보고지침에 따른 논문 심사

한림의대 가정의학과
김수영

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 들어 가야 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

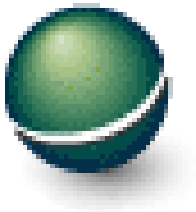
Uniform Requirements for Manuscripts Submitted to Biomedical Journals 2007

주요 보고지침

- 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



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equator network

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Enhancing the QUAlity and Transparency Of health Research

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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 and value of medical research literature by promoting transparent and accurate reporting of research studies.

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We appeal to research funders, publishers and other organisations to support responsible research reporting. Find out how

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Print and display EQUATOR leaflets

EQUATOR Newsletter
New reporting guidelines, events, and other news. **Subscribe** now

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EQUATOR Seminar: Reporting your RCT

Join us on 10 September 2010 in Oxford to learn how to use the updated CONSORT 2010 Statement in reporting your trial. Register now

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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:

NHS National Institute for Health Research | MRC Medical Research Council | CIHR IRSC | Chief Scientist Office | Pan American Health Organization

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.

기타

- Reporting guidelines under development
- Reporting guidelines in other research fields
- Guidance on scientific writing
- Guidance developed by editorial groups
- Medical writers – additional resources
- Research ethics, publication ethics and good practice guidelines
- Resources related to development and maintenance of reporting guidelines
- Editorials introducing reporting guidelines
- Guidelines for peer reviewers
- Case studies: How journals implement reporting guidelines
  Examples of good research reporting
- Useful and interesting presentations
- EQUATOR 'pick' – comments, discussion and other thought provoking articles and interesting quotes

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

ICMJE uniform requirements

Reporting Guidelines for Specific Study Designs

Research reports frequently omit important information. Reporting guidelines have been developed for a number of study designs that some journals may ask authors to follow. Authors should consult the Information for Authors of the journal they have chosen.

The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged also to consult reporting guidelines relevant to their specific research design. A good source of reporting guidelines is the EQUATOR Network (http://www.equator-network.org/home/).

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 design 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 within 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

최근 투고규정에 보고 지침 삽입

- 대한산부인과학회지
- 한국역학회지
- 금연학회지
- 한국유방암학회지
- 한국건강증진학회지

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(+)
- 2001년 부분 수정
- 2010년 문항 수정

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[4 5 6 5])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[4 2])	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

CONSORT-제목과 초록

- 제목
  - 무작위 임상 시험임을 제목에 명시
- 초록
  - 연구 디자인, 방법, 결과, 결론에 대한 구조화된 요약

초록 보고 지침

Item	Description
Authors	Contact details for the corresponding author
Trial design	Description of the trial design (such as parallel, cluster, non-inferiority)
Methods:	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants were allocated to interventions
Blinding (masking)	Whether participants, care givers, and those assessing the outcomes were blinded to group assignment
Results:	
Numbers randomised	Number of participants randomised to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

Analgesic Effects of Tramadol During Panretinal Photocoagulation

Purpose: To evaluate the effectiveness of tramadol for the reduction of pain in panretinal photocoagulation (PRP).
Methods: A double-masked randomized controlled study was performed. Fifty-eight eyes in 29 patients with proliferative diabetic retinopathy were enrolled. The eyes of the patients were randomized into two groups. Group A received an empty capsule. Group B received an oral intake of 100 mg tramadol. The capsule used in Group A had the same appearance as that used in Group B. Pain during PRP was assessed using a visual analog scale. Vital signs, including blood pressure and heart rate, were measured.
Results: The mean pain scores for groups A and B were 4.80±2.10 and 3.83±1.82 (p=0.09). There were no significant differences in the mean pain scores between the two groups. More patients in group A complained of greater pain than moderate intensity (visual analogue scale=4). Systemic blood pressure increased significantly in group A after laser treatment. However, there were no significant differences in the diastolic blood pressure changes between the two groups. We found no statistical correlation in the heart rate changes.
Conclusions: We failed to prove that tramadol is effective for pain relief because of the small sample size. However, tramadol was effective for the relief of more severe pain. It was also found to stabilize vital sign changes, such as systolic blood pressure during PRP.
Korean J Ophthalmol 2009;23:273-276

Key Words: Pain, Panretinal photocoagulation, Tramadol

심사의 예

- 제목과 초록
  - CONSORT에 의하면 제목에 ‘무작위’란 용어를 넣도록 하고 있습니다.
  - 초록에 참여자의 선정기준과 세팅, 무작위 방법, 맹검이 된 대상(참여자, 결과 평가자 등), 무작위된 대상자 수, 분석된 대상자 수, 중재의 부작용, 연구의 registration number 등에 대한 내용이 없습니다.

서론

- 배경과 목적
  - 과학적 배경과 연구 이유의 설명
  - 특정 목적이나 가설

CONSORT-방법

- 연구 디자인
  - 배정비, 연구 디자인(평행, factorial)
  - 연구 진행 중 변경 사항과 그 이유
- 참가자
  - 선정 기준
  - 자료 수집 기관 세팅과 위치
- 중재 : 구체적으로
- 의료결과(outcomes)
  - 일차, 이차 결과를 명확히, 평가 방법
  - 연구 진행 중 변경된 것과 그 이유
- 환자수
  - 환자 수 산정 방법
  - 적용가능하면 중간평가와 중단 지침에 대한 설명

A prospective, double masked, randomized, case-controlled study was conducted in the department of ophthalmology [redacted]l. Data from the patients was collected between April 2007 and December 2007. Informed consent was obtained from all patients prior to their participation. The Ethical Committe[redacted] approved all methodologies. Patients with proliferative diabetic retinopathy and no previous history of PRP were included. Patients were excluded from the study if they had a history of hypersensitivity or contraindication

- 방법에서 자료 구한 장소의 위치와 세팅을 밝히도록 되어 있으나 그렇지 않습니다. 정확한 내용을 기술하여 주십시오.
- 선정기준이 명확하지 않습니다.
- 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.

CONSORT 2 – 방법(무작위)

- 배정의 순서
  - 무작위 배정 순서 생성 방법
  - 무작위 방법, 제한 방법(블록, 블록의 크기)
- 배정 은폐
  - 배정 은폐의 방법(예 : sequentially numbered containers)
- 배정 실행
  - 배정 순서 생성자, 참여자 모집자, 중재 배정자

Box 3 | Steps in a typical randomisation process

Sequence generation

- Generate allocation sequence by some random procedure

Allocation concealment

- Develop allocation concealment mechanism (such as numbered, identical bottles or sequentially numbered, sealed, opaque envelopes)
- Prepare the allocation concealment mechanism using the allocation sequence from the sequence generation step

Implementation

- Enrol participants:
  - Assess eligibility
  - Discuss the trial
  - Obtain informed consent
  - Enrol participant in trial
- Ascertain intervention assignment (such as opening next envelope)
- Administer intervention

무작위 할당

- 두 군의 예후 인자가 평균적으로 분포
- 예측되는 배정법
  - 교대, 생일, 내원일 등 배정 원칙 알게 되는 경우
- 방법
  - 단순 : 주로 컴퓨터나 난수표
  - 제한된 무작위화 : 블록, 층화

배정 은폐(Allocation concealment)

- 연구자가 환자의 할당그룹을 인식하지 못하게 보장하기 위한 절차
- 배정 은폐 없으면 순서 예측 가능
- 배정은폐 없으면 효과의 크기 18%까지 상승
- 방법
  - 제 3자에 의한 중앙 무작위화
  - sequentially numbered, sealed, opaque envelopes
  - Serially numbered Identical container

맹검과 통계

- 맹검
  - 배정 후 맹검 대상(참여자, 결과 평가자, 치료 제공자)
  - 중재가 유사한지에 대한 기술
- 통계 방법
  - 일차, 이차 결과에 대한 통계 분석 방법
  - 추가적 분석 (하부 집단 분석, 보정 분석 등)

맹검

- 연구 배정 이후 배정 상태를 모르는 것
- 결과와 결과 평가에 미치는 영향을 줄이는 것
- 맹검 대상
  - 참여자(환자 혹은 건강인)
  - 보건의료인(진료를맡고 있는 의사나 간호사)
  - 결과 평가자
  - 자료 수집자(결과 자료 측정, 수집자)
  - 결과 분석자(통계학자)

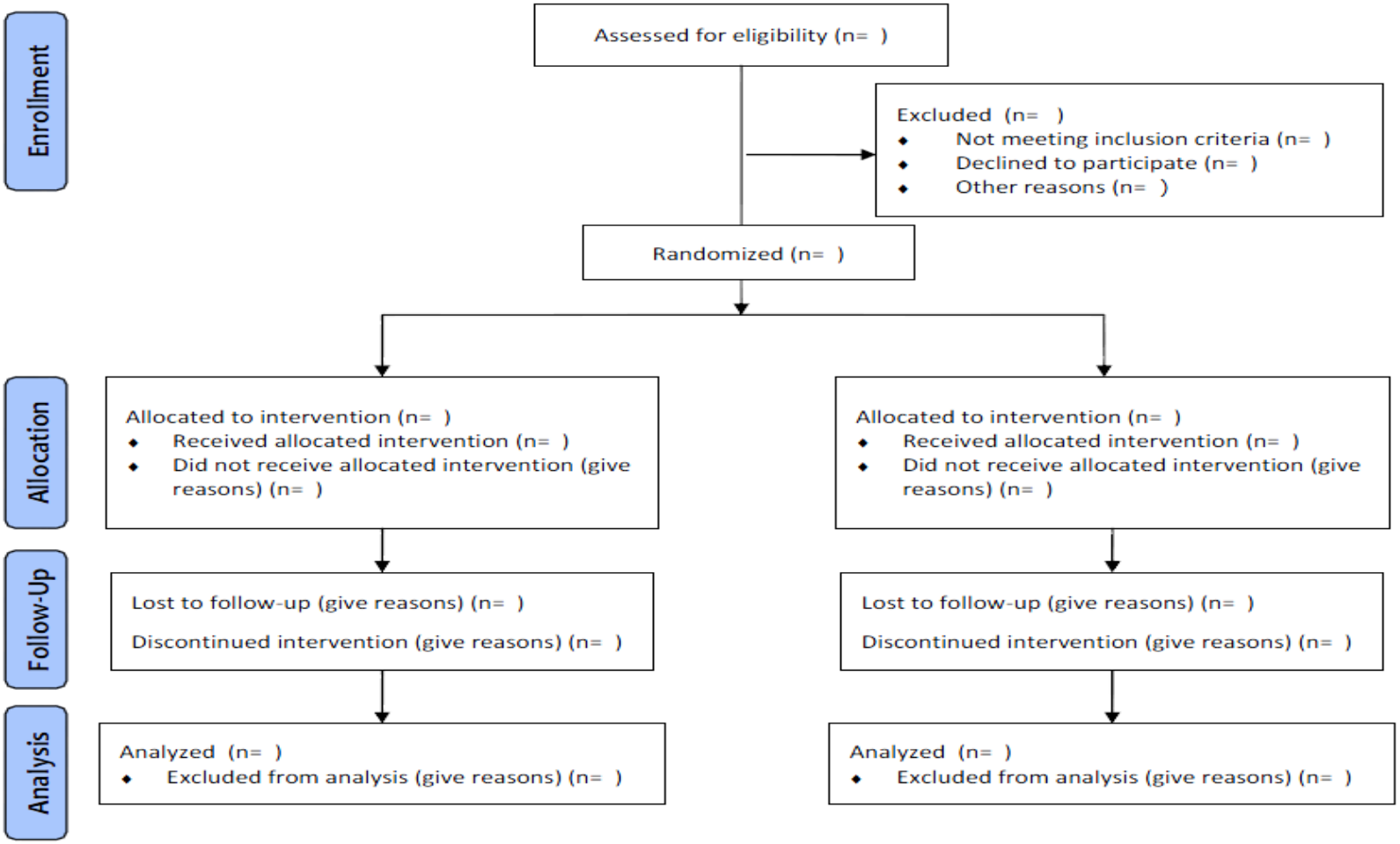
One eye from each patient was randomized to a treatment group. A control group was created using the fellow eye of same patient. Group A received an empty capsule. This capsule had the same appearance as that used in group B. Group B received an oral intake of low dose (100 mg) tramadol (Tridol®; Yuhan corporation, Seoul, Korea). The medication was administered one hour prior to the panretinal photocoagulation procedure.

- 무작위 대조 연구에서 무작위 배정이 되었다고만 하면 안되며 무작위 순서를 어떻게 생성하였는지, 무작위 중 무작위가 어떻게 은폐되었는지 무작위는 누가 수행하고 참여자는 어떻게 배정하는지에 대해서 제시하여야 합니다.
- 맹검(약제의 유사성 등) 시행 방법, 맹검 대상(결과 분석자, 환자, 치료 제공자)에 대해서 기술하여 주시기 바랍니다.

CONSORT-결과

- 참가자 흐름도
  - 각군의 참여자, 무작위 배정, 치료 받은 수
  - 무작위 후 탈락 수와 그 이유
- 모집(기간과 추적관찰)
- 연구 시점 자료
- 분석된 숫자(ITT)
- 결과와 추정치
- 부가적 분석
- 부작용

CONSORT Statement 2010 Flow Diagram



Results

Twenty-six eyes from 13 patients with proliferative diabetic retinopathy were studied, with a total of 32 cases in group A and 24 in group B. The mean age of the patients was 52.90±8.08 years, with a range of 34 to 72 years. All of the patients had type II diabetes. The duration of diabetes history ranged from 1 to 20 years, with a mean of 11.19±6.16 years. Thirteen patients had a history of hypertension and were taking oral systemic anti-hypertension drugs. Histories of other ocular diseases were not reported, except for refractive errors.

There were no significant differences in the mean pain scores between the two treatment groups. The mean pain scores for group A and B were 4.80±2.20 and 3.83±1.82 (p=0.09) (Table 1). In group A, 22 of 32 (68.7%) patients felt more severe pain (VAS>4), as compared to the placebo group. In group B, 9 of 24 (37.5%) patients felt more severe pain, as compared to the placebo group (Table 2). Pain score results for the retinal areas where the laser was applied are summarized on Table 3.

- 각군의 참여자, 무작위 배정, 치료 받은 수, 무작위 후 탈락 수와 그 이유를 기술한 연구 흐름도를 제시하시기 바랍니다.
- 기저상태 차이, 모집기간 등에 대하여 기술하시기 바랍니다.
- 유해 반응에 대하여 명확하게 기술바랍니다.

CONSORT-고찰

- 해석
- 일반화 여부
- 전체적 근거

CONSORT – 다른 정보

- 등록 : 등록처와 등록 번호
- 프로토콜 : 프로토콜 전문 접근 가능한 위치
- Funding : 자금원과 자금원의 역할

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*

	Total No. of Items		Randomization		Double-blinding		Dropouts/ Withdrawals		Total		Unclear Allocation Concealment	
Journal	1994	1998	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)
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 –

실습

- 실습 논문 확인
- 세 가지 체크리스트
  - CONSORT
  - Abstract
  - Flow diagram

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.

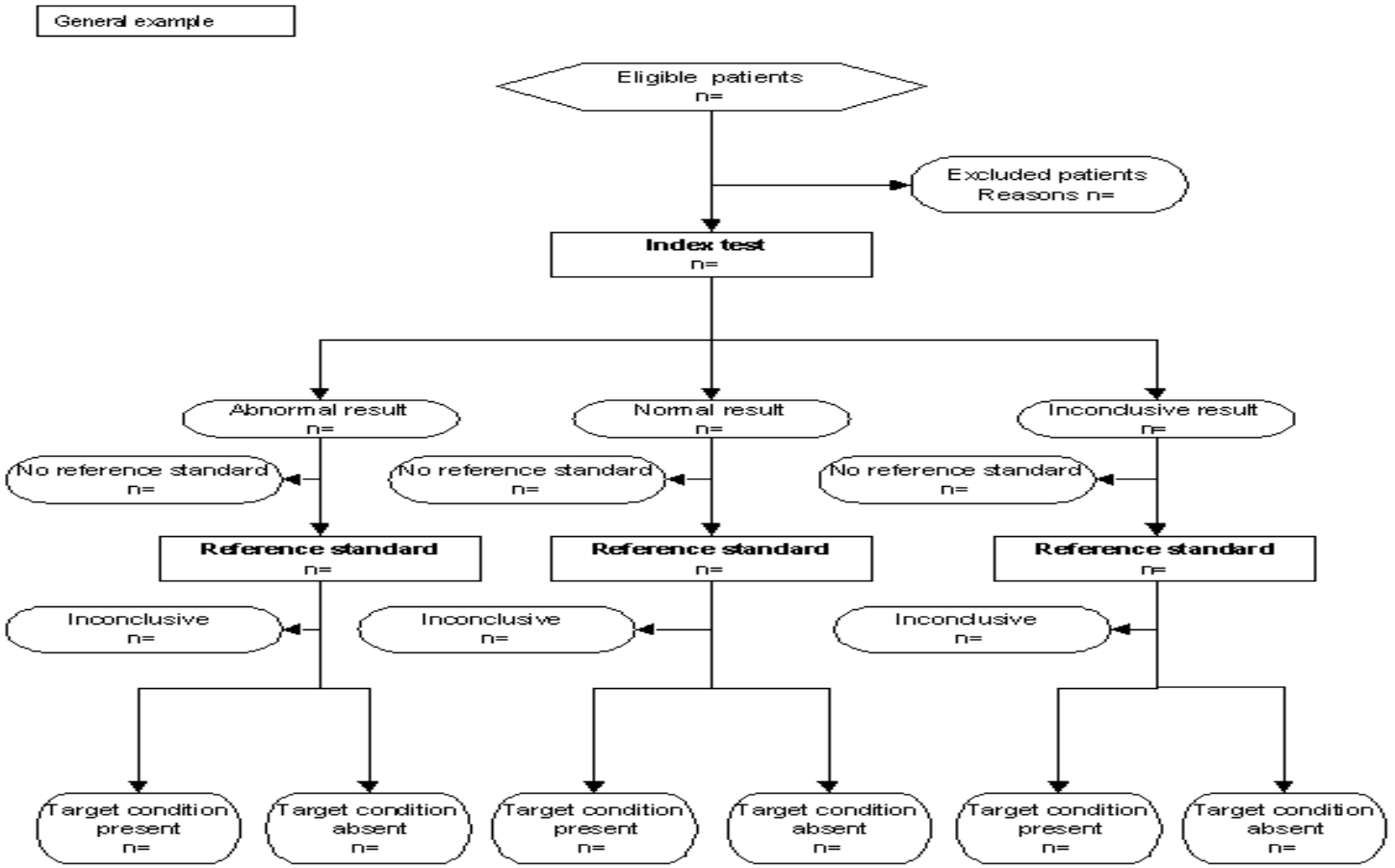
- DNA sequencing

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 인구 의학적 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

우리나라 실태

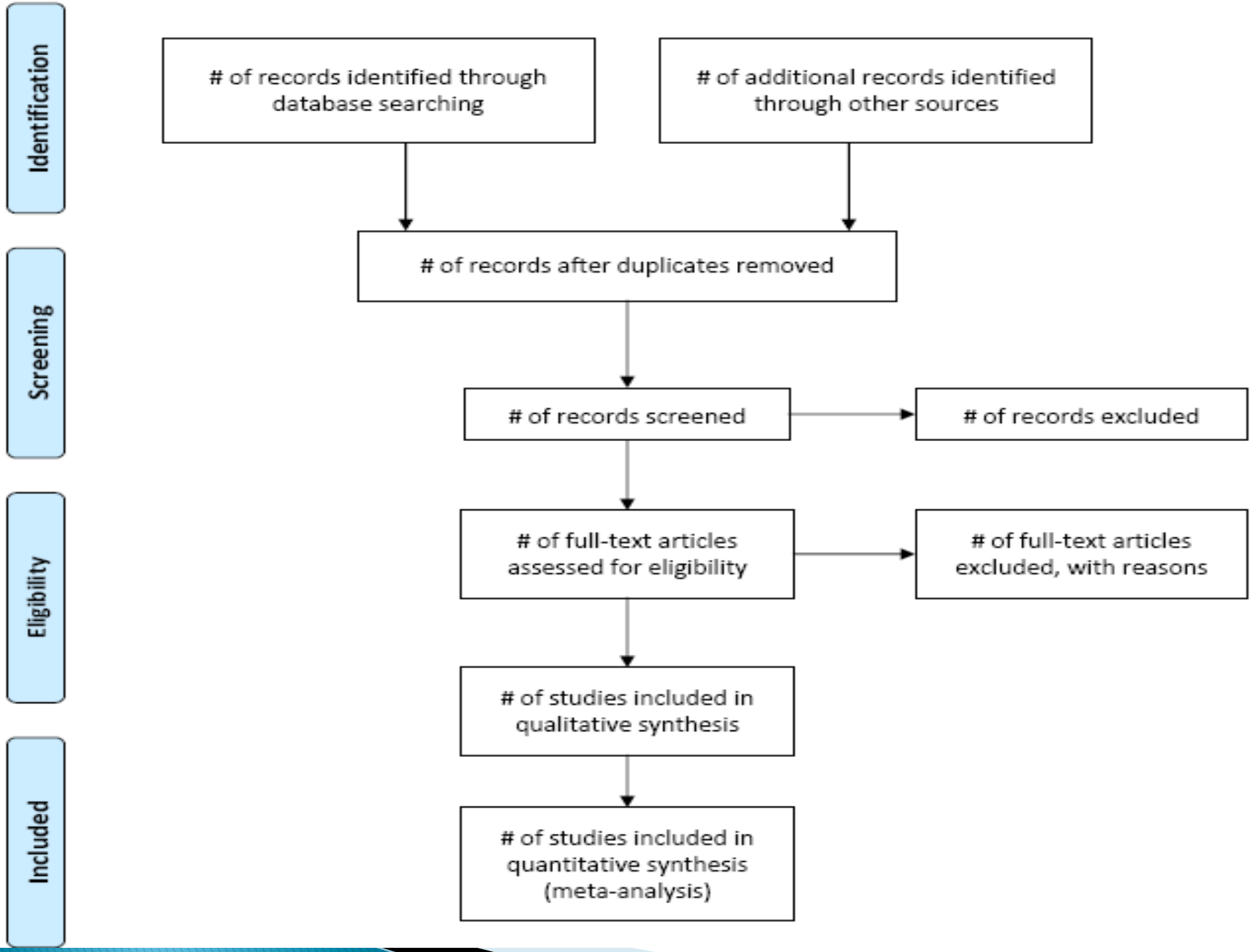
- 가정의학회지 84편
- 보고 비율이 낮은 것
  - 연구 디자인
  - 비뚤림
  - 표본 수
  - 통계적 방법
  - 참여자 기술
  - 연구비 지원

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)

PRISMA Checklist: 국문[6)]

섹션/주제	항목 번호	항목 체크리스트	보고된 페이지
제목			
제목	1	체계적 문헌고찰 또는 메타분석(또는 양쪽 모두) 임을 알 수 있다.	
초록			
구조화된 요약	2	적용 가능한 경우, 다음의 내용을 포함하는 구조화된 요약을 제공한다: 배경, 목적, 자료원, 선정기준, 연구 대상, 중재, 연구의 질, 자료 합성 방법, 결과, 제한점, 결론, 연구 결과의 의의, 체계적 문헌고찰 등록 번호	
서론			
필요성	3	현재까지 알려진 것에 비추어 연구의 필요성에 대해 기술한다.	
연구목적	4	PICOS(연구대상, 중재, 비교중재, (중재)결과, 연구설계) 형식으로 핵심질문을 명확하게 기술한다.	
방법			
프로토콜과 등록	5	프로토콜이 있다면 이를 명시하고, 이에 대한 접근 방법(예: 웹주소)과 등록 번호와 같은 등록 정보를 제시한다.	
선정기준	6	선정기준으로 명시된 연구 특성(예: PICOS, 추적관찰기간)과 보고 특성(예: 연도 제한, 언어, 출판 상태)을 기술하고 그 이유를 제시한다.	
정보원	7	검색에 사용한 모든 정보원(예: 데이터베이스와 해당 데이터베이스의 자료제공 연도, 저자 접촉)과 최종 검색일을 명시한다.	
검색	8	적어도 하나의 데이터베이스에 대하여 검색제한을 포함한 검색전략 전체를 제시하여 검색을 재현할 수 있게 한다.	
문헌선택	9	문헌선택 과정, 예를 들어, 체계적 문헌고찰의 경우 선별, 선정, 포함과정, 그리고 적용 가능한 경우 메타분석의 포함과정에 대해 명시한다.	
자료수집 과정	10	자료추출 방법(예: 시범 평가 후 확정된 추출양식, 독립적 중복 수행)과 연구자로부터 자료를 구득하고 확인하는 과정에 대해 기술한다.	
자료추출 항목	11	자료추출 대상의 목록과 정의를 제시하고(예: PICOS, 연구비 출처) 가정한 내용과 단순화한 내용을 제시한다.	
개별 연구의 비뚤림 위험	12	개별 연구의 비뚤림 위험을 평가한 방법(각 연구 단위 또는 결과변수 단위로 수행 되었는지 여부 포함)이 무엇인지, 평가결과를 자료합성에 어떻게 반영하였는지 기술한다.	
요약 측정치	13	주요 요약 측정치(예: 위험비, 평균 차이)를 명시한다.	
자료합성	14	자료가공 방법 및 결과합성 방법을 제시하고 메타분석을 수행하였다면 개별 분석에서의 일관성 측정 방법(예: I^2)을 기술한다.	

6) 국문판은 영번역-역번역 작업의 결과로서 PRISMA 그룹에 의해 확정을 받은 결과이다.

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 • Structured abstract recommended • **Information on target population or study sample**	Example (title): A nonrandomized trial of a clinic-based HIV counseling intervention for African American female drug users
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.