## P(95%):

Line 50: Adults 18–67 years old referred to physiotherapists or medical doctors at NIMI with pain from the lateral part of the elbow were screened for eligibility.

Line 52: Further inclusion criteria were pain on palpation, increased pain on resisted dorsiflexion of the wrist with the elbow extended and the fingers flexed, and resisted extension of the third finger [3].

Line 54: Other exclusion criteria were treatment with corticosteroid injection within the last 4 weeks, bilateral symptoms, radio-ulna or radio-humeral osteoarthritis, neck or shoulder problems, inflammatory rheumatic disease of the central or peripheral nervous system, or unwillingness to participate in the study.

Line 241: The comorbidities of neck and shoulder pain were selected as exclusion criteria, since the associated patients are reported to have a poorer prognosis in regard to duration of symptoms of LE and treatment outcomes [3, 8].

## I(95%):

Line 67: During a 12-week treatment period, patients received one of three treatments: eccentric exercise alone, acupuncture in addition to eccentric exercise, or manual therapy in addition to eccentric exercise.

Line 69: We instructed all patients to follow an eccentric exercise program for LE in order to strengthen the extensor muscles and tendon [22, 23].

Line 72: Participants were told to increase the load once a week by 10% of the starting weight, or less if their pain intensified.

Line 74: The patients were encouraged to do their exercise at home on a daily basis for the 12 weeks following enrollment.

Line 75: Further, a secretary at NIMI sent all included patients a weekly text message as a reminder to do their daily exercise.

Line 78: For the acupuncture in this study, we gave a generalized treatment, consisting of selected local points recommended by an expert panel for the treatment of LE; we selected LI11 and LI10 over the muscular origin of the lateral extensor group of the forearm and LU5 in the cubical region.

Line 83: Manual therapy

Line 84: Two physiotherapists with specific manual therapy qualifications and long clinical experience performed all the manual therapy sessions according to evidence-based physiotherapy.

Line 85: The manual therapy techniques consisted of Mulligan’s mobilization with movement (MWM) [25].

Line 86: The manual therapists performed a lateral glide with gripping, a posterior-anterior glide on the radial head with supination of the radio-ulnar joint, and a lateral gapping manipulation technique.

Line 87: The mobilization techniques consisted of three sets of eight repetitions [25].

Line 88: The eccentric exercise alone group was instructed once (on the day of randomization) and did not have any further contact with the therapists.

Line 89: They did receive a weekly text message by a secretary of NIMI, to be reminded to do their daily exercise at home.

Line 92: All groups received the same information and advice, including details about the natural course of the condition and expected duration of symptoms.

Line 191: They did receive a weekly text message, from a secretary at NIMI, to be reminded to do their exercise.

Line 195: The patients could also be encouraged to share their concerns with a therapist or research leader via e-mail.

## O(95%):

Line 6: Primary outcomes were patient retention and adherence rates.

Line 7: Secondary outcomes included patient-reported pain (NRS), level of disability (Quick-DASH), and participant's satisfaction with treatment and global perceived effect.

Line 95: Outcome measures

Line 101: Primary outcomes

Line 102: Retention was defined as the percentage of patients enrolled at baseline who completed all follow-up measures.

Line 106: Secondary outcomes

Line 107: Numeric rating scale (NRS)

Line 108: Secondary outcomes included patient-reported pain scores collected at weeks 1, 2, 3, 4, and 12 and 1 year after the start of treatment.

Line 113: Disabilities of the arm, shoulder, and hand (DASH)

Line 148: Outcomes and estimations

Line 150: Primary outcomes

Line 156: Secondary outcomes

Line 157: Patient-reported pain

Line 171: Level of disability of the elbow and arm

Line 176: Patient satisfaction

# COHORT

Metabolic Syndrome and Mortality in Continuous Ambulatory Peritoneal Dialysis Patients: A 5-Year Prospective Cohort Study.

Kidney Blood Press Res

## M(50%):

Line 3: A single-center, prospective, observational cohort study was conducted in CAPD patients enrolled from September 1 to December 31, 2011, and followed up until December 31, 2016.

Line 25: Study Population

## P(50%):

Line 26: All patients came from the PD center of the First Affiliated Hospital of Sun Yat-sen University between September 1 and December 31, 2011, who had accepted CAPD therapy longer than 1 month and visited the PD center regularly.

Line 27: Patients who were younger than 18 years old, or had infection during the last 3 months, or had a history of malignancy, or had incomplete clinical and laboratory data, or unwilling to sign the informed consent were excluded.

Line 38: MS diagnosis criterion was the modified version of the US National Cholesterol Education Program (NCEP), Adult Treatment Panel III (2001) [15].

Line 39: It requires 3 or more of the 5 components below: (1) systolic blood pressure ≥130 mm Hg and/or diastolic blood pressure ≥85 mm Hg or diagnosed hypertension on treatment; (2) serum TG ≥1.7 mmol/L; (3) serum high-density lipoprotein-cholesterol <1 mmol/L in male, or <1.3 mmol/L in female; (4) fasting blood glucose ≥5.6 mmol/L or diagnosed diabetes on treatment; (5) body mass index (BMI) >25 kg/m2 for Asians [21, 22].

Line 116: Many criteria including WHO criterion, International Diabetes Federation criterion, original NCEP and modified NCEP criterion were available.

## O(75%):

Line 4: Demographic, clinical, biochemical and anthropological data were collected.

Line 5: The relationships between MS and mortality and technique failure were assessed using Kaplan-Meier and Cox Regression Survival Functions.

Line 30: Patients’ data including age, gender, primary kidney disease, presence of CVD, PD vintage, glucose load of dialysate, fasting blood glucose, total cholesterol, triglycerides, high-density lipoprotein-cholesterol, low-density lipoprotein-cholesterol, white blood cell (WBC), red blood cell, platelet, blood urea nitrogen, serum creatinine, alkaline phosphatase, high-sensitivity C-reactive protein (HsCRP), globulin and blood uric acid were collected.

Line 32: Residual kidney function, total weekly Kt/V, and the 4th hour dialysate to plasma ratio of creatinine were calculated and reported by PD Adequest Software (Baxter Healthcare Co., Ltd.).

Line 34: The end point of follow-up included death, transferring to other PD centers, transferring to hemodialysis (HD) center, giving up or drop out till December 31, 2016.

Line 35: Diagnosis of CVD, Diabetes and MS

Line 36: CVD was defined as sudden death, myocardial infarction, angina, congestive heart failure, malignant arrhythmia, stroke or peripheral vascular disease with or without amputation [3, 4].

Line 37: Diabetic status was defined according to the 1999 World Health Organization (WHO) diagnostic criterion as type I or type II [5] and was registered as the primary cause of end-stage renal disease.

Line 40: BMI, instead of waist circumference, was employed to depict the abdominal obesity.

Line 43: Results were expressed as frequencies and percentages for categorical variables, mean ± SD for continuous variables, and median (interquartile range) for skewed distributions.

Line 44: Normality of the data was assessed with Kolmogorov-Smirnov test.

Line 47: The intensity of death and technique failure were calculated as the number of incident cases divided by the number of person-years of the follow-up [23].

Line 51: Cox proportional hazard models were used to evaluate the independent associations of MS with the risk of all-cause, cardiovascular mortality and technique failure.

Line 52: In the analysis of all-cause or cardiovascular survival, the end point and censored event were all-cause or cardiovascular death.

Line 56: Patient Characteristics

Line 68: Patient Survival

Line 75: Kaplan-Meier Survival Functions were made.

Line 83: 1 Kaplan-Meier survival functions between MS group versus non-MS group of all-cause mortality in all patients.

Line 86: 2 Kaplan-Meier survival functions between MS group versus non-MS group of cardiovascular mortality in all patients.

Line 89: 3 Kaplan-Meier survival functions between MS group versus non-MS group of cardiovascular mortality in no-diabetic patients.

Line 92: Cox Regression model was done for MS’ impact on all-cause mortality and cardiovascular mortality in all, non-diabetic and diabetic patients.

Line 93: The indicators that may have an effect on mortality such as gender, age, WBC, PLT, HsCRP and eGFR were included.

Line 97: Technique Survival

## I(50%):

Line 28: All patients have used peritoneal dialysate of Baxter (Healthcare Guangzhou Co., Ltd., Guangzhou, China).

## I(30%):

Line 28: All patients have used peritoneal dialysate of Baxter (Healthcare Guangzhou Co., Ltd., Guangzhou, China).

Line 31: Blood sample for the laboratory check was taken under the condition of fasting in the morning and measured by the automatic chemistry analyzer (Hitachi 7180 and Abbott Aeroset) in the clinical laboratory of our hospital.

Line 33: Blood pressure was measured by an experienced nurse using standard sphygmomanometers on the right arm of the patients who had at least 5 min of rest and we took the mean of 3 tests as the final result.

# Old RCT

A clinical trial of the angiotensin-converting-enzyme inhibitor trandolapril in patients with left ventricular dysfunction after myocardial infarction. Trandolapril Cardiac Evaluation (TRACE) Study Group.

[**N Engl J Med.**](https://www.ncbi.nlm.nih.gov/pubmed/7477219)**1995 Dec 21;333(25):1670-6.**

## M(90%):

Line 19: A detailed description of the study and demographic information on the screened population have been reported previously.10,11 In brief, TRACE was a double-blind, randomized, placebo-controlled study conducted at 27 centers in Denmark.

## M(15%):

Line 19: A detailed description of the study and demographic information on the screened population have been reported previously.10,11 In brief, TRACE was a double-blind, randomized, placebo-controlled study conducted at 27 centers in Denmark.

Line 20: The study was registered with the National Board of Health and the Danish Data Protection Agency and was approved by the regional ethics committees.

Line 21: An independent safety committee reviewed quarterly safety reports, as well as three preplanned interim analyses of mortality.

Line 22: SCREENING AND INCLUSION

Line 23: All participating hospitals identified all patients with myocardial infarction within their catchment areas.

Line 30: Double-blind medication was started between day 3 and day 7 after the myocardial infarction.

Line 38: When the results of the Survival and Ventricular Enlargement (SAVE) study were published,5 showing no survival benefit until after almost one year of treatment with ACE inhibitors, the steering committee decided (without any knowledge of the results of the study) to extend the closing date to 24 months after the last random assignment.

Line 43: The committee determined the cause of death independently of its timing.

Line 45: A reinfarction end-point committee evaluated all cases of nonfatal reinfarction reported by the investigators; again, this review was performed before the treatment code was broken.

Line 50: STATISTICAL ANALYSIS

Line 61: Calculations were performed with the SAS software (SAS Institute, Cary, N.C.).

Line 62: PATIENT SELECTION AND DEMOGRAPHIC DATA

Line 74: The three preplanned interim analyses of mortality were conducted in June 1991 (with a total of 673 patients), February 1992 (with a total of 1209), and August 1993 (with a total of 1745).

Line 102: FOLLOW-UP AND WITHDRAWAL

Line 103: The follow-up period was 24 to 50 months.

Line 117: Unlike other large trials of treatment after myocardial infarction, the TRACE study was performed in one small country, Denmark.

Line 145: Supported by grants from Roussel–Uclaf and Knoll.

## P(75%):

Line 1: We screened 6676 consecutive patients with 7001 myocardial infarctions confirmed by enzyme studies.

Line 24: Consecutive patients above the age of 18 years who were hospitalized with myocardial infarction were screened between day 2 and day 6 after the onset of symptoms.

Line 25: The criteria for myocardial infarction were chest pain or electrocardiographic changes suggestive of infarction or ischemia, accompanied by an increase in the level of one or more cardiac enzymes to at least twice the upper limit of the normal value at the laboratory of the participating hospital.

Line 27: Only the following exclusion criteria were used: an absolute or relative contraindication to ACE inhibition or a definite need for ACE inhibition; severe, uncontrolled diabetes mellitus; hyponatremia (<125 mmol of sodium per liter); an elevated serum creatinine level (2.3 mg per deciliter [200 μmol per liter]); pregnancy or lactation; acute pulmonary embolism; vascular collagen disease; nonischemic obstructive heart disease; unstable angina pectoris requiring immediate invasive therapy; severe liver disease; neutropenia; concurrent immunosuppressive or antineoplastic therapy; drug or alcohol abuse; or treatment with another investigational drug.

Line 65: A total of 3920 patients were excluded because they had a wall-motion index that was higher than 1.2, and 475 were excluded because the wall-motion index could not be determined.

Line 69: Of the 2606 eligible patients, 859 were excluded because of mandatory ACE inhibition (150 patients), cardiogenic shock (101), death during screening (70), renal failure or a single kidney (65), intolerance of the test dose of trandolapril (39), lack of consent (218), or other reasons (216).

Line 128: Patients with overt heart failure or active ischemia were specifically excluded from the SAVE study, whereas the TRACE study was designed to include the majority of patients with left ventricular systolic dysfunction.

Line 132: On the other hand, patients with left ventricular dysfunction but without signs of heart failure would have been excluded from the AIRE study.

## P(95%):

Line 1: We screened 6676 consecutive patients with 7001 myocardial infarctions confirmed by enzyme studies.

Line 24: Consecutive patients above the age of 18 years who were hospitalized with myocardial infarction were screened between day 2 and day 6 after the onset of symptoms.

Line 27: Only the following exclusion criteria were used: an absolute or relative contraindication to ACE inhibition or a definite need for ACE inhibition; severe, uncontrolled diabetes mellitus; hyponatremia (<125 mmol of sodium per liter); an elevated serum creatinine level (2.3 mg per deciliter [200 μmol per liter]); pregnancy or lactation; acute pulmonary embolism; vascular collagen disease; nonischemic obstructive heart disease; unstable angina pectoris requiring immediate invasive therapy; severe liver disease; neutropenia; concurrent immunosuppressive or antineoplastic therapy; drug or alcohol abuse; or treatment with another investigational drug.

Line 128: Patients with overt heart failure or active ischemia were specifically excluded from the SAVE study, whereas the TRACE study was designed to include the majority of patients with left ventricular systolic dysfunction.

## I(95%):

Line 32: After two days, the dose was increased to 2 mg of trandolapril once daily or matching placebo.

Line 33: After four weeks, the dose was again increased, to 4 mg once daily or matching placebo.

Line 34: If the highest dose was not tolerated, patients could continue with a dose of 2 mg or 1 mg once daily, but the drug was withdrawn if a dose of 1 mg once daily was not tolerated.

## I(90%):

Line 31: Patients were randomly assigned to receive 1 mg of trandolapril once daily or matching placebo on the basis of a computer-generated assignment scheme with randomization in blocks of four and stratification according to the center and the degree of left ventricular dysfunction (wall-motion index, <0.8 or between 0.8 and 1.2).

Line 32: After two days, the dose was increased to 2 mg of trandolapril once daily or matching placebo.

Line 33: After four weeks, the dose was again increased, to 4 mg once daily or matching placebo.

Line 34: If the highest dose was not tolerated, patients could continue with a dose of 2 mg or 1 mg once daily, but the drug was withdrawn if a dose of 1 mg once daily was not tolerated.

## O(95%):

Line 39: END POINTS

Line 47: The primary end point was death from any cause.

Line 49: Secondary end points were death from a cardiovascular cause, sudden death, progression to severe heart failure (defined as the first of the following events: hospital admission for heart failure, death due to progressive heart failure, or heart failure necessitating the administration of open-label ACE inhibition), recurrent infarction (fatal or nonfatal), and a change in the wall-motion index.

Line 73: MORTALITY

Line 86: Event Rates for the Secondary End Points of Death from Cardiovascular Causes, Sudden Death, Reinfarction, and Severe or Resistant Heart Failure among Patients Receiving Trandolapril or Placebo.

Line 93: OTHER CLINICAL END POINTS

Line 108: Incidence of Adverse Events.

# Multilingual Results:

## M:

Line 1: Methoden: In einer randomisierten, placebokontrollierten klinischen Studie wurden 314 Patienten mit bis zu 3 Tagen bestehenden Symptomen, leichtem bis moderatem Gesichtsschmerz und einem Major Rhinosinusitis Symptom Score (MRSS) ≥ 8 und ≤ 14 für 15 Tage (Tag 0 erster Arztbesuch plus 14 Tage Behandlung) eingeschlossen und mit Sinusitis Hevert SL oder Placebo behandelt.

Line 1: Patienten und Methoden: Prospektive, unkontrollierte Pilotstudie.

Line 12: Unterstützt durch: LETI Pharma, Witten, Deutschland

Line 1: Method of study , a randomized , single-blind and control , treatment period of @ weeks .

Line 8: 方法研究采用随机 、 单盲和对照的方法 , 治疗周期为@周 。

Line 1: 方法于@-@ / @-@在广州市精神病医院普通精神科住院病区中选择符合中国精神障碍分类与诊断标准第三版精神分裂症诊断标准的住院精神分裂症患者@例 , 用掷硬币法随机分为观察组和对照组各@例 , 男女比例各半 。

Line 0: Introduzione.

Line 6: Risultati.

Line 0: Summary.

Line 2: Randomised open label trial.

## P:

Line 1: Methoden: In einer randomisierten, placebokontrollierten klinischen Studie wurden 314 Patienten mit bis zu 3 Tagen bestehenden Symptomen, leichtem bis moderatem Gesichtsschmerz und einem Major Rhinosinusitis Symptom Score (MRSS) ≥ 8 und ≤ 14 für 15 Tage (Tag 0 erster Arztbesuch plus 14 Tage Behandlung) eingeschlossen und mit Sinusitis Hevert SL oder Placebo behandelt.

Line 2: 30 Patienten (22 Frauen, 8 MÄnner), Kellgren-Stadien I–III, mit Fingergelenks- (N = 10), Cox- (N = 8) und Gonarthrose (N = 12) unterzogen sich einer 2-wÖchigen ambulanten Fastenintervention nach Buchinger mit 3 Entlastungstagen, 8 Fastentagen (300 kcal) und 4 Aufbautagen sowie Followup nach 4 und 12 Wochen.

Line 3: Methoden: 184 baumpollenallergische Patienten im Alter von 18–65 Jahren wurden in einer doppelblinden, placebokontrolllierten (DBPC) Studie über 18 Monate behandelt.

Line 1: SUBJECTS|P|Methods @ patients with acute schizophrenia excited patients were randomly divided into the oral risperidone combined intramuscular clonazepam group of @ cases and @ cases of intramuscular haloperidol group therapy , treatment for @ days .

Line 2: Two groups of @ patients , of which @ cases Zhuofei group , the Risperdal group of @ patients included in the efficacy and safety analysis .

Line 8: 结果所有入组的@例精神分裂症患者全部进入结果分析 。

Line 7: Da novembre 2014 ad agosto 2015 sono stati arruolati 57 bambini, 29 nel gruppo sperimentale (50.8%) e 28 nel gruppo di controllo (49.2%).

## I:

Line 1: Methoden: In einer randomisierten, placebokontrollierten klinischen Studie wurden 314 Patienten mit bis zu 3 Tagen bestehenden Symptomen, leichtem bis moderatem Gesichtsschmerz und einem Major Rhinosinusitis Symptom Score (MRSS) ≥ 8 und ≤ 14 für 15 Tage (Tag 0 erster Arztbesuch plus 14 Tage Behandlung) eingeschlossen und mit Sinusitis Hevert SL oder Placebo behandelt.

Line 5: Entgleisungen autonomer bzw.

Line 1: Das Verfahren basiert auf einer Kombination der traditionellen Behandlung (Okklusion) mit einem sensorischen Trainingsreiz (apparative Pleoptik), welcher in den Kontext von Computerspielen implementiert wurde.

Line 5: Ferner wurden spezifische IgE und IgG4 gegen Birkenpollen vor und nach der Behandlung beurteilt.

Line 1: SUBJECTS|P|Methods @ patients with acute schizophrenia excited patients were randomly divided into the oral risperidone combined intramuscular clonazepam group of @ cases and @ cases of intramuscular haloperidol group therapy , treatment for @ days .

Line 6: 方法@例精神分裂症急性期兴奋患者 , 随机分为口服利培酮合并肌肉注射氯硝西泮组@例和肌肉注射氟哌啶醇组@例治疗 , 疗程为@d 。

Line 8: 方法研究采用随机 、 单盲和对照的方法 , 治疗周期为@周 。

Line 1: 方法于@-@ / @-@在广州市精神病医院普通精神科住院病区中选择符合中国精神障碍分类与诊断标准第三版精神分裂症诊断标准的住院精神分裂症患者@例 , 用掷硬币法随机分为观察组和对照组各@例 , 男女比例各半 。

Line 2: 两组患者均接受抗精神病药物维持治疗和常规护理 , 观察组在此基础上增加家庭模式综合技能训练 , 让患者置身于医院内一个经特定布置的模拟家庭环境中训练 。

Line 3: 在护士的指导下 , 患者以@ ～ @人为小组进行 : ① 生活能力训练 。

Line 4: ② 社交基本技能训练 。

Line 5: ③ 社会家庭角色适应能力训练 , 连续@周 。

Line 10: ② 训练@周后观察组住院精神病患者康复疗效评定量表测评总分及其因子分 ( 工疗情况 , 生活能力 , 社交能力 , 讲究卫生能力 , 关心和兴趣 ) 均低于对照组 ( @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ) , 差异有显著性意义 ( t = @,@,@,@,@,@ , P < @ ～ @ ) 。

Line 0: Introduzione.

Line 2: Obiettivo.

Line 4: Metodi.

Line 5: Ai bambini del gruppo sperimentale veniva posizionata, al termine dell’intervento chirurgico, la valva sotto il gesso all’arto inferiore; nel gruppo di controllo il gesso veniva mantenuto in posizione con cuscini.

## O:

Line 2: Den primären Endpunkt bildeten die Responderrate im MRSS (Reduktion ≥ 50%) bei der Abschlussvisite sowie die Rate der Remissionen (komplettes Abklingen aller 5 Hauptsymptome).

Line 3: Sekundäre Zielkriterien bildeten die Einschätzung der Wirksamkeit durch den Prüfer (auf einer 4-Punkte-Skala) und der Sino-Nasal Outcome Test 20 German Adapted Version (SNOT-20 GAV; Selbsterhebung durch die Patienten).

Line 3: Bewertungskriterien: Globale SchmerzintensitÄt (Visuelle Analogskala, VAS); Anlauf-, Belastungs-, Ruheschmerz (VAS); Druckschmerzschwelle (DSS); Gelenkfunktion (Neutral-Null-Durchgangsmethode); Gesundheitsbezogene LebensqualitÄt (SF-36, bestehend aus Physical Component Score und Mental Component Score); Western Ontario and McMasters Universities Arthrose-Index (WOMAC); painDETECT©-Fragebogen (Pfizer); Analgetika-Konsum; KÖrpergewicht, Body-Mass-Index (BMI), Bauchumfang, Blutdruck, Puls sowie umfangreiche serologische Parameter.

Line 4: Ergebnisse: Signifikante Schmerzreduktion, Befindlichkeits- und Gelenkfunktionsverbesserung sowie signifikante Reduktion von KÖrpergewicht und BMI, Abnahme des Bauchumfangs im Fasten-und gesamten Studienzeitraum, Analgetikaverbrauch konnte reduziert werden.

Line 4: Der primäre Endpunkt war der kombinierte Symptom-und Medikationsscore (SMS) während der Frühblüher-Saison 2008.

Line 5: Ferner wurden spezifische IgE und IgG4 gegen Birkenpollen vor und nach der Behandlung beurteilt.

Line 2: Treatment during the assessment of the Positive and Negative Syndrome Scale ( PANSS ) excitement factor ( PANSS-EC ) , and adverse reactions Scale ( TESS ) .

Line 7: 治疗期间评估阳性和阴性症状量表 ( PANSS ) 兴奋因子 ( PANSS-EC ) 和不良反应量表 ( TESS ) 。

Line 3: Positive and Negative Syndrome Scale ( panss ) reduction rate and the clinical global impressions scale - the severity of the disease ( cgi-si ) to evaluate the efficacy the treatment adverse Scale ( tess ) , extrapyramidal adverse the response Inventory ( rsese ) and check vital signs , blood , liver function and ECG to evaluate safety .

Line 10: 用阳性和阴性症状量表 ( panss ) 及其减分率和总体临床印象量表-疾病严重程度 ( cgi-si ) 来评定疗效 , 用治疗中的不良反应量表 ( tess ) , 锥体外系不良反应量表 ( rsese ) 及查生命体征 、 血常规 、 肝功能和心电图等来评价安全性 。

Line 6: 并采用住院精神病患者社会功能评定量表和住院精神病患者康复疗效评定量表于入组前和入组后@周对全部患者进行测评 。

Line 10: ② 训练@周后观察组住院精神病患者康复疗效评定量表测评总分及其因子分 ( 工疗情况 , 生活能力 , 社交能力 , 讲究卫生能力 , 关心和兴趣 ) 均低于对照组 ( @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ; @ ± @,@ ± @ ) , 差异有显著性意义 ( t = @,@,@,@,@,@ , P < @ ～ @ ) 。