# APPENDICES

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Appendix A. Physical focus studies

List 1. Studies set aside after initial electronic screen


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Meyer, J. (1982). Systematic desensitization versus relaxation training and no treatment (controls) for the reduction of nausea, vomiting and anxiety resulting from chemotherapy. Unpublished 8317766, Virginia Commonwealth University, USA.
Palekar, I. S. (1994). *Effect of autogenic relaxation with imagery on chemotherapy side effects, as predicted by personality characteristics*. Unpublished 9517850, The University of Akron, Ohio, USA.


Sodergren, K. A. (1993). *The effect of absorption and social closeness on responses to educational and relaxation therapies in patients with anticipatory nausea and*
vomiting during cancer chemotherapy. Unpublished 9413052, University of Minnesota, USA.


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**List 2. Studies set aside after screening full text**


Appendix B. Foreign language studies that could not be used


Appendix C. Studies that could not be traced


Appendix D. Studies with insufficient sample size


Appendix E. Studies with unusable outcome data


group psychotherapy to support the adaptation of the new consecutive breast cancer patients. *Psychiatria Fennica*(Suppl), 187-197.


* This study was set aside because of an inconsistency and uncertainty in the text. The total n was represented as 43, and it was stated repeatedly that at least 10 were assigned randomly to each of four groups (e.g. p. 95, “a minimum of 10-12”) and yet an examination of the appendices that listed individual data (appendices Z1-Z4) revealed that the intervention group which was the primary focus of the study had only eight members, while the control had 14.
Appendix F. Reports that were only abstract length


Appendix G. Uncontrolled studies and studies with inadequate controls


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Hurst, D. F. (1986). *An adaptation of a psychoeducational program for individuals with cancer to a small group. PhD thesis*, Indiana State University, USA.


*This study could not be included because 36% of its control group was provided with a concentrated brief version of the information provided to the treatment group, but separate outcome data for this subset were not reported.*
Appendix H. Study that used inadequate measures

Appendix I. Studies outside the research domain


Appendix J. Studies coded for analysis


Elsesser, K., Van Berkel, M., Sartory, G., Biermann-Gocke, W., & et al. (1994). The effects of anxiety management training on psychological variables and immune parameters in


Frankel, H. B. (1985). *The effectiveness of a psychosocial intervention with cancer patients.* Unpublished 8609191, Kent State University, Ohio, USA.


Hepworth, S. I. (2004). *An intervention implemented by medical staff to address anxiety related to fears of cancer recurrence inpatients who have been treated for cancer of the head and neck*, Unpublished doctoral thesis, University of Manchester, UK.


Perez, M. A. (2000). Prostate cancer patients and their partners: Effectiveness of a brief communication enhancement intervention prior to undergoing radical prostatectomy. Unpublished 3018027, University of Southern California, USA.


Radcliffe-Branch, D. (2005). *The contribution of interactive health communication (IHC) and constructed meaning to psychosocial adjustment among women newly diagnosed with breast cancer.* Unpublished NR21693, McGill University, Canada.


West, B. L. (1980). *Cognitive behavioural analysis system of psychotherapy (C-BASP) as applied to depression in a cancer population.* PhD thesis, Virginia Commonwealth University, USA.


*The 1995 publication of the Wells 1993 study gave results from a subsample, so, with the author’s agreement (pers. com. 6 August 2008) the 1993 unpublished data was used.*
Appendix K. Outline of research questions

Research Questions as approved 11 September 2007

Ex proposal: *What moderators impact the effectiveness of psychosocial treatments of distress in cancer patients?*

**Overview**

**A. Quality of Methodology**

1. External validity issues
2. Basic internal design of study
3. Other threats to validity

**B. Main effects**

**C. Moderators**

1. Patient variables
   
   (a) sociodemographics

   (b) premorbid status

   psychological variables

   cancer variables

   (c) individual differences

   social support

2. Therapists and therapeutic techniques

   (a) treatment components

   (b) treatment groupings

   (c) theorized mechanisms

   (d) nonspecific therapeutic variables

**D. The longevity of tx impacts (follow-up)**

**E. Practical cost-effective strategies**
Preliminary issue re number of studies for a moderator analysis: (Devine & Westlake, 1995) required 10 or more. Shane has not seen any rule. It’s about the amount of variability captured – looking for reduced variability, overlap, different means. Three big studies may suffice, whereas 10 little ones may not. He and Jo used about five. Perhaps we could take the rule for ‘evidence based’ treatment approval as a lead, ie two big RCT’s heading the same way make for an ‘established’ treatment. We will keep an eye out for an official stance on this.

A. Quality of Methodology

1. External validity issues
   - publication bias
     - do published, peer reviewed have higher ES? fail safe N? funnel plot (Egger, 1997; Greenhouse & Iyengar, 1994)
     - do foreign original language have higher ES?
     - do smaller N have higher ES? (Egger, 1997). Draw a line at 100 (Barsevick, Sweeney, & Haney, 2002) cites authority
   - age of study
   - nationality of participants
   - sample selection strategy (representativeness, ie volunteers etc)
     - age
     - ethnicity
   - discipline of therapists

Analyses:

- descriptives of all of the above
- significance testing for publication biases of ES
- sensitivity analyses re age of study, age, discipline of therapists, checking impact on main effects (only, ie no moderators)
- comment on generalisability
- feed impact of publication bias into the handling of study quality (below)

2. Basic internal design of study

- Design description
- Sample sizes, incl comparison of N in tx and control
- Strategy for dealing with selection effects (unknown, unmeasured moderators), including
  - randomization
  - concealment of allocation to group
  - attrition and missing data (ie where all data has been removed for people who only completed some of the observations over time, bias (Bottomley, 1997) p258)
    - numbers
    - reasons
Analyses:

- Descriptives for all of the above
- Sensitivity analyses for selection effect variables over main effects (only), ie which make a sig difference to ES? (excluding repeat measures studies)
- Impact of different types of control group on ES. Is attention itself a big component of therapy (ie placebos erode most of tx ES?). Diffusion/imitation of treatment / control has elements of treatment (incl assessment of Hawthorne effect, or non-specific therapeutic effect of attention) ie nature of control group type impact on main ES? would subgroup ES’s be important here (diff phases of cancer)?

3. Other internal validity issues

- Expectancy effects/Blinding
  - participants
  - therapists
  - raters
- Screening/floor effect
- Control for somatics that mimic depression
  - comparison of depression measures for validity (around illness specificity) ie are differences evident in ES’s at early and late stage cancer (when spontaneous improvement / deterioration is expected)?
  - control as part of study design * note, this was not raised during quality control discussions
- Treatment fidelity *note, this was not raised during quality control discussions
  - manualised/replicable
  - fidelity checks
- Social desirability
  - Social desirability *note, this has been brought forward from Main Effect Subgroup Analyses tentatively (without discussion). Which assessment mode (self-report, professional interview etc) produces the biggest ES’s?

Analyses:

- Descriptives for all of the above
- Sensitivity analyses for selection effect variables over main effects (only) except where mentioned otherwise, ie which make a sig difference to ES?
- Repeat measures can be analysed in relation to the latter listed variables only. Results kept separate, but compared with indep groups. Perhaps this comparison should be kept for later ie repeat measures brought into discussion of moderators, after discussion of main effects, OR kept for entirely separate consideration
>> Decide how to deal with impacts of both sets of validity threats, one by one

eg, refer (Devine, 2003) and (Cochrane handbook for systematic reviews of interventions)(and refer Cochrane rationale, annexed)

- if it is shown that the great majority of studies do not guard against a particular threat (eg failing to blind or conceal allocation) then unwilling to loose variation in data because of this, but to be taken into account in overall ES.
- decide which measures for depression to use, or how to adjust ES
- exclude or separate some studies because of clear impact of a quality variable(s) on ES, ie form different level groups according to empirically demonstrated threats
- use cumulative m-a or meta-regression strategies to explore impact of validity on ES
- decide which DV measures to use, or whether we average results from studies, or what

• Compare with Newell ie for those studies that cover same period and are drawn from her reference list. Did she (and other authors eg Meyer, and recommendation of Coyne) appropriately discard all non RCT’s? Discuss the general approach to quality of study method (eg ex Cochrane, cannot rely on simple aggregates to provide valid correlations with real impacts of measurement factors on validity of outcomes)

• Comment on the practicalities of dealing with this population/this research, going through each of the descriptives, eg impact of lack of blinding, lack of screening (‘preventative’ tx).

B. Main effects

Taking into account study method quality...

• Combined treatments X each distress outcome as a main effect (ie over all cancer phases together)

• Particular treatments and groups of treatments X each distress outcome:
  o Comparison with Newell using her tx groups etc but our study quality strategy (incl comparison of best and worst study ES’s, if applicable)
  ➢ comment on whether she discarded studies that could have been productively/reliably used.
  o Comparisons with other authors groupings eg depression (Devine & Westlake, 1995): education, beh-CBT, non-beh-non-CBT, relaxation; (T. Sheard & P Maguire, 1999): relaxation, group, group educational, group excluding educational. Choose other groupings to compare with other m-a’s
  o Any further tx grouping of our own (tx alone, or “tx with or without other components” (Devine & Westlake, 1995))

• Subgroup analyses:
• What follow-up times pick up biggest ES?** incorporate below also? Just assess controlled data at this point (repeat measures under separate head).

>> Preliminary to moderator investigation, make choices from main effect investigation of what DV’s or DV groupings, and what tx or tx groupings, are of most interest and have most data available. Assess moderators on them only.

C. Moderators

Descriptives on all of the below.

Analyses as indicated.

All analyses take into account study method quality, and are compared with repeat measures data.

Presumeably each should be reported by each distress outcome?

1. Patient variables

• (a) sociodemographics: age, race, gender, education, income (Andersen, 1992)
  o Age: suggestion in Cella et al 1993 in (Bottomley, 1997) that younger patients benefited more; they are more at risk for depression (Barsevick et al., 2002)
  o Unlikely to be enough data on any other, except gender (Rehse & Pukrop, 2003) males improved more), but must note confounded with cancer type (breast cancer). Comment on lack of data on each of the others

• (b) premorbid status: physical and psychological health (Andersen, 1992):
  o psychological status at baseline: distress screening
    ▪ hypoth: tx delivered to groups screened in for psych distress or risk shows greater effect
  o cancer variables
    ▪ cancer/medical phase
    ▪ time elapsed since diagnosis
    ▪ cancer type
    ▪ cancer prognosis / morbid risk (Andersen)
    ▪ combined ‘magnitude’ of illness, perhaps (looking for highest distress, perhaps use Fawzy grouping)
    ▪ >> make a preliminary decision around which way to carve this data before proceeding with further analyses [and note re cancer type, sexuality/identity issues that distinguish some]

Analyses of these variables:

▪ X overall ES
▪ X particular tx
▪ X tx group X each DV
▪ ie exploratory, p < 0.01
▪ plus particular hypotheses, p < 0.05
• early phase benefits most from education/information, or same plus coping and behavioural skills
• tx phase benefits most from coping skills, behavioural techniques relating to side effects
• recovery/survivor phases benefit most from coping skills and support groups
• terminal phase benefits most from highly supportive (intense one on one or group), ongoing, addressing existential and quality of life issues and behavioural techniques relating to symptom management eg pain
• interaction around intensity of therapist involvement X stage ie late stage benefits more
• it is more effective to treat cancer types separately

(c) individual differences: (psychological and behavioural) (Andersen, 1992):
  o social support
    • marital status
      • X overall ES
      • X cancer phase: hypothesis: most important at terminal phase
      • interaction with therapy types? (Andersen, 2003) p188 refers to a study where women w lo SS responded favourably overall, but those w SS did not respond to education only and responded negatively to peer discussion.
        • involvement of sig others in tx (other than where tx focus is on mutual difficulty eg sexual):
          • hypothesise greater impact on depression (Osborn, Demoncada, & Feuerstein, 2006)
          • compare with Newell
      • group v. individual tx: [note that this is really a nonspecific therapeutic variable]
        • hypothesise group better contrary to usual psychotherapy trends (T. Sheard & P Maguire, 1999)
        • compare with Newell
        • hypothesise more homogeneous groups better (Owen, Klapow, Hicken, & Tucker, 2001) Yalom, 1985 in Bottomley), so try:
          • X single gender
          • X single cancer type, phase, prognosis
          • X single psychological screening status (ie specifically screened in or out)
      • intensity of tx support factors: [note that this is really a nonspecific therapeutic variable]
        • therapist involvement
        • intensity of dose (ie hours x weeks duration > dose response effect)
        • teaching of relational skills (ie improving available social relationships)
      • X overall ES
      • X cancer phase

>> Collect all most positive social support moderators together X DV type X cancer phase

2. Therapists and therapeutic techniques
• (a) treatment components (if it is possible to test these, perhaps “with or without others”)
as in (Devine & Westlake, 1995) X DV
  o see above, cancer variables, phase
  o relaxation comparing (T. Sheard & P Maguire, 1999) with (Luebbert, Dahme,
    & Hasenbring, 2001), particularly for medical treatment phase
• (b) treatment groupings X DV:
  o treatments that fall into only one grouping
  o treatment groupings including studies that involve other types
  o hypothesise education best overall (T. Sheard & P Maguire, 1999)(Rehse &
    Pukrop, 2003)
  o hypothesise structured content better than nondirective support, especially for
    newly diagnosed
  o hypothesise new ACT good for poor prognosis / terminal stage
• (c) theorized mechanisms:
  o perception of control ie see if education/information and coping skills/problem
    solving increase perception of control and how effective they are X DV
  o coping strategy (approach v. avoid/deny)
  o [add: existential/death issues and intense social support for high risk group]
  o Re theorized mechanisms, see Andersen notes in thesis file
• (d) nonspecific therapeutic variables
  • age of treatment (study date)
  • therapist experience level X overall ES
  • professional therapist v. lay, comparing group treatments with similar contents if possible
  • personal v. telephone v. internet chat room/email discussion group v.
    audio/bibliotherapy/website v. indirect (ie through intervention with a professional) (and
    compare results with Newell)
  • intensity of dose (ie hours x weeks duration > dose response effect found in (T. Sheard &
    P Maguire, 1999))
    • brief v. extended duration X tx group
    • setting X tx group
  • Note: group v. indiv., and involvement of significant others really should be placed here,
    but I have placed them under ‘individual differences’ above, so as to incorporate them in an
    overall social support analysis
  • therapy tailoring: hypothesise that it is beneficial (Cwikel & Behar, 1999)
  • homework

D. The longevity of tx impacts (follow-up)

>> Preliminary decision to be made as to whether repeat measures data is to be included so
that these questions can be addressed. Also decide whether to analyse indep measure data, as
that could be analysed without the repeat measure data.

Retain such independent group data as exists, but reproduce it as repeat measures also, and
lean on repeat measures data as the main source on information for the following analyses,
but checking assumptions about what spontaneous improvement or deterioration against
control groups
Select some of the most important findings from above main effects and treatment components/groupings to ask these questions X cancer phase (because of expected improvement or deterioration in cancer):

- are effects preserved over time?
- enhanced?
- hypothesise:
  - benefits of education/training take practice or time for skills to show benefits (Fawzy et al. 1990 in (Bottomley, 1997) p258)
  - benefits of active behavioural coping and positive cognitions enable late mechanisms or psychologic, behavioural or biologic to emerge over time lowering of distress (Anderson pp18-19html)
  - social support offers buffering effect over time (Anderson p18)
  - better when tx over extended duration (Andersen, 1992) html p.18

E. Practical cost-effective strategies.

Attempt to collect together recommendations for practical cost-effective strategies.

Consider also long term effectiveness

From (T. Sheard & P. Maguire, 1999):

- screened
- groups
- short but intensive perhaps
- experienced therapists
- psycho-education

From (Luebbert et al., 2001):

- Easily learned and cheap eg relaxation / hypnosis (Luebbert et al., 2001) though Sheard did not think much of these also
- maybe focus on anx rather than dep, and only moderately and severe risk/distressed
- cheap to train physicians in communication
- cheaper professionals (professional v lay, highly paid professionals v. nurse/socialworker/counselor)
- tx carried out during cancer treatment phase was easier and effective (Cwikel et al., 2000)(Cwikel & Behar, 1999)
- accessibility:
  - written or audio material
  - telephone
  - one off educational tx
- look through all findings for effective ones that are cheap and practical
- also examine outliers
...but most of all, the issue is, ‘what works?’ List the most important moderators.
Appendix L. Coding instrument

**Psycho-Oncology Meta-Analysis**

**Trial Coding Form**

NB: This form is as used for final review of coding

**Today’s date [CODEDATE]:**

**Source(s) of data** ie list all study bibliographic reference(s) and other sources of data (eg. pers comm details) for this trial:

1. **Trial identifying code: [TRIALID]** (use earliest main study name and date as basis for alphanumeric eg FREW89; label multiple trials in same study a, b etc eg FREW89a)

2. **Year: [YEAR]** ie Year of *earliest* published source (if more than one), or of thesis submission, conference etc
   
   Last two digits ________

Means or significance data?

List all relevant constructs and measures:

**Notes** pertaining to this particular study (eg. missing data to be obtained, items that raise ambiguity)
QUALITY OF METHODOLOGY

EXTERNAL VALIDITY ISSUES

. Type of publication: [PUBTYPE] (the one used for coding)

1. Peer reviewed journal article
2. Book / book section
3. Unpublished thesis
4. Conference paper/abstract
5. Other publication
6. Other unpublished study

. Was the original language of this study English? [ORIGLANG]

1. Yes
2. No
999. Unclear

For the following questions re study sample size and attrition:

Answer only in relation to (all) treatment and control groups that are included in this meta-analysis - excludes healthy control groups (or otherwise non comparable groups) and ‘straw’ treatment groups used for comparison, but includes placebo/treatment-as-usual/wait-list control groups.

Where immediate post-test is not applicable because a different measure time that is acceptable to us is taken (‘early’ or ‘late’ mid-term), substitute with that (use ‘early’ by preference).

Answer with reference to patients only – not partners, or non cancer patients

For indirect treatments, still answer in relation to patients

Exclude groups deleted because of imbalanced attrition
. What was the total sample size that expressed intention to treat at start of study?
[TRIALINT]__________________ or 888 or 999

. What was the total sample size at pre-test? [TRIAL_N]____________ or 888 or 999

. What was the total sample size that completed to immediate (or earliest) post-treatment test? [TRIALEND]_____________ or 999

Re attrition questions following: “Attrition” includes number that dropped out from total sample, or where the data or partial data from a person was deleted for any reason. People excluded belatedly as unqualified for admission into the study do not count as ‘attrition’.

. Percentage attrition from intention to treat to post-treatment test: [INT_AT]
  1.__________________

999. Insufficient data reported

. Percentage attrition from pre-test to post treatment test: [P_AT]
  1.__________________

888. Not applicable – no pretest or no attrition

999. Insufficient data reported

. Predominant reason for attrition [REAS_AT]:

  1. Illness or death
  2. Treatment side-effects
  3. Other
  4. Mixed ie more than one large grouping of illness/death/treatment side effects and other

888. Not applicable
999. Not reported

. Nationality of sample [NATSAMP]

1. USA
2. UK
3. Germany
4. Australia / NZ
5. Canada
6. Scandanavia
7. Other European / western
8. Israel
9 Other middle eastern
10. Japan
11. Korea
12. China (note, Chinese in America are ‘USA’)
13. Other Asian
14. Egypt
15. Hong Kong
16. Netherlands
17. Taiwan
18. Greece
19. Italy
20. Puerto Rico
999. Not reported
. **Representativeness of sample (population validity).** What strategy was used to select participants from the patient population? [REPRESENT]. Be sure to distinguish this from screening process.

1. Participants were selected randomly or consecutively from the whole cancer patient pool (eg at particular hospital), or the whole patient pool was asked to participate (eg recruited upon admission)(representative strategy)

2. Participants volunteered (nonrepresentative strategy)

3. Participants were referred (nonrepresentative strategy)

4. Other or mixed strategy that is nonrepresentative of whole cancer patient pool

999. Unclear / Not reported. Used where the true answer could be ‘1’ but report wording is inconclusive (eg. does not say ‘all eligible patients were approached’, only ‘eligible patients...’).

. **Mean age (years) of whole study sample [MEANAGE]** (if mean ages for treatment and control groups being extracted for use in this study are not calculable distinct from that of whole study, use whole study mean age.)

Do not attempt to calculate if only bands of ages are provided

Exclude any treatment group that is excluded because of imbalanced attrition *if possible*

1. __________

999. Not reported

. **Percentage of participants female (N female / (N male + female) X 100)(round to whole number): [SEX]**

Exclude any treatment group that is excluded because of imbalanced attrition *if possible*

1. ________ % female

999. Cannot tell / not reported

. **Percentage of participants white (Caucasian / Anglo Saxon / Pakeha ie white western culture, as opposed to non western (eg Asian, middle eastern, or black, Hispanic,**
indigenous) [RACE] Exclude any treatment group that is excluded because of imbalanced attrition if possible

1. ___________ % white

999. Unknown / unreported

BASIC INTERNAL VALIDITY DESIGN OF STUDY

. Report length (if more than one data source, choose the longest) by number of pages (include part pages and reference list but not thesis appendices; do not worry about different line spacings etc.): [REPLENG] ____________________

NB: Trial design: Need to make decisions re handling cross-over and follow-up data? see Cochrane 8.11.5 and 8.9.1

. What strategy was used to assign participants to conditions? [ASGCOND] ‘Random’ according to Cochrane requires mathematical method of assignment e.g. a random numbers table. But we accept coin flips also. ‘Psuedo- or quasi-random’ processes include sequential or other predetermined methods, odd-even numbers, medical record or social security numbers, days of the week, because regarded as exposed to unforeseen biases. Self selected groups or refuser controls are not acceptable in any category.

1. Random assignment after matching, stratification, blocking etc.

2. Random assignment, simple

3. Psuedo-random after matching, stratification, blocking etc

4. Psuedo-random, simple

5. Non-random assignment, post hoc matching

6. Non-random, other

999. Cannot tell / unreported
. Confidence in judgment as to how participants were assigned to conditions? [CONFASIGN]

1. Method specified or used a statistician
2. Mere assertion – method not specified

888. Inapplicable because previous answer was 999

. Was allocation concealment robust? [ALLOCONC] (ie not known to patient or clinician until unalterable allocation to groups is made, allocation not able to be tampered with)

1. Yes – method specified
3. No – enough info is provided to make this judgment

888. Not applicable (ie non random or non-pseudo-random assignment used)

999. Insufficient info reported

. Were result means adjusted for baseline differences between groups? [ADJMEANS]
(select unadjusted means and enter ‘no’ where there is a choice)

1. Yes
2. No

999. Unknown / not reported

. Were their statistically significant differences between groups at baseline? [SIGDIFF... P,A,D,E,C,F] Require explicit reporting of significance, except where scores are so close and n’s sufficient that there is clearly no doubt.

1. Yes
2. No or not applicable
3. Not reported or not applicable
4. There was a significant difference against treatment group at pretest, but this difference was overcome to reverse the effect direction at posttest.

888. Not applicable – there was no pretest
OTHER INTERNAL VALIDITY ISSUES

. Were the participants blind to (unaware of) their group condition (ie whether they were in treatment or control)? [BLINDPAR]

   1. Yes
   2. No
   999. Unclear / not reported

. Were the therapists blind to whether the participants they were treating were in the treatment condition or the control condition? [BLINDTHE]

   1. Yes
   2. No
   888. Not applicable eg. bibliotherapy, or no group leader
   999. Unclear / not reported

. Were the people responsible for assessing outcomes blind to the group condition? [BLINDASR]

   1. Yes – and the raters were participants
   2. Yes – and the raters were not participants
   3. No – and the raters were the participants
   4. No – and the raters were not the participants
   999. Unclear / not reported

. Was the sample screened for or selected (formally or informally) on the basis of suffering significant psychological distress / needs / high risk / history? [SCRNSAMP]
Do not count cognitive deficit or dementia, active psychosis, alcoholism, suicide risk rendering incapable of participation in treatment. Where there is screening out and screening in, select screened in where that is based on a measure of present distress.
1. Yes, *screened out* (people judged to have psychological needs (eg historic or present psychological illness) were excluded from the study)

2. Yes, *screened in* (only people judged to have psychological needs or referred for this reason (eg distress or coping difficulties or psychological disorder) were included in the study) NB this includes age selection for higher distress (<50 BC patients).

3. No (recruited merely on the basis of cancer diagnosis, self-referral, or being thought suitable by an oncologist but not explicitly because of psychological need).

999. Unknown / not reported

**Therapy is replicable / standardized? [TXREPLIC]** Description of treatment may be in another publication or script.

1. Yes, fully manualised, recorded or described sufficiently for replication

2. Only in part

3. Not at all

999. Unknown / not reported

**Therapy fidelity check: [TXFIDEL]**

1. A specified method of fidelity check was conducted (eg video/audio taped sessions, observer checklists, supervision of therapists with treatment fidelity a primary purpose)

2. It was reported that a fidelity check was undertaken, but method was not specified

3. No fidelity check was undertaken

999. Unknown / not reported

**If a therapy fidelity check was conducted, what was its nature? [FIDELNAT]**

1. Video/audio taped sessions

2. Observer checklists

3. Supervision of therapists with treatment fidelity a primary purpose

4. More than one of the above
5. Other – state:...........................................................

888. Not applicable – there was no fidelity check

999. Specifics unknown / Not reported
MODERATORS
PATIENT VARIABLES

. Predominant level of education for whole sample: [ED_SAMP]
Exclude any treatment group that is excluded because of imbalanced attrition if possible
If there is no one predominant group, pick the average-ish one between them
  1. no formal schooling
  2. ‘elementary school’ / primary
  3. ‘high school’ / secondary
  4. ‘college’ / tertiary (ie at least some tertiary training)
  999. Unknown / not reported

. Predominant occupation / household income for whole sample: [OCC_SAMP]
Exclude any treatment group that is excluded because of imbalanced attrition if possible
If there is no one predominant group, pick the average-ish one between them
  1. Unemployed / very low income
  2. Un/semi-skilled labourer / homemaker / retired / low income
  3. Skilled labourer / self employed / medium income
  4. Professional / business / managerial / high income
  999. Unknown / not reported

Marital status of patients
Exclude any treatment group that is excluded because of imbalanced attrition if possible

. Married or partnered: [MARRIED]
1. __________ %
. Single: [SINGLE]
. Divorced / separated: [DIVORCED]
. Widowed: [WIDOWED]

. Cancer site: [CANCSITE]
   1. Breast
   2. Prostate
   3. Melanoma
   4. Mixed
   5 Gynaecological
   6. Other: State........................................
   7. Colorectal

   1. local / stage I or II at diagnosis. Where response 1 + 2, choose 1 bc tend not metastatic, but prefer response 5 if suitable
   2. regional spread / stage III ; first recurrence for initially stage I disease
   3. distant spread / stage IV; first recurrence for regional disease or all stages of rapidly progressive disease (e.g. lung or pancreatic cancer); ‘late’ stage
   4. More than one major grouping (ie fairly even split in numbers, or open to patients of all treatments and split not reported)

   5. Breast cancer stages 0/I-III
   999. Not known / not reported

. Timing of intervention relative to medical treatment stage: [MEDSTAGE](group these for analysis)
1. Diagnosis
2. Newly/recently diagnosed
3. Pre-treatment
4. Pre- and during treatment
5. During treatment
6. During and post-treatment (includes during for some and post for other patients)
7. Post-treatment / re-integration with life
8. Recurrence / disease progression
9. Palliative treatment only
10. End of life care
11. Survivor
12. Mixed stages
13. Pre-, during, and post-treatment
999. Unknown / not reported


1. Favourable i.e. thyroid, testis, uterus, melanoma of skin, breast, prostate, bladder, Hodgkin’s disease
2. Guarded i.e. colon, rectum, kidney, oral cavity, non-Hodgkin’s lymphoma, leukemia, ovary
3. Dismal i.e. lung/bronchus, esophagus, liver, pancreas
4. Mixed cancer types represented in sample (ie fairly even split in numbers, or open to patients of all treatments and split not reported)

999. Not reported / insufficient data
Predominant type of medical protocol: [MEDICLTX] (cf detail in table 1 Andersen (1992) If recurrent disease, the current protocol.

1. Single treatment (surgery or radiation)
2. Combination treatment (surgery with radiation and or chemotherapy and/or hormonal and/or tamoxifen therapy]
3. Multiple treatment (combination plus possible invasive pain / symptom control)
4. Palliative only
5. Mixed medical protocols represented in sample (ie fairly even split in numbers, or open to patients of all treatments and split not reported)
6. Survivor / in remission - no current treatment [my addition]
7. Watchful waiting
999. Not known / not reported
TREATMENT AND CONTROL DETAILS

. Trial identifying code: [TRIALID]:

. Treatment group identifying code: [TXID]:

(ie TRIALID + specifier) check with Lipsey and Shane ie system for linking data sets. And how do we add specifier Shane?

. Control group identifying code: [CTID]:

. Nature of the control condition? [NATCTRL]

1. Receives nothing / wait list / minimal contact, ie use where the psychological treatment of the control includes no significant component of treatment of a nature similar to that provided for the treatment group

2. Treatment as usual, ie appropriate in cases such as education where some information is provided to controls, but more to treatment group

3. Attention placebo

4. Treatment element placebo

999. Cannot tell / not reported

. Treatment and control group sample sizes and attrition rates

Enter column and row information and then calculate attrition percentages to complete cells. Enter 888 for not applicable (ie, the study did not take measurements at this time period), 999 for insufficient information (ie, there would have been data, but it is not provided).

. Condition attrition rates (eg. intention to treat N – test N / intention to treat N X 100) or 999 if no intention to treat or pre-test data given

Post test period ________

treatment group attrition % from pre-test__________
control group attrition % from pre-test__________

Post test period ________
treatment group attrition % from pre-test__________
control group attrition % from pre-test__________

Post test period ________
treatment group attrition % from pre-test__________
control group attrition % from pre-test__________

**THERAPISTS AND THERAPEUTIC TECHNIQUES**

**Therapy characterization:** Select only those categories that comprise a significant component in the overall therapy package, ie as few as would reasonably describe the therapy

. The treatment can be characterized as

**Education/information provided by a professional** regarding cancer, cancer treatments, facilities (including orientation tour), or adjunctive services, nutrition, exercise, coping strategies or symptom management; includes bibliotherapy or information provided by some technological means, but does not include active rehearsal of new behaviours: [EDUC]

1. Yes
2. No
999. Unclear / not reported

. The treatment can be characterized as

**Relaxation focused cognitive-behavioural treatment,** ie counseling/training in the use of coping strategies that focus on relaxation or stress management, incl. relaxation, mindfulness-based stress reduction, guided imagery, meditation, hypnotherapy, diaphragmatic breathing, autogenic training, systematic desensitization, biofeedback, electromyography, distraction, music: [RELAX]
The treatment can be characterized as

Broadly focused cognitive-behavioural treatment, i.e., counseling/training in the use of coping strategies, that focus on cognitive reappraisal or behaviour modification or reinforcement, such as cognitive restructuring/reappraisal, challenging negative thoughts, positive self-talk, self-monitoring of thoughts or skills taught, problem identification, problem solving, contingency management, goal/expectation setting, activity pacing, behavioural activation, pleasant activity scheduling, assertiveness/communication/relational skills training, disability management, emotional control and anger management, fighting disease, cathartic, active interpretation/reconstruction, and may include role play or modeling. Problem solving can include a wide range of topics, e.g., loneliness and isolation, morale and self-management, sexuality and contact, body self-esteem and general mood, communication, body self-image and social adjustment, existential plight, social alienation and self-identity, emotionality and personal control, dysphoria and depression: [CBT]

1. Yes
2. No
999. Unclear / not reported

The treatment can be characterized as

Non-directive professional counseling/psychotherapy, i.e., interactive verbal interventions, including nondirective, psychodynamic, existential, emotionally supportive/expressive/reflective regarding the disease, its treatment, prognosis, and recovery, disability or death, general or crisis intervention; no specific behavioural or coping skills are taught; includes social support by professionals, but excludes therapist reconstruction: [SUPPORT]

1. Yes
2. No
999. Unclear / not reported

The treatment can be characterized as
Non-professionally led support or counseling eg. survivor testimony, self-help groups, interventions provided by family members, including the teaching of coping skills by lay persons: [NONPROF]

1. Yes
2. No
999. Unclear / not reported

. The treatment can be characterized as

Indirect intervention ie the immediate target of intervention is someone other than the cancer patient (eg training of medical staff or spouse (without patient) in communication skills) but with the intention of benefiting the patient. [INDIRECT] Do not tick other characterizations in combination with this one, ie this one stands alone.

1. Yes
2. No
999. Unclear / not reported

. The treatment can be characterized as

Other (eg written emotional disclosure, acceptance and commitment therapy, practical or informational resources made available) [OTHER]

1. Yes
2. No
999. Unclear / not reported

Therapy components:

Note that education/information includes bibliotherapy or information provided by some technological means, but does not include active rehearsal of new behaviours

Individual therapy components:

Alphanumeric codes will be assigned with prefix [COMP...] plus the number below
Code each of the following (to the immediate left of the numeric listing below):

1. Included in therapy
2. Not included in therapy
999. Insufficient information

1. Education/information provided by a professional regarding cancer or cancer treatments

1 lay (ie same as treatment ‘1’ but delivered by a lay provider)

1A. Educ/info prov by prof re emotion and cancer

1A lay

2. Education/information provided by a professional regarding cancer facilities (including orientation tour), adjunctive services

2 lay

2A. Educ/info prov by prof re cancer prevention behaviour

3. Education/information provided by a professional regarding nutrition or exercise

3 lay

3A. Physical training

4. Education/information provided by a professional regarding coping strategies or symptom management
4A. Educ/info prov by prof re managing symptoms / treatment side-effects / disabilities / prostheses

5. stress management education or training (eg active coping)

6. progressive muscle relaxation

6A. relaxation education/training (unspecified or general)

6B. cue-controlled relaxation training

7. (guided) imagery

7A. virtual reality scenery

8. meditation

8A. education re acupressure

8B. education re massage

8C. Chan-chuang qigong

8D. Tai Chi
9. hypnotherapy / self hypnosis education or training

10. diaphragmatic/deep breathing education or training

11. autogenic training

12. systematic desensitization

13. biofeedback

14. electromyography

15. distraction

16. music

17. mindfulness-based therapy

18. behaviour modification or reinforcement

19. cognitive restructuring/reappraisal

20. challenging negative thoughts

21. positive self talk / imagining success / calming self statements

22. self monitoring of feelings / thoughts or skills taught

22A. stress inoculation training

23. problem identification

24. problem solving (and decision making)
24A. mastery enhancement therapy

24B. taught functional analysis of social situations

25. contingency management

26. goal/expectation setting / plan making

27. activity pacing

28. behavioural activation

29. pleasant activity scheduling

30. assertiveness/communication/relational skills education or training

31. confronting / exploring resistance to change

32. emotional control and anger management

33. fighting disease

34. cathartic

35. psychodynamic psychotherapy

36. emotionally supportive/expressive/reflective regarding existential, life-meaning, spiritual or death issues, grief, including ‘life review’

36 lay

37. emotionally supportive/expressive/reflective regarding the disease, its treatment, prognosis, and recovery, disability, and psychosocial issues
37 lay

38. general social support by professionals – deleted because too amorphous – use therapy delivery characteristics instead

39. non-professionally led support or counseling eg. survivor testimony, self-help groups, interventions provided by family members, including the teaching of coping skills, including relaxation, by lay persons, volunteer visiting, volunteer support dyads

40. Indirect intervention ie the immediate target of intervention is someone other than the cancer patient (eg training of medical staff or spouse (without patient) in communication skills) but with the intention of benefiting the patient

41. written emotional disclosure

42. interpersonal psychotherapy or counselling

43. screening and referral for additional services – deleted – excluded from domain

44. monitoring compliance with medical treatment

45. smoking cessation support / education

45A. alcohol cessation or reduction support / education

46. ‘crisis’ education or counselling

47. artistic emotional expression

48. taught appreciation of social networks

49. empowerment/self esteem encouraged through service to others
50. appreciation of personal growth opportunities in the cancer experience / development of life purpose

51. Establishing or optimizing use of social networks

52. Library or other informational resources made available

53. Practical help / resources made available

54. Body image counselling

55. Education re sexuality, sexual intimacy / sex therapy

56. Features a mechanism for integrating with medical treatment – deleted – too amorphous

57. Identifying / grieving / coming to terms with losses (flawed category – overlap with 36)

- **Therapy recipient**: [TXRECP]
  1. Individual - patient only
  2. Couples (patient and spouse / partner / significant other) only or mixed with patients
  3. Group of patients only
  4. Group of patients and their significant others
  5. deleted
  6. Patients as individuals *and* as groups
7. indirect – individual [see note below]

8. indirect - group [see note below]

999. Unknown / not reported

Note regarding “indirect” therapies (ie. where patient is not the/a direct recipient of therapy):
The following questions regarding the nature and intensity of therapy have been adapted to include responses geared particularly towards these forms of therapy, where needed. Think of the input into the immediate recipient of the therapy (who will not be the cancer patient, but may be, for example, a doctor, nurse or spouse) as you select the appropriate response. Look for particular responses appropriate to indirect therapies towards the end of each response list. The terms ‘participant’ or ‘therapy target’ include recipients of treatment who are not the patient intended to be the ultimate beneficiary.

[[NEW FORM]] Predominant mode of treatment delivery: [MODETX] If two forms equally used, list the cheaper form eg telephone if telephone and in person used equally

1. by therapist in person (with or without take-home material)

2. by telephone or video-telephone

3. by other interactive technology (eg personal letter, personal email, interactive website)

4. by non interactive technology (eg written material, audio-tape, video-tape, website, newsletter)

999. Unknown / not reported

Intensity of therapy

Do not count homework / home reading etc / practice time spent by the patient without the therapist involved

Define therapy session for the purposes of this and following questions as that which is led or facilitated by or with others, not the patient in own time. If patient comes to hospital to use music or other facility privately? > place under homework, because the division is about cost effectiveness

. Was total therapy session time limited? [LMTSESS]
Indirect therapy: interpret in relation to the non-patient directly receiving tx

1. Yes
2. No - not limited
3. No - not limited and varied considerably between patients

888. Not applicable (e.g. bibliotherapy)

999. Not reported

. Number (or average number) of sessions: [NUBSESS] Include separate time given to significant other

__________ or 888 (not limited or not applicable, i.e., there were no sessions, e.g., written info only) or 999

. Approximately how many hours in total was session time? [HOURSESS] Include separate time given to significant other

When variable hours, use average if available because aim is to establish cost.

__________ (hours. Use decimal points to represent tenths of an hour rather than minutes e.g., 1.5 = one and a half hours, not one hour and fifty minutes.)

888. Not applicable (e.g., bibliotherapy, highly varying indefinite length)

999. Not reported

. Duration of the therapy period in weeks: [DURSESS]

1. __________ (weeks) (‘one-off’ = 1 week)

888. Not applicable (e.g., bibliotherapy, highly varying indefinite length)

999. Not reported

. Therapist / therapy facilitator discipline: [THERDISC] Note: therapist, not researcher.

If a therapist belongs to more than one category (e.g., social worker who is a cancer survivor) then choose the most highly paid category (e.g., social worker).
In the case of indirect treatment, answer in relation to the person ultimately – not directly - attempting to directly impact the patient. Discipline also applies to a student’s discipline

1. Psychologist
2. Psychiatrist
3. Social worker
4. Counselor (trained) or specialist therapist (eg music therapist, hypnotherapist)
5. Medical doctor (incl oncology specialist)
6. Nurse (incl oncology specialist) or psychiatric
7. Multidisciplinary professional team
8. Lay (eg. patient peer or survivor, with or without some non-professional training)
9. Mixed lay and professional team
10. Social worker, nurse, counselor etc who is also ‘qualified’ by cancer survivorship
11. ‘research assistant’ discipline unstated
888. Not applicable / not relevant (eg 100% bibliotherapy done at home)
999. Not reported

. Therapist involvement with therapy target: [THERINVL]

1. Minimal (1:1 initial contact i.e. assessment or screening or set-up of research, eg. expressive writing, but not during therapy e.g. bibliotherapy, audiotape used mostly)
2. Group (contact at group sessions and possibly initial 1:1 contact as per response 1.)
3. Predominant (individually delivered or mixed group/individual therapies)
4. Intense (therapist is available at group/individual therapy and beyond the frame of therapy sessions e.g. on crisis call)
888. Not applicable (e.g. written info only)
999. Unknown / not reported

. Level of therapist / facilitator experience (including those delivering intervention to immediate recipients of indirect interventions): [THEREXPR]

80
1. Lay people (incl survivors / patient peers)

2. Students only or predominantly (masters or PhD level) note: could still be experienced, eg through training in a former profession

3. Practitioners / professionals only or predominantly

4. Mixed: lay people and students

5. Mixed: lay people and professionals

6. Mixed: students and professionals

888. Not applicable (delivered by audio / video tape, bibliotherapy / written information only)

999. Unknown / not reported

. **Predominant therapy setting (ie after set-up):** [TXSETTING]

1. Inpatient (hospital) or residential care (other than hospice)

2. Hospice inpatient

3. Outpatient (e.g. hospital or university clinic or professional office or community facility), incl hospice outpatient

4. deleted

5. Participant’s home (in person or written materials)

6. Therapist and patient in different settings (eg using telecommunication)

7. Varied with patient needs (e.g. hospital or home)

888. Indirect therapy – not an applicable question

999. Not reported

. **The therapy content was:** [TAILORCT]

Indirect: participant is non patient

1. Fully tailored - was entirely guided by the needs of the participants

2. Partly tailored - was prescribed in outline or contained some fixed elements, but also remained flexible to meet needs of the participants as they arose
3. Fully structured - Was entirely pre-fixed but may include guided discussion of taught materials, asking questions, a limited opportunity for expression of feelings

999. Unknown / not reported

. The therapy duration (number of sessions) was: [TAILORLT]

1. Flexible to meet the needs of the participants
2. Time limited – preset in advance
888. Not applicable (e.g. written info only)
999. Unknown / not reported

. Nature of the patient’s therapy work: [TXWORK]

1. Passive listening (didactic / lecture, maybe asking questions) with no required homework or skill practice independent of therapist
2. Active participation (interactive discussion or exercises, more than just asking questions of a lecturer) with no required homework or skill practice independent of therapist
3. Mixed passive listening and independent homework/skill practice
4. Mixed active participation and independent homework/skill practice
5. Overwhelmingly homework/reading/practice of skills at home or without therapist.
999. Not reported / Unknown

. Frequency of participant (ie patient or immediate recipient of indirect therapy) homework / skill practice expected: [FREQWORK]

1. One off (eg. reading, provided in one lump)
2. Regularly given or expected with sessions, including daily practice, logging
3. Irregularly expected, eg research options made available to consult as required
4. Optional
5. None expected
Post test period codes:

NB: Choice rule:

If more than one measure was taken in any of periods 2-4, 6-7, choose the one most central in that period. If more than one for period 5, choose the one closest to 12 months.

1/im. immediately post intervention

2/st. short term follow up (up to 1 month after intervention)

3/mt. medium term follow up (> 1 month, < and = 6 months after intervention) six months is very common, as is 3

4/lt. long term follow up (> 6 month, < and = 12 months after intervention)

5/vlt. very long term follow up (> 12 months)

6/emt. early mid-term (3 - 6 months)(use only where no post intervention data available, and use latter observation if more than one in the period)

7/lmt. late mid-term (> 6 months – 12 months)(use only where no post intervention data available, and use latter observation if more than one in the period)

8/mmt. mid medical treatment (e.g. RT), varying by individual (use only if therapy is complete at this time)

9/pmt. post medical treatment (e.g. RT), varying by individual

10/bmt. before medical treatment (e.g. before chemo, BMT, RT, varying by individual (use only if therapy is complete at this time)

11/lpm. late post medical treatment ie more than a month after medical treatment completion
OUTCOME MEASURE AND EFFECT SIZE DETAILS: DV constructs

- Trial identifying code: [TRIALID]:

- Treatment group identifying code: [TXID]:

- Control group identifying code: [CTID]:

- Effect size data identifying code: [ESID]: DV...

- Construct measured: [CONSTRCT]
  1. Depression (‘P’)
  2. Anxiety (‘A’)
  3. Distress (‘D’)

**Construct measure selection decision rule.** Select a measure for the relevant construct according to the following rules:

1. If an illness/cancer specific measure is available, code ES for it
2. If a common measure (POMS, BDI, STAI) measure is available, code ES for it
3. If there are both illness/cancer specific and common measures, code for both (use an additional form) >> do a sensitivity analysis around how much difference it makes >> will choose one or other for main effects and moderators after that
4. If neither of the above are available, code the measure [which appears to have] superior psychometrics [[what if the measure is not well known and psychometrics were not supplied? should we try to look them up?]
5. If I cannot tell which is superior, flip a coin
6. In any case, do not code for a measure known to have alpha reliability under 0.7 > code appropriately
7. In any case, do not code measures that are categorical or dichotomous (must be continuous) > code appropriately
8. Always use appropriate specific subscales where data is available, rather than global measures. Global measures of affect or mental health/adjustment are not acceptable measures of anxiety or depression, though may be accepted for the more general construct ‘distress’. (We will avoid statistical dependency by keeping all main effect sizes separate because distress measures may be compound and include anx or dep scales.)
9. Our construct is ‘distress’, not stress, to avoid confusion with functional measures.

10. Use anxiety state in preference to trait if possible, use global anxiety on STAI if not possible to extract state data. Anxiety includes tension, worry but not ‘stress’.

999. No sufficiently reliable measure was used or insufficient information was provided about the instrument used to make a judgment about its reliability >> end answers relative to this construct here

. The measure for depression/anxiety/distress was:

[DEPMEAS]

[ANXMEAS]

[DISMEAS]

experimenter derived

Other published measure or measure with psychometric information provided showing reliability of at least 0.7 Cronbach’s alpha (state instrument name, subscale (if applicable), author (may use ‘experimenter derived’, or ‘experimenter modified’), date of publication):

. The nature of the measure used was: [NATMEAS]

1. Cancer/illness specific

2. Not cancer/illness specific

888. Not applicable

999. Unknown / not reported

. The source of report was: [SORCMEAS] (Social desirability / denial / memory)

1. Patient (self report)
2. Family member report

3. Professional report

999. Unknown / not reported

. Page number where effect size data found: [DVPGNUM] _________________

OUTCOME MEASURE AND EFFECT SIZE DETAILS: Theoretical Moderators

[EFFICACY] perception of control/ self efficacy/dispositional optimism (sense of coherence) helplessness

[COPING] coping style (note: not coping strategy) / adaptive behaviour

[ESTEEM] self esteem / self concept

[NATMEAS]

[SORCMEAS]

[TMPGNUM]

BREAKOUT EFFECT SIZE DETAILS: Gender

Record data only for the best measure of anxiety and/or depression (i.e. cancer/illness specific if available), and use a separate form for each construct.
BREAKOUT EFFECT SIZE DETAILS:  **Distress**

Record data *only for the best measure of anxiety and/or depression* (i.e. cancer/illness specific if available), and use a separate form for each construct.
Appendix M. Code record sheet

Psycho-Oncology Meta-Analysis

Scoring Sheet

Initials of coder:

*[CODEDATE]*

Source(s) of data ie list all study bibliographic reference(s) and other sources of data (eg. pers comm details) for this trial:

[TRIALID]

[YEAR]

*Means or significance data?

List all relevant constructs and measures:

Notes pertaining to this particular study (eg. missing data to be obtained, items that raise ambiguity)
N.B. This page is blank due to technical limitations associated with the word processing package.
QUALITY OF METHODOLOGY:
EXTERNAL VALIDITY ISSUES

[PUBTYPE]
[ORIGLANG]

[TRIALINT]
[TRIAL_N]
[TRIALEND]

[INT_AT]
[P_AT]

[REAS_AT]

[NATSAMP]
[REPRESNT]

[MEANAGE]
[SEX]
[RACE]
BASIC INTERNAL VALIDITY DESIGN OF STUDY

[REPLENG]

[ASGNCOND] [ALLOCONC]
[CONFASIGN] [ADJMEANS]

[SIGDIFF....]

OTHER INTERNAL VALIDITY ISSUES

[BLINDPAR] [TXREPLIC]
[BLINDTHE] [TXFIDEL]
[BLINDASR] [FIDELNAT]
[SCRNSAMP]

MODERATORS

PATIENT VARIABLES

[ED_SAMP] [PROGNOSI]
[OCC_SAMP] [METASTAS]

[MARRIED]
[SINGLE]
[DIVORCED]
[WIDOWED]
[CANCESITE]
[CANCEXNT]
[MEDSTAGE]
TREATMENT AND CONTROL DETAILS

[TRIALID] [TXID] [CTID] [NATCTRL]

. Condition attrition rates

Post test period ______

 treatment group attrition %: from intention to treat________; from pre-test________

 control group attrition %: from intention to treat________; from pre-test________

Post test period ______

 treatment group attrition %: from intention to treat________; from pre-test________

 control group attrition %: from intention to treat________; from pre-test________

Post test period ______

 treatment group attrition %: from intention to treat________; from pre-test________

 control group attrition %: from intention to treat________; from pre-test________

THERAPISTS AND THERAPEUTIC TECHNIQUES

Therapy characterization:

[EDUC] [NONPROF]
[RELAX] [INDIRECT]
[CBT] [OTHER]
[SUPPORT]
[COMP....]:

Those that are 1. (included in therapy) are listed here:

Those that are 999. are listed here:

The rest are 2. (not included in therapy)

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OUTCOME MEASURE AND EFFECT SIZE DETAILS: DV constructs

[TRIALID] [TXID] [CTID] [ESID]
DV....

Depression (P): HADS-D; HADS-D modified; POMS-D; BDI; BDI-SF; CES-D; Hamilton-D; SCL-90-R-D; BSI-D; Zung’s; Leeds-SAD

Anxiety (A): HADS-A; HADS-A modified; POMS-T; STAI-State; STAI-combined; IES; BSI-Anxiety; SCL-90-R-Anxiety; MAACL, Hamilton-A; Leeds-SAA;

Distress (D): POMS tmd; POMS-SF; SCL-90-R; BSI; SF-36 MCS, SF-36 MHI; Affects Balance Scale; EORTC QLQ-C30-EF; GHQ-60; PAIS-Psychologic Distress; MiniMAC Negative Emotion; QoLC-PWb; SES; WHO QoL SF (HK) Psychological Functioning; PSI-Discomfort

*experimenter derived OR (add to list above) ..........................................
..........................................................................................................................

[NATMEAS] [SORCMEAS] DVPGNUM]

Effect size data:

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<tr>
<th>Time Point</th>
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<th>Direction of effect (+ or -)</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>S or NS</th>
<th>Significance p level (only were M and SD info not available)</th>
<th>Tail s (1 or 2)</th>
<th>Attrition balance</th>
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94
Control:
**OUTCOME MEASURE AND EFFECT SIZE DETAILS: Theoretical Mods**

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<tbody>
<tr>
<td>TM....</td>
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</table>

**Self Efficacy (F):** HLC; Illness Perceptions Questionnaire Revised – Personal Control; Lawler & Cameron Coping Efficacy measure; I-E Locus of Control; MAC helplessness; MAC fighting spirit

**Coping style (C):** DWI-R; MAC avoidance; MiniMAC (Chinese) avoidance

**Self Esteem (E):** Rosenberg; Tennessee Self Concept

*experimenter derived OR other: ...........................................................
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Effect size data:

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<th>Mean</th>
<th>Standard Deviation</th>
<th>S or NS</th>
<th>Significance p level (only were M and SD info not available)</th>
<th>Tail s (1 or 2)</th>
<th>Attrition balance</th>
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96
Control:
BREAKOUT EFFECT SIZE DETAILS: Gender

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<th>[TRIALID]</th>
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<th>[CTID]</th>
<th>BG</th>
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<tbody>
<tr>
<td>[ESID]...</td>
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Measure:..............................................................................................................................

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Effect size data

Means and standard deviations

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<th>Mean male</th>
<th>SD male</th>
<th>N female</th>
<th>Direction of effect female</th>
<th>Mean female</th>
<th>SD female</th>
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## Significance

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<th>Direction of effect</th>
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<th>P level</th>
<th>N female</th>
<th>Direction of effect</th>
<th>S or NS</th>
<th>P level</th>
<th>1 or 2 tails</th>
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### Treatment:

### Control:

### BREAKOUT EFFECT SIZE DETAILS: Distress

- [TRIALID]  [TXID]  [CTID]  BD
- [ESID].......  
  Measure:.................................................................

- [NATMEAS]  [SORCMEAS]  [BDPNUM]
**Effect size data**

**Means and standard deviations**

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**Significance**

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<th>Time Point</th>
<th>N high</th>
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<th>S or NS</th>
<th>P level</th>
<th>N low</th>
<th>Direction of effect low</th>
<th>S or NS</th>
<th>P level</th>
<th>1 or 2 tails</th>
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</tbody>
</table>
Control:
Appendix N. Studies of more vulnerable groups

For the full citations, refer Appendix K or the Reference list.

**Cancer site** (other than breast)

**Prostate:** Berglund et al., 2007; Campbell et al., 2007; B. Joyce Davison, 1997; B. J. Davison & Degner, 1997; Giesler et al., 2005; S. Lepore, Helgeson, Eton, & Schulz, 2003; S. J. Lepore & Helgeson, 1999; Perez, 2000; Bryan Arthur Weber, 2001; B. A. Weber et al., 2004; Bryan A. Weber et al., 2007; Zhang, Strauss, & Siminoff, 2006

**Melanoma:** Boesen et al., 2005; Domar, 1987; Domar, Noe, & Benson, 1987; F. I. Fawzy, Cousins, Fawzy, Kemeny, & et al., 1990; Nancy Wilkens Fawzy, 1991; N. W. Fawzy, 1995; Gordon et al., 1980; Orringer et al., 2005; Trask, Paterson, Griffith, Riba, & Schwartz, 2003

**Colorectal:** Y. Cheung, Molassiotis, & Chang, 2001; Y. L. Cheung, Molassiotis, & Chang, 2003a

**Gynaecological:** Capone, Good, Westie, & Jacobson, 1980; Chan et al., 2005; Houts, Whitney, R., & Bartholomew, 1986; Manne et al., 2007a-a; Petersen & Quinlivan, 2002


**Cancer type**

**Guarded prognosis:** Baider, Peretz, Hadani, & Koch, 2001; Y. Cheung et al., 2001; Y. L. Cheung, Molassiotis, & Chang, 2003b; Hayes, 1981a, 1981b; Hepworth, 2004; Katz et al., 2004; Manne et al., 2007a-b; Petersen & Quinlivan, 2002; Poroch, 1995

**Dismal prognosis:** Goldberg & Wool, 1985; Gordon et al., 1980; Lin et al., 1998; North, Cornbleet, Knowles, & Leonard, 1992; Rummans et al., 2006; Schofield & Payne, 2003

**Cancer stage**

**Regional spread:** Given et al., 2004; Gotay et al., 2007; Lin et al., 1998

**Distant spread:** Ando, Tsuda, & Moorey, 2006; Classen et al., 2001; Clayton et al., 2007; Cumbia, 1985; Edelman et al., 1999; Edmonds, Lockwood, & Cunningham,
Medical treatment protocol

Palliative: Ando et al., 2006; Clayton et al., 2007; Cumbia, 1985; Edelman et al., 1999; Harper, 2001; Lin et al., 1998; Liossi & White, 2001; Savard et al., 2006; Schofield & Payne, 2003; Spiegel et al., 1981; West, 1980

Medical treatment stage

Recurrence: Classen et al., 2001; Gotay et al., 2007; Spiegel et al., 1981

Palliative: Ando et al., 2006; Clayton et al., 2007; Cumbia, 1985; Edelman et al., 1999; Hayes, 1981b; Liossi & White, 2001; Savard et al., 2006; Schofield & Payne, 2003; West, 1980
Appendix O. Relegated Results

Preliminary analyses: External validity

Original language
At first glance, results shown in Table 0-1 appear consistent with English language bias, showing studies that may have been first written in a language other than English yielding effect size mean estimates 0.10 - 0.17 higher across the three outcomes. However, 95% confidence intervals were greatly overlapping, i.e. studies of uncertain linguistic origin - which were the smaller set - showed much broader standard error taking in most of the larger group’s error band width, resulting in non-significant differences between subsets for each outcome. Upon further investigation following discovery of the two internal design confounds underlying the dataset (refer preliminary analysis results under internal validity) it was found that one of them, namely, screening for distress, probably underlay this difference. The investigation was conducted only in relation to the largest n outcome construct, anxiety. It found that after exclusion of two studies with uncertain status on the variable, a disproportionate number (10 of 15) of the remaining studies used screened recruits and produced statistically significantly higher effect sizes ($p = 0.001$). For this reason, and because the small difference that was found between English language studies and those of uncertain linguistic language was not statistically significant (Q statistic $p$’s were 0.149 for anxiety; 0.260, depression; 0.162, distress) the trend can be ignored.

Table 0-1 Sampling bias, original language

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th>Depression</th>
<th>Distress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
</tr>
<tr>
<td>English</td>
<td>0.17 (57)</td>
<td>0.06 – 0.28</td>
<td>0.19 (53)</td>
</tr>
<tr>
<td>Uncertain</td>
<td>0.34 (17)</td>
<td>0.14 – 0.54</td>
<td>0.29 (12)</td>
</tr>
<tr>
<td>Q statistic</td>
<td>0.149</td>
<td></td>
<td>0.260</td>
</tr>
</tbody>
</table>

Early times data. ES = Hedges g effect size point estimate; n = number of studies in subset, 95% CIs = 95% confidence intervals. Only published studies were used in this particular analysis.

Nationality
Studies were included in the dataset with samples from the following countries (numbers are given where they exceed one, and OECD non-member countries are marked with an asterisk): USA (78), UK (12), Canada (16), Australia and New Zealand (9), Scandinavia (seven), Greece (four), Japan (four), Hong Kong* (four), Taiwan* (two), Italy (two), Germany (two), Israel* (two), Egypt*, Netherlands, Puerto Rico*, Spain, and Brazil*.
Collectivist v. individualist culture
Studies were compared on a rough estimation of whether the predominant culture in the country of sample was collectivist or individualist. In practical terms this meant only that two studies from Japan and two from Israel ‘swopped sides’ from the OECD analysis and made no appreciable difference to the outcomes (Table 0-2). Once again the subset for depression was not big enough (n = 3) to warrant inclusion, the numbers of studies from collectivist (generally poorer) nations were relatively few, and the disparity between the mean effect sizes produced by the subsets was large (anxiety $g = 0.73$, distress $0.56$) and statistically significant in favour of nations with collectivist cultures ($Q$ statistic $p = 0.020$, anxiety; $0.010$, distress).

Table 0-2. Culture

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th>Distress</th>
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<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Individualist</td>
<td>0.16 (82)</td>
<td>0.07 – 0.25</td>
</tr>
<tr>
<td>Collectivist</td>
<td>0.89 (7)</td>
<td>0.28 – 1.50</td>
</tr>
<tr>
<td>$Q$ statistic $p$</td>
<td>0.020</td>
<td></td>
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</tbody>
</table>

Relevant notes as for Table 0-1.

These dramatic results warranted further investigation. The two internal design confounds identified in the internal validity section of the Preliminary analyses results and found to be fairly evenly distributed over the dataset were found to be unevenly distributed in these subsets. Out of the 15 studies from countries that were not OECD members or were of collectivist culture, 11 screened potential recruits and 12 used no treatment control comparison groups. As is noted in that chapter, these confounds are each predictors of significantly higher effect sizes. Since the internal design confounds are based on larger subsets than the frequencies yielded for OECD non-members or collectivist cultures, those variables will be preferred as the basis for making distinctions in the main effect analyses.

Finally, it is noted that the disproportionate distributions of the internal validity confounds in themselves may indicate something about the harsh realities imposed by poorer economic conditions in non-OECD countries. The implication may be that generally only those patients with proven distress can be offered treatment, and that the usual comparison group – the ‘usual care’ condition for patients – is no therapy at all.

Year
Meta-regressions of study effect sizes for the three main outcome constructs by year were performed. All three produced scatterplots marked by the striking feature of a very gentle negative slope (using unrestricted maximum likelihood computational model: anxiety, $-0.016$, $p < 0.05$; depression, $-0.011$, n.s.; distress, $-0.013$, n.s.). Where
a slope is statistically significant – as for anxiety - it suggests that psycho-oncological trials are demonstrating decreasing effect sizes over time.

Because slopes are disproportionately influenced by the data points at either end, and the studies prior to 1990 were relatively few and with relatively high effect sizes as is often the case when a field is new, analyses were run again using studies from 1990 onward only. The expected softening in slope resulted (anxiety, -0.012; depression, 0.001; distress, -0.007, all n.s.).

At first blush any negative trend, no matter how small and regardless of statistical significance, may cause alarm - surely therapies should be becoming more effective over time and therefore effect sizes should be increasing, not remaining static or decreasing. However, when it is considered that effect size is a measure of contrast between treatment and control group outcomes, an encouraging possible explanation becomes apparent: the negative slope may not be due to the quality of studies or therapies decreasing over time, but to control group participants becoming psychologically stronger. This could result from ‘self treating’ via greater access to information about the disease and about psychology, or by better incorporation of psychologically impacting components within standard medical care (e.g. more patient education and a more collegial relationship between doctor and patient) or simply because medical treatments are constantly improving and so the distress caused by the death-threat of cancer is constantly decreasing.

In terms of its potential to threaten the external validity of the dataset, it is noted that all three slopes on the post-1990 data were non-significant. Had significance been found, it would still have been necessary to find some fault with the search that may have biased earlier or later studies in order to justify a challenge to the integrity of the dataset on this point. It is difficult to imagine what such a problem could be. Given that, and the lack of statistical significance on the post-1990 data, these results are of no further interest.

**Representativeness of study sample**

1. Studies were coded according to how well the strategy used to select participants represented the cancer patient population from which the sample was drawn. The levels coded were: 1. Participation was representative (participants were randomly or consecutively selected or the whole patient pool was asked to participate); 2. Participants volunteered (they responded to advertisements and flyers); 3. Participants were referred (usually by their medical oncologist); 4. Another or mixed non-representative strategy was used (e.g. advertising and referrals); and 5. The selection strategy was not reported or reporting was unclear. Analysis results are displayed below (Table 0-3). The considerable number of studies that did not report clearly on this variable are excluded.
Table 0.3. Representativeness of study sample

<table>
<thead>
<tr>
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<th>Distress</th>
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<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
</tr>
<tr>
<td><strong>Representative</strong></td>
<td>0.23 (40)</td>
<td>0.10 – 0.35</td>
<td>0.20 (33)</td>
</tr>
<tr>
<td><strong>Volunteer</strong></td>
<td>0.10 (5)</td>
<td>-0.15 – 0.35</td>
<td>0.23 (6)</td>
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<tr>
<td><strong>Referred</strong></td>
<td>0.23 (7)</td>
<td>-0.16 – 0.62</td>
<td>0.44 (8)</td>
</tr>
<tr>
<td><strong>Other / mixed</strong></td>
<td>0.05 (14)</td>
<td>-0.28 – 0.39</td>
<td>0.07 (9)</td>
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<tr>
<td><strong>non-representative</strong></td>
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</table>

| Q statistic p       | 0.671      | 0.677         | 0.253       |

Studies that did not report clearly on this variable (anxiety, n = 23; depression, 21; distress, 42) are excluded. Other relevant notes as for Table 0.1.

For each outcome, confidence interval spreads for the representative category were narrower, reflecting the higher number of studies in this category, but positioned over similar effect sizes for the other categories. Confidence intervals for the ‘referred’ subset were the broadest under each outcome construct, despite the fact that the number of studies contributing to it was never the least. Q statistic p levels are well shy of significance for every outcome (anxiety, 0.671; depression, 0.677; distress, 0.253).

Perhaps the breadth of variation in the ‘referred’ subset reflects differing rationales for referral with some oncologists referring patients for their distress and others for the lack of it. This subset also produces the highest point estimates for each outcome construct (for anxiety it is equal with ‘representative’). Again, this may reflect a tendency for oncologists to refer patients with uncomplicated distress, i.e. patients that they can see would benefit from psychotherapy but have little history of psychological problems so are less likely to need an individualised total package beyond the scope of a research trial. Such a selection mechanism would informally replicate inclusion criteria similar to those employed by some positive outlier studies which screened potential recruits in for distress and, simultaneously, out for psychiatric history (refer ‘floor effect’ in the Preliminary analysis internal validity results).

The subset using ‘other or mixed non-representative’ sample selection strategies produces the lowest effect sizes for both anxiety and depression outcomes and comes close for distress. It also produces broad confidence intervals, though, again, narrower for distress. This subset comprises studies employing an untidy mixture of selection strategies, so these features are not surprising.
The subset comprising volunteers produces effect sizes that are the second lowest (next to ‘other or mixed nonrepresentative’) for anxiety and depression and the lowest for distress, and again the confidence intervals are broad, although the few studies in this subset explains this. The lower effect sizes may be explained by the greater motivation of this group for psychological work, meaning that a large contrast between treated and control patients is less likely.

The conclusion is that while representative and referred subsets tended to yield higher effect sizes, no statistical differences were found so the dataset is regarded as a unity on this variable.

Preliminary analyses: Internal validity

Reporting of allocation to conditions

Many simple random studies merely asserted their design rather than specifying the mechanism of randomisation. Some reviews, in an attempt to uphold high method quality standards, have excluded studies because of this reporting failure which contravenes CONSORT (Consolidated Standards of Reporting Trials, Moher, Schulz, & Altman, 2001) recommendations (e.g. Newell, Simon-Fisher, & Savolainen, 2002). Because the object of this study, and science generally, is to collect and explain variation, it is important not to discard data without proper justification, so it was decided to test empirically whether a distinction around reporting existed.

Results showed (Table 0-4) a difference between those simple random design studies that specified a method of randomisation versus those that did not of a negligible $g = 0.1$ in favour of the subset that specified randomisation method. However, although numbers were sufficient in each subset and confidence intervals were fairly tight, the difference in effect size between subsets was not, and did not approach, statistical significance in relation to any outcome construct. These subsets are therefore treated as homogenous in the present study by the retention of randomised studies that did not specify the mechanism of randomisation.

Table 0-4. Reporting of randomisation method, simple randomised studies

<table>
<thead>
<tr>
<th>Method</th>
<th>Anxiety</th>
<th>Depression</th>
<th>Distress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Specified</td>
<td>0.30 (15)</td>
<td>0.13 – 0.47</td>
<td>0.37 (13)</td>
</tr>
<tr>
<td>Merely asserted</td>
<td>0.28 (39)</td>
<td>0.14 – 0.43</td>
<td>0.29 (28)</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.862</td>
<td>0.591</td>
<td>0.382</td>
</tr>
</tbody>
</table>
Four studies were excluded from this analysis because their coding could not be checked or their status regarding this variable was not clear. Other relevant notes as per Table 0-1.

**Concealment of allocation to groups**

The *Cochrane handbook for systematic reviews of interventions* (Cochrane Collaboration, 2006) paragraph 6.3 warns that failure by researchers to secure the process of allocating participants to their respective treatment or control conditions, so that that assignment is unknown to both participant and researcher until it is fixed beyond possible alteration, can cause a greater threat of bias than inadequacies in the randomisation technique itself. This is because either conscious or unconscious motivations of the participants or researchers can be brought to bear on the allocation, resulting in more patients with a particular characteristic in common ending up in one or other group.

The possible impact of this phenomenon was therefore tested in regard to all studies purporting randomisation, including pseudo-random designs. Studies were coded as either specifying their method of allocation concealment, merely asserting concealment, or not concealing the allocation process (Table 0-5).

The Q statistic $p$’s all exceed 0.500, showing clear homogeneity between the subsets on this variable. It is concluded that for this data set the lack of a reported method for assuring concealment of group allocation does not present a threat to internal validity.

**Table 0-5. Concealment of allocation to groups, all randomised studies**

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th></th>
<th>Depression</th>
<th></th>
<th>Distress</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Concealed, method specified</td>
<td>0.35 (9)</td>
<td>0.12 – 0.57</td>
<td>0.07 (10)</td>
<td>-0.12 – 0.25</td>
<td>0.14 (11)</td>
<td>-0.01 – 0.30</td>
</tr>
<tr>
<td>Concealed, merely asserted</td>
<td>0.17 (2)</td>
<td>-0.05 – 0.38</td>
<td>0.16 (2)</td>
<td>-0.05 – 0.38</td>
<td>0.15 (2)</td>
<td>-0.12 – 0.42</td>
</tr>
<tr>
<td>Not concealed</td>
<td>0.31 (2)</td>
<td>-0.29 – 0.92</td>
<td>0.35 (2)</td>
<td>-0.47 – 1.17</td>
<td>0.25 (3)</td>
<td>-0.14 – 0.64</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.516</td>
<td></td>
<td>0.684</td>
<td></td>
<td>0.889</td>
<td></td>
</tr>
</tbody>
</table>

Two studies with values on this variable that could not be checked (borrowed theses) were excluded from this analysis. Other relevant notes as per Table 0-1.

**Attrition**

**Balance**
As explained in the Methods chapter, imbalanced attrition between the treatment and control groups was recognised as posing a possible threat to the validity of results. In their meta-analysis, Divine and Cook (1983) excluded studies with an overall attrition rate of 15% as well as those with differential attrition between groups exceeding 10%. In the context of the present study, where participants all had a potentially lethal disease, the latter strategy was seen as the important one to protect against a possible selection effect. Studies were therefore coded for any imbalance that exceeded 10% and a heterogeneity analysis conducted between studies that showed balance on this factor and those that did not (Table 0-6).

Q statistic $p$’s exceeded 0.300 on all outcomes, showing no heterogeneity between balanced and imbalanced subsets of data, and therefore no need to exclude data from studies suffering an imbalance in attrition rate.

Table 0-6. Attrition rate, balance

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th></th>
<th>Depression</th>
<th></th>
<th>Distress</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Balanced</td>
<td>0.18 (54)</td>
<td>0.06 – 0.29</td>
<td>0.23 (48)</td>
<td>0.11 – 0.34</td>
<td>0.17 (47)</td>
<td>0.17 – 47.00</td>
</tr>
<tr>
<td>Imbalanced</td>
<td>0.36 (16)</td>
<td>0.14 – 0.58</td>
<td>0.21 (12)</td>
<td>0.09 – 0.34</td>
<td>0.22 (15)</td>
<td>0.22 – 15.00</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.327</td>
<td></td>
<td>0.972</td>
<td></td>
<td>0.944</td>
<td></td>
</tr>
</tbody>
</table>

Other relevant notes as per Table 0-1.

Reasons

Reasons for attrition were categorised by predominance: 1. Illness or death; 2. Treatment side-effects; 3. ‘Other’ (e.g. travelling to therapy was found to be inconvenient, or participant was lost to assessment due to an un-notified change of address); and 4. A fairly balanced mixture (‘mixed’) of illness / death and ‘other’. As can be seen in the table below (Table 0-7) the predominant reasons for attrition were ‘other’ or ‘mixed’, with illness or death at less than half the frequencies of those categories, and treatment side effects hardly showing as such. A substantial proportion of studies did not report reasons, and a similar proportion were coded ‘Not applicable’ because there was no attrition or there was no pre-test from which it could be ascertained.

Anxiety was the only outcome displaying heterogeneity on this variable (Q statistic $p = 0.027$). A difference between the ‘not applicable’ and the ‘not reported’ subsets was not going to be theoretically useful, so these groups were removed and the analysis run again.
This produced an anxiety Q statistic $p$ above the 0.10 threshold (0.118), and a pairwise comparison of the remaining categories located the real difference between illness/death ($g = 0.42$) and ‘other’ reasons (0.08)($Q$ statistic $p = 0.041$). This means that in relation to anxiety, studies that suffered attrition due to illness or death produced effect sizes that were statistically significantly higher than those where attrition was caused by ‘other’ reasons. This is consistent with the finding in a later chapter that more advanced illness causes greater effect sizes. This result could not, however, justify a cut in the dataset because of its isolation to just one outcome construct and the few studies that it involved. The issue is perhaps better regarded as one relating to advanced illness or poor prognosis, which are substantive issues investigated later.

Table 0-7. Attrition rate, reasons

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th></th>
<th>Depression</th>
<th></th>
<th>Distress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Illness/death</td>
<td>0.42 (9)</td>
<td>0.12 – 0.71</td>
<td>0.26 (8)</td>
<td>0.03 – 0.49</td>
<td>0.43 (7)</td>
</tr>
<tr>
<td>Treatment</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.04 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>0.08 (19)</td>
<td>-0.07 – 0.22</td>
<td>0.18 (21)</td>
<td>0.04 – 0.32</td>
<td>0.14 (22)</td>
</tr>
<tr>
<td>Mixed</td>
<td>0.18 (14)</td>
<td>-0.03 – 0.39</td>
<td>0.18 (13)</td>
<td>-0.06 – 0.41</td>
<td>0.28 (10)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.49 (21)</td>
<td>0.23 – 0.76</td>
<td>0.28 (18)</td>
<td>0.04 – 0.52</td>
<td>0.22 (17)</td>
</tr>
<tr>
<td>Not reported</td>
<td>0.09 (20)</td>
<td>-0.08 – 0.26</td>
<td>0.22 (10)</td>
<td>-0.03 – 0.46</td>
<td>0.02 (16)</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.027</td>
<td></td>
<td>0.937</td>
<td></td>
<td>0.351</td>
</tr>
</tbody>
</table>

Other relevant notes as per Table 0-1.

**Therapy types and combinations**

The notes associated with Tables 0-8 and 0-9 in the Therapy characteristics results chapter apply to all of the similar tables in this section.

**Education**

Results are presented for professionally provided education or information defined as an inclusive therapy ‘type’ (education, relaxation, CBT, etc.) and then exclusive therapy ‘combinations’ (e, r, c etc and the unique combinations of therapy types that comprise each study's therapy protocol, e.g. es for a protocol that included education and expressive-supportive components – refer to the notes to Table 0-9 and to the definition of inclusive and exclusive therapy categorisation in the Analysis chapter). Results are set out by early and late assessment time points for each of the three psychological outcomes.
Anxiety

Results are set out for anxiety in Table 0.8 for therapy type, and Table 0.9 for therapy combinations. Recall that the main effect for education was 0.13 at early times increasing to 0.17 at late times, both $p < 0.010$ (Table 6.1 in the Therapy characteristics results chapter). In Table 0.8 it can be seen that when divided by the nature of the control condition, the treated control group comparison overall effect size is precisely zero at early times, whereas for untreated controls it is 0.32 ($p < 0.05$). This implies that there is no incremental gain of this therapy over what could be obtained from placebo or treatment as usual, but that the absolute value is a small $g$ of 0.32.

There were no studies that recruited on the basis of measured baseline distress (no screened in or screened in and out studies) but some screened out for psychological history. An interesting but unexplained contrast between unscreened studies (-0.08, n.s.) and those that screened out (0.48, $p < 0.05$) appears in the treated control row at early times, producing the only comparison on the table that reaches statistical heterogeneity ($Q$ statistic $p = 0.033$).

At late times the only group with sufficient $n$ to justify comment is the treated control by unscreened group, which produces a substantial lift from its null early times score to a statistically significant 0.23 ($p < 0.05$, $n = 10$). This result suggests that benefits from education provided to cancer patients generally (i.e. without screening) may not show immediately but take effect over time.

In sum, compared with controls receiving some element of treatment, education therapies, inclusively defined, did not produce any benefit at all for unscreened patients at early times, but a small effect is picked up over time. Compared with controls receiving no treatment, the result is small to moderate and statistically significant at first, with insufficient late times data to comment. Non-complex cases (i.e. where patients with a history of psychological distress were screened out) produced perplexing medium strength results against treated controls; small against untreated controls. Data from small n at late times suggest that this effect falls away. There were no data for patients who were distressed at baseline.

Table 0.8. Education as a therapy type, anxiety

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated cont</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.28 (3)**</td>
<td>-0.03 – 0.59</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Screened (combined)</td>
<td>Unscreened</td>
<td>Overall effect</td>
<td>Q statistic p</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------</td>
<td>------------</td>
<td>----------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>0.28 (3)**</td>
<td>0.36 (10)*</td>
<td>0.32 (13)**</td>
<td>0.726 (0.726)</td>
</tr>
<tr>
<td></td>
<td>-0.03 – 0.59</td>
<td>0.04 – 0.67</td>
<td>0.09 – 0.54</td>
<td>1.000 (1.000)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>-0.14 (1)</td>
<td>-0.14 (1)</td>
<td>-0.60 – 0.31</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>-0.60 – 0.31</td>
<td>-0.60 – 0.31</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Screened in and out</th>
<th>-</th>
<th>-</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screened in</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Screened out</td>
<td>0.48 (6)**</td>
<td>0.01 – 0.95</td>
<td>0.04 (2)</td>
</tr>
<tr>
<td></td>
<td>Screened (combined)</td>
<td>0.48 (6)**</td>
<td>0.01 – 0.95</td>
<td>0.04 (2)</td>
</tr>
<tr>
<td></td>
<td>Unscreened</td>
<td>-0.08 (19)</td>
<td>-0.27 – 0.12</td>
<td>0.23 (10)**</td>
</tr>
<tr>
<td></td>
<td>Overall effect</td>
<td>0.00 (25)</td>
<td>-0.18 – 0.18</td>
<td>0.21 (12)**</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td>0.033** (0.033**)</td>
<td>0.547 (0.547)</td>
<td></td>
</tr>
</tbody>
</table>

Italicised results (screened in and out, screened in, screened out) are breakouts of the ‘screened (combined)’ result. ‘Distress combined’ is a combination of the two categories that screened in for baseline distress (screened in and out, screened in).

Q statistic p’s relate to the screened v. unscreened comparison; those in brackets and italicised relate to comparison of distress combined v. screened out (i.e. studies that excluded patients with a history of psychological distress, also referred to as ‘non-complex’ samples) v. unscreened.

Where there was uncertainty as to whether or not a treatment group fitted a category (treatment type, screening, or nature of control condition) that group was excluded from computations. The occasional smaller summative n in a confound breakout will be noticed as a result. Relevant notes from Table 0-1 apply.

For education as a ‘pure’ therapy combination (‘e’, refer Table 0-9), the overall effect size at early times is negligible (0.10, n.s.) but rises to small (0.20, n.s.) at late times, though remaining non-significant. This slight strengthening of effect sizes over time can be seen in nearly all the confound rows for both therapy combinations (e and es).

Unscreened results at early times display enough n for comment, but range from negative to negligible in magnitude.

One score that stands out is the high 0.70 (p < 0.10) for e, untreated control at early times. This result, supported by four studies, indicates the strong absolute value that education can have. Since most education studies compare with a treated control, undoubtedly for ethical and practical reasons, this absolute value is usually obscured, but this result highlights the psychological value of information over ignorance. It is a pity that no data are available at late times.
The value of es as a therapy combination appears very poor overall (0.00, early times), but n is very light. For both e and es combinations, nearly all of the confidence intervals fall below zero at both times, meaning that a proportion of treated patients becomes more distressed following therapy and, despite the general trend upward, some stay so.

Therapy ‘combination’ results allow all the therapy components that are subject to analysis to be identified without concern that effect sizes may be heightened or altered by other components of therapy. In this case, it can be seen that education alone can produce some strong effects against untreated controls, but also that there are some people who are negatively impacted by educational intervention.

Education and baseline distress.

From the table above (Table 0-8) it is known that the screened results are all from screened out studies. This means that all of the results in Table 0-9 relate to unscreened cancer patients or those without psychological histories. It would have been interesting to know how the anxiety of patients who are distressed at baseline respond to education. In the absence of hard data, one can only speculate based on individual studies. Two that did not measure baseline distress but for which distress may be inferred from the circumstances for most patients are Ali and Khalil (1989) and Corchado (2006). Both had untreated control comparisons and have been described as outliers (refer Preliminary analyses). Corchado was coded ‘e’ and will have contributed to the high score noted above, but Ali and Khalil was coded ‘en’ for which results are not shown. However, the kind of distress experienced in those studies may be different from what is normally experienced in Anglo-western countries, as those studies were from societies (Egypt and Puerto Rico, respectively) where, at the time of study, the culture greatly restricted discussion of cancer and its treatment. In those cases, the need for education was stark, and when it was provided it showed a massive impact on anxiety. What education might do for distressed patients living in societies with relatively open information about cancer and its medical treatment is unknown. It is also noted that without Corchado, the high result discussed in the last paragraph (0.70, n = 4) would have been lower (notwithstanding that Corchado was windzorised) so it is a result that may be unreliable to generalise between different societies.

Table 0-9 Education as therapy combinations, anxiety

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>e</td>
<td>Overall</td>
<td>0.10 (20)</td>
<td>-0.10 – 0.30</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.339</td>
<td></td>
</tr>
</tbody>
</table>
Only ‘pure’ combinations (e.g. ‘e’ or ‘s’ rather than ‘es’) and those with a frequency of at least three in any one of the three outcomes are tabled.

Therapy combination codes: r = relaxation focused cognitive-behavioural treatment; c = cognitive-behavioural treatment; s = expressive-supportive therapy / non-directive counselling / psychotherapy (‘s’ for supportive).

Relevant notes from Table apply.

Anxiety conclusion for education.
From both approaches, it seems that the impact that education has initially may be null or negligible but firms a little over time. As a pure combination, and against untreated controls, education can have a strong impact on anxiety, but this may be most evident in societies where communication about cancer is severely restricted.

Depression.
The main effect on depression for education as a therapy ‘type’ 0.15 (p < 0.05) at early times which, against the usual trend for education, fell to 0.11 (p < 0.10) at late times (Table 6-1). Table 0-10 shows that this late times figure was derived almost entirely from unscreened studies with treated controls – the study design with poorest outcomes - but this is also the case for the anxiety figures, if not for distress.

The Q statistic p’s all indicate homogeneity between screening categories in each quadrant of the matrix, meaning that the overall effect sizes, which are very close to each other and are all in the negligible to small range are impacted little by the structural confounds. There are also no dramatic visual differences in breakout effect sizes to
peak interest. All of them are between zero and a modest and non-significant 0.25. Once again no studies screened in for distress.

In sum, these figures give no cause for excitement – depression can be treated with negligible to small effect by education, and this effect wanes further to negligible by late times, but no data were available to test the effectiveness of education on distressed patients.

Table 0-10. Education as a therapy type, depression

<table>
<thead>
<tr>
<th>Depression</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>-0.04 (2)</td>
<td>-0.45 – 0.38</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>-0.04 (2)</td>
<td>-0.45 – 0.38</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.21 (3)*</td>
<td>-0.03 – 0.45</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.15 (5)</td>
<td>-0.06 – 0.35</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.313 (0.313)</td>
<td></td>
</tr>
<tr>
<td>Treated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.25 (5)</td>
<td>-0.07 – 0.56</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.25 (5)</td>
<td>-0.07 – 0.56</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.11 (18)</td>
<td>-0.05 – 0.26</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.13 (23)*</td>
<td>0.00 – 0.27</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.434 (0.434)</td>
<td></td>
</tr>
</tbody>
</table>

When education is examined in its pure form (Table 0-11, ‘e’) the picture changes a little in that overall effect sizes rise over time, but loose significance with n (early, 0.13, \(p < 0.10, n = 12\); to 0.19, n.s., n = 4 late). A degree of heterogeneity is evident in the Q statistic \(p\)'s for both times (early, 0.096; late, 0.165). Screened studies – which, again,
must be ‘screened out’ - produce the highest score (early times 0.24, \( p < 0.10, n = 3 \); at late times n is only 1) but has greatly overlapping confidence intervals with the unscreened score (0.09, n.s., \( n = 9 \)). The control group figures have greatly overlapping confidence intervals also, so the heterogeneity is unexplained.

The ‘es’ combination performs poorly again, yielding negligible non-significant overall effect sizes at both times. The flickers of hope seen in the very high scoring sole screened study (1.21, \( p < 0.05 \)) and the moderate scoring sole untreated control study (0.54, \( p < 0.05 \))(both early times) may be due to the expressive-supportive component of this combination, which will be seen to produce some quite spectacular results.

Table 0-11. Education as therapy combinations, depression

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.13 (12)*</td>
<td>-0.02 – 0.29</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.096*</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.24 (3)*</td>
<td>0.00 – 0.49</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>0.09 (9)</td>
<td>-0.10 – 0.29</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.11 (1)</td>
<td>-0.17 – 0.38</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>0.14 (11)</td>
<td>-0.04 – 0.31</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.06 (6)</td>
<td>-0.39 – 0.52</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.788</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>1.21 (1)**</td>
<td>0.55 – 1.87</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>-0.13 (5)</td>
<td>-0.50 – 0.24</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.54 (1)**</td>
<td>0.03 – 1.06</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>-0.03 (5)</td>
<td>-0.53 – 0.47</td>
</tr>
</tbody>
</table>

Depression conclusion for education.
The available evidence is that education has negligible to small effects on depression, which may firm slightly over time. Again, evidence is not available for patients who are distressed at baseline.

**Distress.**
The main effect for distress (Table 6-1) was non existent at 0.03, early, and 0.05, late times. On the study design moderator matrix (Table 0-12) overall effects for untreated
controls improve barely, showing that the main effect is dragged down by disproportionate numbers of treated control studies. Once again the lift in results over time that is characteristic of education is evident, but so are the very poor overall effect sizes.

Disregarding the late times quadrants which have only one screened study each, results vary between screened and unscreened studies but, due to broad confidence intervals, this variation reaches statistical significance at Q statistic $p < 0.10$ only in relation to treated controls where screened out studies yield $0.22 (p < 0.10, n = 5)$ in contrast with unscreened at $-0.02 (n = 15)$. This contrast is in reverse of the non-significant trend shown for untreated controls and is not readily explained given the similarity in the composition of recruits to unscreened and screened out groups and indications of the reverse trend in the untreated control early times quadrant. However, the same trend was seen for all education outcomes, and did reach 0.05 significance for anxiety.

In sum, as an inclusive therapy type, education is seen to produce null to negligible results against distress outcome. Indeed, it seems that for some people, distress could be worsened by education.

**Table 0-12. Education as a therapy type, distress**

<table>
<thead>
<tr>
<th>Distress</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.05 (3)</td>
<td>-0.40 – 0.49</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.05 (3)</td>
<td>-0.40 – 0.49</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.11 (6)</td>
<td>-0.08 – 0.30</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.10 (9)</td>
<td>-0.08 – 0.27</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.807 (0.807)</td>
<td>0.064* (0.064*)</td>
</tr>
<tr>
<td>Treated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.22 (5)*</td>
<td>-0.03 – 0.47</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.22 (5)*</td>
<td>-0.03 – 0.47</td>
</tr>
</tbody>
</table>
Results for specific therapy combinations are set out below (Table 0-13). For ‘pure e’ the characteristic little lift in effect size over time can be seen, with an overall null result at early times (0.01) lifting to a negligible, but still non-significant, 0.10 later. At both times results are statistically homogeneous. Results for es are characteristically very poor.

Table 0-13. Education as therapy combinations, distress

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.01 (15)</td>
<td>-0.09 – 0.11</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.829</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.15 (4)</td>
<td>-0.07 – 0.37</td>
</tr>
<tr>
<td>Unscrened</td>
<td></td>
<td>-0.03 (11)</td>
<td>-0.13 – 0.07</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>-0.03 (2)</td>
<td>-0.26 – 0.21</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>0.02 (11)</td>
<td>-0.11 – 0.14</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>-0.09 (6)</td>
<td>-0.34 – 0.16</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.496</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>-0.42 (1)</td>
<td>-1.10 – 0.25</td>
</tr>
<tr>
<td>Unscrened</td>
<td></td>
<td>-0.05 (5)</td>
<td>-0.32 – 0.23</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.22 (2)</td>
<td>-1.07 – 1.51</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>-0.18 (3)</td>
<td>-0.39 – 0.03</td>
</tr>
</tbody>
</table>

Distress conclusion for education.
In conclusion, using both prongs of approach, education has performed very poorly against the distress outcome. It may be that part of the effect has been lost due to fuzziness in the construct, as it has been operationalised to a broad range of measures. Nonetheless, even against untreated controls results are no better than small. They firm a little over time.
**Education conclusion.**

Education is an unusual intervention in that it characteristically produces null or negligible effects at first that lift to negligible or small after six months. Main effects are adversely impacted by a disproportionate number of treated control comparisons. Presumably treated comparison is preferred for practical and ethical reasons.

Effects are strongest against anxiety, where the potential of this therapy, in its pure form and against untreated controls, can be seen in a high effect size of 0.70. It is speculated that strength of effect may also depend upon how openly a society discusses cancer and its treatment. No comment can be made concerning the impact of education on patients who are distressed at baseline as no data at all were available.

There is some statistically significant evidence, against treated controls, that studies that screened out for psychological history produce stronger results, but this trend runs counter to the non-significant trend displayed by studies with untreated controls and is difficult to understand.

The combination of education with expressive support generally produces particularly poor results. However, this result could be caused by co-variation with other study features, e.g. sampling may be from a poorly scoring subpopulation (such as early stage breast cancer patients, as shall be seen).

Because effect sizes generally range between 0.00 and 0.25, confidence intervals regularly fall below zero, meaning that some people are actually caused distress by this therapy, though numbers decrease as effect sizes lift over time. The lack of studies that screen in for distress and excess of those that compare with treated controls may obscure the true value of education / information, which is an essential ingredient of self efficacy. The late times data suggest that education can be a long term investment in psychological well-being, but its value may depend largely on the information already made available to the patient by way of usual care and through the openness of society to discussing the disease and its treatment.

**Relaxation**

**Anxiety.**

Relaxation main effects on anxiety were 0.31 (p < 0.05) at early times, falling to 0.16 (p < 0.05) late (Table 6-1). The early effect is twice that for education (0.13) but tends to fall rather than firm at late times.

In the early times results on the breakout matrix (Table 0-14) there is disproportionate n in the higher scoring untreated control quadrant (24 compared with 12 in treated) which would distort the main effect upwards. Every quadrant shows homogeneity on the basic screening dichotomy, implying that screening does not moderate the effect of relaxation therapies. However, there are only two studies that screen in for distress, one of which
simultaneously screened out for history. When broken out further into screening types, both early times quadrants become heterogeneous and it is these high scoring studies that create the contrast (untreated, screened in and out, 1.91; treated, screened in, 1.08, both $p < 0.05$). This suggests that baseline distress may in fact moderate relaxation effectiveness, but more results from studies that screen in for distress are required to establish this. The figures also show a consistent trend for ‘screened out’ studies to score higher than unscreened, suggesting that perhaps non-complex cases can take greater advantage of this therapy type, which often involves learning and applying a skill.

At late times, too few screened studies contribute to results to sustain comment. Unscreened effect sizes are both of negligible magnitude (both 0.16), although the untreated control result fell to this while the treated control trajectory rose to it. The falling trajectory is seen to be present a more accurate picture for relaxation when it is noted from Table 0-15 that most of the ‘pure r’ studies had untreated control comparisons, and their trajectory was downward (although with dramatic loss of n). The upward trajectory of the treated control studies in Table 0-14 must therefore have been due to other types of therapy packaged with relaxation.

It is concluded that at early times relaxation produces a small to moderate statistically significant impact against anxiety using an unscreened or screened out sample when comparing with untreated controls. Against treated comparisons the same samples produce a negligible to small effect, but nearly all of the studies that contributed to these scores combined relaxation with another therapy type, so the result may reflect a watering down of what the impact may otherwise have been. On the face of it, however, these data show that relaxation therapies provide little benefit to unscreened or non-complex samples over what can be obtained from placebo or usual treatment. Further, it appears that the trajectory of the effect is downward to negligible at late times. Although there is only one study in each control type for patients who were distressed at baseline, those results are promising, yielding with very high and statistically significant early times effect sizes. Unfortunately no late times data are available for them.

Table 0-14. Relaxation as a therapy type, anxiety

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n) 95% CI's</td>
<td>ES (n) 95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>$1.94 (1)^{**}$ 1.10 – 2.78</td>
<td>-  -</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>$1.94 (1)^{**}$ 1.10 – 2.78</td>
<td>-  -</td>
</tr>
<tr>
<td>Screened out</td>
<td>$0.40 (10)^{**}$ 0.11 – 0.69</td>
<td>0.02 (2) -0.35 – 0.38</td>
</tr>
<tr>
<td>Treated control</td>
<td>Screened (combined)</td>
<td>0.51 (11)**</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.29 (13)**</td>
<td>0.06 – 0.53</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.37 (24)**</td>
<td>0.17 – 0.56</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.288 (0.001**)</td>
<td>0.601 (0.601)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Screened in and out</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened in</td>
<td>1.08 (1)**</td>
<td>0.25 – 1.92</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>1.08 (1)**</td>
<td>0.25 – 1.92</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.23 (2)</td>
<td>-0.09 – 0.56</td>
<td>0.34 (2)*</td>
<td>-0.01 – 0.69</td>
<td></td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.40 (3)*</td>
<td>-0.02 – 0.83</td>
<td>0.34 (2)*</td>
<td>-0.01 – 0.69</td>
<td></td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.07 (9)</td>
<td>-0.05 – 0.19</td>
<td>0.16 (8)**</td>
<td>0.02 – 0.30</td>
<td></td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.09 (12)</td>
<td>-0.02 – 0.21</td>
<td>0.19 (10)**</td>
<td>0.06 – 0.32</td>
<td></td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.140 (0.044**)</td>
<td>0.339 (0.339)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Three specific therapy combinations involving relaxation had sufficient n to be tabled (Table 0-15). Relaxation by itself (‘r’) shows a moderate overall effect size at early times (0.51, \( p < 0.05 \)) fading to negligible and losing significance after six months (0.09). Most of the breakout scores are in the moderate range, with screening lifting to a high of 0.83 (\( p < 0.10 \)). Each of these scores drops away drastically to negligible or less at late times, but from low n.

The combination of relaxation and CBT (‘rc’) seems to produce less powerful early times results but more stability over time (early overall effect, 0.36, \( p = 0.168, n = 6; \) late, 0.25, n.s., \( n = 3 \)). Screening produces high but unstable results from low n (0.78., n.s., \( n = 3 \)) and stands well above scores from the other confound rows. Against treated controls and with unscreened samples, the effect is nothing (0.01, for both) but n is small (1 and 2 respectively). The overall late times effect size may have been a good deal higher had any screened studies remained to contribute.

Relaxation combined with CBT and expressive-support (‘rcs’) produced results that were homogeneous and particularly low (early overall effect, 0.04, n.s., \( n = 5 \), and late, 0.08, n.s., \( n = 3 \)).

In sum, relaxation by itself shows a characteristic of packing all of its moderate magnitude punch early after intervention, and then fading away to almost nothing over six months. Combined with CBT it seems to retain effect better, but the immediate
impact may be watered down. Screened patients stand out as the group who gain most therapeutic benefit, regardless of the therapy combination that relaxation is part of.

Table 0-15. Relaxation as therapy combinations, anxiety

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.51 (16)**</td>
<td>0.26 – 0.77</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.000**</td>
<td>0.451</td>
</tr>
<tr>
<td>r</td>
<td>Screened</td>
<td>0.83 (5)**</td>
<td>0.35 – 1.31</td>
</tr>
<tr>
<td></td>
<td>Unscreened</td>
<td>0.37 (9)**</td>
<td>0.03 – 0.71</td>
</tr>
<tr>
<td></td>
<td>Untx control</td>
<td>0.52 (13)*</td>
<td>0.24 – 0.79</td>
</tr>
<tr>
<td></td>
<td>Tx control</td>
<td>0.51 (3)</td>
<td>-0.40 – 1.41</td>
</tr>
<tr>
<td>Overall</td>
<td>rcs</td>
<td>0.36 (6)</td>
<td>-0.16 – 0.87</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.172</td>
<td>0.282</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.78 (3)</td>
<td>-0.21 – 1.77</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>0.01 (2)</td>
<td>-0.20 – 0.21</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.46 (5)</td>
<td>-0.23 – 1.14</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>0.01 (1)</td>
<td>-0.20 – 0.21</td>
</tr>
<tr>
<td>Overall</td>
<td>rcs</td>
<td>0.04 (5)</td>
<td>-0.13 – 0.20</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.655</td>
<td>0.428</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.13 (3)</td>
<td>-0.19 – 0.45</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>-0.03 (2)</td>
<td>-0.24 – 0.19</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.07 (3)</td>
<td>-0.27 – 0.41</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>0.02 (2)</td>
<td>-0.18 – 0.22</td>
</tr>
</tbody>
</table>

Anxiety conclusion for relaxation.
From the above two sets of findings, it is concluded that relaxation produces a small to moderate strength effect at early times on the anxiety of patients without established baseline distress, but this effect falls away dramatically over six months. There is some evidence that the fall off in effect can be attenuated by combining relaxation with CBT.
Although there are only two early times studies from which an indication can be obtained as to how this therapy impacts patients who are distressed at baseline, the hint is that they can benefit strongly. It seems that the treated control results do not present a fair picture of relaxation because n is overwhelmingly made up of combination studies, which produce different results at respective assessment times. Clearly, studies using distressed patients and following through to late times are needed.

**Depression.**

Main effects for relaxation against depression are lower than for anxiety, as could be expected. Table 6-1 gives an early times main effect of 0.16, \( p < 0.05 \) and late times of 0.10 (n.s.).

In the Table 0-16 matrix, homogeneity is displayed in each quadrant except at early times for untreated controls when the screening categories are broken out (Q statistic \( p = 0.088 \)). Once again it is the distressed categories that score highest but are represented by minimal n and present data for early times only: screened in, 0.47 (n.s., \( n = 1 \)); screened in and out, 1.38, \( p < 0.05 \), \( n = 1 \), combined effect size, 0.93 \( p < 0.05 \). Screened out and unscreened studies in the untreated control quadrant do poorly, with non-significant scores in the zero to small range, although there are no late times data for screened out.

Treated control scores approach perfect homogeneity - notwithstanding that they include one screened in study – all negligible and non-significant, suggesting little incremental impact on depression over placebo or usual care.

By and large these results are very flat. Late times data are sparse, and there are few screened in studies, but they present the only results – and then inconsistently between treated and untreated controls – that suggest that there may be value in this therapy for combating depression.

Table 0-16. Relaxation as a therapy type, depression

<table>
<thead>
<tr>
<th>Depression</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>1.38 (1)**</td>
<td>0.65 – 2.12</td>
</tr>
<tr>
<td>Screened in</td>
<td>0.47 (1)</td>
<td>-0.26 – 1.20</td>
</tr>
<tr>
<td>Distress combined</td>
<td>0.93 (2)**</td>
<td>0.03 – 1.82</td>
</tr>
<tr>
<td>Screened out</td>
<td>-0.04 (6)</td>
<td>-0.28 – 0.20</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.13 (8)</td>
<td>-0.22 – 0.47</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.21 (6)</td>
<td>-0.15 – 0.57</td>
</tr>
</tbody>
</table>
Table 0-17 presents results for r, rc, and rcs. The results for relaxation alone are predictably flat, with the overall effect size not even reaching significance at 0.16. Untreated controls produce the best scores, but still non-significant and small at 0.24 (n = 6).

The combination of relaxation with CBT could be expected to lift scores for depression outcome, and does, but not much. The overall effect at early times is only 0.17 and not statistically significant. Screened studies stand out from the other confound rows, however, yielding a small to moderate 0.39 (p < 0.05, n = 4). Untreated control studies yield a modest non-significant 0.26, and the other confound rows are below zero. At late times n is sparse.

Results are again flat for relaxation combined with CBT and expressive-support, but n is very low.

All round, relaxation combinations do not appear to help depression, except possibly for screened patients.

Table 0-17. Relaxation as therapy combinations, depression

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>r</td>
<td>Overall</td>
<td>0.16 (9)</td>
<td>-0.15 – 0.47</td>
</tr>
<tr>
<td></td>
<td>Overall p</td>
<td>0.304</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened</td>
<td>Unscreened</td>
<td>Untx control</td>
</tr>
<tr>
<td>---------------</td>
<td>----------</td>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>rc</td>
<td></td>
<td>-0.09 (2)</td>
<td>-0.59 – 0.42</td>
</tr>
<tr>
<td></td>
<td>0.14 (5)</td>
<td>-0.36 – 0.63</td>
<td>0.13 (2)</td>
</tr>
<tr>
<td></td>
<td>0.24 (6)</td>
<td>-0.15 – 0.63</td>
<td>0.06 (1)</td>
</tr>
<tr>
<td></td>
<td>-0.02 (3)</td>
<td>-0.54 – 0.49</td>
<td>0.20 (1)</td>
</tr>
<tr>
<td>Overall</td>
<td>0.17 (7)</td>
<td>-0.20 – 0.55</td>
<td>0.04 (3)</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.256</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.39 (4)**</td>
<td>-0.31 – 1.08</td>
</tr>
<tr>
<td></td>
<td>-0.12 (2)</td>
<td>-0.31 – 0.07</td>
<td>0.04 (3)</td>
</tr>
<tr>
<td></td>
<td>0.26 (6)</td>
<td>-0.20 – 0.72</td>
<td>0.05 (2)</td>
</tr>
<tr>
<td></td>
<td>-0.14 (1)</td>
<td>-0.35 – 0.07</td>
<td>0.07 (1)</td>
</tr>
<tr>
<td>Overall</td>
<td>0.10 (3)</td>
<td>-0.31 – 0.51</td>
<td>0.20 (2)</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.636</td>
<td></td>
</tr>
</tbody>
</table>

**Depression conclusion for relaxation.**

These findings do not support relaxation as a therapy for depression, although there may be benefit in it for patients distressed at baseline – more studies of this group, with late times follow-up, are needed.

**Distress.**

The early times main effect for relaxation on distress (Table 6-1) is small (0.22) but between that for anxiety and depression. It does not reach statistical significance notwithstanding high n (33) which may indicate ‘wobbliness’ in the measured outcome construct. The late times result virtually disappears (0.06, n.s.).

In the study design moderator matrix (Table 0-18) the Q statistic p’s at early times are sufficiently low to suggest that more data may have produced heterogeneity, but at late times there are only data for unscreened studies. Some heterogeneity does present in the early times treated control quadrant once screening categories are broken out (Q
statistic $p = 0.75$). Confidence intervals suggest that the point of contrast is between unscreened studies (0.09, n.s., n = 8) and those that screened out (0.55, $p < 0.05$, n = 2). The unscreened effect size remains the same at 0.09 (n.s., n = 6) at late times. The one study that screened in produced a negative effect size (early times, -0.10).

In the untreated control quadrant, although results are statistically homogeneous, the two studies that screened in for baseline distress lead the effect sizes with a combined distress effect size of 0.63 ($p < 0.05$), followed by the screened out studies at 0.37 ($p < 0.05$, n = 10) and then the unscreened studies which fall below statistical significance at 0.17 (n = 8). This latter effect size drops even further at late times (0.06, n.s., n = 5).

In sum, relaxation may have a moderate effect on general distress outcome for patients with baseline distress, but the data are sparse and contradicted between treated and untreated control quadrants. Relaxation does show a consistent and statistically significant moderate benefit for samples that screened out for psychological history however, regardless of the nature of the control. These lifts in screened sample effect sizes are interesting, given that the consistent result for unscreened samples is that of a negligible effect, at both early and late times, implying that there is no appreciable gain from administering therapy to unscreened samples. There are no late times screened data.

Table 0-18. Relaxation as a therapy type, distress

<table>
<thead>
<tr>
<th>Distress</th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td><strong>Untreated control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>0.60 (1)*</td>
<td>-0.07 – 1.28</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>0.67 (1)*</td>
<td>-0.08 – 1.41</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>0.63 (2)**</td>
<td>0.13 – 1.13</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.37 (10)**</td>
<td>0.06 – 0.68</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.41 (12)</td>
<td>0.14 – 0.68</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.17 (8)</td>
<td>-0.10 – 0.44</td>
<td>0.06 (5)</td>
<td>-0.06 – 0.18</td>
</tr>
<tr>
<td><strong>Overall effect</strong></td>
<td>0.29 (20)**</td>
<td>0.10 – 0.48</td>
<td>0.06 (5)</td>
<td>-0.06 – 0.18</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.220 (0.251)</td>
<td>1.000 (1.000)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treated control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-0.10 (1)</td>
<td>-0.88 – 0.68</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-0.10 (1)</td>
<td>-0.88 – 0.68</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
The ‘pure r’ overall effect (Table 0-19) at early times is a moderate magnitude 0.43 (p < 0.05, n = 12) but this figure is boosted by a disproportionate number of untreated control studies (10) which yield 0.55 (p < 0.05). The two treated control studies, by way of contrast, yield a negative effect size (-0.35). Screened studies produce twice the effect (0.60, n = 6) of unscreened (0.23, n =5). There is insufficient n at late times for comment.

Combined with CBT (rc), relaxation produces a surprisingly small overall effect at early times of 0.15 (n.s., n = 5), but this is due to the negative scoring of the unscreened studies (-0.12, n = 2). All studies are untreated control comparisons, so a higher overall effect would have been expected. Again, n is too sparse for comment at late times.

The results for relaxation combined with CBT and expressive-supportive therapy (rcs) are particularly poor – again – but n is light. However, the unscreened effect size is supported by an n of four yet is precisely zero.

For treating general distress, this data conveys the impression that relaxation therapies are best administered on their own, when a moderate effect can be expected. However, it may be that the results for more complex therapy packages are confounded by the covariance of other study features, such as sample selection. Relaxation also appears to have more to offer screened patients. There are few data for studies with treated controls or at late times.

Table 0-19. Relaxation as therapy combinations, distress

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.43 (12)**</td>
<td>0.16 – 0.71</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.002**</td>
<td>0.876</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.60 (6)**</td>
<td>0.18 – 1.02</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>0.23 (5)</td>
<td>-0.19 – 0.65</td>
</tr>
<tr>
<td></td>
<td>Untx control</td>
<td>Tx control</td>
<td>Overall</td>
</tr>
<tr>
<td>--------</td>
<td>--------------</td>
<td>------------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td>0.55 (10)**</td>
<td>-0.35 (2)</td>
<td>0.15 (5)</td>
</tr>
<tr>
<td></td>
<td>0.28 – 0.82</td>
<td>-0.83 – 0.14</td>
<td>-0.21 – 0.52</td>
</tr>
<tr>
<td></td>
<td>0.03 (1)</td>
<td>0.03 (1)</td>
<td>-0.06 (2)</td>
</tr>
</tbody>
</table>

Distress conclusion for relaxation.
In sum, relaxation may have a moderate effect on general distress for patients that screened in for baseline distress, but the data are sparse and contradicted between treated and untreated control quadrants. Relaxation does show a consistent and statistically significant moderate benefit for samples that screened out for psychological history, however, regardless of the nature of the control. This is interesting, given that the equally consistent result for unscreened samples is that of a negligible effect, both early and late times. This is again consistent with the possibility that non-complex patients are better equipped to take full advantage of relaxation therapies. There are no late times screened data.

Relaxation conclusion.
Relaxation is a therapy primarily for anxiety and results show more strongly for anxiety and then distress rather than depression accordingly.

The early magnitude of effect on anxiety is small to moderate for unscreened or screened out patient samples, but characteristically collapses by late times. The early times benefit is negligible when compared with treated controls, suggesting that for
unscreened or non-complex patients most of the benefit of this therapy can be delivered by placebo or as part of a treatment as usual package. Single studies promise very strong effect for patients distressed at baseline. It may be that effects can be prolonged by combination with CBT, but at cost to early impact.

For treating general distress, moderate effect was shown again for screened out samples, and again regardless of the nature of the comparison group. Unscreened groups received only a small and non-significant benefit, which evaporated against treated controls. Again, there were single studies that suggested strong effects for patients who were distressed at baseline.

Depression is not impacted by relaxation therapy, except, again, where the patient is distressed at baseline. Results for relaxation administered in combination with CBT were also disappointing, except for a moderate effect size in relation to screened (unspecified) patients.

Research is needed to test the early and late effect of relaxation therapies on distressed patients for each of the outcomes.

**CBT**

_Angiety_.

The main effect for CBT on anxiety at early times was small, at 0.18 ($p < 0.05$), and the same at late times (Table 6-1). However, treating these results as if they derived from an homogeneous effect base is misleading as CBT is a therapy moderated by distress screening, as shall be seen.

In Table 0-20 each of the four matrix quadrants is statistically homogeneous around the simple dichotomy of screening level but the two early times quadrants come close to heterogeneity with Q statistic $p$’s of 0.114 for those with untreated controls and 0.107 for those with treated controls. In the latter case the contrast is seen between samples that screened out, which yielded a small effect of 0.23 ($p < 0.05$, $n = 3$), and those that did not screen, at near zero (0.03, n.s., $n = 8$). For the untreated controls, when screening types are broken out the Q statistic $p$ becomes significant, highlighting the strong effect of screening in for distress (combined screened in and screened in and out: 0.85, $p < 0.05$) which is established with four studies.

Note also the extremely high effect yielded by the two studies that screened both ways: 1.34 ($p < 0.05$). Of the half dozen times that there are effect sizes reported for studies that screened both ways simultaneously in this chapter, only one produces an effect size of less than 1.00. Perhaps the combination of the motivation provided by baseline distress coupled with a lack of complex psychological history ideally positions patients for this therapy – or therapy generally. Those two studies that only screened in for distress yielded scores less than half the size at 0.53 ($p < 0.05$) and their upper confidence level does not quite reach the combined distress mean.
Studies that only screened out for history performed modestly but consistently across control types at early times: untreated, 0.17 \( (p < 0.10, n = 7) \); treated, 0.24 \( (p < 0.05, n = 3) \).

N declines sharply at late times. However, the one remaining untreated control study that screened in for distress shows a medium strength statistically significant effect \( (0.52, p < 0.05) \). This is an impressive result against anxiety – or would be, if supported by more n. Also notably, the unscreened effect size in the same quadrant more than doubles to 0.37 \( (n = 3) \), but with broad confidence intervals, it does not reach significance. In the treated control quadrant, the unscreened effect size remains negligible at 0.07 \( (\text{n.s., } n = 5) \). Overall effects for both treated and untreated controls rise slightly at late times \( (\text{treated, from 0.06 to 0.08; untreated, from 0.21, } p < 0.05, n = 18, \text{ to } 0.31, p = 0.147, n = 5) \).

These results provide proof of a moderate or strong early times effect of CBT on anxiety for patients who were distressed at baseline, and a hint that a moderate effect may endure. Unscreened and screened out studies, on the other hand, produce zero to small effects initially, although there is some evidence of pick up over time. Against treated controls there is no effect for unscreened patients - equivalent benefit can be delivered to this subpopulation by placebo or treatment as usual. A small benefit was conveyed to screened out (non-complex) samples. There were no treated control studies that screened in for distress.

**Table 0-20. CBT as a therapy type, anxiety**

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.14 (7)</td>
<td>-0.02 – 0.31</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.21 (18)**</td>
<td>0.08 – 0.35</td>
</tr>
<tr>
<td>Q statistic ( p )</td>
<td>0.114 (0.035**)</td>
<td>0.826 (0.178)</td>
</tr>
<tr>
<td>Treated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Untreated control:

- **Screened in and out**: 1.34 \( (2)** \, 0.21 – 2.46
- **Screened in**: 0.53 \( (2)** \, 0.24 – 0.82
- **Distress combined**: 0.85 \( (4)** \, 0.38 – 1.36
- **Screened out**: 0.17 \( (7)** \, -0.02 – 0.36
- **Screened (combined)**: 0.39 \( (11)** \, 0.13 – 0.64
- **Unscreened**: 0.14 \( (7)** \, -0.02 – 0.31

Treated control:

- **Screened in and out**: -
- **Screened in**: -
Results for three CBT combinations are tabled (Table 0-21). The overall effect for ‘c’ alone is 0.24 ($p < 0.05$, $n = 10$) at early times, rising at late times but with $n$ that is insufficient to give confidence in the result (0.37, $p < 0.05$, $n = 2$). The screened result stands out at both early and late times: 0.38 ($p < 0.05$, $n = 6$) and 0.52 ($p < 0.10$, $n = 1$) respectively.

The combinations of CBT with relaxation and with both relaxation and expressive-support have been discussed already (under relaxation). The findings that screened studies provide the highest results for both and that overall effect sizes are fairly stable over time are consistent with the results for CBT alone. However, none of these results reached statistical significance.

Table 0-21. CBT as therapy combinations, anxiety

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.24 (10)**</td>
<td>0.09 – 0.39</td>
</tr>
<tr>
<td>Overall $p$</td>
<td></td>
<td>0.002**</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.38 (6)**</td>
<td>0.19 – 0.56</td>
</tr>
<tr>
<td>Unscrenned</td>
<td></td>
<td>0.11 (4)</td>
<td>-0.05 – 0.27</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.28 (6)**</td>
<td>0.01 – 0.56</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>0.18 (3)**</td>
<td>0.00 – 0.35</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.36 (6)</td>
<td>-0.16 – 0.87</td>
</tr>
<tr>
<td>Overall $p$</td>
<td></td>
<td>0.172</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.78 (3)</td>
<td>-0.21 – 1.77</td>
</tr>
<tr>
<td>Unscrenned</td>
<td></td>
<td>0.01 (2)</td>
<td>-0.20 – 0.21</td>
</tr>
</tbody>
</table>
Anxiety conclusion for CBT.
CBT is shown to be a therapy for patients who are distressed at baseline. For them it can produce moderate or strong effects against anxiety, and there is some evidence that these effects can last over six months. Effects appear to be heightened by screening out for history as well as in for baseline distress. For unscreened patients no immediate effect is apparent compared with treated controls, although a small effect may emerge over time. Screened out samples may enjoy a small initial effect, which may be lasting and could be seen against treated controls.

Depression.
CBT was designed primarily for depression and produces a comparatively strong early times main effect of 0.28 \((p < 0.05, n = 30)\), but this falls with \(n\) to 0.10 (n.s., \(n = 10\)) at late times (Table 6-1). The figures to watch for, however, are not main effects which average over all studies, but those yielded by samples with baseline distress.

The study design moderator matrix (Table 0-22) presents homogeneity on the screening dichotomy for all quadrants, but heterogeneity when screening is broken out in the two quadrants (both untreated controls) that have samples screened in for distress (early times, Q statistic \(p = 0.092\); late, 0.027). Overall effects are negligible and non-significant for all quadrants except for early times untreated control, where the effect is still small (0.25, \(p < 0.05, n = 17\)).

The early times untreated control quadrant is of great interest because it presents results for three studies that screened in and four that screened both ways. Whilst the confidence intervals for these sub-groups do have an overlap of about 0.30, the mean effect sizes are very different: simultaneously screened samples yield a very high 1.07 \((p < 0.05)\), while studies that merely screened in yield a surprisingly small 0.30 \((p < 0.10)\). Once again the upper confidence interval of the screened in sub-group does not reach the average effect size when its results are combined with the simultaneously screened sub-group. The only one of these studies that survives into late times is a
screened in study, which yields a non-significant and disappointing 0.16. The screened in and out result is so strong that it produces statistical heterogeneity when combined with the screened in result and compared with screened out and unscreened results (Q statistic $p = 0.092$). If the screened in and out confidence intervals are compared with others, it can be seen that 0.05 alpha heterogeneity would be likely against screened out and unscreened studies.

Screened out and unscreened untreated control samples yield negligible and non-significant effect sizes at early times with very similar confidence intervals. The unscreened result remains flat at late times, but the screened out row produces an anomalous very high effect size from its one remaining study.

For treated controls, which have no screened in samples, the effect size for the one screened out study is the same as for the nine unscreened ones: of negligible magnitude but significant at $p < 0.10$. The unscreened result is all that survives through to late times, where it fades further to 0.05 ($n = 5$) and loses all statistical significance.

This set of results would fit the pattern displayed by CBT for anxiety if not for the small untreated control screened in result at early times. That defies explanation. The results from studies that simultaneously screened both ways were predictably very strong however, and all the rest predictably poor.

Table 0-22. CBT as a therapy type, depression

<table>
<thead>
<tr>
<th>Depression</th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>1.07 (4)**</td>
<td>0.30 – 1.85</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>0.30 (3)*</td>
<td>-0.04 – 0.64</td>
<td>0.16 (1)</td>
<td>-0.18 – 0.49</td>
</tr>
<tr>
<td>Distress combined</td>
<td>0.75 (7)**</td>
<td>0.20 – 1.31</td>
<td>0.16 (1)</td>
<td>-0.18 – 0.49</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.07 (6)</td>
<td>-0.25 – 0.38</td>
<td>1.04 (1)**</td>
<td>0.35 – 1.72</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.42 (13)**</td>
<td>0.07 – 0.77</td>
<td>0.54 (2)</td>
<td>-0.31 – 1.40</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.13 (4)</td>
<td>-0.17 – 0.43</td>
<td>0.05 (3)</td>
<td>-0.19 – 0.28</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.25 (17)**</td>
<td>0.03 – 0.48</td>
<td>0.08 (5)</td>
<td>-0.14 – 0.31</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.220 (0.092*)</td>
<td></td>
<td>0.273 (0.027**)</td>
<td></td>
</tr>
<tr>
<td>Treated control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
In Table 0-23 results for the three CBT protocol combinations are presented. By itself, ‘c’ presents the strongest overall effect sizes of any ‘combination’ result in this chapter: 0.50 ($p < 0.05$, $n = 11$), early times; 0.32, ($p = 0.148$, $n = 3$), late times. The screened results, untreated controls, are responsible for these impressive overall effect sizes. Screened studies produce a high 0.71 ($p < 0.05$, $n = 7$) at early times. The late times figure looks promising at 0.54 (but n.s., $n = 2$) but from the previous table it is known to be made up of an anomalously high screened out score, and a poor screened in score. The unscreened early times result is only 0.17 ($p = 0.10$ precisely, $n = 4$).

Once again, the results for rc and rcs have already been discussed (see the section in this chapter on relaxation, depression). Rcs comprises n that is too light to sustain comment, but it is noted that rc produces a small and non-significant early times overall effect (0.17, $n = 7$) that is bolstered by a medium strength result for screened studies of 0.39 ($p < 0.05$, $n = 4$). Unfortunately there are no late times data for screened studies using the rc combination. By comparison, unscreened results are around zero (early, -0.12, $n = 2$; late, 0.04, $n = 4$).

Results for c and for rc both demonstrate moderate to strong early times results for screened patients, but there is little evidence regarding the durability of this effect.

**Table 0-23. CBT as a therapy combination, depression**

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c</td>
<td>Overall</td>
<td>0.50 (11)**</td>
<td>0.20 – 0.80</td>
</tr>
<tr>
<td></td>
<td>Overall p</td>
<td>0.001**</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened</td>
<td>0.71 (7)**</td>
<td>0.20 – 1.21</td>
</tr>
<tr>
<td></td>
<td>Unscreened</td>
<td>0.17 (4)</td>
<td>-0.03 – 0.38</td>
</tr>
<tr>
<td></td>
<td>Untx control</td>
<td>0.60 (8)**</td>
<td>0.15 – 1.05</td>
</tr>
</tbody>
</table>
Depression conclusion for CBT.

In this section, CBT has shown very strong results indeed against depression at early times for patients who were both screened in and out and compared with untreated controls. Unfortunately no late times data were available for this group. Surprisingly, studies that merely screened in produced only a small effect, but n was only three. Compared with treated controls, unscreened studies still produced a small effect size, possibly because the form of treatment received by controls did not convey any significant feature of this very specialised form of therapy.

Distress.

The main effect for CBT on distress outcome at early times was 0.19 (p < 0.05) falling away to nothing after six months (0.05, n.s.)(Table 6-1).

In the study design moderator matrix (Table 0-24), the presence of screened studies draws Q statistic p’s towards heterogeneity in three quadrants. In the untreated control early times quadrant, contrasting effect sizes produce heterogeneity from both the dichotomous comparison (Q statistic p = 0.018) and the screening type breakout (0.013). While there is considerable overlap between the confidence intervals for the screened out category and those for unscreened, there is a small magnitude step up in the effect size. Screening out makes a much bigger difference to effect size when
combined with screening in (1.08, \( p < 0.05 \), \( n = 2 \) compared with 0.45, \( p < 0.05 \), \( n = 3 \)) but the lower confidence interval reaches down to much the same level for both subgroups. Once again, when these two groups are merged the combined effect size is higher than the upper confidence level produced by screening in alone. The negligible overall effect for this quadrant (0.14, \( p < 0.05 \)) is rendered meaningless in the light of such dramatic differences caused by screening.

At late times there is a disappointing loss of data from untreated control screened groups, with only one screened in study surviving to produce an effect reduced from moderate to small (0.28, \( p < 0.10 \)). The unscreened effect size remains zero (0.01, \( n = 4 \)).

For treated controls there are no screened in studies. Screening out results in higher scores (0.32, \( p < 0.05 \), \( n = 2 \)) than no screening (0.12, \( p = 0.150 \), \( n = 7 \)), but the difference is not statistically significant (Q statistic \( p = 0.232 \)). There are no late times data.

Once again the matricised data has shown that CBT is sensitive to screening, particularly screening in, and most strongly to screening both ways.

<table>
<thead>
<tr>
<th>Distress</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>1.08 (2)**</td>
<td>0.21 – 1.95</td>
</tr>
<tr>
<td>Screened in</td>
<td>0.45 (3)**</td>
<td>0.18 – 0.73</td>
</tr>
<tr>
<td>Distress combined</td>
<td>0.74 (5)**</td>
<td>0.28 – 1.20</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.19 (7)*</td>
<td>-0.02 – 0.40</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.40 (12)**</td>
<td>0.14 – 0.67</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.02 (6)</td>
<td>-0.16 – 0.20</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.14 (18)**</td>
<td>-0.01 – 0.29</td>
</tr>
<tr>
<td>Q statistic ( p )</td>
<td>0.018** (0.013**)</td>
<td>0170 (0.170)</td>
</tr>
<tr>
<td>Treated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.32 (2)**</td>
<td>0.03 – 0.62</td>
</tr>
</tbody>
</table>
The impact of screening is clear again from the results for CBT alone (c) in Table 0-25. Most of the moderate overall effect size of 0.42 ($p < 0.05, n = 8$) is produced by a disproportionate number of screened studies (0.57, $p < 0.05, n = 6$), with unscreened studies again producing no effect at all (0.01, $n = 2$). The nature of the control group also appears to make a big difference, though low $n$ in the treated group makes that result unreliable (untreated, 0.64, $p < 0.05, n = 5$; treated, 0.15, n.s., $n = 2$). There is only one study at late times.

The results for ‘rc’ and ‘rcs’ combinations have been commented on previously (under relaxation). The impact of screening is again apparent in the rc combination where there is some variance in results (early times: rc, screened, 0.41, $p < 0.10, n = 3$; unscreened, -0.12, $n = 2$). The particularly unsuccessful rcs combination produces results too flat to provide any insight into the impact of confounds (overall effect, -0.02, with no confound effect size exceeding 0.09), but results may be adversely impacted by fewer screened and untreated control studies and also by the possibility of confounding by an unseen substantive co-variate.

In sum, CBT administered on its own or with relaxation to screened patients produces moderate magnitude effects at early times.

Table 0-25. CBT as therapy combinations, distress

| Therapy combination | Confound breakout | Early times | | Late times | |
|---------------------|-------------------|-------------|--------------|-------------|
|                     |                   | ES (n)      | 95% CI's     | ES (n)      | 95% CI's     |
| Overall c           |                   | 0.42 (8)**  | 0.11 – 0.72  | 0.28 (1)    | -0.07 – 0.63 |
| Overall p           |                   | 0.008**     |              | 0.115       |              |
| Screened            |                   | 0.57 (6)**  | 0.22 – 0.93  | -           | -           |
| Unscreened          |                   | 0.01 (2)    | -0.22 – 0.24 | 0.28 (1)    | -0.07 – 0.63 |
| Untx control        |                   | 0.64 (5)**  | 0.22 – 1.06  | 0.28 (1)    | -0.07 – 0.63 |
| Tx control          |                   | 0.15 (2)    | -0.07 – 0.38 | -           | -           |
| Overall rc          |                   | 0.15 (5)    | -0.21 – 0.52 | -0.06 (2)   | -0.26 – 0.14 |
Distress conclusion for CBT.
The conclusion for CBT in relation to distress as an outcome is that screening makes all the difference, producing moderate effects for patients distressed at baseline, and very strong effects for patients who also lack a background of psychological distress. CBT also seems to work well as a combination with relaxation.

**CBT Conclusion.**

CBT produced moderate to strong effects against anxiety and distress and a small effect against depression at early times for patients who were distressed at baseline, with very strong scores (but from low n) for those who were simultaneously screened out for psychological history. The poorer result for screened in depressed patients may also be a result of low n. However it could be that patients need to have a certain amount of psychological strength to derive most benefit from CBT, which is a demanding therapy, and that explains the higher results for the samples that screened both ways (refer to the further discussion of this in the patient characteristics result chapter, simultaneous screening).

Patient samples that were simply screened out produced effect sizes in the small range, with retention of effect but on low n.

Sadly, there were sparse data for either screened group at late times, but hints that some effect was retained, and possibly a moderate effect where screened patients (unspecified type) are administered CBT alone. It is speculated that much of the benefit felt by
screened in patients would remain when compared with treated controls, and would endure over six months, but this can only be speculation in the absence of data, and may occur only in the absence of psychological complexity.

Unscreened patients derive virtually no benefit from CBT. CBT offered alone or in combination with relaxation performs well for screened patients. Predictably, CBT alone is stronger against depression, and with relaxation is stronger against anxiety. The combination with relaxation and expressive-support produces consistently dismal results which raise a question as to cause. Could there be something counterproductively conflictual about running directive (behavioural and cognitive) and non-directive (expressive-supportive) therapies together? More likely these results are the result of confounding by sample characteristics since the comprehensive therapy packages are often administered in large n studies of early stage breast cancer patients, who – we shall see - produce lower effects.

Expressive-support

Anxiety.
The main effects for expressive-supportive therapies on anxiety were 0.23 (p < 0.05) at early times, falling slightly to 0.20 (p < 0.05) at late times (Table 6-1).

The table below (Table 0-26) shows a fairly even spread of frequency between treated control (11) and untreated control (13) early times quadrants. The overall effect sizes show that all of the early times benefit of this therapy accrued against untreated controls (0.27, p < 0.05 v. treated controls, -0.04, n.s.). At late times, however, the situation reversed, with the treated control comparison rising to produce a statistically significant small effect (0.19, p < 0.05) and the untreated comparison slipping, though with greatly reduced n, to a non-significant negligible effect size (0.12, n = 4).

At early times, despite the null overall result for treated controls, there were three studies that screened out for psychological history which produced a mean effect size that was, surprisingly, very high (1.04, p < 0.05) and heterogeneous (Q statistic p < 0.05) from the negative unscreened result (-0.11, n.s.). The trend was different for untreated controls at early times. Both screened out and unscreened scores were small (0.18, n.s., n = 4; 0.21, p < 0.10, n = 7, respectively) with confidence intervals that greatly overlap. This strange pattern, whereby heterogeneity is produced by high scoring screened out studies against treated controls while the opposite trend (though non-significant) is seen against untreated controls, was seen also in relation to education but is unexplained.

Two early times untreated control studies that screened in for distress produced a very high effect size (1.13, p < 0.05) and statistical heterogeneity against screened out and unscreened studies which produced only small effect sizes.
At late times, unscreened studies effect sizes rise a little in relation to both control types (untreated, from 0.21, $p < 0.10$, to 0.36, but losing significance and $n$ only 3; treated, from -0.04 to 0.18, $p < 0.05$). Data were too sparse to allow comment on screened subgroups.

In both late times quadrants $n$ is too small for screened samples to allow comparison with unscreened samples.

Against untreated controls unscreened samples and those that screened out produced small effects, while distress screening produced very high effect sizes which were also significantly higher. This effect size (1.13, $p < 0.05$, but $n$ only 2) considerably exceeds that produced by CBT studies in the same row of the matrix (0.53, $p < 0.05$, but $n$ only 2, Table 0-20).

At late times, unscreened results rise to produce a small effect from samples with treated controls and a non-significant small to moderate effect against untreated controls. A curious cross-over is seen in the screened out rows, whereby the treated control studies produce a very high effect size while the untreateds produce a low effect. There is unfortunately a lack of data for all screened groups at late times.

In sum, for unscreened samples the treated control results showed that expressive-supportive therapies have nothing to offer over placebo or treatment as usual at early times, but a small benefit accrues by late times. There was an unexplained very strong early times result from samples that screened out for history, and an understandable very strong result from samples that screened in for baseline distress. The latter was evidenced by only two studies, but demonstrates the potential of the therapy for distressed patients.

Table 0-26. Expressive-supportive as a therapy type, anxiety

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n) 95% CI's</td>
<td>ES (n) 95% CI's</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untreated control</td>
<td>Screened in and out</td>
<td>- -</td>
<td>- -</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened in</td>
<td>1.13 (2)** 0.62 – 1.64</td>
<td>- -</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distress combined</td>
<td>1.13 (2)** 0.62 – 1.64</td>
<td>- -</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened out</td>
<td>0.18 (4) -0.12 – 0.48</td>
<td>-0.02 (1) -0.49 – 0.44</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened (combined)</td>
<td>0.47 (6)** 0.06 – 0.89</td>
<td>-0.02 (1) -0.49 – 0.44</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unscreened</td>
<td>0.21 (7)* -0.02 – 0.43</td>
<td>0.36 (3) -0.24 – 0.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Overall effect</td>
<td>0.27 (13)** 0.07 – 0.46</td>
<td>0.12 (4) -0.25 – 0.49</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results for specific therapy combinations that include expressive support are detailed in Table 0-27. The overall effect for the pure therapy ('s') is moderate (0.49, $p < 0.05$, n = 5) at early times and holds fairly well to produce a small to moderate effect at late times (0.35, $p < 0.05$, n only 3). Both early and late times overall results are heterogeneous. From very low n, much higher effects are produced by screened studies and untreated controls at early times. Unscreened studies and those with treated controls perform very poorly at early times but pick up at late times to produce small to moderate effect sizes – though also from very low n.

The generally poor effects from combinations of expressive-support with education ('es') and with both relaxation and CBT ('rcs') have been described earlier. It was noted that they may result from confounding with sample characteristics.

On the available ‘therapy combination’ evidence, which is sparse for es and rcs combinations, expressive-supportive therapy delivered alone appears by far the better option against anxiety, producing effect sizes that can be very strong for screened patients and against untreated controls at early times. Results are null from samples with treated controls and for unscreened patients at early times, but pick up to small magnitude over time. Unfortunately there is insufficient n at late times to judge whether screened or untreated control studies retain their effects. The screened results are promising, as are the suggestions that expressive-support is capable of maintaining or even picking up effect against anxiety over time.

Table 0-27. Expressive-supportive as therapy combinations, anxiety

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Confound breakout</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>1.04 (3)**</td>
<td>0.03 – 2.06</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>1.04 (3)**</td>
<td>0.03 – 2.06</td>
</tr>
<tr>
<td>Unscreened</td>
<td>-0.11 (8)</td>
<td>-0.38 – 0.15</td>
</tr>
<tr>
<td>Overall effect</td>
<td>-0.04 (11)</td>
<td>-0.29 – 0.22</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.030** (0.30**)</td>
<td>0.535 (0.535)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>Overall p</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
<td>0.49 (5)**</td>
<td>0.044**</td>
</tr>
<tr>
<td></td>
<td>0.01 – 0.96</td>
<td>0.022**</td>
</tr>
<tr>
<td></td>
<td>0.35 (3)**</td>
<td>0.35 (3)**</td>
</tr>
<tr>
<td></td>
<td>0.05 – 0.64</td>
<td>0.05 – 0.64</td>
</tr>
<tr>
<td></td>
<td>0.35 (3)**</td>
<td>0.35 (3)**</td>
</tr>
<tr>
<td></td>
<td>0.05 – 0.64</td>
<td>0.05 – 0.64</td>
</tr>
</tbody>
</table>

Anxiety conclusion for expressive-supportive. Expressive-supportive therapies show very strong potential against anxiety for distress screened patients, though more data are needed to confirm this. Non-complex (screened out) and unscreened patients yield small early effects – null against treated controls – but there may be some lift over time. The curious phenomenon of an inflated early times screened out score for treated controls, as has been seen for education is seen again, but late times data are insufficient to judge how this might follow through. The available evidence, which may be confounded in relation to therapies that package expressive-support with other therapies, shows that the therapy performs much better when delivered alone.

*Depression.*
Main effects for expressive-support as a therapy type against depression are very poor and do not reach statistical significance at either early (0.13) or late times (0.08)(Table 6-1), but do the structural confounds or distress screening produce any more promising effects?

In the Table 0-28 matrix, the early times overall result for untreated control studies is of small to moderate magnitude (0.30, $p < 0.10$) but there is only one study for untreated controls at late times. Both overall effects against treated controls are negligible and non-significant.

All quadrants of the matrix are statistically homogeneous on the comparison of screened with unscreened rows except treated control, early times, where once again the peculiar phenomenon of a very high scoring screened out study crops up ($1.21, p < 0.05$, Q statistic $p < 0.05$ against unscreened, $-0.01, n = 13$) and counters the trend of results in the untreated control quadrant (screened out, $-0.08, n = 3$; unscreened, 0.27, $n = 3$, both n.s.). Heterogeneity is also found in the breakout of screening types, untreated controls, early times ($Q$ statistic $p < 0.05$), due to the very high effect size generated by two screened in studies ($1.03, p < 0.05$). This result contrasts with the screened out score in the same quadrant already mentioned ($-0.08$), and a small to moderate effect size for unscreened studies ($0.27, p = 0.173$). It also, once again, contrasts with the smallish CBT score for screened in untreated controls ($0.30, p < 0.10, n = 3$, Table 0-22).

The treated control unscreened result is well supported by n at early times (13) which it retains fairly well into late times (8), so should be fairly reliable. It shows that expressive-supportive therapy adds no value to placebo or treatment as usual against depression for unscreened patients at early or late times.

In summary, these results follow the pattern laid down by the anxiety results, although n for all breakout rows in the untreated half of the table is light: distressed patients produce strong results but there is no incremental value over treated control for unscreened patients.

Table 0-28. Expressive-supportive as a therapy type, depression

<table>
<thead>
<tr>
<th>Depression</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>1.03 (2)**</td>
<td>0.55 – 1.51</td>
</tr>
<tr>
<td>Distress combined</td>
<td>1.03 (2)**</td>
<td>0.55 – 1.51</td>
</tr>
<tr>
<td>Screened out</td>
<td>-0.08 (3)</td>
<td>-0.38 – 0.23</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.36 (5)</td>
<td>-0.17 – 0.89</td>
</tr>
</tbody>
</table>
In Table 0-29 expressive-support in is pure form is seen to outstrip combinations with education and with relaxation and CBT once again, at early times: main effects are 0.30, \( p < 0.10 \); 0.06, n.s.; and 0.10, n.s., respectively (but n for the rcs combination is only 3). For ‘s’at early times, the pattern of high scores for screened and untreated controls (0.77, \( p < 0.05 \), in both cases) and very low scores for unscreened and treated control studies (0.05, in both cases) is repeated, and n is again too light for comment at late times.

There is generally insufficient n to sustain comment on the confound breakout data from therapy combinations with expressive-supportive, but for es, unscreened, early times (n = 5), the results are very poor.

In sum, this is not an encouraging set of results, except for the scores produced by this therapy in its pure form for screened patients against untreated controls at early times.

Table 0-29. Expressive-supportive as therapy combinations, depression

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>s</td>
<td>Overall</td>
<td>0.30 (6)*</td>
<td>-0.02 – 0.63</td>
</tr>
<tr>
<td></td>
<td>Overall ( p )</td>
<td>0.070*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened</td>
<td>0.77 (3)**</td>
<td>0.21 – 1.32</td>
</tr>
<tr>
<td></td>
<td>Unscreened</td>
<td>Untx control</td>
<td>Tx control</td>
</tr>
<tr>
<td>----------------</td>
<td>------------</td>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td>0.05 (3)</td>
<td>0.77 (3)**</td>
<td>0.05 (3)</td>
</tr>
<tr>
<td></td>
<td>-0.14 – 0.23</td>
<td>0.21 – 1.32</td>
<td>-0.14 – 0.23</td>
</tr>
<tr>
<td></td>
<td>0.09 (2)</td>
<td>-</td>
<td>0.10 (2)</td>
</tr>
<tr>
<td></td>
<td>-0.14 – 0.33</td>
<td>-</td>
<td>-0.15 – 0.35</td>
</tr>
</tbody>
</table>

Overall $p$ 0.788 0.433

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
<th>Untx control</th>
<th>Tx control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.21 (1)**</td>
<td>-0.13 (5)</td>
<td>0.54 (1)**</td>
<td>-0.03 (5)</td>
</tr>
<tr>
<td></td>
<td>0.55 – 1.87</td>
<td>-0.50 – 0.24</td>
<td>0.03 – 1.06</td>
<td>-0.53 – 0.47</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>0.10 (2)</td>
<td>-</td>
<td>0.10 (2)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>-0.15 – 0.35</td>
<td>-</td>
<td>-0.15 – 0.35</td>
</tr>
</tbody>
</table>

Overall $p$ 0.636 0.549

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
<th>Untx control</th>
<th>Tx control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.10 (1)</td>
<td>0.21 (2)</td>
<td>-0.10 (1)</td>
<td>0.21 (2)</td>
</tr>
<tr>
<td></td>
<td>-0.55 – 0.35</td>
<td>-0.47 – 0.88</td>
<td>-0.55 – 0.35</td>
<td>-0.47 – 0.88</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>0.20 (2)</td>
<td>-</td>
<td>0.20 (2)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>-0.46 – 0.87</td>
<td>-</td>
<td>-0.46 – 0.87</td>
</tr>
</tbody>
</table>

Depression conclusion for expressive-supportive.
Expressive-supportive therapy appears to offer nothing to unscreened patients over what is available through treatment as usual or placebo in the short term, and a negligible non-significant benefit after six months. However, for patients presenting with distress at baseline there may be great value, but there are no late times data and n is light at early times. For non complex patients, the picture is once again confusing, with conflicting trends emerging between treated and untreated control subgroups.

Distress.
The main effect of expressive-supportive therapy (inclusively defined) on the distress outcome at early times is mid-way between those for anxiety and for depression, at a small but significant 0.18, falling away to 0.07 (n.s.) at late times (Table 6-1).

Table 0-30 displays the breakout matrix. N is similar for treated (11) and untreated controls (10). Untreated results are heterogeneous around screening in (Q statistic $p = 0.014$) where two studies produce a very high effect of 1.09 ($p < 0.05$) contrasting with the negligible to small effect for screened out studies (0.16, n.s., n = 3) but a better result for unscreened studies (0.40, $p = 103$, n = 5). This unscreened result retains some
strength along with most of its n at late times (0.28, n.s., n = 4). However, overlapping confidence intervals render the unscreened category homogeneous with screened out, so the correct early times figure will be an average of these, and closer to small than moderate magnitude. Once again, the effect size of 1.09 for screened in untreated controls is very much higher than the comparable CBT score of 0.45 (p < 0.05, n = 3, Table 0-24).

For treated controls, n is grouped in the unscreened category leaving no data for screened breakouts. This unscreened result is zero (-0.02) at early times but follows the trend characteristic of this therapy over time and lifts very slightly to a negligible and non-significant 0.07 at late times.

In sum, expressive-supportive therapy has a moderate absolute value against the general distress outcome for unscreened patients at early times as shown by the untreated result, but offers nothing to them compared with a treated control. However, baseline distress shows potential for very strong effect.

Table 0-30. Expressive-supportive as a therapy type, distress

<table>
<thead>
<tr>
<th>Distress</th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Untreated control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screened in and out</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened in</td>
<td>1.09 (2)**</td>
<td>0.60 – 1.57</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distress combined</td>
<td>1.09 (2)**</td>
<td>0.60 – 1.57</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Screened out</td>
<td>0.16 (3)</td>
<td>-0.26 – 0.57</td>
<td>0.12 (1)</td>
<td>-0.48 – 0.72</td>
</tr>
<tr>
<td>Screened (combined)</td>
<td>0.52 (5)**</td>
<td>0.01 – 1.02</td>
<td>0.12 (1)</td>
<td>-0.48 – 0.72</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.40 (5)</td>
<td>-0.08 – 0.88</td>
<td>0.28 (4)</td>
<td>-0.24 – 0.79</td>
</tr>
<tr>
<td>Overall effect</td>
<td>0.46 (10)**</td>
<td>0.11 – 0.80</td>
<td>0.21 (5)</td>
<td>-0.18 – 0.60</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.746 (0.014**)(0.703)</td>
<td>0.703 (0.703)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 0-31 displays the familiar pattern of ‘s’ alone producing the better overall effects compared to combinations with education, and relaxation and CBT. The early times main effect is a moderate 0.45 ($p = 0.052$, $n = 6$), falling to a negligible 0.07 (n.s., $n = 3$) at late times, compared with a negative early times effect for both of the combinations (es, -0.09, $n = 6$, and rcs, -0.02, $n=5$, both n.s.), which rises a little over time only in the case of rcs (0.21, n.s., n only 2).

The spread of $n$ across confounds permits some comment on each combination. At early times, unscreened patients receive a small and non significant benefit from ‘s’ (0.17, $n = 4$) but no benefit from the other combinations. For s this effect withers at late times and for the others it picks up slightly, but n is low.

Untreated controls show strong effects for s (1.07, $p < 0.05$, $n = 3$), but this is likely the result of distress screening (screened, 1.09, $p < 0.05$, $n = 2$) and there are no follow-up data. There is insufficient n to comment on the other therapy combinations.

The conclusion is much the same as that arrived at above – screening can make a difference, and there can be value against untreated controls. Against treated controls this therapy appears to offer little if anything, but no screened studies were available.

### Table 0-31. Expressive-supportive as therapy combinations, distress

<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>s</td>
<td>Overall</td>
<td>0.45 (6)*</td>
<td>0.00 – 0.90</td>
</tr>
<tr>
<td></td>
<td>Overall p</td>
<td>0.052*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened</td>
<td>1.09 (2)**</td>
<td>0.60 – 1.57</td>
</tr>
<tr>
<td></td>
<td>Unscrened</td>
<td>0.17 (4)</td>
<td>-0.25 – 0.60</td>
</tr>
<tr>
<td></td>
<td>Untx control</td>
<td>1.07 (3)**</td>
<td>0.70 – 1.45</td>
</tr>
<tr>
<td></td>
<td>Tx control</td>
<td>0.05 (2)</td>
<td>-0.20 – 0.30</td>
</tr>
<tr>
<td>es</td>
<td>Overall</td>
<td>-0.09 (6)</td>
<td>-0.34 – 0.16</td>
</tr>
<tr>
<td></td>
<td>Overall p</td>
<td>0.496</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Screened</td>
<td>-0.42 (1)</td>
<td>-1.10 – 0.25</td>
</tr>
</tbody>
</table>
Distress conclusion for expressive-supportive.
Once again results indicate that expressive-supportive therapy provides no incremental benefit over placebo or treatment as usual. That is not to say that there is no absolute value in the therapy in reducing distress for this group, but that is shown by the untreated control figures to be small to moderate and to fade further at late times. The group that has shown real gain from this therapy are those screened in for distress, producing very high results but once again from low n and without follow-up data.

Expressive-support conclusion.
In sum, the results suggest that expressive-supportive therapies can be a powerful tool against depression, anxiety and distress, particularly the latter two, for patients with baseline distress – more powerful than CBT. However, n is light and there are no late times data on these very strong effects. For unscreened patients there is some absolute benefit, but no incremental benefit over placebo or usual care. Screened out results are conflicting and perplexing, but also light on n, and there is some evidence of effects firming over time. More long term assessments and distress screened studies are needed.

Non-professional
No main effect for this therapy type reached statistical significance (Table 6-1 and Table 0-32). However, n was low.

Because of the low study frequencies, the inclusively defined therapy type data (Table 0-32) are presented in the same format as for the exclusively defined therapy combinations (Table 0-33). Note also that the former category includes studies that integrated a non-professional (usually a peer/survivor) component with an otherwise professionally delivered package. The exclusive ‘combination’ data, on the other hand, derive from protocols administered entirely by non-professionals. ‘Non-professionals’
were volunteers who may or may not have had some training in counselling and may have been cancer survivors.

**Table 0-32. Non-professional as a therapy type, all outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Early times</th>
<th></th>
<th>Late times</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type overall</td>
<td>0.39 (4)</td>
<td>-0.37 – 1.16</td>
<td>-0.19 (3)</td>
<td>-0.45 – 0.08</td>
</tr>
<tr>
<td>Overall p</td>
<td>0.314</td>
<td></td>
<td>0.161</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td>0.66 (3)</td>
<td>-0.46 – 1.78</td>
<td>-0.21 (1)</td>
<td>-0.59 – 0.17</td>
</tr>
<tr>
<td>Unscreened</td>
<td>-0.25 (1)</td>
<td>-0.72 – 0.21</td>
<td>-0.17 (2)</td>
<td>-0.54 – 0.20</td>
</tr>
<tr>
<td>Untx control</td>
<td>0.09 (2)</td>
<td>-0.62 – 0.81</td>
<td>-0.14 (1)</td>
<td>-0.60 – 0.31</td>
</tr>
<tr>
<td>Tx control</td>
<td>0.80 (2)</td>
<td>-1.37 – 2.97</td>
<td>-0.21 (2)</td>
<td>-0.54 – 0.11</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type overall</td>
<td>0.27 (4)</td>
<td>-0.16 – 0.69</td>
<td>-0.07 (2)</td>
<td>-0.40 – 0.25</td>
</tr>
<tr>
<td>Overall p</td>
<td>0.220</td>
<td></td>
<td>0.665</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td>0.27 (2)</td>
<td>-0.30 – 0.85</td>
<td>0.00 (1)</td>
<td>-0.38 – 0.38</td>
</tr>
<tr>
<td>Unscreened</td>
<td>0.36 (2)</td>
<td>-0.70 – 1.42</td>
<td>-0.26 (1)</td>
<td>-0.88 – 0.36</td>
</tr>
<tr>
<td>Untx control</td>
<td>0.69 (2)*</td>
<td>0.30 – 1.09</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tx control</td>
<td>-0.09 (2)</td>
<td>-0.29 – 0.12</td>
<td>-0.07 (2)</td>
<td>-0.40 – 0.25</td>
</tr>
<tr>
<td><strong>Distress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type overall</td>
<td>-0.03 (7)</td>
<td>-0.19 – 0.13</td>
<td>-0.11 (5)</td>
<td>-0.34 – 0.12</td>
</tr>
<tr>
<td>Overall p</td>
<td>0.724</td>
<td></td>
<td>0.360</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td>-0.05 (3)</td>
<td>-0.35 – 0.25</td>
<td>-0.12 (2)</td>
<td>-0.45 – 0.22</td>
</tr>
<tr>
<td>Unscreened</td>
<td>-0.02 (4)</td>
<td>-0.22 – 0.17</td>
<td>-0.12 (3)</td>
<td>-0.49 – 0.25</td>
</tr>
<tr>
<td>Untx control</td>
<td>0.07 (4)</td>
<td>-0.22 – 0.37</td>
<td>-0.04 (2)</td>
<td>-0.54 – 0.45</td>
</tr>
<tr>
<td>Tx control</td>
<td>-0.07 (3)</td>
<td>-0.27 – 0.12</td>
<td>-0.17 (3)</td>
<td>-0.46 – 0.13</td>
</tr>
</tbody>
</table>

**Table 0-33. Non-professional as therapy combinations, all outcomes**
<table>
<thead>
<tr>
<th>Therapy combination</th>
<th>Confound breakout</th>
<th>Early times</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ES (n)</td>
<td>95% CI's</td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>-0.25 (1)</td>
<td>-0.61 – 0.11</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.177</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>-0.25 (1)</td>
<td>-0.61 – 0.11</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>-0.25 (1)</td>
<td>-0.61 – 0.11</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>0.27 (4)</td>
<td>-0.16 – 0.69</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.220</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.27 (2)</td>
<td>-0.30 – 0.85</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>0.36 (2)</td>
<td>-0.70 – 1.42</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>0.69 (2)**</td>
<td>0.30 – 1.09</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>-0.09 (2)</td>
<td>-0.29 – 0.12</td>
</tr>
<tr>
<td>Distress</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>-0.05 (5)</td>
<td>-0.22 – 0.13</td>
</tr>
<tr>
<td>Overall p</td>
<td></td>
<td>0.618</td>
<td></td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td>0.06 (2)</td>
<td>-0.25 – 0.38</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td>-0.10 (3)</td>
<td>-0.31 – 0.12</td>
</tr>
<tr>
<td>Untx control</td>
<td></td>
<td>-0.06 (2)</td>
<td>-0.50 – 0.37</td>
</tr>
<tr>
<td>Tx control</td>
<td></td>
<td>-0.04 (3)</td>
<td>-0.24 – 0.15</td>
</tr>
</tbody>
</table>

Study frequencies justify only a general comment on the data displayed in the tables. This is the poorest set of effect sizes reported by therapy type, but is supported by small n. Note that the depression early times data appear to be derived from the same studies in both tables, meaning that the depression results were derived only from interventions.
delivered by purely non-professionals, while anxiety and distress results derive from interventions delivered by a mixture of professionals and non-professionals.

In their pure form non-professional interventions (‘n’ in Table 0-33) are not effective against anxiety or distress. However, they display a small though non-significant impact on depression (0.27, n = 4, early times, both tables), and samples with untreated controls produced a statistically significant moderate to high magnitude effect (0.69, p < 0.05, n is only 2).

Other scores for depression in the table of inclusively defined results (Table 0-32) are non-significant and based on low n. The screened and treated control results for anxiety on that table show potential (early times, screened, 0.66, n = 3, and treated control, 0.80, n = 2, both n.s.). For distress, n is higher but scores are all close to zero.

Other therapies
There were five studies that could not fairly be lumped in under any of the previous therapy type heads. Descriptive details and outcomes are presented in Table 0-34, below.

Three of these studies related to written emotional expression. One provided a small but durable effect (Hughes, 2006, 0.31, p < 0.05); the others, nothing. None of these studies screened for distress.

An additional finding by Zakowski, Ramati, Morton, Johnson, and Flanigan (2004) was that social constraint at home (lack of the social support required to talk matters through) resulted in greater effect. The importance of meeting deficit is a theme that recurs throughout the results chapters of the present study, and perhaps written emotional expression could be used to effect and with efficiency for patients that lack quality social support at home.

The other two studies were each quite different from any others. Treating a specific physical side–effect for prostate patients, in combination with expressive-support, is an idea worth remembering in relation to men, who are typically difficult to reach, but produced a very small effect in the case of Zhang, Strauss, and Siminoff (2006). And finally, the Ho (2007) study brought a Chinese spiritual approach to cancer adjustment. Effects were moderately strong at medium term (0.63, p < 0.05, for distress), but faded away after six months. They may have been more impressive with a diagnostic group other than early stage breast cancer patients (refer medical characteristic results).

Existential expressive-supportive therapies show considerable potential in the therapy components analysis of this paper, and deserve more attention. Again, neither study screened for distress, and results may have been stronger if they had.

Table 0-34. Other therapies, descriptive information

<table>
<thead>
<tr>
<th>Study name and ES (study n), assessment</th>
<th>Descriptive notes</th>
</tr>
</thead>
</table>

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### Written emotional expression studies

<table>
<thead>
<tr>
<th>Confound codes</th>
<th>Point, outcome construct</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hughes (2006), Unsc/untx</td>
<td>0.31** (177) im, distress</td>
<td>Early stage breast cancer patients. Writing was for 30min/day x 3 consecutive days. The effect was stable over six months.</td>
</tr>
<tr>
<td>Walker, Nail, &amp; Croyle (1999), Unsc/Tx</td>
<td>0.01 (26) st anxiety</td>
<td>Early stage breast cancer patients, completing radio therapy. Writing was for 3 x 30min sessions over 3 or 4 days. Effects diminished into negatives over six months.</td>
</tr>
<tr>
<td>Zakowski et al., (2004), Sc.out/Tx</td>
<td>-0.14 (104) mt anxiety</td>
<td>Prostate and gynaecological patients at a variety of stages. Writing was for 20min/day x 3 consecutive days.</td>
</tr>
<tr>
<td></td>
<td>-0.03 (104) mt distress</td>
<td></td>
</tr>
</tbody>
</table>

### Miscellaneous others

<table>
<thead>
<tr>
<th>Confound codes</th>
<th>Point, outcome construct</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhang et al. (2006), Unsc/Tx</td>
<td>0.13 (29) im anxiety</td>
<td>Prostatectomy group learned pelvic floor muscle exercises using biofeedback, and with support group discussion and compliance monitoring. Six sessions.</td>
</tr>
<tr>
<td></td>
<td>0.17 (27) im depression</td>
<td></td>
</tr>
<tr>
<td>Ho (2007), Sc.out/Untx</td>
<td>0.63** (44) mt, distress</td>
<td>This ‘body mind and spirit’ group (‘os’ therapy combination) was one arm of a four arm trial in Hong Kong for early stage breast cancer patients. The other arms were expressive support, a non-professionally run support group, and untreated control. The group aimed to normalise the traumatic experience of cancer, assisting patients to accept the unpredictability of life, to forgive others, love themselves, and find satisfaction in helping others according to Chinese philosophy (therapy by C. Chan et al. 2001). The moderate effect size dropped to 0.12 n.s. at long term.</td>
</tr>
</tbody>
</table>

Assessment point codes: im = immediately after intervention; st = short term follow up, i.e. up to one month after intervention, but not immediately after; mt = medium term, i.e. 1 – 6 months after intervention.

Confound codes: screening status is presented first, then the nature of the control group after the slash: Unclear = screening status was unclear in the report; Unsc = unscreened; Sc.out = screened out for
Therapy delivery mode, dose and therapist variables

Delivery mode variables
To what extent therapy delivery mode variables impact effectiveness is considered in this section. Aspects of delivery mode are the therapy recipient, the type of technology used to deliver the therapy, and the physical setting in which it was delivered. Omnibus outcomes are used in order to muster as much n as possible, using untreated control data unless otherwise specified, and at early times.

Therapy recipient.
The therapy recipient categories were: 1. Individual patients; 2. Individual patients accompanied by a significant other; 3. Group of patients; and 4. Group of patients with their significant others. Significant others were most commonly spouses. Results are set out in Table 0-35.

For both screened and unscreened patients, therapy delivered individually produced the higher effect sizes (screened, 0.62, $p < 0.05$; unscreened 0.37, $p < 0.05$) than that delivered with a significant other (screened, 0.34, $p < 0.05$; unscreened 0.25, $p = 0.12$) or in group mode (screened, 0.37, $p < 0.05$; unscreened 0.27, $p < 0.05$). In neither case was the difference confirmed by statistical significance, though the trend was evident in both columns. In the case of unscreened patients, the negligible difference between individual and group delivery modes suggests that for the sake of efficiency, group delivery could be acceptable.

Table 0-35. Therapy recipient

<table>
<thead>
<tr>
<th>Therapy recipient</th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Individual patient</td>
<td>0.62 (15)**</td>
<td>0.37 (16)**</td>
</tr>
<tr>
<td>Patient and spouse (or significant other)</td>
<td>0.34 (3)**</td>
<td>0.25 (5)</td>
</tr>
<tr>
<td>Group of patients</td>
<td>0.37 (9)**</td>
<td>0.27 (8)**</td>
</tr>
<tr>
<td>Group of patients and significant others</td>
<td>-</td>
<td>-0.06 (1)</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.270</td>
<td>0.295</td>
</tr>
</tbody>
</table>

Omnibus outcome effect sizes are reported, using untreated control data at early times.

ES = Hedges g effect size point estimate; n = number of studies in subset; * statistically significant at $p <$
Interventions can also be delivered indirectly, through a third party. Indirect therapies can be very effective, and hold promise of delivery efficiencies to unscreened populations as part of usual care as well providing a means of benefiting individuals who for reasons relating to their medical condition or socio-demographic status may be difficult to reach directly. As mentioned above, they are discussed in some detail in the therapy types results chapter.

**Delivery technology.**

Studies were coded for the means by which therapy was conveyed to the patient: 1. In person; 2. By telephone; 3. By some other interactive technology (personal letter, email or interactive web site); or, 4. By non-interactive technology (i.e. by means that do not involve patient / therapist interaction, including printed material, video or audio recording, non-interactive web site, or snoezelen environment). The results are set out in Table 0-36.

Effect sizes do not show any statistically significant difference between the different delivery technologies (Q statistic $p = 0.697$, screened; 0.620, unscreened). They also show surprisingly strong results for non interactive technologies (screened, 0.67, $p < 0.10$ but n is only one; unscreened, 0.44, $p = 0.117$, n = 6), which compete with the outcomes from personal delivery (screened, 0.52, $p < 0.05$; unscreened, 0.31, $p < 0.05$). This suggests an efficient means for conveying those types of therapy that lend themselves to written or recorded technology, which, again, may be particularly useful for patients in vulnerable socio-demographic groups who are difficult to reach. However, the non-interactive result, though of moderate strength, was non-significant, indicating that confidence intervals are very broad. This means that there is a wide individual difference in how interventions delivered by this means are received, and many patients will need interaction.

Table 0-36. Delivery technology

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td><strong>Therapist in person</strong></td>
<td>0.52 (27)**</td>
<td>0.31 (22)**</td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
<td>-</td>
<td>0.08 (2)</td>
</tr>
<tr>
<td><strong>Other interactive technology</strong></td>
<td>-</td>
<td>0.09 (2)</td>
</tr>
<tr>
<td><strong>Non-interactive technology</strong></td>
<td>0.67 (1)*</td>
<td>0.44 (6)</td>
</tr>
<tr>
<td><strong>Q statistic p</strong></td>
<td>0.697</td>
<td>0.620</td>
</tr>
</tbody>
</table>

Relevant notes as for Table 0-35.
Therapy setting.

Therapy settings were categorised as: 1. Inpatient or residential care; 2. Outpatient (including hospital or hospice outpatient clinics, professional premises, and community facilities); 3. The patient’s home; or, 4, ‘Split’ i.e. the patient and therapist were in different settings, as for telephone delivery. Results are set out in Table 0-37.

This variable produced almost perfectly homogenous results (screened, Q statistic \( p = 0.906 \); unscreened, 0.907) meaning that it is not material at all to the effectiveness of therapy. Note, however, that some cells are blank and so no comparison could be made (screened, home and split settings; unscreened, inpatient care). Note also that the score for screened inpatients, which is comparable with that for outpatients except that it did not reach statistical significance, nonetheless approached it (\( p = 0.109 \)).

The implication of the available data is that for screened patients, there is no difference on the effect of therapy relative to inpatient or outpatient setting, and for unscreened patients, there is no significant difference between the outpatient result and that for therapy undertaken at home (mostly self-directed) or over the telephone. The latter finding may have implications for efficient and accessible service delivery. The former, regarding the similarity of effect for inpatient and outpatient services to screened patients, is of little practical use given that the nature of the therapies and their timing in relation to medical treatment will have determined the delivery setting.

Table 0-37. Therapy setting

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Inpatient / residential care</td>
<td>0.54 (4)</td>
<td>-</td>
</tr>
<tr>
<td>Outpatient</td>
<td>0.52 (23)**</td>
<td>0.28 (19)**</td>
</tr>
<tr>
<td>Home</td>
<td>-</td>
<td>0.26 (7)</td>
</tr>
<tr>
<td>Split settings</td>
<td>-</td>
<td>0.19 (3)</td>
</tr>
<tr>
<td>Q statistic ( p )</td>
<td>0.966</td>
<td>0.907</td>
</tr>
</tbody>
</table>

The one unscreened study for which this variable was rated inapplicable was excluded from the analysis. Other notes as for Table 0-35.

Dose variables

A number of variables that describe the ‘dose’ of therapy delivered are considered in this section. They include the flexibility of session time, how many hours and weeks sessions cover, how many sessions were delivered, whether or not homework was required of patients and its frequency, and whether or not therapy was tailored to individual patient needs.
Flexibility of session time. Studies were coded according to whether the amount of session time that was available to patients was limited or allowed additional sessions according to patient needs. A further category captured those studies for which the question was not applicable, such as those delivered by non-interactive technology.

Results (Table 0-38) showed no statistically significant difference between the categories for either screened or unscreened patients (Q statistic $p = 0.543$, screened; $0.910$, unscreened). Note also that while the effect sizes for unscreened flexible and not applicable categories did not reach significance, they were not far off ($0.27$, $p = 0.120$ and $0.41$, $p = 0.126$, respectively).

Since in both columns the time limited category produced higher results than the flexible category, and neither column produced a difference that approached significance, it seems that there is nothing to be gained from leaving session time open ended. However, the fact that extra session time was made available in some studies does not mean that it was used. Although coding of use of extra session time was not undertaken, the writer’s recollection from those few studies that reported on it is that it was taken up very little. In application, therefore, there was little practical difference between these two categories.

Table 0-38. Flexibility of session time

|                                | Screened     | Unscreened  |
|                                | ES (n)       | ES (n)      |
| Limited session time           | 0.58 (20)**  | 0.29 (20)** |
| Additional sessions available  | 0.47 (4)**   | 0.27 (4)    |
| Not applicable (no sessions)   | -            | 0.41 (6)    |
| Q statistic $p$                | 0.543        | 0.910       |

Notes as for Table 0-35.

Hours with a therapist. The data describing therapy sessions in terms of the hours allocated with a therapist (as opposed to patients’ self-directed time) were examined by stem and leaf plot and found to be fairly evenly - rather than normally - spread, with a range from two tenths of an hour, to 24 hours, and one outlier at 78 hours. After setting aside the outlier, the distribution was divided into groups designed to extract approximate upper and lower quartiles to heighten contrast: $\leq 4$ hours; $5 – 11$ hours; $\geq 12$ hours; and therapies for which the variable was not applicable (non-interactive delivery).
The results of this analysis (Table 0-39) show remarkable homogeneity between all categorisations with both Q statistic $p$’s around 0.900 and mid range therapy hours (5 – 11 hours) just slightly out-performing those at the upper and lower quartiles ($\geq$ 12 hours and $\leq$ 4 hours) and those studies for which the categorisation was not applicable for both screened and unscreened patients. This suggests that longer therapies do not have any marked advantage over shorter or non-interactive ones at early times. On one level, this could be considered a surprising result – more input should predict more effect. However, it could simply be that doses administered, whether short or long, were about right for the complexity of the problem being addressed.

Table 0-39. Hours with a therapist

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>$\leq$ 4 hours</td>
<td>0.49 (6)**</td>
<td>0.29 (6)*</td>
</tr>
<tr>
<td>5 – 11 hours</td>
<td>0.57 (9)**</td>
<td>0.43 (6)**</td>
</tr>
<tr>
<td>$\geq$ 12 hours</td>
<td>0.46 (2)*</td>
<td>0.39 (7)*</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.60 (7)**</td>
<td>0.27 (10)**</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.943</td>
<td>0.894</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

Another issue is that differences in dose may show differential impact only over time, that is, on the durability of effects. To investigate this a further analysis was performed, breaking assessment points into three categories: immediate and short-term (up to one month after therapy); medium term (one – six months); and combined late times (more than six months)(Table 0-40).

Low frequencies at the later time points thwart definite conclusions from being made, however, three points of interest are noted. First, confirming the finding above, there is no statistically significant difference (and little absolute difference) between the different therapy hours categories for either screened or unscreened patients at immediate / short term. (Note that the effect size of 0.46 for 12 hours or more begins to approach significance at $p = 0.14$.) Second, for screened patients, there is a statistically significant difference in favour of briefer therapies ($\leq$ 4 hours) at the mid term assessment point, with four studies to compare in each of the three categories that involve therapy time (Q statistic $p < 0.10$). This finding is clearly inconsistent with the expectation that therapies involving more session time produce more lasting results.
Although frequencies are too small to sustain judgment at late times, the trend in favour of briefer therapies appears to continue in that column. Third, the not inconsiderable benefits measured for unscreened patients at immediate/short term appear to evaporate altogether by medium term, in contrast to results for screened patients who retain at least small (though non-significant) effects. However, n is low so this result, again, is not reliable. From the Therapy type results chapter it is known that results for patients with baseline distress, for example, are lacking at late times.

Table 0-40. Hours with a therapist, different assessment points

<table>
<thead>
<tr>
<th></th>
<th>Immediate / short term</th>
<th>Medium term</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td><strong>Screened</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 4 hours</td>
<td>0.53 (5)**</td>
<td>0.84 (4)**</td>
<td>-</td>
</tr>
<tr>
<td>5 – 11 hours</td>
<td>0.57 (8)**</td>
<td>0.20 (4)</td>
<td>0.25 (2)*</td>
</tr>
<tr>
<td>≥ 12 hours</td>
<td>0.46 (5)</td>
<td>0.18 (4)</td>
<td>0.03 (2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.974</td>
<td>0.084*</td>
<td>0.357</td>
</tr>
<tr>
<td><strong>Unscreened</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 4 hours</td>
<td>0.44 (7)**</td>
<td>-0.09 (5)</td>
<td>0.26 (3)**</td>
</tr>
<tr>
<td>5 – 11 hours</td>
<td>0.51 (5)**</td>
<td>0.07 (2)</td>
<td>-</td>
</tr>
<tr>
<td>≥ 12 hours</td>
<td>0.29 (6)*</td>
<td>-0.10 (2)</td>
<td>0.28 (2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.49 (6)*</td>
<td>-0.13 (1)</td>
<td>-0.09 (1)</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.855</td>
<td>0.928</td>
<td>0.103</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

The conclusion that such evidence as is available does not support the proposition that therapy effects increase or are maintained more strongly with increased session time should not be accepted without a search for possible confounds, such as patients with baseline distress or therapy types that are conveyed in less hours. Details of therapy type and cancer site were investigated for the twelve screened studies that produced the significant results favouring briefer therapy at medium term assessment. No striking difference was evident in the range of treatment types, but it was notable that the briefest therapy grouping comprised two studies with colorectal patients and two with melanoma, while studies for the longest were all for breast cancer patients, and the 5 – 11 hour category comprised two breast and two mixed site studies. As it has been noted (see Personal characteristics results) that breast cancer produced the lowest results of
any cancer site. This was clear for screened studies with untreated controls. For that subset of studies, prostate cancer was next, while melanoma and colorectal cancers, on the other hand, produced the highest results, with mixed sites close behind them.

Although significance testing was hampered by lack of n for prostate, melanoma and colorectal categories, there was a statistically significant divide between breast cancer at the low end of the range, and the mixed cancer category which was at the bottom of the high scoring trio which included melanoma and colorectal cancers. Therefore the peculiar result found in the present analysis at medium term may well be explained by confounding with cancer site.

The discovery of this possible confound raised the question of whether it may also be producing the homogeneity evidenced at immediate / short term. Frequencies were therefore collated. The table below (Table 0-41) reproduces the (untreated control) screened immediate / short term and medium term results seen in Table 0-40, and sets out alongside those the frequencies of studies using samples from each cancer site. The ‘other’ column is comprised of colorectal and melanoma samples.

Table 0-41. Hours with a therapist, cancer site frequencies

<table>
<thead>
<tr>
<th>Assessment time point</th>
<th>Hours with a therapist</th>
<th>E.S. (n)</th>
<th>Study frequencies by cancer site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breast</td>
</tr>
<tr>
<td>Immediate / short term</td>
<td>≤ 4 hours</td>
<td>0.53 (5)**</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5 – 11 hours</td>
<td>0.57 (8)**</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>≥ 12 hours</td>
<td>0.46 (5)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td>0.974</td>
<td></td>
</tr>
<tr>
<td>Medium term</td>
<td>≤ 4 hours</td>
<td>0.84 (4)**</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>5 – 11 hours</td>
<td>0.20 (4)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>≥ 12 hours</td>
<td>0.18 (4)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td>0.084*</td>
<td></td>
</tr>
</tbody>
</table>

Screened untreated control data only. ‘Other’ cancer sites comprise melanoma and colorectal. There were three studies that did not report cancer site. Other relevant notes as per Table 0-35.

The potential for confounding by cancer site is clearly demonstrated again in the frequencies for the immediate / short term assessment point. Here the higher scoring
mixed and ‘other’ cancers represent three fifths of the studies contributing to the category for ≤ 4 hours session time, and there is only one breast cancer study contributing. The 5 - 11 hour category is fed by a more even balance of the extremes, with four mixed cancer samples contributing and three breast. The ≥ 12 hour category swings in the opposite direction from the ≤ 4 hour category, with only one fifth of contributing studies from a higher scoring site, but four fifths from breast cancer. The pattern seen is therefore that the more hours are spent with a therapist, the more low scoring breast cancer studies contribute to effect sizes, and the less high scoring mixed or ‘other’ cancer site studies appear. The same pattern is clearly illustrated for medium term results. Results from both assessment points are therefore open to confounding by cancer site.

A final point of interest that is suggested by Table 0-41 is that more brief therapy research with high scoring cancer sites would be valuable. Cancer sites were not tabled for unscreened studies. For them, effects were statistically homogeneous at immediate / short term and evaporated at medium term. However, it was of interest to investigate the cancer site distribution sustaining the moderate magnitude result for self-directed therapies at immediate / short term (0.49, p < 0.10) due to the implications that use of this therapy mode have for efficiency. It comprised a balance of three mixed and three breast cancer studies – a balance of cancer sites which enhances the validity of this result and strengthens the implication that self-directed therapies may be used as effectively as therapist delivered therapies for immediate / short term benefit amongst unscreened patients.

Taken without reference to the possible confounding effect of cancer site, the available data suggest that therapeutic ‘punch’ is delivered independently of hours spent with a therapist. Given the distribution of low (breast) and high scoring (mixed, melanoma and colorectal) cancer sites, however, this result is likely confounded. It must also be remembered that the categorisations used in these analyses were arbitrarily derived from a quartile split of the data rather than from any theoretical or clinical rationale - they are not meaningful in themselves, but only relative to each other.

*Weeks of therapy sessions.*

The duration of therapy in weeks was also analysed after examination of stem and leaf data. Other than a peak frequency at one week, an outlier at 52 weeks and another at 78, the distribution was fairly normal though with a skew to the right, ranging from one to 22 weeks, bimodal at six and eight weeks. Once again a split was made roughly on the quartiles in order to separate out the upper (10 – 22 weeks) and lower (1 – 3 weeks) ranges from the mid range (4 – 9 weeks). There remained also a category for those therapies that did not use therapy sessions as such, e.g. they used printed or recorded materials which were posted to patients or handed to them without further interaction.
Effect sizes for the different weeks-of-therapy categories were broken out by assessment point in the same way as was done for the analysis of hours with a therapist, and are produced in Table 0-42, below. There is a high degree of homogeneity at immediate / short term (screened Q statistic $p = 0.845$; unscreened, 0.976) but the trend for the screened subgroup is in the expected direction, with 1 - 3 weeks producing a lower effect size ($0.37, p < 0.05$) than 4 – 9 weeks ($0.50, p < 0.05$) which is again lower than 10 - 12 weeks ($0.65, p < 0.05$). At medium term, similar trends are seen to those shown for hours of therapy, with unscreened benefit falling right away and screened results showing statistical heterogeneity for effect sizes that are inversely related to the number of weeks of therapy (Q statistic $p = 0.001$). At late times n is too small to justify comment.

Table 0-42. Weeks of therapy, different assessment points

<table>
<thead>
<tr>
<th></th>
<th>Immediate / short term</th>
<th>Medium term</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 3 weeks</td>
<td>0.37 (6)*</td>
<td>0.92 (2)**</td>
<td>-</td>
</tr>
<tr>
<td>4 – 9 weeks</td>
<td>0.50 (9)**</td>
<td>0.41 (8)**</td>
<td>0.10 (2)</td>
</tr>
<tr>
<td>10 – 22 weeks</td>
<td>0.65 (5)**</td>
<td>-0.13 (3)</td>
<td>0.18 (2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.845</td>
<td>0.001**</td>
<td>0.775</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 3 weeks</td>
<td>0.39 (5)**</td>
<td>-0.32 (3)</td>
<td>0.39 (3)**</td>
</tr>
<tr>
<td>4 – 9 weeks</td>
<td>0.37 (9)*</td>
<td>-0.05 (4)</td>
<td>0.12 (2)</td>
</tr>
<tr>
<td>10 – 22 weeks</td>
<td>0.37 (7)**</td>
<td>0.05 (1)</td>
<td>0.32 (2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.53 (5)*</td>
<td>-0.13 (1)</td>
<td>-0.09 (1)</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.976</td>
<td>0.809</td>
<td>0.026**</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

Cancer site data were examined again for the screened subgroups at immediate / short term and medium term (Table 0-43). It is interesting to see that the trend in the expected direction seen for the immediate / short term results was produced by a good balance of high scoring (mixed and other) and low scoring (breast) cancer sites in each of the three weeks-of-therapy categories, and that the high self-directed (‘not applicable’) score was produced by only one study which was from a cancer site.
category that has been found to produce higher scores (mixed sites). This balance gives
some confidence that a fairer picture of the effect of this variable is demonstrated, i.e.,
that for screened patients at immediate / short term assessment, more weeks of therapy
does lift effect size - but nowhere near enough to produce statistical heterogeneity.
Perhaps this lack of Q statistic significance is a result of considerable individual
difference in the impact of this variable, i.e. different patients have different needs and
produce different responses to more weeks of therapy.

At medium term the same confounding pattern displayed for hours of therapy is
reproduced. In the category with the fewest weeks of therapy, only high scoring ‘other’
studies contribute (both colorectal), in the middle category there is an even mix of low
scoring breast studies (4) and higher scoring mixed (2) and other sites (2, both 
melanoma), and in the category with the most weeks there are only breast cancer studies
(3). The medium term results are therefore not reliable evidence of the durability of
effectiveness produced by therapies administered for differing numbers of weeks.
However, taken together, the two sets of results shown in Table 0-43 show again the
importance of cancer site as a moderator of therapy effectiveness.

Table 0-43. Weeks of therapy, cancer site frequencies

<table>
<thead>
<tr>
<th>Assessment time point</th>
<th>Weeks of therapy</th>
<th>E.S. (n)</th>
<th>Study frequencies by cancer site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>E.S. (n)</td>
<td>Breast</td>
</tr>
<tr>
<td>Immediate/short term</td>
<td>1 – 3 weeks</td>
<td>0.37 (6)*</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>4 – 9 weeks</td>
<td>0.50 (9)**</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>10 – 22 weeks</td>
<td>0.65 (5)**</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td>0.845</td>
<td></td>
</tr>
<tr>
<td>Medium term</td>
<td>1 – 3 weeks</td>
<td>0.92 (2)**</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>4 – 9 weeks</td>
<td>0.41 (8)**</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>10 – 22 weeks</td>
<td>-0.13 (3)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td>0.001**</td>
<td></td>
</tr>
</tbody>
</table>

Notes as for Table 0-41.
The meta-analysis by Rehse and Pukrop (2003) found that therapies of longer than 12 weeks duration were more effective. A replication of this analysis was attempted at early times (Table 0-44) but did not confirm that finding in relation to either screened or unscreened patients, both of which showed non-significant trends in the opposite direction (screened, < 12 weeks, 0.57, \( p < 0.05 \); ≥ 12 weeks, 0.34, \( p = 0.13 \); unscreened, 0.35, \( p < 0.05 \), and 0.16, \( p < 0.10 \), respectively). Note that self-directed therapies scored relatively well at over 0.40 for both screened and unscreened patients, although the former score has an \( n \) of only two and the latter only approached statistical significance (\( p = 0.126 \)).

The distribution of cancer sites for the attempted Rehse and Pukrop (2003) replication is also shown in Table 0-44. In the screened subgroup the distribution of breast and mixed cancer samples is similar and quite balanced for the < 12 weeks and ≥ 12 weeks categories, except that only the former category has prostate and other (melanoma and colorectal) studies, both of which tend to score better than breast cancer. This bent in the cancer site distribution may have influenced the poorer showing of the ≥ 12 weeks category for screened patients. However, it must be noted that the absolute result for that category (\( g = 0.35 \)) did not even approach statistical significance, despite the presence of two (of five) mixed cancer site samples. Not an impressive outcome. The result for unscreened patients using self directed therapies (0.46, \( p > 0.05 \)) is drawn from a frequency (2) that is too small in itself to sustain comment, but note that relatively strong results frequently appear for this category, and in this case the cancer sites are balanced (one breast and one mixed).

The results for the unscreened subgroup were lower but otherwise followed a pattern similar to the screened group. The < 12 weeks category scored 0.35 (\( p > 0.05 \)) from an upwardly bent but reasonable balance of high and low scoring cancer sites. The ≥ 12 weeks category score (0.16, \( p > 0.10 \)) would have been dragged down by a disproportionate number of studies from low scoring cancer sites (four breast and one ‘other’). The ‘not applicable’ category topped the unscreened analysis with an effect size of 0.41 from an \( n \) of six, but it was non-significant despite a balance of cancer sites that favours higher scorers (four mixed and two breast). Perhaps this non-significance was the product of wide individual differences in how self-directed therapies are received. Nonetheless, it seems that self-directed therapies can more than compete with those delivered by therapists for some unscreened patients.

Table 0-44. Weeks of therapy with cancer site frequencies, Rehse & Pukrop replication

<table>
<thead>
<tr>
<th>Weeks of therapy</th>
<th>E.S. (n)</th>
<th>Study frequencies by cancer site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Breast</td>
</tr>
<tr>
<td>Screened</td>
<td>1 – 11 weeks</td>
<td>0.57 (20)**</td>
</tr>
</tbody>
</table>

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The finding of a trend in favour of more weeks of therapy for screened patients at early times is not statistically heterogeneous and is inconsistent between tables and the screening categories within them.

**Number of therapy sessions.**
A stem and leaf plot for number of therapy sessions (not counting patient-directed therapy) revealed a range from one to 13 sessions, with outliers at 24, 26, and 52 sessions. The distribution was fairly normal around a mode of six, except for a slight skew right with a disproportionate number of studies at the extreme left on one session. Setting the outliers aside, the lower quartile was set to include one to four sessions, and the upper, eight to 13. Once again, following the analysis for therapy hours, the early times assessment point was superseded by a break-down of assessment times to immediate / short-term, medium term, and combined late times (Table 0-45) to check for maintenance of effect.

At immediate / short-term (up to one month after therapy) both screened and unscreened subgroups once again show homogeneity (Q statistic $p = 0.727$ and $0.620$ respectively) and the ranges are quite tight, indicating no difference caused by differing numbers of therapy sessions. All effect sizes reach significance except, interestingly, those for the five to seven session category in each of the immediate / short term subgroups (significance is just missed for screened patients at $p = 0.103$) which also yield the lowest effect sizes (screened, 0.31; unscreened, 0.25). This unexpected result raises the suspicion of confounding, investigated below, but note also that $n$ is relatively low (4). For unscreened patients results further suggest that self-directed therapies ($0.49, p < 0.10$) are as effective as those delivered with therapist session time (which range from 0.25 to 0.58, Q statistic $p = 0.620$).

At medium term the pattern seen in relation to therapy hours reasserts itself, with the fading of all unscreened effect sizes and the appearance of heterogeneity (Q statistic $p = 0.014$) whereby effect size is inversely related to number of sessions for screened
patients (1 - 4 sessions, 0.69, $p < 0.05$; 5 - 7 sessions, 0.28, n.s.; 8 - 13 sessions, 0.01, n.s.; no studies were available for the ‘not applicable’ category).

At late times n is sparse and results cannot be taken as suggestive although they are generally consistent with the trends shown at medium term. It is noted that the screened medium term result for 5-7 sessions (0.28, n.s., n = 3) is retained and gains 0.10 statistical significance despite further attrition (0.26, n = 2). And there is a surprise leap up in the unscreened 1-4 session category, from a null result at medium term from four studies to a statistically significant small result at late times from only two (0.19, $p < 0.05$).

Table 0-45. Number of sessions, different assessment points

<table>
<thead>
<tr>
<th></th>
<th>Immediate / short term</th>
<th>Medium term</th>
<th>Late times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 4 sessions</td>
<td>0.51 (6)**</td>
<td>0.69 (6)**</td>
<td>-</td>
</tr>
<tr>
<td>5 – 7 sessions</td>
<td>0.31 (4)</td>
<td>0.28 (3)</td>
<td>0.26 (2)*</td>
</tr>
<tr>
<td>8 – 13 sessions</td>
<td>0.66 (9)**</td>
<td>0.01 (4)</td>
<td>-0.02 (1)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.727</td>
<td>0.014**</td>
<td>0.308</td>
</tr>
<tr>
<td>Unscreened</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 4 sessions</td>
<td>0.58 (5)**</td>
<td>-0.22 (4)</td>
<td>0.19 (2)**</td>
</tr>
<tr>
<td>5 – 7 sessions</td>
<td>0.25 (5)</td>
<td>0.04 (3)</td>
<td>-0.13 (1)</td>
</tr>
<tr>
<td>8 – 13 sessions</td>
<td>0.34 (10)**</td>
<td>-0.10 (3)</td>
<td>0.04 (2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0.49 (6)*</td>
<td>-0.13 (1)</td>
<td>-</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.620</td>
<td>0.754</td>
<td>0.408</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

To check for possible confounding by cancer site, frequencies for screened studies at immediate / short term and medium term were tabulated (Table 0-46). The distribution of higher scoring mixed and ‘other’ cancer sites with lower scoring breast cancer is again quite balanced across the immediate / short term categories, posing no threat to the validity of findings at that assessment point. The lower score for the intermediate dose of five to seven sessions (0.31, n.s.) stands against the slight and non-significant trend in favour of more sessions (1 - 4 sessions, 0.51, $p < 0.01$; 8 - 13 sessions, 0.66, $p < 0.05$), and reinforces the implication from the homogeneity of the data, namely that number of sessions is unimportant to outcome at immediate / short term.
On the other hand, the screened results at medium term may be attributable, once again, to a confounding concentration of higher scoring cancer site studies at lower dose – two colorectal, two melanoma, one mixed site and only one breast cancer study contribute to the 1 - 4 session category while all but one study in the other two categories (mixed, 8 - 13 sessions) treated patients from the lowest scoring site, breast cancer.

Table 0-46. Number of sessions, cancer site frequencies

<table>
<thead>
<tr>
<th>Assessment time point</th>
<th>Number of therapy sessions</th>
<th>E.S. (n)</th>
<th>Study frequencies by cancer site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breast</td>
</tr>
<tr>
<td>Immediate / short term</td>
<td>1 – 4 sessions</td>
<td>0.51 (6)**</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5 – 7 sessions</td>
<td>0.31 (4)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>8 – 13 sessions</td>
<td>0.66 (9)**</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>0.67 (1)*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Q statistic p</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Medium term           | 1 – 4 sessions             | 0.69 (6)** | 1     | -        | 1     | 4     |
|                       | 5 – 7 sessions             | 0.28 (3) | 3     | -        | -     | -     |
|                       | 8 – 13 sessions            | 0.01 (4) | 3     | -        | 1     | -     |
|                       | Not applicable             | -        | -    | -        | -     | -     |
|                       | Q statistic p              |          |       | 0.014**  |       |       |

Notes as for Table 0-41.

As a whole, and within the limits of n in this data, these analyses convey the impression that there is little incremental gain produced by more than four sessions of therapy – most therapeutic ‘punch’ is delivered at the outset, and returns diminish as dose increases. Just how few sessions would provide optimally efficient return was not investigated, however - the cut-offs used in these analyses derived from a quartile split of the data distribution rather than any more meaningful criteria. It must also be remembered that all of the data in this study is drawn from the rarefied conditions of the controlled research setting, including, in the great majority of cases, patients with favourable diagnoses uncomplicated by other serious medical problems. Furthermore, most of the patients in the screened samples upon which these analyses focussed were known to have no psychological history. This finding is therefore not directly transferable to the clientele that psycho-oncologists see typically. However, the principle may be useful for designing therapy for non-complex patients.
The result for self-directed therapies at immediate / short term (0.49, \( p < 0.10 \), Table 0-45) was well sustained by a balance of three mixed and three breast cancer studies. The score for 1 - 4 sessions delivered by a therapist (0.58, \( p < 0.05 \)) was only negligibly higher, and statistically the two results were homogeneous, implying, once again, that self-directed therapies may be used as effectively as therapist delivered therapies for immediate / short term benefit amongst unscreened patients for immediate / short term results.

**Homework.**

The exploration of the impact of homework on therapy effectiveness was intended to draw from just one study coding item, but in the event, was approached from two. The unintended approach and how it came to contribute to this head are described first.

**Nature of patients’ therapy work.**

This variable allowed categorical description of the nature of what was required of patients receiving therapy: 1. Passive listening, e.g. listening to a lecture, with no required homework or skill practice, but maybe the opportunity to ask questions; 2. Active participation, e.g. interactive discussion or exercises, with no required homework or skill practice; 3. Passive listening plus homework or skill practice; 4. Active participation plus homework or skill practice; and 5. Therapy that was comprised overwhelmingly of reading or skill practice or other self-directed work. In conducting the analysis on the untreated control studies only, it was found that there were only two categories with frequencies of more than one, so data are presented for them alone (Table 0-47).

The way the data fell made interpretation effectively a question of the impact of homework, since both categories comprised active participation, but only one included homework or skill practice. The outcome was quite interesting in that for active participation without homework it showed moderate magnitude statistically significant results for both screened and unscreened studies (0.49 and 0.57 respectively, both \( p < 0.05 \)), and for screened patients, active participation coupled with homework produced very similar results (0.55, \( p < 0.05 \)) but for unscreened studies the addition of homework saw the effect size collapse to a negligible magnitude which was not statistically significant (although it came close, \( g = 0.10, p = 0.112 \)). For screened patients, results were homogeneous (Q statistic \( p = 0.795 \)), but for unscreened patients the clear statistically heterogeneous result favoured no homework (Q statistic \( p = 0.005 \)). This apparent interaction was checked with heterogeneity calculations across the table as well, confirming no statistically significant difference between the moderate magnitude results for screened and unscreened studies where no homework was set (Q statistic \( p = 0.856 \)) but clear heterogeneity when homework or practice was expected (Q statistic \( p = 0.002 \)) favouring the screened subset.
How might this apparent interaction be explained? Perhaps patients who are screened and therefore motivated by distress do well in actively engaging therapies and are prepared to do the homework, while less motivated unscreened patients will cooperate by actively participating in therapy sessions but lack the motivation to do homework, and if the effectiveness of the therapy depends on that, then it fails for them. So active participation in therapy will elicit worthwhile results from both screened and unscreened patients, but there does not appear to be much to be gained by requiring homework from screened patients, and it is actually counter-productive to require it from unscreened patients.

It is interesting to compare these results with a meta-analysis that found homework for behavioural / CBT therapies to produce a moderate magnitude statistically significant correlation with therapy outcome \( r = 0.36 \) and note that participant n – rather than study n - was only 375)(Kazantzis, Deane, & Ronan, 2000). That work drew on a general psychological sample (i.e. non-cancer specific) where it can be assumed that participants were all distressed at baseline, meaning the result is best compared with only the screened category in the present study. It also elicited studies from only the two therapy types that are especially likely to assign homework. Because of the latter distinction, the present analysis was run again isolating CBT and relaxation therapy studies (exclusive categorisation, i.e. studies coded ‘r’, ‘c’, or ‘rc’ only) from the untreated control dataset (Table 0-48).

### Table 0-48. Relaxation and CBT, active participation with and without homework

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
<th>Q statistic p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
<td></td>
</tr>
<tr>
<td>Without homework</td>
<td>0.41 (5)*</td>
<td>1.19 (1)**</td>
<td>0.035**</td>
</tr>
<tr>
<td>With homework / skill practice</td>
<td>0.73 (11)**</td>
<td>0.09 (7)</td>
<td>0.000**</td>
</tr>
</tbody>
</table>
Relaxation and CBT are exclusively defined ("combinations"). Both categories involve active participation in therapy. Other notes as for Table 0-35.

The analysis was hampered by a lack of n in the unscreened x without homework cell, but the results of most interest are in the screened column in any case. In that column, a non significant trend (Q statistic \( p = 0.229 \)) in the same direction as that found by Kazantzis et al. (2000) is apparent (without homework, \( 0.41, p < 0.10 \); with homework, \( 0.73, p < 0.05 \)). This suggests that relaxation or CBT homework may be of incremental value to screened cancer patients, but there is a lot of variation in the response of individuals. Perhaps this variation is introduced by the lack of established distress in the screened out studies that comprise part of this categorisation. A statistically significant difference (Q statistic \( p < 0.05 \)) between the ‘with homework’ results of screened and unscreened patients (0.73, \( p < 0.05 \), and 0.09, n.s., respectively) confirms the finding above, relative to all therapy types, that homework benefits screened patients but not unscreened ones.

Frequency of homework.
An investigation of the impact of frequency of homework or skill practice was also conducted, being the investigation that was originally planned for this variable. Categories of homework frequency, assigned on the basis of therapists’ expectations, were: 1. One-off (e.g. the reading of a literature pack provided at the first or only session); 2. Regularly expected (e.g. with sessions); 3. Irregularly expected; 4. Optional; and, 5. None at all (Table 0-49).

For screened patients there were only two categories with n (recall that this is using untreated control data) which produced homogeneity between regular homework and none at all (0.51, \( p < 0.05 \) and 0.44, \( p < 0.05 \), respectively, Q statistic \( p = 0.698 \)), similar to the trend found in the preceding analysis that included all therapy types. For unscreened patients there were two categories that produced effect sizes significantly larger than the others, and these were the category for one-off homework (0.71, \( p < 0.10 \)) and for none (0.65, \( p < 0.05 \))(Q statistic \( p = 0.011 \)). The other categories produced effects of zero to small magnitude. The Q statistic comparison of screened and unscreened subsets who both had regular homework again reflected the curious interaction seen in the nature of therapy work analysis, whereby statistically homogeneous effects are produced by no homework therapies for screened and unscreened subsets (Q statistic \( p = 0.502 \)) but significantly poorer effects result from requiring regular homework from unscreened patients (\( p = 0.008 \)).

<table>
<thead>
<tr>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
</tbody>
</table>

Table 0-49. Frequency of homework
<table>
<thead>
<tr>
<th></th>
<th>One-off</th>
<th>Regularly expected</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regularly expected</td>
<td>0.51 (16)**</td>
<td>0.13 (14)**</td>
<td>0.008**</td>
</tr>
<tr>
<td>Irregularly expected</td>
<td>-</td>
<td>0.17 (1)</td>
<td>-</td>
</tr>
<tr>
<td>Optional</td>
<td>-</td>
<td>0.02 (3)</td>
<td>-</td>
</tr>
<tr>
<td>None</td>
<td>0.44 (7)**</td>
<td>0.65 (9)**</td>
<td>0.502</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.698</td>
<td>0.011**</td>
<td>-</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

Setting aside the category for which a frequency of only one was recorded (‘irregularly expected’), a pairwise comparison of the unscreened categories was conducted to locate the heterogeneity revealed by the significant Q statistic in that column ($p = 0.011$)(Table 0-50 below).

While interpreting Table 0-50 the low frequencies supporting ‘one-off’($n = 4$) and ‘optional’($n = 3$) categories give cause for caution. The implication of the overall trend of the results for unscreened patients, however, is consistent, i.e. that no homework or one-off homework is more beneficial than regular or optional homework. This is seen in the statistically significant or near significant comparisons between one-off, on the one hand, and regularly expected (Q statistic $p = 0.133$) or optional ($p = 0.088$) on the other, where one-off yields a far higher effect size. The same dynamic is seen again in the statistically significant comparisons between ‘none’ on the one hand, and regularly expected and optional homework (both $p = 0.002$) on the other, with none yielding the higher effect size. Note also that the none x regularly expected comparison is well supported by $n$ on both sides (9 and 14, respectively). Further evidence for the trend is found in the homogeneity of results between the two high scorers, none and one-off ($p = 0.880$) and between the two low scorers, optional and regularly expected ($p = 0.463$).

Table 0-50. Frequency of homework, unscreened heterogeneity comparison

<table>
<thead>
<tr>
<th></th>
<th>One-off</th>
<th>Regularly expected</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regularly expected</td>
<td>0.133</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Optional</td>
<td>0.088*</td>
<td>0.463</td>
<td>-</td>
</tr>
<tr>
<td>None</td>
<td>0.880</td>
<td>0.002**</td>
<td>0.002**</td>
</tr>
</tbody>
</table>

Q statistic $p$’s are shown. * $p < 0.10$; ** $p < 0.05$. Unscreened, untreated control data.

CBT and relaxation therapy studies (exclusive categorisation) were again broken out for the two categories that comprised $n$ of more than one for both screened and unscreened patients (Table 0-51). The interaction is again evident, with regular homework
producing a big advantage for screened patients, \((0.73, p < 0.05, \text{n.s. for no homework; } Q \text{ statistic } p = 0.056)\) and a big disadvantage for unscreened patients \((0.09, \text{n.s. compared with } 0.97, p < 0.05 \text{ for no homework; } Q \text{ statistic } p = 0.000)\) relative to no homework at all. The interaction is confirmed at both points with statistically significant \(Q\) statistic \(p\)’s \((p < 0.05)\) across the table. While not much weight can be placed on this table of results because of the low \(n\) for the no homework category, its value is in its consistency with other trends above. The low frequencies precluded any investigation into the effects of homework on distressed patients.

Table 0-51. Relaxation and CBT, regular v. no homework

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
<th>(Q) statistic (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\text{ES (n)})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regularly expected</td>
<td>0.73 (11)**</td>
<td>0.09 (9)</td>
<td>0.000**</td>
</tr>
<tr>
<td>None</td>
<td>0.21 (3)</td>
<td>0.97 (2)**</td>
<td>0.015**</td>
</tr>
<tr>
<td>(Q) statistic (p)</td>
<td>0.056*</td>
<td>0.000**</td>
<td></td>
</tr>
</tbody>
</table>

Relaxation and CBT are exclusively defined (‘combinations’).

As a matter of interest, the nature of the two no homework studies that produced such an unusually high effect size for unscreened patients \((0.92)\) was investigated. One involved four sessions of clinical hypnosis administered to terminally ill patients (Liossi & White, 2001) producing effect sizes ranging from 1.08 to 1.31 on each subscale of the HADS and the Psychological Distress subscale of the Rotterdam Symptom Checklist. The other was a twenty minute dose of live guitar music and singing tailored to patients’ individual preference during chemotherapy (Ferrer, 2007) which produced a \(g\) of 0.76 on an anxiety visual analogue scale. Each study had 50 participants and assessment was immediately post intervention. Neither could be described as interventions typical of the field, but the potential demonstrated by their effect sizes merits their further investigation.

In conclusion, the message appears to be that therapy for unscreened patients is more effective without homework or skill practice, or only a one-off expectation. Perhaps this is because unscreened patients generally lack the motivation to persevere with homework, and therefore if the therapy relies upon it, it will fail. It would be better to dispense with homework (beyond a one-off requirement) for this group. On the other hand, it could be hypothesised that screened patients have the motivation of their distress to drive perseverance, and therefore they will comply with an expectation that they do homework. However, the incremental gain generally taken from regular homework over none is negligible and non-significant, and given the burdens of
distress, cancer diagnosis and treatment that patients already carry, the argument could well be made that homework (other than, perhaps, a one-off assignment) should be dispensed with for them also. This last comment does not apply so strongly to relaxation therapies and CBT. In the case of these therapies, regular homework, which involves practicing new skills rather than processing experiences, has proven worthwhile for many screened, though not unscreened, patients.

**Tailoring of therapy content.**
The extent to which the content of therapy was tailored to the needs of the particular patient was coded as a three way comparison: Fully tailored, partly tailored, or entirely predetermined. Results of an analysis of this comparison are shown in Table 0-52, below.

No statistically significant difference was found in either screened or unscreened columns (Q statistic $p = 0.289$ and $0.262$, respectively), meaning that this factor was not differentially associated with treatment effectiveness. The considerable difference between the screened and unscreened results for entirely predetermined therapies was tested for heterogeneity, and found to approach it (Q statistic $p = 0.156$). This may suggest that while either form of content will benefit screened patients, unscreened patients, who have no proven distress, benefit little from being herded through a standard therapy, but can benefit from more tailored therapies.

However, the defining and coding of this item was experienced as particularly difficult, and the writer has limited faith in any outcome based upon it. The ‘fully tailored’ category was defined as entirely guided by the needs of the participants, but, of course, within the confines of the therapy type offered. Considerable variation existed as to what those confines would allow in the practical context. ‘Partly tailored’ meant prescribed in outline or containing some fixed elements but also remaining flexible to meet the needs of the participants as they arose, whereas ‘entirely predetermined’ allowed a limited opportunity for expressing feelings or asking questions, but only within guiding constraints. Where, given this operationalisation, does one place an expressive writing therapy, for example? It could be seen as fully tailored or entirely predetermined, because it is inherently about what the particular patient feels. Because of the discomfort the writer has with this categorisation, the results will not form part of the conclusion of this chapter or the general discussion chapter.

**Table 0-52. Tailoring of therapy content**

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td><strong>Fully tailored</strong></td>
<td>0.60 (5)**</td>
<td>0.45 (8)**</td>
</tr>
<tr>
<td><strong>Partly tailored</strong></td>
<td>0.36 (11)**</td>
<td>0.38 (10)**</td>
</tr>
</tbody>
</table>
Therapist variables

The final category of delivery variables relates to therapists and covers their professional discipline, level of professional experience, and level of involvement with patients.

Therapist discipline.

Studies were coded against a list of therapist disciplines, including categories for lay therapists and mixed lay and professional teams (Table 0-53).

The column for screened studies showed 0.10 level heterogeneity (Q statistic $p = 0.097$) with a particularly high score for social workers (0.91, $p < 0.05$) while the unscreened column showed homogeneity (Q statistic $p = 0.358$) with a particularly low score for social workers (-0.03, n.s.) but from an n of only two. The statistically significant and well supported g of 0.41 ($p < 0.05$, n = 6) for psychologists also stands out in the unscreened column, as do the poorly supported but statistically significant high scores for psychiatrists and trained counsellors / therapists (0.68, n = 2, and 0.76, n = 1, both $p < 0.05$, respectively).

Table 0-53. Therapist discipline

<table>
<thead>
<tr>
<th>Therapist Discipline</th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Psychologist</td>
<td>0.27 (9)**</td>
<td>0.41 (6)**</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>-</td>
<td>0.68 (2)**</td>
</tr>
<tr>
<td>Social worker</td>
<td>0.91 (5)**</td>
<td>-0.03 (2)</td>
</tr>
<tr>
<td>Counselor / therapist (trained)</td>
<td>0.38 (1)</td>
<td>0.76 (1)**</td>
</tr>
<tr>
<td>Nurse</td>
<td>0.18 (4)</td>
<td>0.12 (3)</td>
</tr>
<tr>
<td>Multidisciplinary team</td>
<td>0.21 (2)</td>
<td>0.21 (4)</td>
</tr>
<tr>
<td>Lay</td>
<td>0.59 (1)**</td>
<td>0.39 (2)</td>
</tr>
<tr>
<td>Mixed lay and professional team</td>
<td>0.82 (2)</td>
<td>-</td>
</tr>
<tr>
<td>Not applicable (e.g. bibliotherapy)</td>
<td>0.67 (1)*</td>
<td>0.34 (7)</td>
</tr>
</tbody>
</table>
Excluding those categories with an n of less than three, screened studies were analysed for heterogeneity, and the three categories of psychologist, social worker, and nurse were again found to be heterogeneous. They were then compared pairwise (Table 0-54) and it was found that the result for social workers was significantly higher than those for psychologists (0.27, \( p < 0.05, \) Q statistic \( p = 0.009 \)) or nurses (0.18, \( p < 0.05, \) Q statistic \( p = 0.011 \)).

Table 0-54. Therapist discipline, screened, pairwise heterogeneity comparison

<table>
<thead>
<tr>
<th></th>
<th>Social worker</th>
<th>Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>0.011**</td>
<td></td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>0.009**</td>
<td>0.617</td>
</tr>
</tbody>
</table>

Screened, untreated control data. Q statistic \( p \)'s are shown, * \( p < 0.10 \); ** \( p < 0.05 \).

These results show, contrary to the finding in Cwikel and Behar (1999) that social workers are capable of delivering highly effective therapy to screened cancer patients. The five studies that contributed to this high score were, however, disproportionately lifted by one windzorised outlier and an exceptionally high scoring treatment arm of a study whose other treatment arm was ruled out due to non adjustment of significant baseline differences and which was also an outlier (Nezu, Nezu, Felgoise, McClure, & Houts, 2003; Telch & Telch, 1986). Both of these studies screened recruits simultaneously in for distress and out for psychological history. The unscreened column warns that social workers are also capable of delivering highly ineffective therapy! The similarity of the nurse and psychologist screened scores is also interesting given the very different fields of expertise that each has. Clearly, both are relevant to this population. The higher scores shown in the unscreened column for psychologists, psychiatrists, and trained counsellors / therapists may suggest that in order to elicit therapeutic effect from this population, specialised therapeutic skills are required.

These results could be confounded by therapy delivery or component factors, however. In Cwikel and Behar (1999) the poor performance of social workers was explained by the lack of cognitive and behavioural therapies in the protocols administered by them. In the present study the social worker run therapies were all one component CBT or expressive supportive therapies, except one which was expressive supportive and spiritual, whereas the therapies run by the other disciplines were more various, including relaxation and many cases of therapies with multiple components. CBT and expressive supportive therapies have been found to be the higher scorers at early times, and there may be some virtue in running therapies with a single component focus.
Manualisation may be another factor. The psychologist categorisation included five studies that delivered only partially replicable / manualised / standardised therapies whereas between the nurse and social worker categories there was only one such study, run by social workers. It is arguable that the training of psychologists enables them to be more flexible in their delivery, whereas effective delivery by nurses and social workers may generally be tied to more structured therapies. Again, n’s for the latter two groups are too light to propose this with any assurance.

Beutler et al. (2004) has suggested that more important factors than therapist discipline or academic training may be therapist experience in the clinical setting and with therapy generally, and we shall come to that variable next. It should also be remembered that some very solid results have been the product of indirect interventions, where the patient does not have direct contact with the ‘therapist’ at all.

_Therapist level of experience._
Table 0-55 displays results for an investigation into whether the level of the therapist’s experience - lay, student, professional or mixed lay and professional - impacts the effectiveness of therapy.

For unscreened patients, it appears that it makes little difference, with a high degree of homogeneity showing between cells (Q statistic $p = 0.882$). Whilst the professional level reports the only statistically significant outcome in the unscreened column ($0.30, p < 0.05, n = 15$), this category is one of only two sustained by sufficient n and has much the highest of those. The other category is ‘not applicable’, meaning that a therapist was not required to personally interact with patients. The outcome for that subset is actually higher at 0.34, but is not statistically significant due to broader confidence intervals indicating greater variation in patient response to this form of delivery.

For screened patients, category differences distantly approached statistical significance (Q statistic $p = 0.181$). The two categories sustained by an n of three or more were compared on their own. The outcome was statistical confirmation (Q statistic $p = 0.026$) that professionals ($0.49, p < 0.05, n = 16$) produced higher scores than students ($0.04, n.s., n = 3$), although student n was low.

Table 0-55. Therapist level of experience

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Lay</td>
<td>0.59 (1)**</td>
<td>0.39 (2)</td>
</tr>
<tr>
<td>Students (including those with training)</td>
<td>0.04 (3)</td>
<td>0.27 (2)</td>
</tr>
<tr>
<td>Practitioners / professionals</td>
<td>0.49 (16)**</td>
<td>0.30 (15)**</td>
</tr>
</tbody>
</table>
Mixed lay and professionals | 0.48 (1)* | 0.04 (1)
---|---|---
Not applicable | 0.67 (1)* | 0.34 (7)
Q statistic p | 0.181 | 0.882

Notes as for Table 0-35.

Overall, the analysis is consistent with the expectation that professionals deliver better results than non-professionals or other means of delivery, but the lack of n in most cells makes it impossible to reach any conclusive result.

**Therapist involvement.**

The level of therapist involvement with the immediate target of therapy (normally the patient, but in indirect studies, this was the significant other or doctor) was coded for as follows: 1. Minimal, i.e. one on one initial contact for setting up the research only; 2. Group, i.e. contact as part of group delivery and possibly initial one on one contact for set up purposes as well; 3. One on one, i.e. individually delivered therapies or those with both group and individual components; and 4. Intense, i.e. therapist was available at group or individual sessions and also beyond the normal session frame e.g. on crisis call.

The results (Table 0-56) were homogeneous for both screened and unscreened patients, meaning that this is not a factor that moderates therapy success. Even if very low n cells are disregarded, it can be seen that there is little difference between the remaining cells, with perhaps an edge in favour of one-on-one involvement (0.57, p < 0.05) over group delivery (0.44, p < 0.05) for screened patients, though the difference can be thought of only as a trend at most.

The other notable result is the apparently strong showing of ‘not applicable’ studies, i.e. those that did not have any therapist involvement (screened, 0.67, p < 0.10, n = 1; unscreened, 0.42, n.s., n = 6). However, the screened result is produced by only one study, and the unscreened result, though well supported, is not statistically significant, indicating a wide range of outcomes underlying it. It cannot, therefore, be suggested that therapists should be dispensed with, although clearly there are some interventions that can be effectively delivered without them.

Table 0-56. Therapist involvement

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Minimal</td>
<td>-</td>
<td>0.14 (3)</td>
</tr>
<tr>
<td>Group</td>
<td>0.44 (7)</td>
<td>0.32 (9)**</td>
</tr>
</tbody>
</table>
The therapist involvement construct is the other side of the therapy recipient coin, and arrives at essentially the same conclusions, namely, that one-on-one delivery is favoured by a trend in the figures for screened patients, but in the case of unscreened patients, group delivery may be more efficient and similarly effective.

**Patient socio-demographic characteristics**

**Race**

The percentage of patients who were white was coded for each study. Again using the untreated control data, a quick survey of the dataset rows showed that: 48 reported 0% white; 33 a mixture comprising 59 - 79% white; 31, 80 – 89%; 63, 90 – 100%; and 111 rows did not report on the subject. It was decided to sharpen the contrast by comparing studies at each extreme of the set, leaving out the small group with a mixture of races including 59 – 79% white. It was also considered safe to bring in a few of the studies that had not reported on race because their national populations are known to be quite homogeneous relative to the simple classification of race used here. Asian countries (Hong Kong) were brought into the predominantly / exclusively non-white group, and Scandinavian countries into the predominantly (80% or more) white group. This still left some studies from the USA, UK, Canada, Australasia, the Netherlands, Germany, Italy, Greece and Israel coded ‘unreported’ and excluded from analysis, although it is likely that they would have fallen into the predominantly white group. Results based on this split are tabled below (Table 0-57).

| One-on-one | 0.57 (19)** | 0.31 (13)** |
| Intense | 0.39 (1)* | - |
| Not applicable | 0.67 (1)* | 0.42 (6) |
| Q statistic $p$ | 0.821 | 0.624 |

Notes as for Table 0-35.

### Table 0-57. Race

<table>
<thead>
<tr>
<th>Screened</th>
<th>All tx</th>
<th>Educ</th>
<th>Relax</th>
<th>CBT</th>
<th>Exp-sup</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>Non-white</td>
<td>0.56 (7)**</td>
<td>0.03 (3)</td>
<td>0.67 (4)**</td>
<td>-0.03 (1)</td>
<td>0.32 (4)</td>
</tr>
<tr>
<td>Predom. white</td>
<td>0.43 (11)**</td>
<td>0.27 (1)</td>
<td>0.44 (7)**</td>
<td>0.42 (9)**</td>
<td>0.38 (1)</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.632</td>
<td>0.512</td>
<td>0.493</td>
<td>0.133</td>
<td>0.813</td>
</tr>
</tbody>
</table>
### Table 0-58. Gender, 100% men v. 100% women

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
<th>Q statistic p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened</td>
<td>0.57 (4)**</td>
<td>0.38 (15)**</td>
<td>0.405</td>
</tr>
<tr>
<td>Unscrenned</td>
<td>0.81 (4)**</td>
<td>0.26 (14)**</td>
<td>0.165</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.

### Education level

**Main effect**

Studies were coded into four categories for the predominant level of education of their participants: 1. No formal schooling; 2. Primary / elementary; 3. Secondary / high school; 4. Tertiary / college (whether trade school or university, though usually it
transpired to be the latter). A limited number of studies reported on this variable, so it became necessary to use the full 2 x 2 study design moderator matrix, including untreated control group comparisons, in order to have enough data to be able to verify any trend (Table 0-59).

Results show little difference between the groups within each quadrant if the two ‘no formal schooling’ studies are held out. Participants in those studies gained considerably more benefit than participants at the other extreme, i.e. those with tertiary education, but with such small n no trend can be asserted regardless of the fact that the Q statistic p for the screened / treated control quadrant reached significance at 0.001. Note also the appearance of three null effect sizes in the unscreened / treated control quadrant, where the two confounds with dulling effect coincide. However, the one cell that does not conform to this trend is that for the single study with no formal education (0.34, n.s.).

Overall, this table of results cannot be said to provide evidence of any trend, but it may be considered to hint that education level may be relevant in some way – perhaps in relation to therapies that particularly relate to education or cognitive work. Investigation of educational therapies and CBT was consequently undertaken.

Table 0-59. Education level

<table>
<thead>
<tr>
<th>Screened</th>
<th>Untreated control</th>
<th>Treated control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>No formal schooling</td>
<td>-</td>
<td>1.94 (1)**</td>
</tr>
<tr>
<td>Primary</td>
<td>0.54 (4)**</td>
<td>0.15 (3)</td>
</tr>
<tr>
<td>Secondary</td>
<td>0.62 (4)**</td>
<td>0.40 (3)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>0.59 (9)**</td>
<td>0.14 (3)</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.961</td>
<td>0.001**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unscreened</th>
<th>Untreated control</th>
<th>Treated control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ES (n)</td>
<td>ES (n)</td>
</tr>
<tr>
<td>No formal schooling</td>
<td>-</td>
<td>0.34 (1)</td>
</tr>
<tr>
<td>Primary</td>
<td>-</td>
<td>-0.07 (2)</td>
</tr>
<tr>
<td>Secondary</td>
<td>0.35 (8)**</td>
<td>-0.01 (13)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>0.13 (11)*</td>
<td>-0.01 (14)</td>
</tr>
<tr>
<td>Q statistic p</td>
<td>0.244</td>
<td>0.505</td>
</tr>
</tbody>
</table>

Relevant notes from Table 0-35 apply.

*Education*al therapies
The possibility was considered that patients with less education may benefit more from educational therapies, so an analysis was run using only studies that delivered that therapy type (Table 0-60). The only rows that have enough n to sustain comment are those relating to unscreened × treated controls and secondary or tertiary levels of education, but both produced null results.

Table 0-60. Education level, educational therapies

<table>
<thead>
<tr>
<th>Screened</th>
<th>Untreated control</th>
<th>Treated control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal schooling</td>
<td>-</td>
<td>1.94 (1)**</td>
</tr>
<tr>
<td>Primary</td>
<td>-</td>
<td>0.09 (2)</td>
</tr>
<tr>
<td>Secondary</td>
<td>-0.42 (1)</td>
<td>1.18 (1)**</td>
</tr>
<tr>
<td>Tertiary</td>
<td>0.27 (1)</td>
<td>0.11 (2)</td>
</tr>
<tr>
<td><strong>Q statistic p</strong></td>
<td>0.108</td>
<td>0.000**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unscreened</th>
<th>Untreated control</th>
<th>Treated control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal schooling</td>
<td>-</td>
<td>0.34 (1)</td>
</tr>
<tr>
<td>Primary</td>
<td>-</td>
<td>-0.07 (1)</td>
</tr>
<tr>
<td>Secondary</td>
<td>0.44 (5)*</td>
<td>-0.03 (8)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>0.07 (3)</td>
<td>-0.09 (7)</td>
</tr>
<tr>
<td><strong>Q statistic p</strong></td>
<td>0.161</td>
<td>0.489</td>
</tr>
</tbody>
</table>

Relevant notes from Table 0-35 apply.

CBT

The same hypothesis was considered in relation to CBT, i.e. that patients with less education might benefit more from it (Table 0-61). Note that for both screened quadrants the outcomes for each education level are similar regardless, although n is sparse. For unscreened studies, the untreated control comparison between secondary (g = 0.22, p < 0.05) and tertiary (-0.04, n.s.) approaches statistical significance (Q statistic p = 0.138). Perhaps this hints that unscreened participants with less education may benefit more from CBT, but they still do not benefit much as the effect size is small.

Table 0-61. Education level, CBT
Conclusion
No main effect—either trend or statistical moderation—was found for level of education. Due to insufficient frequencies of studies reporting on this variable to sustain the dissection necessary to account for confounds and other important variables, it is not possible to conclude that patients with less education benefit more from educational therapies or CBT.

Marital status
Median split data are presented in the table below (Table 0-62). Nothing remarkable emerged in the results although the small non-significant trend for both screened and unscreened patients was that studies with smaller percentages of married or partnered participants produced higher effect sizes. This was particularly the case for screened patients.

Table 0-62. Marital status, median split

<table>
<thead>
<tr>
<th></th>
<th>Screened</th>
<th>Unscreened</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ES (n)</strong></td>
<td><strong>ES (n)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Over 73.4% of sample married</strong></td>
<td>0.45 (14)**</td>
<td>0.24 (11)**</td>
</tr>
<tr>
<td><strong>Under 73.4% of sample married</strong></td>
<td>0.63 (6)*</td>
<td>0.28 (13)**</td>
</tr>
<tr>
<td>Q statistic $p$</td>
<td>0.588</td>
<td>0.813</td>
</tr>
</tbody>
</table>

Notes as for Table 0-35.