

Ouderen in klinische studies: ervaringen uit het Instituut voor Evidence-based Medicine bij ouderen | IEMO

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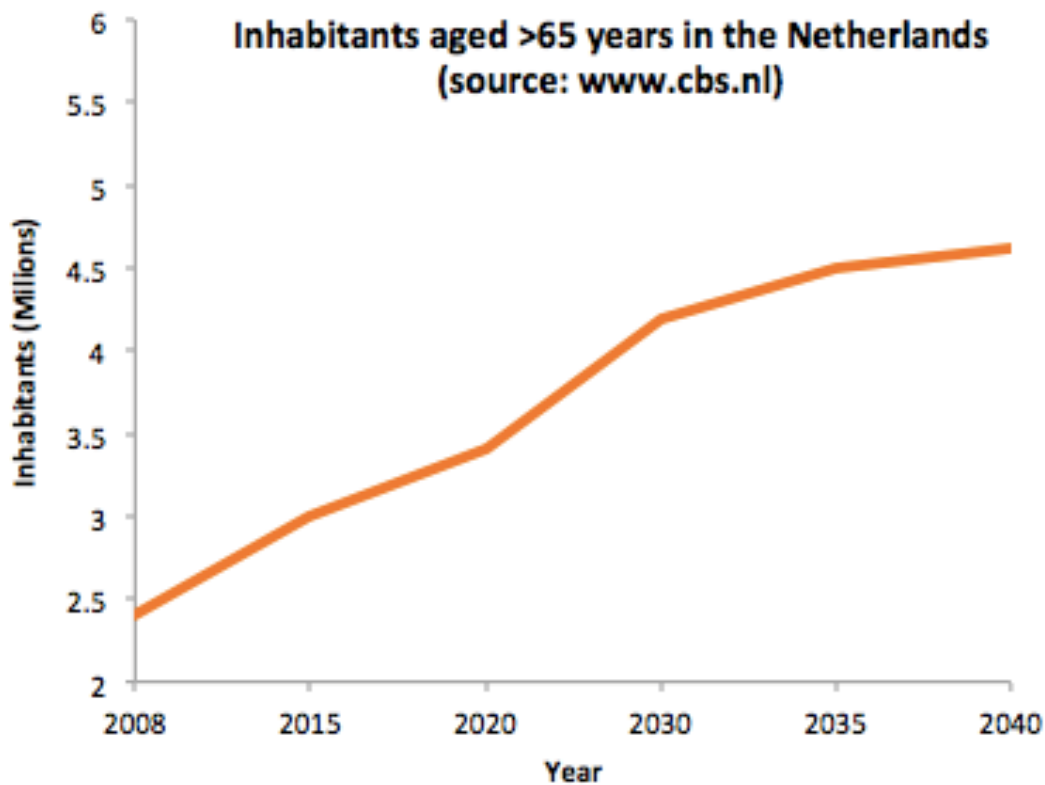


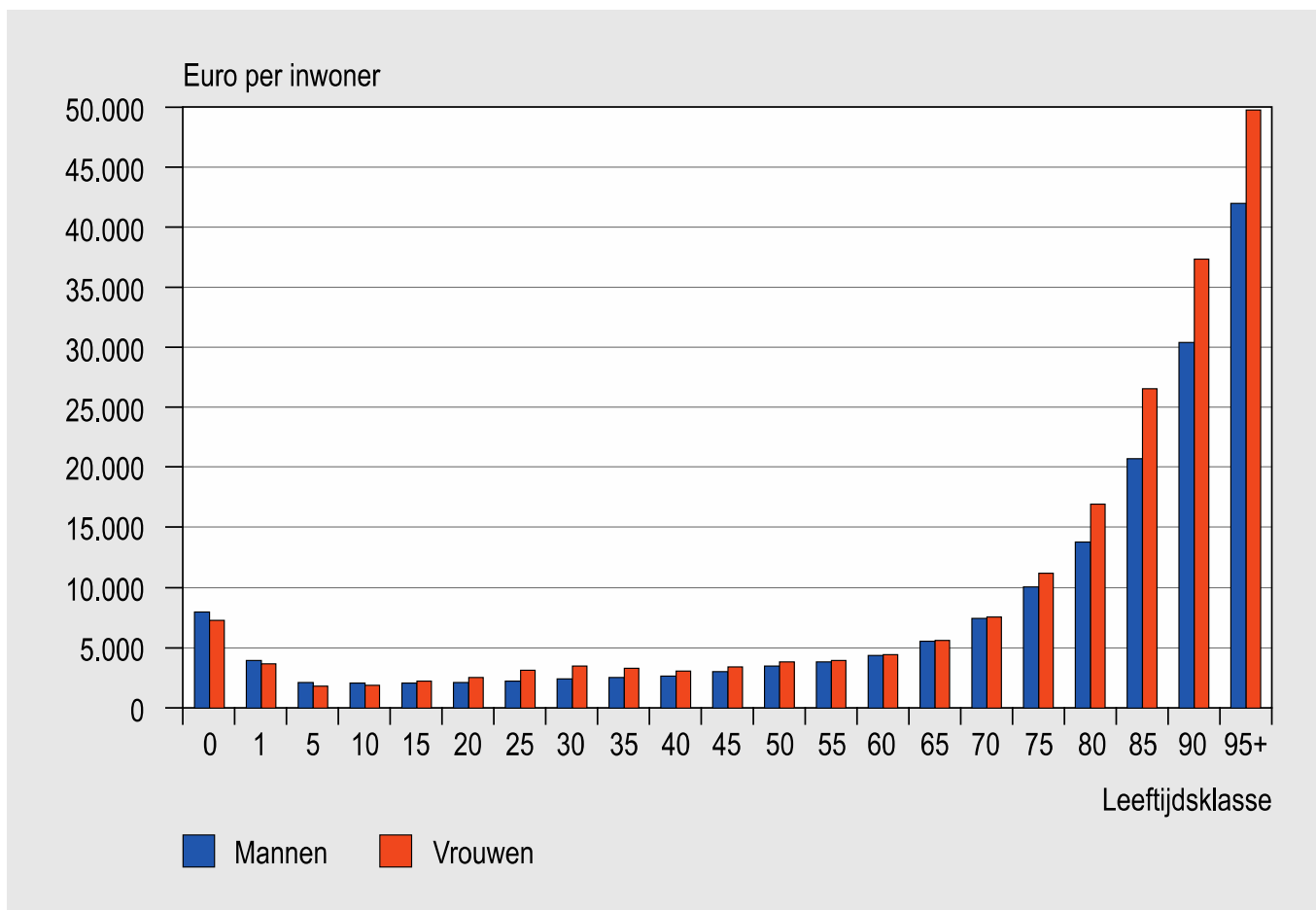
GGG SYMPOSIUM, 7 APRIL 2016

Indeling:

- Evidence-based medicine voor ouderen, waar gaat het fout?
- Lopende projecten in het Instituut voor EBM bij Ouderen
- Conclusies?

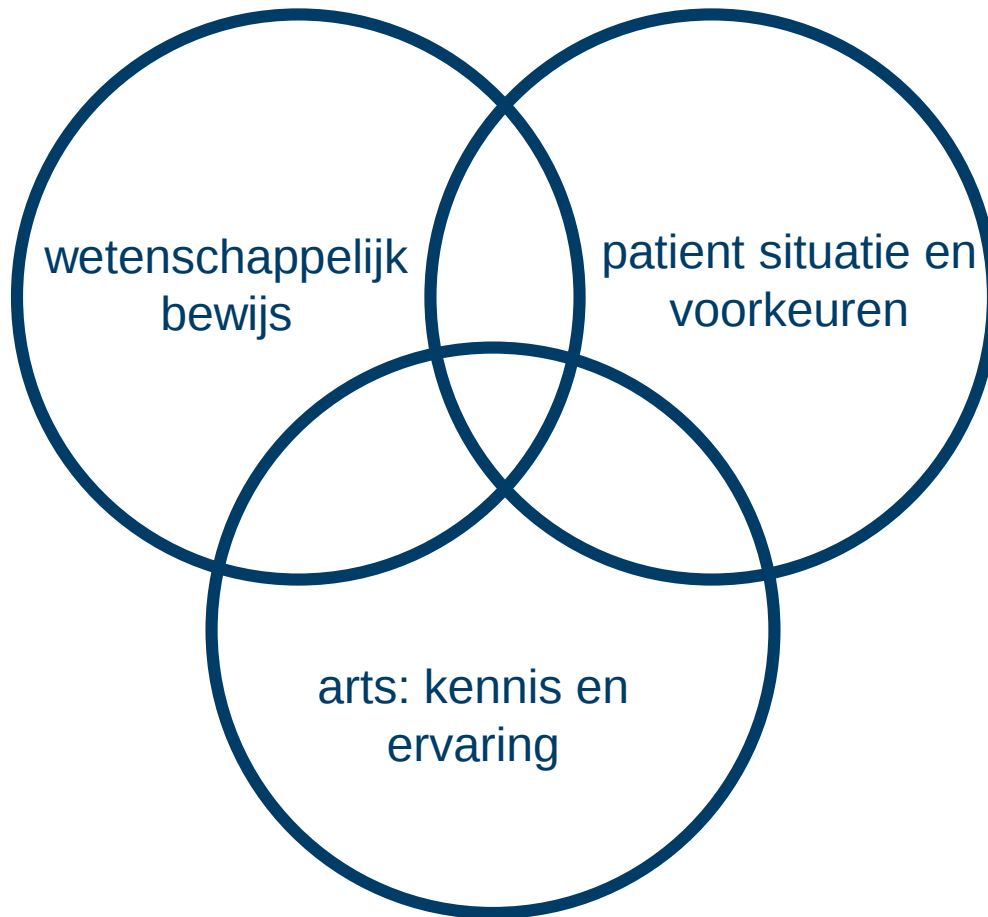
Inleiding





Figuur 1: Gemiddelde zorgkosten per inwoner van Nederland in 2005, naar leeftijd en geslacht. (Bron: Poos et al., 2008.)

wat is EBM?



The NEW ENGLAND JOURNAL of MEDICINE

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THIS WEEK AT NEJM.ORG

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- 1385 Vitamin D and Prevention of Cancer — Ready for Prime Time? J.E. Manson, S.T. Mayne, and S.K. Clinton
- 1387 Defining Safe Use of Anesthesia in Children B. Rappaport and Others
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CLINICAL PRACTICE

- 1441 Latent Tuberculosis Infection in the United States C.R. Horsburgh, Jr., and E.J. Rubin

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CORRECTIONS

NOTICES

CONTINUING MEDICAL EDUCATION



KEVALIDATIE

Richtlijn

voor de revalidatiegeneeskundige
behandeling van mensen met hereditaire
motorische en sensorische neuropathie

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Beleef 3

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Beleef 4

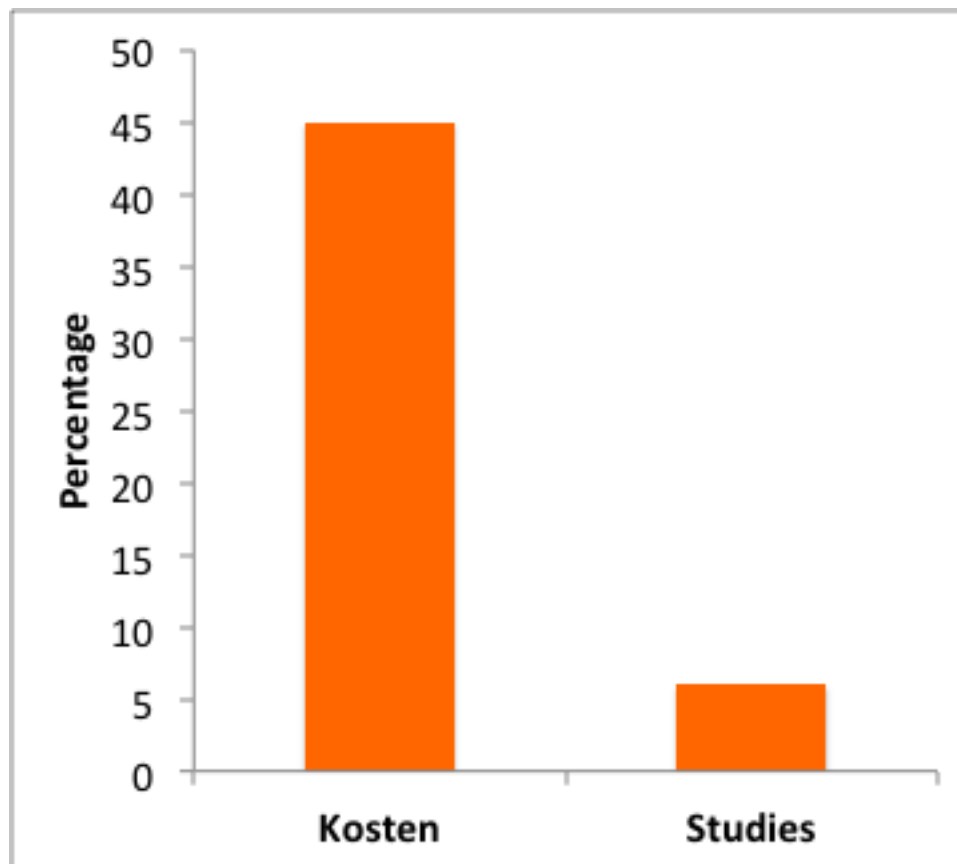
Auteurs 21

Beleef 5

Algemene documentatie 22

HMSN

De richtlijn is een samenvatting van de Nederlandse Revalidatie Richtlijn (NRR), een
document dat ontwikkeld is door de Nederlandse Vereniging van Revalidatieartsen
(NVR) en de Nederlandse Vereniging van Revalidatieartsen (NVR).



Broekhuizen, PLoS ONE, 2015

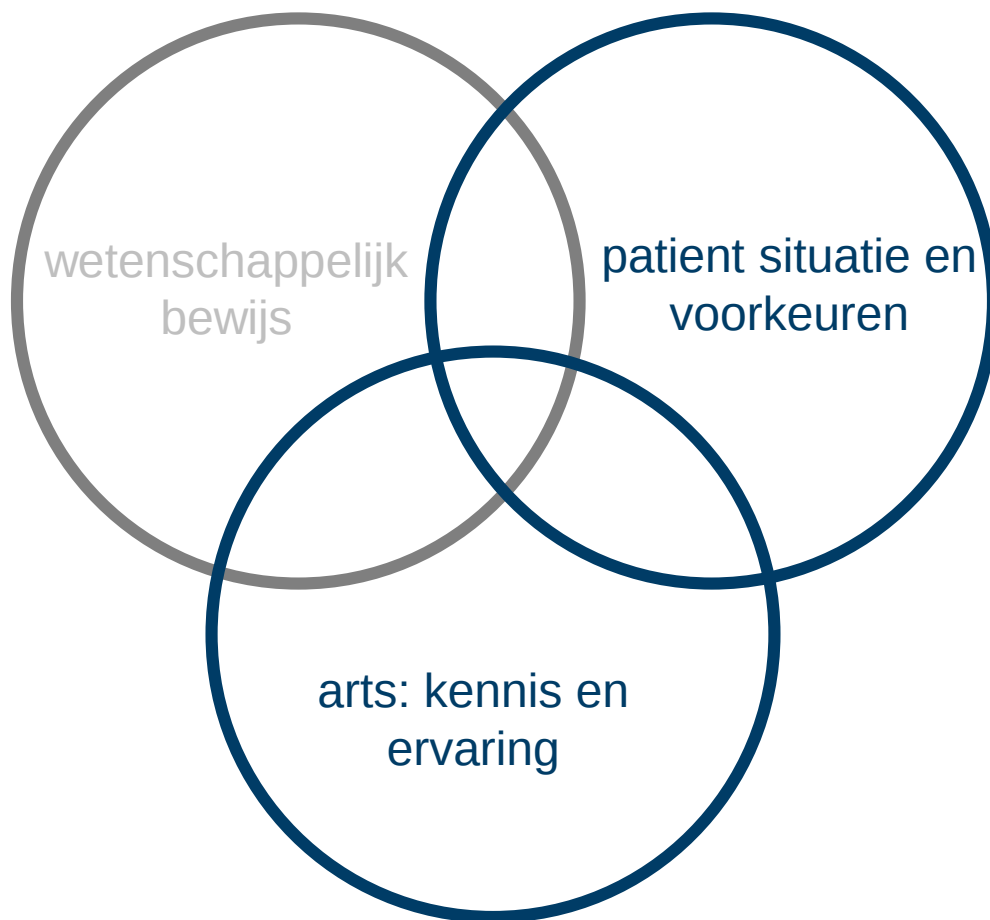
Trials



Treatment



wat is EBM?







*"Het verbeteren
van de
gezondheidszorg
voor ouderen,
door die
wetenschappelijk
te onderbouwen"*



Doel 1

Het vergroten van het aantal oudere deelnemers aan klinische trials

Doel 2

Het innoveren van zowel gezondheidszorg als klinische trials op hoge leeftijd, door gebruik te maken van moderne technologie en door de ontwikkeling van nieuwe methodologie

Doel 3

Het vergroten van kennis van artsen over *evidence-based medicine* bij ouderen

Doel 1: aantal oudere deelnemers aan klinische trials



IEMO Thyroid Trial



Doel 1: aantal oudere deelnemers aan klinische trials

IEMO 80+ Schildklier Studie

Subklinische Hypothyreoidie bij ouderen:

- Strikt biochemische diagnose
- Vaak per toeval gevonden
- Consequenties onduidelijk
- Klinisch dilemma

Doel 1: aantal oudere deelnemers aan klinische trials

Thyroid hormone replacement for subclinical hypothyroidism (Review)

Villar HCCE, Saconato H, Valente O, Atallah AN



- 2013 ETA guideline: management of subclinical hypothyroidism
- 2012: Richtlijn schildklierfunctiestoornissen
- 2010: Rodondi, JAMA, systematic review
- 2004: Gussekloo, JAMA.

AUTHORS' CONCLUSIONS

Implications for practice

Our systematic review could not demonstrate improved survival or reduced cardiovascular morbidity following levothyroxine replacement therapy for asymptomatic subclinical hypothyroidism. Data on health-related quality of life and symptoms did not demonstrate significant differences between intervention groups. Some evidence indicates that levothyroxine replacement improves some parameters of lipid profiles and left ventricular function. Until better data are available, clinical judgment and patients' preferences remain the best manner to decide.

Implications for research

Further controlled, randomised studies in larger groups are necessary. These studies should analyse subgroups with and without previous thyroid disease, initial TSH levels greater than 10 mIU/L or not and with a longer follow up to assess cardiovascular events. In addition, these RCTs should use the Consort statement as a model for reporting RCTs and if possible, report changes from baseline with standard deviation for continuous measures, and number of events and total patients analysed for dichotomous measures. These studies should also analyse patients older than 85 years of age whose safety might be compromised with thyroid hormone replacement.

Doel 1: aantal oudere deelnemers aan klinische trials

Deelnemers:

145 deelnemers van 80 jaar of ouder met minimaal 2x in 3 jaar subklinische hypothyreoidie

Behandeling:

RCT: levothyroxine vs placebo, volgens klinische richtlijnen,

Uitkomsten:

- Cardiovasculaire eindpunten
- Schildklier specifieke kwaliteit van leven (ThyPRO questionnaire)
- Cognitie
- ADL
- Biochemisch (biobank)

Doel 1: aantal oudere deelnemers aan klinische trials

Ervaringen:

- ook oudste ouderen willen aan onderzoek meedoen!
- speciale maatregelen om ouderen te includeren en behouden
- trial design: determinanten en eindpunten relevant voor ouderen

Moeilijkheden:

- Regelgeving
 - Wilsonbekwaamheid, nee tenzij
 - Kwetsbare groep -> CME, CCMO, IGZ
 - Medicatie-trial
 - Monitoring
- Organisatie
 - Landelijke huisbezoeken
 - Afhankelijk laboratoria en huisartsen
- Biochemisch
 - Normalisatie
 - Al onder behandeling

Doel 2: innovatie in gezondheidszorg & trials



Samenwerking tussen:

LUMC

AMC

Erasmus MC

Maastricht University

UMCN St. Radboud

TNO

NIVEL

Doel 2: innovatie in gezondheidszorg & trials



Radboud Universiteit



TNO innovation
for life

Doel 2: innovatie in gezondheidszorg & trials

TrIP – 4 werk pakketten

1. Gebruikswensen → Interviews en focusgroep

van Osch et al. Patient Preference and Adherence 2015:9 857-867

2. Nieuwe methodologie → Regression discontinuity

van Leeuwen et al. Epidemiology 2016

3. iVitality Proof-of-Principle Study

Gebruik smartphone-app voor het meten van gezondheidskarakteristieken in kinderen van patiënten met dementie.

- n=150 (>50 jaar), 6 maanden follow-up

- bloeddruk metingen, cognitie, fysieke activiteit, lifestyle

→ artikel in press

4. Interventiestudie → TELEHYPE studie

internet ondersteuning bij instellen bloeddruk bij hypertensie patiënten

- Ongoing

Doel 2: innovatie in gezondheidszorg & trials

Moeilijkheden:

- nieuwe methodologie wordt niet makkelijk geaccepteerd
- afhankelijkheid van technologische partners
 - Bijv. Ontwikkelen app

Doel 3: Het vergroten van EBM-kennis

Onderwijs aan artsen en wetenschappers:

- papers
- animaties
- e-Learning

Doel 3: Het vergroten van EBM-kennis

WWW.IEMO.NL

HOME

PROJECTEN

PUBLICATIES

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NL | EN



Instituut voor Evidence-Based Medicine voor Ouderen

Welkom bij IEMO

Het Instituut voor Evidence-Based Medicine voor Ouderen | IEMO heeft als doel om de kwaliteit van de gezondheidszorg voor ouderen te verhogen, door hun behandeling wetenschappelijk te onderbouwen.

Het IEMO bereikt haar doel door het initiëren en coördineren van klinische trials waarin meer representatieve ouderen deelnemen. Bovendien innoveert het IEMO het klinische onderzoek bij ouderen door de inzet van moderne technologie en door het ontwikkelen van nieuwe methodologie om zulke studies uit te voeren.

Het instituut is opgezet als samenwerking van de Nederlandse Universitaire Medische Centra en andere organisaties in de gezondheidszorg.

NIEUWS

[Nieuwe IEMO animatie: de oudere patiënt](#)

03-01-2016

Animatie is eerste uit serie.

[IEMO opent onderwijs site](#)

06-09-2015

Regelmatig nieuwe publicaties

[Onderzoekslatform iVitality: preventie van dementie](#)

01-07-2015

[Nieuwsoverzicht](#)

Doel 3: Het vergroten van EBM-kennis

The Netherlands Journal of Medicine

REVIEW

Evidence-based medicine in older patients: how can we do better?

S.P. Mooijaart^{1,2*}, K. Broekhuizen^{1,3}, S. Trompet¹, A.J.M. de Craen¹, J. Gussekloo¹, A. Oleksik¹, D. van Heemst¹, G.J. Blauw¹, M. Muller¹

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ABSTRACT

Evidence-based medicine (EBM) aims to integrate three elements in patient care: the patient situation, scientific evidence, and the doctors' expertise. This review aims 1) to assess how these elements are systematically different in older patients and 2) to propose strategies how to improve EBM in older patients.

The ageing process systematically affects all three elements that constitute EBM. First, ageing changes the physiology of the older body, makes the patient more vulnerable with more multimorbidity and polypharmacy and affects somatic, psychological and social function. The heterogeneity of older patients may lead to overtreatment of vulnerable and undertreatment of fit older patients. Second, representative older patients are underrepresented in clinical studies and endpoints studied may not reflect the specific needs of older patients. Third, adequate clinical tools and schooling are lacking to aid physicians in clinical decision-making. Strategies to improve elements of EBM include: first systematically acknowledging that physical, mental and social function may reveal patients' vulnerability and specific treatment goals. Second, clinical studies specifically targeting more representative older patients and studying endpoints relevant to older patients are warranted. Finally, teaching of physicians may increase their experience and expertise in treating older patients. In conclusion, in older patients the same elements constitute EBM, but the elements need tailoring to the older patient. In the clinic, a thorough assessment of individual patient preferences and physical, mental and social functioning in combination with increased level of experience of the doctor can increase the quality of EBM in older patients.

KEYWORDS

Ageing, elderly, evidence-based medicine, clinical studies, randomized controlled trials

INTRODUCTION

Older people are becoming a more prominent proportion of modern Western societies, both in absolute and relative terms. This is the result of increasing life expectancy, decreasing fecundity rates, and specific changes in population demographics, such as the baby boom after the Second World War. In Europe the number of inhabitants aged 65 years is 88 million (17% of total population) today and is projected to increase to 157 million (30%) in 2060 (Eurostat Statistics). As a result, a sharp increase in health care demand by older people is foreseen in the near future, which will affect nearly all domains of medicine.¹

Evidence-based medicine (EBM) is the hallmark of modern medicine and aims to integrate the individual patient's situation, scientific evidence and the physician's experience and expertise in the process of clinical decision-making.² This review aims 1) to assess how the elements that constitute EBM are systematically different in older patients and how these differences affect the degree of EBM in older patients and 2) to propose strategies how to improve EBM in older patients.

CURRENT SITUATION

To come to strategies to improve EBM for older patients, we will first define the components of EBM. Then we explore



RESEARCH ARTICLE

Characteristics of Randomized Controlled Trials Designed for Elderly: A Systematic Review

Karen Broekhuizen^{1,2}, Axel Pothof¹, Anton J. M. de Craen¹, Simon P. Mooijaart^{1,2*}

¹ Department of Gerontology and Geriatrics, Leiden University Medical Center, Leiden, Netherlands, ² Institute for Evidence-Based Medicine in Old Age, IEMO, Leiden, Netherlands

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Abstract

Objectives

To quantify the proportion of randomized controlled trials (RCTs) specifically designed for elderly, and to assess their characteristics, as compared to RCTs not specifically designed for elderly.

Design

Review and synthesis of published literature.

Measurements

We searched PubMed for articles published in the year 2012. We included RCTs. Articles were excluded if not conducted with human subjects or if findings of secondary analyses were reported. A random sample of 10% was drawn and of this selection the following trial characteristics were extracted: sample size, disease category, age of sample, and age-related inclusion criteria. Clinical trials were defined to be specifically designed for elderly if a lower age cut-off of ≥ 55 years was used, or when participants had an average age of ≥ 70 years.

Results

The search strategy yielded 26,740 articles, from which a random sample was drawn, resulting in 2375 articles. After exclusion, data was extracted from 1369 publications. Of these 1369 RCTs, 96 (7%) were specifically designed for elderly. In comparison with trials not designed for older adults, trials designed for elderly contained a significantly larger median number of participants (125 vs. 80, $p = 0.008$) significantly more trials designed for elderly fell into the disease categories eye (6% vs. 2%, $p = 0.005$), musculoskeletal (13% vs. 7%, $p = 0.023$) and circulatory system (16% vs. 9%, $p = 0.039$). No significant difference was observed with regard to the other disease categories.

OPEN ACCESS

Citation: Broekhuizen K, Pothof A, de Craen AJM, Mooijaart SP (2015) Characteristics of Randomized Controlled Trials Designed for Elderly: A Systematic Review. PLoS ONE 10(5): e0126709. doi:10.1371/journal.pone.0126709

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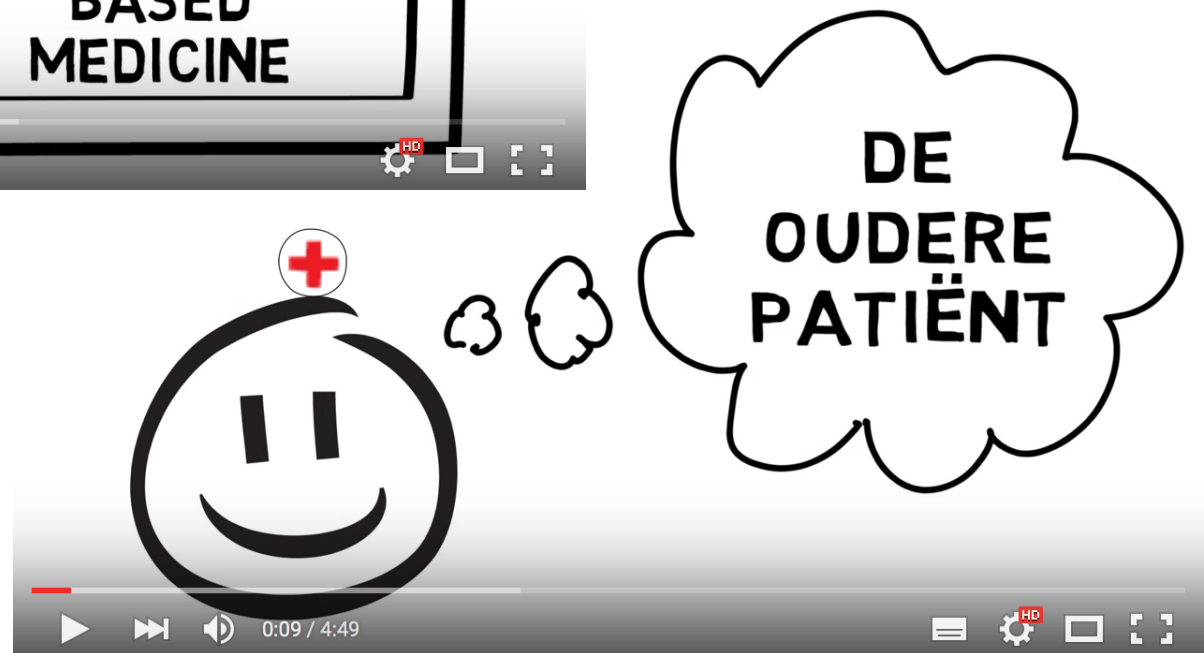
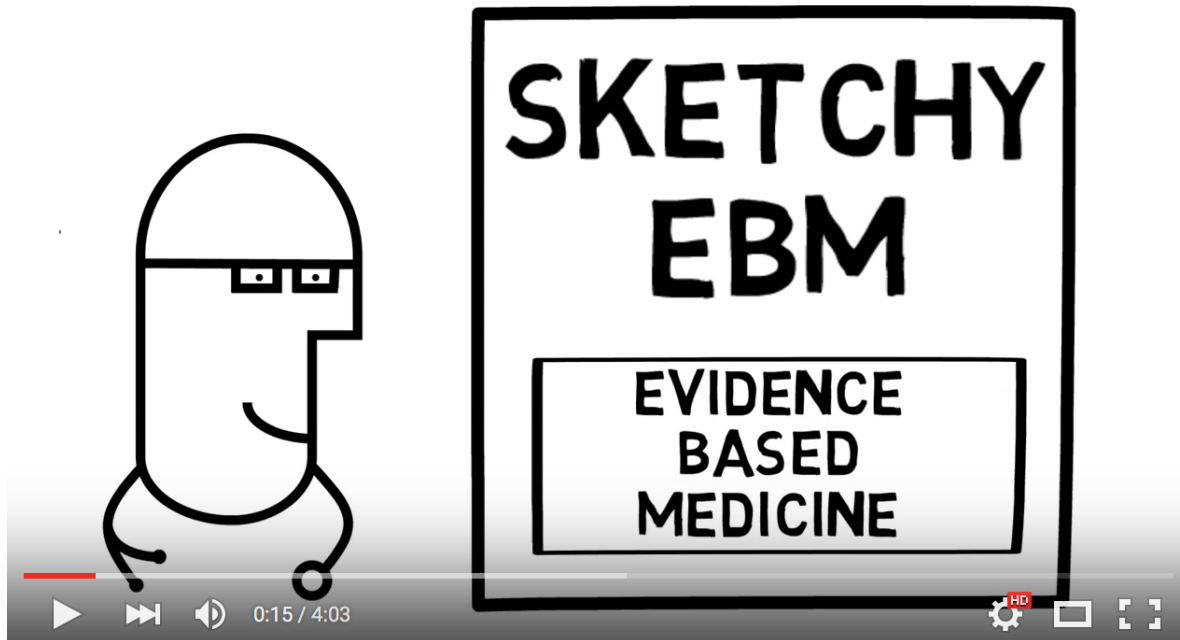
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Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

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

Doel 3: Het vergroten van EBM-kennis



Conclusies

Ouderen ondervertegenwoordigd in klinische studies:

- Te weinig studies richten zich specifiek op ouderen
- Als er al ouderen in studies zitten zijn het er te weinig
- Niet goed gekarakteriseerd
- Investigator driven medicatie-studies zijn haalbaar, maar lastig.
- Nieuwe methodologie en onderzoeksmethoden kunnen helpen bij toekomstig onderzoek
- Veel mogelijkheden voor onderzoek daar waar ouderen toch wel komen: in de kliniek (huisarts, ziekenhuis)

Vragen?

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