CollAborative care for Screen-Positive ElderRs with major depression (CASPER plus): a multicentred randomised controlled trial of clinical effectiveness and cost-effectiveness

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Scientific summary

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Scientific summary

Background

Depression is one of the most common reasons for consulting with a general practitioner (GP), and its associated personal and economic burden is considerable. Depression is often associated with long-term medical conditions but is commonly unrecognised or suboptimally treated. Older people are disproportionately affected by depression, which is associated with poor function and poor outcomes. Strategies to encourage the recognition and management of depression among older people and those with long-term conditions have been proposed. Guidance often encourages GPs to screen for depression, and evidence-supported treatments include the prescription of antidepressants and/or the provision of brief psychological treatments.

Collaborative care involves the provision of low-intensity psychosocial treatment by a case manager working in collaboration with the primary care team. Psychological interventions form part of care and are delivered over the telephone. Collaborative care has a strong evidence base among people with depression. The majority of trials have been conducted in the USA, although evidence from UK trials on the effectiveness of this approach is now accumulating. There are no large-scale trials that focus on older adults, who often have long-term physical health problems. In this trial, we adapted collaborative care for a population of older people whereby an evidence-supported treatment (including behavioural activation and medication management) was delivered by primary care psychological well-being practitioners over the telephone.

Objectives

The CollAborative care for Screen-Positive EldeRs with major depression (CASPER) plus trial was a randomised controlled trial (RCT) of usual GP care compared with the addition of collaborative care for the treatment of clinical depression in older adults. This included concurrent qualitative and economic evaluations. We first conducted an internal pilot trial, the objectives of which were to:

1. establish the clinical effectiveness of a low-intensity intervention of collaborative care for older adults with screen-positive major depression disorder.
2. examine the cost-effectiveness of a low-intensity intervention of collaborative care for older adults with screen-positive major depression disorder across a range of health and social care costs.
3. explore the views and experiences of the CASPER plus intervention within the collaborative care framework for the management of depression in older people from the perspectives of participants, case managers and GPs.

Method

Design

We conducted a pragmatic, multicentred, two-arm, parallel, open RCT. Participants with major depression disorder were individually randomised (1 : 1) to receive either collaborative care in addition to usual GP care, or just usual GP care.

Setting

Participants were recruited from general practices in four centres in the north of England: (1) York centre (the core centre) covering the city of York, Harrogate, Hull and the surrounding areas; (2) Leeds centre and the surrounding area; (3) Durham centre and the surrounding area; and, (4) Newcastle upon Tyne centre, including Northumberland and North Tyneside.

Participants

Potential participants were identified by postal questionnaire and were eligible if they reported depressive symptoms ('screened positive') to the Whooley questions, and were then found to have major depressive disorder according to standardised diagnostic criteria using the Mini International Neuropsychiatric Interview. Respondents with less severe depression ('subthreshold depression') were offered the opportunity to partake in a related Health Technology Assessment-funded trial (CASPER ISRCTN02202951) that is not reported in this monograph. We excluded people with known alcohol dependency, psychotic symptoms, recent evidence of suicidal risk or self-harm, significant cognitive impairment or other factors that would make an invitation to participate in the trial inappropriate, such as recent bereavement or terminal illness.

Interventions

Participants in the intervention group were allocated to receive a manualised low-intensity programme of collaborative care using behavioural activation, designed specifically for those aged ≥ 65 years with depression. Collaborative care was delivered by a case manager [a primary care mental health worker/Improving Access to Psychological Therapies (IAPT) worker]. Participants received on average six sessions over 8–9 weeks, of which, on average, one was delivered face to face and five were delivered over the telephone. Collaborative care in the CASPER plus trial consisted of telephone support, medication management, symptom monitoring and active surveillance, facilitated by a computerised case management. The first session was delivered face to face and subsequent sessions via the telephone.

Participants in the control group were allocated to receive usual GP care; therefore, they received no care additional to the usual primary care management of subthreshold depression offered by their GP. Participants who were allocated to collaborative care received the intervention as well as usual GP care.

Main outcome measures

The primary outcome was self-reported symptoms of depression, assessed by the Patient Health Questionnaire-9 items (PHQ-9) at 4 months post randomisation and also at 12 months and 18 months. Secondary outcomes were, at 4, 12 and 18 months, a dichotomised measure of depression according to 'caseness' (PHQ-9 score of ≥ 10), anxiety [measured by the Generalised Anxiety Disorder-7 item (GAD-7) scale], somatoform complaints [measured by the Patient Health Questionnaire-15 items (PHQ-15)] and health-related quality of life [measured by the Short Form questionnaire-12 items (SF-12)]. We also measured resilience (using the Connor–Davidson Resilience Scale-2 items) and antidepressant use. The economic evaluation resource use was ascertained from administrative primary care records and health-state utility was measured using the Short Form questionnaire-6 Dimensions.

Results

A total of 485 patients (mean age 72 years) were recruited to the trial between May 2012 and August 2014, with 249 participants randomised to collaborative care and 236 to usual GP care. Of these, 390 participants (80%: collaborative care, 75%; usual care, 86%) were followed up at 4 months, 358 participants (74%: collaborative care, 70%; usual care, 78%) were followed up at 12 months and 344 participants (71%: collaborative care, 67%; usual care, 75%) were followed up at 18 months. For those allocated to collaborative care, 83% engaged with the intervention and the average number of sessions completed was six out of the planned eight sessions.

Clinical effectiveness

Adjusted PHQ-9 score means and group differences for the primary analysis model revealed significant differences between trial arms at the 4-month primary outcome in favour of collaborative care [1.92 score points; 95% confidence interval (CI) 0.85 to 2.99 score points; $p < 0.001$]. This represented a standard effect size of 0.34. However, this difference in depression severity was not maintained at the long-term follow-up at 12 months ($p = 0.741$) or 18 months ($p = 0.997$). The results were robust to a number of sensitivity analyses, including adjustment for clustering at the level of the case manager. The proportion of participants with case-level depression at 4 months was reduced in the collaborative care group (odds ratio at 4 months 2.18, 95% CI 1.36 to 3.51; $p = 0.001$), but there was no clear advantage for collaborative care at 12 months (odds ratio 1.40, 95% CI 0.72 to 2.72; $p = 0.319$) or 18 months (odds ratio 0.72, 95% CI 0.31 to 1.71; $p = 0.461$).

Between-group differences were observed in favour of collaborative care for a range of secondary outcomes including anxiety and somatoform complaints. Anxiety was measured using the GAD-7 and was reduced at 4 months (GAD-7 mean score difference 1.68, 95% CI 0.77 to 2.59; $p < 0.001$) and at 12 months (mean score difference 1.09, 95% CI 0.14 to 2.03; $p = 0.024$), but not at 18 months ($p = 0.511$). Somatoform complaints as measured using the PHQ-15 were reduced at 4 months (PHQ-15 mean score difference 1.67, 95% CI 0.98 to 2.36; $p < 0.001$) and 12 months (PHQ-15 mean score difference 1.19, 95% CI 0.47 to 1.90; $p = 0.001$), but not at 18 months ($p = 0.423$). Health-related quality of life was improved in mental domains at 4 months (SF-12 mental component summary score mean score difference 3.02, 95% CI –5.04 to –0.99; $p = 0.004$) but not at 12 months ($p = 0.125$) or 18 months ($p = 0.273$), and there was no difference in physical domains (SF-12 physical component summary score $p = 0.583$ at 4 months; $p = 0.769$ at 12 months; and $p = 0.514$ at 18 months).

Cost-effectiveness analysis

Providing collaborative care was estimated to cost an average of £495 per participant (accounting for costs of training case managers, their expected rate of patient contacts and a standardised agenda case manager). Analysis of routinely collected data collected during the delivery of collaborative care (i.e. as may be provided within a typical IAPT service) suggests the expected cost of collaborative care is £198 per patient and, therefore, lower than assumptions based on the treatment manual. The number of quality-adjusted life-years (QALYs) gained was higher among articipants who were allocated to collaborative care than in the control group (difference in adjusted QALY gains = 0.019; $p = 0.338$). In the base-case analysis, the incremental cost-effectiveness ratio for collaborative care was £26,010 per QALY. The probability that the incremental cost-effectiveness of collaborative care was $<$ £20,000 per QALY was 39%, and the probability that it fell below the £30,000 per QALY willingness-to-pay threshold was 55%. When only participants who engaged with six or more sessions were included in the analysis, the cost per QALY estimate fell to £9876.

Qualitative evaluation

The qualitative study suggests that the intervention was acceptable to a large proportion of participants but that others did not engage. The main reasons for non-engagement were explored and were found to be related to the misgivings of participants about the potential benefits of behavioural-based programmes. The importance of the adaptation of treatment to those with long-term conditions or limitations was underlined. The positive aspects of treatment included the fact that people saw the benefits of behavioural activation and engaged well with their case managers, even if there were initial misgivings. The qualitative evaluation also highlighted the paucity of psychosocial interventions that are available for older people in primary care, and the potential role for collaborative care in 'plugging these gaps'. The role of the case manager was valued by participants in ensuring good communication with the GP and in the co-ordination of care, as well as providing them with the opportunity to talk outside the clinical setting of the primary care consultation room.

Conclusions

This is the first large-scale trial in the UK to test the clinical effectiveness and cost-effectiveness of using collaborative care to treat older people with depression. Collaborative care has been shown to be clinically effective at reducing depression severity in the short term, at 4-month follow-up, but benefits were not sustained at 12 or 18 months, so longer-term efficacy was not demonstrated. The effectiveness of collaborative care for older people with depression was greater for those people who had six or more treatment sessions. This intervention might be delivered as part of the IAPT services in the NHS at an acceptable ratio of benefits to cost – if it were highlighted that a minimum of six sessions were needed for it to be cost-effective.

Implications for health care

- Collaborative care was acceptable for the majority of older people with depression and could readily be delivered by low-intensity IAPT workers over the telephone, following a first face-to-face meeting.
- In this large-scale trial for older people with depression, collaborative care was clinically effective in improving the primary outcome of depression and across a range of secondary outcomes.
- The cost-effectiveness of collaborative care for depression has been robustly estimated within the CASPER plus trial and this could be viewed as cost-effective under conventional willingness-to-pay thresholds.

Recommendations for research

- A significant proportion of older people in the CASPER plus trial had a long-term health problem, and there were some improvements in quality of life across the trial population. Future adaptations and trials of collaborative care could focus on its use in populations with serious physical comorbidities and its impact on physical outcomes.
- More patients in the collaborative care arm discontinued treatment or dropped out of the trial. Further qualitative and quantitative work should explore the reasons for this, how to maximise the acceptability and effectiveness of collaborative care for this population and how to identify the most appropriate target population for the intervention.
- Depression is a recurrent disorder and it would be useful to judge longer-term impact on relapse and the prevention of future depression.
- This was a brief intervention and its benefits disappeared after 12 months. Future research should be conducted to establish how minimal interventions may be offered to ensure that early gains from treatment are sustained. Trials of 12-month top-up sessions for collaborative care (delivered by telephone) are needed.

Trial registration

This trial is registered as ISRCTN45842879.

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