



Corso: La Ricerca Bibliografica Biomedica con PubMed

La qualità delle pubblicazioni scientifiche



L'organizzazione della documentazione

La piramide delle 6 S



(da Haynes 2007 Di Censo et al, 2009)

Sistemi (Linee guida)

- Indicazioni sviluppate sistematicamente per assistere le decisioni di operatori di sanità pubblica su interventi appropriati per specifici problemi di salute e destinatari
- raccomandazioni per la pratica clinica e le politiche sanitarie
- la loro base scientifica è rappresentata dalle revisioni sistematiche e dalle meta-analisi
- devono indicare la consistenza delle evidenze a supporto di una raccomandazione e la stima del relativo impatto sulla pratica clinica e la politica se tale raccomandazione è implementata

Come si valuta la qualità di una linea guida?

AGREE II

APPRAISAL OF GUIDELINES
FOR RESEARCH & EVALUATION II



AGREE II

Checklist per Valutare la Qualità delle Linee Guida

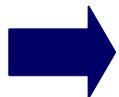
The AGREE Next Steps Consortium

Maggio 2009

Versione italiana a cura della Fondazione Gimbe

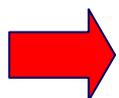
dors

Dimensione 1: Obiettivi e ambiti di applicazione



1. Gli obiettivi generali della linea guida sono descritti in modo specifico
2. I quesiti sanitari trattati dalla linea guida sono descritti in modo specifico
3. La popolazione target (pazienti, cittadini, etc.) a cui applicare la linea guida è descritta in modo specifico

Dimensione 2: Coinvolgimento dei soggetti portatori di interesse (stakeholder)



4. Il gruppo che ha elaborato la linea guida include tutte le categorie professionali rilevanti
5. Sono stati presi in considerazione i punti di vista e le preferenze della popolazione target (pazienti, cittadini, etc.)
6. La linea guida identifica con chiarezza gli utenti target

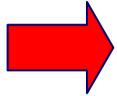
Dimensione 3: Rigore metodologico

7. Sono stati utilizzati metodi sistematici per ricercare le evidenze scientifiche
8. La linea guida descrive con chiarezza i criteri utilizzati per selezionare le evidenze scientifiche
9. La linea guida descrive con chiarezza i punti di forza e i limiti delle evidenze scientifiche
10. La linea guida descrive con chiarezza i metodi utilizzati per formulare le raccomandazioni
11. Nella formulazione delle raccomandazioni sono stati presi in considerazione benefici e rischi conseguenti alla loro applicazione
12. Esiste un legame esplicito tra le raccomandazioni e le evidenze scientifiche che le supportano
13. Prima della pubblicazione la linea guida è stata valutata da esperti esterni
14. È descritta la procedura per l'aggiornamento della linea guida



Dimensione 4: Chiarezza espositiva

15. Le raccomandazioni sono specifiche e non ambigue

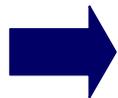


16. La linea guida descrive con chiarezza le diverse opzioni per gestire la condizione clinica o la problematica sanitaria

17. Le raccomandazioni principali sono facilmente identificabili

Dimensione 5: Applicabilità

18. La linea guida descrive i fattori facilitanti e gli ostacoli per l'applicazione delle raccomandazioni

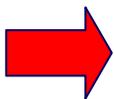


19. La linea guida fornisce suggerimenti e/o strumenti per facilitare l'applicazione delle raccomandazioni

20. Sono state considerate le potenziali implicazioni sulle risorse conseguenti all'applicazione delle raccomandazioni

21. La linea guida fornisce gli indicatori per il suo monitoraggio (audit)

Dimensione 6: Indipendenza editoriale



22. I contenuti della linea guida non sono stati influenzati dagli eventuali sponsor istituzionali o commerciali
23. Gli eventuali conflitti di interesse dei componenti del gruppo che ha elaborato la linea guida sono stati esplicitamente dichiarati e adeguatamente governati

SUMMARIES

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• sono compendi che integrano l'evidenza proveniente da diverse fonti (revisioni sistematiche, studi primari, linee guida), allo scopo di fornire informazioni pratiche per gestire un determinato problema di salute.

- Clinical evidence
- Up to date
- Dynamed



Ambito prettamente clinico
Risorse a pagamento
Compendi point of care

Banzi R, Liberati A, Moschetti I, Tagliabue L, Moja L. A review of online evidence-based practical point of care information summary providers. Journal of Internet medical research 2010; 12 (3): e26

<http://www.jmir.org/2010/3/e26/>

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Diabetes mellitus type 2

Top

- Related Summaries
- General Information
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- Patient Information
- ICD-9/ICD-10 Codes
- References

Send Comment to Editor

Prevention:

- DynaMed commentary*-- not established that prevention (or prethreshold treatment) of diabetes delays or prevents complications, compared with treatment once diabetes is diagnosed, so all prevention studies are (level 3 [lacking direct] evidence) unless reporting additional outcomes such as adverse effects or cardiovascular outcomes
- for patients with prediabetes
 - lifestyle interventions (diet, activity, weight loss) are first-line treatment
 - structured lifestyle-change programs recommended emphasizing dietary changes (including reduced intake of calories and fat), regular physical activity at least 150 minutes/week and 7% weight loss (ADA Grade A for patients with impaired glucose tolerance, ADA Grade E for patients with impaired fasting glucose or HbA1c 5.7%-6.4%)
 - lifestyle interventions reduce rate of progression to type 2 diabetes (level 3 [lacking direct] evidence) and may reduce weight (level 2 [mid-level] evidence)
 - metformin (Glucophage)
 - consider metformin for patients with impaired glucose tolerance (ADA Grade A) or, impaired fasting glucose or HbA1c 5.7%-6.4% (ADA Grade E), especially if body mass index > 35 mg/m², age < 60 years, or history of gestational diabetes mellitus (ADA Grade A)
 - metformin 850 mg orally twice daily may reduce incidence of new-onset diabetes but less effective than lifestyle changes (level 3 [lacking direct] evidence) and may reduce body mass index (level 2 [mid-level] evidence)
 - other interventions shown to reduce progression to diabetes in patients with prediabetes
 - pioglitazone (Actos) 30-45 mg orally once daily (level 3 [lacking direct] evidence)
 - alpha-glucosidase inhibitors (acarbose, voglibose) (level 3 [lacking direct] evidence); acarbose might reduce incidence of myocardial infarction (NNT 50) (level 2 [mid-level] evidence)
 - orlistat (Xenical) 120 mg 3 times daily (level 3 [lacking direct] evidence)
- dietary factors associated with reduced risk for diabetes (level 3 [lacking direct] evidence)
 - increased intake of selected food groups - whole grains, nuts, dairy, fruits, and vegetables
 - light-to-moderate alcohol consumption
 - coffee or tea consumption
- increased physical activity associated with reduced risk for diabetes (level 3 [lacking direct] evidence)
- angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) may reduce risk for new-onset diabetes (level 3 [lacking direct] evidence)

SINOSI

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sono “brevi rapporti (1-2 pagine) di revisioni sistematiche e di singoli studi” che hanno avuto una valutazione critica (critical appraisal). Idealmente, descrivono il quesito di ricerca, la popolazione in studio, gli esiti e le misure di effetto o altri risultati che concorrono alla costruzione dell’evidenza.

Nelle sinossi sono forniti elementi di metodologia della revisione / studio, i risultati più rilevanti, un commento esperto sulla applicabilità e la trasferibilità dei risultati alla pratica

Da Evidence Based Nursing

TREATMENT

117

A care management intervention improved depression after stroke

Williams LS, Kroenke K, Bakas T, *et al*. Care management of poststroke depression: a randomized, controlled trial. *Stroke* 2007;**38**:998–1003.

Q In patients with depression after stroke, does a care management intervention improve depression outcomes more than usual care?

METHODS



Design: randomised controlled trial.



Allocation: concealed.



Blinding: blinded (outcome assessor).



Follow-up period: 12 weeks.



Setting: 4 hospitals in Indianapolis, Indiana, USA.



Patients: 188 patients ≥ 18 years of age (mean age 60 y, 54% women) who had major (74%) or minor (26%) depression after ischaemic stroke (patients were identified at the time of stroke and screened for depression 1–2 mo later), no severe language or cognitive impairment, and a life expectancy ≥ 6 months. Exclusion criteria included active psychosis, suicidality, substance abuse, use of a monoamine oxidase inhibitor, and pregnancy.



Intervention: the “Activate–Initiate–Monitor” care management intervention (n = 94) or usual care (n = 94). The intervention, conducted by nurse care managers, consisted of activation (a 20-min psychoeducational session with patients and their families to help them understand and accept the depression diagnosis and treatment), initiation (recommendation of an antidepressant medication based on an evidence-based algorithm), and monitoring (bimonthly telephone calls to assess symptoms, side effects, and adherence, with adjustment of dose or type of medication as indicated). Patients in the usual care group received similar contact with the study nurse but without reference to depression; they were allowed to take antidepressant medication if prescribed by their physician (56% did so at some time during the study).



Outcomes: depression response (Hamilton Depression Inventory [HAM-D] score < 8 or reduced by $\geq 50\%$), depression remission (HAM-D score < 8 or Patient Health Questionnaire depression scale score < 5), and change in depression severity.

MAIN RESULTS

Depression response and remission occurred more frequently in the intervention group than in the usual care group (table). Mean depression severity decreased in both groups over the course of the study, but the improvement was greater in the intervention group at both 6 and 12 weeks.

CONCLUSION

In patients with depression after stroke, the “Activate–Initiate–Monitor” care management intervention improved depression outcomes more than usual care.

This abstract also appears in Evidence-Based Medicine.

Commentary

Although depression after stroke contributes to lower stroke recovery rates, previous treatment trials have not been sufficiently rigorous to justify practice recommendations.^{1,2} The study by Williams *et al* provides evidence to support the use of the Activate–Initiate–Monitor intervention to encourage depression remission. The methodology (ie, a large sample size, randomisation to treatment, and blinded outcome assessment) is a major strength of this study. However, the relatively young age of the participants (mean age 60 y) and their lack of cognitive deficits limit the generalisability of the results. Patients with more severe cognitive deficits or physical disabilities related to age may not show substantial responses within 12 weeks of treatment. In addition, the study did not address treatment approaches for patients who are not initially depressed after a stroke but go on to develop late-onset depression.

The most important finding of the study is the effect of the intervention despite the control group receiving the same number of study contacts as the treatment group and 56% of the controls taking antidepressants. The results make clear the importance of the Activate and Monitor stages of the intervention. The key implication of this study for clinical practice is that merely prescribing an antidepressant is not sufficient treatment for depression after stroke. Optimal care management of depression after stroke includes helping patients to recognise depression as an illness in need of treatment and monitoring antidepressant treatment responses and side effects closely so that adjustments can be made as necessary.

SINTESI

Sintesi = combinano, usando una metodologia esplicita e rigorosa, i risultati di singoli studi allo scopo di fornire un unico set di risultati.

Comprendono revisioni sistematiche
(possono includere o meno meta-analisi) e
revisioni non sistematiche

Revisioni Cochrane (Comprese in Pubmed)

Le revisioni tradizionali vs le revisioni sistematiche

CARATTERISTICHE	REVISIONE TRADIZIONALE	REVISIONE SISTEMATICA
Domanda	Ampia	Focalizzata su un unico quesito clinico
Fonti e ricerca	Non specificate	Complete ed esplicita
Selezione	Solitamente non specificata	Basata su criteri specifici
Valutazione critica	Variabile	Rigorosa
Sintesi	Qualitativa	Qualitativa/quantitativa (meta-analisi)

Exercise or exercise and diet for preventing type 2 diabetes mellitus (Review)

Focus su quesiti
specifici



OBJECTIVES

To assess the effects of exercise or exercise and diet for preventing type 2 diabetes mellitus.

Criteria rigorosi di inclusione degli studi

Types of studies

Randomized controlled clinical trials of interventions that followed-up participants for at least six months.

Types of participants

Participants of any age, sex or ethnicity belonging to any of the major risk groups for the development of type 2 diabetes ([ADA 2004b](#)):

- impaired glucose tolerance according to the World Health Organisation criteria ([WHO 1999](#));
- impaired fasting glucose according to the American Diabetes Association criteria ([ADA 2004](#));
- previous gestational diabetes;
- hypertension equal to or greater than 140/90 mmHg;
- family history of type 2 diabetes in first degree relatives;
- obesity (that is a body mass index (BMI) equal or greater than 30 kg/m²);
- dyslipidaemia (that is HDL-cholesterol equal or less than 35 mg/dl, triglycerides equal or more than 250 mg/dl, or both);
- high risk ethnic groups (for example African-Americans, Hispanic-Americans, native Americans, Asian-Americans, Pacific Islanders).

Types of interventions

- exercise versus standard recommendations or no intervention;
- exercise and diet versus standard recommendations or no intervention;
- exercise versus diet.

Trials where the intervention or control group comprised the administration of any pharmacological agent were excluded.

Types of outcome measures

Primary outcomes

- development of type 2 diabetes mellitus (incidence);
- diabetes and cardiovascular related morbidity (for example angina pectoris, myocardial infarction, stroke, peripheral vascular disease, neuropathy, retinopathy, nephropathy, erectile dysfunction, amputation).

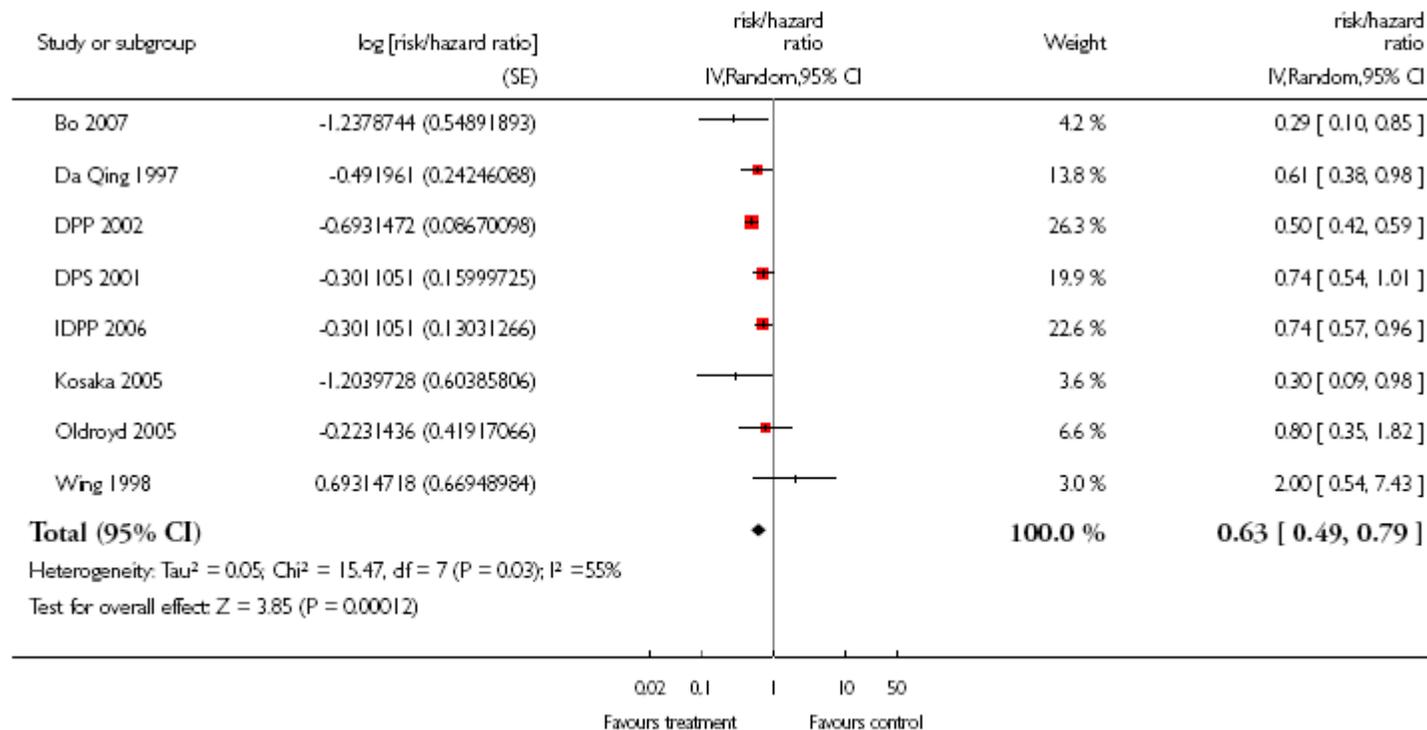
Sintesi quantitativa (meta-analisi)

Analysis 1.1. Comparison 1 Exercise+diet vs standard recommendations (overall analysis), Outcome 1 Diabetes incidence - ITT (RR/HR).

Review: Exercise or exercise and diet for preventing type 2 diabetes mellitus

Comparison: 1 Exercise+diet vs standard recommendations (overall analysis)

Outcome: 1 Diabetes incidence - ITT (RR/HR)



STUDI

Studi = riferiscono alla comunità scientifica i risultati di nuove scoperte.

Osservazionali

Caso-controllo,
Coorte

Sperimentali

Trial clinici con gruppo di controllo (randomizzato e non),

**Quasi
sperimentali**

Prima e dopo con gruppo di controllo
Serie temporali interrotte

In sintesi....

Le fasi di una ricerca bibliografica:

1. Formulazione del quesito di ricerca

2. Ricerca delle evidenze in base al sistema delle 6S, procedendo dall'alto verso il basso

Dove/come si fa? Attraverso l'uso delle banche dati disponibili...

