

**Written emotional disclosure for psychological morbidity among people with long-term physical conditions: Systematic review and meta-analysis of randomised controlled trials**

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**ABSTRACT**

**Objective** To estimate the effect of written emotional disclosure (WED) on psychological morbidity and health status in people with long-term physical conditions, and to assess the process of intervention implementation.

**Design** Systematic review and random effects meta-analysis, using the standardised mean difference (SMD) with 95% confidence interval (CI) as the summary measure of treatment effect.

**Data sources** Electronic databases (01/1984 to 04/2011), bibliographies of included trials and review articles, current journal editions, and correspondence with researchers.

**Eligible studies** Published or unpublished randomised controlled trials of WED that report, as an outcome, psychological morbidity among people with long-term physical conditions.

**Results** The review included 14 trials involving 974 patients with LTPCs. In the pooled analysis of all trials ( $n = 779$ ), WED was associated with significantly lower psychological morbidity (SMD  $-0.22$ ; 95% CI  $-0.36, -0.07$ ; NNT =  $8.06$ ;  $I^2=0\%$ ) and, in 10 trials ( $n = 573$ ), significantly higher health status (SMD  $0.20$ ; 95% CI  $0.03, 0.37$ ; NNT =  $8.93$ ;  $I^2=0\%$ ). In seven trials, 53% (range 36-86%) of eligible patients approached opportunistically during clinic attendance were recruited and, in 14 trials, 84% (419 of 499) of all participants allocated to WED complied with treatment protocol.

**Conclusions** Among people with LTPCs, WED is associated with lower psychological morbidity and higher health status. WED is a brief, inexpensive intervention that appears acceptable to the target population and feasible for implementation in healthcare settings. Moderate quality evidence, however, mandates that findings be considered promising but equivocal in the absence of more robust evidence.

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**INTRODUCTION**

Common mental disorders (CMDs), including different types of depression and anxiety, have at least 25% prevalence among people with long-term physical conditions (LTPCs), with many more patients experiencing symptoms below the diagnostic threshold.<sup>1,2</sup> Subthreshold symptoms are important clinically, since they are associated with decrements in health that do not differ qualitatively from those associated with more severe symptoms.<sup>2,3</sup> Presence of symptoms of CMDs is a risk factor for poor prognosis of physical disease, and is associated with impaired functioning, reduced quality of life, and greater healthcare utilisation.<sup>3,4</sup> Although effective treatment of psychological morbidity is associated with improved physical health outcomes in patients with LTPCs,<sup>4,5</sup> for most patients it remains untreated or treated inadequately, being complicated by factors such as polypharmacy, patient preference for, but limited availability of, psychological interventions, and beliefs that normalise the experience of less severe symptoms of CMDs.<sup>5,6</sup> Without effective intervention, symptoms of CMDs are biased towards chronicity, recurrence and increased risk of long term disability and premature mortality.<sup>6,7</sup>

Expressive writing is a treatment strategy that may not only be efficacious for symptoms of CMDs but may also overcome some of the barriers to effective treatment. With over 100 randomised studies,<sup>8</sup> the most frequently examined form of expressive writing is written emotional disclosure (WED), which involves writing about a stressful experience for 15-20 minutes per day for three to four days.<sup>9</sup> There is substantial evidence that, among healthy volunteers, WED is associated with improved psychological health and health status,<sup>10,11</sup> but evidence in clinical populations has been mixed.<sup>12,13</sup> However, trials have not only often had small samples, but have also implemented modified WED protocols and assessed a range of outcomes in heterogeneous clinical populations, including patients with acute health problems, LTPCs and psychiatric disorders. WED is a brief inexpensive treatment strategy that may have good reach into the target population, but there is uncertainty concerning the effect of WED on psychological morbidity in LTPCs.

LTPCs and co-morbid symptoms of CMDs will have increased incidence in an ageing population, making effective treatment of psychological morbidity in the management of LTPCs a salient public health priority. WED has translational potential and plausible efficacy, but trials in clinical populations have been equivocal, such that there is uncertainty about the effects of WED in patients with LTPCs. The aim of this study was to provide a clinically meaningful synthesis of evidence to support decision making. The primary objective was to estimate the effect of WED on psychological morbidity and health status among patients with LTPCs, and to assess the extent to which effect estimates varied in sub-groups of study or were sensitive to a range of analytic decisions. The secondary objective was to assess the process of intervention implementation in order to consider the translational potential of WED.

## **METHODS**

### **Eligibility criteria**

Studies were eligible for inclusion if they were RCTs of WED that reported, as an outcome, psychological morbidity among patients with LTPCs. The review included trials in patients selected for the presence of a LTPC, which included any chronic physical health problem regarded as manageable but not usually curable.<sup>14</sup> WED was defined as an intervention in which patients were instructed to write, for at least 15 minutes on three or more separate occasions, about their deepest thoughts and feelings concerning a real, as opposed to imagined, personal experience. Any concurrent control intervention that did not incorporate an emotional disclosure component was accepted, including neutral writing, no writing or otherwise specified usual care. We considered psychological morbidity in relation to common mental disorders (CMDs), which include different types of depression and anxiety, the symptoms of which cause distress and impair daily functioning, but do not usually affect insight or cognition.<sup>15</sup> As symptoms of CMDs exist on a continuum of increasing severity, we adopted an inclusive approach based on the presence of symptoms, rather than a restrictive approach based on symptom type and or severity.

### **Study identification**

To identify relevant published, unpublished and ongoing trials, as well as existing systematic reviews, multiple electronic databases were searched from January 1986 to May 2011 (Appendix A). Search parameters were adapted to database requirements, and combined terms for WED and RCTs with no limitations set for outcomes or LTPCs in so as to maximise sensitivity of the search (Appendix B). Bibliographies of included studies and review articles were screened for further references. Search results were recorded to a bibliographic database. One reviewer screened the search results to exclude obviously irrelevant citations. For the remaining citations, full-text papers were obtained and assessed against eligibility criteria by two reviewers independently, with disagreements resolved by discussion. The list of included studies was sent to five international experts (authors of the most cited WED research papers, <5 years) for review and to identify any studies missed in our search strategy.

### **Data extraction**

Data were extracted from each paper by one reviewer and checked for accuracy by another. Summary data were extracted on: (a) design, e.g. N randomised, n per group, and follow-up length; (b) participants, e.g. LTPC, age and gender; (c) WED, e.g. number and length of writing sessions, and the writing period, location and focus; (d) comparison, e.g. exposure type and description; (e) outcomes, e.g. for each outcome and each group, the outcome measure, n assessed, mean and standard deviation (SD); (f) process, e.g. approach method, number of eligible patients invited, and number of WED participants who completed all writing sessions. For outcome measures with data reported as both total and subscale scores, total scores were extracted.

### **Risk of bias assessment**

Two reviewers independently assessed risk of bias in each trial according to the adequacy of sequence generation, allocation concealment, baseline comparability, participant blinding and completeness of follow-up. Each component was assessed as either adequate, inadequate or unclear, using Cochrane risk of bias

criteria.<sup>16</sup> For participant blinding, we distinguished between studies that described a plausible procedure designed to conceal, prior to commencing the first writing session, the experimental manipulation of emotional disclosure (adequate), from studies in which participants were informed about the design and purpose of the research (inadequate), and studies with insufficient information to determine the adequacy of participant blinding (unclear). Overall risk of bias in each study was classified as either low (all criteria graded adequate), moderate ( $\geq 3$  criteria adequate) or high ( $< 3$  adequate).

### Data synthesis

Included studies used different continuous outcome measures to assess both psychological morbidity and health status. We therefore used the standardised mean difference (SMD) as the summary measure of treatment effect. In each trial and for each outcome of interest, we calculated the SMD using the final value mean and SD for each group. Where these data were not reported, they were requested from study authors or calculated from other data reported in the paper.<sup>16</sup> Two trials had three treatment arms; WED and two comparators.<sup>s1,2</sup> We combined groups in one trial (neutral writing and no writing),<sup>s1</sup> but not in the second trial, since the instruction to not write about one's emotions was given to one group (neutral writing) but not the other (benefit finding).<sup>s2</sup> Sub-group data were combined in one trial that reported sample size, mean and SD separately for participants with high or low anxiety in each intervention.<sup>s2</sup>

Scale scores were converted such that beneficial outcomes were indicated by lower scores on measures of psychological morbidity, and higher scores on measures of health status. Trial-level SMDs were combined statistically using the random-effects model. To aid clinical interpretation of the pooled effect sizes, we transformed the SMD into the number needed to treat (NNT),<sup>17</sup> which indicates the number of patients that need to be treated in order to generate an additional positive outcome in one of them. Statistical heterogeneity was assessed by visual inspection of the forest plots and the  $I^2$  test.  $I^2$  represents the percentage of variability among effect estimates above that expected by chance, with values up to 40% considered unlikely to be important.<sup>16</sup>

### Additional analysis

Potential variation in the effect of WED on psychological morbidity was investigated in subgroups of study stratified by symptom severity. The stratification factor (symptom severity) was pre-specified, but strata were determined after data collection. Studies were grouped according to whether the sample mean score on the measure of psychological morbidity would, if applied to individuals, be either a) classified as moderate to severe, or interpreted as a positive screening result, i.e. high symptom severity, or b) classified as mild, or below the screening cut-off score, i.e. elevated symptoms. Sensitivity analyses assessed the extent to which the estimate of the observed effect of WED on psychological morbidity was affected by the inclusion of data from trials with high risk of bias ( $< 3$  adequate criteria) and shorter-term follow-up ( $< 3$  months). Additional unplanned analyses were undertaken where considered necessary for a more informed interpretation of findings. Small study effects were assessed by visual assessment of funnel symmetry in the plots of each trial's SMD against its standard error (SE).<sup>16</sup>

To evaluate the process of the intervention implementation, we expressed the number of patients randomised as a proportion of the total number of eligible patients invited to participate. We distinguished between trials in which eligible patients were identified and approached opportunistically during clinic attendance (uptake), from trials in which eligible patients were identified from among those who self-referred to the research team. We estimated compliance to the intervention protocol by expressing the number of WED patients who completed all of the required writing sessions, as a proportion of the total number of patients allocated to WED.

## RESULTS

After removal of duplicates, 10,693 distinct citations were identified by the search strategy (Figure 1). Full-text papers were sought for 73 citations that could not be excluded in the initial screening. Five citations, all conference abstracts, were excluded as they could not be traced as full-text papers and requests to authors yielded no further information. Assessment of 68 full-text papers identified 14 studies that met the inclusion criteria.<sup>s1-14</sup> The main reasons for exclusion were use of non-randomised designs and no assessment of psychological morbidity at follow-up.

(Figure 1 here)

### Characteristics of included studies

Of the 14 included trials (Table 1), 11 were conducted in the USA and 3 were UK-based. The trials together randomised 974 participants, with mean sample size of 90 and 63 for trials conducted in the UK and USA, respectively. Follow-up ranged from eight<sup>s8</sup> to 28<sup>s12</sup> weeks, with 11 trials completing follow-up to 12 or more weeks. Trials were conducted in people with a range of different LTPCs, with the most frequent being cancer (six trials). Eight trials approached and invited patients to participate in the study during clinic attendance, whilst six trials advertised for potential participants using clinic posters, patient newsletters, and online discussion groups.<sup>s1</sup> Across trials, the principle eligibility criteria were the specific LTPC, ability to speak and write in English, and no psychiatric illness. None of the included trials assessed psychological morbidity for participant eligibility.

(Table 1. here)

The WED interventions involved 3-4, 20 minute writing sessions, with each session completed on a separate day. Nine trials required participants to complete the writing task within five days, with the remaining trials allowing two,<sup>s9</sup> three<sup>s1,2,7</sup> or four<sup>s3</sup> weeks for completion. In six trials,<sup>s1,5,6,10,11,13</sup> participants were free to write about any troublesome experience that was personally relevant, whilst the remaining trials instructed participants to focus on experiences concerning their LTPC.<sup>s2-4,7-9,12,14</sup> WED was compared to neutral writing,<sup>s2,3,5-8,11,13,14</sup> no writing,<sup>s4,9,10,12</sup> or a control group consisting of both neutral and no writing participants.<sup>s1</sup> Writing was completed by participants at home in most trials, and in three trials writing sessions were completed in a clinical setting.<sup>s1-3</sup> In one trial,<sup>s10</sup> participants completed the first writing session in the clinic, and the remaining sessions at home.

Psychological morbidity was assessed with different symptom checklists. Six trials used a checklist for depressive symptoms,<sup>s1,2,6,7,10,11</sup> including the Beck Depression Inventory (BDI),<sup>18</sup> the Hospital Anxiety and Depression Scale (HADS),<sup>19</sup> the Patient Health Questionnaire (PHQ 9),<sup>20</sup> and the Centre for Epidemiologic Studies Depression scale (CESD).<sup>21</sup> The remaining eight trials<sup>s3-5,8,9,12-14</sup> used various measures to assess affective symptoms, including the Positive and Negative Affect Schedule – Expanded (PANAS-X - negative affect subscale),<sup>22</sup> the Profile of Mood States (POMS)<sup>23</sup> and the Brief Symptoms Inventory (BSI – global severity index).<sup>24</sup>



For baseline psychological morbidity, the sample mean score, if applied to individuals, was above the screening cut-off score in one trial (CESD = 17.26, SD = 10.07),<sup>s2</sup> and within the range of moderate symptom severity in two trials (BDI = 20.3, SD = 11.5; <sup>s1</sup> PHQ-9 = 13.5, SD = 5.45).<sup>s10</sup> In the remaining trials, the sample mean score at baseline indicated psychological morbidity that was, on average, elevated but subsyndromal in severity.

Four trials<sup>s2,12-14</sup> provided no usable data for assessing the effects of WED on health status. In five trials<sup>s1,3,7,8,10</sup> health status was assessed with a generic measure, including the SF-12,<sup>25</sup> the General Health Survey (GHS - overall health subscale),<sup>26</sup> the Perceived Stress Scale (PSS),<sup>27</sup> the Somatic Symptoms Checklist (SS)<sup>28</sup> and the Sickness Impact Profile (SIP - physical and daily functioning subscales).<sup>29</sup> Five trials<sup>s4-6,9,11</sup> assessed health status using a disease-specific measure, which included the Functional Assessment of Cancer Therapy (FACT),<sup>30</sup> the Fibromyalgia Impact Questionnaire (FIQ),<sup>31</sup> the Bath Ankylosing Spondylitis Functional Index (BASFI)<sup>32</sup> and the Dermatology Life Quality Index (DLQI).<sup>33</sup>

Risk of bias varied among the included studies (Table 2), with risk assessed as high in six trials,<sup>s3,9,10,12-14</sup> moderate in five,<sup>s2,4,7,8,11</sup> and low in three.<sup>s1,5,6</sup> Across the 14 trials a total of 40 (57%) risk of bias items were assessed as adequate, 19 (27%) were unclear and 11 (16%) were inadequate. The most common known methodological limitations were failure to make any attempt to blind participants or to conceal the allocation sequence, which together accounted for all items assessed as inadequate. Lack of detail in some studies hindered the risk of bias assessment, particularly concerning the method used to generate the allocation sequence, whether the sequence was concealed from those enrolling participants, and the comparability of groups at baseline.

**(Table 2. here)**

### **Effect of WED**

*Psychological morbidity:* The summary measure of treatment effect on psychological morbidity in each trial ranged from SMD -0.68 to 0.03 (Figure 2.). In all but one trial<sup>s12</sup> the estimate of effect indicated lower psychological morbidity among participants allocated to WED, although in no trial was the effect statistically significant. The synthesis of data from 14 trials (n = 779) produced a small but statistically significant (P = 0.003) effect in which WED was associated with lower psychological morbidity (SMD = -0.22; 95% CI = -0.36, -0.07; NNT = 8.06). There was no evidence of statistical heterogeneity among the pooled estimates (I<sup>2</sup> = 0%).

**(Figures 2 & 3. here)**

*Health status:* Trial-level estimates of the effect of WED on health status ranged from SMD 0.06 to 0.55 (Figure 3.) Each trial-level estimate of effect indicated higher health status among WED participants at follow-up, but none was statistically significant. The pooled analysis of data from 10 trials (n = 573) yielded a small, statistically significant (P = 0.02) effect in which WED was associated with higher health status (SMD = 0.20; 95% CI = 0.03, 0.37; NNT = 8.93). There was no evidence of statistical heterogeneity among the pooled estimates (I<sup>2</sup> = 0%).

### Additional analyses

Subgroup and sensitivity analyses were conducted for the effect of WED on psychological morbidity (Table 3). Separate analyses of subgroups of study stratified by symptom severity similarly yielded small estimates of effect in which WED was associated with lower psychological morbidity. More specifically, in the synthesis of three trials<sup>s1,2,10</sup> with high mean severity of symptoms the SMD was -0.32 (95% CI = -0.64, 0.00;  $I^2 = 0\%$ ) and in the remaining 11 trials with elevated mean symptom severity the SMD was -0.20 (95% CI = -0.36, -0.04;  $I^2 = 0\%$ ). The pooled estimate of the effect of WED on psychological morbidity was comparable in a planned analyses that excluded six trials<sup>s3,9,10,12-14</sup> with high risk of bias (SMD = -0.20; 95% CI -0.38, -0.02) and three trials<sup>s3,8,13</sup> with shorter-term follow-up (SMD = -0.22; 95% CI = -0.37, -0.06).

**(Table 3. here)**

A small effect favouring WED emerged consistently in unplanned analyses that were restricted to three trials<sup>s1,5,6</sup> with low risk of bias (SMD = -0.32; 95% CI = -0.60, -0.04), five trials<sup>s1,4,9,12,14</sup> with more than three months follow-up (SMD = -0.22; 95% CI = -0.44, 0.00), and eight trials<sup>s1,3,4,9,10,12-14</sup> in which patients were approached and recruited opportunistically during clinic attendance (SMD = -0.25; 95% CI = -0.44, -0.05), as well as when the synthesis excluded three trials<sup>s1,5,8</sup> in which the LTPC was a non-specific syndrome (SMD = -0.20; -0.37, -0.04).

**(Figure 4. here)**

There was no evidence of small study effect, including publication bias, from a visual inspection of the funnel plot (Figure 4). All but three trials<sup>s5,9,13</sup> reported the number of eligible patients invited to participate. Mean uptake was 52% (36-86%) in six of eight trials that approached patients opportunistically during clinic attendance, and 82% (69-100%) in five of six trials recruiting among patients who self-referred following advertising of the trial. Overall, 499 patients were allocated to WED, of whom 419 (84%) completed all required writing sessions.

**DISCUSSION**

There is moderate quality evidence that, in patients with LTPCs, WED has a small beneficial effect, being associated with lower psychological morbidity and higher health status. Additional analyses show that pooled effect estimates are robust, such that small statistically significant effects emerged from syntheses that excluded trials with higher risk of bias or shorter term follow-up. Small effects favouring WED were observed in separate analyses of studies classified as having either high or elevated symptom severity, as well as in unplanned analyses that excluded trials in which LTPCs were non-specific syndromes, or that included only trials that recruited patients opportunistically during clinic attendance. Data on the process of intervention implementation demonstrate high uptake and compliance, such that half of all eligible patients approached opportunistically during clinic attendance were recruited, and more than 80% of all patients allocated to WED were compliant with the treatment protocol.

**Strengths and weaknesses of the study**

The study adhered to a protocol that specified valid methods to identify, evaluate and synthesise relevant evidence. A comprehensive search for published and unpublished studies, which included multiple electronic databases, scanning of bibliographies, handsearching journals and validation by experts, yielded 14 trials, all of which were published studies. Absence of data from unpublished studies is a potential weakness, since effects estimated from published studies may be inflated because of bias towards the non-publication of small studies with null effects. However, none of the included studies yielded a trial-level statistically significant effect on psychological morbidity, and in no trial was psychological morbidity identified as an eligibility criterion or a primary outcome. This mitigates concerns about publication bias, since decisions to publish trials of WED appear independent of the observed effect on our primary outcome.

There was at least a moderate risk of bias in all but three of the included trials, with six trials assessed as having high risk of bias. As study quality and effect size typically show an inverse association, the underlying risk of bias may have inflated the treatment effect obtained in this study. Our assessment included an item on participant blinding, which accounted for 64% (7/11) of all items assessed as inadequate. In studies where blinding is not possible, it is typically removed from the assessment. We retained the item because seven studies explicitly sought to conceal the purpose of the study from participants to reduce the risk of bias associated with lack of blinding. Acknowledging greater control of bias within some studies increased the assessed risk across studies. Sensitivity analyses yielded a small, statistically significant effect favouring WED when trials with high risk of bias were excluded, and a comparatively larger, but still small effect when only trials with low risk of bias were synthesised. These data are inconsistent with the suggestion that bias due to poor methodological quality may have inflated the observed effect of WED on psychological morbidity.

A strength of the study is that it has clinical validity by design. Eligibility criteria enabled the inclusion of trials in patients with a range of LTPCs, and psychological morbidity that varied in symptom type and severity. Such evidence reflects more completely the heterogeneity of patients encountered routinely in clinical practice, and recognises that many patients present with subthreshold symptoms. Our strategy of combining symptoms of CMDs, recognises not only that symptoms frequently co-exist, but that, as symptom assessment and classification can be difficult in LTPCs, treatments that are independent of symptom

differentiation may have greater translational potential than symptom-specific treatments. An inclusive approach in which outcomes were synthesised across LTPCs, increased the pool of available evidence and allowed the effect of WED to be estimated with greater precision and wider applicability.

An important strength of the study is the consistency of estimates of the effect of WED. In our pooled analyses there was no evidence of statistical heterogeneity, indicating that pooled effects were estimated from a set of homogenous trial-level effects, such that they differed no more than would be expected by chance. More specifically, all but one of the 14 included trials indicated a small effect favouring WED, although none were statistically significant. For the primary outcome, we examined the sensitivity of the pooled estimate to different analytic assumptions in separate analyses that excluded trials with characteristics that might have biased the observed effect. All of these analyses, however, yielded a small, statistically significant effect favouring WED.

The study assessed the process of intervention implementation in order to inform on the acceptability of WED to patients with LTPCs, and the feasibility of implementing WED in healthcare settings. A strength of this assessment is not only the completeness of reporting of process data, but also that data are drawn from the same set of trials used to estimate the effects of WED. In all but three trials there were sufficient data to determine the proportion of eligible patients who were invited and recruited to the study, how and where eligible patients were identified and invited, and the proportion who complied with the WED protocol.

### **Comparison with other studies**

Previous syntheses of WED have reported medium to large effect sizes for psychological well-being ( $d = 0.66$ ) and health status ( $d = 0.44$ ) in healthy volunteers,<sup>11</sup> and for negative mood ( $d = 0.51$ ) and anxiety ( $d = 0.40$ ) from synthesis of studies in healthy and clinical populations.<sup>13</sup> A synthesis of physical and psychological health outcomes from nine studies in patients with acute health problems, LTPCs and psychiatric disorder, yielded a small effect for health ( $d = 0.19$ ), for which there was evidence of statistical heterogeneity.<sup>12</sup> Previous studies have quantified WED effects in the presence of statistical, methodological and clinical heterogeneity, and have yielded findings that are difficult to interpret and apply clinically.

This study is the first to quantify the effect of WED on psychological morbidity and health status among patients with LTPCs. Our findings suggest the effects of WED among patients with LTPCs are more modest than among those without LTPCs. This is an important finding that should inform the design of future trials. An ongoing trial of WED in patients with heart disease,<sup>34</sup> for example, has been designed to detect a much larger effect size ( $d = 0.8$ ) on health status than our findings would suggest is realistic. Results from underpowered trials will likely add to, rather than reduce, uncertainty concerning the effect of WED in LTPCs. More generally, the size and consistency of our estimate of the effect of WED compares favourably to the effect of selective serotonin reuptake inhibitors (SSRIs) on depression severity (SMD = -0.19; 95% CI -0.36, -0.02;  $I^2 = 50\%$ ), which was similarly estimated from moderate quality evidence in patients with LTPCs and elevated symptoms of depression.<sup>35</sup>

### **Implications of the study**

WED has a small effect on psychological morbidity (SMD = 0.22) and health status (SMD = 0.20), and at least eight people would need to be treated in order to generate an additional positive outcome in one of them. To help interpret clinical importance, SMD can be expressed as points on the original scale and compared to the baseline value. Based on the mean SD reported in the trials, a SMD of 0.22 approximates 2.5, 2.0 and 0.8 points on the BDI (SD 10.9), CESD (SD 9.7) and HADS (SD 3.6), respectively, which, for each measure, corresponds to a reduction of ~20% (range 16-23%) in symptom severity compared to baseline. For measures of mood disturbance (POMS and PANAS-X) the effect size corresponds to a difference of ~25% (range 22-28%) in symptom severity. We consider a difference of 20-25% in psychological morbidity or, more precisely, the severity of symptoms of CMDs, to be clinically important.

The findings of this study are based on evidence from RCTs that implemented WED using a standardised protocol among patients with a range of LTPCs. Analyses yielded consistent estimates of effect, for which there was no evidence of statistical heterogeneity or of sensitivity to inclusion of trials with characteristics that might distort the observed effect, including trials with higher risk of bias and shorter term follow-up. Whilst the quality of trials was less than ideal, the body of evidence on the effect of WED on psychological morbidity and health status among people with LTPCs can be considered to be of moderate quality.<sup>36</sup>

The finding that WED has a small, clinically important beneficial effect on psychological morbidity and health status, has general applicability to patients with LTPCs and elevated, but sub-threshold, symptoms of CMDs. The findings may have limited applicability for patients with more severe physical illness, since several trials excluded patients classified as too ill, whilst other trials likely included people with less severe physical illness. Similarly, as none of the included trials required psychological morbidity for patient eligibility, and some trials excluded patients with psychiatric disorder, it is unclear if our findings are applicable to patients with more severe symptoms, such as those that satisfy diagnostic criteria for CMDs.

Findings on the intervention implementation process indicate that WED is acceptable to patients with LTPCs and feasible for implementation in primary care and out-patient clinical settings. In this context, a small but clinically important effect at the individual level, may translate into a substantial effect at the population level. Research to reduce residual uncertainty associated with moderate quality evidence should be considered a public health priority. This research should be in the form of a RCT with sufficient power to detect a small effect among patients with a range of LTPCs, which might also usefully stratify randomisation by severity of psychological morbidity and or severity of physical illness.

## **Conclusion**

Among people with LTPCs, WED is associated with lower psychological morbidity and higher health status. The finding that WED has a small, consistent and clinically important effect, whilst promising, remains equivocal in the presence of moderate quality evidence. WED is brief, inexpensive and appears acceptable to patients with a range of LTPCs and feasible for implementation in healthcare settings that afford maximum contact opportunity. There is extant need for a methodologically robust pragmatic evaluation of WED among patients with LTPCs.

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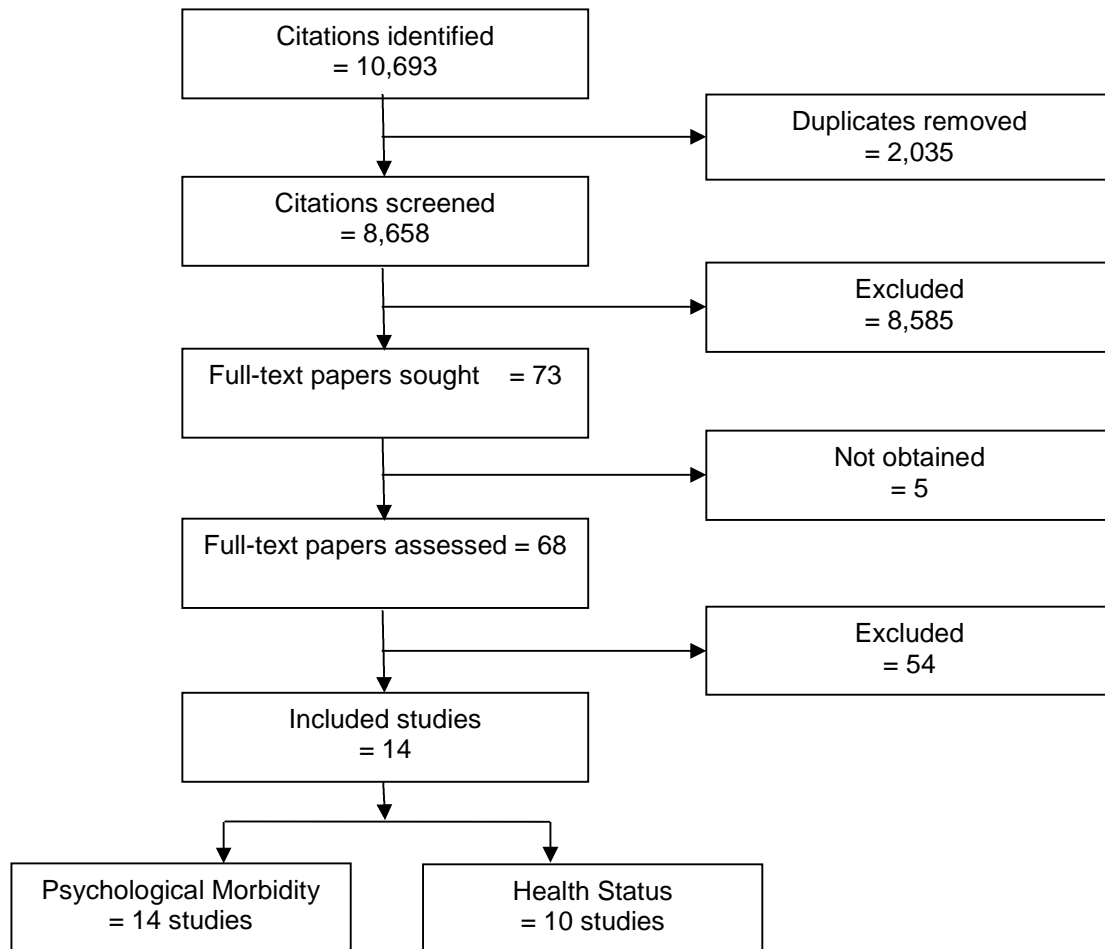
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Figure 1. Flow Diagram Of Study Selection



**Table 1. Study details**

<b>Study:</b> Author (Year); Country	<b>Participants:</b> LTFC (Approach <sup>†</sup> ); N; M age (% female)	<b>WED Intervention<sup>†</sup>:</b> N, length (period); Foci; Location; Comparison	<b>Process:</b> Uptake <sup>‡</sup> ; Adherence <sup>§</sup>	<b>Outcomes:</b> N (Follow-up); Measures <sup>¶</sup>
Broderick <sup>s1</sup> (2005); USA	Fibromyalgia (Clinic) 92; 49 years (100%)	3, 20 mins (21 days); Any; Clinic; Neutral & no writing	38% (92 / 243) 94% (29 / 31)	83 (16 weeks); BDI; GHS
Danoff-Burg <sup>s2</sup> (2006); USA	Arthritis (Ads) 48; 51 years (83%)	4, 20 mins (21 days); LTFC; Clinic; Neutral writing	91% (75 / 82) 96% (23 / 24)	40 (12 weeks); CESD; -
de Moor <sup>s3</sup> (2002); USA	Cancer (Clinic) 42; 56 years (14%)	4, 20 mins (28 days); LTFC; Clinic; Neutral writing	86% (42 / 49) 86% (18 / 21)	37 (10 weeks); POMS; PSS
Gellaitry <sup>s4</sup> (2009); UK	Cancer (Clinic) 93; 58 years (100%)	4, 20 mins (4 days); LTFC; Home; No writing	36% (93 / 260) 91% (42 / 46)	80 (24 weeks); POMS; FAC-B
Gillis <sup>s5</sup> (2006); USA	Fibromyalgia (Ads) 83; 50 years (97%)	4, 20 mins (4 days); Any; Home; Neutral writing	- (83 / NR) 82% (37 / 45)	68 (12 weeks); PANAS-X; FIQ
Hamilton-West <sup>s6</sup> (2007); UK	Arthritis (Ads) 107; 52 years (32%)	3, 20 mins (3 days); Any; Home; Neutral writing	80% (107 / 133) 62% (44 / 71)	67 (12 weeks) HADS; BASDAS
Low <sup>s7</sup> (2010); USA	Cancer (Ads) 76; 54 years (100%)	4, 20 mins (21 days); LTFC; Home; Neutral writing	69% (76 / 110) 97% (37 / 38)	62 (12 weeks) CESD; SS
Norman <sup>s8</sup> (2004); USA	Pain (Ads) 60; 38 years (100%)	3, 20 mins (3 days); LTFC; Home; Neutral writing	77% (60 / 78) 90% (27 / 30)	48 (8 weeks) PANAS-X; SIP
Rosenberg <sup>s9</sup> (2002); USA	Cancer (Clinic) 30; 70 years (0%)	4, 30 mins (14 days); Mixed; Home; No writing	- (30 / NR) 100% (16 / 16)	30 (24 weeks) POMS; FAC-P
Taylor <sup>s10</sup> (2003); USA	Cy. fibrosis (Clinic) 70; >18 years (69%)	3, 20 mins (5 days); Any; Mixed; No writing	86% (70 / 81) 78% (18 / 23)	39 (12 weeks) PHQ; SF12
Vedhara <sup>s11</sup> (2007); UK	Psoriasis (Ads) 69; 50 years (39%)	4, 20 mins (4 days); Any; Home; Neutral writing	100% (69 / 69) 75% (31 / 41)	59 (12 weeks) HADS; DLQI
Walker <sup>s12</sup> (1999); USA	Cancer (Clinic) 35; 54 years (100%)	3, 30 mins (5 days); LTFC; Home; No writing	70% (35 / 50) 84% (16 / 19)	28 (28 weeks) PANAS-X; -
Wetherell <sup>s13</sup> (2005); USA	Arthritis (Clinic) 42; 61 years (83%)	4, 20 mins (4 days); Any; Home; Neutral writing	- (42 / NR) 90% (19 / 21)	34 (10 weeks) POMS; -
Zakowski <sup>s14</sup> (2004); USA	Cancer (Clinic) 127; 60 years (52%)	3, 20 mins (7 days); LTFC; Home; Neutral writing	73% (127 / 175) 85% (62 / 73)	104 (24 weeks) BSI; -

\* Invitation to participate received during clinic attendance (clinic) or via advertising (ads).

† Number and length of writing sessions required; period for completion (days); disclosure foci specified in instructions (LTFC-specific or any); writing location (clinic, or home).

‡ Proportion of eligible patients invited, who were recruited (N randomised).

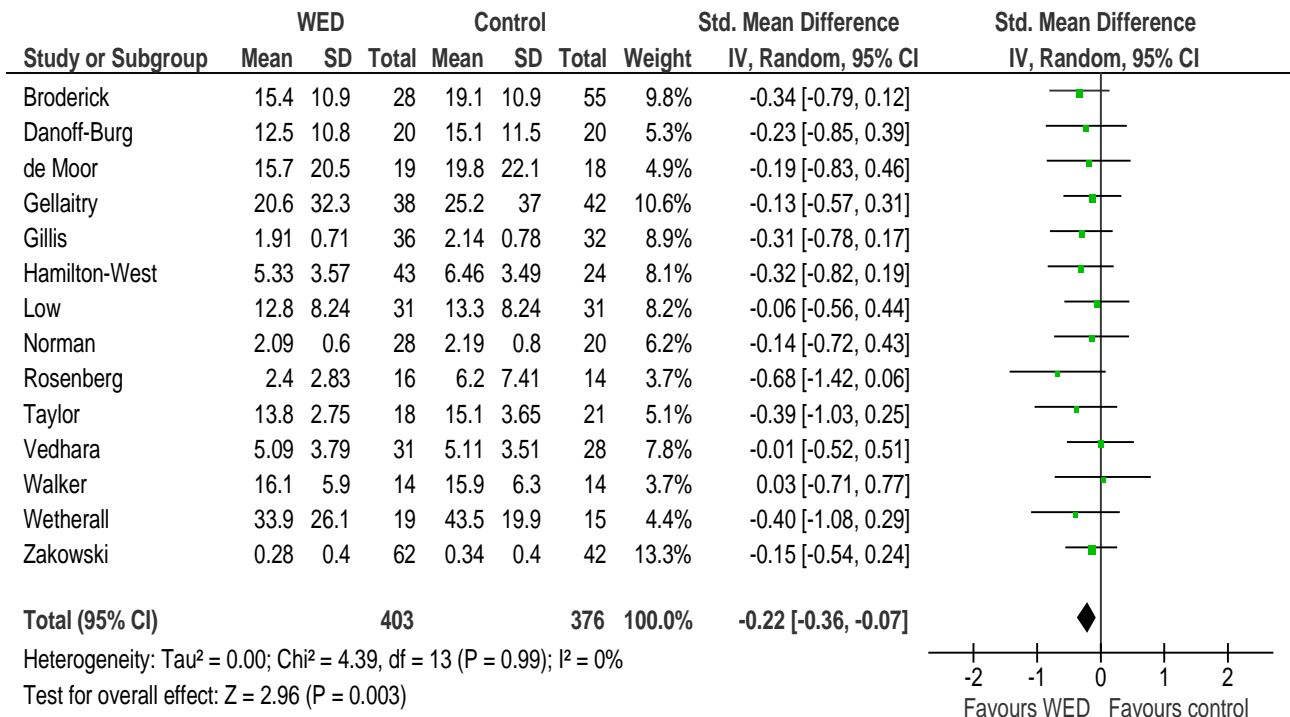
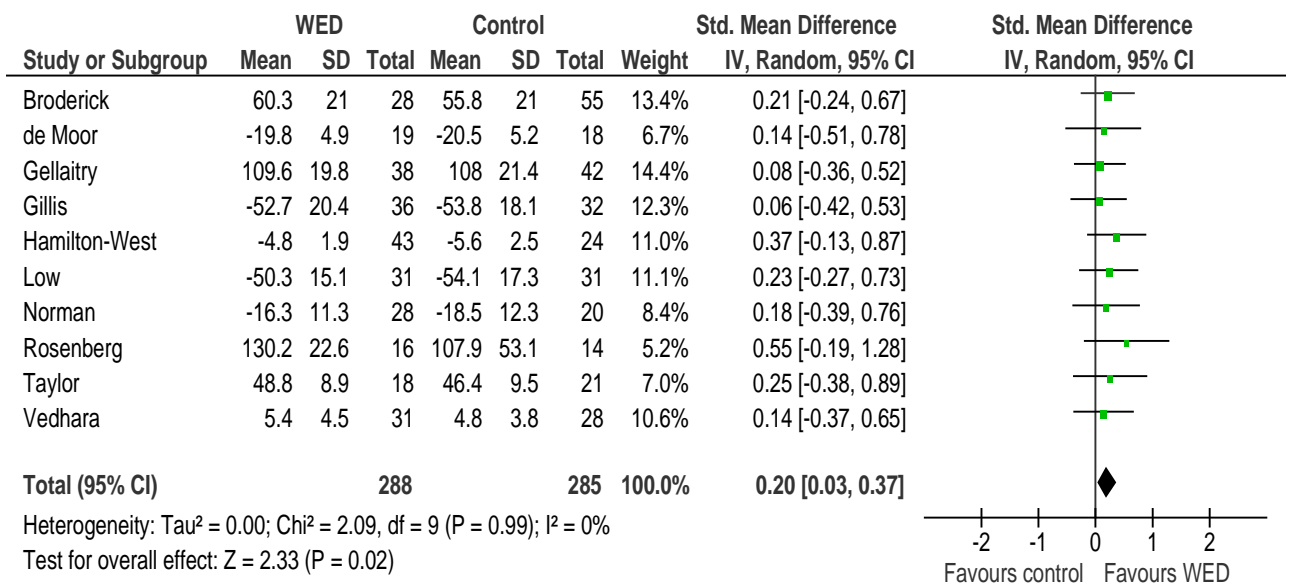
§ Proportion of participants allocated to WED, who completed all writing sessions.

¶ Synthesised data source (psychological morbidity; health status).

**Table 2. Risk of bias assessment**

Study	Assessment Domains					Overall risk of bias
	Random sequence	Concealed allocation	Baseline comparability	Blinded participants	Complete follow-up	
Broderick <sup>s1</sup>	Y	Y	Y	Y	Y	Low
Danoff-Burg <sup>s2</sup>	?	?	Y	Y	Y	Moderate
de Moor <sup>s3</sup>	?	?	Y*	N	Y	High
Gellaitry <sup>s4</sup>	Y	N	Y	N	Y	Moderate
Gillis <sup>s5</sup>	Y	Y	Y	Y	Y	Low
Hamilton-West <sup>s6</sup>	Y	Y	Y*	Y	Y	Low
Low <sup>s7</sup>	Y	Y	?	N	Y	Moderate
Norman <sup>s8</sup>	?	Y	Y	Y	Y	Moderate
Rosenberg <sup>s9</sup>	?	?	?	N	Y	High
Taylor <sup>s10</sup>	?	N	Y*	N	Y	High
Vedhara <sup>s11</sup>	?	?	Y*	Y	Y	Moderate
Walker <sup>s12</sup>	N	N	?	N	Y	High
Wetherell <sup>s13</sup>	?	?	?	Y	?	High
Zakowski <sup>s14</sup>	?	N	Y*	N	Y	High

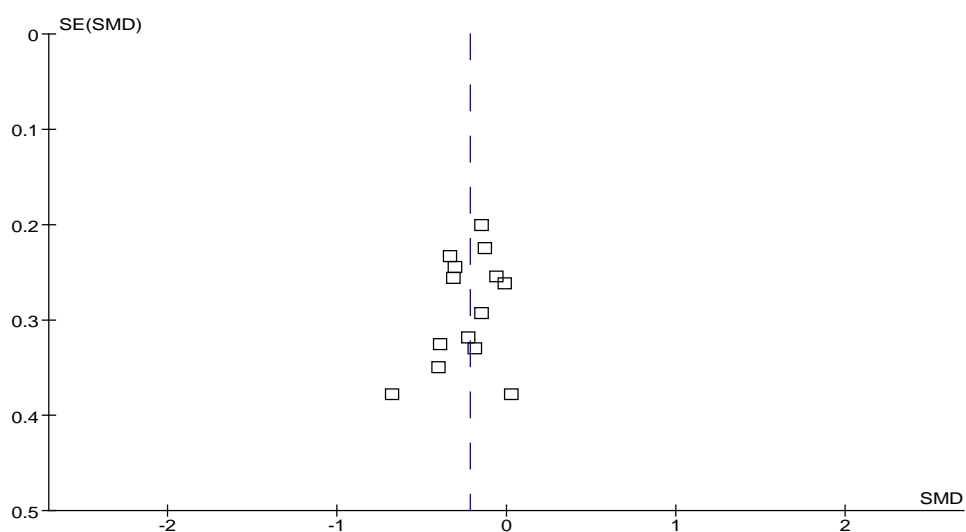
\* Baseline imbalance accounted for appropriately in analyses

**Figure 2. Effect of WED on psychological morbidity****Figure 3. Effect of WED on health status**

**Table 3. Summary results for the effects of WED on psychological morbidity and health status**

Outcome	Strata:	Subgroup	N Trials (Patients)	SMD (95% CI)*	P value
<b>Psychological morbidity</b>	-	-	<b>14 (779)</b>	<b>-0.22 (-0.36, -0.08)</b>	<b>0.003</b>
Symptom severity:		High	3 (162)	-0.32 (-0.64, 0.00)	0.05
		Elevated	11 (617)	-0.20 (-0.36, -0.04)	0.02
Follow-up:		≥3 months	11 (660)	-0.22 (-0.37, -0.06)	0.006
		>3 months	5 (325)	-0.22 (-0.44, 0.00)	0.05
Risk of bias:		Low-Moderate	8 (507)	-0.20 (-0.38, -0.02)	0.03
		Low	3 (218)	-0.32 (-0.60, -0.04)	0.02
Health condition:		Physical disease	11 (580)	-0.20 (-0.37, -0.04)	0.02
Approach		Clinic attendance	8 (435)	-0.25 (-0.44, -0.05)	0.01
<b>Health status</b>	-	-	<b>10 (573)</b>	<b>0.20 (0.03, 0.37)</b>	<b>0.02</b>

\*  $I^2 = 0\%$  for all syntheses.

**Figure 4. Funnel plot for the effect of WED on psychological morbidity.**

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## Appendix A: Databases to be searched

### Published health research:

- Medline, Embase and PsycInfo (Ovid SP)
- Cinahl (EBSCOhost), Lilacs (Bireme) and PEDro ([www.pedro.org.au/](http://www.pedro.org.au/))
- CDSR (The Cochrane Library): <http://www.thecochranelibrary.com/view/0/index.html>
- DARE and PROSPERO: [http://www.york.ac.uk/inst/crd/index\\_databases.htm](http://www.york.ac.uk/inst/crd/index_databases.htm)

### Grey literature:

- ISI Conference Proceedings:  
[http://isiwebofknowledge.com/products\\_tools/multidisciplinary/webofscience/cpci](http://isiwebofknowledge.com/products_tools/multidisciplinary/webofscience/cpci)
- Australasian Digital Theses Program: <http://adt.caul.edu.au/>
- Theses Canada: <http://www.collectionscanada.gc.ca/thesescanada/index-e.html>
- Index to Theses (UK and Ireland): <http://www.theses.com/>
- DATAD: <http://www.aau.org/datad/index.htm>
- SIGLE (2005): <http://www.cardiff.ac.uk/insrv/eresources/databases/sigle.html>
- OpenGrey: <http://www.opengrey.eu/>
- Meeting Abstracts: <http://gateway.nlm.nih.gov>
- Dissertation Abstracts (US and Canadian): <http://library.dialog.com/bluesheets/html/bl0035.html>

### National and international trials registers:

- CentreWatch Clinical Trials Listing Service: [www.centrewatch.com](http://www.centrewatch.com)
- CENTRAL (The Cochrane Library): <http://www.thecochranelibrary.com/view/0/index.html>
- Current Controlled Trials: (covers Action Medical Research; UK-MRC; NIHR HTA; US-NIH; ISRCTN; ClinicalTrials.gov; The Wellcome Trust): [www.controlled-trials.com/mrct](http://www.controlled-trials.com/mrct)
- IFPMA Trials: [http://clinicaltrials.ifpma.org/no\\_cache/en/myportal/index.htm](http://clinicaltrials.ifpma.org/no_cache/en/myportal/index.htm)
- NIHR Clinical Research Network Portfolio: <http://public.ukcrn.org.uk/search/>
- UK Clinical Trials Gateway: [www.controlled-trials.com/ukctg](http://www.controlled-trials.com/ukctg)

**Appendix B: Example search strategy****PsycINFO (OVID SP)**

1. creative writing/ or expressive writing/ or therapeutic writing/
2. written emotional disclosure/
3. ((emotion\$ or disclos\$ or express\$) adj3 (writ\$ or journal or diary)).ti,ab.
4. Or/1-3
5. treatment effectiveness evaluation/
6. clinical trials/
7. placebo/
8. mental health program evaluation/
9. placebo\$.tw.
10. random\$.tw.
11. (clinical adj3 trial\$).tw.
12. (research adj3 design).tw.
13. (evaluat\$ adj3 stud\$).tw.
14. (prospectiv\$ adj3 stud\$).tw.
15. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$ or dummy)).tw.
16. or/5-15
17. (animal not ((human or inpatient or outpatient) and animal)).po.
18. 16 not 17
19. 4 and 18