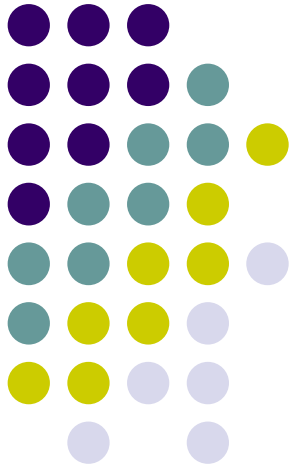
보고지침

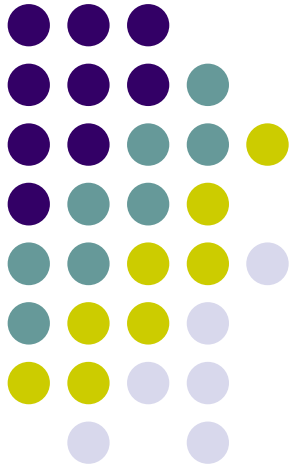
한림의대 가정의학과
김수영



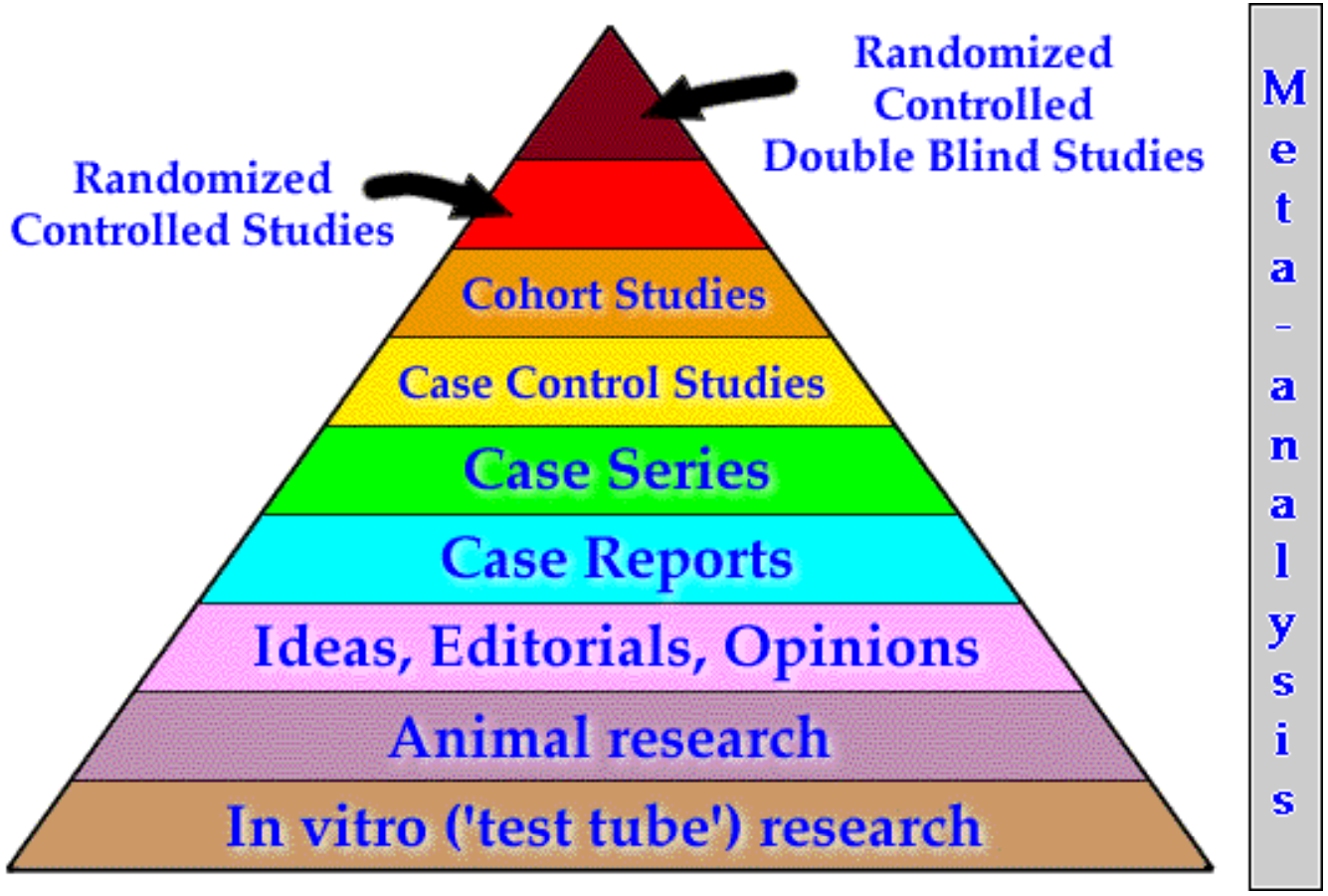
Outlines

- 연구 문헌의 분류
- 보고 지침이란?
- 보고지침
  - CONSORT
  - STARD
  - PRISMA(QUOROM)
  - MOOSE
  - STROBE

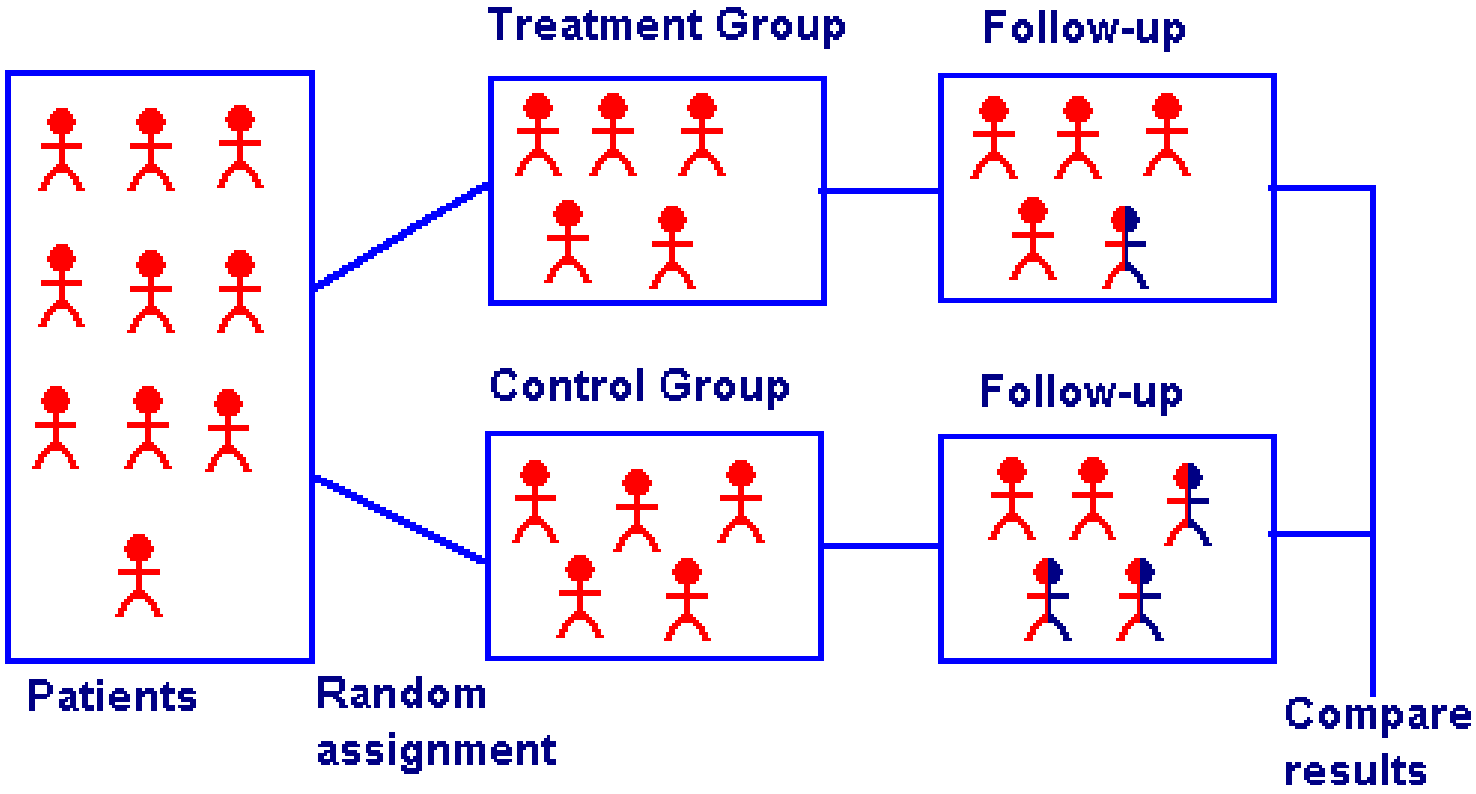
의학 연구 논문의 분류



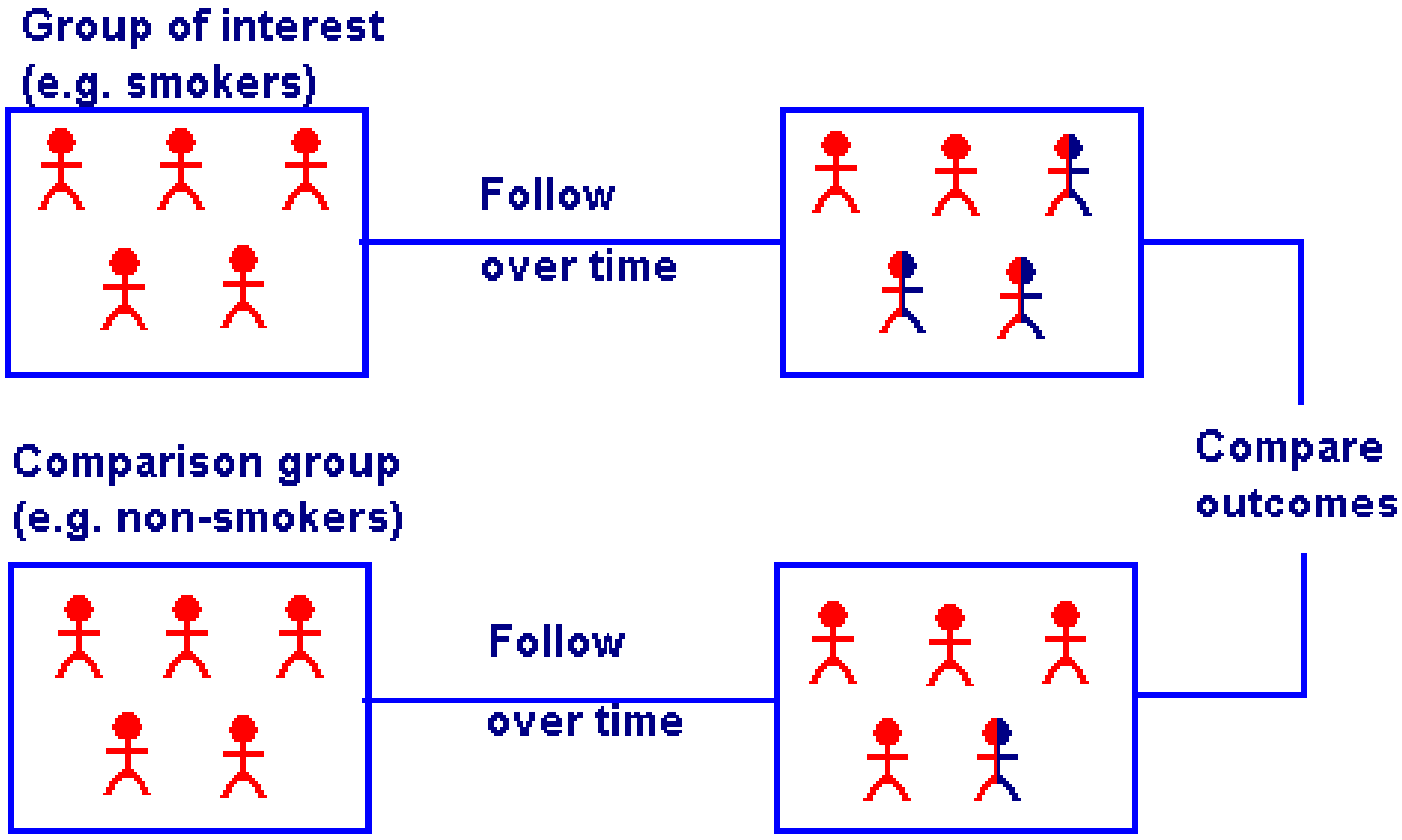
Evidence Pyramid



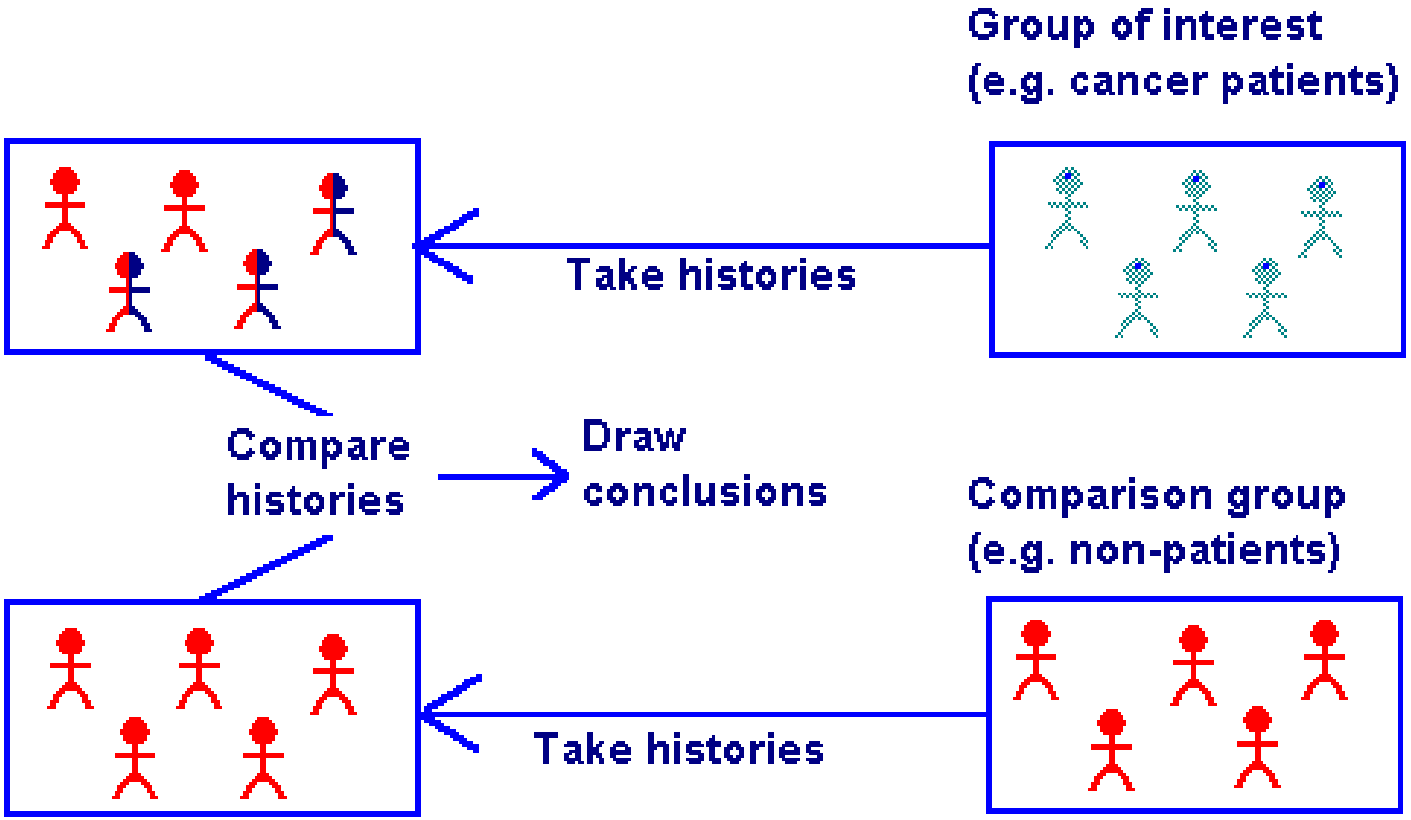
무작위 대조 연구


Treatment Group
Follow-up
Control Group
Follow-up
Patients
Random assignment
Compare results

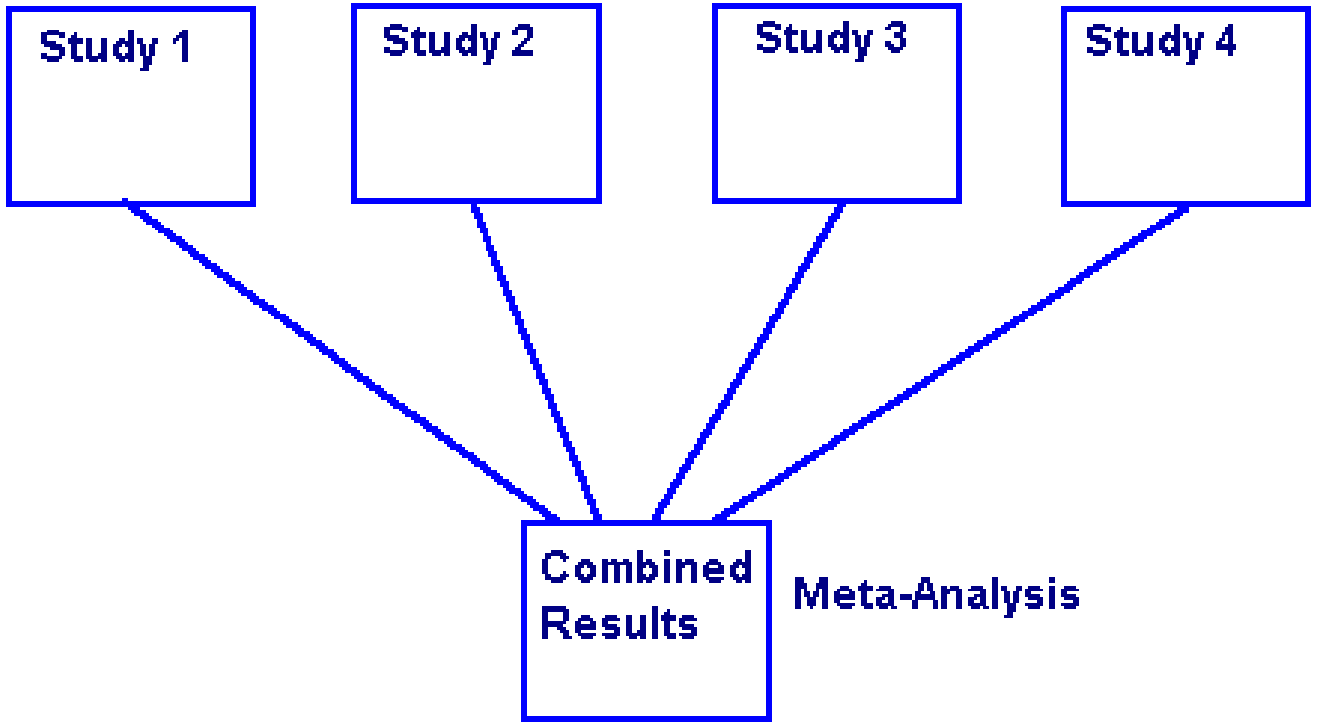
코호트 연구


Group of interest
(e.g. smokers)
Follow
over time
Comparison group
(e.g. non-smokers)
Follow
over time
Compare
outcomes

환자-대조군 연구


Group of interest
(e.g. cancer patients)
Take histories
Compare
histories
Draw
conclusions
Comparison group
(e.g. non-patients)
Take histories

메타분석


Study 1
Study 2
Study 3
Study 4
Combined Results
Meta-Analysis

유사 무작위 임상 시험

- *Quasi-randomised trial*
- 대상자는 연구자에 의해 중재군과 대조군으로 배정됨.
- 하지만 진정한 무작위화와 은폐배정이 이루어지지 않음

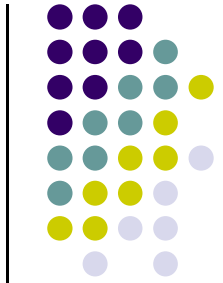
  예) allocated by date of birth, hospital record number 등

비무작위 시험/유사 시험 연구

- *Non-randomised trial/quasi-experimental study*
- 연구자가 배정을 하지만 무작위 방법을 쓰지 않음

  예) 환자 혹은 의사의 선호에 따라서
- 코호트 연구와 차이점은 관찰 보다는 실험 연구임

Observational designs

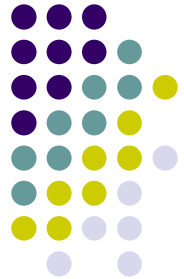


- *Controlled before-and-after study*
- *Concurrent cohort study*
- *Historical cohort study*
- *Case-control study*
- *Before-and-after study*
- *Cross-sectional study*
- *Case series*

전후 비교

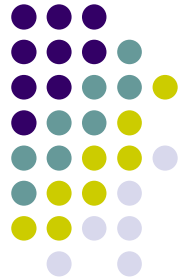
- *Before-and-after study*
- 중재 전후의 결과 비교
- 동일한 집단 혹은 다른 집단
- 연구자가 중재에 대해 통제하거나, 조절할 수 있으면 실험 연구로 간주함

동시적 코호트 연구



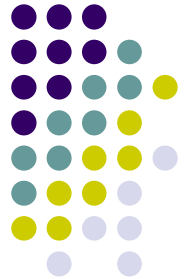
- *Concurrent cohort study*
- 중재를 받은 사람과 그렇지 않은 사람의 결과 비교
- 연구자들은 동일 기간 동안 추적관찰 함
- 전향적 혹은 후향적

역사적 코호트 연구



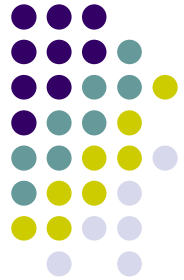
- *Historical cohort study*
- 전통적 코호트에 대한 변이적 형태
- 특정 기간 동안 새로운 중재에 대한 결과와 과거 중재를 받지 않은 사람들의 결과와 비교
- 참여자는 동시에 평가되지 않는다.

환자-대조군 연구

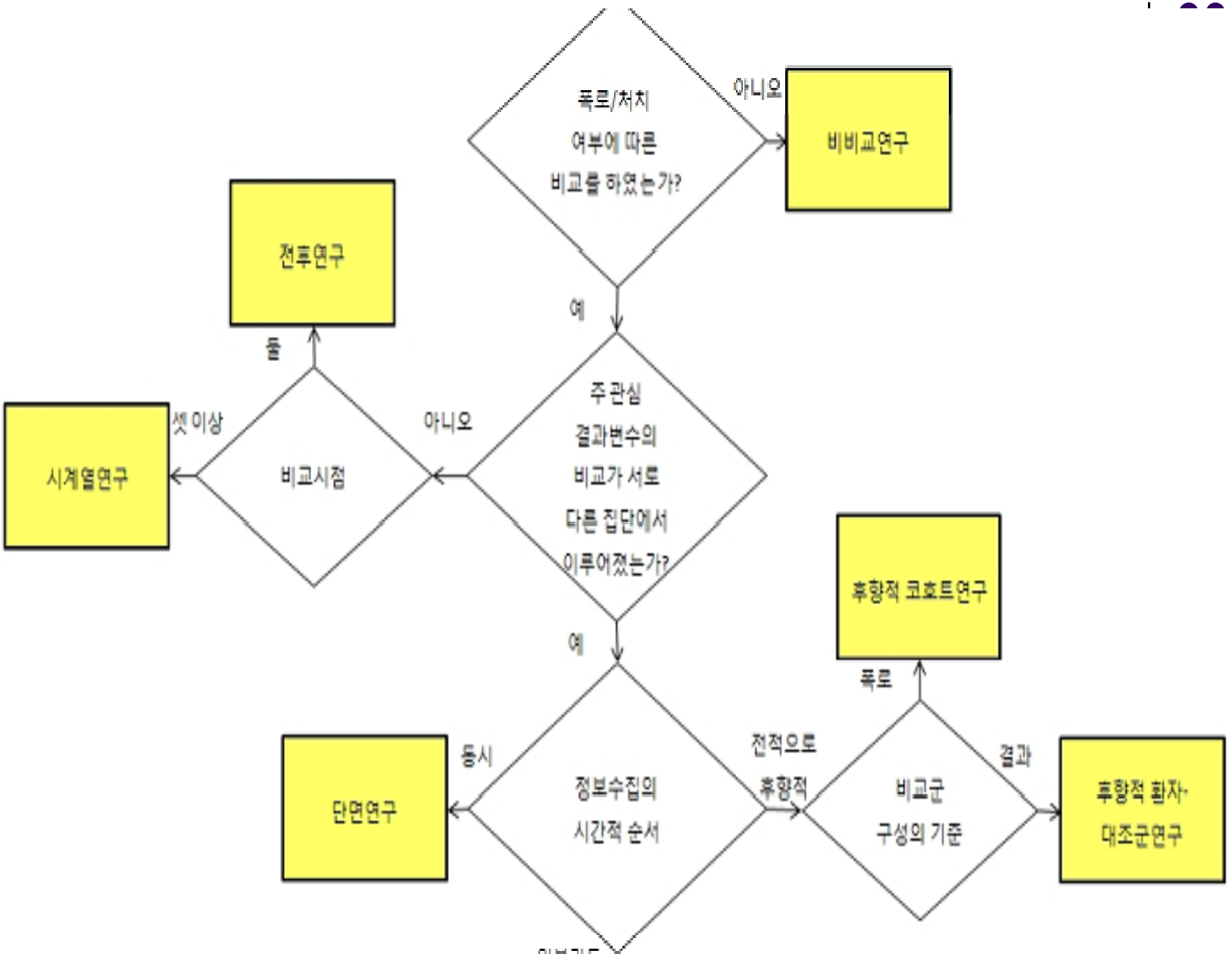


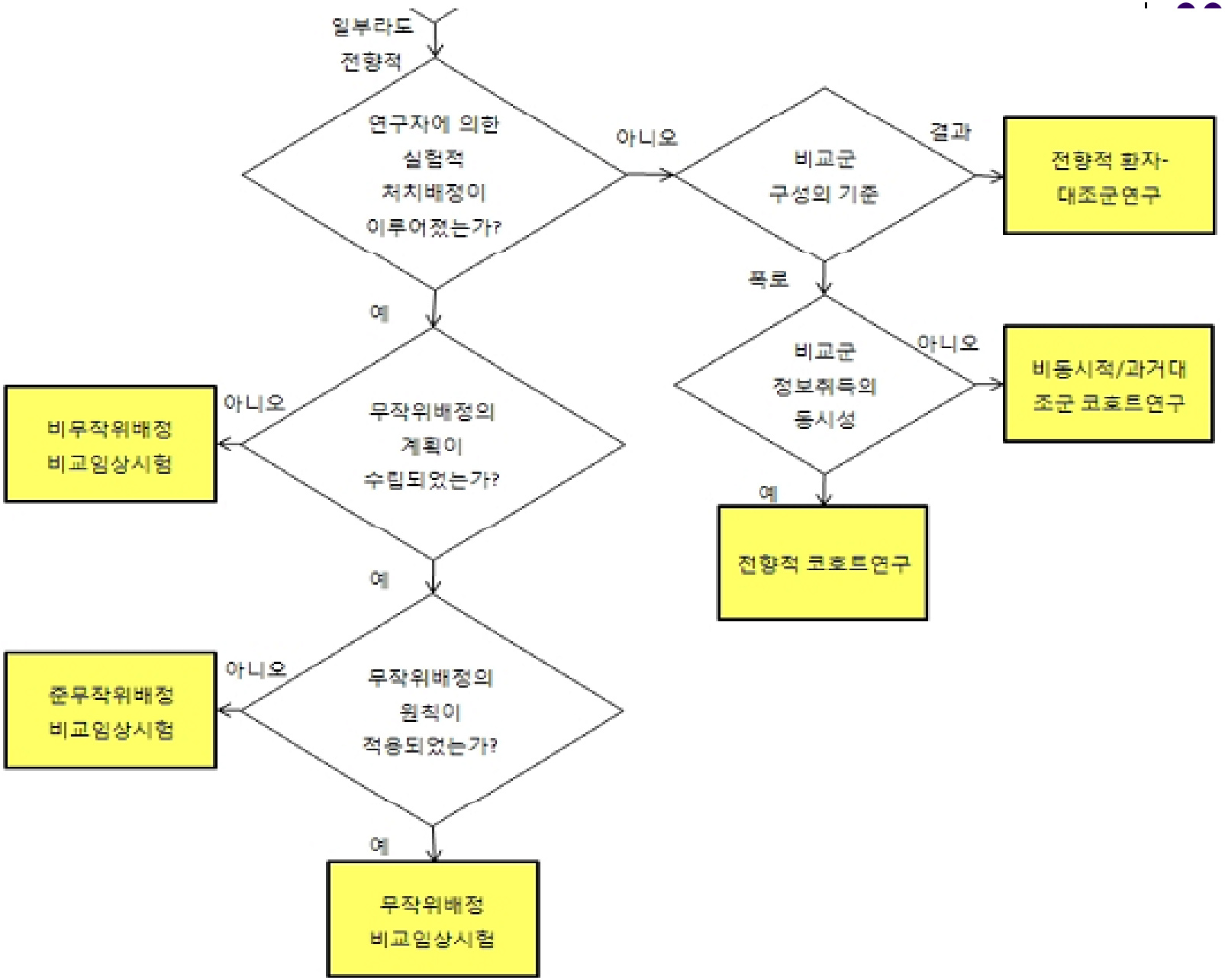
- *Case-control study*
- 해당 결과나 나타난 사람과 그렇지 않은 사람 (환자와 대조군)
- 해당 중재가 제공된 정도를 비교

환자 사례군

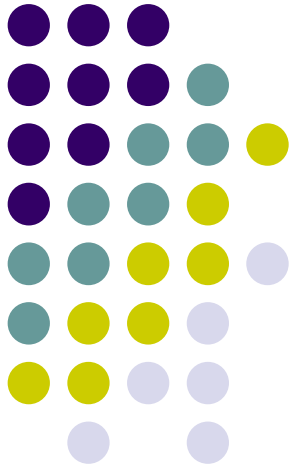


- *Case series : 주로 4례 이상*
- 중재와 결과에 대한 기술적 분석(대조군과 비교하지 않음)


독로/처치
여부에 따른
비교를 하였는가?
아니오
비비교연구
예
주관심
결과변수의
비교가 서로
다른 집단에서
이루어졌는가?
아니오
비교시점
셋 이상
시계열연구
둘
전후연구
예
정보수집의
시간적 순서
동시
단면연구
전적으로
후향적
비교군
구성의 기준
결과
후향적 환자-
대조군연구
독로
후향적 코호트연구


일부라도
전향적
연구자에 의한
실험적
처치배정이
이루어졌는가?
아니오
비교군
구성의 기준
결과
전향적 환자-
대조군연구
폭로
비교군
정보취득의
동시성
아니오
비동시적/과거대
조군 코호트연구
예
전향적 코호트연구
예
무작위배정의
계획이
수립되었는가?
아니오
비무작위배정
비교임상시험
예
무작위배정의
원칙이
적용되었는가?
아니오
준무작위배정
비교임상시험
예
무작위배정
비교임상시험

보고지침



보고지침 (Reporting guidelines)

- 연구 결과와 방법을 어떻게 보고할까에 대해 알려주는 기술
- 주로 체크리스트, 흐름도,
- 근거와 해당 분야 전문가 특히 방법론 전문가와 편집인의 합의로 결정

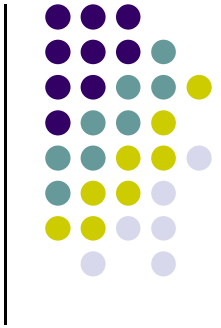
보고지침

- 정의
  - 연구 디자인에 따라서
  - 제목, 초록, 서론, 방법, 결과, 고찰에 반드시 들어가야 하는 지침
  - 최근 연구의 질 강조와 함께 중요한 화두로 등장

보고지침

- 필요 이유
  - 연구의 장점과 단점 파악
  - 논문의 질 평가
  - 적용 가능성의 평가
- 보고지침은 보고된 것을 판단하고 문헌의질 평가는 보고된 것이 적절한지를 판단한다
  - 예) 분석을 per protocol로 하였다.
    - 보고(+), 문헌의 질(-)

보고지침-종류



Initiative	Type of study	Source
CONSORT	randomized controlled trials	http://www.consort-statement.org
STARD	studies of diagnostic accuracy	http://www.stard-statement.org
QUOROM	systematic reviews and meta-analyses	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf
STROBE	observational studies in epidemiology	http://www.strobe-statement.org
MOOSE	meta-analyses of observational studies in epidemiology	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf

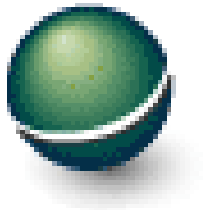
Uniform Requirements for Manuscripts Submitted to Biomedical Journals 2007

보고지침 -2009 update

- CONSORT Statement (reporting of randomized controlled trials)
- STARD (reporting of diagnostic accuracy studies)
- STROBE (reporting of observational studies in epidemiology)
- PRISMA (reporting of systematic reviews), which recently replaced QUOROM
- MOOSE (reporting of meta-analyses of observational studies)

EQUATOR network

- Enhancing the QUAlity and Trandparency Of health Research
- an international initiative
- to enhance reliability of medical research
- literature
- by promoting transparent and accurate reporting of research studies



equator network

Search: Go

Enhancing the QUAlity and Transparency Of health Research

Home | About EQUATOR | Resource Centre | Courses Events | Research Projects | Contact | News | Forum

Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability of medical research literature by promoting transparent and accurate reporting of research studies.

Find out how, or get involved.

Latest news

more news

PRISMA Statement now published

New guidance, superseding the existing QUOROM Statement, for reporting systematic reviews and meta-analyses is now available.

Read the full story

Highlights

EQUATOR Network at the Peer Review Congress 2009

9 September, Vancouver, Canada Workshop for editors and 2nd **Annual Lecture** presented by Dr Richard Horton, The Lancet

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Information about new reporting guidelines, events, and other news. **Subscribe** now

Reporting guidelines

Library for Health Research Reporting

Authors

Information for authors of research reports

Editors

Resources for journal editors and peer reviewers

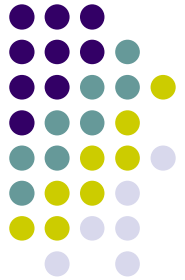
Developers

Resources for developers of reporting guidelines

The EQUATOR Network is funded by:

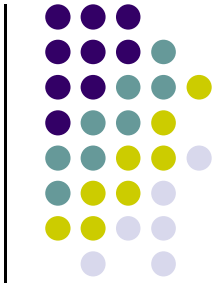
MRC Medical Research Council | CIHR IRSC | NHS

Listing of reporting guidelines



- Experimental studies
- Observational studies
- Diagnostic accuracy studies
- Systematic reviews
- Qualitative research
- Economic evaluations
- Quality improvement studies
- Other reporting guidelines
- Sections of research reports
- Specific conditions or procedures.

Reporting experimental studies



- RCT : CONSORT Statement
- Infection control intervention studies : ORION
- Non-randomised studies : TREND
- Neuro-oncology trials - phase I and II : GNOSIS
- STRICA : controlled trial of acpuncture, Behaviourla medicine, Occupational therapy

관찰 연구

Observational studies in epidemiology	STROBE
STROBE의 varient	
Genetic association studies	STREGA
Infection control intervention studies	ORION
Longitudinal observational studies in rheumatology	
Case series	
	acupuncture (conduct, reporting)
Case-control studies (participation)	
Case reports	
	Cases Journal
	BMJ guidance
Adverse event reports	
Tumour marker prognostic studies	REMARK
Prognostic studies with missing covariate data	
Genetic results in research studies	
Internet e-surveys	

현재 개발되고 있는 것

- The SPIRIT initiative (Standard Protocol Items for Randomized Trials)
- WIDER recommendations for reporting of behaviour change interventions
- Guidelines for reporting biomedical images in scientific journals

검색 순위

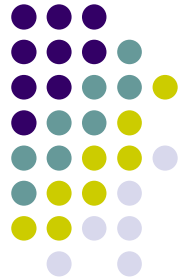
Download the most frequently-used reporting guidelines:

- CONSORT checklist
- CONSORT flowchart
- CONSORT extensions
- STARD checklist & flowchart
- STROBE checklists
- PRISMA checklist
- PRISMA flow diagram

NEJM

- In manuscripts that report on randomized clinical trials, authors may provide a flow diagram in CONSORT format and all of the information required by the CONSORT checklist. When restrictions on length prevent the inclusion of some of this information in the manuscript, it may be provided in a separate document submitted with the manuscript. The CONSORT statement, checklist, and flow diagram are available at http://www.consort-statement.org.

BMJ



- the original protocol for a clinical trial or, if the protocol has been published in an open access online journal, its reference and url
- for a randomised controlled trial, the appropriate completed CONSORT checklist showing on which page of your manuscript each checklist item appears, the CONSORT-style structured abstract, and the CONSORT flowchart (CONSORT has several extension statements, eg for cluster RCTs). To find research reporting guidelines and statements such as CONSORT you may find it easiest to go to the website of the EQUATOR network, where they are all available in one place. Because we aim to improve *BMJ* papers' reporting and increase reviewers' understanding we ask our research authors to follow such reporting guidelines and to complete the appropriate reporting checklist before submission (or before external peer review if not done sooner). We do not, however, use reporting guidelines as critical appraisal tools to evaluate study quality or filter out articles.
- PRISMA checklist and flowchart for a systematic review or meta-analysis of randomised trials and other evaluation studies (the PRISMA guidelines have superceded the QUOROM guidelines)
- MOOSE checklist and flowchart for a meta-analysis of observational studies
- STARD checklist and flowchart for a study of diagnostic accuracy
- STROBE checklist for an observational study

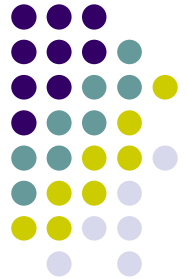
Annals of Internal Medicine

Requirements for all categories of articles largely conform to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," developed by the International Committee of Medical Journal Editors (ICMJE). Authors should write for a sophisticated general medical readership; follow principles of clear scientific writing (Gopen, Huth, CBESMC) and statistical reporting (Bailar, Lang); and prepare manuscripts according to recommended reporting guidelines and checklists (EQUATOR) whenever possible.

Ophthalmology

2. Design: identifies the study design using a phrase such as cross-sectional study, clinical trial, evidence based study, etc. New study desigr types are available in the Ophthalmology's Study Design Scheme and Worksheets section of this guide. Please select a study design from the choices listed there. Worksheet #1 (*modified CONSORT agreement*) for randomized controlled trials has been required since 1996 and is available online. Use of the other worksheets, while strongly recommended, remains voluntary and updated versions will be available online withir approximately 45 days.

대한가정의학회지

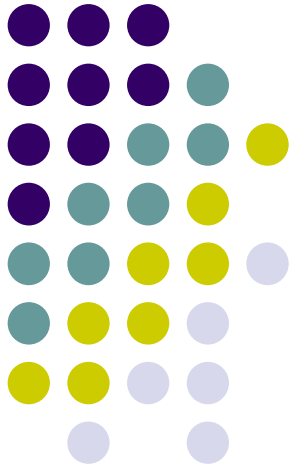


3. 보고권장 지침의 준수

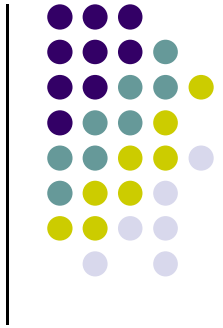
저자는 연구 디자인에 따라서 연구내용에 꼭 들어가야 할 정보를 파악하고 이를 원고에 반영하도록 하여야 한다. 무작위 대조연구는 CONSORT, 진단연구는 STARD, 관찰연구는 STROBE, 체계적 고찰은 QUOROM과 MOOSE를 참고한다.

약어	연구 디자인	웹주소
CONSORT	무작위 대조연구	http://www.consort-statement.org
STARD	진단 정확도 연구	http://www.consort-statement.org/stardstatement.htm
QUOROM	체계적 고찰	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf
STROBE	관찰 연구	http://www.strobe-statement.org
MOOSE	관찰 연구의 메타분석	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf

주요 보고 지침에 따른 논문 심사



CONSORT



- Consolidated Standards of Reporting Trials
- 무작위 대조 연구의 보고 지침
- 1996년 CONSORT group
- ICMJE, CSE, WAME 등에서 채택
- 도입 후 보고의 질 향상(+)

CONSORT-제목과 서론

- 제목/초록 : 배정방법(무작위 등)
- 서론/배경 : 과학적 배경과 근거설명

Safety and efficacy of piroxicam patches for treating knee osteoarthritis

Background/Aims : We wanted to compare the efficacy and safety of a Murupe® patch, which is a newly-developed piroxicam patch, with the Trast® patch for the treatment of knee osteoarthritis.

Methods : Two hundred ten patients with radiologically confirmed symptomatic osteoarthritis of the knee were included in a randomized, open-labeled controlled trial and they were treated with a 48 mg piroxicam patch once every 48 hours for 4 weeks. The main outcome measures were the pain intensity on movement and the spontaneous pain intensity during rest, and these were measured using the 10 cm Visual Analogue Scale (VAS) categorical pain scores, as measured by the patient and the investigator.

Results : One hundred sixty-seven of the 210 enrolled patients completed the 4 week study. The pain intensity on movement was significantly reduced in both the Trast® and Murupe® groups (p<0.001) after 4 weeks of treatment; the improvement on the VAS was significantly higher in the Murupe® group (n=82) than that in the Trast® group (n=85) (4.5 cm versus 2.2 cm, respectively, p<0.001). Both treatment groups also showed reductions in all the other parameters of pain intensity, including spontaneous pain intensity during rest, the categorical pain scores and the 15 meter-walking time. There was no difference in adverse events between both groups.

Conclusions : The superior analgesic activity of Murupe® patch indicates that the topical route of non-steroidal anti-inflammatory drug (NSAID) administration may be a safe, effective alternative to the oral route for the treatment of knee OA, and that the newly developed NSAID patch with its improved transdermal drug delivery may increase the efficacy of topical NSAIDs. (Korean J Med 74:537-545, 2008)

심사의 예

PAPER SECTIONAnd topic	Item	Descriptor	심사 내용
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	무작위 대조 연구의 보고지침인 CONSORT에 의하면 제목과 초록 모두에 무작위 대조 연구임을 나타내는 것을 권장합니다. 가능하면 제목도 "무작위 대조 연구" 등의 문구를 삽입하였으면 합니다.

CONSORT-방법

- 참여자 : 포함기준과 세팅
- 중재 : 구체적으로
- 연구 목표와 가설
- 결과 : 일차, 이차 결과를 명확히, 측정 질 향상 방법 기술
- 환자수 계산
- 배정의 순서
- 배정 은폐
- 배정 실행
- 맹검
- 통계 방법

시험군과 대조군은 모두 2004년 2월 1일부터 2004년 5월 10일까지 본원에서 무릎 관절의 골관절염으로 진단받은 환자들 중 임의로 정한 선정 기준과 제외 기준을 만족하는 환자를 대상으로 하였으며, 각 군당 105명씩, 모두 210명의 환자를 모집하여 조사하였다.

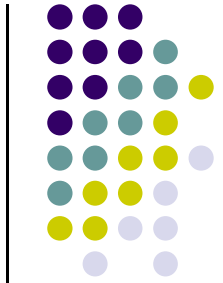
METHODS ***Participants***	3	***Eligibility criteria for participants and the settings and locations where the data were collected.***	방법에서 자료원의 위치와 세팅을 밝히도록 되어 있으나 그렇지 않습니다. 정확한 내용을 기술하여 주십시요

Sample size	7	***How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.***	각 군의 수는 어떻게 결정되었는지 명백히 밝혀야 합니다. (또한 가능하면 사전에 중간 분석를 시행할 계획이 있는지, 중간 분석을 바탕으로 임상시험을 중단할 계획이 있는지에 대해서 밝혀야 합니다.)

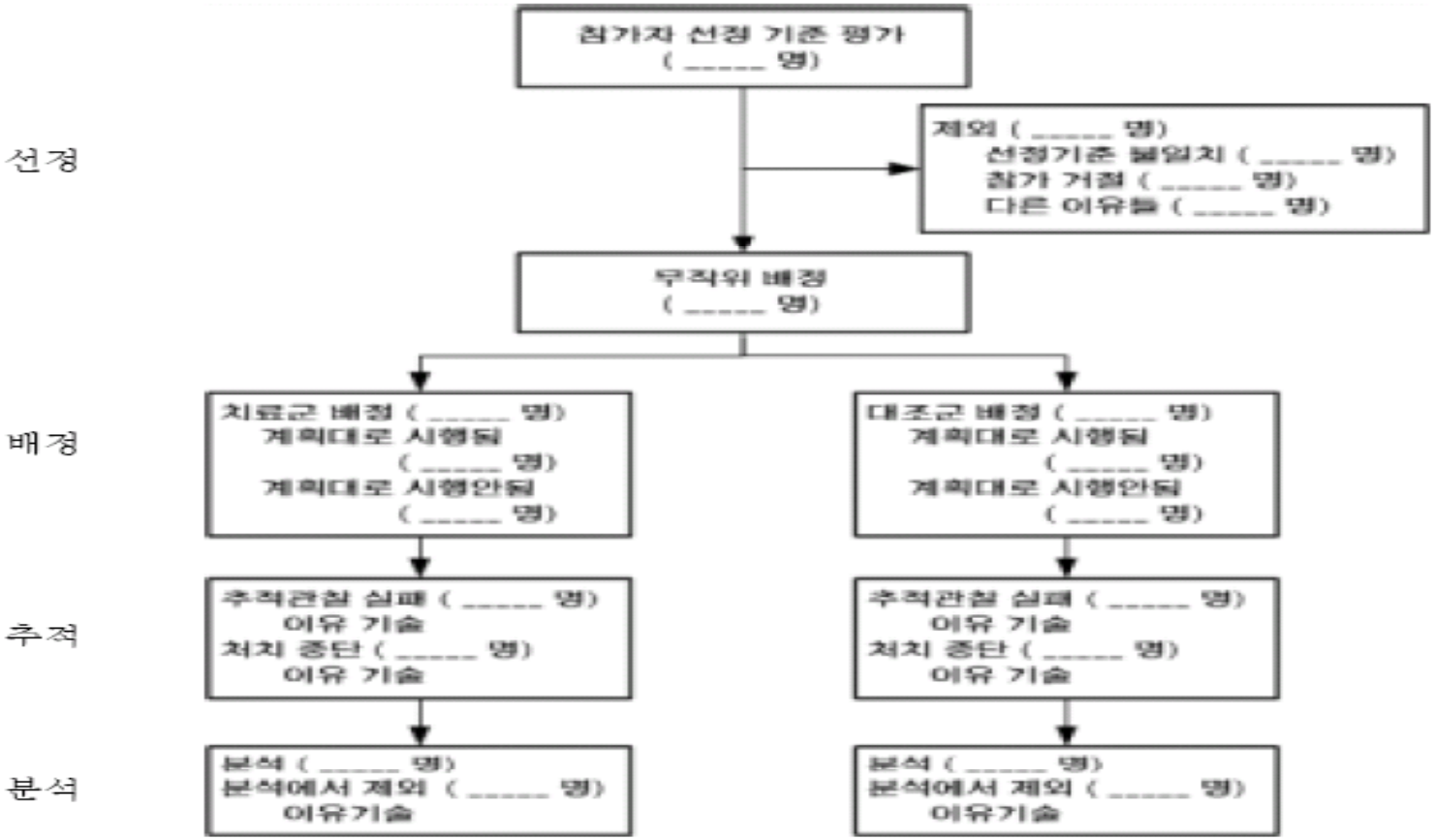
대상 환자는 무작위로 각각 105명씩 시험군(무르페군)과 대조군(트라스트군)으로 나누었으며 각각의 환자에게 해당 패취를 2일에 1매씩 4주간 증상이 있는 무릎 관절에 첩부하도록 하였고, 첩부 2주와 4주 후에 외래를 방문하여 유효성 평가와 안전성 평가를 실시하도록 하였다.

Randomization --Sequence generation	8	*Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)*	무작위 대조 연구에서 무작위 되었다고만 하면 안되며 무작위 순서를 어떻게 생성하였는지, 무작위 중 무작위가 어떻게 은폐되었는지 무작위는 누가 수행하고 참여자는 어떻게 배정하는지에 대해서 제시하여야 합니다.
Randomization --Allocation concealment	9	*Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.*	
Randomization –Implementation	10	*Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.*	

CONSORT-결과



- 참가자 흐름도
- 모집(기간과 추적관찰)
- 연구 시점 자료
- 분석된 숫자(ITT)
- 결과와 추정치
- 부가적 분석
- 부작용



RESULTS ***Participant flow***	***13***	***Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.***	CONSORT에 의하면 무작위 대조 연구의 경우 위와 같은 참여자 흐름도를 반드시 제시하여야 합니다. 그림과 같이 선정, 배정, 추적, 분석의 수를 제시하여 주시기 바랍니다.

모든 통계분석은 프로토콜에 준한 분석(per-protocol analysis)로 수행하였으며, 시험약제의 효과는 처리 의향 분석 결과에 근거하여 판단하였다. 통계적 유의성검정은 유의수준 0.05를 기준으로 하며, 통계 패키지 SAS (Ver 8.1)를 이용하여 분석하였다.

선정 기준과 제외 기준을 모두 만족하여 피험자로 선정되었던 환자는 모두 210명이었으며, 이 중 4주간의 임상시험을 완료한 환자는 무르페 군이 82명 트라스트 군이 85명이었다. 무르페 군의 평균 연령은 60.3세, 여자 환자의 비율

Table 2. Comparison of pain intensity on movement between the Murupe® and Trast® groups*

	Murupe®	Trast®	*p*-value	mean difference (95% C.I.)
	Mean (S.D)	Mean (S.D)		
Baseline	5.1 (1.6)	4.7 (1.4)	0.121	-0.363 (-0.823, 0.097)
After 2 weeks of treatment	2.6 (1.6)	3.5 (1.4)	<0.001	0.921 (0.467, 1.374)
After 4 weeks of treatment	0.6 (1.0)	2.5 (1.6)	<0.001	1.908 (1.501, 2.316)

*measured by the visual analogue scale, S.D: standard deviation, C.I: confidence interval

Numbers analyzed	***16***	***Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).***	분석을 PP, ITT로 하였는지 명확하게 제시하였지만 표 등에 분석한 참여자의 수를 제시하는 것이 도움이 됩니다.

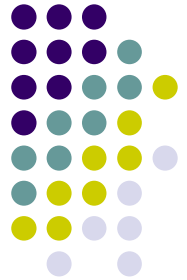
CONSORT-고찰

- 해석
- 일반화 여부
- 전체적 근거

일반화 가능성과 전체적인 근거

Generalizability	21	Generalizability (external validity) of the trial findings.	현재 임상 시험에서 얻은 결과의 일반화 가능성(외적 타당도)에 대해서 기술하여 주시기 바랍니다. 즉 현재의 결과가 다른 세팅, 다른 중증도를 가진 환자에게도 적용될 수 있는지에 대해서 기술하여 주시기 바랍니다.
Overall evidence	22	General interpretation of the results in the context of current evidence.	임상 시험의 결과가 전체적인 현존의 근거에 비추어 어떻게 해석할 수 있을지에 대해서 기술하여 주시기 바랍니다.

Extension of CONSORT



- Cluster trials
- Non-inferiority and equivalence trials
- Herbal medicinal interventions
- Non-pharmacological treatment interventions
- Harms
- Abstracts

CONSORT 전후 비교

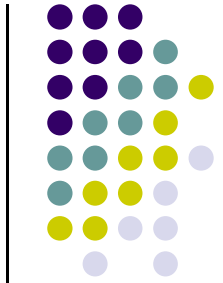
Table 2. Quality of Reports of Randomized Trials, Using an Assessment Tool, for Articles Published in *BMJ*, *JAMA*, *The Lancet*, and *The New England Journal of Medicine* (*NEJM*) During the First Half of 1994 and 1998*

			Randomization		Double-blinding		Dropouts/ Withdrawals		Total		Unclear Allocation Concealment	
	Total No. of Items		1994, Mean (SD)	1998, Change (95% CI)	1994, Mean (SD)	1998, Change (95% CI)	1994, %	1998, % Change (95% CI)	1994, Mean (SD)	1998, Change (95% CI)	1994, %	1998, % Change (95% CI)
Journal	1994	1998										
BMJ	14	20	1.1 (0.4)	0.4 (0.04 to 0.8)†	0.2 (0.6)	0.1 (–0.4 to 0.5)	71	–6 (–40 to 28)	2.1 (0.9)	0.4 (–0.3 to 1.2)	79	–29 (–62 to 4)
JAMA	29	20	1.3 (0.6)	0.1 (–0.3 to 0.4)	0.9 (0.8)	0.2 (–0.3 to 0.8)	76	4 (–21 to 29)	3.0 (1.0)	0.4 (–0.3 to 1.0)	59	–14 (–43 to 16)
Lancet	28	37	1.2 (0.4)	0.4 (0.1 to 0.6)†	0.6 (0.8)	0.3 (–0.2 to 0.7)	96	1 (–8 to 10)	2.8 (0.9)	0.7 (0.1 to 1.2)‡	54	–24 (–48 to 1)
Total Adopters	**71**	**77**	1.2 (0.5)	0.3 (0.1 to 0.4)†	0.6 (0.8)	0.2 (–0.1 to 0.4)	83	1 (–11 to 13)	2.7 (1.0)	0.4 (0.1 to 0.8)§	61	–22 (–38 to –6)‖
NEJM comparator	26	37	1.4 (0.5)	0.02 (–0.2 to 0.3)	0.8 (1.0)	0.3 (–0.4 to 0.5)	92	–6 (–21 to 10)	3.1 (1.0)	–0.01 (–0.6 to 0.5)	69	–8 (–33 to 17)

*CI indicates confidence interval.
†$P<.05$ (2-sided).
‡$P = .01$ (2-sided).
§$P = .02$ (2-sided).
‖$P = .008$ (2-sided).

– JAMA 2005 –

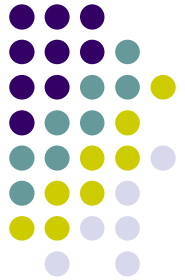
우리나라 CONSORT 준수



- KoreaMed 2005
- 총 125편
- 보고 비율이 낮은 것
  - Random sequence implementation (0%)
  - estimated effect size and its precision (0%)
  - sample size determination (8.9%)
  - method of random sequence generation (7.3%)
  - allocation concealment (3.2%)
  - participant flow (4.8%)
  - any other analysis (7.3%)
  - generalizability of the trial findings (0.8%)

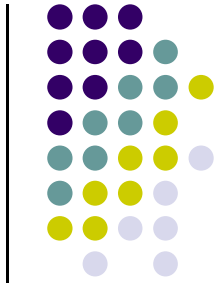
– KJFM 2008 –

STARD



- Standards for Reporting of Diagnostic Accuracy
- 진단검사 정확도의 보고의 질
- 25개 항목과 흐름도
- 2003년 제정

STARD – 제목, 초록



- 연구 디자인 제목/초록/주제어에 명백히 표현('sensitivity and specificity 추천)
- 연구 목적 분명히(검사들 간의 정확도 비교)

아벨리노 각막이상증 진단에 있어 DNA 칩의 민감도 및 특이도 평가

목적: βigh3 유전자 변형에 의한 각막이상증을 진단하는데 DNA 칩을 이용하는 방법의 민감도와 특이도를 평가하고자 한다.

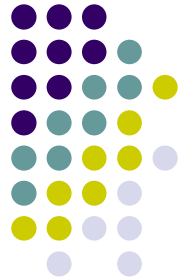
대상과 방법: 2006년 7월 1일부터 2007년 9월 30일까지 신촌 세브란스병원 안과 각막이상증 클리닉을 내원한 환자 중 병력청취와 의무기록 검토를 통해 각막이상증 이환여부의 진단이 필요한 227명을 대상으로 세극등현미경을 이용한 진단법과 DNA 칩을 활용한 새로운 진단법을 기존의 DNA sequencing을 이용한 진단법과 비교함으로써 두 가지 진단 방법의 정확도(민감도와 특이도)를 알아보고자 하였다.

결과: 227명의 대상자 중 기존의 DNA sequencing 방법으로 검사한 결과 각막이상증 환자가 124명(54.6%), 정상이 103명(45.4%)이었고, 세극등현미경을 이용한 방법은 민감도 99.19%, 특이도는 100%였고, DNA 칩을 이용한 방법은 민감도와 특이도 모두 100%였다.

결론: DNA 칩을 이용한 각막이상증 진단법은 시간이 덜 들고 간단한 방법이면서 민감도와 특이도가 모두 100%로 기존의 DNA sequencing 방법과 동일한 정확도를 보였다.

〈한안지 49(8):1220-1225, 2008〉

방법



- 참여자 : 연구 대상 모집단 기술, 모집 방법, 모집 추출방법, 자료 수집 방법
- 연구 검사 방법 : 참고 표준과 그 이유, 검사의 특징과 방법, 검사자, unit에 대한 정의, 결과 확인자의 맹검 여부
- 통계적 방법 : 불확실성을 다루는 방법(95% CI)

2006년 7월 1일부터 2007년 9월 30일까지 [redacted] 병원 안과 각막이상증 클리닉에 내원한 환자 중에서 병력청취와 진료기록을 검토하여 적합한 대상자를 선정하였다. 채혈이 가능한 생후 1개월 이상 환자로 각막이상증이 의심되거나 라식 및 라섹수술 등이 예정되어 있어서 각막이상증 검사가 필요하다고 판단되거나 가족 중 βigh3 변형 유전자 질환을 가진 환자를 대상으로 하였다. 모든 대상자에게 DNA sequencing과

METHODS Participants	*3*	***The study population**: The inclusion and exclusion criteria, setting and locations where data were collected.*	현재 병원의 위치나 병원 규모 등에 대한 기술이 필요합니다.
	5	***Participant sampling**: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.*	연구 대상자의 모집이 consecutive인지 여부에 대한 기술이 필요합니다.
	6	***Data collection**: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?*	연구가 전향적으로 이루어졌는지 후향적으로 이루어졌는지에 대한 기술이 필요합니다.

- 세극등현미경검사

세극등현미경을 이용하여 피험자의 각막을 관찰하였으며 특징적인 각막혼탁 여부를 관찰하여 아벨리노 각막이상증(GCD II) 이환 여부를 판단하였다.

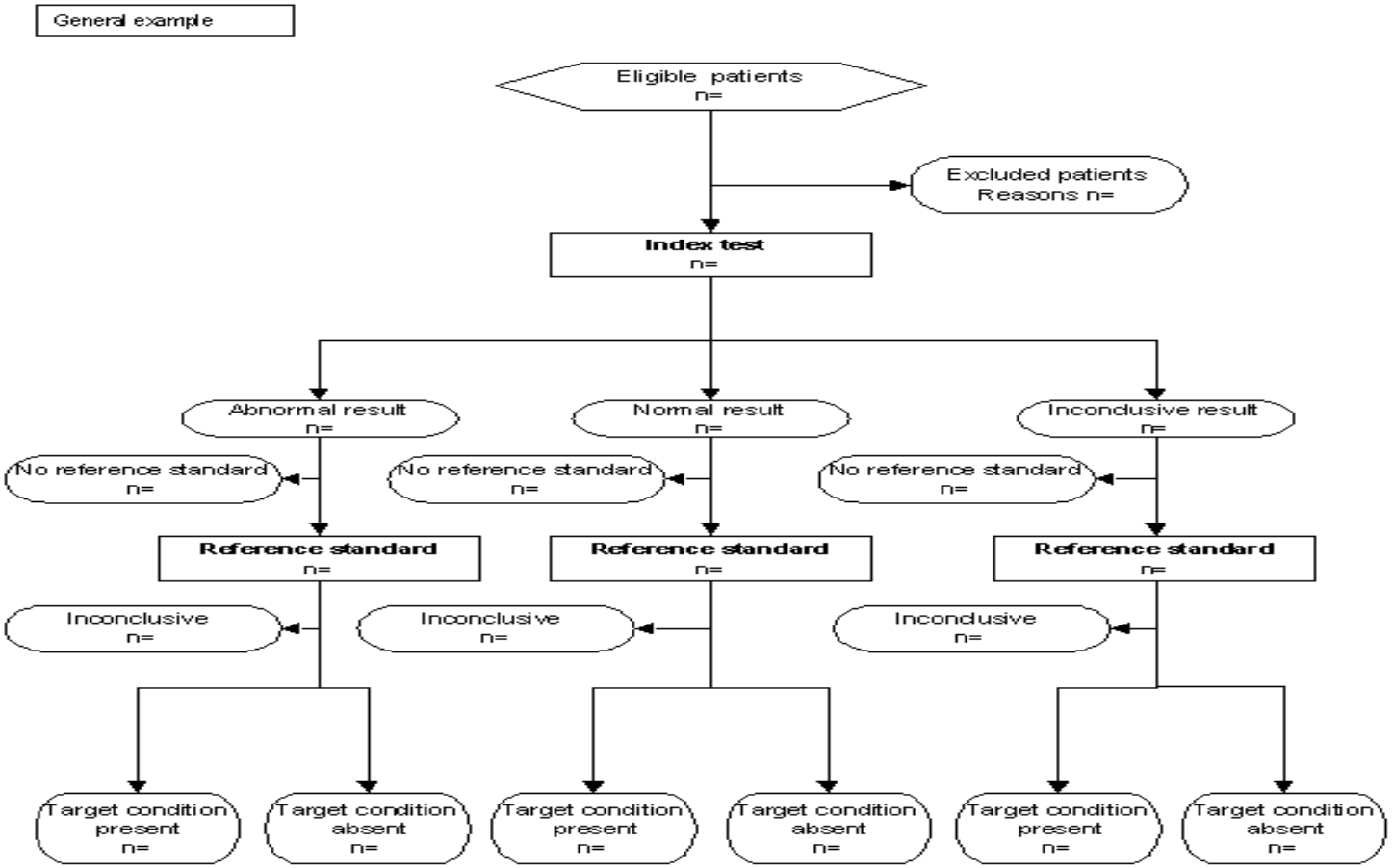
- DNA sequencing

피험자의 혈액 5 ml를 채취한 후, QIAmp DNA Blood Kit (Qiagen, Hilden, Germany)를 사용하여 genomic DNA를 채취하였다. βigh3 유전자의 primer를 이용하여 Polymerase Chain Reaction (PCR)을 수행하였다. 반응이 끝난 PCR 생산물의 일정량을 1.5% agarose gel에서 전기영동을 한 후 ethidium bromide 염색을 통해 확인하였다. 추가적인 염기 서열의 변이 여부를 관찰하기 위해 PCR 생산

Test methods	*7*	*The reference standard and its rationale.*	
	10	*The number, training and expertise of the persons executing and reading the index tests and the reference standard.*	검사는 누가 하고 숙련도를 고려한 훈련 등이 시행되었는지에 대한 기술이 필요합니다.
	11	*Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.*	결과에 대한 맹검이 이루어졌는지 등에 대한 기술이 필요합니다.

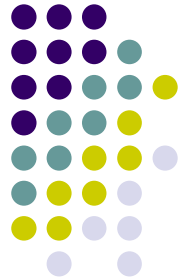
결과

- 참여자 : 연구 완료자, 연구 참여자의 임상적 인구의학적 특정, 검사 기준을 만족하는 사람의 수
- 검사 결과 : 검사간 시간 간격, 질병 심각도에 대한 보고, 두 검사간 동시 비교, 부작용 보고
- 추정 : 정확도와 통계적 추정치, 하부 집단 분석, 검사 신뢰도에 대한 정보



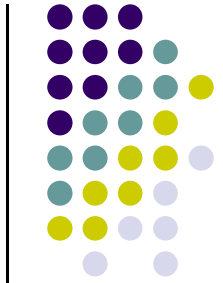
	16	*The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a **flow diagram** is strongly recommended).*	참여자에 대한 기술이 필요하며 참여자 흐름도를 권장합니다.

STARD 이후 호전



- STARD items ; 1.8개
- 호전 된 것
  - methods for calculating test reproducibility of the index test (16% vs 35%)
  - distribution of the severity of disease and other diagnoses (23% vs 53%)
  - estimates of variability of diagnostic accuracy between subgroups (39% vs 60%)
  - a flow diagram (2% vs 12%)

우리나라 실태



- 가정의학회지 31편
- 한 번도 보고되지 않은 것
  - 흐름도
  - 지표검사의 맹검 여부
  - 참조표준검사의 재현성을 계산하는 방법에 대한 설명
  - 연구과정 동안 생긴 검사에 의한 부작용
  - 참조표준검사의 재현성 측정

STROBE

- Strengthening the Reporting of Observational studies in epidemiology
- 관찰 연구
- 종류
  - 전체 체크리스트
  - 코호트, 환자-대조군, 단면 연구
- 2003. 1월 제정
- 2007. 10 제 4판

STROBE Statement

STrengthening the Reporting of OBservational studies in Epidemiology

STROBE checklist, version 4 (as published in Oct / Nov 2007)

STROBE checklist for cohort, case-control, and cross-sectional studies (combined)	pdf download Word download
Checklist for cohort studies	pdf download Word download
Checklist for case-control studies	pdf download Word download
Checklist for cross-sectional studies	pdf download Word download

Please, comment by contacting the STROBE Initiative.

Strobe-1

- 제목과 초록
  - 연구 디자인 명시, 초록에 충분한 정보가 있을 것
- 배경
  - 과학적 배경과 연구 이유 합리적으로 표현
  - 연구 목적과 가설 제시
- 방법
  - 연구 디자인 : 연구 디자인의 핵심 요소 제시
  - 세팅
  - 참여자 : 추적방법, 포함/배제 기준
  - 변수 : 결과, 노출, 혼란 변수, 진단 기준 등
  - 자료원/측정
  - 비뚤림 : 비뚤림 가능성에 대한 언급

STROBE-2

- 방법
  - 표본의 수
  - 양적 변수
  - 통계적 방법
- 결과
  - 참여자/기술 자료
  - 결과 자료/주요 결과/다른 분석
- 고찰
  - 주요 결과/한계/해석/일반화 가능성
- 다른 정보 : 연구비 지원

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

QUOROM

- *QU*ality *O*f *R*eporting *O*f *M*eta-analyses
- RCT의 메타분석
- 1999
- 18문항, 흐름도

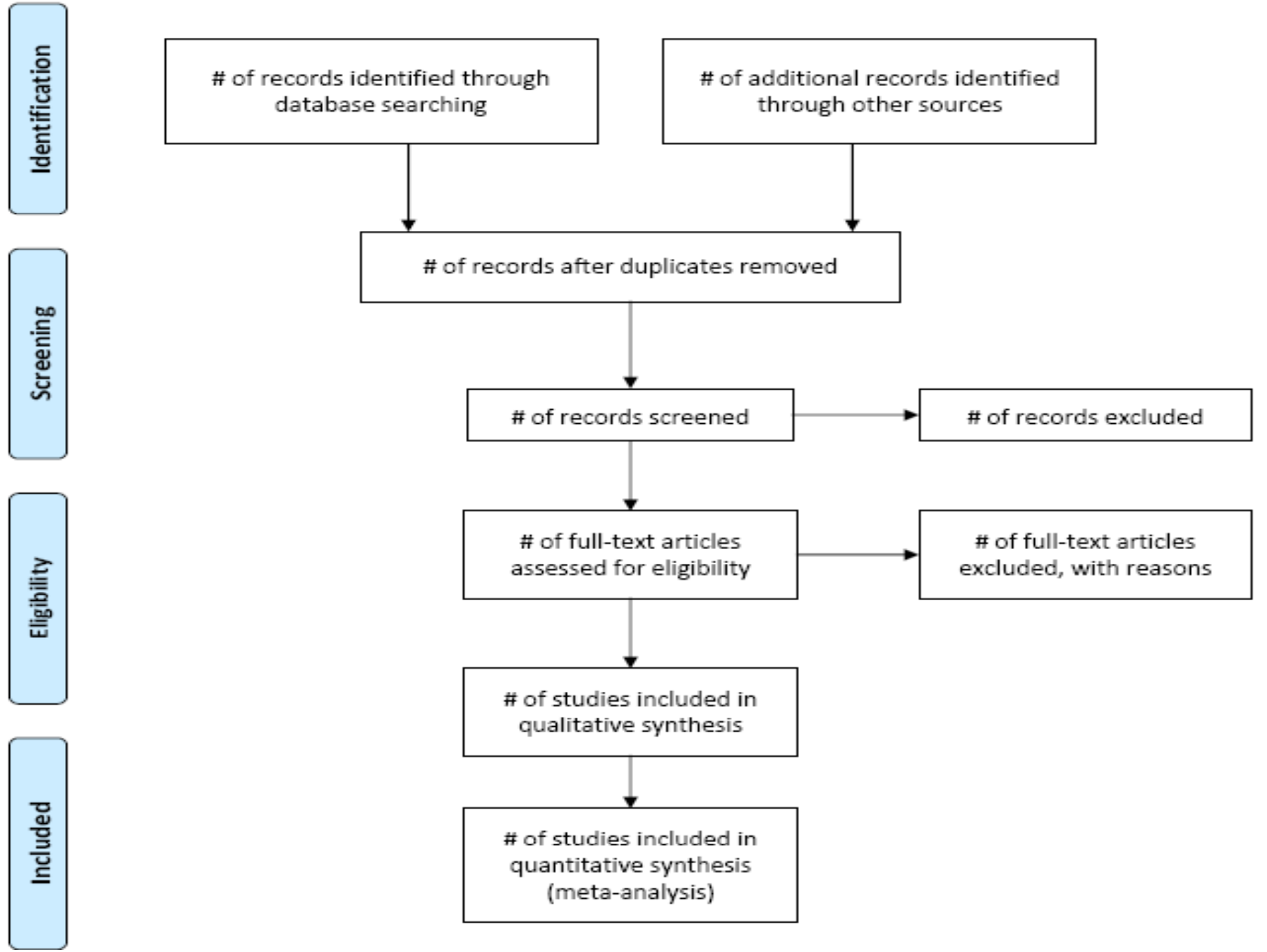
Heading	Subheading	Descriptor
Title		Identify the report as a meta-analysis [or systematic review] of RCTs[25]
Abstract		Use a structured format[27]
	Objectives	Describe The clinical question explicitly
	Data sources	The databases (ie, list) and other information sources
	Review methods	The selection criteria (ie, population, intervention, outcome, and study design); methods for validity assessment, data abstraction, and study characteristics, and quantitative data synthesis in sufficient detail to permit replication
	Results	Characteristics of the RCTs included and excluded; qualitative and quantitative findings (ie, point estimates and confidence intervals); and subgroup analyses
	Conclusion	The main results
		Describe
Introduction		The explicit clinical problem, biological rationale for the intervention, and rationale for review
Methods	Searching	The information sources, in detail[28] (eg, databases, registers, personal files, expert informants, agencies, hand-searching), and any restrictions (years considered, publication status,[29] language of publication[30,31])
	Selection	The inclusion and exclusion criteria (defining population, intervention, principal outcomes, and study design[32]
	Validity assessment	The criteria and process used (eg, masked conditions, quality assessment, and their findings[33-3
	Data abstraction	The process or processes used (eg, completed independently, in duplicate)[34,35]
	Study characteristics	The type of study design, participants' characteristics, details of intervention, outcome definitions, &c,[31] and how clinical heterogeneity was assessed
	Quantitative data synthesis	The principal measures of effect (eg, relative risk), method of combining results (statistical testing and confidence intervals), handling of missing data; how statistical heterogeneity was assessed;[36] a rationale for any a-priori sensitivity and subgroup analyses; and any assessment of publication bias[36]
Results	Trial flow	Provide a meta-analysis profile summarising trial flow (see figure)
	Study characteristics	Present descriptive data for each trial (eg, age, sample size, intervention, dose, duration, follow-up period)
	Quantitative data synthesis	Report agreement on the selection and validity assessment; present simple summary results (for each treatment group in each trial, for each primary outcome); present data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses (eg 2×2 tables of counts, means and SDs, proportions)
Discussion		Summarise key findings; discuss clinical inferences based on internal and external validity; interpret the results in light of the totality of available evidence; describe potential biases in the review process (eg, publication bias); and suggest a future research agenda

PRISMA

- 2009년 QUOROM Statement update
- Preferred Reporting Items of Systematic reviews and Meta-Analyses
- RCT에 초점을 맞추고 있지만 다른 연구 디자인도 적용 가능
- 질평가에 유용하기는 하지만 질평가 도구는 아님
- 27개 문항과 flow chart

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	


Identification
Screening
Eligibility
Included
# of records identified through database searching
# of additional records identified through other sources
# of records after duplicates removed
# of records screened
# of records excluded
# of full-text articles assessed for eligibility
# of full-text articles excluded, with reasons
# of studies included in qualitative synthesis
# of studies included in quantitative synthesis (meta-analysis)

MOOSE

- Meta-analysis of Observational Studies in Epidemiology
- 관찰 연구의 메타분석
- 2000년

Reporting of background should include
- Problem definition
- Hypothesis statement
- Description of study outcome(s)
- Type of exposure or intervention used
- Type of study designs used
- Study population

Reporting of search strategy should include
- Qualifications of searchers (eg, librarians and investigators)
- Search strategy, including time period included in the synthesis and keywords
- Effort to include all available studies, including contact with authors
- Databases and registries searched
- Search software used, name and version, including special features used (eg, explosion)
- Use of hand searching (eg, reference lists of obtained articles)
- List of citations located and those excluded, including justification
- Method of addressing articles published in languages other than English
- Method of handling abstracts and unpublished studies
- Description of any contact with authors

Reporting of methods should include
- Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested
- Rationale for the selection and coding of data (eg, sound clinical principles or convenience)
- Documentation of how data were classified and coded (eg, multiple raters, blinding, and interrater reliability)
- Assessment of confounding (eg, comparability of cases and controls in studies where appropriate)
- Assessment of study quality, including blinding of quality assessors; stratification or regression on possible predictors of study results
- Assessment of heterogeneity
- Description of statistical methods (eg, complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated
- Provision of appropriate tables and graphics

Reporting of results should include
- Graphic summarizing individual study estimates and overall estimate
- Table giving descriptive information for each study included
- Results of sensitivity testing (eg, subgroup analysis)
- Indication of statistical uncertainty of findings

Reporting of discussion should include
- Quantitative assessment of bias (eg, publication bias)
- Justification for exclusion (eg, exclusion of non–English-language citations)
- Assessment of quality of included studies

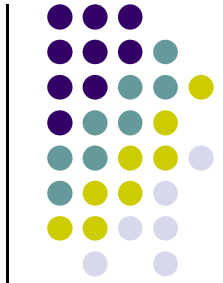
Reporting of conclusions should include
- Consideration of alternative explanations for observed results
- Generalization of the conclusions (ie, appropriate for the data presented and within the domain of the literature review)
- Guidelines for future research
- Disclosure of funding source

TREND

- Transparent Reporting of Evaluations with Nonrandomized Designs
- CONSORT와 유사한 포멧

– *Am J Public Health.* 2004 –

주요 내용



- 제목과 초록/배경 : Use of theory
- 방법
  - 중재와 대조 중재의 기술
  - 배정방법(연구 디자인)
  - 통계 방법/분석의 단위
- 결과
  - 기저 상태 자료와 동질성
  - ITT 여부 등

TREND checklist

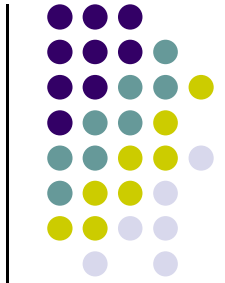


TABLE 1—The TREND Checklist (Version 1.0)

Paper Section/Topic	Item No.	Descriptor	Examples From HIV Behavioral Prevention Research
Title and abstract	1	• Information on how units were allocated to interventions	Example (title): A nonrandomized trial of a clinic-based HIV counseling intervention for African American female drug users
		• Structured abstract recommended	
		• **Information on target population or study sample**	
Introduction		• Scientific background and explanation of rationale	
Background	2	• **Theories used in designing behavioral interventions**	Example (theory used): the community-based AIDS intervention was based on social learning theory
Methods			
Participants	3	• Eligibility criteria for participants, **including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)**	
		• Method of recruitment (e.g., referral, self-selection), including the **sampling method** if a systematic sampling plan was implemented	Example (sampling method): using an alphanumeric sorted list of possible venues and times for identifying eligible subjects, every tenth venue–time unit was selected for the location and timing of recruitment
		• **Recruitment setting**	Examples (recruitment setting): subjects were approached by peer opinion leaders during conversations at gay bars
		• Settings and locations where the data were collected	
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	
		Content: what was given?	
		Delivery method: how was the content given?	
		Unit of delivery: how were subjects grouped during delivery?	Example (unit of delivery): the intervention was delivered to small groups of 5–8 subjects
		Deliverer: who delivered the intervention?	
		Setting: where was the intervention delivered?	Examples (setting): the intervention was delivered in the bars; the intervention was delivered in the waiting rooms of sexually transmitted disease clinics
		Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Examples (exposure quantity and duration): the intervention was delivered in five 1-hour sessions; the intervention consisted of standard HIV counseling and testing (pretest and posttest counseling sessions, each about 30 minutes)
		Time span: how long was it intended to take to deliver the intervention to each unit?	Examples (time span): each intervention session was to be delivered (in five 1-hour sessions) once a week for 5 weeks; the intervention was to be delivered over a 1-month period.
		Activities to increase compliance or adherence (e.g., incentives)	Example (activities to increase compliance or adherence): bus tokens and food stamps were provided

요약

- 연구 혹은 논문의 연구 디자인 분류
- 디자인 분류에 맞는 보고지침
- 같은 디자인에서도 다양한 영역에 따른 분류
- Flow diagram의 활용

활용

- 활용의 주체
  - 연구자
  - 심사자
  - 편집인


경청해 주셔서 감사합니다.