

Appendices

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Final Version

31 July 2003

1. Guideline title

Obsessive-compulsive disorder: the management of obsessive-compulsive disorder in adults and children in primary and secondary care.

1.1 Shorttitle

Obsessive-compulsive disorder (OCD).

2. Background

- a) The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Mental Health to develop a clinical guideline on the management of anxiety disorders for use in the NHS in England and Wales. This follows referral of the topic of anxiety disorders, by the Department of Health and Welsh Assembly Government (see Appendix). This document provides further detail on the specific issues relating to OCD and is a development of the original scope agreed for the anxiety disorders. The guideline will provide recommendations for good practice that are based on best available evidence of clinical and cost effectiveness.
- b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.

3. Clinical need for the guideline

- a) Obsessive-compulsive disorder (OCD) is a potentially life-long disabling disorder. Diagnostic features include recurrent obsessions or compulsions that are distressing, time-consuming, that interfere with occupational or educational functioning and social activities or relationships.
- b) In the UK, the prevalence of OCD is 1.2% of the adult population between 16-64 years of age, with it affecting a slightly higher proportion of women (1.5%) than men (1.0%). DSM IV estimates a lifetime prevalence of 2.5% and 1-year prevalence of 1.5%-2.1%. The disorder can occur at any age. Because OCD is often a "hidden" disorder, it is neither identified nor reported accurately. Thus, these figures should be viewed as underestimates.
- c) Individuals with OCD and related disorders are currently treated in a range of NHS settings including primary care services; general mental health services and specialist secondary care mental health services. The provision and uptake of such services varies across England and Wales and in part reflects presence or absence of specialist services.

- d) A number of guidelines, consensus statements and local protocols exist. This guideline will review evidence of clinical and cost effective practice, together with current guidelines, and will offer guidance on best practice.

4. The guideline

- a) The guideline development process is described in detail in three booklets that are available from the NICE website (see 'Further information'). The Guideline Development Process – Information for Stakeholders describes how organisations can become involved in the development of a guideline.
- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see Appendix).
- c) The areas that will be addressed by the guideline are described in the following sections.

4.1. Population

4.1.1. Groups that will be covered

The recommendations made in the guideline will cover management of the following groups.

- a) Children and adults who meet the standard diagnostic criteria of obsessive-compulsive disorder and body dysmorphic disorders.

4.1.2. Groups that will not be covered

- a) Although the guidelines will be of relevance to all people with OCD whether or not it is accompanied by other illnesses, it will not address separately or specifically the management of individuals with other physical or psychiatric conditions.

4.2. Healthcare setting

- a) The guideline will cover the care provided in primary and secondary care and that provided by health care professionals who have direct contact with and make decisions concerning the care of patients with OCD.
- b) The guideline will also be relevant to the work of, but will not provide specific recommendations to the following non NHS services. However it will consider the interface between health care services and these services:

- Social services
- Voluntary sector
- Education

4.3. Clinical management – areas that will be covered

The guideline will cover the following areas of clinical practice:

- a) The full range of care routinely made available by the NHS with regard to OCD.
- b) Clarification and confirmation of diagnostic criteria currently in use and therefore the diagnostic factors that trigger the use of this guideline and assessment and instruments that might be used in this process. The definition of the condition in relation to other anxiety disorders will be precise.
- c) Pathways to treatment.

- d) Psychological interventions including type, format, frequency, duration and intensity. This will include computerised cognitive behaviour therapy (CCBT).
- e) Pharmacological treatments including type, dose and duration. When referring to pharmacological treatments, normally guidelines will recommend within the licence indications. However, where the evidence clearly supports it, recommendations for use outside the licence indications may be made in exceptional circumstances. It is the responsibility of prescribers to be aware of circumstances where medication is contra-indicated. The guideline will assume that prescribers are familiar with the side-effect profile and contraindications of medication they prescribe for patients with depression. The guideline will consider the side effects, toxicity and other disadvantages of treatments.
- f) Appropriate use of combined pharmacological and psychological interventions.
- g) Psychosurgery and deep brain stimulation.
- h) Self-care.
- i) Sensitivity to cross-cultural and religious factors.
- j) The role of the family in the treatment and support of patients.

a. Clinical management - areas that will not be covered

The guideline will not cover treatments that are not normally available on the NHS.

b. Audit support within the guideline

The guideline will include review criteria for audit, for key recommendation, which will enable objective measurements to be made of the extent and nature of local implementation of this guidance, particularly its impact upon practice and outcomes for people with OCD.

c. Status

i. Scope

This is the final version of the scope. It has been derived from the scope on generalised Anxiety which formerly included OCD and which was subject to a 4-week period of consultation with stakeholders and review by the Guidelines Advisory Committee. As a result of that consultation, a decision was taken to prepare a separate guideline for OCD and this separate scope was drafted and submitted to the Institute's Guideline Programme Director and Executive Lead for approval.

ii. Guideline

The development of the guideline will begin in June 2003.

b) Further information

Information on the guideline development process is provided in:

- *The Guideline Development Process – Information for the Public and the NHS*
- *The Guideline Development Process – Information for Stakeholders*
- *The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups.*

Appendix – Referral from the Department of Health and Welsh Assembly Government

The Department of Health and Welsh Assembly Government asked the Institute:

“To prepare a clinical guideline and audit tool for the NHS in England and Wales for ‘talking’ therapies, drug treatments and prescribing for anxiety and related common mental disorders, including generalised anxiety disorder (GAD), panic disorder (with or without agoraphobia), post-traumatic stress disorder, and obsessive-compulsive disorder (OCD). The audit tool should include a dataset, database and audit methodology.”

Appendix 2: Stakeholders who responded to early requests for evidence

Amicus

British Association of Behavioural and Cognitive Psychotherapy

CIS'ters

College of Occupational Therapy

Cyberonics

Eating Disorders Association

Inner Cities Mental Health Group

National Phobics Society

Pfizer

Royal College of Nursing

Solvay Healthcare Ltd.

Wyeth

Appendix 3: Stakeholders and experts who responded to the first consultation draft of the guideline

Appendix 4: Researchers contacted to request information about unpublished or soon-to-be published studies

Jonathan Abramowitz
Margaret Altemus
Jambur Ananth
Martin M. Antony
Lee Baer
Donald Black
Pierre Blier
Martine Bouvard
Alexander Bystritsky
Maria Lynn Buttolph
Daniel Albert Geller
Cheryl Carmin
Diane L. Chambless
David A. Clark
Edwin H. Cook Jr.
Jean Cottraux
Jonathan Robert Davidson
Pedro Delgado
Paul M.G. Emmelkamp
Brian A. Fallon
Martine Flament
Edna Foa
Martin Franklin
Randy Frost
Tim M. Gale
Daniel Geller
Wayne K. Goodman
Tana A. Grady-Weliky
Benjamin D. Greenberg
John H. Greist
Gregory L. Hanna
Jeffrey E. Hecker
William Hewlett
Eric Hollander
Jonathan D. Huppert
Bruce M. Hyman
James W. Jefferson
Michael A. Jenike
David J. Katzelnick
Suck Won Kim
Lorrin M Koran
Michael J. Kozak
James F. Leckman
Henrietta Leonard
Charles Mansueto
Isaac Marks
Arturo Marrero
Christopher McDougle
Richard J. McNally
Fugen A. Neziroglu
Michele Pato
Maggie Pekar
Frederick Penzel
Katharine A. Phillips
Teresa A. Pigott
Alec Pollard
Lawrence Price
S. Rachman
Adam S. Radomsky
Judith L. Rapoport
Scott Rauch
Mark Riddle
Jerilyn Ross
Barbara Rothbaum
Paul Salkovskis
H. Blair Simpson
Jeffrey M. Schwartz
David A. Spiegel
Dan J. Stein
Gail Steketee
Susan E. Swedo
Richard Swinson
Dana S. Thordarson
Barbara Van Noppen
Dr Patricia Van Oppen
Lorne Warneke
Maureen Whittal
Tim Williams
Jose Yaryura-Tobias

A. Psychological intervention	
1.	For people with OCD, does behaviour therapy (BT), when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
2.	For people with OCD, does cognitive therapy (CT), when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
3.	For people with OCD, does cognitive-behavioural therapy (CBT), when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
4.	For people with OCD, does rational-emotive therapy (RET), when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
5.	For people with OCD, does psychoanalysis, psychoanalytic psychotherapy, psychodynamic psychotherapy or supportive psychotherapy, when compared to wait-list control/ relaxation/ anxiety management - behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
6.	For people with OCD, does MBT, when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
7.	For people with OCD, does family therapy, when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
8.	For people with OCD, does any other psychological intervention*, when compared to wait-list control/ relaxation/ anxiety management, behavioural stress management/ another active psychological intervention produce benefits/ harms on the specified outcomes?
B. Pharmacological interventions	
1.	For people with OCD (BDD), do tricyclic antidepressants (excluding clomipramine)*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
2.	For people with OCD (BDD), does clomipramine, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
3.	For people with OCD (BDD), do SSRIs*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
4.	For people with OCD (BDD), do atypical SRIs, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
5.	For people with OCD (BDD) do SNRIs*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
6.	For people with OCD, do MAOIs*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?

7.	For people with OCD (BDD), do anxiolytics*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
8.	For people with OCD (BDD), do antipsychotics, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
9.	For people with OCD (BDD), does any other pharmacological intervention*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
10.	For people with OCD, do augmentation strategies*, when compared to placebo/ comparator drug, produce benefits/ harms on the specified outcomes?
11.	For people with OCD, does any drug treatment, when compared to any psychological intervention, produce benefits/ harms on the specified outcomes?
12.	For people with OCD, does the combination of a drug treatment and a psychological intervention, when compared to a drug treatment alone/ psychological intervention alone, produce benefits/ harms on the specified outcomes?
C. Other Biological Interventions	
1.	For people with OCD, does neurosurgery*, when compared to placebo/ wait-list control/ drug treatment/ any psychological intervention, produce benefits/ harms on the specified outcomes?
2.	For people with OCD, does deep brain stimulation*, when compared to placebo/ wait-list control/ drug treatment/ any psychological intervention, produce benefits/ harms on the specified outcomes?
3.	For people with OCD, does transcranial magnetic stimulation, when compared to placebo/ wait-list control/ drug treatment/ any psychological intervention, produce benefits/ harms on the specified outcomes?
4.	For people with OCD, does ECT, when compared to placebo/ wait-list control/ drug treatment/ any psychological intervention, produce benefits/ harms on the specified outcomes?
5.	For people with OCD, do other interventions, when compared to placebo/ wait-list control/ drug treatment/ any psychological intervention, produce benefits/ harms on the specified outcomes?

OCD search filter

MEDLINE, CINAHL, EMBASE, PsycINFO

1. compulsive behavior.sh.
2. obsessive-compulsive disorder.sh.
3. obsessive behavior.sh.
4. compulsions.sh.
5. obsession.sh.
6. body dysmorphic disorder.sh.
7. obsessive compulsive neuros\$.tw.
8. obsessive compulsive disorder\$.tw.
9. (recurr\$ adj obsession\$).tw.
10. (recurr\$ adj thought\$).tw.
11. (obsession or obsessions or obsessional).tw.
12. (clean\$ adj response\$).tw.
13. OCD.tw.
14. Osteochondr\$.tw.
15. ((obsess\$ adj ruminat\$) or scrupulosity or body dysmorphi\$ or dysmorphophobi\$ or imagine\$ ugl\$).mp.
16. (compulsion or compulsions or compulsional).tw.
17. ((symmetr\$ or count\$ or arrang\$ or order\$ or wash\$ or repeat\$ or hoard\$ or clean\$ or check\$) adj compulsi\$).mp.
18. or/1-11
19. 13 not 14
20. or/15-19

BDD search filter

1. body dysmorphic disorder.sh.
2. (body dysmorphi\$ or dysmorphophobi\$ or imagine\$ ugl\$).mp.
3. 1 or 2
4. remove duplicates from 3

Systematic review search filter

MEDLINE, CINAHL, EMBASE, PsycINFO

1. meta analysis/
2. meta analysis.fc.
3. meta-analysis.pt.
4. (review,academic or review,multicase).pt.
5. exp literature searching/
6. systematic review.pt.
7. (metaanaly\$ or meta analy\$ or meta?analy\$).tw.
8. ((systematic or quantitative or methodologic\$) adj (overview\$ or review\$)).tw.
9. (research review\$ or research integration).tw.
10. (handsearch\$ or ((hand or manual) adj search\$)).tw.
11. (mantel haenzel or peto or dersimonian or der simonian).tw.
12. (fixed effect\$ or random effect\$ or (pooled adj data)).tw.
13. (medline or embase or scisearch or science citation or isi citation or "web of science").tw.
14. or/1-13

Randomised controlled trials search filters

MEDLINE, CINAHL, EMBASE, PsycINFO

1. exp clinical trials/ or cross-over studies/ or random allocation/ or double-blind method/ or single-blind method/
2. random\$.pt.

3. exp clinical trial/ or crossover procedure/ or double blind procedure/ or single blind procedure/ or randomization/
4. exp clinical trials/ or crossover design/ or random assignment/
5. exp clinical trials/ or double blind method/ or random allocation/
6. random\$.mp.
7. (cross-over or cross?over or (clinical adj2 trial\$) or single-blind\$ or single?blind\$ or double-blind or double?blind\$ or triple-blind or triple?blind).tw.
8. or/1-7
9. animals/ not (animals/ and human\$.mp.)
10. animal\$/ not (animal\$/ and human\$/)
11. meta-analysis/
12. meta-analysis.pt.
13. systematic review/
14. or/9-13
15. 8 not 14

Search strings supporting specific reviews

Other Psychological

Date of search	30.10.2003	
Databases searched	MEDLINE, CINAHL, EMBASE, PsycINFO	
No. of hits	406	Dedup'ed: 369

[1-20 OCD search filter above]

21. psychoanalysis.sh.
22. (gestalt therapy or counseling or hypnosis or transactional analysis).sh.
23. exp psychoanalysis/
24. exp hypnotherapy/ or exp counseling/ or (supportive psychotherapy or eye movement desensitization therapy).sh.
25. (psychoanaly\$ or psychodynamic\$ or support\$ psychotherap\$).tw.
26. (EMDR or eye movement desensiti\$ or gestalt or counseling or hypnotherap\$ or transactional analys\$ or cognitive analytic).tw.
27. or/23,25
28. 20 and 27
29. remove duplicates from 28
30. or/22,24,26
31. 20 and 30
32. remove duplicates from 31

Augmentation

Date of search	13.11.2003	
Databases searched	MEDLINE, CINAHL, EMBASE, PsycINFO	
No. of hits after Dedup'ed	369	

[1-20 OCD search filter above]

21. (adjunct\$ or augment\$ or "add on" or addition\$ or supplement\$ or resist\$ or refract\$ or nonrespon\$ or intractable).ti,ab.
22. 20 and 21
23. remove duplicates from 22
24. exp inositol/ or exp pindolol/ or exp antipsychotic agents/ or exp tryptophan/ or (valproic acid or lithium).sh.
25. exp antipsychotic agents/ or (inositol or lithium or valproic acid or tryptophan).sh.
26. exp lithium/ or exp tryptophan/ or exp neuroleptic drugs/ or valproic acid.sh.
27. exp neuroleptic agent/ or (gabapentin or inositol or lithium or pindolol or valproic acid or tryptophan).sh.
28. (anti-testosterone or gabapentin or inositol or lithium or pindolol or valproate or valproic acid or triptans or tryptophan).ti,ab.

29. (benperidol or chlorpromazine or flupentixol or fluphenazine or haloperidol or levomepromazine or methotrimeprazine or perioyazine or perphenazine or pimozide or prochlorperazine or promazine or sulphiride or thioridazine or trifluoperazine or zuclopenthixol or amisulpride or clozapine or olanzapine or quetiapine or risperidone or sertindole or zotepine).mp.
 30. (loxapine or pericyazine or buspirone or fenfluramine or trazodone).mp.
 31. or/24-30
 32. 20 and 31
 33. remove duplicates from 32
 34. 23 and 33

Other Pharmacological

Date of search	29.04.2004
Databases searched	CINAHL : 48 hits EMBASE: 549 hits PsychINFO: 147 hits MEDLINE: 230 hits
No. of hits	48

1. inositol or pindolol or tryptophan or gabapentin or triptans or anti-testosterone or john* wort or kava kava or ginkgo biloba or ginkgo biloba or amphetamine or oxytocin or clonidine or practolol or beta-blocker* or ondansetron or ritanserin or anti-androgen or cyproterone
2. OCD not osteochondr*
3. (obsess* near ruminat*) or scrupulosity or body dysmorphi* or dysmorphophobi* or (imagin* ugl*)
4. obsessive compulsive neuros* or obsessive compulsive disorder* or (recurr* near obsess*) or (recurr* near thought*) or obsession or obsessions or obsessional or compulsion or compulsions or compulsiona
5. (compulsive behavior or obsessive-compulsive disorder or obsessive behavior or compulsions or obsession or body dysmorphic disorder)

Other Medical

Date of search	20.10.2003	
Databases searched	MEDLINE, CINAHL, EMBASE, PsycINFO	
No. of hits	843	Dedup'ed: 602

[1-20 OCD search filter above]

21. neurosurgery.sh.
22. psychosurgery.sh.
23. exp brain stimulation/
24. electroconvulsive therapy.sh.
25. electroconvulsive shock therapy.sh.
26. brain depth stimulation.sh.
27. transcranial magnetic stimulation.sh.
28. tractotomy.sh.
29. (neurosurg\$ or brain stimulat\$ or transcranial or TMS or magnetic stimulat\$ or ECT or electroconvulsive).tw.
30. (cingulotom\$ or cingulectom\$ or leucotom\$ or leukotom\$ or capsulotom\$ or tractotom\$ or electric\$ capsular\$).tw.
31. or/21-30
32. 20 and 31
33. remove duplicates from 32

Child Psychotherapy

Date of search	05.11.2003
Databases searched	MEDLINE, CINAHL, EMBASE, PsycINFO

No. of hits after Dedup'ed	791
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- [1-20 OCD search filter above]
21. exp child/ or exp adolescent/
 22. exp pediatrics/
 23. (child\$ or adolescen\$).tw.
 24. or/21-23
 25. 20 and 24
 26. limit 25 to (adult <19 to 44 years> or aged <65 to 79 years> or "aged <80 and over>" or middle age <45 to 64 years>)
 27. limit 26 to (all adult <19 plus years> or "all aged <65 and over>")
 28. limit 27 to adulthood <18+ years>
 29. limit 28 to (adult <18 to 64 years> or aged <65+ years>)
 30. 25 not 29
 31. exp psychotherapy/
 32. (cognitive therapy or behavior therapy or family therapy).sh.
 33. psychotherapy, rational-emotive.sh.
 34. rational emotive therapy.sh.
 35. systematic desensitization therapy.sh.
 36. ((cognitive or behavior\$ or behaviour\$ or family or systemic or strategic or structural) adj1 (therap\$ or treatment\$)).tw.
 37. (rational emotive or RET or CBT or (multimodal adj1 (behavior or behaviour)) or MBT).tw.
 38. or/31-37
 39. 30 and 38
 40. remove duplicates from 39

Psychoanalysis

- [1-20 OCD search filter above]
21. psychoanalysis.sh.
 22. (gestalt therapy or counseling or hypnosis or transactional analysis).sh.
 23. exp psychoanalysis/
 24. exp hypnotherapy/ or exp counseling/ or (supportive psychotherapy or eye movement desensitization therapy).sh.
 25. (psychoanaly\$ or psychodynamic\$ or support\$ psychotherap\$).tw.
 26. (EMDR or eye movement desensiti\$ or gestalt or counseling or hypnotherap\$ or transactional analys\$ or cognitive analytic).tw.
 27. or/23,25
 28. 20 and 27
 29. remove duplicates from 28
 30. or/22,24,26
 31. 20 and 30
 32. remove duplicates from 31
 33. 29 not 32

Screening

Date of search	05.11.2003
Databases searched	PsycINFO
No. of hits after Dedup'ed	130

- 1.(RELIABILITY OR SENSITIVITY OR SPECIFICITY OR SCREENING).AB.
- 2.OBSESSIVE ADJ COMPULSIVE ADJ DISORDER
- 3.OBSESSIVE-COMPULSIVE-DISORDER.DE.
- 4.3 AND 1
- 5.3 AND 1
- 6.(TEST OR QUESTIONNAIRE OR SCALE OR INVENTORY).AB.
- 7.6 AND 5
- 8.primary ADJ care

9.PRIMARY-HEALTH-CARE.DE. OR PHYSICIANS.W..DE. OR FAMILY-PHYSICIANS.DE. OR
GENERAL-PRACTITIONERS.DE.
10.7 AND 9
11.primary ADJ care
12.general ADJ practitioner
13.physician
14.7 AND (11 OR 12 OR 13)
15.10 OR 14

Depression Guideline Quality checklist for a systematic review (notes for reviewer are in italics)			
Checklist completed by:		Report reference ID:	
SECTION 1: VALIDITY			
Evaluation criteria		Comments	
1.1	Does the review address an appropriate and clearly focused question?		
<i>Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.</i>			
1.2	Does the review include a description of the methodology used?		
<i>A systematic review should include a detailed description of the methods used to identify and evaluate individual studies. If this description is not present, it is not possible to make a thorough evaluation of the quality of the review, and it should be rejected as a source of Level 1 evidence. (Though it may be useable as Level 4 evidence, if no better evidence can be found.) Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.</i>			
1.3	Was the literature search sufficiently rigorous to identify all relevant studies?		
<i>Consider whether the review used an electronic search of at least one bibliographic database (searching for studies dating at least 10 years before publication of the review). Any indication that hand-searching of key journals, or follow-up of reference lists of included studies, were carried out in addition to electronic database searches can normally be taken as evidence of a well-conducted review.</i>			
1.4	Was study quality assessed and taken into account?		
<i>A well-conducted systematic review should have used clear criteria to assess whether individual studies had been well conducted before deciding whether to include or exclude them. At a minimum, the authors should have checked that there was adequate concealment of allocation, that the rate of drop out was minimised, and that the results were analysed on an "intention to treat" basis. If there is no indication of such an assessment, the review should be rejected as a source of Level 1 evidence. If details of the assessment are poor, or the methods considered to be inadequate, the quality of the review should be downgraded.</i>			
SECTION 2: OVERALL ASSESSMENT		Comments	Code
2.1	Low risk of bias	<i>All or most criteria met</i>	A
	Moderate risk of bias	<i>Most criteria partly met</i>	B
	High risk of bias	<i>Few or no criteria met</i>	C

Appendix 8: RCT methodological quality checklist

Depression Guideline Quality checklist for an RCT			
Report reference ID:			
Checklist completed by:		Date completed:	
SECTION 1: INTERNAL VALIDITY			
Evaluation criteria		How well is this criterion addressed?	
1.1	Was the assignment of subjects to treatment groups randomised?		
<p><i>If there is no indication of randomisation, the study should be rejected. If the description of randomisation is poor, or the process used is not truly random (e.g., allocation by date, alternating between one group and another) or can otherwise be seen as flawed, the study should be given a lower quality rating.</i></p>			
1.2	Was an adequate concealment method used?		
<p><i>Centralised allocation, computerised allocation systems, or the use of coded identical containers would all be regarded as adequate methods of concealment, and may be taken as indicators of a well-conducted study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating, and can be rejected if the concealment method is seen as inadequate.</i></p>			
SECTION 2: OVERALL ASSESSMENT		Comments	Code
2.1	Low risk of bias	Both criteria met	A
	Moderate risk of bias	One or more criteria partly met	B
	High risk of bias	One or more criteria not met	C

Study characteristics extraction form

NCCMH Study Database

File Edit View Insert Format Records Tools Window Help

Main Data Entry Form

ReferenceID Basic Data | ReferenceID Data Extraction | ReferenceID Results and Conclusions (if applicable)

ReferenceID
ALBERT2002

Secondary Reference

Reprint Status
In File

Source
Electronic Search

Published or Unpublished Data?
Published Data Only

References Checked for Additional Papers?

Includes Cost Data?
 Yes
 No
 Unchecked

Reference
Albert, U., Aguglia, E., Maina, G., & Bogetto, F. (2002). Venlafaxine versus clomipramine in the treatment of obsessive-compulsive disorder: a preliminary single-blind, 12-week, controlled study. *Journal of Clinical Psychiatry*, 63, 1004-1009.

Record: 1 of 1

Status within Topic Groups, Clinical Questions and Comparisons

Topic Group: Pharmacological

Status for this Topic Group: Included Excluded Awaiting Assessment

Reason for Exclusion/Awaiting Assessment

For papers relevant to more than one Clinical Question or Comparison, scroll between records below

Clinical Questions and Comparisons relevant to this paper

Clinical Question
1.02 Clomipramine

Comparison
Clomipramine vs other drugs

These records are locked. To update, please click the button on the right. Update Clinical Question or Comparison

Record: 1 of 2

For papers relevant to more than one group, scroll between records below

Record: 1 of 1

Form View NUM

NCCMH Study Database

File Edit View Insert Format Records Tools Window Help

Main Data Entry Form

ReferenceID Basic Data | ReferenceID Data Extraction | ReferenceID Results and Conclusions (if applicable)

ReferenceID
ALBERT2002

Methods

Type of study: RCT

Blindness: Single blind

Description of study: Allocation: random (no details), allocation to venlafaxine or clomipramine on a 1:2 ratio

	Lower	Mean	Upper	Length of Followup (text)
Duration (days)				12 weeks

Setting: Outpatient

No. people screened, excluded and reasons: Not reported

Notes: Country of study: Italy; Analysis: ITT

Participants

No. Participants Included in Study: 73

Sex (no. males and females)	Male	Female	No info
	35	38	

Age (in whole years)	Lower	Mean	Upper
		30	

Exclusions: OCD duration < 1 year, Y-BOCS < 16, HRSD-17 > 14, current diagnosis of MDD, currently or previously treated with SSRIs

Diagnoses

For multiple Diagnoses, scroll between records below

Diagnosis: OCD % of Sample With This Diagnosis

Diagnosis Tool: DSM-IV

Record: 1 of 1

Notes: OCD duration: 5.15 years, baseline Y-BOCS 25.4

Interventions

Interventions for This Group: Clomipramine Number of Participants in this Group: 47

Intervention: Clomipramine

Intervention Details: 50mg/d, increased to minimum 150mg/d, upto a maximum of 225mg/d; mean daily dose (in completers) 168.1+28.9mg

For this group's other interventions, move to the next record below

Record: 1 of 1

For the next group's interventions move to the next record below

Record: 1 of 2

Outcomes

OutcomeID	Usable	Reason
Responder (OCD/BDD)	<input checked="" type="checkbox"/>	

Record: 1 of 5

Notes: Responders: improvement from baseline in YBOCS score of 35% or more and a CGI score equal to or less than 2

Form View NUM

Data extraction form for a randomised controlled trial												
Completed by:						Report reference ID:						
1 TREATMENT GROUP:												
Dropouts		Treatment Responders			Side Effects (total)							
<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>			
Definition of responders												
Post-treatment means												
	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>
Other data												
	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>		

2 TREATMENT GROUP:												
Dropouts		Treatment Responders			Side Effects (total)							
<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>			
Definition of responders												
Post-treatment means												
	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>
Other data												
	<i>n</i>	<i>N</i>	<i>n</i>	<i>N</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>		

Comparisons entered:

Appendix 10: Formulae for calculating standard deviations

The following formulae were used to calculate standard deviations (SD) where these were not available in study reports:

(n = sample size of group)

$$SD = \text{Standard Error} \times \sqrt{n}$$

$$SD = \frac{(\text{upper 95\% Confidence Interval} - \text{mean})}{1.96} \times \sqrt{n}$$

$$SD = \frac{(\text{mean}_1 - \text{mean}_2)}{\sqrt{F} (\sqrt{1/n_1} + \sqrt{1/n_2})}$$

(If F ratio is not given, then $F = t_2^2$)

Appendix 11: Health Economics Search Strategy

Date of search	08.04.2004
Databases searched	PsycINFO

- #1 (obsessive compulsive disorder or compulsions or obsessions or body dysmorphic disorder) in DE,SU (6196 records)
#2 obsessive compulsive neuros* or obsessive compulsive disorder* or obsession or obsessions or obsessional (8579 records)
#3 OCD not osteochondr* (2409 records)
#4 scrupulosity or body dysmorphi* or dysmorphophobi* or imagine* ugl* (446 records)
#5 #1 or #2 or #3 or #4 (9446 records)
#6 (burden near illness) or (burden near disease) or (cost* near evaluat*) or (cost* near benefit*) or (cost* near utilit*) or (cost* near minimi*) or (cost* near illness) or (cost* near disease) or (cost* near analys*) or (cost* near assess*) or (cost* near study) or (cost* near studies) or (cost* near allocation) or (cost* near outcome*) or (cost* near consequence*) or (cost* near offset*) or (cost* near off-set*) or (cost* near effect*) or (cost* near treatment*) (20441 records)
#7 (economic near evaluat*) or (economic near analys*) or (economic near burden) or (economic near study) or (economic near studies) or (economic near assess*) or (economic near consequence*) or (economic near outcome*) or (health service* near (us* or utili*)) or (health care near (us* or utili*)) or (healthcare near (us* or utili*)) or health utility or health utilities or quality adjusted life year* or quality-adjusted-life-year* or qaly* or (resource near (us* or utili* or allocation*)) or expenditure* (38791 records)
#8 explode 'economics' or explode 'costs and cost analysis' (9300 records)
#9 #6 or #7 or #8 (57686 records)
#10 #5 and #9 (141 records)

Date of search	08.04.2004
Databases searched	Medline

- #1 cost* (226082 records)
#2 economic (75343 records)
#3 health service or health care or healthcare (378473 records)
#4 quality adjusted life year* or qaly or resource utili* or resource allocation* or expenditure* (34265 records)
#5 (obsessive compulsive disorder or compulsive behavior or obsessive behavior) in KW,MESH,PS (7109 records)
#6 obsessive compulsive neuros* or obsessive compulsive disorder* or obsession or obsessions or obsessional (7133 records)
#7 OCD not osteochondr* (1867 records)
#8 scrupulosity or body dysmorphi* or dysmorphophobi* or imagine* ugl* (334 records)
#9 #5 or #6 or #7 or #8 (8688 records)
#10 #1 and #9 (105 records)
#11 #2 and #9 (30 records)
#12 #3 and #9 (216 records)
#13 #4 and #9 (9 records)
#14 #10 or #11 or #12 or #13 (318 records)

Date of search	08.04.2004
Databases searched	EMBASE

- #1 (obsessive compulsive disorder or compulsion or obsession or body dysmorphic disorder) in SU (8256 records)
#2 obsessive compulsive neuros* or obsessive compulsive disorder* or obsession or obsessions or obsessional (7554 records)
#3 OCD not osteochondr* (2159 records)
#4 scrupulosity or body dysmorphi* or dysmorphophobi* or imagine* ugl* (469 records)
#5 #1 or #2 or #3 or #4 (9129 records)

#6 (burden near illness) or (burden near disease) or (cost* near evaluat*) or (cost* near benefit*) or (cost* near utilit*) or (cost* near minimi*) or (cost* near illness) or (cost* near disease) or (cost* near analys*) or (cost* near assess*) or (cost* near study) or (cost* near studies) or (cost* near allocation) or (cost* near outcome*) or (cost* near consequence*) or (cost* near offset*) or (cost* near off-set*) or (cost* near effect*) or (cost* near treatment*) (91709 records)

#7 (economic near evaluat*) or (economic near analys*) or (economic near burden) or (economic near study) or (economic near studies) or (economic near assess*) or (economic near consequence*) or (economic near outcome*) or (health service* near (us* or utili*)) or (health care near (us* or utili*)) or (healthcare near (us* or utili*)) or health utility or health utilities or quality adjusted life year* or quality-adjusted-life-year* or qaly* or (resource near (us* or utili* or allocation*)) or expenditure* (60659 records)

#8 (explode 'cost' / all subheadings or explode 'economics' / all subheadings or explode 'health economics' / all subheadings) in SU (154319 records)

#9 #6 or #7 or #8 (218918 records)

#10 #5 and #9 (242 records)

Date of search	08.04.2004
Databases searched	EconLit

#1 obsessive or compulsive or obsession or obsessions or obsessional or compulsion or compulsions or compusal or body dysmorphi* or dysmorphophobi* or OCD (116 records)

Date of search	08.04.2004
Databases searched	NHS EED

“obsess*” = 2

Cost-of-illness/ economic burden studies

1. There was no restriction placed on language or publication status of the papers.
2. Studies published between 1980 and 2004 were included. This date restriction was imposed in order to obtain data relevant to current healthcare settings and costs.
3. Only studies from the UK/OECD were included, as the aim of the review was to identify economic burden information relevant to the national context.
4. Selection criteria based on types of clinical conditions and patients were identical to the clinical literature review.
5. Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable.

Economic evaluations

1. Studies were included provided they had used cost-minimisation analysis, cost-effectiveness analysis, cost-utility analysis or cost-benefit analysis.
2. Clinical evidence from a meta-analysis, a randomised controlled trial, a quasi-experimental trial or a cohort study was used.
3. There was no restriction placed on language or publication status of the papers.
4. Studies published between 1980 and 2004 were included. This date restriction was imposed in order to obtain data relevant to current healthcare settings and costs.
5. Only studies from the UK/OECD were considered, as the aim of the review was to identify economic evaluation information relevant to the national context.
6. Selection criteria were based on types of clinical conditions, patients, treatments and settings to which agreed by the GDG (2004).
7. Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable.
8. In cases where no published data were available, estimations were made by the GDG (2004) based upon expert opinions.

Health state and utility studies

1. Studies reporting health state and utilities for OCD were considered for inclusion.
2. There was no restriction placed on language or publication status of the papers.
3. Studies published between 1980 and 2004 were included.
4. Only studies from OECD countries were considered to assure the generalisability of the results to the UK context.
5. Selection criteria based on types of clinical conditions, patients, treatments and settings were identical to the clinical literature review.

Appendix 13: Data extraction form for economic studies

Reviewer: Date of review:
Authors: Publication date:
Title:
Country: Language:

Interventions compared:

Treatment:

Comparator:

Patient population:

Setting:

Economic study design:

CEA CMA

CBA CCA

CUA CA

Perspective of the analysis:

Health care system	Societal
Health care provider	Patient and family
Third party payer	Other:

Time frame of the analysis:

Modelling:

NO YES

Source of data for effect size measures:

	Meta-analysis
	Non-systematic review
RCT	RCT
Quasi-experimental study	Quasi-experimental study
Cohort study	Cohort study
Mirror-image (before after) study	Mirror-image (before after) study
	Expert opinion

Comments:

Primary outcome measures:

Costs included:

<u>Direct medical</u>	<u>Direct non-medical</u>	<u>Lost productivity</u>
direct treatment	social care	income forgone due to illness
inpatient	social benefits	income forgone due to death
outpatient	travel costs	income forgone by caregiver
day care	caregiver out-of-pocket	

community health care
medication

criminal justice
training of staff

or

Staff

Medication

Consumables

Overhead

Capital equipment

Real estate

Others:

Source of resource use and unit costs:

Currency:

Price year:

Discounting (costs / benefits):

Sensitivity analysis:

Effectiveness results:

Cost results:

Cost-effectiveness results:

Authors' conclusions:

Comments - limitations:

Author: Date of publication:

Title:

Study design

1. The research question is stated	Yes	No
2. The economic importance of the research question is stated	Yes	No
3. The viewpoint(s) of the analysis are clearly stated and justified	Yes	No
4. The rationale for choosing the alternative programmes or interventions compared is stated	Yes	No
5. The alternatives being compared are clearly described	Yes	No
6. The form of economic evaluation used is stated	Yes	No
7. The choice of form of economic evaluation used is justified in relation to the questions addressed	Yes	No

Data collection

1. The source of effectiveness estimates used are stated	Yes	No	
2. Details of the design and results of effectiveness study are given (if based on a single study)	Yes	No	N/A
3. Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	Yes	No	N/A
4. The primary outcome measure(s) for the economic evaluation are clearly stated	Yes	No	
5. Methods to value health states and other benefits are stated	Yes	No	N/A
6. Details of the subjects from whom valuations were obtained are given	Yes	No	N/A
7. Indirect costs (if included) are reported separately	Yes	No	N/A
8. The relevance of indirect costs to the study question is discussed	Yes	No	N/A
9. Quantities of resources are reported separately from their unit costs	Yes	No	
10. Methods for the estimation of quantities and unit costs are described	Yes	No	
11. Currency and price data are recorded	Yes	No	
12. Details of currency, price adjustments for inflation or currency conversion are given	Yes	No	
13. Details of any model used are given	Yes	No	N/A
14. The choice of model used and the key parameters on which it is based are justified	Yes	No	N/A

Analysis and interpretation of results

1. Time horizon of costs and benefits is stated	Yes	No	
2. The discount rate(s) is stated	Yes	No	N/A
3. The choice of rate(s) is justified	Yes	No	N/A
4. An explanation is given if costs or benefits are not discounted	Yes	No	N/A
5. Details of statistical tests and confidence intervals are given for stochastic data	Yes	No	N/A
6. The approach to sensitivity analysis is given	Yes	No	N/A
7. The choice of variables for sensitivity analysis is given	Yes	No	N/A
8. The ranges over which the variables are varied are stated	Yes	No	N/A
9. Relevant alternatives are compared	Yes	No	
10. Incremental analysis is reported	Yes	No	N/A
11. Major outcomes are presented in a disaggregated as well as aggregated form	Yes	No	
12. The answer to the study question is given	Yes	No	
13. Conclusions follow from the data reported	Yes	No	
14. Conclusions are accompanied by the appropriate caveats	Yes	No	

Validity score: Yes/No/NA: