

# Pomen EBM za kakovost in varnost obravnave bolnikov – v čem se uradna medicina razlikuje od alternativne

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# Cilji



- Zakaj je vrednotenje komplementarnih in alternativnih metod (CAM) potrebno?
- Raziskovalni projekt evropske skupnosti
- Kakšne podatke imamo za področje družinske medicine ?
- Rezultati raziskav



# Izbira bolnika?



Opolnomočenje bolnika je v porastu, zato bolnika vse pogosteje umestimo na voznikov sedež, tako da prevzema vodenje in nadzor nad lastnim zdravjem. Bolniki lahko prosto izbirajo, ali želijo biti oskrbljeni s konvencionalnim ali komplementarnim zdravljenjem. Katerokoli zdravljenje, ki kaže boljše rezultate z nižjimi stroški, je korak naprej na poti k bolj vzdržnim zdravstvenim sistemom.

- Vir: Tonio Borg Evropski komisar za zdravje, Bruselj, 27. junija 2013

# Izbira zdravnika?



V vseh evropskih državah se regulatorni in izobraževalni sistemi glede CAM razlikujejo. Obstoječa regulativa EU in izobraževalni kaos na področju CAM onemogočajo zdravstvenim strokovnjakom, da bi zagotavljali varnost bolnikom in klientom.

- Vir: Prof. Vinjar Fonnebo, Univerza Tromso

# Izbira politike?



Belgijski svet ministrov je 12. julija 2013 določil, da je homeopatija medicinski akt.

Samo doktorji medicine, zobozdravniki in babice jo lahko izvajajo. Zobozdravniki in babice v okviru njihovih kompetenc.

Kraljevski dekret je nastal kot rezultat 21. sestankov med predstavniki ministrstva, profesorji univerz in izvajalci.

# Kakšna so vaša osebna stališča?



- Ali je sploh umestno uporabljati naziv alternativna medicina?
- Ali izvajalci alternativnih praks ne vabijo bolnikov tudi s svojim nazivom?
- Gre za zdravilsko prakso?
- Ali je mogoče brez moralnega konflikta združevati profesionalno in zdravilsko delo?



## Complementary and Alternative Medicine (CAM)

- Meditation
- Hypnosis
- Guided Imagery
- Biofeedback
- Relaxation Therapy
- CBT
- Prayer and Spirituality
- Homeopathy
- TCM
- Bodywork and Movement Therapy
- Acupuncture
- Ayurvedic Medicine
- Physical Medicine
- Chiropractic Therapy
- Energy Medicine
- Dietary Medicine
- Herbal Medicine
- Massage Therapy
- Naturopathy
- Neural Therapy
- Magnet Therapy

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# STANJE V SLOVENIJI

**7. marec  
1992**  
sprejet  
Zakon o  
zdravstveni  
dejavnosti



**2007**  
sprejet  
Zakon o  
zdravilstvu



**2009**  
pričetek  
usklajevanj  
o predlogu  
Zakona o  
zdravilski  
dejavnosti



**2011**  
sprejet  
odložitni  
veto na  
Zakon o  
spremembah  
in  
dopolnitvah  
Zakona o  
zdravilstvu



**2016**  
sprejeta  
Resolucija o  
nacionalnem  
planu  
zdravstvene  
ga varstva  
2016-2025



**27.  
november  
2017**  
izdan  
dokument o  
Okvirnih  
izhodiščih za  
Zakon o  
dopolnilnih,  
tradicionalnih  
in  
alternativnih  
oblikah  
diagnostike,  
zdravljenja in  
rehabilitacije

Manjkal  
predpis o  
urejanju  
AKM

Napačna  
uporaba  
pojma  
„zdravilstvo“  
Kazen za  
zdravnike  
650-1200  
EUR

Stvari  
ostale  
nerazrešene

Zaveza  
ministrstva  
da bo  
uredilo  
področje  
AKM

Odprava  
neskladij  
vse od 1992



# Raziskava Evropske skupnosti

- A-pan European research network for Complementary and Alternative Medicine (CAM)
- **EU 7 Framework**
- EC prispevek 1 498 597 EUR
- Trajanje 36 mesecev



# Kako vrednotite raziskave?



[BMC Public Health](#). 2004 Mar 4;4:6.

## Measuring the effects of acupuncture and homoeopathy in general practice: an uncontrolled prospective documentation approach.

[Güthlin C](#)<sup>1</sup>, [Lange O](#), [Walach H](#).

### Author information

#### Abstract

**BACKGROUND:** Despite the increasing demand for acupuncture and homoeopathy in Germany, little is known about the effects of these treatments in routine care. We set up a pragmatic documentation study in general practice funded within the scope of project launched by a German health insurer. Patients were followed-up for up to four years.

**METHODS:** The aim of the project was to study the effects and benefits of acupuncture and/or homoeopathy, and to assess patient satisfaction within a prospective documentation of over 5000 acupuncture and over 900 homoeopathy patients. As data sources, we used the documentation made available by therapists on every individual visit and a standardised quality-of-life questionnaire (MOS SF-36); these were complemented by questions concerning the patient's medical history and by questions on patient satisfaction. The health insurer provided us with data on work absenteeism.

**RESULTS:** Descriptive analyses of the main outcomes showed benefit of treatment with middle to large-sized effects for the quality of life questionnaire SF-36 and about 1 point improvement on a rating scale of effects, given by doctors. Data on the treatment and the patients' and physicians' background suggests chronically ill patients treated by fairly regular schemes.

**CONCLUSION:** Since the results showed evidence of a subjective benefit for patients from acupuncture and homoeopathy, this may account for the increase in demand for these treatments especially when patients are chronically ill and unsatisfied with the conventional treatment given previously.

# Kako vrednotite preiskovane populacije?



Kristoffersen et al. *BMC Complementary and Alternative Medicine* 2012, **12**:1  
<http://www.biomedcentral.com/1472-6882/12/1>



RESEARCH ARTICLE

Open Access

## Any difference? Use of a CAM provider among cancer patients, coronary heart disease (CHD) patients and individuals with no cancer/CHD

Agnete E Kristoffersen<sup>\*</sup>, Arne J Norheim and Vinjar M Fønnebo

### Abstract

**Background:** Although use of complementary and alternative medicine (CAM) among cancer patients has been described previously, prevalence of use has not commonly been compared to other disease groups in a true population sample where CAM use or cancer is not the main focus. The aims of the present study are to (1) examine how CAM use in cancer patients differs from people with a previous CHD diagnosis and people with no cancer or CHD diagnosis in an unselected general population and (2), investigate the use of a CAM provider among individuals with a previous cancer diagnosis.

**Methods:** A total of 8040 men and women aged 29 to 87 in the city of Tromsø, Norway filled in a questionnaire developed specifically for the Tromsø V study with questions on life style and health issues. Visits to a CAM provider within the last 12 months and information on cancer, heart attack and angina pectoris (heart cramp) were among the questions. 1449 respondents were excluded from the analyses.

**Results:** Among the 6591 analysed respondents 331 had a prior cancer diagnosis, of whom 7.9% reported to have seen a CAM provider within the last 12 months. This did not differ significantly from neither the CHD group (6.4%,  $p = 0.402$ ) nor the no cancer/CHD group (9.5%,  $p = 0.325$ ).

**Conclusion:** According to this study, the proportion of cancer patients seeing a CAM provider was not statistically significantly different from patients with CHD or individuals without cancer or CHD.

### Background

Cancer patients' self-reported use of complementary and alternative medicine (CAM) is increasing, [1-3] although studies report substantial differences in the level of use, ranging from 7 [4] to 91% [5]. Younger, highly educated women are the most frequent users [6-8]. Frequent use is also reported among patients with symptoms and symptom progression related to their cancer [9-13].

CAM treatment is mostly offered outside the national health care service in Norway and paid out-of-pocket by the patients. Prior to 2004 only physicians and dentists could legally treat cancer patients [14]. The proportion of cancer patients reporting CAM use in Norway varies between 11.1 and 72% [15,16] depending on how CAM is defined [15]. When defined as "at least one visit to a

CAM provider during the previous 12 months" the variation narrows down to 16.1% [16] to 22.7% [15].

CAM use among cancer patients has rarely been reported in an unselected general population sample, and even more rarely been compared to use among other patient groups in this type of sample [17].

Coronary heart disease (CHD) and cancer constituted 58% of all deaths in Norway in 2009 [18], and are the two most common causes of death. In planning, administering and monitoring health care provisions, knowledge about the choices and health care-related behaviours made by these patient groups is important, particularly the choices and behaviours related to treatments outside the national health care service.

The magnitude of use of conventional health care in CHD patients is well known. Few studies have, however, examined CAM use in these patients, most of them in highly selected population subgroups. Substantial

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# Slabosti obstoječih raziskav



- Umetni pogoji, z ozkimi vključitvenimi in izključitvenimi kriteriji.
- Nizka generalizacija.
- Nerandomizirani bolniki
- Vključeni tisti z preferencami.

# Kaj so odkrili avstralski raziskovalci? National Health and Medical Research Council, 2014



NHMRC DRAFT INFORMATION PAPER: EVIDENCE ON THE EFFECTIVENESS OF HOMEOPATHY FOR TREATING HEALTH CONDITIONS [APRIL 2014] - Adobe Reader

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NHMRC DRAFT INFORMATION PAPER [APRIL 2014]	
<p>There is no reliable evidence that homeopathy is as effective as the other therapies for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• acute otitis media or otitis media with effusion (inflammation of the middle ear) in children (compared with antibiotics, mucolytic medicines, secretolytic medicines, antipyretic medicines, nasal sprays, or monitoring the condition but not providing treatment [“watchful waiting”])</li> <li>• allergic rhinitis (compared with antihistamines, cortisone or intranasal cromolyn sodium)</li> <li>• anxiety or stress-related conditions (compared with lorazepam, diazepam or cognitive behavioural therapy)</li> <li>• depression (compared with fluoxetine or diazepam)</li> <li>• eczema (compared with corticosteroids, antihistamines, or other unspecified therapies)</li> <li>• non-allergic rhinitis (compared with aspirin, xylometazoline or other therapies)</li> <li>• osteoarthritis (compared with paracetamol or various nonsteroidal anti-inflammatory drugs)</li> <li>• upper respiratory tract infection (compared with anti-inflammatory drugs, antibiotics or other therapies).</li> </ul>	<p>For each condition, although some studies reported that homeopathy was as effective as or more effective than another treatment, these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants to give a meaningful result, or both.</p>
<p>There is no reliable evidence on which to draw a conclusion about the effectiveness of homeopathy, compared with placebo, for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• acne vulgaris</li> <li>• acute otitis media (inflammation of the middle ear) in children</li> <li>• acute ankle sprain</li> <li>• acute trauma</li> <li>• amoebiasis and giardiasis (gastrointestinal conditions caused by parasites)</li> <li>• ankylosing spondylitis</li> <li>• boils and pyoderma (types of skin infections)</li> <li>• Broca’s aphasia in people who have had a stroke</li> <li>• bronchitis</li> <li>• cholera</li> <li>• cough</li> <li>• chronic polyarthritis</li> <li>• dystocia (difficult labour)</li> <li>• eczema</li> <li>• heroin addiction</li> <li>• knee joint haematoma (bruising)</li> <li>• lower back pain</li> <li>• nausea and vomiting associated with chemotherapy</li> <li>• oral lichen planus</li> <li>• osteoarthritis</li> <li>• proctocolitis</li> </ul>	<p>For each condition, only one study that compared homeopathy with placebo was found, and this study was unreliable. It was either poor quality (poorly designed or poorly done) or unknown quality, or it had too few participants to give a meaningful result, or both.</p>

# Kriteriji ocene učinkovitosti



- Objavljeni sistematični znanstveni pregledi
  - Ocena informacij, ki so jih posredovale interesne homeopatske skupine ali javnost
  - Smernice klinične prakse ali vladnih poročil, ki so jih objavili v drugih državah.
- 
- Ključno vprašanje: Ali je homeopatija učinkovito zdravljenje zdravstvenih stanj, če to primerjamo z drugimi zdravljenji ali pristopom brez homeopatije.
  - Od leta 2000v dalje je NHMRC investirala več kot 86 milijonov dolarjev v raziskovanje komplementarnih in alternativnih praks.

## NHMRC DRAFT INFORMATION PAPER [APRIL 2014]

There is no reliable evidence that homeopathy is as effective as the other therapies for the treatment of these health conditions:

- acute otitis media or otitis media with effusion (inflammation of the middle ear) in children (compared with antibiotics, mucolytic medicines, secretolytic medicines, antipyretic medicines, nasal sprays, or monitoring the condition but not providing treatment [‘watchful waiting’])
- allergic rhinitis (compared with antihistamines, cortisone or intranasal cromolyn sodium)
- anxiety or stress-related conditions (compared with lorazepam, diazepam or cognitive behavioural therapy)
- depression (compared with fluoxetine or diazepam)
- eczema (compared with corticosteroids, antihistamines, or other unspecified therapies)
- non-allergic rhinitis (compared with aspirin, xylometazoline or other therapies)
- osteoarthritis (compared with paracetamol or various nonsteroidal anti-inflammatory drugs)
- upper respiratory tract infection (compared with anti-inflammatory drugs, antibiotics or other therapies).

For each condition, although some studies reported that homeopathy was as effective as or more effective than another treatment, these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants to give a meaningful result, or both.

There is no reliable evidence on which to draw a conclusion about the effectiveness of homeopathy, compared with placebo, for the treatment of these health conditions:

- acne vulgaris
- acute otitis media (inflammation of the middle ear) in children
- acute ankle sprain
- acute trauma
- amoebiasis and giardiasis (gastrointestinal conditions caused by parasites)
- ankylosing spondylitis
- boils and pyoderma (types of skin infections)
- Broca’s aphasia in people who have had a stroke
- bronchitis
- cholera
- cough
- chronic polyarthritis
- dystocia (difficult labour)
- eczema
- heroin addiction
- knee joint haematoma (bruising)
- lower back pain
- nausea and vomiting associated with chemotherapy
- oral lichen planus
- osteoarthritis
- proctocolitis

For each condition, only one study that compared homeopathy with placebo was found, and this study was unreliable. It was either poor quality (poorly designed or poorly done) or unknown quality, or it had too few participants to give a meaningful result, or both.

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# Standing committee of European doctors (CPME)



- Medicinsko zdravljenje je utemeljeno na znanstvenih podlagah anatomije in fiziologije človekovega telesa in na patofiziologiji bolezni.
- Zdravniki se pri zdravljenj lahko sklicujemo in ga utemeljujemo le na klinično preverjenih procedurah.
- Zdravila, ki jih uporabljajo pri ljudeh, morajo temeljiti na izsledkih intenzivnih študij o učinkovitosti in varnosti.
- Sredstva, ki so na nacionalni ravni namenjena zdravstvu, se ne smejo uporabljati za takoimenovano komplementarno in alternativno zdravljanje.





# Placebo učinek



- Znanstveno je dokazano, da ima sam terapevtski odnos, oziroma proces moč zdravljenja tudi, kadar sploh ne uporabljamo učinkovitih zdravil.
- Ta fenomen imenujemo placebo učinek.
- Placebo efekt lahko razumemo tudi kot učinek oskrbe. Oskrba je del klasične medicinske obravnave in jo uporabljajo tudi pri CAM. Vemo da placebo učinek nima močne, izrazite jakosti zdravljenja. V mnogih študijah se je pokazal kot šibek in časovno prehoden.

# Ranljive skupine



- Pri morebitni rabi alternativnih pristopov je potrebno izpostaviti še nekatere skupine bolnikov, pri katerih nerazumevanje razlik med alternativno in konvencionalno medicino lahko ogroža življenje.
- Te skupine so: bolniki z rakom, bolniki z duševnimi boleznimi, bolniki s kroničnimi boleznimi in otroci.
- Bolniki morajo biti vedno obveščeni o negativnih učinkih prekinitve medicinskega zdravljenja in vpliva nadomestitve z drugimi metodami, ki niso bile dokazane kot učinkovite.

# Zaključek



- Naše delo mora temeljiti na znanstvenih dokazih in preverljivih metodah zdravljenja.