Guideline Summary NGC-7641

Guideline Title
Non-pharmaceutical management of depression in adults. A national clinical guideline.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.

Scope

Disease/Condition(s)
Depression

Guideline Category
Counseling
Management
Treatment

Clinical Specialty
Family Practice
Geriatrics
Internal Medicine
Nursing
Nutrition
Psychiatry
Psychology

Intended Users
Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Patients
Pharmacists
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)
- To examine the evidence for depression treatments which may be used as alternatives to prescribed pharmacological therapies.
- To examine psychological therapies, exercise and lifestyle interventions, and complementary and alternative treatments many of which are not routinely available within the National Health Service
Target Population
Adults 18 years or older with depression

Interventions and Practices Considered

Treatment/Management
1. Psychological therapies
   - Behavioural activation
   - Cognitive behavioural therapy
   - Interpersonal therapy
   - Mindfulness-based cognitive therapy
   - Problem solving therapy
   - Psychodynamic psychotherapy
2. Self help
   - Guided self help
   - Computerised self help
3. Structured exercise

Major Outcomes Considered
- Reduction in depressive symptoms
- Illness duration
- Relapse rate
- Quality of life
- Patient satisfaction

Methodology

Methods Used to Collect/Select the Evidence
- Hand-searches of Published Literature (Primary Sources)
- Hand-searches of Published Literature (Secondary Sources)
- Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review
The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, Cinahl, PsycINFO, AMED, and the Cochrane Library. The year range covered was 1998-2008 with variations depending on topic. Internet searches were carried out on various websites including the US National Guideline Clearinghouse. A complete search narrative, including search strategies and date ranges for each key question, is available on the SIGN website (see the "Availability of Companion Documents" field). The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Defining the Patient Group
Studies were excluded where there was no formal diagnosis by International Classification of Disease (ICD) 9, ICD 10, Diagnostic and Statistical Manual (DSM)-III or DSM-IV, or use of a recognised, validated and reliable measurement scale specifically for depressive symptoms.

Studies in patient groups with clear indicators of severe depression or with significant psychological comorbidities were excluded as below:
- Psychotic depression
- Depression in the perinatal period (which includes postnatal depression)
- Bipolar disorder
- Personality disorder
- Dysthymia
- Seasonal affective disorder
- Primary addiction
- Significant cognitive impairment (brain injury or dementia)
• Learning disability

Studies in patients with significant physical comorbidities were also excluded.

A large number of studies of depression had mixed patient groups, typically with anxiety disorders and personality disorders. Individual studies were excluded unless there was clear analysis of the depression subgroup. Where recommendations were based on systematic reviews which included studies with mixed patient groups this was taken into account when grading recommendations.

The guideline development group recognised the limitations of adopting such specific diagnostic criteria in terms of applicability to routine care populations, but required a clear remit to assure rigour in study selection and analysis.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. The Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN Executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.\(^在这个.
Description of Methods Used to Formulate the Recommendations

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. The summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of study findings
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

The group are finally asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

Patient Involvement

In addition to the identification of relevant patient issues from a broad literature search, the Scottish Intercollegiate Guidelines Network (SIGN) involves patients and carers throughout the guideline development process in several ways. SIGN recruits a minimum of two patient representatives to guideline development groups by inviting nominations from the relevant "umbrella", national and/or local patient-focused organisations in Scotland. Where organisations are unable to nominate, patient representatives are sought via other means, e.g., from consultation with health board public involvement staff.

Further patient and public participation in guideline development was achieved by involving patients, carers and voluntary organisation representatives at the National Open Meeting (see section 11.3.1 in the original guideline document). Patient representatives were invited to take part in the peer review stages of the guideline and specific guidance for lay reviewers was circulated. Members of the SIGN patient network were also invited to comment on the draft guideline section on provision of information.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook," (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2+

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2
Cost Analysis
Published cost analyses were reviewed.

Method of Guideline Validation
External Peer Review
Internal Peer Review

Description of Method of Guideline Validation
A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held on 10 September 2008 and was attended by 290 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

Peer Review
All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to at least two lay reviewers in order to obtain comments from the patient's perspective.

It should be noted that all reviewers are invited to comment as individuals, not as representatives of any particular organisation or group. Corporate interests, whether commercial, professional, or societal, have an opportunity to make representations at the national meeting stage where they can send representatives to the meeting or provide comment on the draft produced for that meeting. Peer reviewers are asked to complete a declaration of interests form.

The comments received from peer reviewers and others are carefully tabulated and discussed with the Chair and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

Recommendations

Major Recommendations

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Psychological Therapies

Behavioural Activation
A - Behavioural activation is recommended as a treatment option for patients with depression.

Cognitive Behavioural Therapy (CBT)
A - Individual CBT is recommended as a treatment option for patients with depression.

Interpersonal Therapy
A - Interpersonal therapy is recommended as a treatment option for patients with depression.

Mindfulness Based Cognitive Therapy
B - Mindfulness based cognitive therapy in a group setting may be considered as a treatment option to reduce relapse in patients with depression who have had three or more episodes.

Problem Solving Therapy
B - Problem solving therapy may be considered as a treatment option for patients with depression.

Psychodynamic Psychotherapy
B - Short term psychodynamic psychotherapy may be considered as a treatment option for patients with depression.

Self Help

Guided Self Help
A - Guided self help based on CBT or behavioural principles is recommended as a treatment option for patients with depression.

Computerised Self Help
A - Within the context of guided self help, computerised CBT is recommended as a treatment option for patients with depression.
Exercise and Lifestyle Modification

Exercise
B - Structured exercise may be considered as a treatment option for patients with depression

Definitions:
Grade of Recommendations
A: At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++, and directly applicable to the target population; or
A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 1++ or 1+
C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 2++
D: Evidence level 3 or 4; or
Extrapolated evidence from studies rated as 2+

Level of Evidence
1++: High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3: Non-analytic studies (e.g., case reports, case series)
4: Expert opinion

Clinical Algorithm(s)
None provided

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations
The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits
Appropriate nonpharmaceutical management of patients with depression

Potential Harms
There is a risk that patients will not respond to therapy.

Qualifying Statements

Qualifying Statements
• This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgment should only be arrived at following discussion of the options with the patient, covering the diagnostic
and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient’s case notes at the time the relevant decision is taken.

- Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions corrections will be published in the web version of this document, which is the definitive version at all times. This version can be found on the Scottish Intercollegiate Guidelines Network website, www.sigin.ac.uk.

**Implementation of the Guideline**

**Description of Implementation Strategy**

This guideline provides recommendations for a range of alternative treatments. Resource implications will depend on local availability of psychological services, support for guided self help and exercise referral schemes.

Current provision of psychological therapy services across Scotland is patchy, idiosyncratic and largely uncoordinated. National Health Service (NHS) Education for Scotland is working in partnership with the Scottish Government, NHS Boards and other service providers to increase the capacity within the current NHS workforce to deliver psychological therapies, to support service change, and to ensure that the new resource is used effectively in practice.

**Auditing Current Practice**

A first step in implementing a clinical practice guideline is to gain an understanding of current clinical practice. Audit tools designed around guideline recommendations can assist in this process. Audit tools should be comprehensive but not time consuming to use. Successful implementation and audit of guideline recommendations requires good communication between staff and multidisciplinary team working.

Audit of implementation of the guideline will be assisted through implementation and accreditation of local Integrated Care Pathways for management of patients with depression. Information on the pathways is available at www.icptoolkit.org.

The guideline development group has identified the following as key points to audit to assist with the implementation of this guideline:

- Have non-pharmaceutical treatment options been discussed/considered?
  - Psychological therapies
  - Guided self help
  - Structured exercise
- If patient is using or contemplating using herbal remedies has there been careful consideration of potential drug interactions?
- Has the patient been made aware that although one therapy may not have been helpful trying another may be beneficial?

National Health Service (NHS) Quality Improvement Scotland has validated National Institute of Health and Clinical Excellence (NICE) Technology Appraisal Guidance 97, ‘Computerised cognitive behaviour therapy (CCBT) for depression and anxiety.’

**Implementation Tools**

Audit Criteria/Indicators

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

**Institute of Medicine (IOM) National Healthcare Quality Report Categories**

**IOM Care Need**

- Living with Illness
- Staying Healthy

**IOM Domain**

- Effectiveness
- Patient-centeredness

**Identifying Information and Availability**

**Bibliographic Source(s)**

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2010 Jan

Guideline Developer(s)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

Source(s) of Funding

Scottish Executive Health Department

Guideline Committee

Guideline Development Group

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

Guideline Status

This is the current release of the guideline.

Guideline Availability


Availability of Companion Documents

The following are available:


Key points to audit are available in the original guideline document.

Additional resources, including a slide set and the Scottish Government Guide to Resources for practitioners, are available in the Depression implementation pack from the SIGN Web site.
Patient Resources

The following is available:


Additional patient self-help resources are available in the Depression implementation pack from the SIGN Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline’s content.

NGC Status

This summary was completed by ECRI Institute on October 20, 2010.

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