

Structured Abstract Development of East Asian Traditional Medicine and Health Foods

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Classical classification of abstract

- Informative abstract (報知的抄錄)
 - describe contents
 - aim to understand contents without reading main text
- Indicative abstract (指示的抄錄)
 - describe theme and scope
 - aim to help to decide to read main text or not

Abstract as Published

Twelve patients with refractory rheumatoid arthritis were treated with weekly pulse methotrexate in a double-blind, placebo-controlled, crossover study. After 13 weeks of therapy, patients receiving methotrexate showed greater improvement, judged by degree of joint swelling and tenderness, duration of morning stiffness, and subjective assessments of clinical condition, compared with those receiving placebo ($p \leq 0.002$). This improvement was associated with a decrease in sedimentation rate and decreases in levels of IgG, IgM, and IgA; no changes were seen in serum rheumatoid factor titer or complement protein levels. Proportions of mononuclear cell subsets that were abnormal before treatment (decreased percentage of total T cells, increased percentage of monocytes) improved toward normal after therapy with methotrexate. However, no changes were seen in elevated pretreatment Leu-3/Leu-2 ratios, in in-vitro proliferative responses of lymphocytes to mitogens, or in immunoglobulin secretory responses to pokeweed mitogen. Weekly pulse methotrexate is effective in the short-term treatment of refractory rheumatoid arthritis. Little evidence for cellular immune suppression was associated with this clinical benefit.

Structured Abstract

- 1 **Study Objective:** To determine the efficacy of weekly pulse methotrexate in refractory rheumatoid arthritis.
- 2 **Design:** Randomized, double-blind, placebo-controlled, crossover trial with 13-week treatment periods.
- 3 **Setting:** Referral-based rheumatology clinics at two army medical centers.
- 4 **Patients:** Sequential sample of 15 patients with active definite or classical rheumatoid arthritis and previous treatment failure. Twelve patients (80%) completed the study; 1 patient removed because of drug toxicity (pancytopenia).
- 5 **Interventions:** Nonsteroidal anti-inflammatory drugs and prednisone were continued. Methotrexate 5 mg intramuscular test dose was given at week 1, increased in 5-mg steps to a maximum of 25 mg/wk if clinically needed. Intramuscular saline placebo given in control periods.
- 6 **Measurements and Main Results:** The following results (statistically significant findings, $p < 0.05$) were in favor of methotrexate compared with placebo: number of swollen joints 6.9 (5.2, SD) with methotrexate and 19.4 (12.1) with placebo; number of tender joints 12.6 (14.2) and 26.2 (17.0); minutes of morning stiffness 78 (117.8) and 242 (131.6); joint pain (scale 0-10) 1.1 (2.1) and 4.8 (3.1); 50-foot walk (seconds) 16.1 (10.0) and 23.1 (16.3). Laboratory tests showing differences ($p < 0.05$) favoring methotrexate included erythrocyte sedimentation rate and IgG. Other tests of physical and laboratory function, including immunologic tests, did not show important differences.
- 7 **Conclusions:** Weekly pulse methotrexate results in improvement of multiple measures of disease activity in refractory rheumatoid arthritis. The mechanism of methotrexate action is uncertain with little evidence of short-term cellular immune suppression. Larger and longer trials are needed to assess the safety of methotrexate for refractory rheumatoid arthritis.

Figure 1. Published and structured abstracts for an article by Andersen and colleagues (24).

Table 1. Key Information Needed by Clinicians for Selecting Articles of High Relevance and Quality

Original Articles

1. Objective: the exact question(s) addressed by the article
2. Design: the basic design of the study
3. Setting: the location and level of clinical care
4. Patients or participants: the manner of selection and number of patients or participants who entered and completed the study
5. Interventions: the exact treatment or intervention, if any
6. Main outcome measures: the primary study outcome measure as planned before data collection began
7. Results: the key findings
8. Conclusions: key conclusions including direct clinical applications



Review Articles

1. Purpose: the primary objective of the review article
 2. Data sources: a succinct summary of data sources
 3. Study selection: the number of studies selected for review and how they were selected
 4. Data extraction: rules for abstracting data and how they were applied
 5. Results of data synthesis: the methods of data synthesis and key results
 6. Conclusions: key conclusions, including potential applications and research needs
-

**Hayes RH, Mulrow CD, Huth EJ, Altman DG, Gardner MJ.
More informative abstract revisited. *Ann Int Med* 1990; 113: 69-76**

CONSORT Extensions for Abstracts

Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of the study as randomized.	
Authors *	Contact details for the corresponding author.	
Trial design	Description of the trial design (e.g. 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.	
Randomization	How participants were allocated to interventions.	
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment.	
Results		
Numbers randomized	Number of participants randomized 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.	

*this item is specific to conference abstracts.

BEFORE

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

Jan Jelrik Oosterheert, Marc J M Bonten, Margriet M E Schneider, Erik Buskens, Jan-Willem J Lammers, Willem M N Hustinx, Mark H H Kramer, Jan M Prins, Peter H Th J Snee, Karin Kaasjager, Andy I M Hoepelman

Objectives To compare the effectiveness of an early switch to oral antibiotics with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.

Design Multicentre randomised controlled trial.

Setting Five teaching hospitals and 2 university medical centres in the Netherlands.

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics.

Main outcome measures Clinical cure and length of hospital stay.

Results 302 patients were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients for intention to treat analysis. Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval -3% to 8%). **Clinical cure was 83% in the intervention group and 85% in the control group (2%,-7% to 10%).** Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) v 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) v 11.5 (4.9) days; 0.6 to 3.2), respectively.

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.

Trial registration Clinical Trials NCT00273676.

Text highlighted in blue signifies where items are reported from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	
Trial design	
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	
Blinding (masking)	
Results	
Number randomized	
Recruitment	
Number analysed	
Outcome	✓
Harms	
Conclusions	✓
Trial registration	✓
Funding	

Word count: 248

Oosterheert JJ, Bonten MJ, Schneider MM, Buskens E, Lammers JW, Hustinx WM, Kramer MH, Prins JM, Snee PH, Kaasjager K, Hoepelman AI. Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial. *BMJ*. 2006;333(7580):1193.

AFTER

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

Jan Jelrik Oosterheert, Marc J M Bonten, Margriet M E Schneider, Erik Buskens, Jan-Willem J Lammers, Willem M N Hustinx, Mark H H Kramer, Jan M Prins, Peter H Th J Slec, Karin Kaasjager, Andy I M Hoepelman

Correspondence to: i.m.hoepelman@umcutrecht.nl

Objectives Effectiveness of early switching to oral antibiotics compared with standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.

Design Multicentre **parallel** randomised controlled, **open label**, trial. **A central randomisation centre used computer generated tables to allocate treatments.**

Setting Five teaching hospitals and 2 university medical centres in the Netherlands.

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. **Follow-up 28 days.**

Main outcome measures Clinical cure and length of hospital stay.

Results 302 patients (**early switch n=152; standard care n=150**) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 (**n=132; n=133**) patients for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, -7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) v 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) v 11.5 (4.9) days; 0.6 to 3.2), respectively. **Mobility and other side effects were comparable across groups.**

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.

Trial registration Clinical Trials NCT00273676.

Funding Dutch Health Insurance Council, OG 99-64.

Text highlighted in red signifies where items have been added from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	✓
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	✓
Blinding (masking)	✓
Results	
Number randomized	✓
Recruitment	✓
Number analysed	✓
Outcome	✓
Harms	✓
Conclusions	✓
Trial registration	✓
Funding	✓

Word count: 260

Who writes abstract ?

Author

→ Third party

Systematic review

- Quantitative systematic review
 - with synthesis / meta-analysis
- Qualitative systematic review
 - without synthesis
 - outcome is evidence table
or structured abstracts with third party
comments

Part 1

- Kampo medicine
- traditional east Asian medicine (TEAM)
- As a chair of the Committee of EBM, the Japanese Society for Oriental Medicine (JSOM) since 2005

Type A:Kampo drug 漢方製剤



Type B: Crude herbal product 生薬



Type C: Finished herbal product

生薬製剤（その他の生薬及び漢方処方に基づく医薬品）



•Herbal “drug” products in Japan

(2006, US\$ mil)

Type	Ethical	OTC/others	Total
A: Kampo drug	<u>895</u>	181	1,076
B: Crude herbal product	21	10	31
C: Finished herbal product	15	47	62
Total	932	237	1,169

1961: Universal health insurance

1967: Separation between ethical and OTC

(US \$1=JPY100)

“Production of Herbal drug products” (19 Mar 2009)

by Japan Kampo Medicines Manufactures Association (JKMA)

(From “ Annual Report of Pharmaceutical Production in Japan 20

1) The Cochrane Library (C)

Kampo RCTs were searched using the Cochrane Central Register of Controlled Trials (CENTRAL), a worldwide RCT database organized by the Cochrane Collaboration. Since the CENTRAL covers all RCTs in the Medline, searches using the Medline were not performed.

On 26 November 2012, searches were performed by the following search formula, limited to publications in and after 1986:

- #1 MeSH descriptor Medicine, East Asian Traditional explode all trees
- #2 MeSH descriptor Medicine, Kampo explode all trees
- #3 MeSH descriptor Medicine, Chinese Traditional explode all trees
- #4 MeSH descriptor Drugs, Chinese Herbal explode all trees
- #5 MeSH descriptor Herb-Drug Interactions explode all trees
- #6 MeSH descriptor Herbal Medicine explode all trees
- #7 MeSH descriptor Plants, Medicinal explode all trees
- #8 MeSH descriptor Plant Structures explode all trees
- #9 MeSH descriptor Plant Extracts explode all trees
- #10 MeSH descriptor Materia Medica explode all trees
- #11 MeSH descriptor Phytotherapy explode all trees
- #12 (Kampo):ti,ab,kw
- #13 (Kanpo):ti,ab,kw
- #14 (Japanese):ti,ab,kw
- #15 (Oriental):ti,ab,kw
- #16 (Traditional):ti,ab,kw
- #17 (East Asia):ti,ab,kw
- #18 (East-Asia):ti,ab,kw
- #19 (Herb*):ti,ab,kw
- #20 (Chinese):ti,ab,kw
- #21 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20), from 1986 to 2012
- #22 (HS-EKAT)
- #23 (#21 AND NOT #22)

On 19 November 2012, randomized controlled trials of Kampo medicines were searched by the following search formula using *Igaku Chuo Zasshi* (Japana Centra Revuo Medicina [JCRM], Ichushi) Web (in Japanese). Words in square brackets indicate equivalent English words.

Search formula:

(漢方薬 [Kampo medicine]/TH or 漢方 [Kampo]/AL) and (メタアナリシス [meta-analysis]/RD or ランダム化比較研究 [randomized controlled trial]/RD or 準ランダム化比較研究 [quasi-randomized controlled trial]/RD) and (DT=1986: 2012)

Since the Ichushi Web tags meta-analyses, randomized controlled trials, and quasi-randomized controlled trials, the present search targeted references that were tagged (メタアナリシス [meta-analysis]/RD or ランダム化比較研究 [randomized controlled trial]/RD or 準ランダム化比較研究 [quasi-randomized controlled trial]/RD), had "漢方薬 [Kampo medicine]" (漢方薬 [Kampo medicine]/TH) as a keyword (control term), or a title or abstract including the term "Kampo [漢方]" (漢方 [Kampo]/AL), and were published between 1986 and 2012 (DT=1986:2012).

3) Database offered by the Japan Kampo Medicines Manufacturers Association (N)

The database offered by the Japan Kampo Medicines Manufacturers Association (JKMA) (unpublished) is the second database on Kampo and crude drugs, constructed by exhaustively searching existing databases including JST, JAPIC, *Igaku Chuo Zasshi*, Medline, and EMBASE with the keywords "漢方 [Kampo]," "東洋医学 [Oriental medicine]," "和漢 [Wakan]," "生薬 [crude drug]," "Kampo" and "Chinese Medicine," and hand-searching several tens of Kampo-related journals. At present, the database includes approx. 100,000 references.

メタアナリシス (meta-anarisisu, meta-analysis); メタ解析 (meta-kaiseki, meta-analysis); メタ分析 (meta-bunseki, meta-analysis); RCT; ランダム (randamu, random); 無作為, 無作意 (musakui, random); 封筒 (futo, envelope); 来院順 (raijinjun, order of presentation); 受診順 (jushinjun, order of presentation); 診断順 (shindanjin, order of diagnosis); 割付, 割り付け (;waritsuke, allocation); ブラインド (buraindo, blind); 盲検, 盲験 (mouken, blind), 遮蔽, 遮へい, シャへい (shahei, mask), マスク (masuku, mask); マスキング (masukingu, masking); クロスオーバー (kurosuoba, crossover), 交叉, 交差 (kosa, crossover), 比較臨床 (hikaku rinsho, controlled clinical); random; cross over; meta analysis; envelope



Evidence Reports of
Kampo Treatment 2013 :
402 RCT
(EKAT 2013)

- ▶ [Notes on the current version](#)
- ▶ [History of version upgrades](#)
- ▶ [Executive summary](#)
- ▶ [1. Lists of structured abstracts](#)
- ▶ [2. Background](#)
- ▶ [3. Purpose](#)
- ▶ [4. Steps for development of structured abstracts](#)
- ▶ [5. Included and excluded references](#)
- ▶ [6. Relation to other projects](#)
- ▶ **7. Lists of excluded references**

7. Lists of Excluded References (159 references)

- 1.Infections (including Viral Hepatitis) (4 references)
- 2.Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs) (15 references)
- 3.Blood diseases including anaemia (2 references)
- 4.Metabolism and Endocrine Diseases (12 references)
- 5.Psychiatric/Behavioral Disorders (21 references)
- 6.Nervous System Diseases (including Alzheimer's Disease) (8 references)
- 8.Ear Diseases (1 reference)
- 9.Cardiovascular Diseases (6 references)
- 10.Respiratory Diseases (including Influenza and Rhinitis) (8 references)
- 11.Gastrointestinal, Hepato-Biliary-Pancreatic Diseases (16 references)
- 12.Skin Diseases (6 references)
- 13.Diseases of the Musculoskeletal System and Connective Tissue (4 references)
- 14.Genitourinary Tract Disorders (including Climacteric Disorders) (11 references)

Reasons for exclusion were classified as follows:

- 1) Clinical studies that were not RCTs or meta-analyses.
- 2) Studies using medicines that were not approved as Kampo preparations in Japan (Kampo tozai [decoctions], Chinese preparations, and others).
- 3) Studies using Kampo preparations manufactured before 1985 (their quality being different from that currently available).
- 4) Studies citing existing RCT papers.
- 5) Studies with unclear content.
- 6) Others (reasons are described in the list).

▪ **1.Infections (including Viral Hepatitis) (4 references)**

ICD10	Research Question	Kampo Formula	References	Reason for exclusion	Source
A09	Effects of Kampo prescriptions on inflammatory bowel disease (IBD)	Various prescriptions	Okumi H. An EBM evaluation of Kampo prescriptions related to inflammatory bowel disease (IBD). <i>Nihon Toyo Shinshin Igaku Keknkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)</i> . 2010; 25: 95-9 (in Japanese with English abstract).	4) RCT review	I
			Clinical research group for coix seed (yokuinin)		

1. Infections (including Viral Hepatitis)**References**

Yoshiya K, Nakazawa S. A controlled study of TSUMURA Saireito (柴苓湯) for rotavirus infection*. *Nihon Shonika Rinsho (Japanese Journal of Pediatrics)*. 1992; 45: 1889-91 (in Japanese).

Yoshiya K, Nakazawa S. A controlled study of TSUMURA Saireito (柴苓湯) for rotavirus infection*. *Dai 9-kai Nihon Shoni Toyo Igaku Kenkyukai Koen Kiroku Nihon Shoni Toyo Igakkaishi (Proceedings of the 9th meeting of the Japan Pediatric Society for Oriental Medicine)* 1993; 9: 20-3 (in Japanese).

1. Objectives

To evaluate the efficacy of saireito (柴苓湯) for rotavirus infection.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

No mention of participating centers (the authors are from the Department of Pediatrics, Kobe Teishin Hospital), Japan.

4. Participants

Forty infants diagnosed with rotavirus infection using Rotalex.

5. Intervention

Patients were allocated alternately to the two treatment groups in the order of consultation.

Arm 1: one intestinal infusion of powdered TSUMURA Saireito Extract Granules (0.3 g/kg body weight) dissolved in 20 mL of warmed saline solution administered by soft catheter immediately after rotavirus diagnosis (n=20).

Arm 2: no treatment (n=20).

6. Main outcome measures

Number of days with diarrhea and total number of vomiting episodes compared before and after administration and between groups; number of transfusion cases and number of hospitalized cases compared between groups.

7. Main results

The mean number of days with diarrhea (1.3–3.4 in arm 1 and 1.1–3.6 in arm 2) was not significantly different between groups. The mean number of vomiting episodes decreased significantly from 3.6 before administration to 0.6 after administration in arm 1 ($P<0.01$), but not in arm 2 (the numbers being 3.3 and 2.8, respectively). There was no significant between-group difference in the number of transfusion cases (8 in arm 1 and 14 in arm 2) and number of hospitalized cases (2 in arm 1 and 6 in arm 2).

8. Conclusions

Saireito administered by intestinal infusion for rotavirus infection effectively decreases the number of vomiting episodes.

9. From Kampo medicine perspective

Saireito was used because it is a combination of shosaikoto (小柴胡湯), which is effective for inflammation, and goreisan (五苓散), which is effective for vomiting.

10. Safety assessment in the article

No adverse effects from saireito intestinal infusion were observed.

11. Abstractor's comments

This clinical study investigated the efficacy of saireito for vomiting and diarrhea due to rotavirus infection. Given the difficulties of following up acute infection after examination, it is a valuable study because it does follow up 40 participants with no dropouts. However, the authors do not mention whether the blood sample taken at initial consultation or the blood sample taken after drug administration was tested, making it unclear whether the presented test results were included to compare severity between groups, or to indicate there is no safety issue with saireito. It is also unclear whether the intestinal infusion itself had any effect on vomiting because the authors did not carry out intestinal infusion using saline solution alone in arm 2, although this is pointed out in the paper. Yet, the authors have devised a possibly groundbreaking therapy, which appears to have relatively few adverse effects, for a disease that has lacked a good therapy, even though it affects many infants each year in winter. A future clinical study with a better defined control group is anticipated.

12. Abstractor and date

Goto H, 31 December 2013.

Kampo concept in inclusion criteria

•Reference

- Furue M, Tanaka Y, Kobayashi H, et al. Efficacy of Kanebo Hochuekkito in patients with atopic dermatitis with “qikyo” – a multicenter, double-blind trial*. *Arerugi (Japanese Journal of Allergology)*. 2005; 54: 1020 (in Japanese).

•Objectives

- To assess the efficacy of hochuekkito (補中益気湯) for the treatment of atopic dermatitis.

•Participants = Inclusion criteria

- Patients with atopic dermatitis and “qikyo” (気虚, qi deficiency) n=77

•Intervention

- Arm 1: hochuekkito (補中益気湯) n=37

- Arm 2: placebo n=40

•Results:

- Reduction of skin lesion scores : not significantly different between two arms

- Changes in “qikyo” scores : not significantly different between two arms

Use of Kampo Diagnosis in Randomized Controlled Trials of Kampo Products in Japan: A Systematic Review



Yoshiharu Motoo^{1*}, Ichiro Arai², Kiichiro Tsutani³

1 Department of Medical Oncology, Kanazawa Medical University, Ishikawa, Japan, **2** Department of Kampo Medicine, Nihon Pharmaceutical University, Saitama, Japan, **3** Department of Drug Policy and Management, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Tokyo, Japan

Abstract

Background: The Committee for Evidence-based Medicine (EBM) of the Japan Society for Oriental Medicine started compiling Evidence Reports of Kampo Treatment (EKAT) in 2007. EKAT is a compilation of structured abstracts of randomized controlled trials (RCTs), along with comments by a third party reviewer. As of 31 December, 2012, there were 378 RCTs of Kampo medicines in Japan. The primary research question of this study is "How frequently is Kampo diagnosis used in RCTs of Kampo medicines?" The secondary research question is "When is Kampo diagnosis used in RCTs?"

Materials and Methods: The structured abstract (SA) of each RCT article was reviewed to examine how Kampo diagnosis was used in RCTs, especially how Kampo diagnosis was used in the randomization process.

Results: Kampo diagnosis was used before randomization in 27 RCTs (7.1%), after randomization in 31 RCTs (8.2%), and not used in 320 RCTs (84.7%). Before randomization, Kampo diagnosis was used as a criterion for inclusion in 10 RCTs, criterion for exclusion in 9 RCTs, and criteria for both inclusion and exclusion in 2 RCTs. Kampo formulas were determined according to Kampo diagnosis in 7 RCTs. After randomization, subgroup analyses according to Kampo diagnosis were done in 27 RCTs, and grade of disease severity at Kampo diagnosis was used for analysis as an endpoint in 4 RCTs.

Conclusions: Kampo diagnosis was used before randomization only in approximately 15% of RCTs, and the number of RCT articles using Kampo diagnosis after randomization was almost the same as that before randomization. Further studies to determine the good RCTs conforming to CONSORT requirements and good systematic reviews conforming to PRISMA requirements are needed to clarify the significance of Kampo diagnosis.

Citation: Motoo Y, Arai I, Tsutani K (2014) Use of Kampo Diagnosis in Randomized Controlled Trials of Kampo Products in Japan: A Systematic Review. PLoS ONE 9(8): e104422. doi:10.1371/journal.pone.0104422

Editor: Natalie Walker, The National Institute for Health Innovation, New Zealand

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Copyright: © 2014 Motoo et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Funding: The authors have no support or funding to report.

Competing Interests: The authors have declared that no competing interests exist.

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Quality of Kampo RCT Papers (1/3)

■ EKat 2009
□ Japanese RCT 2004

1. TITLE & ABSTRACT

2. INTRODUCTION / Background

3a. METHODS / Participant Eligibility criteria

3b. METHODS / Participants Settings and locations

4. METHODS / Interventions

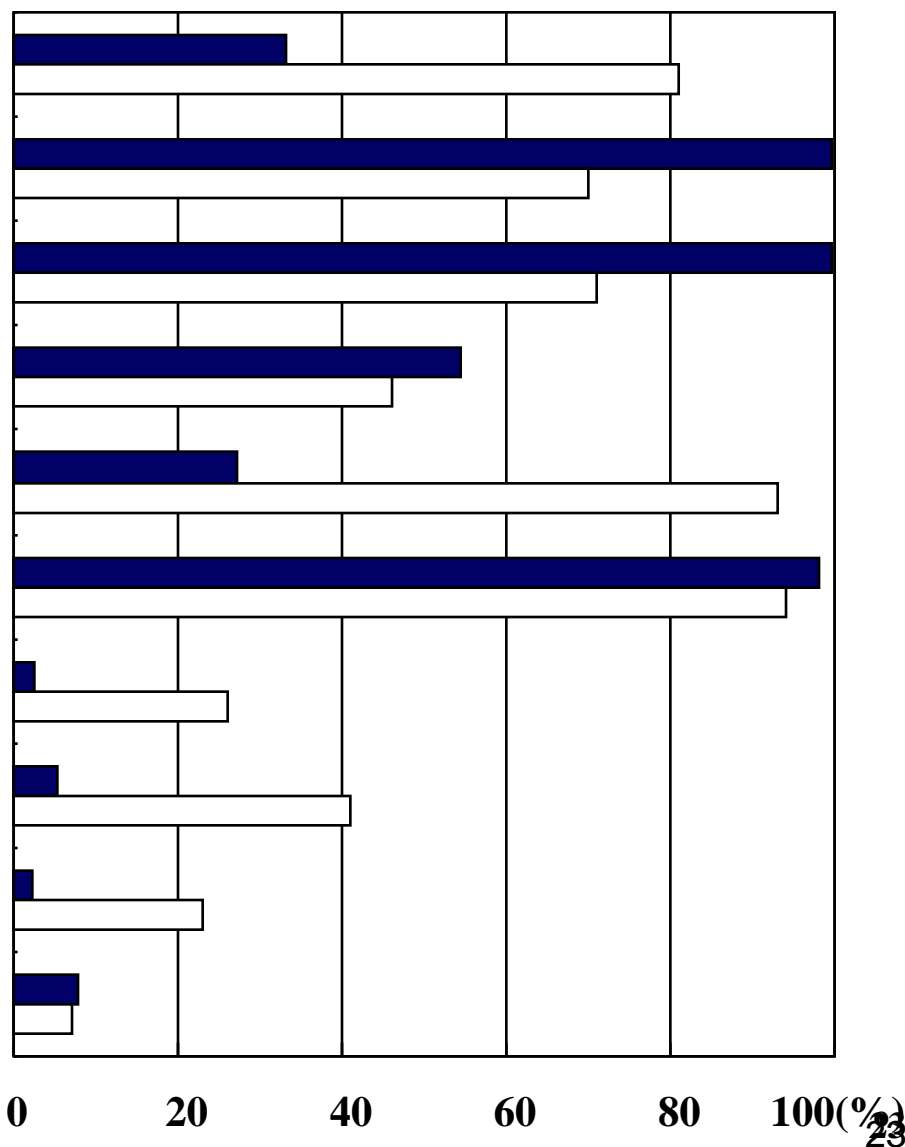
5. METHODS / Objectives

6a. METHODS / Outcomes Primary and secondary outcome

6b. METHODS / Outcomes Enhancement the quality of measurements

7a. METHODS / Sample size How sample size was determined.

7b. METHODS / Sample size Interim analyses and stopping rules



Quality of Reports on Randomized Controlled Trials Conducted in Japan: Evaluation of Adherence to the CONSORT Statement

Kae Uetani¹, Takeo Nakayama¹, Hiroshi Ikai³, Naohiro Yonemoto² and David Moher⁴

Abstract

Objective The Consolidated Standards for Reporting of Trials (CONSORT) statement was developed to improve the quality of randomized controlled trial (RCT) reports. We assessed the quality of current Japanese RCT reports by conducting a cross-sectional study to examine the extent to which they adhere to the CONSORT statement.

Methods Reports of RCTs conducted in Japan that were published in medical journals between January and March 2004 were sampled from MEDLINE. The proportion of adherence to each item in the CONSORT checklist was evaluated for each report. Additionally, information on ethics reporting and funding sources was collected.

Results A total of 98 RCT reports from Japan were evaluated, and adherence to the CONSORT statement was found to be suboptimal. Only 6 of 29 items in the checklist were described in more than 80% of reports. Adherence to key methodological items of the CONSORT statement was as follows: 23% for sample size determination, 39% for random sequence generation, 17% for allocation concealment, 29% for blinding, 53% for numbers analyzed, and 6% for inclusion of a flow diagram. Adherence to additional items was 82% for ethics committee approval, 92% for receiving informed consent, and 20% for disclosing funding sources.

Conclusion Our study on adherence of recent RCT reports from Japan to the CONSORT statement reveals that there is a significant need for improvement. Further investigation on the quality of RCT reports and ways to improve reporting quality is required.

Quality of Kampo RCT Papers (2/3)

■ EKat 2009
 □ Japanese RCT 2004

8a. METHODS/Randomization --Sequence generation
 Method of random allocation sequence

8b. METHODS/Randomization --Sequence generation
 Details of any restriction

9. METHODS/Randomization --Allocation concealment

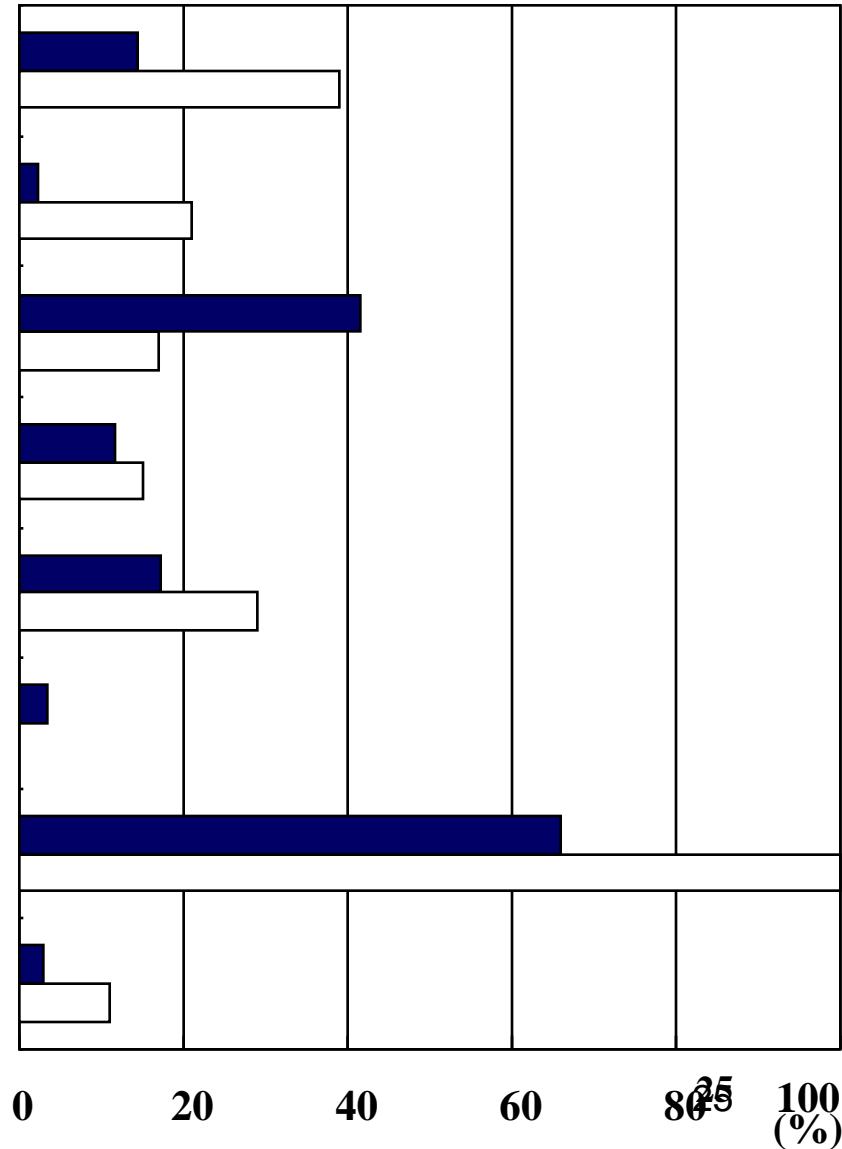
10. METHODS/Randomization --Implementation

11a. METHODS/Blinding (masking)
 Blinded to group assignment

11b. METHODS/Blinding (masking)
 Success of blinding

12a. METHODS/Statistical methods
 For primary outcome

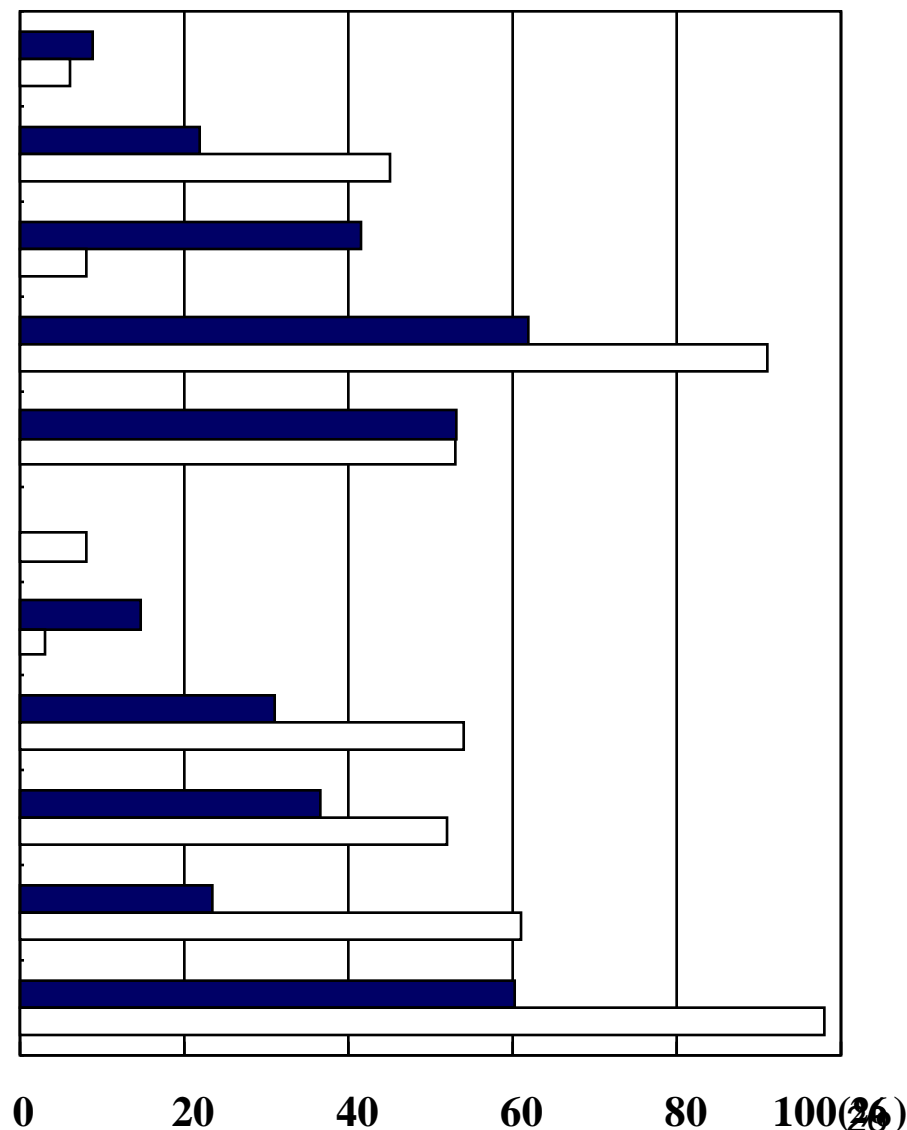
12b. METHODS/Statistical methods
 Additional analyses



Quality of Kampo RCT Papers (3/3)

■ EKAT 2009
□ Japanese RCT 2004

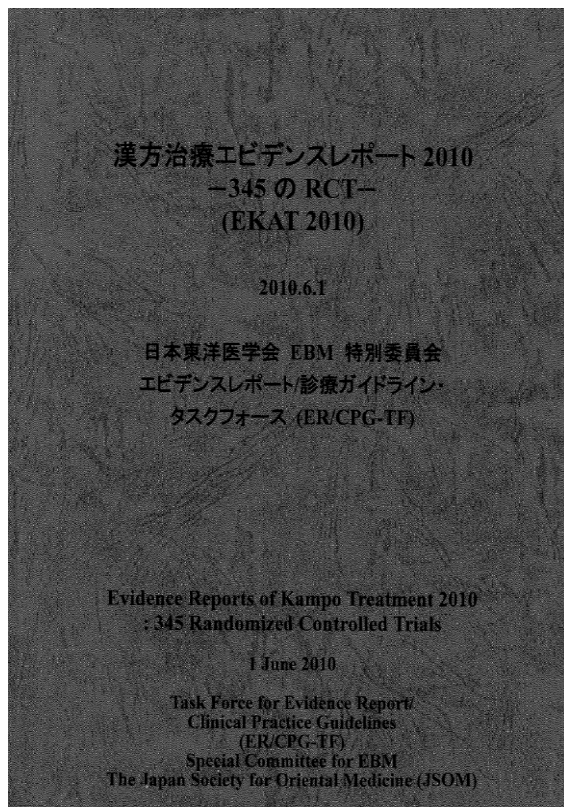
- 13a. RESULTS/Participant flow
Flow diagram
- 13b. RESULTS/Participant flow
protocol deviations
- 14. RESULTS/Recruitment
- 15. RESULTS/Baseline data
- 16. RESULTS/Numbers analyzed
- 17. RESULTS/Outcomes and estimation
- 18. RESULTS/Ancillary analyses
- 19. RESULTS/Adverse events
- 20. DISCUSSION/Interpretation
- 21. DISCUSSION/Generalizability
- 22. DISCUSSION/Overall evidence



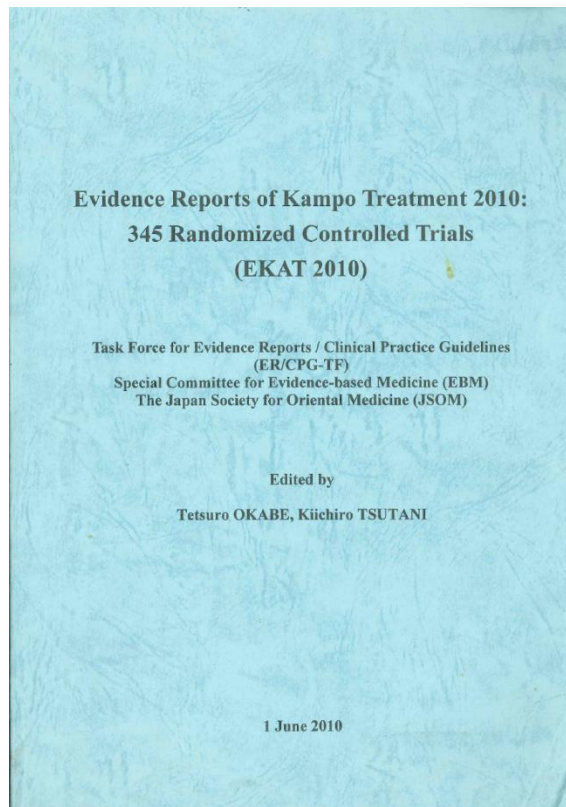
“PNP” methods was used in abstractors comment

- **Developed for simulated patients in medical education**
- **Positive \Rightarrow Negative \Rightarrow Positive**
- **“PNP” workshop to develop abstractor’s comments**
- **The Cochrane Review**
 - **Implication for Practice**
 - **Implication for Research**

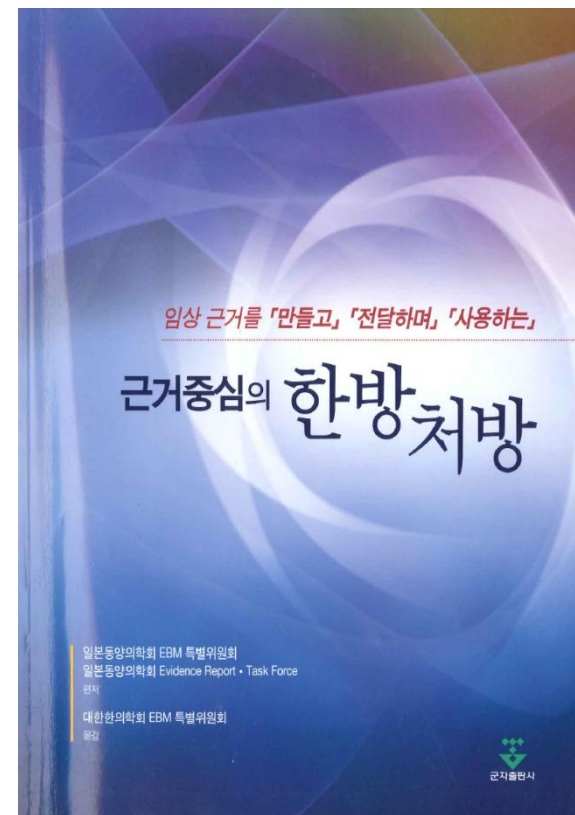
Evidence Report of Kampo Treatment (EKAT)



In Japanese



In English



In Korean

<http://www.jsom.or.jp/medical/ebm/>

EKAT Website

EBM委員会 Committee for EBM, The Japan Society for Oriental Medicine (JSOM)

日本東洋医学会では EBM特別委員会が 2001年に設立され、下記に示すようなプロジェクトを行なっております。いくつかのプロジェクトのアウトカムは以下のとおりです。

☐ 漢方治療エビデンスレポート 2013 -403のRCT
(EKAT 2013)



☐ Evidence Reports of Kampo Treatment 2013 -403 Randomized Controlled Trials
(EKAT 2013)



<http://www.jsom.or.jp/medical/ebm/index.html>



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from The Cochrane Collaboration

SEARCH

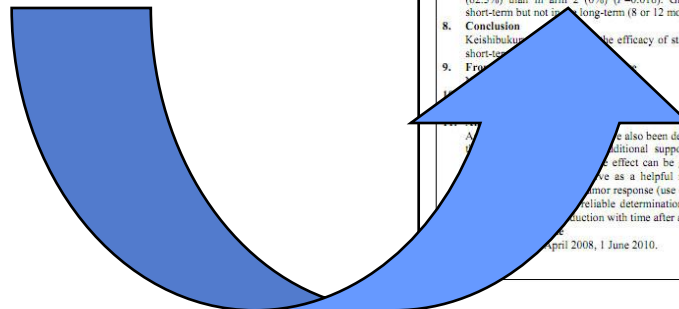
Title, Abstract or Keywords

Advanced Search > MeSH Search >

Search History > Saved Searches >

The Cochrane Central Register of Controlled Trials (CENTRAL) 2011 Issue 4
Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

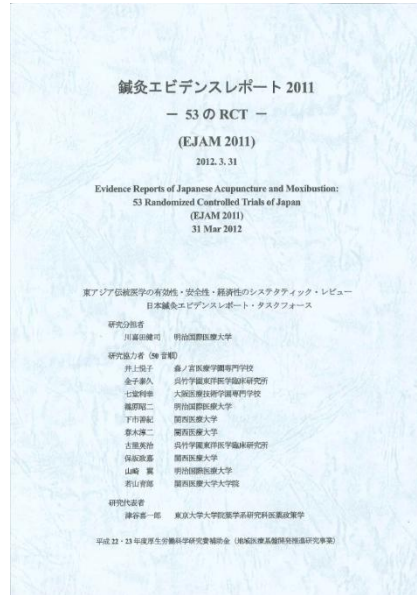
Title	[Efficacy of keishibukuryogan for hysteromyoma/uterine adenomyosis] Links Export Central Citation
Author(s)	Yamamoto K., Hirano F., Ikoma N.
Source	Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)
Date of Publication	2003
Volume	20
Pages	135-7
Review Group keywords	Kampo
Study Design	RCT
Cochrane Group Code	HS-EKAT; SR-COMPMD; HS-HANDSRCH
Language	jpn
Full Text URL	http://www.jsom.or.jp/medical/ebm/ere/pdf/030002e.pdf
ID	CN-00793495



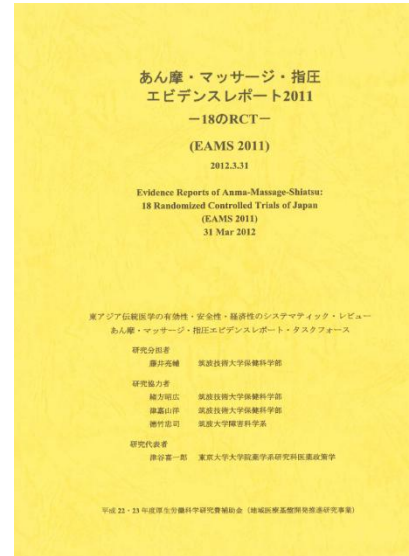
Evidence Reports of Kampo Treatment 2010	
Task Force for Evidence Reports / Clinical Practice Guideline Special Committee for EBM, the Japan Society for Oriental Medicine	
Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)	
Reference	Yamamoto K, Hirano F, Ikoma N, et al. Efficacy of keishibukuryogan for hysteromyoma/uterine adenomyosis. <i>Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)</i> 2003; 20: 135-7 (in Japanese). Ichushi Web ID: 2004068783
1. Objectives	To evaluate the anti-tumor effect of keishibukuryogan (桂枝茯苓丸) in patients with hysteromyoma/uterine adenomyosis.
2. Design	Randomized controlled trial (RCT).
3. Setting	Single hospital (Department of Obstetrics and Gynecology, Sakai Hospital, Kinki University School of Medicine).
4. Participants	The 24 patients seen at the above institution and diagnosed with hysteromyoma or uterine adenomyosis were randomized into two arms: 1) the gonadotropin-releasing hormone (GnRH) analogue + keishibukuryogan arm (mean age, 45.9 years; mean tumor diameter, 35.7 mm) and 2) the GnRH analogue arm (mean age, 46.3 years; mean tumor diameter, 34.1 mm).
5. Intervention	Arm 1: subcutaneous injection of a GnRH analogue (1.88 mg) once monthly for 4 consecutive months + oral administration of a sachet of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (2.5 g) i.i.d. (before meals) for 12 months (n=14). Arm 2: subcutaneous injection of a GnRH analogue (1.88 mg) once monthly for 4 consecutive months (n=10).
6. Main outcome measures	Tumor response was evaluated on a 3-point scale: tumor diameter reduction: remarkably effective, ≥50%; effective, >0 - 50%; not effective, 0%. Evaluation was performed at baseline, 4, 8, and 12 months after intervention.
7. Main results	Four months after treatment, complete response was achieved in 42.9% (6/14) of arm 1 and 10% (1/10) of arm 2, showing that GnRH + keishibukuryogan tended to have a higher anti-tumor effect although there were no between-group differences in tumor size reduction 8 or 12 months after treatment. Analysis limited to hysteromyoma revealed that 4-month treatment produced complete response in a significantly higher percentage of arm 1 (50%) than arm 2 (0%) ($P=0.012$). When the analysis was limited to the GnRH analogue leuprorelin, 4-month treatment produced a significantly higher complete response rate in arm 1 (62.5%) than in arm 2 (0%) ($P=0.016$). GnRH + keishibukuryogan exerted clinical efficacy in the short-term but not in the long-term (8 or 12 months after treatment).
8. Conclusion	Keishibukuryogan may improve the efficacy of standard GnRH therapy for tumor size reduction in 4-month, short-term treatment.
9. From	Journal of Evidence-Based Medicine, April 2008, 1 June 2010.

Scope was expanded in 2010 using health ministry fund

Acupuncture

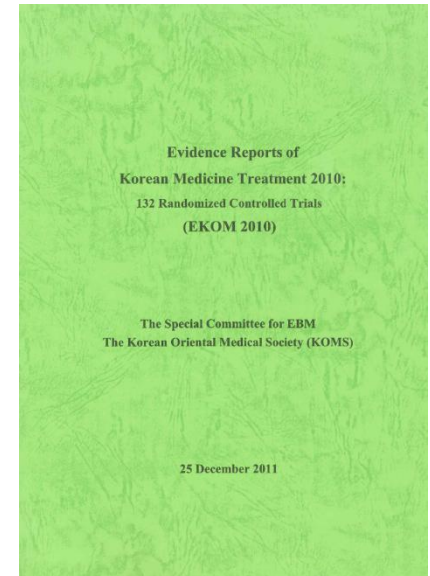
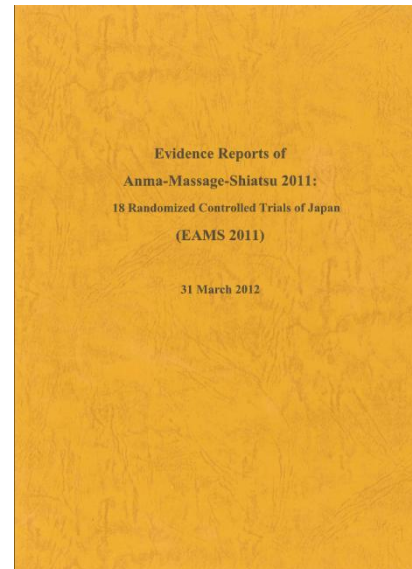
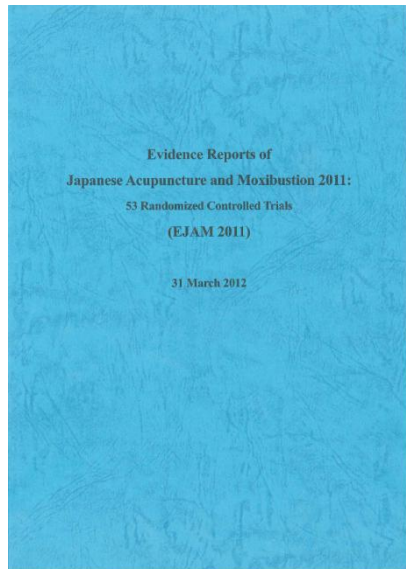


Anma-Massage-Shiatsu



In Japanese

Korean Medicine



In English

Information site for evidence-based Japanese Integrative Medicine (eJIM)

28 Mar 2014 Outcome of FY 2013

(to public)

(To health professionals)

厚生労働省「統合医療」に係る情報発信等推進事業

「統合医療」情報発信サイト

Information site for evidence-based Japanese Integrative Medicine (eJIM)

ご利用にあたって (文献調査委員会と利益相反関連事項) 意見・感想

グルコサミン



一般の方へ

医療関係者の方へ

「統合医療」とは?

情報の見極め方

冊子・資料

国内のサイト

海外のサイト

「統合医療」情報発信サイト (eJIM:「イージム」と読みます) は、民間療法をはじめとする相補(補完)・代替療法*と、どのように向き合い、利用したらよいのかどうかを考えるために、エビデンス(科学的根拠)に基づいた情報を紹介しています。決して個人の責任で実施するさまざまな療法を制限するものではなく、また特定の療法を勧めるものでもありません。*相補(補完)・代替療法：近代西洋医学と組み合わせられる各種療法



詳しくはこちら

このサイトの使い方

「統合医療」情報発信サイトは、患者さんやご家族の方をはじめ、一般の方や医療専門家に対して、統合医療について信頼できる、正しい情報をわかりやすく紹介しているウェブサイトです。下記の点にご留意頂いたうえで、「統合医療」情報発信サイトを、ぜひご活用ください。

コンテンツについて

▶ **「統合医療」とは?**
「統合医療の定義」について解説しています。

▶ **情報の見極め方**

Part 2: health food

健康食品 (Japan)

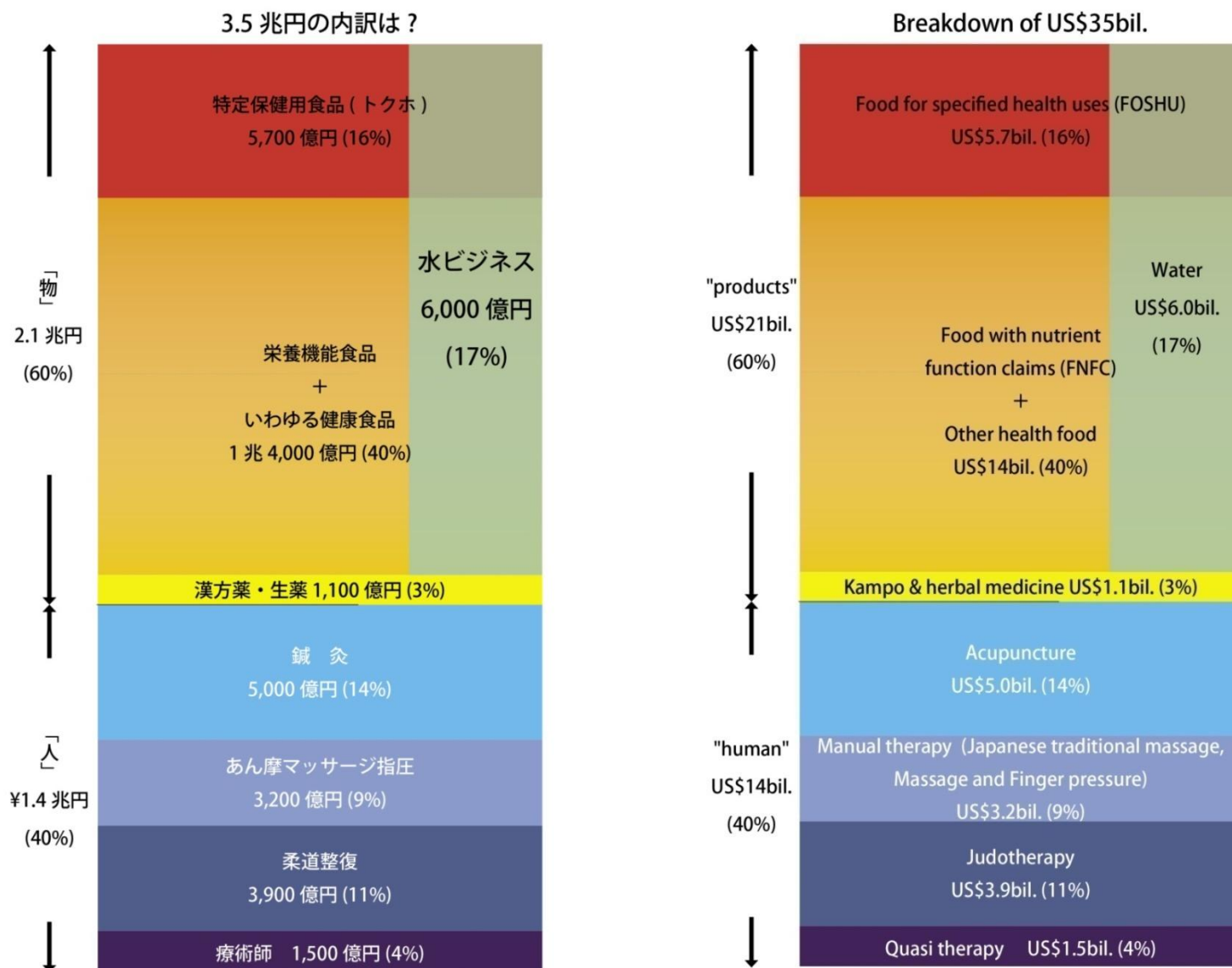
保健食品 (China)

健康機能食品 (Korea)

Dietary supplement (US)

Food supplement (EU)

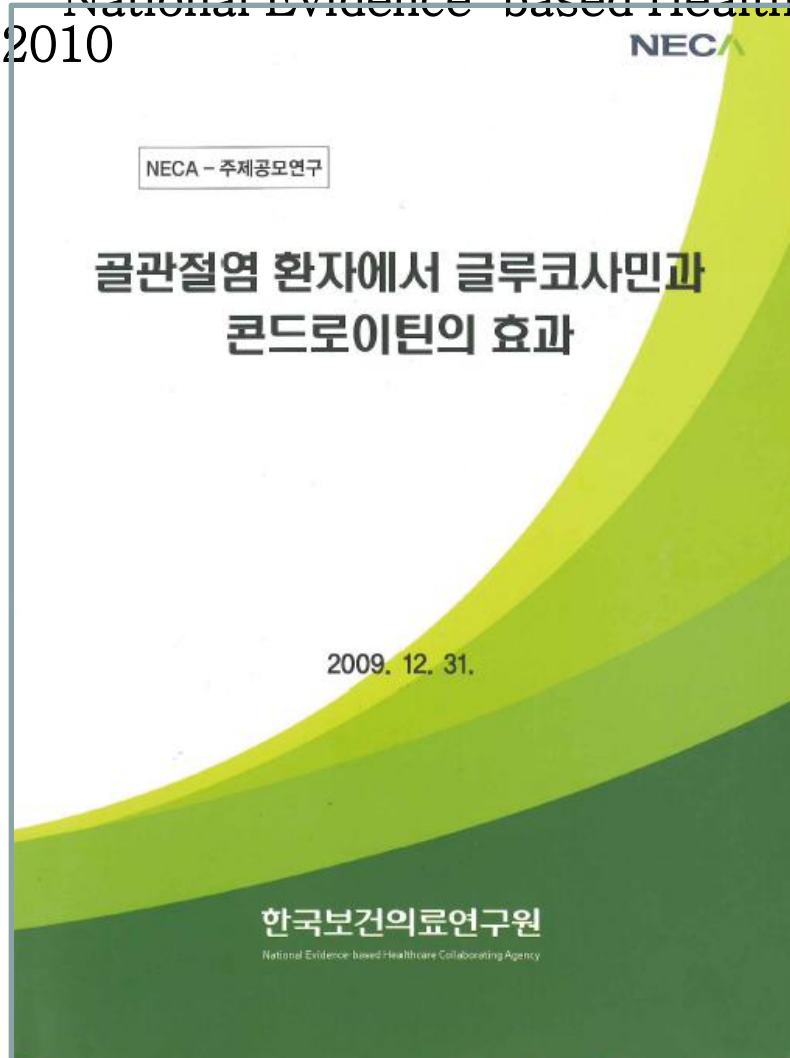
Japanese spent US\$ 35 bil for TCAM (2002)



• <http://www.f.u-tokyo.ac.jp/~pecout/cij/JSCPTCAM.pdf>

Health Technology Assessment Report of Glucosamine

National Evidence-based Healthcare Collaborating Agency (NECA), Seoul, 2010



By systematic review, that there was lack of data to reach conclusions that glucosamine is effective for treatment and prevention of osteoarthritis.

Bae SC. Glucosamine and chondroitin products: Are they being used appropriately?: NECA News 35 letter EVIDENCE & VALUE 29. Sep. 2010; 20-1

http://neca.re.kr/ebook/vol4/eng/vol4_eng_all/EBook.htm

Glucosamine: same evidence, different policies

		Drug		Food
		ethical	OTC	
Reimburse <u>-ment</u>	No		Japan Germany Scotland Sweden Ireland	U.S.A. (food supplement) Canada (nutritional product) Austria (complementary medicine) Malaysia (health supplement) Singapore (health supplement) Korea
	Yes	Korea Taiwan Thailand		

Same brand name “Flexpower” in both as OTC drug and “so-called” health food



OTC drug
(No information of glucosamine in the label. It is used as additive)

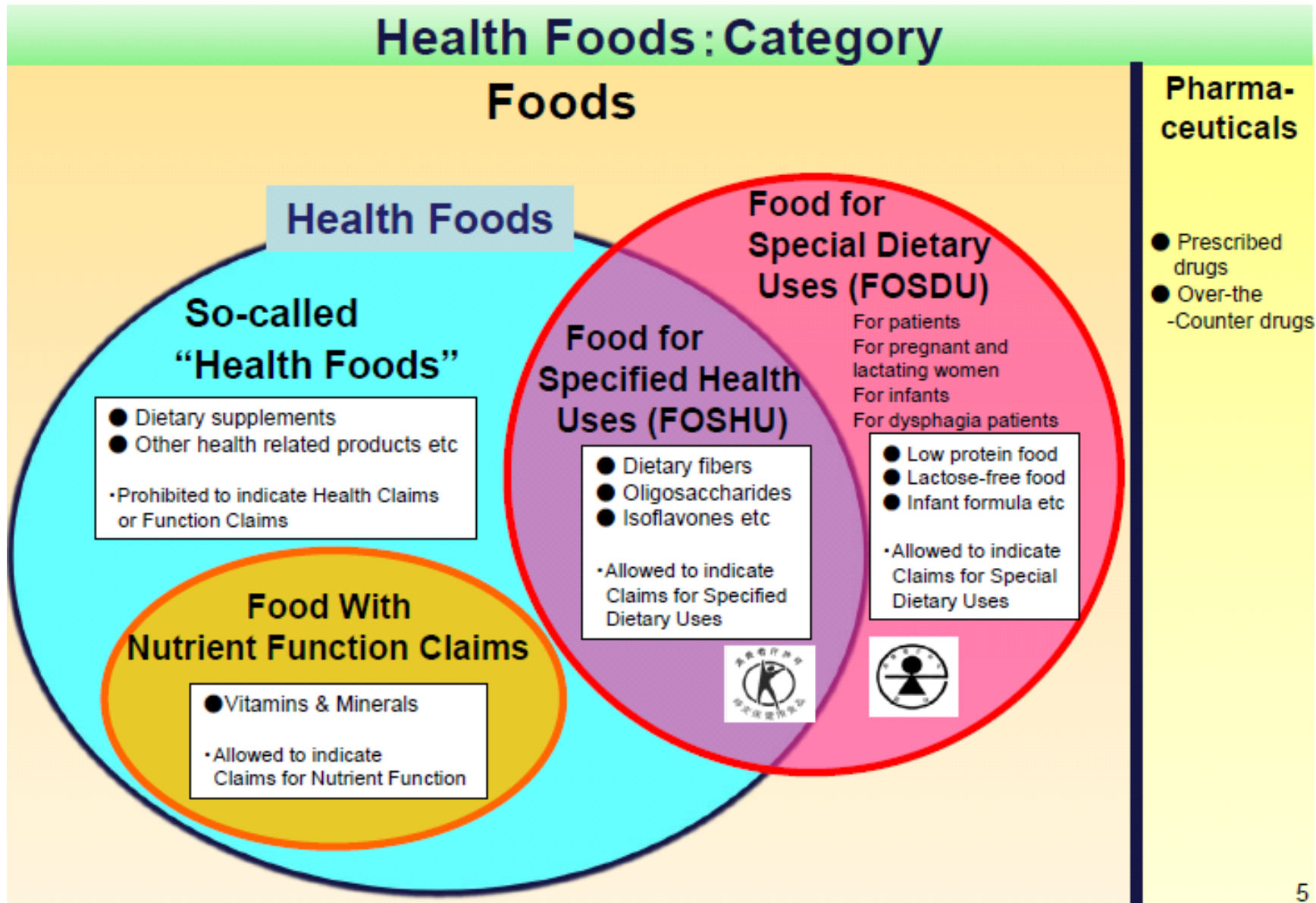


健康補助食品
 (“health supplementary food”)
A kind of “so-called” health food

•Glucosamine: same evidence, different policies

		Drug		Food
		ethical	OTC	
Reimbursement	No	Italia England	Germany Scotland Sweden Ireland <u>Korea</u>	Japan (health food) U.S.A. (dietary supplement) Canada (nutritional product) Austria (complementary medicine) Malaysia (health supplement) Singapore (health supplement) Korea (health supplement)
	Yes	Korea Taiwan Thailand	<u>Korea</u>	

•Confusing category of health food in Japan - “gray area”



特別用途食品および栄養療法のエビデンス等
に関する情報の収集整理業務

平成 20 年度報告書
(特別用途食品エビデンスレポート 2008)

財団法人 医療経済研究・社会保険福祉協会
「特別用途食品および栄養療法」調査班

2009 (平成 21)年 3 月

MHLW funded project
“Evidence of Food for
Special Dietary Uses”
(FOSDU)
Report in Mar 2009

First systematic review
used in “health food” in
Japan

Low protein food
Allergen removed food
Non lactose food
Thick liquid food
Modified food for infant
Food for dysphagia

Germinated Barley Foodstuff (GBF)
Low protein milk (L.P.K)
Fine Rice
OS 1

1-E5-4 低たんぱく質食品／慢性腎不全 (CN-00089432)

文献

Wingen AM, Fabian-Bach C, Mehls O. Multicentre randomized study on the effect of a low-protein diet on the progression of renal failure in childhood: one-year results. *Miner Electrolyte Metab.* 1992; 18: 303-8, CN-00089432, PMID: 1465080

1. 目的

1) 慢性腎不全を有する小児における任意のたんぱく質とカロリー摂取、2) たんぱく質制限食の腎不全進行率に対する影響、3) たんぱく質制限食の成長と発達に対する影響、4) 長期間の低たんぱく質食の実行可能性と許容性の評価

2. 研究デザイン

ランダム化比較試験 (RCT)

3. セッティング

European Study Group for Nutritional Treatment of Chronic Renal Failure in Childhood

4. 参加者

年齢 2 - 18 歳、クレアチニンクリアランス 15 - 60 mL/分/1.73m²、保存的治療によって良く管理されている小児腎疾患患者 284 名 (登録 284 名, ランダム化 226 名)。割付後 1 年終了 165 名 (男性の割合 68%, 年齢 10.3 ± 4.3 歳, 割付前の 6 ヶ月間の観察期間において糸球体濾過量 (GFR) の低下が 1.5 mL 未満の非進行患者 86 名, GFR の低下が 1.5 mL 以上の進行性患者 79 名)

5. 介入

Arm 1: 低たんぱく質食 (該当年齢の WHO safe level : たんぱく質 0.8-1.1 g/kg 理想体重 /日) 群 81 名 (非進行患者 40 名, 進行患者 41 名)

Arm 2: たんぱく質非制限群 84 名 (非進行患者 46 名, 進行患者 38 名)

6. 主なアウトカム評価項目

糸球体濾過量 (GFR)、身長標準偏差スコア (SDS)、体重

7. 主な結果

- ・ 低たんぱく質食群のたんぱく質摂取量は WHO safe level の 126% で、たんぱく質非制限群が 187% より有意に低かった。カロリー摂取量は低たんぱく質食群 (WHO 推奨の 85%) とたんぱく質非制限群 (WHO 推奨の 90%) で同様であった。
- ・ 身長 SDS と体重にたんぱく質摂取制限は影響しなかった。
- ・ 非進行患者では、GFR は低たんぱく質食群 $40.5 \pm 15.3 \text{ mL/分/1.73 m}^2$ 、たんぱく質非制限群 $40.6 \pm 16.1 \text{ mL/分/1.73 m}^2$ 、1 年当たりの GFR の変化は低たんぱく質食群 -1.3 ± 6.0 、たんぱく質非制限群 -1.1 ± 4.3 で差はなかった。
- ・ 進行患者では、GFR は低たんぱく質食群 $22.7 \pm 13.7 \text{ mL/分/1.73 m}^2$ 、たんぱく質非制限群 $28.4 \pm 15.6 \text{ mL/分/1.73 m}^2$ で有意な差はなかった。1 年当たりの GFR の変化は低たんぱく質食群 -6.5 ± 5.6 で、たんぱく質非制限群 -4.0 ± 5.7 と比較して有意であった。(P=0.03)。

8. 結論

1 年間の結果では、たんぱく質の摂取制限は明らかな利点も不利もなかった。3~4 年継続した試験による評価が必要である。

•CONTENTS

[特別用途食品エビデンスレポート2008](#) 

[同 別冊1: 低たんぱく質食品](#)

[- 検索・スクリーニングプロセスと43構造化抄録 -](#) 

[同 別冊2: アレルゲン除去食品](#)

[- 検索・スクリーニングプロセスと25構造化抄録 -](#) 

[同 別冊3: 無乳糖食品](#)

[- 検索・スクリーニングプロセスと21構造化抄録 -](#) 

[同 別冊4: 総合栄養食品\(いわゆる濃厚流動食\)](#)

[- 検索・スクリーニングプロセスと15構造化抄録 -](#) 

[同 別冊5: 個別評価型病者用食品](#)

[- 検索・スクリーニングプロセスと32構造化抄録 -](#) 

[同 別冊6: 乳児用調製粉乳](#)

[- 検索・スクリーニングプロセスと49構造化抄録 -](#) 

[同 別冊7: えん下困難者用食品](#)

[- 検索・スクリーニングプロセスと18構造化抄録 -](#) 

•http://www.shafuku.jp/healthfood/other_activity_page.html

https://www.google.co.jp/

ファイル(F) 編集(E) 表示(V) お気に入り(A) ツール(T) ヘルプ(H)

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グルコサミン

tsutanik@gmail

ウェブ 画像 ショッピング 動画 ニュース もっと見る 検索ツール

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[広告](#) [www.suntory-kenko.com/](#)

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[広告](#) [www.taisho-direct.jp/](#)

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10周年記念。先着限定で初回半額以下！ ギンギン悩みに。たっぶり潤う力を。

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[サントリー グルコサミン 無料](#) [グルコサミン 比較](#) [グルコサミン 口コミ](#)

[グルコサミン - Wikipedia](#)

[ja.wikipedia.org/wiki/グルコサミン](#)

グルコサミン(Glucosamine, 化学式C₆H₁₃NO₅)は、グルコースの一部の水酸基がアミノ基に置換されたアミノ糖の一つである。動物においては、アミノ基がアセチル化されたN-アセチルグルコサミンの形で、糖タンパク質、ヒアルロン酸などグリコサミングリカン(…

[グルコサミン & コンドロイチン - サントリーウエルネスオンライン](#)

[www.suntory-kenko.com](#) > [健康食品](#) > [サプリメント](#)

グルコサミン & コンドロイチンならサントリーウエルネスのサプリメント通販。自然界のカニやエビなどを主要成分とした「グルコサミン」と「コンドロイチン」の2つの成分にケルセチン、配糖体を独自配合

グルコサミン

グルコサミンは、グルコースの一部の水酸基がアミノ基に置換されたアミノ糖の一つである。動物においては、アミノ基がアセチル化されたN-アセチルグルコサミンの形で、糖タンパク質、ヒアルロン酸などグリコサミングリカンの成分となっている。[ウィキペディア](#)

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http://www.ejim.ncgg.go.jp/

厚生労働省「統合医療」に係る情報発信等推進事業

「統合医療」情報発信サイト

Information site for evidence-based Japanese Integrative Medicine (eJIM)

ご利用にあたって (文献調査委員会と利益相反関連事項)

ご意見・ご感想



一般の方へ

医療関係者の方へ

「統合医療」とは?

情報の見極め方

冊子・資料

国内のサイト

海外のサイト

「統合医療」情報発信サイト (eJIM:「イージム」と読みます) は、

民間療法をはじめとする **相補(補完)・代替療法***と、どのように向き合い、利用したらよいのかどうかを考えるために、**エビデンス(科学的根拠)**に基づいた情報を紹介しています。決して個人の責任で実施するさまざまな療法を制限するものではなく、また特定の療法を勧めるものでもありません。*相補(補完)・代替療法：近代西洋医学と組み合わせられる各種療法



▶ 詳しくはこちら

○ このサイトの使い方

「統合医療」情報発信サイトは、患者さんやご家族の方をはじめ、一般の方や医療専門家に対して、統合医療について信頼できる、正しい情報をわかりやすく紹介しているウェブサイトです。下記の点にご留意頂いたうえで、「統合医療」情報発信サイトを、ぜひご利用ください。

● 本サイトの掲載内容

「統合医療」は、近代西洋医学と相補(補完)・代替療法や伝統医学等とを組み合わせる療法であり、多種多様なものが存在します。このサイトでは、各種相補(補完)・代替療法や伝統医学に関して、現時点でわかっている科学的な情報を分かりやすく紹介しています。

○ コンテンツについて

▶ 「統合医療」とは?

「統合医療の定義」について解説しています。

▶ 情報の見極め方

インターネットやマスメディアの健康・医療情報の見極め方の極意を紹介しています。

▶ 冊子・資料

行政機関が発行しているパンフレットを紹介しています。

グルコサミン

hfnet.nih.go.jp/contents/detail24.html

グルコサミンは糖の一種で、グルコースにアミノ基 (-NH₂) が付いた代表的なアミノ糖であり、動物の皮膚や軟骨、甲骨類の殻に含まれている。工業的にはカニやエビなどの 甲殻から得られるキチンを塩酸などで分解して製造される。俗に「関節の動きをなめらか ...

グルコサミン

https://hfnet.nih.go.jp/contents/indiv_agreement.html?24



健康食品の素材情報を正しく理解して頂くために、特に消費者の方は、必ず下記事項を 了解した上で、当ページ下の同意ボタンを押し、次の画面へ。[データの無断転用、引用、商用目的の利用は厳禁]。健やかで心豊かな生活を送るためにこのバランスのとれた食 ...

グルコサミン [英]Glucosamine [学名]

hfnet.nih.go.jp/contents/detail24lite.html

グルコサミンは糖の一種で、グルコースにアミノ基 (-NH₂) が付いた代表的なアミノ糖であり、動物の皮膚や軟骨、甲骨類の殻に含まれている。工業的にはカニやエビなどの 甲殻から得られるキチンを塩酸などで分解して製造される。俗に「関節の動きをなめらか ...

N-アセチルグルコサミン

hfnet.nih.go.jp/contents/detail589.html

N-アセチルグルコサミンは、糖の一種であるグルコサミンからグルコサミン6-リン酸を経て合成されるアミノ糖である。動物体内では複合糖質の構成成分である。俗に、「美肌 効果がある」「関節によりなど」といわれているが、ヒトでの有効性については信頼できる ...

服用患者におけるグルコサミン併用の安全性に関して声明を公表 (111214)

hfnet.nih.go.jp/contents/detail1844.html

2011年12月8日、欧州食品安全機関 (EFSA) は、クマリン抗凝固剤 (特にワルファリン) を処方されている患者におけるグルコサミン併用の安全性に関して以下の声明を公表 (1)。EFSA は、クマリン抗凝固剤の服用患者におけるグルコサミンの安全性に関する ...

Filtering is important

グルコサミン

by google.co.jp

1,240,000

by ejim.ncgg.go.jp

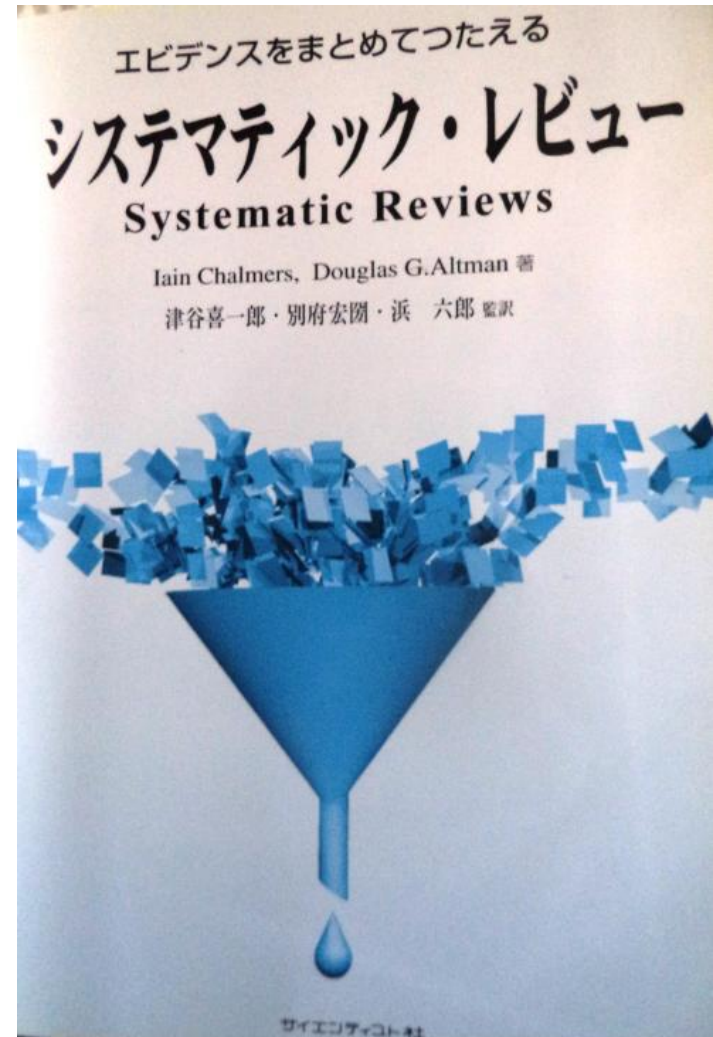
99

Glucosamine

by google.com

10,700,000

(as of 16 Aug 2014)



1st ed. 1995

Thank you

Arigato