### Comparisons Included in this Clinical Question

<table>
<thead>
<tr>
<th>case management vs. standard care</th>
<th>Collaborative care vs. any form of standard care</th>
<th>Psychiatric liaison vs. standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BANERJEE1996</strong></td>
<td><strong>BOGNER2008</strong></td>
<td><strong>SCHRADER2005</strong></td>
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<td></td>
<td><strong>COLE2006</strong></td>
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<td></td>
<td><strong>CULLUM2007</strong></td>
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<td></td>
<td><strong>DOWIGHTJOHNSON2005</strong></td>
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<td><strong>ELL2007</strong></td>
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<td><strong>ELL2008</strong></td>
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<td></td>
<td><strong>FORTNEY2007</strong></td>
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<tr>
<td></td>
<td><strong>KATON2004</strong></td>
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<td></td>
<td><strong>KATZELNICK2000</strong></td>
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<td><strong>LANDIS2007</strong></td>
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<td><strong>LIN2003</strong></td>
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<td><strong>OSLIN2003</strong></td>
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<td><strong>STRONG2008</strong></td>
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<td></td>
<td><strong>WILLIAMS2004</strong></td>
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### Characteristics of Included Studies

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<tr>
<th>Methods</th>
<th>Participants</th>
<th>Outcomes</th>
<th>Interventions</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>BANERJEE1996</strong></td>
<td>n=69</td>
<td><strong>Data Used</strong></td>
<td><strong>Interventions</strong></td>
<td><strong>Notes</strong></td>
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<tr>
<td>Study Type: RCT</td>
<td>Age:</td>
<td>Mortality</td>
<td>Group 1 N=33</td>
<td>Multidisciplinary teams - Assigned a case manager who coordinated care with the psychogeriatric team and conducted home visits and follow up. Each case was presented to a multidisciplinary team. A management plan was formulated on an individual basis.</td>
</tr>
<tr>
<td>Study Description: <em>ITT included all randomised participants. Only those who completed the study were included in the logistic regression Type of Analysis: ITT</em></td>
<td>Sex: 12 males 57 females</td>
<td>Remission (below cut-off)</td>
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<tr>
<td>Blindness: No mention</td>
<td>Diagnosis: 100% Depression by AGECAT</td>
<td>MADRS</td>
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<tr>
<td>Duration (days): Mean 182</td>
<td>Exclusions: 185 years old</td>
<td>Notes: TAKEN AT: Baseline and 6 months post randomisation (end of treatment) DROP OUT: Intervention: 4/33 Control: 4/36</td>
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<tr>
<td>Setting: UK, London</td>
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<tr>
<td>Notes: RANDOMISATION: computer generated three digit random number</td>
<td>Info on Screening Process: 441 subjects eligible for screening, 317 completed the screen with 180 scoring above 8, 154 were interviewed, 17 refused informed consent. 69 people entered the study</td>
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Results from this paper: 
Quality assessment score +

**BOGNER2008**

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<td>Study Type: RCT</td>
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<td><strong>Data Used</strong></td>
<td><strong>Interventions</strong></td>
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<tr>
<td>Study Description: No details of drop out reported - unclear whether ITT has been used Type of Analysis: Completer</td>
<td>Age:</td>
<td>Physical health outcomes</td>
<td>Group 1 N=32</td>
<td>Collaborative care - Integrated care provided an individualised programme, integrating depression and hypertension management, care manager addressed factors to antidepressant and hypertension medication adherence, patient education, assessed side effects and progress.</td>
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<tr>
<td>Blindness: No mention</td>
<td>Sex: 15 males 49 females</td>
<td>Adherence to physical health medication CES-D</td>
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<tr>
<td>Duration (days): Mean 49</td>
<td>Diagnosis: 100% Depression by Current diagnosis</td>
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<td>Setting: US, Philadelphia</td>
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### Results from this paper:

#### Quality assessment score +

#### COLE2006

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<td>RCT</td>
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<tr>
<td>Study Description</td>
<td>Paper states ITT was applied but over 50% drop out not accounted for in analysis</td>
</tr>
<tr>
<td>Type of Analysis</td>
<td>Completer</td>
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<tr>
<td>Blindness</td>
<td>Single blind</td>
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<td>Setting</td>
<td>Canada, Montreal</td>
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<tr>
<td>Notes: RANDOMISATION</td>
<td>Block size randomisation with allocation concealment</td>
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#### Data Used

- Satisfaction with care
- Remission (below cut-off)
- Response (>50 reduction from baseline)
- Mortality

#### Group 1 N= 78

- Collaborative care - assessment and treatment with a general hospital psychiatrist, which included antidepressant medication and/or supportive psychotherapy, followed up by a case manager who liaised with the PCP and monitored progress and coordinated care

#### Group 2 N= 79

- Standard care - Usual care before and after discharge from hospital

#### Results from this paper:

- Collabative care component score - 15/26

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### Results from this paper:

#### Quality assessment score +

#### CULLUM2007

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<td>Type of Analysis</td>
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<td>Setting</td>
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<td>Notes: RANDOMISATION</td>
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</table>

#### Data Used

- Satisfaction with care
- Remission (below cut-off)
- Response (>50 reduction from baseline)
- Mortality

#### Group 1 N= 62

- Collaborative care - liaison psychiatric nurse supervised by the local CMHT-OP acted as case manager, who was responsible for assessing and formulating a care plan addressing psychological and social needs including the need for antidepressant medication. Liaison with PCP

#### Results from this paper:

- Collaborative care component score - 11/26 (only basic details about intervention provided in paper)
<table>
<thead>
<tr>
<th>Study Type: RCT</th>
<th>Study Description: ITT using IOCF</th>
<th>Type of Analysis: ITT</th>
<th>Bias: Single blind</th>
<th>Setting: US, California</th>
<th>Notes: RANDOMISATION: procedure not reported</th>
<th>Info on Screening Process: 401 eligible patients, 269 agreed to undergo screening. Of the 81 eligible patients, 55 agreed to participate and 53 completed baseline assessments</th>
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<tr>
<td>Number:</td>
<td>N = 28</td>
<td>Group 1</td>
<td>Collaborative care -liniciaStepped care approach with patient education about depression. Case managers supervised by psychiatrist. Problem solving therapy or antidepressant therapy. Case manager involved in medication management, follow up. Oncologist or physician consulted</td>
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<tr>
<td>Number:</td>
<td>N = 27</td>
<td>Group 2</td>
<td>Standard care - Participants were advised to consult with their physician about depression and a note was placed on their clinical record to indicate the presence of depression.</td>
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<tr>
<td>Data Used</td>
<td>Mortality</td>
<td>Adherence to physical health medication</td>
<td>Functional Assessment of Cancer Therapy-General</td>
<td>Response (&gt;50 reduction from baseline)</td>
<td>Notes: TAKEN AT: Baseline and 8 weeks (end of intervention)</td>
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<tr>
<td>Notes:</td>
<td>DROP OUT: Intervention 11/28 Control 15/27</td>
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<td>Diagnosis:</td>
<td>100% Depression by PHQ-9</td>
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<td>100% Cancer by Clinical judgement</td>
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<td>- cancers other than carcinoma of the cervix or breast cancer (stages I-II)</td>
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<td>- not meeting criteria for major depression or dysthymia or persistent depressive symptoms at both baseline and 1 month later</td>
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<td>Duration (days):</td>
<td>- gross cognitive impairment</td>
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<tr>
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<td>- unable to speak English or Spanish</td>
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<tr>
<td>Setting:</td>
<td>Baseline: no differences at baseline: PHQ-9 Intervention 12.6(7.0) Control 13.40(7.2)</td>
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**Results from this paper:**

**Quality assessment score +**

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<tr>
<th>Study Type: RCT</th>
<th>Study Description: Observed case analysis. ITT using LOCF analysis also conducted but not reported</th>
<th>Type of Analysis: Observed case</th>
<th>Bias: No mention</th>
<th>Setting: US, California (home healthcare)</th>
<th>Notes: RANDOMISATION: procedure not reported</th>
<th>Info on Screening Process: 9178 screened, 696 eligible for study, 272 refused to participate, 25 unable to consent.</th>
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<tbody>
<tr>
<td>Number:</td>
<td>N = 155</td>
<td>Group 1</td>
<td>Collaborative care - Existing staff acted as Clinical Depression Specialist and used a stepped care depression treatment algorithm. First-line treatment was choice of structured psychotherapy, problem solving therapy or antidepressant medication.</td>
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<tr>
<td>Number:</td>
<td>N = 156</td>
<td>Group 2</td>
<td>Enhanced standard care - Routine PHQ-9 screening at admission to home health care. If the participant screened positive, the primary care physician was informed.</td>
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<tr>
<td>Data Used</td>
<td>Numbers receiving pharmacological interventions</td>
<td>Response (&gt;50 reduction from baseline)</td>
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<td>Notes: TAKEN AT: Baseline and 12 months post randomisation (end of treatment)</td>
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<td>Bias: No mention</td>
<td>Setting: US, California</td>
<td>Notes: RANDOMISATION: Method not reported</td>
<td>Info on Screening Process: 2,334 screened for</td>
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<tr>
<td>Number:</td>
<td>N = 242</td>
<td>Group 2</td>
<td>Collaborative care component score: 20/26</td>
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<tr>
<td>Data Used</td>
<td>Pain intensity SF-12 PHQ-9 Mortality</td>
<td>Response (&gt;50 reduction from baseline)</td>
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eligibility, 571 met criteria for depression or dysthymia, 99 excluded.

- <18 years
- PHQ-9 <10
- Acute suicidal ideation
- advanced cancer or other condition limiting life expectancy to less than 6 months
- Scoring > 8 on Alcohol Use Disorders Identification Tool.
- Inability to speak English or Spanish

Notes: Time since diagnosis >90 days with advanced cancer excluded
Baseline: No baseline differences reported: PHQ9
Intervention: 12.79(4.4) Control: 13.17(4.51)

Cluster randomised
Collaborative care component score: 18/26

Data Used:
- Satisfaction with care
- SCL 20
- Response (>50 reduction from baseline)

Notes: All participants were on the GHC population based diabetes register
Baseline: Baseline SCL-20 score: Intervention 1.6(0.45)

Group 2 N= 230
Enhanced standard care - ll participants in the control condition received medical centre standard oncology care and supportive services routinely provided to all patients with cancer. Additionally received patient and physician education and depression treatments.

Results from this paper:
Quality assessment score +

FORTNEY2007

Study Type: RCT
Study Description: ITT with missing values were imputed using multiple imputation
Type of Analysis: ITT
Blindness: No mention
Duration (days): Mean 365
Setting: US, VA medical centres
Notes: RANDOMISATION: Unit of randomisation was the VA clinic
Info on Screening Process: 430 participants were enrolled in the study, of these 35 did not provide informed consent

n= 395
Age: Mean 60
Sex: 362 males 33 females
Diagnosis: 100% Depression by PHQ-9
Exclusions: - Serious mental illness
- current suicide ideation
- recent bereavement
- pregnancy
- substance dependence
- cognitive impairment
- receiving specialty mental health treatment
Notes: Even though not recruited specifically for a chronic physical health problem, 99% of the sample had at least 1 current chronic health problem
Baseline: No significant differences at baseline: PHQ-9
Intervention: 16.3(3.4) Control: 16.4(3.4)

Data Used:
- Quality of life (physical)
- Satisfaction with care
- Medication adherence
- Remission (no longer meeting diagnosis)
- Remission (below cut-off)

Notes: TAKEN AT: Baseline and 12 months post randomisation (end of treatment)
DROPOUT: Intervention: 31/177, Control: 29/218

Group 1 N= 177
Collaborative care - TEAM intervention, stepped care approach with watchful waiting or ADs as step one. Care management included symptom monitoring, education, assessing treatment barriers, follow-up of adherence, side effects and symptoms.

Group 2 N= 218
Enhanced standard care - All providers and patients received education. Results of depression screening were logged into electronic medical records.

Results from this paper:
Quality assessment score +

KATON2004

Study Type: RCT
Study Description: ITT - no details provided, used for modelling not dichotomous data (completer only)
Type of Analysis: ITT
Blindness: Single blind
Duration (days): Mean 365
Setting: US, Washington
Notes: RANDOMISATION: computerised algorithm
Info on Screening Process: 851 screened, 375 eligible, 329 randomised (46 refused randomisation, 42 refused, 4 did not provide consent)

n= 329
Age: Mean 58
Sex: 115 males 214 females
Diagnosis: Depression by PHQ-9
Exclusions: - no diagnosis of diabetes or depression
- hearing difficulties which would prevent telephone conversations
- currently in care of a psychiatrist
- bipolar disorder or schizophrenia
- use of antipsychotic or mood stabiliser medication
- mental confusion
- PHQ-9 score <10
Notes: TAKEN AT: Baseline and 12 months post randomisation (end of maintenance phase)
DROP OUT: Intervention 18/164 Control: 23/165

Data Used:
- Satisfaction with care
- SCL 20
- Response (>50 reduction from baseline)

Notes: TAKEN AT: Baseline and 12 month post randomisation (end of treatment)
DROPOUT: Intervention98/242 Control: 116/230

Group 1 N= 164
Collaborative care - Stepped care. Patient education followed by choice of first line treatment with either antidepressant medication or problem-solving treatment for primary care. If depression persisted, treatments were switched or participant referred for consultation

Group 2 N= 165
Standard care - usual care with those screening positive for depression advised to consult with their primary care physician regarding the depression
### Control: 1.7(0.51)

Results from this paper:

**Quality assessment score +**

<table>
<thead>
<tr>
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<td>Notes: RANDOMISATION: procedure not reported</td>
<td>info on Screening Process: 1465 screened positive for depression, of these 1295 agreed to complete second interview. 410 had HAM-D score &gt;15, of these 407 agreed to participate</td>
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<td>Response (&gt;50 reduction from baseline)</td>
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<td>Notes: TAKEN AT: BASELINE and 52 weeks post randomisation (end of maintenance treatment) DROP OUT: Intervention 15/218 Control 12/189</td>
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<td>Collaborative care - All patients received psychoeducation materials. Followed a medication algorithm with care coordinators telephoning patients to treatment adherence, side effects and response. Feedback and consultation with primary care physician</td>
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### KATZELNICK2000

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### LANDIS2007

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<th>Study Description: No mention of ITT</th>
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<td>Duration (days): Mean 168</td>
<td>Setting: US, North Carolina</td>
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<tr>
<td>Notes: RANDOMISATION: stratified by clinic and whether patient was receiving medication. Random numbers generated</td>
<td>Info on Screening Process: All adult medicaid patients were screened, with those eligible for the study contacted to participate. No further details.</td>
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<tr>
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<tr>
<td>SF-12</td>
<td>HAM-D</td>
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<tr>
<td>PHQ-9</td>
<td>Notes: TAKEN AT: Baseline and 6 months post randomisation (end of treatment) DROP OUT - not reported</td>
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<tr>
<th>Notes:</th>
<th>Group 1 N= 22</th>
<th>Group 2 N= 23</th>
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<tbody>
<tr>
<td>Collaborative care - General care manager monitored treatment adherence, side effects and response to ADs, routine follow-up via telephone, monitoring process of care, patient education and instruction in self-management techniques. GCMs also co-ordinated with PCPs</td>
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### LIN2003

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<th>Study Description: ITT analysis of repeated measures</th>
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<td>Duration (days): Mean 365</td>
<td>Setting: US, various clinics</td>
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<tr>
<td>Notes: RANDOMISATION: procedure not reported</td>
<td>info on Screening Process: All adult medicaid patients were screened, with those eligible for the study contacted to participate. No further details.</td>
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<tr>
<td>Pain intensity</td>
<td>Numbers receiving psychological treatment</td>
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<tr>
<td>Numbers receiving pharmacological interventions</td>
<td>Mortality</td>
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<tr>
<td>Mortality Response (&gt;50 reduction from baseline)</td>
<td>Notes: TAKEN AT: Baseline and 6 months post randomisation (end of treatment) DROP OUT - not reported</td>
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<table>
<thead>
<tr>
<th>Notes:</th>
<th>Group 1 N= 495</th>
<th>Group 2 N= 1001</th>
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<tbody>
<tr>
<td>Collaborative care - Stepped care with depression clinical specialist (case manager). Received an education video and booklet. First line treatment antidepressants or PST. Case manager contacted on average 9 times over 12 months. Reviewed progress and outcomes with PCP.</td>
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</table>

| Notes: | Sub-group analysis of Unutzer et al. (2002) IMPACT trial |

Cluster randomised - physician practices the unit of randomisation Collaborative care component score - 14/26
### Setting: US, multicentre

Notes: RANDOMISATION: stratified by recruitment centre and used a random computer number generator

Info on Screening Process: 2102 people eligible, 180 randomised (301 refused SCID or didn't complete it) 1001 people included in sub-group with arthritis

#### Notes:
- TAKEN AT: Baseline and 12 months post randomisation (end of study)
- DROPOUT: Intervention: 77/495 Control 74/506 (including mortality)

#### Notes:
- discussed with GP.

### 2 N= 506 Group

#### Standard care - Usual care from primary care physician

### Notes:
- RANDOMISATION: stratified by recruitment centre and used a random computer number generator

### Setting: US, multicentre

Notes: RANDOMISATION: cluster randomised with individual physician as the unit of randomisation

Info on Screening Process: 2489 selected for screening of which 838 consented. 45.3% were positive for depression with 61.7% of rheumatology and 47.5% of cardiology screenign positive for depression

### Notes:
- TAKEN AT: Baseline and 12 weeks post randomisation (end of treatment)
- DROPOUT: Intervention 57/331 Control 40/338

#### Notes:
- cluster randomised collaborative care component score - 15/26 Depression only data used 77/97 participants.

<table>
<thead>
<tr>
<th><strong>Results from this paper:</strong></th>
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<tr>
<td><strong>OSLIN2003</strong></td>
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</table>

**Study Type: RCT**

**Study Description:** Participants who withdrew from the study were considered in the primary outcome as having a negative outcome.

**Type of Analysis:** ITT

**Blindness:** Single blind

**Duration (days):** Mean 112

Setting: US, VA clinics including 23 physicians from cardiology clinics and 4 from rheumatology)

Notes: RANDOMISATION: cluster randomised with individual physician as the unit of randomisation

Info on Screening Process: 2489 selected for screening of which 838 consented. 45.3% were positive for depression with 61.7% of rheumatology and 47.5% of cardiology screenign positive for depression

### Notes:
- n= 97
- Age: Mean 62
- Sex: 93 males 4 females
- Diagnosis: 100% Depression by DSM-IV
- Exclusions: - <18 years
- active suicidal ideation
- regular use of illegal substances
- current hallucinations or a history of a primary psychotic disorder
- history of mania or hypomania

Notes: =50% of total participants were recruited from cardiology or rheumatology clinics, with a higher % for depression only sample used in the analysis.

Baseline: No differences at baseline: HDRS Intervention 14.3(5.6) control 15.5(5.4)

### Data Used

**Mortality**

**Diagnosis of MDD**

### Notes:
- TAKEN AT: Baseline and 4 months post randomisation (end of treatment)
- DROPOUT: not reported for depression only cases

### Group 1 N= 34

Collaborative care - Behavioural health specialist nurse maintained regular telephone contact to monitor treatment effectiveness, adverse events, treatment adherence and to offer support and education. AD's and psychosocial support provided. Nurse collaborated with GP

### Group 2 N= 43

Enhanced standard care - Usual care from the primary care physician or specialist. Yearly screening for depression. Providers educated on existing treatment guidelines, screening patients attending clinic, diagnostic information provided and general treatment suggestions given.

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<tr>
<td><strong>SCHRADER2005</strong></td>
<td></td>
</tr>
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</table>

**Study Type: RCT**

**Study Description:** ITT no further details provided

**Type of Analysis:** ITT

**Blindness:** No mention

**Duration (days):** Mean 365

Setting: Australia, Adelaide

Notes: RANDOMISATION: based on GP

Info on Screening Process: 669 screened positive for depression, with 872 not eligible for trial

### Notes:
- n= 669
- Age: Sex: no information
- Diagnosis: 100% Depression by CES-D
- 100% Cardiovascular disease by Clinical judgement
- Exclusions: - <18 or >64 years old
- CES-D <16

Notes: Participants were admitted to hospital with MI, unstable anguna, arrhythmia, congestive heart failure, coronary artery bypass surgery or angioplasty

Baseline: No differences at baseline reported

### Data Used

**Mortality**

**Diagnosis of MDD**

### Notes:
- TAKEN AT: Baseline and 12 weeks post randomisation (end of treatment)
- DROP Out: Intervention 57/331 Control 40/338

### Group 1 N= 331

Psychiatric consultation - Consultations followed routine practice, screening scores were sent to GP who took part in a 15-30 min telephone case conference with the attending psychiatric registr and cardiac rehab nurse, management tailored to patient based on consultation

### Group 2 N= 338

Standard care - standard cardiac and non-cardiac care

<table>
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<tr>
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<tr>
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</tbody>
</table>

**Notes:**
STRONG2008

Study Type: RCT

Study Description: ITT included all participants who were randomised and had available outcome data

Type of Analysis: ITT

Blindness: No mention

Duration (days): Mean 182

Setting: UK, Edinburgh

Notes: RANDOMISATION: no details reported

Info on Screening Process: 880 participants with MDD screened for eligibility, 328 did not meet inclusion criteria, 134 refused to participate

Data Used

Remission (below cut-off)

Response (>50 reduction from baseline)

Notes: TAKEN AT: Baseline and 6 month post randomisation (end of treatment)

DROPOUT: Intervention 15/101, Control 17/99

N= 101

Group

Collaborative care - Depression care for people with cancer. Included patient education, problem-solving therapy with a nurse, progress monitoring via monthly telephone calls. Psychiatrist reviewed progress. Nurse discussed ADs with patient and collaborated with GP

Collaborative care component score - 16/26

Data Used

Physical health outcomes

Mortality

SCL 20

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

Notes: RANDOMISATION: stratified by recruitment centre and used a random computer number generator

Setting: US, multicentre

Duration (days): Mean 365

Blindness: Single blind

Study Type: RCT

Study Description: ITT analysis of repeated measures

Type of Analysis: ITT

Data Used

Mortality

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in

Setting: US, Indianapolis

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in

Data Used

Mortality

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

N= 89

Group

Collaborative care - Three nurse-led components: psychoeducational sessions for patients and their families, initiating antidepressants and monitoring treatment effectiveness with PHQ-9. Monthly follow-up and treatment adjusted with senior supervision.

Collaborative care component score - 12/26

Collaborative care component score - 15/26

Sub-group analysis of Unutzer et al. (2002) IMPACT trial

Collaborative care component score - 15/26

Collaborative care component score - 12/26

Notes: FIXED analysis of repeated measures

Setting: US, multicentre

Duration (days): Mean 84

Blindness: Single blind

Study Type: RCT

Study Description: ITT using LOCF

Type of Analysis: ITT

Data Used

Mortality

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in

Setting: US, Indianapolis

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in

Data Used

Mortality

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

N= 93

Group

Standard care - Usual care

Collaborative care component score - 16/26

Notes: RANDOMISATION: stratified by recruitment centre and used a random computer number generator

Setting: US, multicentre

Duration (days): Mean 365

Blindness: Single blind

Study Type: RCT

Study Description: ITT analysis of repeated measures

Type of Analysis: ITT

Data Used

Mortality

PHQ-9

HAM-D

Response (>50 reduction from baseline)

Remission (below cut-off)

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in

Setting: US, Indianapolis

Notes: RANDOMISATION: computer generated list and treatment assigned concealed in
Info on Screening Process: 1175 potentially eligible subjects, 783 excluded (495 non depressed, 344 declined 148 no follow up)

- Severe language impairment and/ inability to speak and understand English
- Life expectancy <6 months
- Hemorrhagic stroke
- Active psychosis
- Suicidality
- Substance abuse
- Currently taking any MAOIs
- Women who were pregnant at time of stroke

Notes: Ischemic stroke
Baseline: No differences at baseline: HAM-D: Intervention 18.0(5.4) control: 19.2(5.9)

Results from this paper:
Quality assessment score - +

<table>
<thead>
<tr>
<th>Reference ID</th>
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<tbody>
<tr>
<td>BOGNER2008</td>
<td>(Published Data Only) Bogner, H. R. &amp; De, V. (2008). Integration of depression and hypertension treatment: A pilot, randomized controlled trial. Annals of Family Medicine, 6, 295-301</td>
</tr>
<tr>
<td>BOUMAN2008</td>
<td>No extractable data</td>
</tr>
<tr>
<td>HU2003A</td>
<td>Post-stroke rehab - not focussed on depression</td>
</tr>
<tr>
<td>KROENKE2008</td>
<td>No extractable data - scores for depression not conducted on a recognised scale</td>
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<td>KRAHN2006</td>
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<td>RABINS2000</td>
<td>Intervention does not meet definition (outside scope SMI outreach)</td>
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<tr>
<td>RAHIMI2008</td>
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<tr>
<td>KLEINE2009</td>
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<tr>
<td>STIEFEL2008</td>
<td>No extractable data</td>
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<td>TRIEF2007</td>
<td>Not depressed at baseline</td>
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References of Excluded Studies

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<td>HARINGSMA2006</td>
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<td>HU2003A</td>
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<td>Joubert2006</td>
<td>Prevention study</td>
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DWIGHTJOHNSON2005  (Published Data Only)

ELL2007  (Published Data Only)

ELL2008  (Published Data Only)

FORTNEY2007  (Published Data Only)

KATON2004  (Published Data Only)

KATZELNICK2000  (Published Data Only)

LANDIS2007  (Published Data Only)

LIN2003  (Published Data Only)

OSLIN2003  (Published Data Only)

SCHRADER2005  (Published Data Only)

STRONG2008  (Published Data Only)

WILLIAMS2004  (Published Data Only)

WILLIAMS2007  (Published Data Only)

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BURNS2007A

COLE2006a
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JOUBERT2006
(Published Data Only)

JOUBERT2008

KOIKE2002
(Published Data Only)

KRAHN2006

KRAHN2006

KROENKE2008

LEWIN2007
(Published Data Only)
Lewin, R.J., Coulton, S., Frierelle, D.J., (2007) A brief cognitive pre-implantation and rehabilitation programme for patients receiving an implantable cardioverter defibrillator improves physical health and reduces psychological morbidity and unplanned re-admissions. Heart,

OSLIN2004
(Published Data Only)

RABINS2000
(Published Data Only)
Rabins, P.V., Black, B.S., Roca, R. et al. (2000) Effectiveness of nurse-based outreach program for identifying and treating psychiatric illness in the elderly
RAHIMI2008

ROLLMAN2009 (Published Data Only)
Rollman, B.L., Belnap, B.H., Lenenger, M.S. et al. (2009) The bypassing the blues treatment protocol stepped collaborative care for healing post CABG depression. Psychosomatic medicine, feb, e-pub

SIREY2007 (Published Data Only)

STIEFEL2008 (Published Data Only)

TRIEF2007 (Published Data Only)

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### Comparisons Included in this Clinical Question

<table>
<thead>
<tr>
<th>Group-based cognitive and behavioural skills intervention versus standard care</th>
<th>Health education versus standard care</th>
<th>Individual guided self-help intervention versus standard care</th>
<th>Individual-based cognitive and behavioural skills intervention versus counselling</th>
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<tr>
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<td></td>
<td><strong>LUSTMAN1998</strong></td>
</tr>
<tr>
<td><strong>HECKMAN2007</strong></td>
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<tr>
<td><strong>HENRY1997</strong></td>
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<tr>
<td><strong>KELLY1993</strong></td>
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<tr>
<td><strong>LARCOMBE1984</strong></td>
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<tr>
<td><strong>LII2007</strong></td>
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<tr>
<td><strong>MARKOWITZ1998</strong></td>
<td></td>
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</tr>
</tbody>
</table>

### Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Methods</th>
<th>Participants</th>
<th>Outcomes</th>
<th>Interventions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADDOLORATO2004</strong></td>
<td>n= 66</td>
<td>Remission (below cut-off)</td>
<td>Group 1 N= 33</td>
<td>Do not perform sensitivity analysis as participants recruited for depression. Intervention modified to the physical illness.</td>
</tr>
<tr>
<td>Study Type: RCT</td>
<td>Age: Mean 31</td>
<td></td>
<td>Individual based cognitive and behavioural skills - Modified &amp; adapted to physical health problem. Stress management; cause &amp; effect of problems related to CD; every day difficulties;</td>
<td></td>
</tr>
<tr>
<td>Blindness: No mention</td>
<td>Sex: 29 males 37 females</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration (days): Mean 180</td>
<td>Diagnosis: 100% Depression/Anxiety by Zung (modified for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes: Details on randomisation not adequately</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Type: RCT</td>
<td>Participant numbers: N=101</td>
<td>Data Used: POMS-D</td>
<td>Group 1 N=76</td>
<td>Participants were not recruited for depression but had a mean BDI in the clinical range at baseline - study will be used in a sensitivity analysis. Intervention for stress management (not specific to depression).</td>
</tr>
<tr>
<td>----------------</td>
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</tr>
<tr>
<td>Study Description: *Analysed 101/130; those with an undetectable viral load were excluded (N=15 - treatment; N=14 - control). Includes LTfu &amp; non-completer</td>
<td>Age: Mean 42</td>
<td>BD1-21 item</td>
<td>Group based cognitive and behvioural skills - Cognitive behavioral stress management + medication adherence training that focused on adherence &amp; medical side effects. 10 weekly 135 min group sessions (4-9 men). Homework assign. Therapist = postdoctoral fellows/graduate students. Monitored fidelity.</td>
<td></td>
</tr>
<tr>
<td>Info on Screening Process: 257 HIV+ gay men were approached; 81 refused; 46 were excluded. Began trial with 130 men analysed only 101 with a detectable HIV viral load at baseline.</td>
<td>Sex: all males</td>
<td>Diagnosis: 100% HIV by Not specified</td>
<td>Group 2 N=54</td>
<td>Control - Medication adherence training only = licensed clinical pharmacists 1-H session at baseline, 30 min maintenance sessions at post-treatment &amp; 6-month follow-up. Gave information on medication, side effects and importance of adherence.</td>
</tr>
<tr>
<td>Exclusions: - prescribed medications with immunomodulatory effects (i.e. interferon)  - history of chemotherapy or whole body radiation treatment for cancer - history of chronic illness associated with permanent changes in the immune system - antibiotic use for an acute infection with the past 2 weeks - changes in the Highly Active Antiretroviral Therapy (HAART) - acute bodily infection during the past month - hospitalization for surgery within the past 3-months - intravenous drug use within the past 6-months - cognitive impairment - inability to read at the 6th grade level - current psychosis, drug or alcohol dependence and panic disorder - active suicidality - not between the ages of 18 and 65 - not gay</td>
<td>Notes: Average time since HIV diagnosis = 7.8 years (SD = 5.1); reported on average 6 HIV symptoms (range 0-12)</td>
<td>Notes: TAKEN AT: pre- and post-treatment (3-months) &amp; follow-up at 6-, 12-months. DROP OUTS: LTfu - N=22 treatment, N=23 control; Discontinued participation - N=2 treatment, N=5 control; EXCLUDED: N=15 treatment, N=14 control after randomisation.</td>
<td>Notes: TAKEN AT: pre- and post-intervention (6-months post-baseline). DROP OUTS: none reported.</td>
<td>Notes: TAKE AT: Family members at times participated. Individual. 1 session every 2 weeks.</td>
</tr>
<tr>
<td>Setting: Setting not reported</td>
<td>Follow-up: 6- and 12-months</td>
<td>Setting: US</td>
<td>Setting not reported</td>
<td>Follow-up: 6- and 12-months</td>
</tr>
<tr>
<td>Notes: Randomisation: no. id's were drawn from a box for assignment to conditions by the project manager &amp; overseen by principal investigator.</td>
<td></td>
<td>Duration (days): Mean 70</td>
<td></td>
<td>Duration (days): Mean 70</td>
</tr>
<tr>
<td>Results from this paper: Quality assessed: +</td>
<td></td>
<td>Study Type: RCT</td>
<td>Data Used: CES-D</td>
<td>Study Type: RCT</td>
</tr>
<tr>
<td>Type of Analysis: No mention</td>
<td>Notes: Average time since HIV diagnosis = 7.8 years (SD = 5.1); reported on average 6 HIV symptoms (range 0-12)</td>
<td>Study Description: *Analysed 101/130: those with an undetectable viral load were excluded (N=15 - treatment; N=14 - control). Includes LTfu &amp; non-completer</td>
<td>Group 1 N=15</td>
<td>Psychoeducation plus other - Individual. 4 x weekly. 75 min. 1. express feelings of HIV/medication. 2. Education regarding HIV. 3. barriers to medication. 4. roles of</td>
</tr>
<tr>
<td></td>
<td>Baseline: No baseline differences between treatment and control on depressed mood. Baseline scores of depression for treatment group (BD1-21 item) = 11.6 (SD = 8.0) and control group = 12.4 (SD = 9.2).</td>
<td></td>
<td>Group 2 N=54</td>
<td>Do not need to perform sensitivity as results are reported for a sub-group with depression. Component of intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data Used: POMS-D</td>
<td>Group 1 N=76</td>
<td>Group based cognitive and behvioural skills - Cognitive behavioral stress management + medication adherence training that focused on adherence &amp; medical side effects. 10 weekly 135 min group sessions (4-9 men). Homework assign. Therapist = postdoctoral fellows/graduate students. Monitored fidelity.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Notes: TAKEN AT: pre- and post-intervention (6-months post-baseline). DROP OUTS: none reported.</td>
<td>Group 2 N=54</td>
<td>Control - Medication adherence training only = licensed clinical pharmacists 1-H session at baseline, 30 min maintenance sessions at post-treatment &amp; 6-month follow-up. Gave information on medication, side effects and importance of adherence.</td>
</tr>
</tbody>
</table>
### BARTH2005

**Study Type:** RCT  
**Study Description:** Analyse data for participants who provided outcome data  
**Type of Analysis:** non-ITT  
**Blindness:** No mention  
**Duration (days):** Range 21-28  
**Follow-up:** No follow-up  
**Setting:** GERMANY  
**Type of Analysis:** Computer-generated  
**Info on Screening Process:** 5898 consecutive admission; 1709 screened; 441 had mental distress (HADS >17); 268 excluded from interview; 107 did not have depressive disorder as assessed in interview, further 7 excluded; 59 randomised; lost to follow-up: 0 - treatment, 4 - control.

- **n = 59**  
- **Age:** Mean 58  
- **Sex:** 45 males 14 females  
- **Diagnosis:** 100% Cardiovascular disease by Currently receiving treatment for disorder  
- **Exclusions:** HADS < 17 and no DSM-IV diagnosis of unipolar affective disorder  
- **Notes:** Myocardial infarction = 57.6%; coronary artery bypass graft = 33.9%; percutaneous transluminal coronary angioplasty = 22.0%; unstable angina pectoris 5.0%

### Results from this paper:

- **Quality assessed:** +

### BRODY2006

**Study Type:** RCT  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 42  
**Setting:** US  
**Notes:** Randomisation: computer-generated.

- **n = 32**  
- **Age:** Mean 82  
- **Sex:** 11 males 21 females  
- **Diagnosis:** 100% Macular degeneration  
- **Exclusions:** - did not meet criteria for DSM-IV major or minor depression - GDS-15 < 5  
- **Notes:** TAKEN AT: baseline and 6-month FU. DROP OUTS: only used completers who had depression at baseline.

### Results from this paper:

- **Quality assessed:** +
### BROWN1993

**Study Type:** RCT  
**Study Description:** *Did not include the 12 subjects who dropped out of treatment before completion of final post-treatment assessment*  
**Type of Analysis:** *Completers*  
**Blindness:** No mention  
**Duration (days):** Mean 84  
**Followup:** 3-, 9-, & 15-month  
**Setting:** US  
**Hospital**  
**Notes:** Details on randomisation not reported.  
**Info on Screening Process:** 54/107 met all the study criteria: reasons for exclusions included chronic, severe depression and/or anxiety preceeding the cardiac event; 14/54 excluded as dropped out of the study before final post-treatment assessment.  
**Data Used**  
- SCL 90  
- BDI-21 item  
**Notes:** TAKEN AT: pre- & post-treatment; 3-, 9- & 15-months follow-up. DROP OUTS: 12/54; in addition, when some participants dailed to complete some assessments, their scores were removed from those analyses.  
**1N = 20**  
- Group 
  - Individual based cognitive and behaviourial skills - 12 weekly x 1H sessions. Delivered by clinical psychogist/psychiatrist. Included pleasant activities, relaxation, cognitive restructuring, anger management. Therapist, patient + partner. Intervention for depression.  
**2N = 20**  
- Group 
  - Counseling - Therapists activities included expression of support, warmth & empathy. Offered interpretation, reflections & clarifications of the participants' feelings. Based on Rogers.  
**Notes:** Details on randomisation not reported.  
**Followup:** 3-, 9-, & 15-month  
**Setting:** US  
**Hospital**  
**Duration (days):** Mean 84  
**Blindness:** No mention  
**Study Type:** RCT  
**Study Description:** *Did not included the 12 subjects who dropped out of treatment before completion of final post-treatment assessment*  
**Info on Screening Process:** 54/107 met all the study criteria: reasons for exclusions included chronic, severe depression and/or anxiety preceeding the cardiac event; 14/54 excluded as dropped out of the study before final post-treatment assessment.  
**Type of Analysis:** *Completers Diagn*  
**Quality assessment:** +

### CHESNEY2003

**Study Type:** RCT  
**Study Description:** *Only includes participants with outcome data*  
**Type of Analysis:** Completers*  
**Blindness:**  
**Duration (days):** Mean 70  
**Followup:** 6-, 12-months (not for WLC)  
**Setting:** US, San Francisco  
**Hospital**  
**Notes:** Details on randomisation not reported. Allocation concealment not addressed.  
**Info on Screening Process:** 165 met entry criteria, 149 entered the study; 54 group based cognitive-behavioural; 51 health education; 44 control. Post-treatment: 128/149 (86%) retained.  
**Data Used**  
- CES-D  
**Notes:** TAKEN AT: pre- and post-intervention (not including: booster sessions) + 6-, 12-month FU (for two treatment conditions only). DROP OUTS: 21/149 (14%) at 3-month FU.  
**1N = 149**  
- Age: Mean 39 Range 24-58  
- Sex: all males  
- Diagnosis:  
  - 100% HIV/AIDS by Self-report  
  - 100% Depression by CES-D  
**Exclusions:** - not self-identified as gay or bisexual - not between the ages of 21 and 60 - self-reported CD4 levels not between 200 and 700 cells/mm3 - score less than 10 on the CES-D - major depressive disorder & psychotic disorders - history of alcohol dependence or substance use disorder in the past year - currently in psychotherapy or were using therapeutic doses of psychoactive medication on a regular basis - CD4 T-cell count to confirm diagnosis of AIDS  
**Notes:** Mean CD4 count was 403 (SD = 109); 7% had an AIDS-defining condition. Information on time since diagnosis not specified.  
**Baseline:** No significant differences at baseline. Baseline scores of CES-D: 17.9 (SD = 9.6) - group based cognitive-behavioural intervention; 15.7 (SD = 9.5) - health education; 16.9 (SD = 9.2) control.  
**Group 1 N= 54**  
- Group based cognitive and behaviourial skills - Group based (6-8). Cognitive theory aimed at stress & coping. Homework assigned. 10 weekly 90 min sessions + 6 maintenance sessions for remainder of year. Adaptation for HIV-related stressors. Co-therapists = graduate social worker/clinical psychology  
**Group 2 N= 51**  
- Health-education - 10 weekly group 90 min sessions on HIV-related topics & resources. Including information on clinical trials, legal issues. 6 maintenance sessions for remainder of year.  
**Group 3 N= 44**  
- Control - Waitlist control. After post-intervention and whilst other treatment conditions were receiving booster sessions during follow-up, received group based cognitive-behavioural intervention.  
**Results from this paper:**  
**Quality assessment:** +

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**Results from this paper:**

**Quality assessment:** +
### CLARK2003

**Study Type:** RCT  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 150  
**Setting:** Australia, Adelaide Community  
**Notes:** Randomisation = computer-generated. Allocation by sealed envelopes.  
**Info on Screening Process:** 139 admissions to rehabilitation unit, 32 excluded, 107 registered, 68 randomised: 33 - treatment, 35 - control. 62 completed: 30 - treatment, 32 - control.

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 30</th>
<th>N= 32</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Used</strong></td>
<td>GDS-15 item SF-36</td>
<td>Notes: TAKEN AT: pre - and post-intervention. DROP OUTS: 3/33 (9%) - treatment &amp; 3/35 (8%) - control.</td>
</tr>
<tr>
<td><strong>Group 1</strong></td>
<td>Psychoeducation plus other - Individual. Information package on stroke, practical coping suggestions, resources in community &amp; support structures. Therapist = social worker. Counselling for patient + spouse for stroke related stresses. 3 x 1H sessions at home over 5 months.</td>
<td>No treatment - No mention on the control group other than they did not receive the intervention. All participants discharged into community - assume it is a no treatment control.</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Randomisation = computer-generated. Allocation by sealed envelopes. Setting: Australia, Adelaide Community</td>
<td>Followup: 6-weeks Duration (days): Mean 42 Blindness: No mention Study Type: RCT Info on Screening Process: All participants were appropriate for the study; 4 declined. 2 participants in Waitlist dropped out.</td>
</tr>
<tr>
<td><strong>Type of Analysis:</strong> Completers</td>
<td><strong>Quality assessed:</strong> +</td>
<td><strong>Quality assessed:</strong> +</td>
</tr>
</tbody>
</table>

### DAVIS1984

**Study Type:** RCT  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Followup:** 6-weeks  
**Notes:** Details on randomisation not reported.  
**Info on Screening Process:** All participants were appropriate for the study; 4 declined. 2 participants in Waitlist dropped out.

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 8</th>
<th>N= 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Used</strong></td>
<td>BDI</td>
<td>Notes: TAKEN AT; pre- and post treatment. DROP OUTS: 0/9 CBT, 2/7 WLC. *NO STANDARD DEVIATIONS REPORTED.</td>
</tr>
<tr>
<td><strong>Group 1</strong></td>
<td>CBT - 6 weekly 2 hour classes. Group therapy. Led by social workers. Homework assigned. Therapy designed to treat depression. Please activities, physical exercise, self-talk, thought stopping, increasing positive cognitions. FU class (6-weeks after last session)</td>
<td>Waitlist - Offered treatment after post-assessment.</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Randomisation by computer-generated</td>
<td>Followup: 6-weeks Duration (days): Mean 42 Blindness: No mention Study Type: RCT Info on Screening Process: All participants were appropriate for the study; 4 declined. 2 participants in Waitlist dropped out.</td>
</tr>
<tr>
<td><strong>Type of Analysis:</strong> Completers</td>
<td><strong>Quality assessed:</strong> +</td>
<td><strong>Quality assessed:</strong> +</td>
</tr>
</tbody>
</table>

### DESROSiers2007

**Study Type:** RCT  
**Study Description:** Single blind = rater only blinded  
**Type of Analysis:** Completers  
**Blindness:** Single blind  
**Setting:** CANADA Community  
**Notes:** Randomisation by computer-generated

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 33</th>
<th>N= 29</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Used</strong></td>
<td>HRQOL CES-D</td>
<td>Notes: TAKEN AT: pre- and post-intervention. DROP OUTS: 4/33 - treatment, 2/29 - control.</td>
</tr>
<tr>
<td><strong>Group 1</strong></td>
<td>Social support - Leisure education program: aim to optimize leisure experiences. 8-12 sessions x 1H. Focused on leisure awareness, self-awareness &amp; competency development. Therapist = occupational/recreational. Delivered home/community.</td>
<td>Social support - Leisure education program: aim to optimize leisure experiences. 8-12 sessions x 1H. Focused on leisure awareness, self-awareness &amp; competency development. Therapist = occupational/recreational. Delivered home/community.</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Randomisation by computer-generated</td>
<td>Randomisation by computer-generated</td>
</tr>
<tr>
<td><strong>Type of Analysis:</strong> Completers</td>
<td><strong>Quality assessed:</strong> +</td>
<td><strong>Quality assessed:</strong> +</td>
</tr>
</tbody>
</table>

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**Results from this paper:**  
**Quality assessed:** +  
**Quality assessed:** +  
**Quality assessed:** +
with stratification based on functional independence.

<table>
<thead>
<tr>
<th>Study Type:</th>
<th>RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Design:</td>
<td>only those for whom all data were collected including FU data.</td>
</tr>
<tr>
<td>Type of Analysis:</td>
<td>Completers</td>
</tr>
<tr>
<td>Blindness:</td>
<td>No mention</td>
</tr>
<tr>
<td>Duration (days):</td>
<td>Mean 56</td>
</tr>
<tr>
<td>Followup:</td>
<td>6-month</td>
</tr>
<tr>
<td>Setting:</td>
<td>USA</td>
</tr>
<tr>
<td>Outpatient:</td>
<td>Yes</td>
</tr>
<tr>
<td>Info on Screening Process:</td>
<td>95 patients scheduled for radiation treatment; 78 had a CES-D of 16+ and were randomized.</td>
</tr>
</tbody>
</table>

**EVANS1995**

- **Participants recruited for depression and chronic physical health problems; intervention for depression.**
- **Data Used**
  - CES-D
- **Notes:** TAKEN AT: post-treatment and 6-month follow-up. DROP OUTS: 6 lost to FU because of death/illness;

<table>
<thead>
<tr>
<th>Group 1</th>
<th>N= 27</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT - 8-week, group therapy 1 hour per week, 6-9 patients led by social worker. Included homework assignments. Intervention designed for depression/ anxiety.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>N= 21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer Support - 8-week, group therapy 1 hour per week, 6-9 patients led by social worker. Modeled after support groups typically used in chronic illness. Members encouraged to describe feelings about having cancer.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 3</th>
<th>N= 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment - Did not attend intervention. Offered crisis intervention + individual therapy at no charge outside study protocol (only 2 persons took up offer).</td>
<td></td>
</tr>
</tbody>
</table>

**FOLEY1987**

- **Participants recruited for depression and chronic physical health problems; intervention for depression.**
- **Data Used**
  - BDI
- **Notes:** TAKEN AT: pre- and post-intervention. DROP OUTS: 5/4.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>N= 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual based cognitive and behavioural skills - 6 session cognitive-behavioural + shortened progressive deep-muscle relaxation. Therapist = advanced clinical psychologist. Focused on psychosocial stressors.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>N= 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control - Waitlist control, received treatment after 5 week delay. In the mean time received TAU: all received minimum of 2H supportive psychotherapy, N=2 antidepressants, 2 family counseling, 3 individual counseling.</td>
<td></td>
</tr>
</tbody>
</table>

**Results from this paper:**

1.1 Poorly addressed
1.2 Not reported
1.3 Not addressed
1.4 Not addressed
1.5 Adequately covered
1.6 Not addressed
1.7 Well covered
1.8 7.7% in total
1.9 Not addressed
1.10 Not applicable

2.1 +
### HECKMAN2007

**Study Type:** RCT  
**Study Description:** Perform analysis on participants who completed assessment form.  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 56  
**Follow-up:** 4-, 8-month  
**Setting:** US  
**Notes:** Details on randomisation/allocation concealment not reported.  
Info on Screening Process: 360 eligible; 61 excluded; 299 randomized; 257 completed post-assessment; 243 completed 4-month FU; 223 completed 8-month FU  
**Data Used**  
- HIV-Related Life-Stressor Burden Scale  
- SCL 90  
- BDI-21 item  
**Notes:** TAKEN AT: pre- and post-assessment & 4-, 8-month follow-up. DROP OUTS: Complete post-assessment 94/07 (usual care), 66/84 (psycho-education), 97/108 (cognitive-behavioural)  
**Group 1 N=107**  
- TAU - AIDS service organisations - case management, support groups, social services assistance.  
**Group 2 N=108**  
- Group based cognitive and behavioural skills - Coping Improvement Group Intervention - 8 weekly sessions. 6-8 per group. Therapist = Masters/PhD level clinicians. 90 mins. Separate groups for gay men. Cognitive-behavioural principles. Conducted using teleconference. Intervention aimed at stress/coping  
**Followup:** 4-, 8-month  
**Setting:** Primary care  
**Primary care**  
**Duration (days):** Mean 42  
**Blindness:** No mention  
**Study Type:** RCT  
**Study Description:** *'ITT' analysis does not include the two participants who discontinued their involvement in the programme for medical reasons.*  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 42  
**Follow-up:** No follow-up  
**Setting:** AUSTRALIA, Sydney  
**Primary care**  
**Notes:** Details on randomisation not reported.  
Info on Screening Process: 32 potential subjects, 21 met screening criteria, 2 discontinued treatment.  
**Data Used**  
- BDI  
**Notes:** TAKEN AT: pre- and post-assessment. DROP OUTS: two participants discontinued their involvement in the programme for medical reasons  
**Group 1 N=10**  
- CBT - 6 weekly 1.5-hour sessions. Group therapy. Muscle relaxation + cognitive coping skills training (i.e. monitor negative self-statements, problem solving). Homework assignments. Designed to cope with stress & anxiety.  
**Group 2 N=9**  
- Waitlist - Participants received treatment immediately following the past-treatment assessment period.  
**Perform sensitivity analysis as participants were not recruited for depression and chronic physical health problems. Sub-group analysis as intervention aimed at psychosocial stressors (stress and coping).**  

### HENRY1997

**Study Type:** RCT  
**Study Description:** Perform analysis on participants who completed assessment form.  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 42  
**Follow-up:** No follow-up  
**Setting:** Australia, Sydney  
**Primary care**  
**Notes:** Details on randomisation not reported.  
Info on Screening Process: 32 potential subjects, 21 met screening criteria, 2 discontinued treatment.  
**Data Used**  
- BDI  
**Notes:** TAKEN AT: pre- and post-assessment. DROP OUTS: two participants discontinued their involvement in the programme for medical reasons  
**Group 1 N=10**  
- CBT - 6 weekly 1.5-hour sessions. Group therapy. Muscle relaxation + cognitive coping skills training (i.e. monitor negative self-statements, problem solving). Homework assignments. Designed to cope with stress & anxiety.  
**Group 2 N=9**  
- Waitlist - Participants received treatment immediately following the past-treatment assessment period.  
**Perform sensitivity analysis as participants were not recruited for depression and chronic physical health problems. Sub-group analysis as intervention aimed at psychosocial stressors (stress and coping).**  

### KELLY1993

**Study Type:** RCT  
**Study Description:** Perform analysis on participants who completed assessment form.  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 42  
**Follow-up:** No follow-up  
**Setting:** Australia, Sydney  
**Primary care**  
**Notes:** Details on randomisation not reported.  
Info on Screening Process: 32 potential subjects, 21 met screening criteria, 2 discontinued treatment.  
**Data Used**  
- BDI  
**Notes:** TAKEN AT: pre- and post-assessment. DROP OUTS: two participants discontinued their involvement in the programme for medical reasons  
**Group 1 N=10**  
- CBT - 6 weekly 1.5-hour sessions. Group therapy. Muscle relaxation + cognitive coping skills training (i.e. monitor negative self-statements, problem solving). Homework assignments. Designed to cope with stress & anxiety.  
**Group 2 N=9**  
- Waitlist - Participants received treatment immediately following the past-treatment assessment period.  
**Perform sensitivity analysis as participants were not recruited for depression and chronic physical health problems. Sub-group analysis as intervention aimed at psychosocial stressors (stress and coping).**
### Study Type: RCT
**Type of Analysis:** Completers
**Blindness:** No mention
**Duration (days):** Mean 56
**Followup:** 3-month
**Setting:** Milwaukee

Notes: Details on randomisation not reported.

On Info on Screening Process: 115 completed pre-intervention assessment and had CES-D >16. Only participants for whom all data were collected, including long-term follow-up were included in the analysis.

**Data Used**
**Blindness:** No mention
**Duration (days):** Mean 56
**n= 68**

- **Age:** Mean 34
- **Sex:** all males
- **Diagnosis:** HIV by Not specified
- **100% Depression by CES-D**

**Exclusions:** - a CES-D score < 16
- female

Notes: N=56 were asymptomatic or had symptoms of immune compromise; N= 12 had illnesses that met Centers for Disease Control criteria for AIDS. Mean duration of knowledge of symptoms = 31 months

Baseline: No significance test conducted. Baseline scores of CES-D: 27.4 (SD = 8.9) - cognitive and behavioural; 28.1 (SD = 8.5) - peer support; 31.0 (SD = 6.6) - control

**Notes:** TAKEN AT: pre- and post-intervention and 3-month follow-up. DROP OUTS: only report outcomes for completers.

**Group 1 N= 27**
- **CBT - 8 week group therapy (8-9 participants).** 90 minutes. Led by psychologists, counsellors or psychiatry residents. Also discussed safer sex practice. Aimed to reduce anxiety & depression.

**Group 2 N= 14**
- **Peer Support - 8 week group therapy (8-10 participants).** 90 minutes. Led by psychologists, counsellors or psychiatry residents. Encouraged members to describe their feelings about having HIV.

**Group 3 N= 27**
- **No treatment - Offered crisis intervention outside study protocol.**

---

### Results from this paper:

**Quality assessed:** +

#### KISSANE2007

**Study Type:** RCT
**Type of Analysis:** ‘Completers
**Blindness:** Open
**Duration (days):** Mean 37 Range 1-226
**Setting:** AUSTRALIA, Melbourne (multisite)

Notes: Randomisation: independent using an ‘adaptive biased coin design’. Allocation concealment not addressed.

On Info on Screening Process: 485 referred; 258 not assessed or randomised; 227 randomised: 147 intervention, 80 control; *117/147, 60/80 analyzed for psychosocial outcomes.

**n= 227**

- **Age:** Mean 52 Range 25-69
- **Sex:** all females
- **Diagnosis:** Cancer by Histologically confirmed

**Exclusions:** - did not have stage IV breast cancer
- not geographically accessible
- had a life expectancy of less than 1 year
- over 70 years
- history of other cancers (except basal cell carcinoma)
- inadequate English
- intellectual disability of dementia

Notes: Stage IV Breast cancer

Baseline: No baseline differences between groups for percentage with depression. 34/147 (23%) - treatment and 20/80 (25%) - control had a diagnosis of depression; meta-analysis refers only to this sub-population.

**Data Used**

**Remission (no longer meeting diagnosis)**
**Notes:** TAKEN AT: baseline, 6-, 12-, 18-, 24-months. DROP OUTS:

**Group 1 N= 147**
- **Group existential therapy - Group therapy (12).** Weekly 90 min, advised for 1 year. Aim: improve interpersonal relationships; create network of social support; coping skills. Provides safe form to express feelings/confront existential issues. Co-therapist = psychologist/social worker.

**Group 2 N= 80**
- **Control - x3 relaxation classes, 1H over 3-week period.** Progressive muscular relaxation, guided imagery, manualized method. Encouraged to practice. Also delivered to treatment group. Delivered by occupational therapist.

---

### Results from this paper:

**Quality assessed:** +

#### KOUKOUVOU2004

**Study Type:** RCT
**Type of Analysis:** Completers
**Blindness:** No mention
**Duration (days):** Mean 180
**Setting:** GREECE, Thessaloniki

Notes: Details on randomisation not reported. Allocation concealment not addressed.

On Info on Screening Process: Details not reported.

**n= 29**

- **Age:** Mean 53 Range 36-66
- **Sex:** all males
- **Diagnosis:** 100% Cardiovascular disease by Clinical judgement

**Exclusions:** - did not have a diagnosis of CHF mainly based on clinical signs, radiological findings, echocardiographically determined ejection fraction/shortening fraction -myocardial infarction/unstable angina, aortic stenosis, diabetes mellitus, uncontrolled hypertension, musculoskeletal limitations or other contraindications for

**Data Used**

**Physical health outcomes**
- **Minnesota Living with Heart failure Questionnaire**
- **Quality of Life Index**
- **HADS**
- **BDI-21 item**

**Notes:** TAKEN: pre- and post-intervention. DROF OUTS: 2/18 - treatment, 1/11 - control.

**Group 1 N= 11**
- **Control - No further information.**

**Group 2 N= 18**
- **Exercise - 6-months supervised exercise.** 2-4 weeks institution-based training. 3-months aerobic training then added resistance exercises. Exercised 50-70% of peak VO2 for 60min (+5min per month) x 3-4 weekly. Progression of exercise duration, freq, intensity.

Participants recruited for depression; cognitive-behavioural intervention designed to reduce depression - discussed safer sex practice.
participating in an exercise program
- not clinically stable for <3-months
- not on stable medication or diet

Baseline: No differences at baseline. Baseline scores of depression: HADS-D = 13.1 (SD = 3.13) - treatment, 11.6 (SD = 2.3) - control; BDI = 18.6 (SD = 4.65) - treatment, 18.5 (SD = 5.1) - control. Only 1 patients was found without depression, 7 mild (scores 10-15), 14 moderate (16-23) & 4 severe (>23).

### Results from this paper:
**Quality assessed:** +

#### KUNIK2008

**Study Type:** RCT

**Study Description:** "Completed assessments

**Type of Analysis:** Completers*

**Blindness:** Single blind

**Duration (days):** Mean 56

**Followup:** 12-month

**Setting:** US

**Notes:** Randomisation numbers generated by statistician. Allocation concealment not addressed.

**Info on Screening Process:** 1981 screened, 1351 eligible for pre-treatment testing, 747 presented for testing, 256 eligible, 238 randomised.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>N= 63</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>N= 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-education - 8 sessions COPD education. 45 lectures/15 discussion. Same therapists. Discussed breathing strategies, medication use, end of life planning.</td>
<td></td>
</tr>
</tbody>
</table>

#### LAI2006

**Study Type:** RCT

**Study Description:** Single blind = observer blinded

**Blindness:** Single blind

**Duration (days):** Mean 84

**Followup:** 6-month

**Setting:** US, Kansas Home

**Notes:** Randomisation by random-number generator. Allocation concealment with sealed envelopes.

**Info on Screening Process:** 582 in registry, 117 consented & eligible, 100 passed cardiac stress test & enrolled, 100 randomised.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>N= 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise - Delivered at home.3 x week, 36 sessions, 12-weeks. Supervised by a physical/occupational therapist. Equipment supplied i.e. stationary bike, elastic bands.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group 2</th>
<th>N= 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAU - Health rehabilitation services as ordered by their physicians. Visted by RA every 2 weeks to provide education about stroke prevention.</td>
<td></td>
</tr>
</tbody>
</table>

#### Data Used

**KUNIK2008**

- BDI-II
- SF-36

**LAI2006**

- SF-36
- GDS-15 item

#### Data Not Used

- Physical health outcomes - no data

**Notes:** TAKEN AT: baseline, mid-point, post-intervention, 4-, 8-, 12-month FU. Drop outs (at 12-month FU): 37/89 (CBT); 36/92 (Health education).

#### Notes: Randomisation numbers generated by statistician. Allocation concealment not addressed.

#### Info on Screening Process: 1981 screened, 1351 eligible for pre-treatment testing, 747 presented for testing, 256 eligible, 238 randomised.

#### Baseline: No significant baseline differences. Depression at baseline (BDI): cognitive and behavioural - 23.44 (12.49); health education - 21.12 (12.09).

#### Notes: 32.9% had a history of psychiatric treatment.

#### Perform sensitivity analysis as participants are not recruited for depression "sub-threshold depression". Aim of intervention is to reduce depression.
**Results from this paper:**

<table>
<thead>
<tr>
<th>Quality assessed: +</th>
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</table>

<table>
<thead>
<tr>
<th>LANDREVILLE1997</th>
</tr>
</thead>
</table>

**Study Type:** RCT  
**Study Description:** “study used on data from 23 participants who completed study”  
**Type of Analysis:** “Completers”  
**Blindness:** Open  
**Duration (days):** Mean 28  
**Setting:** CANADA  
**Notes:** Details on randomisation not reported. Allocation concealment not addressed.

**Data Used**  
- Functional Autonomy Measurement System  
- GDS  
- BDI-21 item

**Notes:** TAKEN AT: pre- and post-treatment and 6 month follow-up for treatment group only. DROP OUTS: 4 (9%) dropped out.

**Group 1**  
- **N= 10**  
- Self-help - Bibliotherapy based on Feeling Good - cognitive therapy for depression.  
- Monitor depressive symptoms. Contacted by telephone once a week to ask about progress & answer questions.

**Group 2**  
- **N= 13**  
- Waitlist - Contacted by therapist via telephone once a week to monitor condition & to encourage group to perseverve until treatment became available. Did not offer counselling, telephone lasted 15 mins.

<table>
<thead>
<tr>
<th>LARCOMBE1984</th>
</tr>
</thead>
</table>

**Study Type:** RCT  
**Blindness: No mention**  
**Duration (days):** Mean 42  
**Followup:** 1-month (treatment group only)  
**Setting:** Not specified  
**Notes:** Details on randomisation not reported.  

**Data Used**  
- HDRS  
- BDI

**Notes:** TAKEN AT: pre- and post-intervention and 1-month follow-up (for treatment group only). DROP OUTS: none reported.

**Group 1**  
- **N= 9**  

**Group 2**  
- **N= 10**  
- Waitlist - Treatment delayed for 6-weeks.

**Participants recruited for depression and chronic physical health problems; intervention aimed at depression. 1 participant in the treatment and 2 in the waiting list group were receiving antidepressant medication.**

---

**Lived in nursing home prior to stroke**

**Baseline:** No significant differences between groups at baseline. Baseline GDS score = 3.4 (SD = 2.8) - treatment & 3.8 (SD = 2.7) - control.
### LESPERANCE2007

**Study Type:** RCT  
**Type of Analysis:** ITT  
**Blindness:** Double blind  
**Setting:** CANADA 9 academic centres  
**Outpatient**  
**Notes:** RANDOMISATION: computer generated and concealed in opaque envelopes  
**Info on Screening Process:** 370 screened, 30 did not have depression, 30 HAMD <20, 6 psychiatric reasons, 6 medical reasons, 5 logistics, 9 refused

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>Citalopram - 10mg/d week1, 20mg/d, if HAMD &gt;8 increased to max 40mg/d. Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.</td>
</tr>
</tbody>
</table>
| 2     | 67 | Placebo  
Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. |
| 3     | 75 | IPT - Individual IPT. 12 weekly sessions+placebo: up to 4 sessions via telephone. Focused on dealing with interpersonal conflicts, life transitions, grief, and loss. Conducted by Doctoral or Masters level therapists with mean 15 years experience. Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. |
| 4     | 67 | Citalopram + IPT - citalopram and IPT provided as described  
Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. |

### LII2007

**Study Type:** RCT  
**Study Description:** *Patients in the treatment arm who missed group therapy x2 were dropped from the study  
**Type of Analysis:** *Completers  
**Blindness:**  
**Followup:** None  

<table>
<thead>
<tr>
<th>N</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>48</td>
<td></td>
</tr>
</tbody>
</table>
**Age:** Mean 58  
Sex: 214 males 70 females  
**Diagnosis:** 100% Depression by DSM-IV  
100% Cardiovascular disease by Histologically confirmed  
Exclusions: - <18 years of age  
- HAMD <20  
- depression due to general medical condition  
- psychosis, bipolar,  
- substance abuse  
- suicide risk  
- current use of antidepressants, lithium, anticonvulsants for mood disorder  
- current psychotherapy  
- previous absence of response to citalopram or IPT  
- 2 or more previous unsuccessful treatment for the index depression  
- lifetime history of early termination of citalopram or 2 other SSRIs because of adverse events  
- MMSE < 24  
- clinician judgement that the patient would not adhere to study regime  
- coronary bypass graft surgery planned during the next 4 months  
- Canadian Cardiovascular Society Angine Class of 4  
- unable to speak French/English  
Notes: severe depression according to APA criteria  
Baseline: Total: HAM-D: 29.68 BDI = 30.3; HAM-D: 30.0 - IPT (+ Placebo), 30.3 - control; BDI = 29.1 - IPT (+ Placebo), 31.3 - control. |

<table>
<thead>
<tr>
<th>Data Used</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
</table>
| Cardiovascular outcomes | Citalopram - 10mg/d week1, 20mg/d, if HAMD >8 increased to max 40mg/d. Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. | Placebo  
Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. | IPT - Individual IPT. 12 weekly sessions+placebo: up to 4 sessions via telephone. Focused on dealing with interpersonal conflicts, life transitions, grief, and loss. Conducted by Doctoral or Masters level therapists with mean 15 years experience. Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. | Citalopram + IPT - citalopram and IPT provided as described  
Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone. |
| Response (>50 reduction from baseline) | Remission (below cut-off) | BDI-II | HDRS-24 | BDI-21 item |
| SF-36 | | | | |
Notes: Randomisation done by independent researcher using random computer-generated list.

Info on Screening Process: 60 patients recruited from haemodialysis unit; 12 dropped out (10 - treatment, 2 - control)

Notes: TAKEN AT: pre- and post-intervention (1-month after intervention). DROP OUTS: 10/30 - treatment and 2/30 - control

2N = n = 28

Group 1 N = 25
Group 2 N = 23

TAU - Routine nursing care and a self-care bookley normally provided by the unit.

LUSTMAN1998

Study Type: RCT
Study Description: "ITT did not include 1 participant who did not begin intervention in treatment group
Single blind = rater only
Type of Analysis: 'ITT

Notes: Randomised via computer algorithm; concealed in sealed envelopes

Info on Screening Process: 135 eligible; 84 excluded; 51 randomised; treatment: 1, control: 0 didn't begin; treatment: 4, control: 4 didn't complete intervention; treatment: 20, control: 22 completed intervention + post-assessment; treatment: 20, control: 21 completed FU

Data Used
Response (>50 reduction from baseline)
Remission (below cut-off)

Notes: Randomisation done by independent researcher using random computer-generated list.

Setting: US, Philadelphia, New Jersey, Delaware, Pennsylvania

Type of Analysis: ITT
Blindness: Open

Followup: 3-, 6-months**


Type of Analysis: ITT

Setting: US, Philadelphia, New Jersey, Delaware, Pennsylvania

Notes: Assigned randomly by research assistant stratified by baseline BDI.

Diagnosis: - 100% Cancer by Current diagnosis

Exclusions: - patient was not diagnosed with primary gynecological cancer
- Karnofsky Performance Status of <80 or an Eastern Cooperative Oncology Group (ECOG) score not equal to 0 or 1
- not living within 2H commuting distance from

Results from this paper:
Quality assessed: +

MANNE2007

Study Type: RCT
Type of Analysis: ITT
Blindness: Open

Followup: 3-, 6-months

Setting: US, Philadelphia, New Jersey, Delaware, Pennsylvania

Notes: Assigned randomly by research assistant stratified by baseline BDI.

Diagnosis: - 100% Cancer by Current diagnosis

Exclusions: - patient was not diagnosed with primary gynecological cancer
- Karnofsky Performance Status of <80 or an Eastern Cooperative Oncology Group (ECOG) score not equal to 0 or 1
- not living within 2H commuting distance from

Results from this paper:
Quality assessed: +
**Counseling**
- **6 x 1** individual sessions + phone booster session. Aim: emotional expression, support existing coping behaviours, enhanced self-esteem & autonomy. Conversational in style. Discuss reactions to cancer. Manualized. Therapist = social work/psychologist

**TAU - Social work consultations.**
- Referrals to a psychiatrist/pyschologist could be made by physician.

**.markowitz1998**
- **Study Description:** included participants who refused randomisation (n=4) or received minimal treatment (n=15).
- **Type of Analysis:**ITT
- **Setting:** USA
- **Outpatient**
- **Randomized:** patients to treatment in a balanced design using a computer-generated random number sequence sealed in individual envelopes.
- **Info on Screening Process:** Details not reported.
- **Participants:**
  - **n = 101**
  - **Age:** Mean 37 Range 24-59
  - **Sex:** 86 males 15 females
  - **Diagnosis:**
    - 100% HIV by Not specified
    - 53% Depression by DSM-III-R
  - **Exclusions:**
    - not HIV-positive for 6 months or more
    - a score of 14 or less on the HDRS-24 item
    - not judged by clinician to have significant depressive symptoms
    - poor physical health that inhibits outpatient treatment
    - non-HIV medical disease
    - schizophrenia, bipolar disorder, current substance abuse
    - contraindication to imipramine
    - MMSE score < 25
    - inability to speak English
    - concurrent psychiatric treatment aside from HIV self-help or support groups
  - **Baseline:** There were no significant differences between groups at baseline. **HAM-D (24 items)** baseline scores:
    - 20.4 (4.5) - cognitive and behavioural
    - 20.4 (5.6) - IPT + pharm
  - **Participants recruited for depression and chronic physical health problems. Cognitive-behavioural therapy aimed at reducing depression. IPT modified for physical health problem.**

**moehr2000**
- **Study Description:** ITT and Completers
- **Type of Analysis:** ITT and Completers
- **Blindness:** No mention
- **Setting:** USA
- **Outpatient**
- **Randomized:** patients to treatment in a balanced design using a computer-generated random number sequence sealed in individual envelopes.
- **Info on Screening Process:** Details not reported.
- **Participants:**
  - **n = 32**
  - **Age:** Mean 42
  - **Sex:** 9 males 23 females
  - **Diagnosis:**
    - 100% Multiple Sclerosis by Not specified
    - Depression by POMS-D
  - **Exclusions:**
    - No diagnosis of relapsing MS
    - Score of < 15 on POMS-Depression-Dejection scale
  - **Participants recruited for depression; intervention modified for physical health problems. Cognitive-behavioural therapy aimed at reducing depression. IPT modified for physical health problem.**

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<table>
<thead>
<tr>
<th><strong>Results from this paper:</strong> quality assessed: +</th>
<th><strong>Results from this paper:</strong> quality assessed: ++</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants recruited for depression; intervention modified for physical health problems. Cognitive-behavioural therapy aimed at reducing depression. IPT modified for physical health problem.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Participants recruited for depression; intervention modified for physical health problems. Cognitive-behavioural therapy aimed at reducing depression. IPT modified for physical health problem.</strong></td>
<td></td>
</tr>
</tbody>
</table>
### Results from this paper:

**Quality assessed:** +

**MOHR2001**

<table>
<thead>
<tr>
<th>Study Type: RCT</th>
<th>Data Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Analysis: ITT</td>
<td>Longitudinal Interval Follow-up Evaluation-II</td>
</tr>
<tr>
<td>Blindness: No mention</td>
<td>HDRS</td>
</tr>
<tr>
<td>Duration (days): Mean 112</td>
<td>BDI</td>
</tr>
<tr>
<td>Followup: 6-month follow-up</td>
<td>Notes: TAKEN AT: pre- and post-intervention and at 6-month follow-up.</td>
</tr>
<tr>
<td>Setting: USA, California</td>
<td></td>
</tr>
<tr>
<td>Notes: 1st 6 patients to still meet MDD criteria after 4 week criteria were assigned to group therapy - less than 6 were assigned to CBT or sertraline</td>
<td></td>
</tr>
<tr>
<td>Info on Screening Process: 177 patients showed some signs of depression and received a thorough screening assessment; 63 met inclusion/exclusion criteria.</td>
<td></td>
</tr>
<tr>
<td>n = 63</td>
<td>Group 1 N = 20</td>
</tr>
<tr>
<td>Age: Mean 44</td>
<td>CBT - 4 psychologists with 1-8 years of postdoctoral experience. Individual therapy. 16 weekly 50 min sessions. Standard CBT + specific skills for management of MS-related symptoms.</td>
</tr>
<tr>
<td>Sex: 17 males 46 females</td>
<td>Group 2 N = 22</td>
</tr>
<tr>
<td>Diagnosis: 100% Multiple Sclerosis</td>
<td>Group existential therapy - Group therapy (5-9 patients) for people with medical diagnoses + 2 therapists. 16 weekly 90 min sessions. Aim is to facilitate the emotional expressions related to MS. 5 psychologists with 1-9 years postdoctoral experience. NOT RANDOMISED TO THERAPY</td>
</tr>
<tr>
<td>Depression</td>
<td>Group 3 N = 21</td>
</tr>
<tr>
<td>Exclusions: - an unconfirmed diagnosis of MS - a relapsing-remitting or secondary progressive disease course not confirmed by a neurologist - no diagnosis of MDD (DSM-IV; SCID) - a score less than 16 on the HRS-D-17 and BDI - unwillingness to abstain from psychological/pharmacological treatment for depression other than that provided during treatment - other serious psychological disorders - dementia - severe suicidality - initiation of interferon medication with the previous 2 months - other disorders of the CNS - current/planned pregnancy - current psychological/pharmacological treatment for depression</td>
<td>Sertraline - Initiated at 50 mg per day and increased by 50 mg every 4-weeks until a dosage of 200 mg was reached or until full remission was achieved.</td>
</tr>
<tr>
<td>Baseline: There were no significant differences between groups at baseline. Baseline BDI scores: 24.8 - treatment, 23.5 - control. Baseline HAM-D scores: 21.0 - treatment, 20.5 - control.</td>
<td></td>
</tr>
</tbody>
</table>

### MOSSEY1996

<table>
<thead>
<tr>
<th>Study Type: RCT</th>
<th>Data Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Analysis: Completers</td>
<td>GDS</td>
</tr>
<tr>
<td>Blindness:</td>
<td>Notes: TAKEN AT: pre- and post-intervention (3-months), 6-12-month FU. DROP OUTS: 9/35 - treatment, 4/41 - control.</td>
</tr>
<tr>
<td>Duration (days): Mean 70</td>
<td></td>
</tr>
<tr>
<td>Followup: 6-, 12-months</td>
<td></td>
</tr>
<tr>
<td>Setting: US, Pennsylvania</td>
<td></td>
</tr>
<tr>
<td>Notes: Details on randomisation not reported. Allocation concealment not addressed.</td>
<td></td>
</tr>
<tr>
<td>Info on Screening Process: Age-eligible N = 4883; 1804 approached, 1530 completed screening, 362, 287, 89 met GDS, MMSE &amp; SCID criteria (respectively). n=76 completed</td>
<td></td>
</tr>
<tr>
<td>n = 76</td>
<td>Group 1 N = 35</td>
</tr>
<tr>
<td>Age: Mean 71</td>
<td>IPT - 10 weekly sessions. 80 min. Individual Intervention for depression. Modified to accomodate physical health i.e. longer/more intensity/flexible appts.</td>
</tr>
<tr>
<td>Sex: 17 males 59 females</td>
<td>Group 2 N = 41</td>
</tr>
<tr>
<td>Diagnosis: 100% General Medical (hospitalized) by Currently receiving treatment for disorder 100% Subsydymthic depression by GDS</td>
<td>TAU - No further information besides usual care.</td>
</tr>
<tr>
<td>Exclusions: - not between the ages of 60 &amp; 91</td>
<td></td>
</tr>
<tr>
<td>- GDS score &lt; 11</td>
<td></td>
</tr>
<tr>
<td>- MMSE score &lt; 22</td>
<td>Do not perform sensitivity analysis as participants recruited for depression &amp; physical health problem.</td>
</tr>
<tr>
<td>- DSM-III-R criteria for current major depression, dystymia or another Axis I disorder</td>
<td></td>
</tr>
</tbody>
</table>

### Baseline:

There were no significant differences between groups at baseline. Baseline scores of POMS-D = 33.1 - treatment, 27.9 - control.
### Results from this paper:

**SAVARD2006**

<table>
<thead>
<tr>
<th>Study Type: RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Description: Single blind: assessor blinded to treatment allocation therefore HAM-D is rated blindly</td>
</tr>
<tr>
<td>Type of Analysis: Completers*</td>
</tr>
<tr>
<td>Setting: CANADA</td>
</tr>
<tr>
<td>Notes: Stratified by location of recruitment; assigned randomly via computer-generated random no. table; group allocation contained in sealed envelopes. Info on Screening Process: 497 approached; 333 screened; 45 randomised; 37 analysed*</td>
</tr>
</tbody>
</table>

- **n=37**
- **Age:** Mean 51
- **Sex:** all females
- **Diagnosis:**
  - 100% Cancer by Current diagnosis
  - 73% Depression by DSM-IV
- **Exclusions:**
  - no diagnosis of metastatic breast cancer (stage IV)
  - a score of <7 on the HADS-D or < 15 on the BDI
  - terminal stage of the disease defined as a life expectancy < 2-months
  - DSM-IV criterial for severe psychiatric disorder other than major depression
  - severe suicidal ideations with risk of acting out - Scale for Suicide Ideation
  - having recently (within the past 2-months) started on antidepressant medication or recently altered the dosage
  - currently receiving a psychological intervention targeting depression

Baseline: No significant differences at baseline for depression; cognitive-behaviour treatment group had longer time passed since initial cancer diagnosis. Baseline BDI scores of depression: 21.13 - treatment, 20.10 - control; HAM-D: 14.21 - treatment, 14.40 - control.

**Data Used**

- **Physical health outcomes**
  - EORTC Quality of Life Questionnaire
  - EORTC Breast Cancer- Specific QoL Questionnaire
  - HAM-D
  - BDI-21 item
  - HADS

**Notes:** TAKEN AT: pre- and post-treatment; 3-, 6 month FU. DROP OUTS: 4/25 - treatment; 4/20 - control - analysed only completers

**Group 1**

- **N=20**
- Control - Waitlist control

**Group 2**

- **N=21**
  - Individual based cognitive and behavioural skills - 8 weekly individual sessions. 60-80 min.3 booster sessions every 3 weeks. CBT slightly adapted for women with cancer i.e. targeting negative thoughts specific to cancer. Therapist = licensed psychologist

Do not perform sensitivity analysis - participants recruited for depression.

### SIMONI2007

<table>
<thead>
<tr>
<th>Study Type: RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Description: Single blind = rater only blinded</td>
</tr>
<tr>
<td>Type of Analysis: &quot;Completers&quot;</td>
</tr>
<tr>
<td>Setting: US, New York HIV primary care outpatient clinic</td>
</tr>
<tr>
<td>Notes: Randomisation based on a computer-generate sequence prepared by an external statistician. Allocation concealment via numbered, opaque, sealed envelop</td>
</tr>
<tr>
<td>Info on Screening Process: 53% of eligible patients approached declined; 71 assign to treatment, 59 (83%) completed FU; 65 assign to control, 57 (88%) completed FU.</td>
</tr>
</tbody>
</table>

- **n=136**
- **Age:** Mean 43
- **Sex:** 75 males 61 females
- **Diagnosis:**
  - 100% HIV by Current diagnosis
- **Exclusions:**
  - less than 18 years
  - not proficient in English
  - not prescribed on HAART regimen
  - with dementia or psychosis
  - Years since HIV diagnosis: 7.8 years (SD = 4.6)

Baseline: No significant differences at baseline for outcome measures. Baseline scores of CES-D depression: 19.9 (SD = 12.4) - treatment, 19.6 (SD = 11.2) - control.

**Data Used**

- **Physical health outcomes**
  - CES-D

**Notes:** TAKEN AT: pre- and post-intervention & 3-month FU.

**Group 1**

- **N=71**
  - Peer Support - Delivered by trained peers who = HIV+ & on HAART. 3-months, 6 twice-monthly 1H group therapy @ clinic. Plus, 3 x weekly phone calls from trained peers who were assigned to individ by researcher. Discussed shared experiences in groups/problem-solving.

**Group 2**

- **N=65**
  - TAU - Standard medical care from the clinic. Were given social & mental health referrals when requested.

Perform sensitivity analysis as participants were not recruited for depression and physical health problems.
### Results from this paper:

**Quality assessed: +**

#### SIMS2009

**Study Type:** RCT  
**Study Description:** "Does not include 2 drop outs in the control group"  
**Type of Analysis:** ITT  
**Blindness:** No mention  
**Duration (days):** Mean 70  
**Setting:** Australia, Community  
**Notes:** Randomisation by independent person using computer generated block randomisation list. Allocation concealment not addressed.  
**Info on Screening Process:** 1550 invited, 233 responded, 104 depressed, 59 medical exclusions, 45 entered trial.  
**Data Used:** Remission (below cut-off)  
**Quality of Life Index**  
**CES-D**  
**Notes:** TAKEN AT: baseline, post-intervention & 6-month FU. DROP OUTS: 2/22 control group; 0/23 intervention group.  
**Group 1 N= 23**  
**Group 2 N= 22**  
Waitlist - Waitlist controls receiving usual care.  
**Recruited for depression.**

#### SIMSON2008

**Study Type:** RCT  
**Blindness:** No mention  
**Duration (days):** Mean 5, Range 3-11  
**Setting:** GERMANY - Inpatient  
**Notes:** Randomisation procedure not reported. Allocation concealment not addressed.  
**Info on Screening Process:** 111 screened.  
**Data Used:** Response (>50 reduction from baseline)  
**Remission (below cut-off)**  
**HADS**  
**Notes:** TAKEN AT: baseline and post-intervention (discharged from hospital). DROP OUTS: none reported.  
**Group 1 N= 15**  
Group existential therapy - An average of 5 sessions, 30 min, weekly.  
**Group 2 N= 15**  
TAU - Standard treatment, including medical and surgical care.  
**Recruited for depression.**

#### STEIN2007

**Study Type:** RCT  
**Type of Analysis:** Completers  
**Blindness:** No mention  
**Duration (days):** Mean 122  
**Setting:** 514 screened, 69 ineligible, 180  
**Data Used:** Response (>50 reduction from baseline)  
**Remission (below cut-off)**  
**Notes:** Do not need to perform sensitivity analysis as participants recruited for depression & physical health problems.
refused, 177 assessed & randomised, 79 (90%) - treatment & 81 (91%) - control completed FU (N = 160 at FU)

Exclusions: - less than 18 years
- did not speak either English or Spanish
- did not have regular access to a telephone
- did not have competency to sign informed consent
- did not have a BDI score > 9

Notes: HIV + for 91.0 (SD = 72.9) months; 28.1% diagnosed within the last 12-months.
Baseline: No significant differences at baseline. The mean BDI score at baseline was 22.7 (SD = 9.6): 40% in the mild to moderate stage, 36.3% moderate to severe and 23.8% severely depressed.

Notes: TAKEN AT: pre- and post-intervention. DROP OUTS: 9 (90%) - treatment & 81 (91%) - control completed FU (N = 160 at FU)

Results from this paper:
Quality assessed: +

WEISS2003
Study Type: RCT
Type of Analysis: Completers
Blindness: No mention
Duration (days): Mean 16
Setting: Netherlands
Notes: Randomisation using a computerized minimisation program.
Info on Screening Process: 150 contacted study staff; 116 completed screening. 110 accepted; 85 randomised.

Data Used
POMS-D
BDI-21 item

Notes: TAKEN AT: baseline, 4-months, 9-months (post-treatment), 6-month FU. DROP OUTS: 4/44 (treatment); 7/41 (control)

Perform sensitivity analysis as participants are not recruited for depression. Subthreshold depression

YU2006
Study Type: RCT
Blindness: Single blind
Duration (days): Mean 84
Followup: None
Setting: CHINA
Notes: Details on randomisation not reported. Allocation concealment not addressed.
Info on Screening Process: Details not reported.

Data Used
Quality of Life Index
HADS

Notes: TAKEN AT: baseline and at 12-weeks.

Participants not recruited for depression.
## Characteristics of Excluded Studies

<table>
<thead>
<tr>
<th>Reference ID</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTONI2000</td>
<td>Excluded men with current psychopathology &amp; depression severity using a corrected 17-HRSD score of &gt; 15 to take into account possible HIV-related organic symptoms.</td>
</tr>
<tr>
<td>ARVING2007</td>
<td>Population is not recruited for depression - excluded ongoing psychiatric diagnosis. Baseline scores of depression on HADS-D is below cut-off: 4 (SD = 4) - treatment and 4 (SD = 3) - TAU.</td>
</tr>
<tr>
<td>BADGER2007</td>
<td>Treatment group - CES-D = 16.44 (SD = 1.7); Control - CES-D = 9.88 (SD = 1.7)</td>
</tr>
<tr>
<td>BASLER1991</td>
<td>Unclear whether population is depressed</td>
</tr>
<tr>
<td>BERGER2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>BILLHULT2007</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>BLANCH2002</td>
<td>Design - not an RCT (no control group)</td>
</tr>
<tr>
<td>CHANG2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>CLASSEN2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>DAVIES2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>DETER2007</td>
<td>Outcomes not relevant</td>
</tr>
<tr>
<td>DOBKIN2007</td>
<td>Design - not an RCT (no control group)</td>
</tr>
<tr>
<td>EDELMAN1999</td>
<td>Population not depressed: median of POMS-D is 6 for treatment group and 5 for control group</td>
</tr>
<tr>
<td>EDELMAN1999A</td>
<td>Baseline scores of depression as assessed by POMS-D = 11.39 for treatment and 12.17 for control.</td>
</tr>
<tr>
<td>ELCI2008</td>
<td>Rehabilitation program (outside the scope of the guideline)</td>
</tr>
<tr>
<td>FREEMAN2005</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>GALLAGHER2003</td>
<td>Population does not have depression: control group - 6.1 (SD = 3.40 on HADS-D and treatment group - 6.3 (SD = 3.5)</td>
</tr>
<tr>
<td>GITLIN2007</td>
<td>Not an intervention trial</td>
</tr>
<tr>
<td>GIVEN2004</td>
<td>Data is not extractable</td>
</tr>
<tr>
<td>GOODWIN2001</td>
<td>Population does not have depression.</td>
</tr>
<tr>
<td>GOTAY2007</td>
<td>Less than 50% were above the clinical cut off for depression as assessed by a CES-D score of greater than 16.</td>
</tr>
<tr>
<td>GREER1992</td>
<td>Population - Baseline scores of HADS-D: 6.2 (SD 4.0) - treatment and 5.8 (SD 3.5) - control group.</td>
</tr>
<tr>
<td>HOFFMANN2007</td>
<td>Population not depression: means HADS-D for treatment and control = 5.</td>
</tr>
<tr>
<td>HOPKO2005</td>
<td>Design: no control group (pre and post scores for 6 patients receiving treatment)</td>
</tr>
<tr>
<td>ISMAIL2008</td>
<td>Does not meet minimal criteria for depression, PHQ-9: M ~ 6</td>
</tr>
<tr>
<td>JERANT2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>JOHNSON2008</td>
<td>Population not depressed at baseline</td>
</tr>
<tr>
<td>JONKERS2007</td>
<td>Do not report data on clinical efficacy of the intervention. Report: dropout, fidelity, dose-received exposure/satisfaction, barriers; look out for clinical efficacy study to be published</td>
</tr>
<tr>
<td>KARAPOLAT2008</td>
<td>Population not depressed</td>
</tr>
</tbody>
</table>
Prevention study. Combine three scales to assess overall psychological well-being (one of the including depression - Zung Short). Does not look at depression specifically.

KENNEDY2003 Design - not an RCT

KOHN2000 Only has a BDI score at follow-up therefore cannot assess whether population has depression or not [only report biological indicators at baseline]

LEONPIZARRO2007 Population not depressed

LEPORE2003 Population not depressed: baseline scores of CES-D depression = 0.46 (control); 0.54 (education); 0.49 (education +)

LINCOLN2003 Data: only report medians

LIU2008 Intervention does not meet definition criteria

LOLAK2008 Did not meet criteria for depression HADS: M ~ 5

MARTIRE2007 Do not report depression outcomes for participants with chronic physical health problems because there were differences between treatment groups at baseline (do not report baseline scores).

MAY2002 Participants not depressed - 24.3% treatment & 29.2% control reached scores higher than the 95% of the reference population for depression. Looked at depression as a moderator of efficacy. Zung depression baseline = 13.94 - control and 12.49 - treatment

MEAD2007 Population not depressed

MENDOZA2001 Intervention not relevant - memory note book

MOADEL2008 Commentary

MOHR2001 Not randomised to group existential therapy

MOHR2001A No comparisons between interventions (treatment groups collapsed); aim to examine the relationship between depression, treatment of depression and interferon gamma

MULDER1994 Population did not all have depression - 12% were within the range of depression on the BDI and 46% on the GHQ.

NEIDIG2003 Participants do not meet minimal criteria for depression

NUNES2007 Excluded clinical depression

PAYNE2008 Population not depressed at baseline

POWELL2008 Population not depressed

RIGBY2008 Population not depressed

ROBINSONWHELEN2007 No extractable data

SCHOLZ2006 Cannot assess depression as participants are not recruited for depression nor do they report baseline score of depression. Papers is look at associations of depression with variables not not the efficacy of the intervention on depressive symptoms.

SMITH2004 Population not all depressed. Only report medians so cannot use data.

SMITH2008 Randomisation not adequately done.

SNOEK2008 No extractable data for depression

SOMMARUGA1995 Cannot assess whether participants meet criteria for depression.

STEEL2007 Population not depressed at baseline

SUH2002 Before and after study with no control group

SULLIVAN2009 Design not an RCT

THOMAS1999 Intervention for physical health problem and not psychosocial factors
Only 26% met diagnosis of depression; baseline scores on the Zung = 47.3 (SD = 7.8) - treatment & 48.1 (SD = 10.1) - control. Cut-off Zung = 50.

Population not depressed: baseline GDS (30 item) score = 6 (treatment) and 7 (control).

No extractable data

Participants not depressed - 10.9% in treatment group and 10.4% in control group (10.6% total). Report association between depression and outcome but not outcomes for depressed patients.

Intervention does not meet definition

Population not depressed: GDS-15 (short form) cut off for depression is traditionally set at 5; means GDS score for treatment group = 2.49 (SD = 3.015) and for control group = 1.97 (SD = 2.358)

No depression outcomes

No measure of depression at baseline and no recognised depression scale

References of Included Studies

ADDOLORATO2004 (Published Data Only)

ANTONI2006 (Published Data Only)


References of Excluded Studies

LII2007  (Published Data Only)

LUSTMAN1998  (Published Data Only)

MANNE2007  (Published Data Only)

MARKOWITZ1998  (Published Data Only)

MOHR2000  (Published Data Only)

MOHR2001  (Published Data Only)

MOSEY1996  (Published Data Only)

SAVARD2006  (Published Data Only)

SIMONI2007  (Published Data Only)

SIMS2009  (Published Data Only)

SIMSON2008  (Published Data Only)

STEIN2007  (Published Data Only)

WEISS2003  (Published Data Only)

YU2006  (Published Data Only)

References of Excluded Studies

ANTONI2000  (Published Data Only)
ARVING2007  

BADGER2007  

BASLER1991  

BERGER2008  

BILLHULT2007  

BLANCH2002  

ELCI2008  
FREEMAN2005  (Published Data Only)

FRIZELLE2004  (Published Data Only)

GALLAGHER2003  (Published Data Only)

GALLAGHER2003  (Published Data Only)

GITLIN2007  (Published Data Only)

GIVEN2004

GOODWIN2001 (Published Data Only)

GOTAY2007  (Published Data Only)

GREER1992  (Published Data Only)

GREER1992  (Published Data Only)


HOFFMANN2007  (Published Data Only)

HOPKO2005

ISMAIL2008

JERANT2008  (Published Data Only)

JOHNSON2008  (Published Data Only)

JONKERS2007

KARAPOLAT2008  (Published Data Only)
KARLSEN2004  (Published Data Only)

KENNEDY2003  (Published Data Only)

KOHN2000  (Published Data Only)

LEONPIZARRO2007  (Published Data Only)

LEPORE2003  (Published Data Only)

LINCOLN2003  (Published Data Only)

LIU2008

LOLAK2008

MARTIRE2007  (Published Data Only)

MAY2002  (Published Data Only)

MEAD2007  (Published Data Only)

MEAD2007

MENDOZA2001  (Published Data Only)

MOADEL2008  (Published Data Only)

MOHR2001  (Published Data Only)
MOHR2001A

MULDER1994

NEIDIG2003

NUNES2007

PAYNE2008

POWELL2008

RIGBY2008

ROBINSONWHELEN2007

RIGBY2008

SCHOLZ2006

SMITH2004

SMITH2008

SNOEK2008

SOMMARUGA1995
STEEL2007

SUH2002

SULLIVAN2009

THOMAS1999

TIMONEN2002

TIMONEN2002

TSANG2003

VOS2007

WANG2003

WANG2008

WEBER2007

WILLIAMS2007A

ZAUTRA2008

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### Depression in Chronic Physical Health Problems - Psychosocial interventions in combination with pharmacology and in comparison with pharmacology

#### Comparisons Included in this Clinical Question

<table>
<thead>
<tr>
<th>Psychosocial intervention plus pharmacology versus pharmacology alone</th>
<th>Psychosocial intervention plus pharmacology versus psychosocial intervention alone</th>
<th>Psychosocial intervention versus pharmacology</th>
</tr>
</thead>
<tbody>
<tr>
<td>LESPERRYANCE2007</td>
<td></td>
<td>LESPERRYANCE2007</td>
</tr>
</tbody>
</table>

#### Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Study Type: RCT</th>
<th>Type of Analysis: ITT</th>
<th>Blindness: Double blind</th>
<th>Duration (days): Mean 84</th>
<th>Setting: CANADA 9 academic centres Outpatient</th>
<th>Notes: RANDOMISATION: computer generated and concealed in opaque envelopes</th>
</tr>
</thead>
</table>

### LESPERRYANCE2007

**Participants recruited for major depression; intervention modified for illness**

**Methods**

- **Study Type:** RCT
- **Type of Analysis:** ITT
- **Blindness:** Double blind
- **Duration (days):** Mean 84
- **Setting:** CANADA 9 academic centres Outpatient
- **Notes:** RANDOMISATION: computer generated and concealed in opaque envelopes
- **Info on Screening Process:** 370 screened, 30 did not have depression, 30 HAMD <20, 8 psychiatric reasons, 6 medical reasons, 5 logistics, 9 refused

**Participants**

- **n = 284**
  - **Age:** Mean 58
  - **Sex:** 214 males 70 females

**Diagnosis:**

- 100% Depression by DSM-IV
- 100% Cardiovascular disease by Histologically confirmed

**Exclusions:**

- <18 years of age
- HAMD <20
- Depression due to general medical condition
- Psychosis, bipolar
- Substance abuse
- Suicide risk
- Current use of antidepressants, lithium, anticonvulsants for mood disorder
- Current psychotherapy
- Previous absence of response to citalopram or IPT
- 2 or more previous unsuccessful treatment to the index depression
- Lifetime history of early termination of citalopram or 2 other SSRIs because of adverse events
- MMSE < 24
- Clinician judgement that the patient would not adhere to study regime
- Coronary bypass graft surgery planned during the next 4 months
- Canadian Cardiovascular Society Angina Class of 4
- Unable to speak French/English

**Notes:** Severe depression according to APA criteria

**Baseline:**

- Total: HAM-D: 29.68 BDI = 30.3; HAM-D: 30.0 - IPT (+ Placebo); 30.3 - control; BDI = 29.1 - IPT (+ Placebo), 31.3 - control.

**Data Used**

- Cardiovascular outcomes
- Response (>50 reduction from baseline)
- Remission (below cut-off)
- BDI-II
- HDRS-24

**Notes:**


**Interventions**

- **Group 1 N = 75**
  - Citalopram - 10mg/d week1, 20mg/d, if HAMD >8 increased to max 40mg/d.
  - Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.

- **Group 2 N = 67**
  - Placebo
  - Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.

- **Group 3 N = 75**
  - IPT - Individual IPT, 12 weekly sessions + placebo: up to 4 sessions via telephone. Focused on dealing with interpersonal conflicts, life transitions, grief, and loss. Conducted by Doctoral or Masters level therapists with mean 15 years experience.
  - Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.

- **Group 4 N = 67**
  - Citalopram + IPT - citalopram and IPT provided as described
  - Clinical management - information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.

### MARKOWITZ1998

**Participants recruited for depression and chronic physical health problems. Cognitive-behavioural therapy aimed at reducing**

**Study Type: RCT**

**Study Description:** * included participants who refused randomisation (n=4) or received minimal treatment (n=15).

**Type of Analysis:** ITT

**Participants**

- **n = 101**
  - **Age:** Mean 37 Range 24-59
  - **Sex:** 86 males 15 females

**Data Used**

- 100-point Karnofsky scale
- CD4 cell count
- HDRS-24
- HDRS-17

**Interventions**

- **Group 1 N = 27**
  - CBT - Therapists all PhD psychologists. Homework assigned. 16 x 50 minute sessions within 17-week period.
  - Designed for depression. Individual
Funding: California AIDS Center. Participants recruited for depression. Psychosocial intervention modified for physical health problem.

### TARG1994
**Study Type:** RCT
**Study Description:** "2 drop outs were not included in analysis"
**Type of Analysis:** "Completers"
**Blindness:** Double blind
**Setting:** US
**Notes:** RANDOMISATION: no further details. ALLOCATION CONCEALMENT: not addressed.

#### Data Used
- Physical health outcomes
  - SCID
  - POMS-D
  - HDRS
  - Notes: Dropouts: Fluoxetine 1/10 Placebo 1/10

#### Group 1 N= 10
Fluoxetine. Mean dose 20mg/day - 15 minute medication visits; questioned on medication compliance and side effects. Supportive psychotherapy - 12 weeks: weekly sessions relaxation techniques, problem solving skills training. Group therapy (6-8). Included HIV-related concerns. Therapist = 4th year psychiatric residents.

#### Group 2 N= 10
Placebo
Supportive psychotherapy - 12 weeks: weekly sessions relaxation techniques, problem solving skills training.

### ZISOOK1998
**Study Type:** RCT
**Study Description:** "ITT: all participants given medication + 1 follow-up assessment; used last observation carried forward"
**Type of Analysis:** "ITT"
**Blindness:** Double blind
**Setting:** US, California
**Notes:** No further details on randomisation. Allocation concealment not addressed.

#### Data Used
- BDI-13 item
- HDRS-17
- CGI-S - no data
- CGI-I - no variability measure
  - Notes: Dropouts: Fluoxetine 4/25 Placebo 6/22

#### Group 1 N= 25
Fluoxetine. Mean dose 20-60mg - 1 capsule (20mg) each day for the first 3 weeks. Depending on side effects/response the dose could in increased to 2 capsules (40mg) daily in the 4th week and to 3 capsules daily (60mg) by 5th week. At any time dose could be decreased.
Supportive psychotherapy - Minimum of 7 weeks. Education about HIV and depression, mutual support, coping strategies. Group therapy.
<table>
<thead>
<tr>
<th>Reference ID</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>KEMP2004</td>
<td>Non-randomised control trial</td>
</tr>
<tr>
<td>ROBINSON2008</td>
<td>Population not depressed</td>
</tr>
<tr>
<td>SCHIFFER1990</td>
<td>Compares Desipramine with placebo</td>
</tr>
</tbody>
</table>

### References of Included Studies

**LESPERANCE2007** (Published Data Only)


**MARKOWITZ1998** (Published Data Only)


**TARG1994** (Published Data Only)


**ZISOOK1998** (Published Data Only)


### References of Excluded Studies

**KEMP2004** (Published Data Only)


**ROBINSON2008** (Published Data Only)


**SCHIFFER1990** (Published Data Only)


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## Depression in Chronic Physical Health Problems - Pharmacological interventions

### Comparisons Included in this Clinical Question

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Study Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline vs. Nomifensine</td>
<td>ROBERTSON1985</td>
</tr>
<tr>
<td>Citalopram vs Reboxetine</td>
<td>RAMPELLO2004</td>
</tr>
<tr>
<td>Duloxetine vs Placebo</td>
<td>WISE2007</td>
</tr>
<tr>
<td>Fluoxetine vs Desipramine</td>
<td>HOLLAND1998</td>
</tr>
<tr>
<td></td>
<td>SCHWARTZ1999</td>
</tr>
<tr>
<td>Fluoxetine vs. paroxetine</td>
<td>GULSEREN2005</td>
</tr>
<tr>
<td>Fluoxetine vs. placebo</td>
<td>BLUMENFIELD1997</td>
</tr>
<tr>
<td>Maprotiline vs. mianserin</td>
<td>SCHIFANO1990</td>
</tr>
<tr>
<td>Mianserin vs. placebo</td>
<td>COSTA1985</td>
</tr>
<tr>
<td></td>
<td>VANHEERINGEN1996</td>
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<tr>
<td>Mirtazapine versus placebo</td>
<td>VANDENBRINK2002</td>
</tr>
<tr>
<td>Mirtazapine vs Imipramine</td>
<td></td>
</tr>
<tr>
<td>Paroxetine vs Amitriptyline</td>
<td>BIRD2000</td>
</tr>
<tr>
<td></td>
<td>PEZZELLA2001</td>
</tr>
<tr>
<td>Paroxetine vs Desipramine</td>
<td>MUSSELMAN2006</td>
</tr>
<tr>
<td>Paroxetine vs Nortriptyline</td>
<td>NELSON1999</td>
</tr>
<tr>
<td></td>
<td>POLLOCK2002</td>
</tr>
<tr>
<td>Paroxetine vs Doxepin</td>
<td>LI2005</td>
</tr>
<tr>
<td>psychostimulant (SAMe) vs placebo</td>
<td>ANCARANI1993</td>
</tr>
<tr>
<td>SSRI vs Other drug</td>
<td>BARONE2006</td>
</tr>
</tbody>
</table>
**Characteristics of Included Studies**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Participants</th>
<th>Outcomes</th>
<th>Interventions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANCARANI1993</strong></td>
<td></td>
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</tr>
<tr>
<td>Study Type: RCT</td>
<td>n = 53</td>
<td>Data Used</td>
<td>Group 1 N = 41</td>
<td>funding: BioResearch, BASF group, Milan, Italy.</td>
</tr>
<tr>
<td>Study Description: 1/42 treatment, 1/11 placebo withdrawn, no reason given</td>
<td>Age: Mean 55</td>
<td>IPAT-DS</td>
<td>TCA vs placebo</td>
<td></td>
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<tr>
<td>Type of Analysis: completers*</td>
<td>Sex: 30 males 23 females</td>
<td>HARD</td>
<td>RAFFAELE1996</td>
<td></td>
</tr>
<tr>
<td>Blindness: Double blind</td>
<td>Diagnosis: 100% Renal disease by Diagnosed by physician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration (days): Mean 21</td>
<td>100% Depression by DSM-III-R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting: 5 neurology units, ITALY</td>
<td>Exclusions: on dialysis for less than 4 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes: no info on randomisation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Info on Screening Process: 53 enrolled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SSRI vs TCA**

- ANDERSEN1994
- BROWN2005A
- CHEN2002
- DEVOS2008
- EHDE2008
- EISER2005
- EVANS1997
- FISCH2003
- FRUEHWALD2003
- GLASSMAN2002
- GOTTIEB2007
- LACASSE2004
- LEENTJENS2003
- LESPERANCE2007
- LUSTMAN2000
- LUSTMAN2006
- MAURI1994
- MCFARLANE2001
- MENZA2008
- MOHAPATRA2005
- MORROW2003
- MURRAY2005A
- MUSSELMAN2006
- PAILEHYVARINEN2003
- PAILEHYVARINEN2007
- RABKIN1999
- RABKIN2004
- RAZAVI1996
- ROBINSON2000
- SCT-MD-24
- STRIK2000
- TOLLEFSON1993
- WERMUTH1998
- WIART2000
- YANG2002

**TCA versus placebo**

- ANDERSEN1980
- BORSON1992
- KIMURA2000
- LAKSHMANAN1986
- LIPSEY1984
- LUSTMAN1997A
- MENZA2008
- RABKIN1994
- ROBINSON2000
- TAN1994

**SSRI vs placebo**

- ANTONINI2006
- CHEN2002
- DEVOS2008
- HUANG2005
- MENZA2008

**TCA vs placebo**

- ANDERSEN1980
- BORSON1992
- KIMURA2000
- LAKSHMANAN1986
- LIPSEY1984
- LUSTMAN1997A
- MENZA2008
- RABKIN1994
- ROBINSON2000
- TAN1994

**Trazadone vs placebo**

- RAFFAELE1996
more info.
Baseline: IPAT-DS: 36.24 (1.67) SAMe, 36.20 (3.41) placebo
HARD: 25.73 (1.11) SAMe, 20.66 (2.14) placebo

Notes: TAKEN AT: day 0 (start), day 10, day 21 (end).
DROP OUT: 1 participant from each group (2.38 SAMe, 9.09 placebo)

Results from this paper:
Quality assessment = +

ANDERSEN1980
Study Type: RCT
Blindness: Double blind
Duration (days):
Setting: Denmark

n = 22
Age: Mean 59
Sex:
Diagnosis:
Depression
Parkinson's Disease
Exclusions: - other somatic diseases
- dementia

Data Not Used
Anderson depression scale - no data
Notes: depression data not usable as in medians not in means

Group 1 N = 10
Nortriptyline
Group 2 N = 12
Placebo

ANDERSEN1994
Study Type: RCT
Blindness: Double blind
Duration (days): Mean 42
Setting: Denmark, patients with acute stroke admitted to hospital
Notes: RANDOMISATION: no further details

n = 66
Age: Mean 67
Sex: 26 males 40 females
Diagnosis:
100% Stroke
Depression
Exclusions: - subarachoid hemorrhage orBinswanger's disease
- previous degenerative or expansive neurological diseases
- psychiatric illness other than depression

Baseline: HDRS: Citalopram 19.4 (3.1) Placebo 18.9 (2.6)

Data Used
Response (>50 reduction from baseline)
HDRS-17
Notes: Dropouts: Citalopram 7/33 Placebo 2/33

Group 1 N = 33
Citalopram
Group 2 N = 33
Placebo

Funding: Lundbeck Foundation, Medical Research Foundation for North Jutland, the Aalborg Diocese Research Foundation

ANTONINI2006
Study Type: RCT
Blindness: Single blind
Duration (days): Mean 84
Setting: Italy
Notes: no further details on randomisation

n = 31
Age: Mean 70
Sex: 14 males 17 females
Diagnosis:
100% Depression by DSM-IV
100% Parkinson's Disease
Exclusions: - severe motor fluctuations
- psychosis
- dementia

Baseline: HDRS: Sertraline 20.3 (3.9) Amitriptyline 19.7 (2.8)

Data Used
Remission (below cut-off)
Response (>50 reduction from baseline)
Physical health outcomes
HDRS
Notes: Dropouts: 4/16 Sertraline Amitriptyline 4/1

Group 1 N = 12
Sertraline. Mean dose 50mg
Group 2 N = 11
Amitriptyline. Mean dose 25mg

Funding: Pfizer
BARONE2006

Study Type: RCT

Blindness: Single blind
Duration (days): Mean 84
Setting: Italy
Notes: no further details on randomisation

Data Used
- Remission (below cut-off)
- Response (>50 reduction from baseline)

Funding: no information

Notes: Dropouts: Pramipexole 1/33 Sertraline 7/34

Baseline: HDRS: Sertraline 21.33 (4.4) Pramipexole 19.7 (3.5)

Data Used
- HDRS

Notes: no further details on randomisation

Setting: Italy
Duration (days): Mean 84
Blindness: Single blind
Study Type: RCT

Notes: no further details on randomisation

BIRD2000

Study Type: RCT

Study Description: ITT: LOCF
Type of Analysis: ITT
Blindness: Double blind
Duration (days): Mean 56
Setting: 34 centres throughout UK, Ireland, Germany, Italy and Belgium.
Notes: RANDOMISATION: procedure not reported
Info on Screening Process: 210 entered, 191 randomised, 3 more dropped out from Amitriptyline group for lack of does efficacy and lack of good clinical practice.

Data Used
- PGE
- Physical health outcomes (self-report)
- CGI-I
- Adverse events
- MADRS

Notes: TAKEN AT: Baseline, weeks 4, 8 and end of treatment
DROP OUT: 18(19.1) Paroxetine, 19 (20.2) amitriptyline
Leaving due to adverse events: 15 (16.0) paroxetine, 14 (14.9) amitriptyline

Notes: RANDOMISATION: procedure not reported
Setting: 34 centres throughout UK, Ireland, Germany, Italy and Belgium.
Duration (days): Mean 56
Blindness: Double blind
Study Type: RCT

Notes: no further details on randomisation

Type of Analysis: completers*
Info on Screening Process: no info

Results from this paper:
Quality assessment result: +

BLUMENFIELD1997

Study Type: RCT

Study Description: * 1/7 treatment left study, all placebo participants completed
Type of Analysis: completers*
Blindness: Double blind
Duration (days): Mean 56
Setting: 2 hospitals, New York, US.
Notes: Details on randomisation not reported.
Info on Screening Process: no info

Data Used
- HADS
- BDI

Notes: TAKEN AT: DROP OUT:

Funding: no information

Notes: Details on randomisation not reported.
Setting: 2 hospitals, New York, US.
Duration (days): Mean 56
Blindness: Double blind
Study Type: RCT

Notes: Details on randomisation not reported.
- other psychiatric disorder other than major depressive disorder
- received psychotropic medication in the week prior to study
- received MAOIs two weeks prior to service
- not satisfy the criteria for major depressive disorder
- pregnant or woman of child bearing age not using contraception
- involved in any other drug study prior to this study

Notes: all subjects on dialysis
Baseline: not stated, although all participants scored at least 16 on the HADS.

Results from this paper:
Quality assessment = +

BORSON1992

Study Type: RCT
Type of Analysis: Completer
Blindness: Double blind
Duration (days): Mean 84
Setting: VA medical centres and private practices
SEATTLE, US
Notes: RANDOMISATION: Assignment to treatment was conducted by a psychiatrist blind to the study questions using a random number table
Info on Screening Process: Not reported

n = 36
Age: Mean 61
Sex: 22 males 14 females

Diagnosis:
100% COPD by Not specified
100% Depression by DSM-III

Exclusions: - Primary diagnosis not moderate to severe COPD
- No diagnosis of depression
- Another medical illness more disabling than lung disease
- MMSE <25 indicating severe cognitive impairment
- Recent stroke or myocardial infarction
- Currently abusing alcohol
- If other psychotropics couldn’t be withdrawn
- Taking <40mg of prednisone daily and those who began home oxygen treatment within the month

Notes: All participants were outpatients with 39% receiving care from VA physicians and 61% from community providers.
Baseline: HAM-D: 29.6(7.6) Nortriptyline; 29.5(6.4) placebo

Results from this paper:
Quality assessment = +

BROWN2005A

Study Type: RCT
Study Description: * Analysis included those who completed baseline + <= one post-baseline evaluation regardless of study completion LOCF used for missing data
Type of Analysis: ITT*
Blindness: Double blind
Duration (days): Mean 84
Setting: Asthma Clinic
DALLAS, US
Notes: RANDOMISATION: procedure not reported
Info on Screening Process: Not reported

n = 90
Age: Mean 41
Sex: 16 males 66 females

Diagnosis:
100% Asthma by Clinical judgement
Depression by Two-item screening tool

Exclusions: - Unable to speak English or Spanish
- No physician diagnosis of asthma and not currently taking asthma medication
- <17 on HAM-D
- Current substance abuse
- Psychosis
- High suicide risk
- Clinically significant hypothyroidism
- Severe cognitive impairment

Data Used
IDS-SR
Adverse events
AQLO
ACQ
HAM-D
Remission (below cut-off)
Response (>50 reduction from baseline)
Notes: TAKEN AT: Baseline, wks, 1-12, End of treatment
DROPOUT: Citalopram: 23/41; Placebo: 16/41
Leavinf due to adverse events

Results from this paper:
Quality assessment = +

Group 1 N = 41
Citalopram. Mean dose 20mg/d
Group 2 N = 41
Placebo

Although 90 participants were randomised, the paper only presents and analyses data from 83 participants
Results from this paper:
Quality assessment score = +

<table>
<thead>
<tr>
<th>CHEN2002</th>
<th>Study Type: RCT</th>
<th>Blindness: No mention</th>
<th>Duration (days): Mean 56</th>
<th>Setting: China,</th>
<th>Notes: RANDOMISATION: no further details</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 60</td>
<td>Age:</td>
<td>Sex: no information</td>
<td>Diagnosis: 100% Stroke</td>
<td>Exclusions: - prestroke psychiatric illness - cognitive impairment - suicidal ideation</td>
<td></td>
</tr>
<tr>
<td>Data Used</td>
<td>ADL</td>
<td>HDRS-17</td>
<td>Notes: Dropouts: Paroxetine 0/24 Doxepine 8/16 (all Aes) Placebo 4/20 (lack of efficacy)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTA1985</th>
<th>Study Type: RCT</th>
<th>Study Description: Efficacy assessments were based on LOCF in which missing scores from patients who dropped out before day 21 had the last observation score assigned. Type of Analysis: ITT and completer</th>
<th>Blindness: Double blind</th>
<th>Duration (days): Mean 28</th>
<th>Setting: In-patient (70/73 participants)</th>
<th>Notes: RANDOMISATION: procedure not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 73</td>
<td>Age: Mean 52</td>
<td>Sex: all females</td>
<td>Diagnosis: Depression by Clinical judgement</td>
<td>Exclusions: - age &lt;18 - no diagnosis of depression according to criteria proposed by Stewart et al and Kathol &amp; Petty - Depression not succeeding or parallel development of cancer - Zung self-rating score &lt;41, Ham-D &lt;16 - diagnoses of alcoholism, drug use disorder, personality disorder, schizoaffective disorder, depressive syndrome superimposed on residual schizophrenia, organic mental disorder - epilepsy - Vomiting resistant to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Used</td>
<td>Adverse events</td>
<td>HDRS-17</td>
<td>CGI-S</td>
<td>Brief Zung Self-rating Depression Scale</td>
<td>Notes: TAKEN AT: Baseline and and of treatment DROPOUT: Mianserin 7/36 (19%) placebo 15/37 (41%) Leaving the study early due to side effects: Mianserin 1/36 Placebo 1/37</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Used</th>
<th>GROUP 1</th>
<th>n = 24</th>
<th>Funding not mentioned</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDRS-17</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Used</th>
<th>GROUP 2</th>
<th>n = 20</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL</td>
<td>Paroxetine. Mean dose 200mg/d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDRS-17</td>
<td>Placebo. Mean dose 30mg/d - Guvitamine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Used</th>
<th>GROUP 3</th>
<th>n = 16</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL</td>
<td>Doxepine. Mean dose 25mg/d</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results from this paper:
1.1 Adequately addressed
**DEVOS2008**

**Study Type:** RCT  
**Study Description:** All participants were included in the analysis for primary data

<table>
<thead>
<tr>
<th>Data Used</th>
<th>Group 1 N= 16</th>
<th>Group 2 N= 15</th>
<th>Group 3 N= 17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Used</strong></td>
<td><strong>Placebo - Three placebo tablets</strong></td>
<td><strong>Citalopram. Mean dose 20mg/day - Citalopram treatment consisted of one 20mg tablet and two placebo tablets</strong></td>
<td><strong>Desipramine. Mean dose 75mg/day - Desipramine treatment consisted of two 25mg tablets and one placebo tablet for 2 days followed by three 25mg tablets for last 28 days</strong></td>
</tr>
<tr>
<td><strong>Diagnosis:</strong></td>
<td>100% Depression by DSM-IV</td>
<td>&lt;20 MADRS</td>
<td>Parkinson’s Disease by Clinical judgement</td>
</tr>
<tr>
<td><strong>Exclusions:</strong></td>
<td>- &gt;80 years</td>
<td>- not receiving optimal dose of dopaminergic treatment</td>
<td>- not being treated with medications that might affect the outcome of this study</td>
</tr>
<tr>
<td><strong>Baseline:</strong></td>
<td>No significant differences at baseline between groups: MADRS: placebo 27, Citalopram 25, Desipramine 29</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Reports demographic data for 42/48 participants</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Study Supported by Non-drug company funded (funded by French Ministry of Health grant)**

**EHDE2008**

**Study Type:** RCT  
**Study Description:** All outcomes analysed using ITT regardless of participant’s adherence to protocol. For the main analyses, baseline values were substituted for missing values

<table>
<thead>
<tr>
<th>Data Used</th>
<th>Group 1 N= 22</th>
<th>Group 2 N= 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Used</strong></td>
<td><strong>Paroxetine. Mean dose 10-40mg/day - Initial dose 10mg/day (one capsule) for one week. Dose increased to 20mg/day if tolerated. On each visit the psychiatrist adjusted the study medication up to 4 capsules (40mg/day) depending on clinical outcome and side effects</strong></td>
<td><strong>Placebo - up to 4 capsules of placebo could be given</strong></td>
</tr>
<tr>
<td><strong>Diagnosis:</strong></td>
<td>Multiple Sclerosis by Clinical judgement</td>
<td>Multiple Sclerosis by Clinical judgement</td>
</tr>
<tr>
<td><strong>Exclusions:</strong></td>
<td>- Age &lt;18 years</td>
<td>- Age &gt;18 years</td>
</tr>
<tr>
<td><strong>Baseline:</strong></td>
<td>No significant differences at baseline between groups: MADRS: placebo 27, Citalopram 25, Desipramine 29</td>
<td></td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Reports demographic data for 42/48 participants</td>
<td></td>
</tr>
</tbody>
</table>

**Study supported by Non-industry grant. Drugs provided by GlaxoSmithKline**
### EISER2005

- **Study Type:** RCT
- **Study Description:** 6 week double-blind placebo controlled study followed by a 3 month open-label extension period
- **Type of Analysis:** Completer
- **Blindness:** Double blind
- **Setting:** Lewisham, UK
- **Notes:** RANDOMISATION: procedure not reported
- **Info on Screening Process:** 135 people were screened, 47 screened positive for depression of which 28 received a diagnosis and agreed to participate

#### Data Used
- **SGRQ**
- **MADRS**
- **Physical health outcomes**
- **BDI**
- **HADS**

#### Notes:
- TAKEN AT: baseline and end point (end of double-blind stage)
- DROPOUT: 4/14 Paroxetine; 0/14 Placebo

#### Funding
- Not reported

#### Results from this paper:
- Quality assessed: +

### EVANS1997

- **Study Type:** RCT
- **Study Description:** ITT included all those who completed at least 3 weeks of treatment. Discontinuations prior to 3 weeks were excluded from the analysis.
- **Type of Analysis:** ITT
- **Blindness:** Double blind
- **Setting:** UK, LIVERPOOL
- **Notes:** RANDOMISATION: procedure not reported
- **Info on Screening Process:** 144 patients were diagnosed with depression, 58 were not included int eh trial due to refusal, physician's decision, medical contraindication, and other reasons

#### Data Used
- **Enroix ate events**
- **Response (>50 reduction from baseline)**

#### Notes:
- Exclusions: - <65 years old
- - Suicidal intent or severe depression requiring ECT
- - Serious mental illness
- - Already receiving psychotropic medication other than hypnics
- - Unstable epilepsy
- - Severe cognitive impairment (MMSE <10)

#### Funding
- Drug-company sponsored (Lilly Industries Ltd)

#### Results from this paper:
- Quality assessment score +
**FISCH2003**

Study Type: RCT

Study Description: All participants with at least one follow-up were assessable for the primary outcome. Generalised estimating equation used for missing data.

Type of Analysis: ITT and completer

Blindness: Double blind

Duration (days): Mean 84

Setting: 15 sites of the Hoosier Oncology group, US (3 academic centres, 12 community sites)

Notes: RANDOMISATION: Patients were stratified on the basis of Eastern Cooperative Oncology Group performance. The randomisation was performed centrally.

Info on Screening Process: Not reported

---

**FRUEHWALD2003**

Study Type: RCT

Blindness: Double blind

Duration (days): Mean 90

Followup: 3 months then open label follow up

Setting: France, neurorehabilitation unit

Notes: RANDOMISATION: generated by computer programme independently of the research team

---

**Data Used**

**Group 1 N= 83**

- Fluoxetine
- Mean dose 20mg - The study drug was self-administered by the patient once daily in the morning

**Group 2 N= 80**

- Placebo
- Patients received an identical placebo tablet which was self-administered once daily in the morning

**Data Used**

- Functional Assessment of Cancer Therapy-General
- Brief Zung Self-rating Depression Scale
- Response (>50 reduction from baseline)

Notes: TAKEN AT 3-6 weeks into treatment

DROP OUT Fluoxetine 19/83, Placebo 15/80

Discontinued study drug due to adverse events: Fluoxetine 4/83, Placebo 2/80

---

FRUEHWALD20003

Study Type: RCT

Blindness: Double blind

Duration (days): Mean 90

Followup: 3 months then open label follow up

Setting: France, neurorehabilitation unit

Notes: RANDOMISATION: generated by computer programme independently of the research team

---

**Data Used**

- MMSE
- HDRS
- BDI

Notes: Dropouts: Fluoxetine 2/28, Placebo 2/26

**Group 1 N= 28**

- Fluoxetine

**Group 2 N= 26**

- Placebo

Supported in part by Mary Margaret Walther program for Cancer Care Research. Fluoxetine, placebo and study notebooks provided by Eli Lilly
### GLASSMAN2002

**Study Type:** RCT  
**Study Description:** Intention to treat  
**Blindness:** Double blind  
**Duration (days):** Mean 168  
**Setting:** Outpatient cardiology and psychiatry clinics US, Canada, Europe, Australia  
**Notes:** RANDOMISATION: no description  
**Info on Screening Process:** 11546 screened, 8191 did not have MI or angina, 2799 did not have depression; 187 did not meet DSM criteria  

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 186</th>
<th>Group</th>
<th>N= 183</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sertraline</strong> Mean dose 50-200mg - Flexible dosing: Received 50mg/d first 6 weeks, depending on response could be increased to 100mg/d at end of 6 weeks, and max 200mg/d at end of week 12.</td>
<td><strong>Placebo</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Data Used  
**Cardiovascular outcomes**  
**HDRC-17**  
**Notes:** Dropouts: Sertraline 53/186 Placebo 46/183  
**Deaths:** Sertraline 2/186 Placebo 5/183  
**Adverse events:** Sertraline 16/186 Placebo 11/18.  

#### Data Not Used  
**SF-36 - Individual scales provided without total score**  
**Notes:** TAKEN AT: BASELINE AND END OF TREATMENT (wk12)  
**DROP OUT:** Flex 1/12 Prx 2/11  

#### Diagnosis:  
**Age:** Mean 57  
**Sex:** 234 males 135 females  
**Diagnosis:**  
- MI  
- Angina  
  100% Depression by DSM-IV  
**Exclusions:**  
- uncontrolled hypertension  
- cardiac surgery in next 6 months  
- renal dysfunction  
- substance abuse  
- psychosis, bipolar, dementia  
**Baseline:** HAMD = 19.6  

---

### GOTTLIEB2007

**Study Type:** RCT  
**Blindness:** Double blind  
**Duration (days):** Mean 84  
**Setting:** Heart Failure Clinic Veterans Affairs, US  
**Notes:** RANDOMISATION: no details  

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 14</th>
<th>Group</th>
<th>N= 14</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paroxetine</strong> Controlled release: started at 12.5mg/d, if tolerated well increased to 25mg/d after 2 weeks</td>
<td><strong>Placebo</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Data Used  
**SF-36**  
**Remission (below cut-off)**  
**Notes:** Dropouts: Paroxetine 1/14 Placebo 1/14  
**Death:** Paroxetine 1/14 Placebo 0/14  

#### Data Not Used  
**SF-36 - Individual scales provided without total score**  
**Notes:** TAKEN AT: BASELINE AND END OF TREATMENT (wk12)  
**DROP OUT:** Flex 1/12 Prx 2/11  

#### Diagnosis:  
**Age:** Mean 62  
**Sex:** 24 males 4 females  
**Diagnosis:**  
- 100% Cardiovascular disease  
- 100% Depression by BDI  
**Exclusions:**  
- MI within 1 month  
- unstable angina  
- BDI <10  
- substance abuse  
- psychosis  
**Baseline:** BDI median = 21.5  

---

### GULSEREN2005

**Study Type:** RCT  
**Type of Analysis:** Completer  
**Blindness:** Rater only blind  
**Duration (days):** Mean 84  
**Setting:** Patients were all outpatients being monitored at the endocrinology unit at a local hospital TURKEY, Izmir  
**Notes:** RANDOMISATION: details not reported  
**Info on Screening Process:** 25 people meet the inclusion criteria but two were excluded prior to randomisation as they reported that they could not be present for regular follow ups  

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 12</th>
<th>Group</th>
<th>N= 11</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluoxetine</strong> Mean dose 20mg/day</td>
<td><strong>Paroxetine</strong> Mean dose 20mg/day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Data Used  
**Adverse events**  
**Physical health outcomes**  
**Response (score from baseline)**  
**CGI**  
**HAM-A**  
**HAM-D**  

#### Data Not Used  
**SF-36 - Individual scales provided without total score**  
**Notes:** TAKEN AT: BASELINE AND END OF TREATMENT (wk12)  
**DROP OUT:** Flex 1/12 Prx 2/11  

#### Diagnosis:  
**Age:** Mean 57  
**Sex:** 3 males 17 females  
**Diagnosis:**  
- Diabetes  
- Depression by DSM-IV  
**Exclusions:**  
- HAM-D score <16  
- Active suicidal ideation  
- History of any psychiatric disorder  
- A physical disease or mental incapacity that would prevent them from performing an interview  
- currently taking psychoactive_educations  
**Notes:** Type II diabetes  
**Baseline:** HAM-D: Flx 17.5(2.4) Prx 18.8(3.0)  
HAM-A: Flx 15.7(8.5) Prx 17.2(7.2)  

---

**Results from this paper:**  
**Quality assessment:** +
Study Type: RCT
Study Description: ITT - LOCF for all participants who received at least one dose of study drug
Type of Analysis: ITT
Blindness: Double blind
Duration (days): Mean 42
Setting: Six investigation sites New York, US
Notes: RANDOMISATION: Not reported
Info on Screening Process: 2 patients withdrew before receiving active drug and one randomised patient discontinued without starting the drug.

Results from this paper:
1. Adequately addressed
2. Not reported adequately
3. Not addressed
4. Well covered
5. Well covered
6. Not addressed
7. Poorly addressed
8. Fluoxetine: 6/21 (28%), Desipramine: 7/17 (41%)
9. Well covered
10. Adequately addressed

HUANG2005

KIMURA2000
Study Type: RCT
Blindness: Double blind
Duration (days): Mean 84
Setting: US, hospitals in Iowa and Baltimore

Results from this paper:
1. Adequately addressed
2. Not reported adequately
3. Not addressed
4. Well covered
5. Well covered
6. Not addressed
7. Poorly addressed
8. Nortriptyline - Iowa: 20 mg/d first week, 50mg/d for weeks 2-3, 75 mg/d weeks 4-6, 100mg from 7-12weeks Baltimore: 20mg/d first week, 50mg/d for weeks 2-3, 70mg/d week 4, 100mg from

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HOLLAND1998
Study Type: RCT
Study Description: ITT - LOCF for all participants who received at least one dose of study drug
Type of Analysis: ITT
Blindness: Double blind
Duration (days): Mean 42
Setting: Six investigation sites New York, US
Notes: RANDOMISATION: Not reported
Info on Screening Process: 2 patients withdrew before receiving active drug and one randomised patient discontinued without starting the drug.

Results from this paper:
1. Adequately addressed
2. Not reported adequately
3. Not addressed
4. Well covered
5. Well covered
6. Not addressed
7. Poorly addressed
8. Fluoxetine: 6/21 (28%), Desipramine: 7/17 (41%)
9. Well covered
10. Adequately addressed

Drug company sponsored:
Eli Lilly
**LACASSE2004**

**Study Type: RCT**

**Study Description:** Worst possible score was substituted for those dropping out of intervention group with the best score substituted for those dropping out of placebo.

**Type of Analysis:** ITT and Completer

**Blindness:** Double blind

**Duration (days):** Mean 84

**Setting:** Respiratory care home service

**Notes:** RANDOMISATION: random number table used to allocate patients. Process under the responsibility of one hospital pharmacist not involved in trial.

**Info on Screening Process:** 342 assessed for eligibility, 237 ineligible, 82 refused.

**Data Used**

- **Adverse events**
- **Data Not Used**

**Notes:** TAKEN AT: Baseline and week 12 (post treatment)

**Dropout:** 4/12 prx, 4/11 placebo

**Diagnosis:**

- 100% Depression
- Exclusions: - aphasia, dementia, decreased levels of consciousness
- HAMD <10

**Study Type: RCT**

**Study Description:** Problems recruiting participants aimed for 40

**Type of Analysis:** ITT and Completer

**Blindness:** Double blind

**Duration (days):** Mean 67

**Setting:** Netherlands

**Notes:** Randomisation: no further details

**Results from this paper:**

**Quality assessed:** = +

**LAKSHMANAN1986**

**n= 29**

**Age:** Mean 76

**Sex:**

**Diagnosis:**

- 100% Depression

**Exclusions:**

- Suicidal thoughts
- Glaucoma
- Cardiac disease
- Poorly controlled seizures
- Severe pulmonary or renal disease
- Aphasia
- MMSE <20

**Notes:** Used HAMD

**Baseline:** HAMD: Doxepin 31.5 (11.0) Placebo 29.3 (7.8)

**LEENTJENS2003**

**n= 12**

**Age:** Mean 67

**Sex:** 8 males 4 females

**Diagnosis:**

- 100% Depression by DSM-IV

**Data Used**

- **Response (>50 reduction from baseline)**

**Notes:** Sertraline - Starting dose 25mg, 50mg after 1 week, doubled to 100mg if no response at 6 weeks

**Group 1 N= 6**

**Setting:** Netherlands

**Notes:** Problems recruiting participants aimed for 40
**LESPERANCE2007**

**Study Type:** RCT

**Type of Analysis:** ITT

**Blindness:** Double blind

**Duration (days):** Mean 84

**Setting:** CANADA 9 academic centres

**Notes:** RANDOMISATION: computer generated and concealed in opaque envelopes

**Info on Screening Process:** 370 screened, 30 did not have depression, 30 HAMD <20, 6 psychiatric reasons, 6 medical reasons, 5 logistics, 9 refused

**Data Used**

**Cardiovascular outcomes**

- Response (>50 reduction from baseline)
- Remission (below cut-off)

**BDI-II**

**HDRS-24**

Notes: Dropout: IPT + Placebo 2/67 IPT + Placebo 6/75 Citalopram 3/75 Placebo 6/67

**Notes:** 100% Parkinson's Disease

**Notes:** No dropouts

**Group 1 N = 85**

**Citalopram - 10mg/d week1, 20mg/d, if HAMD >8 increased to max 40mg/d.**

**Clinical management - Information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.**

**Group 2 N = 67**

**Placebo**

**Clinical management - Information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.**

**Group 3 N = 75**

**IPT - Individual IPT, 12 weekly sessions +/- placebo: up to 4 sessions via telephone.**

**Focused on dealing with interpersonal conflicts, life transitions, grief, and loss. Conducted by Doctoral or Masters level therapists with mean 15 years experience.**

**Clinical management - Information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.**

**Group 4 N = 67**

**Citalopram + IPT - citalopram and IPT provided as described**

**Clinical management - Information about depression and medication use, encourage adherence, evaluate adverse events. Individual. 20-25 mins. Up to 4 could be done via telephone.**

**Notes:** 100% Depression by DSM-IV

**Notes:** 100% Cardiovascular disease by Histologically confirmed

**LI2005**

**Study Type:** RCT

**Study Description:** Raters were blind to treatment allocation but unclear from paper whether participants were also blinded

**Type of Analysis:** Completer

**Blindness:** Open

**Duration (days):** Mean 56

**Setting:** Neurology unit, CHINA, Shaanxi Province

**Notes:** RANDOMISATION: performed by coin toss

**Info on Screening Process:** 89 participants were thought to be eligible, 9 were excluded, 86 entered, 67 completed, 50% of completers were blind to treatment allocation

**Data Used**

**Adverse events**

- HAM-D
- HAM-A

**Response (>50 reduction from baseline)**

Notes: TAKEN AT: Baseline and end of treatment

**DROP OUT - 0/33 trx, 3/34 (9%) control**

**Notes:** Funding not reported

**Group 1 N = 33**

**Paroxetine. Mean dose 20-40mg - Paroxetine taken daily at a starting dose of 10mg/d, increased to 20mg/d after one week. After 4 weeks if there was a HAMD reduction <50% dose was increased to 30-40mg/d**

**Group 2 N = 34**

**Doxepine. Mean dose 100mg/d - Starting dose of 25mg/d was adjusted according to response. Mean 100 mg/d (12.5mg/d)**

**Notes:** Severe depression according to APA criteria

**n= 284**

**Age:** Mean 58

**Sex:** 214 males 70 females

**Diagnosis:**

100% Depression by DSM-IV

100% Cardiovascular disease by Histologically confirmed

**Exclusions:**

- < 18 years of age
- HAMD <20
- depression due to general medical condition
- psychosis, bipolar,
- substance abuse
- suicide risk
- current use of antidepressants, lithium, anticonvulsants for mood disorder
- current psychotherapy
- previous absence of response to citalopram or IPT
- 2 or more previous unsuccessful treatment for index depression
- lifetime history of early termination of citalopram or 2 other SSRIs because of adverse events
- MMSE < 24
- clinician judgement that the patient would not adhere to study regimen
- coronary bypass graft surgery planned during the next 4 months
- Canadian Cardiovascular Society Angina Class of 4
- unable to speak French/English

**Notes:** severe depression according to APA criteria

**Baseline:** Total: HAM-D: 29.68 BDI = 30.3; HAM-D: 30.0 - IPT (+ Placebo), 30.3 - control; BDI = 29.1 - IPT (+ Placebo), 31.3 - control.

**n= 67**

**Age:** Mean 34

**Sex:** 32 males 35 females

**Diagnosis:**

- Epilepsy by Diagnosed by physician
- Depression by CCMD-3

**Exclusions:**

- No diagnosis of epilepsy
- No CCMD-3 diagnosis of depression
- HAM-D <18
- Comorbid neurological or physical illness or substance misuse
- Refusal to consent

**Notes:** Diagnosis of epilepsy from clinical assessment and

**Notes:** Severe depression according to APA criteria

**n= 67**

**Age:** Mean 34

**Sex:** 32 males 35 females

**Diagnosis:**

- Epilepsy by Diagnosed by physician
- Depression by CCMD-3

**Exclusions:**

- No diagnosis of epilepsy
- No CCMD-3 diagnosis of depression
- HAM-D <18
- Comorbid neurological or physical illness or substance misuse
- Refusal to consent

**Notes:** Diagnosis of epilepsy from clinical assessment and
Results from this paper:
Quality assessment score = +

LIPSEY1984

Study Type: RCT
Study Description: LOCF (if in study for at least week)
Blindness: Double blind
Duration (days):
Setting: US, patients in rehabilitation hospitals or outpatients
Notes: RANDOMISATION: random number table

Data Used
Remission (below cut-off)
Notes: Dropouts: Nortriptyline 3/14 Placebo 2/20

Group 1 N= 14
Nortriptyline - 6 week regimen: 20 mg/d week1, 50 mg/d week 2-3, 70mg/d week4, 100mg/d weeks 5-6
4 weeks regimen: 50mg/d week1, 70mg/d weeks 2-3, 100mg/d week4

Group 2 N= 20
Placebo

Funding: NIH grant, Sandoz Pharmaceutical company provided medication

LUSTMAN1997A

Study Type: RCT
Study Description: Personnel preparing treatment packs were different from those monitoring progress. Dummy reports were produced to ensure blinding of raters.
Type of Analysis: Completer only
Blindness: Double blind
Duration (days): Mean 56
Setting: US, Washington, St louis
Notes: RANDOMISATION: details not reported
Diabetes management regimes kept constant during the study unless clinically indicated
Info on Screening Process: 180 patients evaluated to determine eligibility, 66 were excluded on et basis of their psychiatric interview. Present study looks at 35 subjects with active depression diagnosis

Data Used
Remission (below cut-off)
BDI
Data Not Used
Physical health outcomes - F-value only without means
Notes: TAKEN AT: Baseline and end of treatment (wk8)
DROPOUT: - does not give drop out for depressed only. Total study drop out = 14%

Group 1 N= 14
Nortriptyline. Mean dose 25 - 50mg/day - 25mg/day increased to 50mg/day during second visit. Subsequent adjustments were made to ensure that a plasma nortriptyline level remained within the range of 50-150 ng/ml

Group 2 N= 20
Placebo

Paper reports a subset of a 1988 unpublished study. Paper only reports on those who were depressed and had poor glycemic control. Data for depressed patients presented seperately (data for non-depressed not entered into the analysis

LUSTMAN2000

Study Type: RCT
Study Description: Paper provides both ITT and completer for the dichotomous outcomes, completer only for continuous
Type of Analysis: ITT and completer

Data Used
Physical health outcomes
BDI
HAM-D

Group 1 N= 27
Fluoxetine. Mean dose 20-40mg/day - Dosing began at 20mg/day and could be increased to a max of 40mg/day

Drug-company funded - Eli Lilly
Demographics and baseline for completers only

Results from this paper:
Quality assessment score = +
Results from this paper:

Quality assessment +

**LUSTMAN2006**

Study Type: RCT

Study Description: ITT with patients who did not complete the protocol being censored at the point of discontinuation I the survival estimates

Type of Analysis: ITT

Blindness: Double blind

Duration (days): Mean 365

Setting: Outpatient clinics

USA, Washington, Seattle and Arizona

Notes: RANDOMISATION: Patients were randomised using a computer generated algorithm. Randomisation was stratified according to site. Allocation concealment.

Info on Screening Process: 389 screened, 351 satisfied the inclusion criteria and were enrolled in the open label phase of the trial. 156 completed the induction phase of trial which 152 entered the maintenance phase of the trial (presented here)

n= 152

Age: Mean 53

Sex: 61 males 91 females

Diagnosis: Diabetes

Exclusions: - Non-recovery from depression during open-label phase of trial (Initially patients were excluded if BDI <14 or HAM-D <15)

- Aged <18

- No diagnosis of type I or II diabetes

- Active suicidal ideation or a history of attempted suicide

- Current alcohol or substance misuse disorder

- Medical contraindication to sertraline treatment

Notes: Study is looking at the prevention of relapse in patients who recovered from depression during an open-label phase of the trial. See notes for further details

Baseline: Maintenance phase:

BDI: sertraline 4.4(3.0) Placebo 3.5(2.6)

Drug-company sponsored study - Pfizer NY

Recovery from depression was defined per DSM-IV criteria as a period of >=2 months during which there were no significant symptoms of depression

Results from this paper:

Quality assessment ++

**MAURI1994**

Study Type: RCT

Blindness: Double blind

Duration (days): Mean 56

Setting: Italy

Notes: RANDOMISATION: no further details

n= 26

Age: Mean 35

Sex: 19 males 6 females

Diagnosis: 100% Depression by DSM-III-R

Data Used

HDRS

Notes: no information on dropouts

Group 1 N= 16

Fuvoxamine. Mean dose 100-150mg/d

Group 2 N= 10

Placebo

Drug-company sponsored study - Pfizer NY

Recovery from depression was defined per DSM-IV criteria as a period of >=2 months during which there were no significant symptoms of depression
**MCFARLANE2001**

**Study Type:** RCT  
**Blindness:** Double blind  
**Duration (days):** Mean 180  
**Setting:** Coronary Care Unit, Canada  
**Notes:** RANDOMISATION: no further details

n=38  
Age: Mean 62  
Sex: 23 males 15 females  
Diagnosis:  
100% Cardiovascular disease  
Exclusions: - <15 Inventory to Diagnose Depression before discharge and 2 weeks later -

**Data Used**  
Cardiovascular outcomes  
Notes: Dropouts: Sertraline 6/18 Placebo 5/20

**Group 1**  
N=18  
Sertraline. Mean dose 50mg/d

**Group 2**  
N=20  
Placebo  
Sponsorship by Heart and Stroke Foundation of Ontario  
All received access to multidisciplinary care: exercise rehab, nutrition, counselling

**MENZA2008**

**Study Type:** RCT  
**Blindness:** Double blind  
**Duration (days):** Mean 56  
**Setting:** US  
**Notes:** Randomisation: no further details

n=52  
Age: Mean 63  
Sex: 27 males 25 females  
Diagnosis:  
100% Depression by DSM-IV  
100% Parkinson's Disease  
Exclusions: - MMSE <26  
- psychiatric diagnosis other than depression or anxiety

Baseline: HAMD: Paroxetine 18.82 (5.6) Nortriptyline 21.12 (5.64) Placebo 19.29 (5.64)

**Data Used**  
Response (>50 reduction from baseline)  
HAM-D

**Group 1**  
N=18  
Paroxetine. Mean dose 28.4mg - Flexible dosing started at 12.5mg and could be increased to 37.5mg

**Group 2**  
N=17  
Nortriptyline. Mean dose 48.5mg - Flexible dosing started at 25mg could be increased to 75mg

**Group 3**  
N=17  
Placebo

**MOHAPATRA2005**

**Study Type:** RCT  
**Blindness:** Single blind  
**Duration (days):** Mean 180  
**Setting:** Cardiology and Psychiatry departments, India  
**Notes:** Randomisation: no further information

n=17  
Age: Mean 56  
Sex: 10 males 7 females  
Diagnosis:  
100% Depression by DSM-IV  
MI  
Exclusions: -history of depression before cardiac problems  
- substance abuse  
- recovering from bypass surgery

**Data Used**  
Cardiovascular outcomes  
Remission (below cut-off)  
Notes: no dropouts

**Group 1**  
N=11  
Sertraline. Mean dose 50-200mg/d

**Group 2**  
N=6  
TAU  
Sponsorship by Quality of Life Research and Development Foundation

**MORROW2003**

**Study Type:** RCT  
**Study Description:** * Data analysis was limited to patients who provided complete data. LOCF was used for 43 patients who provided cycle 3 but not cycle 4 data  
**Type of Analysis:** completer*  
**Followup:** up to cycle 4 of chemotherapy  
**Setting:** 18 oncology private-practice groups, US

n=549  
Age: Mean 56  Range 23-84  
Sex: 116 males 363 females  
Diagnosis:  
Cancer  
32% Depression by CES-D  
Exclusions: - <18 yrs  
- cancer patients who were not scheduled to begin the first of

**Data Used**  
POMS  
CES-D

**Group 1**  
N=277  
Paroxetine. Mean dose 20mg

**Group 2**  
N=272  
Placebo - Identical looking placebo  
Drug company sponsored: GlaxoSmithKline  
Supoprted by a National Cancer Institute Grant
Notes: RANDOMISATION: accomplished centrally using a computer-generated random-numbers table.

Info on Screening Process: 902 patients met initial medical eligibility criteria.
- 198 (22%) did not continue as they were no longer medically eligible, did not complete the baseline questionnaires or refused random assignment
- 155 patients did not meet the fatigue criteria

Results from this paper:
1.1 Adequately addressed
1.2 Adequately addressed
1.3 Not addressed
1.4 Well covered
1.5 Well covered
1.6 Not addressed
1.7 Well covered
1.8 Paroxetine: 33/277 (12%), placebo: 37/272 (13%)
1.9 Poorly addressed
1.10 Not addressed

2.1 +

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<td>Exclusions: - MADRS &lt;10 - severe ability to communicate - acute MI - psychiatric illness other than depression - significant risk of suicide - current use of psychotropic or analgesic drugs</td>
<td>Response (&gt;50 reduction from baseline)</td>
<td></td>
</tr>
<tr>
<td>Notes: RANDOMISATION: conducted at the Central Pharmacy in Stockholm, each centre pharmacy received presealed treatment packages.</td>
<td>Remission (below cut-off)</td>
<td>CGI-S</td>
<td></td>
</tr>
<tr>
<td>Exclusions: - MADRS &lt;10 - severe ability to communicate - acute MI - psychiatric illness other than depression - significant risk of suicide - current use of psychotropic or analgesic drugs</td>
<td>HAM-D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes: RANDOMISATION: conducted at the Central Pharmacy in Stockholm, each centre pharmacy received presealed treatment packages.</td>
<td>HAM-A</td>
<td></td>
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</table>

Data Used

<table>
<thead>
<tr>
<th>MUSSELMAN2006</th>
<th>Data Used</th>
<th>Group 1 N= 35</th>
<th>Group 2 N= 61</th>
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</thead>
<tbody>
<tr>
<td>Study Type: RCT</td>
<td>ADL</td>
<td>Sertraline</td>
<td>Placebo</td>
</tr>
<tr>
<td>Study Description: ITT population with LOCF approach applied for the missing data</td>
<td>MADRS</td>
<td>Notes: Dropouts: Sertraline 24/62 Placebo 30/61</td>
<td></td>
</tr>
<tr>
<td>Setting: 2 centres</td>
<td>Notes: Data Used</td>
<td>Adverse events</td>
<td>Response (&gt;50 reduction from baseline)</td>
</tr>
<tr>
<td>Type of Analysis: ITT and completer</td>
<td>Remission (below cut-off)</td>
<td>CGI-S</td>
<td></td>
</tr>
<tr>
<td>Exclusions: - Aged &lt;18 or &gt;75 - Pregnant women and women of childbearing potential not</td>
<td>HAM-D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes: RANDOMISATION: not reported</td>
<td>HAM-A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
using contraception, lactating women
- Serious suicidal risk
- History of urinary retention, intracranial metastases, angina pectoris, MI, arrhythmia, presence of conduction defects or any serious CVD
- Serious illness including cardiac, hepatic, renal, respiratory, endocrinologic, neurologic or hematologic disease of such instability that hospitalisation is likely in the next 2 months
- DSM-III-R diagnosis of organic mental disorder, alcohol and/or substance use disorder, paranoid or psychotic symptoms, or bipolar disorder

Baseline: HAMD: Paroxetine: 21.00 (5.66), Desipramine 23.00 (6.16), Placebo 23.91 (4.99)
HAMA: Paroxetine: 19.62 (7.19), Desipramine 18.45 (6.67), Placebo 21.82 (8.54)
CGI-S: Paroxetine: 3.85 (0.69), Desipramine 4.00 (0.77), Placebo 4.18 (0.40)

Results from this paper:
1.1 Well covered
1.2 Not reported adequately
1.3 Not addressed
1.4 Well covered
1.5 Poorly addressed
1.6 Not addressed
1.7 Well covered
1.8 Paroxetine: 5/13 (38%), Desipramine: 5/11 (45%), Placebo: 5/11 (45%)
1.9 Well covered
1.10 Not addressed

NELSON1999

Study Type: RCT
Study Description: ITT (LOCF)
Blindness: Double blind
Duration (days): Mean 42
Setting: US
Notes: RANDOMISATION: no further details

Data Used
Remission (below cut-off)
Response (>50 reduction from baseline)
Notes: Dropouts: Paroxetine 4/41 Nortriptyline 14/40 - due to adverse events: Paroxetine 2/41 Nortriptyline 10/40

PAILEHYVARINEN2003

Study Type: RCT
Study Description: LOCF used for patients who completed at least 2 weeks of the trial
Type of Analysis: ITT
Blindness: Single blind
Duration (days): Mean 70
Setting: Not stated
Notes: RANDOMISATION: computerised and competing interests: non declared

Data Used
RAND-36
HbA1c
BMI
Blood glucose
BDI
MADRS
HAM-A

Group 1 N=11 Paroxetine. Mean dose 20mg/day - 20mg once daily
Group 2 N=8 Placebo

Group 1 N=41 Paroxetine - Starting dose of 20mg/day unless over 65 years (then 10mg/day). After week 3 increased to 30mg/day if required up to a max of 40mg/day.
Group 2 N=40 Nortriptyline - Nortriptyline plasma concentrations determined at week 1, 2 and 6. Dose adjusted to obtain blood level between 50 and 150 ng/ml

Sponsored by drug company (Smith Kline Beecham) severe depression
concealed to both patient, investigators and treating physicians until inclusion and informed consent was established.

Info on Screening Process: 22 participants were screened of which 7 were excluded as they failed to meet inclusion criteria

Notes: 
- pre-menopausal, aged <50
- unstable antidiabetic medication in previous 3 months
- GHbA1c <6.5% or fasting blood glucose <7.0 mmol/l
- MADRS score <2.5 or >12
- Major complications due to diabetes including CVD, renal failure
- Glaucoma,
- Use of warfarin
- Use of any kind of antidepressant

Notes: All participants had unsatisfactory glycemic control

Baseline: MADRS: Paroxetine 7.4(2.9), Placebo 6.4(4.0) 
BDI: Paroxetine 13.7(7.4), Placebo 13.0(9.2)

Results from this paper:
Quality assessment +

PAILEHYVARINEN2007

Study Type: RCT

Study Description: Identical tablets were packed in identical vials according to the randomisation schedule.

Type of Analysis: Completer only

Blindness: Double blind

Duration (days): Mean 182

Setting: Outpatients FINLAND, Helsinki

Notes: RANDOMISATION: computerised and concealed to participants, investigators and treating physicians. Investigators were not involved in treatment.

Info on Screening Process: 73 interview, 23 did not meet incusion criteria. Most common reason for exclusion was good glycemic control. 6 participants withdrew consent before starting medication

Results from this paper:
Quality assessment +

PEZZELLA2001

Study Type: RCT

Study Description: ITT: all patients who had taken at least one dose of study medication and who had at least one on-dose efficacy assessment. LOCF used for missing data

Type of Analysis: ITT

Blindness: Double blind

Duration (days): Mean 56

Setting: 25 centres in Austria, Belgium, Canada, Germany, Italy and The Netherlands

Notes: RANDOMISATION: details not reported Double-dummy technique used to ensure blindness

Info on Screening Process: 194 were eligible for entry into the study 179 participants were randomised with 175 receiving at least one dose of study medication

Notes: TAKEN AT: Baseline and end of treatment
DROP OUT: Paroxetine 0/7, placebo 2/8
Adverse events: Paroxetine 4/7, placebo 3/7

Results from this paper:
Quality assessment +

Data Used

<table>
<thead>
<tr>
<th>Group</th>
<th>N = 23</th>
<th>Group</th>
<th>N = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxetine. Mean dose 20mg/day</td>
<td>Placebo</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Drug company sponsored - GlaxoSmithKline

Baseline demographics only provided for the 43 participants who received medication

Notes: TAKEN AT: Baseline and post-treatment

DROPOUT: Prx: 1/24 (4%), Placebo 11/25 (44%)

Paroxetine. Mean dose 20-40mg - Administered at 20mg/day for 3 weeks, thereafter dose could be increased to 30mg/d . After week 5 dose could be further increased to 40mg/day or reduced to 20mg/d

Amitriptyline. Mean dose 75-150mg - Initial dose titration of 25mg/day for 3 days, followed by 50mg/day days 4-7 then 75mg/day for 2 weeks, thereafter dose could be increased to 100mg/day. After week 5 dose could be further increased to 150mg/day or reduced to 75mg/day
- Considered to be at risk of suicide
- Breast feeding, likely to become pregnant
- Diagnosis of schizophrenia, bipolar disorder or other psychoses
- Known abusers of alcohol or drugs
- Clinically significant ECG or abnormal laboratory values
- Previously treated with paroxetine or known sensitivity to SSRIs or TCAs
- If likely to need surgery, scheduled for total body irradiation, spinal or abdominal radiotherapy
- undergoing formal psychotherapy

Baseline: FLC: Paroxetine 87.5 (18.6), Amitriptyline 95.0 (20.0)

Results from this paper:
1. Well covered
2. Not reported adequately
3. Not addressed
4. Well covered
5. Well covered
6. Adequately addressed
7. Well covered
8. Paroxetine: 17/89 (19%), Amitriptyline 22/90 (22%)
9. Well covered
10. Not addressed

POLLOCK2002

Study Type: RCT
Blindness: Double blind
Duration (days): Mean 42
Setting: US
Notes: RANDOMISATION: non further details

Data Used
Cardiovascular outcomes
Notes: no information on dropouts

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

Paroxetine - Initiated at 10mg/d, 20mg/d at second week
Nortriptyline - Adjusted to achieve plasma drug concentration ranging from 50-120ng/ml

RABKIN1994

Study Type: RCT
Blindness: Double blind
Duration (days): Mean 42
Setting: US
Notes: RANDOMISATION: no further details

Data Used
Remission (below cut-off)
Response (>50 reduction from baseline)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
</tr>
</tbody>
</table>

Imipramine - 50mg/d for 3days, 100mg/d for 4 days, 150mg/d for a week then 200mg/d for rest of study
Placebo
RABKIN1999
Study Type: RCT
Blindness: Double blind
Duration (days): Mean 56
Setting: US
Notes: RANDOMISATION: no further details

- n = 120
- Age: Mean 39
- Sex: 117 males 3 females
- Diagnosis: 100% Depression by DSM-IV 100% HIV
- Exclusions: - psychosis or bipolar
- - substance misuse
- - panic disorder
- - suicide risk
- - significant cognitive impairment
- - HIV wasting syndrome
- - significant diarrhea

Baseline: HDRS: Fluoxetine 19.6 (4.7) Placebo 18.6 (5.1)

Data Used
Remission (below cut-off)
Response (>50 reduction from baseline)

Notes: Dropouts: Fluoxetine 24/81 Placebo 9/39

Group 1 N = 81 Fluoxetine - 20mg/d starting dose, increased by further 20mg/d bi-weekly depending on response
Group 2 N = 39 Placebo

Funding: NIMH grant, Eli Lilly provided medication

RABKIN2004
Study Type: RCT
Blindness: Double blind
Duration (days): Mean 56
Setting: US
Notes: RANDOMISATION: computer generated numbers

- n = 123
- Age: Mean 41
- Sex: all males
- Diagnosis: 100% Depression by DSM-IV 100% HIV by DSM-IV
- Exclusions: - substance abuse
- - psychosis
- - suicide risk
- - cognitive impairment
- - unstable medical condition

Baseline: HRSD: Fluoxetine 18.2 (4.5) Placebo 16.8 (3.3)

Data Used
Remission (below cut-off)
Response (>50 reduction from baseline)

Notes: Dropouts: Fluoxetine 16/46 Placebo 9/39 Testosterone 8/38

Group 1 N = 39 Placebo
Group 2 N = 38 Testosterone
Group 3 N = 46 Fluoxetine

Funding: NIMH grant, Lilly provided medication

RAFFAELE1996
Study Type: RCT
Blindness: No mention
Duration (days): Mean 30
Setting: Italy, stroke rehabilitation program
Notes: RANDOMISATION: no further details

- n = 22
- Age: Mean 70
- Sex: 13 males 9 females
- Diagnosis: Stroke Depression
- Exclusions: - aphasia

Baseline: Zung depression scale: Trazadone 62.4 (11.8) Placebo 59.2 (10.3)

Data Used
ADL
Zung

Group 1 N = 11 Trazadone. Mean dose 300mg
Group 2 N = 11 Placebo

Funding: no information on funding provided

RAMPELLO2004
Study Type: RCT
Blindness: Double blind
Duration (days): Mean 112
Setting: Italy community-based

- n = 74
- Age: Mean 74
- Sex: 35 males 39 females
- Diagnosis: Stroke Depression
- Exclusions: - aphasia

Baseline: Zung depression scale: Trazadone 62.4 (11.8) Placebo 59.2 (10.3)

Data Used
HDRS
BDI

Group 1 N = 37 Citalopram. Mean dose 20mg/d
Group 2 N = 37 Reboxetine. Mean dose 4mg/d

Funding: no information on funding provided
Notes: RANDOMISATION: computer generated by physician not involved in evaluation of patients

Info on Screening Process: 95 screened, 16 did not meet eligibility criteria, 5 refused to participate

Diagnosis:
- Stroke

100% Depression by DSM-IV

Exclusions:
- HDRS <20
- BDI <15
- previous degenerative or expansive neurological diseases, tumours, MS, Binswanger's disease,
- psychiatric illness (except depression)
- severe aphasia, cognitive deficit, impaired consciousness, heart disease

Baseline: HDRS for anxious depression: Citalopram 22.39 (2.09) Placebo 22.83 (2.41)
HDRS for retarded depression: Citalopram 22.75 (1.71) Placebo 22.66 (1.37)

RAZAVI1996

Study Type: RCT
Study Description: ITT based on all randomised patients for success rate response rate and side-effects. Completer data used for scale results.
Type of Analysis: ITT and completer
Blindness: Double blind
Duration (days): Mean 30
Setting: Multicentre
Notes: RANDOMISATION: stratification based on centre, no further details reported
Info on Screening Process: 24 patients were not randomised after the 1-week placebo trial due to (n):
- HADS <13 (9)
- Non-compliant (13)
- Concomitant medical events (2)
- Manic episode (1)
- unspecified reasons (3)

n= 91
Age: Mean 53
Sex: 17 males 74 females
Diagnosis:
- Depression by DSM-III

Exclusions:
- HADS <13
- Major depressive disorders with melancholic features, Bipolar disorder
- Alcohol abuse in previous year
- Uncontrolled pain, uncontrolled somatic comorbidities
- Brain tumors or those receiving CNS-targeted treatments
- Life expectancy <3 months
- undergoing abdominal or thoracic surgery in last 6 weeks,
>15 days corticosteroid treatment
- Women who were pregnant or breast feeding
- Psychotropic drug use in previous 2 weeks or taking antidepressants, neuroleptics, lithium or procarbazine
- Fluoxetine or MAOI treatment in previous 6 weeks

Notes: Patients had to suffer from an adjustment disorder (with depressive mood or mixed features) or a major depressive disorder in relation to the cancer disease that had been diagnosed for a period between 6 weeks - 7 years
Baseline: Not reported for whole sample, completers only

Results from this paper:
1.1 Well covered
1.2 Not reported adequately
1.3 Not addressed
1.4 Well covered
1.5 Well covered
1.6 Adequately addressed
1.7 Well covered
1.8 Fluoxetine 15/45 (33%), Placebo 7/46 (15%)
1.9 Adequately addressed
1.10 Adequately addressed
2.1 +

ROBERTSON1985

Notes: Dropouts: anxious depressed - Citalopram Group 3 N= Reboxetine
2/22 Reboxetine 3/22
retarded depressed - Citalopram 1/15
Reboxetine 0/15

Data Used
- Global Severity Index (GSI)
- MADRS
- HAM-A
- HADS
- Remission (below cut-off)
- Response (>50 reduction from baseline)

Notes: TAKEN AT: Baseline, end of treatment
DROPOUT: Fluoxetine 15/45 (33%), Placebo 7/46 (15%)
Leaving the study due to adverse effects:
Fluoxetine 7/45, Placebo 2/46

Group 1 N= 46
Placebo

Group 2 N= 45
Fluoxetine. Mean dose 20mg/day

Drug company sponsored:
Lilly France and Lilly Benelux
**ROBINSON2000**

- **Study Type:** RCT
- **Blindness:** Double blind
- **Duration (days):** Mean 84
- **Setting:** US, Rehabilitation Centre
- **Notes:** RANDOMISATION: no further details

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Group</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23</td>
<td>2</td>
<td>16</td>
</tr>
</tbody>
</table>

- **Data Used**
  - **Response:** (>50 reduction from baseline)
  - **Notes:** TAKEN AT: Baseline and 28 days (end of treatment)

<table>
<thead>
<tr>
<th>Data Used</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
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<tbody>
<tr>
<td>MMSE</td>
<td>Fluoxetine</td>
<td>Nortriptyline</td>
</tr>
<tr>
<td>Functional independence</td>
<td>10mg/d for first 3 weeks, 20mg/d for weeks 4-6, 30mg/day for weeks 7-9, 40mg/d final 3 weeks</td>
<td>25mg/d first week, 50mg/d weeks 2-3, 75mg/d weeks 3-6, 100mg final 6 weeks</td>
</tr>
<tr>
<td>HAD-A</td>
<td></td>
<td>final 6 weeks</td>
</tr>
<tr>
<td>HADS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>Dropout: Fluoxetine 9/23 Nortriptyline 3/16 Placebo 4/17</td>
<td></td>
</tr>
</tbody>
</table>

**SCHIFANO1990**

- **Study Type:** RCT
- **Study Description:** No details given - assumed completer only
- **Type of Analysis:** No mention
- **Blindness:** Double blind
- **Duration (days):** Mean 28
- **Setting:** Italy
- **Notes:** RANDOMISATION: procedure not reported

<table>
<thead>
<tr>
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<th>Group</th>
<th>N</th>
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<tbody>
<tr>
<td>1</td>
<td>25</td>
<td>2</td>
<td>23</td>
</tr>
</tbody>
</table>

- **Data Used**
  - **Response:** (>50 reduction from baseline)
  - **Notes:** TAKEN AT: Baseline and 28 days (end of treatment)

<table>
<thead>
<tr>
<th>Data Used</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDS</td>
<td>Mianserin</td>
<td>Maprotiline</td>
</tr>
<tr>
<td>Response</td>
<td>2 capsules</td>
<td>2 capsules</td>
</tr>
<tr>
<td>(&gt;50 reduction from baseline)</td>
<td>administered in the first week (45mg), dosage increased to 3 capsules (67.5mg) for remaining weeks. The investigator was able to increase dosage to 4 capsules (90mg) on the basis of response and side-effects.</td>
<td>administered in the first week (75mg), dosage increased to 3 capsules (112.5mg) for remaining weeks. The investigator was able to increase dosage to 4 capsules (150mg) on the basis of response and side-effects.</td>
</tr>
</tbody>
</table>

- **Details of funding not reported**
Results from this paper:
Quality assessment score +

### SCHWARTZ1999

**Study Type:** RCT  
**Blindness:** Double blind  
**Duration (days):** Mean 42  
**Setting:** US  
**Notes:** RANDOMISATION: no further details

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>Fluoxetine. Mean dose 20-40mg</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Desipramine. Mean dose 75-100mg</td>
</tr>
</tbody>
</table>

#### Data Used
**HDRS-17**  
Notes: Dropouts: Fluoxetine 0/8 Desipramine 2/6

#### Notes:(Randomisation: no further details

**Setting:** US  
**Duration (days):** Mean 42  
**Blindness:** Double blind  
**Study Type:** RCT  
**Study Description:** ITT using LOCF  
**Type of Analysis:** ITT  
**Exclusions:**  
- <14 HDRS-17  
- other Axis I and II psychiatric disorders  
- substance abuse  
- use of other psychotropic drugs

Baseline: HRSD: Fluoxetine 20.88 (6.01) Desipramine 22.00 (10.82)

### SCT-MD-24

**Study Type:** RCT  
**Study Description:** ITT using LOCF  
**Type of Analysis:** ITT  
**Blindness:** Double blind  
**Duration (days):** Mean 84  
**Setting:** US  
**Notes:** Randomisisation: no further details

<table>
<thead>
<tr>
<th>Group</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>Escitalopram - 10-20mg flexible dosing</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Placebo</td>
</tr>
</tbody>
</table>

#### Data Used
**Response (>50 reduction from baseline**
**MADRS**

#### Notes: Randomisation: no further details

**Setting:** US  
**Duration (days):** Mean 84  
**Blindness:** Double blind  
**Study Type:** RCT  
**Study Description:** ITT using LOCF  
**Type of Analysis:** ITT  
**Exclusions:**  
- pregnant or breast feeding women  
- bipolar disorder, schizophrenia, personality disorder  
- learning disabilities

Baseline: HAMD: Escitalopram 26.16 Placebo 27.67

### STRIK2000

**Study Type:** RCT  
**Blindness:** Double blind  
**Duration (days):** Mean 63  
**Followup: continuation phase for further 16 weeks**  
**Setting:** Departments of Cardiology and Psychiatry, Netherlands  
**Notes:** RANDOMISATION: no further details

<table>
<thead>
<tr>
<th>Group</th>
<th>N= 27</th>
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</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>Fluoxetine - Starting dose 20mg/d, could be increased to 40mg/d in week 3, 60mg/d in week 6</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Placebo</td>
</tr>
</tbody>
</table>

#### Data Used
**Cardiovascular outcomes**
**HDRS**  
Notes: dropouts: Fluoxetine 2/27 placebo 5/27 (9 week acute phase)

Baseline: HAMD = 21.6

### TAN1994
### Study Type: RCT

**Type of Analysis:** Completer only

**Blindness:** Double blind

**Duration (days):** Mean 36

**Setting:** UK, LONDON

**Notes:** RANDOMISATION: procedure not reported

**Info on Screening Process:** No details reported

#### Data Used

- **Adverse events**
- **GDS MADRS**

**Notes:** TAKEN AT: Baseline and 36 days post randomisation (28 days of intervention) (end of treatment)

**Group 1** N=32

- Ifepramine. Mean dose 70mg - Active drug and placebo tablets were identical and administered in same fashion

**Group 2** N=31

- Placebo - Active drug and placebo tablets were identical and administered in same fashion

---

### Study Type: RCT

**Study Description:** ITT using LOCF

**Type of Analysis:** ITT

**Blindness:** Double blind

**Duration (days):** Mean 42

**Setting:** US, California

**Notes:** RANDOMISATION: procedure not reported

**Info on Screening Process:** of the 671 participants to enter the study, 82.7% had at least one current chronic illness.

#### Data Used

- **HAM-D**
- **HDRS**

**Notes:** Dropouts: 8weeks - Mirtazapine 10/47 Placebo 3/44 24weeks - Mirtazapine 15/47 Placebo 23/41

**Group 1** N=301

- Fluoxetine. Mean dose 20mg/day

**Group 2** N=295

- Placebo

---

### Study Type: RCT

**Study Description:** Nested RCT within MIND-IT trial

**Type of Analysis:** Completer only

**Blindness:** Double blind

**Duration (days):** Mean 56

**Setting:** Netherlands, nested RCT within MIND-IT trial

**Notes:** no further information on randomisation

#### Data Used

- **BDI**
- **HDRS**

**Notes:** Dropouts: 8weeks - Mirtazapine 10/47 Placebo 3/44 24weeks - Mirtazapine 15/47 Placebo 23/41

**Group 1** N=47

- Mirtazapine - 30mg/d for weeks 1-2, lowered to 15mg/d if adverse events or increased to 45 mg/d if lack of response

**Group 2** N=44

- Placebo

---

**TOLLEFSON1993**

- **n** = 63
- **Age:** Mean 80
- **Sex:** 21 males 42 females
- **Diagnosis:** 100% Depression by GDS

**Exclusions:**
- <65 years old
- Moderate or severe cognitive impairment (AMT >7/10)
- Life-threatening illness
- Pre-existing antidepressant therapy
- Medical contraindications
- History of dysrhythmias, urinary retention, glaucoma and previous allergies
- Suicidal ideation
- GDS <15

**Notes:** Participants were recruited from general medical wards and had a range of medical illnesses

**Baseline:** No differences at baseline: GDS Lofepramine 17.0(4.3) Placebo 16.6(3.3)

**Results from this paper:**

**Quality assessment score +

**VANDENBRINK2002**

- **n** = 596
- **Age:** Mean: 58
- **Sex:** no information
- **Diagnosis:** 100% Depression by DSM-III-R

**Exclusions:**
- No diagnosis of depression according to DSM-III-R criteria
- ≤60 years old
- HAM-D < 16
- ≤26 MMSE
- Serious suicidal risk
- Serious or unstable medical co-morbidity
- Other DSM-III-R axis I disorders or presence of psychosis

**Notes:** All participants included in the analysis had at least one current chronic illness, the most common illnesses were joint disease and CVD

**Baseline:** No differences reported at baseline: HAMD: Flx approx 24 Placebo approx 24

**Results from this paper:**

**Quality assessment score +

**VANDENBRINK2002**

- **n** = 94
- **Age:** Mean 58
- **Sex:** 73 males 21 females
- **Diagnosis:** 100% Depression by DSM-IV

**Exclusions:**
- Other psychiatric problem
- <18 years

**Results from this paper:**

**Quality assessment score +

**Sponsored by Netherlands Heart Foundation and unrestricted grants from drug companies (Lundbeck and Organon)**
**VANHEERINGEN1996**

Study Type: RCT  
Study Description: ITT included those patients who had received at least one post-baseline efficacy assessment. LOCF analysis used to substitute missing data  
Type of Analysis: ITT  
Blindness: Double blind  
Duration (days): Mean 42  
Setting: University hospital, Gent, BELGIUM  
Notes: RANDOMISATION: details not reported  

**Data Used**  
Adverse events  
Response (>50 reduction from baseline)  
HAM-D  
Notes: TAKEN AT: Baseline, day 14, Day 28 and Day 42 (end of treatment)  
DROPOUT: Mianserin 6/28 (21%), placebo 15/27 (56%)  
Leaving the study due to adverse events: Mianserin 2/28, placebo 4/27  

**Notes**  
N = 28 Group Mianserin. Mean dose 60mg - 30mg/day for week 1, increased to 60mg/day for the remainder of the study  
N = 27 Group Placebo - Indistinguishable capsules given as a single night-time dose  

**Results from this paper:**  
1.1 Adequately addressed  
1.2 Not reported adequately  
1.3 Not addressed  
1.4 Well covered  
1.5 Adequately addressed  
1.6 Not addressed  
1.7 Well covered  
1.8 Mianserin 6/28 (21%), Placebo 15/27 (56%)  
1.9 Well covered  
1.10 Not applicable  
2.1 +

**WERMUTH1998**

Study Type: RCT  
Blindness: Double blind  
Duration (days): Mean 42  
Followup: 52 week continuation  
Setting: Denmark, outpatients  
Notes: no further details on randomisation  

**Data Used**  
Response (>50 reduction from baseline)  
HDRS  
Notes: Dropouts: Citalopram 5/18 Placebo 2/19 (6 weeks acute phase)  
Citalopram 12/18 Placebo 15/19 (52 weeks - data not usable)  

**Notes**  
N = 18 Group Citalopram - Starting dose of 10mg if over 65 years or 20mg if under 65 years. Dose reassessed at 6 weeks - non-responders dose was doubled.  
N = 19 Group Placebo  

**WIART2000**

Study Type: RCT  
Blindness: Double blind  
Duration (days): Mean 45  
Setting: France, Neurorehabilitation unit  
Notes: RANDOMISATION: no further details  

**Data Used**  
Response (>50 reduction from baseline)  
MMSE  
MADRS  

**Notes**  
N = 16 Group Fluoxetine  
N = 15 Group Placebo  
Drug company? Lilly France
Characteristics of Excluded Studies

<table>
<thead>
<tr>
<th>Reference ID</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMSTERDAM2006</td>
<td>Non RCT</td>
</tr>
<tr>
<td>ARSLAND2000</td>
<td>Non RCT</td>
</tr>
<tr>
<td>BROWN2007D</td>
<td>Non RCT</td>
</tr>
<tr>
<td>CANKURTARAN2008</td>
<td>Mixed depression and anxiety, low % depressed in both groups</td>
</tr>
<tr>
<td>CHEMERINSKI2001</td>
<td>pooled analysis of trials</td>
</tr>
<tr>
<td>CHEN2001</td>
<td>Looks at combining SSRI treatment with chinese herbal medicine</td>
</tr>
<tr>
<td>CHEN2003</td>
<td>Unable to obtain English papers</td>
</tr>
<tr>
<td>CHOIKWON2006</td>
<td>no depression diagnosis</td>
</tr>
<tr>
<td>CHUCK2000</td>
<td>Non-RCT</td>
</tr>
<tr>
<td>COULEHAN1997</td>
<td>Not physically ill; randomisation combines psychosocial and pharmacological interventions in analysis</td>
</tr>
<tr>
<td>CURRIER2003</td>
<td>no control group</td>
</tr>
<tr>
<td>DALESSANDRO2007</td>
<td>not randomised</td>
</tr>
<tr>
<td>DELLOMO2007</td>
<td>TMS only - no phram / relevant comparator</td>
</tr>
<tr>
<td>ELLIOTT2002</td>
<td>not RCT</td>
</tr>
</tbody>
</table>

Notes: Dropouts: Fluoxetine 2/16 Placebo 0/15

WISE2007

Study Type: RCT
Blindness: Double blind
Duration (days): Mean 7
Setting: US
Notes: Randomisation: no further details

n= 233
Age: Mean 73
Sex: 83 males 150 females
Diagnosis: 100% Depression

Exclusions: - psychiatric diagnosis other than MDD or mild dementia
- moderate to severe dementia or learning disability
- over 65 years of age

Baseline: MADRS: Fluoxetine 28.5(7.7) Placebo 27.2(6.3)

Data Used
Response (>50 reduction from baseline)
Remission (below cut-off)
HAM-D

Group 1 N=155
Duloxetine. Mean dose 60mg

Group 2 N=78
Placebo

YANG2002

Study Type: RCT
Blindness: No mention
Duration (days): Mean 112
Setting: China, 2-6 months after a stroke
Notes: RANDOMISATION: no further details

n= 121
Age: Mean 64
Sex: 75 males 46 females
Diagnosis: 100% Stroke
100% Depression

Exclusions: - HDRS-17 <7

Data Used
ADL
Response (>50 reduction from baseline)
Remission (below cut-off)

Group 1 N=64
Paroxetine. Mean dose 20mg/d

Group 2 N=57
Placebo

References:

References: Dropouts: Fluoxetine 2/16 Placebo 0/15

Info on Screening Process: 121 screened

Exclusions: - MADRS <19
- MMSE <23
- severe aphasia
- previous stroke

Baseline: MADRS: Fluoxetine 28.5(7.7) Placebo 27.2(6.3)
FAKHOURY2007  No relevant comparison group
GLEASON2004  no relevant comparison group
GOODNICK1997  Non RCT
GORDON1985  Looking at desipramine versus placebo only
GRASSI2004  Non RCT
GRAY1992A  No diagnosis of Depression
HE2002  Non-RCT
HOLLAND1991  Not an antidepressant
HU2002  Unable to obtain English version
HU2005A  No comparator (control group just received treatment as usual)
HUANG2003  not RCT
INDACO1988A  Participants non-depressed
IOSIFESCU2003  No comparison
JANSEN1999  not RCT
JIA2005  No comparator (control group just received treatment as usual)
KENNEDY1989A  Non-RCT
KIMURA2003  pooled analysis of other trials
KOK2007  Not physically ill (psychiatric inpatient not medical inpatient)
KONG2003  participants were not depressed
KRISHNAN2001  pooled analysis of two trials
KUHN2003  Non-RCT
LAITINEN1969  did not use validated scales
LASKA2005  did not assess depression
LAURITZEN1994  augmentation trial
LECHIN1998  Population were children and adolescents <18 years
LIANG2005  No useable comparison - treatment group did not receive placebo or any intervention
LUSTMAN2007  Non RCT
MA2006  No useable comparison - control group did not receive placebo or any other intervention
MACFARLANE1986  Participants are not depressed. Intervention aimed at reducing pain
MAYO2007  No pre-cross over data, query regarding randomisation method
MITCHELL2008  Protocol only
MORASCO2007A  Prevention study - outside scope
MOSS2006  Non RCT
MUSSelman2001  Prevention study - outside scope
NIEDERMAIER2004  prevention of depression after stroke
PAE2004  Non RCT
PARK2008  Not a relevant comparison (drug not an antidepressant)
PENG2005  Range of psychological disorders, unclear % with depression
RABEY1996  Conference abstract
RABKIN1994A  fluoxetine not randomised
REDING1986  no depression outcomes
References of Included Studies

ANCARANI1993 (Published Data Only)

ANDERSEN1980 (Published Data Only)

ANDERSEN1994 (Published Data Only)

ANTONINI2006 (Published Data Only)

BARONE2006 (Published Data Only)

BIRD2000 (Published Data Only)
BLUMENFIELD1997  (Published Data Only)

BORSON1992  (Published Data Only)

BROWN2005A  (Published Data Only)

BORSON1992  (Published Data Only)

CHEN2002  (Published Data Only)

CO005452  (Published Data Only)

DEVOS2008  (Published Data Only)

EHDE2008  (Published Data Only)

EISER2005  (Published Data Only)

EVANS1997  (Published Data Only)


FISCH2003  (Published Data Only)

FRUEHWALD2003  (Published Data Only)

GLASSMAN2002  (Published Data Only)


GOTTLIEB2007 (Published Data Only)

GULSEREN2005 (Published Data Only)

HOLLAND1998 (Published Data Only)

HUANG2005 (Published Data Only)

KIMURA2000 (Published Data Only)

LACASSE2004 (Published Data Only)

LAKSHMANAN1986 (Published Data Only)

LEENTJENS2003 (Published Data Only)

LESPERANCE2007 (Published Data Only)

LI2005 (Published Data Only)

LIPSEY1984 (Published Data Only)

LUSTMAN1997A (Published Data Only)

LUSTMAN2000 (Published Data Only)

LUSTMAN2006 (Published Data Only)

MAURI1994 (Published Data Only)

MCFARLANE2001 (Published Data Only)


SCT-MD-24 (unpublished trial) A double-blind flexible dose comparison of the safety and efficacy of Escitalopram and placebo in the treatment of major depression disorder in diabetic patients


References of Excluded Studies

Tollefson1993 (Published Data Only)

Vandenbrick2002 (Published Data Only)

Vanheeringen1996

Wermuth1998 (Published Data Only)

Wiert2000 (Published Data Only)

Wise2007 (Published Data Only)

Yang2002 (Published Data Only)

References of Excluded Studies

Amsterdam2006 (Published Data Only)

Arsland2000
BROWN2007D

CANKURTARAN2008

CHEMERINSKI2001

CHENGDU2003
Chen, W.G., Liu, F.Y. & Yang, A.P. Study of effect of integrative Chinese herbs with fluoxetine on rehabilitation of neurological impairment in patients with post-stroke depression. Chengdu University of Traditional Chinese Medicine, 24, 20-23

CHEN2003

CHOIKWON2006

CHUCK2000

COULEHAN1997

COURRIER2003

DALESSANDRO2007

DELOLMO2007

ELLIOITT2002

FAKHOURY2007

GLEXON2004

GOODNICK1997

GORDON1985


WANG2005

WERNICKE2000

WHEATLEY1986

WILSON1974

WU2003A

YOHANNES2001

ZEPHIR2003

ZHANG2007