**Participant Flow**

**Analysed at 6 months (n=30/33; 90.9%)**

Patients not analysed (n=3):

Could not be contacted (n=3)

**Analysed at 6 months (n=30/33; 90.9%)**

Patients not analysed (n=3):

Could not be contacted (n=2)

Withdrawn (n=1)

**Included in CBT alone group (n=33)**

**Included in Stepped Care group (n=33)**

Randomised in error (n=2)

Randomised (n=68)

**Baseline Characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Stepped Care (n=33)** | **CBT alone (n=33)** | **Total (n=66)** |
| **Sex**FemaleMale | 22 (66.7)11 (33.3) | 19 (57.6)14 (42.4) | 41 (62.1)23 (34.8) |
| **Age (years)**Means (SD) | 42.5 (13.6) | 44.1 (12.1) | 43.3 (12.8) |
| **Revised CIS-R total score 1**Means (SD) | 26.2 (4.8) | 26.8 (5.9) | 26.5 (5.4) |
| **ICD-10 diagnosis 2**MildModerateSevere | 2 (6.1)19 (57.6)12 (36.4) | 4 (12.1)14 (42.4)15 (45.5) | 6 (9.1)33 (50.0)27 (40.9) |
| **History of depression**Previous episode | 20 (60.6) | 24 (72.7) | 44 (66.7) |
| **Secondary Diagnosis**Any anxiety disorderLongstanding illness or disability | 23 (69.7)14 (42.4) | 26 (78.8)19 (57.6) | 49 (74.2)33 (50.0) |
| **Antidepressant treatment**Prescribed antidepressants | 14 (42.4) | 21 (63.6) | 35 (53.0) |

Notes: 1 Revised CIS-R = Clinical Interview Scheduled-Revised (Lewis et al, 1992) – a standard clinical interview for the identification of *Diagnostic and Statistical Manual of Mental Disorders* (DSM) Major Depressive Disorder; 2 ICD-10 = International Classification of Diseases version 10.0.

**Outcome Measures**

Treatment outcomes at baseline and six month follow-up

|  |  |  |  |
| --- | --- | --- | --- |
|  | **All** | **Stepped Care** | **CBT alone** |
|  | **n** | **Mean** | **SD** | **n** | **Mean** | **SD** | **n** | **Mean** | **SD** |
| BDI at baseline 1 | 66 | 27.4 | 6.9 | 33 | 26.9 | 6.4 | 33 | 27.9 | 7.4 |
| BDI at 6 months | 59 | 13.9 | 10.0 | 30 | 13.7 | 9.6 | 29 | 14.2 | 10.5 |
| **BDI difference from 0 to 6 m** | **59** | **-13.5** | **8.8** | **30** | **-13.4** | **8.6** | **29** | **-13.6** | **9.1** |
| GAD-7 at baseline 2 | 66 | 13.8 | 4.3 | 33 | 14.1 | 4.2 | 33 | 13.5 | 4.5 |
| GAD-7 at 6 months | 60 | 6.6 | 5.2 | 30 | 7.2 | 5.2 | 30 | 6.0 | 5.3 |
| **GAD-7 difference from 0 to 6 m** | **60** | **-7.3** | **5.7** | **30** | **-7.2** | **5.6** | **30** | **-7.3** | **5.9** |
| SF-36 PCS at baseline 3 | 66 | 51.5 | 10.3 | 33 | 52.4 | 11.1 | 33 | 50.7 | 9.5 |
| SF-36 PCS at 6 months | 59 | 49.4 | 10.7 | 29 | 50.9 | 8.7 | 30 | 47.9 | 12.3 |
| **SF-36 PCS difference from 0 to 6 m** | **59** | **-2.0** | **11.1** | **29** | **-1.4** | **10.7** | **30** | **-2.6** | **11.6** |
| SF-36 MCS at baseline 4 | 66 | 18.6 | 9.5 | 33 | 16.8 | 9.0 | 33 | 20.5 | 9.7 |
| SF-36 MCS at 6 months | 59 | 40.4 | 14.0 | 29 | 38.7 | 13.0 | 30 | 42.0 | 14.9 |
| **SF-36 difference from 0 to 6 m** | **59** | **21.3** | **12.5** | **29** | **21.2** | **10.7** | **30** | **21.3** | **14.2** |

Notes: 1 BDI = Beck Depression Inventory – version 1.0 (Beck et al, 1961); 2 GAD-7 = Generalised Anxiety Disorder-7 item questionnaire (Spitzer et al, 2006); 3 SF-36 PCS = Short Form Health Survey–36 Physical Component Scale (Ware et al, 2007); 4 SF-36 MCS = Short Form Health Survey-36 Mental Component Scale.

**Adverse Events**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **All** **(n=66)** | **Stepped Care (n=33)** | **CBT alone (n=33)** |
|  | **n** 1 | **%** | **n** | **%** | **n** | **%** |
| **Serious Adverse Events** |  |  |  |  |  |  |
| Physical health condition – life-threatening | 1 | 1.5 | 0 | 0 | 1 | 3.0 |
| Fatality | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total** | **1** | **1.5** | **0** | **0** | **1** | **3.0** |
| **Adverse Events** |  |  |  |  |  |  |
| Physical health condition – non-life threatening* Requiring hospitalisation
* No hospital stay required
 | 936 | 13.64.59.1 | 615 | 18.23.015.2 | 321 | 9.16.13.0 |
| Self-harm | 2 | 3.0 | 1 | 3.0 | 1 | 3.0 |
| Panic attack | 1 | 1.5 | 0 | 0 | 1 | 3.0 |
| **Total** 2 | **9** | **13.6** | **6** | **18.2** | **3** | **9.1** |

Notes: 1 n = number of patients affected; 2 Two patients’ experienced more than one adverse event of different types; the total number of patients affected by an adverse event does not, therefore, equate to the sum of patients affected by different adverse event types.