

TMD and Evidence - based medicine

Asbjørn
Jokstad

Is Temporomandibular
dysfunction - TMD - a
“new” affliction?

TMD – is not a “new” affliction

1840, Evens, articulator

1896, Walker, complex articulator--->gnathology

1899, Snow, face bow

1952, Shore, equilibration

1877, Kingsley, splint

1881, Goodwillie, pivot appliance

1960, Gelb, MORA splint

1887, Annandale, surgical repositioning

1909, Lantz, removal of discus

1918, Prentiss, “pressure atrophy”

1934, Costen, “overclosure” --> vertical dimension

1959, Schwartz, emotional tension

Since there is a long tradition for treating TMD....

it seems logical that there should be a large body of

empirical clinical experience

to solve several issues related to the diagnosis and management of TMD patients...

TMD - what is the consensus?

- How common and how big is the problem?
- What is the etiology of TMD?
- What is the reliability of different diagnostic tests?
- What is the natural history of TMD?
- Should/can TMD be prevented?
- Which specific TMD treatment is superior and can be supported?
 - What is the validity of different treatment outcomes?
 - Do different splints have the same success rates and why?
-

Who should treat these
patients – i.e. what is
the evidence base for
effective treatments

Physiotherapy?

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[Physiotherapy in Chelsea - Physiotherapy - Jaw joint pain \(TMJ\)](#)

TemporoMandibular Joint (TMJ) problems are treated following a careful treatment of all possible elements affecting this problem. ...

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[TMJ and CRANIOFACIAL PAIN](#)

This relatively common disorder is termed TMJ dysfunction. ... **Physiotherapy** modalities are often required to return the muscles to normal comfort and ...

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[Temporomandibular \(TMJ\) Disorders](#)

The temporomandibular joint (TMJ) is also known as your jaw bone socket. ... Physical Therapy: A variety of **physiotherapy** techniques such as jaw exercises, ...

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[Bridgeland Physiotherapy - Services - TMJ](#)

TMJ dysfunction can occur by itself or be apart of a more complex problem. There is usually more than one factor involved. Some factors can include: ...

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[BestBETs: Physiotherapy Treatment for myogenic TMJ pain...](#)

A 23 year old female has been referred to **physiotherapy** with a 6 month history of temporomandibular joint (TMJ) pain without disk displacement. ...

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[Temporo Mondibular Joint Syndrome](#)

TMJ Syndrome must be diagnosed by a dentist or physician. A **Physiotherapist** can detect



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[The International Journal of Applied Kinesiology and Kinesiologic ...](#)

Dental kinesiology offers a study of the motions, structures, and functions of the jaw, ... Key words: **dental kinesiology**, kinesiologic occlusal position, ...
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Applied kinesiology is sometimes referred to as contact reflex analysis, **dental kinesiology**, behavioral kinesiology or muscle testing. ...
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Dental Kinesiology - AK: Dr George Eversaul PhD LAS VEGAS NEVADA USA Ph: Fax: e-mail: Course details will be here when supplied.....
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[Defining standards in clinical Posturology](#)

Is it possible to make standards in clinical **Posturology**?

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[Introduction to clinical posturology](#)

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[\[Posturology. Methodological problems and scientific evidence\]](#)

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[Manual of Posturology](#)

Les Cahiers de l'Etape. Français. Manual of **Posturology**. "Man spends a lifetime fighting his tyrant, gravity" Victor HUGO ...

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[A critique of posturology: towards an alternative neuroanatomy?](#)

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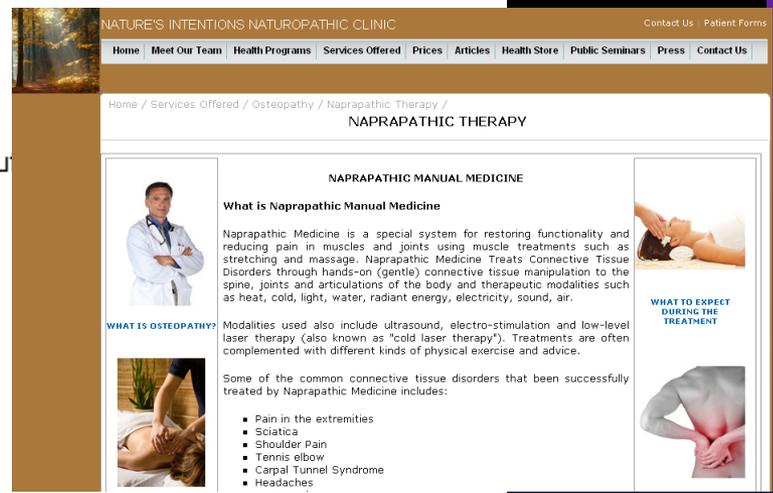
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NAPRAPATHIC MANUAL MEDICINE

What is Naprapathic Manual Medicine

Naprapathic Medicine is a special system for restoring functionality and reducing pain in muscles and joints using muscle treatments such as stretching and massage. Naprapathic Medicine Treats Connective Tissue Disorders through hands-on (gentle) connective tissue manipulation to the spine, joints and articulations of the body and therapeutic modalities such as heat, cold, light, water, radiant energy, electricity, sound, air.

WHAT IS OSTEOPATHY? Modalities used also include ultrasound, electro-stimulation and low-level laser therapy (also known as "cold laser therapy"). Treatments are often complemented with different kinds of physical exercise and advice.

Some of the common connective tissue disorders that been successfully treated by Naprapathic Medicine includes:

- Pain in the extremities
- Sciatica
- Shoulder Pain
- Tennis elbow
- Carpal Tunnel Syndrome
- Headaches



Craniosacral therapy?

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by John E Upledger - 2001 - 124 pages
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[Craniosacral therapy](#) - Wikipedia, the free encyclopedia
Craniosacral therapy (also called CST, cranial osteopathy, also spelled **CranioSacral** bodywork or **therapy**) is a method of Complementary and alternative ...
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October 25-28th, 2007 Nashville National Symposium Overview

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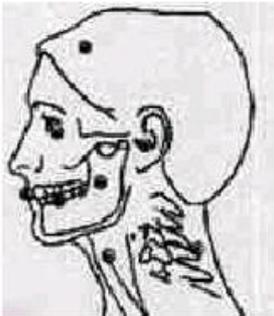
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This adjustable, TMJ friendly splint is made with Vitallium framework and composite material bonded to the occlusal surfaces, which is kind to opposing teeth



 **Dentures/Partials**

ANODYNE BITE RESTORER

THE LONG TERM PAIN-RELIEVING SPLINT FOR TMD SUFFERERS

Johns Dental Laboratories has long been aware of TMJ syndrome and the related discomfort it causes. The dysfunction of the temporomandibular joint results in stress on muscles, often causing head, neck, shoulder and back pain.

With proper treatment, relief for TMJ pain does exist. The initial use of a bite opening acrylic splint from Johns Dental Laboratories (such as Gelb, Farrar, Mays, Sears, Witzig and others) is recommended to guide the jaws into alignment whenever the wearer occludes. In most cases pain begins to disappear in a remarkably short time. Much of the discomfort vanishes soon after the splint is inserted.

Can adjustments be made?

As changes take place in the joint during treatment, adjustments in the occlusal contacts can be made by grinding and/or adding additional acrylic. Once the new occlusion is firmly established with the acrylic splint, treatment may proceed with a more permanent type of restoration.

Can Bite Restorers work for older patients?

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Dentists?

PowerBite Mouthguard - Netscape

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PowerBite Mouthguard

PROVIDING MAXIMUM PROTECTION WITH INCREASED ATHLETIC STRENGTH

"An athletes strength will increase between 5-20% with the use of a PowerBite Mouthguard...using weightlifting as a measurement."

John Witzig, D.D.S. - noted Authority on all Mouthguards & TMJ treatment -Minneapolis, MN

All mouthguards protect to a certain degree, but there should be more to it than just protecting the teeth. What about protection against concussions, TMJ and neck injuries? How about improving comfort and fit? Can it make breathing easier? Can it increase a players strength and endurance?

These are all added benefits that a PowerBite mouthguard from Johns Dental Laboratories can provide your patients.

Protect teeth, TMJ, Neck and reduces concussions.

The primary reason to get



The women's freshman basketball squad at St. Mary of the woods in Indiana took a break from practice to show off their custom PowerBite Mouthguards in matching team colors. Partnering up with local high schools and colleges is a great way to gain exposure in your community and can lead to many referrals.

The PowerBite increases strength and endurance.

In addition to the protection the PowerBite Mouthguard provides, it can also increase strength and endurance and can show a noticeable difference in athletic



A local dentist and certified dental assistant were able to take impressions for the entire women's basketball team in under an hour.



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Jaw posture may affect muscular strength in sports?!!

Journal of Oral Rehabilitation 2001 **28**; 732–739

The influence of different jaw positions on the endurance and electromyographic pattern of the biceps brachii muscle in young adults with different occlusal characteristics

VIRGILIO F. FERRARIO*[†], CHIARELLA SFORZA*[†], GRAZIANO SERRAO*,
NICOLA FRAGNITO[†] & GIANPIERO GRASSI[†] *Functional Anatomy Research Center (Farc), *Laboratorio di Anatomia Funzionale dell'Apparato Stomatognatico (LAFAS) and [†]Laboratorio di Anatomia Funzionale dell'Apparato Locomotore (LAFAL), Dipartimento di Anatomia Umana, Facoltà di Medicina e Chirurgia and Facoltà di Scienze Motorie, Università degli Studi, via Mangiagalli, Milano, Italy*

SUMMARY To investigate the hypothesis of a functional coupling between the stomatognathic motor apparatus and the muscles of other body districts, as well as between occlusal conditions and neuromuscular performance, two groups of men (age range 20–26 years), with either normal occlusion (14 men) or malocclusion (15 men), sustained with their dominant arm a dumbbell weighing 80% of their maximum while maintaining different jaw positions: mouth open, without dental contact; mouth close, with light dental contact; maximum volun-

frequency were also computed for 2-s windows, and values as a function of time were interpolated by a linear regression analysis. Data were compared between groups and trials by using a factorial analysis of variance. The malocclusion group subjects could perform the exercise for a longer time span than the normal occlusion individuals ($P < 0.005$). During this endurance time their biceps brachii muscles contracted with different patterns: on average, in the malocclusion group they had a larger EMG amplitude ($P < 0.005$), and a shift of the power

Dentists?!

<http://www.doctorlarrymoore.com/tmj.htm#treatmentstmj>

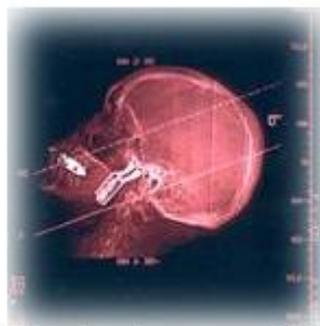
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What kind of treatment is available for TMJ problems?

Problems with the Temporomandibular Joint can be treated in a variety of ways, from an orthotic appliance (like a retainer) that fits in the mouth at night to prevent bruxism and clenching, to arthroscopy (exploration of the joint with a tiny camera), to full joint replacement.

The treatment that is right for you depends on the type of TMJ problem and its severity. Only by an in-depth consultation can your Oral Surgeon determine the nature of your problem. He or she will discuss your symptoms in detail with you, and may order X-rays, MRI's, or CT Scans to pinpoint the cause of pain or limited range of motion.

Because the symptoms of TMJ disorders can be similar to the symptoms of other medical problems, it's important if you are experiencing any of these symptoms to see your Doctor or Oral and Maxillofacial Surgeon for an evaluation.



Total Joint Replacement, Side View



Total Joint Replacement, Frontal View

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Surgery

TMJ surgery involves separating the two parts of the jaw joint. Plastic **surgery** techniques are used to prevent disfigurement and scarring from the incision. ...

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Dr. Mark A. Piper, Surgical Treatment of Facial, Bite and TMJ ...

Dr. Mark A. Piper is a graduate of Harvard College, Harvard School of Dental Medicine and Vanderbilt Medical School. He completed residency training in ...

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Bergen Oral & Maxillofacial Surgery -- Procedures: TMJ

The **TMJ** or temporomandibular joint is the small joint located directly in front of the ear. This joint allows for movement of the lower jaw during opening ...

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TMJ Disease Treatment - Mayo Clinic

Arthroplasty refers to all types of open **surgery** for **TMJ**, including disk repositioning, ... Although **TMJ surgery** is highly successful in reducing pain and ...

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Connecticut Maxillofacial Surgeons llc. - OMFS Advisor Topic ...

About **TMJ Surgery**. Although the term **surgery** is frightening to us all, ... **Surgery** of the **TMJ** is almost always performed in a formal operating room as an ...

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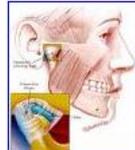
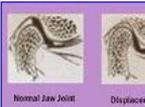
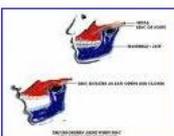
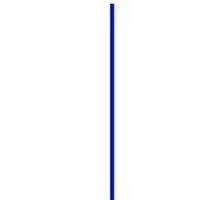
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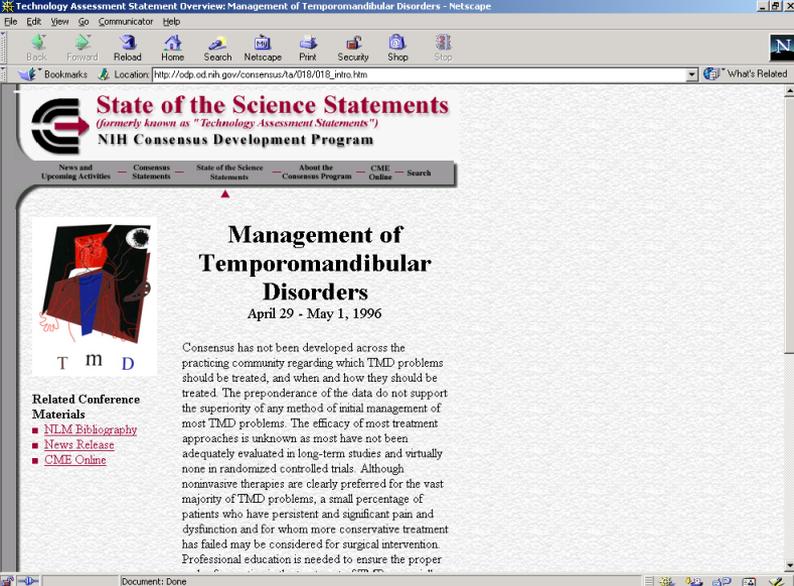
National Institutes of Health, USA 1996:

Rationale for addressing the issue (!)

- Concern about the safety and efficacy of the care provided to patients with TMD
- Absence of clear, valid, and reliable guidelines for diagnosis
- Dearth of proven rationales for a full range of treatment methods
- Many may attempt therapy with approaches that have not been adequately tested in scientifically based research studies

NIH Technology assessment Conference on TMD. 29.4-1.5-1996

The screenshot shows a Netscape browser window with the title "Technology Assessment Statement Overview: Management of Temporomandibular Disorders - Netscape". The address bar shows the URL "http://odp.od.nih.gov/consensus/ta/018/018_intro.htm". The main content area features a header for "State of the Science Statements (formerly known as 'Technology Assessment Statements') NIH Consensus Development Program". A navigation menu includes "News and Upcoming Activities", "Consensus Statements", "State of the Science Statements", "About the Consensus Program", "CME Online", and "Search". The main heading is "Management of Temporomandibular Disorders" with the dates "April 29 - May 1, 1996". To the left is an illustration of a human head in profile with a red and blue anatomical diagram of the jaw and neck, labeled "TMD". Below this is a section titled "Related Conference Materials" with links to "NLM Bibliography", "News Release", and "CME Online". The main text begins with "Consensus has not been developed across the practicing community regarding which TMD problems should be treated, and when and how they should be treated. The preponderance of the data do not support the superiority of any method of initial management of most TMD problems. The efficacy of most treatment approaches is unknown as most have not been adequately evaluated in long-term studies and virtually none in randomized controlled trials. Although noninvasive therapies are clearly preferred for the vast majority of TMD problems, a small percentage of patients who have persistent and significant pain and dysfunction and for whom more conservative treatment has failed may be considered for surgical intervention. Professional education is needed to ensure the proper..."



NIH Technology Assessment Conference on TMD. 29.4-1.5-1996

1. Oral Surg Oral Med Oral Pathol 1997; 83. Clark et al. Kierviskari et al. McNamara

NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

- Creation of a strong conflict between “pragmatists” and “scientists”.

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- ⊕ **I.V. Vitamin & Mineral Support**
- ⊕ **B.T.A.** (Biological Terrain Analysis)
- ⊕ **Dark Field** (Live Blood Analysis)
- ⊕ **Weight Loss Management**
- ⊕ **Massage Therapy**
- ⊕ **Chiropractic Therapy**
- ⊕ **Craniosacral Therapy**
- ⊕ **Hypnotherapy**
- ⊕ **MRT** (Matrix Regeneration Therapy)
- ⊕ **Vega Expert** (Biofeedback Analysis)
- ⊕ **QEEG** (Complete Brain Mapping)
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NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

- Creation of a strong conflict between “pragmatists” and “scientists”.
- A series of protests and letters from “The Alliance of TMD Practitioners”

**American Alliance of TMD
Organizations**

Peter A. Neff, DDS, Chairman • Bryan Keropian, DDS, Vice Chairman

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- Several statement and editorials staking out new courses



TEMPOROMANDIBULAR DISORDERS (TMD)

The AADR recognizes that temporomandibular disorders (TMDs) encompass a group of musculo-skeletal conditions that involve the temporomandibular joint (TMJ) or joints, the masticatory muscles, or both. The consequences of these disorders can lead to difficulties in chewing and other oral function, acute and/or chronic pain, absence from or impairment of work or social interactions, and overall reduction in the quality of life.

Based on the evidence from clinical trials:

(1) It is recommended that the differential diagnosis of TMDs or related orofacial pain incorporate information obtained from the patient's history, clinical examination, and, when indicated, TMJ or other imaging. The choice of adjunctive procedures should be based upon published, peer-reviewed data showing diagnostic efficacy. Diagnostic tests that may be proven in future scientific reports to show the sensitivity and specificity required to separate normal subjects from TMD patients or to distinguish among TMD subgroups may be useful. Use of unproven adjunctive tests and devices may present risk for clinicians and patients of reaching either false-positive or false-negative diagnoses.

(2) It is strongly recommended that, unless there are specific and justifiable indications to the contrary, treatment be based on the use of conservative and reversible therapeutic modalities. While no specific therapies have been proven to be uniformly effective, many of the conservative modalities have provided at least palliative relief from symptoms without producing harm.

(adopted 1996)

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- Several statement and editorials staking out new courses
- Call for appeals to common sense



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1: Cranio 1997 Apr;15(2):170-8

Related Articles, **NEW** Books, LinkOut

Guide to evaluation of permanent impairment of the temporomandibular joint. American Academy of Head, Neck and Facial Pain; American Academy of Orofacial Pain; American Academy of Pain Management; American College of Prosthodontists; American Equilibration Society and Society of Occlusal Studies; American Society of Maxillofacial Surgeons; American Society of Temporomandibular Joint Surgeons; International College of Cranio-mandibular Orthopedics; Society for Occlusal Studies.

Phillips DJ Jr, Gelb M, Brown CR, Kinderknecht KE, Neff PA, Kirk WS Jr, Schellhas KP, Biggs JH 3rd, Williams B.

Department of Oral Medicine and Pathology, NYU College of Dentistry, NY 10022, USA.

- Publication Types:
- o Consensus Development Conference
 - o Guideline
 - o Practice Guideline
 - o Review

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NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

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- Several statements and editorials staking out new courses
- Call for appeals to common sense
- Public interest

Temporomandibular Disorders Interagency Working Group (TMDIWG)

TMJDIWG - Microsoft Internet Explorer

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- [Schedule of TMJDIWG Meetings and Speakers](#)
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- [Federal Agency TMJD-Related Electronic Documents](#)

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International Consortium for RDC/TMD-Based Research

Mission Statement

Our goal is to advance the scientific knowledge of temporomandibular disorders and related pain conditions through international multi-site research based on the use of a common set of tools applicable to both research and clinical settings. The core tool is the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), and our methods include population studies, clinical epidemiology and clinical trials, and experimental human studies.

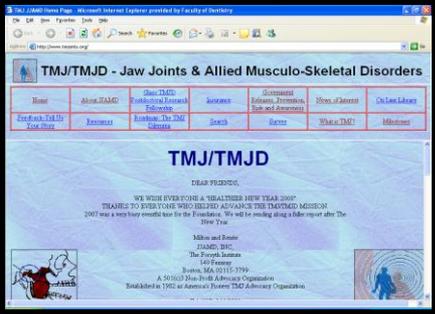
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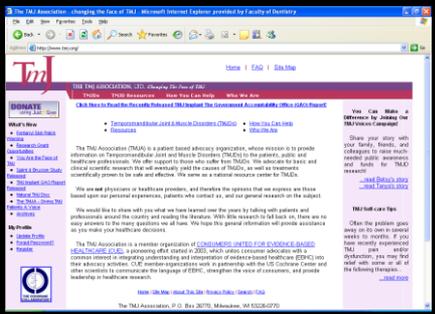


Patient advocacy associations

Jaw Joints & Allied Musculoskeletal Disorders Foundation, Inc



The TMJ Association



Practice versus science

1. On what should diagnosis and management of patients with TMD be based?

Optimal management of TMD patients?

- by anecdote
- by press cutting
- by expert opinion (from others)
- by cost minimization
- by critical appraisal of science

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?

Research = science ?

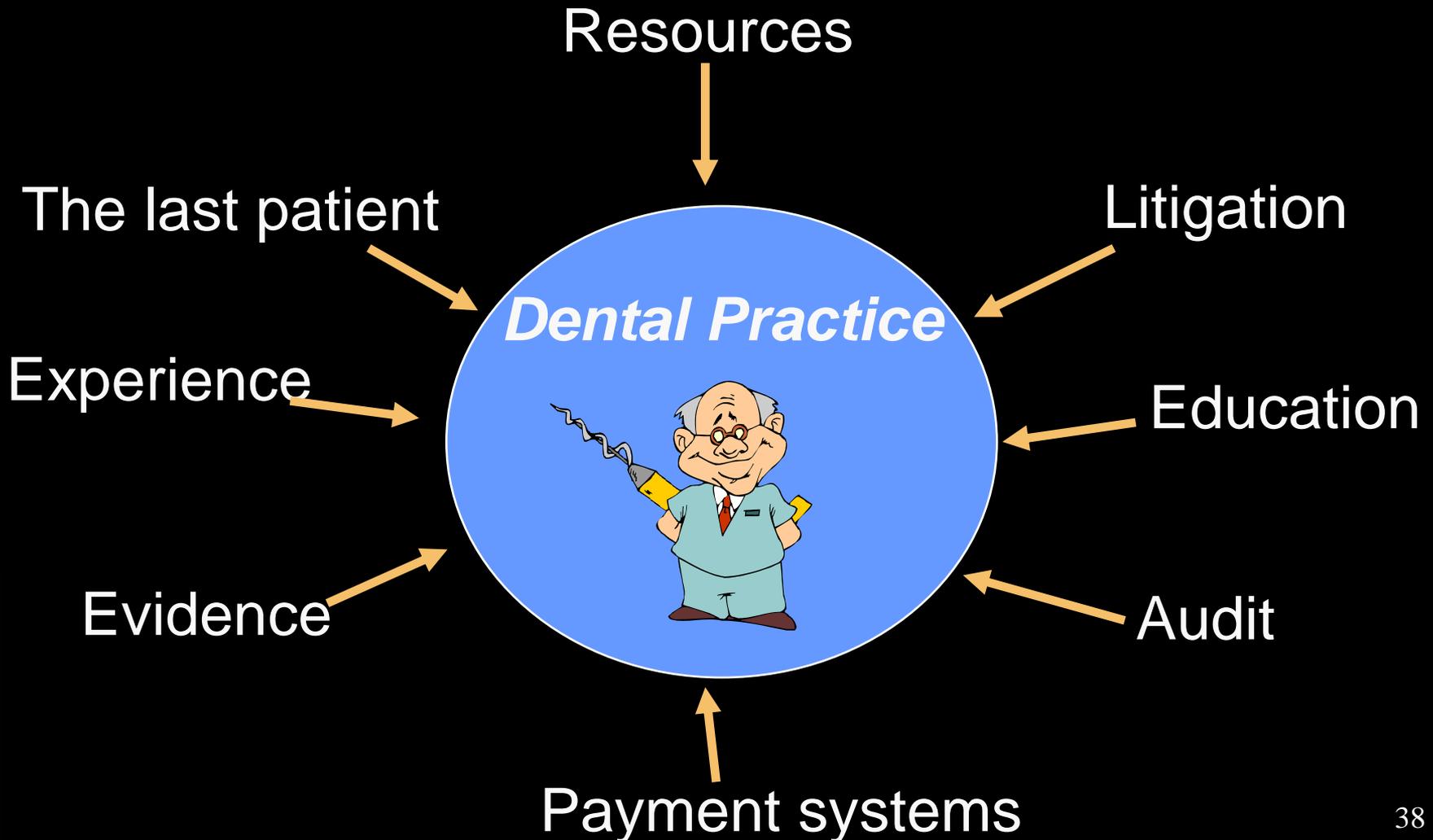
Compilation of:

- Empirical knowledge
- Science
 - Observational studies
 - Laboratory
 - Clinical
 - Experimental studies
 - Laboratory
 - Clinical

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How are clinical decisions made?

Influences on treatment decisions

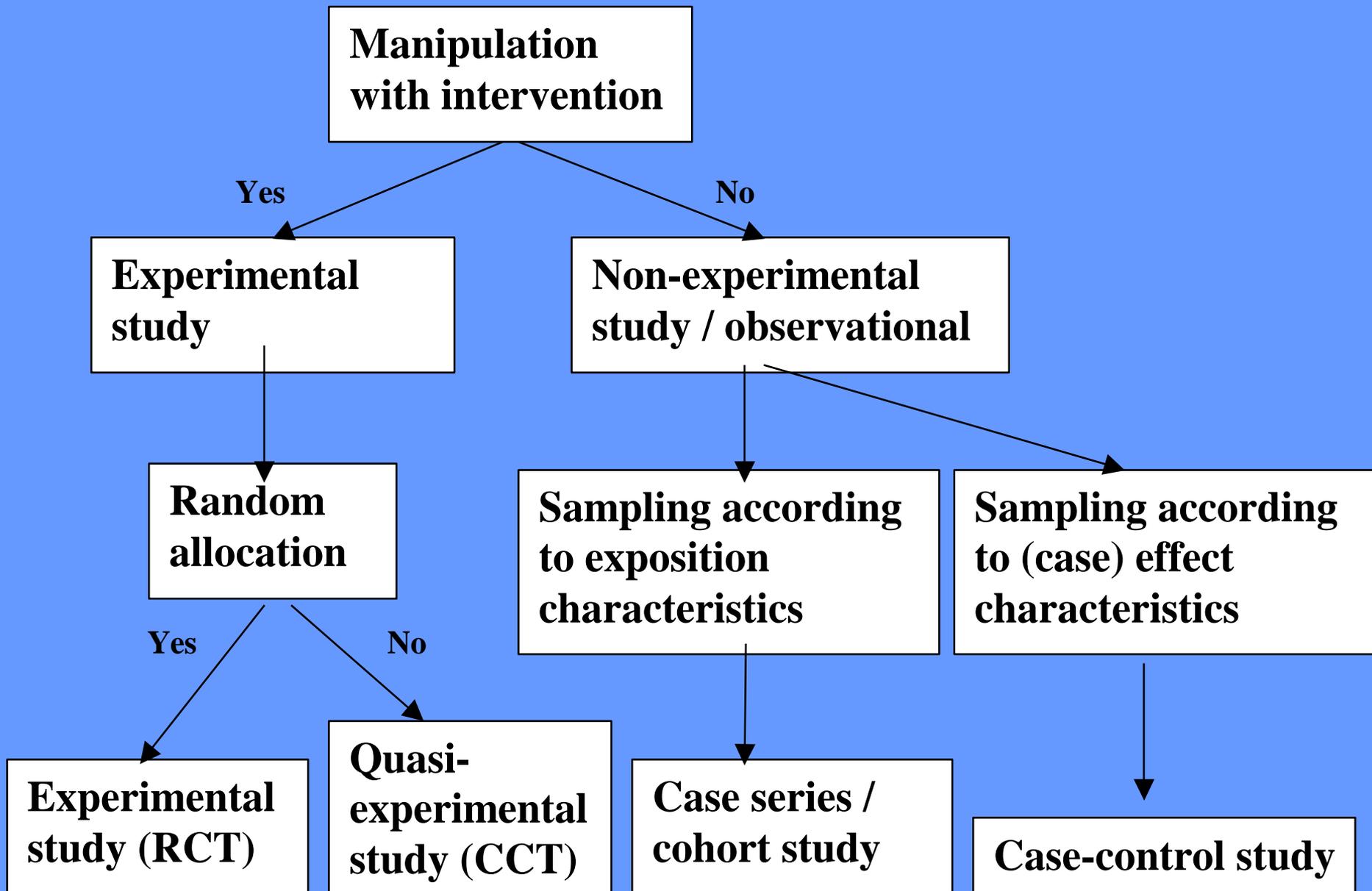


Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How is a clinical decision made?
4. Is there consensus on optimal study design to elucidate issues in patient care?

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
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1b	Individual RCT (with narrow <u>Confidence Interval†</u>)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with <u>good†††</u> reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	<u>All or none§</u>	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
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Clinical trial terminology - tower of Bable?

analytical study

case control study (89)

case serie

case study, case report

cause-effect study

clinical trial (79)

cohort study (89)

cohort study with historical controls

controlled clinical trial (95)

cross-sectional study (89)

descriptive study

diagnostic meta-analysis

diagnostic study

double blind randomized therapeutical trial with cross-over design

ecological study

etiological study

experimental study

explorative study

feasibility study (79)

follow-up study (67)

historical cohort study

incidence study

intervention study

longitudinal study (79)

N=1 trial

non-randomized trial with

contemporaneous controls

non-randomized trial with

historical controls

observational study

prospective cohort study

prospective follow-up study, observational or experimental

prospective study (67)

quasi-experimental study

randomized clinical trial, RTC

randomized controlled trial, RCT (89)

retrospective cohort study

retrospective follow-up study

retrospective study (67)

surveillance study

survey, descriptive survey

therapeutic meta-analysis

trohoc study

Descriptions reduced to three questions:

1. Study objective?

Descriptive, no comparison conducted
Comparison as process research
Comparison as cause-effect research

2. Procedure, intervention?

Experimental allocation of procedure
Survey

3. Data collection?

Retrospective
Cross-sectional
Prospective / Cohort / Longitudinal

Clinical study designs (MESH terms):

- (Case study/series)
- Case-Control Study
- Cohort Study
- Cross-Sectional Survey
- Randomised Controlled Trial

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How is a clinical decision made?
4. Is there consensus on optimal study design to elucidate issues in patient care?
5. What types of research strategies should be applied to support scientific theories on management of TMD?

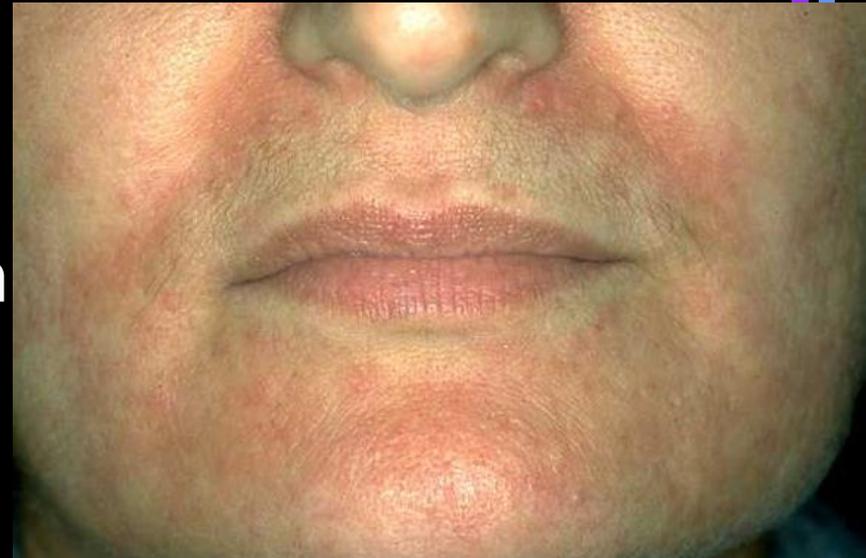
Central issues of TMD treatment

1. Clinical findings:

How to properly gather the most relevant findings from the history and physical examination, and interpret these correctly?

2. Etiology:

How to identify causes for TMD (including its iatrogenic forms) ?



Central issues of TMD treatment

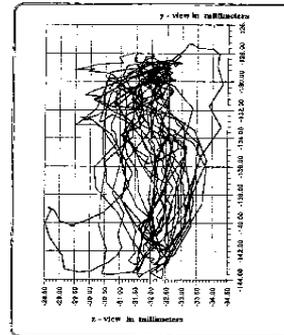
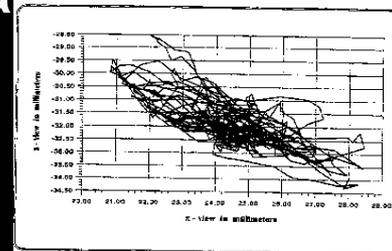
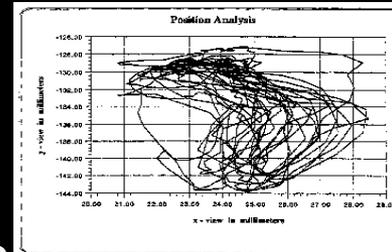
3. Differential diagnosis:

When considering the possible causes of a patient's TMD problems, how to rank them by likelihood, seriousness and treatability ?

Level of Organization	Example of problem or disorder
Organ System	Neurologic Disorders
Pathologic similarities	Demyelinating Disorders
Causative agent	Viral Diseases
Symptom Similarities	Headaches

4. Diagnostic tests

How to select and interpret tests, in order to confirm or exclude a diagnosis, based on precision, accuracy, acceptability, expense, safety, etc?



Central issues of TMD treatment

5. Prognosis:

How to estimate the patient's likely clinical course over time with and without treatment and anticipate likely complications?



6. Therapy:

How to select treatments to offer patients that do more good than harm and that are worth the efforts and costs of using them?



Central issues of TMD treatment

7. Prevention:

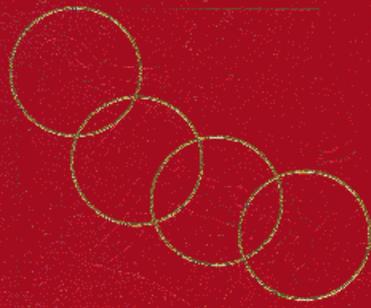
How to reduce the chance of TMD by identifying and modifying risk factors and how do we diagnose TMD early by screening?



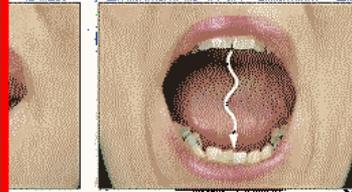
8. Self-improvement:

How to keep up to date, improve our clinical skills to provide best treatment of TMD?

EVALUATION,
DIAGNOSIS, AND
TREATMENT OF
OCCLUSAL PROBLEMS



PETER E. DAWSON



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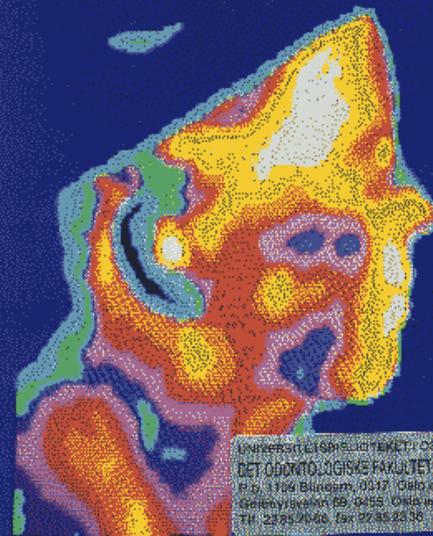
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NEW CONCEPTS IN
CRANIOMANDIBULAR AND
CHRONIC PAIN MANAGEMENT



Edited by
Harold Gelb

22 Contributors

UNIVERSITÄT SIBIRIENSKIY OSLO
DET ODONTOLOGISKE FAKULTETS BIBLIOTEK
P.O. 1104 Blindern, 0317 Oslo, Norway
Senter for Oral og Kjevelsmedisin
TH 2285/2046, fax 2245/2336

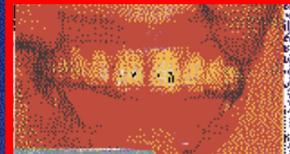
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Clinical Management of
**HEAD, NECK
and TMJ PAIN**
and **DYSFUNCTION**



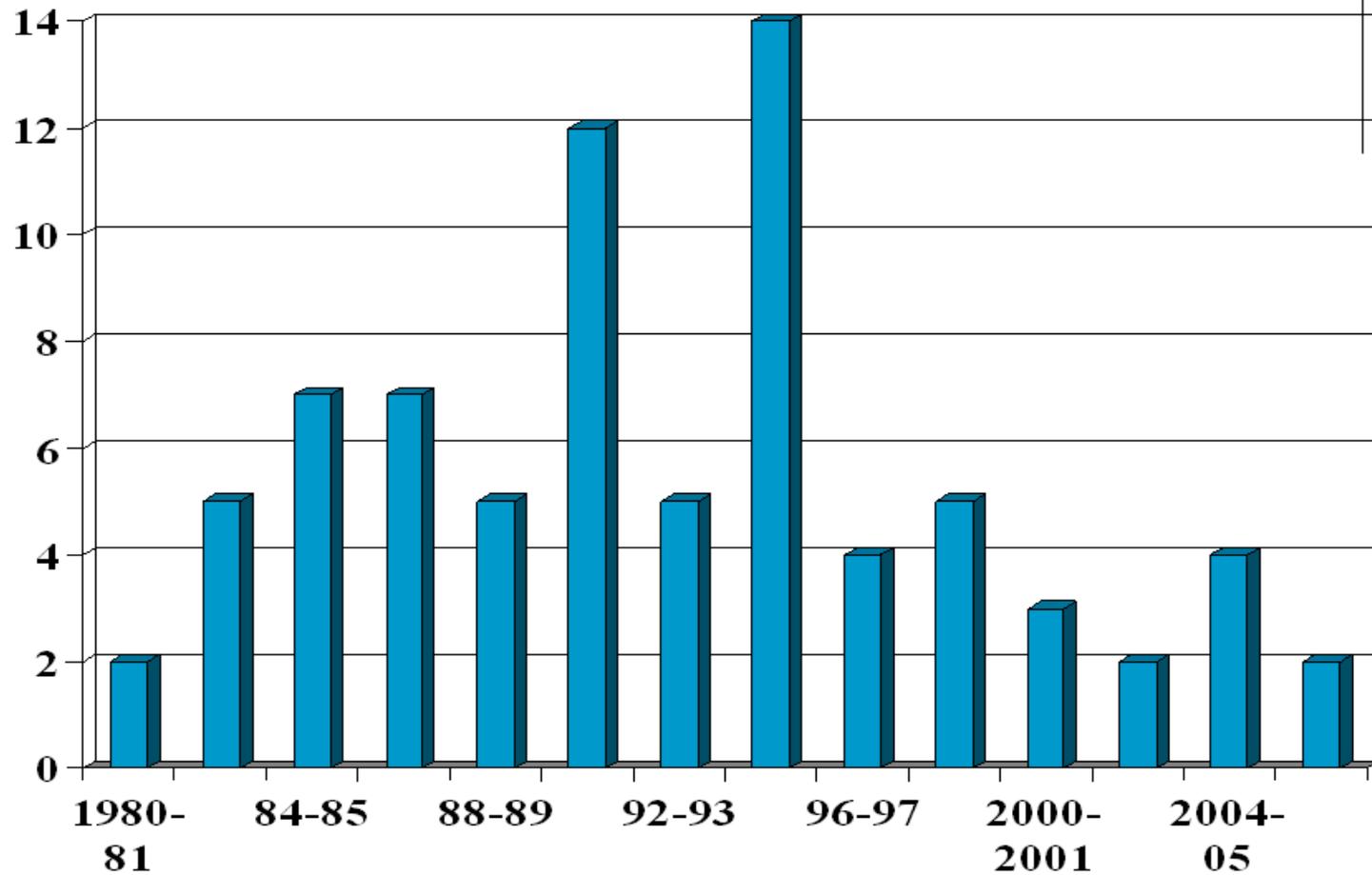
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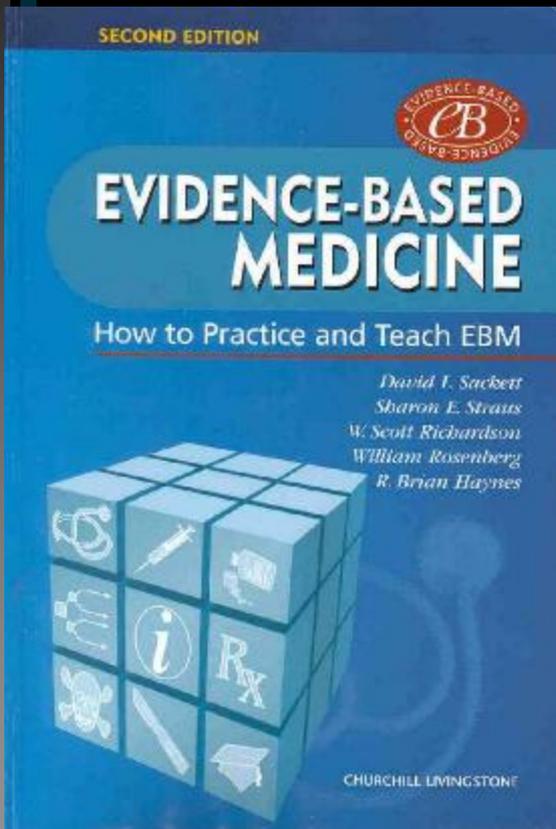


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Textbooks on TMD



Asbjørn Jokstad, University of Toronto. 2008©



Evidence of doing more good than harm depends on adequate study design*

Therapy

*Sackett DL, Strauss SE, Richardson WS, Rosenberg W, Haynes RB. *Evidence-based Medicine. 2nd. edit. Churchill Livingstone, 2000.*

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

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Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnostic Accuracy	Economic and decision analyses
1a	SR (with <u>homogeneity*</u>) of RCTs	SR (with <u>homogeneity*</u>) of RCTs	SR (with <u>homogeneity*</u>) of RCTs	SR (with <u>homogeneity*</u>) of Level 1 economic studies
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Level 1 Therapy/Prevention, Aetiology/Harm

1a SR (with homogeneity*) of RCTs

1b Individual RCT (with narrow Confidence Interval†)

1c All or none§

2a SR (with homogeneity*) of cohort studies

2b Individual cohort study (including low quality RCT; e.g., <80% follow-up)

2c "Outcomes" Research; Ecological studies

3a SR (with

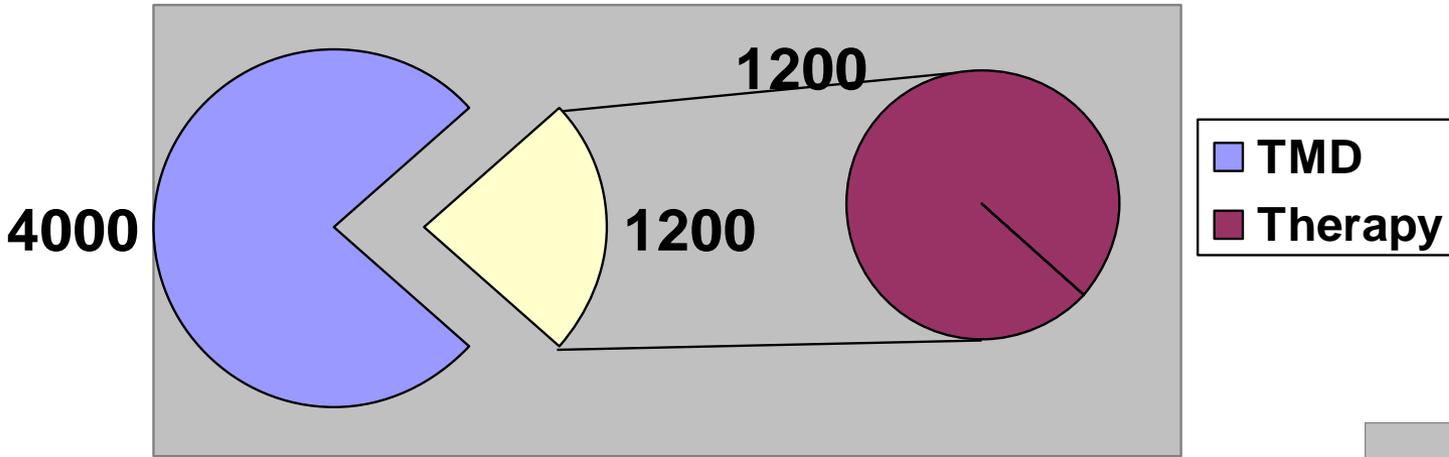
3a SR (with homogeneity*) of case-control studies

3b Individual Case-Control Study

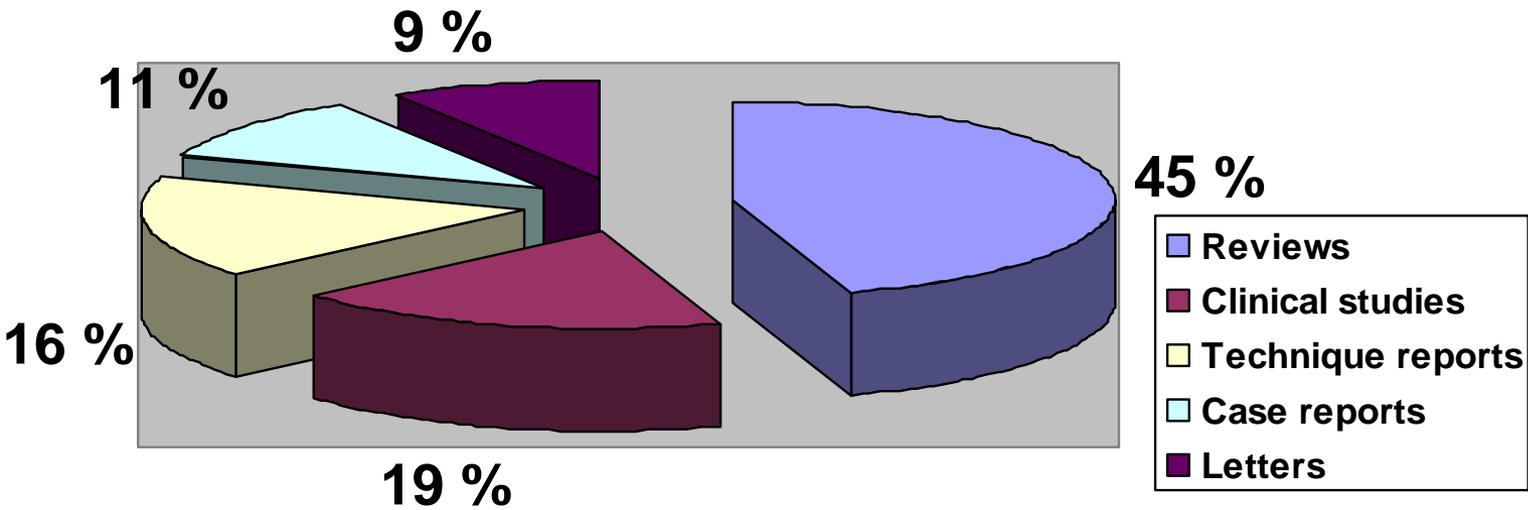
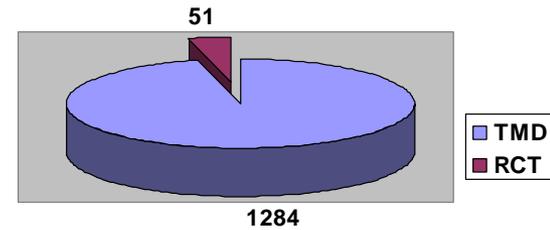
4 Case-series (and poor quality cohort and case-control studies§§)

5 Expert opinion without explicit critical appraisal, or based on physiology.

TMD studies 1980-92



RCT studies



Appropriate Study Designs

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				★	★★
Therapy				★	★★
Prognosis				★★★	
Screening			★	★	★★
Views/beliefs perceptions	★★★				
Prevalence/hypothesis generation	★★★	★★★			

Cross-Sectional Survey

Advantages

1. Cheap and simple
2. Ethically safe

Disadvantages

1. Establishes association at most, not causality
2. Recall bias susceptibility
3. Confounders may be unequally distributed
4. Group sizes may be unequal

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Case-Control Studies

Advantages:

1. Quick and cheap
2. Only feasible method for very rare disorders or those with long lag between exposure and outcome
3. Fewer individuals needed than cross-sectional studies

Disadvantages:

1. Rely on recall/records to determine exposure status
2. Confounders
3. selection of control groups is difficult
4. Potential bias: recall, selection

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Poor case-control studies are recognized by:

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Failure to:

- clearly define comparison groups
- measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls
- identify or appropriately control known confounders.

Cohort Study

Advantages:

1. Ethically safe
2. individuals can be matched
3. Can establish timing and directionality of events
4. Eligibility criteria and outcome assessments can be standardised
5. Administratively easier and cheaper than RCT

Disadvantages:

1. Controls may be difficult to identify
2. Exposure may be linked to a hidden confounder
3. Blinding is difficult
4. Randomisation not present
5. For rare disease, large sample sizes or long follow-up necessary

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Poor cohort studies are recognized by:

Failure to :

- clearly define comparison groups and/or
- measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or
- identify or appropriately control known confounders and/or
- carry out a sufficiently long and complete follow-up of patients.

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Randomised Controlled Trial - RCT

Advantages

1. Unbiased distribution of confounders
2. Blinding more likely
3. Randomisation facilitates statistical analysis

Disadvantages

1. Size, time and money - Expensive!
2. Volunteer bias
3. Ethically problematic at times

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

Cohort & RCT Crossover Design

Advantages

1. All individuals serve as own controls -> error variance is reduced -> reduced need of large sample size
2. All individuals receive treatment (at least some of the time)
3. Statistical tests assuming randomisation can be used
4. Blinding can be maintained

Disadvantages

1. All individuals receive placebo or alternative treatment at some point
2. Washout period lengthy or unknown
3. Cannot be used for treatments with permanent effects

Scientific studies can be graded
according to the
theoretical possibility
of an
incorrect conclusion.

This is reflected by the
design of the study.

...we will never know exact answers in science....

What can you show with a trial?

The truth

A is better than B

A is no better than B

What the trial shows

A is better than B

A is no better than B

✓	X
X	✓

What can you show with a trial?

Type 1 error
Alfa error
Optimism error

The truth

A is better
than B

A is no better
than B

✓

X

X

✓

**What the
trial shows**

A is better
than B

A is no better
than B

Type 1 errors - fallacies of observed clinical success

- Spontaneous remission
- Placebo response
- Multiple variables in treatment
- Radical versus conservative treatment
- Over-treatment
- Long-term failure
- Side effects and sequelae of treatment

What can you show with a trial?

The truth

A is better than B

A is no better than B

✓

X

A is better than B

A is no better than B

X

✓

What the trial shows

Type 2 error
Beta error
Pessimism error

Type 2 errors - fallacies of observed clinical failures

- Wrong diagnosis
- Incorrect cause-effect correlations
- Multifactorial problems
- Lack of cooperation
- Improper execution of treatment
- Premature evaluation of treatment
- Limited success of treatment
- Psychological barriers to success

The easy approach to evaluate treatment effects

- Compare a single group of patients given the new treatment with a group previously treated with an alternative treatment.
- Usually such studies compare two consecutive series of patients in the same settings.

The easy approach is seriously flawed:

- Multiple examples in medicine where results from RCTs negates findings from clinical trials using inadequate study designs
- Controlled trials yield in general more optimistic results than randomised trials.
(Altman DG. BMJ 1991;302:1481)
- Can never satisfactorily eliminate possible biases due to other factors (apart from treatment) that may have changed over time

The easy approach and risk of bias:

- If the clinician chooses which treatment to give each patient there will probably be differences in the clinical and demographic characteristics of the patients receiving the different treatments.

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- Much the same will happen if patients choose their own treatment or if those who agree to have a treatment are compared with refusers.
- Similar problems when the different treatment groups are at different clinics or under different operators.
- Systematic differences will lead to an overestimate or underestimate of the difference between treatments.
- Bias can be avoided by using random allocation.

Three general questions

1. Is the study valid?
2. What are the results ?
3. Are the results relevant to my question / problem?

1. Is the Study Valid ?

- Is there a clear question?
- Is the most appropriate study design to answer the question used?
- Was the study conducted reliably?
- Can you follow what the authors did?

2. What are the results?

- Are the results presented in a clear and simple manner ?
- Is there a clear bottom line ?
- Are they clinically important ?

3. Are the results relevant to my question / problem ?

- Are the participants similar to my patients ?
- Is it realistic for me to apply the study methodology and results to my patients ?

Internal and external validity

Internal validity: extent to which systematic error (bias) is minimised in clinical trials

External validity: extent to which results of trials provide a correct basis for generalisation to other circumstances

Internal validity - systematic bias

- Selection bias: biased allocation to comparison groups
- Performance bias: unequal provision of care apart from treatment under evaluation
- Detection bias: biased assessment of outcome
- Attrition bias: biased occurrence and handling of deviations from protocol and loss to follow up

External validity

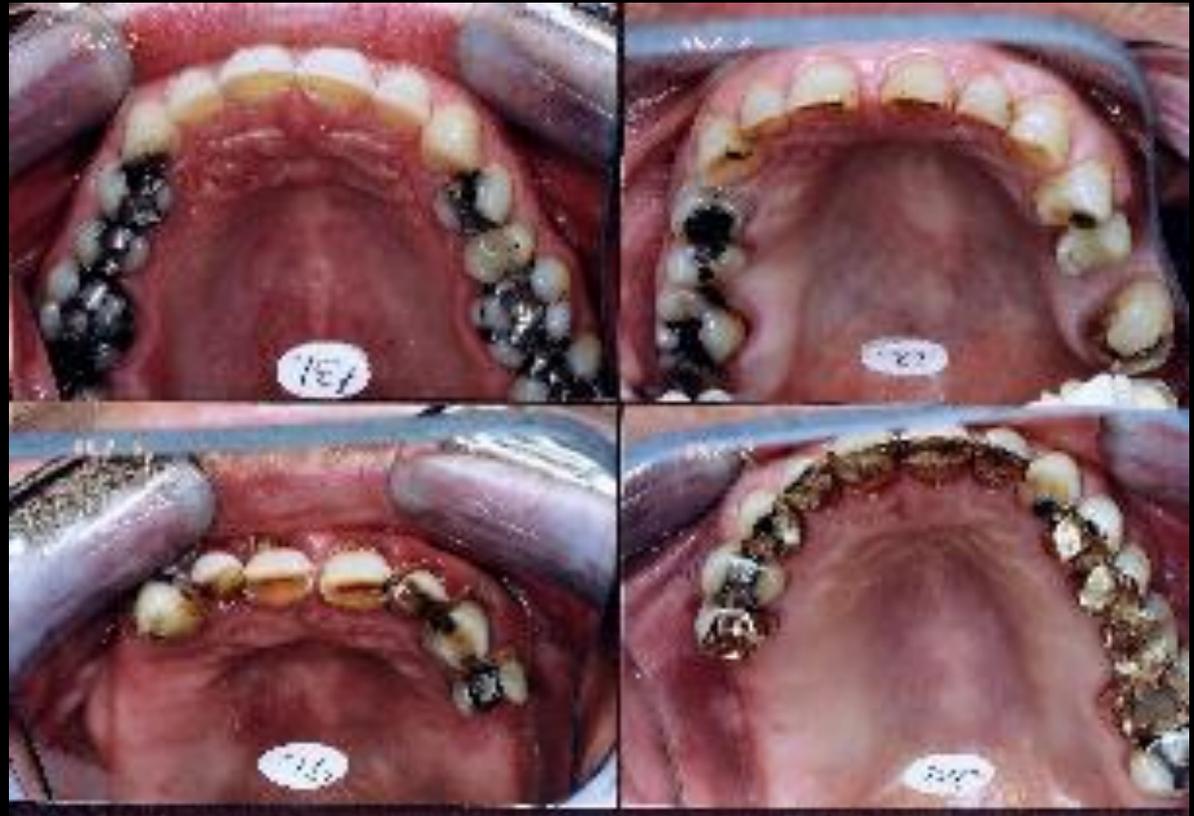
- Patients: age, sex, severity of disease and risk factors, co-morbidity
- Treatment regimens: dosage, timing and route of administration, type of treatment within a class of treatments, concomitant treatments
- Settings: level of care (primary to tertiary) and experience and specialisation of care provider
- Modalities of outcomes: type or definition of outcomes and duration of follow up

Critical Appraisal Criteria

Exists for studies focused on e.g. :

- therapy
- diagnosis
- screening
- harm
- prognosis
- causation of disease (etiology)
- quality of care
- economic analyses

Central issues of TMD treatment



2. Etiology:

How to identify causes for TMD
(including its iatrogenic forms) ?

Etiology - Harm - Causation

- Clearly identified comparison group for those at risk for, or having, the outcome of interest
- Masking of observers of outcomes to exposures
- Observers of exposures masked to outcomes for case-control studies and individuals masked to exposure for all other study designs
- A statistical analysis consistent with the study design.

Central issues of TMD treatment

3. Differential diagnosis:

When considering the possible causes of a patient's TMD problems, how to rank them by likelihood, seriousness and treatability ?

Level of Organization

Organ System

Pathologic similarities

Causative agent

Symptom

Similarities

Example of problem or disorder

Neurologic Disorders

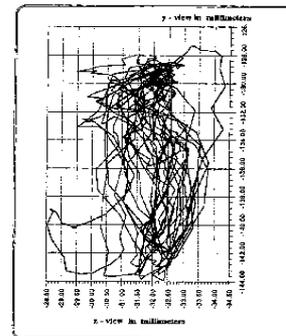
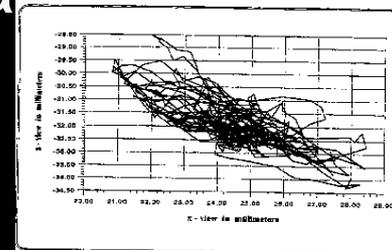
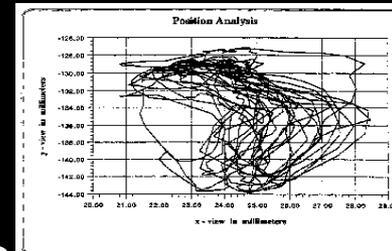
Demyelinating Disorders

Viral Diseases

Headaches

4. Diagnostic tests

How to select and interpret tests, in order to confirm or exclude a diagnosis, based on precision, accuracy, acceptability, expense, safety, etc?



Diagnostic tests, Differential diagnosis

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
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Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

- Clearly identified comparison groups, at least one of which is free of the target disorder
- Either an objective diagnostic standard/contemporary clinical diagnostic standard with reproducible criteria for any objectively interpreted component
- Interpretation of the test without knowledge of the diagnostic standard result
- Interpretation of the diagnostic standard without knowledge of the test result
- A statistical analysis consistent with study design

Central issues of TMD treatment

5. Prognosis:

How to estimate the patient's likely clinical course over time with and without treatment and anticipate likely complications?



Prognosis

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

- An inception cohort of persons, all initially free of the outcome of interest
- Follow-up of at least 80 per cent of patients until the occurrence of either a major study criteria or the end of the study
- A statistical analysis consistent with the study design.

Central issues of TMD treatment

6. Therapy:

How to select treatments to offer patients that do more good than harm and that are worth the efforts and costs of using them?



7. Prevention:

How to reduce the chance of TMD by identifying and modifying risk factors



Therapy / Prevention / Education

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/hypothesis generation	☆☆☆	☆☆☆			

- Random allocation of the participants to the different interventions
- Outcome measures of known or probably clinical importance for at least 80 per cent of participants who entered the investigation
- A statistical analysis consistent with the study design.

Appropriate Study Designs

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis					
Therapy				Kierviskari Koh	
Prognosis				Olsson	
Screening					
Views/beliefs perceptions					
Prevalence/ hypothesis generation		John	Landi Pahkala	English	