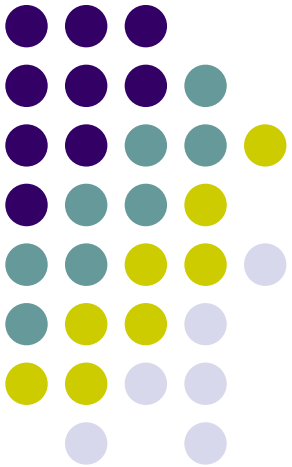
연구 문헌의 구성과 종류

한림의대 가정의학교실
의편협 정보위원회
김수영



강의 내용

- 연구 논문의 구조
- 임상 논문
- 논문보고의 질
- Publication type

논문의 구조

- 논문 구조화의 목적
  - 독자들이 논문 내용을 통해
    - 관찰 한 내용을 평가
    - 원하면 실험을 다시 할 수 있도록 함
    - 결론이 실제 데이터와 부합하는지 판단
  - 을 할 수 있도록 함

논문의 구조

- Introduction(서론) : 연구를 시작한 이유?
- Method(방법) : 어떤 연구이었는가?
- Results(결과) : 연구결과 발견한 사실은?
- And(그리고)
- Discussion(토론) :결과는 무엇을 의미?

서론

- 연구 배경 설명
- 논문에서 제기하는 문제의 성격과 중요성 언급
- 연구나 관찰의 특수한 목적이나 가설 기술
- 연구목적이나 관찰의 근거를 요약
- 주 목적과 부차적인 목적 제시
- 계획한 하부 집단 분석 기술

방법

- 대상자의 선정과 배정
  - 포함과 배제 기준
  - 연령이나 성별
- 중재, 관찰의 내용
- 보려고 하는 결과의 내용
- 기술적인 정보
- 통계

결과

- 표, 그림을 이용하여 논리에 맞게 중요한 순서대로
- 상세한 정보는 부록이나 전자저널로
- 표나 그림은 논점 증명에 필요한 것만

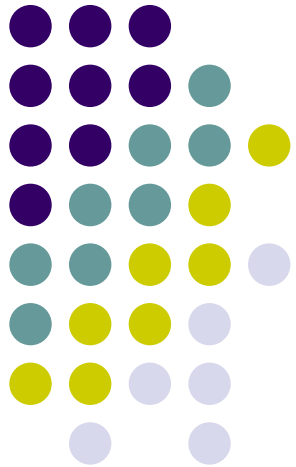
고찰

- 연구 요약
- 결과의 기전과 의의
- 다른 유사한 결과와 비교

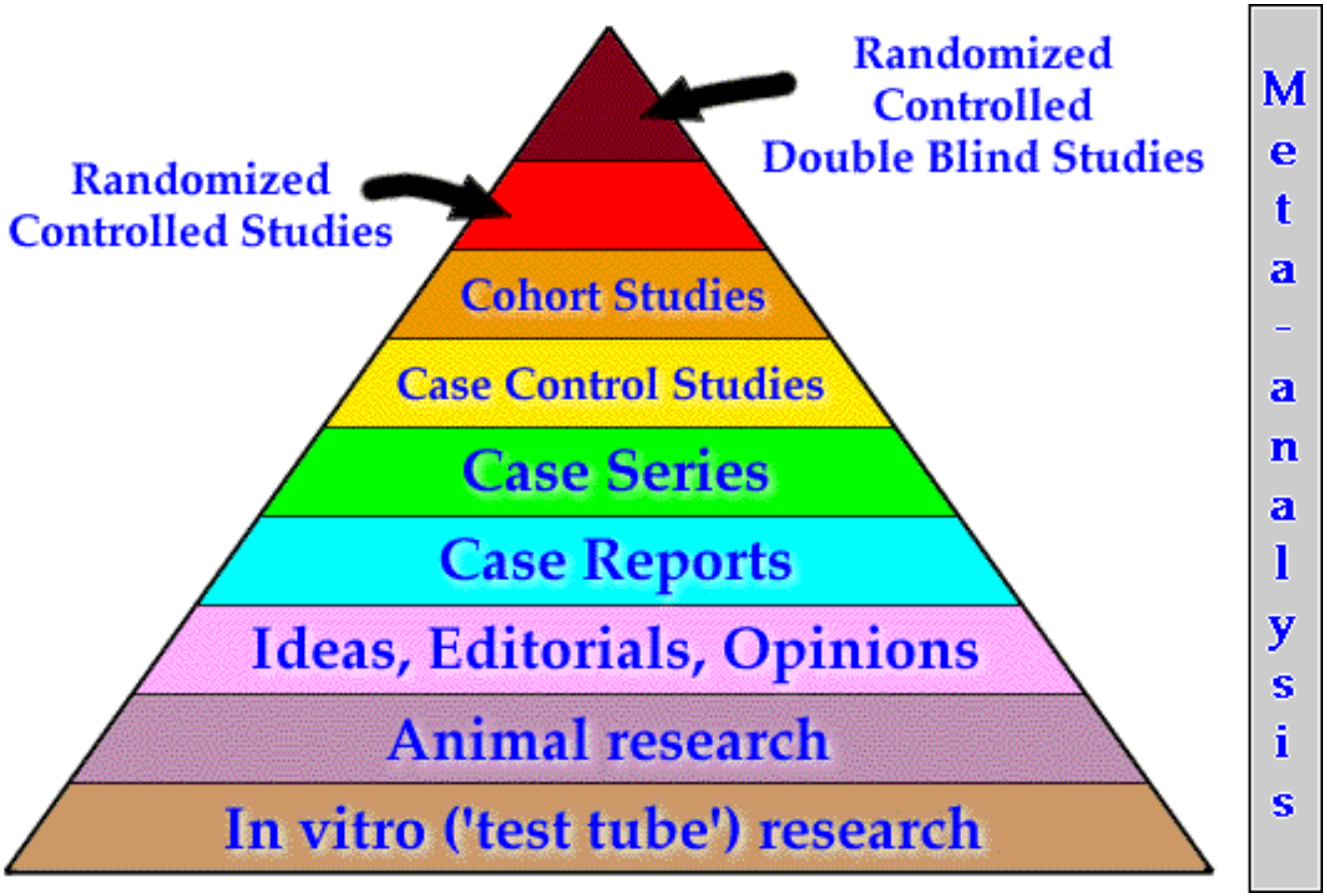
원저 이외의 논문 구조

- 증례보고 : 서론, 증례, 고찰
- 종설 : 서론, 본론, 결론
- 논평, 단신 : 서술식

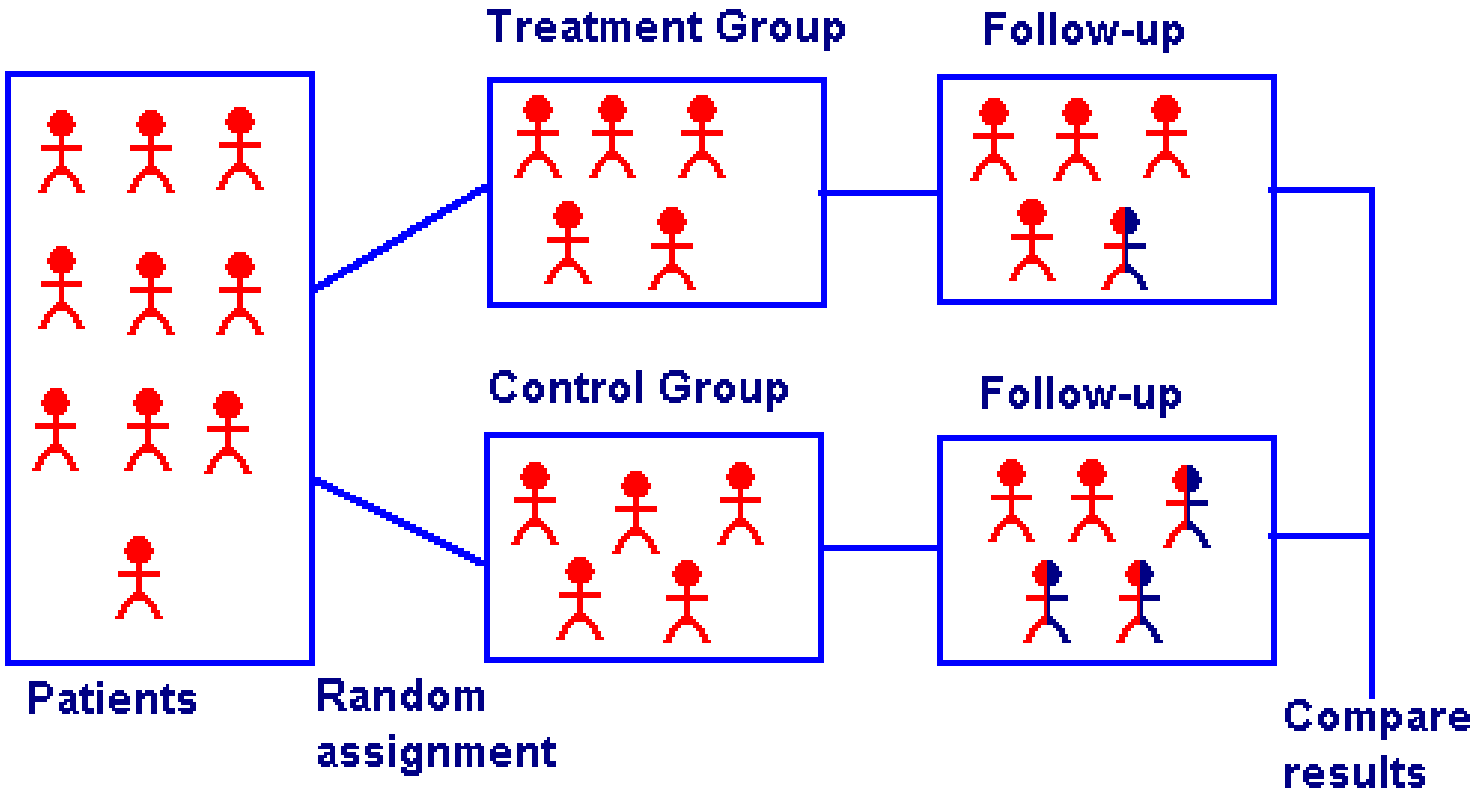
주요 의학 논문의 개념



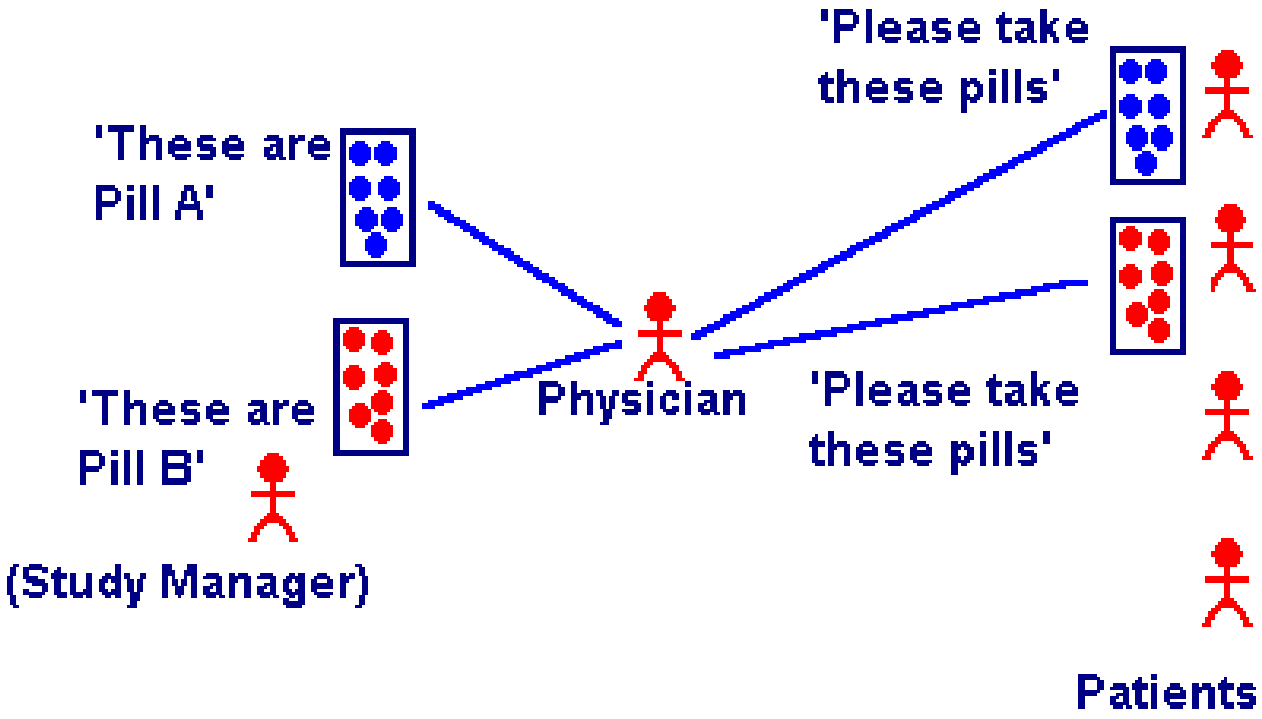
Evidence Pyramid



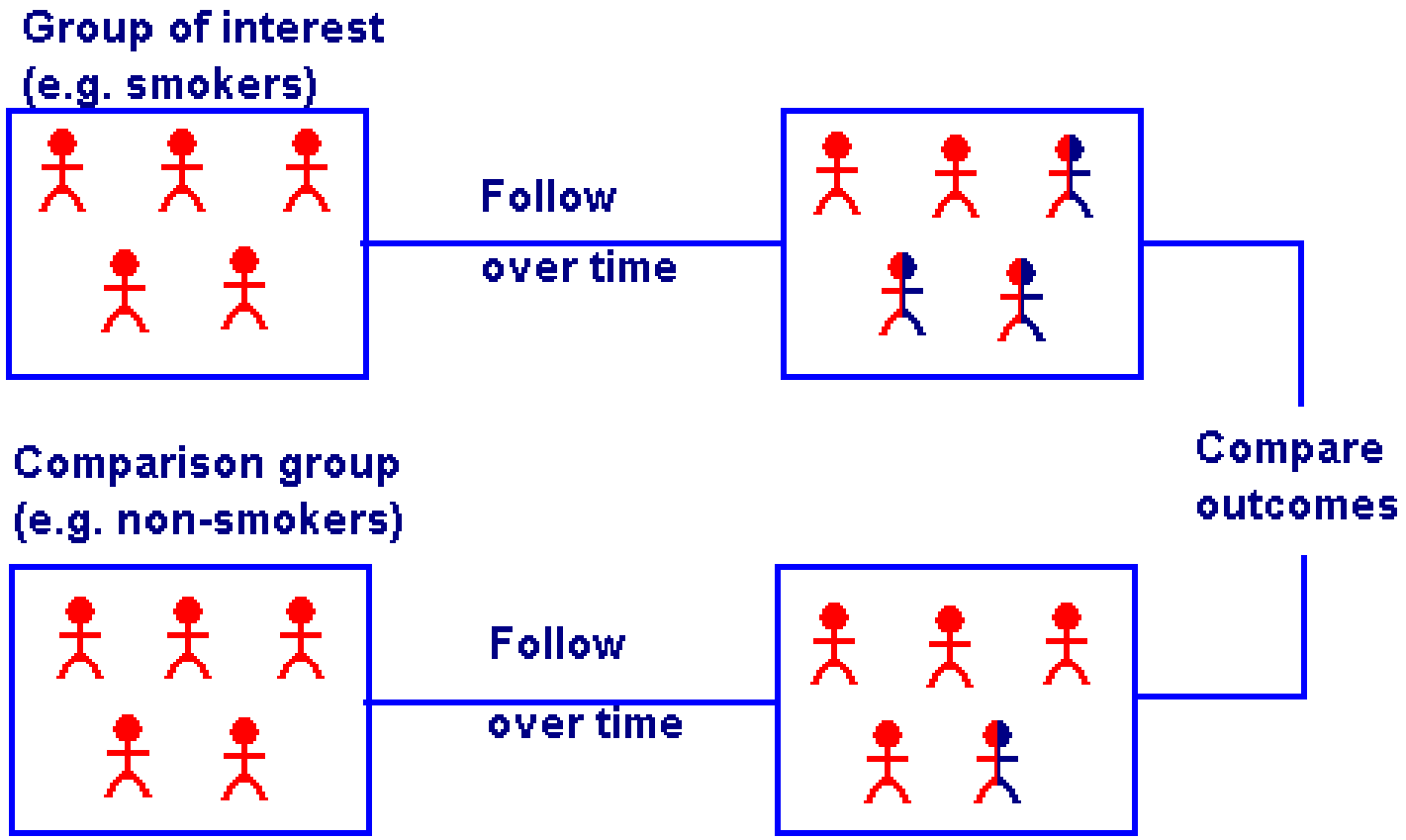
무작위 대조 연구


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

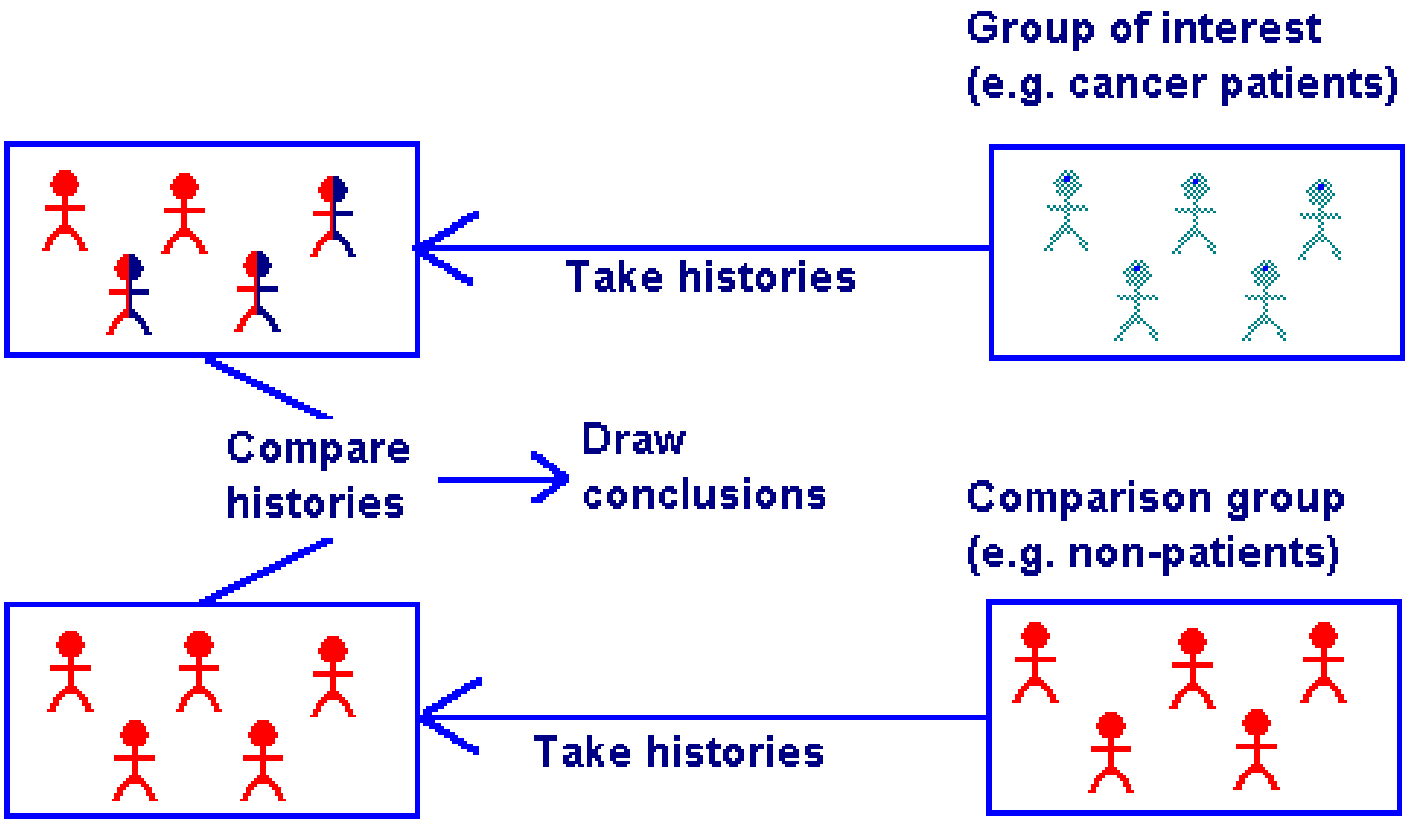
이중 맹검법


'Please take these pills'
'These are Pill A'
'These are Pill B'
Physician
'Please take these pills'
(Study Manager)
Patients

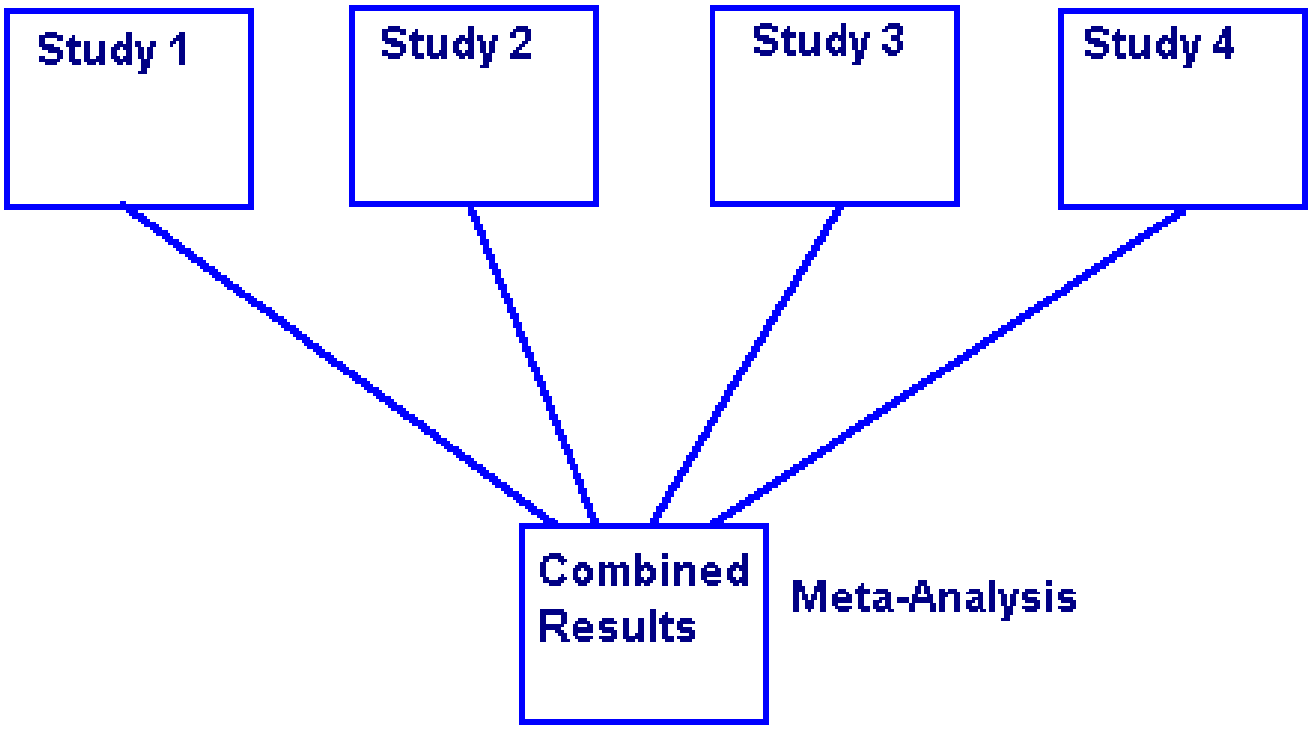
코호트 연구


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

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

여러 가지 용어

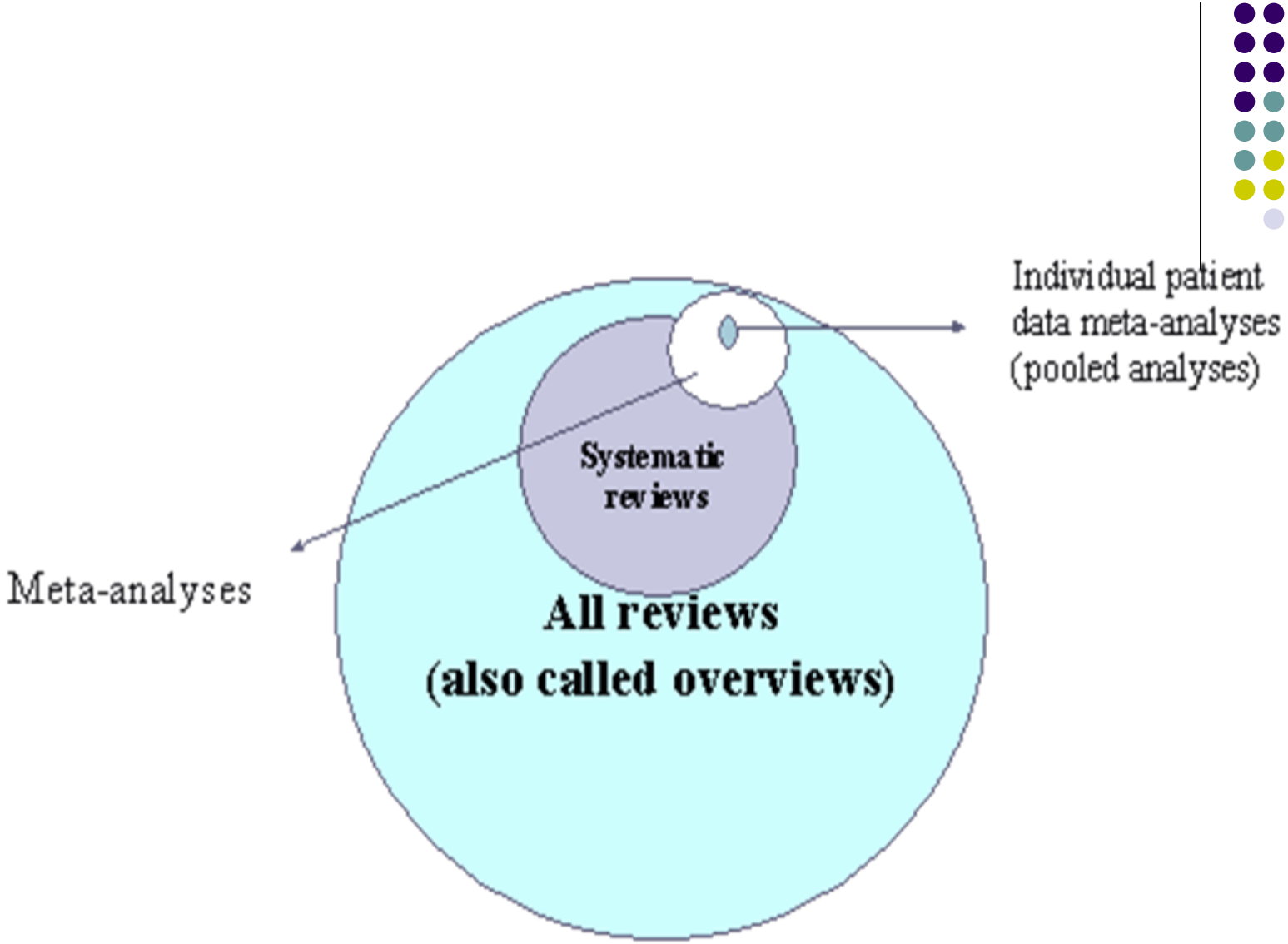
- Review
- Overview
- Narrative review
- Systematic review
- Meta-analysis
- Review, tutorial
- 구별
  - Scientific Integrity Review
  - Guidelines

종설의 분류

- 비 체계적 종설(Narrative review)
  - 기존의 대부분의 종설
- 체계적 종설(Systematic review)
  - 문헌 수집
  - 평가
  - 증거 제시에 체계적인 형식

비교

- 메타분석
  - 최소한 2개 이상의 연구 결과를 통계적으로 결합
  - 체계적 고찰 중 일부가 아닌 경우 있음
- 개별 환자 자료 메타분석 (Individual patient data analyses, pooled analyses)
  - 임상 시험의 환자 자료를 직접적으로 다시 분석


Individual patient
data meta-analyses
(pooled analyses)
Systematic
reviews
Meta-analyses
All reviews
(also called overviews)

- Clinical Trial [V03.200]
  - Clinical Trial, Phase I [V03.200.100]
  - Clinical Trial, Phase II [V03.200.200]
  - Clinical Trial, Phase III [V03.200.300]
  - Clinical Trial, Phase IV [V03.200.400]
  - Controlled Clinical Trial [V03.200.500]
  - Multicenter Study [V03.200.600]
  - Randomized Controlled Trial [V03.200.700]

임상 시험의 phase

- Phase I trials
  - Preliminary studies of toxicity
  - Establish MTD
- Phase II trials
  - Preliminary studies of efficacy
  - Further study of toxicity
- Phase III trials
  - Definitive studies of efficacy in newly diagnosed
  - Randomized

임상 시험 단계

- 제 1상
  - 20-80명 건강인
  - 안전성과 용량, 약동학
  - 부작용 발생 때까지 서서히 용량 증가
- 제 2상
  - 100-200명 환자, 2년
  - 다양한 병기, 여러 단계 디자인
  - 대부분 무작위 배정 하지 않는다.

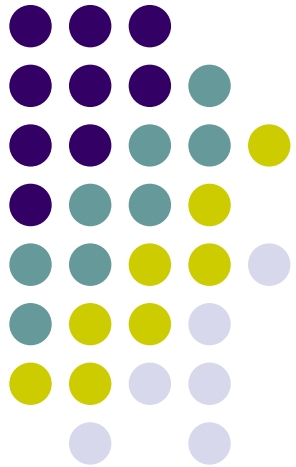
임상시험 단계(2)

- 제 3상
  - 환자군과 대조군 무작위 배정
  - 효능과 안정성 확정
  - 3년 정도
- 제 4상
  - Post-marketing surveillance
  - 대규모 추적 연구
  - 특수 환자군에 대한 임상 시험

임상 시험

- 정의
  - 연구자가 일정 정도 연구 상황에 대한 통제
  - 특히 치료군 배정
- 종류
  - 무작위 대조 연구(radnomized controlled trial)
  - 유사 무작위 시험(quasi-randomized trial)
  - 비 무작위 시험/유사 시험 연구(Non-randomized trial/quasi-experimental study)

중재 논문의 종류



무작위 대조 연구

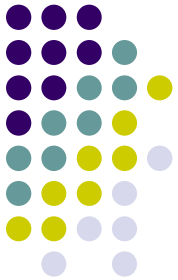
- 결과의 차이를 보기 위해서 중재군 혹은 대조군에 무작위로 배정
- 배정 은폐와 무작위화를 통해 두 군 사이에 알려진 혹은 알려지지 않은 요인이 균등하게 배분됨

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

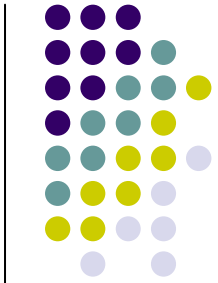
비무작위 시험/유사 시험 연구



- *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*

임상시험일 수 있음

- *Controlled before-and-after study*
- *Before-and-after study*

대조군 전후 시험

- *Controlled before-and-after study*
- 중재를 받은 사람과 받지 않은 사람에 대한 추적관찰
- 중재 전후 결과 비교
- 비교 집단이 비슷하면 최종 값, 그렇지 않으면 변화 값
- 연구자가 중재 여부에 대해 통제할 수 있으면 실험 연구에 포함시킴

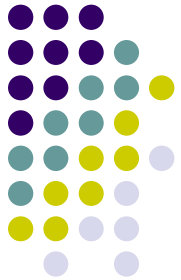
전후 비교

- *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

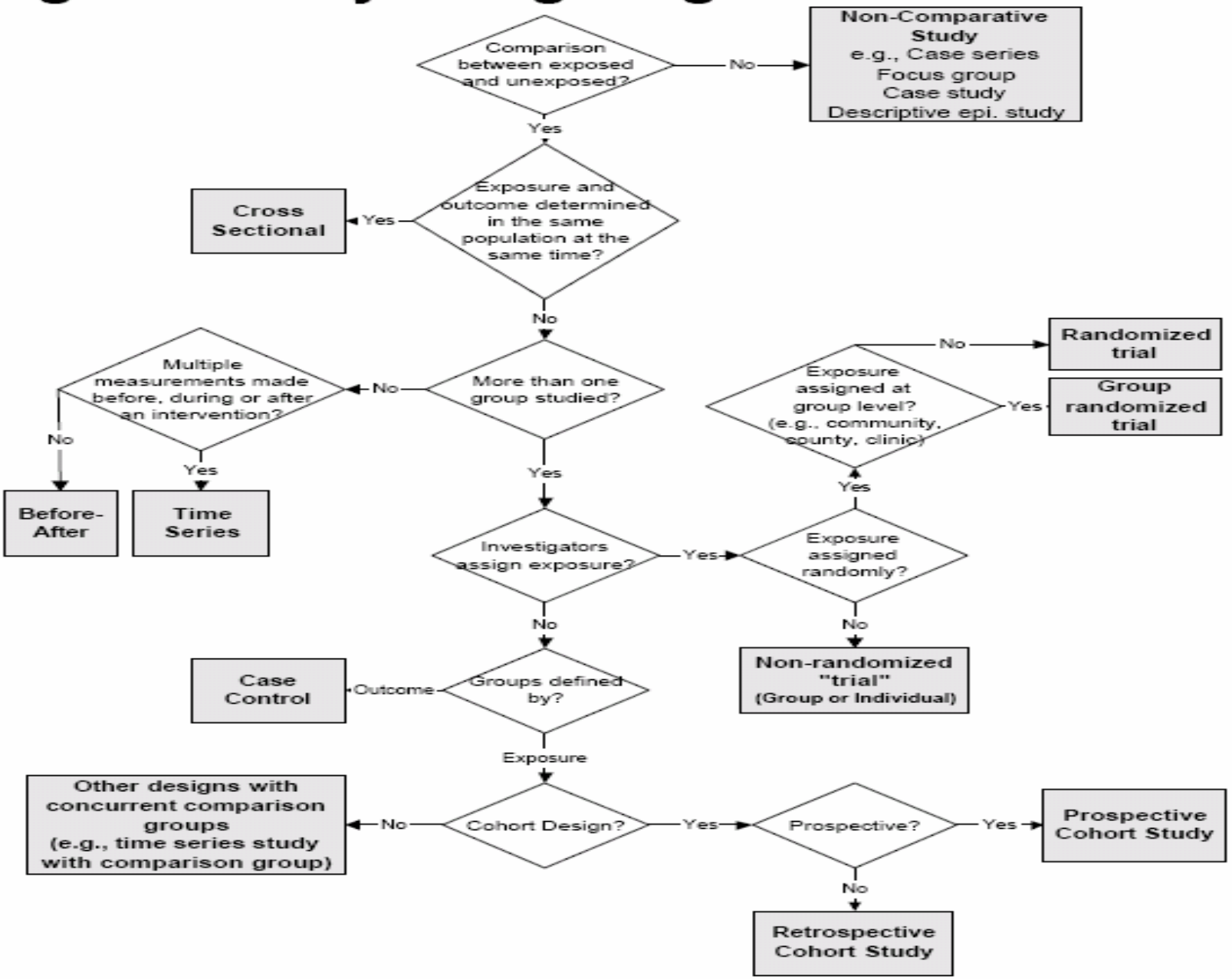
단면 연구

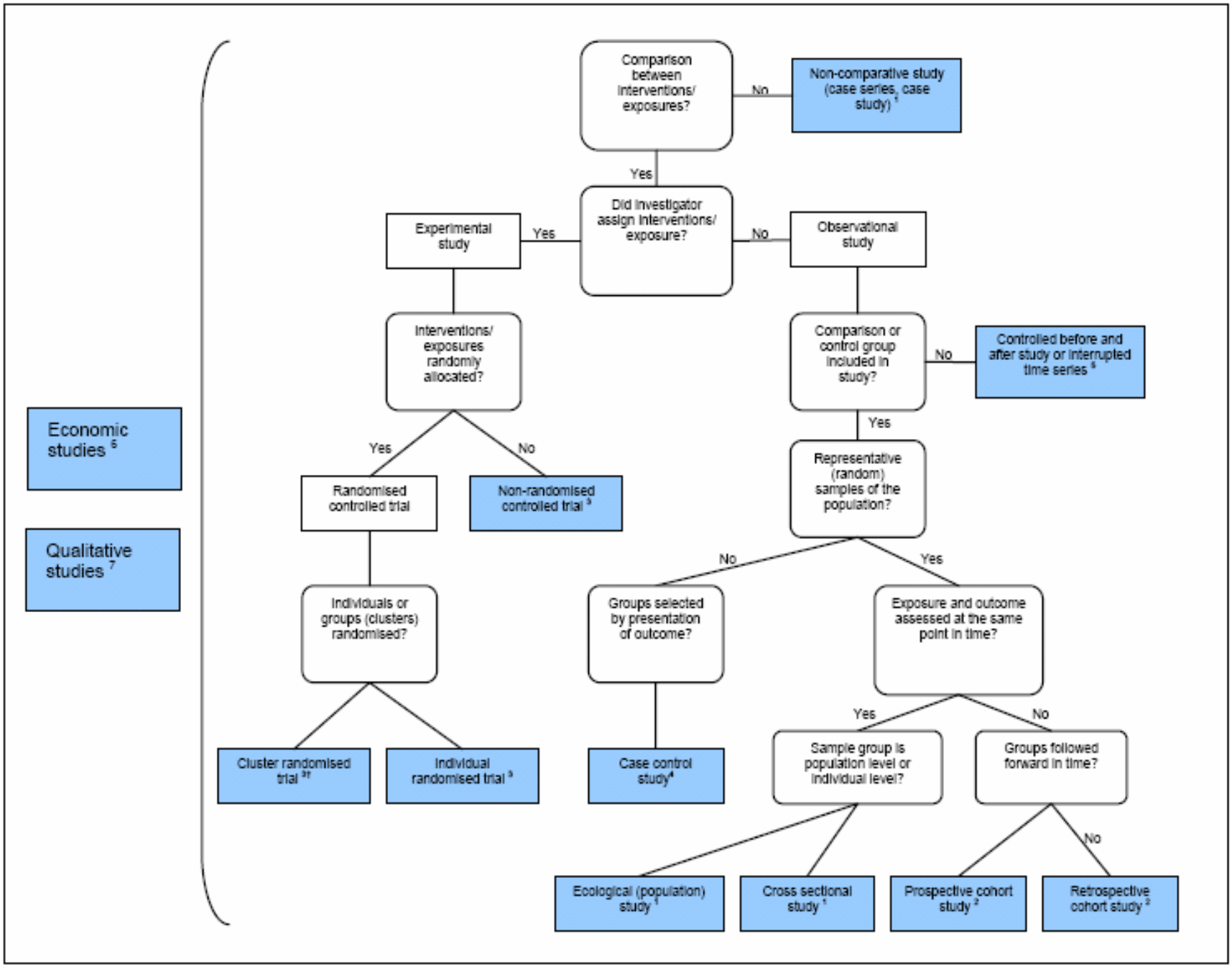
- *Cross-sectional study*
- 특정 시점에서 질병과 특정 변수와의 관련성에 대해서 연구함

환자 사례군

- *Case series*
- 중재와 결과에 대한 기술적 분석(대조군과 비교하지 않음)

Figure. Study Design Algorithm




Economic studies [6]
Qualitative studies [7]
Comparison between interventions/ exposures?
No
Non-comparative study (case series, case study) [1]
Yes
Did investigator assign interventions/ exposure?
Experimental study
Yes
No
Observational study
Interventions/ exposures randomly allocated?
Comparison or control group included in study?
No
Controlled before and after study or interrupted time series [5]
Yes
Yes
No
Randomised controlled trial
Non-randomised controlled trial [3]
Representative (random) samples of the population?
No
Yes
Individuals or groups (clusters) randomised?
Groups selected by presentation of outcome?
Exposure and outcome assessed at the same point in time?
Yes
No
Cluster randomised trial [3f]
Individual randomised trial [3]
Case control study [4]
Sample group is population level or individual level?
Groups followed forward in time?
No
Ecological (population) study [1]
Cross sectional study [1]
Prospective cohort study [2]
Retrospective cohort study [2]

예1

Purpose: The purpose of this study was to evaluate the effect of web-based diabetic education on plasma glucose and serum lipids in obese people with diabetes.

Method: A random allocation design with control and experimental groups being assessed pre- and post-intervention was used. Eighteen patients were randomly allocated to an intervention group and 16 to a control group. Participants were requested to input their blood glucose levels weekly for 3 months at http://www.biodang.com by cellular phone or wire Internet. The researcher sentoptimal recommendations to each patient weekly for 3 months using a short message service (SMS) of the cellular phone and wire Internet.

Results: Patients in the intervention group had a mean decrease of 1.2% in glycosylated haemoglobin (HbA1c) levels and those in the control group had no difference in HbA1c levels. There was a significant mean change in 2-hour post prandial blood glucose (2HPPG) for the intervention group, with a mean change of - 120.1 mg/dl. The mean change in the control group, however, was not significant.

Conclusion: These findings indicate that this web-based intervention using SMS of the cellular phone for 3 months improved HbA1c and 2HPPG, but did not affect total cholesterol, triglyceride, and high density lipoprotein cholesterol in obese type 2 diabetic patient.

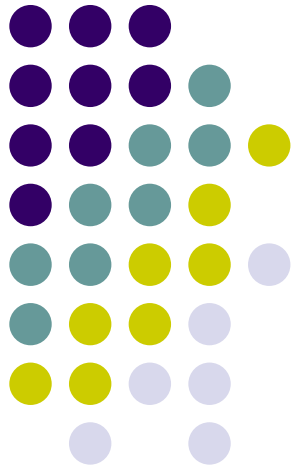
예 2

웹기반 영양상담 프로그램은 당뇨병 환자를 위한 영양상담 프로그램에 환자들의 추후관리를 위해 추후관리 프로그램을 개발하여 삽입하였다. 개발된 추후관리 프로그램은 혈당수첩, 식품섭취빈도 조사, 식습관 평가 및 대화방으로 구성되었다. 8주간의 인터넷을 이용한 영양상담 후 체질량지수는 비합병증군과 합병증군 모두에서 약간은 감소하였으나 유의한 차이가 없었다. 허리/엉덩이 둘레비 역시 두군 모두에서 조금씩 감소하였으나 유의한 차이가 없었다. 영양상담 후 공복혈당은 비합병증군($p < 0.05$)과 합병증군($p < 0.01$) 모두에서 유의하게 감소하였고, 당화혈색소는 비합병증군에서는 감소하였으나 유의한 차이가 없는데 반하여 합병증군($p < 0.01$)에서는 유의하게 감소하였다. 혈청지질은 비합병 증군에서는 총콜레스테롤과 LDL-콜레스테롤은 영양상담 후 감소하여 유의($p < 0.05$)한 차이를 보인 반면에 HDL-콜레스테롤은 약간 증가하고, 중성지방은 감소하였으나 유의한 변화는 없었다. 합병증군에서는 총콜레스테롤, LDL-콜레스테롤, 중성지방은 영양상담 후 각각 유의($p < 0.05$)하게 감소하였고, HDL-콜레스테롤은 증가하였다. 영양소 섭취의 변화는 두군 모두에서 영양상담 후 열량 섭취량이 감소하였으며, 당질 및 지방의 섭취수준은 감소한 반면에 단백질의 섭취는 증가하여 환자들의 열량영양소의 섭취비가 권장되는 비율로 변하고 있음을 알 수 있었다. 또한 1,000 ㎉ 당 영양소 섭취량을 비교하여 보면 비타민 B2, 비타민 B6, 비타민 C, 엽산, 칼슘, 아연의 섭취량은 영양상담 후 오히려 높아져 영양상담 후 두 군 모두에서 환자들은 열량은 낮으면서 영양소 밀도가 높은 식품을 선택하였다. 본 연구의 결과로 웹기반을 이용한 영양상담이 당뇨병 환자의 열량 및 영양소 섭취상태를 개선하고 혈당 및 혈청지질에 긍정적인 효과를 나타냄으로서 정보화 시대에 맞는 새로운 상담매체로서의 인터넷의 가능성과 영양상담의 추후관리를 위한 대안이 제시되었다고 할 수 있다. 그러나 대상자의 연령이나 학력 등에 따라 웹기반 영양상담 프로그램에 대한 반응이 다르게 나타났기에, 이러한 개인별 차이점을 고려한 맞춤형 영양상담 프로그램의 형태로 좀 더 다양화된 상담 프로그램이 개발될 필요성이 있었다. 또한 본 연구는 영양상담 기간이 8주간의 단기였기에 그 효과를 나타내는데 미흡한 점이 있었으므로 추후 장기간의 영양상담에 따른 추가 연구도 필요할 것 같다.

예3

This study was carried out to investigate the effect of nutrition education program for diabetic patients on the glycemic control at the public health center. The study subjects, aged 61.7 ± 9.4 years, were 93 sex-and age-matched patients with type 2 diabetes mellitus. They were divided into three groups: nutrition education & diet practice group (EDG), nutrition education-only group (EG), and the control group (CG). Height, weight, and the postprandial 2 hour blood glucose (PP2) were measured at baseline, and 4, 6 and 8 week after the diabetic nutrition education program. At baseline there were no differences in height, weight, and blood glucose levels among the three groups. Nutrition education programs, especially that with group lunch practice sessions were found to be effective in lowering the blood glucose levels in patients with NIDDM patients. At 4 week blood glucose levels were decreased by 40.6% and 19.6% in EDG and EG, respectively, which was further dropped by 50.2% and 35.1% at 8 week, as compared to the CG group. For the EDG group, the total energy intake, which was 162.3% of the prescription before the diet counselling session, was decreased to 113.6% of the prescription after the lunch visit, with most decrease coming from the reduction in carbohydrate and fat intake. Multiple stepwise regression analysis revealed that the total energy intake explained 47.9% and 57% of blood glucose changes for men and women, respectively, and that percent energy intake from protein explained 15.8% for women. These results demonstrate that the public health center nutrition education programs for diabetic patients, especially that with group lunch practice sessions are very effective for the glycemic control in patients with diabetes mellitus.

보고지침



보고지침

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

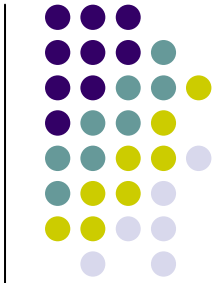
보고지침

- 필요 이유
  - 연구의 장점과 단점 파악
  - 논문의 질 평가
  - 적용 가능성의 평가
- ‘보고’되지 않은 것은 ‘하지’않은 것으로 판단한다.

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

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

위염 환자에서 글립타이드®정(Sulglycotide 200 mg)의 치료 효과를 평가하기 위한 단일맹검, 무작위 배정, 비교약 대조, 다기관 임상시험

가톨릭대학교 의과대학 내과학교실

정정조 · 최명규 · 최 황 · 박재명 · 오정환 · 전은정
이보인 · 이인석 · 김상우 · 최상욱 · 최규용 · 정인식

Single Blinded, Randomized, Active Drug Comparative, Multi-center Study to Evaluate the Therapeutic Efficacy of Gliptide® Tab (Sulglycotide 200 mg) in Gastritis Patients; Phase IV Study

CONSORT-방법

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

2. 방법

본 시험은 무작위 배정, 단일 맹검, 비교약 대조, 다기관 임상 시험으로 설계되었으며, 임상 시험 전에 각 기관으로부터 임상시험 심사위원회를 통과 후 임상 시험을 시작하였다. 시험에 사용된 약제는 시험약인 글립타이드®정(sulglycotide 200 mg)과 비교약인 무코스타®정(rebamipide 100 mg)이다. 피험자 선정/제외 기준에 적합한 위염 환자를 대상으로, 무작위 배정을 통하여 시험약 또는 비교약을 3주간(1일 3회 공복 시 복용) 투여, 관찰하였다. 3주의 투약이 끝난 후 위내시경 검사, 자타각 증상 평가, 임상 검사 등을 통하여 안전성과 유효성을 평가하였다.

CONSORT-결과

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

결 과

1. 대상 환자의 특성

본 임상시험에 등록된 전체 피험자는 74명이었고 이 중 한 명은 투약 전에 동의 철회하여 투약이 이루어진 피험자는 73명이었다(ITT분석 대상자). 투약이 이루어진 73명의 환자 중에 11명은 중도 탈락하였고, 3명은 연구가 종결되었으나 프로토콜을 위반하였다. 임상시험을 계획서대로 완료한 예는 59명이었고(PP분석 대상자), 전체 시험탈락률은 19.2%였다. 73명의 ITT 분석 대상 환자 중 시험군은 36명, 대조군은 37명이었다. 시험군에서의 탈락은 9명(동의철회 4명, 추적실패 2명, 복약순응도 미달 2명, 유효성 검사 누락 1명)이었고, 대조군에서의 탈락은 5명(동의철회 2명, 추적실패 2명, 투약 부적합 1명) 으로, PP 분석 대상자는 시험군이 27명, 대조군이 32명이었다. 각 투여군 간에는 성별, 연령, *H. pylori* 감염 유무, 선행약제 유무, 병용약제 유무, 미란 정도와 수 및 자각 증상 점수에서 양 군 간에 유의한 차이는 없었다(Table 1).

Table 2. Analysis of Non-inferiority in ITT and PP Analysis

		Gliptide 200 mg	Mucosta	Gliptide-Mucosta
ITT analysis	Endoscopic cure rate (%)	22.2	21.6	0.10
	90% confidence interval	(10.8, 33.6)	(10.5, 32.8)	(−0.32, 0.52)
	Endoscopic certificate rate (%)	50.0	54.1	−0.47
	90% confidence interval	(36.3, 63.7)	(40.6, 67.5)	(−1.36, 0.42)
	Ameliorative rates of symptoms (%)	44.4	48.7	−0.14
	90% confidence interval	(30.8, 58.1)	(35.1, 62.2)	(−0.92, 0.65)
PP analysis	Endoscopic cure rate (%)	29.6	25.0	0.17
	90% confidence interval	(12.4, 46.9)	(10.0, 40.0)	(−0.26, 0.06)
	Endoscopic certificate rate (%)	63.0	62.5	−0.72
	90% confidence interval	(47.7, 78.3)	(48.4, 76.6)	(−1.53, 0.08)
	Ameliorative rates of symptoms (%)	51.9	53.1	−0.51
	90% confidence interval	(36.0, 67.7)	(38.6, 67.6)	(−1.21, 0.19)

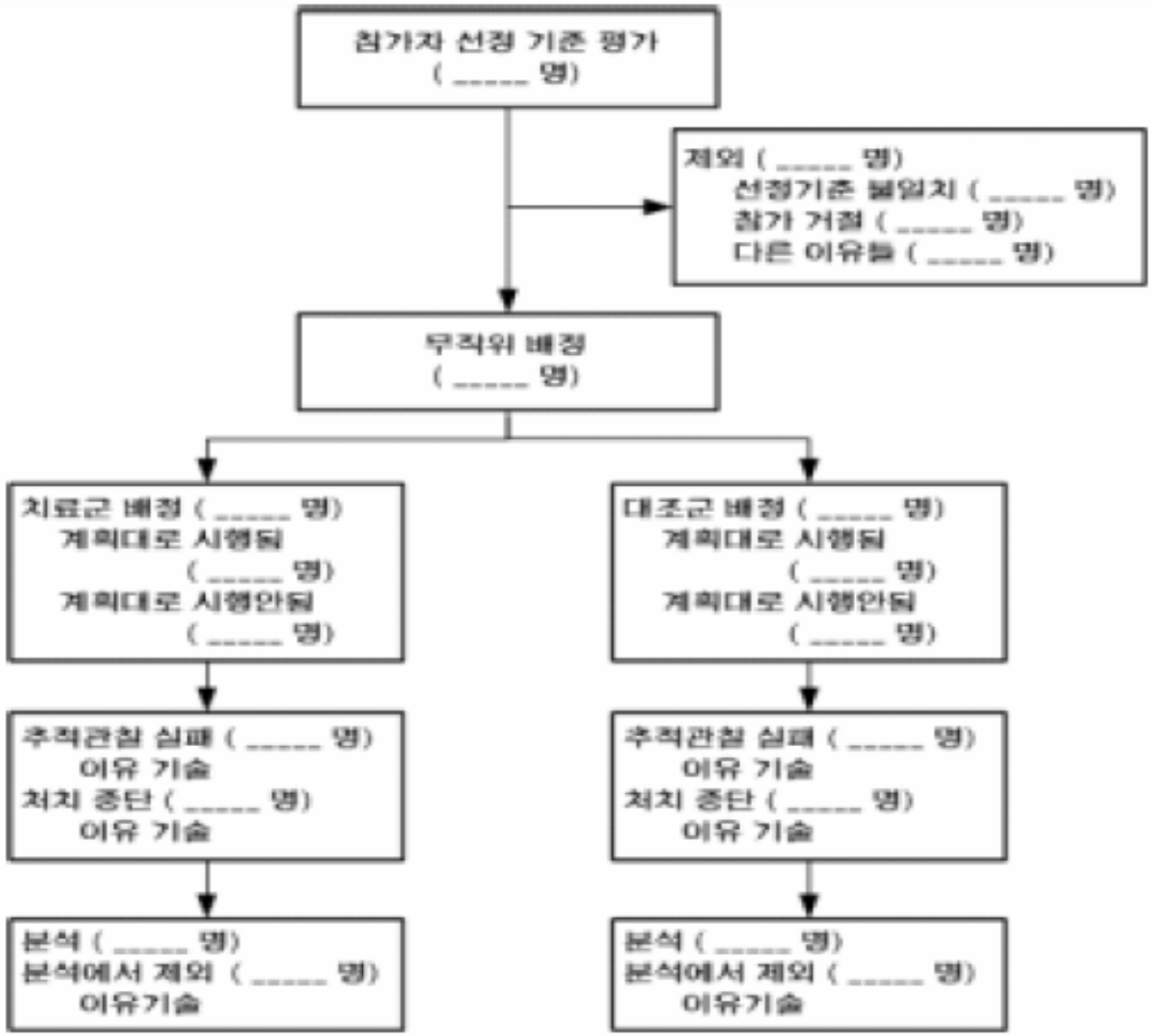
ITT, intention to treat; PP, per-protocol.

선정

배정

추적

분석


참가자 선정 기준 평가
(_____ 명)
제외 (_____ 명)
선정기준 불일치 (_____ 명)
참가 거절 (_____ 명)
다른 이유들 (_____ 명)
무작위 배정
(_____ 명)
치료군 배정 (_____ 명)
계획대로 시행됨
(_____ 명)
계획대로 시행안됨
(_____ 명)
대조군 배정 (_____ 명)
계획대로 시행됨
(_____ 명)
계획대로 시행안됨
(_____ 명)
추적관찰 실패 (_____ 명)
이유 기술
처치 중단 (_____ 명)
이유 기술
추적관찰 실패 (_____ 명)
이유 기술
처치 중단 (_____ 명)
이유 기술
분석 (_____ 명)
분석에서 제외 (_____ 명)
이유기술
분석 (_____ 명)
분석에서 제외 (_____ 명)
이유기술

CONSORT-고찰

- 해석
- 일반화 여부
- 전체적 근거

Extension of CONSORT

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

STARD

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

STARD checklist for reporting diagnostic accuracy studies

Section and topic	Item	Description
Title, abstract, and keywords	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading "sensitivity and specificity")
Introduction	2	State the research questions or aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups
Methods:		
Participants	3	Describe the study population: the inclusion and exclusion criteria and the settings and locations where the data were collected
	4	Describe participant recruitment: was this based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?
	5	Describe participant sampling: was this a consecutive series of participants defined by selection criteria in items 3 and 4? If not, specify how participants were further selected
	6	Describe data collection: was data collection planned before the index tests and reference standard were performed (prospective study) or after (retrospective study)?
Test methods	7	Describe the reference standard and its rationale
	8	Describe technical specifications of material and methods involved, including how and when measurements were taken, or cite references for index tests or reference standard, or both
	9	Describe definition of and rationale for the units, cut-off points, or categories of the results of the index tests and the reference standard
	10	Describe the number, training, and expertise of the persons executing and reading the index tests and the reference standard
	11	Were the readers of the index tests and the reference standard blind (masked) to the results of the other test? Describe any other clinical information available to the readers.
Statistical methods	12	Describe methods for calculating or comparing measures of diagnostic accuracy and the statistical methods used to quantify uncertainty (eg 95% confidence intervals)
	13	Describe methods for calculating test reproducibility, if done
Results:		
Participants	14	Report when study was done, including beginning and ending dates of recruitment
	15	Report clinical and demographic characteristics (eg age, sex, spectrum of presenting symptoms, comorbidity, current treatments, and recruitment centre)
	16	Report how many participants satisfying the criteria for inclusion did or did not undergo the index tests or the reference standard, or both; describe why participants failed to receive either test (a flow diagram is strongly recommended)
Test results	17	Report time interval from index tests to reference standard, and any treatment administered between
	18	Report distribution of severity of disease (define criteria) in those with the target condition and other diagnoses in participants without the target condition
	19	Report a cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, report the distribution of the test results by the results of the reference standard
	20	Report any adverse events from performing the index test or the reference standard
Estimates	21	Report estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals)
	22	Report how indeterminate results, missing responses, and outliers of index tests were handled
	23	Report estimates of variability of diagnostic accuracy between readers, centres, or subgroups of participants, if done
	24	Report estimates of test reproducibility, if done
Discussion	25	Discuss the clinical applicability of the study findings

QUOROM

- RCT의 메타분석
- 1999
- 18문항, 흐름도

Heading	Subheading	Descriptor
Title		Identify the report as a meta-analysis [or systematic review] of RCTs[26]
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[33,34]
	Data abstraction	The process or processes used (eg, completed independently, in duplicate)[35,36]
	Study characteristics	The type of study design, participants' characteristics, details of intervention, outcome definitions, &c.,[37] 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;[38] a rationale for any a priori sensitivity and subgroup analyses; and any assessment of publication bias[39]
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

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

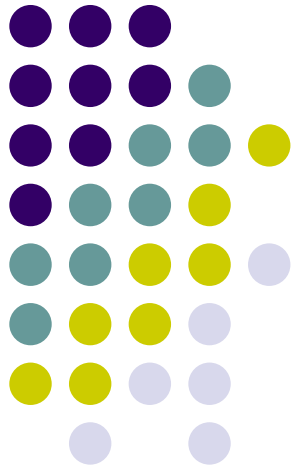
	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background 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

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

Publication type



Publication type

- 1991년 : citation type 47개
- 2006년 MeSH로 바뀜 : Publication Characteristics(트리 V)의 범주아래
- 현재 총 136개

Publication type

15. - Publication Characteristics [V]
    - Publication Components [Publication Type] [V01] +
    - Publication Formats [Publication Type] [V02] +
    - Study Characteristics [Publication Type] [V03] +
    - Support of Research [V04] +

- Publication Components [Publication Type] [V01]
  - Abstracts [Publication Type] [V01.070]
  - Advertisements [Publication Type] [V01.100]
  - Animation [Publication Type] [V01.110]
  - Architectural Drawings [Publication Type] [V01.140]
  - Bibliography [Publication Type] [V01.165] +
  - Biography [Publication Type] [V01.175]
  - Book Illustrations [Publication Type] [V01.185] +
  - Bookplates [Publication Type] [V01.195]
  - Charts [Publication Type] [V01.200]
  - Comment [Publication Type] [V01.205]
  - Editorial [Publication Type] [V01.250]
  - English Abstract [V01.260]
  - Letter [Publication Type] [V01.445]
  - News [Publication Type] [V01.630]
  - Patient Education Handout [Publication Type] [V01.665]
  - Published Erratum [Publication Type] [V01.700]
  - Retraction of Publication [Publication Type] [V01.775]

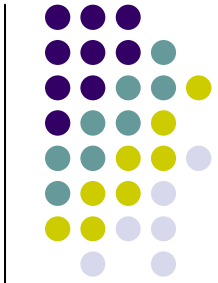
Publication Formats [Publication Type] [V02]

- Abbreviations [Publication Type] [V02.025]
- Abstracts [Publication Type] [V02.035]
- Academic Dissertations [Publication Type] [V02.050]
- Account Books [Publication Type] [V02.060]
- Addresses [Publication Type] [V02.070] +
- Advertisements [Publication Type] [V02.100]
- Almanacs [Publication Type] [V02.110]
- Anecdotes [Publication Type] [V02.115]
- Animation [Publication Type] [V02.120]
- Annual Reports [Publication Type] [V02.130]
- Architectural Drawings [Publication Type] [V02.140]
- Atlases [Publication Type] [V02.150]
- Bibliography [Publication Type] [V02.165] +
- Biography [Publication Type] [V02.170] +
- Book Reviews [Publication Type] [V02.180]
- Broadsides [Publication Type] [V02.200]
- Caricatures [Publication Type] [V02.225]
- Cartoons [Publication Type] [V02.235]
- Journal Article [Publication Type] [V02.600] +
- Laboratory Manuals [Publication Type] [V02.605]
- Legal Cases [Publication Type] [V02.610]
- Legislation [Publication Type] [V02.620]
- Letter [Publication Type] [V02.625]
- Manuscripts [Publication Type] [V02.630]
- Meeting Abstracts [Publication Type] [V02.650]
- Monograph [Publication Type] [V02.660] +
- News [Publication Type] [V02.665]
- Newspaper Article [Publication Type] [V02.667]
- Outlines [Publication Type] [V02.670]
- Overall [Publication Type] [V02.672] +
- Patents [Publication Type] [V02.675]
- Periodical Index [Publication Type] [V02.682]
- Periodicals [Publication Type] [V02.690]
- Pharmacopoeias [Publication Type] [V02.695] +
- Pictorial Works [Publication Type] [V02.700] +
- Popular Works [Publication Type] [V02.725] +
- Published Erratum [Publication Type] [V02.737]
- Resource Guides [Publication Type] [V02.750]
- Retracted Publication [Publication Type] [V02.800]
- Retraction of Publication [Publication Type] [V02.825]
- Review [Publication Type] [V02.912] +

Journal article [pt]

- Original full text and review
- Original article (research)
  - not exclusively based on a summary, review or synthesis of earlier publications on the subject of research (wikepedia)

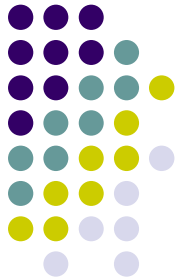
Review [pt]



- 특정 주제에 대하여 이미 간행된 내용을 고찰

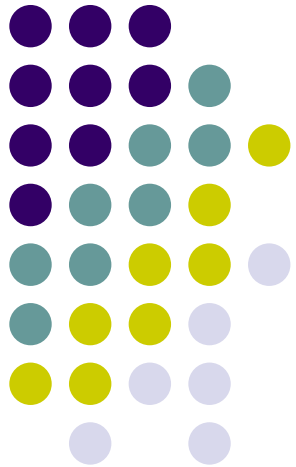
- Study Characteristics [Publication Type] [V03]
  - Case Reports [Publication Type] [V03.100]
  - Clinical Conference [Publication Type] [V03.150]
  - Clinical Trial [Publication Type] [V03.200] +
  - Comparative Study [V03.250]
  - Consensus Development Conference [Publication Type] [V03.300] +
  - Evaluation Studies [Publication Type] [V03.400]
  - In Vitro [V03.500]
  - Meta-Analysis [Publication Type] [V03.600]
  - Multicenter Study [Publication Type] [V03.650]
  - Scientific Integrity Review [Publication Type] [V03.800]
  - Twin Study [Publication Type] [V03.900]
  - Validation Studies [Publication Type] [V03.950]

Support of Research



- Support of Research [V04]
  - Research Support, Non-U.S. Gov't [V04.124]
  - Research Support, U.S. Gov't, Non-P.H.S. [V04.249]
  - Research Support, U.S. Gov't, P.H.S. [V04.500]
    - Research Support, N.I.H., Extramural [V04.500.500]
    - Research Support, N.I.H., Intramural [V04.500.750]

주요 출판 유형



- Addresses 연설
  - 특정 집단을 대상으로 한 공식적인 연설
- Bibliography 서지 (목록, 출판 목록)
  - 특정 주제에 관한 출판물과 자료들의 목록
- Case Reports 증례보고
  - 임상 사례 발표
- Classical Article 고전논문
  - 의학이나 과학의 역사에 이정표를 남긴 과거의 독창적인 논문을 현재에 다시 출판한 것
- Clinical Conference 임상회의
  - 입원 중인 환자의 여러 임상적인내용을 다루는 의사들의 회의 내용

1: Sen R, Baltimore D.

Multiple nuclear factors interact with the immunoglobulin enhancer sequences. Cell 1986. 46: 705-716.

J Immunol. 2006 Dec 1;177(11):7485-96. No abstract available.
PMID: 17114415 [PubMed]

2: Wirth T, Baltimore D.

Nuclear factor NF-kappa B can interact functionally with its cognate binding site to provide lymphoid-s

EMBO J. 1988 Oct;7(10):3109-13.
PMID: 3141147 [PubMed - indexed for MEDLINE]

3: Sen R, Baltimore D.

Multiple nuclear factors interact with the immunoglobulin enhancer sequences.

Cell. 1986 Aug 29;46(5):705-16.
PMID: 3091258 [PubMed - indexed for MEDLINE]

- Comment 논평
  - 기 출판된 논문이나 다른 발표문에 대해 토론이나, 지지, 논쟁을 하기 위해 쓰여진 비평
- Comparative Study 비교연구
  - 둘 이상의 연구 대상에 대해 서로를 비교하는 연구
- Consensus Development Conference 합의 도출 회의
  - 선택한 주제에 대해서 전문가들이 회의를 통해 합의에 도달한 내용
- Corrected and Republished Article 수정 재출판 논문
  - 본래 출판된 논문의 본문과 데이터를 수정, 부연하거나 복구하기 위해 논문을 재발행한 저작물

1: Acad Med. 2006 Nov;81(11):1008-12.

A controlled trial of a short course to improve residents' communication with patients at the end of life.

Alexander SC, Keitz SA, Sloane R, Tulsky JA.

Durham VA Medical Center, North Carolina, USA. alexa054@mc.duke.edu

PURPOSE: High-quality palliative care requires physicians who communicate effectively, yet many do not receive adequate training. Leading efforts to demonstrate the effectiveness of such training have involved time-intensive programs that included primarily attending physicians, which have been conducted outside of the United States. The goal was to evaluate the effect of a short course to improve residents' communication skills delivering bad news and eliciting patients' preferences for end-of-life care. METHOD: This prospective trial enrolled internal medicine residents at Duke University Medical Center from 1999 to 2001. The course consisted of small-group teaching with lecture, discussion, and role-play. The outcome measure was observed communication skills delivering bad news and eliciting patients' preferences for end-of-life treatment, assessed via audio-recorded standardized patient encounters before and after receiving the intervention. RESULTS: Thirty-seven residents received the intervention and 19 were in the control group. Residents attending the course demonstrated statistically significant increases in their overall skill ratings in the delivery of bad news, with improvement in the specific areas of information giving and responding to emotional cues. Although cumulative scores for discussions about patient preferences for treatment did not increase, residents demonstrated enhanced specific skills including discussing probability, presenting clinical scenarios, and asking about prior experience with end-of-life decision making. CONCLUSION: A relatively short, intensive course can improve the end-of-life communication skills of U.S. medical residents.

- Duplicate Publication 이중게재
  - 이전 출판물의 승인 없이 다른 곳에 이미 출판된 자료와 동시에 혹은 잇따라 출판한 논문이나 책.
- Editorial 사설
  - 의학적으로나 과학적으로 중요한 현 문제에 관해 학술지 편집자 등의 성명문.
- Evaluation Studies 평가 연구
  - 과정, 인력, 장비의 효율성이나 유용성을 결정하는 연구.
- Festschrift 기념 논문집
  - 특정인의 명예를 기념하기 위해 그들의 주요 사건에 대해 학생, 동료 등이 기고한 평론 등 저작물.

1: N Engl J Med. 2007 Mar 1;356(9):921-34.

Comment in:
N Engl J Med. 2007 Jun 7;356(23):2422-4; author reply 2422-4.
N Engl J Med. 2007 Jun 7;356(23):2422-4; author reply 2422-4.
N Engl J Med. 2007 Jun 7;356(23):2422-4; author reply 2422-4.
N Engl J Med. 2007 Jun 7;356(23):2422-4; author reply 2422-4.
N Engl J Med. 2007 Mar 1;356(9):951-3.

Improving the management of chronic disease at community health centers.

Landon BE, Hicks LS, O'Malley AJ, Lieu TA, Keegan T, McNeil BJ, Guadagnoli E.

Department of Health Care Policy, Harvard Medical School, Boston, MA 02115, USA.
landon@hcp.med.harvard.edu

BACKGROUND: The Health Disparities Collaboratives of the Health Resources and Services Administration (HRSA) were designed to improve care in community health centers, where many patients from ethnic and racial minority groups and uninsured patients receive treatment. METHODS: We performed a controlled preintervention and postintervention study of community health centers participating in quality-improvement collaboratives (the Health Disparities Collaboratives sponsored by the HRSA) for the care of patients with diabetes, asthma, or hypertension. We enrolled 9658 patients at 44 intervention centers that had participated in the collaboratives and 20 centers that had not participated (external control centers). Each intervention center also served as an internal control for another condition. Quality measures were abstracted from medical records at each health center. We created overall quality scores by standardizing and averaging the scores from all of the applicable measures. Changes in quality were evaluated with the use of hierarchical regression models that controlled for patient characteristics. RESULTS: Overall, the intervention centers had considerably greater improvement than the external and internal control centers in the composite measures of quality for the care of patients with asthma and diabetes, but not for those with hypertension. As compared with the external control centers, the intervention centers had significant improvements in the measures of prevention and screening, including a 21% increase in foot examinations for patients with diabetes, and in disease treatment and monitoring, including a 14% increase in the use of antiinflammatory medication for asthma and a 16% increase in the assessment of glycated hemoglobin. There was no improvement, however, in any of the intermediate outcomes assessed (urgent care or hospitalization for asthma, control of glycated hemoglobin levels for diabetes, and control of blood pressure for hypertension). CONCLUSIONS: The Health Disparities Collaboratives significantly improved the processes of care for two of the three conditions studied. There was no improvement in the clinical outcomes studied.

PMID: 17329699 [PubMed - indexed for MEDLINE]

- Historical Article 역사적인 기사
  - 중요한 과거 사건이나 상황을 설명하는 논문
  - Davidson JR, Thase ME. A history of the concept of atypical depression. J Clin Psychiatry. 2007 Feb;68(2):e03.
- In Vitro
  - 세포 밖에서의 실험
  - Park WK, Kim MH, Ahn DS, Chae JE, Jee YS, Chung N, et al. Myocardial depressant effects of desflurane: Mechanical and electrophysiologic actions in vitro. Anesthesiology. 2007 May;106(5):956-66.
- Overall
  - 다양한 분야의 여러 논문을 다룬 하나의 인용물
- Published Erratum 출판된 정오표
  - 출판사, 편집자 또는 저자가 발간한 오류 정정 문건
  - Pai S, Eng HL, Lee SY, Hsaio CC, Huang WT, Huang SC, et al. Correction: Pleuropulmonary blastoma, not rhabdomyosarcoma in a congenital lung cyst. Pediatr Blood Cancer. 2007 Mar;48(3):370-1. Erratum for: Pediatr Blood Cancer. 2005 Nov;45(6):841-5.

- Retracted Publication 철회 출판물
  - 저자 등이 논문 전체나 일부분을 철회하는 논문
  - Guo H. Images in clinical medicine. complication of central venous catheterization. N Engl J Med. 2007 Jan 11;356(2):e2. Retraction in: Guo H. N Engl J Med. 2007 Mar 8;356(10):1075.
- Retraction of Publication 출판물의 철회
  - 논문, 저자 등이 연구 참여의 취소, 부정을 진술하는 문건
  - Guo H. Retraction: Guo H. complication of central venous catheterization. N Engl J Med 2007; 356: E2. N Engl J Med. 2007 Mar 8;356(10):1075. Retraction of: Guo H. N Engl J Med. 2007 Jan 11;356(2):e2.

1: N Engl J Med. 2007 Mar 8;356(10):1075.

Retraction of:
Guo H. N Engl J Med. 2007 Jan 11;356(2):e2.

Retraction: Guo H. Complication of central venous catheterization. N Engl J Med 2007; 356: e2.

Guo H.

PMID: 17347468 [PubMed - indexed for MEDLINE]

1: N Engl J Med. 2007 Jan 11;356(2):e2.

Retraction in:
Guo H. N Engl J Med. 2007 Mar 8;356(10):1075.

Images in clinical medicine. Complication of central venous catheterization.

Guo H.

Shaoxing People's Hospital, Shaoxing, Zhejiang 31200 China. ghangyuan@hotmail.com

PMID: 17215525 [PubMed - indexed for MEDLINE]

- Scientific Integrity Review 과학 윤리 검토
  - 미국 보건성 연구진실성관리국(Office of Research Integrity)이 작성한 보고서
  - Findings of research misconduct. NIH Guide Grants Contracts. 2007 Jan 12:NOT,OD-07-035.
- Technical Report 기술보고서
  - 의학이나 기타 과학적 문제에 대한 연구와 결과를 자세히 설명해 놓은 공식 보고서.
  - Lynn M, Friedman WA. Hyperbaric oxygen in the treatment of a radiosurgical complication: Technical case report. Neurosurgery. 2007 Mar;60(3):E579
- Twin Study 쌍생아연구
  - 쌍생아를 이용한 연구
- Validation Studies 타당성 연구
  - 특정한 목적으로 정한 절차가 신뢰할 만하고 적절한지를 연구한 저작물.
  - Roy M, Forest F. Assessment of body image distortion in eating and weight disorders: The validation of a computer-based tool (Q-BID). Eat Weight Disord. 2007 Mar;12(1):1-11.


경청해 주셔서 감사합니다.