

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Centre for Clinical Practice

### *Review consultation document*

#### **Review of Clinical Guideline (CG91) – Depression in adults with a chronic physical health problem: treatment and management**

## **1. Background information**

Guideline issue date: 2009

3 year review: 2012

National Collaborating Centre: Mental Health

## **2. Consideration of the evidence**

### **Literature search**

Through an assessment of abstracts from a high-level randomised controlled trial (RCT) search, new evidence was identified relating to the following clinical areas within the guideline:

- Service level interventions
- Psychological and psychosocial interventions
- Pharmacological interventions

Through this stage of the process, a sufficient number of studies (n=35) relevant to the above clinical areas were identified to allow an assessment for a proposed review decision. These are summarised in [Table 1](#) below.

All references identified through the high-level RCT search, initial intelligence gathering and the focused searches can be viewed in [Appendix 1](#)

**Table 1: Summary of articles from the high level search**

<b>Clinical area 1: Service level interventions</b>		
<b>Clinical question</b>	<b>Summary of evidence</b>	<b>Relevance to guideline recommendations</b>
<p>Q1: In the treatment of depression for people with a chronic physical health problem, which service-level interventions improve outcomes compared with standard care?</p> <ul style="list-style-type: none"> <li>• collaborative care</li> <li>• stepped care</li> <li>• case management</li> <li>• stratified (matched) care</li> <li>• attached professional model</li> <li>• chronic disease (disease management) model.</li> </ul>	<p>Through an assessment of the abstracts from the high-level RCT search, 5 studies relevant to the clinical questions were identified.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>1</sup> on coordinated care management of patients with depression and poorly controlled diabetes, coronary heart disease, or both, was found. Patients were randomly assigned to usual-care or to a medically supervised nurse, who worked with each patient's primary care physician, and provided guideline-based, collaborative care management, with the goal of controlling risk factors associated with multiple diseases. The authors concluded that compared to usual care, an intervention involving nurses who provided guideline-based, patient-centred management of depression and chronic disease significantly improved control of medical disease and depression.</li> </ul>	<p>No new evidence was identified which would invalidate current guideline recommendation(s).</p>

<p>Are different models appropriate to the care of people in different phases of the illness, such as treatment resistant depression and relapse prevention?</p> <p>Q2: In the treatment of depression for people with a chronic physical health problem, what systems promote more effective access to care, for example for black and minority ethnic groups, people with learning difficulties, people in care homes and people experiencing social deprivation?</p>	<ul style="list-style-type: none"> <li>• One RCT<sup>2</sup> assessed the impact of a collaborative, team-based, care management program for complex patients (TEAMcare) with poorly controlled diabetes or coronary heart disease with coexisting depression. In the TEAMcare program, a nurse care manager collaborated closely with primary care physicians, patients, and consultants to deliver a treat-to-target approach across multiple conditions. Measures included medication initiation, adjustment, adherence, and disease self-monitoring. Results showed that compared to usual care, TEAMcare improved control of depression, diabetes and heart disease, with no change in medication adherence rates.</li> <li>• One RCT<sup>3</sup> on the integrated management of type 2 diabetes and depression treatment to improve medication adherence was found. Patients were randomly assigned to an integrated care intervention or usual care. Integrated care managers collaborated with physicians to offer education and guideline-based treatment recommendations and to monitor adherence and clinical status. Results showed that patients who received the intervention were more likely to achieve HbA1c levels of</li> </ul>	
---	---	--

<p><b>Relevant section of the guideline</b></p> <p>6.3 Stepped care 6.4 Service-level interventions</p> <p><b>Recommendations</b></p> <p>Section 6.7 Recommendations 6.7.1.1 to 6.7.1.5</p>	<p>less than 7% and remission of depression in comparison with patients in the usual care group at 12 weeks.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>4</sup> determined the effectiveness of PEARLS, a home-based, collaborative care intervention consisting of problem solving treatment, behavioural activation, and psychiatric consultation program for managing depression in adult individuals with epilepsy and clinically significant acute and chronic depression. Patients were randomly assigned to the PEARLS intervention or usual care, and assessed at baseline, 6 months, and 12 months. Results showed that compared with patients who received usual care, patients assigned to the PEARLS intervention achieved lower depression severity. The authors concluded that the PEARLS program effectively reduces depressive symptoms in adults with epilepsy and comorbid depression.</li> <li>• One study<sup>5</sup> presented the long-term effectiveness of PEARLS. Results showed that patients assigned to PEARLS achieved lower depression severity, lower suicidal ideation, and better emotional well being over 18 months, compared with patients</li> </ul>	
---	---	--

	<p>given the usual care. The authors' conclusion was that the PEARLS program significantly reduces depressive symptoms in adults with epilepsy, and this effect is maintained for 18 months after baseline and for more than 1 year after completion of home visits.</p> <p><u>Summary</u></p> <p>In summary, the identified studies relate to the use of the collaborative care approach for people with depression and a chronic physical health problem. The findings are in line with current guideline recommendations.</p>	
<b>Clinical area 2: Psychological and psychosocial interventions</b>		
<b>Clinical question</b>	<b>Summary of evidence</b>	<b>Relevance to guideline recommendations</b>
<p>Q1: In the treatment of depression for people with a chronic physical health problem, do any of the following (either alone or in</p>	<p>Through an assessment of the abstracts from the high-level RCT search, 21 studies relevant to the clinical questions were identified.</p> <p><i>Diabetes (5 studies)</i></p> <ul style="list-style-type: none"> <li>• A 3-year follow-up of a multicentre cluster RCT<sup>6</sup> on the</li> </ul>	<p>No new evidence was identified which would invalidate current guideline recommendation(s).</p>

<p>combination with pharmacotherapy) improve outcomes compared with other interventions (including treatment as usual):</p> <ul style="list-style-type: none"> <li>• cognitive and behavioural interventions (including problem solving therapy, acceptance and commitment therapy, self-help/guided self-help, CCBT)</li> <li>• counselling/person-centred therapy</li> <li>• IPT</li> <li>• psychodynamic psychotherapy</li> <li>• family, couples and systemic interventions</li> </ul>	<p>effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus was found. Results showed that glycated haemoglobin (HbA<sub>1c</sub>) levels at three years had decreased in both groups with no significant difference between the groups. The groups did not differ for the other biomedical and lifestyle outcomes and drug use. The significant benefits in the intervention group across four out of five health beliefs seen at 12 months were sustained at three years. Depression scores and quality of life did not differ at three years.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>7</sup> evaluated the effectiveness of a web-based CBT for treatment of depression in adults with type 1 or type 2 diabetes. The trial was conducted in the Netherlands in adult diabetic patients with elevated depressive symptoms. Results showed that the web-based CBT depression treatment was effective in reducing depressive symptoms and emotional distress in depressed patients with diabetes</li> <li>• One RCT<sup>8</sup> on mindfulness-based stress reduction (MBSR) intervention for patients with type 2 diabetes was found.</li> </ul>	
--	--	--

<ul style="list-style-type: none"> <li>• psychoeducation</li> <li>• solution-focused therapy</li> <li>• occupational therapy</li> <li>• support (including groups, befriending and non-statutory provision)</li> <li>• programmes to facilitate employment</li> <li>• physical activity.</li> </ul> <p>Does mode of delivery (group-based or individual) impact on outcomes?</p> <p>Does setting impact on outcomes?</p> <p>Are brief interventions (for example, 6–8 weeks) effective?</p> <p>Are psychological interventions harmful?</p>	<p>Patients with type 2 diabetes and microalbuminuria were randomized to a mindfulness-based intervention or a treatment-as-usual control group. At the first year follow up, the MBSR group showed lower levels of depression and improved health status compared with the control group.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>9</sup> assessed the effect of lifestyle intervention on depressive symptoms during a 36-month study designed to prevent Type 2 diabetes. Middle-aged participants, who were overweight or obese and had impaired glucose tolerance, were randomized to the lifestyle intervention or control group in the Finnish Diabetes Prevention Study. The authors concluded that participation in the study lowered depression scores, with no specific group effect. Among the lifestyle changes, particularly successful reduction of body weight was associated with the greater reduction of depressive symptoms.</li> <li>• One RCT<sup>10</sup> on motivational interviewing for people with type 2 diabetes was found. People with Type 2 diabetes were randomly allocated into either the motivational interview group or the usual care group from baseline to 3 months follow-up.</li> </ul>	
---	--	--

<p>Q2: In people with a chronic physical health problem whose depression has responded to treatment, what psychological, psychosocial and pharmacological strategies are effective in preventing relapse (including maintenance treatment, continued support)?</p> <p><b>Relevant section of the guideline</b></p> <p>7.2 Review of clinical evidence for psychological and psychosocial interventions</p> <p><b>Recommendations</b></p> <p>Section 7.5</p>	<p>Results showed that the motivational interview significantly improved participants in self-management, self-efficacy, quality of life, and HbA1c but not depression, anxiety and stress compared to the control group, at 3 months follow-up.</p> <p><i>Heart disease (4 studies)</i></p> <ul style="list-style-type: none"> <li>• One Cochrane review<sup>11</sup> on psychological and pharmacological interventions for depression in patients with coronary artery disease (CAD) was found. Results showed that psychological interventions and pharmacological interventions with selective serotonin reuptake inhibitors (SSRIs) may have a small yet clinically meaningful effect on depression outcomes in CAD patients. No beneficial effects on the reduction of mortality rates and cardiac events were found. The authors concluded that overall, however, the evidence is sparse due to the low number of high quality trials per outcome and the heterogeneity of examined populations and interventions.</li> <li>• One RCT<sup>12</sup> assessed the impact of a modified, stage-of-change-matched, gender-tailored cardiac rehabilitation (CR) program for reducing depressive symptoms among women</li> </ul>	
---	--	--

<p>Recommendations 7.5.1.1 to 7.5.1.18</p>	<p>with coronary heart disease (CHD). Depressive symptoms of women in a traditional 12-week CR program were compared to those completing a tailored program that included motivational interviewing guided by the transtheoretical model of behaviour change. The authors concluded that the modified, gender-tailored CR program reduced depressive symptoms in women when compared to a traditional program.</p> <ul style="list-style-type: none"> <li>• One pilot RCT<sup>13</sup> compared the effects of a nondenominational spiritual retreat, Medicine for the Earth (MFTE), on depression and other measures of well-being six- to 18-months post acute coronary syndrome (ACS). Participants were randomised to MFTE, Lifestyle Change Program (LCP), or usual cardiac care. The MFTE intervention included guided imagery, meditation, drumming, journal writing, and nature-based activities. The LCP included nutrition education, exercise, and stress management. Both retreat groups received follow-up phone coaching biweekly for three months. The authors concluded that the MFTE intervention can be used to increase hope while reducing depression in patients with ACS.</li> </ul>	
--	--	--

	<ul style="list-style-type: none"> <li>• One open trial<sup>14</sup> examined the effectiveness of tailored cognitive-behavioural therapy (CBT) for veterans with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) with comorbid symptoms of depression and/or anxiety. Results showed that symptoms of depression and anxiety were improved at 8 weeks and maintained at 3-month follow-up compared to baseline; physical disease outcomes were also improved for COPD and CHF. The authors concluded that modifications to traditional CBT approaches have the potential to address the emotional and physical health challenges associated with complex cardiopulmonary patients but that additional trials are needed.</li> </ul> <p><i>Breast cancer (4 studies)</i></p> <ul style="list-style-type: none"> <li>• One RCT<sup>15</sup> evaluated the efficacy of an interactive self-help workbook in reducing distress, and improving quality of life (QOL) and coping for women recently diagnosed with breast cancer. The authors' conclusion was that a self-help workbook can be an effective, short-term intervention for improving posttraumatic stress, cognitive avoidance, and certain</li> </ul>	
--	---	--

	<p>depressive symptoms in women recently diagnosed with breast cancer. However, issues related to body image need to be dealt with differently.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>16</sup> investigated the impact of pilates exercises on physical performance, flexibility, fatigue, depression and quality of life in women who had been treated for breast cancer. Patients in the intervention group performed pilates and home exercises while patients in the control group performed only home exercises. The authors concluded that pilates exercises are effective and safe in female breast cancer patients and that there is a need for further studies so that its effect can be confirmed.</li> <li>• One RCT<sup>17</sup> tested the efficacy of behavioural activation treatment for depression (BATD) compared to problem-solving therapy for depressed breast cancer patients. No significant group differences were found at posttreatment and treatment gains were maintained at 12-month follow-up, with some support for stronger maintenance of gains in the BATD group. The authors concluded that BATD and problem-solving</li> </ul>	
--	---	--

	<p>interventions represent practical interventions that may improve psychological outcomes and quality of life among depressed breast cancer patients.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>18</sup> on the effects of a physical exercise rehabilitation group program on anxiety, depression, body image, and health-related quality of life among breast cancer patients was found. Women with primary non-metastatic breast cancer after a minimum 4-week period post chemotherapy and/or radiotherapy completion were randomly assigned to the intervention group or the waiting group. The authors concluded that the 10-week physical exercise intervention significantly improved psychosocial wellbeing, individual body image, and physical fitness.</li> </ul> <p><i>HIV (2 studies)</i></p> <ul style="list-style-type: none"> <li>• One systematicreview<sup>19</sup> of evaluated interventions related to HIV and depression was found. The review revealed that the interventions were diverse and could broadly be categorized into psychological, psychotropic, psychosocial, physical, HIV-specific health psychology interventions and HIV treatment-</li> </ul>	
--	--	--

	<p>related interventions. Psychological interventions were particularly effective and in particular interventions that incorporated a cognitive-behavioural component. Psychotropic and HIV-specific health psychology interventions were also generally effective. Evidence was not clear-cut regarding the effectiveness of physical therapies and psychosocial interventions were generally ineffective. Interventions that investigated the effects of treatments for HIV and HIV-associated conditions on depression found that these treatments often decreased depression.</p> <ul style="list-style-type: none"><li>• One pilot trial<sup>20</sup> on a brief interpersonal psychotherapy delivered via telephone to reduce psychiatric distress among persons living with HIV-AIDS in rural areas in the United States was found. The authors concluded that the telephone-delivered interpersonal therapy intervention showed potential to reduce depressive and psychiatric symptoms among HIV-infected persons in rural areas and that on the basis of these encouraging findings, additional research examining this intervention with this clinical population is warranted.</li></ul>	
--	--	--

	<p><i>Other conditions (6 studies)</i></p> <ul style="list-style-type: none"> <li>• One RCT<sup>21</sup> evaluated the effectiveness of a brief psychosocial-behavioural intervention in those with poststroke depression. Clinically depressed patients with ischemic stroke within 4 months of index stroke were randomly assigned to an 8-week brief psychosocial-behavioural intervention plus antidepressant or usual care, including antidepressant. The primary end point was reduction in depressive symptom severity at 12 months after entry. Results showed that the intervention reduced poststroke depression significantly more than usual care.</li> <li>• One RCT<sup>22</sup> assessed the efficacy of a scheduled telephone intervention for ameliorating depressive symptoms during the first year after traumatic brain injury (TBI). The treatment group received up to 7 scheduled telephone sessions over 9 months designed to elicit current concerns, provide information, and facilitate problem solving in domains relevant to TBI recovery. The authors concluded that compared to usual care telephone-based interventions using problem-solving and behavioural activation approaches may be effective in ameliorating</li> </ul>	
--	---	--

	<p>depressive symptoms following TBI.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>23</sup> assessed the effect of telephone-administered cognitive-behavioural therapy on quality of life among patients with multiple sclerosis. Participants with multiple sclerosis and depression were randomly assigned to either a telephone-administered CBT (T-CBT) or telephone-administered supportive emotion-focused therapy (T-SEFT) intervention. The authors concluded that T-CBT provided greater QOL improvements and benefits compared with T-SEFT.</li> <li>• One RCT<sup>24</sup> assessed the effects of electrical stimulation (ES) program on trunk muscle strength, functional capacity, quality of life, and depression in the patients with chronic low back pain (CLBP). Patients in the intervention group received an ES program and exercises while patients in the control group had only exercises. Results showed that except depression and social function, the improvements for all the parameters were better in the ES group than in the control group. The authors concluded that the ES program was very effective in improving QOL, functional performance and isometric strength.</li> </ul>	
--	---	--

	<ul style="list-style-type: none"> <li>• One RCT<sup>25</sup> of cognitive behaviour therapy for psychosis in a routine clinical service was found. Participants were randomised into immediate therapy or waiting list groups. The intervention group was offered 6 months of therapy and followed up 3 months later. The waiting list group received therapy after waiting 9 months. Results showed that depression improved in the combined therapy group at both the end of therapy and follow-up.</li> <li>• One study<sup>26</sup> on social and vocational skills training to reduce self-reported anxiety and depression among young adults on the autism spectrum was found. Results showed that at post intervention, participants who received the training reported significantly lower depression and anxiety compared to pre intervention. Responses on a measure of peer relationships were also improved post-intervention, although this did not reach significance. The authors concluded that although preliminary, their findings demonstrate the broader, positive impact that such programs may have.</li> </ul> <p><u>Summary</u></p>	
--	--	--

	In summary, the identified studies relate to the use psychological and psychosocial interventions for people with depression and a chronic physical health problem. The findings are generally in line with current guideline recommendations.	
<b>Clinical area 3: Pharmacological interventions</b>		
<b>Clinical questions</b>	<b>Summary of evidence</b>	<b>Relevance to guideline recommendations</b>
<p>Q1: In the treatment of depression for people with a chronic physical health problem, which drugs improve outcomes compared with placebo:</p> <ul style="list-style-type: none"> <li>• SSRIs (for example, escitalopram)</li> <li>• ‘Third generation’ antidepressants (for example, venlafaxine, desvenlafaxine,</li> </ul>	<p>Through an assessment of the abstracts from the high-level search, 9 studies relevant to the clinical questions were identified.</p> <ul style="list-style-type: none"> <li>• One systematic review and meta-analysis<sup>27</sup> on the safety and efficacy of pharmacological interventions for people with depression and chronic physical health problems was found. Sixty-three studies met inclusion criteria. The authors concluded that antidepressants are efficacious and safe in the treatment of depression occurring in the context of chronic physical health problems and that the SSRIs are probably the antidepressants of first choice given their demonstrable effect on quality of life and their apparent safety in cardiovascular disease.</li> </ul>	<p>No new evidence was identified which would invalidate current guideline recommendation(s).</p>

<p>agomelatine, duloxetine, mirtazapine, reboxetine)</p> <ul style="list-style-type: none"> <li>• MAOIs</li> <li>• TCAs</li> <li>• antipsychotics (for example, quetiapine)</li> <li>• trazodone</li> <li>• maprotiline</li> </ul> <p>Q2: In the treatment of depression for people with a chronic physical health problem, to what extent do the following factors affect the choice of drug:</p> <ul style="list-style-type: none"> <li>• interactions with physical health medications</li> <li>• adverse events (in particular, cardiotoxicity), including long-term</li> </ul>	<ul style="list-style-type: none"> <li>• One Cochrane review<sup>28</sup> investigated the efficacy and tolerability of pharmacologic treatments for depression in patients with multiple sclerosis (MS). Two trials - one of desipramine and the other of paroxetine - were included. There was a trend towards efficacy of both treatments compared to placebo, but this difference was not statistically significant except for one outcome. Both treatments were associated with adverse effects, with significantly more patients treated with paroxetine suffering from nausea or headache. The authors concluded that further clinical research on the treatment of depression in MS addressing efficacy and tolerability in the long term and comparing antidepressant treatments head-to-head is needed.</li> <li>• One RCT<sup>29</sup> on the use of citalopram for adults with schizophrenia or schizoaffective disorder and subsyndromal depression was found. Patients were randomly assigned to flexible-dose treatment with citalopram or placebo (in addition to their current antipsychotic medication(s) which was stable for 1 month). The authors concluded that citalopram</li> </ul>	
---	---	--

<p>adverse events</p> <ul style="list-style-type: none"> <li>• discontinuation problems</li> <li>• physical health</li> </ul> <p>medications that have depressive effects (for example tetrabenazine, reserpine, beta blockers [such as propranolol], calcium antagonists [verapamil], interferon, retinoids [such as isotretinoin]).</p> <p>Q3: In the pharmacological treatment of depression for people with a chronic physical health problem, what are the most effective strategies for treating patients experiencing side effects, for</p>	<p>augmentation of antipsychotic treatment in middle aged and older patients with schizophrenia and subsyndromal depression may improve social and mental health functioning as well as quality of life. Thus they suggest that it is important for clinicians to monitor these aspects of functioning when treating this population of patients with schizophrenia with SSRI agents.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>30</sup> compared the antidepressant effects of citalopram with fluoxetine and their effect on glycaemic control in diabetic patients. Patients with type II diabetes and suffering from major depression were randomly assigned to receive either 40 mg/d of fluoxetine or citalopram. After 12 weeks of treatment, both groups showed significant improvement in severity of depression, FBS, and HbA1c. There were no significant differences between the 2 groups in terms of improvement in depression and diabetic status. The authors concluded that fluoxetine and citalopram can effectively reduce the severity of depression in diabetic patients without an adverse effect on glycaemic control.</li> </ul>	
--	--	--

<p>example sexual dysfunction and weight gain?</p> <p>Q4: In people with a chronic physical health problem whose depression does not respond, or responds inadequately, to treatment, which</p> <ul style="list-style-type: none"> <li>• strategies for switching antidepressants are effective?</li> <li>• strategies for sequencing antidepressants are effective?</li> <li>• strategies for switching between pharmacological treatment and psychological treatment are most effective and</li> </ul>	<ul style="list-style-type: none"> <li>• One study<sup>31</sup> on the effect of levetiracetam on depression and anxiety in adult epileptic patients was found. Adults with uncontrolled partial seizures and concomitant depressive symptoms were treated with levetiracetam and evaluated for depression and anxiety with several psychometric measures. Results showed that treatment with levetiracetam may improve depression and anxiety in patients with partial seizures. The authors cautioned that as the sample of patients was limited and the possibility of a placebo effect cannot be excluded, these findings must be considered preliminary and should be replicated under placebo-controlled conditions.</li> <li>• One RCT<sup>32</sup> on the effect of adalimumab on reducing depression symptoms in patients with moderate to severe psoriasis was found. Results showed that compared with the placebo group, the adalimumab group experienced an additional 6-point reduction in the Zung Self-rating Depression Scale (ZDS) score by week 12 or early termination. Depression improvement was correlated with improvement in Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality</li> </ul>	
--	--	--

<p>minimise adverse reactions?</p> <ul style="list-style-type: none"> <li>• augmentation strategies are safe and effective?</li> </ul> <p>Q5: What are appropriate ways to promote adherence for depression and physical health medication?</p> <p><b>Relevant section of the guideline</b></p> <p>8.2 Efficacy of pharmacological interventions</p> <p>8.3 Adverse effects of pharmacological interventions</p> <p>8.4 Interactions between medications for treating physical health problems and antidepressants</p> <p>8.5 Antidepressant</p>	<p>Index. The authors concluded that adalimumab treatment reduced psoriasis symptoms, reduced depression symptoms, and improved health-related quality of life in patients with moderate to severe psoriasis.</p> <ul style="list-style-type: none"> <li>• One RCT<sup>33</sup> on the treatment of depressive symptoms in patients with early stage breast cancer undergoing adjuvant therapy was found. Newly diagnosed patients were screened for depressive symptoms prior to the initiation of adjuvant therapy and those with depressive symptoms were randomized to a daily oral fluoxetine or a placebo. Results showed that the use of fluoxetine for 6 months resulted in an improvement in quality of life, a higher completion of adjuvant treatment and a reduction in depressive symptoms, compared to patients who received placebo. The authors concluded that an antidepressant should be considered for early stage breast cancer patients with depressive symptoms who are receiving adjuvant treatment.</li> <li>• One RCT<sup>34</sup> examined the effects of citalopram augmentation of antipsychotics on suicidal ideation in middle-aged and older</li> </ul>	
--	--	--

<p>discontinuation symptoms</p> <p><b>Recommendations</b></p> <p>Section 8.9</p> <p>Recommendations 8.9.1.1 to 8.9.1.36</p>	<p>people with schizophrenia and subthreshold depressive symptoms. Patients with schizophrenia or schizoaffective disorder and subthreshold depressive symptoms were randomly assigned to flexible-dose citalopram or placebo augmentation of their antipsychotic for 12 weeks. Results showed that in participants with no baseline suicidal ideation, there were no significant differences between citalopram and placebo regarding "emergent" ideation. In participants with baseline suicidal ideation, citalopram reduced suicidal ideation, especially in those whose depressive symptoms responded to treatment.</p> <ul style="list-style-type: none"> <li>• One open-label pilot study<sup>35</sup> on duloxetine pharmacotherapy and Depression and Pain Care Management (DPCM) in older adults with major depressive disorder (MDD) and chronic low back pain (CLBP) was found. Results showed significant improvements in mental health-related quality of life, anxiety, sleep quality, somatic complaints, and both self-efficacy for pain management and for coping with symptoms. Physical health-related quality of life, back pain-related disability, and</li> </ul>	
---	--	--

	<p>self-efficacy for physical functioning did not improve. The authors concluded that serotonin and norepinephrine reuptake inhibitors like duloxetine delivered with DPCM may be a good choice to treat these linked conditions in older adults.</p> <p><u>Summary</u></p> <p>In summary, the identified studies relate to the use of pharmacological interventions for people with depression and a chronic physical health problem. The findings are in line with current guideline recommendations.</p>	
--	---	--

## **Ongoing clinical trials**

2 clinical trials were identified:

- Intervention study of depression in breast cancer patients (expected completion date December 2012)
- Behavioral activation therapy for rural veterans with diabetes and depression (expected completion date March 2016)

## **Guideline Development Group perspective**

A questionnaire was distributed to GDG members to consult them on the need for an update of the guideline. Two responses were received. One respondent stated that they do not think the guideline needs to be updated at this point in time. The other respondent's view was that the guideline needs to be updated as there is new evidence emerging rapidly, especially on diabetes and depression, that is generally supportive of or confirming guideline recommendations. This respondent provided references.

One respondent highlighted that they are involved in on two large RCTs that are both close to completion and that when published next year, the findings are very likely to be of relevance to the guideline.

All abstracts of references provided by the GDG members were included, assessed and are incorporated in Table 1.

## **Implementation and post publication feedback**

The NICE implementation team identified a number of studies from published literature relating to the guideline. These include:

- Low cost depression treatments 'not funded by NHS' (Health Insurance 2011)
- HI Magazine uncovers six month waits for NHS counselling (Health Insurance 2011)
- Community Mental Health Survey 2011 (Care Quality Commission 2011)

- Quarterly analysis of Improving Access to Psychological Therapies (IAPT) Key Performance Indicators (KPIs) Q1 Apr-11-June-11 (The NHS Information Centre for Health and Social Care 2011)
- Postnatal Depression Services: An Investigation into NHS Service Provision (The Patients Association 2011)
- National Audit of Psychological Therapies for Anxiety and Depression, National Report 2011 (Royal College of Psychiatrists 2011)
- An audit of the management of depression in a community population with intellectual disabilities in accordance with NICE guidance (Da Costa et al. 2011 British Journal of Development Disabilities 57 (2) 147-157).

In terms of qualitative input from the field team, no comments were identified that were directly related to this guideline (CG91 Depression with a chronic physical health problem). However, a number of comments were raised in relation to the Depression in adults guideline (CG90, published October 2009) that may apply to this guideline. These follow:

- The guideline (along with other NICE guidance) may have contributed to a general overhype of CBT (one person).
- The guideline may place too much emphasis on CBT and other psychological therapies should be given more consideration (one person).
- The costing tool is not realistic in terms of the cost impacts (one person).
- The guideline is excellent and has been helpful in developing a local care pathway jointly with GPs, and NICE's involvement in the field of mental health has been very positive and hugely helpful (one person).
- The guideline is difficult to implement as it cross cuts 3 divisions and no specialty ownership can be identified to lead implementation (one person).
- It is not clear what to do when treatment options in guidelines have been exhausted (one person).

- Despite PCTs developing shared care arrangements with primary care for schizophrenia, depression and physical care, GPs may be unwilling to take on the prescribing cost in primary care (one person).

In total 39 enquiries were received from post-publication feedback, most of which were routine. No new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

### Relationship to other NICE guidance

The following NICE guidance is related to CG91:

Guidance	Review date
Depression. NICE Pathway May 2011	To be confirmed
Depression in adults: Quality Standard. March 2011	To be confirmed
Service user experience in adult mental health: Quality Standard December 2011	To be confirmed
Alcohol dependence: Quality Standard August 2011	To be confirmed
Depression in adults: Evidence update April 2012	To be confirmed
Depression in adults with a chronic physical health problem: Evidence Update March 2012	To be confirmed
TA97 Computerised cognitive behaviour therapy for depression and anxiety. February 2006	The recommendations in this technology appraisal relating to the treatment of depression have been replaced by recommendations in the two depression clinical guidelines (CG90 and CG91); the recommendations that deal with phobia will be updated within an ongoing clinical guideline

PH 24 Alcohol-use disorders: preventing harmful drinking June 2010	May 2013
PH 22 Promoting mental wellbeing at work. November 2009	October 2012
PH16 Mental wellbeing and older people October 2008	November 2014
PH 19 Management of long-term sickness and incapacity for work. March 2009	The review of this guidance has been deferred in light of 3 new referrals that were received from Ministers
IPG330 Vagus nerve stimulation for treatment-resistant depression. August 2009	To be confirmed
IPG242 Transcranial magnetic stimulation for severe depression. November 2007	To be confirmed
CG15 Type 1 diabetes: Diagnosis and management of type 1 diabetes in children, young people and adults. July 2004	To be confirmed
CG16 Self-harm: The short-term physical and psychological management and secondary prevention of self-harm in primary and secondary care. July 2004	February 2015
CG37 Postnatal care. October 2006	Following the recent review recommendation, it has been decided not to update this guideline at this stage. The guideline will be reviewed for update again in July 2015
CG38 Bipolar disorder. July 2006	Following the recent review recommendation, an update of this guideline is currently in the process of being scheduled into the work programme

CG45 Antenatal and postnatal mental health. February 2007	An update of this guideline is currently in the process of being scheduled into the work programme
CG88 Low back pain: Early management of persistent non-specific low back pain. May 2009	An update of this guideline is currently in the process of being scheduled into the work programme
CG96 Neuropathic pain: The pharmacological management of neuropathic pain in adults in non-specialist settings. March 2010	An update of this guideline is currently in the process of being scheduled into the work programme
CG110 Pregnancy and complex social factors. September 2010	September 2013
CG113 Anxiety. January 2011	To be confirmed
CG115 Alcohol dependence and harmful alcohol use February 2011	To be confirmed
CG123 Common mental health disorders. May 2011	To be confirmed
CG133 Self-harm (longer term management) November 2011	To be confirmed
CG136 Service user experience in adult mental health. December 2011	To be confirmed
<b>Related NICE guidance in progress</b>	
The following relevant Quality Standards are in development <ul style="list-style-type: none"> <li>• Self-harm</li> <li>• Drug-use disorders</li> </ul>	To be confirmed To be confirmed
The following relevant Quality Standards have been referred <ul style="list-style-type: none"> <li>• Anxiety</li> <li>• Self harm (vulnerable groups, children and young people)</li> </ul>	To be confirmed To be confirmed

### **Anti-discrimination and equalities considerations**

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The guideline addresses the treatment of depression in people with chronic physical health problems in the NHS in England and Wales.

### **Conclusion**

Through the process no new evidence was identified which would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations.

## **3. Review recommendation**

The guideline should not be considered for an update at this time.

Centre for Clinical Practice  
August 2012

## References

1. Katon WJ, Lin EH, Von KM et al. (30-12-2010) Collaborative care for patients with depression and chronic illnesses. *New England Journal of Medicine* 363:2611-2620.
2. Lin EH, Von KM, Ciechanowski P et al. (2012) Treatment adjustment and medication adherence for complex patients with diabetes, heart disease, and depression: a randomized controlled trial. *Annals of Family Medicine* 10:6-14.
3. Bogner HR, Morales KH, De Vries HF et al. (2012) Integrated management of type 2 diabetes mellitus and depression treatment to improve medication adherence: a randomized controlled trial. *Annals of Family Medicine* 10:15-22.
4. Ciechanowski P, Chaytor N, Miller J et al. (2010) PEARLS depression treatment for individuals with epilepsy: a randomized controlled trial. *Epilepsy & Behavior* .
5. Chaytor N, Ciechanowski P, Miller JW et al. (2011) Long-term outcomes from the PEARLS randomized trial for the treatment of depression in patients with epilepsy. *Epilepsy & Behavior* .
6. Khunti K, Gray LJ, Skinner T et al. (2012) Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *BMJ* 344:e2333.
7. van Bastelaar KM, Pouwer F, Cuijpers P et al. (2011) Web-based depression treatment for type 1 and type 2 diabetic patients: a randomized, controlled trial. *Diabetes Care* .
8. Hartmann M, Kopf S, Kircher C et al. (2012) Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients: design and first results of a randomized controlled trial (the Heidelberger Diabetes and Stress-study). *Diabetes Care* 35:945-947.
9. Ruusunen A, Voutilainen S, Karhunen L et al. (2012) How does lifestyle intervention affect depressive symptoms? Results from the Finnish Diabetes Prevention Study. *Diabetic Medicine* .
10. Chen SM, Creedy D, Lin HS et al. (2012) Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: a randomized controlled trial. *International Journal of Nursing Studies* 49:637-644.
11. Baumeister H, Hutter N, and Bengel J. (2011) Psychological and pharmacological interventions for depression in patients with coronary

- artery disease. [Review]. Cochrane Database of Systematic Reviews 2011.
12. Beckie TM, Beckstead JW, Schocken DD et al. (2011) The effects of a tailored cardiac rehabilitation program on depressive symptoms in women: A randomized clinical trial. *International Journal of Nursing Studies* .
  13. Warber SL, Ingerman S, Moura VL et al. (2011) Healing the heart: a randomized pilot study of a spiritual retreat for depression in acute coronary syndrome patients. *Explore: The Journal of Science & Healing* - Aug.
  14. Cully JA, Stanley MA, Deswal A et al. (2010) Cognitive-behavioral therapy for chronic cardiopulmonary conditions: preliminary outcomes from an open trial. *Primary care companion to the Journal of clinical psychiatry* 12.
  15. Beatty LJ, Koczwara B, Rice J et al. (2010) A randomised controlled trial to evaluate the effects of a self-help workbook intervention on distress, coping and quality of life after breast cancer diagnosis. *Medical Journal of Australia* 2010.
  16. Eyigor S, Karapolat H, Yesil H et al. (2010) Effects of pilates exercises on functional capacity, flexibility, fatigue, depression and quality of life in female breast cancer patients: a randomized controlled study. *European journal of physical & rehabilitation medicine*.
  17. Hopko DR, Armento ME, Robertson SM et al. (2011) Brief behavioral activation and problem-solving therapy for depressed breast cancer patients: randomized trial. *Journal of Consulting & Clinical Psychology* .
  18. Mehnert A, Veers S, Howaldt D et al. (2011) Effects of a physical exercise rehabilitation group program on anxiety, depression, body image, and health-related quality of life among breast cancer patients. *Onkologie* .
  19. Sherr L, Clucas C, Harding R et al. (2011) HIV and depression--a systematic review of interventions. [Review]. *Psychology Health & Medicine* .
  20. Ransom D, Heckman TG, Anderson T et al. (2008) Telephone-delivered, interpersonal psychotherapy for HIV-infected rural persons with depression: a pilot trial. *Psychiatric Services* .
  21. Mitchell PH, Veith RC, Becker KJ et al. (2009) Brief psychosocial-behavioral intervention with antidepressant reduces poststroke depression significantly more than usual care with antidepressant: living well with stroke: randomized, controlled trial. *Stroke* .

22. Bombardier CH, Bell KR, Temkin NR et al. (2009) The efficacy of a scheduled telephone intervention for ameliorating depressive symptoms during the first year after traumatic brain injury. *Journal of Head Trauma Rehabilitation* -Aug.
23. Cosio D, Jin L, Siddique J et al. (2011) The effect of telephone-administered cognitive-behavioral therapy on quality of life among patients with multiple sclerosis. *Annals of Behavioral Medicine* .
24. Durmus D, Akyol Y, Alayli G et al. (2009) Effects of electrical stimulation program on trunk muscle strength, functional capacity, quality of life, and depression in the patients with low back pain: a randomized controlled trial. *Rheumatology International* .
25. Peters E, Landau S, McCrone P et al. (2010) A randomised controlled trial of cognitive behaviour therapy for psychosis in a routine clinical service. *Acta Psychiatrica Scandinavica* .
26. Hillier AJ, Fish T, Siegel JH et al. (2011) Social and vocational skills training reduces self-reported anxiety and depression among young adults on the autism spectrum. [References]. *Journal of Developmental and Physical Disabilities* 23:267-276.
27. Taylor D, Meader N, Bird V et al. (2011) Pharmacological interventions for people with depression and chronic physical health problems: systematic review and meta-analyses of safety and efficacy. [Review]. *British Journal of Psychiatry* .
28. Koch MW, Glazenborg A, Uyttenboogaart M et al. (2011) Pharmacologic treatment of depression in multiple sclerosis. [Review]. *Cochrane Database of Systematic Reviews* .
29. Kasckow J, Lanouette N, Patterson T et al. (2010) Treatment of subsyndromal depressive symptoms in middle-aged and older adults with schizophrenia: Effect on functioning. [References]. *International Journal of Geriatric Psychiatry* 25:183-190.
30. Khazaie H, Rahimi M, Tatari F et al. (2011) Treatment of depression in type 2 diabetes with Fluoxetine or Citalopram? *Neurosciences* .
31. Mazza M, Martini A, Scoppetta M et al. (2008) Effect of levetiracetam on depression and anxiety in adult epileptic patients. [References]. *Progress in Neuro-Psychopharmacology & Biological Psychiatry* 32:539-543.
32. Menter A, Augustin M, Signorovitch J et al. (2010) The effect of adalimumab on reducing depression symptoms in patients with moderate to severe psoriasis: a randomized clinical trial. *Journal of the American Academy of Dermatology* .

33. Navari RM, Brenner MC, and Wilson MN. (2008) Treatment of depressive symptoms in patients with early stage breast cancer undergoing adjuvant therapy. *Breast Cancer Research & Treatment* .
34. Zisook S, Kasckow JW, Lanouette NM et al. (2010) Augmentation with citalopram for suicidal ideation in middle-aged and older outpatients with schizophrenia and schizoaffective disorder who have subthreshold depressive symptoms: a randomized controlled trial. *Journal of Clinical Psychiatry* .
35. Karp JF, Weiner DK, Dew MA et al. (2010) Duloxetine and care management treatment of older adults with comorbid major depressive disorder and chronic low back pain: Results of an open-label pilot study. [References]. *International Journal of Geriatric Psychiatry* 25:633-642.