

# **Surveillance report – Depression in adults with a chronic physical health problem (2009) NICE guideline CG91**

November 2015

## **Surveillance decision**

We will not update the guideline at this time.

### ***Reason for the decision***

We found 67 new studies relevant to the guideline through the surveillance process.

This included new evidence on the experience of care of people with depression and a chronic physical health problem that is in line with current recommendations.

We identified new evidence on case identification and recognition of depression in people with a chronic physical health problem that mostly supports current recommendations.

We found new evidence on service-level interventions for people with depression and a chronic physical health problem that was mostly in line with current recommendations. Of particular interest was a new UK randomised controlled trial on collaborative care for the management of depression in people with a chronic physical health problem (see below). We asked topic experts whether this new evidence would affect current recommendations on collaborative care. Generally, topic experts thought that an update was not needed at this time.

We identified new evidence on psychological and psychosocial interventions. Of particular interest was a preliminary report of a randomised controlled trial on internet-based psychosocial interventions for depression in people with cancer. We asked topic experts whether this new evidence would affect

current recommendations and generally, the topic experts thought that an update was not needed at this time.

We also found new evidence on pharmacological interventions that are essentially supportive of the guideline recommendations.

None of the new evidence considered in surveillance of this guideline was thought to have an effect on current recommendations.

See [how we made the decision](#) for further information.

## Commentary on selected new evidence

With advice from topic experts we selected 3 studies for further commentary.

### [Stepped care – Service-level interventions \(collaborative care\)](#)

We selected the [COINCIDE trial](#) for a full commentary because it is a relevant new UK study on collaborative care for the management of depression in people with a chronic physical health problem.

#### **What the guideline recommends**

Recommendation [1.5.4.1](#) of the guideline states that collaborative care should be considered for patients with moderate to severe depression and a chronic physical health problem with associated functional impairment whose depression has not responded to initial high-intensity psychological interventions, pharmacological treatment or a combination of psychological and pharmacological interventions.

This recommendation is under the section on [step 3](#) of the stepped care approach, the focus of which is “persistent subthreshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions; moderate and severe depression”.

Recommendation [1.5.4.2](#) of the guideline further states that collaborative care should normally include the following:

- case management which is supervised and has support from a senior mental health professional
- close collaboration between primary and secondary physical health services and specialist mental health services
- a range of interventions consistent with those recommended in this guideline, including patient education, psychological and pharmacological interventions, and medication management
- long-term coordination of care and follow-up.

At [step 2](#), the following are recommended: low-intensity psychosocial interventions, psychological interventions, medication and referral for further assessment and interventions (section [1.2](#)). The guideline does not currently recommend collaborative care at step 2.

## **Methods**

[Coventry et al. \(2015\)](#) conducted a cluster randomised controlled trial (RCT) (COINCIDE trial) to test the effectiveness of an integrated collaborative care model for people with depression and long-term physical conditions. A total of 39 general practice clinics from the North West of England were recruited, and patients from these practices with diabetes or coronary heart disease who also had depressive symptoms for at least 2 weeks were included.

A central randomisation service was used to allocate the practices as they were recruited, with the allocation sequence concealed from both the general practice staff and all research staff, except a handful of senior investigators.

Blinding of participants was ensured during the initial phase of the trial. But because the trial used face-to-face psychological treatments, it was not possible to preserve the blinding of participants beyond baseline or to blind the health professionals delivering the intervention. However, blinding of outcome assessment was ensured as the trial investigators who collected outcome data remained blinded throughout the course of the trial.

Participants in the collaborative care arm received up to 8 sessions of psychological treatment in their GP clinics over 3 months. Treatment sessions were carried out by psychological wellbeing practitioners who served as case managers. Psychological wellbeing practitioners received a 5-day special training from a multidisciplinary team in the COINCIDE care model, and weekly supervision by an experienced psychological therapist.

In the first session, participants were interviewed about their main concerns, and a problem statement and goals were established. In subsequent sessions, participants undertook behavioural activation, cognitive restructuring, graded exposure and lifestyle changes.

The second and last treatment sessions were jointly delivered with the practice nurse. Participants in both arms received usual care from their general practitioners and practice nurses. This included referral for psychological therapy and prescription of antidepressant medications. However, control group participants did not receive treatment from psychological practitioners taking part in the COINCIDE trial.

The primary outcome was decline in depression scores on a 13-item checklist called SCL-D13, at 4 months post-randomisation. SCL-D13 is the depression component of the self-reported symptom checklist-90 (SCL-90).

Secondary outcomes included physical health outcomes measures, such as global quality of life (using the World Health Organization [WHO] quality of life measure, WHO-QOL-BREF), disease-specific quality of life (using the Diabetes quality of life and Seattle angina questionnaires) and disability (using the Sheehan disability scale). They also included change in behaviours and perception about managing long-term conditions by assessment of self-management (via the health education impact questionnaire), self-efficacy and illness beliefs (via the multimorbidity illness perceptions scale).

## **Results**

Three general practices, 2 from the intervention group and 1 from the control group, withdrew from the trial before patients were recruited. Hence a total number of 387 participants were randomised from across 36 general practices: 17 practices (191 participants) to collaborative care and 19 practices (196 participants) to usual care.

Follow-up data were collected on 350 (90%) participants, with an attrition rate of 10%. However, missing outcome data was balanced in numbers across the 2 groups (170 participants were followed up in the collaborative care group [89.0%] compared with 180 in the usual care group [91.8%]) Reasons for missing data were similar across groups (21 participants lost to follow-up in the collaborative care group [11.0%] compared with 16 lost to follow-up or died [13 loss to follow up, 3 died] in the usual care group [8.2%]).

Baseline characteristics of the participants showed that:

- over 75% were from practices located in moderately-to-heavily deprived areas, with over 50% being categorised as highly deprived,
- 75% were not in paid work
- nearly 65% had moderate or severe depression
- 75% had anxiety
- 50% were prescribed antidepressants or anti-anxiety drugs
- there was a high degree of multimorbidity, with participants having an average of 6 other medical problems in addition to diabetes or coronary heart disease.

For the primary outcome, mean depression scores on the SCL-D13 at 4 months were 0.23 points lower (95% confidence interval [CI] 0.41 to 0.05 lower) for collaborative care compared with usual care. This equated to an effect size of  $-0.30$  (95% CI  $-0.54$  to  $-0.07$ ).

For secondary outcomes, there were no significant differences between groups in global quality of life (effect size 0.13, 95% CI  $-0.10$  to 0.36), self-efficacy (effect size 0.13, 95% CI  $-0.09$  to 0.34), disability (effect size  $-0.11$ , 95% CI  $-0.29$  to 0.08) and social support (effect size 0.01, 95% CI  $-0.18$  to 0.20). Core aspects of self-management on 5 of the 8 domains of the health education impact questionnaire (heiQ) improved significantly in the collaborative care group compared with the usual care group.

## **Strengths and limitations**

### ***Strengths***

- The study is a relatively large, well conducted UK RCT with a population that closely matched that looked at in the guideline.
- Low risk of selection bias due to adequate randomisation and allocation concealment.
- Low risk of detection bias as there was blinding of outcome assessment. Researchers who collected outcome data remained blinded to treatment allocation throughout the course of the trial.

- Low risk of attrition bias due to minimal loss to follow up. Follow-up data was collected for 90% of participants, with an attrition rate of 10%. Missing outcome data was balanced in numbers across intervention groups, with similar reasons for missing data across groups. In addition, the authors used multiple imputations for the main analysis to take account of missing data.

### ***Limitations***

- The main limitation, acknowledged by the authors of the study, is that the trial was able to assess only the short-term effectiveness of collaborative care. We do not know if the positive effects persist beyond 4 months.
- Despite the use of self-reported questionnaires and masking of research staff to allocation, all outcome data were collected face to face at follow-up. Researchers might have been made aware of treatment allocations, leading to assessment bias.

### **Impact on guideline**

The COINCIDE trial suggests that patients with high levels of mental and physical comorbidity can gain modest but additional benefits from brief low-intensity psychological interventions when delivered in partnership with practice nurses when compared with usual care (which may have included low-intensity psychological therapy or medicines). However, many of the study participants were already receiving antidepressant medication, which may suggest that they would already fit the criteria for collaborative care specified in the guideline. In addition, the study findings are limited by a short follow-up period, and the cost-effectiveness of the COINCIDE care model is unknown.

More research outputs from the COINCIDE trial may be published. In addition, NICE is currently developing a guideline on multimorbidity. The NICE guideline on [depression in adults](#) is being updated, with the update being triggered mainly by recent studies on collaborative care for adults with depression. Therefore, the COINCIDE study does not provide sufficient evidence to update the guideline at this in time. It should be flagged for the next surveillance review, when there may be additional relevant evidence.

## **Step 1: recognition, assessment and initial management in primary care and general hospital settings – Case Identification**

We selected the systematic review by [Thombs et al. \(2013\)](#) for a full commentary because it strengthens the evidence base against routine screening for depression in people with a chronic physical health problem.

### **What the guideline recommends**

The guideline does not recommend routine screening for depression in adults with a chronic physical health problem but instead advocates the use of 2 questions to identify depression when it is suspected and a further 3 questions to improve the accuracy of the assessment of depression in people with a chronic physical health problem (recommendations [1.3.1.1](#) to [1.3.1.3](#)).

### **Methods**

Thombs et al. (2013) carried out a systematic review of evidence on depression screening in coronary heart disease (CHD). The systematic review updated a previous review from November 2008. There were 3 review questions:

- Key Question 1 – What is the accuracy of depression screening instruments in CHD?
- Key Question 2 – Does treatment of depression in CHD improve depressive symptoms or cardiac outcomes?
- Key Question 3 - Does depression screening in CHD improve depression outcomes?

For Key Question 1, diagnostic accuracy studies were included reporting data that allowed determination of sensitivity, specificity, positive predictive value and negative predictive value compared with a DSM (Diagnostic and Statistical Manual of Mental Disorders) diagnosis of major depressive disorder (MDD) or an ICD (International Classification of Diseases) depressive episode. This was established with a validated diagnostic interview administered within 2 weeks of the screening tool.



For Key Question 2, RCTs were included that compared treating depression with placebo or usual care among CHD patients with MDD or an ICD depressive episode based on a validated diagnostic interview. For trials of patients with MDD and other conditions (for example, minor depression), original study data was sought for patients with MDD for trials with 80% power to detect a 0.50 standardised mean difference effect size (n=64 per group).

For Key Question 3, RCTs that compared depression outcomes between CHD patients who underwent depression and those who did not were included.

The authors searched the CINAHL, Cochrane, EMBASE, ISI, MEDLINE, PsycINFO and SCOPUS databases from January 2008 to December 2011. Studies of screening accuracy (Key Question 1) and RCTs of depression treatment (Key Question 2) and screening (Key Question 3) were identified. Additional searching of reference lists and citations of included articles, relevant systematic reviews, selected journals and trial registries were done.

Data extraction was independently done by 2 investigators who also assessed the quality of included studies, with consensus used when disagreements arose. For Key Question 1, study quality was assessed with the revised Quality Assessment for Diagnostic Accuracy Studies (QUADAS) tool. The Cochrane Risk of Bias tool was used for Key Question 2. No studies were identified for Key Question 3, so no quality assessment tool was specified.

## **Results**

Results were not pooled quantitatively.

Key Question 1:

- 18 articles on 15 diagnostic accuracy studies of various populations, screening tools and cut-offs were included.
- Two studies reported the diagnostic accuracy of using a cut-off of 10 or above on the Beck Depression Inventory:

- in patients admitted to hospital after a myocardial infarction (MI): sensitivity of 82% (95% CI 66% to 91%) and specificity of 78% (95% CI 71% to 83%)
- in hospitalised patients with heart failure: sensitivity of 88% (95% CI 80% to 92%) and specificity of 58% (95% CI 54% to 63%).
- Two studies reported the diagnostic accuracy of using a cut-off of 14 or more on the Beck Depression Inventory-II in patients with acute coronary syndrome:
  - hospitalised patients: sensitivity of 89% (95% CI 79% to 95%) and specificity of 74% (95% CI 70% to 78%)
  - outpatients: sensitivity of 91% (95% CI 81% to 96%) and specificity of 78% (95% CI 74% to 80%).
- The diagnostic accuracy of the Patient Health Questionnaire (PHQ-9) was:
  - cut-off of 10 or more in a US study: sensitivity of 54% (95% CI 47% to 60%) and specificity of 90% (95% CI 88% to 92%)
  - cut-off of 6 or more in the US study: sensitivity of 83% (95% CI 78% to 87%) and specificity of 76% (95% CI 73% to 79%).
  - cut-off of 6 or more in an Australian study: sensitivity of 83% (95% CI 67% to 92%) and specificity of 78% (95% CI 71% to 84%).

#### Key Question 2:

- A total of 8 RCTs of heterogeneous patient samples, therapeutic interventions and treatment durations were included. There were 6 antidepressant studies:
  - 3 with post-MI patients that tested mirtazapine, sertraline and fluoxetine
  - 2 with heart failure patients that tested citalopram and sertraline
  - 1 with stable CHD patients that tested citalopram.
- The 4 studies in post-MI and stable CHD patients all reported positive, albeit small, effects for reduced symptoms of depression compared with placebo or usual care (Hedges's *g* ranged between 0.20 and 0.38). The 2 studies that treated patients with heart failure, on the other hand, did not

find that citalopram or sertraline reduced symptoms of depression compared with placebo.

- There were 2 studies on psychotherapy (no studies reported improved cardiac outcomes):
  - the ENRICHED trial found that cognitive behavioural therapy compared with usual care reduced depressive symptoms (Hedges's  $g$  0.20, 95% CI 0.07 to 0.33)
  - the CREATE trial (which also included a comparison of citalopram with placebo) showed no significant differences between groups (Hedges's  $g$  -0.23, 95% CI -0.46 to 0.00).

No eligible studies were identified for Key Question 3.

The authors concluded that there is evidence that treatment of depression results in modest improvement in depressive symptoms in patients after MI and stable CHD, but not in patients with heart failure. There is no evidence that routine screening for depression improves depression or cardiac outcomes.

## **Strengths and limitations**

### ***Strengths***

This study is a relatively well conducted systematic review of relevant studies. The review adhered to pre-defined objectives and eligibility criteria. The search included an appropriate range of databases and electronic sources for published reports, and methods additional to database searching were used to identify relevant reports. Methodological quality of included studies was assessed using appropriate tools and all relevant study results were collected for use in the synthesis of findings.

### ***Limitations***

The studies were mostly conducted in Europe and North America, but only among adults with depression and CHD and not chronic diseases in general. Therefore the trial population is only a partial match to the guideline population.

## **Impact on guideline**

The guideline does not recommend routine screening for depression. It advocates the use of 2 questions to identify depression and a further 3 questions for depression in chronic physical health problems.

This approach is supported by this systematic review, which concluded that there is no evidence to support routine screening for depression in people with CHD.

### **[Step 2: recognised depression in primary care and general hospital settings - persistent subthreshold depressive symptoms or mild to moderate depression – Psychological and psychosocial interventions](#)**

We selected the [Borosund et al. \(2014\)](#) study for a full commentary because it presents preliminary findings of a trial on web-based interventions. This is likely to be a key development area in the future.

## **What the guideline recommends**

Internet-based interventions are generally not mentioned in the guideline. The only web-based intervention recommended in the guideline relates to delivery of computerised cognitive behavioural therapy (CCBT) as part of Step 2 care (recommendation [1.4.2.1](#)). The guideline states that CCBT should be provided via a stand-alone computer-based or web-based programme for:

- patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and
- patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem (recommendation [1.4.2.5](#)).

## **Methods**

[Borosund et al. \(2014\)](#) reported preliminary findings from 6 months' follow-up data in a 12-month trial of e-communication, web-based self-management support and usual care among breast cancer patients in Norway. The authors' aim was to compare, in regular care, the effects of the following on symptom

distress, anxiety and depression (primary outcomes), and self-efficacy (secondary outcome):

- an Internet-based patient provider communication service (IPPC)
- WebChoice, a web-based illness management system for breast cancer patients (IPPC included)
- usual care (followed up as usual at the hospital where they were treated).

Study participants were recruited from 3 hospitals in Norway. Eligible patients scheduled for surgery or coming in for check-ups after surgery or treatment were identified by the study nurses at the hospitals and provided with information about the study. Consenting patients completed baseline questionnaires before randomisation.

Patients were randomised according to a pre-defined automated computerised block randomisation with a block size of 42 stratified by site. Allocation concealment was not reported. Because of the content of the interventions, patients could not be blinded to which arm they were randomised. Care providers were not entirely blinded to the intervention group assignment because this was sometimes disclosed by patients through the messages.

The nurse-administered IPPC allowed patients to send secure e-messages to and receive e-messages from healthcare personnel at the hospital where they were treated. In addition to the IPPC, WebChoice contains components for symptom monitoring, tailored information and self-management support, a diary, and communication with other patients. A total of 20 care providers (11 nurses, 6 physicians, and 3 social workers) were trained to answer questions from patients. Outcomes were measured with self-administered questionnaires at study entry and at study months 2, 4, and 6. Linear mixed models for repeated measures were fitted to compare effects on outcomes over time.

## Results

The 176 patients who agreed to participate in the study were randomised after filling in baseline questionnaires. Nine patients were excluded due to incomplete baseline data. This left a sample of 167 patients recently diagnosed with breast cancer and undergoing treatment in three Norwegian hospitals.

Patients were randomly assigned to the WebChoice group (n=64), the IPPC group (n=45), or the usual care group (n=58). At the 6-month measurement, 62% (104/167) answered the questionnaires: WebChoice 62% (40/64), IPPC 57% (25/45), and usual care group 67% (39/58). There was a 14% (23/167) attrition rate during the 6 months of follow-up. Reasons for withdrawal were not given; however, there was no association between baseline characteristics and those who left the study.

Among those with access to WebChoice, 64% (41/64) logged on more than once and 39% (25/64) sent e-messages to care providers. In the IPPC group, 40% (18/45) sent e-messages. Linear mixed models analyses revealed that the WebChoice group reported significantly lower symptom distress (mean difference 0.16, 95% CI 0.06 to 0.25), anxiety (mean difference 0.79, 95% CI 0.09 to 1.49), and depression (mean difference 0.79, 95% CI 0.09 to 1.49) compared with the usual care group.

The IPPC group reported significant lower depression scores compared with the usual care group (mean difference 0.69, 95% CI 0.05-1.32, P=0.03), but no differences were observed for symptom distress or anxiety.

No significant differences in self-efficacy were found among the study groups (mean differences 8.81, 95% CI -0.92 to 18.53 and -4.89, 95% CI -15.90 to 6.12 on the Cancer Behavioural Inventory, for WebChoice and IPCC compared to usual care, respectively).

The results of the study indicated that both interventions resulted in significantly lower depression compared to usual care, but that the

multicomponent web-based self-management intervention had additional positive effects.

## **Strengths and limitations**

### ***Strengths***

A strength of the study is that it is a randomised trial with a low risk of selection bias due to adequate randomisation. Patients were randomised according to a pre-defined automated computerised block randomisation with a block size of 42 stratified by site.

### ***Limitations***

The trial population (people with breast cancer) is only a partial match to the guideline population. In addition, the trial has weaknesses in reporting and methodology due to unclear allocation concealment, lack of blinding and a high attrition rate.

The following limitations were reported in the study:

- the sample size is relatively small; a larger sample would have increased the validity of the study and also increased statistical power
- low use of the interventions: the analyses of the intervention groups compared with the usual care group therefore compare the effects of a little-used intervention.

### **Impact on guideline**

Internet-based interventions are generally not mentioned in the guideline. The only web-based intervention recommended in the guideline relates to delivery of CCBT as part of step 2 care.

Although the results of this trial are positive, this is a preliminary report of the trial. The intervention has potential for patient groups with long-term conditions as it could improve their accessibility to psychological interventions, However, further research is needed to confirm these preliminary findings before considering for inclusion in the guideline.

## **How we made the decision**

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 6 years after the publication of [Depression in adults with a chronic physical health problem](#) (2009) NICE guideline CG91.

For details of the process and update decisions that are available, see [ensuring that published guidelines are current and accurate](#) in 'Developing NICE guidelines: the manual'.

The previous [surveillance update decision](#) for the guideline is on our website.

### ***New evidence***

We found 43 new studies in a search for systematic reviews published between 1 April 2012 and 26 February 2015. We also considered 24 additional studies identified by members of the Guideline Committee who originally worked on this guideline.

Evidence identified in previous surveillance 3 years after publication of the guideline and the [evidence update](#) (2012) was also considered. This included 35 studies identified by search in the 3-year surveillance decision and 16 studies in the evidence update, although 6 studies included in the evidence update were also included in the 3-year surveillance review.

From all sources, 112 studies were considered to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: decision matrix for summaries and references for all new evidence considered in surveillance of this guideline.

### ***Views of topic experts***

We considered the views of topic experts, including those who helped to develop the guideline.



## ***Views of stakeholders***

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication. Because this was a 6-year surveillance review, and the decision was not to update, we did not consult on the decision.

See [ensuring that published guidelines are current and accurate](#) in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

## ***Date of next surveillance***

Our next surveillance to decide whether the guideline should be updated is scheduled for 2017.

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