Written Emotional Disclosure for Improving Depression for Adults with Long-term Physical Conditions: The Case of Type 2 Diabetes

Two volumes (volume one)

by

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Table of contents

Page

Volume one

Volume two

Tables and figures

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Declaration

I declare that this thesis is all my own work except where I have otherwise stated and that this thesis has not been submitted for a degree at any other University.

Signed.....

Abbreviations

ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BCF	Baseline observation carried forward
BDI	Beck Depression Inventory
BHF	British Heart Foundation
BMA	British Medical Association
BMI	Body mass index
BSI	Brief Symptom Inventory
CAD	Coronary artery disease
CBT	Cognitive Behavioural Therapy
cCBT	Computerised CBT
CD(s)	Compact disc(s)
CDC	National Centre for Disease Control and Prevention
CES-D scale	Centre for Epidemiological Studies Depression scale
CHD	Coronary heart disease
CLRN	Comprehensive Local Research Network
CONSORT statement	Consolidated Standards of Reporting Trials statement
CPD	Continued professional development
CR	Conditioned response
CRD	Centre for Reviews and Dissemination
CRN	Clinical Research Network
CRUK	Cancer Research UK
CS	Conditioned stimulus
CTU	Clinical Trials Unit
CVD	Cardiovascular disease
DLQI	Dermatology Life Quality Index
DMSES UK	UK version of the Diabetes Management Self-efficacy Scale
DNA	Did not arrive
DoH	Department of Health
DSED	Diabetes specific emotional distress
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition
DSN(s)	Diabetes specialist nurse(s)
DSQ(s)	Depression-screening questionnaire(s)
DUK	Diabetes UK
E&CP	Emotional and cognitive processing
E&P	Emotional and psychological
EA	Emotional activation
EA&H	Emotional activation and habituation

ED	Emotional disclosure
EDID Research Consortium	European Depression in Diabetes Research Consortium
EOIF	Expression of interest form
EQ-5D	EuroQoL
FACT-B	Functional Assessment of Cancer Therapy – Breast
FACT-P	Functional Assessment of Cancer Therapy – Prostate
FIQ	Fibromyalgia Impact Questionnaire
GCP	Good Clinical Practice
GMS	General Medical Services
GP(s)	General practitioner(s)
HADS	Hospital Anxiety & Depression Scale
HbA1c	Glycosylated haemoglobin
HCA(s)	Health care assistant(s)
HCP(s)	Health care providers(s)
HCU	Health care use
HIV	Human immunodeficiency virus
HSSREC	Human and Social Sciences Research Ethics Committee
IAPT	Improving Access to Psychological Therapies
ICC(s)	Intra-class correlation(s)
ICD-10	International Classification of Diseases and Related Health Problems, 10th Revision
IES	Impact of Events Scale
IIRS	Illness Intrusiveness Rating Scale
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention to treat
LIWC	Linguistic Inquiry and Word Count
LOCF	Last observation carried forward
LOT-R	Life Orientation Test-Revised
LTPC(s)	Long-term physical condition(s)
MANCOVA	Multivariate analysis of covariance
MDD	Major depressive disorder
MI	Myocardial infarction
MRC	Medical Research Council
MS	Metabolic syndrome
n	Number
NICE	National Institute for Clinical Excellence NHS National Health Service
NIHR	National Institute for Health Research
NS	Neutral stimulus
NSF(s)	National Service Framework(s)
OR	Odds ratio
PAID scale	Problem Areas in Diabetes scale
PaIS	Patient/participant information sheet

PANAS	Positive and Negative Affect Schedule
PANAS-X	Positive and Negative Affect Schedule (expanded version)
PCRN	Primary Care Research Network
PCT(s)	Primary care trust(s)
PHQ	Patient Health Questionnaire
PIN(s)	Personal identification number(s)
PM	Practice manager
POMS	Profile of Mood States
POMS-SF	Short form of the Profile of Mood States
PRIME-MD questionnaire	Primary Care Evaluation of Mental Disorders questionnaire
PrIS	Practice information sheet
PRISM	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Perceived Stress Scale
PTSD	Post-traumatic stress disorder
QALY	Quality adjusted life year
QoF	Quality and Outcomes Framework
QoL	Quality of life
R&D	Research and development
RCTs	Randomised controlled trial(s)
REC	Research Ethics Committee
SD	Standard deviation
SDCAQ	Summary of Diabetes Self-care Activities Questionnaire
SE	Standard error
SF-12	Short form 12
SF-36	Short form-36
SMB(s)	Self-management behaviour(s)
SMD(s)	Standardized mean difference(s)
SSQ6	6 item version of the Social Support Questionnaire
SSRI(s)	Selective serotonin re-uptake inhibitor(s)
TAS-20	Toronto Alexithymia Scale (revised version)
TCAs	Tricyclic antidepressant(s)
UCR	Unconditioned response
UCS	Unconditioned stimulus
UK	United Kingdom
USA	United States of America
VAS	Visual analogue scale
WDREUG	Warwick Diabetes Research and Education User Group
WED	Written emotional disclosure
WHO	World Health Organisation
WMS	Warwick Medical School
95% CI(s)	95% confidence intervals
η^2	Eta squared

η_p^2	Partial eta squared
ω^2	Omega squared
r	Pearson's correlation co-efficient
d	Cohen's d
b	Unstandardized regression co-efficient
SEb	Standard error of the unstandardized regression co-efficient
ß	Standardized regression coefficient

Abstract

Depression is twice as prevalent among people with long-term physical conditions (LTPCs), and it confers an increased risk of additional morbidity and early mortality. Psychological interventions such as those based on cognitive behavioural therapy (CBT), can improve outcomes but widespread provision is problematic. Written emotional disclosure (WED) is a brief, inexpensive intervention that may offer a pragmatic solution. Its effects, however, are unclear, since reviews have drawn different conclusions and used inadequate methodology.

A methodologically robust systematic review of RCTs, evaluating WEDs effects on psychological health and quality of life (QoL) in adults with LTPCs, concluded that WED may be effective for reducing negative affect including depression, and some associated outcomes. However, future endeavours must improve methodological rigor and explore WED for LTPCs impacted by negative affect. Type 2 diabetes is consistent with this specification yet understudied in WED.

An exploratory RCT investigating WED for improving depressive symptom severity, and some secondary outcomes, in adults with Type 2 diabetes was undertaken. A test of WEDs anticipated effect, further exploration of this and an investigation of feasibility was initially intended. However, ethical and recruitment issues necessitated that the objectives be narrowed down to a focus on feasibility and a very much exploratory analysis of the effectiveness of WED. Recruitment was via primary care supplemented with online support groups, albeit secondary care was also attempted. The study identified that WED may be acceptably and feasibly implemented as part of general practice in the UK and for use with LTPCs in this context, specifically Type 2 diabetes. However, ethical and recruitment also issues necessitated delivery of WED to patients with none or very low-level depressive symptoms, for whom it may cause iatrogenic harm. However, a number of methodological issues substantially undermined these findings. Further research addressing the pitfalls associated with previous endeavours is required before consideration of WED in primary care for LTPCs including Type 2 diabetes.

Chapter 1 Long-term physical conditions and psychological morbidity

Overview of chapter

The present thesis was born out of an interest in and previous study on the psychological impact of LTPCs, and a desire to identify feasible and effective means of ameliorating this impact which could reasonably be implemented as part of routine clinical care. Consequently, the initial chapter presents an overview of psychological morbidity in LTPCs. LTPCs are described briefly, after which the notable consequences for psychological health are considered, with an emphasis on depression and its prevalence, pathophysiology and prognosis in LTPCs. The expressed need, and policy imperatives, for emotional and psychological (E&P) support in LTPCs are then described, as are recent changes in clinical practice intended to achieve this and persisting barriers to E&P support in LTPCs.

LTPCs

LTPCs such as heart disease, diabetes, cancer, asthma and arthritis, are conditions that cannot, at present, be cured but can be controlled by medication and other therapies (Department of Health (DoH), 2008). The global prevalence of LTPCs is increasing (World Health Organisation (WHO), 2002). In 2002, LTPCs accounted for 60% of the global burden of disease (WHO, 2002), and in developed countries they account for 80% of the disease burden (WHO, 2003). In England, 33% of the population report having a LTPC (DoH, 2008). The increased and rising prevalence of LTPCs is a consequence of an aging population, which is owing to advances in medicine and public health and is problematic because the risk of LTPCs increases with age. It is also due to a rise in preventable, modifiable risk factors, for example poor diet and physical inactivity, which adversely affect physiological parameters that are implicated in LTPCs (DoH, 2009; DoH, 2008; WHO, 2002; WHO, 2003).

LTPCs are associated with reduced QoL (Sprangers, de Regt, Andries, van Agt, Bijl, de Boer, Foets, Hoeymans, Jacobs, Kempen, Miedema, Tijhuis & de Haes, 2000), early mortality (e.g. deaths before the age of 65) (British Heart Foundation (BHF), 2006 & 2008; Cancer Research UK (CRUK), 2009) and increased and increasing health care use (HCU) and costs (Bagust, Hopkinson, Maslove & Currie, 2002; BHF, 2008; Wolff, Starfield & Anderson, 2002). They are also associated with additional morbidity that exacerbates this impact (Fillenbaum, Pieper, Cohen, Coroni-Huntley & Guralnik, 2000; Heyworth, Hazell, Linehan & Frank, 2009; Wolff et al, 2002). In the UK, numerous policy imperatives directing the management of LTPCs have therefore recently emerged (discussed later), with some impact upon incidence, morbidity and mortality rates (BHF, 2008; CRUK, 2010a; 2010b; WHO, 2003; DoH, 2009). Indeed, it is only now that people survive longer post-diagnosis that cancer is considered a LTPC rather than an acute condition. However, there is still much to be done, and as described below targeting the psychological impact of LTPCs may offer some additional means of ameliorating this impact.

Globally, and in the UK, cardiovascular disease (CVD), cancer and diabetes are flagged as priorities given their prevalence and burden, and because they are particularly amenable to intervention in that much of the morbidity and mortality is preventable (DoH, 2008). For ease, these LTPCs will be discussed herein.

LTPCs and psychological morbidity

LTPCs can have a significant, negative impact upon the lives of sufferers with important implications for psychological health (Dobbie & Mellor, 2008; Silverman, Nutini, Musa, Schoenberg & Albert, 2009).

Psychological morbidity can be conceptualised as a non-specific term encapsulating mild, moderate and severe forms of both transient and persistent mood states ranging from normal emotional responses to adversity such as illness, for example sadness and frustration, to psychological distress and symptoms of disorders such as anxiety and depression (i.e. negative affect) (Carney & Freedland, 2002). Adjustment reactions are common in approximately one quarter of individuals with a LTPC (MacHale, 2002). However, the evidence suggests that negative affect, particularly depression, is especially relevant.

Epidemiology

Prevalence of depression in LTPCs

The prevalence of depression in LTPCs has been reported in a number of large population-based, randomly sampled and nationally representative epidemiological studies from a number of countries including the UK. Prevalence rates have also been identified for primary and secondary care patients (i.e. more selectively sampled health seeking populations with variable disease severity), albeit these may be underestimated as they reflect patients willing and able to attend regular medical appointments. The prevalence rates in each of these sampling contexts are presented in Table 1. In endeavouring to explain the variation in estimates a distinction is made for the operationalisation of depression. This has varied greatly between studies such that the estimates reflect different aggregations of psychological conditions and vary in the range of severity of disorder included. These studies are also heterogeneous on a number of characteristics that may further explain the variation in estimates. For example, the estimates reflect different aggregations of LTPCs with some additionally including acute physical conditions, and they differ in the method of psychological assessment; most have employed diagnostic clinical interviews, yet there is variation in the diagnostic criteria

employed[1] and these are generally not administered by appropriately qualified clinicians (i.e. a psychiatrist; the gold standard). This raises concerns about inter-rater reliability and the inclusion of LTPCs symptoms in depression diagnoses (i.e. false positives).

Table 1 Prevalence of depression in LTPCs

Sampling context	**Operationalisation of depression**	**Prevalence**
Community	Major depressive disorder (MDD)	8.8%[2]
	Depression episode	9.3-23%[3]
	Non-psychotic psychiatric morbidity (including depression)	19.5%[4]
Primary care	Common mental disorders (including affective disorders ranging from sub-threshold diagnoses and minor disorders to major disorders)	56.8%[5]
Secondary care	Depression (unspecified)	28.2% (minor (15%), major (10%) & severe depression (4%)[6]

Importantly, though, these studies suggest that across sampling contexts, having an LTPC significantly elevates the risk of having depression, ranging from sub-threshold diagnoses and minor disorders to major disorders, for example MDD (Egede, 2007; Filipčić et al, 2007; Gili et al, 2010; Moussavi et al, 2007). These studies have also provided strong and consistent evidence that the prevalence of depression increases as the additional co-morbidity conferred by LTPCs increases (i.e. the number of LTPCs increases) (Cooke et al, 2007; Egede, 2007; Gili et al, 2010; Moussavi et al, 2007). Studies have been variable, however, in the extent to which analyses have been adjusted for potentially confounding factors, especially clinical factors (e.g. medical co-morbidity and past/family history of depression).

[1] Whether the International Classification of Diseases and Related Health Problems,10th Revision (ICD-10) or Diagnostic and Statistical Manual of Mental Disorders, 4th Edition DSM-IV) criteria was applied.
[2] Egede (2007).
[3] Moussavi, Chatterji, Verdes, Tandon, Patel & Ustun (2007); WHO World Health Survey administered in 60 countries.
[4] Cooke, Newman, Sacker, DeVellis, Bebbington & Meltzer (2007).
[5] Gili, Comas, García-García, Monzón, Antoni & Roca (2010).
[6] Filipčić, Popović-Grle, Marčinko, Bašić, Hotujac, Pavičić, Hanjšnek & Aganović (2007).

Indeed, the increased prevalence of depression for diabetes is apparently largely related to the presence of medical co-morbidity (Cooke et al, 2007), which other studies and systematic reviews have supported (Ali, Stone, Davies & Khunti, 2006; Egede, 2005; Engum, Mykletun, Midthjell, Holen & Dahl, 2005).

Incidence of depression in LTPCs

The aforementioned prevalence data has been derived in cross-sectional studies. Consequently, they do not speak about the direction of the association and whether LTPCs are associated with the onset of depression (i.e. incidence). Prevalence rates are additionally potentially confounded as they reflect the incidence but also the duration of depression; should LTPCs prolong depression rates are inflated in the absence of an increase in incidence (Patten, 2001). Prospective data is therefore more informative to this end.

However, population based, randomly sampled and nationally representative cohort studies and systematic reviews including longitudinal studies with unselected samples from countries including the UK, have generally supported this prospective relationship. In a Canadian study of people with no MDD at baseline, those with a LTPC experienced double the risk of incident depression (4%) compared to those without a LTPC two years later (Patten, 2001). It is notable, however, that in this study depression may have emerged and resolved within the follow up, diluting the effect had this occurred equally across groups or deriving a positive bias again should LTPCs prolong depression. Moreover, a past history of MDD was apparently not ruled out or controlled for (only demographic factors were controlled). The systematic review evidence reports that the incidence of depression is inflated in cardiac disease (OR 1.37), but not hypertension (OR 2.15), diabetes (OR 1.50) and cancer survivorship (OR .87), albeit only older samples were included (Chang-Quan, Bi-Rong, Zhen-Chan, Ji-Rong & Qing-Xiu, 2010). Importantly though, effect

heterogeneity and an absence of adequately powered studies were noted for diabetes and hypertension, and the search employed was lacking in comprehensiveness; a seemingly eligible study reporting an increased risk of incident depression in diabetes was not included (de Jonge, Roy, Saz, Marcos & Lobo, 2006).

Trajectory of depression in LTPCs

The aforementioned incidence evidence does not then, however, speak about how LTPCs might be implicated in the course of depression (i.e. recurrence and chronicity). Some longitudinal evidence has however indicated that the course of depression, even at lower-levels, is persistent in LTPCs; over 40% remain depressed at follow up (Di Benedetto, Linder, Hare & Kent, 2007; McKenzie, Clarke, McKenzie & Smith, 2010).

Bidirectional relationship between LTPCs and depression

The evidence presented thus far therefore suggests that depression is prevalent in LTPCs and that LTPCs are a risk factor for both the development and course of depression. However, it must be noted that depression may also occur prior to and thus be implicated in the development of LTPCs. Indeed some population-based, prospective research typically controlling for important prognostic variables supports such a bidirectional relationship. In fact, contrary to expectations depression is apparently a more notable risk factor for LTPCs than the reverse association.

For example, metabolic syndrome (MS) is a cluster of factors that increase the risk for morbidity and mortality from CVD and Type 2 diabetes, for example impaired glucose and lipid metabolism, obesity and hypertension. Evidence suggests that MDD is consistently associated with an increased risk for the onset of MS (OR 1.21-

1.82) (Goldbacher, Bromberger & Matthews, 2009; Räikkönen, Matthews & Kuller, 2007). In diabetes, a recent systematic review of prospective studies indicated that depression is associated with a 60% increase in the risk of onset Type 2 diabetes (OR 1.60) whilst Type 2 diabetes is modestly associated with incident depression (OR 1.15) (Mezuk, Eaton, Albrecht & Golden, 2008). Indeed, these bidirectional effects were confirmed within one large, multiethnic and landmark longitudinal study by Golden, Lazo, Carnethon, Bertoni, Schreiner, Diez Roux, Lee & Lyketsos (2008). Research in cancer is more limited but longitudinal studies have suggested that negative affect is associated with an increased risk of cancer onset over nine years, although this was restricted to only a few cancers and associations were weak (White, English, Coates, Lagerlund, Borland & Giles, 2007). Apparently stress may play a more important role in cancer onset (Chen, David, Nunnerley, Michell, Dawson, Berry, Dobbs & Fahy, 1995).

Pathophysiology of the bidirectional relationship between LTPCs and depression

There is a dearth of literature explicitly delineating the mechanisms of the bi-directional relationship between LTPCs and depression. However, a number of pathways have been suggested. Depression may cause LTPCs directly, for example CHD via disturbances in blood clotting mechanisms and alterations in inflammatory processes (Goldsten & Baillie, 2008) and Type 2 diabetes via increased counter-regulatory hormone release (e.g. glucocorticoids) and alterations in glucose utilisation and inflammatory processes, which are posited to raise blood glucose levels and or increase insulin resistance (Mussleman, Betan, Larsen & Phillips, 2003; Williams, Clouse & Lustman, 2006). Indeed, cross-sectional studies support an association between depression and disturbed glucose metabolism (Adriaanse, Dekker, Heine, Snoek, Beekman, Stehouwer, Bouter, Nijpels & Pouwer,

2008; Eriksson, Ekbom, Granath, Hilding, Efendic & Östenson, 2008; Gale, Kivimaki, Lawlor, Carroll, Philips & Batty, 2010) and insulin resistance (Timonen, Salmenkaita, Jokelainen, Laakso, Härkönen, Koskela, Meyer-Rochow, Pietso & Kienänen-Kiukaanniemi, 2007), albeit causality cannot be inferred here. It is posited that alterations in inflammatory processes in CHD and diabetes may also produce depression (Goldsten & Baillie, 2008; Mussleman et al, 2003).

Importantly, the aforementioned and additional prospective evidence has suggested some indirect mechanisms underpinning the incidence of depression/LTPCs. Depression may cause incident LTPCs via use of antidepressants (Andersohn, Schade, Suissa & Garbe, 2009; Delaney, Oddson, Kramer, Shea, Psaty & McClelland, 2010), negative lifestyle factors (Golden et al, 2008; Goldbacher et al, 2009) and central adiposity in diabetes, which may operate indirectly via an exacerbation of insulin resistance (Everson-Rose, Meyer, Powell, Pandey, Torréns, Kravitz, Bromberger & Matthews, 2004). Some research suggests that diabetes may cause incident depression via the burden of a LTPC and its management (Golden et al, 2008), with which various other prospective and cross-sectional studies concur (Knol, Heerdink, Egberts, Geerlings, Gorter, Numans, Grobbee, Klungel & Burger, 2007; Knol, Geerlings, Grobbee, Egberts & Heerdink, 2009). Clinicians additionally speculate that side effects of LTPC medication may be implicated in the development of depression (House & Stark, 2002; MacHale, 2002). However, in most of these studies mediation cannot be presumed as formal mediation models were not performed and or causal models were not established (formal mediation analysis is discussed in chapter five). Typically, mediators were identified having attenuated the prospective relationship observed, yet it cannot be presumed that the baseline condition caused the mediator where these were measured at the same time.

It is clear, however, that psycho-social factors and illness-related stressors, apparently experienced at any point in a LTPCs trajectory, play an important role in depression in LTPCs.

Psycho-social factors

Prospective studies have indicated that trait anxiety in cancer (De Vries, Van der Steeg & Roukema, 2009) and illness beliefs, for example that the condition has severe consequences, in coronary artery disease (CAD) (Stafford, Berk & Jackson, 2009), predict depression at follow up and changes in depression over time respectively. Cross-sectional evidence suggests that illness beliefs predict depression only when these are experienced in combination with general stress, albeit here depression may have preceded these beliefs (Traeger, Penedo, Gonzalez, Dahn, Lechner, Schneiderman & Antoni, 2009).

Prospective studies in cancer have indicated that perceived emotional support is associated with improvement in depressive symptoms over time (Manne, Rini, Rubin, Rosenbaum, Bergman, Edelson, Hernandez, Carlson & Rocereto, 2008; Talley, Molix, Schlegel & Bettencourt, 2010). Cross-sectional studies have also supported this association in diabetes (Koopmans, Pouwer, de Bie, Leusink, Denollet & Pop, 2009) and heart failure (Trivedi, Blumenthal, O'Connor, Adams, Hinderliter, Dupree, Johnson & Sherwood, 2009), although here depression may have caused people to withdraw (Mind, 2011). Nonetheless, emotional support apparently buffers the negative emotional impact of a LTPC. Some prospective mediation analyses have also demonstrated that perceived emotional support with illness-related issues produces improvements in negative affect via improvements in cognitive processing (i.e. fewer intrusive thoughts). However, that the change in intrusive thoughts produced the change in negative affect cannot be presumed as

these occurred concurrently (Christie, Meyerowitz, Giedzinska-Simons, Gross & Agus, 2009).

It is also worth pointing out that prospective studies eliciting the psycho-social determinants of depression in LTPCs have identified predictors of depression at follow up or changes in depression (i.e. the course of depression), rather than depression onset (i.e. aetiology). Most have controlled for baseline depression, amongst other potential confounders, yet this merely removes the confounding effect of this prognostic variable and does not offer causal information. Disappointingly few studies, besides those described earlier, have examined precursors of incident depression in LTPCs. Moreover, the precise mechanisms by which these factors may influence depression have infrequently been empirically examined.

Illness-related stressors

Research has identified an array of demographic and clinical predictors of depression in LTPCs, which are largely the same as those in non-LTPC samples (Egede, 2007; Engum et al, 2005). Examples are included in Table 2, albeit this is not an exhaustive list. It is noteworthy that some studies have produced somewhat inconsistent results, for example for HbA1c (Connell, Storandt & Lichty, 1990); whilst speculative it could be that the associations are less evident for certain sub-groups (Pouwer & Snoek, 2000). Typically studies have been cross-sectional, and indeed some of the factors described, for example BMI, treatment burden and medical co-morbidity could also result from depression (discussed later). However, some prospective evidence has reported that such clinical factors, for example physical symptoms, are associated with increases in depression over time, for example in diabetes (Vileikyte, Peyrot, Gonzalez, Rubin, Garrow, Stickings, Waterman, Ulbrecht, Cavanagh & Boulton, 2009).

Importantly, however, it is plausible that some of these clinical factors may be experienced as stressful (i.e. as illness-related stressors) and related to depression. Indeed, the evidence indicates the same factors are also associated with general emotional/illness-related distress. Again, a non exhaustive list of examples is included in Table 2, yet the aforementioned causality issue again applies to these cross-sectional studies. In further support of this assertion, it is well established that stressful life events are associated with depression (Kessler, 1997); depression can result when people do not have the opportunity or ability to deal effectively with the negative emotions evoked by stressful events (Diabetes UK (DUK), 2008c; Mind, 2011). A positive association between general emotional and or illness-related distress and depression has also been supported in cancer (Graves et al, 2007), post acute coronary syndrome (Di Benedetto et al, 2007) and diabetes (Adriaanse, Pouwer, Dekker, Nijpels, Stehouwer, Heine & Snoek, 2008; Koopmans et al, 2009).

These studies are again cross-sectional, thus while they indicate that distress may cause depression, depression may also cause people to experience LTPCs as stressful; a bi-directional relationship is again probable. Indeed, in diabetes longitudinal data suggests a history of MDD is predictive of developing diabetes-specific emotional distress (DSED) (Fisher, Mullan, Skaff, Glasgow, Arean & Hessler, 2009) and that higher baseline DSED is associated with persistence of significant depressive symptoms 12 months later, albeit this finding does not indicate causality (Pibernik-Okanovic, Begic, Peros, Szabo & Metelko, 2008).

Table 2 Socio-demographic and or clinical predictors of depression and general emotional/illness-related distress in LTPCs[7]

LTPC	Depression		Distress
	Demographic	**Clinical**	**Clinical**
Cancer	Younger age (13, 15). Being female (15).	Symptom burden (3). Greater disease severity/burden (13, 15).	Treatment burden (11) Poorer physical functioning (9).
CVD	Being female (12).	Functional limitations (6)	
Diabetes	Being female (2, 7, 16). Lower level of education (2, 7, 8). Being widowed or divorced (10; 16).	Higher BMI (2). Multiple medications (2, 10). Self-management burden (17). Poor HbA1c (10, 16). Poorer physical functioning (2). Medical co-morbidities (1, 2, 8, 14, 16)	Poor HbA1c (4). Greater disease severity/burden (5, 18). More invasive treatment (i.e. insulin) (5, 18).

[7] The references supporting these predictors are: 1.Adriaanse & Bosman (2010); 2.Bell, Smith, Arcury, Snively, Stafford & Quandt (2005); 3.Chen & Chang (2004); 4.Chouhan & Shalini (2006); 5.Delahanty, Grant, Wittenberg, Bosch, Wexler, Cagliero & Meigs (2007); 6.Dunlop, Lyons, Manheim, Song & Chang (2004); 7.Egede & Zheng (2003); 8.Engum et al (2005); 9.Graves, Arnold, Love, Kirsh, Moore & Passik (2007); 10. Hänninen, Takala, Keinänen-Kiukaanniemi (1999); 11.Henselman, Helgeson, Seltman, de Vries, Sanderman & Ranchor (2010); 12.McKenzie, Simpson & Stewart (2010); 13.Norton, Manne, Rubin, Carlson, Hernadez, Edelson, Rosenblum, Warshal & Bergman (2004); 14. Shehatah, Rabie & Al-Shahry (2010); 15.Strong, Waters, Hibberd, Rush, Cargill, Storey, Walker, Wall, Fallon & Sharpe (2007); 16.Tellez-Zenteno & Cardiel (2002); 17.Weijman, Ros, Rutten, Schaufeli, Schabracq & Winnubst (2005); 18.West & McDowell (2002).

Nonetheless, it is apparent that targeting illness-related stressors and general/illness-related distress in addition to depression in LTPCs may optimise improvement in depression. Such intervention trials are therefore indicated. There is some promising evidence that interventions aimed at reducing general emotional distress can improve both this and depressive symptoms, for example stress-management interventions in cancer (Bohlmeijer, Prenger, Taal & Cuijpers, 2010) and CHD (Olivo, Dodson-Lavelle, Wren, Fang & Oz, 2009). The interdependence of improvements in distress and depression is yet to be established however.

Prognosis of depression in LTPCs

Just as depression is seemingly implicated in the aetiology of LTPCs, research suggests that it can additionally influence their course.

Self-management behaviours (SMBs) and clinical outcomes

A vast amount of cross-sectional and systematic review evidence suggests that depression in LTPCs has a universal and adverse effect on SMBs, for example poor adherence to patient-initiated SMBs that are difficult to maintain (e.g. exercise and diet) yet not preventative services (e.g. retinopathy screening) in diabetes (Lin, Katon, Von Korff, Rutter, Simon, Oliver, Ciechanowski, Ludman, Bush & Young, 2004), adverse health behaviours, for example smoking in diabetes (Katon, Simon, Von Korff, Ludman, Ciechanowski, Walker, Russo, Bush, Lin & Young, 2004a), and non-compliance with medication (DiMatteo, Lepper, Croghan, 2000). The latter is true even for mild to moderate depressive symptoms in CHD, albeit to a less significant extent (Gehi, Haas, Pipkin, & Wooley, 2005). Depression also has an adverse effect on important clinical outcomes in LTPCs conferring additional morbidity and worsening prognosis, for example cardiac risk factors in CVD (Kop, Kuhl, Barasch, Jenny, Gottleib & Gottdiener, 2010), and hyperglycemia (Lustman,

Anderson, Freedland, DeGroot, Carney & Clouse, 2000), other aspects of metabolic control (e.g. increased blood pressure, cholesterol and triglyceride levels) (Gary, Crum, Cooper-Patrick, Ford, Brancati, 2000) and long-term medical complications (DeGroot, Anderson, Freedland, Clouse & Lustman, 2001) in diabetes.

Emerging prospective evidence

However, these cross-sectional studies are of limited utility because, as described above, these outcomes are additionally likely implicated in the aetiology and course of depression in LTPCs. Importantly, then, prospective evidence has recently demonstrated that in LTPCs, baseline depression predicts these outcomes at long-term follow up or better yet a change in them over time. In diabetes, both mild and major depression predict non-compliance with and discontinuation of medication over a follow up period (Kalsekar, Madhavan, Amonkar, Douglas, Makela, Elswick & Scott, 2006; Kalsekar, Madhavan, Amonkar, Makela, Scott, Douglas & Elswick, 2006), and in fact a systematic review suggests that longitudinal designs report larger effects on SMBs, for example for diet SMBs (Gonzalez, Peyrot, McCarl, Collins, Serpa, Mimiaga & Safren, 2008b). In diabetes, depression is associated with poorer glycaemic control (Chiu, Wray, Beverly & Dominic, 2010; McKellar, Humphreys & Piette, 2004) and the onset of CHD (Clouse, Lustman, Freedland, Griffith, McGill & Carney, 2003) over time. In CHD, depression is associated with increased risk of future cardiac events (e.g. heart failure, MI, stroke, transient ischemic attack or death) over time (Whooley, de Jonge, Vittinghoff, Otte, Moos, Carney, Ali, Dowray, Na, Feldman, Schiller & Browner, 2008), and again a systematic review suggests that prospective studies report more consistent effects (Frasure-Smith & Lesperance, 2005). There is additionally some evidence that this is true for even for mild depression in coronary artery bypass graft patients (Rafanelli, Roncuzzi & Milaneschi, 2006).

Exactly how depression influences these parameters is unclear. It is likely the processes implicated in the development of LTPCs in depression may also explain how depression influences their course. Indeed, the aforementioned prospective studies of the effect of depression on LTPC course have indicated that controlling for inflammatory markers attenuates the relationship between depression and future cardiac events (Whooley et al, 2008). Again, it is posited that depression may cause the onset of LTPCs via lifestyle factors, and indeed some prospective evidence suggests that poorer SMBs may explain the effect of depression on clinical outcomes in CHD (Whooley et al, 2008) and diabetes (McKellar et al, 2004). Importantly, a study in diabetes actually confirmed this indirect effect, in addition to a direct effect of depression on HbA1c, in a structural equation model with variables measured such that causality can be established (Chiu et al, 2010). Interestingly, cross-sectional studies suggest that lower self-efficacy (i.e. the belief that one is capable of performing certain behaviours to attain certain goals) may explain the effect of depression on SMBs (Wagner, Tennen & Osborn, 2010) and clinical outcomes (Cherrington, Wallston & Rothman, 2010) in diabetes.

QoL

Depression in LTPCs has been demonstrated to be associated with an increased risk of functional disability (Schmitz, Wang, Malla & Lesage, 2007) and impairments in role functioning (Lee, Guo, Tsang, He, Huang, Liu, Zhang, Shen & Kessler, 2009) in cross-sectional studies, increased medial symptom burden in prospective studies (Katon, Lin & Kroenke, 2007), and therefore unsurprisingly reduced QoL in systematic reviews (Ali, Stone, Skinner, Robertson, Davies & Khunti, 2010; Stafford, Berk, Roddy & Jackson, 2007) and prospective studies (Howren, Christensen, Karnell & Funk, 2010; Schram, Baan & Pouwer, 2009).

HCU and costs

Patients with CHD and depressive symptoms are substantially more likely to report doctor-patient communication deficits (Schenker, Stewart, Na & Whooley, 2009). Research in the USA has also indicated that in LTPCs having depression, even lower-levels, is associated with double the odds of using secondary care services (Himelhoch, Weller, Wu, Anderson & Cooper, 2004) and twice the odds of incurring paid sick and health and disability costs (Druss, Rosenheck & Sledge, 2000). Studies in diabetes suggest productivity losses are inflated (i.e. prolonged bed days and lost work days) (Subramaniam, Sum, Pek, Stahl, Verma, Liow, Chua, Abdin & Chong, 2009; Vamos, Mucsi, Keszei, Kopp & Novak, 2009) and medical costs are inflated five-fold (Egede, Zheng & Simpson, 2002), which is not accounted for by increased mental health care costs (Finkelstein, Bray, Chen, Larson, Miller, Tompkins, Keme & Maderscheid, 2003; Simon, Katon, Lin, Ludman, Von Korff, Ciechanowski & Young, 2005). Although the precise magnitude of this impact cannot be generalized to the UK owing to differences in health service delivery and costs, the observed associations undoubtedly apply.

Early mortality

Research has additionally indicated that having depression is associated with a greater mortality risk in acute coronary syndrome (Kronish, Reickmann, Schwartz, Schwartz & Davidson, 2009) and diabetes (Egede, Nietert & Zheng, 2005). In fact, even mild depression may inflate mortality rates in diabetes, but perhaps only for those people with more severe medical illness (Zhang, Norris, Gregg, Cheng, Beckles & Kahn, 2005). It is also interesting that new onset depression apparently confers a greater mortality risk than previous/recurrent depression, for example in post-myocardial infarction (MI) patients (Dickens, McGowan, Percival, Tomenson, Cotter, Heagerty & Creed, 2008; Carney, Freedland, Steinmeyer, Blumenthal, de Jonge, Davidson, Czajkowski & Jaffe, 2009).

Depression in LTPCs is therefore associated with a clear worsening of their course and an adverse effect on other important outcomes, typically even after controlling for important prognostic and potentially confounding clinical variables. As such, depression in LTPCs furthers the aforementioned impact of LTPCs upon QoL, early mortality, and HCU and costs. The identification and treatment of depression in individuals with LTPCs is therefore important as it is prevalent in this population, and because as mentioned earlier this may offer an additional means of ameliorating the impact of LTPCs. This is again important given the limited scope for directly improving these outcomes in LTPCs.

Current provision of E&P support in LTPCs

Over recent years, evidence of inadequate provision of E&P support in LTPCs has been commonplace. Individuals with LTPCs have stated that they want and need yet lack E&P support. In the USA, between 21 and 33% of LTPC patients (i.e. diabetes, hypertension and CHD) reporting some psychological distress in primary care have expressed a need for E&P support, and of these 63% to 72% have reported that this need is unmet (Sherbourne, Jackson, Meredith, Camp & Wells, 1996). Similar research in cancer has additionally suggested that despite the high prevalence of psychological morbidity, only a small proportion of individuals receive treatment or access to mental health services (Norton et al, 2004). Such issues are anticipated in the UK. Indeed, the white paper our health, our care, our say (DoH, 2006b) recognised in 2006 that it was not possible to meet the complex psychological needs of patients within existing primary care services, nor could they all be referred to secondary care which is focussed on those with severe enduring mental illness.

Policy imperatives for improving provision of E&P support in LTPCs

E&P support should be a fundamental component of the care individuals with LTPCs receive. Indeed, a number of recent UK policy documents, mentioned earlier, have responded to the unmet need, highlighting the importance of E&P need and support in LTPCs.

White papers

Choosing health (DoH, 2004) underpins the approach to LTPCs. It outlines the public and governments shared priority for a healthier future, which includes improving the known risk factors for LTPCs (e.g. obesity, exercise and smoking), and improving mental health. Mental health is recognised as a precursor to making healthy lifestyle choices, physical health and employment. The next steps in achieving this objective are reported, which includes a shift in focus from treatment to prevention and health promotion with better provision of support to people with mental health conditions, for example new approaches to helping them manage their own care and health, and return to work.

Our health, our care, our say (DoH, 2006b) set a new direction for the health and social care system. Amongst its main objectives was more support for people with LTPCs, for instance empowering self-management in line with patients' preferences for care delivery, and again a shift of resources to prevention services with earlier intervention including support to maintain mental health and emotional well-being. The latter was identified as a top priority amongst patients. Mental health is considered as important as physical health. It is also advocated that people must receive help in managing depressive disorder, but also the 'widespread misery that does not reach the threshold for clinical diagnosis yet nevertheless reduces QoL of thousands of people'. Talking therapies are posited to offer a real alternative to

medication for lower-level E&P need. New technology, such as computerised CBT (cCBT), is also highlighted a means of increasing treatment options in mental health care, disseminating E&P support into the community and facilitating self-management of mental health. Finally, primary care is specified as an opportunity for provision of psychological therapies for mild to moderate mental health problems.

LTPC-specific imperatives

Supporting people with long-term conditions to self-care – an NHS and social care model to support local innovation and integration (DoH, 2005) provided a model for supporting local NHS and social care organisations in improving services for people with LTPCs, advocating a shift from care in secondary care to primary care, the community or home, personalised care, and the provision of self-care support to assist people in making healthier lifestyle choices. Specifically for vulnerable patients with complex conditions case management is advocated, which entails a comprehensive needs assessment including psychological needs and wishes.

Supporting people with long-term conditions to self-care – a guide to developing local strategies and best practice (DoH, 2006c) outlines how health and social care services can support people with LTPCs to self-care, recognising that this necessitates assuming responsibility for staying both physically and mentally healthy, and dealing with the emotional changes produced by a LTPC and its impact on daily life. This is anticipated to improve mental health and reduce depression.

Generic choice model for long-term conditions (DoH, 2007) highlights how the care planning process, in which the full range of patients' needs, goals and preferences are identified, can and should inform commissioning of more personalised services

in which patients with LTPCs have more control over and choice in the care they receive. It specifies that commissioners should provide a genuine menu of options that are attractive to patients and offer real alternatives, informed by the content of care plans. E&P needs, goals and preferences should be elicited via discussion and routine screening during the course of living with a LTPC. Health care providers (HCPs) and patients should then be able to identify tailored services from the range of treatment options derived from patients' choices and commissioned thereafter. Examples of treatment options include psychological therapies such as CBT, counselling and emotional support groups. In 2007 the implementation of this approach was explored in diabetes 'year of care' pilot sites.

Common core principles to support self care – a guide to support implementation (Skills for Health & Skills for Social Care, 2008) describes the behaviours required by HCPs to effectively support people with LTPCs to self-manage, conceptualised as making the most of life, coping with difficulties and taking actions to meet psychological needs and maintain health and well-being. Examples include supporting and enabling development of self-care skills and use of technology to support self-care.

Supporting people with long-term conditions: commissioning personalised care planning - a guide for commissioners (DoH, 2009) provides commissioners with information and support with respect to how personalised care planning can be embedded into their localities, which again involves discussion of E&P needs and patients preferences for meeting these. It is recognised that this will derive demand for psychological therapies such as CBT, which could be used as an adjunct or alternative to medication. The anticipated result of this holistic approach, which extends beyond medical needs, is improved mental health and well-being.

Your health your way – a guide to long-term conditions and self-care (DoH, 2009) advocates supported self-care in LTPCs and the need to embed this into clinical care. This approach, for example encouraging use of self-help and internet resources, is anticipated to enable people to manage the impact of their condition on emotional life and meet their psychological needs. Support networks are identified as key to empowering and supporting people with LTPCs, underscoring the importance of both practical and emotional support.

Improving the health and well-being of people with long-term conditions: world class services for people with long-term conditions – information tool for commissioners (Department of Heath, 2010) describes a common vision of good services in LTPCs and offers practical suggestions for commissioners to achieve this. Personalised care planning, self-care support and provision of care in more appropriate settings for example primary care and at home is advocated. The importance of moving beyond the medical model and addressing the full range of patients' needs, including E&P needs, by offering a broad range of services required to meet these holistic needs, for example access to psychological therapies, is additionally emphasised

The importance of proving 'talking therapies' as a form of E&P support in health care is now being campaigned by five leading mental health charities (Mental Health Foundation, Mind, Rethink, The Sainsbury Centre for Mental Health, Young Minds, 2006).

Recent changes in UK clinical practice with respect to E&P support in LTPCs

These imperatives have spurred endeavours to improve service delivery, the most notable of which are described below.

National Service Frameworks (NSFs) for LTPCs

The NSFs for specific LTPCs are intended to improve the quality of care and health, and reduce inequalities. The NSFs for CHD and diabetes each outline 12 standards, rationales, key interventions, service models and performance indicators for achieving this. The areas in which E&P needs and support are acknowledged are highlighted below.

CHD

The CHD NSF advocates that psychological support is offered to people with uncontrollable symptoms or those at the end of life. Specifically, standard 12 identifies that psychological needs should be assessed before discharge from hospital and early in the post-discharge phase to facilitate cardiac rehabilitation, with psychological interventions then received according to an agreed plan. Referral to psychological services is advocated for long-term maintenance of change as clinically indicated (DoH 2000a; 2000b).

Diabetes

Standard 3 in the diabetes NSF recognises that diabetes and its diagnosis can have an adverse effect on psychological adjustment, which then adversely impacts self-care. Provision of psychological support in diabetes is therefore crucial. Standard 12 also emphasises that for people with diabetes that develop complications and require complex care, QoL can be improved with psychological support.

Psychological support is conceptualised as empowering people to self-manage and develop strategies to deal with the psychological consequences of diabetes, which will assist them in identifying any emotional or behavioural barriers to effective self-management. The development of a comprehensive evidence base of appropriate psychological interventions and their effect upon self-management is specified as a future research priority (DoH, 2001; 2003).

GPs Quality and Outcomes Framework (QoF)

In the UK, detection of depression in some LTPCs recently became a general practice performance indicator, underscoring the importance of detection and management of depression in primary care. Specifically, as part of the General Medical Services (GMS) QoF for primary care in the UK, participating general practices now receive points and thus financial reward in accordance with their achievement of national, evidence-based quality standards. In 2006, three indicators relating to the identification and assessment of depression in high risk groups of adults, namely those with significant physical conditions causing disability (i.e. CHD and diabetes), were introduced (BMA & NHS Employers, 2009). These are described below.

Indicator 1: Patients are to be asked two case finding questions every 15 months.[8] Individuals responding positively to either or both are identified as potentially experiencing depression that should be investigated further. The evidence relating to the diagnostic accuracy of these questions for identifying depression in primary care is reported in chapter four. The specificity of diagnoses (i.e. rate of false positives) is modestly improved by additionally asking those responding positively

[8] These questions are: During the last month, have you often been bothered by feeling down, depressed or hopeless? & During the last month, have you often been bothered by having little interest or pleasure in doing things?

whether this is something with which they would like help (Arroll, Goodyear-Smith, Kerse, Fishman & Gunn, 2005).

Indicator 2: For individuals responding positively, subsequent assessment of severity using a tool validated for use in primary care is advocated to inform appropriate intervention. Self-report depressive symptom measures are employed,[9] for which cut-points that indicate whether depressive symptoms warranting intervention are present have been agreed upon. Higher scores indicate greater severity requiring different types of treatment, for example antidepressants can be targeted to only moderate to severe depression (discussed below). Additional factors must also be considered, however, for example degree of functional impairment and family/previous history of depression.

Indicator 3: If the initial severity assessment indicates potential problems, a further assessment is advocated 5-12 weeks later, to identify whether very mild symptoms not immediately requiring intervention have worsened (i.e. watchful waiting) and treatment has sufficiently resolved more substantial symptoms, which as described earlier are typically chronic in LTPCs.

National Institute for Clinical Excellence (NICE) guidance for the treatment of depression in adults with LTPCs

HCPs are expected to take NICE clinical guidelines into account when exercising clinical judgement. These are recommendations about the treatment of people with specific conditions in the NHS in England and Wales, informed by careful review of the evidence base (NICE, 2009). The NICE guidelines for the treatment of depression in adults have recently been adapted to LTPCs. Both diagnosable

[9] The self-reported depression measures employed include the Patient Health Questionnaire–9 (PHQ-9), the Hospital Anxiety and Depression Scale (HADS) and the Beck Depression Inventory (BDI).

depression and sub-threshold symptoms are considered problematic and warranting intervention, yet intervention should be tailored and a stepped model of care is advocated.

At step one patients' are assessed on the severity of their condition, degree of functional impairment, duration of the depressive episode and other factors that influence the course of depression (i.e. past/family history and interpersonal/social difficulties). Vigilance for depression in LTPCs, especially in the presence of functional impairment, is advocated, hence as are the QoF indicators described above. Patients are then matched with the most appropriate service depending on their level of need, with the least intrusive and most effective intervention provided first. Should efficacy be insufficient, an appropriate intervention from the next step up is offered, each step up representing increasingly complex intervention to meet increasingly complex need. The treatment options at each step and thus level of need defined by diagnostic criteria (i.e. DSM-IV) are outlined below.

- Step 1: General support, psycho-education and active monitoring (i.e. watchful waiting) where symptoms do not meet the criteria for the next steps.

- Step 2: Low-intensity psychosocial intervention for patients presenting with persistent sub-threshold symptoms (i.e. present for several months and despite active monitoring), mild to moderate depression or sub-threshold depressive symptoms that complicate LTPC care. Examples include structured group physical activity, group-based peer support (self-help), individual guided self-help based on CBT principles and cCBT. Treatment choice is guided by patient preference.

- Step 3: High-intensity psychological intervention is offered to patients with persistent sub-threshold symptoms or mild to moderate depression with an inadequate response to initial intervention (i.e. low-intensity) or patients presenting with moderate to severe depression. Examples include group-based CBT, individual CBT (where group format is declined, not appropriate or unavailable) and behavioural couple's therapy as appropriate. Collaborative care[10] should be considered only for moderate to severe depression in LTPCs that are associated with functional impairment, which has not responded to high-intensity psychological interventions, antidepressants or both.

- Step 4: Practitioners provide treatment in specialist mental health services for patients with complex and severe depression associated with a risk of self-neglect and harm.

  Antidepressants are not advocated for sub-threshold symptoms and mild depression owing to a poor risk-benefit ratio, unless there is a past history of moderate to severe depression, mild depression that complicates LTPC care, sub-threshold symptoms that have persisted for more than two years (i.e. dysthymia), or sub-threshold symptoms or mild depression that has persisted after other interventions. They are, however, to be considered at step three after trying high-intensity psychological intervention, or in combination with this where patients present with more severe depression.

[10] Collaborative care involves case-management supervised by a senior mental health professional, and collaboration between primary and secondary physical health services and specialist mental health services to deliver a range of the aforementioned interventions and pharmacological treatment/medication management.

Improving access to psychological therapies (IAPT)

In 2005, the labour parties' general election manifesto specified intentions to improve access to therapies for mental health problems in primary and secondary care. IAPT is a government funded NHS initiative launched in 2007 aimed at supporting PCTs in implementing the aforementioned NICE guidelines, by improving access to evidence-based talking therapies in the NHS (i.e. via expansion of services and workforce). LTPCs are considered a priority group, and a four year plan of action has recently been specified which states that models of care specifically for people with LTPCs will be developed by 2015 (IAPT, 2011).

The IAPT service model entails a team of therapists taking referrals predominantly from primary care but also self-referrals. Consistent with NICE, needs assessment, step allocation and then delivery of step-appropriate NICE-compliant therapies (i.e. watchful waiting or low- or high-intensity interventions)[11] is executed, again with stepping up following insufficient response. Concurrent use of antidepressants is similarly not advocated for milder symptoms. Owing to greater prevalence of mild to moderate psychological problems, the model requires significant investment in low-intensity interventions. Consistent with the policy imperatives described earlier, commissioners are also required to make a range of the evidence-based, NICE-approved psychological treatments available to facilitate patient choice. This is posited to be critical for obtaining positive outcomes given the variation between patients in tolerance for different treatments (IAPT, 2008a).

Routine outcome assessment has demonstrated effectiveness and clinical excellence (IAPT, 2008a). Two pilot sites (PCTs) established to inform the national

[11] Low intensity psychological interventions for mild to moderate anxiety and depression at step 2 include cCBT, pure self-help (i.e. un-facilitated e.g. books on prescription), guided self-help (i.e. facilitated and based on CBT principles), behavioural activation, structured exercise and other therapies, and high-intensity treatment for more severe disorder at step 3 includes CBT (i.e. cognitive therapy, problem solving and behavioural activation), interpersonal therapy and couples' therapy.

role out saw up to 4, 000 patients in their first year, thus access was improved, and reported recovery of symptoms for 50% of patients receiving at least one treatment session and long-term maintenance of treatment gain. The authors note, however, that in the absence of a waitlist control condition it is unclear whether this improvement exceeds the natural trajectory of symptoms. An emphasis on low-intensity interventions achieved a high throughput of patients, underscoring the importance of offering this level of service to appropriate patients (Clark, Layard, Smithies, Richards, Suckling & Wright, 2009).

Problems associated with current provision of E&P support

There are, however, problems associated with current provision of E&P support in LTPCs.

HCP-level

HCP-level barriers to the identification of E&P need and provision of E&P support in LTPCs include the dismissal of somatic features of depression (e.g. fatigue, loss of appetite and insomnia) that can result from an LTPC and its treatment, which can also prohibit patients recognition of depression (Haddad, 2009; MacHale, 2002), judgements that medical problems are a more immediate concern (IAPT, 2008b; Nutting, Rost, Dickinson, Werner, Dickinson, Smith & Gallovic, 2002), attribution of mental health problems to the LTPC (IAPT, 2008b), lack of recognition that psychological symptoms can be treated (IAPT, 2008b) and reluctance to prescribe owing to problematic side effects and drug interactions (discussed below) (Haddad, 2009; MacHale, 2002).

Patient-level

Patient-level barriers include distraction from depression owing to the LTPC (Haddad, 2009; IAPT, 2008b), prohibited treatment seeking behaviour due to embarrassment, stigma or denial (IAPT, 2008b; Kaltenthaler, Brazier, De Nigris, Tumur, Ferriter, Beverley, Parry, Rooney & Sutcliffe, 2006; Whooley & Simon, 2000), an expectation that no support options are available (DUK, 2007b), that HCPs are too busy (DUK, 2008c), that the consultation is for physical problems and that emotional problems are not relevant to the LTPC (Pouwer, Beekman, Lubach & Snoek, 2006), prohibited travel owing to illness (i.e. to therapy sessions) (IAPT, 2008b; MacHale, 2002) and treatment burden, namely adverse drug reactions and long therapy sessions (discussed below). Indeed, premature discontinuation of both physical and psychological intervention is commonplace (Whooley & Simon, 2000), albeit there is some evidence that people with a LTPC prefer talking therapies to antidepressants (Hodges, Butcher, Kleiboer, McHugh, Murray, Walker, Wilson & Sharpe, 2009).

Problems associated with current treatment options

Intervention currently advocated for psychological co-morbidity in LTPCs is also problematic.

Pharmacological intervention

Effectiveness

Antidepressants have demonstrated efficacy for improving psychological and clinical markers in LTPCs. An early Cochrane systematic review of randomised controlled trials (RCTs) testing selective serotonin re-uptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and atypical antidepressants reported consistent improvements in depressive symptoms (Gill & Hatcher, 1999). More recent RCTs

testing TCAs in diabetes (i.e. Nortriptyline) (Lustman, Griffith, Clouse, Freedland, Eisen, Rubin, Carney, McGill, 1997a) and SSRIs in CVD (Lespérance, Frasure-Smith, Koszycki, Lalibérte, van Zyl, Baker, Swenson, Ghatavi, Abramson, Dorian & Guertin, 2007; Thombs, de Jonge, Coyne, Whooley, Frasure-Smith, Mitchell, Zuidersma, Eze-Nliam, Lima, Smith, Soderlund & Ziegelstein, 2008) and diabetes (i.e. Fluoxetine, Sertraline & Paroxetine) (Goodnick, Kumar, Henry, Buki & Goldberg, 1997; Gülseren, Gülseren, Hekimsoy & Mete, 2004; Lustman, Freedland, Griffith, Clouse, 2000; Lustman, Clouse, Nix, Freedland, Rubin, McGill, Williams, Gelenberg, Ciechanowski & Hirsch, 2006) concur. The improvement incurred is apparently indistinguishable to that derived for people without LTPCs (Simon, Von Korff & Lin, 2005).

In LTPCs antidepressants apparently also produce concurrent improvements in SMBs, such as diet and exercise (Goodnick et al, 1997; Lustman, Williams, Sayux, Nix & Clouse, 2007), QoL (Gülseren et al, 2004) and HbA1c (Gülseren et al, 2004; Lustman et al, 2006; Lustman et al, 2000; Lustman et al, 2007) in diabetes, but not cardiac event free survival in CVD, albeit this finding is based on very few studies (Thombs et al, 2008). Concurrent improvements in HbA1c have been attributed to improvement in depression in some (Lustman et al, 2007) but not other trials, where it is more likely that the antidepressant directly altered HbA1c (Gülseren et al, 2004; Lustman, et al, 2000).

Limitations

However, in LTPCs, antidepressants confer a risk of drug interactions, metabolic complications, complication of self-care and or increased sensitivity to medication side effects (MacHale, 2002), which must be considered in treatment decisions (NICE, 2009). TCAs are not well tolerated (Gill & Hatcher, 1999), and they can produce carbohydrate cravings, weight gain and have an adverse impact upon

clinical outcomes (Goodnick, Henry & Buki, 1995; Goodnick, 2001; Lustman et al, 1997; MacHale, 2002; Simon, 2002; Whooley & Simon, 2000). SSRIs are the least problematic and thus the first line pharmacological treatment for depression in LTPCs (Goodnick et al, 1995; NICE, 2009; Simon, 2002). However, they can still incur intolerable side effects (Gülseren et al, 2004; Lespérance et al, 2007) and discontinuation symptoms (NICE, 2009), they are contraindicated with a number of LTPC medications (NICE, 2009) and they can produce sedation, weight gain and have an adverse impact upon clinical outcomes (Goodnick et al, 1995; MacHale, 2002). Indeed, it is recognised that antidepressant trials reporting negative effects are often unpublished (Pouwer, 2009). Furthermore, in LTPCs SSRIs do not always produce depression remission (Lustman et al, 2006; Lustman et al, 2007), and relapse is often rapid and associated with a decline in clinical markers, for example HbA1c in diabetes (Lustman, Griffith, Freedland & Clouse, 1997b). Maintenance treatment lengthens the time until depression recurrence in LTPCs (Lustman et al, 2006; Lustman et al, 2007), yet this incurs substantial health care costs (Jacobson & Weinger, 1998) and does not always prevent recurrence (Lustman et al, 2006). Psychological and collaborative interventions are therefore indicated.

Psychological intervention

Effectiveness

RCTs of NICE concordant psychological interventions, and collaborative care, have demonstrated comparable efficacy for improving psychological and clinical markers in LTPCs. CBT has produced improvement in depression in cancer (Tatrow & Montgomery, 2006) and sustained remission of MDD in Type 2 diabetes (Georgiades, Zucker, Friedman, Mosunic, Applegate, Lane, Feinglos & Surwit, 2007; Lustman, Griffith, Freedland, Kissel & Clouse, 1998; Simon et al, 2004), with concurrent improvements in HbA1c in diabetes (Lustman et al, 1998) and pain in cancer (Tatrow & Montgomery, 2006). Some CBT studies have, however,

demonstrated no concurrent change in HbA1c and or no association between changes in depression and HbA1c/pain (Georgiades et al, 2007; Lustman et al, 1998; Tatrow & Montgomery, 2006). Interpersonal therapy has produced improvements in depressive symptoms in diabetes (Simson, Nawarotzky, Friese, Porck, Schottenfeld-Naor, Hahn, Scherbaum & Kruse, 2008) and a trend for improvement in CAD (Lespérance et al 2007), albeit the latter effect was likely diluted as many participants in each group, and thus controls, also received antidepressant therapy. In fact, a comprehensive systematic review of RCTs in diabetes has indicated that psychological interventions including CBT and psychodynamic therapy can produce reductions in HbA1c large enough to influence the development and progression of micro vascular complications, where transitory fluctuations are averaged out. Equivocal effects are achieved when interventions are delivered by generalist rather than specialist clinicians, yet more intensive therapy derives greater improvement (Alam, Sturt, Lall & Winkley, 2009; Ismail, Winkley & Rabe-Hesketh, 2004).

Limitations

Psychological interventions such as CBT are expensive, the treatment period spans several weeks and they require involvement of highly skilled professionals[12] (Kaltenthaler et al, 2006; Mayor, 2006; MacHale, 2002; NICE, 2009). This prohibits widespread availability (the impact of the recent changes in UK clinical practice, including the IAPT programme, is discussed below).

[12] Groups based CBT entails groups of six to eight participants with a common LTPC and lasts for about six to eight weeks, individual CBT is delivered until symptoms have remitted, which for moderate depression typically takes six to eight weeks with two follow up sessions within six months from the end of treatment and for severe depression can take 16-18 weeks with twice weekly sessions required initially and again two to three follow up sessions within 12 months post treatment (NICE, 2009).

Collaborative care

Effectiveness

Collaborative care interventions in the USA, for example the Improving Mood-Promoting Access to Collaborative Treatment (IMPACT) programme and the Pathways study programme delivered to primary care patients with current MDD or dysthymia and a LTPC have evidenced improvements in depressive symptoms, some SMBs (i.e. only exercise in some instances) and cardiac events but not HbA1c (Davidson, Reickmann, Clemow, Schwartz, Shimbo, Medina, Albanese Kronish, Hegel & Burg, 2010; Harpole, Williams, Olsen, Stechuchak, Oddone, Callahan, Katon, Lin, Grympa & Unützer, 2005; Katon, Von Korff, Lin, Simon, Ludman, Russo, Ciechanowski, Walker, & Bush, 2004b; Lin, Katon, Rutter, Simon, Ludman, Von Korff, Young, Oliver, Ciechanowski, Kinder & Walker, 2006; Williams, Katon, Lin, Nöel, Worchel, Cornell, Harpole, Fultz, Hunkeler, Mika & Unützer, 2004). The null effect on HbA1c was, however, potentially due to a floor effect and dilution of the effect on depression again owing to antidepressant treatment in usual care controls.

It is additionally noteworthy that there is evidence from these collaborative care trials that treating depression, including mild to moderate symptoms, may improve HCU and produce cost-savings. Studies have demonstrated acceptable incremental medical costs for additional benefits (i.e. depression free days) conferred over usual care (Katon, Unützer, Fan, Williams, Schoenbaum, Lin & Hunkeler, 2006), and additional benefit (i.e. depression free days) yet also reduced medical costs relative to usual care (Katon, Russo, Von Korff, Lin, Ludman & Ciechanowski, 2008; Simon, Katon, Lin, Rutter, Manning, Von Korff, Ciechanowski, Ludman and Young, 2007). Thus, an initial investment in services to improve depression will be offset by long-term savings in medical costs (Katon, et al, 2008), not to mention the potential for wider cost reductions from societal and patient perspectives.

Limitations

Collaborative care does not always produce depression remission (Katon et al, 2004b; Koike, Unutzer & Wells, 2002).

Lower level E&P need and low-intensity psychological intervention

Provision of E&P support is also hampered by the complexity of E&P need amongst people with LTPCs, the different levels of which require different types of support consistent with NICE guidelines. Again, low-intensity psychological intervention is advocated for lower-level need. For these patients, high-intensity psychological intervention and collaborative care represent over investment of valuable resources. Antidepressants are not advocated, and consistent with the poor risk to benefit ratio reported by NICE there is evidence that they have limited effectiveness for milder symptoms, for example in Type 2 diabetes (Pailie-Hyvarian, Wahlbeck & Erikkson, 2007).

Effectiveness

Low-intensity interventions have demonstrated clinical and cost-effectiveness, for example some cCBT packages, which are now advocated by NICE (Mayor, 2006; Kaltenthaler et al, 2006). Whilst evidence supporting their use in LTPCs is still to surface, psycho-education has demonstrated significant improvements in depressive symptoms and HbA1c in patients with diabetes and mild to moderate depressive symptoms (Pibernik-Okanovic, Begic, Ajdukovic, Andrijasevic & Metelko, 2009). This improvement did not differ from that observed in controls, yet the control group received non-specific psychological support and qualitatively reported benefiting from this. Facilitated self-help interventions are also popular amongst patients with LTPCs and lower-level E&P need (Lyons, Nixon & Coren, 2006).

Limitations

However, low-intensity interventions vary in the extent of professional contact, which ranges from monitoring to facilitation by trained practitioners[13] and treatment is also still relatively intensive and burdensome[14] (NICE, 2009). Some cCBT packages are also expensive, which is an important disadvantage in a group already incurring substantial health care costs (Kaltenthaler et al, 2006). These issues prohibit widespread availability (again, the impact of the recent changes in UK clinical practice, including the IAPT programme, is discussed below). cCBT also necessitates a certain degree of computer literacy to enable efficient use.

Impact of the QoF, NICE guidelines and IAPT programme

The evidence suggests that the QoF standards, and NICE guidelines, have improved screening and influenced treatment provision. Many practices now report administering the QoF questions to around 90% of patients with diabetes and/or CHD within the previous 15 months and then administering a severity assessment to the majority of those attaining a new diagnosis of depression (NHS The Information Centre for Health and Social Care, 2011). An audit of UK general practice medical records has additionally suggested that depression treatment is positively related to severity scores (Kendrick, Dowrick, McBride, Howe, Clarke, Maisey, Moore & Smith, 2009). However, in this study treatment rates were lower for patients with LTPCs, which it was posited may reflect HCPs concerns about drug side effects (as described above), HCPs not wanting to medicalise distress or label patients not complaining of depression, or patient's unwillingness to accept treatment having been routinely screened rather than self-referred. Access to psychological intervention, especially low-level intervention, was also seemingly

[13] Group based peer support necessitates facilitation by a practitioner with knowledge of the LTPC and its association with depression, individual guided self-help based on CBT involves support from a trained practitioner who facilitates the programme and computerised CBT is a stand-alone computer or web-based programme but with limited facilitation by a trained practitioner (NICE, 2009).

[14] These interventions typically take place over eight to 12 weeks, with weekly or only slightly fewer sessions, and are additionally usually face to face, with the exception of cCBT (NICE, 2009).

restricted; inconsistent with NICE guidelines, patients with minimal to moderate depression were prescribed antidepressants more often than referral to mental health specialists occurred (Kendrick et al, 2009). In fact, it is speculated that HCPs are more likely to prescribe antidepressants where specialist psychological treatment is less readily available (Kendrick et al, 2009). Since its national role out in recent years, the IAPT programme has undoubtedly improved access to low- and high-intensity psychological therapies. To date, 97% of the PCTs in England have a service from this programme in at least part of their area; 60% of the adult population has access (IAPT, 2011). Evidently, though, there is room for improvement in service provision, and indeed eight to 12 week waiting lists are still reported locally for referring patients with diabetes (JS[15], 2011).

Conclusions

In sum, depression is prevalent in LTPCs, particularly lower-level need. The aetiological evidence is confused and suggests a bidirectional relationship with unclear mechanisms, yet some indication that targeting illness-related stressors and general/illness-related distress may optimise improvement in depression. Whether intervention derived improvements in distress are related to improvement in depression is yet to be established though. Intervention for depression is warranted as it has a clear and substantial adverse impact on important outcomes in LTPCs, which is evident even for lower-level need. This suggests that while the NICE guidelines direct treatment according to distinctions in depression severity defined by diagnostic criteria (e.g. DSM-IV) (i.e. level of need), these distinctions are apparently more quantitative than qualitative. The conceptualisation of depression as a continuum may hence be more appropriate. In LTPCs, both high- and low-intensity psychological intervention improves depression and has produced

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concurrent improvements in other important outcomes, albeit evidence for the latter is equivocal and whether changes in these outcomes are related to improvements in depression is unclear (i.e. this has either not been investigated or is supported in some but not other instances). There is also some evidence that depression treatment, even for lower-level need, can produce cost savings. Unmet E&P need in LTPCs is identified as a national priority, particularly lower-level need owing to its prevalence and somewhat equivocal impact. Whilst access to E&P support has improved with recent changes in UK clinical practice, barriers persist across the continuum of depression/E&P need. Investigation of alternatives that overcome these barriers is therefore warranted.

Overview of thesis

This thesis considers a theoretically appropriate low-intensity psychological intervention, which is consistent with the current policy context for improving depression in adults with LTPCs and offers pragmatic advantages over existing alternatives; written emotional disclosure (WED). The author's initial interest in WED emerged when it was encountered in previous study on the psychological impact of LTPCs. The aforementioned properties of WED, described fully in the next chapter, made it an attractive and apparently viable means of ameliorating the psychological impact of LTPCs that could reasonably be implemented as part of routine clinical care.

The intervention, its theoretical grounding and the existing evidence base is reviewed, with relevant effectiveness RCTs considered systematically and attention paid to WEDs effects for negative affect, including depression, in LTPCs. The development, implementation and findings of an exploratory trial, informed by the

systematic review, testing WED for improving depressive symptom severity for individuals Type 2 diabetes is then described and evaluated.

Chapter 2 WED for adults with a LTPC

Chapter overview

This chapter describes WED and its theoretical and pragmatic appropriateness for improving depression for adults with a LTPC, in addition to its consistency with the policy context outlined in chapter one and its acceptability to patients and clinicians. The existing evidence base is then discussed in a preliminary sense, with attention to the evidence that suggests WED is selectively effective and which delineates some fairly consistently supported moderating influences. The evidence for hypothesised mechanisms of effect and similarities in the mechanisms of effect underpinning WED and other effective psychotherapies are considered, which suggest some possible critical processes in WED and provide some support for its anticipated effectiveness. The chapter concludes with a critical discussion of previous systematic reviews of WED and their informative potential and clinical utility for determining the effect of WED on negative affect, including depression, in LTPCs.

WED description

WED is a technique developed by Pennebaker and Beall (1986), which targets emotional aspects of stressors. It involves writing about a stressful event, exploring in detail thoughts and feelings surrounding this, for approximately 15-20 minutes a day for three to four days within a short time period, usually consecutive days. Where effectiveness is demonstrated, an initial mild increase in negative affect is typically yet quickly subsides, producing salutary health effects compared to control participants who write about emotionally neutral topics, such as their plans for the day, or receive usual care.

The appropriateness of WED for LTPCs

Theoretical appropriateness

Chapter one identified that illness-related stressors and general/illness-related distress are associated with depression in LTPCs, thus targeting this may optimise improvement in depression. WED targets emotional aspects of stressors and presumably distress, consequently improvement in depression may be optimised. Stressors are self-selected ensuring universal coverage of the wide range of stressors associated with depression in LTPCs (described in chapter one). By improving depression, even lower-levels, WED may additionally improve the outcomes adversely impacted by this, for example QoL, SMBs, clinical outcomes and HCU and costs. Again, concurrent improvements in these outcomes have been demonstrated in trials of low- and high-intensity depression treatment, albeit as described in chapter one the evidence is equivocal and it is unclear whether these changes are related to improvement in depression.

Policy context

Chapter one identified that supported self-management, prevention/early intervention, and management of mental health in the home, community and primary care are a priority in LTPCs. WED is self-administered at home, engaging people with an LTPC in their treatment. Moreover, in chapter one lower-level depression was demonstrated to be particularly prevalent, impactful and a national priority in LTPCs, with some existing barriers to lower-level E&P support. Consistent with NICE WED is a low-intensity intervention that would serve the large proportion of people with a LTPC and lower-level need. Specifically, WED may protect individuals at risk of developing depression (i.e. delaying the onset of symptoms) and act as a remedial intervention for lower-level depression (i.e. delaying the

progression of significant symptoms), yet also provide a useful adjunct for more severe depression (i.e. supervised implementation of WED).

Pragmatic advantages over existing low-intensity E&P support in LTPCs

WED additionally overcomes some existing barriers to provision of low-intensity intervention in LTPCs. It is easily accessible, not labour intensive, inexpensive and does not exacerbate patient burden in that it is brief, portable, available 24 hours a day and seven days a week, and entirely self-administered with no requirement for computer literacy or access. Completed in anonymity, WED additionally provides a safe disclosure context that is not impeded by the social constraints reported by people with LTPCs with respect to E&P issues (see chapter one); it can access patients that are difficult to reach, for example those for whom interpersonal disclosure is unacceptable (Smyth & Helm, 2003).

Acceptability to patients and clinicians

WED is consistent with LTPC patients' expressed need to talk. Indeed, people report WED to be a valuable experience (Pennebaker, 1997; Francis & Pennebaker, 1992; Pennebaker & Seagal, 1999), including LTPC patients (Gellaitry, Peters, Bloomfield & Horne, 2010; Morgan, Graves, Poggi & Cheson, 2008). WED has also demonstrated a lower attrition rate than other therapist-lead and self-help interventions (Stice, Burton, Bearman & Rhode, 2006). That negative effects post-writing are not prolonged is confirmed by LTPC patients, and typically none report being upset or request additional support as a result of participation (Broderick, Stone, Smyth & Kaell, 2004; Gellaitry et al, 2010). WED is additionally advocated by clinicians (Baikie & Wilheim, 2005).

It is noteworthy that written disclosure may be considered to be more appropriate than verbal disclosure in LTPCs. Therapeutic gain (Murray & Seagal, 1994) and long-term health effects (Pennebaker, 1997; Frattaroli, 2006) are equivocal, yet LTPC patients report a preference for writing as this is less restrictive in that one cannot hear themselves saying things they are reluctant to disclose to others (Byrne-Davis, Wetherell, Dieppe, Weinman, Byron, Donovan, Horne, Brooks & Vedhara, 2006).

Preliminary overview of the evidence base for WED

A large evidence base of RCTs suggests that WED can derive notable improvements in physiological and psychological health, and HCU, in healthy samples, typically students tested in a laboratory (Pennebaker, Kiecolt-Glaser & Glaser, 1988; Pennebaker & Beall, 1986). However, this does not indicate whether WED is effective for those with clinical need; WED may interact with unique characteristics of clinical samples and the treatment they receive (Smyth, 1998), or whether it has ecological validity; WED may be less effective in more naturalistic settings with less experimental control. These questions must be answered before WED can be applied in practice (Baikie & Wilheim, 2005; Smyth & Helm, 2003), and indeed such research has recently begun to emerge. For samples with greater clinical need more modest yet still potentially notable effects are reported (Baikie & Wilheim, 2005), for example on physical and psychological health, and HCU, in adults with current or past experience of a stressful event, for example caregivers (Campbell, 2003), with LTPCs ranging from those with a lower mortality risk for example arthritis (Smyth, Stone, Hurewitz & Kaell, 1999) to terminal illnesses such as cancer (Stanton, Danoff-Burg, Sworowski, Collins, Branstetter, Rodriguez-Hanley, Kirk & Austenfeld, 2002), and with psychiatric/psychological problems for example psychiatric prison inmates (Richards, Beal, Seagal & Pennebaker, 2000)

and individuals with lower- and higher-levels of depression (Gortner, Rude & Pennebaker, 2006; Stice et al, 2006; Sloan & Marx, 2006). However, effects upon psychological health are generally not as consistent or notable as those on physical health (Baikie & Wilheim, 2005; Frisina, Borod & Lepore, 2004).

Results have, however, been mixed with evidence of null effects on physical and psychological health, and HCU, amongst healthy participants (Swanbon, Boyce & Greenberg, 2008), and patients with traumatic injuries (Bugg, Turpin, Mason & Scholes, 2008), asthma (Harris, Thoresen, Humphreys & Faul, 2005), HIV (Rivkin, Gustafson, Weingarten & Chin, 2006) and eating disorders (Frayne & Wade, 2006). This inconsistency likely reflects heterogeneity in risk of bias and other study-specific artefacts; study parameters have been unsystematically manipulated in search of the most effective design. Indeed, WED studies are highly variable with respect to a) participants (i.e. selection criteria and recruitment approach), b) the intervention (i.e. the number, length and spacing of writing sessions, whether the disclosure topic is self-selected (e.g. any stressor) or prescribed (e.g. a LTPC), whether past versus current and traumatic versus stressful events are disclosed, whether the disclosure structure is participant-generated or guidance is received, whether topic switching across writing sessions is allowed, and whether the standard WED paradigm (e.g. genuine stressors) is implemented as opposed to variants of this (e.g. imagined stressors or positive events), c) the outcomes assessed and the measures employed, and d) the comparison exposure (i.e. alternative treatment, neutral writing or usual care). Interpretation of the evidence base is therefore extremely difficult.

It should additionally be noted that a small number of studies have identified a negative effect of WED. Most have included samples defined by significant distress or individuals experiencing highly stressful situations, for example studies have

evidenced increased HCU in patients with apparent PTSD (Gidron, Peri, Connolly & Shalev, 1996), more fatigue in students with trauma history (Greenberg, Wortman & Stone, 1996) and high risk surgical patients (Solano, Pepe, Donati, Persichetti, Laudani & Colaci, 2007) and reduced satisfaction with prostheses in lower limb amputees (Gallagher & MacLachlan, 2002). WED apparently increases avoidance in these samples (Cohen, Sander, Slavin & Lumley, 2008; Gidron et al, 1996; Greenberg et al, 1996), which may be taken to reflect early but incomplete processing of evoked stressors. It is posited that in this context WED may merely activate distress, which is too upsetting to confront or for which more disclosure sessions and/or additional assistance are required to achieve resolution (Cohen et al, 2008; Gallagher & MacLachlan, 2002; Gidron et al, 1996; Solano et al, 2007). These studies are limited, however, as in some instances effects were partially explained by improvement in controls (Cohen et al, 2008; Gidron et al, 1996) and the intervention deviated from the standard WED paradigm, for example additional use of mood induction procedures (Greenberg et al, 1996) and verbal elaboration (Gidron et al, 1996). Nonetheless, it is widespread clinical opinion that WED is not appropriate with very distressed patients (i.e. unsupervised) (Baikie & Wilheim, 2005; Esterling, L'Abate, Murray, & Pennebaker, 1999; Honos-Webb, Harrick, Stiles & Park, 2000; Murray & Seagal, 1994; Pennebaker, 2004; Sloan & Marx, 2006; Smyth & Helm, 2003). WED has demonstrated some negative effects in unselected student samples, yet this was again apparently due to avoidance and an absence of proper resolution of evoked stressors (Honos-Webb et al, 2000; Rogers, Wilson, Gohm & Merwin, 2007). To date no negative effects have been reported in LTPCs (Baikie & Wilheim, 2005).

Moderators of WEDs effects: Interpersonal determinants of whether and to what extent WED is effective

Research suggests that WED may be selectively effective for individuals possessing particular traits. This may explain the heterogeneity between apparently similar trials in that traits which maximise WEDs effects may be differently represented across samples. No moderator has consistently discriminated those that do and do not benefit from WED (Lumley, 2004); some studies demonstrate a particular moderating effect (i.e. WED is more effective for sub-group A than B) whilst others report no moderating effect for the same variable or an effect in the opposite direction (i.e. WED is more effective for sub-group B than A) (Smyth & Pennebaker, 2008). However, this is again likely due to heterogeneity between studies. Nonetheless, two traits for which the evidence is fairly consistent are described below.

Alexithymia

Unsurprisingly, some evidence suggests that WED may be less effective for people that experience difficulty identifying and describing emotions and instead focus on more external processes, a trait termed alexithymia (Lumley, 2004). Perhaps the stronger effects of WED observed in students is a function of lower alexithymia. In fact, it is posited that WED may merely make alexithymic individuals acutely aware of distress resulting in increased perception of symptoms (Lumley, 2004). Indeed, for individuals with high alexithymia WED has derived worse physical and psychological health outcomes, including negative affect, compared to controls in chronic pain (Norman, Lumley, Dooley & Diamond, 2004; cited in Lumley, 2004) and migraine (Kraft, Lumley, D'Souza, Robertson, Stanislawski & Ramos et al, 2003; cited in Lumley, 2004) samples. Other studies including LTPC samples have reported worse outcomes only for WED participants with particular facets of

alexithymia rather than the overall trait, namely more difficulty identifying emotions (Lumley & Provenzano, 2003; cited in Lumley, 2004; Norman et al, 2004; cited in Lumley, 2004) and externally oriented feelings (Baikie McIlwian, 2008; Lumley & Provenzano, 2003; cited in Lumley, 2004; O'Connor & Ashley, 2008). Consistent with the evidence described above, it seems that for alexithymic individuals WED may increase intrusive thoughts and avoidance, which again may be taken to reflect early but incomplete processing of evoked stressors (Baikie & McIlwain, 2008). Similar to those reporting significant distress, alexithymic individuals may additionally require more disclosure sessions or additional assistance (Baikie & McIlwain, 2008; Lumley, 2004; Lumley & Provenzano, 2003; cited in Lumley, 2004).

Some studies have reported no moderating effect of alexithymia (Van Middendorp & Geenen, 2008), however this study adapted WED to explicitly instruct emotional and cognitive processing (E&CP), which perhaps facilitated disclosure for alexithymics. Others report more benefit to be associated with higher alexithymia (Baikie & McIlwain, 2008; Paez, Velasco & Gonzalez, 1999; Solano, Donati, Pecci, Persichetti & Colaci, 2003). However, these analyses and or studies examined only the difficulty describing feelings facet of alexithymia. This is only marginally related to the other facets (Lumley, 2004) and confounded by inhibition (Paez et al, 1999), which is typically associated with more benefit from WED (discussed below).

Optimism

Evidence suggests that WED may be effective for optimists, who have a generalised disposition toward positive expectations/outcomes and therefore may cope well with evoked stress using the opportunity to resolves issues and derive insight. Conversely, for pessimists, with negative expectations about outcomes, it may promote rumination on the negative aspects of an issue with less success

achieving resolution (Cameron & Nicholls, 1998). Indeed, an increase in word use reflecting optimism across writing sessions has been found to predict improvement in psychological health including negative affect specifically for WED participants (Mackenzie, Wiprzycka, Hasher & Goldstein, 2008). There is also preliminary evidence of this moderating effect in LTPCs, for example HIV patients, although this refers to cognitive adaptability including optimism (Wagner, Hilker, Hepworth & Wallston, 2008). Research also suggests that WED typically evokes positive expectancies that it will reduce the emotional impact of an event and that benefits are restricted to these participants, whereas for those with negative expectancies negative effects are more likely (Langens & Schüler, 2007). Although speculative, the benefits apparently derived by optimists may be explained by concomitant positive expectancies about WED. Some studies have reported no moderating effect of optimism (Harrist, Carlozzi, McGovern & Harrist, 2007) or more benefit associated with less optimism (Mann, 2001). However these studies explored writing about life goals and a positive future with HIV respectively, rather than stressful issues, which may be contraindicated for optimists should reality not match their expectations (Mann, 2001).

Why WED might be effective for treating psychological morbidity and improving health

WED is seemingly associated with empirically supported influencing mechanisms

WED was not derived from an established theoretical framework. However a number of mechanisms have been proposed and somewhat supported empirically, suggesting that WED may be considered to have a sound theoretical grounding for achieving improvements in health. This support is, however, variable such that no one theory has fully explained the observed effects (Sloan & Marx, 2004a;

Pennebaker, 2004), albeit these theories have yet to be adequately tested (Sloan & Marx, 2004a). It is possible that a number of these mechanisms, which are not mutually exclusive, operate simultaneously. The proposed mechanisms and the empirical support associated with each are presented below.

Inhibition-confrontation approach

It is posited that inhibition of a traumatic event necessitates cognitive monitoring and is a physiological drain (Baikie & Wilheim, 2005; Pennebaker, 1985; Pennebaker, 1997; Sloan & Marx, 2004a). Autonomic nervous system activity is increased with physiological discharge along hidden channels, for instance increased electrodermal activity and thus increased skin conductance levels (i.e. greater hand perspiration) (Baikie & Wilheim, 2005; Pennebaker, 1985; Pennebaker & Susman, 1988; Petrie, Booth & Pennebaker, 1998). People switch to lower-level processing with a narrower, superficial focus on the event and attention directed to other superficial topics, yet rumination and intrusive thoughts result which are physiologically arousing and psychologically harmful (Baikie & Wilheim, 2005; Pennebaker, 1985; Petrie et al, 1998). This prolonged autonomic arousal and psychological stress functions as a chronic, low-level, cumulative stressor, which adversely affects stress-related immune parameters (i.e. circulating lymphocytes) and the immune influencing parameters of the nervous system. Immune mediated disease processes are impacted and the associated risk of illness is thus enhanced (Pennebaker, 1985; Pennebaker & Susman, 1988; Pennebaker, 1997; Petrie et al, 1998). WED was thus originally posited to permit suppressed traumatic experiences and the associated emotion to be relived, releasing inhibited thoughts and emotion and reducing the associated physiological, cognitive and psychological problems (Baikie & Wilheim, 2005; Pennebaker, 1997; Sloan & Marx, 2004a).

Evidence for the inhibition-confrontation approach

It has long been asserted that emotional inhibition is associated with poor health and disease and that releasing this can derive benefit (i.e. catharsis). Evidence in LTPCs concurs (Gross, 1989; Nyklíček, Vingerhoets & Denollet, 2002; Panagopoulou, Kersbergen & Maes, 2002; Stanton, Danoff-Burg, Cameron, Bishop, Collins, Kirk, Sworowski & Twillman, 2000). There is also evidence that release of inhibition may underpin the health effects of WED. Thought suppression during WED has a detrimental effect upon outcomes (Petrie et al, 1998) and WED is more effective for individuals exhibiting more inhibition (McGuire, Greenberg & Gevirtz, 2005; Gortner et al, 2006; Porter, Keefe, Baucom, Hurwitz, Moser, Patterson & Kim, 2009). WED also improves physiological markers of inhibition, for instance skin conductance levels (Pennebaker, Hughes & O'Heeron, 1987; Pennebaker & Susman, 1988; Petrie, Booth, Pennebaker, Davison & Thomas, 1995), with some evidence of greater benefit for individuals exhibiting more verbal disclosure and a corresponding drop in skin conductance levels (Pennebaker, Barger & Tiebout, 1989). Patient feedback about WED in LTPCs also supports inhibition as a mechanism (Byrne-Davis et al, 2006; Gellaitry et al, 2010).

Evidence against the inhibition-confrontation approach

Inconsistent with this model, however, WED reportedly derives benefit where trauma has previously been disclosed (Greenberg & Stone, 1992), although full disclosure may not have been achieved interpersonally (Sloan & Marx, 2004). Studies have also reported no moderating effect of inhibition (Smyth, Anderson, Hockemeyer & Stone, 2002; Esterling, Antoni, Kumar & Schneiderman, 1990; Esterling, Antoni, Fletcher, Margulies & Schneiderman, 1994) and more benefit for individuals exhibiting less inhibition (Francis & Pennebaker, 1992), although this may be because inhibitors avoid or do not engage in disclosure (Lumley, 2004). Health benefits are additionally not consistently related to post-writing negative

affect (i.e. taken as a proxy for emotional release) (Smyth, 1998), and in fact a short-term increase in negative affect rather than emotional relief post-writing is counterintuitive to this model (Baikie & Wilheim, 2005). Moreover, there is some evidence that evocation of stressors without resolution in WED produces adverse effects (discussed earlier). Finally, other forms of emotional expression, for example dance therapy (Krantz & Pennebaker, 1996, as cited in Pennebaker 1997) and drawing (Pantchenko, Lawson & Joyce, 2003) have not replicated WEDs effects. This suggests that while release of inhibition may play a role other processes are also seemingly implicated in WEDs effects.

Cognitive processing approach

It is posited that memories of traumas are fragmented, disorganised and inconsistent with other memory structures, and thus associated with persistent, distressing and intrusive thoughts, rumination, hyperactivity and avoidance. WED purportedly derives benefit by submitting these memories (i.e. the associated thoughts and feelings) to a linguistic format, forcing the labelling, re-structuring and re-organisation of the memory. This, it is proposed, promotes understanding of the event and the emotional responses to it (i.e. insight is derived, the cause and meaning of the event are ascertained and a coherent narrative is constructed), and reduces the associated emotion (Pennebaker, 1997; Pennebaker, 2000; Pennebaker & Francis, 1996; Pennebaker, Mayne & Francis, 1997; Smyth & Helm, 2003) (i.e. there is emotional and cognitive processing (E&CP) of the event). The narrative is then supposedly simplified such that only information consistent with the story is recalled, and becomes biased as information is added in an unconscious effort promote cohesiveness (Pennebaker, 2000; Pennebaker & Seagal, 1999). The memory can then be stored and forgotten more efficiently, enabling a reduction in the associated symptoms.

The experiential model specifically posits that traumas are inconsistent with mental representations of the world (e.g. the belief that the world is a safe place), and are therefore associated with cognitive, affective and autonomic tension. WED is posited to resolve this incongruency by integrating the new information into existing schemas or altering them such that understanding of the event, or the world, is changed and the problematic symptoms are reduced (Baikie & Wilheim, 2005; Byrne-Davis et al, 2006; Sloan & Marx, 2004a).

Evidence for the cognitive processing approach

Defining and measuring E&CP, to identify whether this mediates WEDs effects, is difficult. Studies have therefore investigated whether linguistic features of WED presumed to reflect, or influence, the anticipated E&CP predict health improvement. Review of WED essay content has demonstrated more self-reflection, thoughtfulness, emotional openness (Graham, Lobel, Glass & Lokshina, 2008; Pennebaker, 2000) and the construction of a coherent narrative (Pennebaker, 1993) to be related to improvement. Objective language analysis of WED essays has also demonstrated no association between average use of words reflecting insight and causal thinking (Pennebaker, 1993), yet an association between increases in use of words reflecting insight and causal thinking (i.e. reflecting cognitive processing) across writing sessions and improvement in predominantly physical but also psychological health (Pennebaker, 1993; Pennebaker et al, 1997; Pennebaker & Francis, 1996). This association has also been demonstrated in LTPCs, although the improvements in health have not consistently been significant (Rivkin et al, 2006; van Middendorp & Geenen, 2008) and the evidence is equivocal (Hamilton-West & Quine, 2007; Walker, Nail & Croyle, 1999).

In contrast, research investigating whether word use reflecting emotional processing is associated with health improvements is highly ambiguous. Initially, whether

average use of emotional words across writing sessions is related to WEDs effects was examined, as it was anticipated that the mere expression and labelling of emotions facilitates integration of emotional responses into ones understanding of the event and reduces the associated emotion (Pennebaker & Francis, 1996; Pennebaker et al, 1997). Improvement in WED has been linked to use of more negative and less positive emotion words overall (i.e. akin to cathartic expression of negative emotion) (Pennebaker, 1993), but more consistently and in more sophisticated analyses to use of more positive relative to less negative emotion words overall, with a moderate reference to negative emotion apparently being optimal (i.e. perhaps suggesting adaptive emotional processing wherein one has come to terms with the experience and achieved a positive emotional balance) (Baikie, Wilheim, Johnson, Boskovic, Wedgwood, Finch & Huon, 2006; O'Connor & Ashley, 2008; Pennebaker & Francis, 1996; Pennebaker et al, 1997; van Middendorp & Geenen, 2008). However, the evidence has not consistently indicated a prognostic effect of a higher average use of positive emotion words (Rivkin et al, 2006; Walker et al, 1999).

In view of the equivocal evidence relating to average use of emotional words, some albeit few studies including those with LTPC samples have additionally examined whether a change in use of positive and negative emotion words across writing sessions is associated with WEDs benefits. An increase in positive emotion words has been demonstrated to be associated with improvement in physical and psychological health, including depressive symptoms, specifically for WED participants (i.e. perhaps suggesting the temporal achievement of a positive emotional balance), albeit the improvements in health have not always been significant (Hamilton-West & Quine, 2007; Mackenzie et al, 2008). One study identified significant improvements in psychological health for WED participants with a concurrent increase in expression of affect-related words across writing sessions,

yet did not report on trends for changes in positive and negative emotion words separately nor examined the association between changes in word use and health. (Mankad & Gordon, 2010). A decrease in negative emotion words across writing sessions has been found to be associated with significant improvements in physical health for WED participants (i.e. perhaps suggesting successful temporal emotional processing of and habituation to the associated emotion) (Hamilton-West & Quine, 2007).

Few studies have, however, examined whether emotional word use mediates WEDs effects in formal mediation analyses (again formal mediation analysis is described in chapter five). One study in cancer identified a decrease in negative emotion words across writing sessions that was exclusive to WED participants and was associated with improvement in health, yet did not mediate WEDs effects in a formal mediation analysis. None of the positive emotion word variables tested emerged as likely mediators of WEDs effects (Low, Stanton & Danoff-Burg, 2006). However, the authors acknowledge limited power to detect significant mediators of effects, and in this study no change in cognitive processing word use was observed across writing sessions. Indeed, while tentative another study has suggested that reduction in negative emotion words for WED participants may be prognostic only where successful cognitive processing has also occurred (Schwartz & Drotar, 2004).

It is also problematic that it is unclear whether the linguistic changes observed to predict health improvements in these studies actually reflect the anticipated real world E&CP; they could reflect other processes. Interestingly, however, WED has also improved proxy measures of cognitive change, for instance working memory suggesting pre-occupation with the event is reduced (Kellogg, Mertz & Morgan, 2010; Klein & Boals, 2001; Yogo & Fujihara, 2008). In fact, the original WED study suggested that writing with only emotional expression or cognitive processing alone

is insufficient, rather both are required for benefit (Pennebaker & Beall, 1986), and enhancing aspects of cognitive processing, for instance cognitive re-structuring (Broderick et al, 2004; Gellaitry et al, 2010) and narrative structure (Smyth, True & Souto, 2001) has also demonstrated improvement/more improvement in WED, although this evidence is inconsistent (Danoff-Burg, Mosher, Seawell & Agee, 2010; Graybeal, Sexton & Pennebaker, 2002; Lichtenthal & Cruess, 2010). Patient feedback about WED in LTPCs additionally supports E&CP as a mechanism (Byrne-Davis et al, 2006; Gellaitry et al, 2010; Pennebaker, Colder & Sharp, 1990; Theadom, Smith, Horne, Bowskill, Apfelbacher & Frew, 2010).

In sum, emotional and cognitive processing of stressors is seemingly required in WED. However, should this be the case, exactly which real world processes occur and the specific stages of change involved have yet to be delineated. The precise nature of the emotional processing component is particularly unclear as the evidence base is particularly under-developed, inconsistent and ambiguous, yet suggests that successful temporal emotional processing of and habituation to negative emotion and temporal attainment of a positive emotional balance may be required.

Exposure approach

Consistent with social learning theory, it is posited that the memory of an unresolved trauma is a faulty cognitive structure of erroneous information. Specifically, a traumatic event presents as an unconditioned stimulus (UCS), which evokes an unconditioned response (UCR) (i.e. fear and arousal). The memory of the event, initially a neutral stimulus (NS), becomes paired with the UCS (i.e. becomes a conditioned stimulus; CS) and elicits the negative emotional response (i.e. a conditioned response; CR) on its own. This CR is then reinforced by avoidance of the CS; that the CS might not produce the CR is never realised (Baikie & Wilheim,

2005; Sloan & Marx, 2004a). Emotional processing of this fear structure, posited to underpin WED, is supposedly achieved via three stages; a) activation of the memory structure, the CS, b) modification of this via repeated exposure to and the provision of corrective information about the CS, c) gradual extinction of the UCS/CS association such that the CS no longer elicits the CR and associated symptoms such as intrusive thoughts and avoidance (Foa & Kozac, 1986). This is reflected by initial negative emotional arousal (i.e. emotional activation; EA), which then dissipates across exposure sessions (i.e. habituation; H).

Evidence for the exposure approach

There is some evidence that EA&H is observed in WED and that it may account for its effects. In samples defined by trauma, significantly more physiological activation (i.e. salivary cortisol reactivity) and subjective EA to the initial WED session and a reduction in this across writing sessions has been demonstrated relative to no such change in controls (Petrie et al, 1995; Smyth, Hockemeyer & Tulloch, 2008; Sloan & Marx, 2004b; Sloan, Marx & Epstein, 2005; Sloan & Marx, 2006; Sloan, Marx, Epstein, Lexington, 2007; Smyth et al, 2008). This pattern of activation has then been shown to be associated with clinically meaningful improvements in PTSD symptoms, depressive symptoms and physical health for disclosure participants (Sloan & Marx, 2004b; Sloan et al, 2005; Sloan & Marx, 2006), even in formal meditation analyses (again formal mediation analysis is discussed in chapter five) (Sloan et al, 2007). In LTPCs larger increases in current negative mood post-writing have been observed for the first session compared to successive sessions (Smyth, Stone, Hurewitz & Kaell, 1999, cited in Lepore, Greenberg, Bruno & Smyth, 2002), and WEDs effects are reportedly explained by within-session heart rate habituation reflecting preliminary EA&H again in formal mediation analyses (Low et al, 2006). Indeed, EA&H would explain the initial increase in negative mood that is typical in WED studies, yet dissipates quickly.

Some WED studies have additionally demonstrated superior effects of emotional expression alone compared to writing facilitating cognitive processing when sufficient sessions are provided to achieve proper processing via exposure principles (Sloan et al, 2007). This suggests that while cognitive processing may be important, other process are also likely implicated in WEDs effects. Finally, WED is consistent with exposure principles in that repeated exposure to the same stimuli is apparently required to achieve EA&H and thus an improvement in symptoms (Sloan et al, 2005; Sloan & Marx, 2006). In WED topic switching is typically allowed and is variably implemented by participants, which may explain the mixed evidence base (Baikie & Wilheim, 2005; Sloan & Marx, 2004a).

Evidence against the exposure approach

However, WED is also inconsistent with exposure principles in some respects. Improvement is demonstrated irrespective of topic switching (Baikie & Wilheim, 2005), which is not consistently related to effects (Pachankis & Goldfried, 2010), and even though the number, length and spacing of sessions is less than that typically required to facilitate emotional habituation[16] (Baikie & Wilheim, 2005; Greenberg et al, 1996; Sloan & Marx, 2004a). Moreover, some WED studies with non-trauma samples have failed to confirm a pattern of E&AH, which is apparently not attributable to topic switching (Kloss & Lisman, 2002). However, in the absence of an overall effect WED may have failed to successfully produce E&AH in this study, which may still be attributable to topic switching given that this finding was unconvincing; the pattern of change was compared for individuals exhibiting more and less topic switching whereas topic switching versus no topic switching may have identified a difference. However, studies with LTPC samples have also failed to demonstrate EA&H (D'Souza, Lumley, Kraft & Dooley, 2008; Gillis, Lumley,

[16] Exposure therapies typically involve six sessions of 90 minute duration.

Mosley-Williams, Leisen & Roehrs, 2006; Norman, Lumley, Dooley & Diamond, 2004), some of which have reported a positive effect of WED (Gillis et al, 2006; Norman et al, 2004). The explanatory power of the exposure approach in WED is therefore uncertain, at least in non-traumatised samples. It seems that while exposure may be important other processes are also likely implicated in WEDs effects.

It is noteworthy that the three aforementioned theories are also supported in that WED seemingly produces health improvements by buffering the negative effect of and/or reducing intrusive thoughts (Lepore, 1997; Lepore & Greenberg, 2002) and avoidance (Zakowski, Ramati, Morton, Johnson & Flanigan, 2004) (i.e. this effect is integral to each approach).

There are additionally some alternative theories and mediating processes that hold some explanatory potential for WED effects (Sloan & Marx, 2004a).

Behaviour change approaches

Some research has posited that WED positively influences aspects of behaviour, which in turn results in improved health.

Health behaviour change approach

It is posited that WED increases awareness of health threats which people endeavour to rectify, namely by increasing positive and reducing negative health behaviours (Byrne-Davis et al, 2006; Pennebaker & Seagal, 1999; Pennebaker, 2000). Systematic reviews have reported no effect of WED on health behaviours, with one exception that reviewed predominantly healthy samples yet included HCU (Mogk, Otte, Reinhold-Hurley & Kroner-Herwig, 2006), improvements in which are consistently reported for healthy samples (Harris, 2006). While speculative,

improvements are apparently restricted to substance use for psychologically stressed/problematic populations (Pennebaker, 1997; Pennebaker & Seagal, 1999; Pennebaker, 2000; Pennebaker & Graybeal, 2001), for example cocaine use/cravings in intensive treatment for dependence (Grasing, Mathur & Desouza, 2010), abstinence from smoking for those attending a smoking cessation intervention (Ames, Patten, Offord, Pennebaker, Croghan, Tri, Stevens & Hurt, 2005; Ames, Patten, Werch, Schroeder, Stevens, Fredrickson, Echols, Pennebaker & Hurt, 2007) and alcohol use amongst recently unemployed professionals (Spera, Morin, Buhrfeind & Pennebaker, 1994). Indeed, null effects are reported for exercise, smoking and substance use in healthy students (Pennebaker & Beall, 1986; Pennebaker, Colder & Sharp, 1990; Pennebaker et al, 1988; Greenberg & Stone, 1992) and exercise for people experiencing stressful situations (Spera et al, 1994). Evidence in LTPCs is underdeveloped yet mixed with no effect on diet, medication and substance use (Bodor, 2002; Stone, Smyth, Kaell & Hurewitz, 2000) but effects on exercise, diet, smoking and other unspecified positive changes (Bodor, 2002; McLaughlin, 2000; Rivkin et al, 2006).

Social behaviour change approach

It is posited that inhibition and rumination about a traumatic event can impede social functioning and create a distance from social networks (Pennebaker, 2000; 2004). WED purportedly improves seeking of and thus satisfaction with social support; people are less afraid to talk about the event (Brown & Heimberg, 2001) and they seek guidance owing to changes in the way they think and feel about the event (Andersson & Conley, 2008; Pennebaker, 2004). In doing this others are alerted to the person's psychological state and the person feels socially tied (Pennebaker, 2000; Pennebaker & Graybeal, 2001). This is beneficial to health. Indeed, studies have shown that following WED people disclose to others more (Pennebaker, 2004; Pennebaker & Graybeal, 2001; Pennebaker, Barger, Tiebout, 1989; Range, Kovac

& Marion, 2000; Sloan & Marx, 2006) and spend more time with them interacting in a more positive and socially integrated manner (Kim, 2009; Pennebaker, 2002; Pennebaker, 2004; Slatcher & Pennebaker, 2006).

Some research additionally suggests that WED may derive benefit by improving perceptions of emotional support; in LTPCs WED is more effective for people with lower perceived emotional support suggesting that it may facilitate improvement in this (Low, Stanton, Bower & Gyllenhammer, 2010) and maintenance of satisfaction with perceived emotional support has been reported for WED participants (Gellaitry et al, 2010). This evidence is somewhat inconsistent, though, with some studies reporting no effect of WED on perceptions of practical support (Gellaitry et al, 2010) and illness-related support (Cohen, Lumley, Macklem, Leisen & Mosley-Williams, in preparation; Gillis et al, 2006). Importantly, there is also evidence that social changes in WED (i.e. an increase in social-theme words) are linked to health, albeit this finding is of limited informative potential because the effect on health was not significant (Rivkin et al, 2006). Moreover, this change may not reflect real world social changes and if it does it is unclear which changes it reflects. Encouragingly though, an unpublished dissertation has suggested that in chronic pain patients, where WED produces improvements in physical and psychological health, including depression, this is accompanied by concurrent improvements in social functioning. However, this was a case study with six participants thus this finding requires replication (Lee, 2002). It is notable, though, that some argue that this theory is too vast to explain WED effects (Andersson & Conley, 2008).

Recent comprehensive approaches

Recently some variants of the original WED paradigm have demonstrated equivocal and even superior effects, for example writing about stressful topics (Gortner et al, 2006; Hamilton-West & Quine, 2007; Stice et al, 2006; Lu & Stanton, 2010),

imaginary trauma (Greenberg et al, 1996), positive events (Burton & King, 2004; 2009; Marlo & Wagner, 1999) including one's best possible self (King, 2001; 2002), a positive future (Mann, 2001), life goals (Austenfeld & Stanton, 2008; Harrist et al, 2007) or positive aspects of stressors (i.e. benefit finding) (Danoff-Burg, Agee, Romanoff, Kremer & Strosberg, 2006; King & Miner, 2000; Lichtenthal & Cruess, 2010; Lu & Stanton, 2010; Segal, Tucker & Coolidge, 2009; Stanton et al, 2002). Consequently, additional theories have been offered that would explain benefits derived from all variants of WED.

Self-regulatory approach

It is posited that under-regulation (i.e. control) of emotions is associated with chronic activation of the nervous and endocrine systems with an adverse effect on associated disease processes, and over-regulation of emotion produces the adverse health effects of inhibition (Lepore, Greenberg, Bruno & Smyth, 2002). WED purportedly facilitates optimal emotional-regulation by promoting skills, strategies and self-efficacy for emotion-regulation (i.e. WED is a mastery experience wherein people observe themselves controlling emotion) (Greenberg et al, 1996; Lepore et al, 2002). As such simply confronting any emotions and exercising control over them should improve outcomes via improved emotion-regulation capabilities (i.e. not just genuine trauma) (Greenberg et al, 1996; King, 2002; Lepore et al, 2002). From a wider self-regulatory perspective, the original paradigm and the additional variants of WED are also purported to promote awareness and clarification of one's goals and priorities and thus attainment of these (King, 2002).

This model is somewhat supported in that WED is apparently more effective for people with greater emotion-regulation capabilities as they are able to engage with it (i.e. consistent with low alexithymia) (O'Connor, Allen & Kaszniak, 2005; Sloan & Epstein, 2005), and enhancing this aspect of WED has derived improvement in self-

efficacy for emotional processing (Kirk, Schutte & Hine, 2011) and equivocal or superior health benefits including improved mood (Cameron & Nicholls, 1998; Lu & Stanton, 2010). Patient feedback about WED in LTPCs also supports improved emotion-regulation capabilities as a mechanism (Byrne-Davis et al, 2006), and WED adapted for eating disorders has evidenced symptom reduction that is associated with improvements in perceived mood-regulation abilities, although this was additionally observed from controls and the symptom reduction was not clinically significant in this study (Johnston, Startup, Lavender, Godfrey & Schmidt, 2010). However, some have questioned the validity of the evidence supporting this model as self-regulation is too difficult a concept to operationalise (Andersson & Conley, 2008).

It should be noted that this model overlaps with the cognitive processing and exposure models in proposing that key emotion-regulation processes in WED are habituation (i.e. initial affective immersion then increased ability to modulate evoked emotion) and cognitive adaptation (i.e. an understanding of emotion that evolves across writing sessions) (Lepore et al, 2002). Thus the evidence supporting these earlier approaches may, to some extent, additionally support this model (Lepore et al, 2002).

Perceived control approach

Again, it is posited that stress and trauma disrupt beliefs about a predictable and controllable world, which reduces perceived control over experiences, for example self-efficacy, with an adverse effect upon both physical and psychological health. WED purportedly restores perceived control specifically via the acquisition of meaning and formation of a coherent narrative. As such, writing about any emotional event may engender positive control expectations (i.e. not just genuine trauma) (Andersson & Conley, 2008). Indeed, WED has evidenced some

improvements in hopelessness (Segal, Bogaards, Becker & Chapman, 1999; Segal, Chatman, Bogaards & Becker, 2001) and 'control-compromised populations', for example patients with a LTPC apparently benefit from WED (Andersson & Conley, 2008). In fact, in migraine sufferers WED has been demonstrated to be more effective for physical and psychological health including negative affect for those reporting lower self-efficacy for managing headaches, suggesting that WED may facilitate improvement in this. However, in this study self-efficacy also moderated the effect of other interventions suggesting that it may simply predict intervention success in general (Kraft, Lumley, D'Souza & Dooley, 2008). Encouragingly, the aforementioned unpublished dissertation reported that WED produced a trend for improvement in self-efficacy for managing pain in chronic pain patients post-intervention, which was not observed for controls and was accompanied by subsequent improvements in physical and psychological health including depression. However, again this was a case study with six participants thus this finding requires replication (Lee, 2002).

It is important to point out, however, that the aforementioned additional approaches have yet to be properly tested, namely in formal meditation analyses with causal models established (i.e. variables measured such that causality can be inferred); variables should be measured such that they demonstrate WED produces a change in behaviour, self-regulation or perceived control which is then related to health (again formal mediation analysis is discussed in chapter five).

There is similarity in the mechanisms of effect proposed to underpin WED and other effective psychotherapies

The processes proposed to underpin WED mirror basic processes involved in face-to-face psychotherapies, and facilitated self-help interventions based on these, with

established efficacy (described in chapter one). Emotional disclosure (ED) is present yet the nature of this differs across modalities (Gidron et al, 1996; Pennebaker, 1997; Smyth & Helm, 2003). E&CP is also mandatory across modalities (Whelton, 2004; Murry & Seagal, 1994; Pennebaker, 1985; Pennebaker & Graybeal, 2001), which is similarly achieved by submitting problems to a linguistic format (Pennebaker & Graybeal, 2001) and constructing a coherent narrative (Pennebaker, 1997; Pennebaker & Segal, 1999; Pennebaker, 2000). CBT entails identifying, challenging and modifying maladaptive thought processes (Kaltenthaler et al, 2006; Mayor, 2006), while WED is similarly proposed to involve identifying, labelling and discussing the causes and consequences of the event (Pennebaker, 1997). Behavioural approaches such as flooding and implosive therapy are underpinned by the three stages of emotional processing of fear that are apparently present in WED (Foa & Kozac, 1986). Both WED and humanistic/experiential therapies advocate introspection, expansion of awareness of experience and the discovery of meaning from this awareness (Whelton, 2004). Finally, NICE advocated group-based peer support similarly entails sharing experiences and feelings associated with having an LTPC (NICE, 2009).

While therapist-led and group-based interventions offer interpersonal and supportive factors, the additional benefit may extend no further than an absence of the initial upsurge in negative mood observed in WED (Murray & Seagal, 1994). WED has evidenced equivocal outcomes to some face to face therapies and other facilitated self-help strategies (Donnelly & Murray, 1991; Largo-March & Spates, 2002; Murray, Lamnin & Carver, 1989; Smyth, 1998; Stice et al, 2006). It is cautioned, however, that further research is required before it can be asserted that WED is capable of producing effects comparable to traditional, therapist-led psychotherapy (Esterling et al, 1999).

Previous WED systematic reviews

In view of the equivocal evidence yet potential for WED improving psychological health outcomes, including depression, in LTPCs, it is important to systematically review the evidence base to obtain a more accurate picture, and guide research endeavours. Systematic reviews are important as they review evidence on a clearly formulated question, and employ systematic, explicit and scientifically rigorous methods to identify, evaluate, and synthesise primary research. As such, the risk of bias is reduced. They also identify weaknesses and gaps in the evidence base, improving the quality of and promoting meaningful future research. Existing systematic reviews of WEDs effects on health were therefore initially identified and critically appraised according to established criteria (Bridle, 2003; Greenhalgh, 1997). Particular attention was paid to their utility for delineating WED effects for psychological health outcomes, especially negative affect including depression, in LTPCs. To date, more than 100 RCTs have evaluated WED and this evidence base has been synthesised in six systematic reviews.

Overall findings and conclusions

Smyth (1998) meta-analysed 13 RCTs and reported WED significantly improves physical health, psychological well-being, physiological functioning, yet not health behaviours in health samples with an overall positive, medium-sized effect size (d=.47) representing a 23% improvement in overall health (Smyth, 1998). The effect size varied significantly across outcome categories and was particularly large for psychological heath.

Frisina, Borod & Lepore (2004) meta-analysed nine RCTs examining WED for improving physical and psychological health in physical and psychiatric disorders and reported a more modest yet positive and significant overall effect size of d=.19.

Effects were significantly larger for physical compared to psychological health, which was not significant. However, certain aspects of psychological health were influenced for example depressive symptoms and mood. WED was less effective for psychiatric than physically ill samples.

Meads, Lyons & Carroll (2003)[17] reviewed 61 trials examining ED for physical and psychological health, and HCU, in healthy volunteers, pre-existing physical conditions and those screened for stress/a psychological diagnosis. In contrast to the previous reviews, the pattern of results portrayed a mixed picture; positive effects, for example for depressive symptoms, were offset by null or unreported effects (a third of all outcomes measured were unreported). There was a slight trend for more negative mood for people with pre-existing physical conditions. The authors concluded that based on the available evidence there was no clear indication of effectiveness for any outcomes assessed, however re-assessment in light of further high quality, better reported research was advocated (Meads et al, 2003; Meads & Nouwen, 2005).

Mogk et al (2006) meta-analysed 30 RCTs investigating WED for psychological and physical health, and health behaviours, for healthy students, high risk individuals with experience of an adverse event, and clinical samples (i.e. physical and psychological conditions). It was concluded that WED has no significant overall effect (g=.04) with no evidence of different effects for different outcome categories, although there was a significant positive effect for health behaviours.

Harris (2006) reviewed 30 RCTs, all examining the impact of WED upon HCU for healthy samples, samples with pre-existing medical conditions and samples

[17] This was a Health Technology Assessment (HTA) review that was later additionally published in a peer reviewed journal; Meads & Nouwen (2005).

meeting psychological criteria. He concluded that WED reduces HCU in healthy samples only, with an effect size of g=.16.

Frattaroli (2006) meta-analysed 146 RCTs investigating ED for healthy samples or those defined by a history of stress or poor physical or psychological health, and the outcomes examined by Smyth (1998). She concluded that ED has a positive and significant overall effect size of d=.75. Consistent with Smyth (1998), effects were significant for all of the main outcome categories except health behaviours. WED was also selectively effective for subcategories within these outcome types, for instance within psychological health; distress and depressive symptoms yet not stress were improved. Having a physical illness or a history of trauma or stress, yet not having a psychological illness, was associated with a larger effect for some of the main outcome categories (i.e. having a physical illness was associated with larger effects for reported but not psychological health).

Existing reviews thus report a mixed picture; three report positive overall effects, one reports a positive effect on HCU for the healthy population only, and two report no overall effect or an inability to draw conclusions. They all suggest that WED may be differentially effective for unique outcomes and populations. The heterogeneous conclusions are likely explained by differences in review conduct. Each imposed slightly different selection criteria and thus reviewed slightly different studies; some are more focussed in terms of populations, intervention implementation, comparisons and outcomes, and they vary in the potential for bias in review processes. The approach to data synthesis and exploration of heterogeneity has also been variable, as has the handling of poor reporting of outcome data. The characteristics of each review, and the observed effects, are reported in the appendix. Importantly, each has been limited in some way that reduces their informative potential for determining the effects of WED for unique psychological

health outcomes, for example negative affect including depression, in distinct LTPCs.

Variability in selection criteria

Existing reviews have explored effects for a variable range of clinical and healthy samples, and again while Smyth (1998) reviewed only healthy samples this cannot be generalised to clinical populations. Most included only the original WED paradigm, however some included other variants of WED; written or verbal ED and any variant of written[18] (Meads et al, 2003), or any variation of ED for example writing or talking, and writing about an imagined rather than genuine stressful event and a positive rather than negative event (Frattaroli, 2006). Moreover, while Mogk et al (2006) reviewed only the original paradigm, where more than one disclosure group was reported effects were combined and thus cannot be attributed specifically to WED. Harris (2006) reviewed one relatively homogeneous outcome, HCU, yet the other reviews examined a variable range of health outcomes. The averaged effect sizes are thus usually confounded by notable clinical and methodological heterogeneity, which may be accompanied by heterogeneity in effects, with variable examination of this source of effect heterogeneity (discussed below).

That differences in review conduct may have influenced the findings and conclusions drawn is demonstrated in that Mogk et al (2006) acknowledge that owing to different selection criteria they reviewed only one of the studies considered by Frisina et al (2004), which prohibits comparison. Indeed, different conclusions were derived in these reviews. Moreover, Smyth (1998) and Mogk et al (2006) included only trials with a neutral writing control group, whilst the others included any neutral comparison. Mogk et al (2006) concluded, in contrast to the other

[18] However, it should be noted that in this review only two included studies described a verbal or combined written and verbal disclosure and there was only limited evidence or writing about positive rather than negative issues.

reviews, that WED is not effective. However, it cannot be assured that controls did not emotionally disclose in the included studies, which would underestimate effects. Finally, most of the reviews included outcomes measured at least one month post-intervention, whereas Meads et al (2003) and Frattaroli (2006) included outcomes measured at least one week and one day post-intervention respectively. Frattaroli (2006) reported larger effects for studies with follow ups less than one month compared to longer. The other reviews may have provided a restricted representation of the effectiveness of WED, which may explain the heterogeneity in conclusions.

Variation in the potential for bias in review processes

Searching

Smyth (1998) and Frisina et al (2004) employed narrow searches, in which key databases and search terms were omitted, search terms were limited and there was an inadequate attempt to identify unpublished literature (Meads & Sheffield, 2005). Indeed, attempts to replicate these searches identified some potentially relevant yet omitted studies available at that time, one of which reported a negative effect of WED (Meads et al, 2003). Interestingly, though, the number of excluded studies reporting null effects required to reduce the observed effects to non-significance in these reviews (i.e. fail safe N) was relatively large. Nonetheless, this may explain the more modest effects derived in reviews that achieved more comprehensive searches; unpublished studies are less likely to report positive and significant effects thus reducing the impact of publication bias (Frattaroli, 2006; Harris, 2006; Meads et al, 2003). It is also notable, however, that despite more adequate search strategies, in Meads et al's (2003) and Frattaroli's (2006) reviews a substantial number of potentially relevant studies, predominantly theses, were excluded as full

details could not be obtained (i.e. 15 and 20 studies respectively). A review including these studies is required.

Risk of bias assessment

Some of the existing reviews have not drawn inferences about the effectiveness of WED in light of the risk of bias associated with the evidence (Frisina et al, 2004; Mogk et al, 2006; Smyth, 1998). In fact, both Mogk et al (2006) and Meads et al (2003) concluded there was no evidence to suggest WED is effective, yet Meads et al (2003) identified that this may be due the vast limitations of the evidence base at that time; a very different and arguably more accurate conclusion.

Duplication in review processes

Existing reviews have reported variable but generally insufficient duplication in review processes, namely inclusion decisions, data interpretation/extraction and risk of bias assessment. Duplication is reported for data extraction only. This has varied from all (Smyth, 1998) to only a subset (Frattaroli, 2006; Meads et al, 2003; Mogk et al, 2006) of included studies, and has occasionally been limited to certain variables (Frattaroli, 2006; Meads et al, 2003) and even undertaken by the same reviewer at a later date rather than independent reviewers (Meads et al, 2003). Review processes may therefore have been influenced by reviewer's sub-conscious expectations about whether WED is effective.

Variability in the approach to data synthesis and exploration of heterogeneity

Again, a number of the reviews combined conceptually distinct (i.e. clinically heterogeneous) outcomes and populations in averaged effect sizes, for which WED may be differentially effective, with variable exploration of this as a source of effect

heterogeneity (Frattaroli, 2006; Frisina et al, 2004; Mogk et al, 2006; Smyth, 1998). The approach to synthesis in each review and the degree to which effect sizes were reported for unique outcomes and populations is highlighted where the observed effects are reported in the appendix.

Indeed, as described earlier where sources of effect heterogeneity were explored, WED was apparently differentially effective for the main outcome and population categories reviewed. It follows that for the distinct outcomes and populations within these main categories WEDs effects may additionally be heterogeneous. Indeed, Frattaroli (2006), and Mogk et al (2006) to some degree, examined effects for such outcome subcategories and supported this (as described earlier). Frisina et al (2004) discussed effects within distinct outcome sub-categories, for example depressive symptoms, and identified a trend for positive effects in some but not other sub-categories (as also described earlier). Effects for the population sub-groups may also be statistically heterogeneous (Meads & Sheffield, 2005), and may reflect condition-specific differences, yet this has not been examined.

Frattaroli (2006) went a step further than the aforementioned reviews in examining the moderating effect of the three main population categories on the overall effects and some of the main outcome categories. However, no reviews examined the effect of WED for each distinct outcome sub-category (i.e. distinct psychological health outcomes) for each distinct population sub-category (i.e. different LTPCs). Consequently, they are of limited informative potential and clinical utility; they do not represent WEDs effect in any specific context. The purpose of systematic reviews of effectiveness is to inform HCPs who make decisions about health care policy and influence practice, about whether an intervention effects the specific outcomes of interest in certain populations of interest/concern, for example negative affect

including depression in cancer. It is therefore crucial to delineate exactly which outcomes in which populations WED is effective for.

With this in mind, two of the reviews did not inappropriately combine heterogeneous outcomes and populations. Harris (2006) reviewed one relatively homogeneous outcome and reported effects separately for populations reviewed, albeit these populations still contained some distinct subcategories. However, HCU cannot be presumed to be synonymous with health, thus this reviews is also of limited clinical utility. Meads et al (2003) included a range of heterogeneous outcomes and populations, yet presented effects separately for each distinct outcome and there was discussion for distinct populations within these albeit this was variable; synthesis was predominantly narrative with meta-analysis performed only where more than two RCTs reported the same outcome and had relatively homogeneous populations. However, this review was differently limited in that in the absence of sufficient data for meta-analysis effects were considered in terms of their significance (i.e. vote counting). As such, the magnitude and direction (i.e. effect size), and precision (i.e. confidence intervals) of effects could not be considered (Meads et al, 2003). Trials were identified as likely underpowered, thus consideration of small but potentially clinically important effects regardless of significance was important.

In fact, the other reviews additionally demonstrated a tendency to interpret average effects in terms of significance. Whilst meta-analysis facilitates larger sample sizes and thus greater statistical power, given the small number of studies often available there is still a risk that some effects of a potentially important magnitude were omitted owing to insufficient power. Indeed, Mogk et al (2006) identified no significant effect of WED on clinical samples, yet this included a very small number of studies (n=4) to detect a very small but potentially meaningful effect (i.e. g=.08).

Inadequate exploration of heterogeneity relating to intervention implementation posed a further and substantial limitation in Frattaroli's (2006) review. Again, any variant of ED was reviewed, which served to enhance the applied relevance of the review, statistical power and the precision of effects. However, this was at the cost of substantial interpretative problems. Implementation was examined as a moderator of effects, namely verbal versus written disclosure and whether the disclosure topic was positive or negative. However, these comparisons apparently still included heterogeneous interventions within each sub-group, for example writing about genuine and imagined negative events and then positive events or positive aspects of negative events were apparently considered together. Moreover, in such analyses there is a loss of randomisation thus a third variable may explain the observed effect, and the small number of studies within each sub-group compared introduces a loss of statistical power and thus a risk of Type 2 errors. Consequently, these analyses should be considered exploratory and require further support. In sum, the effect of each unique variant of WED, including the original paradigm, cannot be inferred in this review. In systematic reviews of effectiveness it is crucial that specific interventions are reviewed so that HCPs can determine exactly what was effective and how it should be implemented.

One final note about investigation of heterogeneity is that it is important for systematic reviews to explore a range of sources of effect heterogeneity, even in the absence of significant effect heterogeneity, to determine the extent to which the averaged effects and patterns of results may have been influenced by this. This is especially important for WED studies as again they have typically been heterogeneous on study-specific artefacts, and this is likely related to heterogeneity in effects; some studies have seemingly implemented WED under more optimal conditions than others. Indeed, this may explain the less modest effects observed in

reviews that contained slightly less heterogeneous studies (Smyth, 1998). Some of the existing reviews examined additional moderators of WEDs effects for example gender (Frattaroli, 2006; Harris, 2006; Smyth, 1998), whilst others did not (Frisina et al, 2004; Meads et al 2003), in one instance owing to a non-significant intervention effect and test of heterogeneity (Mogk et al, 2006). However, this may be explained by an absence of sufficient statistical power in analyses. Meads et al (2003) noted substantial heterogeneity to be present, which may explain the very mixed pattern of results that was observed.

Variation in the handling of poor reporting of outcome data

The existing reviews have also varied in their approach to poor reporting of outcome data within studies, namely outcomes that are described as measured in the methods section but for which no data is reported or data is reported yet not that required for meta-analysis. Such reporting prohibits inference about the true trend of results. As it is unlikely that unreported outcomes were positive and significant, where this is not accounted for review conclusions are potentially influenced by reporting bias such that WEDs effects may have been overestimated. An effort to obtain missing data was reported in some reviews (Frattaroli, 2006; Harris, 2006; Mogk et al, 2006) or this was attempted for studies identified early on (Meads et al, 2003). Otherwise, no attempts were apparent. Only Meads et al (2003) then adequately reported on all outcomes whether they were reported or not, counting them as unreported where no results were reported at all or again vote counting where adequate summary data were not provided. Their conclusions were therefore less likely to be influenced by reporting bias, which may explain the mixed pattern of results and the reduced confidence in WEDs effectiveness compared to most of the other reviews.

Study-level limitations

Existing reviews have also served to identify study-level limitations (Frattaroli, 2006; Meads et al, 2003), which cast further doubt over their conclusions and must be addressed in future endeavours. Studies have generally been pilot RCTs employing small samples (n<50); effects may be imprecise and again analyses underpowered to identify potentially clinically important effects as significant. Risk of bias assessment indicated that a range of biases may have additionally influenced trial results. In Meads et al's (2003) review the average Jadad Scale score was 0 (i.e. scores range from 0 to five); typically the method of randomisation was not described, allocation concealment and blinding were rarely mentioned, attrition and the proportion of participants receiving the intervention as intended was unreported, attrition was significant (>20%) and or imbalanced across groups where this was reported, and an intention to treat (ITT) analysis was infrequent; the participants available at follow up rather than those randomised were analysed. Consequently, effects may have been overestimated (discussed further in chapter three). However, Frisina et al (2004) acknowledged that studies that were adequately controlled and thus associated with a lesser risk of bias reported more positive and significant effects, suggesting WED may be effective for clinical samples. Again, poor reporting of outcome data and heterogeneity amongst studies also presented a substantial problem.

Conclusions

In sum, WED is an acceptable, theoretically appropriate and pragmatically advantageous low-intensity psychological intervention that is consistent with current policy for improving depression in LTPCs. WED has may be considered to have a sound theoretical grounding for improving health in that it is seemingly underpinned by empirically supported influencing mechanisms, which are similar to those

underpinning other effective psychotherapies. There is evidence that suggests WED may improve negative affect including depression in LTPCs, yet the plethora of RCTs and systematic reviews in the area are associated with various limitations such that there is still uncertainty about this. The existing WED systematic reviews are additionally now outdated given that the latest searches were undertaken in 2004 (Frattaroli, 2006; Harris, 2006; Mogk et al, 2006). An updated systematic review addressing the inadequacies of and updating previous endeavours was therefore required. It was anticipated that consistent with the recommendations of previous reviews more large scale, carefully conducted and better reported RCTs testing WED with clinical samples including LTPCs had since been conducted and completed. Indeed, Harris (2006) noted that since Smyth's (1998) review 74 additional WED trials had been undertaken.

The evidence base does, however, suggest some possible critical processes in WED. WED may operate by facilitating E&CP and EA&H and promoting emotion-regulation capabilities, perceived control over LTPCs and seeking of and thus satisfaction with emotional support. Consequently, WEDs effects may be optimised by targeting these mechanisms of change and mediating processes. Furthermore, targeting WED to individuals with lower alexithymia and higher optimism, or manipulating these traits before applying WED, may optimise improvement in outcomes. However, this evidence base is under-developed, inconsistent, ambiguous and yet to be adequately tested.

Chapter 3 Systematic review of WED for psychological health in adults with LTPCs

Chapter overview

This chapter presents a systematic review of WED for psychological health, and QoL, in adults with LTPCs. Psychological health outcomes and QoL were considered, rather than negative affect including depression alone, to provide a somewhat more comprehensive consideration of WEDs effects. Moreover, as described in chapter one, QoL is adversely impacted by depression in LTPCs, and it is asserted that by resolving depression, even at lower-levels, WED may improve the outcomes adversely impacted by this. Again, concurrent improvements in these outcomes have been demonstrated in trials of low- and high-intensity depression treatment, yet the evidence is inconsistent and it is unclear whether these changes are related to improvement in depression. It is therefore of interest to identify whether WED may additionally influence QoL.[19] Importantly, the review extends previous endeavours by adopting a more focussed question with respect to the participants, intervention and outcomes (i.e. minimising clinical and methodological heterogeneity), exercising more duplication in review processes and employing a more appropriate approach to data synthesis, which acknowledges deficiencies in statistical power and includes an adequate exploration of clinical (i.e. outcomes and population) and the influence of methodological (i.e. trial methodology) sources of effect heterogeneity. This approach was intended to highlight exactly which psychological health and QoL outcomes, and specific LTPCs within these, that WED is likely effective for thus informing future research endeavours.

[19] Investigation of WEDs effect upon secondary outcomes, namely physical health outcomes, SMBs and HCU, was also considered initially given that these outcomes are adversely impacted by depression in LTPCs and potentially improved with depression treatment. However, SMBs were infrequently measured and the identified trials otherwise presented a range of heterogeneous outcomes that could not be meaningfully combined and interpreted. These outcomes were therefore not included.

Review objectives

The aim of the present review was therefore to synthesise relevant evidence of the effects of WED for improving psychological health and QoL among people with LTPCs, focussing on a) effectiveness and b) effect heterogeneity by outcome and condition.

Method

The review adhered to the NHS Centre for Reviews and Dissemination (CRD) guidelines on undertaking systematic reviews of research on effectiveness (NHS CRD, 2009) and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISM) statement (Moher, Liberati, Tetzlaff, Altman & The PRISM Group, 2009).

Review evidence

Inclusion criteria

Published or unpublished primary studies were eligible for inclusion if they were RCTs that included adults (i.e. ≥18 years) with a LTPC and evaluated the effects of WED on psychological health and or QoL measured at least one week post intervention. A trial was accepted as a RCT if the allocation of participants to treatment and comparison groups was reported as randomised. Only RCTs were included, consistent with the previous WED systematic reviews, as the initial scope of the WED literature suggested that most trials employed this design, to reduce heterogeneity in study design and risk of bias between included trials, and because this is considered to provide the most robust investigation of effectiveness to inform evidence-based practice (discussed further in chapter four).

One week was appropriate as WED effects can be seen as early as two weeks after completing writing (Frattaroli, 2006; Hamilton-West & Bridle, in preparation; Pennebaker, 2000), even in LTPC samples albeit this refers to objective physiological outcomes (Smyth et al, 1999). Consistent with the National Centre for Disease Control and Prevention (CDC) (2008), LTPCs were defined as conditions that are prolonged, do not resolve spontaneously and are rarely cured completely.

Studies were accepted as evaluating WED if they required participants to disclose in writing a genuine, as opposed to imagined, stressful event during at least three 15 minute sessions, consistent with the original WED paradigm and subsequent evidence base. Any control comparison was included. WED was to be delivered alone and not in combination with any other intervention, unless both groups received exactly the same treatment other than WED.

Search strategy

The search was initially conducted in December 2007 and then updated in May 2009. Research databases were searched, without language restrictions and from 1986 where possible corresponding with the date of the first WED trial (Pennebaker & Beall, 1986). This included the following: PsychINFO and PsychARTICLES (1986-2009) (OVID, updated in CSA), CINAHL (1986-2009) (OVID, updated in EBSCO Host), Medline and Embase (1986-2009) (OVID), Cochrane Central Register of Controlled Trials (1986-2009) (2007, Issue 2, updated in 2009, Issue 3), Science Citation Index, Social Science Citation Index and ISI Proceedings (updated in Conference Papers Citation Index) (1986-2009) (Web of Science), Sociological Abstracts (earliest-2009) (CSA), Conference Papers Index (1986-2009) (CSA), FRANCIS and ERIC (1986-2009) (OCLC), and Proceedings First and Papers First (earliest-2009) (OCLC). Ongoing research databases were also searched to identify trials yet to be completed; UK National Research Register (updated with the

National Institute for Health Research (NIHR) portal from December 2007-May 2009), Medical Research Council (MRC) research register, *meta*Register of Controlled Trials (including the International Standardized Randomised Controlled Trial Number (ISRCTN) register), Health Services Research Projects in Progress and Computer Retrieval of Information on Scientific Projects database.[20] [21]

In consultation with library information specialists, search strategies were adapted to each database, and based on intervention index terms informed by the previous WED systematic reviews and wider evidence base; written emotional disclosure, written emotional expression, emotional disclosure, emotional expression, written disclosure, written expression, disclose/disclosure/disclosing, self disclosing/disclosure, expressive writing, therapeutic writing, affective writing, emotive writing, writing therapy, emotional disclosure/expression and/in writing, disclosure/expression and/in writing, expression, Pennebaker, creative writing, catharsis, journal, stressful/critical life events and writing, written communication, rehearsal, writing, and emotion/emotions.

The internet was additionally utilised to search via search engine Google,[22] The British Library's Document Supply Grey Literature Collection of theses, proceedings and reports and Professor J.W. Pennebaker's website, conduct a significant author citation search (performed via Science Citation Index and Social Science Citation

[20] Databases that were intended to be searched but for which access could not be obtained included Sociofile, Chronic Disease Prevention, Combined Health Information Database, and System for Information on Grey Literature in Europe.

[21] The following reference databases were originally searched for dissertations and theses: UMI ProQuest Digital Dissertations, Index to Theses, WorldCat Dissertations and the Networked Digital Library of Theses and Dissertations (Scirus ETD search). Eight hundred and seventy-six additional references were retrieved (plus an additional three retrieved via search alerts for these databases after completion of searching), of which 35 full copies were sought for detailed examination yet 18 (51%) were not obtainable. Therefore all were excluded and are not reported. The 18 unobtainable dissertations and the obtainable and eligible yet excluded dissertations are presented in the appendix.

[22] The first 100 references of searches for key terms were screened.

Index databases)[23] and contact key researchers.[24] The full search strategies are provided in the appendix.

Current and recent editions of relevant journals were additionally searched retrospectively from the 12 months prior to the original search: Psychosomatic Medicine (January 2007-May 2009), Journal of Psychosomatic Research (December 2006-May 2009), Health Psychology (January 2007-May 2009), Psychology and Health (Issue 1 2007-Issue 5 2009), British Journal of Health Psychology (February 2007-May 2009), Journal of Health Psychology (January 2007-May 2009), Journal of Consulting and Clinical Psychology (December 2006-June 2009), Journal of Health Communication (Issue 1 2007-Issue 4 2009), Behavior Therapy (March 2007-June 2009), Behaviour, Research and Therapy (January 2007-May 2009), and Journal of the American Medical Association (January 2007-may 2009).

As available, current and recent editions of relevant conference proceedings were additionally searched retrospectively from the 24 months prior to the original search: The British Psychological Society (2006, 2007, 2008 & 2009 Annual Conferences), Division of Health Psychology (2006, 2007 & 2008 Annual Conferences), The American Psychosomatic Society (2006 and 2007 Annual Conferences), The International Congress of Behavioural Medicine (2004 and 2006 Biannual Conferences), and The Association for Psychological Science[25] (2006, 2007 & 2008 Annual Conventions).

[23] Performed for Professor J.W. Pennebaker, Professor M.A. Lumley, Dr J.M. Smyth and Dr S.J. Lepore.
[24] Contacted Professor J.W. Pennebaker, Professor M.A. Lumley, Dr J.M. Smyth, Dr A.H. Harris and Dr J. Frattaroli with the list of included studies.
[25] For The Association for Psychological Science conference proceedings key index terms were used to search the vast poster collection.

Finally, bibliographies of previous systematic reviews as well as primary studies selected for inclusion were then scanned for potentially relevant references.

Journal and database search email alerts were established wherever possible following the updated search and any relevant papers identified were also included up until October 2010.

Data collection and assessment

Study selection

Search results were recorded to bibliographic software where possible. One reviewer (KD) screened the search results (i.e. titles and, where available, abstracts) against the inclusion criteria, excluding those that were clearly not relevant and ordering full-text copies of the remainder. A sub-set of titles and abstracts for which no clear decision could be made (N=254, 3%) and all full-text copies were screened against the inclusion criteria by two reviewers independently (KD and CB[26]), achieving a good level of inter-rater agreement (*Kappa*=.82). Differences were resolved by discussion and consensus. The screening decision checks are presented in the appendix. Foreign papers were translated. Where a trial was reported in more than one record only one was included, preferably peer reviewed publications. Authors were contacted once to obtain studies where these were otherwise unobtainable.

Data extraction and risk of bias assessment

Data extraction and risk of bias assessment templates were developed and piloted on a small number of papers by each reviewer to ensure sufficiency and accuracy of data capture. Overall, data extraction and risk of bias assessment was duplicated or at least checked for accuracy by a second reviewer (CB or JS). Again differences

[26] PhD supervisor Dr Christopher Bridle.

were resolved by discussion and consensus. Predefined data fields included details of the study design (i.e. sample size and final follow up), participants (e.g. demographics and LTPC), intervention and comparison exposure, process (i.e. intervention fidelity and compliance), outcomes (i.e. self-report measures) and results (i.e. final endpoint data).

Study-level assessment of risk of bias was undertaken, and then heterogeneity in the risk of bias at the outcome-level was considered. Trials were assessed on criteria derived from the Cochrane risk of bias tool (i.e. randomisation, concealment of allocation, blinding of participants and outcome assessment, and completeness of outcome data; whether there was less than 20% overall attrition) (Cochrane, 2009). The Cochrane risk of bias tool was selected as in contrast to many other tools, this assesses only the dimensions of trial methodology that have been empirically proven to be related to intervention effects/bias (Jüni, Altman & Egger, 2001; Schultz, Chalmers, Hayes & Altman, 1995).

Criteria were assessed in terms of whether these were met (Y), were not met (N) or it was unclear whether they were met (?). This provided an overall indication of the risk of bias at the study-level as low if all criteria were scored as Y (i.e. unlikely to seriously alter results), uncertain if one or more criteria were scored as ? (i.e. raising some doubts about results), or high if one or more criteria were scored as N (i.e. seriously weakening confidence in results).

Data analysis

Outcome specification

Outcome data were pooled statistically into the following categories: positive affect (i.e. positive emotions such as happiness), negative affect (i.e. low mood, anxiety

and depression), stress and general emotional distress and QoL. The independence rather than bipolarity of positive and negative well-being has been supported empirically; these constructs are differently related to demographic, health and social variables and there is evidence of individuals scoring as high, or low, on both at the same time (Huppert & Whittington, 2003).

Where studies reported more than one relevant outcome for each category, for example depression and anxiety, which represent different features of a tendency to experience negative affect, these were combined since treating them independently would give the study too much weight in a meta-analysis (Slavin, 1995). Individual effects were thus calculated for each measure and then combined within study.

Effect measures

As outcomes were reported as continuous data, standardized difference in means (SMDs) and 95% confidence intervals (95% CIs)[27] were calculated (Revman 5.0), for which effect sizes of .2, .5 and .8 are conventionally interpreted as small, medium and large, respectively (Cohen, 1988; 1992). Cohen's conventions for interpreting effect sizes are grounded in logic, reflect observable effects and are important for comparing effect sizes across studies. However, their use is controversial, and it is crucial to further interpret effect sizes in terms of clinical importance (Ellis, 2010). As discussed later on, it is difficult to interpret the clinical significance of effects based on SMDs, yet even small SMDs of .15 can have a substantial impact on outcomes at the population level. Consequently, to avoid omission of potentially clinically important effects, effect sizes greater than .15 were considered potentially meaningful, regardless of statistical significance as recommended (Altman, 2005). Weighted mean differences could not be estimated

[27] Confidence intervals (i.e. 95%) reflect the imprecision and thus range of possible values of the estimate when a 5% risk that these intervals do not contain the population effect is accepted; if the intervals were estimated many times 95% would contain the true parameter and 5% would not.

as identical measures were not employed within each outcome category (Cochrane, 2009).

Effects were based on final endpoint values, unadjusted or adjusted as available, with one exception where group means and associated standard deviations (SDs) had been averaged across five follow ups (de Moor, Sterner, Hall, Warneke, Gilani, Amato & Cohen, 2002). The authors of this trial were unable to provide final endpoint data owing to the time that had elapsed since the data were analysed. However, they did provide assurance that the absolute differences between groups did not vary over time. Change scores were not included because they are influenced when outcomes are unstable or difficult to measure precisely, as is the case with patient reported outcomes such as psychological health and QoL (Cochrane, 2009). Moreover, change scores cannot be combined with final end-point data as SMDs because the SDs reflect differences in reliability for the different types of data rather than differences in the measurement scale used (Cochrane, 2009). Unreported SDs were derived by converting reported standard errors (SEs)[28] (Cochrane, 2009).

For ease of interpretation, effects were computed so that a positive value represented a superior effect in the WED group and a negative value a superior effect in the control comparison (i.e. the direction of scoring of the outcome measures was accounted for).

[28] SD= $SE\sqrt{n}$ (where n is the number of participants in that group).

Heterogeneity assessment

Effect heterogeneity for each outcome category was assessed by visual inspection of forest plots and statistical test (Revman 5.0). The I^2 index represents the percentage of variability amongst effect estimates above that expected by chance. Percentages of 25%, 50% and 75% indicate low, medium and high heterogeneity respectively (Higgins, Thompson, Deeks & Altman, 2003).

Data synthesis and sub-group analyses

Effects were combined in random effects meta-analyses, which presumes different but related effects are being estimated and accounts for these differences even in the absence of statistically significant heterogeneity (Cochrane, 2009). This was appropriate in view of the anticipated heterogeneity between trials. This was supplemented with pre-planned narrative sub-group analyses based on sub-groups of study stratified by condition type. Pre-planned sub-group analyses based on sub-groups of study stratified by the type of QoL outcome measured were additionally performed given the heterogeneity between measures of health-related QoL (i.e. the general experience of QoL in relation to health status) and disease-specific QoL (i.e. the general experience of QoL in relation to disease-specific health status). Insufficient data prohibited statistical sub-group comparisons.

Sensitivity analysis

The robustness of results to variations in trial methodology: a) comparison type (neutral writing versus no writing) and b) length of follow-up (<3 versus ≥3 months) was investigated narratively.

Risk of publication bias was assessed by visual inspection of funnel symmetry in the plots of each trial's SMD against its SE (i.e. funnel plots).

Results

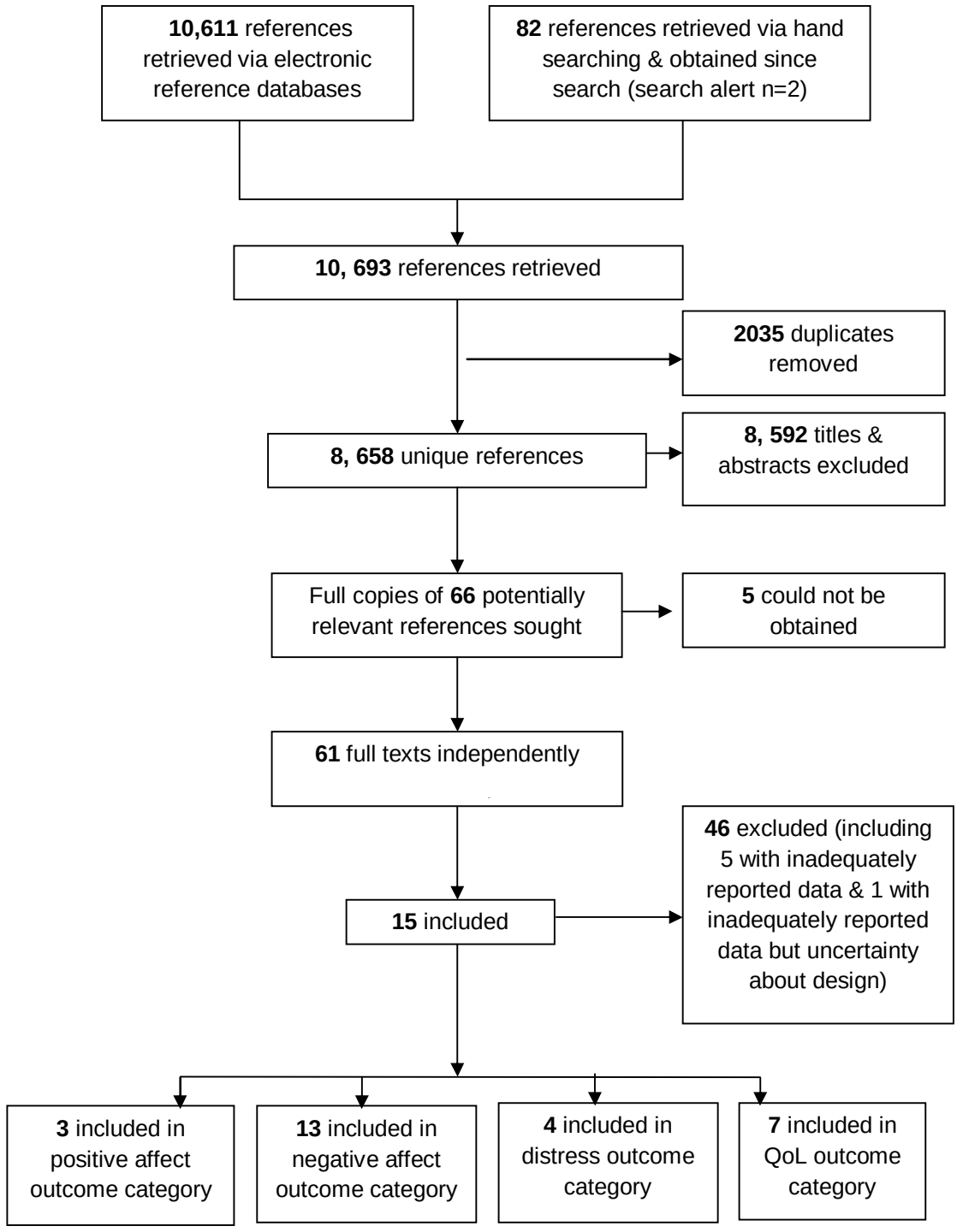
Available data

10, 693 references were retrieved, 2035 duplicates were removed and 8, 658 unique titles/abstracts were screened for potential relevance, of which 8, 592 were excluded. Full texts were sought for 66 references, five of which were conference abstracts for which further information could not be obtained from authors (listed in the appendix).

Full text of 61 papers were thus obtained and independently screened. Fifteen trials met the inclusion criteria: 12 from the electronic database search, two from hand searching conference proceedings/author contact and one retrieved in journal/search alerts after completion of searching. Study flow is illustrated in Figure 1. The included trials contained a total of 27 outcomes for psychological health or QoL, with a mean of two per study (range of one to three). There was no evidence of publication bias as endorsed by symmetrical funnel plots at the outcome-level (presented in the appendix) and numerous small, non-significant studies.

Five additional trials met the inclusion criteria describing relevant outcomes as measured in the methods section, yet did not report data sufficient for statistical synthesis (Broderick, Junghaenel & Schwartz, 2005; Broderick et al, 2004; Rivkin et al, 2006; Stanton et al, 2002; Wagner et al, 2008). For a further trial data were insufficient but it additionally could not be clarified whether the final follow up was measured at least one week post-intervention (Cepeda, Chapman, Miranda, Sanchez, Rodriguez, Restrepo, Ferrer, Linares & Carr, 2008). Moreover, one of the included trials did not provide sufficient data for some additional relevant outcomes that were measured (Rosenberg, Rosenberg, Ernstoff, Wolford, Amdur, Elshamy, Bauer-Wu, Ahles & Pennebaker, 2002).

Figure 1 Study flow diagram



Omissions ranged from not reporting data at all and stating instead that there was no significant effect, to reporting some data but not group final endpoint data for composite measures or the main sub-scales (i.e. change scores, differences between means, regression co-efficients and final endpoint data but for numerous individual sub-scales e.g. the eight Short Form-36 (SF-36) sub-scales). Primary authors were contacted once for unreported data.

Three included trials did not report adequate data in the published paper but provided this for all (Danoff-Burg et al, 2006; Hamilton-West & Quine, 2007), or again some (Rosenberg et al, 2002), of the unreported relevant outcomes on request.

Description of studies

Descriptive details of the included trials are provided in Table 3. Thirteen trials were published between 1999 and 2010, one was in preparation and one was under review. The data extracted for the individual studies are presented in the appendix. The total number of participants that were randomised to the intervention groups included in the present review was 1174; range 30 to 179 with a mean of 78. The length of the final follow up ranged from eight weeks to seven months; twelve trials assessed outcomes at 12 or more weeks.

Table 3 Trial details[29] [30]

Trials	de Moor et al (2002)	Gellaitry et al (2010)	Low et al (2010)	Rosenberg et al (2002)	*Walker et al (1999)	Zakowski et al (2004)	Gillis et al (2006)	Norman et al (2004)	*Cohen et al (in prep)	*Danoff – Burg et al (2006)	Hamilton-West & Quine (2007)	Wetherell et al (2005)	Vedhara et al (2007)	Taylor et al (2003)	Willmott et al (under review)
Participants															
Condition	Cancer	Cancer	Cancer	Cancer	Cancer	Cancer	Pain	Pain	Arthritis	Arthritis & Lupus	Ankylosing Spondylitis	Arthritis	Psoriasis	Cystic fibrosis	Post 1st MI
Mean age (years)	56	58	54	70	54	60	50	38	54	51	52	61	50	69% ≥19	62
Gender (% female)	14	100	100	0	100	52	97	100	87	83	32	83	37	?	16
Time since diagnosis (years)	?	100% ≤12 months	7.9	?	?	1.4	5.9	12.7	12	15	16	14.7	22	?	?
Country	USA	UK	USA	USA	USA	USA	USA	USA	USA	USA	UK	USA	UK	USA	UK
N	42	93	76	30	35	127	83	60	113	48	107	42	69	70	179

[29] NW=neutral writing, UC=usual care control, TM=writing about time management, LTPC-F=writing about LTPC facts, HB=writing about health behaviours, PT/F=writing about thoughts and feelings about positive life events. CD=consecutive days. ?=unreported.

[30] *Three studies included more than the two intervention groups included in the present review thus sample sizes are presented for only the included groups. Where studies presented data by group, demographic data are presented for the full sample (i.e. the average was taken).

Trials	de Moor et al (2002)	Gellaitry et al (2010)	Low et al (2010)	Rosenberg et al (2002)	*Walker et al (1999)	Zakowski et al (2004)	Gillis et al (2006)	Norman et al (2004)	*Cohen et al (in prep)	*Danoff – Burg et al (2006)	Hamilton-West & Quine (2007)	Wetherell et al (2005)	Vedhara et al (2007)	Taylor et al (2003)	Willmott et al (under review)
Intervention															
Session: *No.*	3	4	4	4	3	3	4	3	4	4	3	4	3	3	3
Length (minutes)	?	20	20	20-30	30	20	15-20	20	20	20	20	20	20	20	10-20
Spacing	4 weeks	CD	3 weeks	?	5 days	CD or 1week	CD	CD	?	3 Weeks	CD	CD	CD	5 days	CD
Writing topic	LTPC	LTPC	LTPC	LTPC	LTPC	LTPC	Any	LTPC	?	LTPC	Any	Any	Any	Any	LTPC
Comparison	NW /HB	UC	NW/ LTPC-F	UC	UC	NW/ TM	NW/ TM	NW/ PT/F	NW/ TM	NW/ LTPC-F	NW/ TM	NW/ TM	NW/ TM	UC	NW/ TM
Outcomes															
+ve affect					✓			✓	✓						
-ve affect	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	
Distress	✓					✓			✓					✓	
QoL		✓		✓			✓				✓		✓	✓	✓
Final follow up (weeks)	10	24	12	24	28	24	12	8	24	12	12	10	12	12	20

Participants

Six trials evaluated WEDs effects in cancer patients (breast, prostate, gynaecological and renal cell cancer), four trials in patients with rheumatic conditions (i.e. ankylosing spondylitis, lupus and or rheumatoid arthritis), two trials in chronic pain patients (pelvic pain and fibromyalgia), and WEDs effects in psoriasis patients, cystic fibrosis patients and patients recovering from their first MI were investigated in one trial in each instance. Samples had mean ages ranging from 38 to 62 years, were predominantly female ranging from 14% to an entirely female sample, and the mean duration of patients' illness ranged from less than one year to 22 years. Trials were either conducted in the USA (10) or the UK (5).

It is noteworthy that one trial included some participants that were younger than 18 years of age (i.e. 15-18) (Taylor, Wallander, Anderson, Beasley & Brown, 2003). However, this trial was included because the proportion of participants that fell in to this category was small and unlikely to substantially influence the findings.

Intervention

In the majority of trials participants wrote for 20 minutes per session (10), over three (8) or four (7) writing sessions. The spacing of writing sessions across studies was consecutive days (7), within five days/one week (2), either of the latter (1), within three or four weeks (3), or this was not reported (2). Trials directed participants to write about any stressful event (5), their condition (9) or this was unreported (1).

It should be noted that in three trials either a small number of participants verbally disclosed (Cohen et al, in preparation; Wetherell, Byrne-Davis, Dieppe, Donovan, Brookes, Byron, Vedhara, Horne, Weinman & Miles, 2005), or the intervention included writing about thoughts and any emotions (i.e. negative or positive) (Willmott et al, under review) or more guided writing instructions than in the original

WED paradigm, namely emotional disclosure with cognitive appraisal, benefit-finding and looking to the future encouraged across writing sessions (Gellaitry et al, 2010). However, these trials were included because the proportion of participants that verbally disclosed was small and although adapted slightly the basic WED paradigm was dominant. These deviations were thus unlikely to substantially influence the findings.

Comparison exposure

Where more than one control comparison was investigated in a study, placebo writing tasks were given preference to non-writing controls. Where more than one writing control comparison was reported, the most emotionally neutral was included (i.e. writing about the facts relating to a LTPC rather than positive thoughts and feelings about a LTPC). Control comparisons included usual care (4) or placebo writing (11), for example writing about time management (7), facts about the LTPC (i.e. non-emotional) (2) and health behaviours (1). It is notable that in one additional trial only one comparison was available in which control participants wrote about thoughts and feelings about positive life events. This was justified by the authors as a superior placebo writing task in that it controls for writing about an emotionally engaging topic, has face validity and will not create a negative response.

Outcomes and outcome measures

Three trials measured positive affect with the Positive and Negative Affect Schedule (PANAS) positive affect sub-scale (Cohen et al, in preparation; Norman et al, 2004) and Positive and Negative Affect Schedule (expanded version) (PANAS-X) positive affect sub-scale (Walker et al, 1999). One further trial measured positive affect but with only one sub-scale from a measure comprised of many sub-scales and generally representative of different outcome category (i.e. only the Vigor sub-scale

of the Profile of Mood States (POMS), principally a measure of mood disturbance) (Danoff-Burg et al, 2006). This outcome was thus excluded.

Thirteen trials measured negative affect with the PANAS negative affect sub-scale (Cohen et al, in preparation; Walker et al, 1999), PANAS-X negative affect sub-scale (Gillis et al, 2006; Norman et al, 2004), Centre for Epidemiological Studies Depression (CES-D) scale (Danoff-Burg et al, 2006; Low et al, 2010), HADS (Hamilton-West & Quine, 2007; Vedhara, Morris, Booth, Horgan, Lawrence & Birchall, 2007), Profile of Moods States (POMS) (de Moor, Sterner, Hall, Warneke, Gilani, Amato & Cohen, 2002; Gellaitry et al, 2010; Vedhara et al, 2007), Short Form of the Profile of Mood States (POMS-SF) (Wetherell et al, 2005; Rosenberg et al, 2002), and PHQ (i.e. anxiety and depression sub-scales) (Taylor et al, 2003).

Four trials measured distress with the Perceived Stress Scale (PSS) (Cohen et al, in preparation; de Moor et al, 2002), Brief Symptom Inventory (BSI) general severity index (Zakowski et al, 2004) and PHQ stressful life events sub-scale (Taylor et al, 2003). Four trials additionally reported outcomes measured with the Impact of Events Scale (IES) (deMoor, Sterner, Hall, Gilani, Amato, Warneke & Cohen, 2002; Low et al, 2010; Walker et al, 1999; Zakowski et al, 2004). While occasionally described within papers as a measure of distress this is primarily a measure of intrusive thoughts and avoidance, which is less consistent with the general concept of distress (Horowitz, Wilner & Alvarez, 1979). These outcomes were thus excluded.

Seven trials measured health-related QoL with the SF-36 (Willmott, Harris, Gellaitry & Horne, under review), Short Form-12 (SF-12) (Taylor et al, 2003), Fibromyalgia Impact Questionnaire (FIQ) (Gillis et al, 2006), Functional Assessment of Cancer Therapy -Breast (FACT-B) (Gellaitry et al, 2010) & -Prostate (FACT-P) (Rosenberg

et al, 2002) scales, Dermatology Life Quality Index (DLQI) (Vedhara et al, 2007), and Bath Ankylosing Spondylitis – Global Score (BAS-G) (Hamilton-West & Quine, 2007).

Studies reporting more than one relevant outcome for an outcome category

Data were combined within study for four outcomes across three trials. The depression and anxiety sub-scales of the PHQ were combined in Taylor et al (2003), and the depression and anxiety sub-scales of the HADS, and the POMS (i.e. mood disturbance), were combined in Vedhara et al (2007) as they are all components of negative affect. In Taylor et al (2003) and Willmott et al (under review) the physical health and mental health sub-scales of the SF-12 or SF-36 respectively were combined as these are both components of health-related QoL. The effects to be combined were usually in the same direction, yet there was one exception (Vedhara et al, 2007). The data for each sub-scale combined within study are provided in the appendix.

Study-level risk of bias

The risk of bias for the included trials is illustrated in Table 4. Risk was assessed as high in nine trials, moderate in four trials and low in only one trial. Risk of bias assessment was not undertaken for one trial, obtained as a conference presentation, owing to insufficient data (Cohen et al, in preparation). However, earlier included trials undertaken by the same research group (Gillis et al, 2006; Norman et al, 2004) suggested that this presented at least a comparable risk of bias to the other included trials. Moreover, repeating the analysis without this study did not alter the results significantly, which in fact became slightly more positive; more notable effects emerged suggesting significantly less negative affect for the WED group relative to controls overall and less negative effect for the WED group relative

to controls specifically for rheumatic conditions which was approaching significance. This post-hoc sensitivity analysis is presented in the appendix. The inclusion of this trial therefore provided a more conservative estimate of effects. There was no heterogeneity in the risk of bias at the outcome-level; the risk of bias for each outcome category was generally consistently high. Issues associated with each criterion are summarised below, and the full risk of bias assessment for each individual study is presented in the appendix.

Randomisation

Six trials described the method used to generate the allocation sequence in sufficient detail to determine whether groups were likely comparable at baseline. In five trials the method was appropriate (i.e. computerised generated table of random numbers or minimisation) (deMoor et al, 2002; Gellaitry et al, 2010; Gillis et al, 2006; Hamilton-West & Quine, 2007; Low et al, 2010). However, one reported an inadequate method (e.g. sequential assignment to groups) (Walker et al, 1999). The remaining eight stated that the trial was randomised yet did not report the method.

Allocation concealment

Three trials described the method used to conceal the allocation sequence in sufficient detail to determine whether group allocation could have been predicted before enrolment and reported an adequate method (e.g. sealed, opaque, sequentially numbered envelopes) (Gillis et al, 2006; Low et al, 2010; Norman et al, 2004). Four trials stated enrolment was blind yet did not clearly report an appropriate method (Danoff-Burg et al, 2006; Hamilton-West & Quine, 2007) or did not describe how this was achieved at all (Rosenberg et al, 2002; Wetherell et al, 2005). Seven trials either stated that researchers were not blind (Willmott et al, under review) or did not describe an attempt at allocation concealment at all

(deMoor et al, 2002; Gellaitry et al, 2010; Taylor et al, 2003; Vedhara et al, 2007; Walker et al, 1999; Zakowski et al, 2004).

Blinding

In WED trials, the information provided to participants at enrolment must be vague with respect to the nature of the intervention/study purpose so that when the writing instructions are received participants are not able to infer their group assignment. For example, participants have previously been told that the study 'is intended for us to learn more about writing and psychology' (Pennebaker & Seagal 1999). Seven trials described an adequate attempt to blind participants (Danoff-Burg et al, 2006; Gillis et al, 2006; Hamilton-West & Quine, 2007; Norman et al, 2004; Vedhara et al, 2007; Wetherell et al, 2005; Willmott et al, under review). Specifically, there was a placebo writing comparison and the information provided at enrolment was sufficiently vague. For example, participants were either informed that they would be writing with no information about topics (Norman et al, 2004; Vedhara et al, 2007; Wetherell et al, 2005; Willmott et al, under review), that they would be writing about aspects of life/experiences (Gillis et al, 2006; Hamilton-West & Quine, 2007) or that they would be writing about their condition, which both the intervention and control group were then instructed to write about (Danoff-Burg et al, 2006). In some instances participants were also informed that the objective was to simply examine whether writing influences adjustment and health (Gillis et al, 2006; Norman et al, 2004; Wetherell et al, 2005).

Table 4 Study risk of bias assessment[31]

Study	Risk of Bias Item: Randomisation	Allocation concealment	Blinding	Completeness of outcome data	Study-level Risk of Bias
de Moor et al (2002)	Y	N	N	?	High
Gellaitry et al (2009)	Y	N	N	Y	High
Low et al (2010)	Y	Y	N	Y	Moderate
Rosenberg et al (2002)	?	?	N	Y	High
Walker et al (1999)	N	N	N	Y	High
Zakowski et al (2004)	?	N	N	Y	High
Gillis et al (2006)	Y	Y	Y	Y	Low
Norman et al (2004)	?	Y	Y	Y	Moderate
Danoff-Burg et al (2006)	?	?	Y	Y	Moderate
Hamilton-West & Quine (2007)	Y	?	Y	N	High
Wetherell et al (2005)	?	?	Y	?	Moderate
Vedhara et al (2007)	?	N	Y	Y	High
Taylor et al (2003)	?	N	N	Y	High
Willmott et al (under review)	?	N	Y	Y	High

[31] Criteria met (Y), criteria not met (N) or unclear whether criteria was met (?). Low = all items Y; Moderate = ≥1 items ?; High = ≥1 items N

However, in seven trials an adequate attempt was not described, namely the information provided at enrolment was not sufficiently vague. For example, the information provided was not described at all (deMoor et al, 2002; Low et al, 2010; Rosenberg et al, 2002; Walker et al, 1999; Zakowski et al, 2004) or potentially compromised blinding (i.e. participants were informed they would be randomised to a writing or non-writing group (Gellaitry et al, 2010) or that the study was about relationship between feelings and health (Taylor et al, 2003). In some instances there was also no placebo writing comparison (Gellaitry et al, 2010; Rosenberg et al, 2002; Taylor et al, 2003; Walker et al, 1999). As the included outcomes were subjective and self-administered, outcome assessment was blind only in instances where participant blinding was achieved.

Completeness of outcome data

In 10 trials, participants who were randomised but did not complete the final follow up were adequately described and there was less than 20% overall attrition and exclusions from analyses (Danoff-Burg et al, 2006; Gellaitry et al, 2010; Gillis et al, 2006; Low et al, 2010; Norman et al, 2004; Rosenberg et al, 2002; Vedhara et al, 2007; Walker et al, 1999; Willmott et al, under review; Zakowski et al, 2004). In one further trial there was again less than 20% overall attrition, but it is noteworthy that less than 80% of participants were included in analyses owing to exclusions of patients found not to be relevant post-randomization (Taylor et al, 2003). The extent of attrition was greater than 20% in one trial, yet there was no evidence of group imbalance in attrition and data were imputed for the randomised participants that completed the baseline assessment (i.e. last observation carried forward, LOCF) (Hamilton-West & Quine, 2007). The completeness of outcome data could not be accurately inferred in the remaining two trials (deMoor et al, 2002; Wetherell et al, 2005).

It was initially intended that ITT analyses would be included where ever possible. However, only one trial stated that an ITT analysis was undertaken (i.e. missing data imputed with baseline observation carried forward (BCF), and in this trial group final end point data was reported only for the 'completer' analysis (Gillis et al, 2006).

Intervention fidelity and compliance

Intervention fidelity (i.e. contamination)

Four studies reliably analysed participants' writing to establish the extent to which emotional words were used in the intervention compared to the control group using appropriate software: the Linguistic Inquiry and Word Count (LIWC) (LIWC, 2007) (de Moor et al, 2002; Gillis et al, 2006; Vedhara et al, 2007; Willmott et al, under review). Eight trials employed other fidelity checks, five of which did so without conducting a LIWC analysis. These included a stress/arousal checklist completed by participants post-writing (Wetherell et al, 2005), examination of essay content (i.e. adherence to instructions and topics disclosed) (Danoff-Burg et al, 2006; Gillis et al, 2006; Low et al, 2010) and or participant testimony (e.g. the extent to which writing was personal, emotionally revealing, meaningful and previously undisclosed) (Low et al, 2010; Norman et al, 2004; Vedhara et al, 2007; Wetherell et al, 2005; Willmott et al, under review; Zakowski et al, 2004). Intervention fidelity was generally confirmed. However, one trial did not report on intervention fidelity (Hamilton-West & Quine, 2007), and in the remaining four trials this was not applicable owing to a usual care comparison.

Compliance

Nine trials (de Moor et al, 2002; Gellaitry et al, 2010; Gillis et al, 2006; Hamilton-West & Quine, 2007; Low et al, 2010; Norman et al, 2004; Rosenberg et al, 2002; Taylor et al, 2003; Walker et al, 1999) clearly reported the proportion of randomised

patients failing to complete all writing sessions, which ranged from approximately three to 38% in the WED group and three to 33% in the control group. The remaining five trials did not clearly report this information.

Intervention fidelity and compliance could not be inferred in one trial again owing to insufficient data (Cohen et al, in preparation).

Synthesis

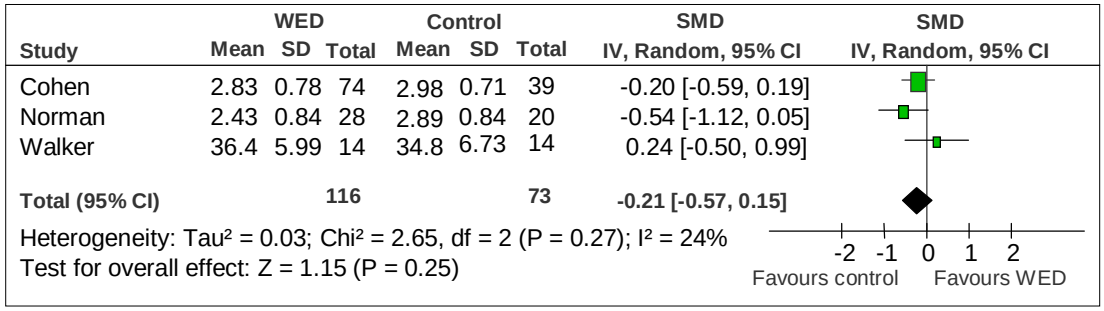
The individual study data/effects, and the pooled effects for each outcome category and then each condition within each outcome category are presented in Figures 2 to 10 below. No significant heterogeneity was detected.

Positive affect

Three studies reporting outcomes on positive affect were meta-analysed (n=189; WED=116, control= 73) (Cohen et al, in preparation; Norman et al, 2004, Walker et al, 1999), revealing a non-significant trend for a small negative effect (-.21; 95%CI (-.57 to .15) (i.e. less positive affect for the WED group relative to controls), with some evidence to suggest effect heterogeneity (I^2=24%).

Specifically, non-significant trends for negative effects that were small (-.20) and medium-sized (-.54) were observed in rheumatic and chronic pain conditions respectively, while a non-significant trend for a small positive effect (i.e. more positive affect in the WED group relative to controls) was observed among cancer patients (.24).

Figure 2 Pooled effect for positive affect across conditions



Negative affect

Thirteen studies reporting outcomes on negative affect were meta-analysed (n=705; WED=387, control=318) (Cohen et al, in preparation; Danoff-Burg et al, 2006; de Moor et al, 2002; Gellaitry et al, 2010; Gillis et al, 2006; Hamilton-West & Quine, 2007; Low et al, 2010; Norman et al, 2004; Rosenberg et al, 2002; Taylor et al, 2003; Vedhara et al, 2007; Walker et al, 1999; Wetherell et al, 2005), revealing an effect that was marginally inconclusive yet approaching significance in a positive direction (.13; 95%CI (-.02 to .28) (i.e. less negative affect for the WED group relative to controls), with no evidence of effect heterogeneity (I^2=0%).

It is notable, however, that this effect comprised non-significant trends for small positive effects in chronic pain conditions (.21) and cystic fibrosis (.34), yet non-significant and inconclusive effects in cancer (.11), rheumatic conditions (.12) and psoriasis (.07).

Figure 3 Pooled effect for negative affect across conditions

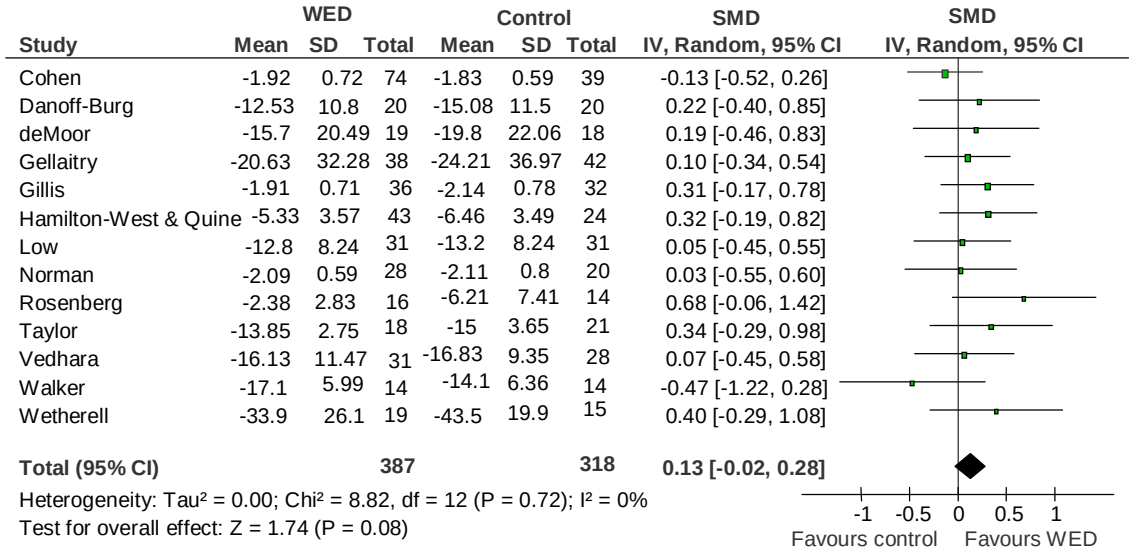


Figure 4 Pooled effect for negative affect in cancer

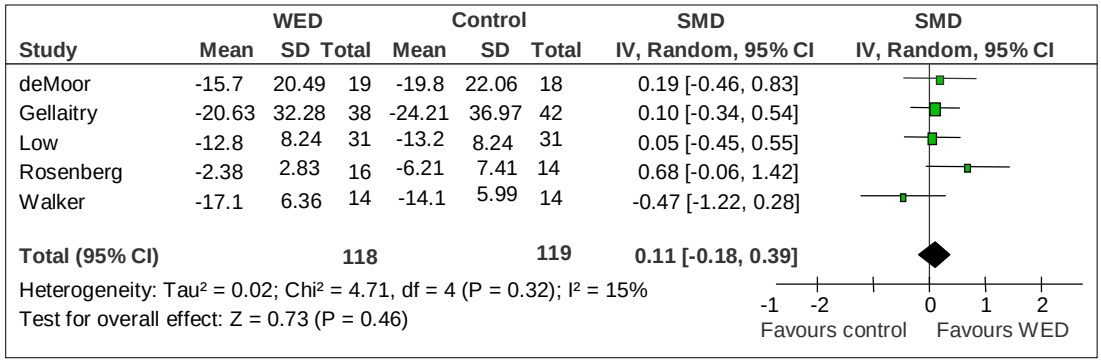


Figure 5 Pooled effect for negative affect in chronic pain

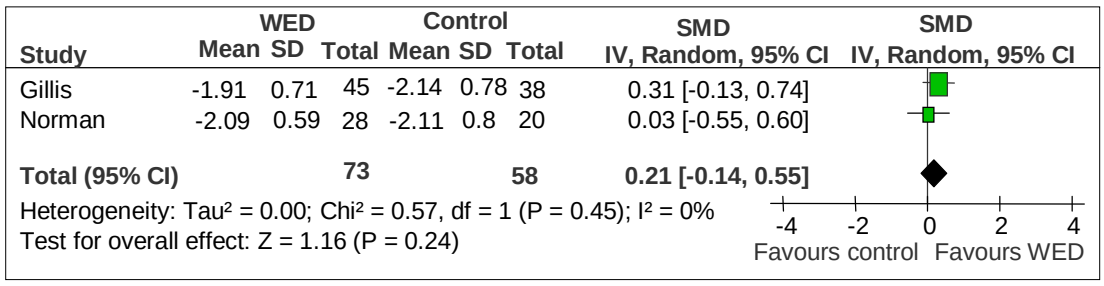
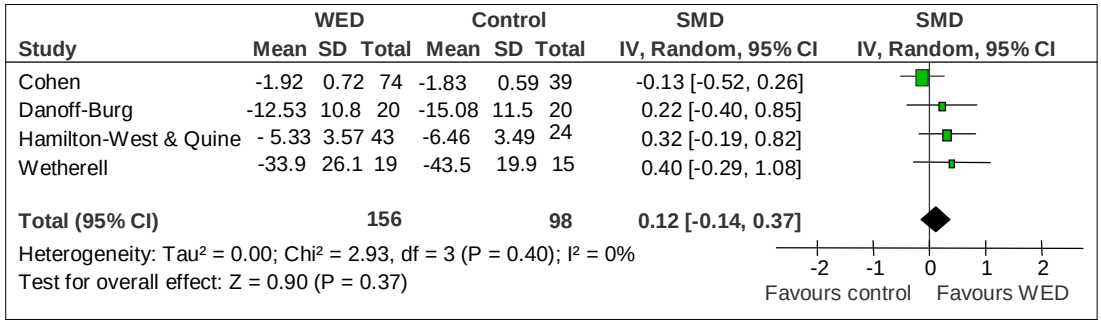


Figure 6 Pooled effect for negative affect in rheumatic conditions



Distress

Four studies reporting outcomes on distress were meta-analysed (n=293; WED=173, control=120) (Cohen et al, in preparation; de Moor et al, 2002; Taylor et al, 2003; Zakowski et al, 2004), revealing an overall effect that was non-significant and inconclusive (-.04; 95%CI (-.27 to .20), with no evidence of effect heterogeneity in condition-specific sub-groups (I^2=0%); cancer (.03), rheumatic conditions (-.11) and cystic fibrosis (-.09).

Figure 7 Pooled effect for distress across conditions

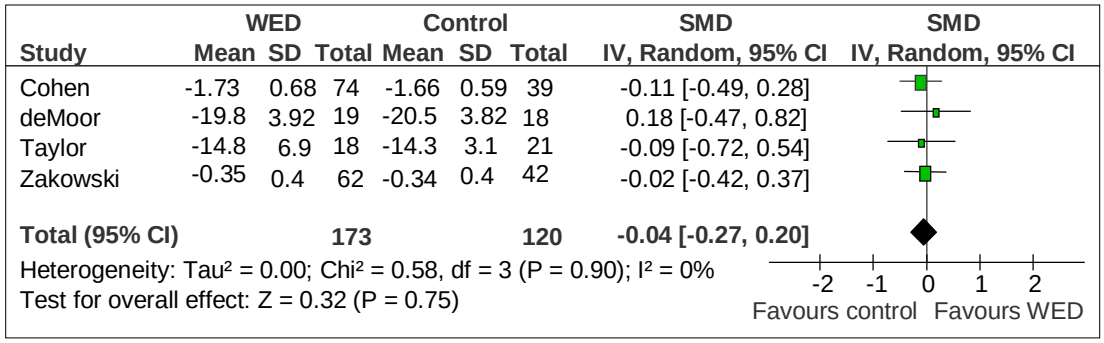
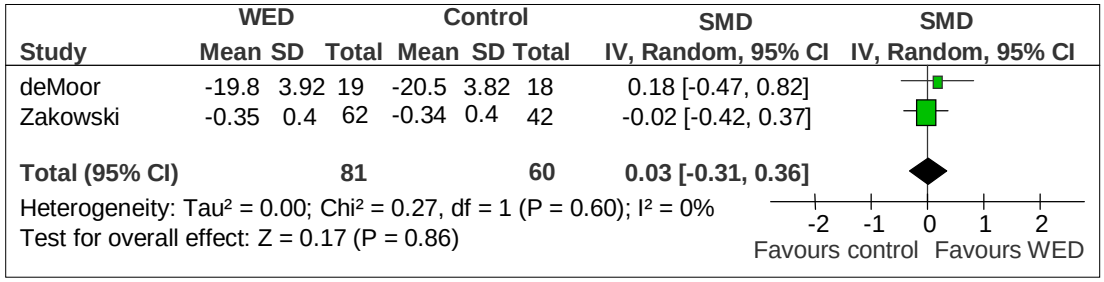


Figure 8 Pooled effect for distress in cancer



QoL

Seven studies reporting outcomes on QoL were meta-analysed (n=499; WED=261, control=238) (Gillis et al, 2006; Gellaitry et al, 2010; Hamilton-West & Quine, 2007; Rosenberg et al, 2002; Taylor et al, 2003; Vedhara, et al, 2007; Willmott et al, under review), revealing a small positive effect that was significant (.20; 95%CI (.02 to .38) (i.e. better QoL in the WED group relative to controls), with no evidence of effect heterogeneity (I^2=0%). It is notable, however, that this effect comprised a marginally significant small positive effect in post MI patients (.31), non-significant trends for positive effects that were small in cancer (.17) and cystic fibrosis (.25) and medium-sized in rheumatic conditions (.44), yet non-significant and inconclusive effects in chronic pain (.06) and psoriasis (-.13).

Figure 9 Pooled effect for QoL across conditions

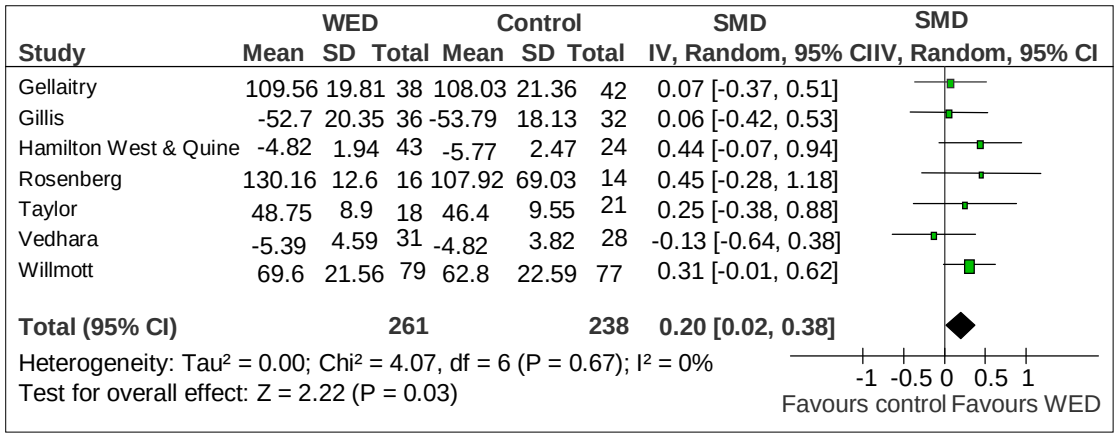
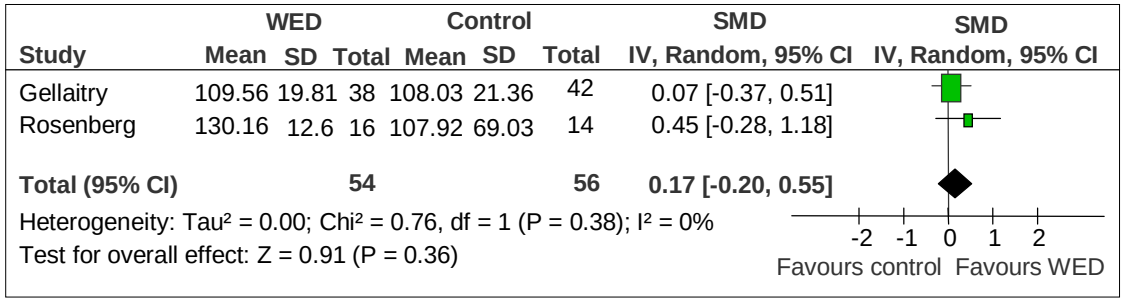


Figure 10 Pooled effect for QoL in cancer

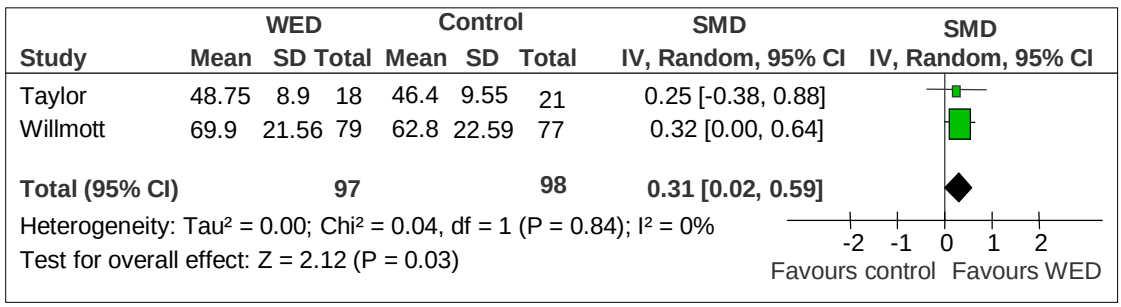


QoL sub-group analysis

The pooled effects for each QoL outcome sub-category and then each condition within each QoL outcome sub-category are presented in Figures 11 to 13 below. No significant heterogeneity was detected.

The two studies reporting outcomes on health-related QoL (n=195; WED=97, control=98) (Taylor et al, 2003; Willmott et al, under review) revealed a small positive effect that was significant (.31; 95%CI (.02 to .59) (i.e. better QoL in the WED group relative to controls), with no evidence of effect heterogeneity in condition-specific sub-groups (I^2=0%). However, it is notable that this effect comprised a small positive effect that was significant for patients post first MI (.32) and a non-significant trend for a small positive effect in cystic fibrosis (.25).

Figure 11 Pooled effect for health-related QoL across conditions



The five studies reporting outcomes on disease-specific QoL (n=304; WED=164, control=140) (Gillis et al, 2006; Gellaitry et al, 2010; Hamilton-West & Quine, 2007; Rosenberg et al, 2002; Vedhara et al, 2007) revealed an overall effect that was non-significant and inconclusive (.14; 95%CI (-.09 to .37), with no evidence of effect heterogeneity (I^2=0%). However, it is notable that this effect comprised non-significant and inconclusive effects in chronic pain conditions (.06) and psoriasis (-.13), yet non-significant trends for positive effects that were small in cancer (.17), and a medium-sized in rheumatic conditions (.44) (i.e. better QoL for the WED group relative to controls).

Figure 12 Pooled effect for disease-specific QoL across conditions

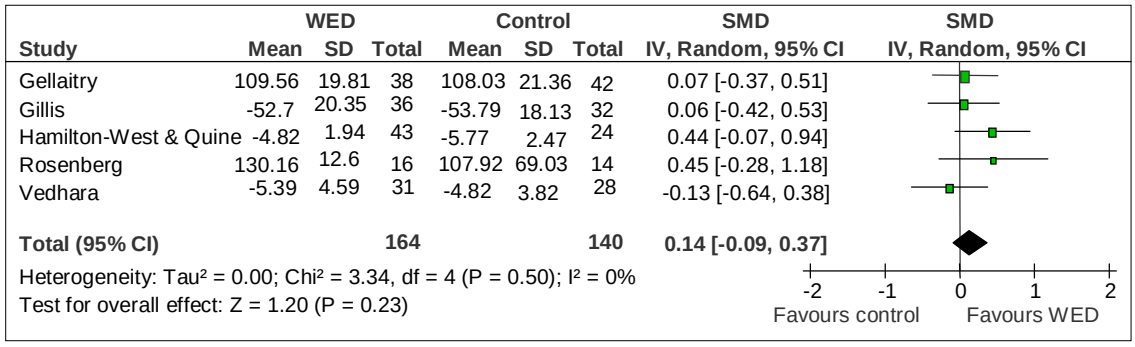
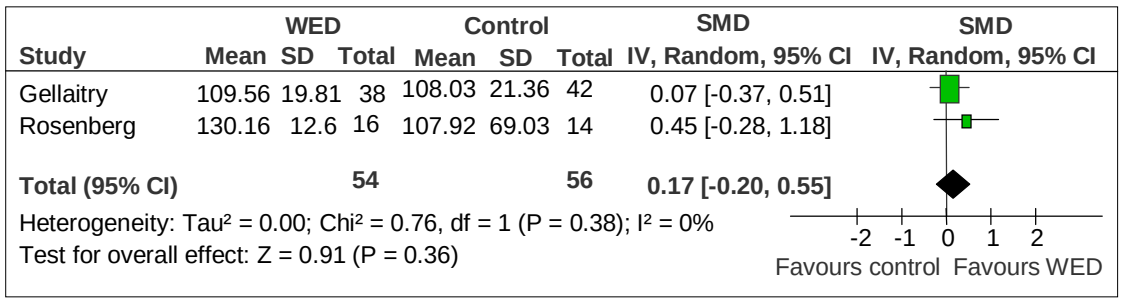


Figure 13 Pooled effect for disease-specific QoL in cancer



Methodological heterogeneity sensitivity analyses

Conclusions for each outcome were generally robust to/not notably influenced by the sources of methodologically heterogeneity investigated with a couple of

exceptions. With regards to type of comparison, positive affect, negative affect and distress were apparently robust, whilst QoL was not. When only trials with a neutral writing comparison were included, the small positive and significant effect on QoL (.20; 95%CI (.02 to .38) (i.e. better QoL for the WED group relative to controls) was only approaching significance (.20; 95%CI (-.02 to .42). With regards to the length of follow up, negative affect, distress and QoL were apparently robust, whilst positive affect was not. When only trials with a follow up of three months or greater were included the non-significant trend for a small negative effect on positive affect (-.21; 95%CI (-.57 to .15) (i.e. less positive affect for the WED group relative to controls) became non-significant and inconclusive (-.10; 95%CI (-.46 to .27). These sensitivity analyses are provided in the appendix.

Discussion

Summary of main findings

The evidence relating to the effects of WED for psychological health and QoL in LTPCs is mixed. Some support for a beneficial effect was observed for QoL and negative affect. For QoL, a small yet significant effect was observed identifying better QoL for the WED group relative to controls. For negative affect, an effect that was marginally inconclusive yet approaching significance in a positive direction was observed (i.e. suggesting less negative affect for the WED group relative to controls). With respect to the effect of WED for these outcomes in distinct LTPCs, there were non-significant trends, and even marginally significant effects, indicating reduced negative affect or better QoL for the WED group for some conditions. There were, however, a number of non-significant and inconclusive effects in other conditions. Importantly, though, there was little evidence of a detrimental effect on these outcomes. Other outcomes demonstrated little evidence of an overall effect. In fact, a non-significant trend for reduced positive affect for the WED group relative

to controls was observed, albeit there was heterogeneity across different LTPCs with a trend for a slight improvement in positive affect in one condition. There was no evidence that WED influenced distress.

Comparison with previous review findings

The observed effects were of a comparable magnitude to those derived for psychological health outcomes in previous WED reviews, which included amongst other samples people with LTPCs; d=.12 (sig.)[32] (Frattaroli, 2006) and d=.07 (non-sig.) (Frisina et al, 2004). This may be taken to support the assertion that small yet clinically important effects can be expected in LTPCs (Baikie & Wilheim, 2005). Smyth and Pennebaker (2008) argue that for such a brief and inexpensive intervention to have any effect is impressive, thus should they be genuine these effects are encouraging. However, in contrast to previous endeavours, the present review investigated effect heterogeneity by outcome and condition type, highlighting the specific psychological health and QoL outcomes, and LTPCs within these, for which WED may be effective. Additionally in contrast to previous endeavours, the present review considered effects that were of a potentially clinically important magnitude regardless of significance, owing to ongoing deficiencies in sample size and thus statistical power. Consequently, a slightly more optimistic conclusion was derived.

[32] Frattaroli (2006) reported r=.06, which can be converted to d using the following formula (Ellis, 2010):

$$d = \frac{(2r)}{\sqrt{1 - r^2}}$$

Interpretation of findings

That WED may be more effective for negative than positive affect is unsurprising given that it is advocated to resolve the former rather than encourage elevated mood, and might imply that WED should be directed to people experiencing some existing level of low mood. However, that WED may potentially reduce positive affect in the long-term is not only surprising but concerning. This effect should be interpreted with caution, though, given that the largest negative effect on positive affect was for the trial in which the control comparison wrote about thoughts and feelings about positive events; it is unsurprising that positive effect was elevated for controls relative to WED participants.

The apparent absence of an effect on distress is additionally surprising. As described in chapters one and two, illness-related stressors and general/illness-related distress are associated with depression in LTPCs, thus targeting this may optimise improvement in depression. WED targets emotional aspects of stressors and presumably distress, consequently improvement in depression may be optimised. However, the present findings do not support the presumption that WED targets distress and influences depressive symptoms via a concurrent reduction in this in LTPCs. In fact, improvement in negative affect in the absence of an effect of WED upon distress has been reported in non-LTPC samples (Koopman, Ismailji, Holmes, Classen, Palesh & Wales, 2005; Smyth et al, 2008). Whether WED targets distress and may thus improve depression via a concurrent reduction in this in LTPCs should be clarified.

Relative to controls, WED participants evidenced significantly better health-related QoL, yet only slightly better disease-specific QoL. Whilst this sub-group analysis was pre-specified, the comparison should be interpreted with caution in view of the

loss of randomisation between groups. Nonetheless, it is possible that WED may improve the general experience of health-related QoL (i.e. perceived functional health and well-being), with less influence on perceived disease-specific functional health and well-being. It should be noted, however, that the effect heterogeneity observed across the sub-groups may merely reflect condition-specific differences in WEDs effect upon QoL. Indeed, the sub-groups comprised completely different conditions, and the disease-specific QoL sub-group actually comprised both non-significant trends for positive effects and non-significant and inconclusive effects when LTPCs were considered separately.

It should be acknowledged, though, that should they be genuine other phenomena may explain the observed effects. Positive effects indicating improvement for WED participants may reflect a worsening in controls and no change in the intervention group as a result of a) a protective effect of WED against variation in symptoms, but also b) a negative response to the control task or c) pre-disclosure priming, wherein participants are advised, or derive an expectation, that they may be asked to emotionally disclose after which controls are forced to inhibit rather than resolve evoked stressors. That neutral writing in WED trials can be emotive and in such instances related to deterioration in disease activity has been reported in arthritis patients (Byrne-Davis et al, 2006). Moreover, in some of the included trials participants were warned that it was possible they could find their writing topic upsetting (Vedhara et al, 2007; Wetherell et al, 2005). In fact in one of these trials, improvements were apparently due to a slight improvement in the WED group relative to a decline in controls, and pre-disclosure priming was confirmed by participants' anecdotal reports (i.e. frustration owing to an urge to emotionally disclose in the absence of an opportunity for this) (Wetherell et al, 2005). Further examination of exactly how effects are derived is thus indicated.

Moreover, the null effects, and again should they again be genuine the non-significant trends for positive effects, that were observed may be due to a ceiling effect such that there was little room for improvement; none of the samples in the included trials were selected for having psychological problems. Pre-intervention distress is an established moderator of psychosocial treatment effectiveness in LTPCs, for example cancer (Schneider, Moyer, Knapp-Oliver, Sohl, Cannella & Targhetta, 2010). Indeed, negative affect has emerged as a significant moderator of WEDs effects in non-LTPC samples (Koopman et al, 2005). In fact, some of the included studies offered some support for this assertion; one reported greater effects for those reporting higher baseline negative affect in a moderation analysis (discussed later) (Norman et al, 2004), and for another that reported a trend for a positive effect on negative affect the baseline data indicated that a large proportion of participants had a history of depression (Danoff-Burg et al, 2006). Frattaroli's (2006) review identified a greater effect of ED for some outcomes for individuals with higher baseline stress and worse physical health, albeit no moderating effect of mood. However, the latter analysis was based on only one or two studies of ED. Indeed, it is acknowledged that this evidence base is inconsistent, yet suggests on a whole that WED is more effective for psychological health when patients' symptoms are clinically more prominent (Baikie & Wilheim, 2005). Furthermore, arthritis patients reporting subjective benefits of WED have been shown to exhibit greater mood disturbance and more disease activity than those deriving no such benefit, although this association was not upheld for actual improvement (Byrne-Davis et al, 2006).

Chapter two reported that the evidence suggests, and widespread clinical opinion is, that it is not appropriate to use WED unsupervised with patients with more severe psychological problems. It therefore seems that WED may be most appropriate and effective for individuals with LTPCs and lower-level negative affect. The evidence

does not, however, provide any indication of, or importantly any means of operationalising, the level of negative affect for which WED is likely to be most effective.

Effects may have additionally been influenced by compliance issues, namely slight deficiencies in completion of the intervention. There was also evidence of a bias towards female participants, who arguably emotionally disclose more readily than males (Kring & Gordon, 1998). Some WED studies have reported a superior effect for men (Manier & Olivares, 2005), yet the evidence is inconsistent and others report a superior effect for women (Pennebaker et al, 1990) or no moderating effect (Epstein, Sloan & Marx, 2005). The relationship between gender and WED is likely complex and requires further study (Langer, 2010; Range & Jenkins, 2010; Stickney, 2010). Studies were additionally predominantly conducted in the USA. It has been argued that popularisation of WED in the lay literature as a self-help strategy may explain positive effects in USA samples (Greenhalgh, 1999); in many of the included trials participants may have deduced their group assignment upon receiving the instructions thus potentially compromising blinding. More UK based trials are therefore indicated.

Issues associated with included trials

The observed effects should, however, be interpreted with caution. Firstly, a moderate to high risk of bias was consistently identified for the included studies. This substantially undermines the findings. This is in agreement with an earlier systematic review (Meads et al, 2003), suggesting that risk of bias is an ongoing problem. Effects may have been influenced by selection, detection and performance bias, and systematic attrition/exclusions from analyses (discussed further in chapter nine). A higher risk of bias has been demonstrated to be associated with

overestimated intervention effects (Schultz et al, 1995; Moher, Jones, Cook, Jadad, Moher, Tugwell & Klassen, 1998). The observed effects may have been consistently overestimated, and in fact a high risk of bias was identified for the trials with the greatest effects for negative affect and QoL.

It should be noted, however, that poor reporting hindered risk of bias assessment and may have actually masked adequate trial implementation (Huwiler-Műntener, Jűni, Junker & Egger, 2002). A substantial number of studies satisfying the inclusion criteria were also currently lacking in their contribution to the evidence base; despite requesting it from authors, adequate data were not provided for the relevant outcomes that were measured. As such the review may be biased owing to the omission of small, non-significant but potentially clinically important effects. Omitting this detail is considered unethical practice (Moher, Schultz & Altman, 2001). It should also be noted that the 95% CIs associated with the effects were wide, suggesting that the observed effects were relatively unstable and should be interpreted with caution.

Limitations of the review

Condition-specific differences in WEDs effects may be considered surprising given the relatively generic psychosocial burden associated with LTPCs (WHO, 2002). Consequently, while effect heterogeneity was seemingly explained by condition-specific differences, it should be noted that this may be attributable to other sources of heterogeneity. Individual studies generate effects sizes that vary owing to study specific artefacts and risk of bias (Ellis, 2010), which is certainly true for WED studies (as described in chapter two). Indeed, whilst the focus of the review was intended to minimise the methodological heterogeneity between the included studies, heterogeneity in study characteristics, and to a lesser extent risk of bias,

was identified amongst the included trials. Moreover, effects for some outcomes were somewhat influenced by the sources of heterogeneity investigated (i.e. trial methodology). Whether the risk of bias associated with the included trials influenced the observed pattern of results could not be investigated as too few were assessed as low risk. Nonetheless, given the small number of trials included in each condition-specific sub-group, this offers a plausible, alternative explanation for the apparent condition-specific differences.

The approach adopted where studies reported more than one relevant outcome for an outcome category was not ideal, for example in one trial the effects combined within study for the negative affect outcome category were in different directions. However, sub-scales from the same measures were combined, none of the combined effects were significant, the difference in the point estimates was usually small and the 95% CIs were wide and overlapped considerably. While tentative, it could be argued that if the studies were repeated in a different sample from the same population, the point estimates could fall anywhere within their respective confidence limits potentially reducing any difference in the direction and or magnitude of effects. Whilst not ideal, the data for the separate sub-scales combined within studies is again provided in the appendix, and this approach was considered preferable to selectively including outcomes.

It is additionally unclear what influence the potentially relevant yet unobtainable trials, and the dissertations that were largely unobtainable and thus excluded, might have had. Furthermore, despite a concerted effort it was not feasible to duplicate the entire review process in order to further reduce risk of bias. The results of the present review can additionally only be generalised to the LTPCs included, the standard WED paradigm, and psychological health outcomes (i.e. not physical health).

Implications for practice

The present review suggests that, should the observed effects be genuine, in LTPCs WED may deliver beneficial effects that are modest yet potentially clinically important on some outcomes, perhaps for certain LTPCs. Specifically WED may hold potential as a low-intensity psychological intervention for improving depressive symptoms, and some associated outcomes namely health-related QoL, in adults with LTPCs. As mentioned earlier, it is crucial to interpret effect sizes in terms of their clinical importance. The clinical importance of effects based on SMDs is, however, difficult to interpret as the difference is expressed in SD units rather than the measurement scale employed. Even then differences are difficult to interpret as the change in a person's actual state that corresponds with a unit change on these self-report symptom measures is not known (Ellis, 2010; Nezu & Nezu, 2008). Regardless, though, when produced for a number of people even small and seemingly unimportant effects can accumulate to large effects that have a substantial impact on outcomes at the population level (Ellis, 2010). As such, again should they be genuine, the slight improvements observed in depressive symptoms could have a large, favourable impact on the range of important clinical and service level outcomes adversely impact by depression in LTPCs (see chapter one).

To illustrate that the observed effects could have a substantial impact at the population level, SMDs can be expressed as the percentage of non-overlap of the distribution of scores for the intervention groups, namely the U_3 statistic (Cohen, 1988). Specifically, this illustrates the proportion/percentage of scores in the WED group that are lower/higher than the average score in the control group.[33] The SMDs of .13 for negative affect and .31 for health-related QoL are equivalent to

[33] It should be noted that this relies on the intervention groups being normally distributed and equally variable/numerous.

55% and 62% of WED participants having lower depressive symptom severity and better health-related QoL than the average control participant. Put another way, 5% and 12% respectively of the population may do better than would be expected by chance alone (i.e. U_3=.55 and .62 respectively[34]). Before WED can be recommended in practice, however, methodologically sound studies are required.

Recommendations for future research

Twenty-one potentially relevant ongoing trials were identified indicating a strong interest in this area. Importantly, future RCTs may benefit from adherence to the Consolidated Standards of Reporting Trials (CONSORT) statement (Schultz, Altman & Moher, 2010). Specifically, trials should investigate the effectiveness of WED for reducing negative affect, for example depressive symptoms, for LTPCs that are associated with negative affect and in which negative affect has a significant impact. Ideally, patients should be experiencing lower-level negative affect. This is consistent with the appropriate clinical application of WED, and as such would enhance the relevance of trials whilst importantly protecting patient safety. It would also potentially maximise effectiveness. The effect of WED on associated outcomes, particularly health-related QoL, should also be investigated, and again, whether WED targets distress and may thus improve depression via a concurrent reduction in this in LTPCs should additionally be clarified.

It was initially intended that the present review would identify within study evidence of moderators (i.e. variables that determine whether and to what extent WED is effective), mechanisms of change (i.e. measures of intervention processes that may underlie WEDs benefits), mediators (i.e. variables that may be changed by WED to produce benefits) and cost-effectiveness. It was anticipated this would identify whether WED works differently for different people and for whom it works best, and

[34] These statistics are derived from Cohen's table of equivalents of d (Cohen, 1988).

the effective intervention components (Mackinnon & Luecken, 2008). As suggested earlier, this information can then be used to optimise improvements in outcomes. Valuable health resources can be directed to patients with the greatest anticipated benefit or prognostic traits could be manipulated before applying WED. Effective intervention components can also be targeted. The cost-effectiveness of psychological health interventions must be proven before implementation in practice can be considered, the importance of which has been advocated for some time (Glasgow, 2008; Taylor, 1987).

However, only a few trials investigated a heterogeneous range of moderators, mechanisms of change and mediators.[35] These could not be meaningfully combined and interpreted, and because the trials were likely underpowered to detect effects in these analyses they were of limited utility, Furthermore, no trials undertook a cost-effectiveness evaluation, and only one provided cost data that was of limited utility.[36] Consequently, future trials must incorporate such exploratory/cost-effectiveness analyses. In fact, if moderators are not examined effects may be missed (i.e. where heterogeneous effects for distinct sub-groups are essentially averaged). This recommendation is underscored by current opinion in the field, which purports that research has shown WED does work 'at least some of the time for some people', thus examination of moderators and ideographic implementation of WED are a priority (Pennebaker, 2004; Sloan & Marx, 2004a; Smyth & Pennebaker, 2008). Potential moderating traits and explanatory processes were derived from the WED evidence base reported in chapter two. However, it was noted that this evidence base is under-developed, inconsistent, ambiguous and yet to be adequately tested.

[35] The included trials undertook the following exploratory analyses a) moderators; social support and time since diagnosis (Low et al, 2010), perceived social constraints over emotional expression (Zakowski et al, 2004), ambivalence over emotional expression, catastrophizing and negative affect (Norman et al, 2004) and trait anxiety (Danoff-Burg et al, 2006), b) mechanisms of change; association between change in emotional and cognitive word use and change in outcomes (Hamilton-West & Quine, 2007; Walker, 1999) and c) mediators; avoidance and intrusive thoughts (Zakowski et al, 2004).
[36] This trial reported costs based on psychologist fees associated with administration of WED, which is of limited utility given that WED is intended to be self-administered (Taylor et al, 2003).

Further exploration of these specific moderating traits and explanatory processes in this context is therefore warranted.

Conclusions

The evidence suggests that, should the effects be genuine, in LTPCs WED may be effective for some outcomes, perhaps in particular for reducing negative affect including depressive symptoms and improving some associated outcomes, namely health-related QoL, and perhaps specifically for some LTPCs. However, the moderate to high risk of bias consistently identified for the included studies and certainly present for the trials reporting the greatest effects for these outcomes, suggests that the effects may be overestimated and substantially undermines the findings. Consequently, before firm conclusions about effectiveness can be drawn, in agreement with previous reviews, it is crucial that further methodologically rigorous and adequately reported trials are undertaken. These must be directed, with investigation in the populations and for the outcomes for which benefits may be anticipated. Future trials must additionally be inquisitive about the mechanisms of change and the moderators and mediators of WEDs effects, derived from the WED evidence base, and cost-effectiveness.

Chapter 4 Methodology for an exploratory RCT evaluating WED for improving depressive symptom severity in adults with Type 2 diabetes

Chapter overview

This chapter identifies the appropriate the methodology for a trial of WED for improving depression in adults with a LTPC, which meets the requirements specified in chapter three. The appropriate design, population, intervention implementation, comparison exposure, outcomes, approach to effectiveness analyses, exploratory analyses, measures, data collection schedule and feasibility investigation are considered, in addition to the substantial patient safety issues encountered in this context and the measures required to address them. Finally, the user and expert consultation process is described briefly.

Design

The MRC framework for complex interventions is an established framework that delineates the sequential phases of investigation in the evaluation of complex interventions, identifying the objectives to be met before progressing to the next stage (Campbell, Fitzpatrick, Haines, Kinmouth, Sandercock, Speigelhalter & Tyer, 2000; Craig, Dieppe, Macintyre, Michie, Nazareth & Petticrew, 2008; MRC, 2000). In phase one trials, the intervention is modelled, which entails improving understanding of the intervention and identifying and defining the key components (i.e. the active ingredients). For example, these data might be obtained via qualitative interviews and focus groups with patients and HCPs. In phase two 'exploratory' trials design-related issues are identified prior to a full effectiveness trial; the optimal trial and intervention design are defined. Specifically, the anticipated treatment effect is identified and tested, intervention and trial parameters are piloted, and other feasibility issues are identified (i.e. the feasibility/effectiveness

of delivering the intervention and the trial protocol is established). Importantly, variations of the intervention can be tested to identify which seem to be the most appropriate for a full scale trial. This entails a direct comparison of two of more variations of an intervention; the only way to provide conclusive evidence of the utility, practicality or desirability of one approach over another (MRC, 2000).

Chapters two and three identified that the WED evidence base is confounded by heterogeneity, as study parameters have been unsystematically manipulated in search of the most effective design. Few studies have modelled WED and systematically manipulated it's parameters to identify the optimal design or 'recipe' (e.g. manipulated the number of writing sessions or the spacing of sessions within study). Such studies, consistent with phase one trials and the intervention development element of phase two trials, are certainly required. This would have been an interesting and important piece of research. However, it would entail a dedicated programme of research addressing each of the many parameters of WED, which given the constraints on time was beyond the scope of the present study. The objective of the present study was additionally to identify the preliminary effectiveness and feasibility of WED when applied to the clinical issue of depression in LTPCs.

Consequently, it was decided that given the remit and objectives of the present endeavour the most appropriate study design was a phase two trial, focussing on testing preliminary effectiveness, piloting intervention and trial parameters and identifying other feasibility issues, with some further exploration of the former. Consistent with the objective of testing the evidence gained thus far the anticipated effect should be explored further, specifically whether WED works as anticipated and whether it works differently for different people as anticipated should be explored, and a prior economic analysis should be undertaken. Some of the trials

considered in the systematic review specifically investigated feasibility (Broderick et al, 2004; Gellaitry et al, 2010; Taylor et al, 2003; Walker et al, 1999), yet these were few and are required. Whilst not the ideal scenario, the WED evidence base was considered as a whole and the optimal parameters of WED were inferred from this (discussed below). The MRC phases and corresponding objectives, and the status of the investigation of WED for improving depression for adults with LTPCs in relation to each phase are illustrated in Table 5.

It is typical for phase two trials to include a before and after design in order to gauge the preliminary effectiveness of an intervention. However, in the absence of a control group any change observed cannot be attributed specifically to the intervention. In these designs internal validity is compromised; causal inferences cannot be drawn (Nezu & Nezu, 2008). It is not uncommon, however, for a RCT design to be employed in feasibility trials including those testing WED (Klapow, Schmidt, Taylor, Roller, Li, Calhoun, Wallander & Pennebaker, 2001) and other psycho-social interventions in diabetes (Sturt, Whitlock, Hearneshaw, Farmer, Wakelin, Eldridge, Griffiths & Dale, 2008). A RCT provides the most robust investigation of effectiveness to inform evidence-based practice (Barton, 2000); randomization minimizes systematic variation between groups promoting the equal distribution of confounding variables and thus enhancing the degree to which any effect can be attributed to the intervention. In order to provide the most informative assessment of WEDs preliminary effectiveness for improving depression in LTPCs, a RCT was considered appropriate.[37]

[37] Incidentally a RCT was preferable to natural and quasi-experimental designs as WED is not currently employed in practice thus natural allocation to groups is unavailable and in the absence of controlled manipulation and or randomisation alternative explanations for observed effects cannot be ruled out (again internal validity is compromised and causal inferences cannot be drawn) (Nezu & Nezu, 2008).

Table 5 MRC framework for complex interventions and the status of WED in LTPCs

Phase/objectives for each phase	Status of WED & how objectives have been/should be met
Pre-clinical/theoretical phase	
Establish the theoretical basis/evidence base that the intervention is likely to have the anticipated effect (i.e. before substantial evaluation an intervention must be developed to a point where it can reasonably expected to be effective)	Satisfied: The WED evidence base is inconsistent and the mechanisms of WEDs effects are unclear. However, there is reason to believe that it may be effective for improving depression in LTPCs and it is seemingly associated with various empirically supported influencing mechanisms, which are similar to those underpinning other effective psychotherapies. Hence it may be considered to have a sound theoretical grounding for improving health (chapter two). There is also evidence that interventions like WED which target emotional aspects of stressors and thus presumably distress may optimise improvement in depression in LTPCs (chapters one & two)
If there is no high quality systematic review evidence of the relevant evidence one should be conducted	Satisfied: Previous systematic reviews have been limited in their utility for determining the effect of WED for depression in LTPCs (chapter two). A more focussed review with more appropriate methodology was thus conducted, and identified that WED may be effective for improving depression and associated outcomes perhaps for specific LTPCs (chapter three).
Identify the likely/anticipated processes of change	Satisfied: The likely/anticipated mechanisms of change/mediating processes underpinning WEDs effects have been offered and again somewhat supported empirically yet require further testing (chapter two).
Identify strategic design issues	Satisfied: The systematic review (chapter three) and the LTPC/depression & WED evidence (presented below) provide some indication of the methodological parameters within which WED should be tested. Ethical review identified further design-related issues (discussed below).
Phase 1: Modelling	
Improving understanding of the intervention and identifying and defining the key components (i.e. the active ingredients)	*Required but beyond the scope of and not consistent with the objectives of the present study.*
Phase 2: Exploratory trial: defining optimum trial and intervention design	
Testing variations of the intervention to identify which seem to be the most appropriate for a full scale trial	*Required but beyond the scope of and not consistent with the objectives of the present study.*
Testing the evidence gathered thus far (e.g. obtaining evidence to support theoretically expected treatment effect and anticipated effect sizes)	*Required: Whether WED is likely effective for improving depression, and associated outcomes, in LTPCs, and the anticipated effect sizes should be estimated.* *Whether WED works as anticipated and whether it works differently for different people as anticipated should also be explored.*
Undertake a prior economic evaluation	*Required: This should be attempted for WED in LTPCs.*
Investigating the feasibility/effectiveness of intervention delivery (e.g. compliance, intervention fidelity & acceptability)	*Required: These issues must be established for WED in LTPCs.*
Investigating the feasibility/effectiveness of a trial protocol (i.e. identifying an appropriate control group, follow up, outcome measures, estimates of recruitment/retention & other issues that may undermine a main effectiveness trial e.g. feasibility and effectiveness of the randomization method)	*Required: These issues must be established for WED in LTPCs.*
Phase 3: Main effectiveness RCT	
Testing a fully defined intervention with a theoretically defensible protocol, and with attention to achieving adequate statistical power and standard features of well-designed trials (e.g. randomisation, blinding & allocation concealment)	Requires completion of phase 2.
Phase 4: Long-term surveillance	
Determining whether the intervention and results can be reliably replicated in uncontrolled settings in the long-term	Requires completion of phase 2.

Indeed, randomization is advocated to identify and estimate anticipated effect sizes, which inform sample size calculations (Campbell et al, 2000). Piloting of the method of randomization and as such establishing the feasibility and effectiveness of this prior to a full effectiveness trial is also recommended practice (MRC, 2000).

The RCT design should be parallel groups, wherein the intervention and control are applied simultaneously to two separate groups of participants. This is preferable to alternative designs, for example cross-over RCTs in which participants are randomly assigned to a sequence of treatments (i.e. they all receive the same treatments in a different order). This design affords further control of confounders yet requires long 'wash-out periods' to avoid carry-over of treatment effects and is susceptible to order effects (i.e. the order in which people receive the treatments may influence effects) and learning effects (i.e. WED participants may react to a neutral writing control task in a different way than naive controls). Moreover, withholding WED from controls was justified (discussed below).

Phase two exploratory trials do not normally attend to issues such as internal validity/risk of bias and statistical power. These issues could additionally be considered in a preliminary manner, however, to further maximise the informative potential of the trial with respect to identifying and estimating anticipated effects and feasibility issues with regards to achieving these standards. Specifically, trials could endeavour to adhere to the CONSORT standards of randomisation, allocation concealment (i.e. preventing researcher's prediction of group allocations before enrolment and thus allocation based on baseline characteristics) and blinding (i.e. preventing participants' inference of group assignment) (Moher et al, 2001). An à priori sample size calculation could additionally be specified, with the feasibility of achieving the sample size requirements and the appropriateness of the parameters identified.

As identified in chapter three, achieving blinding in WED trials is particularly complicated. Ideally, the trial should be double blind. In endeavouring to achieve this, a placebo comparison must be employed and the information received at enrolment must be sufficiently vague to prevent participants' inference of allocations on receipt of writing; the exact nature of the intervention and the existence of an intervention and control group must be withheld. This additionally prevents contamination in controls and pre-disclosure priming (i.e. protecting patent safety, discussed in chapter three). Given the difficulty in achieving blinding, the success of participant blinding should be specifically assessed. Participants should also self-administer the intervention and self-reported outcome measures, such that intervention implementation/outcome assessment is additionally blind.

HCPs will need to be aware of the study purpose but should not be informed of participating patients' group allocation, and the risk of discussion between patients and HCPs about the study should be minimised.

Population

Piloting WED for improving depression in diabetes

WED should be considered for improving depression in diabetes. The research team had a keen clinical interest in diabetes, and incidentally to date, no published studies had investigated this. This investigation is, however, timely and warranted, the reasons for which are discussed below.

Diabetes

The amount of glucose in the blood is controlled by insulin, a hormone produced by the pancreas. This moves glucose derived from the food we eat, from the blood

stream into cells where it is broken down to energy. Diabetes is a metabolic disorder in which the body is unable to break glucose down to energy. In type 1 diabetes the pancreas is unable to produce insulin (insulin-dependent diabetes) and in Type 2 diabetes the pancreas is unable to produce enough insulin or the cells in the body are unable to utilise the insulin that is produced (i.e. cells require insulin to absorb glucose); termed insulin resistance (i.e. non-insulin dependent diabetes). In both, hyperglycemia (i.e. high blood glucose levels) can result and produce long-term microvascular complications including retinopathy (i.e. damage to the retina at the back of the eye), neuropathy (i.e. nerve damage), foot ulcers (i.e. damage to the nerves of the foot) nephropathy (i.e. kidney disease), sexual dysfunction (i.e. erectile problems owing to damage to nerves and blood vessels), and macrovascular complications such as CAD and stroke. Diabetes cannot be cured, instead the treatment goal is to maintain blood glucose levels as close to normal as possible to prevent the development of the aforementioned medical complications later in life. In Type 1 diabetes this is achieved via patient initiated SMBs including adjustment in diet and exercise, self-monitoring of blood glucose and importantly self-administering insulin. Type 2 diabetes is usually managed initially via adjustment in diet and exercise, and weight loss, yet some cases additionally require oral hypoglycemic agents and perhaps insulin (i.e. it is a progressive condition).

Diabetes is one of the biggest health challenges facing the UK (DUK, 2010a). The UK is facing an obesity epidemic, which is a particular risk factor for Type 2 diabetes (DUK, 2010a). Indeed, it is estimated 2.6 million people have diabetes (DUK, 2010a), with many more cases unrecognised (Holt, Stables, Hippisley-Cox, O'Hanlon & Majeed, 2008; NHS The Information Centre for Health and Social Care, 2008). Indeed, the incidence (Shaw, Sicree & Zimmet, 2010) and thus prevalence (Wild, Sicree, Roglic, King & Green, 2004) of diabetes is increasing, more notably

than for other LTCPs (DoH, 2009). Again, diabetes is a major risk factor for further LTPCs (Fillenbaum et al, 2000; WHO, 2002) and with the aging population people are now living longer hence the impact of complications is increasing (Rubin, Walen & Ellis, 1990). Indeed, a decline in mortality rates is reported for some LTPCs (see chapter one), yet not diabetes.

Depression in diabetes

To maximise effectiveness, the systematic review recommended investigation of WED for reducing negative affect, for example depressive symptoms, in LTPCs that are associated with negative affect and in which negative affect has a significant impact. Systematic reviews of cross-sectional studies have consistently indicated that having diabetes doubles the risk of elevated depressive symptoms and MDD, which is consistent across diabetes type and equates to one in six people with diabetes (17.6%) being likely to experience depression of a magnitude that may impair functional health (Anderson, Freedland, Clouse & Lustman, 2001; Ali et al, 2006). Depression is also particularly persistent in diabetes; at follow up, up to 47% still report significant depressive symptoms (Fisher, Skaff, Mullan, Arean, Glasgow & Masharani, 2008; Hermanns, Kulzer, Kubiaz & Haak, 2004; Peyrot & Rubin, 1999; Pibernik-Okanovic et al, 2008) and 79% of those with MDD report dysthymia or at least one recurrent episode (average 4.2 episodes) despite some form of treatment during this period (Lustman, Griffith & Clouse, 1988). Indeed, 37% of patients indicating remission experience significant symptoms at follow up (Peyrot & Rubin, 1999). The substantial impact of depression upon important outcomes in diabetes was presented in chapter one.

Current access to E&P support in diabetes

Whilst an improvement on previous years, in 2008 only just over half of the PCTs in the UK agreed that psychological support was provided to adults with diabetes

(DUK, 2007d; 2009a). A survey of psychological input into secondary care diabetes services for UK adults also reported that only 15% have access to specialist service provision, thus 85% of people with diabetes have no defined access to E&P support or at best have access to local generic services (i.e. with no diabetes input). Moreover, where specialist services do exist, only 13% have input into primary care, 17% report unacceptable waiting times and 3% comply with all relevant NSF standards (DUK, 2008). Indeed, HCPs report that they can recognise E&P need yet they lack the time and skill to deal with this and insist more training and psychological input is required; only 38-61% feel able to meet this need and 51-65% perceive external support (DUK, 2008; DUK, 2007c; DUK, 2006a; DUK, 2005b; Pouwer et al, 2006). This unmet need consistently ranks amongst the top concerns reported by people with diabetes and HCPs (DUK, 2007a; 2009c; 2010b), and has been confirmed in a number of patient surveys reported in Table 6.

Policy imperatives for improving provision of E&P support in diabetes

As the prevalence of diabetes rises, the impact of depression will increase and the unmet support need will worsen, thus action is required now (DUK, 2008). There have been a number of diabetes specific-initiatives prioritising E&P support, recognising this as a barrier to SMBs and advocating that this should be integral in diabetes care, and receive Government investment, increased resource allocation and research investigating the benefits associated with different types of support (DUK, 2007c; DUK, 2006a; DUK, 2005a; DUK, 2005b; DUK, 2008). DUK have joined the campaign advocating the importance of talking therapies described in chapter one (Mental Health Foundation, Mind, Rethink, The Sainsbury Centre for Mental Health & Young Minds, 2006) and advocates that all self-management, education and empowerment programmes should comprise components targeting E&P need (DUK, 2007c). Indeed, as reported in chapter one provision of E&P support is a diabetes NSF standard.

Table 6 Patient surveys identifying an unmet need for E&P support in diabetes

Year	Survey	Finding
2005	Diabetes Dialogue[38]	A lack of E&P support available is a significant gap in the provision of diabetes services.
2006	Diabetes Listening Project 2[39]	At diagnosis 40% report receiving E&P support but 36% reported wanting and not receiving this.
2006	Health Care Commission diabetes patient survey[40]	3% expressed a need for specialist psychological support yet only 53% received this.
2006	DUK Membership Survey[41]	48% reported receiving emotional support and 4% expressed a need for specialist psychological support yet 51% could not access this.
2006	A UK service development consultation in diabetes[42]	Access to psychological support was the most requested priority (identified by 36% of responders), and people that wanted to talk about emotional problems were those experiencing significant depressive symptoms.
2009	DUK Membership Survey[43]	42% of members report wanting to talk primarily to their HCP, of which 74% were able to do so.

Recent changes in UK clinical practice with respect to E&P support in diabetes

These imperatives have spurred endeavours to improve service delivery. In addition to the introduction of the QoF indicators for depression in LTPCs including diabetes, the NICE guidelines for the treatment of depression in LTPCs and the IAPT programme (described in chapter one), NHS Diabetes have published a commissioning toolkit which outlines a means of integrating E&P support into diabetes services (NHS Diabetes, 2009). Moreover, NHS Diabetes and DUK have established an E&P Working Group, which has developed an evidence-based model of E&P support that can be integrated into diabetes services. This is based on a five level pyramid model of E&P need in diabetes, illustrated in Figure 14, in which there is an inverse relationship between the prevalence and severity of need with the latter determining the intervention required (NHS Diabetes & DUK, 2010).[44]

[38] DUK (2005a).
[39] DUK (2006b).
[40] Health Care Commission (2007).
[41] DUK (2007b).
[42] Davies, Dempster & Malone (2006).
[43] DUK (2009b).
[44] The researcher was a member of the working group from 2008 to 2009, and contributed much of the evidence synthesis contained within the report. This is acknowledged in the report (NHS Diabetes & DUK, 2010).

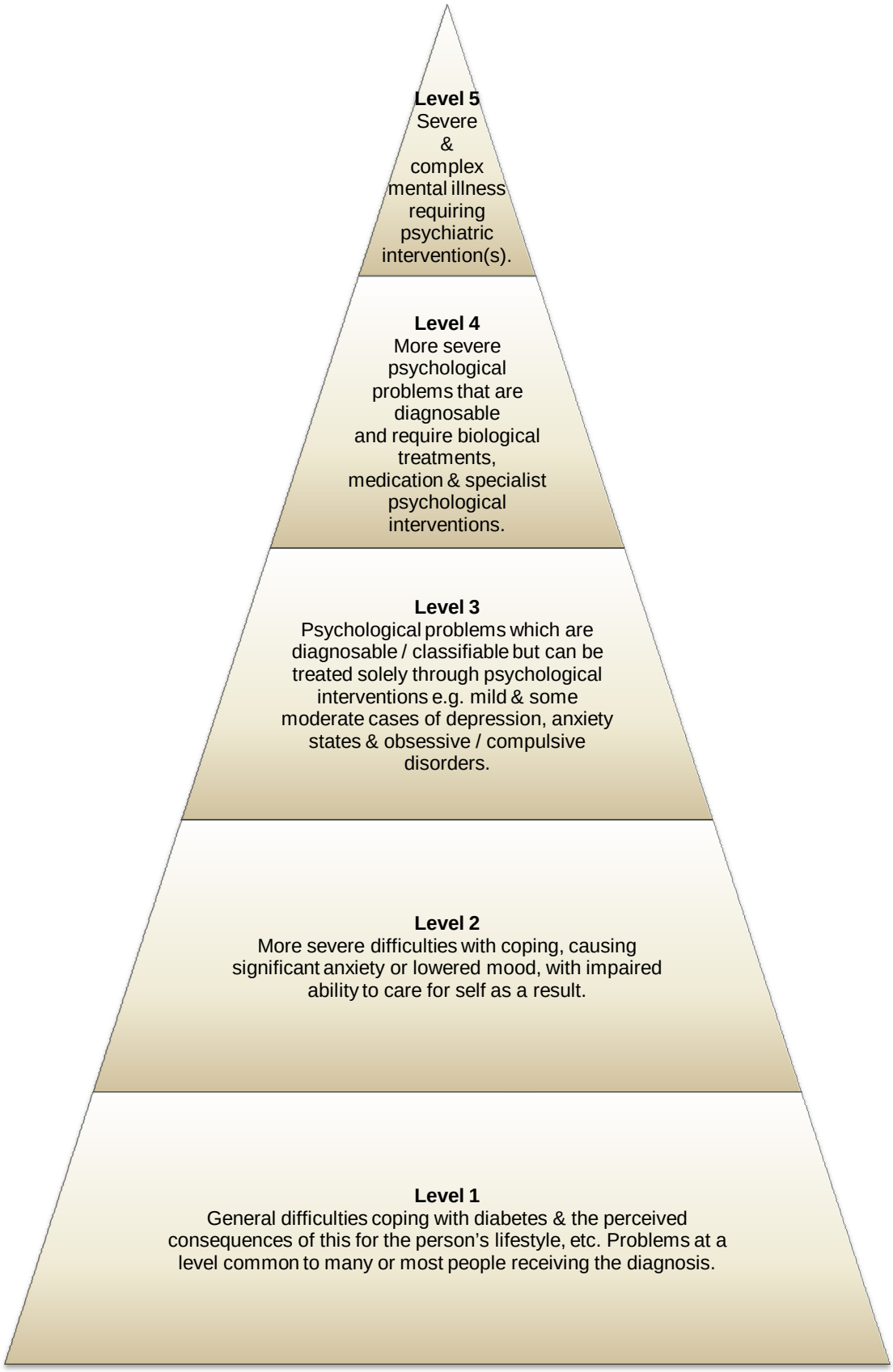
WED and depression in diabetes

WED is appropriate specifically in diabetes

SMBs are particularly important in diabetes and owing to its simplicity WED presents minimal interruption to these, which is important given the interruption already imposed by depression. WED also overcomes HCPs lack of confidence in addressing E&P need and provides a means of empowering patients to meet the substantial day to day demands they face. WED is also consistent with the service model proposed by NHS Diabetes and DUK (2010); it is a low-intensity psychological intervention that may provide a means of serving the large proportion of people with diabetes and lower-level E&P need.

It is important to note that there are some reasons why WED may not be appropriate for use with the diabetes population in the UK. Firstly, diabetes is particularly prevalent in ethnic minorities, for example South Asians (DUK, 2009). WED is apparently likely to be culturally acceptable; as discussed in chapter nine WED has demonstrated improvements across samples that are heterogeneous on ethnicity, and there is evidence that it may be particularly effective for ethnic minorities perhaps as the privacy of WED may offer an acceptable means of disclosure (Lu & Stanton, 2010). However, WED may be pragmatically inappropriate for such individuals as English is not their first language and they may not possess sufficient English writing ability. In these instances it would be necessary adapt WED for ethnic minorities, yet this was beyond the scope of the present study.

Figure 14 The NHS Diabetes and DUK E&P Working Group pyramid model of E&P support in diabetes



WED is also likely to be pragmatically inappropriate for individuals with very advanced medical complications, for example individuals with advanced retinopathy and those hospitalised for more severe nephropathy (i.e. receiving dialysis or a kidney transplant), CAD and stroke. WED should additionally not be implemented for individual with more severe psychological problems (as discussed in chapters two and three), yet the literature suggests that significant depression is prevalent in diabetes (discussed in chapter one and above). These issues must be reflected in the study exclusion criteria (discussed below).

WED may be specifically effective in diabetes

As described in earlier chapters, illness-related stressors and general/illness-related distress are associated with depression in LTPCs, thus targeting this may optimise improvement in depression. WED targets emotional aspects of stressors and presumably distress, consequently improvement in depression may be optimised. Specifically in diabetes, diabetes-related emotional problems and thus DSED are prevalent. In the UK, 81% of primary care patients report 'some degree' of DSED (West & McDonald, 2002), and at least one serious emotional problem is reported by 60% of patients seen in diabetes clinics (Polonsky, Anderson, Lohrer, Welch, Jacobson, Aponte & Schwartz, 1995). The emotional problems most frequently relate to worry about high blood sugar, hypoglycemia and the risk of future complications (Delahanty et al, 2007; Hermanns, Kulzer, Krichbaum, Kubiak & Haak, 2006; Kokoszka, Pouwer, Jodko, Radzio, Mućko, Bienkowska, Kuligowska, Smoczynska & Skłodowska, 2009; Polonsky et al, 1995; Snoek, Welch, Pouwer & Polonsky, 2000; Welch, Jacobson & Polonsky, 1997; West & McDonald, 2002) and feeling guilty when getting off track with diabetes management (Delahanty et al, 2007; Hermanns et al, 2006; Polonsky et al, 1995; Pouwer, Skinner, Pibernik-Okanovic, Beekman, Cradock, Szabo, Metelko & Snoek, 2005; Snoek et al, 2000; West & McDonald, 2002).

As mentioned in chapter one, a large body of research has also demonstrated that DSED is associated with depression; DSED is more common in patients with high levels of depressive symptoms compared to those with low levels (Adriaanse et al, 2008; Connell et al, 1990; Fisher, Skaff, Mullan, Arean, Mohr, Maharani, Glasgow & Laurencin, 2007; Hermanns et al, 2006; Lee, Chiu, Tsang, Chow & Chan, 2006; Polonsky, Fisher, Earles, Dudl, Lees, Mullan & Jackson, 2005; Pouwer et al, 2005; Gonzalez, Delahanty, Safreb, Meigs & Grant, 2008a; Kokoszka et al, 2009; Zhang, Ye & Deng, 2006; Zhang, Tse, Ye, Lin, Chen & Chen, 2009). In fact, as also described in chapter one, a bi-directional relationship between DSED and depression is likely. Indeed, it is acknowledged specifically in diabetes that interventions that target DSED may also improve mood (Pouwer et al, 2005; Kokoszka et al, 2009; DUK, 2006a; DUK, 2007c) and the unacceptable absence of RCTs testing this assumption is noted (Pouwer, 2009).

It is additionally noteworthy that should it improve both DSED and depression, WED would also address two independent influences on important outcomes maximising any improvement in them (Polonsky et al, 1995). Indeed, DSED has an adverse impact upon SMBs and clinical outcomes (i.e. HbA1c and complications) (Nakahara, Yoshiuchi, Kumano, Hara, Suematsu & Kuboki, 2006; Nichols, Hillier, Javour & Brown, 2000; Pouwer et al, 2005), which is independent of the impact of depressive symptoms (Fisher et al, 2007) and MDD (Fisher et al, 2008). In fact, it is agreed DSED and depressive symptoms are related yet independent constructs with both shared and different relationships with diabetes endpoints (Gonzalez et al, 2008a).

There are additional reasons to believe WED may be effective in diabetes. Some research suggests people may inhibit their diabetes (i.e. do not discuss their

condition/feelings with others), which is associated with depression (Cheng & Boey, 2000; Lee et al, 2006). These studies were, however, conducted in China, thus cultural differences somewhat limit generalization to the UK.

Indeed, two unpublished dissertations from the USA investigating WED have reported fewer incidences of physical illness and fewer depressive symptoms, but no effect on glycaemic control, in Type 1 diabetes (Bodor, 2002), and a trend for decreased DSED and improved well-being in seniors with Type 2 diabetes (Taylor, 2001). However, owing to small samples and thus potentially unstable effects/inadequate statistical power, the effect of WED for adults with diabetes is unclear. Furthermore, these studies were conducted in the USA and may have suffered compromised blinding as identified in chapter three, which advocated that UK studies are needed. It is also important to identify the effect of WED across the entire age range of adults with Type 2 diabetes. Finally, these studies did not report on feasibility, nor identify moderators and mediators of effects, mechanisms of change and cost-effectiveness.

Piloting WED for improving depression in Type 2 diabetes

It is more appropriate to investigate WED for improving depression in Type 2 rather than Type 1 diabetes. These conditions differ in their aetiology, onset, course and treatment requirements and should not be considered as a whole. In Type 2 diabetes, depressive symptoms are more persistent (Peyrot & Rubin, 1999) and have a stronger association with DSED (Aikens, Perkins, Piette & Lipton, 2008). Furthermore, WED for adults with LTPCs was of interest and examined in the systematic review, and Type 2 diabetes affects the majority of adults with diabetes in England (90%) (Forouhi, Merrick, Goyder, Ferguson, Abbas, Lachowycz & Wild, 2005). Targeting individuals with Type 2 diabetes may derive an older study

population. There is little evidence that age moderates WEDs effects (Frattaroli, 2006). Moreover, as described above a preliminary WED trial in seniors with Type 2 diabetes identified trends for beneficial effects (Taylor, 2001). However, WED may not be pragmatically appropriate for those with age-related difficulties with writing.

Piloting WED for improving depression in established Type 2 diabetes

WED should be piloted for patients six months post Type 2 diabetes diagnosis. Research has suggested distress and depression emerge in diabetes once people have realised its implications and have begun to experience long-term complications, whereas those with a new diagnosis are still accessing information and relatively naive to the condition (Tellez-Zenteno & Cardiel, 2002; West & McDowell, 2002). Indeed, within the first six months people with diabetes are still relatively well-supported by the NHS.

Piloting WED for lower-level depression in Type 2 diabetes

WED should be piloted specifically for lower-level depression in Type 2 diabetes. Chapter three identified that patients should be experiencing lower-level negative affect. This is consistent with the appropriate clinical application of WED, and as such would enhance the applied relevance of trials whilst importantly protecting patient safety. It would also potentially optimise effectiveness. This is additionally warranted because, consistent with the evidence reported in chapter one and above, the diabetes evidence base suggests lower-level depressive symptoms are particularly prevalent, have a significant impact, are a national priority and whilst access to low-intensity E&P support has improved some barriers persist. This is discussed in more detail below.

Prevalence

Having diabetes significantly increases, and potentially doubles, the risk of having lower-level depression (Almawi, Tamim, Al-Sayed, Arekat, Al-Khateeb, Tutanji & Kamel, 2008; Lin & Von Korff, 2008), and the risk of incident lower-level depression, controlling for past history of depression preceding diabetes (Aarts, van den Akker, van Boxtel, Jolles, Winkens & Metsemakers, 2009). Prevalence rates from cross-sectional studies of lower-level depression in diabetes are presented in Table 7. A distinction is made for the method of depression assessment as this has varied greatly between studies such that the estimates represent different operationalisations and severities of lower-level need; some have applied diagnostic clinical interviews (i.e. ICD-10/DSM-IV criteria) while others have employed various self-report symptom measures and thresholds, which tap slightly different conceptualisations of lower-level depressive symptoms, and others have combined these approaches. Studies have also varied on a number of characteristics that may further explain the variation in estimates (see chapter one for examples). In fact, lower-level depressive symptoms are a known precursor of more severe symptoms (Judd, Akiskal & Paulus, 1997; Kessler, Zhao, Blazer & Swartz, 1997), the progression of which must be prevented in diabetes (Hermanns et al, 2006).

Impact

Cross-sectional evidence indicates that in diabetes lower-level depressive symptoms have an adverse effect upon self-care (Ciechanowski, Katon, Russo & Hirsch, 2003; Ciechanowski, Katon & Russo, 2000; Egede, Ellis & Grubaugh, 2009; Gonzalez et al, 2007), symptom reporting (Ciechanowski et a, 2003), disability (Von Korff, Katon, Lin, Simon, Ludman, Oliver, Chiechanowski, Rutter & Bush, 2005), complications (Katon et al, 2004a), and early mortality (Ismail et al, 2007; Katon et al, 2005; Zhang et al, 2005). Prospective studies are few yet suggest an increased

risk for incident long-term complications, disability and mortality along a gradient wherein increasing symptoms confers a greater risk (Black et al, 2003).

Table 7 Prevalence of lower-level depression in diabetes

Depression assessment method	Prevalence
Diagnostic clinical interview	Minor depression: 8.1%; Dysthymia: 9.2%[45]
Symptom measures incorporating DSM-IV diagnostic criteria	Minor depression: 7.9% to 8.5%[46]
Scoring above threshold for significant symptoms on symptom measures but not MDD by diagnostic clinical interviews	19 to 24%[47]
Scoring below threshold for significant depressive symptoms yet above an arbitrary lower threshold on various symptom measures	Minimal/mild symptoms: 12.3% to 19.7%; mild to moderate or moderate symptoms 6% to 8.5%[48]
Scoring below threshold for significant depressive symptoms but not scoring as having no symptoms on various symptom scales (i.e. at least some depressive symptoms)	64%[49]

Current provision of low-intensity E&P support

It is also apparent that access to E&P support is particularly limited for lower-level depression in diabetes. As described in chapter one, antidepressants are not advocated and have limited effectiveness for lower-level depressive symptoms in diabetes, whereas the low-intensity psychological intervention recommended has improved outcomes. However, in diabetes people with minor depression are more likely to experience a poorer quality of care than those with MDD (Egede et al, 2009). Indeed, diabetes service teams report needing help with this level of E&P

[45] Ismail, Winkley, Stahl, Chalder & Edmonds (2007); Larijani, Bayat, Gorgani, Bandarian Akhondzadeh & Sadjadi (2004).
[46] Katon, Von Korff, Ciechanowski, Russo, Lin, Simon, Ludman, Walker, Bush & Young (2004a); Katon, Rutter, Simon, Lin, Ludman, Ciechanowski, Kinder, Young & Von Korff (2005); Li, Ford, Strine & Mokdad (2008); Lin, Heckbert, Rutter, Katon, Ciechanowski, Ludman, Oliver, Young, McCulloch & Von Korff (2009).
[47] Kokoszka et al (2009); Hermanns, Kulzer, Krichbaum & Haak (2005); Hermanns et al (2006).
[48] Black, Markides & Ray (2003); Collins, Corcoran & Perry (2009); Egede et al (2009); Lloyd, Dyer & Barnett (2000); Ruddoch, Fosbury, Smith, Meadows & Crown (2010); Yu, Y-Hua & Hong (2010).
[49] Gonzalez, Safren, Cagliero, Wexler, Delahanty, Wittenberg, Blais, Meigs & Grant (2007).

need for which reported referral pathways are especially lacking (DUK, 2008). Moreover, policy documents advocate lower-level E&P need is as important to treat as more severe manifestations, yet is usually afforded less consideration (DUK, 2008; NHS Diabetes & DUK, 2010). Again, IAPT has likely improved the situation yet there is still work to do (see chapter one).

Ensuring inclusion of participants with lower-level depression

The study selection criteria should therefore ensure that participants with lower-level depression are included. To achieve this, it could be required that primary care patients have screened positive to the QoF depression-screening questions within the previous 12 months. This data is routinely obtained in general practice (described in chapter one). This 'ultra short' instrument was developed as previously validated tools are too cumbersome and time consuming to be feasibly implemented in primary care (Mitchell & Coyne, 2007). The questions were taken from the Primary Care Evaluation of Mental Disorders (PRIME-MD) designed to facilitate the identification of common mental disorders in primary care (on which the PHQ-9 is based). A positive screen is a yes response to either of the two questions, which ask about depressed mood and anhedonia (i.e. loss of interest or pleasure in doing things). These questions are employed because according to DSM-IV criteria the essential feature of MDD is a period of at least two weeks during which there is either of these symptoms; they are designed to inform on DSM-IV criteria based psychiatric diagnosis (Whooley, Avins, Miranda & Browner, 1997).

As noted in chapter one, NICE recommends screening for depression in at risk groups and suggests that this can be achieved with these two screening questions, albeit no specific evidence is cited (Mitchell & Coyne, 2007). Consequently, validation studies have since examined whether this case-finding instrument can

accurately detect depression in primary care. Studies in which the QoF questions were self-administered (Spitzer, Williams, Kroenke, Linzer, deGruy, Hahn, Brody & Johnson, 1994; Whooley et al, 1997) and administered verbally by GPs (Arroll, Khin & Kerse, 2003) have reported high sensitivity for detecting MDD (86-97%) compared to diagnostic clinical interview. Negative predictive values have also been high (98 and 99%) and likelihood ratios for a negative test low (.05 and .07), suggesting that depression is highly unlikely for those responding negatively. Such studies have thus concluded that the questions are sufficient as they detect most cases of depression.

However, these studies additionally report only reasonable specificity (57-75%), and importantly they consistently demonstrate low positive predictive values (18 and 33%) and relatively low likelihood ratios for a positive test (2.2 and 2.9) compared to diagnostic clinical interview (Arroll et al, 2003; Spitzer et al, 1994; Whooley et al, 1997). Thus most of those screening positively are not actually depressed, and may be inappropriately treated or referred should these questions be relied on alone. This is an important limitation because in primary care where screening is widespread such a high rate of false positives would be unmanageable, over-treatment is a current concern, and there is the added complication that the additional symptoms identified for false positive individuals must also be dealt with (Gilbody, Richards, Brealey & Hewitt, 2007; Mitchell & Coyne, 2007). Indeed, a relatively recent systematic review of two and three item 'ultra short' screening instruments including the QoF questions identified that at best they provide a means of ruling out depression (i.e. they are adequate only for this purpose) (Mitchell & Coyne, 2007). It is hence widely advocated that these questions should only be employed when there are sufficient resources to follow up positive screening results with a more accurate case finding instrument (Arroll et al, 2003; McManus, Pipkin & Whooley, 2005; Mitchell & Coyne, 2007; Whooley et al, 1997).

The diagnostic accuracy of the QoF questions for identifying depression specifically in LTPCS, and for additionally identifying lower-level depression (i.e. any disorder rather than only MDD) has not been established (Mitchell & Coyne, 2007). Nonetheless, this criterion could be implemented as it is anticipated this would identify patients with both lower- and higher-level depression. However, due to feasibility issues associated with this criterion it had to be removed early in the recruitment phase of the present trial, the reasons for which are described in detail in chapter six.

Piloting recruitment approaches

The effect of WED for adults with Type 2 diabetes in primary care was of interest as this is where the majority of those with Type 2 diabetes, and indeed those with lower-level depression, are managed. As described in chapter one, there are now policy imperatives in LTPCs that advocate a shift in delivery of mental health care to primary care. However, numerous recruitment problems were encountered in primary care, thus recruitment was also piloted in secondary care and then in support groups owing to further recruitment problems experienced in secondary care (discussed in chapter six).

This was considered justified as WED has been implemented in support groups for LTPCs including Type 2 diabetes (i.e. online and local meetings) (Craft, 2006; Possemato, 2007; Taylor, 2001), primary care (Hannay & Bolton, 1999; Klapow et al, 2001) and secondary care LTPC clinics (Morgan et al, 2008; Taylor et al, 2003), demonstrating acceptability, feasibility, benefits and no apparent adverse effects. Moreover, it is advocated that RCTs should widen their selection criteria and include more heterogeneous samples to enhance their external validity and applied

relevance (Coates, 2010; Glasgow, 2008; Nezu & Nezu, 2008). Such participants represent the continuum of lower-level E&P need; presumably better adjusted individuals (e.g. support seeking individuals and patients managed in primary care) to those with more diabetes-related problems (e.g. secondary care patients). These three distinct routes to accessing participants should therefore be piloted.

The recruitment approaches adopted by the studies that were included in the systematic review were considered in terms of identifying the most appropriate and efficient strategies. The recruitment strategies employed by the included studies are reported within the data extracted for the individual studies (again presented in the appendix). The studies typically recruited in secondary care and support group contexts. The studies that reported the largest initial samples sizes (i.e. ≥90 randomised participants) were a) those that recruited in outpatient clinics where the consultant either provided patients with the study information or referred them to the study which was followed up by researchers (Cohen et al, in preparation; Gellaitry et al, 2010; Zakowski et al, 2004), and b) those that advertised the study in a disease-specific charitable organisation newsletter and presented the study information to disease-specific support groups (Hamilton-West & Quine, 2007). The studies that reported the smallest initial sample sizes (<50 randomised participants) were those that recruited in outpatient clinics yet researchers approached patients (Rosenberg et al, 2002), who were occasionally identified by consultants (Wetherell et al, 2005). Other relatively successful strategies (i.e. from studies that recruited >70 to <90 participants) included advertising the study on disease-specific online resources (Low et al, 2010).

It is noteworthy that some of the studies included in the systematic review employed community based recruitment methods amongst other methods, for example mass media advertisements (Norman et al, 2004) and advertisement in a local newspaper

(Vedhara et al, 2007) with some success (i.e. approximately 60 participants). However in response to the recruitment problems experienced in primary then secondary care, support groups were attempted initially given that the studies included in the systematic review suggested this to be a potentially successful recruitment context. An attempt at recruiting in the community was then not feasible within the time scale for the study.

Consequently, the present study sought to employ the successful recruitment strategies identified; consultants introducing the study to patients in secondary care rather than having the researcher be the first point of contact, and advertising the study on disease-specific online resources, in disease-specific charitable organisation newsletters and presenting the study information to disease-specific support groups. This was achieved with variable degrees of success owing to the recruitment and feasibility issues identified. These issues are again reported in chapter six, and the final methodology that was employed is reported in chapter five.

None of the studies included in the systematic review were executed specifically in primary care. Consequently for primary care the recruitment strategy was adapted from that employed in other WED studies undertaken in primary care and other areas of primary care research. In a WED feasibility study undertaken in primary care clinics in the USA, patients were identified in consultation by their HCP and then recruited by a project manager with minimal refusal reported (n=45), albeit this study offered a financial reimbursement to patients for participation (Klapow et al, 2001). An Israeli study of an ED intervention based on WED in primary care had physicians recruit patients directly, and again reported minimal refusal (n=50) (Gidron, Duncan, Lazar, Biderman, Tandeter & Shvartzman 2002). However, a UK feasibility study of therapeutic writing in primary care in which GPs similarly directly recruited patients, reported that four GPs recruited 23 patients while two failed to

recruit any owing to an inability to complete the additional study-related paper work given non-study related workload, an inability to integrate recruitment into their consulting pattern, and a concern about intruding on patients. GPs also reported reservations of opening up issues with which it would be difficult to deal (Hannay & Bolton, 1999).

In contrast, a primary care study of an ED intervention based on WED in the Netherlands recruited by means of an initial mass mail out of a screening questionnaire, and recruited a more substantial number of eligible patients despite significant loss during screening (n=161) (Schilte, Portegijs, Blankenstein, van der Horst, Latour, van Eijk & Knottnerus, 2001). Consequently, the most appropriate and likely effective approach in primary care was deemed to be a mass mail out. This was also the most time and cost efficient means of practices identifying participants.

This strategy is consistent with other diabetes studies, namely epidemiological depression studies and psycho-social intervention studies undertaken in primary care, including in the UK, which have recruited high numbers of participants (Katon et al, 2004a; 2005; Sturt et al, 2008). Incidentally, it is also in accordance with recent UK guidelines to assist recruitment in primary care published by the NIHR School for Primary Research and Primary Care Research Network (PCRN) (NIHR & PCRN, 2010).

Intervention and comparison exposure

Piloting WED instructions

Participants should receive the original WED instructions (Pennebaker & Beall, 1986), which entail writing about thoughts and feelings about the most traumatic

experience in life, in an attempt to resolve some of the heterogeneity in the implementation of WED which currently plagues the evidence base and its interpretation (discussed in chapter two). Many WED studies have employed these instructions reporting benefits and no apparent adverse effects (reported in chapter two), which are in fact more acceptable to patients with elevated levels of depression than currently implemented interventions in terms of attrition rates (Stice et al, 2006).

Identifying an appropriate control group task

The control group should engage in a neutral writing activity (i.e. time management), without discussing thoughts or feelings. This is consistent with the majority of the studies included in the systematic review (see chapter three). Patients with a LTPC report that the standard time management task is not experienced negatively (Byrne-Davis et al, 2006). This offers face validity as meaningful task to protect blinding (Nezu & Nezu, 2008) and distinguishes writing from content (Smyth & Helm, 2003). WED compared to no active treatment was appropriate for establishing whether it can deliver 'any' benefit and because there was no sensible treatment comparison. Whilst effective treatment must not be withheld from patients with depression in RCTs (Rifkin, 1999; Shorr & Miller, 1999), this is justified where no patients are experiencing substantial depression and given that it is not known whether WED is effective in this context. Nonetheless, usual care and treatment seeking should not be restricted in any way.

Piloting writing parameters

Both groups should write at home for 20 minutes on three days over the course of one week. This is consistent with the majority of the studies included in the systematic review (see chapter three). Writing at home also offers greater ecological

validity as it is anticipated WED would be implemented in this way. Studies have typically employed three or four 15-20 minute sessions with no evidence of differential benefit (Frattaroli, 2006). Writing has usually been over consecutive days, however there is no evidence that one week is less effective (Sheese, Brown & Graziano, 2004) and some indication it may be more effective (Smyth, 1998). Importantly, WED should be adapted to the constraints of a situation (i.e. reducing participant burden) (Smyth & Helm, 2003; Klapow et al, 2001). Consistent with the original paradigm and the parameters that apparently derive greatest benefit (Baikie & Wilheim, 2005; Frattaroli, 2006), patients should write in private, switch topics across sessions if desired, impose their own structure with minimal examples provided and write continuously with repetition if necessary and no regard for spelling or grammar.

Importantly, participants should self-select the disclosure topic. It is advocated that the content of writing is unimportant, rather exploration of thoughts and feelings is key (Pennebaker, 2000), and benefits are apparently observed in WED whether a LTPC or unrelated topics are disclosed (Baikie & Wilheim, 2005). Indeed, this seemed to be the case in the systematic review. Self-selection additionally facilitates universal coverage of the wide range of personally salient diabetes-related stressors (see chapter one) and diabetes-related emotional problems (discussed above) associated with depression. It is noteworthy that should non-diabetes-related stressors be disclosed, an improvement in DSED and depression can still be anticipated because general stressors/stress are associated with incident DSED (Fisher et al, 2009) and depression in diabetes independent of the influence of diabetes-related stressors (Fisher, Chesla, Mullan, Skaff & Kanter, 2001). In fact, person centred interventions, which address the full spectrum of stressors impacting on depression in diabetes are advocated (Fisher et al, 2001).

Piloting the mode of disclosure

Handwriting is consistent with the majority of the WED evidence base, and certainly the studies included in the systematic review where the mode of disclosure was reported. Logically, it seems that handwriting would slow people down and facilitate proper processing. However, it seems there are only subtle differences between handwriting and typing. Recent studies have delivered WED by email, reporting benefits and no apparent negative effects (Sheese et al, 2004) and demonstrating acceptability to patients (Johnston et al, 2010). Moreover, no moderating effect of handwriting versus typing has been identified (Frattaroli, 2006).

Piloting the approach to intervention delivery

Intervention delivery should be by post or email as personal contact and extensive discourse with the researcher risks additional intervention, influences from experimenter expectancies/bias, compromised blinding, treatment diffusion and pre−disclosure priming (Nezu & Nezu, 2008). This is typical in WED studies and consistent with the likely implementation of WED, thus enhancing the applied relevance of the trial (Coates, 2010).

Identifying and estimating the anticipated effect: preliminary effectiveness analysis

Piloting the outcome specification

Pennebaker (2004) argues WED research should adopt the 'taxpayer's perspective' investigating economically relevant outcomes (e.g. physical health, health behaviours and HCU). However, psychological outcomes such as QoL are important to patients (Ghandi, Murad, Fujiyoshi, Mullan, Flynn, Elamin, Swiglo, Isley, Guyatt & Montori, 2008), and ultimately represent the way in which physical symptoms are negatively experienced (Kaplan, 1990).

Primary outcome

Depressive symptom severity should be the primary outcome, because as described in chapter one and above, depression is a significant problem in diabetes and a national health care objective, with an adverse effect on economically relevant outcomes. Importantly, the systematic review suggested WED may improve depression. Depressive symptom severity is specifically appropriate because measures of this were employed in the studies that examined depression in the systematic review (see chapter three). Moreover, given that WED should be implemented for lower-level depression; MDD is not applicable. In fact, elevated depressive symptoms are actually more prevalent, persistent and potentially more related to diabetes endpoints (i.e. SMBs and HbA1c) than MDD in Type 2 diabetes (Fisher et al, 2007; Fisher, et al, 2008). It is noteworthy that assessment of sub-threshold and minor depressive disorders is additionally not appropriate because the gold standard for identifying depressive disorder, diagnostic clinical interview based on DSM-IV criteria (Lustman, Harper, Griffith & Clouse, 1986), is expensive and requires administration by trained professionals.

Secondary outcomes

DSED should be a secondary outcome. As above, WED is anticipated to be specifically effective in diabetes because it targets emotional aspects of stressors and presumably DSED, which are associated with depression. Consequently, improvement in depression may be optimised. However, the systematic review reported in chapter three identified an effect of WED on negative affect yet not distress, which has additionally been observed in non-LTPC samples. It was therefore advocated that whether WED targets distress and thus improves depression via a concurrent reduction in this in LTPCs should be clarified. Whether WED can reduce DSED is also worthy of investigation. As discussed above, DSED

is prevalent in diabetes and it has an independent adverse effect on economically relevant outcomes. Despite this, however, screening for DSED is not a QoF indicator, neither is it addressed in the NICE guidelines. Occasionally, the Problem Areas in Diabetes (PAID) scale which assesses DSED is employed in clinical practice, but this is not an enforced standard. Indeed, DSED is less likely treated than depression in diabetes (Fisher et al, 2007).

Health-related QoL and diabetes SMBs should additionally be secondary outcomes because, as described in earlier chapters and above, they are adversely impacted by high and low-level depression in diabetes, thus improving depression, even at lower levels, may produce improvements in these associated outcomes. Indeed, low- and high-intensity depression treatment has produced concurrent improvements in these outcomes, albeit again as described in earlier chapters, whether these changes are related to improvement in depression is unclear.[50] Furthermore, the systematic review identified that WED may improve health-related QoL and it is unclear whether WED may influence SMBs in LTPCs (health behaviour change theory; chapter two).

Piloting outcome measures

Selection of measures was informed by relevance to theory, practice and research, and minimising participant burden. The European Depression in Diabetes (EDID) Research Consortium is an internationally represented group committed to achieving consensus on issues relating to depression in diabetes, which

[50] It was initially intended that HbA1c would be included as an outcome measure for this reason, and because WED has been demonstrated to produce clinically significant changes in physiological parameters in LTPCs (Smyth et al, 1999; see chapter two). However it was considered unlikely that any change over a three to 12 month period could be attributable to WED and in general practice HbA1c is routinely checked six monthly or annually. Another outcome that was intended to be included was HCU, but this had to be removed owing to delays experienced in implementing the study (reported in chapter five)

recommends use of a number of key measures (EDID, 2011). These were employed wherever possible.

Primary outcome

Depressive symptom severity should be measured with the CES-D. This was amongst the measures used to assess negative affect within the systematic review (see chapter three). This assesses current level of depressive symptoms, with an emphasis on the affective component of depressed mood (Radloff, 1977). It has 20 items scored on a Likert scale. A total score is derived, with scores ranging from 0-60 and higher scores representing more symptom severity. The CES-D has demonstrated content, concurrent and discriminant validity, and sensitivity to change resulting from psychotrophic medication in community, depressed and psychiatric samples (Weismann, Sholomskas, Pottenger, Prusoff, & Locke, 1977). The CES-D has been validated in Type 2 diabetes (Fisher et al, 2001), and internal and test-retest reliability have been demonstrated in LTPCs (Devins, Orme, Costello, Binik, Frizzell, Stam & Pullin, 1988)

Unlike other measures of depressive symptom severity scores are not confounded by physical symptoms related to LTPCs (Devins et al, 1988), at no cost to predictive efficacy in diabetes (McHale, Hendrikz, Dann & Kenardy, 2008; Peyrot & Rubin, 1997). The CES-D is a core EDID measure that is consistently employed in diabetes studies. Moreover, both general and diabetes-related stressors and DSED, which are purportedly targeted by WED, have specifically been demonstrated to be related to depressive symptom severity measured via the CES-D (Fisher et al, 2001; Fisher et al, 2007). It was therefore selected over the plethora of alternative depressive symptom severity measures available, including those derived from DSM-IV criteria (i.e. the BDI and PHQ-9). In fact many of the alternative depressive

symptom severity measures are typically employed for screening purposes or must be purchased (i.e. the BDI).

Secondary outcomes

DSED could be measured with the PAID Scale (Polonsky et al, 1995). This taps the extent to which emotional responses to diabetes (i.e. negative emotions, treatment-related problems, food-related problems and lack of social support) are currently problematic. It has 20 items scored on a Likert scale. A total score is calculated and transformed to scale of 0-100, higher scores indicating more DSED. In diabetes, the PAID has demonstrated internal (Polonsky et al, 1995; Welch et al, 1997) and test-retest (Snoek et al, 2000) reliability, concurrent, convergent (Polonsky et al, 1995; Snoek et al, 2000; Welch et al, 1997) and discriminant validity (Snoek et al, 2000; Welch et al, 1997), and responsiveness to change (Welch, Weinger, Anderson & Polonsky, 2003). This is an EDID core measure that has been more widely employed in diabetes studies than alternatives.

Health-related QoL should be measured with the EuroQoL (EQ-5D). This taps five dimensions relevant to health-related QoL (i.e. mobility, usual activities, pain, anxiety/depression and self-care). For each, people rate their agreement with three statements representing different levels of severity in relation to their health state that day (i.e. no problems, some problems or severe problems). Responses are converted to a utility index by applying a formula in which a weight is attached to the level indicated for each dimension, these weights having been derived from valuations of each level for each dimension from the general population. A maximum score of 1 can be derived (i.e. no problems for any dimension). Respondents also indicate their current health state on a visual analogue scale (VAS) ranging from 0 (worst possible state) to 100 (best possible state). Both measures have demonstrated convergent and discriminant validity with respect to

groups of patients with different diabetes-related characteristics in Type 2 diabetes (Matza, Boye & Yurgin, 2007). The EQ-5D has been used extensively in Type 2 diabetes, is brief and produces utilities used to compute quality adjusted life years (QALYS) for undertaking a cost effectiveness evaluation, which again should be considered in line with the recommendations in chapter three.

Diabetes SMBs should be measured with the revised version of the Summary of Diabetes Self-care Activities Questionnaire (SDSCA) (Toobert, Hampson, & Glasgow, 2000). This measures diabetes SMBs; general diet, specific diet, exercise, blood glucose monitoring, foot care and smoking. For the first five sub-scales people rate the frequency with which each activity was performed within the previous seven days or per week over the past month. For the additional smoking sub-scale people indicate whether they smoked cigarettes in the past seven days, and if so how many were smoked per day. In the interest of including only continuous outcome variables in analyses, however, this sub-scale should be excluded. The SDSCA has demonstrated adequate internal and test-retest reliability, sensitivity to change in relation to interventions targeting SMB change, and concurrent validity (Toobert et al, 2000). The revised scale is briefer yet contains the core and optimally performing items from the original scale (Toobert et al, 2000). This is again an EDID core measure and has been more widely employed in diabetes studies than alternatives.

Piloting the approach for preliminary effectiveness analysis

Primary outcome

ITT effectiveness analyses should be undertaken, analysing all of the participants that were randomised according to their original group assignment. This enhances statistical power and preserves randomisation avoiding bias associated with non-

random loss of participants potentially related to treatment response (Moher, Hopewell, Schultz, Montori, Gøtsche, Devereaux, Elbourne, Egger & Altman, 2010). Where some participants do not complete the intervention or follow up as intended, strict ITT analysis is not possible yet it is next best practice to impute missing observations. This should be by means of baseline observations carried forward, therefore assuming no change and providing a conservative estimate of effect as is typically employed in RCTs (Moher et al, 2010). Disappointingly few of the studies included in the systematic review adopted this approach (see chapter three).

Where baseline observations are missing these should be replaced with follow up observations, thus again assuming no change. An alternative approach is to replace missing baseline values with the mean baseline score for the same variable and group (i.e. provided the participant's follow up score was comparable to the mean at follow up for the same variable and group). However, this suppresses the true value of the SD and thus SE (i.e. for replaced cases there is no difference between the score and the mean, which is unlikely had the data been collected). This presents a serious problem when samples are small and a number of values are missing; smaller SEs may derive significant effects that are a result of imputation rather than a genuine effect (Field, 2005).

A pre-specified sensitivity analysis should then be performed to identify the validity of the ITT assumptions, which may underestimate effectiveness (Moher et al, 2010). Specifically, effectiveness analyses should be repeated with participants that provide both baseline and follow up observations (i.e. complete case analysis). Per protocol analysis is not necessary (i.e. excluding participants that did not complete the intervention), because whether participants completed the writing sessions as intended was self-report, rather the effect of offering the intervention was of interest. Instead, intervention fidelity data should be presented.

Analysis of covariance (ANCOVA) should be employed assessing the between-groups difference in depressive symptom severity at follow up, controlling for baseline depressive symptom severity (i.e. accidental bias; the chance variation between groups on this prognostic variable which if substantial enough may otherwise bias effects based on analysis of final end-point scores) (Vickers & Altman, 2001).[51] Including covariates in analysis of variance (ANOVA) additionally reduces the within-group error variance in the dependent variable (i.e. the unexplained variance). This enhances the statistical power of the F test, which compares the variance explained by the between-group effect to the unexplained variance; the effect can be more reliably determined (Field, 2005). Inclusion of additional covariates is therefore also justified, provided that they are a) not influenced by the independent variable, b) not correlated with one another thus ensuring unique adjustments and avoiding computational difficulties due to multicollinearity, and c) related to the outcome and reliably measured (i.e. maximizing the adjustment/preventing under adjustment). Age and gender would meet these criteria in diabetes and depression (Larijani et al, 2004).[52]

ANCOVA is superior to ANOVA based on change from baseline scores (Vickers & Altman, 2001). This is because, owing to regression to the mean, the latter does not actually control for chance variation between groups at baseline; baseline values are negatively correlated with change in that people with lower scores generally improve more than those with high scores (Vickers & Altman, 2001). In contrast, ANCOVA simply adjusts each score for the baseline value (i.e. the linear effects of

[51] This has been employed in numerous WED studies with LTPC samples (Danoff-Burg et al, 2006; Gellaitry et al, 2010; Hamilton-West & Quine, 2007; Low et al, 2010; Walker et al, 1999; Willmott et al, under review).

[52] Given their anticipated association with the primary outcome, age and gender are potentially related to the baseline levels of this (i.e. another covariate). However, the potential benefit of including these covariates likely outweighs the potential for an absence of unique adjustment or multicollinearity issues.

the covariates are removed before the ANOVA is performed). ANOVA is preferable to multiple regression because it is fairly robust where data are not normally distributed and it is less sensitive to small samples sizes (Field, 2005).[53]

A standardized estimate of the anticipated effect, and the associated 95% CIs, should also be derived to identify the magnitude and direction, and uncertainty, of the effect, consistent with the CONSORT guidelines for reporting parallel group RCTs (Moher et al, 2010). The effect size estimate typically derived for ANCOVA is eta squared (η^2); the proportion of the total variability in the dependent variable (i.e. the variance to be explained) that is accounted for (i.e. explained) by variation in the independent variable (Ellis, 2010; Levine & Hullett, 2002). It is calculated with the following formula (Field, 2005; Levine & Hullett, 2002):

$$\eta^2 = \frac{\text{SSm (between} - \text{groups effect)}}{\text{SSt}}$$

SPSS (version 17) also provides partial eta squared (η_p^2); the proportion of unexplained variance explained by the between-groups effect (i.e. ignoring the variance explained by other variables), which prevents underestimation of effects. It is calculated with the following formula (Levine & Hullett, 2002):

$$\eta_p^2 = \frac{\text{SSm (between} - \text{groups effect)}}{\text{SSm (between} - \text{groups effect)} + \text{SSr}}$$

However, η_p^2 artificially inflates effect size estimates compared to η^2, especially in complex ANOVA designs (Levine & Hullett, 2002). Moreover, η^2 is more easily

[53] For regression 15 participants per variable are typically recommended, however many more are actually required to reliably gauge the effect estimate (R^2) and achieve adequate statistical power when effects are small (Field, 2005).

interpreted; when there is one degree of freedom in the numerator (i.e. a focussed effect), the square root of η^2 is analogous to the Pearson's correlation co-efficient r (described in chapter five) (Ellis, 2010; Levine & Hullett, 2002), and in η^2 all components of variation sum to 1 which represents 100% of the variance in the dependent variable. Therefore η^2 can be converted to a percentage of the total variance in the dependent variable. However, η^2 is also upwardly biased, especially where samples are small; it is inflated by sampling error or rather chance/random fluctuations in the data which do not reflect the population effect, known as shrinkage (Ellis, 2010).

A corrected, unbiased estimate of η^2 is omega squared (ω^2), which adjusts for the fact that the effect is an estimate of the population effect. Specifically, ω^2 incorporates the error variance or rather the unsystematic variance explained by unsystematic factors/not explained by the model. ω^2 for ANCOVA with a single between-groups contrast is calculated with the following formula (Olejnik & Algina, 2000):

$$\omega^2 = \frac{\mathrm{SSm(between-groups\ effect)} - \mathrm{MSr}}{\mathrm{SSt} + \mathrm{MSr}}$$

Therefore ω^2 is preferable as it is the most conservative estimate, which provides the best estimate of the population effect. Ideally though all three effect sizes should be estimated (Ellis, 2010). The adjusted estimated marginal means and SEs for each group should be inspected to identify whether there is a potentially clinically important difference on the primary outcome and thus gage the applied relevance of any effect. This has been addressed in a few WED trials with LTPC samples, albeit only in relation to physical health outcomes (Broderick et al, 2004; Hamilton-West & Quine, 2007; Harris et al, 2005; Smyth et al, 1999).

Secondary outcomes

The same analytic strategy should be employed for secondary outcomes, including the same covariates to promote consistency. It is not necessary to control for the Type 1 error rate, for example by applying a Bonferroni correction (i.e. $p<.05$/number of tests) or conducting a multivariate analysis of covariance (MANCOVA), provided that the primary outcome is pre-specified and analyses for pre-specified and theoretically relevant secondary outcomes are interpreted as exploratory. In fact, the Bonferroni correction indicates whether there is less than 5% chance that the groups differ by chance on all variables measured rather than on specific variables, which is of limited utility, it means interpretation of effects is dependent on the number of variables and it increases the risk of Type 2 errors (Ellis, 2010; Perneger, 1998).

Exploratory analyses

Exploring whether WED works differently for different people as anticipated: testing anticipated moderators and piloting moderator measures

As described in chapters two and three it is important to investigate moderators of WEDs effects (i.e. variables that determine whether and to what extent WED is effective). If this is not investigated, it is not possible to use this information to optimise improvement in outcomes and effects may be missed (i.e. when effects for distinct sub-groups are essentially averaged). It is also apparent that interpersonal traits may be relevant, particularly alexithymia (i.e. an inability to process and describe emotions) and dispositional optimism (i.e. generalized expectancies for positive outcomes). However, the evidence base, particularly for optimism, is underdeveloped and requires replication in LTPCs.

Alexithymia should therefore be measured with the Toronto Alexithymia Scale (revised version) (TAS-20) (Bagby, Parker & Taylor, 1994). This has 20 items scored on a Likert scale, with three factor sub-scales; difficulty identifying feelings, difficulty describing feelings and externally oriented feelings. A total score can be derived with higher scores indicating greater alexithymia. The TAS-20 has demonstrated internal and test-retest reliability in student and psychiatric samples (Bagby et al, 1994) and convergent, discriminant and concurrent validity (Bagby, Taylor & Parker, 1994). Dispositional optimism should be measured with the Life Orientation Test-Revised (LOT-R) (Scheier, Carver & Bridges, 1994). It has 10 items scored on a Likert scale, four of which are fillers. A total score is derived for the six non-fillers, with higher scores indicating more optimism. The LOT-R has demonstrated good internal and test-retest reliability, and convergent and discriminant validity (Schieier et al, 1994).

Exploring whether WED works as anticipated: testing anticipated explanatory processes and piloting explanatory measures

As described in chapters two and three it is important to identify how WED influences health by investigating mechanisms of change (i.e. measures of intervention processes that may underlie benefits) and mediators (i.e. variables that may be changed by WED to produce benefits). If this is not investigated, it is not possible to use this information to optimise improvement in outcomes.

Mechanisms of change

Specification of mechanisms of change

As described in chapter two, it seems that WED may improve health via E&CP of stressors; reflected in an increase in words reflecting cognitive processing and

positive emotion, and a decrease in words reflecting negative emotion, across writing sessions (i.e. cognitive processing and self-regulatory approaches). The evidence for this theory is, however, under-developed, inconsistent, ambiguous, and requires replication in LTPCs. Moreover, should an overall intervention effect and these changes be observed, their absence in controls should be confirmed and whether they explain WED effects should be established in formal mediation analyses (again discussed in chapter five). This has infrequently been explored to date. It is also apparent that WED may improve health via EA&H; specifically subjective EA to the initial WED session then a reduction in this across writing sessions (i.e. exposure and self-regulatory approaches). However, the evidence for this theory is underdeveloped and inconsistent specifically in LTPCs, thus it requires replication.

Measurement of mechanisms of change

E&CP should be measured via analysis of written texts with the LIWC 2007 software (LIWC2007). This counts the number of words in a text that are included in pre-defined categories of word use within its internal dictionary, which comprises almost 4, 500 words/word stems. It derives the percentage of the total number of words that belong to each category of word use (i.e. deriving a percentage controls for the variable length of texts). Typically 80% of words in a text are identified by the dictionary. The positive emotion category includes words such as love, nice and sweet, the negative emotion category includes words such as hurt, ugly and nasty, the insight category includes words such as think, how and consider and the causation category includes words such as because, effect and hence (Pennebaker, Booth & Francis, 2007a; Pennebaker, Chung, Ireland, Gonzalez & Booth, 2007b).

LIWC analysis has consistently been employed in WED research for this purpose, from the original studies (Pennebaker & Francis, 1996; Pennebaker et al, 1997) to those including LTPC samples (Hamilton-West & Quine, 2007; Rivkin et al, 2006; Walker et al, 1999) (as reported in chapter two). The LIWC software has demonstrated internal reliability for the aforementioned categories of word use (i.e. an adequate item-total correlation between the percentage word use for a single word and the percentage word use for all other words in that category) (Pennebaker et al, 2007b; Tausczik & Pennebaker, 2010), construct validity with a similar profile of word use across emotional texts in LTPCs (Alpers, Winzelberg, Classen, Roberts, Dev, Koopman & Taylor, 2005), and concurrent (Alpers et al, 2005) and convergent validity (Bantum & Owen, 2009) in terms of good agreement with judges ratings of the degree of emotional expression in texts, with superior properties to alternative computerized coding methods (Bantum & Owen, 2009).

EA&H should be measured with the negative affect sub-scale of the PANAS (Watson, Clark & Tellegen, 1988). This is a 20 item mood adjective checklist; 10 reflect negative affect (i.e. aversive mood states) and 10 reflect positive affect (i.e. the extent to which a person feels enthusiastic, active and alert). The instructions can be changed such that people rate each adjective from 1 (very slightly or not at all) to 5 (extremely) depending on how they feel 'right then', in which format the scale is sensitive to mood fluctuations. The PANAS has demonstrated adequate internal and test-retest reliability for both sub-scales in student and psychiatric samples, and convergent and discriminant validity (Watson et al, 1988). It is often employed for measuring the short-term influence of WED on immediate negative mood and even EA&H in LTPC samples (D'Souza et al, 2008; Gillis et al, 2006; Norman et al, 2004).

Mediators

Specification of mediators

As described in chapter two, it seems that WED may deliver benefits by improvement in perceived social support, specifically emotional support, and perceived control over experiences, including self-efficacy for managing LTPCs. It is also reasonable to speculate that resolution of stressors in WED may reduce the extent to which diabetes is perceived to intrude on life (i.e. illness interference), which is different to health-related QoL as it refers to the stressors resulting from LTPCs (i.e. the disruption they cause to meaningful activities) rather than the impact of this upon perceived health status (i.e. functional health and well-being (Devins, 2010).

Indeed, cross-sectional evidence in diabetes suggests that depressive symptoms are associated with lower self-efficacy for diabetes SMBs (Sacco, Wells, Vaughan, Friedman, Perez & Matthew, 2005; Sacco, Wells, Friedman, Matthew, Perez & Vaughan, 2007), lower perceived emotional support yet not diabetes-related social support (i.e. assistance specifically with diabetes needs) (Cheng & Boey, 2000; Connell, Davis, Gallant Sharpe, 1994) and more perceived interference of diabetes with life (Bailey, 1996; Brooks & Roxburg, 1999; Cheng & Boey, 2000; Paschalides, Wearden, Dunkerley, Bundy, Davies & Dickens, 2004). In fact, structural equation modelling in such studies has demonstrated that stress is associated with depressive symptoms via greater perceived illness interference, albeit causality cannot be inferred here (Talbot, Nouwen, Gingras, Bélanger & Audet, 1999). Interventions to improve self-efficacy (Sturt et al, 2008) and social support (Huang, Song & Li, 2001) have additionally improved psychological health including depression.

However, these mediating processes have yet to be properly tested, namely should an overall intervention effect be observed in formal meditation analyses, with variables measured such that causality can be inferred; variables should be measured such that they demonstrate WED produces a change the mediator which is then related to health (again formal mediation analysis is discussed in chapter five).

Mediator measures

Self-efficacy for diabetes SMBs could be measured with the UK version of the Diabetes Management Self-efficacy Scale (DMSES UK) (Sturt, Hearneshaw & Wakelin, 2010). This assesses efficacy expectations for performing SMBs known to influence blood glucose. It has 15 items scored on a Likert scale. A total score is derived, with higher scores indicating greater self-efficacy. The DMSES UK has demonstrated internal and test-retest reliability, criterion-related and construct validity (Sturt et al, 2010), and sensitivity to change resulting from a diabetes self-management intervention in Type 2 diabetes (Sturt et al, 2008).

Perceived emotional support should be measured with the six item version of the Social Support Questionnaire (SSQ6) (Sarason, Sarason, Shearin & Pierce, 1987). Each item has two parts; the number of available others in different situations and then the degree of satisfaction with support available in each situation, each scored on a Likert scale. Total scores are derived for the two sub-scales, higher scores indicating more perceived support. The SSQ6 is briefer than the original measure yet has demonstrated a strong association with it, and each sub-scale indicates equivocal psychometric properties; it has demonstrated internal and test-retest reliability and construct validity in a student sample (Sarason et al, 1987). This is the measure of social support recommended by the EDID.

Perceived illness-interference should be measured with the Illness Intrusiveness Rating Scale (IIRS) (Lorig, Sobel, Ritter, Laurent & Hobbs, 2001). This assesses the extent to which people feel their LTPC and or its treatment interferes with meaningful activity (i.e. lifestyle, activities and interests). It has 13 items scored on a Likert scale, with five sub-scales; physical well-being and diet, work and finances, marital, family and sexual relations, recreation and social relations, and other aspects of life. A total score can be derived, higher scores indicating more interference. The IIRS has demonstrated internal consistency in Type 2 diabetes, and test-retest reliability, construct, discriminant and criterion-related validity, and sensitivity to change resulting from interventions designed to impact QoL in LTPCs (Devins, 2010).

Prior economic evaluation

As described in chapter three, the cost-effectiveness of WED in LTPCs, and indeed any sample, has yet to be investigated. Should effectiveness be demonstrated, a prior cost-effectiveness analysis should be undertaken.

Piloting the data collection schedule

Measurement of mediator variables post-intervention but preceding the outcome assessment is again required to establish mediation. Mediators should therefore be measured at two weeks post-intervention because, as described in chapter three, the evidence suggests WED effects can emerge around this time. Follow up should then be three months post-intervention, which is consistent with the original WED study (Pennebaker & Beall, 1986), the wider evidence base (Frattaroli, 2006), a substantial proportion of the trials included in the systematic review (see chapter three) and other WED trials in LTPCs indicating improvement at around this interval

which is not maintained longer-term (Broderick et al, 2005; Sloan, Feinstein & Marx, 2009).

Feasibility investigation

Piloting intervention and trial parameters

The appropriate intervention and trial parameters specified throughout this chapter should be piloted.

Investigating the feasibility/effectiveness of intervention delivery

This data is important when WED is not implemented in the laboratory and thus experimental control is attenuated. Compliance with the writing instructions should be obtained, and as patients continuing writing following completion of WED has been noted previously (Baikie & Wilheim, 2005) this should additionally be identified. Intervention fidelity, or rather contamination data (i.e. whether ED and EA are observed in the WED group only), should also be obtained, using the LIWC and PANAS data already collected. As described in chapter three, other WED studies with LTPC samples have sought intervention fidelity via measures of post-writing EA, including the PANAS-X, and or LIWC analysis of the four aforementioned categories of word use (D'Souza et al, 2008; Willmott et al, under review). The latter is recommended practice. The acceptability of the intervention and comparison exposure should also be explored (i.e. reasons for not writing as instructed and for not writing at all).

Investigating the feasibility/effectiveness of the trial protocol

In addition to identifying the feasibility/effectiveness of the randomisation and allocation concealment methods, checking blinding success and reporting on the feasibility/appropriateness of the sample size calculation (as described earlier),

estimates of and issues associated with recruitment and retention should be obtained.

Qualitative data collection

Consistent with the objectives of a phase two exploratory trial, to investigate the feasibility of and barriers and opportunities for recruitment interviews should be conducted with primary care providers whose recruitment falls outside one SD of the norm. The feasibility of implementing the intervention and the acceptability of both the intervention and control condition should additionally be examined by conducting interviews with participants. This was therefore an original objective of the thesis. However an upgrading panel, which reviewed the thesis at an early stage, advised that this be removed owing to the volume of work proposed and the time constraints of the study.

Patient safety issues and changes necessitated by ethical review

An initial application to an NHS Research Ethics Committee (REC) for the exploratory RCT based on the aforementioned methodology with recruitment in primary care was rejected (September 2008), and major revisions to the study protocol were required and resubmitted (December 2008). The ethical rejection and approval letters are presented in the appendix. Patient safety issues, the issues raised by the REC in relation to these and the changes necessitated are presented below.

REC concern 1: Exclusion of at risk participants

Original application:

As described in earlier chapters and above, the evidence suggests, and widespread clinical opinion is, that it is not appropriate to use WED unsupervised with patients

with more severe psychological problems. People experiencing significant symptoms of depression and at risk of self-harm may experience re-traumatisation as a result of engaging in WED. Exclusion of individuals for whom WED is unsuitable is therefore important, for example individuals with a psychiatric disorder, those who are acutely ill and those already receiving treatment for depression or any other psychological therapy. These exclusion criteria were presumed to be sufficient to exclude patients at risk of re-traumatisation. However, the REC felt that the screening process was not sufficiently robust to ensure exclusion of such patients (i.e. some instances of significant depression may not have already been identified and treated).

Revised application:

It was therefore acknowledged that additional inclusion criteria should be enforced such that patients are excluded if they are at risk of self-harm/suicide, or had any other psychological vulnerabilities. The need to implement an eligibility check was also acknowledged (i.e. to ensure that patients indicating significant depressive symptoms and thus at risk of re−traumatisation were excluded). Specifically, participants should complete a DSQ prior to enrolment with those scoring above a threshold for significant symptoms being excluded. A score of ≥16 on the CES-D has good sensitivity, 99%, for detecting MDD (Weismann et al, 1977). Specifically in Type 2 diabetes it provides adequate indication of significant depressive symptoms (i.e. sensitivity) (Fisher et al, 2007; Stahl, Sum, Lum, Liow, Chan, Verma, Chua & Chong, 2008) and has preferable predictive efficacy to many other self-report symptom measures (McHale et al, 2008). Similar measures have been taken in other WED trials including patients with elevated but not significant depressive symptoms (Gortner et al, 2006; Stice et al, 2006). Patients scoring as experiencing significant symptoms must then be referred to an appropriate HCP. This should be arranged with GPs when practices are recruited to the study.

REC concern 2: Potential negative emotional response to writing, or screening, and clinical support in the event of contact with patients experiencing concerns/soliciting emotional support

Original application:

Patients may develop concerns as a result of completing WED. As described in chapter two, an immediate yet mild and transient increase in negative affect is usual and necessary to produce health benefits that outweigh this. It was therefore initially intended that participants would be warned about this, advised to stop writing if they were worried about how they felt and provided with contact details of potentially helpful organisations. This is consistent with implementation of the original paradigm, WED trials with mildly depressed samples (Stice et al, 2006) and other 'at risk' samples (i.e. students screened for suicidality) (Kovac & Range, 2002), and opinion in the field (Baikie & Wilheim, 2005). It was also intended that participants would have the research teams contact details for further information about the study. However, the REC was concerned because the research team did not possess the skill to evaluate participants at potential risk; there was no clinical support in place should participants experience problems/contact the research team soliciting emotional support.

Revised application

It was therefore acknowledged that participants should additionally be encouraged to contact their GP should they experience any concerns as a result of writing, or indeed should the depression-screen (i.e. introduced post-ethical review) raise concerns or should they wish to discuss their DSQ score. This should again be arranged with GPs when practices are recruited to the study. Furthermore, participants should be encouraged to contact their GP rather than the research

team about anything other than information about the trial. However, should participants contact the research team about any other issues, a procedure must be in place for obtaining immediate clinical support from an appropriate professional. Such emergency response plans are consistent with WED trials with mildly depressed samples (Stice et al, 2006).

REC concern 3: Procedure for disclosures requiring action and disclosure of limits to confidentiality

Original application

It is possible that participants may disclose in writing information which suggests a risk to themselves or others, and requires action. It was therefore initially intended that should disclosures requiring action be evidenced in writing, for example relating to self-harm, the researcher would make a subjective judgement upon reading essays about whether to refer them to the study supervisors and then a patient safety group including appropriate professionals. Moreover, there were no plans for participants to be advised about this potential breach of confidentiality prior to providing consent. The REC was again concerned that the research team did not possess the skill to evaluate participants at potential risk, and that there was a lack of understanding of the limits to confidentiality where participants and/or others may be at serious risk of harm.

Revised application

It was therefore acknowledged that a procedure, which entails immediate consultation with appropriate professionals, should be implemented should disclosures requiring action arise. This is consistent with implementation of the original paradigm and WED studies with 'at risk' samples (Kovac & Range, 2002). It was also intended that participants would be advised prior to consent that if they

disclosed information of a certain nature in their writing, for example indicating a serious risk to themselves or others, this could be disclosed to an appropriate party.

REC concern 4: Issues surrounding previously undisclosed trauma

Original application:

Again, it was initially intended that participants would receive the original WED instructions advocated by Pennebaker and Beall (1986), which entail writing about the most traumatic experience in life. However, the REC was concerned about the research team's lack of understanding of the issues surrounding previously undisclosed trauma; they felt that these instructions may unearth serious, previously undisclosed trauma such as childhood abuse, which is not appropriate outside the clinical setting.

Revised application:

It was therefore acknowledged that it is more appropriate for participants to write about only current or very recent stressors, which is less likely to evoke serious, previously undisclosed trauma. In retrospect, the original WED studies typically involved participants writing in the laboratory and the researcher, usually Pennebaker himself, discussing the study with participants (i.e. any problems and psychotherapy options available). Moreover, as described in chapter two, some individuals in samples not necessarily defined by distress have experienced a negative response to WED when traumatic events are disclosed. Indeed, more recent studies advocate the importance of providing adequate care when people disclose about the most stressful experiences of their lives, which cannot easily be achieved when implementation of WED is by post or email and there is a loss of interaction with the experimenter (Sheese et al, 2004). It is noteworthy that implementing the original instructions but improving the adequacy of support was

not feasible in view if the limited availability of relevant clinical expertise for the present study. It is also apparent that writing about past trauma many not be important (Smyth & Pennebaker, 2008) and in fact some assert that greater benefits have been observed when current stress is disclosed, at least for samples not defined by trauma history (Frattaroli, 2006; Pennebaker, 1997; Sloan & Marx, 2004a; Smyth, 1998). Indeed, other WED trials with LTPC (Hamilton-West & Quine, 2007; Lee, 2002) and mildly depressed (Gortner et al, 2006; Stice et al, 2006; Lu & Stanton, 2010) samples have employed similar instructions reporting some benefits and no adverse effects.

Consultation

User

The Warwick Diabetes Research and Education User Group (WDREUG) is a group of lay people with an active interest in diabetes research (i.e. individuals with diabetes or their carers). The group was involved in the development of the study and suggested additional E&P support is wanted and needed by people with diabetes. They reviewed the acceptability of and provided recommendations for all study materials, which included completion of the study questionnaires so that participants could be informed about the anticipated burden prior to providing consent. They also considered ethical issues associated with the trial design, for example they indicated withholding information about the exact nature of the study (described earlier) would not concern participants.

Expert

Research nurses based at Warwick Medical School (WMS) advised on the identification of potential primary care practices, the feasibility of the recruitment strategy in primary care, appropriate exclusion criteria and study materials. Local

GPs advised about potential practices and the clinical parameters of the sample size calculation. Indeed, research into the incentives and disincentives for GPs to participate in primary care research has indicated that input from practitioners at the design stage is crucial to maximising recruitment later on (Graham, Spano, Stewart, Staton, Meers & Pace, 2007). A local GP and an associate clinical professor and honorary consultant physician in diabetes was consulted about the recruitment strategy for secondary care, and again the clinical parameters of the sample size calculation. The WMS Clinical Trials Unit (CTU) was consulted to identify primary care practices that had previously participated in diabetes trials, and about trial procedures and the appearance of study materials. An honorary consultant psychiatrist and a GP and expert in clinical ethics at WMS were consulted about the eligibility check, the appropriateness of the intervention instructions, the process of screening essays for disclosure requiring action and the other patient safety issues/measures. The analytic strategy and again the sample size calculation were informed by consultation with a professor of medical statistics and statistician at WMS, and the director of the University of Warwick Risk Initiative and Statistical Consultancy Unit. Finally, the study website for recruitment via online support groups (discussed in chapter five) was developed in consultation with the e-learning advisor for WMS.

Conclusions

An exploratory RCT of WED for improving depressive symptom severity and associated outcomes for adults with Type 2 diabetes was timely and warranted, and should follow the methodology outlined above.

Chapter 5 Methods for the exploratory RCT evaluating WED for improving depressive symptom severity in adults with Type 2 diabetes

Chapter overview

This chapter describes the operationalisation of the methodology presented in chapter four, outlining the objectives and methods for the exploratory RCT of WED for improving depressive symptom severity, and associated outcomes, for adults with Type 2 diabetes.

Objectives

Preliminary effectiveness analysis

1. *Does WED produce the anticipated effect?*

   Identifying and estimating the anticipated effect of WED on the primary outcome depressive symptom severity, and a range of secondary psychological and behavioural outcomes in adults with Type 2 diabetes.

Exploratory analyses

2. *WED work differently for different people as anticipated and who does it work best for?*

   Test whether anticipated interpersonal traits moderate whether and to what extent WED is effective.

3. *Does WED work as anticipated?*

   Improve understanding of how WED influences health by testing anticipated mechanisms of change and mediators (i.e. explanatory processes).

4. *Prior economic evaluation*

Undertake a prior cost-effectiveness evaluation.

Feasibility investigation

5. *Pilot appropriate trial and intervention parameters*

6. *Feasibility/effectiveness of intervention delivery*

Collect information about compliance, contamination and the acceptability of the intervention and comparison exposure.

7. *Feasibility/effectiveness of the trial protocol*

Estimate recruitment and retention, identify associated issues, report on the feasibility of achieving sample size requirement and the appropriateness of the sample size calculation parameters, identify the feasibility/effectiveness of the randomisation and allocation concealment methods and check the success of blinding.

Design

The study design was an exploratory parallel group RCT (ISRCTN 18442976).

Participants

Recruited were adults with Type 2 diabetes aged ≥18 years diagnosed for at least six months.

Exclusion criteria included:

- Ever received a diagnosis of psychotic or bipolar disorder.

- Receiving any treatment for depression or psychological therapy for any reason.
- Any history of self harm, suicidal ideation or suicide attempts.
- A HCP (e.g. GP) assessment as unsuitable (e.g. receiving end of life care, acutely ill, or any past or present psychological vulnerabilities).

Recruitment approaches

As explained in chapter four, participants were recruited from primary and secondary care, and support groups. The recruitment strategy was necessarily adapted to each setting.

Recruitment strategy

Primary care

Practices

A comprehensive list of practices was obtained from Research and Development (R&D) leads for Coventry, Warwickshire and Worcestershire PCTs. Those with a relevant specialist interest were identified by means of searching a practice website or if this was unavailable information on the NHS website and then contacted. The specialist interests identified are listed in Table 8.

Further practices in these PCTs were identified by:

- Obtaining information about practices that had previously participated in diabetes trials at WMS.[54]
- Consultation with a local GP with a specialist interest in diabetes.
- Consultation with a research nurse at WMS about practices recently accepting money to consider research.

[54] Practices that had previously participated in diabetes trials at WMS were thanked.

Table 8 Relevant specialist interests for primary care practices

- Diabetes (i.e. a diabetes clinic, support and education offered to patients with diabetes, or staff (i.e. diabetes specialist nurses (DSNs) or GPs) with an additional interest or training in diabetes).
- Mental health (i.e. a counselling clinic, a mental health care professional in post, a professed holistic practice, or staff (i.e. DSNs or GPs) with additional interest or training in mental health).
- Clinical trials.
- Research (i.e. including diabetes studies).
- Patient initiative programmes (i.e. Expert Patient Programme).
- Practices with GPs in post that lecture and or hold honorary posts at WMS.

Practice managers (PMs) were sent a letter and practice information sheet (PrIS) explaining the study background, required involvement and potential benefit to them, which was followed up with telephone calls (or emails where there was no response to calls) until a definite answer was obtained.[55] Direct contact with GPs and practice visits were requested and arranged wherever possible.

The Data Protection Act (1998) has made it difficult to limit the imposition of research on practices. Within current guidelines only members of the clinical care team may search electronic records in primary care to identify potentially eligible patients and the list of potentially eligible patients should only be seen by those with a legitimate right to see these patient details. Consequently, practice involvement was limited to minimal work that the researcher was unable to do themselves in an attempt to maximise recruitment, and this was emphasised in the information practices received about the study. Specifically, researchers prepared as much of the study materials as was possible without seeing identifiable patient data for

[55] Where practices advised they had not received the information it was re-sent and followed up again.

practices to then mail out.[56] This is consistent with recent UK guidelines to assist recruitment in primary care (NIHR & PCRN, 2010). Indeed research into the incentives and disincentives for GPs to participate in primary care research has consistently indicated that demonstrating studies to be feasible to implement in practices is important to maximise recruitment (Graham et al, 2007).

Patients

Practice staff screened diabetes registers (i.e. computerised search) and compiled a list of potentially eligible patients, which was checked by a clinician (i.e. typically a GP) and any unsuitable patients were removed. Staff then mailed pre-prepared invitation packs to the remaining patients. It was anticipated patients would be recruited over a six month period.

Secondary care[57]

Clinics

Consultants with a specialist interest in diabetes and an affiliation with WMS based at teaching hospitals in Coventry and Warwick were approached with a letter and clinic information sheet, as in primary care, and a meeting was arranged to discuss the study.

Patients

Health care assistants (HCAs) identified people with Type 2 diabetes from clinic notes. The researcher then approached them in a waiting room prior to their consultation offering more information about the study. Eligibility was checked against five questions for those agreeing to this:

[56] The cost of consumables (i.e. producing materials and postage) were covered by the university; practices and clinics provided a template for materials to be sent by them to be produced on headed paper. Practices were asked only to print labels with patients' details for invitation and consent packs.
[57] Ethical approval to recruit via secondary care was obtained from the NHS REC that approved the protocol for primary care (i.e. a substantial amendment was submitted).

- Do you have Type 2 diabetes? (yes required)
- Have you been diagnosed more than six months? (yes required)
- Are you at least 18 years old? (yes required)
- Have you ever been asked to see a member of a mental health team? (no required)
- Are you currently taking antidepressants? (no required)

Consultation with a local GP confirmed these questions would satisfy the study exclusion criteria. Patients satisfying all of the questions were provided with an invitation pack. It was anticipated clinics would be attended daily for one month initially in order to gage the feasibility of recruitment, with more time invested should this be deemed effective.

Online support groups[58]

Groups

Online diabetes forums were identified via the DUK website and a Google search. Site moderators for each were contacted for permission to post information about the study.

Participants

The study was posted with a link to a study website[59], which included summary information and direction to an icon for the full information (i.e. the patient/participant information sheet, PaIS), for approximately one month. The study website was set to close one month from the date that the last forum was posted on. The study website was developed using site builder and piloted before going live. The pages comprising the webpage are presented in the appendix. Interested members

[58] Ethical approval to recruit via support groups was obtained from the University of Warwick Human and Social Sciences Research Ethics Committee (HSSREC).
[59] http://www2.warwick.ac.uk/fac/med/staff/dennick/

submitted a form confirming that they met the five eligibility questions described earlier, and provided an email address. Responses were checked daily and eligible individuals were emailed an invitation pack.

Local support groups (Identified via DUK)

Permission was sought to present the study at a local support group via DUK. Any interested members were to be asked the five eligibility questions, and eligible patients would have been provided with an invitation pack. However, permission was not obtained (see chapter six).

Eligibility check[60]

Primary care

Invitation packs included a letter, PaIS, expression of interest form (EOIF) and the DSQ. Interested patients returned the EOIF and DSQ in business reply envelopes to the university, which were then forwarded, unopened, to the appropriate practice (i.e. noted on the envelope). Returned DSQs were screened by the researcher at two-day intervals, which was appropriate as no items asked about self-harm.[61] This was anonymous because practice staff had assigned personal identification numbers (PINs) to potentially eligible patients, and this was the only identifying information on the DSQ; the PIN assignments and EOIFs were never seen by the researcher. Thus, no identifiable patient data was seen by the research team prior to obtaining consent.

Practice staff mailed consent packs (i.e. two consent forms; one collecting contact details for return to the research team and one to be retained by patients, and a

[60] In secondary care and the support groups, exclusion criteria was confirmed by self-report, and for support groups the HCP assessment exclusion criteria could additionally not be enforced, thus it was even more important that the eligibility check was in place.

[61] For any patients returning only an EOIF or a partially completed DSQ that could not be scored, practices re-sent the DSQ with a letter requesting that it be completed properly.

baseline questionnaire) to eligible patients (CES-D <16) for return to the researcher.[62] For ineligible patients (CES-D ≥16) staff passed their DSQ to a GP to be dealt with by them, for which their agreement was obtained at recruitment.[63] Patients were not referred to GPs as cases as the CES-D only identifies potentially significant symptoms and is not a diagnostic tool. Instead they were informed that the patient may be experiencing potentially significant symptoms. All CES-D scores and their corresponding PINs were recorded by the researcher.

Secondary care

The invitation pack contained a letter, PaIS, the DSQ and the two consent forms described above. Interested patients were to return the relevant consent form and DSQ to the researcher. Eligible patients (CES-D <16) were to be sent a baseline questionnaire, once an HCP assessment as suitable was obtained. Ineligible patients (CES-D ≥16) were to be dealt with accordingly by their GP (i.e. contacted by the research team). However, no patients returned an invitation pack (see chapter six).

Support groups

The invitation pack included the DSQ and two consent forms. Interested patients returned the relevant consent form and DSQ to the researcher. Eligible patients (CES-D <16) were sent a baseline questionnaire, and ineligible patients (CES-D ≥16) received a standard letter advising that they were unable to participate and to contact their HCP. Contact could not be made by the researcher as recruitment via support groups did not entail interfacing with HCPs. In an attempt to prevent causing undue distress, people were not informed that they were cases as again the

[62] In instances where patients returned a consent form with no address, practices were asked to send subsequent materials and reminders with a request for the address until this was obtained.
[63] This afforded patients more opportunity to discuss any problems with their GP than advising them to contact their GP themselves.

CES-D is not a diagnostic tool. Instead they were informed that they were unable to participate as the study was only suitable for some people thus they may not benefit, and that everyone unable to participate was being advised to contact their HCP, as there was a possibility that they may not be coping as well as they could be.

Trial procedure/enrolment

Figures 15 to 17 illustrate the trial design in primary and secondary care and support groups respectively. Consented participants were randomized to either the intervention or control group, and received the appropriate writing pack for completion after the baseline questionnaire.[64] At this point, primary care practices were contacted for enrolled patients PINs so that their DSQ could be identified and used as baseline depressive symptom severity data (i.e. DSQs for eligible patients were retained by the researcher for this purpose).

With participants consent obtained in the consent form, GPs received a letter advising them of primary care patients' enrolment into the trial (plus a copy of the returned consent form). Again, as the researcher did not interface with HCPs, support group participants were advised to notify their HCP of their enrolment into the trial.

[64] Writing packs were sent out as quickly as possible after the receipt of consent and or baseline to ensure that this was provided to patients while they were still enthusiastic and able to take part, which was considered to be particularly important given the demands of the task.

Figure 15 Trial design in primary care

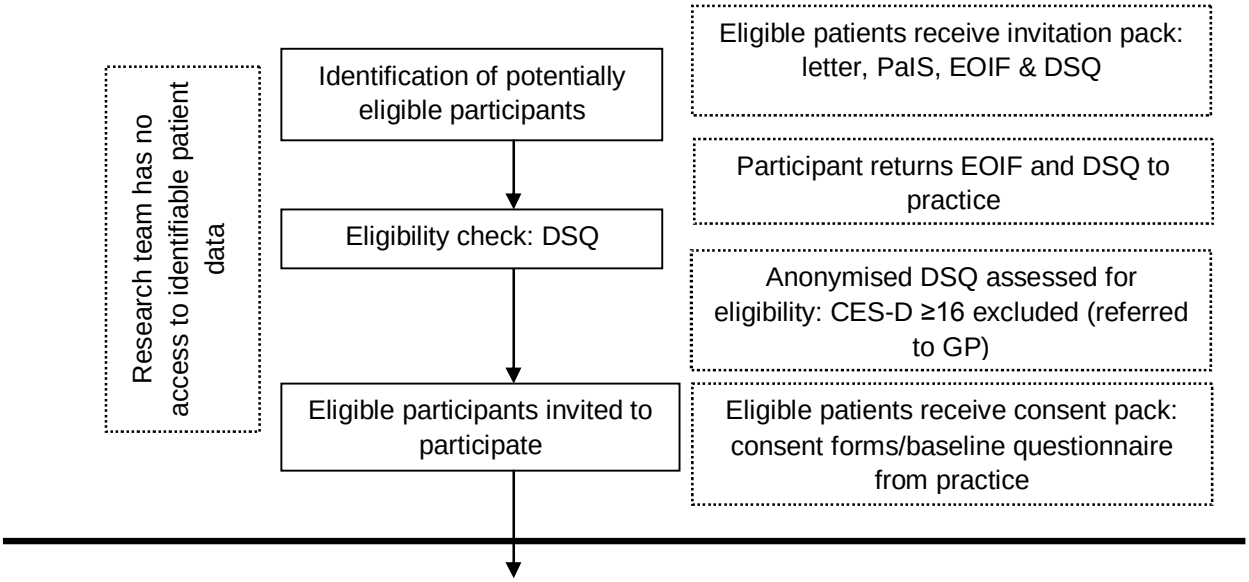


Figure 16 Trial design in secondary care

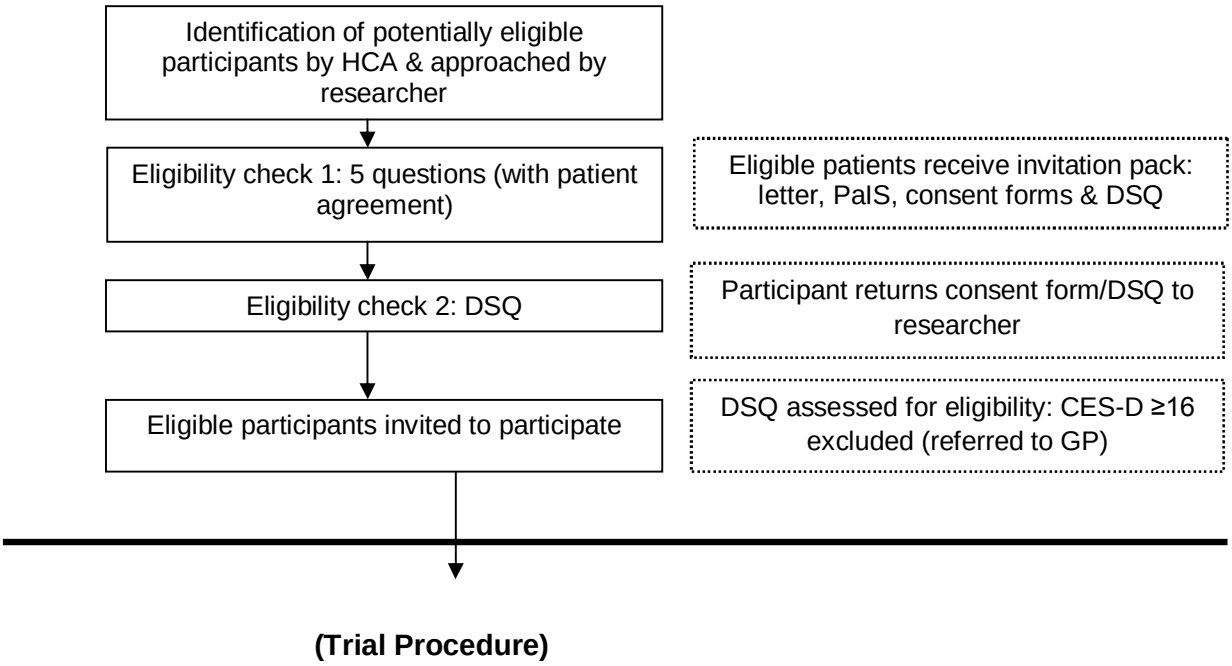
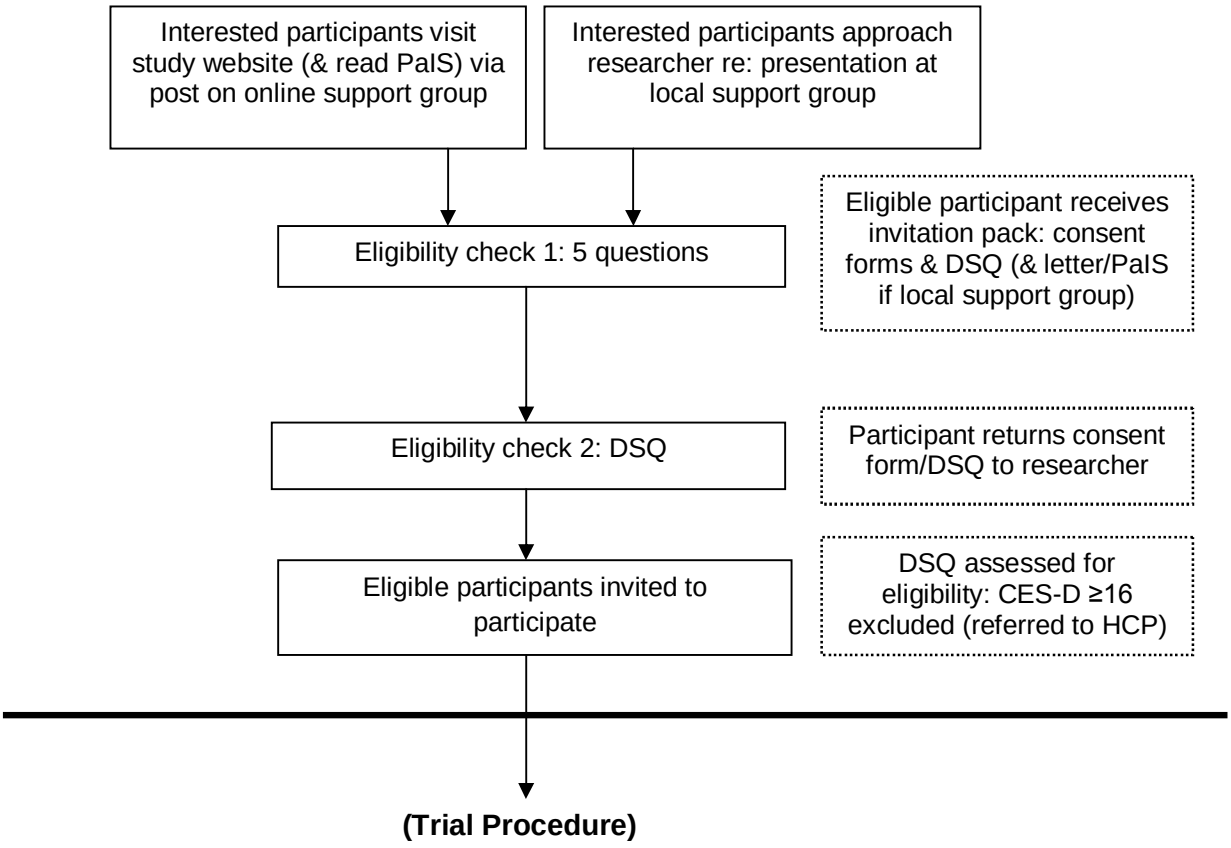
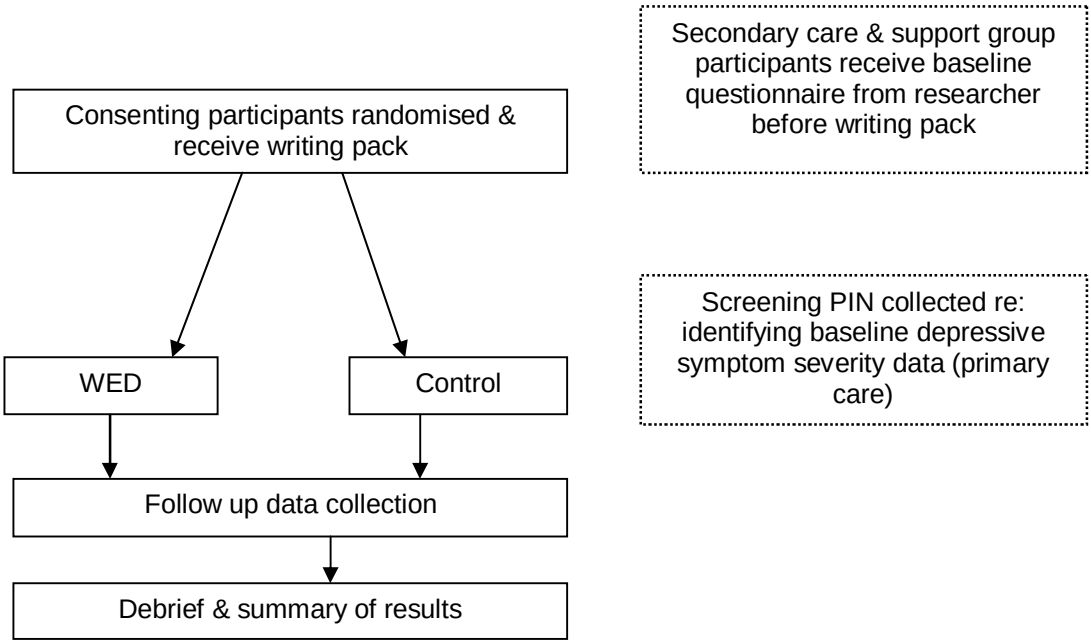


Figure 17 Trial design in support groups



Trial Procedure



Intervention and comparison exposure

The intervention group wrote their thoughts and feelings about any stressful experience encountered over the last month, or any worries or concerns that were currently troubling them. The control group wrote a fact-based description of the previous days' activities, without discussing thoughts or feelings. Both groups wrote at home for 20 minutes on three days over the course of one week. Patients self-selected the disclosure topic, wrote in private, were allowed to switch topics across sessions, imposed their own structure (i.e. with minimal examples provided, e.g. suggestions to link the topic to relationships with others) and wrote continuously with repetition if necessary and no regard for spelling or grammar. The WED group wrote by hand, whereas online support group participants received WED by email and thus typed their essays, albeit they were offered the opportunity to receive hardcopies. Usual care and treatment seeking was not restricted in any way.

Randomisation and allocation concealment

Randomisation was at the individual rather than practice level as the feasibility of recruiting a sufficient number of practices was not known. The allocation ratio was 1:1 and randomisation was blocked to protect against unbalanced group sizes, which is likely with unrestricted randomisation in small RCTs and reduces statistical power and complicates the use of ANOVA. Random block sizes of four, six and eight were employed to protect against selection bias (i.e. the possibility that the researcher could predict some of the next treatment assignments should they infer the block size). Randomisation was stratified by recruitment approach to ensure that the groups were balanced on recruitment approach. The project supervisor (CB) generated a list of random numbers via Clinstat, which the researcher never saw. To achieve allocation concealment in primary care the list was used to allocate

sealed, opaque, serially numbered writing packs. The researcher mailed the next pack in the sequence each time a participant was enrolled. As online support group participants received writing packs electronically, the project supervisor was contacted for the next allocation in the sequence each time a participant was enrolled. The order of participant enrolment, and thus the consistency with the allocation sequence, was assured by the date and time of receipt of the email to which the returned consent form and DSQ was attached.

Blinding

The study was double blind. The control group received a neutral writing task (identical to the WED groups except for the writing foci) and participants were informed that the study was looking at ways of improving the health of people with Type 2 diabetes and whether and how writing about different aspects of life might affect their health. This was consistent with a study that was included in the systematic review and was the only one assessed as having a low risk of bias overall (Gillis et al, 2006). They were also informed that a treatment comparison was being drawn. Participants also self-administered the intervention and self-report baseline and follow up measures at home, receiving and returning these by post/email. In primary care, HCPs were informed about the nature of the study but not participating patients' group allocation. Significant contact with patients after receipt of the information pack was not anticipated. Nonetheless, staff were instructed to encourage any patients requesting information about the study to contact the researcher.

Variables

Preliminary effectiveness analysis

Primary outcome

The primary outcome was depressive symptom severity measured with the CES-D.

Secondary outcomes

DSED was measured with the PAID scale, health-related QoL was measured with the EQ-5D *and d*iabetes SMBs was measured with the SDSCA.

Exploratory analyses

Moderators

Alexithymia was measured with the TAS-20 and dispositional optimism was measured with the LOT-R.

Explanatory processes

Mechanism of change

EA&H was measured as change in post-writing negative affect across writing sessions via the PANAS negative affect sub-scale, completed after each writing session. E&CP was measured as change in percentage word use reflecting positive emotion, negative emotion, insight and cause across writing sessions, obtained via LIWC software. Texts for each writing session for each participant were transcribed in accordance with the instructions for preparing essays for LIWC analysis, for example Microsoft Word's Spellchecker was used to correct misspellings, important abbreviations were spelt out and inappropriate word use was corrected (i.e. 'gotta was change to 'got to'). Words that could not be identified were transcribed as a non-sense word (i.e. xxxx), which the LIWC recognises yet does not assign to a

category. Texts were saved as text files, processed by the LIWC software and the data were exported to SPSS (version 17).

Mediators

Self-efficacy for diabetes SMBs was measured with the DMSES UK, perceived emotional support was measured with the SSQ6 and perceived interference of illness was measured with the IIRS.

Feasibility investigation

Feasibility/effectiveness of intervention delivery

Compliance data

The number of days writing completed and the time spent writing per session were obtained within writing packs. Whether participants undertook further self-directed writing was collected in the three month follow up questionnaire.

Contamination data

To check the presence of ED and EA in the WED group only, groups were compared on the average degree of ED (i.e. LIWC data; average percentage word use for each of the four aforementioned categories) and EA (i.e. PANAS data; average post-writing negative affect) across sessions.

Acceptability

Reasons for not writing at all or following the protocol as instructed were noted with respect to the acceptability of the intervention and comparison exposure.

Feasibility/effectiveness of the trial protocol

Randomisation and allocation concealment methods

The feasibility/effectiveness of the randomisation and allocation concealment methods was noted.

Blinding success

Blinding success was checked with three questions at debriefing, namely whether patients inferred the true nature of the study and their group assignment:

- Were you aware that there were two different groups?
- Having read this debriefing sheet had you guessed what the other group was writing about?
- Having read this debriefing sheet and now knowing what group you were in, had you already guessed the purpose of your writing task?

Recruitment, retention and sample size

Recruitment flow and recruitment/retention issues were noted, and an à priori sample size calculation was specified (described below) with the feasibility of achieving sample size requirement and the appropriateness of the sample size calculation parameters also noted.

Data collection schedule

Data were collected at baseline, during the intervention, post-intervention (i.e. two weeks), three months and debriefing. Table 9 depicts the schedule.[65]

It should be noted that mediators were additionally measured at three months for primary care patients. This is because they were the first sample recruited and initially a six month follow up was intended for which mediators at three months were to be measured. However a decision was made not to implement this

[65] Postal/email delivery facilitated recruitment across a greater distance and reached participants that are physically restricted and requiring support. Pre-paid envelopes were provided for return of materials by post.

additional follow up (i.e. it was removed owing to the delays imposed by the ethical review (described in chapter four) and the recruitment difficulties experienced (reported in chapter six)[66], yet collection of the three month mediator data had already been initiated for these participants.

Table 9 Data collection schedule

Time 1 (Baseline): Demographic (i.e. age, gender, ethnicity, education & relationship status) (& nationality/country of residence for online support group participants should non-UK participants be recruited). Clinical (i.e. time since diagnosis, diabetes complications, diabetes medication & HCU. BMI (i.e. height and weight) and HbA1c were collected from routine medical records for primary care patients and were self-report for support group participants. Moderator and mediator measures. Baseline assessment of outcome variables. Time 2 (During intervention): Written essays, mechanisms of change measures and compliance, contamination and acceptability data. Time 3 (2 weeks): Mediator measures. Time 4 (3 months): Outcome measures and compliance data (& mediator measures for primary care patients). Debriefing: Check of blinding success.

[66] It was initially intended that HCU would be included as an outcome as this is adversely impacted by high- and low-level depression in diabetes thus improving depression, even at lower levels, may produce improvement in this outcome (see chapter one). Additionally, the WED evidence base suggests that HCU may be improved by WED at least for healthy patients (as reported in chapter two). However, this was intended to be measured at six months as the Stanford Patient Education Research Centre Diabetes Health Care Utilisation measure employed asks about HCU during the previous six months. This outcome was therefore lost when the six month follow up was removed.

The practice letter, PrIS, patient letter, PaIS, EOIF, DSQ, consent forms and debriefing sheet administered in primary care are provided in the appendix. The materials administered specifically in secondary care and support groups were essentially the same with only minor changes where necessary and are therefore not presented. The writing packs and baseline/follow up questionnaires are also provided in the appendix, albeit it is noteworthy that these are the hardcopies rather than the electronic versions administered to support group participants. Materials administered electronically merely had a slightly different response format to the hardcopies, for example in the questionnaires participants were required to embolden and italicise rather than circle responses and place an X in boxes rather than ticking them.

Schedule for reminders

Reminders were sent to, and reasons for withdrawal sought from, consenting participants who failed to return subsequent materials. The schedules for reminders in primary care and support groups are illustrated in Tables 10 and 11. Right to withdraw without indicating reasons was always emphasised.

Primary care

A reminder letter and additional writing pack/questionnaire as appropriate was mailed initially, followed by up to two telephone calls in the event of no response.[67]

Support groups

Participants were sent a reminder email with the offer of additional materials, and in the event of no response reasons for non-return were sought when subsequent materials were forwarded.

[67] Where no contact could be made, these materials were chased again should patients be contacted about non-return of subsequent materials.

Table 10 Schedule for reminders for primary care

Writing pack:
Sent immediately after return of baseline questionnaire.
REMINDER: letter 21 days after sending; if no response after another 21 days telephone call (2 attempts).

Follow up questionnaires:
2 week -sent 14 days after receipt of writing pack (or 14 days after patient responds to writing letter reminder and advises no longer wishes to write or 14 days after 2 unsuccessful writing telephone reminders).
3 month -sent on the same date 3 months after receipt of writing e.g. if received 1st January sent 1st April (or 3 months after patient responds to writing letter reminder and advises no longer wishes to write or 3 months after 2 unsuccessful writing telephone reminders).
REMINDER: letter 14 days after sending; if no response after another 14 days telephone call (2 attempts).

Debriefing:
Sent immediately after receipt of 3 month follow up questionnaire.
REMINDER: letter 21 days after sending; if no response after another 21 days telephone call (2 attempts).

Table 11 Schedule for reminders for support groups

Writing pack:
Sent immediately after return of baseline questionnaire.
REMINDER: email 21 days after sending; if no response request feedback at 2 week follow up.

Follow up questionnaires:
2 week follow up –sent 14 days after receipt of writing pack (or 14 days after patient responds to writing email reminder and advises no longer wishes to write or if no response to writing email reminder 14 days from the date of that reminder).
3 month follow up -sent on the same date 3 months after receipt of writing e.g. if received 1st January sent 1st April (or 3 months after patient responds to writing email reminder and advises no longer wishes to write or if no response to writing email reminder 3 months from the date of that reminder).
REMINDER: email 14 days after sending; if no response request feedback at 3 month follow up or debriefing respectively.

Debriefing:
Sent immediately after receipt of 3 month follow up questionnaire.
REMINDER: email 21 days after sending.

À priori sample size calculation

An anticipated effect size from a trial consistent with the present study was not available. However, a 5-point difference on the primary outcome as measured with the CES-D (SD=8.5; derived in a representative community sample of adults (Radloff, 1991), discriminates between important levels of severity and is potentially clinically meaningful. To detect this difference at a .05 significance level (two tailed such that an effect in either direction could be detected)[68] with 80% power[69] 110 participants were required, assuming 20% attrition.

Primary care (& secondary care)

It was assumed each practice would have approximately 200 adults with Type 2 diabetes registered, that at most 20% of invited patients would be recruited and that no more than 15% would receiving intervention for depression already (i.e. estimated by a local GP). Thus each practice could provide 34 eligible and interested patients. The proportion of individuals excluded during the eligibility check was expected to be negligible, rather this was a precaution to protect patients.

People within practices are related and this correlation reduces statistical power, thus potential clustering within practices was accounted for. An intra-class correlation (ICC) of .03 was assumed based on the pattern of ICCs typically observed in cluster based studies in primary care (Adams, Gulliford, Ukoumunne, Eldridge, Chinn & Campbell, 2004). With a cluster size of 34, and thus inflation

[68] Statistical significance is the risk of a Type 1 error (i.e. the probability of an effect at least that large if the null hypothesis is true; the risk that the sample based estimate represents sampling error (i.e. random fluctuations in the data/between the groups) rather than the population effect). The acceptable level of risk is 5% (i.e. $p<.05$).

[69] The power of a statistical test is the likelihood that a genuine effect will be detected as significant (i.e. as there being less than a 5% risk that the effect is due to sampling error; $p<.05$), and is inversely related to the risk of making a Type 2 error (i.e. missing a genuine effect), the acceptable level of which is set at 20% (i.e. 80% power).

factor of 1.99, a sample of at least 219 was actually required.[70] Recruitment of eight practices was thus estimated to provide 272 eligible and interested patients, albeit a small proportion may have been diagnosed for less than six months.

It is noteworthy that for secondary care a diabetes clinician estimated that approximately 20% of patients with diabetes attending a secondary care clinic would have Type 2 diabetes; 40 of the 200 patients typically seen in one month. Moreover, a similar proportion to that in primary care would be receiving intervention for depression, yet few patients diagnosed less than six months ago would be attending secondary care. Thus, again assuming a conservative recruitment rate of 20%, it was anticipated secondary care recruitment would additionally provide seven patients per month per clinic.

Online support groups

The online support groups that were approached indicated that the average membership at the time they were approached was 12, 364, of which it was indicated on the websites that approximately 28% would log in within one month (i.e. average of 3, 462 per forum). It was assumed most would be adults and thus have Type 2 diabetes (i.e. 75%), as children/parents of children with Type 1 would access specialised websites. An average of 2, 597 adults with Type 2 diabetes was therefore anticipated per forum per month. Assuming a conservative recruitment rate of 1% (i.e. indicated by the proposed websites), it was expected an average of 26 people viewing the post would answer the eligibility questions per forum. It was also assumed that of these people the proportion receiving treatment for depression would be similar to primary care; if it were less because users were treatment

[70] The inflation factor is computed with the following equation; 1+[(cluster size-1)xICC]. The required sample size (i.e. 110) is then multiplied by the inflation factor.

seeking by visiting the groups (and expressing an interest in the study)[71] or because visiting the group was satisfying any treatment need, this would be a conservative estimate. This would leave an average of 22 people per site. Presuming that 10% would then have been diagnosed for less than six months (i.e. again for the first six months people with diabetes are relatively well supported by the NHS), 20 eligible and interested participants were expected to be identified per site in one month. Thus recruitment of six sites could provide a sample of 120 participants within one month.

Handling of patient safety issues

A number of patient safety issues were identified in chapter four. The handling of these is either described earlier (i.e. the eligibility check) or below.

Potential negative emotional response to writing or screening

Participants were warned about this in the PaIS and advised to stop writing if they were worried about how they felt. GP contact was encouraged should patients experience any concerns or wish to discuss their screening score (in the PaIS and debriefing sheet), with specific contact details provided and GP agreement obtained during practice recruitment. Contact details of potentially helpful organisations (i.e. local citizen's advice bureaus, Mind, NHS Direct and Samaritans) were also provided. Where participant recruitment was not via the NHS (e.g. support groups) participants were advised to contact their HCP, yet specific contact details could not be provided and this could not be arranged beforehand as recruitment would not involve in interfacing with HCPs.

[71] Any people at risk but not currently treated would be excluded in the eligibility check.

Clinical support in the event of contact with patients experiencing concerns/soliciting emotional support

All participants were encouraged to contact their HCP rather than the research team about anything other than information about the trial. However, should a patient contact the researcher about anything else, a procedure was in place. Specifically, honorary consultant psychiatrist, Professor Scott Weich, at WMS was consulted immediately for expert clinical advice and support with individual cases, for which his agreement was obtained.

Review of essay content and procedure for disclosures requiring action and disclosure of limits to confidentiality

Essays were read within one working day of receipt by the researcher, who assessed the risk of self-harm against a checklist of risk factors informed by Professor Scott Weich and a standard psychiatry resource recommended by him (Gelder, Harrison & Cowen, 2006) (presented in the appendix). Patients were required to show no evidence of distress or morbid thoughts in relation to each risk factor in their writing (e.g. in relation to bereavement, statements such as 'I wish I was with the person'). If any of these risk factors, or any other concerning information, were evident the researcher immediately consulted a patient safety group, which was convened within one working day to consider the information and provide expert advice. Contact arrangements were made such that advice could always be sought within this time frame. Individuals that agreed to be included in this group were Professor Scott Weich, Dr Anne-Marie Slowther a GP and expert clinical ethics and Dr David Ellard a clinical trialist.[72] Participants were advised in the

[72] The patient safety group was also intended to evaluate and advise about any other issues that arose during the trial, such as new information about intervention safety. Ongoing information gathering strategies were employed during the course of the study (i.e. journal/database search alerts and subscription to professional list server groups). However no new, significant information about the intervention was identified. A data monitoring committee was not convened due to insufficient follow up to enable interim analyses.

PaIS that if they disclosed information of a certain nature in writing, for example indicating a serious risk to themselves or others, this may necessitate a breach of confidentiality and could be disclosed to an appropriate party.

Handling of standard ethical issues[73]

There were a number of standard ethical issues to be addressed and these are described below.

Informed consent

Informed written consent was obtained prior to enrolment and randomisation. The PaIS advised participants about the trial requirements, the risks and benefits and that they were free to reply if and when they chose. Research team contact details were provided for more information. The PaIS was considered at home allowing at least 24 hours consideration, and people were not coerced or contacted about the study. The consent form sought confirmation that participants had read the PaIS, understood this, had the opportunity to consider the information, ask questions, and have these answered satisfactorily.[74] The study materials achieved a Flesch-Kincaid Readability score of 7 to 8 indicating they were easy to understand.

Right to withdraw

Participants were assured in the PaIS that they were free to withdraw at any time without giving a reason and that declining participation would not affect them. Confirmation that participants understood this was obtained in the consent form.

[73] A number of ethical and good clinical practice (GCP) guidelines were consulted in the design of the trial and study materials; the WMS CTU Standard Operating Procedures guidelines, the NHS National Patient Safety Agency's National Research Ethics Service guidelines, and the MRC guidelines for good clinical practice in clinical trials. The project researcher attended the Principles of GCP course at University Hospital Coventry and Warwickshire and the Chief Investigators course at the WMS CTU.
[74] This was particularly important for online support group participants because the PaIS was simply an icon on the study website to which people were directed.

Participants were also warned that should they withdraw after consent the information already provided would still be used.

Procedure in the event of unreturned documents

Participants were warned in the PaIS that should they not return documents they would still be followed up as per the protocol in the PaIS and therefore they could receive a reminder letter and telephone calls, unless they explicitly withdrew consent for this.

Screening for eligibility

Participants were advised in the PaIS (and on the study website) that they would be screened to assess their current well-being and that this would be used to determine their suitability for the trial (i.e. eligibility questions and or a DSQ). Participants were advised that their screening questionnaire data would be seen by their HCP and that this may be acted on (primary and secondary care), or that they may be required to advise their HCP about this (support groups). Confirmation that support group participants understood this was obtained in the consent form. For secondary care and support groups, the DSQ was returned to the researcher with the consent form. The consent form therefore obtained explicit permission for the researcher to screen for eligibility (and, for secondary care participants, permission for the researcher to pass the information to their HCP if necessary). In primary care, participants were advised that their screening data would be obtained by the research team for baseline data should they consent to take part.

Advising HCPs about enrolment

In primary and secondary care, patients were informed in the PaIS that HCPs would be advised about their entry into the trial, and confirmation that patients understood

this was obtained in the consent form. Support group participants were informed that they would be advised to inform their HCP about their participation, with confirmation that patients had understood this again collected in the consent form.

Clinical data collection

Primary and secondary care patients were advised in the PaIS that their HCPs would provide the researcher with information from their medical records unless they explicitly withdrew consent for this, and the consent form sought agreement that their medical records may be accessed by individuals from the University of Warwick.

Withholding information

Again, there was a need to withhold some information from participants (see chapter four). However, participants were fully debriefed once the study was completed.

Postal/email consent and intervention delivery

Although intervention delivery was by post or email, patient safety measures were in place such that any issues were dealt with as they would be in practice. Where consent was taken by email, consent forms could not be signed by hand thus they obtained additional confirmation that participants were providing signed consent (i.e. where an electronic signature could not be provided).

Handling of participant data

It was not possible to anonymise materials given the need to link data collected at different points and identify to whom materials should be forwarded and when. However, confidentiality was maintained. Materials received by email were printed

and the email destroyed. Consent forms contained participant's details, yet other materials were marked only with a PIN (generated by participants; not the PIN assigned by practices). Materials were stored in a locked filing cabinet in a locked office on university premises and did not leave. Only information stored on a university computer, protected by a password, linked participant's details and PINs. Only the research team had access to participant data. Participants were informed about this in the PaIS, and also that their data may be seen by NHS R&D offices for monitoring and auditing purposes, for which consent was obtained in the consent form. The data obtained were only used in the present study, and once complete all electronic data were transferred to two CDs (i.e. and stored with the paper documentation with the project supervisor). This will be destroyed after five years. Participants were also informed about this in the PaIS.

Provision of information on the study website

Information provided on the study website was secure because the site was located on the researcher's staff webpage, to which only the researcher and the WMS web management team had access. Security was assured by the eLearning advisor for WMS. Participants were assured about this, and that the information provided would not be used to forward anything other than the study materials, in privacy statements on the site.

Process of obtaining clinical data

Any information that left practices had participant's details removed. Arbitrary information codes were used to facilitate this. Participants were informed about this in the PaIS.

Data analysis plan

Variable definition

Variables analysed statistically

The variable definition for those analysed statistically, including the demographic covariates to be included in effectiveness analyses, is provided in Table 12. The hypotheses for these analyses are provided below.

Hypotheses for variables analysed statistically

Outcomes: It was hypothesised that for the primary and secondary outcomes a difference in mean scores would be observed which favoured the intervention; participants that received WED would report lower depressive symptom severity, and improvements in DSED, health-related QoL and SMBs, compared to the control group.

Moderators: It was hypothesised that the effect of WED on the primary outcome would be different at different levels of the moderator variables.

Explanatory processes - mechanisms of change: It was hypothesised that WED would produce the anticipated EA&H and E&CP described in chapters two and four, specifically a) a decrease in post-writing negative affect across writing sessions and b) an increase in percentage word use reflecting cause, insight and positive emotion, and a decrease in percentage word use reflecting negative emotion, across writing sessions. This would be reflected by an increase/reduction in the mean values for each variable across successive writing sessions.

Table 12 Variable specification for those to be analysed statistically

Variable	Measure	Direction of scoring of measure	Self-report versus objective data	Continuous versus dichotomous data	Data obtained	Assessment interval data obtained at	Data obtained from measures at each assessment interval / *score derived*
Primary outcome							
Depressive symptom severity	CES-D	Higher scores more depressive symptoms	Self-report	Continuous	Means & SDs	Baseline & 3 months	Total score
Secondary outcomes							
DSED	PAID	Higher scores more DSED	Self-report	Continuous	Means & SDs	Baseline & 3 months	Total score
Health-related QoL	EQ-5D	Higher scores better health-related QoL	Self-report	Continuous	Means & SDs	Baseline & 3 months	2 sub-scale scores: utility & VAS
Diabetes SMBs	SDSCA	Higher scores better SMBs	Self-report	Continuous	Means & SDs	Baseline & 3 months	5 sub-scale scores: general diet, specific diet, exercise, blood glucose testing & foot care
Confounding variables							
Age			Self-report	Continuous	Means & SDs	Baseline	
Gender			Self-report	Categorical	Frequencies & %	Baseline	

Variable	Measure	Direction of scoring of measure	Self-report versus objective data	Continuous versus dichotomous data	Data obtained	Assessment interval data obtained at	Data obtained from measures at each assessment interval / *score derived*
Moderators							
Alexithymia	TAS	Higher scores more alexithymia	Self-report	Continuous	Means & SDs	Baseline	Total score
Optimism	LOT-R	Higher scores more optimism	Self-report	Continuous	Means & SDs	Baseline	Total score
Mechanisms of change variables							
EA&H: change in post-writing negative affect across writing sessions	PANAS – negative affect sub-scale	Higher scores more negative affect	Self-report	Continuous	Means & SDs	After each writing session	Total score
E&CP: change in % word use reflecting positive emotion, negative emotion, insight & cause across writing sessions	LIWC	Higher scores greater % of words reflecting that category	Objective	Continuous	Means & SDs	Derived for each writing session	4 category scores (positive emotion, negative emotion, insight & cause)
Mediators							
Self-efficacy for diabetes SMBs	DMSES UK	Higher scores more self -efficacy	Self-report	Continuous	Means & SDs	Baseline & 2 weeks (& 3 months for primary care patients)	Total score
Perceived illness-interference	IIRS	Higher scores more interference	Self-report	Continuous	Means & SDs	Baseline & 2 weeks (& 3 months for primary care patients)	Total score
Perceived emotional support	SSQ6	Higher scores more support perceived	Self-report	Continuous	Means & SDs	Baseline & 2 weeks (& 3 months for primary care patients)	2 sub-scale scores: number & satisfaction

Variable	Measure	Direction of scoring of measure	Self-report versus objective data	Continuous versus dichotomous data	Data obtained	Assessment interval data obtained at	Data obtained from measures at each assessment interval / *score derived*
Contamination							
Average degree of ED: average % word use reflecting positive emotion, negative emotion, insight & cause across writing sessions	LIWC	Higher scores greater % of words reflecting that category	Objective	Continuous	Means & SDs	Derived for each writing session	4 category scores (positive emotion, negative emotion, insight & cause) / *for each word use category mean of scores for each writing session derived*
Average degree of EA: average post-writing negative affect across writing sessions	PANAS – negative affect sub-scale	Higher scores more negative affect	Self-report	Continuous	Means& SDs	After each writing session	Total score / *mean of scores for each writing session derived*

Explanatory processes - mediators: It was hypothesised that the effect of WED on the primary outcome would be mediated by these variables, reflected by a reduced association between the intervention and primary outcome when the mediator was controlled.

Feasibility/effectiveness of intervention delivery - contamination: It was hypothesised that a difference in mean scores would be observed which indicated a greater degree of ED and EA in the intervention group compared to the control group.

Variables analysed descriptively

Feasibility/effectiveness of intervention delivery

Compliance: The time spent writing per session was self-report and provided continuous data reported as the mean and SD, and the number of days writing completed was self-report and provided categorical data reported as frequencies and percentages (one, two or three days). Whether participants undertook further self-directed writing since completing the intervention was also self-report and provided categorical data (yes or no) reported as frequencies and percentages.

Feasibility/effectiveness of the trial protocol

Blinding success: Whether participants inferred the true nature of the study and their group assignment was self-report and provided categorical data (yes or no) reported as frequencies and percentages. A score was derived for each of three questions that were asked.

Data preparation

Handling missing data on continuous measures

Continuous measures were scored according to the scoring keys provided. Some included instructions to impute missing responses where these were below a certain threshold (e.g. ≤4 items). Others provided information about the acceptable extent of missing responses with which a score could still be derived (e.g. ≤4 items). For the remaining measures, scores were derived if responses to ≤5% of the items comprising the scale/sub-scale were missing. Otherwise, scores were considered missing. The availability of data was then described. To identify missing observations (i.e. individual participant scores) the frequencies for each measure were produced (i.e. reported as the number (and percentage) of observations missing for each measure each time the measure was administered). To identify missing item responses per observation, whether observations could or could not be derived, the dataset was visually inspected (i.e. reported as the number (and percentage) of item responses missing, or imputed, for each observation for each measure each time the measure was administered).

Screening the data and checking assumptions for parametric tests: normality

The continuous variables that were to be included in analyses were screened by group at baseline and follow up (i.e. each time they were administered), to establish whether the assumption of normality was met such that the parametric analyses would be accurate. Boxplots were visually inspected for outliers. Shapiro Wilk tests, considered more accurate than alternative deviation tests (Field, 2005) then tested whether the data were significantly different to a normal distribution, and the extent of deviation was identified via inspection of histograms and skewness and kurtosis

statistics converted to z scores[75]; values greater than 2.58 in small samples suggest the data are significantly different to a normal distribution (Field, 2005).

Correcting distributional problems in the data

The effectiveness analysis for the primary outcome was based on ANOVA (discussed below), which is again fairly robust to violations of normality. All other analyses were exploratory. Nonetheless, attempts were made to correct for any distributional problems in the data. Where outliers were identified the raw data was checked and any data entry errors were corrected.[76] Variables that remained skewed were then transformed by taking the log or square root of each value, and adding a constant to all scores where some were zero. This reduces the impact of extreme scores and thus improves the distribution by squashing the right tail of the distribution and bringing larger values closer to the centre respectively (Field, 2005). Therefore, where data were negatively skewed scores were reversed prior to transforming them (i.e. all scores were subtracted from the highest score for that variable). Reversed scores were then converted back to facilitate interpretation of analyses. The transformation that best corrected the data was applied. Where a variable was transformed, all variables with which it was to be analysed were transformed, preferably in the same way, regardless of whether they were skewed initially. This was because transformation does not change the relationship between variables yet it does alter the unit of measurement of each variable.

[75] This was achieved by dividing these statistics by their associated SE.
[76] Outliers were not removed as there was no reason to believe that they were not from the population that was intended to be sampled and singling out and altering individual scores was not justified (Field, 2005).

Additional assumption checks

Homogeneity of variance for between-participants analyses (i.e. that the variance of scores is the same for each level of the between-participants factor; Levene's test) and sphericity for within-participants analyses (i.e. that the variance of the differences between different levels of the within-participants factor are the same; Mauchly's test), were checked prior to conducting analyses. Where sphericity had been violated the degrees of freedom used to assess the observed F ratio were corrected using Greenhouse-Geisser estimates of sphericity (Field, 2005). Homogeneity of regression slopes (i.e. that the magnitude and direction of the relationship between the covariate and outcome is the same for each level of the between-participant factor) was checked prior to conducting ANCOVA.

Preparation of the dataset

For primary and secondary outcomes, ITT analysis was performed. Missing follow up observations were replaced by that participant's baseline observation for that outcome (i.e. baseline carried forward) and missing baseline observations were replaced with that participants follow up observation for that outcome, as available. On the rare occasion that data were missing at both baseline and follow up for an outcome this participant was excluded from the analysis as complete imputation was not considered justified. A complete case analysis was then performed; effectiveness analyses were repeated with participants that provided both baseline and follow up observations.

Baseline descriptive statistics

Psychometric properties of each continuous measure are reported for the baseline data, or for the first writing session for the PANAS, as the mean, SD and range.

Internal reliability[77] was reported as Cronbach's alpha for scales/sub-scales that comprised ≥5 items. Cronbach's alphas between .70 and .90 reflect a desirable balance between internal reliability and redundancy of items, which otherwise suggests limited scope and questionable validity (Streiner & Norman, 2003). The EQ-5D utility sub-scale comprises five items, however Cronbach's alpha was not calculated as a single construct is not explicitly measured thus a substantial correlation was not anticipated.

As random allocation can still result in chance variation between groups (i.e. accidental bias), which if substantial enough for prognostic variables may bias effects, the baseline comparability of the groups was examined (Moher et al, 2010). Statistical tests were not employed given that the trial was inadequately powered to detect small yet potentially important effects (see numbers recruited in chapter six) and thus Type 2 error was probable. Moreover, even when significant at $p<.05$ such tests could reflect the anticipated chance variation between groups and thus do not provide information about any other source of bias (i.e. they do not indicate whether the chance variation if substantial enough to bias effects) (Altman & Dore, 1990). Rather, it is systematic differences of a notable magnitude on important prognostic variables that is important.

Data from primary care and support groups were combined in an attempt to increase statistical power and precision. However, it should be acknowledged that there are reasons why it might not be justified to combine these data. Support group participants represent support seeking individuals, which introduces further selection bias and constitutes a non-representative sample. Consequently, baseline data and psychometric properties were compared for these groups to rule out

[77] Internal reliability/consistency refers to the degree to which the items in a scale are correlated and measure the same thing (i.e. the degree of common variance explained by a common source or rather the latent construct), and thus measure the intended construct.

systematic differences of a notable magnitude on important prognostic variables. Particular attention was paid to clinical data, namely HbA1c, as this was potentially affected by self-report biases for support group participants given that it could not be obtained from routine medical records as in primary care.

Statistical analyses

Preliminary effectiveness analysis[78]

The summary measure of treatment effect was the between-groups difference in mean severity of depressive symptoms at three months, controlling for baseline variation in depressive symptom severity. ANCOVA thus tested the significance of variation in mean depressive symptom severity at three months, with group (intervention or control) as a fixed effect and baseline depressive symptom severity as a covariate. Age and gender were additionally included as covariates.

Standardized estimates of the treatment effect were also derived, namely η^2, η_p^2 and ω^2 (see chapter four for calculations). ω^2 is reported, however η^2 and η_p^2 are reported in the appendix for comparative purposes and to maintain consistency with the existing evidence base. η^2, and thus η_p^2 and ω^2, are interpreted at .01, .06 and .14 as small, medium-sized and large respectively (Cohen, 1988). ω^2 may be negative when the F ratio is less than one. In such instances the effect size was considered to be .00 (Olejnik & Algina, 2000). The associated 95% CIs could not be estimated without bootstrapping (i.e. sampling the data many times to estimate the SE of the effect and thus the confidence intervals), which is difficult to perform. Consequently, the 95% confidence intervals associated with the regression

[78] It was not considered necessary to account for clustering within practices in analyses as a small number of practices actually provided participants (i.e. three), and in fact most of the participants were from one practice (i.e. 22; 63%); the other two practices provided only three (9%) and 10 (29%) patients (see chapter six).

parameters for the between group effect provided an indication of the stability of the estimates. The adjusted estimated marginal means and their SEs were also inspected for each group. In line with the sample size calculation described above, a five point difference on the primary outcome/CES-D is considered potentially clinically important. To facilitate interpretation of any effect this was also represented graphically.

The same analytic strategy was employed for the secondary outcomes of DSED, health-related QoL and diabetes SMBs.

Exploratory analyses

Sub-group (moderator) analyses

To assess whether treatment effects on the primary outcome varied among pre-specified sub-groups, formal tests of interaction were conducted within ANCOVAs. The median split was used to stratify alexithymia and optimism. Specifically, factorial ANCOVAs tested group differences in depressive symptom severity at three month follow up for each level of the moderator, with group (intervention or control) as the first between-participant variable and moderator (high versus low alexithymia or high versus low optimism) as the second between-participant variable. This is consistent with current recommendations regarding sub-group analysis in RCTs (Moher et al, 2010).[79] Baseline levels of the primary outcome were again controlled, yet given the exploratory nature of these analyses demographic characteristics were not controlled. Analyses were performed for the complete case dataset. Effect sizes were not derived for the interaction as this represents an unfocussed comparison, which is thus difficult to interpret and of limited utility (Field,

[79] This approach has previously been employed in WED studies with LTPC samples (Danoff-Burg et al, 2006).

2005). Observed effects were explored with adjusted estimated marginal means and their SEs, and interaction plots (group x moderator).

Explanatory analyses

Mechanisms of change - E&CP: Change in percentage word use reflecting positive emotion, negative emotion, insight and cause across writing sessions was examined with a one-way repeated measures ANOVA for each category of word use, with writing session (session one, two and three) as the within-participants variable. Effect sizes were not derived for main effects as again these represent unfocussed comparisons, are difficult to interpret and are thus of limited utility. Repeated planned contrasts then compared each level of the independent variable to the previous level, which are recommended in instances of measurements at successive time intervals (Field, 2005).

Contrasts for these analyses, and those described below, were undertaken regardless of the statistical significance of the overall effect, given the probable lack of power to detect small yet potentially clinically important effects (again see chapter six). Whilst genuine effects within contrasts were additionally unlikely to be detected as statistically significant, this enabled the effect size for each contrast (i.e. focused comparison), r, to be estimated. The effect size, r represents the Pearson's correlation coefficient, yet this is also a measure of the strength of an experimental effect and is interpreted at .10, .30 and .50 as small, medium and large respectively (Cohen, 1988; Field, 2005). r^2 then indicates the proportion of the total variance in the dependent variable (i.e. the outcome) that is explained by the independent variable (i.e. the effect), for example an effect size of r=.30 explains .09 (9%) of the total variance (Field, 2005).

In these analyses, r was estimated by converting the F ratio for each contrast using the following equation, which was possible because the F ratios for the model had one degree of freedom (i.e. they represent a focused and interpretable comparison). F(1,dfR) refers to the F ratio and dfR refers to the degrees of freedom associated with the error term (Field, 2005):

$$r = \frac{\sqrt{F(1, dfR)}}{F(1, dfR) + dfR}$$

Means and SDs were additionally consulted to inform interpretation of effects.

A factorial repeated measures ANOVA with writing session (session one, two and three) as one within-participants variable and word use category (positive emotion, negative emotion, insight and cause) as a second within-participants variable was not performed because effect sizes for the changes across writing sessions for each category of word use were of interest. Moreover, again all secondary analyses were exploratory and interpreted in view of an inflated Type 1 error rate relating to multiple analyses.

Mechanisms of change - EA&H: It was intended that change in post-writing negative affect across successive writing sessions would also be examined in a one-way repeated measures ANOVA. However, this data remained highly skewed despite transformation (reported in chapters seven and eight, and the appendix), and distributional problems in small samples, as was obtained for the analyses based on the PANAS data (reported in chapter seven), are a cause for concern (Altman &

Bland, 2009). Given that a non-parametric equivalent to the repeated measures ANOVA is available, this test was performed.[80]

A Freidman's ANOVA was thus conducted, again with writing session (session one, two and three) as the within-participants variable. The exact significance test was applied as this is accurate even when samples are small and data are particularly poorly distributed (Field, 2005; SPSS v17). Effect sizes were not derived for main effects as again these represent unfocussed comparisons, are difficult to interpret and are thus of limited utility.

Wilcoxon tests (i.e. contrasts) then compared session one and two, two and three, and one and three. Exact significance tests were again applied and the one tailed significance values were consulted as the direction of the effect had been anticipated (i.e. a decrease in negative affect across sessions). A Bonferroni correction was applied to control for the number of comparisons here; a critical significance value of .0167 was applied (i.e. .05/the number of comparisons) as recommended (Field, 2005). The effect size for the Wilcoxon tests, r, was estimated by dividing the Z score for each contrast by the square root of the total number of observations (Field, 2005).

Medians, which are more appropriate than means for non-parametric tests, and ranges were additionally consulted to inform interpretation of effects.

Should an overall intervention effect and the anticipated changes in percentage word use and post-writing negative affect be observed, it was intended that the absence of such changes in the control group would be explored. If this was

[80] Parametric analyses do not require data to follow a particular distribution as they are based on ranked data; they utilize the rank order of observations rather than the measurements themselves (Altman & Bland, 2009).

additionally confirmed, it was intended that the changes observed for the intervention group would be examined as mediators of the effect of WED on the primary outcome, by means of the approach to formal mediation analysis described below.

Mediators: Baron and Kenny's (1986) three stage procedure assessed the extent to which the mediator variables (i.e. self-efficacy for diabetes SMBs, perceived illness-interference and perceived emotional support) (i.e. B) mediated any relationship between the intervention group (i.e. A) and the primary outcome (i.e. C), where a) A is correlated with C, b) B is correlated with C (controlling for A such that any observed relationship is not attributable to the fact that both are caused by this), and c) the strength of the relationship between A and C is reduced/eliminated when the effect of B is controlled (Baron & Kenny, 1986)[81]. Baseline levels of the primary outcome, but not demographic variables, were again controlled and analyses were performed for the complete case dataset. Missing values were excluded listwise; only participants with scores for all variables were included in the analyses, as advised (Field, 2005).

Specifically, hierarchical multiple regression models were constructed to test each mediation step. For each model, variables that were to be controlled were entered in the first bock and the variable for which the additional contribution was sought was entered in the second block, with forced entry employed within each block (i.e. the predictors were forced into the model simultaneously). Stepwise entry wherein predictors are entered into the model in an order determined by computer-assessed mathematical criterion was not necessary as the purpose of the analysis was not to build exploratory models (Field, 2005).

[81] This approach has previously been employed in WED studies with LTPC samples (Zakowski et al, 2004).

The approach adopted is summarized in Table 13.

Table 13 Approach to the mediation analyses

Mediation step	Regression models
Step 1 A – C	Block 1 Baseline depressive symptoms
	Block 2 Baseline depressive symptoms **Intervention group (A)**
Step 2 B – C (controlling A)	Block 1 Baseline depressive symptoms Intervention group (A)
	Block 2 Baseline depressive symptoms Intervention group (A) **Mediator variable (B)**
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms Mediator variable (B)
	Block 2 Baseline depressive symptoms Mediator variable (B) **Intervention group (A)**

The parameters of interest for each mediation step and thus regression model were:

a) The amount of variance explained by each model fitted to the data relative to how much variance there is to be explained (R^2), specifically the change in the amount of variance explained by model with the addition of block two (i.e. the predictor of interest) (ΔR^2). R^2 is an effect size interpreted at .02, .13 and .26 as small, medium sized and large respectively (Cohen, 1988). It can also be converted to a percentage of the total variance in the dependent variable (Field, 2005).

b) The corresponding change in the F ratio; the ratio of improvement in prediction of the outcome resulting from fitting the model to the data relative to the inaccuracy that still exists in the model (i.e. the ability of the model to predict the outcome). If F >1 the improvement due to the model notably exceeds the inaccuracy in the model.

c) The significance of any change in the F ratio; whether the change in the models ability to predict the outcome was significant (i.e. the significance of ΔR^2).

d) The unique contribution of the predictor of interest (i.e. entered in block two):
   i. The unstandardized regression co-efficient (b): the degree to which the outcome changes as a result of one unit change in the predictor when the effects of all other predictors are held constant; a positive value indicates a positive relationship and a negative value indicates a negative relationship.
   ii. The SE of the unstandardized regression co-efficient (SEb): the extent to which b would vary across different samples.
   iii. The standardized regression coefficient (ß): the number of SDs the outcome changes as a result of one SD change in the predictor when the effects of all other predictors are held constant.
   iv. The p value for the t-statistic (i.e. the test of whether the regression coefficient for this predictor is significantly different from zero): whether the predictor made a significant contribution to the model (i.e. contributes to the ability to predict the outcome).

Where samples are small R^2 is inflated by sampling error or rather random fluctuations in the data which do not represent the population effect, again known as shrinkage (Field, 2005). Therefore, adjusted R^2 was also estimated; the amount of variance in the outcome that would be explained by model if it had been derived

from the population from which the sample was drawn (i.e. rather than the sample obtained). Where R^2 exceeds adjusted R^2 this indicates shrinkage and suggests the model obtained may not generalize to the target population.

The mediation analyses were first performed for the mediator variables measured at two weeks; variables that were measured post-intervention but preceding the outcome assessment consistent with the conditions required to establish mediation. The analyses were then repeated where the mediator variables were measured at three months (i.e. for primary care patients). Although these variables were measured at the same time as the outcome, these analyses were exploratory and included to explore whether it may take longer than two weeks for WED to influence mediators and thus outcomes.

Prior cost-effectiveness analysis

Should effectiveness be demonstrated, cost-effectiveness was intended to be investigated based on the cost of programme implementation, cost per 1% reduction in depression risk and cost per QALY consistent with the approach currently adopted within the NHS.

Feasibility investigation

Feasibility/effectiveness of intervention delivery

Contamination - average degree of ED: A mixed factorial ANOVA tested group differences in the average percentage word use for the four aforementioned categories across writing sessions, with group (intervention or control) as the between-participants variable and category of word use (positive emotion, negative emotion, insight or causation) as the within-participants variable. Effect sizes were not derived for the interaction effect as again these represent unfocussed comparisons, are difficult to interpret and are thus of limited utility.

Deviation (first) planned contrasts compared the effect of group for each word use category, except the first, with the overall experimental effect. The analysis was then re-run with deviation (last) planned contrasts, which compared the effect of group for each word use category, except the last, with the overall experimental effect. This ensured that the effect of group for each word use category was compared to the overall experimental effect. The effect size for the contrasts, r, was estimated by converting the F ratio for each contrast using the equation provided above, which was again possible because the F-ratios for the model had one degree of freedom (i.e. they represented a focused and interpretable comparison) (Field, 2005).

The main effect of group across word use categories was additionally examined with effect size r derived via a simple contrast and again conversion of the F ratio as above, as recommended for complex factorial designs (Field, 2005).

Means, SEs and an interaction plot (group x word use category) were additionally consulted.

Contamination - average degree of EA: It was intended that group differences in average post-writing negative affect across writing sessions would be examined in an independent samples t-test. However, again this data remained highly skewed despite transformation (reported in chapters seven and eight, and the appendix). Given that a non-parametric equivalent to the independent samples t-test is available this was performed. A Mann Whitney U test therefore tested group differences in the average post-writing negative affect. Exact significance tests were applied for the aforementioned reasons, and again the one tailed significance values were consulted as the direction of the effect had been anticipated (i.e. a

higher average degree of EA for the WED group). The effect size, r, was estimated for the main effect. Effect size r was estimated by dividing the Z score associated with the Mann-Whitney U test statistic by the square root of the total number of observations (Field, 2005).

Medians and ranges were additionally consulted to inform interpretation of effects.

Descriptive analyses and qualitative data

Feasibility investigation

Feasibility/effectiveness of intervention delivery

Compliance: The number of days writing completed, the time spent writing per session and whether or not participants undertook further self-directed writing since completing the intervention were tabulated by group (i.e. analysed descriptively).

Acceptability: Reasons for not writing at all or following the protocol as instructed were described qualitatively.

Feasibility/effectiveness of the trial protocol

Randomisation and allocation concealment methods: The feasibility/effectiveness of the randomisation and allocation concealment methods was described qualitatively (i.e. with respect to the baseline comparability of the intervention groups).

Blinding success: Responses to the three questions ascertaining whether patients had inferred the true nature of the study and their group assignment were tabulated by group per question (i.e. analysed descriptively).

Recruitment, retention and sample size: Recruitment flow, recruitment and retention issues, and the feasibility of achieving sample size requirement and the appropriateness of the sample size calculation parameters, were described qualitatively.

The chapters that follow report the findings from the exploratory RCT described above. The findings relating to recruitment, retention and sample size are discussed initially, as this describes the target population that was intended to be sampled and the way in which the study sample was derived. The baseline characteristics of the sample obtained are then presented, followed by the pre-specified analyses and remaining feasibility investigation. Finally, the findings from some additional post-hoc investigations and analyses are then presented, specifically feasibility data that was collated unintentionally and consideration of writing content with some exploratory analyses undertaken to facilitate interpretation of the pre-specified analyses.

Chapter 6 Recruitment, retention and sample size

Chapter overview

As part of the feasibility investigation, specifically the feasibility/effectiveness of the trial protocol, this chapter reports the recruitment flow for the relevant organisations and participants for each mode of recruitment (i.e. estimates of recruitment and retention). The recruitment and retention issues encountered in each context are additionally described, incorporating consideration of the sample size calculation initially specified; the feasibility of achieving the sample size requirement and the appropriateness of the sample size calculation parameters. Again, this data is presented here as it describes the target population that was intended to be sampled and the way in which the study sample, upon which the analyses and remaining feasibility investigation are based, was derived. The chapter closes with the specification of revisions required to the trial protocol, owing to the issues experienced in ethical review (reported in chapter four) and recruitment issues discussed in this chapter.

Recruitment flow

Primary care

Practice recruitment and retention

PMs of 113 general practices across Coventry, Warwickshire and Worcestershire were contacted about the study once ethical (December 2008) and R&D (March 2009) approval had been obtained (i.e. between March 2009–January 2010; most were contacted between March 2009 and July 2009) (i.e. over 11 months). One practice contacted the researcher in response to the initial letter (i.e. before this was followed up), otherwise the average number of contacts abut recruitment post letter

was four (range 1-13). Primary care practice recruitment and retention is illustrated in Figure 18, including reasons for non-participation where these could be obtained.

One hundred and five of the practices were not recruited.

A definite 'no' response was obtained for 61 (54%) of these practices, generally provided by the PM and typically on behalf of the practice GPs or nurses. In a small number of instances where it could be arranged, GPs or nurses were liaised with directly. Three of these practices did advise enquiring again at a later date, but not within the time allocated to recruitment.

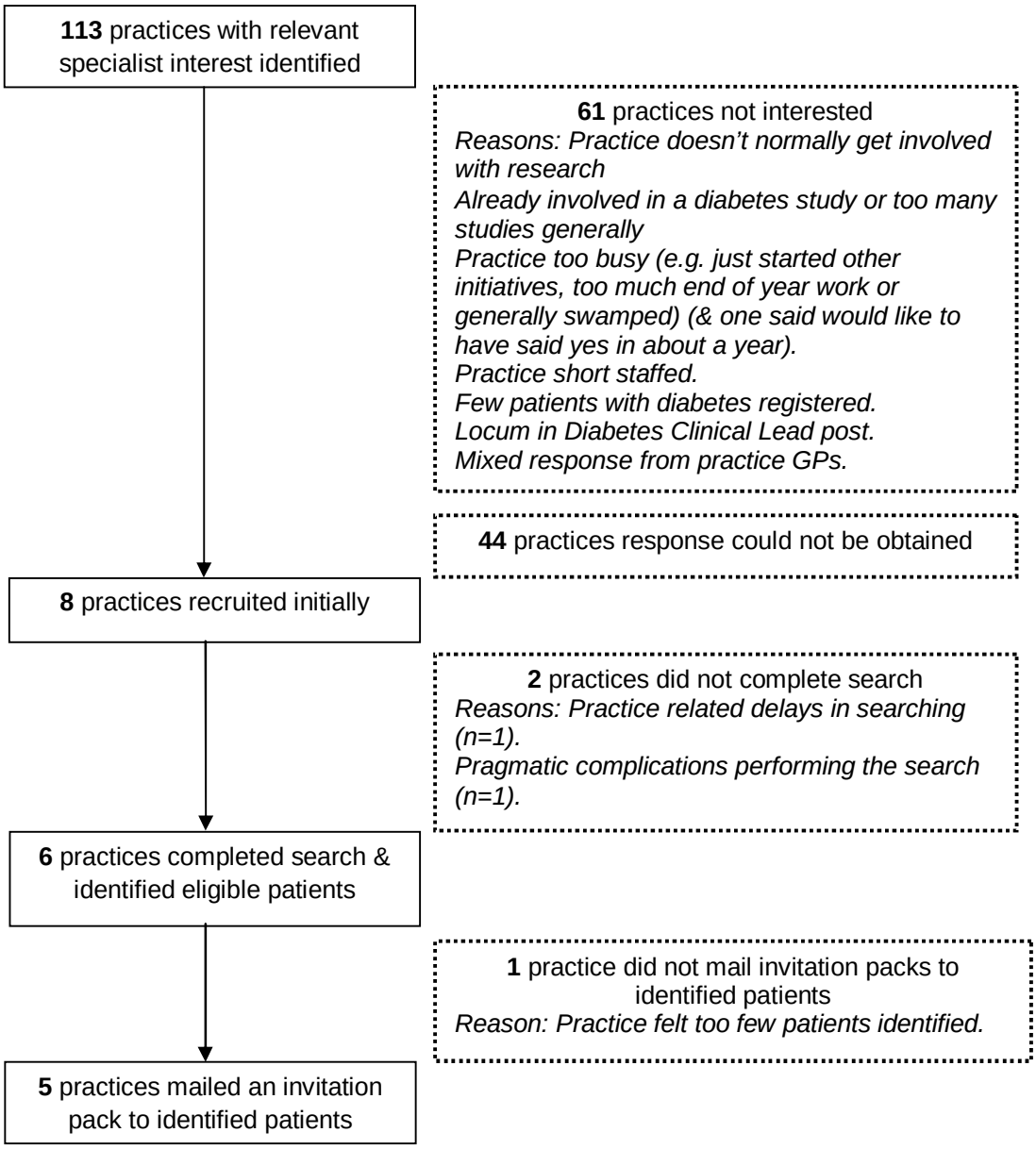
A definite response could not be obtained for the remaining 44 (39%) practices. Typically there was a series of unsuccessful attempts to speak with the PM, and in most instances receptionists advised that the research team would be contacted should the practice be interested yet no contact was made. In other instances, direct GP contact was advised by practice staff, yet they could not be reached[82]. In some instances, there was no appropriate person in post to speak with about the study.

Eight (7%) practices were thus recruited initially. Four of these were visited to present the study in person (once n=2 and twice n=2). However, three of the eight recruited practices were lost before any patients were mailed invitation packs. Two of these practices did not perform the search to identify patients at all, despite initial agreement. For practice F completion of the search was delayed by a number of practice-related issues including swine flu related work load,[83] depleted staff over the summer period and PM's annual leave. Moreover, as the PM was unable to complete the search themselves assistance from a records clerk was required yet

[82] GPs were difficult to reach by telephone and an email address for them could not be obtained.
[83] The recent swine flu epidemic coincided exactly with practice recruitment.

this was never achieved. Practice B dropped out due to pragmatic complications associated with performing the search (described further below). The remaining practice, practice C, completed the search yet did not mail invitation packs to identified patients as very few were identified and the practice did not perceive this number to be useful (discussed further below).

Figure 18 Primary care practice recruitment and retention



Characteristics of the eight primary care practices recruited initially, and the dates at which searches/mail outs were performed, the time and effort invested, and the dates at which attempts to involve practices ended, are illustrated in Table 14.

Table 14 Characteristics of recruited primary care practices

Practice	PCT	Specialist interest	Date search & mail out performed (or practice dropped out)
Recruited & retained			**Search & mail out performed**
Practice A	Warwickshire PCT (Leamington Spa)	Previously took part in diabetes studies at the University of Warwick; Practice has GP with specialist interest in diabetes; Practice has diabetic clinic.	January 2010 (initial search and mail out June 2009; discussed later)
Practice D	Coventry PCT	Practice has diabetic clinic.	August 2009 (initial search May 2009; discussed later)
Practice E	Warwickshire PCT (Nuneaton)	GP based at WMS; Practice has GP with specialist interest in diabetes; Practice offers support and education courses to patients with diabetes; Practice has diabetic clinic.	August 2009
Practice G	Warwickshire PCT (Leamington Spa)	Practice has chronic disease management clinic including diabetes; Practice has mental HCP in place.	June 2009
Practice H	Coventry PCT	Practice has GP with specialist interest in diabetes.	September 2009
Recruited but not retained			**Practice dropped out**
Practice B	Coventry PCT	Previously took part in diabetes studies at the University of Warwick.	June 2009: contacted 13 times in relation to recruitment & organising the search but not visited.
Practice C	Warwickshire PCT (Leamington Spa)	GPs lecture at Warwick University; Practice has diabetic clinic.	December 2009: contacted 13 times in relation to recruitment & organising the search; visited once (initial search July 2009; discussed later).
Practice F	Worcestershire PCT	Practice has diabetic clinic.	December 2009: contacted 28 times in relation to recruitment & organising the search; visited twice.

Patient recruitment and retention

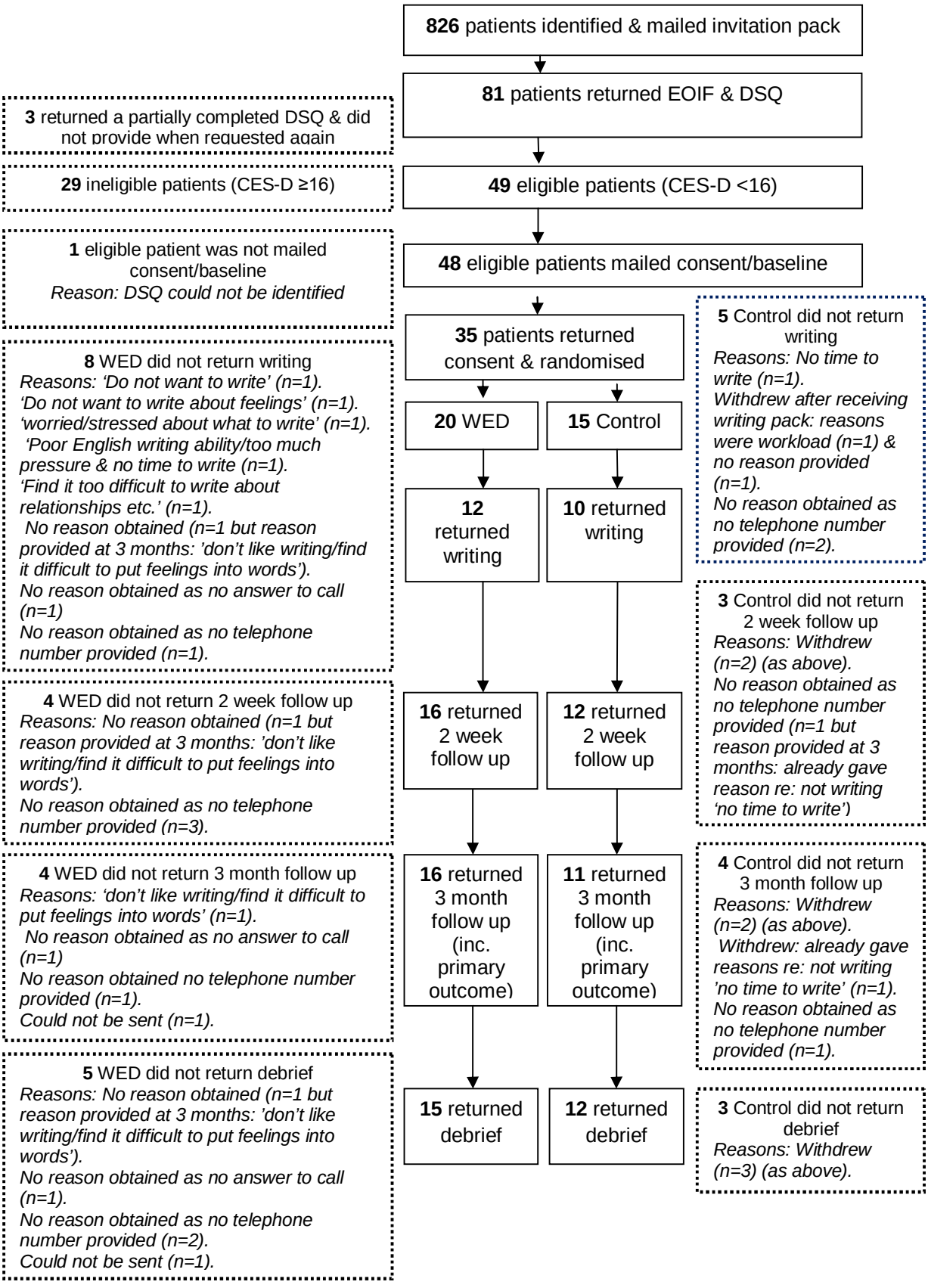
Primary care patient recruitment and retention throughout the trial is illustrated in Figure 19, including reasons for non-participation where these could be obtained. Patient recruitment and retention by individual practices until consent was obtained is illustrated in Table 15. Patients were enrolled between August 2009 and April 2010 (i.e. over nine months), and completed the trial between January 2010 and November 2010.[84]

Together, the five retained practices identified 826 eligible patients and these were mailed an invitation pack. Eighty one patients (10%) returned the initial materials; an EOIF and DSQ (from four of the practices). Forty nine (60%) scored below the cut point for significant symptoms of depression (CES-D <16; mean 7 (SD 4.9) in the eligibility check and were thus able to participate. However, 29 patients (36%) scored as ineligible (CES-D ≥16; mean 26 (SD 8.0), and these patients were excluded and identified to their GP. The remaining three patients (4%) returned a DSQ that was partially completed yet did not return it completed when requested. Forty eight of the patients meeting the eligibility check were then mailed consent forms and a baseline questionnaire; one eligible patient was not mailed this because their DSQ could not be identified.[85]

Thirty five patients (4%) then returned a consent form and baseline questionnaire (from three of the practices). Of the 35 consented patients, 22 (63%) returned the writing task, 28 (80%) returned the two week follow up questionnaire, 27 (77%) returned the three month follow up questionnaire and provided data for the primary outcome (i.e. CES-D), and 27 (77%) returned the debriefing sheet.

[84] The reason for the variable time taken to complete the trial is that this depended upon whether and how quickly participants returned materials.
[85] This was an error that occurred when packs were prepared.

Figure 19 Primary care patient recruitment and retention[86]



[86] The research team took a call from a patient who advised that they had received the writing pack but could not complete it as they had so many problems writing; this patient could not be identified but was one of those for whom the reason for non-return of writing was not obtained.

It should be noted that one patient was not sent some materials because they did not provide an address in the consent form; the three month follow up questionnaire and debrief questions. While practices usually agreed to forward materials in these instances with a request for an address each time, on this occasion they did not.

It is notable that sometimes patients did not return any other materials if they did not return writing; five (38%) of the 13 patients that did not write. However, that left eight (62%) patients that did not write yet provided at least some of the follow up materials, namely both the questionnaires and the debrief questions (n=6), the two week questionnaire and the debrief questions only (n=1) or the two week questionnaire only (n=1). In fact, five of these eight patients actually advised when were chased about reasons for not writing that they did not mind 'ticking boxes', it was just the writing task they did not wish to complete. Of the 22 patients that did write, most returned both the questionnaires and debrief questions (n=20), however some returned the three month questionnaire only (n=1) or did not return any other materials (n=1).

Reasons for non-return of materials were generally obtained unless contact telephone numbers were not provided in returned consent forms. For instance, reasons were not obtained for seven patients not returning materials at one or more stages; for most this was because they did not provide a contact number (n=6) otherwise there was no response to calls (n=1).

Table 15 Primary care patient recruitment and retention by individual practice prior to consent

Practice	No. patients identified	Recruitment rate (expression of interest)	Eligibility check (% of no. expressing interest)			Recruitment rate (consent/ baseline returned)
			Eligible	Ineligible	Partially complete (& not returned when requested again)	
A	239	20 (8%)	14 (70%)	5 (25%)	0	10 (4%)
D	2	1 (50%)	0	1 (100%)	0	0
E	438	55 (13%)	29 (53%)	20 (36%)	1 (2%)	22 (5%)
G	3	0	0	0	0	0
H	144	13 (9%)	6 (46%)	3 (23%)	2 (15%)	3 (2%)
Total	**826**	**81 (10%)**	**49 (60%)**	**29 (36%)**	**3 (4%)**	**35 (4%)**

Secondary care

Clinic recruitment

One teaching hospital in Coventry and Warwick was approached prior to obtaining ethical and R&D approval (18th June 2009 –Hospital A), and another was approached once ethical approval had been obtained (20th July 2009 – Hospital B).[87]

Hospital A (Nuneaton) was not recruited. While the consultant initially contacted was on board, other clinic staff declined when presented with the study at a staff meeting (3rd July 2009). Concerns were that patients were already being asked to take part in too many studies and that patients probably would not be willing and able to complete the writing intervention.

Hospital B (Coventry) was recruited. Within a specialist centre for complex cases of diabetes, endocrine and metabolic conditions, permission was obtained to attend a weight management and a renal clinic held one day per week for four weeks during

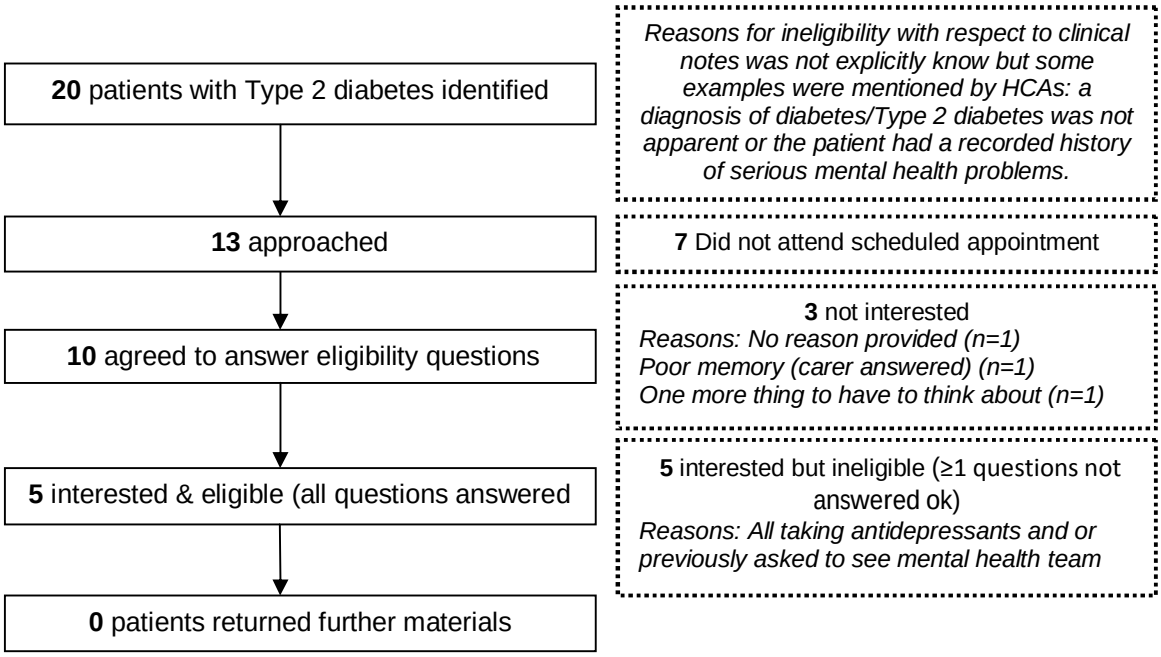
[87] Ethical approval for recruitment in secondary care (i.e. the substantial amendment) was obtained on the 6th July 2009).

December 2009 (i.e. for one month).[88] However, the renal clinic was attended once only because most patients had Type 1 diabetes and were thus ineligible. Consequently, five clinics were attended across four days within one month.

Patient recruitment

Secondary care patient recruitment and retention is illustrated in Figure 20, including reasons for non-participation where these could be obtained.

Figure 20 Secondary care patient recruitment and retention



Twenty potentially eligible patients were identified from clinic notes across the clinics attended. Thirteen of these patients (65%) were approached and offered the opportunity to receive more information about the study/answer the eligibility questions. The remaining seven patients (35%) did not arrive for their schedule clinic appointment. Of the patients that were approached, 10 (77%) agreed to receive information about the study and answer the eligibility questions; three (23%) patients did not agree to this. Of those that answered the eligibility questions, five

[88] This was arranged and commenced once R&D approval had been obtained (October 2009).

(50%) met the study selection criteria and were provided with an invitation pack, while five (50%) did not satisfy one or more of the criteria. Unfortunately, no patients then returned consent forms and the baseline questionnaire.

Support groups

Online group recruitment

Site moderators for 18 independent online support forums were approached about posting information about the study on their forums. DUK was also contacted about posting the study on their online forums; DUK Facebook and DUK Supporting Members Area.[89] Twenty online support groups were thus approached (January 2010-March 2010).[90] Online support group recruitment and retention is illustrated in Figure 21.

Permission to post was not obtained for 13 of the independent forums, most of which did not respond to the request (n=12). One provided permission subject to a review of further information about the study, which was provided but no response could be obtained thereafter. Permission to post in the DUK Supporting Members Area was not granted, no reason was provided.

Six sites (30%) therefore provided permission to post the study information in their forum (five independent forums and DUK Facebook). However, DUK Facebook withdrew permission once the study had been posted for approximately one day. Written permission was initially obtained from DUK, yet once the study was posted DUK[91] removed it advising the researcher that site policy prohibits such posts because it is not possible to check and accommodate all researchers wanting to do

[89] This is an online resource including a discussion forum.
[90] Ethical approval for the study was obtained in February 2010.
[91] This was a different member of DUK to the person that initially provided consent.

this. Thus only five (25%) of the sites that were approached agreed for the study to be posted for the full period of time.

Characteristics of the initially recruited forums, the location of the study post (i.e. instructed by the site moderator) and the dates over which the study was posted are illustrated in Table 16.

Figure 21 Online support group recruitment and retention

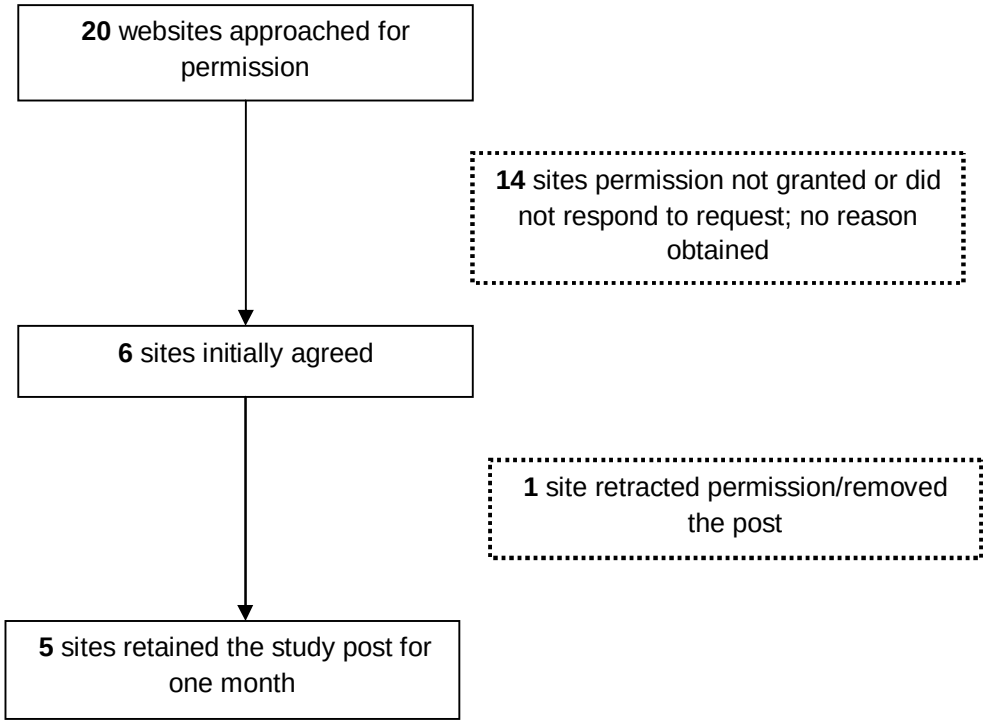


Table 16 Characteristics of online support groups[92]

Forum address	Community		Site membership (at recruitment)	Location of study post	Recruitment period (no. days study posted)	No. of views during recruitment period
	Diabetes type	Nationality				
Recruited and retained						
http://www.diabetes-support.org.uk	Diabetes (all types)	UK based but English language: presumably intended for that nationality but open to international membership	1, 076 (March 2010)	Research sub-forum: 'Research'	12/03/10 – 12/04/10 (31 days)	183
http://www.diabetes.co.uk	Diabetes (all types)	UK based but English language: presumably intended for that nationality but open to international membership	21, 193 (March 2010)	Type 2 diabetes sub-forum: 'Type 2 diabetes'	12/03/10 – 12/04/10 (31 days)	534
http://www.diabetesdaily.com	Diabetes (all types)	USA based but English language: presumably intended for that nationality but open to international membership	21, 436 (February 2010)	Research sub-forum: 'Promotions, surveys & trial recruitment'	08/03/10 – 12/04/10 (35 days)	126
http://www.dlife.com	Diabetes (all types)	USA based but English language: presumably intended for that nationality but open to international membership	43, 155 (February 2010)	Research sub-forum: 'Community centre: diabetes events & fundraisers'	08/03/10 – 12/04/10 (35 days)	46
http://www.dailystrength.org/	Open to 500+ communities (i.e. LTPCs including diabetes & mental health conditions)	USA based but English language: presumably intended for that nationality but open to international membership	Not reported	Research sub-forum: 'Medical Research & Clinical Trials'	10/03/10-12/04/10 (33 days)	Not reported
Recruited but not retained						
http://www.facebook.com/diabetesuk	Diabetes (all types)	UK based but English language: presumably intended for that nationality but open to international membership	10, 028 (March 2010)	No sub-forum: posted on main site	08/03/10 – 09/03/10 (1 day)	Not reported

[92] The study was typically posted for a period of 31 to 35 days; this slight variation is because permission for some forums was obtained slightly later than for others and the study website was closed when the latest post had been on that forum for one month.

Online support group participant recruitment and retention

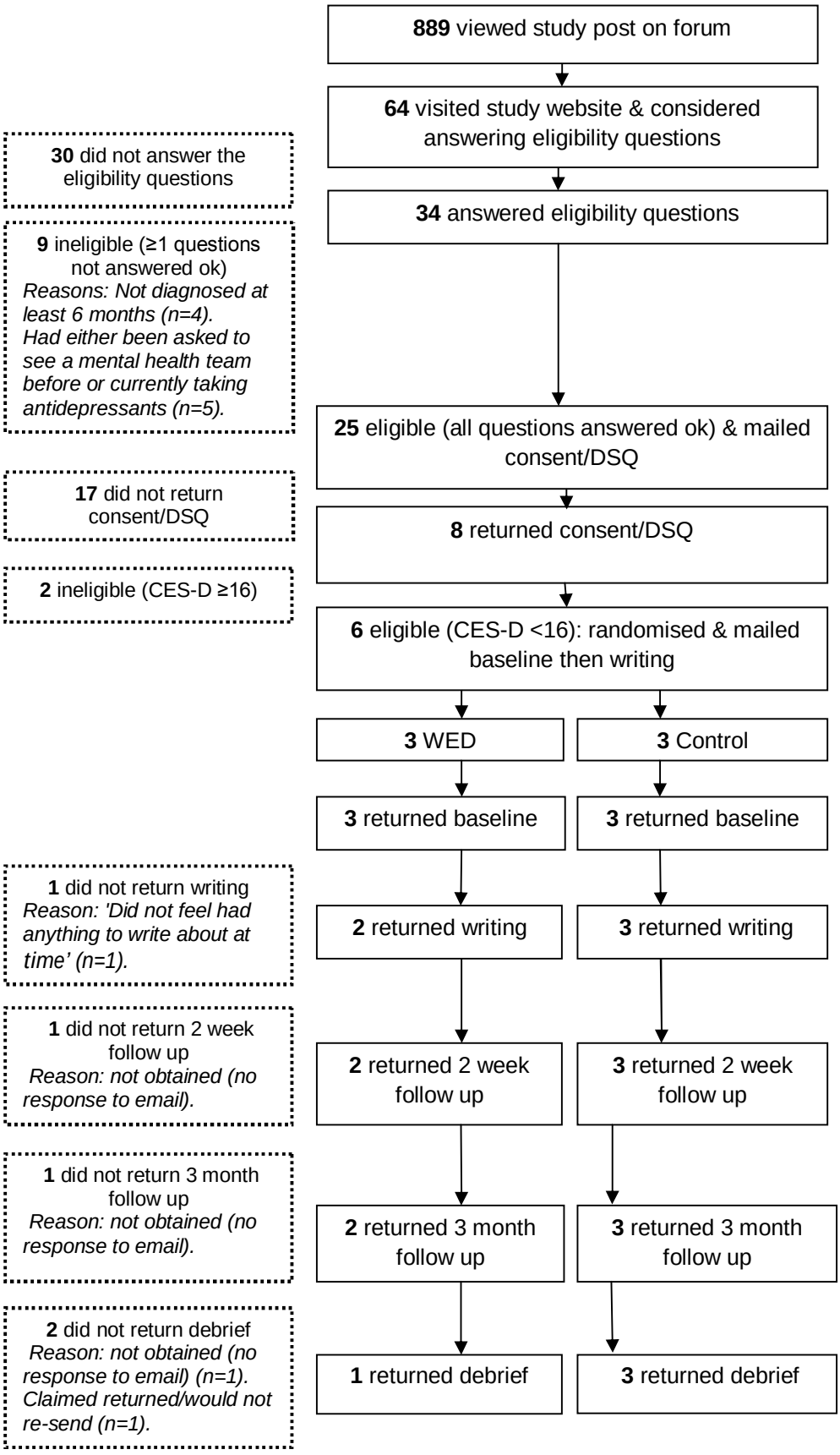
The number of people viewing the study post on each forum is included in Table 16 and online support group participant recruitment and retention is illustrated in Figure 22, including reasons for non-participation where these could be obtained. It was not possible to identify the number of people from each forum that went on to visit the study website, answer the eligibility questions, complete the eligibility check and then provide consent. However, threads about the study on the two UK-based independent forums indicated that some were from these.[93] Patients were enrolled during March 2010, and completed the trial between July 2010 and October 2010.[94]

Over the recruitment period, at least 889 people viewed the study post (i.e. one of the five forums retained did not provide this information). Of the people viewing the study post in the forum, 64 (7%) visited the study website *and* considered answering the eligibility questions.[95] However, only 34 (4%) submitted responses to the eligibility questions, 25 (74%) of whom were eligible (i.e. all questions were satisfied) and nine (26%) were not (i.e. one or more questions were not satisfied).

Eight people (1%) returned a consent form and the DSQ. Six (75%) scored below the threshold for significant depressive symptoms (CES-D <16; mean 6 (SD 3.87) and were thus able to participate. However, two (25%) scored as ineligible (CES-D ≥16; mean 24 (SD 4.24), these patients were excluded and instead were advised to contact their HCP.

[93] It is possible, albeit unlikely, that some participants were obtained via DUK Facebook because a small number of people from either this forum or the other forums posted in on the same date had answered the eligibility questions before the DUK Facebook post was removed.
[94] The reason for the variable time taken to complete the trial is that this depended upon whether and how quickly participants returned materials.
[95] This was known because the study website consisted of two pages; individuals read the information about the study on the first page and then when prompted visited a second page comprising the eligibility questions, which was recorded. The number of people that visited the study website but did not consider answering the eligibility questions was not known.

Figure 22 Online support group participant recruitment and retention



Of the six consented patients, five (83%) returned the writing task, five (83%) returned the two week questionnaire, five (83%) returned the three month questionnaire and four (67%) returned the debrief questions. Of the five participants that did write, most returned both the follow up questionnaires and debrief questions (n=3), however some returned both questionnaires but not the debrief questions (n=1) or did not return any other materials (n=1).The participant that did not return their writing returned both the questionnaires and the debrief questions.

As participants were emailed rather than called about reasons for non-return of materials, emails were often not responded to and thus reasons not obtained.

Local group recruitment

DUK was additionally contacted about the possibility of including the study in newsletters and visiting local DUK volunteer groups (January 2010). Only permission to approach DUK voluntary groups was granted. The Coventry DUK voluntary group was contacted (February 2010), via DUK, who provided them with information about the study (i.e. a PaIS) and the research teams contact details. However, no response was obtained.

Interested and untreated yet too screen-depressed participants

It is evident that a significant proportion of the primary care population of adults with Type 2 diabetes are currently not receiving the support they would like for some degree of E&P need. Primary care patients that expressed an interest in the study were not currently treated for depression or receiving psychological therapy for any other reason. However, expressing an interest in this study may be taken to reflect treatment seeking in that patients were informed that the study was looking at ways of improving the health of people with Type 2 diabetes and whether and how writing

about different aspects of life might affect their health; it is likely that they inferred psychological health was being targeted. In fact, feedback in support group forums supported this inference (reported later). Indeed, of those that expressed an interest 36% screened as experiencing significant depressive symptoms. The mean CES-D score for these patients was 26 (SD 8.0), and one patient even scored 43.

The recruitment and eligibility check data from the online support groups concurred. Of those that expressed an interest/answered the eligibility questions, 85% were not currently receiving E&P support. It is difficult to know how many of these individuals would then have demonstrated significant depressive symptoms and been excluded in the eligibility check because so few returned consent and completed the DSQ. However of those that did complete this, 25% screened as experiencing significant depressive symptoms; mean CES-D 24 (SD 4.24). It seems reasonable to speculate that the proportion would be similar, unless the reason people did not complete the DSQ was systematically related to mood (i.e. people were too depressed to complete it or conversely did not perceive it to be relevant to them).

It is also noteworthy that E&P support is potentially sought not only by untreated patients with longer established diabetes, but also those within six months of their diagnosis (i.e. when one might presume these individuals were still being well supported by the NHS); 14% of the online support group members that expressed an interest in the study and were not currently treated had been diagnosed for less than six months.

Recruitment and retention issues

Three routes to accessing participants were attempted. The unique issues experienced in terms of recruitment and retention at both an organisational and patient level are now described for each approach.

Primary care recruitment and retention

Primary care practice recruitment

Feedback from practices

The reasons provided by practices that declined to take part were reported earlier in this chapter (i.e. where these could be obtained). Additional feedback from practices during the course of recruitment served to further highlight the issues that were experienced and potentially explain reasons for non-participation where these were not otherwise obtained. The concerns frequently expressed by practices and the measures taken in attempting to address them are presented in Table 17.

Research portfolio issue

Recruitment of practices was also notably hindered by recent changes in regulations relating to health service research. Studies that are externally funded by NIHR funding partners (NIHR, 2010), are now eligible for inclusion in the NIHR Clinical Research Network (CRN) portfolio and as such receive support from the NIHR CRNs, for example the PCRN. Practices recruited for such studies are reimbursed for research activity, and a research nurse is made available to assist with practice and patient recruitment, and any other resource costs. Indeed, the value and contribution of primary care research networks is widely acknowledged (Graham et al, 2007).

Table 17 Concerns frequently expressed by primary care practices and the attempts to address them

Primary care practice concerns	Measures taken to address concerns
The PrIS depicted the study as complex and necessitating a significant amount of practice involvement.	It was explained that the study actually necessitated minimal practice involvement limited to help with identifying participants that would not significantly add to their workload.
The PrIS indicated that GPs would be required to deal with patients demonstrating significant depressive symptoms, patients' questions about their screening score and patients' concerns as a result of screening or writing.	It was explained that this was anticipated to be infrequent because most at-risk patients would be excluded by the study selection criteria, and that the evidence suggests most people report engaging in WED to a be a positive experience.
Practices were deterred by the amount they were asked to do (even though practice involvement was kept to a minimum).	The researcher offered to be present while practices performed the search and mailed envelopes (i.e. to help in any way without seeing identifiable patient data), and do any other work in order to free staff to undertake this.[96]
Practices were concerned about the cost to be incurred by them (i.e. postage costs).	It was explained that the cost of consumables would be covered by the University. This was not explained in the PrIS, however, as in the absence of funding[97] it was originally intended that they would be asked to cover these costs. The researcher later undertook paid work commissioned by the DoH (NHS Diabetes & DUK, 2010), which provided a means to cover these costs.

However, the present study was not externally funded and therefore not eligible for adoption onto the portfolio. Indeed, it was apparent that some practices were deterred by this issue; some expressed an interest in the study yet indicated that they did not have the resources to participate and on occasion inquired about how much they would be paid. A stance of portfolio only studies was also apparent for some practices. This impact on institutionally or self-funded PhD research suggests that primary care research training experiences may be limited in the future.

This finding confers with the literature that has explored the involvement of GPs in primary care, and the incentives and disincentives for GP participation. Specifically, one UK study interviewed GPs that declined participation in a primary care research study, reporting that practice participation is typically low and that GPs primarily

[96] One practice agreed to this and to have the researcher search data with identifiable features removed, however they dropped out before this could be undertaken (practice F).
[97] The study was competitively awarded internal funding, which covered the stipend and fees for a PhD studentship yet did not provide a means of covering costs associated with the research.

expressed a lack of time for research and an already overwhelming workload. However, were they to be paid GPs would consider research in their own time, and in fact some commented that an indication of payment is sought before deciding whether the study information is worthy of further consideration. Indeed, research was considered low value in its potential to inform clinical practice and facilitate career progression within primary care (Salmon, Peters, Rogers, Gask, Clifford, Iredale, Dowrick & Morris, 2007). Despite mounting pressure for GPs to participate in research such that the NHS can become more evidence-based, as specified in recent policy imperatives for instance 'Best research for best health' (DoH, 2006a), this study additionally identified a sense of entitlement to non-participation since there are no such expectations of GPs (i.e. it is not in the GP contract) (Salmon et al, 2007). Indeed, it is widely acknowledged that many primary care practices will not consider collaboration without payment as research is not a core activity for primary care (NIHR & PCRN, 2010).

The QoF criterion issue

Practice recruitment and retention was further adversely influenced by a study design flaw. As reported in chapter four, the study selection criteria originally additionally required that within the past 12 months patients had screened positive (i.e. answered yes) to at least one of the two QoF depression-screening questions (introduced in chapter one). It was anticipated that this QoF criterion would promote practice recruitment, providing a means of treating patients indicating that they are experiencing lower-level depression in a climate of limited treatment options (as discussed in chapter one IAPT was not fully implemented when practices were recruited). Indeed, this potential benefit was emphasised in the PrIS as a means of incentivising GPs. Research into the incentives and disincentives for GPs to participate in primary care research has consistently indicated that studies must highlight the relevance of the research to practices and sell the potential benefits of

the study to practices beyond the merits of the research (Graham et al, 2007; Johnston, Liddy, Hogg, Donskov, Russell & Gyorfi-Dyke, 2010). However, two problems were encountered in relation to this criterion:

1. Practices conducted computerised searches and many were unable to apply this criterion as responses to the QoF questions are recorded free text and they were not willing to search manually (practices B, E and H).

2. Enforcing this criterion recovered no or very few participants; four of the eight practices recruited initially searched including this criterion; the numbers identified were 0 (Practice D), 3 (Practice G), 13 (Practice A) and the number was retained for one practice as it was low and considered by the practice not to be useful (Practice C). These practices indicated that it was this criterion which greatly reduced the number of eligible patients.

It is noteworthy that because patients currently receiving depression/psychological treatment were excluded, it seems that either:

a) There are virtually no people with Type 2 diabetes that have lower-level depression; all have no need or a significant need that obviously requires treatment. This is unlikely in view of the literature/evidence base outlined in chapter four, which suggests that lower-level need is experienced by the highest proportion of people with Type 2 diabetes (NHS Diabetes & DUK, 2010). Moreover, consultation with a local GP when developing the study protocol indicated that enforcing the QoF criterion and excluding patients with a significant need/currently receiving treatment was a valid approach for identifying these patients.

b) The QoF questions detect only higher-level depression, most of which most is currently being treated. Three observations in the present study may be taken to support this assertion. Firstly, one practice advised that most patients with diabetes say no when asked these questions hence a search based on this would identify few patients (Practice C). Secondly, of the patients that were identified via searches including the QoF criterion and mailed out to (n=16), one response was received and this patient was excluded in the eligibility check having screened as experiencing significant depressive symptoms. Finally, in practices that had achieved good QoF depression-screening scores (i.e. generally approximately 90% of patients having been screened on one occasion during the previous 15 months), a substantial number of patients with Type 2 diabetes were found to be experiencing significant depressive symptoms that were untreated. This may be taken to suggest that the QoF questions do not detect the full spectrum of depression.

   This scenario is unlikely, though, given the evidence reported in chapter four, which suggests that the QoF questions perform sensitively and detect most true cases of depression, but they also have a high false positive rate and thus additionally identify a substantial number of patients with lesser symptoms.

c) The QoF questions do detect all levels of need including lower-level depression, yet most of these are currently treated. This explanation is consistent with the aforementioned diagnostic accuracy evidence (again as reported in chapter four), and provides some support for the concern that false positive cases identified by the QoF questions may result in 'over-treatment'. As described in chapter one, although IAPT has recently improved access to psychological intervention this is still somewhat limited and indeed it was at the time of practice recruitment. Although again speculative this suggests antidepressants may have been prescribed for

lower-level need, which NICE specifies should be reserved for moderate to severe depression. As also described in chapter one, it has previously been speculated that practitioners may prescribe antidepressants where psychological treatment is less readily available (Kendrick et al, 2009). Indeed, the QoF depression indicators have now been retired owing to widespread complaints about poor diagnostic ability, specifically over-diagnosis of individuals as depressed and appropriate for antidepressants (PulseToday, 2011).

Audits of eligible patients on the diabetes and CHD registers for two rural general practices in the UK, excluding those with known depression, have similarly identified that of those patients screened with the QoF questions (approximately 80%) only 1% (Subramanian & Hopayian, 2008) and 2% (Croxford, 2008) responded positively. The explanations offered have included low detection rates for the QoF questions and adequate recognition of depression irrespective of the QoF questions, somewhat consistent with the explanations offered above (i.e. b) and c) respectively). Interestingly in one study of the two patients responding positively to the QoF one was assessed as having minimal depression whilst for the other moderate to severe depression was identified (Croxford, 2008), suggesting that the third assertion above is again more likely (i.e. that the QoF questions do detect lower-level depression yet most of these are currently treated). Additional albeit seemingly less likely assertions offered are that patients with depression may be those refusing screening to avoid a probable diagnosis and errors in audit data collection/factors specific to the sample, yet this is unlikely given that this finding is emerging across different studies.

It was not a pre-specified objective of the exploratory RCT to identify the feasibility of targeting patients with Type 2 diabetes and lower-level E&P need, yet this finding provides valuable information about the difficulty in achieving this; obviously other

means of achieving this must be identified. Owing to the problems encountered, a substantial amendment was obtained to remove the QoF criterion (July 2009), which indeed boosted the number of identified patients. However, this amendment meant that patients with none and some, rather than only some, level of E&P need were included. Thus the initial endeavour to enhance the applied relevance of the trial and maximise effectiveness was thwarted. Indeed, the level of need amongst interested and eligible, and then consented, patients was relatively low (CES-D mean 7; see chapter seven).

In terms of the influence of the QoF criterion upon practice recruitment, it is likely the need for some practices to manually search responses to the QoF questions played a role in the 105 that chose not to participate. A number of practice retention problems can also be attributed this:

- The loss of three practices: As described earlier one practice initially agreed to participate yet withdrew due to pragmatic complications associated with searching; they were amongst the practices that were unable to apply this criterion in a computerised search. By the time the amendment to remove this criterion had been organised, their situation had changed and they were no longer able to take part (Practice B). After removing the QoF criterion the four practices that had already completed the search were asked to re-search without it (and then mail out to any additional patients). However, two practices were unable to do this. For one the GP was performing the search, thus they had limited time and resource (due to QoF related workload); this was the practice for which the number of patients identified initially was very small and not retained (Practice C). The other practice was overrun with swine flu when the second search was requested; this was the practice that identified and

mailed to three patients initially, and who actually commented at the time that they had identified 80 patients before the QoF criterion was applied (Practice G).

- The time delay in searching: the remaining practices that were unable to apply this criterion in a computerised search agreed to search once the criterion had been removed, yet there was an inevitably long delay from when the practice was approached to when the search was performed while ethical approval for the substantial amendment was obtained (Practices E & H). Additionally, two practices agreed to repeat their initial search once the QoF criterion had been removed, but again there was a delay in arranging this and also finding the resources to search again (Practices A and D).[98]

It is noteworthy that, as mentioned earlier, beside the complication of the QoF criterion, completion of searches by practices was often delayed for other reasons. The most notable, observed across practices, were swine flu related/QoF-related work overload, practices being short staffed over the summer when searches were attempted and PM annual leave.

Additional efforts to recruit practices

In view of the recruitment issues that were anticipated and then experienced, additional means of recruiting primary care practice were attempted. These are described below.

[98] It is also noteworthy that despite being asked not to mail out to the same patients initially identified and mailed out to in the QoF search, when the search was repeated without the QoF criteria it was apparent that one of these practices may have done this (practice A); a patient that initially declined received a further invitation pack and called the research team to decline again. Consequently, the number mailed out to may have been slightly less than indicated; 814. Moreover, one of the 81 patients that expressed an interest may be a duplicate; one patient from this practice expressed an interest and screened as ineligible in the first mail out and may have responded again had the pack been re-received.

Recruiting within additional PCTs

It was initially intended that practices from Hereford PCT would additionally be approached. Consequently, an application to Hereford PCT R&D was intended. However, whilst enquiring about the application process it was discovered that local collaborators (i.e. general practices) were to be identified as a means of providing evidence that GPs would be happy to participate before an application could be made. Furthermore, detailed information was required about the costs to the NHS and sources of funding for covering this, and it was advised that studies were unlikely to be approved if there was a cost to practices in the absence of a financial incentive.

A non-obligatory expression of interest was therefore sought from a small sample of practices in Hereford. Seven with evidence of a special interest in diabetes and or mental health were identified via a search of practice websites and as recommended by local research nurses, which included practices that had previously taken part in diabetes studies at WMS. Practices were mailed a letter and PrIS, which additionally outlined the cost implications for the practice and indicated these to be minimal (i.e. as agreement with this aspect of the study was required by R&D). They were advised to contact the research team should they be interested, yet were followed up once. Only one practice responded to indicate that they were not interested, with no reason provided. Thus, in the event of no funding to cover the costs to practices, however minimal, and an inability to obtain support from local collaborators, the R&D application was not pursued.

Attempts to obtain external funding

Attempts to obtain funding to cover the cost to practices were made whilst preparing the application to Hereford PCT R&D, for example contacting the West Midlands South Comprehensive Local Research Network (CLRN) and local R&D managers,

for example for Hereford PCT. However, no support was obtained. The research team also submitted a funding bid to DUK, which was well received but unsuccessful in the absence of pilot data.

Direct GP contact

In addition to contacting practices, a departmental email was sent to GPs working within WMS explaining the recruitment difficulties and requesting assistance, reiterating the positive aspects of the study. Such an approach is advocated by studies that have identified the incentives and disincentives for GPs to participate in primary care research (Johnston et al, 2010). However, no additional responses were obtained.

Attempts to minimise the impact upon practice resources

As advised by a local GP, arrangements were made to advertise the study in a flyer made available at a meeting at the West Midlands Deenery for doctors undertaking GP speciality training. Specifically, this offered the study as a means of meeting a course requirement. However, no responses were received.

Attempts to elicit minimal assistance from research nurses

Local research nurses were approached for assistance in initiating contact with practices. However, they were unable to help because the study was not a NIHR CRN portfolio study.

Primary care patient recruitment

The research did not seek to formally collect data about reasons for patients not wanting to participate and therefore from an empirical stance these reasons are not known. However, issues that were raised by practices and patients contacting

practices or the research team about the study provide some insight into patient recruitment problems. The problems identified, and the supporting evidence, are provided in Table 18.

Table 18 Primary care patient recruitment problems with supporting evidence

Primary care patient recruitment problem	Evidence
The DSQ created some concerns amongst patients; some took it to imply they were unsuitable & some found it difficult to complete.	Three patients contacted the research team to enquire whether they could still participate given that they did not really have any worries/were not depressed and therefore they were uncertain that they would be of any help (i.e. none of the depression-screening questions were relevant to them). In fact, another patient contacted the research team citing similar reservations as their reasons for not completing the baseline questionnaire (& thus not consenting to the study). Seven patients returned a DSQ that was partially completed & 3 of these did not complete/return it again when requested. Reasons were obtained for one patient who stated that they had 'never really thought about these things'.
Some patients were concerned about their writing ability.	Despite re-assurances that it was unimportant in the PaIS, some patients expressed concerns about poor writing ability when they called the research team about the invitation pack.
Some patients were confused & caused to question the authenticity of the project when they found practice reception staff were unaware of the study.	One patient contacted a practice with a query about the study (even though the patient letter/PaIS advised contact with the research team) and then contacted the research team advising that no one at the practice seemed to know about the study.
Patients were confused about an oversight in the study design; the PaIS instructed patients to return the EOIF and DSQ to their practice, yet the business reply envelope provided was addressed to the university.	Some patients called the research team and practices confused about this oversight.
Some patients were concerned that too much time had elapsed to reply to the invitation pack.	One patient contacted the research team a few months after invitation packs were sent out to enquire whether it was too late to participate.
Practices mailed out to some ineligible patients.	Four patients contacted the research team to explain that they were ineligible because they had Type 1 diabetes, were blind or the patient invited had dementia (i.e. a carer called).
Some patients were experiencing difficult personal situations, in which writing/study participation presented an additional burden.	One participating patient noted on their returned materials that they were a full time carer for their disabled spouse.
Other personal circumstances.	One patient contacted the research team to advice that the invitation pack was not wanted as they were 'going away'.
Many identified patients were likely from ethnic minorities and unable to participate owing to insufficient English writing ability (i.e. English writing ability was not an inclusion criterion).	One practice advised that they would probably identify few patients that could participate because approximately 80% of those on their diabetes registers were from ethnic minorities (based in Leamington Spa). Indeed, as noted in chapter four, diabetes is particularly prevalent in these groups, for instance South Asians. This was likely an even more substantial issue for practices from particularly multi-ethnic areas (e.g. Coventry).

Primary care patient retention

The reasons why patients did not consent to take part in the study were not known other than because a large proportion of interested patients screened ineligible in the eligibility check. Reasons why patients did not return the writing pack and subsequent materials were sought and were reported earlier in this chapter, albeit again for some patients these were not obtained. However, a number of issues encountered during the trial provided some insight into patient retention problems. The problems identified, and the supporting evidence, are provided in Table 19.

Table 19 Primary care patient retention problems with supporting evidence

Primary care patient retention problem	Evidence
Practice administration issues.	A significant number of eligible patients did not return the baseline questionnaire & consent; figures for individual practices were 21%, 29% and 50% and for the latter practice the PM's annual leave created a substantial delay in these materials being sent to patients. It may be important to send these straight away before patients lose interest.
Inability to chase non-return of materials.	Of the reminder letters that were sent, 50% resulted in returned materials. However, as no address was provided in their consent forms some patients could not be sent some reminders; three patients were not sent reminders about writing packs and or two week questionnaires that were never returned. While practices usually agreed to forward materials in these instances with a request for an address each time, on these occasions they did not. Telephone reminders also often resulted in return of materials. However, as patients often did not provide a contact telephone number, some could not be called about materials that were never returned. This not only meant that reasons were not obtained but these patients were additionally not encouraged to return the materials.
Patient illness during the trial.	Perhaps due to the age of some consented participants (i.e. range 41-84 years) illness was occasionally mentioned in the follow up questionnaires or as reasons for delays in returning these. One patient mentioned not feeling well, another had a double bypass operation and another was admitted to hospital with heart failure (i.e. atrial fibrillation) during the follow up period.
Patient safety issues.	GP referral as a result of a review of essay content may have deterred one patient who was referred as high risk/requiring action, as they did not then return any materials post-writing.

Secondary care recruitment and retention

In response to the recruitment problems experienced in primary care, recruitment in secondary care was organised and attempted.

Secondary care clinic recruitment and retention

One secondary care clinic was initially recruited but not retained, the reasons for which were reported earlier. As described in chapter four, the recruitment strategy for secondary care was developed in consultation with an appropriate clinician, but from this unretained clinic. When recruitment was attempted in the clinic that was recruited a number of feasibility problems were encountered, namely because clinical support was much less available than initially anticipated. The recruitment strategy was thus adapted in consultation with the staff and consultant at the clinic that was recruited. The issues experienced and changes necessitated are described below, as they highlight the difficulties in undertaking recruitment in a clinical setting which is effective and satisfies ethical requirements when limited clinical support is available.

Attendance at clinics

It was also only possible for the researcher to attend a much smaller number of clinics over the course of the month than was originally intended (i.e. one day per week rather than daily), which hindered the pace of recruitment considerably.

Identifying patients

It was intended clinicians/clinic staff would initially identify patients meeting the study selection criteria and their subjective HCP assessment of suitability in consultations, inviting them to be introduced to the researcher in order to receive study information and screen for eligibility in the waiting room (as recommended in chapter four). However, this was not possible as clinic staff did not have the time. Consequently, as described in chapter five, HCAs identified patients with Type 2 diabetes from clinic notes, who the researcher then approached in the waiting room enquiring whether they would be willing to receive more information about the study

and screen for eligibility. As identified in chapter four, this strategy has typically been less successful in WED studies with LTPC samples recruited in secondary care. Indeed, recruitment to WED trials in pain clinics is noted to be particularly poor where researchers that are non clinic staff hand invitation packs to patients (Brown, Dick & Berry, 2010).

This created also some ethical issues. Firstly, patients were approached by the researcher, without them having advised clinic staff that they would agree to this. It was emphasised, though, that this was not obligatory and they were free to say no. Secondly, patients were asked to provide information of sensitive nature in a waiting room, rather than them being assessed for eligibility in the privacy of their consultation. However, patients were asked to read the questions silently and respond only with yes or a no. Finally, if patients did not satisfy the eligibility questions, they had to be advised that because of the answers they gave they were not able to take part, rather than patients being informed about the study only if they were eligible. This was uncomfortable for patients and not appropriate in a waiting room. Whilst not ideal, it was advised as tactfully as possible that the questions were simply to ensure that the study was offered to suitable people.

Eligibility check and negative emotional response to screening/writing

It was intended that upon completion of the eligibility check, patients meeting the criteria for significant depressive symptoms would be dealt with accordingly by the secondary care clinician, for which specific agreement would be obtained at clinic recruitment. Moreover, contact with the clinician was to be encouraged should patients wish to discuss their screening score, or should they experience any concerns as a result of screening or writing, with specific contact details provided and specific agreement again obtained at clinic agreement. However, this was not agreed to as the consultant advised that they would refer such patients to their GP.

Consequently, the strategy was changed such that for ineligible patients GPs would be notified about their screening result. Patients were also signposted to their GP. This was potentially problematic in that GP agreement had not been obtained, and indeed GP contact details could not be offered to patients for this reason.

Secondary care patient recruitment

Both of the initially recruited consultants indicated that they expected a large number of eligible patients could be provided by their clinics. However, as described earlier, this was not the case. For the hospital that was retained, many patients did not attend for scheduled appointments, and clinic staff complained about consistently high rate of such 'DNAs'. Moreover, for one clinic the patient notes did not arrive, thus eligible patients could not be identified. When patients did attend clinic and clinic notes were available, few potentially eligible patients were identified; the researcher attended weight management and renal clinics at which only some diabetes patients presented. Moreover, when potentially eligible and interested patients were identified, only half met the study exclusion criteria; it seems that many patients attending secondary care suffer from psychological problems that mean that they may be at risk of re-traumatisation from WED.

Support group recruitment and retention

In response to the recruitment problems experienced in primary and secondary care, recruitment from support groups was organised and attempted.

Support group recruitment and retention

A number of problems were experienced in relation to support group recruitment. With respect to the independent online forums, it was difficult to identify specific contact details for site moderators in order to request permission to post the study in

forums. Often messages were sent via forms provided on the websites which were easily ignored, hence most sites that were approached did not reply to the request. It was additionally difficult to identify the appropriate contact with regards to recruitment efforts via DUK. Indeed, as described earlier conflicting advice was obtained with respect to DUK Facebook. Conflicting advice was also obtained with respect to approaching DUK voluntary groups; one contact advised that this was not allowed, whereas another contacted a local support group on behalf of the research team giving the impression that direct contact with groups was not possible. Another contact later provided contact details for local groups, however further groups were not approached as by that time online recruitments efforts had provided few patients and it was considered unlikely this would identify many more. Given the time constraints of the project it was necessary to draw a line under recruitment.

Support group participant recruitment

As in primary care, the research did not seek to formally collect data about reasons for support group members not wanting to participate and therefore from an empirical stance these reasons are not known. However, a number of observations and feedback from participants provided some insight into support group participant recruitment problems. The problems identified, and the supporting evidence, are provided in Table 20.

Table 20 Support group participant recruitment problems with supporting evidence

Support group participant recruitment problem	Evidence
Exposure to the study information was limited as the study often had to be posted in research sub-forums; individuals not routinely visiting these sections were not approached.	The greatest response in terms of views of the post and comments in a thread about the study on the forum was achieved for the forum in which the study was posted in a Type 2 diabetes sub-forum.
International forum users seemingly incorrectly inferred that the study was intended for UK residents only.	Recruitment was apparently more successful in UK based forums; there were many more views of the study post and more comments about the study in threads on these forums, and all of the individuals returning the consent form and the DSQ were from the UK. Indeed, one individual that returned these materials enquired about whether they could still participate as they were English but now lived in France.
The DSQ created some concerns amongst patients; some took it to imply they were unsuitable (i.e. as in primary care).	When one support group participant returned the consent form and DSQ they expressed concern that their responses may have been too positive.
Formatting problems.	A large proportion of people did not return the consent form and DSQ. Reasons for this were not obtained, however some participants indicated that they chose not take part because the materials had somehow become confused and unanswerable without significant work to unscramble them. Hardcopies of the materials were offered to these patients, others that had already received them yet not replied and any people satisfying the eligibility questions thereafter. However, none agreed to this.
Returning materials electronically sometimes lead to confusion.	There were a number of instances of participants accidently deleting materials and thus some requesting them again, and believing that they had returned materials when they had not.

Support group participant retention

The reasons why support group participants did not consent to take part in the study were not known other than as in primary care because a large proportion of interested patients screened ineligible in the eligibility check. Reasons why participants did not return the writing pack and subsequent materials were sought and were reported earlier in this chapter, albeit again for some patients these were not obtained. However, again a number of issues encountered during the trial provided some insight into participant retention problems. The problems identified, and the supporting evidence, are provided in Table 21.

Table 21 Support group participant recruitment problems with supporting evidence

Support group participant retention problem	Evidence
Formatting problems were experienced with respect to all study questionnaires.	Two participants commented that the forms were difficult to complete, particularly marking the text boxes (i.e. with an 'X') and completing the EQ-5D. One support group participant that seemed to be particularly impacted by formatting problems in the baseline questionnaire that was returned, and who requested a hardcopy of the writing pack, did not return any materials post-writing.[99]
Participants apparently grew tired of completing the same measures.	One participant commented that they only partially completed a follow up questionnaire because they had recently completed the same questions and did not see the point in repeating this (i.e. the SSQ6).

Comments on support group forums

Some patients' comments in threads about the study provided additionally insight into the reasons for support group members not wanting to participate. These are outlined below. The researcher replied only where questions were explicitly asked, yet was usually afforded opportunities to dispel misconceptions about the study without providing information beyond that presented in the PaIS.[100]

Scepticism about the project

Concerns about academic rather than patient gain

Two members from different forums suggested that the study was principally intended to enhance academic study rather than help people with diabetes, given that the project researcher was a student and presumably a person without diabetes.

[99] Electronic questionnaires were forwarded to this participant with hardcopies of questionnaires offered but not accepted.

[100] Individuals were assured that the project supervisors had academic and clinical expertise and were committed to diabetes care, the project was competitively awarded internal funding in a peer review process before the student researcher was involved, a large evidence base suggests writing may be helpful in LTPCs (perhaps even for physical health) yet better quality trials were required (information about WED was not provided), the project was subject to rigorous internal and external (i.e. NHS) ethical review in which anticipated benefit for patients is paramount and must be proved, there was at that time a large scale five year externally funded trial being undertaken in the USA by an established research group (noted in chapter nine), a similar trial was already being run by the research team in primary care (i.e. with NHS support), the study was small yet it was a pilot intended to inform a funding bid for a larger trial which would add to the growing evidence base, and that such studies could potentially encourage Government investment should writing be shown to be effective given that it is relatively inexpensive.

Scepticism about anticipated benefit

One member expressed they were unsure there would be any durable benefit for people with diabetes and as such wondered whether the study was worth being involved in. Another was sceptical that there could be any physical health benefit, only psychological benefit if any at all.

Belief in benefit but concern about likely implementation/preference for other assistance

One member stated that there was no point getting involved because while the benefits of writing are known, such a small scale study would not encourage Government investment, and in fact they would rather the Government provided free monitors and strips.

Concern about study materials

One member joked that having completed the baseline questionnaire they felt that somebody would know enough about them to 'lock them up and throw away the key'. Another user commented that they had received the consent forms and DSQ, yet they were not intending to return this as they found the questions to be odd.

Preference for writing in forums

One member explained that they found little time for writing outside work, which was reserved for the online forums.

Absence of proper consideration of study information

It was evident that some members made a decision about the study via the post and website having not read the PaIS. For example, one member enquired about whether written texts or the physical act of writing was being investigated.

Concern about the connotations of the study

Some members speculated that the study was derived from the notion that people with diabetes often suffer depression, and others read this indicating that they did not agree with this presumption about diabetes. These, and other, people may have been deterred by these initial posts.

Concern about screening

One patient commented that she had applied to take part yet was not able to because apparently she was slightly depressed, joking that she now felt more depressed. Reading this may have deterred others.

In fact each of the aforementioned comments may have deterred others from taking part. However, it should be noted that there were some positive comments about the study, which may have encouraged participation. A few members expressed a general interest in the study and others articulated a belief in the beneficial effect of writing, in particular private disclosure of thoughts and feelings, whilst suggesting catharsis and other mechanisms of effect. One member involved in the discussion explicitly went on to disclose about some negative experiences.

Additional potential recruitment issues

It is noteworthy that there were some additional issues that may have prohibited recruitment and retention, even though supporting evidence was not obtained for

these issues. It is possible that participants may have been deterred by the PaIS given that it was relatively long and detailed. However, this information was again an ethical requirement. Patients may have additionally been deterred by their HCP seeing their screening data and perhaps being rejected from the trial on this basis, or the warning with respect to the potential negative response to writing or screening. It is also possible patients were deterred by the consent form, specifically signing to agree to people seeing their medical records. Support group participants may have been deterred by the need to contact their HCPs about their participation in the trial and possibly their screening score. Finally in view of feedback obtained from support group participants, it is possible that primary care practices and patients were similarly deterred by the researcher being a student. However, whilst the patient and practice letters indicated that the principle researcher was a student, they additionally noted that the project was supervised.

Á priori sample size calculation

The feasibility of achieving sample size requirement

The sample size calculation indicated that at least 110 participants were required, presuming 20% attrition (as was observed). However, only 37% of the number required was recruited before attrition. In fact, when accounting for clustering within practices, at least 219 participants were required, yet only 16% of the number required was recruited in primary care. This was obviously owing to the recruitment and retention problems discussed above. The sample size was, however, consistent with many of those included in the systematic review (chapter three), and is attributed to the burden associated with WED (Sheese et al, 2004).

The appropriateness of the sample size calculation parameters

The parameters of the sample size calculation initially specified require revision owing to observations made in the present study.

Primary care

As required, eight practices were recruited, yet three were lost. On average, each practice provided the anticipated number of patients with Type 2 diabetes not currently treated for depression (i.e. approximately 170). However, a 20% recruitment rate was anticipated, yet on average 10% was observed. Moreover, losses in the eligibility check (i.e. 36% of initially recruited patients were too screen-depressed to participate) and between the eligibility check and consent (27% of the eligible patients did not return the consent form) were not originally accounted for. Perhaps having to agree twice was too much for interested but wary patients.

Secondary care

Attending clinics only once per week for one month identified 20 patients with Type 2 diabetes, which was more than anticipated (i.e. 40 with daily attendance). However, the loss of potentially eligible patients owing to unattended appointments (i.e. 35%) or unwillingness to answer the eligibility questions seemingly because patients were already too burdened to consider the study (i.e. 23% of those approached) was not anticipated. The number of those answering the eligibility questions that would already be treated was also very much underestimated (i.e. 50% not 15%). As anticipated, however, no patients were excluded for having been diagnosed for less than six months. Importantly though, the recruitment rate was 0% not 20%.

Online support groups

As required, six sites were recruited, yet one was lost. However, the average number of people that were expected to view the study post per forum was overestimated (i.e. 222 not 3,462), which was likely because, unexpectedly, visiting the forum did not automatically equate to viewing the post; again this was in a specific sub-forum, typically research-related, which only some members visit and then view selected posts. However, all, rather than 75%, of those viewing the study post likely had Type 2 as the link to the post specified it was for people with Type 2. Recruitment was apparently better than anticipated (i.e. 4% rather than 1% of those viewing the post answered the eligibility questions), yet this is likely overestimated as number of people viewing the post for one forum was not known. It should be noted that 7% of those viewing the post actually visited the study website, yet of these only 53% then answered the eligibility questions.

The proportion of those answering the eligibility questions that were currently treated was as expected and concordant with that anticipated for primary care (i.e. 15%). While speculative, this may be taken to suggest that despite receiving treatment from the NHS some people were still seeking support elsewhere (i.e. support groups and the study). As anticipated approximately 10% had then been diagnosed for less than six months. However, losses between the eligibility questions and the eligibility check/consent (i.e. 68% of potentially eligible people did not return the consent form/DSQ) and again the in eligibility check (i.e. 25% of initially recruited individuals) was not accounted for. It seems that a one month recruitment period was appropriate; the forums were checked approximately five months after the close of the recruitment period and only 591 additional patients had viewed the post.

Conclusions

A number of recruitment and retention issues were encountered. Some suggest the potential for significant barriers to primary care research training experiences in the future, while others that raise doubts about recent screening practices and suggest an unacceptable presence of untreated E&P need amongst adults with Type 2 diabetes, particularly primary care patients. On a positive note, however, the problems identified provided a wealth of invaluable information to inform future endeavours. The sample size requirement was obviously not met owing to the recruitment and retention problems identified, and revisions to the parameters of the initial sample size calculation are required. Based on this data future attempts can set realistic expectations and better plan for contingencies that would otherwise greatly reduce the sample size obtained and limit the informative potential of the trial. Finally, alternative means of identifying people with Type 2 diabetes and at least some yet not significant depression are additionally required.

Required revision of trial objectives

The revisions that had to be made to the trial methodology as a result of the constraints applied by the ethical review (i.e. the eligibility check; additionally discussed in chapters four and nine) and the difficulties experienced in recruitment/retention (i.e. described above/in this chapter) meant that a very small sample was derived, with insufficient time and resource available to address these issues (i.e. in part owing to the delays imposed by the ethical review and recruitment difficulties experienced). This meant that the trial objectives delineated in chapter five had to be narrowed to those that the thesis was subsequently able to

address; a focus on the feasibility with a very much exploratory analysis of the effectiveness of WED.[101]

As such, the original objective asking 'does WED work as anticipated' became too ambitious; no conclusions can be drawn from these explanatory analyses. Consequently, these analyses were proceeded with in a hypothesis generating way and because this may aid interpretation of any main effect. The original objective asking 'does WED work differently for different for different people as anticipated and who does it work best for' similarly became too ambitious. In fact, the informative potential of the moderation sub-groups analyses was particularly limited by the size of the database. Hence, these analyses are mentioned only very briefly in relation to the main effect again in a hypothesis generating way. The prior cost effectiveness analysis was no longer sensible or informative and was thus removed.

The revised objectives were therefore:

Feasibility investigation

1. *Pilot appropriate intervention and trial parameters*

2. *Feasibility/effectiveness of intervention delivery*

   Collect information about compliance, contamination and the acceptability of the intervention and comparison exposure.

[101] It should be noted that specification of depressive symptom severity as a primary outcome became somewhat inappropriate given that patients with none or only very few symptoms were included, owing to the constraints applied by the REC and the failure of the QoF inclusion criteria to ensure inclusion of patients with at least some lower-level depression. In fact, a focus on DSED, which WED is purported to target, perhaps became a more sensible primary outcome. However, as the effect of WED upon depressive symptom severity in LTPCs was the focus of the thesis as justified in chapters one (i.e. the problem specification), and three (i.e. the systematic review), this was still considered the outcome of primary interest.

3. Feasibility/effectiveness of the trial protocol

Estimate recruitment and retention, identify associated issues, report on the feasibility of achieving sample size requirement and the appropriateness of the sample size calculation parameters (as discussed in the present chapter), identify the feasibility/effectiveness of the randomisation and allocation concealment methods and check the success of blinding.

Preliminary effectiveness analysis

An exploratory consideration of the potential effect of WED on depressive symptom severity and a range of other psychological and behavioural outcomes, with some exploration of the mechanisms of change and mediators anticipated to underpin WEDs effect on depressive symptom severity.

Chapter 7 Baseline characteristics, preliminary effectiveness analysis and exploratory explanatory analyses

Chapter overview

This chapter presents the baseline characteristics (i.e. descriptive statistics) of and describes the data that was available for the sample obtained. The preliminary effectiveness analysis are then presented, followed by the exploratory explanatory analyses proceeded with in a hypothesis generating way and simply to aid interpretation of any main effect. The findings from the moderation sub-group analyses are then mentioned very briefly in relation to the main effect again in a hypothesis generating way.

Baseline descriptive statistics

Demographic and clinical data, outcome, moderator and mediator data, and the internal reliability of the outcome, moderator, mediator and mechanisms of change (i.e. PANAS) measures for primary care patients and then support group participants are indicated in Tables 22 to 27.[102] Data for the primary care and support group samples did not apparently exhibit systematic differences of a notable magnitude on important prognostic variables, although importantly the online support group participants had slightly more DSED. This may reflect the involvement of these support seeking individuals in the online groups. Specifically with regards to the clinical data it did not seem to be the case that self-reported HbA1c from support group participants had been under reported consistent with

[102] It must be noted that there was a problem with baseline alexithymia questionnaire for some primary care patients. A typing error meant that for the first few patients receiving it, the response format was slightly ambiguous; there were two strongly agree options (i.e. and no strongly disagree option). However, the mean scores, SDs and Chronbach's alphas were compared for the primary care patients for whom this was potentially a problem (n=12; 29%) and the remainder of the primary care sample, and no differences were apparent. It was thus considered appropriate to combine the data. This was also justified as those for whom this was potentially a problem had an equal chance of being randomised to each group.

social desirability bias (i.e. the tendency to respond in a manner that will be perceived favourably); the SDs and ranges were similar to those for the objectively derived data and thus apparently represented the true range of values. The psychometric properties of the measures employed were generally consistent across these groups, albeit lower reliability was observed for the DMSES UK completed by support group participants. This is likely owing to sampling differences rather than sample size (Peterson, 1994). Ultimately, though, self-efficacy for diabetes SMBs may not have been reliably measured for support group participants.

Again there are a number of reasons why it might not be justified to combine these data (see chapter five). Indeed, the differences observed suggest that this may be the case. However, the number of support group participants recruited was very small and balanced across intervention groups (i.e. only three per group), thus any potential bias would hopefully have been equally distributed and diluted once the data were combined. Consequently, whilst not withstanding limitations combining the samples was considered to be the most sensible approach given the limited utility of separate analyses with such a small number of participants. The demographic and clinical data, outcome, moderator and mediator data, and the internal reliability of the outcome, moderator, mediator and mechanisms of change (i.e. PANAS) measures for the combined sample are reported in Tables 28 to 30.

Psychometric properties

Internal reliability, Cronbach's alpha, for the outcome, mediator and moderator measures that were investigated was generally between .70 and .90 and was thus adequate.

Table 22 Primary care baseline demographic and clinical data[103]

	Total sample	n	WED	n	Control	n
Age*	67(10.1; 41-84)	35	70(10.4; 52-84)	20	64(9.4; 41-80)	15
Gender	Male 21(60%); Female 14 (40%)	35	Male 12(60%); Female 8 (40%)	20	Male 9 (60%); Female 6 (40%)	15
Ethnicity	White/British 34(97%); Black Irish 1(3%)	35	White/British 19(95%); Black Irish 1(5%)	20	White/British 15(100%)	15
Education	Level 1 10(39%); Level 2 7(26%); Level 3 2(8%); Level 4/5 7(27%)	26	Level 1 7(46.7%); Level 2 3(20%); Level 3 2(13.3%); Level 4/5 3(20%)	15	Level 1 3(27.3%); Level 2 4(36.4%); Level 4/5 4(36.4%)	11
Relationship	S 6(17.1%); CH 4(11.4%); M 25(71.4%)	35	S 2(10%); CH 4(20%); M 14(70%)	20	S 4(26.7%); M 11(73.3%)	15
BMI*	31.3(6.3; 21.8-49.7)	34	31.5(5.8; 21.8-43.5)	20	31.2(7.0; 22.6-49.7)	14
HbA1c	7.1(.96; 5.3-9.3)	27	7.2(.9; 5.3-9.3)	16	7.1(1.1; 5.8-9.3)	11
Time since diagnosis (months)*	87.3 (78.9;12-390)	34	74.6 (57.3; 12-192)	20	105.5 (102; 12-390)	14
Medication	D/E 11(31%); T 20(57%); T/I 3(9%); I 1(3%)	35	D/E 8(40%); T 11(55%); T/I 1(5%)	20	D/E 3(20%); T 9(60%); T/I 2(13.3%); I 1(6.7%)	15
HCU: physician visits (in the last 6 months)*	2.7(3.6; 0-20)	34	2.9(4.4; .0-20)	19	2.5(2.1; .0-7)	15
HCU: hospital emergency room (no. times in the last 6 months)*	.12(.33; 0-1)	33	.11(.32; 0-1)	19	.14(.36; 0-1)	14
HCU: nights in hospital (in the last 6 months)*	1.8(7.0; 0-35)	34	1.8(7.8; 0-35)	20	1.9(5.8; 0-22)	14
HCU: last eye examination (months)*	16.8(14.7; 0-58)	33	21.7(16.8; .0-58)	18	10.9(9.0; .0-24)	15
HCU: feet examination (no. times in the last 6 months)*	1.0(.6; 0-2)	35	1.1(.55; 0-2)	20	.80(.56; 0-2)	15
No. with 1 complication	9(26%): HD/S 4(44.4%); R 2(22.2%); S/U 3(33.3%)		3(15%): S/U 3(100%)		6(40%): HD/S 4(67%); R 2(33%)	
No. with 2 complications	7(20%): HD/S&R 2(28.6%); HD/S&S/U 2(28.6%); S/U&KD/F 1(14.3%); S/U&R 2 (28.6%)		6(30%): HD/S&R 2(33.3%); HD/S & S/U 2(33.3%); S/U&R 2 (33.3%)		1(7%): S/U&KD/F 1(100%)	
No. with 3 complications	1(3%): HD/S, KD/F&H 1(100%)		1(5%): HD/S, KD/F&H 1(100%)		0	

[103] EDUCATION: Level 1=1 to 4 O level passes, 1 to 4 CSE/ GCSE any grades, NVQ level 1 or Foundation GNVQ; Level 2=5 or more O level passes, 5 or more CSEs (grade 1), 5 or more GCSEs (grades A-C), School Certificate, 1 A level, 1 to 3 AS levels, NVQ level 2, Intermediate GNVQ; Level 3=2 or more A levels, 4 or more AS levels, Higher School Certificate, NVQ level 3, Advanced GNVQ; Level 4/5= First degree, higher degree, NVQ levels 4 and 5, HNC, HND, Qualified Teacher Status, Qualified Medical Doctor, Qualified Dentist, Qualified Nurse, Midwife, Health Visitor. RELATIONSHIPS: S=single (inc. separated, divorced & widowed); CH=co-habiting 4; M=married/re-married. MEDICATION: D/E: diet & exercise; T=tablets; T/I=tablets & insulin; I=insulin. COMPLICATIONS: HD/S=heart disease/stroke; R=retinopathy; S/U=sexual & urological problems; KD/F=Kidney disease/failure; H=hypoglycemia. Where n is less than 35 (WED=20; Control=15) observations were missing for these patients. *Mean (SD; range) presented.

Table 23 Primary care baseline outcome, moderator and mediator data[104]

	Total sample	n	WED	n	Control	n
Depressive symptom severity	6.8 (5.1; 0-15)	35	7.0 (5.2; 0-15)	20	6.7 (5.1; 0-15)	15
DSED	34.2 (9.0; 25-55)	33	35.2 (9.2; 25-53.8)	19	32.8 (9.0; 25-55)	14
Health-related QoL: EQ-5D utility	.87 (.14; .62-1)	32	.85 (.14; .62-1)	19	.90 (.13; .69-1)	13
Health-related QoL: EQ-5D VAS	77.8 (18.8; 39-99)	32	78.6 (19.1; 39-99)	19	76.6 (19.0; 41-99)	13
Diabetes SMBs: general diet	5.7(1.5; 0-7)	34	5.6 (1.6; .0-7)	20	6.0 (1.4; 2.5-7)	14
Diabetes SMBs: specific diet	4.8 (1.1; 1.5-7)	33	4.7 (1.1; 1.5-5.5)	19	5.0 (1.2; 2.5-7)	14
Diabetes SMBs: exercise	3.3 (2.4; 0-7)	34	4.0 (2.4; .0-7)	20	2.2 (2.1; .0-5)	14
Diabetes SMBs: blood glucose testing	1.4 (2.1; 0-7)	30	1.3 (1.8; .0-7)	17	1.6 (2.4; .0-6.5)	13
Diabetes SMBs: foot care	2.8 (2.5; 0-7)	35	3.3 (2.7; .0-7)	20	2.0 (2.0; 0-7)	15
Diabetes SMBs: smoking status / No. cigarettes	No 33(94%); Yes 2(5.7%) / 15 (7.1; 10-20)	35 / 2	No 18(90%); Yes 2(10%) / 15 (7.1; 10-20)	20 / 2	No 15(100%) / 0	15 / 0
Illness interference	22 (9.8; 3-51)	34	24.2 (10.9; 13-51)	20	18.9 (7.2; 3-32)	14
Self-efficacy for diabetes SMBs	125.8 (27.5; 33-150)	34	124.9 (31.1; 33-150)	19	127 (23.2; 77-150)	15
Perceived emotional support (number)	2.3 (1.6; 0-6.5)	33	2.6 (1.7; 1-6.7)	20	1.9 (1.3; .0-5)	13
Perceived emotional support (satisfaction)	5.8 (.47; 4-6)	31	5.9 (.24; 5-6)	18	5.7 (.67; 4-6)	13
Optimism	22.2 (4.4; 14-30)	32	21.4 (4.4; 14-30)	20	23.6 (4.2; 17-30)	12
Alexithymia	49.4(14.4; 20-74)	34	49.4 (15.1; 20-74)	20	49.4 (14; 32-74)	14

[104] Where n is less than 35 (WED=20; Control=15) observations were missing for these patients. Mean (SD; range) presented.

Table 24 Internal reliability of outcome, moderator, mediator and mechanisms of change measures in primary care[105]

Scale/sub-scale	CES-D	PAID	IIRS	DMSES UK	SSQ6 (number)	SSQ6 (satisfaction)	LOT-R	TAS-20	PANAS (negative affect)
Alpha	.68	.88	.80	.94	.93	.95	.75	.88	.91
No. items	20	20	13	15	6	6	6	20	10
n	34	32	34	34	33	31	32	34	13
Missing responses	1 patient (with 1 item missing)	3 patients (with 1, 3 or 12 items missing)	1 patient (with 5 items missing)	1 patient (with 5 items missing)	2 patients (with 1 item missing)	3 patients (with 1 item missing) & 1 patient (with 2 items missing)	2 patients (with 1 item missing) & 1 patients (with 2 items missing)	1 patient (with 7 items missing)	22 patients (with 7 9 or 10 items missing)

[105] Where n is less than 35 (WED=20; Control=15) ≥1 item responses were missing for these patients thus the patient was excluded.

Table 25 Online support groups baseline demographic and clinical data[106]

	Total sample	n	WED	n	Control	n
Age*	59.3(6.3; 54-71)	6	61.7(8.6; 54-71)	3	57(3; 54-60)	3
Gender	Male 4(67%); Female 2(33%)	6	Male 2(67%); Female 1(33%)	3	Male 2(67%); Female 1(33%)	3
Ethnicity	White/British 6(100%)	6	White/British 3(100%)	3	White/British 3(100%)	3
Education	Level 1 1(16.7%); Level 3 1(16.7%); Level 4/5 4(66.7%)	6	Level 1 1(33%); Level 4/5 2(67%)	3	Level 3 1(33%); Level 4/5 2(67%)	3
Relationship	S 1(17%); M 5(83%)	6	M 3(100%)	3	S 1(33%); M 2(67%)	3
Nationality	British 5(100%)	5	British 3(100%)	3	British 2(100%)	2
Country of residence	UK 5(100%)	5	UK 3(100%)	3	UK 2(100%)	2
BMI*	25 (4.4; 19.4-30.8)	6	24.9(4.0; 20.7-28.7)	3	25.2(5.7; 19.4-30.8)	3
HbA1c	6(.6; 5.5-7.1)	5	6.2(.8; 5.6-7.1)	3	5.7(.3; 5.5-5.9)	2
Time since diagnosis (months)*	65.3 (36.9; 23-120)	6	92(30.2; 60-120)	3	38.7(19.1; 23-60)	3
Medication	D/E 1(17%); T 5(83%)	6	T 3(100%)	3	D/E 1(33%); T 2(67%)	3
HCU: physician visits (in the last 6 months)*	2.2 (1.6; 1-5)	6	1.7(1.2; 1-3)	3	2.7(2.1; 1-5)	3
HCU: hospital emergency room (no. times in the last 6 months)*	0	6	0	3	0	3
HCU: nights in hospital (in the last 6 months)*	0	6	0	3	0	3
HCU: last eye examination (months)*	28 (18.9; 4-48)	6	36 (10.6; 24-44)	3	20 (24.3; 4-48)	3
HCU: feet examination (no. times in the last 6 months)*	.67 (.5; 0-1)	6	.67 (.6; 0-1)	3	.67 (.6; 0-1)	3
No. with 1 complication	3(50%): R 2(67%); S/U 1(33%).		2(67%): R 2(100%)		1(33%): S/U 1(100%)	
No. with 4 complications	1(17%): R, N, S/U, KD/F 1 (100%)		0		1(33%): R, N, S/U, KD/F 1 (100%)	

[106] EDUCATION: Level 1=1 to 4 O level passes, 1 to 4 CSE/ GCSE any grades, NVQ level 1 or Foundation GNVQ; Level 2=5 or more O level passes, 5 or more CSEs (grade 1), 5 or more GCSEs (grades A-C), School Certificate, 1 A level, 1 to 3 AS levels, NVQ level 2, Intermediate GNVQ; Level 3=2 or more A levels, 4 or more AS levels, Higher School Certificate, NVQ level 3, Advanced GNVQ; Level 4/5= First degree, higher degree, NVQ levels 4 and 5, HNC, HND, Qualified Teacher Status, Qualified Medical Doctor, Qualified Dentist, Qualified Nurse, Midwife, Health Visitor. RELATIONSHIPS: S=single (inc. separated, divorced & widowed); CH=co-habiting 4; M=married/re-married. MEDICATION: D/E: diet & exercise; T=tablets; T/I=tablets & insulin; I=insulin. COMPLICATIONS: HD/S=heart disease/stroke; R=retinopathy; S/U=sexual & urological problems; KD/F=Kidney disease/failure; N=Neuropathies. Where n is less than 6 (WED=3; Control=3) observations were missing for these participants. *Mean (SD; range) presented.

Table 26 Online support groups baseline outcome, moderator and mediator data[107]

	Total sample	n	WED	n	Control	n
Depressive symptom severity	6.2 (3.9; 0-10)	6	7.0 (3.6; range 3-10)	3	5.3 (4.7; 0-9)	3
DSED	43.5 (16.2; 28.8-73.8)	6	52.1 (19.4; 36.3-73.8)	3	35 (7.8; 28.8-43.8)	3
Health-related QoL: EQ-5D utility	.95 (.09; .8-1.0)	6	.93 (.1; .8-1)	3	.96 (.1; .9-1)	3
Health-related QoL: EQ-5D VAS	91.5 (7.8; 79-100)	6	95.3 (6.4; 88-100)	3	87.7 (8.1; 79-95)	3
Diabetes SMBs: general diet	5.8 (1.7; 2.5-7)	6	6.5 (.5; 6-7)	3	5.2 (2.4; 2.5-7)	3
Diabetes SMBs: specific diet	4.7 (1.3; 3.5-6.5)	6	4.5 (1.3; 3.5-6)	3	4.8 (1.4; 4-6.5)	3
Diabetes SMBs: exercise	3.6 (2.6; 0-7)	6	2 (1.8; 0-3.5)	3	5.2 (2.4; 2.5-7)	3
Diabetes SMBs: blood glucose testing	5.5 (2.1; 3-7)	5	5.8 (2.0; 3.5-7)	3	5 (2.8; 3-7)	2
Diabetes SMBs: foot care	3.1 (2.4; .5-6.5)	5	2.7 (3.3; .5-6.5)	3	3.8 (.4; 3.5-4)	2
Diabetes SMBs: smoking status / No. cigarettes	No 5(83%); Yes 1(17%) / 13 (0.0;13-13)	6 / 1	No 3(100%) / 0 (0.0; 0-0)	3 / 0	No 2(67%); Yes 1(33%) / 13 (0.0; 13-13)	3 / 1
Illness interference	20.5 (5.2; 15-28)	6	22.7 (6.1; 16-28)	3	18.3 (4.2; 15-23)	3
Self-efficacy	121.5 (11; 110-135)	6	120.3 (11.9; 112-134)	3	122.7 (12.5;110-135)	3
Perceived emotional support (number)	1.7 (1.4; .3-4.3)	6	2.3 (1.8; 1-4.3)	3	1.2 (1.0; .3-2.3)	3
Perceived emotional support (satisfaction)	5.2 (.9; 3.8-6)	6	4.8 (1.0; 3.8-5.8)	3	5.6 (.7; 4.8-6)	3
Optimism	20.8 (3.5; 16-26)	6	21.7 (4; 18-26)	3	20 (3.6; 16-23)	3
Alexithymia	48.3 (8.6; 34-61)	6	53 (6.9; 49-61)	3	43.7 (8.4; 34-49)	3

[107] Where n is less than 6 (WED=3; Control=3) observations were missing for these participants. Mean (SD; range) presented.

Table 27 Internal reliability of outcome, moderator, mediator and mechanisms of change measures in online support groups[108]

Scale/sub-scale	CES-D	PAID	IIRS	DMSES UK	SSQ6 (number)	SSQ6 (satisfaction)	LOT-R	TAS-20	PANAS (negative affect)
Alpha	.66	.81	.63	.39	.88	.81	.83	.70	.70
No. items	20	20	13	15	6	6	6	20	10
n	5	5	6	6	6	6	6	6	4
Missing responses	1 participant (with 1 item missing)	1 participant (with 1 item missing)							2 participants (with 10 items missing)

[108] Where n is less than 6 (WED=3; Control=3) ≥1 item responses were missing for these participants thus the participant was excluded.

Table 28 Combined baseline demographic and clinical data[109]

	Total sample	n	WED	n	Control	n
Age*	65.6 (9.9; 41-84)	41	63.9 (9.2; 41-80)	23	67.8 (10.7; 52-84)	18
Gender	Male 25(61%); Female 16(39%)	41	Male 14(61%); Female 9(39%)	23	Male 11(61%); Female 7(39%)	18
Ethnicity	White/British 40(98%); Black Irish 1(2%)	41	White/British 22(96%); Black Irish 1(4%)	23	White/British 18(100%)	18
Education	Level 1 11(34%); Level 2 7(22%); Level 3 3(9%); Level 4/5 11(34%)	32	Level 1 8(44%); Level 2 3(17%); Level 3 2(11%); Level 4/5 5(28%)	18	Level 1 3(21%); Level 2 4(29%); Level 3 1(7%); Level 4/5 6(43%)	14
Relationship	S 7(17%); CH 4(10%); M 30(73%)	41	S 2(9%); CH 4(17%); M 17(74%)	23	S 5(28%); M 13(72%)	18
BMI*	30.4 (6.4; 19.4-49.7)	40	30.6 (6; 20.7-43.6)	23	30.1 (7.1; 19.4–49.7)	17
HbA1c	7.0 (1; 5.3-9.3)	32	7 (.96; 5.3-9.3)	19	6.9 (1.10; 5.5-9.3)	13
Time since diagnosis (months)*	84.0 (74.2; 12-390)	40	76.9 (54.4; 12-192)	23	93.7 (95.9; 12-390)	17
Medication	D/E 12(29%); T 25(61%); T/I 3(7%); I 1(2%)	41	D/E 8(35%); T 14(61%); T/I 1(4%)	23	D/E 4(22%); T 11(61%); T/I 2(11%); I 1(6%)	18
HCU: physician visits (in the last 6 months)*	2.7(3.3; 0-20)	40	2.8(4.2; .0-20)	22	2.5(2.1; .0-7)	18
HCU: hospital emergency room (no. times in the last 6 months)*	.10 (.31; 0-1)	39	.1 (.3; 0-1)	22	.1 (.3; 0-1)	17
HCU: nights in hospital (in the last 6 months)*	1.6 (6.4; 0-35)	40	1.6 (7.3; 0-35)	23	1.5 (5.3; 0-22)	17
HCU: last eye examination (months)*	18.5 (15.7; 0-58)	39	23.8 (16.7; 0-58)	21	12.4 (12.2; 0-48)	18
HCU: feet examination (no. times in the last 6 months)*	.93 (.57; 0-2)	41	1.0 (.6; 0-2)	23	.8 (.5; 0-2)	18
No. with 1 complication	12(29%): HD/S 4(33%); R 4(33%); S/U 4(33.3%)		5(22%): R 2(40%); S/U 3(60%)		7(39%): HD/S 4(57%); R 2(29%); S/U 1(14%)	
No. with 2 complications	7(17%): HD/S&R 2(29%); HD/S&S/U 2(29%); S/U&KD/F 1(14%); S/U&R 2 (29%)		6(26%): HD/S&R 2(33%); HD/S&S/U 2(33%); S/U&R 2 (33%)		1(6%): S/U&KD/F 1(100%)	
No. with 3 complications	1(2%): HD/S, KD/F & H 1(100%)		1(4%): HD/S, KD/F & H 1(100%)		0	
No. with 4 complications	1(2%): R, N, S/U, KD/F 1 (100%)		0		1(6%): R, N, S/U, KD/F 1 (100%)	

[109] EDUCATION: Level 1=1 to 4 O level passes, 1 to 4 CSE/ GCSE any grades, NVQ level 1 or Foundation GNVQ; Level 2=5 or more O level passes, 5 or more CSEs (grade 1), 5 or more GCSEs (grades A-C), School Certificate, 1 A level, 1 to 3 AS levels, NVQ level 2, Intermediate GNVQ; Level 3=2 or more A levels, 4 or more AS levels, Higher School Certificate, NVQ level 3, Advanced GNVQ; Level 4/5= First degree, higher degree, NVQ levels 4 and 5, HNC, HND, Qualified Teacher Status, Qualified Medical Doctor, Qualified Dentist, Qualified Nurse, Midwife, Health Visitor. RELATIONSHIPS: S=single (inc. separated, divorced & widowed); CH=co-habiting 4; M=married/re-married. MEDICATION: D/E: diet & exercise; T=tablets; T/I=tablets & insulin; I=insulin. COMPLICATIONS: HD/S=heart disease/stroke; R=retinopathy; S/U=sexual & urological problems; KD/F=Kidney disease/failure; H=hypoglycemia. Where n is less than 41 (WED=23; Control=18) observations were missing for these participants. * Mean (SD; range presented).

Table 29 Combined baseline outcome, moderator and mediator data[110]

	Total sample	n	WED	n	Control	n
Depressive symptom severity	6.7 (4.9; 0-15)	41	7 (4.9; 0-15)	23	6.4 (5; 0-15)	18
DSED	35.6 (10.7; 25-73.8)	39	37.5 (12; 25-73.8)	22	33.1 (8.6; 25-55)	17
Health-related QoL: EQ-5D utility	.89 (.13; .62-1)	38	.87 (.14; .62-1)	22	.91 (.12; .69-1)	16
Health-related QoL: EQ-5D VAS	80 (18.1; 39-100)	38	80.9 (18.7; 39-100)	22	78.7 (17.8; 44-99)	16
Diabetes SMBs: general diet	5.8 (1.5; 0-7)	40	5.7 (1.6; 0-7)	23	5.8 (1.5; 2.5-7)	17
Diabetes SMBs: specific diet	4.8 (1.1; 1.5-7)	39	4.6 (1.1; 1.5-6)	22	4.9 (1.2; 2.5-7)	17
Diabetes SMBs Diabetes SMBs: exercise	3.3 (2.4; 0-7)	40	3.8 (2.4; 0-7)	23	2.7 (2.4; 0-7)	17
Diabetes SMBs: blood glucose testing	2 (2.5; 0-7)	35	2 (2.5; 0-7)	20	2.1 (2.7; 0-7)	15
Diabetes SMBs: foot care	2.8 (2.4; 0-7)	40	3.2 (2.7; 0-7)	23	2.2 (1.9; 0-7)	17
Diabetes SMBs: smoking status / No. cigarettes	No 38(93%); Yes 3(7%) / 14.3 (5.1; 10-20)	41 / 3	No 21(91%); Yes 2(9%) / 15 (7.1; 10-20)	23 / 2	No 17(94%); Yes 1(6%) / 13 (0; 13-13)	18 / 1
Illness interference	21.8 (9.2; 3-51)	40	24 (10.3; 13-51)	23	18.8 (6.7; 3-32)	17
Self-efficacy	125.2 (25.6; 33-150)	40	124.3 (29.1; 33-150)	22	126.3 (21.5; 77-150)	18
Perceived emotional support (number)	2.2 (1.6; 0-6.7)	39	2.6 (1.7; 1-6.7)	23	1.7 (1.3; 0-5)	16
Perceived emotional support (satisfaction)	5.7 (.59; 3.8-6)	37	5.8 (.56; 3.8-6)	21	5.7 (.64; 4-6)	16
Optimism	22 (4.2; 14-30)	38	21.4 (4.2; 14-30)	23	22.9 (4.2; 16-30)	15
Alexithymia	49.3 (13.6; 20-74)	40	49.9 (14.2; 20-74)	23	48.4 (13.1; 32-74)	17

[110] Where n is less than 41 (WED=23; Control=18) observations were missing for these participants. Mean (SD; range) presented.

Table 30 Internal reliability of outcome, moderator, mediator and mechanisms of change measures in the combined sample[111]

Scale/sub-scale	CES-D	PAID	IIRS	DMSES UK	SSQ6 (number)	SSQ6 (satisfaction)	LOT-R	TAS-20	PANAS (negative affect)
Alpha	.67	.87	.78	.92	.92	.90	.76	.87	.90
No. items	20	20	13	15	6	6	6	20	10
n	39	37	40	40	39	37	38	40	17
Missing responses	2 participants (with 1 item missing)	2 participants (with 1 item missing), 1 participant (with 3 items missing) & 1 participant (with 12 items missing)	1 participant (with 5 items missing)	1 participant (with 5 items missing)	2 participants (with 1 item missing)	3 participants (with 1 item missing) & 1 patient (with 2 items missing)	2 participants (with 1 item missing) & 1 participant (with 2 items missing)	1 participant (with 7 items missing)	24 participants (with 7, 9 or 10 missing)

[111] Where n is less than 41 (WED=23; Control=18) ≥1 item responses were missing for these participants thus the participant was excluded.

Baseline comparability

The intervention groups were additionally comparable on demographic and clinical data and outcome, moderator and mediator data at baseline. It seemed that the control group had a slightly higher level of education, were more likely to be single, had been diagnosed with diabetes for a longer period of time, were more likely to be on insulin, had an eye exam more recently and were less likely to have two complications. However, these differences were not substantial or prognostic. There were no apparent differences for the outcome, mediator and moderator variables.

With respect to whether participants were currently involved in any other research, of those that answered this question in the baseline questionnaire (37, 90%), 31 (84%) were not while six (16%) stated that they were. By group, four participants in the intervention group (17%) and two control participants (11%) stated that they were currently involved in other research. One intervention participant indicated that the research they were involved in was a longitudinal study of the aetiology of LTPCs, with no intervention.

Available data

Missing data on continuous measures

The missing observations for each continuous measure and the missing/imputed item responses for each observation for each continuous measure at each administration are provided in Table 31.

Table 31 Extent of missing observations and missing item responses per observation for each continuous measure at each time point

Measure	Number of observations (number of items (% of total number of items) missing per observation where an observation could still be derived or imputed per observation)	Number of items (% of total number of items) missing per missing observation
Baseline (n=41 returned questionnaire pack)		
CES-D (scoring key: items scored if <4 missing)	41 (2 participants had only 1 item (5%) missing)	
PAID	39 (2 participants had only 1 item (5%) missing)	1 participant with 12 (60%) missing; 1 participant with 3 (15%) missing
EQ-5D utility	38	1 participant with 5 (100%) missing; 1 participant with 3 (60%) missing; 1 participant with 1 (20%) missing
EQ-5D VAS	38	3 participants missing response
SDSCA: general diet	40	1 participant with 1 (50%) missing
SDSCA: specific diet	39	2 participants with 1 (50%) missing
SDSCA: exercise	40	1 participant with 2 (100%) missing
SDSCA: blood glucose testing	35	6 participants with 1 (50%) missing
SDSCA: foot care	40	1 participant with 1 (50%) missing
LOT-R (items 2, 5, 6 & 8 are filler items & not included)	38	1 participant with 2 (33%) missing; 2 participants with 1 (16%) missing
TAS-20 (scoring key: items imputed if ≤2/3 missing from total scale & ≤1 missing per factor sub-scale (with mean of answered items for that person on the same factor sub-scale)	40 (*data imputed for 4 participants; each 1 item (5%) missing)*	1 participant with 7 (35%) missing

Measure	**Number of observations (number of items (% of total number of items) missing per observation where an observation could still be derived or imputed per observation)**	**Number of items (% of total number of items) missing per missing observation**
During intervention (n=27 returned writing pack)		
PANAS (negative affect) session one	17	6 participants with 10 (100%) missing; 3 participants with 9 (90%) missing; 1 participants with 7 (70%) missing
PANAS (negative affect) session two	17	7 participants with 10 (100%) missing; 2 participants with 9 (90%) missing; 1 participants with 7 (70%) missing
PANAS (negative affect) session three	17	8 participants with 10 (100%) missing; 1 participants with 9 (90%) missing; 1 participants with 8 (80%) missing
Two weeks (n=33 returned questionnaire pack)		
IIRS (scoring key: if responses are not consecutive do not score (thus if any items were missing scale not scored)	33	
DMSES UK (scoring key: items imputed if ≤4 missing (with mean of answered items for that person) (thus if more than 4 items missing scale not scored)	33 *(data imputed for 10 participants; 5 had 3 items (20%) missing, 2 had 2 items (13%) missing; 3 had 1 item (7%) missing)*	
SSQ6 (number)	29	1 participant with 6 (100%) missing; 1 participant with 4 (67%) missing; 1 participant with 2 (33%) missing; 1 participant with 1 (17%) missing
SSQ6 (satisfaction)	29	1 participant with 6 (100%) missing; 1 participant with 4 (67%) missing; 1 participant with 2 (33%) missing; 1 participant with 1 (17%) missing

Measure	Number of observations (number of items (% of total number of items) missing per observation where an observation could still be derived or imputed per observation)	Number of items (% of total number of items) missing per missing observation
Three months (n=32 returned questionnaire pack)		
CES-D (scoring key: items scored if <4 missing)	32 (3 participants had only 1 item (5%) missing)	
PAID	32	
EQ-5D utility	32	
EQ-5D VAS	32	
SDSCA: general diet	32	
SDSCA: specific diet	32	
SDSCA: exercise	32	
SDSCA: blood glucose testing	28	3 participants with 1 (50%) missing; 1 participant with 2 (100%) missing
SDSCA: foot care	32	
Three month mediators; only collected for primary care patients (n=27 primary care patients returned questionnaire pack)		
IIRS (scoring key: if responses are not consecutive do not score (thus if any items were missing scale not scored)	27	
DMSES UK (scoring key: items imputed if ≤4 missing (with mean of answered items for that person) (thus if more than 4 items missing scale not scored)	27 *(data imputed for 9 participants; 1 had 4 items (27%) missing; 2 had 3 (20%) items missing, 3 had 2 items (13%) missing; 3 had 1 item (7%) missing)*	
SSQ6 (number)	26	1 participant with 1 (17%) missing
SSQ6 (satisfaction)	25	2 participants with 1 (17%) missing

Screening the data, checking the assumption of normality and correcting distributional problems in the data

For some variables the distribution of scores was significantly/notably different to a normal distribution and this could not be attributed to data entry errors, thus transformation was performed. For all statistical analyses at least some variables were skewed therefore all variables were transformed. The types of transformation performed for the variables included in each analysis are provided in the appendix. Post-transformation, the assumption of normality was checked again to ensure any problems had been largely corrected. The initial and post-transformation assumption checks are also provided in the appendix. Transformation largely resolved problems in the data with the exception of the PANAS variables (i.e. per session and the average across sessions), for which non parametric analysis was thus performed (as reported in chapters five and eight).[112]

Preliminary effectiveness analysis[113]

ITT analysis

For ease of interpretation the results for the analyses with the untransformed data are reported. The conclusions were generally consistent with those for the transformed data, with some exceptions where artificially inflated effect sizes and smaller p values were derived from analyses with transformed data, albeit the

[112] Transformation did not entirely resolve the distributional problems for some other variables for which equivalent non-parametric analyses were not available, namely the EQ-5D utility variables examined in ANCOVAs and perceived emotional support satisfaction variables examined in regression analyses. Again, ANOVA is is fairly robust where data are not normally distributed, nonetheless the findings for the variables may be slightly inaccurate.

[113] It is noteworthy that, as anticipated, ω^2 provided the most conservative and thus best estimate of the population effect, which were at most of a medium size and were generally small (all effect size estimates are presented in the appendix for visual inspection). Interestingly, as anticipated η_p^2 consistently overestimated both η^2 and ω^2 and on occasion derived the conclusion of a larger effect, as this compares the variance explained by the between-groups effect to the unexplained variance, ignoring any variance explained by other variables (i.e. reducing the denominator). η^2 was additionally consistently inflated compared to ω^2, which reflects shrinkage resulting from sampling error owing to the small sample obtained (i.e. ω^2corrects for this), albeit this was slight and did not often derive different conclusions.

discrepancies were slight and infrequent. This was unsurprising given that transformation reduces the variance in the data and improves its symmetry, which increases statistical power. In addition, as the distribution of the data is altered the group means are 'moved' differentially, which can inflate or decrease the difference between them and thus the effect size. The most conservative approach was thus to report the findings for the untransformed data. The adjusted group means and the associated SEs for the ITT analysis on the primary and secondary outcomes at three month follow up are presented in Table 32.

Table 32 Adjusted group endpoint data for the ITT analyses on the primary and secondary outcomes at three month follow up[114]

Outcome	**WED**		**n**	**Control**		**n**
	Mean	**SE**		**Mean**	**SE**	
Depressive symptom severity	9.9	1.08	23	5.1	1.2	18
DSED	35.3	1.41	23	34.4	1.6	18
Health-related QoL: EQ-5D utility	.86	.03	23	.87	.03	18
Health-related QoL: EQ-5D VAS	77.4	2.75	22	82.1	3.0	18
Diabetes SMBs: general diet	5.8	.24	23	5.8	.27	18
Diabetes SMBs: specific diet	4.5	.19	23	5.1	.21	18
Diabetes SMBs: exercise	3.5	.28	23	4.0	.31	18
Diabetes SMBs: blood glucose testing	2.5	.39	22	2.5	.46	16
Diabetes SMBs: foot care	3.2	.24	23	3.0	.27	18

Primary outcome

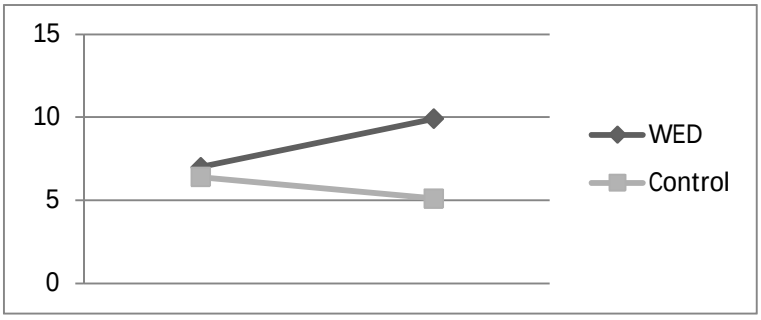
Depressive symptom severity

Assumption checks indicated homogeneity of variance (F(1,39)=3.20, p=.081) and regression slopes for the covariates (baseline depressive symptom severity F(1,33)=2.10, p=.157); age (F1,33)=.06, p=.808); gender (F(1,33)=.02, p=.886). Baseline depressive symptom severity was significantly related to depressive symptom severity at three month follow up F(1,36)=33.34, p=.000. There was also a significant effect of WED on depressive symptom severity at follow up, controlling

[114] There was one participant (WED) for whom both baseline and follow up EQ-5D VAS scores were missing and three participants (one WED & two control) for whom both baseline and follow up blood glucose testing scores were missing.

for baseline depressive symptom severity F(1,36)=8.47, p=.006. The adjusted group means at three month follow up indicated greater depressive symptom severity in the WED group compared to the control group, which represented a potentially clinically important difference: 4.8. In fact, the 95% CIs associated with these means for the WED group (7.7 to 12.1) and control group (2.7 to 7.6) did not overlap at all. The change in depressive symptom severity from baseline to three month follow up by group in the ITT analysis is illustrated in Figure 23. It is apparent that the observed effect represents an increase in depressive symptom severity for the WED group but also a decrease in depressive symptom severity for the control group. The effect size ω^2 was .09, which represents a medium sized effect. η^2 derived the same conclusion while η_p^2 indicated a large effect at .19 (b=-4.8, 95%CIs -8.1 to -1.4).

Figure 23 Change in depressive symptom severity from baseline to three month follow up by group in the ITT analysis



Secondary outcomes

DSED

Assumption checks indicated homogeneity of variance (F(1,39)=.63, p=.431) and regression slopes for the covariates (baseline DSED F(1,33)=1.71, p=.200); age (F1,33)=.29, p=.592); gender (F(1,33)=.00, p=.987). Baseline level of DSED was significantly related to DSED at three month follow up F(1,36)=77.46, p=.000. There

was no significant effect of WED on DSED at follow up, controlling for baseline levels of DSED F(1,36)=.20, p=.658. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which indicates no effect. η^2 derived the same conclusion while η_p^2 indicated a small effect at .01 (b=-.97, 95%CIs -5.4 to 3.4).

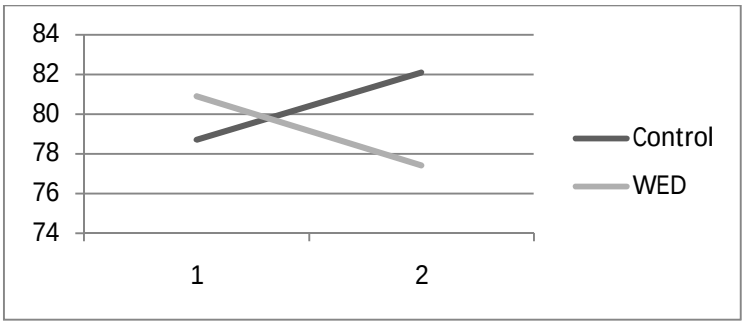
Health-related QoL

EQ-5D utility: Assumption checks indicated homogeneity of variance (F(1,39)=.05, p=.829) and regression slopes for the covariates (baseline health-related QoL F(1,33)=1.50, p=.230); age (F1,33)=.49, p=.488); gender (F(1,33)=1.61, p=.214). Baseline level of health-related QoL was significantly related to health-related QoL at three month follow up F(1,36)=49.66, p=.000. There was no significant effect of WED on health-related QoL at follow up, controlling for baseline levels of health-related QoL F(1,36)=.01, p=.907. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=.01, 95%CIs -.07 to .08).

EQ-5D VAS: Assumption checks indicated homogeneity of variance (F(1,38)=.62, p=.436) and regression slopes for the covariates (baseline health-related QoL F(1,32)=.00, p=.984; age (F1,32)=3.53, p=.069); gender (F(1,32)=.820, p=.372). Baseline level of health-related QoL was significantly related to health-related QoL at three month follow up F(1,35)=43.40, p=.000. There was no significant effect of WED on health-related QoL at follow up, controlling for baseline levels of health-related QoL F(1,35)=1.27, p=.268. The adjusted group means at three month follow up confirmed that the WED group had marginally worse health-related QoL compared to the control group. The change in health-related QoL from baseline to

three month follow up by group in the ITT analysis is illustrated in Figure 24. It is apparent that the observed effect represents a decrease in health-related QoL for the WED group but also an increase for the control group. The effect size ω^2 was .01, which represents a small effect. η^2 and η_p^2 derived the same conclusions (b=4.7, 95%CIs -3.7 to 13.1).

Figure 24 Change in EQ-5D VAS from baseline to three month follow up by group in the ITT analysis



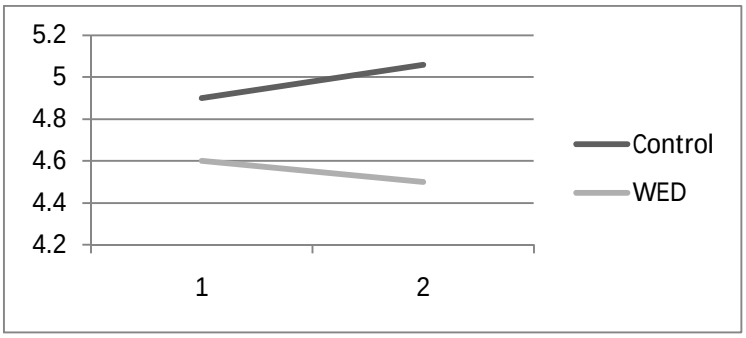
Diabetes SMBs

General diet: Assumption checks indicated homogeneity of variance (F(1,39)=.28, p=.598) and regression slopes for most of the covariates (age (F1,33)=1.51, p=.228); gender (F(1,33)=.1.04, p=.316). The assumption of homogeneity of regression slopes for baseline general diet was apparently violated for the untransformed data (F(1,33)=9.73, p=.004), yet this was not the case for the transformed data, analysis of which generally derived the same conclusions. Thus, for ease of interpretation the untransformed data is reported. Baseline level of general diet was significantly related to general diet at three month follow up F(1,36)=15.38, p=.000. There was no significant effect of WED on general diet at follow up, controlling for baseline levels of general diet F(1,36)=.05, p=.826. The adjusted group means at three month follow up confirmed that there was no

important difference. The effect size ω² was .00, which represents no effect. η² and η_p^2 derived the same conclusions (b=.08, 95%CIs -.66 to .82).

Specific diet: Assumption checks indicated homogeneity of variance (F(1,39)=.03, p=.869) and regression slopes for the covariates (baseline specific diet F(1,33)=.17, p=.684); age (F1,33)=1.98, p=.169); gender (F(1,33)=.06, p=.806). Baseline level of specific diet was significantly related to specific diet at three month follow up F(1,36)=37.77, p=.000. There was a marginally significant effect of WED on specific diet at follow up, controlling for baseline levels of specific diet F(1,36)=3.87, p=.057. The adjusted group means at three month follow up confirmed that there was a slight difference such that the intervention group had a slightly poorer specific diet than controls. Moreover, the 95% confidence intervals associated with these means for the WED group (4.12 to 4.88) and control group (4.63 to 5.49) only marginally overlapped. The change in specific diet from baseline to three month follow up by group in the ITT analysis is illustrated in Figure 25. It is apparent that the observed effect represents a decline in specific diet for the WED group but also an improvement for the control group. The effect size ω² was .03, which represents a small effect. η² derived the same conclusion, while η_p^2 indicated a medium-sized effect at .10 (b=.56, 95%CIs -.02 to 1.1).

Figure 25 Change in specific diet from baseline to three month follow up by group in the ITT analysis



Exercise: Assumption checks indicated homogeneity of variance (F(1,39)=.10, p=.753) and regression slopes for the covariates (baseline exercise F(1,33)=.24, p=.624); age (F1,33)=.09, p=.765); gender (F(1,33)=2.37, p=.134). Baseline level of exercise was significantly related to exercise at three month follow up F(1,36)=98.54, p=.000. There was no significant effect of WED on exercise at follow up, controlling for baseline levels of exercise F(1,36)=1.40, p=.245. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=.50, 95%CIs -.36 to 1.4).

Blood glucose testing: Assumption checks indicated homogeneity of variance (F(1,36)=.24, p=.628) and regression slopes for the covariates (baseline blood glucose testing F(1,30)=.02, p=890); age (F1,30)=2.78, p=.106); gender (F(1,30)=.85, p=.364). Baseline level of blood glucose testing was significantly related to blood glucose testing at three month follow up F(1,33)=54.14, p=.000. There was no significant effect of WED on blood glucose testing at follow up, controlling for baseline levels of blood glucose testing F(1,33)=.01, p=.922. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=-.06, 95%CIs -1.3 to 1.2).

Foot care: Assumption checks indicated homogeneity of variance (F(1,39)=.003, p=.957) and regression slopes for the covariates (baseline foot care F(1,33)=.2.10, p=.156); age (F1,33)=.21, p=.653); gender (F(1,33)=.06, p=.807). Baseline level of foot care was significantly related to foot care at three month follow up F(1,36)=139.57, p=.000. There was no significant effect of WED on foot care at follow up, controlling for baseline levels of foot care F(1,36)=.10, p=.755. The

adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=-.12, 95%CIs -.87 to .63).

Pre-specified sensitivity analyses: complete case analysis

Again, for ease of interpretation the results for the analyses with the untransformed data are reported. The conclusions were again generally consistent with those for the transformed data, with some exceptions where artificially inflated effect sizes were derived from analyses with transformed data, albeit the discrepancies were again slight and infrequent. The most conservative approach was thus again to report the findings for the untransformed data.

The adjusted group means and associated SEs for the complete case analysis on the primary and secondary outcomes at three month follow up are presented in Table 33.

Table 33 Adjusted group endpoint data for the complete case analyses on the primary and secondary outcomes at three month follow up

Outcome	**WED**		**n**	**Control**		**n**
	Mean	**SE**		**Mean**	**SE**	
Depressive symptom severity	10.6	1.4	18	5.1	1.5	14
DSED	33.5	1.8	17	32.8	2.1	13
Health-related QoL: EQ-5D: utility	.83	.03	17	.84	.04	12
Health-related QoL: EQ-5D: VAS	74.8	3.5	18	82.2	4.3	12
Diabetes SMBs: general diet	5.6	.31	18	5.6	.36	13
Diabetes SMBs: specific diet	4.2	.25	17	5.0	.28	13
Diabetes SMBs: exercise	3.6	.36	18	4.0	.43	13
Diabetes SMBs: blood glucose testing	3.2	.60	13	2.7	.62	12
Diabetes SMBs: foot care	2.9	.31	18	2.7	.37	13

Primary outcome

Depressive symptom severity

Assumption checks indicated homogeneity of variance (F(1,30)=3.12, p=.087) and regression slopes for the covariates (baseline depressive symptom severity (F(1,24)=1.36, p=.255); age (F1,24)=.00, p=.982); gender (F(1,24)=.05, p=.819). Baseline depressive symptom severity was significantly related to depressive symptom severity at three month follow up F(1,27)=21.45, p=.000. There was also a significant effect of WED on depressive symptom severity at follow up, controlling for baseline depressive symptom severity F(1,27)=7.18, p=.012. The adjusted group means at three month follow up indicated greater depressive symptom severity in the WED group compared to the control group, which represented a potentially clinically important difference: 5.5. Moreover, the 95% confidence intervals associated with these means for the WED group (7.84 to 13.42) and control group (1.96 to 8.28) only marginally overlapped. The effect size ω^2 was .10, which represents a medium-sized effect. η^2 derived the same conclusion while η_p^2 indicated a large effect at .21 (b=-5.5, 95%CIs -9.7 to -1.3).

It is noteworthy that further investigation of the changes in depressive symptom severity over time for the WED group identified that seven participants actually exhibited a potentially clinically important increase in depressive symptom severity (i.e. ≥5 point increase on the CES-D), five (71%) of whom increased such that they scored above the cut point indicative of significant symptoms at follow up (i.e. CESD ≥16).

Secondary outcomes

DSED

Assumption checks indicated homogeneity of variance (F(1,28)=.74, p=.398) and regression slopes for the covariates (baseline DSED F(1,22)=.84, p=.368); age (F1,22)=.07, p=.799); gender (F(1,22)=.06 p=.817). Baseline level of DSED was significantly related to DSED at three month follow up F(1,25)=12.58, p=.002. There was no significant effect of WED on DSED at follow up, controlling for baseline levels of DSED F(1,25)=.06, p=.815. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=-.65, 95%CIs -6.4 to 5.0).

Health-related QoL

EQ-5D utility: Assumption checks indicated homogeneity of variance (F(1,27)=.19, p=.671) and regression slopes for the covariates (baseline health-related QoL F(1,21)=.28, p=.600); age (F1,21)=.69, p=.416); gender (F(1,21)=1.87, p=.186). Baseline level of health-related QoL was significantly related to health-related QoL at three month follow up F(1,24)=24.03, p=.000. There was no significant effect of WED on health-related QoL at follow up, controlling for baseline levels of health-related QoL F(1,24)=.01, p=.917. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=.01, 95%CIs -.10 to .12).

EQ-5D VAS: Assumption checks indicated homogeneity of variance (F(1,28)=.19, p=.664) and regression slopes for the covariates (baseline health-related QoL F(1,22)=.00, p=.968); age (F1,22)=3.85, p=.062); gender (F(1,22)=.88, p=.358).

Baseline level of health-related QoL was significantly related to health-related QoL at three month follow up F(1,25)=25.70, p=.000. There was no significant effect of WED on health-related QoL at follow up, controlling for baseline levels of health-related QoL F(1,25)=1.84, p=.187. The adjusted group means at three month follow up confirmed that the WED group had very slightly worse health-related QoL compared to the control group. The effect size ω^2 was .02, which represents a small effect. η^2 derived the same conclusion while η_p^2 indicated a medium sized effect at .07 (b=7.5, 95%CIs -3.9 to 18.8).

Diabetes SMBs

General diet: Assumption checks indicated homogeneity of variance (F(1,29)=.00, p=.970) and regression slopes for most of the covariates (age (F1,23)=5.60, p=.121); gender (F(1,23)=.83, p=.373). However, for baseline general diet the assumption of homogeneity of regression slopes was apparently violated for the untransformed data (F(1,23)=5.55, p=.027), yet this was not the case for the transformed data, analysis of which generally derived the same conclusions. Thus, for ease of interpretation the untransformed data is reported. Baseline level of general diet was significantly related to general diet at three month follow up F(1,26)=6.49, p=.017. There was no significant effect of WED on general diet at follow up, controlling for baseline levels of general diet F(1,69)=.00, p=.999. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect. η^2 and η_p^2 derived the same conclusions (b=.001, 95%CIs -.97 to .97).

Specific diet: Assumption checks indicated homogeneity of variance (F(1,28)=.35, p=.562) and regression slopes for the covariates (baseline specific diet F(1,22)=.11, p=.746); age (F1,22)=2.45, p=.132); gender (F(1,22)=.13, p=.719). Baseline level of

specific diet was significantly related to specific diet at three month follow up F(1,25)=18.79, p=.000. There was a significant effect of WED on specific diet at follow up, controlling for baseline levels of specific diet F(1,25)=4.59, p=.042. The adjusted group means at three month follow up confirmed that there was a slight difference such that the intervention group had a slightly poorer specific diet than controls. Moreover, the 95% confidence intervals associated with these means for the WED group (3.65 to 4.66) and control group (4.38 to 5.54) only marginally overlapped. The effect size ω^2 was .07, which represents a medium-sized effect. η^2 derived the same conclusion while η_p^2 indicated a large effect at .16 (b=.80, 95%CIs .03 to 1.6).

Exercise: Assumption checks indicated homogeneity of variance (F(1,29)=.00, p=.985) and regression slopes for the covariates (baseline exercise F(1,23)=.07, p=.971); age (F1,23)=.04, p=.844); gender (F(1,23)=2.58, p=.122). Baseline level of exercise was significantly related to exercise at three month follow up F(1,26)=54.33, p=.000. There was no significant effect of WED on exercise at follow up, controlling for baseline levels of exercise F(1,26)=.68, p=.417. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω^2 was .00, which represents no effect, while η^2 and η_p^2 indicated a small effect at .01 and .03 respectively (b=.47, 95%CIs -.70 to 1.6).

Blood glucose testing: Assumption checks indicated homogeneity of variance (F(1,23)=.26, p=.616) and regression slopes for the covariates (baseline blood glucose testing F(1,17)=.01, p=.908); age (F1,17)=3.60, p=.075); gender (F(1,17)=.96, p=.341). Baseline level of blood glucose testing was significantly related to blood glucose testing at three month follow up F(1,20)=23.36, p=.000. There was no significant effect of WED on blood glucose testing at follow up,

controlling for baseline levels of blood glucose testing F(1,20)=.34, p=.564. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω² was .00, which represents no effect, while η² and η_p^2 indicated a small effect at .01 and .02 respectively (b= -.51, 95%CIs -2.3 to 1.3).

Foot care: Assumption checks indicated homogeneity of variance (F(1,29)=.17, p=.680) and regression slopes for the covariates (baseline foot care F(1,23)=.2.08, p=.163); age (F1,23)=.28, p=.603); gender (F(1,23)=.16, p=.696). Baseline level of foot care was significantly related to foot care at three month follow up F(1,26)=58.57, p=.000. There was no significant effect of WED on foot care at follow up, controlling for baseline levels of foot care F(1,26)=.22, p=.641. The adjusted group means at three month follow up confirmed that there was no important difference. The effect size ω² was .00, which represents no effect, while η² and η_p^2 indicated a small effect at .01 (b=-.23, 95%CIs -1.2 to .78).

Exploratory explanatory analyses

Mechanisms of change

EA&H

As transformation did not influence the distributional problems in the PANAS data non-parametric tests were performed with the untransformed data (as described in chapters five and seven, and the appendix). The medians, range, means, associated SDs and mean ranks for post-writing negative affect for each writing session for the WED group are reported in Table 34.

Table 34 Post-writing negative affect for each writing session for the WED group[115]

Session	Median	Range	Mean	SD	Mean rank	n
1	16.0	10-35	17.3	7.6	1.9	**10**
2	14.5	10-40	19.0	11.0	1.9	
3	17.5	10-45	21.0	11.8	2.3	

Post-writing negative affect did not change significantly across the writing sessions ($\chi^2(2)=1.45$, p=.516). Contrasts revealed that post-writing negative affect did not change significantly from session one to session two (T=17, p=.273, r= -.15), from session two to session three (T=12.5, p=.242, r= -.17) or from session one to session three (T=12, p=.063, r= -.35). The effect sizes indicated an increase in negative affect across writing days (i.e. session one < session two; session two < session three; session one < session three). The increase was small between sessions but medium-sized overall. This was consistent with the pattern indicated by the means. However, it is noteworthy that the medians indicated a decrease from session one to two and then an increase from session two to three. This was because for session two the scores were generally close to the lower bound yet there were a small number of large outliers, which are accounted for more by the means than the medians. Regardless however, the effect of an important magnitude was the change from the first to last session.

E&CP

Again, for ease of interpretation the results for the analyses with the untransformed data are reported as the conclusions were the same as those for the transformed data. There was one exception where analyses with the untransformed data produced effect sizes that were more consistent with the raw data than those derived from analyses from the transformed data. Specifically, for the 'insight' word use category the transformed data suggested a more substantial difference

[115] Fourteen WED participants returned their writing and 10 of these provided observations for the PANAS negative affect sub-scale.

between sessions two and three compared to one and two whereas the raw data and the analyses with the untransformed data suggested the reverse; a more substantial difference between sessions one and two compared to two and three. The probable reasons for such discrepancies in effect size estimates resulting from transformation were described in relation to the preliminary effectiveness analysis reported in chapter seven.

The means and associated SDs reflecting the percentage word use for the four categories indicative of E&CP for each writing session for the WED group are reported in Table 35.

Table 35 Percentage word use for the four categories indicative of E&CP for each writing session for the WED group[116]

Word use category	Session	Mean	SD	n
Positive emotion (%)	1	3.1	1.2	12
	2	3.9	3.0	
	3	4.0	1.8	
Negative emotion (%)	1	2.5	1.0	12
	2	2.6	1.6	
	3	2.3	1.2	
Insight (%)	1	2.1	1.0	12
	2	2.5	1.5	
	3	2.7	1.4	
Cause (%)	1	1.0	.49	12
	2	1.5	.82	
	3	1.1	.67	

Positive emotion

Mauchly's test indicated that the assumption of sphericity had been violated $\chi^2(2)=.50$, $p=.032$, therefore degrees of freedom used to assess the F ratio were corrected using Greenhouse-Geisser estimates of sphericity ($\varepsilon=.67$). There was no significant effect of writing session upon percentage word use reflecting positive emotion $F(1.33, 14.68)=1.14$, $p=.324$. Contrasts revealed no significant change in

[116] Fourteen WED participants returned their writing pack, twelve of whom completed all three sessions and could be included in analyses.

percentage word use reflecting positive emotion from session one to session two ($F(1,11)=.94$, $p=.354$, $r=.28$) or from session two to session three ($F(1,11)=.01$, $p=.922$, $r=.03$). However, the mean percentage word use scores for each writing session and effect sizes for the contrasts suggested a slight increase in positive emotion words across successive writing sessions, in particular between sessions one and two for which a small effect size was estimated.

Negative emotion

Mauchly's test indicated that the assumption of sphericity had not been violated $\chi^2(2)=.93$, $p=.687$. There was no significant effect of writing session upon percentage word use reflecting negative emotion $F(2,22)=.31$, $p=.738$. Contrasts revealed no significant change in percentage word use reflecting negative emotion from session one to session two ($F(1,11)=.03$, $p=.871$, $r=.05$) or from session two to session three ($F(1,11)=.77$, $p=.399$, $r=.26$). The mean percentage word use scores for each writing session and effect sizes for the contrasts confirmed that there were no differences between sessions with respect to negative emotion words, only a slight decrease from session two to three for which a small effect size was estimated.

Insight

Mauchly's test indicated that the assumption of sphericity had not been violated $\chi^2(2)=.98$, $p=.913$. There was no significant effect of writing session upon percentage word use reflecting insight $F(2,22)=.94$, $p=.406$. Contrasts revealed no significant change in percentage word use reflecting insight from session one to session two ($F(1,11)=.92$, $p=.357$, $r=.28$) or from session two to session three ($F(1,11)=.10$, $p=.753$, $r=.10$). However, the mean percentage word use scores for each writing session and effect sizes for the contrasts suggested a slight increase in

insight related words across successive writing sessions, in particular between sessions one and two. The increases between each session were estimated as small effect sizes.

Cause

Mauchly's test indicated that the assumption of sphericity had not been violated $\chi^2(2)=.89$, $p=.544$. There was no significant effect of writing session upon percentage word use reflecting cause $F(2,22)=2.03$, $p=.155$. Contrasts revealed a change in percentage word use reflecting cause from session one to session two that was approaching significance ($F(1,11)=4.09$, $p=.068$, $r=.52$) yet no significant change from session two to session three ($F(1,11)=1.92$, $p=.193$, $r=.39$). The mean percentage word use scores for each writing session and effect sizes for the contrasts suggested an increase in causal words from session one to two estimated as a large effect size, and a reduction from session two to three estimated as a medium effect size.

In the absence of adequate confirmation of the anticipated changes in post-writing negative affect and percentage word use presumed to reflect E&CP across writing sessions the presence or absence of such changes in the control group, and then the potential mediating effect of these change on the primary outcome were not explored.

Mediators

Again, for ease of interpretation the results for the analyses with the untransformed data are reported as the conclusions were generally consistent with those for the transformed data. There were a small number of exceptions for certain mediation steps for certain mediators tested at certain intervals, namely very slightly artificially

inflated effect sizes and slightly smaller p values (as in chapter seven); if at step two the mediator was apparently a slightly better predictor of the outcome and if at step three the relationship between the intervention and outcome was very slightly less attenuated (i.e. a slightly smaller p value was observed), and one instance of a slightly underestimated effect size and slightly larger p value (in step two the mediator was slightly less predictive of the outcome) in analyses with transformed data. The most conservative approach was to report the findings for the untransformed data. Regardless, however, the overall conclusions about mediation were unaffected by the discrepancies thus they were not considered to be important.

The model for the first mediation step (i.e. intervention group as a predictor of depressive symptom severity at three months, controlling for baseline depressive symptom severity), which applies to all of the mediation analyses, is presented in Table 36.

Table 36 Model for the first step in all mediation analyses[117] [118]

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	b	SEb	ß (p)	n
Step 1 A - C	Block 1 Baseline depressive symptoms	.40	.38						32
	Block 2 Baseline depressive symptoms	.53	.49	.12	7.6 (.010)				
	Intervention group (A)					5.6	2.0	.35 (.010)	

[117] A=intervention group and C=primary outcome (depressive symptom severity at three months). adjR^2=adjusted R^2. ΔR^2=change in R^2. ΔF(p)=change in F ratio (and significance of ΔF). b=unstandardized regression coefficient. SEb=standard error of b. ß(p)=standardized regression coefficient (and significance of ß).

[118] Where n is less than 41 participants were missing because they did not have scores for all variables included in the analysis.

Two weeks

Self-efficacy for diabetes SMBs

Controlling for baseline depressive symptom severity and intervention group, self-efficacy for diabetes SMBs was not a significant predictor of depressive symptom severity at three months (ß=.02, p=.902) and explained no additional variance in the outcome (ΔR^2=.00). The model for the final mediation step is presented in Table 37; the relationship between the intervention group and outcome (p=.010) was not notably attenuated by controlling for self-efficacy for diabetes SMBs (p=.020) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was reduced by only .01 representing no effect (ΔR^2=.11).

Table 37 Model for the final mediation step for self-efficacy for diabetes SMBs measured at two weeks post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	b	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms	.42	.38						31
	Self-efficacy (B)								
	Block 2 Baseline depressive symptoms	.53	.48	.11	6.2 (.020)				
	Self-efficacy (B)								
	Intervention group (A)					5.6	2.3	.35 (.020)	

Perceived illness interference

Controlling for baseline depressive symptom severity and intervention group, perceived illness interference was not a significant predictor of depressive symptom severity at three month follow up (ß=.21, p=.165), and explained a small amount of additional variance in the outcome (ΔR^2=.03). The model for the final mediation step is presented in Table 38; the relationship between the intervention group and outcome (p=.010) was not notably attenuated by controlling for perceived illness interference (p=.013) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was not reduced (ΔR^2=.12).

Table 38 Model for the final mediation step for perceived illness interference measured at two weeks post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	B	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms Perceived illness interference (B)	.45	.41						31
	Block 2 Baseline depressive symptoms Perceived illness interference (B)	.56	.51	.12	7.0 (.013)				
	Intervention group (A)					5.4	2.1	.34 (.013)	

Perceived emotional support (number)

Controlling for baseline depressive symptom severity and intervention group, perceived emotional support (number) was not a significant predictor of depressive symptom severity at three months (ß=.16, p=.303), and explained a small amount of additional variance in the outcome (ΔR^2=.02). The model for the final mediation step is presented in Table 39; the relationship between the intervention group and outcome (p=.010) was not notably attenuated by controlling for perceived social emotional (number) (p=.016) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was not reduced (ΔR^2=.12).

Table 39 Model for the final mediation step for perceived emotional support (number) measured at two weeks post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	B	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms Perceived emotional support (number) (B)	.44	.40						28
	Block 2 Baseline depressive symptoms Perceived emotional support (number) (B)	.56	.51	.12	6.7 (.016)				
	Intervention group (A)					5.9	2.3	.36 (.016)	

Perceived emotional support (satisfaction)

Controlling for baseline depressive symptom severity and intervention group, perceived emotional support (satisfaction) was not a significant predictor of depressive symptom severity at three months (ß=.05, p=.703), and explained no additional variance in the outcome (ΔR^2=.00). The model for the final mediation step is presented in Table 40; the relationship between the intervention group and outcome (p=.010) was not attenuated by controlling for perceived emotional support (satisfaction) (p=.009) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was not reduced (ΔR^2=.15).

Table 40 Model for the final mediation step for perceived emotional support (satisfaction) measured at two weeks post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	b	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms	.39	.34						28
	Perceived emotional support (satisfaction) (B)								
	Block 2 Baseline depressive symptoms	.55	.49	.15	8.1 (.009)				
	Perceived emotional support (satisfaction) (B)								
	Intervention group (A)					6.4	2.3	.39 (.009)	

Three months

Self-efficacy for diabetes SMBs

Controlling for baseline depressive symptom severity and intervention group, self-efficacy for diabetes SMBs was potentially related to depressive symptom severity at three months but did not emerge as a significant predictor (ß=-.27, p=.089), and explained a small amount of additional variance in the outcome (ΔR^2=.05). However, this was unimportant given that the relationship between the intervention group and outcome (p=.010) was not attenuated by controlling for self-efficacy for diabetes SMBs (p=.007) and the amount of variance in the outcome explained by

intervention group (ΔR^2=.12) was not reduced (ΔR^2=.15). The model for the final mediation step is presented in Table 41.

Table 41 Model for the final mediation step for self-efficacy for diabetes SMBs measured at three months post-intervention

Mediation step	Models	R^2	adj R^2	ΔR^2	ΔF (p)	b	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms	.47	.42						27
	Self-efficacy (B)								
	Block 2 Baseline depressive symptoms	.62	.56	.15	8.9 (.007)				
	Self-efficacy (B)								
	Intervention group (A)					6.8	2.3	.41 (.007)	

Perceived illness interference

Controlling for baseline depressive symptom severity and intervention group, perceived illness interference was not a significant predictor of depressive symptom severity at three months (ß=-.06, p=.753), and explained no additional variance in the outcome (ΔR^2=.00). The model for the final mediation step is presented in Table 42; the relationship between the intervention group and outcome (p=.010) was not notably attenuated by controlling for perceived illness interference (p=.024) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was reduced by only .01 representing no effect (ΔR^2=.11).

Table 42 Model for the final mediation step for perceived illness interference measured at three months post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	b	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms	.45	.41						27
	Perceived illness interference (B)								
	Block 2 Baseline depressive symptoms	.56	.51	.11	5.8 (.024)				
	Perceived illness interference (B)								
	Intervention group (A)					5.8	2.4	.34 (.024)	

Perceived emotional support (number)

Controlling for baseline depressive symptom severity and intervention group, perceived emotional support (number) measured was not a significant predictor of depressive symptom severity at three months (ß=-.07, p=.657), and explained no additional variance in the outcome (ΔR^2=.00). The model for the final mediation step is presented in Table 43; the relationship between the intervention group and outcome (p=.010) was very slightly attenuated by controlling for perceived emotional support (number) (p=.035) and the amount of variance in the outcome explained by intervention group (ΔR^2=.12) was reduced by .02 representing a small effect (ΔR^2=.10).

Table 43 Model for the final mediation step for perceived emotional support (number) measured at three months post-intervention

Mediation step	Models	R^2	adj R^2	ΔR^2	Δ F (p)	b	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressives	.45	.40						26
	Perceived emotional support (number) (B)								
	Block 2 Baseline depressive symptoms	.55	.49	.10	5.1 (.035)				
	Perceived emotional support (number) (B)								
	Intervention group (A)					5.2	2.3	.33 (.035)	

Perceived emotional support (satisfaction)

Controlling for baseline depressive symptom severity and intervention group, perceived emotional support (satisfaction) was potentially related to depressive symptom severity at three months but did not emerge as a significant predictor (ß =-.27, p=.094), and explained a small amount of additional variance in the outcome (ΔR^2=.06). However, this was unimportant given that the relationship between the intervention group and outcome (p=.010) was not attenuated by controlling for perceived emotional support (satisfaction) (p=.009) and the amount of variance in

the outcome explained by intervention group (ΔR^2=.12) was not reduced (ΔR^2=.15). The model for the final mediation step is presented in Table 44.

Table 44 Model for the final mediation step for perceived emotional support (satisfaction) measured at three months post-intervention

Mediation step	Model	R^2	adj R^2	ΔR^2	ΔF (p)	B	SEb	ß (p)	n
Step 3 A – C (controlling B)	Block 1 Baseline depressive symptoms	.47	.42						25
	Perceived emotional support (satisfaction) (B)								
	Block 2 Baseline depressive symptoms	.62	.56	.15	8.4 (.009)				
	Perceived emotional support (satisfaction) (B)								
	Intervention group (A)					6.6	2.3	.40 (.009)	

Sub-group (moderator) analyses

No significant interaction effects were observed (p>.05), yet there was a tentative indication in the pattern of the means (and the interaction plots) that WED may have been associated with greater depressive symptom severity compared to controls at follow up for individuals with high alexithymia (WED: Mean=11.2, SE=1.7 versus control: Mean=3.8, SE=2.6) but not low alexithymia (WED: Mean=9.3, SE=2.4 versus control: Mean=5.0, SE=2.0) and low optimism (WED: Mean=12.6, SE=1.9 versus control: Mean=5.2, SE=3.0) but not high optimism (WED: Mean=8.7, SE=1.9 versus control: Mean=4.8, SE=2.1).

Written Emotional Disclosure for Improving Depression for Adults with Long-term Physical Conditions: The Case of Type 2 Diabetes

Two volumes (volume two)

by

Kathryn Joanne Dennick

A thesis submitted in partial fulfilment of the requirements for the degree of

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Table of contents

Page

Volume two

Chapter 8 Feasibility findings and post-hoc investigation and analyses

Chapter overview

This chapter presents the remaining feasibility investigation; the investigation of the feasibility/effectiveness of intervention delivery (i.e. compliance, contamination and acceptability data), and the remaining aspects of the investigation of the feasibility/effectiveness of the trial protocol (i.e. the feasibility/effectiveness of the randomisation and allocation concealment methods and the check of blinding success). The findings from some additional post-hoc investigations and analyses are then presented, specifically feasibility data that was collated unintentionally yet is nonetheless consistent with the objectives of an exploratory trial (as described in chapter four), and consideration of writing content with some exploratory analyses undertaken to facilitate interpretation of the pre-specified analyses.

Feasibility investigation

Feasibility/effectiveness of intervention delivery

Contamination

Average degree of EA

Again as transformation did not influence the distributional problems in the PANAS data non-parametric tests were performed with the untransformed data (as described in chapters five and seven, and the appendix). The medians and mean ranks for post-writing negative affect averaged across writing sessions and by group are reported in Table 45.

Table 45 Average degree of post-writing negative affect across writing sessions by group[119]

Session	Median (range)	Mean rank	n
WED	16.7(10.3–40.0)	11.9	10
Control	10.0 (10.0-14.3)	4.9	7

Average post-writing negative affect was significantly different for the WED group compared to the control group (*U*=6.0, z= -2.853, p=.001). The average post-writing negative affect scores indicated more post-writing negative affect for the WED group compared to the control group. This represented a large effect (*r*=-.69).

Average degree of ED

For ease of interpretation the results for the analyses with the untransformed data are reported. The conclusions were generally consistent with those for the transformed data, with some exceptions where artificially inflated effect sizes and slightly smaller p values were derived from analyses with transformed data (again as in chapter seven).

The most conservative approach was thus to report the findings for the untransformed data. The means and associated SEs reflecting the average percentage word use for the four categories indicative of ED across writing sessions by group are reported in Table 46.

[119] Twenty-seven participants returned their writing (WED 14; Control 13) and 17 (WED 10; Control 7) of these provided an observation for the PANAS negative affect sub-scale.

Table 46 Average percentage word use for the four categories indicative of ED across writing sessions by group[120]

Word use category	Total sample (Mean; SE)	n	WED (Mean; SE)	n	Control (Mean; SE)	n
All word use categories			2.4 (.12)	14	1.0 (.13)	13
Positive emotion (%)	2.5 (.25)	27	3.5 (.35)	14	1.6 (.36)	13
Negative emotion (%)	1.6 (.16)	27	2.4 (.22)	14	.79 (.22)	13
Insight (%)	1.5 (.18)	27	2.2 (.25)	14	.82 (.26)	13
Cause (%)	1.1 (.09)	27	1.3 (.12)	14	.98 (.13)	13

Assumption checks indicated homogeneity of variance for percentage word use reflecting positive emotion ($F(1,25)=1.99$, $p=.171$), negative emotion ($F(1,25)=1.61$, $p=.216$) and cause ($F(1,25)=.35$, $p=.562$). The assumption of homogeneity of variance was apparently violated for percentage word use reflecting insight for the untransformed data ($F(1,25)=4.74$, $p=.039$), yet this was not the case for the transformed data, analysis of which derived the same conclusions. Thus, for ease of interpretation the untransformed data is reported. Mauchly's test indicated that the assumption of sphericity had been violated $\chi^2(5)=.53$, $p=.011$, therefore degrees of freedom used to assess the F ratio were corrected using Greenhouse-Geisser estimates of sphericity ($\varepsilon=.69$).

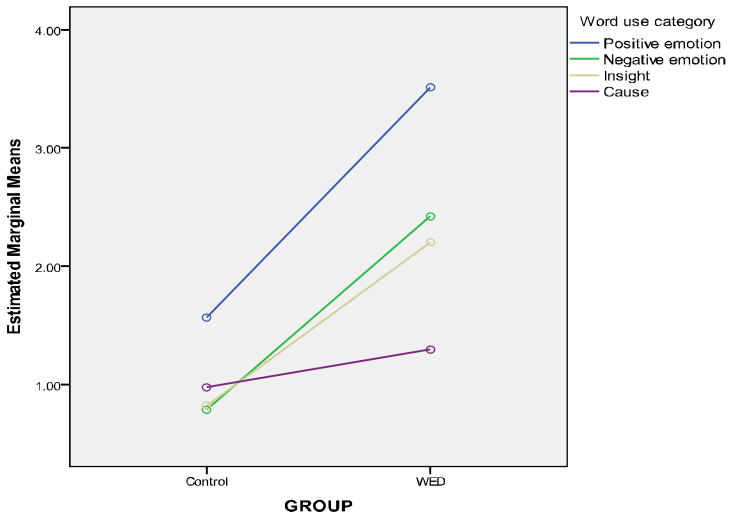
There was a significant effect of group ($F(1,25)=58.10$, $p=.000$). This was a large effect ($r=.84$). The intervention group included more words reflecting ED than the control group across all categories.

There was additionally a significant interaction between group and category of word use ($F(2.079, 51.977)=3.83$, $p=.027$). Contrasts revealed that there was no difference between the main effect of group across word use categories (i.e. greater percentage word use for the WED group compared to the control group) and the

[120] Twenty-seven participants returned their writing (WED 14; Control 13).

effect of group specifically for the positive emotion (F(1,25)=2,14, p=.156, r=.28), negative emotion (F(1,25)=1.27, p=.270, r=.22) and insight (F(1,25)=.05, p=.832, r=.04) word use categories. However, there was a significant difference between main effect of group across word use categories and the effect of group for the causal word use category (F(1,25)=18.65, p=.000). This was a large effect (r=.65). Examination of the means revealed that while there was greater percentage word use reflecting cause for the WED group compared to the control group this difference was reduced compared to the overall effect of group. The average percentage word use by group and word use category is presented in Figure 26.

Figure 26 Average percentage word use across writing sessions by group and word use category



Compliance

The number of days writing completed

The number of writing sessions that participants completed is illustrated in Table 47. Participants that returned their writing generally wrote for three sessions. It is noteworthy that one intervention patient noted in their pack that they wrote for '3+'

sessions. Support group participants all completed three writing sessions as instructed.

Table 47 Number of writing sessions participants completed[121]

No. days completed	Total sample (n=27)	WED (n=14)	Control (n=13)
Three	24 (89%)	12 (86%)	12 (92%)
Two (session 1 & 2)	1 (4%)	1 (7%)	0
Three (session 1 only)	2 (7%)	1 (7%)	1 (8%)

The length of time spent writing per session

The length of time participants spent writing per session is illustrated in Table 48. In general, participants only marginally deviated from the instructions to write for 20 minutes per session. However there were some outliers. In one of the worst instances of this, a primary care patient in the intervention group wrote for 120 minutes in session two and noted that they took long breaks within each session for meals, household jobs and spending time with their wife. Another primary care patient in the control group wrote for 781 minutes in session one and commented that the time taken varied as they felt they had something to say and couldn't stop until they had finished. Presumably this participant also took breaks.[122]

[121] Twenty-seven participants returned their writing (WED 14; Control 13).

[122] It is also noteworthy that participants were required to indicate the time at which they started and finished writing, specifying whether this was am or pm in each instance (i.e. deleting as appropriate). This led to some discrepancies for some patients in that it was not clear whether the start and or finish times were am or pm or there were obvious errors (e.g. the start time was 8:00 am and the finish time was 8:20 pm). Such discrepancies were interpreted logically (i.e. in view of that participant's writing in other sessions, the length of the text and the times provided, e.g. 4:00 was considered less likely to be am), yet a presumption was made nonetheless. For example, the patient that wrote for 120 minutes in session two indicated that for session three they wrote from 9:40 to 10:20; both were presumed to be am and therefore 40 minutes but had one time been am and the other pm this session would have been considerably longer. Consequently, it may be that some patients actually wrote for longer for some sessions.

Table 48 Length of time participants spent writing per session[123]

Writing session	Total sample (Mean minutes (SD; range)	n	WED (Mean minutes (SD; range)	n	Control (Mean minutes (SD; range)	n
1	55.4 (145.6; 10-781)	27	30.4 (15.4; 20-70)	14	82.4 (210.1; 10-781)	13
2	29.1 (20.5; 15-120)	25	31.0 (27.0; 19-120)	13	27.1 (10.5; 15-55)	12
3	26.0 (8.6; 15-45)	24	24.9 (9.0; 15-45)	12	27 (8.5; 17-45)	12

Overall, for those that returned their writing compliance with the instructions in terms of both the number of days completed and amount of time spent writing was relatively good. However, 14 (34%) participants failed to return their writing at all.

Further self-directed writing

Whether participants carried on writing after completing the writing task is illustrated in Table 49. A significant proportion of patients indicated that they had undertaken further writing since the intervention task, especially in the WED group. However, it is notable that this could reflect other forms of writing (i.e. not ED); two WED patients responding positively to this question also commented in their writing/stated in a follow up questionnaire that they were currently writing a book/family history and or that they kept a daily diary. Moreover, the majority of support group participants responded positively to this question. However, this may reflect writing within the forum from which they were recruited.

[123] Twenty seven participants returned their writing: where n is less than 27 (WED=14; Control=13) patients did not return writing for that day.

Table 49 Whether participants carried on writing since completing the writing task[124]

Carried on writing?	Total sample (n=23)	WED (n=11)	Control (n=12)
Yes	10 (43%)	6 (55%)	4 (33%)
No	13 (57%)	5 (45%)	8 (67%)

Acceptability

Reasons participants provided for not writing at all were presented in chapter six. The reasons provided for not undertaking the intervention as instructed were as follows. The two WED participants that did not complete all three sessions commented that this was because they found it difficult to write (completed two sessions) or had better things to do than keep repeating themselves (completed one session). The control patient that completed only one session commented that he considered the task to be juvenile and could not identify its relevance or use with respect to diabetes.

Feasibility/effectiveness of the trial protocol

Randomisation and allocation concealment methods

The randomisation and allocation concealment methods were easily implemented and were apparently successful as there were no substantial systematic differences on prognostic variables apparent at baseline (i.e. there was no evidence of selection bias – as reported in chapter seven).

Check of blinding success

Whether participants inferred the true nature of the study and their group assignment was again collated at debriefing and is illustrated in Table 50. Blinding was apparently successful for the majority of participants. However, a number

[124] Twenty seven participants returned their writing (WED=14; Control=13) and 23 (WED=11; Control=12) of these answered the question asking whether they had carried on writing since the initial task.

indicated that they were aware of the two groups, what the other group was writing about and that they had guessed the purpose of their writing task. No group differences were apparent with respect to compromised blinding. It is noteworthy, however, that for both groups slightly more participants agreed to being aware of the purpose of the other group's task and of their own tasks purpose than to being aware of there being two groups; while blinding was apparently completely compromised for some participants it seems that others may have merely guessed theirs was an active or inert task. Blinding was apparently consistently successful for support group participants that answered these questions (i.e. none responded positively to any of the questions). In fact, two support group participants provided additional comments about the blinding aspect of the study in the debriefing sheet. One intervention participant reiterated that they had not identified the two groups and a control group participant indicated that they had not thought about possible study groupings, but having read the debriefing sheet it seemed obvious what the purpose of the study was.

Table 50 Whether participants inferred the true nature of the study and their group assignment[125]

Question asked	**Total sample (n=31)**		**WED (n=16)**		**Control (n=15)**	
	Yes	No	Yes	No	Yes	No
Were you aware that there were 2 different groups?	3 (10%)	28 (90%)	1 (6%)	15 (94%)	2 (13%)	13 (87%)
Having read this debriefing sheet had you guessed what the other group was writing about?	9 (29%)	22 (71%)	5 (31%)	11 (69%)	4 (27%)	11 (73%)
Having read the debriefing sheet & now knowing what group you were in, had you already guessed the purpose of your writing task?	7 (23%)	24 (77%)	4 (25%)	12 (75%)	3 (20%)	12 (80%)

[125] Forty one participants were randomised (WED=23; Control=18) and 31 (WED=16; Control=15) of these returned and answered the debrief questions.

Post-hoc investigation/analyses: additional feasibility data

Valuable additional information about intervention fidelity, the acceptability of the intervention and comparison exposure, participants' general experience of the study, the appropriateness of the measures employed and the feasibility of the data collection schedule was collated unintentionally and is presented below.

Intervention fidelity: self-reports of negative emotional response post-writing

A number of intervention participants provided comments in their writing pack that supported intervention fidelity. One acknowledged a 'lowering of spirit', another stated that thinking about what they were concerned about enough to write about notably diminished their positive mood, and another indicated that despite usually being a positive person, writing evoked negativity and contemplation of stressful issues in the following days.

Acceptability of the intervention and comparison exposure

A number of participants provided comments about their writing task in the packs provided. These are described below.

Acceptability of writing per se

Poor health prohibiting writing

One participant wrote for three days yet commented that they experienced difficulty due to arthritic pain in both hands, sight problems and generally not being well (control).

Feeling restricted by the time allocated

One participant commented that they could have written more had they had more time (control). Another commented that the allocated time passed quickly and that they did not feel they had actually said anything (WED).

Finding writing difficult to fit in with life

One participant commented that they had found it difficult to find time to start writing (WED). Another commented that it was difficult to complete the writing sessions within one week due to work commitments (WED). However, control participants did not experience this problem; one noted that they had managed to complete their writing task within one week and another noted that they had actually written on consecutive days.

Negative feelings about handwriting

Some participants commented that they were not used to handwriting, joked about having cramp in their hand after writing, and one actually requested that they typed their disclosure (one WED & one control). Despite the apparent preference for typing however, one support group intervention participant requested a hardcopy of the writing pack as they felt their thoughts would flow more freely (i.e. again all support group participants were offered this).

Acceptability of WED content

A number of participants indicated that they found it difficult to relate to the WED task and that they were uncertain about what was required or what they could write about as they did not dwell on emotions or stressful experiences, did not have any problems, were not stressed or depressed and were optimistic and able to make the best of life even when faced with difficulties (seven WED). It is noteworthy that a number of these participants were amongst those that also wrote about positive

issues (discussed later), and this may explain why. Interestingly, one intervention participant commented that they found writing about their innermost thoughts to be difficult as they usually concealed their problems to avoid worrying others.

Acceptability of the comparison exposure: time management

One participant explained that they did not follow the allotted task because they would have found that too boring; this was the control participant who wrote for 781 minutes in session one and who also seemingly emotionally disclosed (discussed below). Another commented that they had added the term 'bored' to the list of mood adjectives which participants were required to rate post-writing in terms of their current mood, as this better represented how they felt.

Possible restriction owing to readership

Some participants expressed concern about the quality of their writing despite stating that they were aware this was not important, often apologising for writing which they felt was illegible (two control). Other participants returned their writing packs with a note to say that they hoped their writing was as required and informative (one control) and apologised as they felt they had rambled and that their writing was uninteresting (one WED). Indeed, most patients wrote as if it were a narrative for a reader, for example introducing themselves and using the term 'dear reader', and some explicitly questioned whether their writing would be read within their text.

General feedback about the study

One intervention participant commented in the three month questionnaire that they did not expect their diabetic control would be influenced (WED). Other participants provided additional comments about their experience of the study within the

debriefing sheet that was returned; two control participants stated that they found the writing task/study to be interesting and one expressed that it had been a pleasure to take part.

Appropriateness of measures

Participants' comments in the questionnaires and the debriefing sheet provided some insight into the acceptability of the measures employed and suggested some interpretative issues. The researcher additionally observed some interpretative problems associated with the measures employed that warrant a mention.

Participant comments

General

One elderly primary care patient noted that they felt many of the questions were not applicable given their age. Another patient commented that they felt they were constantly repeating themselves, that the questionnaires were based on the assumption that everyone felt negatively about diabetes, and that few of the questions felt relevant to them as they were not concerned about diabetes, were managing this well and were more concerned about other conditions such as mental deterioration.

It was evident that the incident illness unrelated to diabetes reported by some participants within the trial may have influenced responses to questionnaires given the nature of the questions. As mentioned in chapter six, one patient had a double bypass operation and another was admitted to hospital with heart failure (i.e. atrial fibrillation) during the follow up period. Both noted in the three month questionnaire that their answers were likely influenced by this/this would explain the change in their answers.

Measure-specific

Comments associated with missing responses: To identify whether missing item responses were missing at random or related to certain items, the dataset was visually inspected and frequencies for each item within each measure were produced (i.e. reported as the number (and percentage) of observations missing for each item for each measure each time the measure was administered).

The missing observations per item for each continuous measure at each administration are illustrated in Table 51. Missing item responses were not entirely missing at random; they were related to certain items within certain continuous measures (i.e. responses for certain items were commonly missing across participants). Missing responses were most notable for the items in the SDSCA that ask about blood glucose monitoring (items 7 and 8[126]), and the items in the DMSES UK that ask about blood glucose monitoring (items 1-3[127]) and adjusting medication when ill (item 15[128]). Patients often commented adjacently to missing responses that these items were not applicable to them, for instance because their HCP does not advise them to monitor their blood glucose levels or they check more than that recommended by their HCP (SDSCA items 7 and 8), they rely on their HCP to monitor their blood glucose and they do not experience problems with high/low blood sugar that would require correction (DMSES UK items 1-3), and they do not adjust their medication on their own/without professional advice or a situation in which they have been ill and required to do this has not arisen (DMSES UK item 15).

[126]SDSCA item 7: On how many of the last seven days did you test your blood sugar? SDSCA item 8: On how many of the last seven days did you test your blood sugar the number of times recommended by your health care provider?

[127] DMSES UK item 1: I am able to check my blood sugar if necessary. DMSES UK item 2: I am able to correct my blood sugar when the sugar level is too high. DMSES UK item 3: I am able to correct my blood sugar when the blood sugar level is too low.

[128] DMSES UK item 15: I am able to adjust my medication when I am ill.

Moreover, missing responses for the SSQ6 items that asked about being down in the dumps and upset (items 9 and 11[129]) were notable. Indeed, participants often commented adjacently to missing responses that these items were not applicable (i.e. “don’t get very upset” & “never down in the dumps”). Similarly, participants often commented adjacently to missing responses to a DMSES UK item that asks about self-efficacy for diabetes SMBs when feeling stressed or anxious (item 13[130]) that this is was not applicable to them.

The PANAS measure (i.e. list of mood adjectives which participants were required to rate in terms of their current mood post-writing) was often not completed at all or very few adjectives were rated such that no score for the negative affect sub-scale could be derived. Indeed, data for the PANAS exhibited the highest degree of missing observations; of the 41 participants that were enrolled, 27 returned their writing pack and for 10 (37%) of these a total PANAS negative affect sub-scale score could not be derived. As mentioned above, one control participant commented in their writing pack that none of the adjectives represented how they felt. This may explain why others omitted this measure. It is noteworthy that the full PANAS measure was actually administered (i.e. the positive and negative affect sub-scales), and where people completed only a few of the adjectives they answered either only positive or only negative adjectives. It therefore seems that these people only responded to the few adjectives that represented their current mood.

Comments about certain measures: The IIRS asks how much your illness and/or its treatment interferes with your life and thus did not specifically refer to diabetes. One

[129] SSQ6 item 9: Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps? SSQ6 item 11: Who can you count on to console you when you are very upset?
[130] DMSES UK item 13: I am able to adjust my eating plan when I am feeling stressed or anxious.

participant stated that they had answered this with respect to other health problems; for example a recent double bypass operation (as above) and angina. The SSQ6 was also apparently somewhat tedious for some patients. As mentioned in chapter six, one participant indicated that while they had completed all other measures in the two week questionnaire, they did not complete the SSQ6 as they answered it in a previous questionnaire and did not wish to repeat it.

Comments about certain items in certain measures: Consistent with the comments associated with missing responses, for a DMSES UK item that asks about taking medication as prescribed (item 14), participants commented adjacently to responses that this item was not applicable and commented that they did not take medication for diabetes. Participants also often commented adjacently to responses to the IIRS item enquiring about the impact of illness on sex life (item 8) that this was not applicable due to age and that this information was private (i.e. they felt uncomfortable providing it). Finally, participants commented that they found other items in SDSCA and DMSES UK difficult to answer because they did not have an eating plan as presumed, they were unable to exercise due to health problems/old age or they were not advised by their HCP to exercise.

Receipt of materials electronically: As described in chapter six, some support group participants noted formatting problems when completing questionnaires as these were received electronically/by email, especially for the EQ-5D. Participants experienced difficulties where they were required to mark text boxes (i.e. with an 'X'), and indeed the EQ-5D requires such responses. It also requires the use of an arrow to indicate a point on a vertical scale, which was additionally susceptible to substantial formatting problems. Formatting problems were also experienced for the

SSQ6, which already has a relatively complex response format (presented in the appendix and discussed below).

Interpretation of responses

The most substantial interpretative problems observed for the materials employed were for the SSQ6. Again, the response format for this measure is relatively complex, and indeed participants varied in their approach to completing it often deviating from the instructions/example provided. It was, however, usually possible to decipher the intended responses, and a conservative approach was adopted applying the same logic in each instance in order to promote consistency in interpretation. Other measures for which participants varied in their approach to completion included the SDSCA (i.e. participants did not always circle only the number of days for which a behaviour was performed as required) and the EQ-5D VAS measure (i.e. participants did not always precisely indicate a point on the vertical scale with the arrow as required). However, these problems were less notable and again it was typically possible to decipher the intended response. It is also noteworthy that across the measures employed participants occasionally wrote their responses as comments or underlined text rather than responding to the items as instructed. In these instances no response was presumed.

The formatting problems experienced by support group participants additionally created interpretative problems. Indeed, responses were often not initially interpretable, especially for the EQ-5D, yet they could usually be deciphered. Electronic materials were also vulnerable to participants not answering in the correct response format, for example unsystematically deleting proportions of Likert scales to indicate a response rather than simply marking the appropriate number as instructed.

Table 51 Extent of missing observations per item for each continuous measure at each time point

Measure	Item no. with missing responses (x number of missing observations; % of total number of observations)
Baseline (n=41 returned questionnaire pack)	
CES-D (scoring key: items scored if <4 missing)	16(x1; 2%); 17(x1; 2%)
PAID	1(x1; 2%); 6(x1; 2%); 9(x1; 2%); 10(x1; 2%); 11(x1; 2%); 12(x1; 2%); 13(x1; 2%); 14(x2; 5%); 15(x2; 5%); 16(x1; 2%); 17(x1; 2%); 18(x2; 5%); 19(x1; 2%); 20(x1; 2%)
EQ-5D utility	Mobility (x3; 7%); Self-care (x2; 5%); Usual activities (x1; 2%); Pain & discomfort (x2; 5%); Anxiety & depression (x1; 2%)
SDSCA: general diet: items 1&2	2(x1; 2%)
SDSCA: specific diet: items 3&4	4(x2; 5%)
SDSCA: exercise: items 5&6	5(x1; 2%); 6(x1; 2%)
SDSCA: blood glucose testing (items 7&8)	**8(x6; 15%)**
SDSCA: foot care (items 9&10)	9(x1; 2%)
LOT-R (items 2, 5, 6 & 8 are filler items & not included)	1(x2; 5%); 7(x1; 2%); 9(x1; 2%)
TAS-20 (scoring key: items imputed if no more than 2 or 3 missing from total scale & no more than 1 missing per factor sub-scale (with mean of answered items for that person on the same factor sub-scale)	NOT IMPUTED: 6(x1; 2%); 10(x1; 2%); 15(x1; 2%); 16(x1; 2%); 17(x1; 2%); 19(x1; 2%); 20(x1; 2%) *IMPUTED: 10(x1; 2%); 14(x1; 2%); 1(x1; 2%); 16(x1; 2%)*
During intervention (n= 27 returned writing pack)	
PANAS (negative affect) session 1	**3(x9; 33%); 6(x7; 23%); 8(x10; 37%); 9(x9; 33%); 10(x10; 37%); 11(x9; 33%); 15(x10; 37%); 16(x10; 37%); 17(x10; 37%); 19(x10; 37%)**
PANAS (negative affect) session 2	**3(x9; 33%); 6(x9; 33%); 8(x9; 33%); 9(x10; 37%); 10(x10; 37%); 11(x9; 33%); 15(x10; 37%); 16(x9; 33%); 17(x10; 37%); 19(x10; 37%)**
PANAS (negative affect) session 3	**3(x9; 33%); 6(x9; 33%); 8(x10; 37%); 9(x10; 37%); 10(x10; 37%); 11(x9; 33%); 15(x10; 37%); 16(x10; 37%); 17(x10; 37%); 19(x10; 37%)**

Measure	Item no. with missing responses (x number of missing observations; % of total number of observations)
Two weeks (n=33 returned questionnaire pack)	
IIRS (scoring key: if responses are not consecutive do not score (thus if any items were missing scale not scored)	
DMSES UK (scoring key: items imputed if ≤4 missing (with mean of answered items for that person) (thus if more than 4 items missing scale not scored)	*IMPUTED:* ***1(x4; 12%); 2(x4; 12%); 3(x5; 15%);*** *7(x1; 3%); 10(x1; 3%);* ***13(x3; 9%);*** *14(x1; 3%);* ***15(x3; 9%)***
SSQ6 (number): items 1, 3, 5, 7, 9 & 11	1(x1; 3%); 3(x2; 6%); 5(x2; 6%); 7(x1; 3%); **9(x3; 9%); 11(x4; 12%)**
SSQ6 (satisfaction): items 2, 4, 6, 8, 10 & 12	2(x1; 3%); 4(x2; 6%); 6(x2; 6%); 8(x1; 3%); **10(x3; 9%); 12(x4; 12%)**
Three months (n=32 returned questionnaire pack)	
CES-D (scoring key: items scored if <4 missing)	3(x1; 3%); 5(x1; 3%); 7(x1; 3%)
PAID	
EQ-5D utility	
SDSCA: general diet: items 1&2	
SDSCA: specific diet: items 3&4	
SDSCA: exercise: items 5&6	
SDSCA: blood glucose testing (items 7&8)	7(x1; 3%); **8(x4; 13%)**
SDSCA: foot care (items 9&10)	
Three month mediators; only collected for primary care patients (n=27 primary care patients returned questionnaire pack)	
IIR (scoring key: if responses are not consecutive do not score (thus if any items were missing scale not scored)	
DMSES UK (scoring key: items imputed if ≤4 missing (with mean of answered items for that person) (thus if more than 4 items missing scale not scored)	*IMPUTED: 1(x2; 7%);* ***2(x5; 19%); 3(x5; 19%****); 7(x1; 4%); 10(x2; 7%); 13(x1; 4%);* ***15(x3; 11%)***
SSQ6 (number) items 1, 3, 5, 7, 9 & 11	5(x1; 4%)
SSQ6 (satisfaction): items 2, 4, 6, 8, 10 & 12	6(x1; 4%); 10(x1; 4%)

Importantly, any uncertainties were checked with another person (CB) to promote accuracy and consistency in interpretation.

Feasibility of the data collection schedule[131]

Primary care

For primary care patients that received materials by post there were some issues that meant follow up questionnaires were not completed at the intended time (i.e. two weeks and three months post-intervention[132]). The two week questionnaire (i.e. intended at approximately 14 days post-intervention) was returned on average 29 days (i.e. four weeks) post-intervention (range 17 to 71 days). The three month questionnaire (i.e. intended at approximately 90 days/three calendar months post intervention) was returned on average 106 days (i.e. 3.5 months) post-intervention (range 96-139 days). It is notable that while there was a delay for some patients in returning the questionnaires this may not necessarily mean that they were completed this late; whilst somewhat unlikely some patients may have completed it but then delayed posting.

Probable reasons for the delay were that patients were sent materials on the day that they were due to complete them, materials were sent second class to reduce postage costs, and there was a delay in sending some follow up materials for some patients; again practices were asked to do this where patients had not provided an address in their consent form yet there was an instance of a notable delay obtaining their agreement (i.e. four patients were sent the two week questionnaire an average of 20 days after the date at which they were due to complete it (range 13-42 days).

[131] These data are presented separately for primary care and support group participants given the differences in the means of obtaining data.
[132] Post-intervention equated to the return of writing, once patients had confirmed that they were not intending to return their writing when chased or once a decision that writing was unlikely to be returned was made owing to unsuccessful reminders.

There was additionally a delay in patients completing and returning materials, reasons for which were provided when patients were chased or in returned materials. These included a) illness; one patient was admitted to hospital with heart failure (as mentioned earlier; the three month questionnaire was received late), and b) circumstantial reasons; two patients returned their writing pack late explaining that they had misplaced the return envelope and or the pack. It is noteworthy that one patient indicated at the end of their writing pack that they wanted a break for a few weeks; this may explain the delay in some patients returning the two week follow up, and indeed not returning it at all where reasons for this were not obtained. Moreover, the three month follow up was the one at which most reminders were sent and successful in retrieving materials; given that this questionnaire was received some time after patients consented to the study and completed materials, they may have lost interest and only responded when prompted.

Support groups

No problems with respect to timing of follow up were evident for support group participants that typically received materials electronically; the two week follow up questionnaire was returned on average 20 days post intervention and the three month follow up was returned on average 95 days post intervention.

Post-hoc investigation/analyses: consideration of writing content

To facilitate interpretation of the findings from the pre-specified analyses, the content of the intervention and control participants' essays was considered and some exploratory analyses of the writing content were undertaken.

What participants wrote about

WED

Of the 14 intervention participants that returned their writing, it is notable one support group participant did not apparently personally disclose rather they discussed a number of issues (i.e. music, persecution, and politics, war and terrorism) from a religious perspective, which was more akin to a sermon (in fact this participant noted his involvement in such work). The topics disclosed with quotes providing examples of each are indicated in Tables 52 and 53.

Participants did not consistently write about diabetes-related topics, and interestingly a number of positive (or neutral) diabetes and non-diabetes related topics were discussed in addition to stressful experiences (see Tables 52 and 53). The extent to which people wrote about diabetes and positive topics was thus derived. Specifically, writing sessions were inspected to identify whether diabetes-related/positive topics were discussed at all in each session, and then individuals were classified as having written about diabetes/positive issues if they had written about this in at least two of the three writing sessions (or in at least one session where only one or two were completed). Given that diabetes-related/positive topics may still have been discussed relatively infrequently for these participants, the proportion of the total number of topics disclosed by these participants across the writing sessions that related to diabetes or were positive was then estimated and averaged across participants.

Table 52 Diabetes-related topics disclosed by participants

Diabetes-related	
Stressful	**Positive**
Diabetes SMBs *Frustration with respect to dietary constraints and speculation about the necessity of this* "I am finding it hard to motivate myself about food – it just seems to be a real headache thinking about it and preparing it. In fact the last week I have tried just about every ready meal in Marks and Spencer's and I am feeling quite sorry for myself lately and I am wondering if I really am a diabetic because I am not on any medication and I have been like this for 16 months I have blood tests and have had my eye test at the hospital and I don't feel any different apart from being frustrated with food". (P13; session 2) "Ok change the subject – let's consider my diabetes for a while. For the first few years I thought I was doing ok because the clinic said as much, but a couple of years ago quite by accident I discovered a diet which actually helped me to lose weight and as a real bonus my blood sugar / glucose readings improved beyond recognition. So why – oh why have I gradually slipped into eating the kind of diet I used to eat. I know I'm putting weight back on, I know my readings are rising: I have decided it is a 'blip'. I hope it is. I need to get back into the low carbohydrate foods again – soon. I have a check up in July – I really – really should be back into the 5 club." (P6; session 2) *Frustration about weight loss* "I love clothes always buying them wish I could lose some weight but although I don't take sugar (never have) I do like evening meal so I suppose that is why I do not lose weight, I do not smoke drink very occasionally so I might as well cut my throat if I can't have a nice meal." (P8; session 1) "I wish I could just will away a lot of weight, I think it would help my knee, although I'm not excessively over weight but I do have to be careful which is very boring." (P10; session 3) *Tension between medication & weight loss* "I think the thing that bothers me the most is my weight, when my general practitioner changed my medication a few months ago, the weight I had managed to lose went straight back on! and more. I am trying very hard and the problems with my tooth (I hope) has helped because I had trouble eating. I don't eat sweets or chocolate but do like crisps and cheese. I also try to eat healthily but find it difficult to eat my 5 a day." (P10; session 1) **Impact of diabetes** *Problems relating to diabetes complications* "I had my eyes photographed at my surgery two years ago. The operator thought I had had diabetes longer than I said due to slight blood veins in the eyes. September 2008 I had a blood vessel leak, and the sight in the left eye was affected. It was lazered December of that year." (P3; session 1)	**Diabetes SMBs** *Success achieving dietary restraint* "I have, on diagnosis, totally changed my eating habits to meet the new requirements. I do not make concessions to sweet items as a favour to myself. With that discipline my tastes have changed and savoury food is now the norm. " (P14; session 2) "I was diagnosed with type 2 diabetes in 2000. I took this on board and followed the diet and exercise, and medication to keep my weight down and my blood sugar levels under control. I did this and did quite well." (P12; session 1) **Impact of diabetes** *No impact/coping with the impact of diabetes on health* "To date the disorder has been managed with no external or internal apparent affect on my general state of health. Long may it continue." (P14; session 2) I then developed a sight problem over the years I have had numerous laser treatments to keep this under control but the whole world is blurred to me. Again I took this on board and continued to keep my weight and blood levels under control." (P12; session 1) **Relationships** *Good relationship with HCPs* "My doctor tells me that it is the pills that are keeping me on the path of good health, I do wonder, but he is a good man and I trust him with my health." (P7; session 1) "As far as the medical service is concerned I have had excellent attention from the practice for now, over 70 years." (P14; session 2) *Feeling supported by work colleagues* "I'm very fortunate to have good work colleagues and a boss who are all very supportive. And allow me regular breaks to eat as I am supposed to because of my diabetes." (P13; session 1)

Stressful	Positive
Relationships *Negative experience with/lack of confidence in HCP* "My blood pressure over the years since the operation has been slightly raised, the doctor did not bring it down, but at that time suited me, thinking the doctor does not really think I need tablets. September 2003 before going on holiday I asked the doctor for blood pressure tablets, which he refused to give, and on holiday a blood vessel in the eye leaked, and my sight has been affected. The optician considered it was the blood pressure – He wrote to the doctor saying as much, which the doctor did not take likely - The problem here is all the concerns I had asked him about, and dismissed are now worrying – I would have thought this doctor would have been thinking heart disease, diabetes etc. The blood pressure should have been much lower. I have now changed my doctor and my condition checked regularly." (P3; session 2) **Control of diabetes** *Worry about high blood sugar levels* "My blood sugar is a little high I test it three times a week. I wonder if this is due to the fact that I am not active because of my knee operation." (P1; session 1) "My own health continues to jog along had a good winter not even a really bad cold and haven't had lost any "sick" time at work, had a scare in January when having my six monthly check it was found that my Blood Sugar levels had risen, that was a panic for a while." (P7; session 1) *Concern about change in diabetes medication (i.e. more tablets/initiating insulin)* "Sometimes I worry in case I need to have insulin instead of the tablets." (P1; session 1) "Have 3 months to try and get it (blood sugar) down before we start talking about more tablets, you will gather as you go on through this exercise that I don't really like tablets." (P7; session 1) **Impact of stress and low mood on diabetes SMBs** "Having the extra worry I find that I am losing control of my weight, because I am eating more at night when I am up. I am still keeping blood levels ok but unfortunately eat too much although is the correct food." (P12; session 1) I'm really fed up and food just doesn't seem important right now, I haven't really been eating the way I should during the week and when I do at the weekend it doesn't really make any difference, I still feel down." (P13; session 2) **Illness representations** *Speculation about the cause of diabetes* "I have been treated for relatively modest raised blood pressure for the last 35 years. It was considered, from the outset, to be in my long-term interest. I wonder whether that treatment has had any effect on weakening the effectiveness of the pancreas. I have never been overweight, eaten regularly and modestly. Never smoked, only very modest alcohol consumption and have no known family history of the condition before 80 years of age." (P14; session 2)	

Table 53 Non-diabetes related topics disclosed by participants

Non-diabetes related	
Stressful	**Positive**
Relationships *Marital issues* "Married a great woman, my second marriage –only problem is she has two sons, both in 20's who are morons. This has something to do with the father. I have my own two, polite, well educated who went to university and both got B.A.'s and M.A.'s, the boy now doing his PhD. She feels that hers deserve more than mine and having spent thousands on them I don't want anything to do with them as they are ungrateful and use their mother to try and get more out of me. This causes stress between us, but I will live with it. Oh the joys of married life. Grown up step children, who needs them." (P2; session 1). "I have been happily married next year for 40 years, she is eleven years older, and I am confused why I have been suffering erectile dysfunction over many years." (P3; session 1) *Concern about/ disappointment in children* "I have three children (grown up, and left home) a daughter living in New Zealand with husband troubles, a son married to a stock broker, he is ok, and my eldest son who is a big problem – he has a drinking problem, does not work, is on a sex register, and is appealing a 2 year prison sentence in Germany, he has three children he cannot see, and lives away – I have not seen or heard from him in 10 weeks – I have made it clear there is no home here, and I am not prepared to give him money sub-consciously this is very stressful." (P3; session 3) "Granddaughter starts new job today hope she likes it I worry about her she has a daughter of 11 months [daughter's name] who is lovely but it is hard does not want to have benefits, still that is how my family are we have always worked for our living which gives me great pride." (P8; session 2) *Emotional reaction to children moving on* "My daughter and husband emigrated to Grand Cayman having lived in Guernsey for the previous nine years (left for career reasons). It was a big wrench for me to see her leave these shores knowing that once moved on, she was unlikely to return and settle in England in our life time." (P14; session 3) *Difficult relatives* "[sister's name] is my only relative apart from her daughter [niece's name] who is married to a self-indulgent, ignorant big head. And I haven't much time for my niece either – a completely dysfunctional couple...My sister is divorced from a successful dentist she was completely unreasonable in her demands. They both are manipulative (sister and daughter)." (P9; session 2)	**Relationships** *Good relationships with loved ones* "I have 2 children and four grandchildren and must say I am very fortunate with my family I get on well with my son who is separated from his wife and he has been back at home for nearly 2 years now. His two sons come for tea every Thursday and stay all weekend unless my son has to go to work. My daughter lives within walking distance and her 2 daughters usually stay with me on a Saturday night while their mum is at work. So little time for a rest! at the weekend." (P10; session 1) "I live with my wife and we are in daily companionship and go out together several times.....We also lead independent lives with certain separate interests."(P14; session 1) *Support from loved ones* "Went for a walk today with boyfriend went to Crakly Woods in Kenilworth it was nice and romantic, it is nice when he surprises me which is not very often as he is not really romantic even after 15 years together but I love him, he makes me feel special, loved and he loves me for me. He is very supportive and will be with me every step of the way when I eventually go and have my fibroids done going to book a couple of days off work to look after me, bless him I would be lost without him and I wouldn't meet anybody like him again." (P11; session 2) *Pride for loved ones* "My other granddaughter is going to Birmingham University on my birthday [date of birthday] which will be a wonderful experience for her I'm very proud of them all. Jack my 14 years grandson wants to do medicine, he is very bright but we were laughing he would have to sell A KIDNEY TO PAY for it, still we'll see. Thank god for your children and grandchildren although I've only got a small family it is great to have them." (P8; session 2) *Affection for pets* "I have 2 cats who I find very comforting. The eldest is Tootsie (mummy) and her son Yogy." (P10; session 1)

Stressful	Positive
Bereavement "I think at the moment my husband is causing me the most concerns in my life, and this may sound strange and not that stressful to some people, but to me it is, it is something that cannot be shared with everyone as only people who have been through a similar experience would understand. I am now a widow, although I am living with a new partner. My husband died 2 and a half years ago aged 59 years, and last weekend September 6th would have been our 40th wedding anniversary, I had a lovely flower arrangement made – all red! And went off to the crematoria and sat and talked to the spot where we have a tree where my husband's ashes are scattered, I felt sad and guilty and wondered if I could have been a better wife, I also felt that my sadness was not fair on my new partner so most of my feelings were kept in my head and my heart." (P5; session 1) "I really miss my husband although its eight years since he died it still feels like yesterday." (P8; session 1) **Health-related concerns** *Current health concerns and their impact on daily life* "I had an appointment with a consultant about my mild angina following two stints about 4 - 5 years ago. Luckily I am of a contented nature and outwardly more cheerful than is perhaps the case. I thought the consultant would say that my angina was not too bad and I should continue with the tablets for it (I take 15 a day including 6 for diabetes which incidentally is now so well controlled that sometimes my urine is sugar free). Much to my surprise he said that my heart was in a poor way and he wanted me in the hospital for a double bypass operation. I felt no fear but mild excitement at the prospects of a major operation but disappointment that I would be out of action for a couple of months –there is so much to do. Rotary, charity work (two mornings a week), gardening, reading etc." (P9; session 1) "The thing that is concerning me at the moment is coping with my illness...I now have developed an irritable bladder problem and the side effects increased my nightly visits to the toilet, and this has made me very tired in the mornings. I walk to work about 3 miles daily, and I find that the prostate and bladder problems give me some pain and soreness and discomfort....I think I have a fairly active social life with my family but I now find that due to my prostate - bladder problems have curtailed my travel, and I feel I have slowed down. I am always mindful for the need to be near a toilet so we now travel a lot by train, and I find it difficult to fly." (P12; session 1) *Worry related to poor health of loved ones* "If I have one real concern at this time it is my partners' health, we think it may be the onset of the change she has consulted the doctor about it and is awaiting test results" (P7; session 1) "I am concerned about my sister-in-law who is terminally ill with cancer, and her time is getting near. She has 3 young children and my brother is coping well. I have a feeling of helplessness, that I cannot help more, this is a strange feeling of guilt and futility. My sister-in-law has been very brave, but I am anxious how my brother will cope without her, with the children. Subconsciously you try to put this out of your mind but I dread the phone call." (P12; session 2)	**Attitudes towards the future** *No concerns about future physical health problems* "Looking to the future, I have no special reason for viewing it with great concern. As part of a large family and 70 years hindsight I have seen many family and relatives pass on. Some have experienced serious disorders from a young age and lived into their eighties. Others have died from totally unrelated disorders from the long-term medical condition." (P14; session 2) **Recreation** *Active social life* "Had to arrange my ladies club meeting (I'm on the committees) 80 ladies are in this club and they are all like one big family. I moved to Nuneaton 4 years ago and deem myself lucky to have come among them they are GREAT." (P8; session 1) Got a lot of shows to see, I'm going to see 'Oliver in London, "Scrooge" in Birmingham and 'Les Miserable's" in Birmingham so I feel that life has always got something to look forward to. I enjoy life very much (as best I can) it is all so short and perhaps when I'm older I will not want to go out so much." (P8; session 3) *Holidays* "Been thinking must sort my clothes out what I'm taking on holiday, always get to my destination and wish I'd got other things with me. I have about four small holidays a year which breaks the year up nicely.2 (P8; session 3) *Hobbies and recreational activities* "My interests particularly are the Parish Council, Community Hall Management, golf, walking, travel, entertaining at home, computer work mainly for the preparation of the Family History which I have written over the last few years. I have followed politics virtually all my life. I have read extensively on the personalities of the last fifty years. I am not emotionally involved with any of it. It is an interest." (P14; session 1)

Stressful	Positive
Guilt related to not being able to care for sick relatives *"*Over the past couple of years my mother has developed dementia....things have got progressively worse ....[relatives' names] are no longer able to cope and have, reluctantly, had to find a suitable residential care home for mum...The atmosphere is pleasant but I'm pleased that mum, although she already calls it home, is probably unable to understand quite where she is. I would hate to think that she gets really lucid recollections and realises where she has ended up. Two years ago she would not have believed she would be in a home let alone one that specialises in dementia patients." (P6; session 1) **Concerns about the future** *Worries related to aging and future physical health problems* "I find my age very stressful and do worry about the slightest health problems – I always find the worst scenario. I cannot reassure myself about my future, and therefore anxiety can set in." (P3; session 3) "Yes I am concerned about growing old but I try to do it disgracefully hate the thought of not being fit and able to be like I am now, I don't want to be dependent on others." (P7; session 2) *Worry related to aging and mental deterioration* "I reflect that I take 15 pills a day for my problems, heart, blood pressure, angina, chronic indigestion - luckily now almost completely controlled, diabetes and for me life is great but the thought of a heart attack carrying me off doesn't worry me a bit and I would really like it since I don't want my faculties to degenerate. I don't consider suicide. I don't want [wife's name] to have to nurse me and look after me which she would, and does do, marvellously just to be left on her own with no family but good friends to face the future." (P9; session 3) *Thoughts and feelings about mortality* "My day to day routine sometimes feels pointless and a feeling of what is the use creeps in....I am quite aware that dying is a fact of life, but I push these feelings to the back of your mind and then try to keep your mind busy, but when I am up in the night I sometimes dwell on these worries." (P12; session 2)	**Education, work and finances** *Education* *"*I hated school from day one. Was so pleased to be able to leave at the age of fifteen, straight into work on a farm. Over the years of various employments I have come to learn the value of education, and taken advantage of work related education courses, at the ripe old age of 63 recently achieved an N.V.Q. certificate, so the old "ish" must still be working (sometimes)." (P7; session 3) *Employment* "I had quite a varied time at work until I married at the age of 23. Then I went to work for the Air Ministry, then moved house and went to the Inland Revenue. I had time off while I had the children unfortunately the marriage broke down in 1980 so I found a new home with my children and went to work for the National Health Service where I stayed until I retired at 61." (P10; session 2) *Retirement & volunteer work* "Having retired from a well paid and rewarding career as a finance manager in the motor industry and subsequently experiencing nearly fourteen years of enjoyable retirement I have no particular concerns." (P14; session 1) "After a year of retiring I felt I needed to do something so I got a part time job at a garden nursery...which I loved but it was only seasonal. So I went to work with meals on wheels which I did for nearly 4 years and thoroughly enjoyed and am still in touch with everyone. I also did some voluntary work at the hospital museum...I found this very interesting and only left when the Health Authority closed the museum due to cuts in expenditure." (P10; session 2) "I have in the past always been involved within the community doing various work, but now over the years I have curtailed my various works. I have tried not to get depressed and throw myself into various into work."(P12, session 1) *Financial security* *"*With financial things life is much better, and I calm things down by meditations." (P3; session 3)

Stressful	Positive
Faith *Speculation about the meaning of life, life after death and questioning religious faith in view of loved ones becoming ill* "My brother-in-law is now at his mother's – and gradually feeling a little better, I just wish that he could get better, he is a kind gentle person, never cause any hurt to anyone, and doesn't deserve to be ill – it sometimes makes me think is there a god? I know so many people who have recently been taken from us by cancer good people, people who did the 'right' things with their lives, people who were loved and a credit to society – worked hard, raised happy families, so why are they taken? There are so many idle yobs roaming around, they are no good to anyone and wouldn't be missed so what is god playing at?? It shakes your faith but I still hold on to it, we have to believe that there is more than this. When someone dies and you are left to sort things out, the banks, insurance companies, even the television licensing, just treat it as matter of fact OK we will take their name off, it is as if they never mattered, and you think of all the things they did, worried about, tried to change, the help they gave to everyone, it is as if none of it counted for anything, and you look around and think why? Why do I worry about this and that? Why am I bothered about getting the house decorated? Sometimes it seems pointless." (P5; session 3) "This puts all my other concerns in perspective, life is like a lottery sometimes, it wears you down and I often wonder if there is life after this one and if so will we have to go through so much pain, I hope not." (P13; session 3) **Work and finance** *Work-related stress and fear of redundancy* "I work in a bank which has recently been taken over, I am very conscious not to be a nuisance or cause any problems for my colleagues. We all work hard and have to support each other. Today one of them has found out she is being made redundant at the end of the year. No point worrying now, can't afford to get depressed – I am worried about my job, but we would manage as long as my husband kept his." (P13; session 1) *Sadness about retirement* "I decided to retire this year – most stressful."(P3; session 3) *Financial concerns* "Talking about afford I've lost a lot of money in Bonds and I.S.A.'s in this recession still I'm alive and kicking it is only money. We have to spare a thought for the poor souls who are losing their homes and jobs." (P8; session 1)	**Positive events** *Happy childhood* "I suppose I should be telling you about my childhood well it was basically a very happy one, the youngest of a family of five. Spoilt by my three sisters and mother, lived in a lovely country village. I think I am very lucky to have had what is to me a normal happy childhood preparing me for a hardworking adult life." (P7; session 3) "I had a very happy childhood. I lived with my grandparents for a few years as my mother was working during the war and my father was in the Royal Air Force...I attended grammar school in the 50's then was enrolled at a secretarial school." (P10; session 2) **Religion** *Religious beliefs* "Although brought up in the Church of England with twenty years in the boy's / men's choir I am an atheist.....We live in a universe 4.5 billion years old and is likely to continue for as long again or eternity. The earth is as insignificant in this concept as one bucket of water in the Atlantic Ocean...My, and the current generation of mankind, are unlikely to have any special significance in the overall scheme of things. We therefore are unlikely to have a God that we can prey to and be in personal communication with. I find the works of Professor Dawkins (The God Delusion) in time with my feelings."(P14; session 2) *Music from a religious perspective* "Singing is a very important part of my life... I am a scientist, with a keen interest in conservation matters, and a Christian with a concern for people. Music is of tremendous importance in conveying the message."(P4; session 1)

Stressful	Positive
Adverse events *Negative childhood experience* "The only the only sad part [of childhood] was my father suffered with chronic asthma, which at that time was very frightening to see, "none of the magic drugs like we have today" (P7; session 3) *Traumatic events* "My house caught fire in December and I was at home alone for the weekend and fortunately my cats woke me up at 2:30 a.m. and I rang for the Fire Brigade...The mess was horrific. In fact I don't think I've really got over it all yet and there are still some jobs to finish but I can't bring myself to get on with it all now, but I'm gradually getting there." (P10; session 1) "In September 2004 I (with my wife) were cruising on the Norfolk Broads when I received a telephone call from her (daughter) to say that Hurricane Ivan was heading for the island and they would be evacuated to Montreal within hours, by their employer. The hurricane struck at force 4 - 5 and devastated the island. They were safe but their vision of a paradise in the Caribbean was shattered in hours. We visited six weeks later. The devastation was horrific." (P14; session 3) "My sorrow, shock, sadness this week, at work – a fatality at work, although I didn't actually know the man the whole place is shocked. Nobody expects to go to work in the morning and not go home at night do they?" (P6; session 3) *Current events* "Tomorrow a young 18 year old soldier is being buried in our town, he died in the war! This puts problems into perspective. What a sad world we live in." (P13, session 1) **Emotional issues** *Loneliness* "I hate the dark nights they are so long and lonely I don't go out much in the evenings and like to go out to lunch and back home before dark. Thank god for telephone and flat screen Television Codebreakers, crosswords and of course a good book."(P8; session 1) "I've been thinking about Christmas although it is weeks away...Christmas really isn't the same for me without David (he loved it) but for the families sake I enter into the spirit of the occasion. Fancy thinking of Christmas in September, still when live on your own you spend many a moment thinking it is better than talking to yourself) AH! ." (P8; session 3) *Feeling depressed* "I am worrying about everything lately and I don't seem to be able to relax, when I go to bed I can't sleep, when I try to read a book I can't concentrate everything seems like such an effort.....I'm trying very hard to keep up with washing, ironing, and I've given up trying to Hoover or dust I don't see the point anymore.....In fact this last month has probably been one of the worst times in a long time (years). My husband thinks I am getting depressed."(P13; session 2)	*Politics, war and terrorism from a religious perspective* "Gordon Brown and the Iraq enquiry. 'We' were all sure that the real reason for the Iraq war was George Bush's obsession with finishing the job his father 'failed' to do...The church of which I share the leadership has a few English in membership. We seek to bring the Gospel of peace to those around us....As for Brown – he was so blatantly lying about his role in the affair – it was unthinkable that the right hand man with Blair did not realise the web of lies that were being woven to try to convince Parliament and win public support...The net result is that millions of Iraqi and Afghanis are suffering and have died because of an obsession. They have dug our countries into a pit that we cannot climb out of, as killing terrorists only makes more terrorists - and builds ever more hatred." (P4; session 2) *Persecution from a religious perspective* "Persecution of Christians. In many countries around the world, Christians are suffering persecution.... Why?... A Christian owes his allegiance to the Lord Jesus Christ. That in a way separates him at every level. He also has a message for society: "we are all sinners in the sight of a holy God. We need forgiveness of sin...That places every Christian apart. However compliant he is within society, society see him as an outsider. He will not bow down to family gods, and will not acknowledge any other god. Jesus is Lord. A lonely Christian poses no threat to society, but it is a matter of pride that they demand that he conform... Mohand Ghandi was horrified at the proposal to have separate countries for Muslim and Hindu as he insisted that everything they needed was common to all regardless of religion. Hopefully we can demonstrate this in England where in towns like Southall we co-exist & work, shop and go to school together without problems." (P4 session 3)

Writing about diabetes-related topics

Of the 14 intervention participants, four (29%) were classified as having written about diabetes-related topics over the sessions (i.e. whereas 10 (71%) were not. On average, of the number of topics disclosed by these participants across the sessions, 28% related to diabetes.

Writing about positive topics

Of the 14 intervention participants, seven (50%) were classified as having additionally written about positive topics whereas seven (50%) were not. On average, of the number of topics disclosed by these participants across the sessions, 56% related to positive topics).

Topic switching

WED participants typically discussed a number of topics both within and across sessions. There was little evidence of consistency in the topics discussed across sessions. Ten (77%) of the WED participants mentioned one or more topics in more than one session, yet only two (15%) participants discussed a topic in all three sessions. However, even when topics were mentioned in more than one session, they were typically amongst a number of other topics in each session.

Control

Of the 13 control participants that returned their writing, 10 (77%) provided an objective description of the previous day as requested. The remaining three participants seemed to exhibit some degree of ED. Two described some stressful issues, yet briefly and in the context of their daily activities. The remaining participant apparently disclosed in a similar manner to patients in the intervention

group, with minimal reference to daily activities.[133] This participant justified their deviation from the instructed topic by explaining that the problems described represented the mundaneness of daily life, and that they could not help but discuss these things. They also added that writing about these problems had helped.

Exploration of WED writing content

As a means of providing some insight into and facilitating interpretation of the preliminary effectiveness analysis, exploratory analyses were conducted to identify whether the linguistic features of WED presumed to reflect E&CP were related to changes in depressive symptom severity and the secondary outcomes investigated. Consequently, the linguistic parameters investigated and demonstrated to be related to changes in health outcomes in previous WED studies (i.e. presumed to reflect E&CP; see chapter two); a) change in word use reflecting insight and cause across writing sessions and b) average/change in positive emotion and negative emotion words across writing sessions were correlated with change from baseline to follow up in each of the outcome variables.

Change scores were derived by subtracting baseline/first writing session scores from follow up/third writing session scores. Computed variables were screened for normality (see chapter five), and some were identified to be skewed thus non-parametric correlations were employed (Spearman's Rho).[134] The assumption checks for the additional variables that were computed are presented in the appendix. Given the very small number of participants included in analyses, correlations of a potentially important magnitude were considered regardless of significance, namely where ≥9% of the variance in the change in the outcome

[133] This was the participant that wrote for 781 minutes in session one and explained that they did not follow the allotted task because they would have found that too boring.
[134] Two tailed significance tests were employed given that the direction of the associations was not predicted.

variable is explained by the LIWC variable tested (i.e. r>.30; see conventions specified in chapter five).

These correlations are presented in Table 54. They suggested that a higher average use of negative emotion words (r=.55, p=.063), a change in the direction of more insight words across writing sessions (r=.50, p=.141) and a change in the direction of fewer causal words across writing sessions (r=-.42, p=.226) were apparently associated with a change in the direction of an increase in depressive symptom severity over time. The correlations were of a medium-sized to large magnitude, and approached significance for the average use of negative emotion words.

The correlations for the secondary outcomes investigated generally concurred. A change in the direction of a reduction in health-related QoL (EQ-5D utility and VAS) and specific diet, exercise, blood glucose testing and foot care SMBs were apparently associated with a change in the direction of an increase in insight words and or a change in the direction of a decrease in causal words.

Table 54 Exploratory associations between LIWC variables and change in the outcome variables over time[135] [136]

LIWC variable	Change in depressive symptom severity	Change in DSED	Change in health-related QoL: EQ5D utility	Change in health-related QoL: EQ5D VAS	Change in SMBs: general diet	Change in SMBs: specific diet	Change in SMBs: exercise	Change in SMBs: blood glucose testing	Change in SMBs: foot care
Cognitive processing									
Insight	r=.50 (p=.141) n=10	r=.20 (p=.606) n=9	r=-.75* (p=.019) n=9	r=-.41 (p=.241) n=10	r=-.22 (p=.538) n=10	r=.16 (p=.673) n=9	r=-.50 (p=.141) n=10	r=-.40 (p=.373) n=7	r=-.20 (p=.583) n=10
Cause	r=-.42 (p=.226) n=10	r=-.13 (p=.732) n=9	r=.77* (p=.015) N=9	r=.38 (p=.281) n=10	r=.05 (p=.893) n=10	r=.46 (p=.217) n=9	r=.07 (p=.852) n=10	r=.76* (p=.049) n=7	r=.56 (p=.094) n=10
Positive emotion									
Average	r=.07 (p=.828) n=12	r=-.31 (p=.354) n=11	r=.36 (p=.281) n=11	r=.31 (p=.329) n=12	r=.07 (p=.825) n=12	r=-.25 (p=.461) n=11	r=.25 (p=.429) n=12	r=.16 (p=.673) n=9	r=.54 (p=.069) n=12
Change	r=-.04 (p=.920) n=10	r=-.10 (p=.798) n=9	r=.37 (p=.332) n=9	r=-.30 (p=.402) n=10	r=-.61 (p=.061) n=10	r=-.24 (p=.539) n=9	r=.60 (p=.067) n=10	r=.80* (p=.030) n=7	r=-.17 (p=.632) n=10
Negative emotion									
Average	r=.55 (p=.063) n=12	r=-.21 (p=.545) n=11	r=-.29 (p=.383) n=11	r=-.17 (p=.609) n=12	r=-.28 (p=.374) n=12	r=-.15 (p=.651) n=11	r=-.09 (p=.784) n=12	r=-.66* (p=.054) n=9	r=-.50 (p=.102) n=12
Change	r=-.01 (p=.973) n=10	r=.28 (p=.460) n=9	r=-.31 (p=.422) n=9	r=.01 (p=.987) n=10	r=.34 (p=.339) n=10	r=-.09 (p=.815) n=9	r=-.25 (p=.492) n=10	r=-.54 (p=.216) n=7	r=-.20 (p=.571) n=10

[135] Positive correlations reflect an increase in the LIWC score (higher mean usage/a change in the direction of an increase over time) and a change in the direction of an increase in the outcome variable over time (i.e. an increase in depressive symptom severity and DSED, and an improvement in health-related QoL and SMBs). Negative correlations reflect a reduction in the LIWC score (i.e. lower mean usage/a change in the direction of a decrease over time) and a change in the direction of an increase in the outcome variable over time). An increase/decrease in change scores was interpreted as a change in the direction of an increase/decrease in the scores respectively because change scores for each variable typically comprised both increases (i.e. positive scores) and decreases (i.e. negative scores) and no change. *Significant correlation (p<.05).

[136] Fourteen WED participants returned their writing, 12 of who completed all sessions and thus for whom LIWC change scores could be computed. Where n is less than 14 for LIWC average variables and 12 for LIWC change variables outcome changes scores could not be computed for these participants (i.e. owing to missing data at one or both time points).

A higher average use of negative emotion words and or a change in the direction of an increase in negative emotion words was apparently associated with a change in the direction of a reduction in health-related QoL (EQ-5D utility), and blood glucose testing and foot care SMBs.[137] It should be pointed out that negative emotion words were not apparently associated with change in the outcome variables for which a trend for a negative effect of WED was observed (i.e. EQ-5D VAS and specific diet SMBs), however the correlations were typically in the anticipated direction.

Associations between the positive emotion word use variables and change in outcomes were more heterogeneous. However, it is noteworthy that a higher average use of/a change in the direction of a increase in positive emotion words was typically associated with a change in the direction of improvement in the outcome variables for which no apparent negative effect of WED was observed (i.e. a change in the direction of a reduction in DSED and an improvement in health-related QoL (i.e. EQ-5D utility) and exercise, blood glucose testing and foot care SMBs).[138] However, this was not typically apparent for those outcomes for which it seems that WED may have had a negative effect; changes in these outcomes demonstrated no association with positive emotion words use (i.e. depressive symptom severity and specific diet) or at most marginal heterogeneous associations (i.e. EQ-5D VAS).

[137] There was one exception in which a change in the direction of a reduction in negative emotion words was apparently associated with a change in the direction of a reduction in general diet SMBs. However, this was marginal, was not an outcome for which a trend for a negative effect of WED was observed and owing to the applicability issues described earlier the data for this sub-scale are particularly ambiguous.

[138] There was one exception in which a change in the direction of an increase in positive emotion words was associated with a reduction in general diet SMBs, yet again owing to the acceptability issues described earlier data for this sub-scale are particularly ambiguous.

Summary

Intervention fidelity was confirmed, and was most pronounced for positive emotion word use closely followed by negative emotion word use yet was least pronounced for causal word use. As such it was apparent that both groups had adhered to their assigned instructions, and there was little evidence of contamination for controls. Moreover, in line with the instructions provided, issues that were currently stressful, rather than traumatic events, were disclosed. A third of the participants that were randomised did not return their writing pack, yet participants that did generally complied with the instructions. However, some apparently exceeded the request (i.e. wrote for longer than requested with breaks within sessions and may have written for more than three sessions). Moreover, approximately half of the participants may have engaged in further self-directed writing. Reasons for not completing all writing sessions related to difficulty writing and a negative evaluation of the nature of the WED and control tasks. However, the post-hoc feasibility data provided some valuable additional information about intervention fidelity but most importantly the acceptability of both the intervention and control tasks, and participant's experience of the study. A particularly notable finding was that many WED participants indicated that they were unsure what to write about as they did not feel they had any stressors to discuss, many of whom were amongst those that also wrote about positive issues perhaps for this reason. In sum, negative feedback about WED seemed to be related to the sample obtained.

The methods of randomisation and allocation concealment were demonstrated to be feasible and apparently effective, yet there was some evidence that blinding may have been compromised to some degree for approximately a quarter of the participants. The post-hoc feasibility data additionally provided some valuable information about the appropriateness of the study questionnaires. A key finding

was that items asking about issues which participants felt were not applicable to them lead to missing and or ambiguous responses. Indeed, a number of acceptability and interpretative issues were identified for the measures employed and thus the data obtained, and problems associated with administering materials electronically were highlighted. Issues were also identified with respect to administration of materials by post (i.e. delays), and the importance of prompting participants was underscored.

To facilitate exploration of the findings from the pre-specified analyses, the content of the participants' essays was considered. Relatively few WED participants were considered to have discussed diabetes and those that did not discuss it extensively. However, half of the WED participants were considered to have discussed positive diabetes and non-diabetes related topics in additional to stressors, and for those that did positive topics accounted for approximately half of the topics disclosed across writing sessions. WED participants also exhibited little evidence of continuity in the topics discussed across writing sessions. Nonetheless, the topics disclosed by WED participants afforded a valuable insight into the emotional factors impinging upon life in Type 2 diabetes (i.e. what people with Type 2 diabetes talk about when asked to emotionally disclose). In fact, there was face validity in these topics given that these are the issues that people with diabetes typically discuss in consultation (JS). A small proportion of control participants exhibited some degree of ED, seemingly because writing about daily activities very occasionally evoked emotion where these were experienced as such.

Finally, exploratory correlations identified that a change in the direction of an increase in depressive symptom severity was generally associated with a higher use of negative emotion words and changes in the direction of an increase in insight words yet a decrease in causal words across writing sessions. Correlations between

the linguistic features of WED and the secondary outcome variables generally concurred, including for the outcomes for which it seems that WED may have had a negative effect (although there were limited associations between negative emotion word use and change in these outcomes). Interestingly more use of and an increasing focus on positive emotion words was generally associated with a change in the direction of an improvement in outcomes, yet this was typically not the case for those outcomes for which WED may have had a negative effect. Importantly, that a) a higher use of positive emotion words, b) a lower use of negative emotion words, c) a change in the direction of an increase in causal and positive emotion words and d) a change in the direction of an decrease in negative emotion words were typically associated with a change in the direction of improvement in outcomes was somewhat consistent with the literature reported in chapter two.

Chapter 9 Exploratory RCT discussion

Chapter overview

This chapter initially includes a discussion of the feasibility findings relating to research into WED and the implementation of WED in primary care in the UK, given that in view of the limitations observed this was the primary focus of the thesis. The interpretation of the preliminary effectiveness analysis is then presented, informed by the feasibility findings, the pre-specified exploratory explanatory analyses and the post-hoc exploratory investigation and analyses employed, namely the consideration of writing content. The study strengths and limitations are then discussed, focussing initially on additional limitations associated with the research design and methods employed, and then the preliminary effectiveness analysis and further exploration of the observed effect, specifically issues such as statistical conclusion, internal and external validity and problems associated with the analytical approach.

Summary of feasibility findings

Feasibility of WED for use in general practice in the UK whether for diabetes or other patient groups

The present study demonstrated that WED may be acceptably and feasibly implemented as part of general practice in the UK. GP practices did not cite WED as their reason for not participating, rather reasons related to practice workload, costs (i.e. resource and materials) and occasionally payment, with some practices indicating that they would have liked to take part in the future. When spoken to GPs were also generally positive about WED. However, one practice was unable to participate owing to a 'mixed response from GPs', should this related to WED it indicates that acceptability to GPs may be mixed.

For patients, willingness to engage in WED was less than initially anticipated (i.e. than indicated in the user consultation). Recruitment rates were relatively low especially for support groups, which may be owing to the fact that the invitation was not received from their GP practice and that these individuals were already writing within the forums. Negative posts within the support group forum may have additionally deterred participants. Although this data could not be formally collected, the feedback that was obtained from patients at recruitment was not apparently related to writing; at most some people were concerned about whether their writing ability would suffice. There was evidence of scepticism about the study and writing within the support group forums, yet others expressed interest in the study and a belief in the potential benefit of writing. These heterogeneous opinions may have additionally been present amongst primary care patients. Regardless, though, many patients were interested and an unmet treatment need was identified, suggesting that there may be a place for WED.

Only about two thirds of the sample returned their WED writing pack, however, and the feedback that was obtained indicated non-return was due to a dislike for writing and or the content of WED and age-related problems with writing but also not having anything to write about; non-return may have partly been due to the sample obtained. Those that apparently engaged in WED were however typically willing and able to do so (i.e. the topics disclosed had face validity, intervention fidelity was confirmed and compliance with the instructions was good). Similar compliance was observed amongst the studies included in the systematic review (see chapter three). Some participants even exceeded the request. This is encouraging considering the associated burden. Negative feedback from those that returned their writing was again apparently largely due to the sample obtained; age-related difficulties with writing and not having anything to write about. There was also some positive

feedback in that some participants implied they could have written more had they had the opportunity, and feedback about participating in the study was positive with many participants taking it upon themselves to provide additional information within the materials. Evidently, patient acceptability is also mixed, yet there is a sub-group of individuals for whom WED may be a welcome source of support.

Importantly, there was minimal evidence of a negative subjective response to WED. One participant was deemed high risk/requiring action and referred to their GP advising that they should be seen or referred to a specialist as a result of the content of their writing (as mentioned in chapter six and later on). However, this response was at least partly owing to a friend having been diagnosed with cancer during their writing period. As anticipated, it seems important that WED is administered to those with some current problems yet not to those potentially at risk of re-traumatisation. There were no reports of individuals seeing their GP with problems as a result of writing, although this data was not purposefully collated. This finding is consistent with a previous feasibility study of therapeutic writing in primary care in the UK; GPs felt that some people may require additional support as writing can evoke issues that one must possess the skills to deal with, yet that this is infrequent and may well have happened under other circumstances (Hannay & Bolton, 1999).

Finally, any resource costs were associated with the study protocol, rather than WED. This is again consistent with the previous feasibility study of therapeutic writing in primary care in the UK (Hannay & Bolton, 1999). As reported in chapter four, that acceptability and feasibility of WED based interventions to patients and providers in primary care including in the UK has been demonstrated previously (Gidron et al, 2002; Hannay & Bolton, 1999; Klapow et al, 2001; Schilte et al, 2001). In some of these studies the intervention was incorporated into routine clinical

practice thus enhancing ecological validity; writing was offered in practice and then completed at home (Hannay & Bolton, 1999; Klapow et al, 2001). Consultation time associated with the intervention was minimal and consistent with the time allotted for consultations, suggesting that WED need not be costly and time consuming to GPs.

Insights gained about the difficulties of undertaking research into WED

A number of insights were gained about the difficulties of undertaking research into WED. Importantly, there are a number of ethical issues that must be acknowledged, some of which were highlighted by the patient safety issues raised by the NHS REC and the changes necessitated, for instance the requirement for detailed preventative measures and contingency plans when implementing an intervention with psychologically vulnerable samples and the importance of acknowledging the limitations faced when such research is conducted by a non-clinician/student. This review also identified a contention between designing studies that are feasible in clinical settings and consistent with ideal methodology derived from the evidence base, yet which satisfy ethical requirements. For example, the eligibility check that was introduced in accordance with the RECs recommendations exacerbated the imposition of the research on primary care practices (i.e. two mail outs were required).

The study also identified that the constraints imposed in ethical review and the measures taken to address them can be impactful, yet are nonetheless required. The eligibility check that was implemented meant the loss of a significant number of interested participants, some of whom may have actually been able to participate (discussed below), and importantly was apparently partly responsible for inadvertently deriving a sample for who WED is potentially contraindicated

(discussed later in relation to the findings from the preliminary effectiveness analysis). That is not to say that the check was not necessary; without something in place it is possible that at risk participants could have been inappropriately included. Indeed, a significant proportion of primary care patients expressing an interest in the study scored as experiencing significant depressive symptoms in the eligibility check, some of whom scored very highly on the CES-D (i.e. 43). Evidently some patients with significant depressive symptoms had not been identified and treated by GPs already, thus the RECs concern and addition of the eligibility check was justified.[139]

It is worth pointing out that a number of the other changes necessitated by the review were additionally observed to be important. The REC were right to insist that the researcher should not be the point of contact for any problems and that clinical support was in place should this occur; there was an instance of a patient calling for more information about the study yet stating that they felt depressed and exhibiting suicidal ideation in relation to completing the DSQ. Perhaps it was necessary to place an even greater emphasis on the fact that participants should contact relevant professionals not the researcher about such issues. This occurrence additionally highlighted the importance of planning for contingencies; Professor Weich was on annual leave at this time,[140] consequently arrangements were made for immediate consultation in such instances. Furthermore, ensuring participants were fully informed about the potential breach of confidentiality owing to the content of their

[139] It is noteworthy that GPs were notified about those patients exhibiting a potentially clinically important increase in depressive symptom severity such that they exhibited significant symptoms at follow up (all were primary care patients), yet not those that exhibited a clinically important increase but did not score above the threshold for significant symptoms at follow up as they were not deemed to be clinically at risk. This was consistent with the study protocol approved by NHS ethics (i.e. GPs were notified about participants meeting this threshold/clinically at risk in the eligibility screen), and consultation with the study's clinical advisor, Professor Weich.

[140] Fortunately on this occasion advice was sought from another psychiatrist.

writing was justified as this did indeed occur and in some albeit few instances contact with GPs was made (mentioned in chapter six and above).[141]

A related insight was that it is difficult to find an appropriate means of ensuring inclusion of participants with lower-level albeit not higher-level depression. The strategy employed, namely including those responding positively to the QoF questions yet excluding those currently being treated, failed to ensure the inclusion of patients with lower-level depression to enhance the applied relevance of the trial and maximise effectiveness (i.e. seemingly owing to the over-treatment of false positive cases identified by these questions that has now resulted in their retirement). In fact, this criterion also had a substantial adverse impact upon practice recruitment and retention. Secondly, with regards to the eligibility check it seems that the CES-D and the threshold of ≥16 may have excluded some people who could have actually taken part. The CES-D is more reflective of general distress than MDD, and indeed 70% of people with Type 2 diabetes meeting CES-D ≥16 do not meet criteria for MDD according to diagnostic clinical interview; while sensitivity is good the positive predictive value is low (Fisher et al, 2007; Stahl et al, 2003).

Randomisation and allocation concealment were not apparently problematic. However, as anticipated, achieving patient blinding in WED trials is particularly difficult. Blinding was apparently compromised for approximately a quarter of

[141] Seven primary care patients' essays were reviewed by Professor Weich. In instances where concern was confirmed the researcher was advised to contact the GP and inform them that the patient was either, a) potentially at risk; three patients were not currently depressed but at risk in the event of future distressing events, or b) high risk/requiring action: one patient demonstrated numerous risk factors for moderate to severe depression (as mentioned in chapter six and above). In the latter instance, the researcher was advised to contact the patient's GP that day advising that they should be seen/referred to specialist. This patient did not then return any materials after the writing pack (mentioned in chapter six & above). Whilst potentially because of their state of well-being at that time it is also possible that they were unhappy about their GP being informed about their writing.

primary care participants; it was apparently completely compromised for some of these participants whereas it seems that others may have merely guessed theirs was an active or inert task. Perhaps the information provided was not sufficiently vague to prevent participants' inference of their group assignment. While initially anticipated to offer face validity and having been employed in numerous WED trials in LTPCs (see chapter three), perhaps the control task was too obviously a placebo; indeed one participant commented that they found it to be juvenile and irrelevant. Furthermore, discussion between primary care patients and practice staff/GPs that were aware of the study purpose was minimised, yet may have occurred. However, that this explains the substantial extent of apparently compromised blinding is unlikely. Regardless, though, the apparently compromised participant blinding may explain the observed effect of WED in the present study (discussed later).

Identifying an appropriate control group is also difficult. Where WED was associated with a worsening in outcomes, this was consistently partly accounted for by an improvement for controls. There was no notable evidence of treatment diffusion, although there may be a potential contamination issue such that writing about daily activities very occasionally evokes emotion where these are experienced as such. Many control participants did carry on writing post-intervention though, and may have emotionally disclosed there. In other WED studies with LTPC samples, patients have similarly exhibited/reported difficulty restricting emotion in describing daily events (Byrne-Davis et al, 2006; Rivkin et al, 2006). In fact in such studies, even in the absence of evoked emotion these tasks have been described as meditative (Rivkin et al, 2006) and are posited to facilitate self-discovery (i.e. realisation that one is able to cope with the condition) (Byrne-Davis et al, 2006) and derive a transient increase in perceptions of control, which positively influences outcomes yet this effect dissipates when such control beliefs are not realised (Gillis et al, 2006). Writing without the 'clouding effect' of emotion is purportedly helpful

(Byrne-Davis et al, 2006). That placebos can have a positive effect is also widely acknowledged (Dixon, Sweeny & Gray, 2008). Should this be the case, there is apparently a contention between employing a task that has face validity to protect blinding yet one which is inert to avoid intervention for controls.

However, some participant feedback about the control task was unfavourable, and of the 18 control participants, only 13 (72%) returned their writing and 12 (67%) completed all sessions; the observed improvement may not be due to the task. The improvement may therefore be attributable to the natural progression of depressive symptoms (i.e. maturation), practice effects (i.e. familiarity with the experimental situation and or the measures being used) (Field, 2005; Nezu & Nezu, 2008), or even simply the fact that they were being studied (i.e. owing to the interest shown in them; the 'Hawthorne' effect).

Submission of writing is typical in WED studies and was necessary to examine mechanisms of change, intervention fidelity and compliance given that experimental control was limited. However, an additional insight derived was that this meant that participants expected their writing would be read. Indeed, this was very much evident in participants writing. It is not clear what impact this might have had upon the observed effect of WED in the present study (discussed later). Indeed, clinicians advocate against submission of WED transcripts in practice (Baikie & Wilheim, 2005).

Summary of preliminary effectiveness analysis findings

Severity of depression was significantly higher for the intervention (WED) participants compared to control participants at three month follow up, which represented a potentially clinically important difference and an increase in

depressive symptom severity for the WED group yet also an improvement for controls. Differences on other measures were non-significant, albeit there were trends for small effects suggesting poorer specific diet SMBs and lower health-related QoL respectively for the WED group relative to controls.

Interpretation of preliminary effectiveness analysis findings

Depressive symptom severity

A possible explanation for the effect on the primary outcome, should it be genuine, is that the sample was selected as not experiencing any significant depressive symptoms, in an attempt to enhance the applied relevance of the trial but primarily protect patient safety. Moreover, inclusion of those with at least some symptoms (i.e. again to enhance the applied relevance of the trial but also to potentially maximise effectiveness), was not achieved. Indeed, the sample was generally well-adjusted at baseline; the average CES-D score (i.e. 6.7) was below that reported for people with diabetes in the community (i.e. 11.5) (Zhang et al, 2005) and secondary care (i.e. 15.6) (Hermanns et al, 2006). Hence, the sample did not represent the target population requiring support. It is possible that WED as it was delivered in the present study may have evoked rather than resolved current stressors that were not previously acknowledged. Participant feedback somewhat supported this explanation. A number reported not being stressed and thus being unsure what to write about and one participant did not return their writing for this reason. Some also commented that they were not depressed but when they thought about what they could write about and did so they noticed diminished positive mood and more contemplation of the stressors (i.e. during and after writing). Indeed, despite being generally well-adjusted, many participants went on to discuss some troubling issues, for example terminal illness amongst relatives, worry about mental deterioration and bereavement. To some extent the WED literature also supports

this explanation. Frattaroli (2006) commented in her review that some researchers have noted a distinct subset of participants who report never having experienced trauma (Frattaroli, 2001), not having anything to write about and even annoyance at having to repeatedly write about such an event. That WED is only beneficial where people have something to disclose is additionally acknowledged (Lumley, 2004).

Should this be the case it is noteworthy that WED could have evoked current stressors that were not previously acknowledged specifically for people at risk. It could be that some participants had few depressive symptoms when screened, yet they were at risk for this. Indeed, as described in chapter four, depression in diabetes is known to fluctuate and people self-selected into the study which, as noted in chapter six, may be taken to reflect treatment seeking. Indeed, one WED participant that scored only nine on the CES-D at baseline was deemed to be at high risk of experiencing clinical depression as a result of their writing content (as noted previously and in chapter six).

That an array of psychological treatments can cause iatrogenic, or rather 'doctor-induced', harm has been acknowledged, albeit this has typically been reported for samples with existing psychological problems consistent with appropriate application of such treatments (Lilienfeld, 2007).

As described in chapter two, previous WED studies with healthy samples and diabetes patients have typically reported positive effects of WED on outcomes including depressive symptoms. Moreover, chapter three did not identify any notable evidence of a negative effect of WED on negative affect including depressive symptoms in LTPCs, albeit again these studies were associated with a substantial risk of bias which may have overestimated the effects. Nonetheless, in none of these studies were participants selected because they were not

experiencing any significant depressive symptoms. As described in chapter two, however, WED has evidenced some negative effects, typically for samples defined by high distress or individuals experiencing highly stressful situations, yet also for unselected students. Importantly, the studies reported in chapter two, and some additional studies, have suggested that negative effects across these sampling contexts may potentially be due to some underlying processes that reflect evocation yet avoidance and or an absence resolution of stressors. There was some indication that these processes may have been present in this study. The processes purported to underpin WEDs negative effects in these studies[142] and possible evidence of their operation in the present study is reported below.

Processes purported to underpin negative effects in WED

As described in chapter two, it seems that WED may increase avoidance in very distressed samples, which may be taken to reflect early yet incomplete processing of evoked stressors. At least for samples defined by high distress/highly stressful situations WED may merely activate distress, which is too upsetting to confront or for which more disclosure sessions and/or additional assistance are required to achieve resolution. In both distressed and unselected student samples, some evidence of avoidance has been observed in the writing of people for whom WED is associated with worse outcomes, for example emotional suppression (Greenberg et al, 1996), thought suppression (Rogers et al, 2007), denial and rejection of feelings (Solano et al, 2007) and discussion of trauma only in the last session with little opportunity for genuine integration (Honos-Webb et al, 2000). Indeed, it is asserted that over-regulation after an initial evocation of emotion would explain the negative effects observed in WED from the self-regulatory perspective (self-regulatory approach; chapter two) (Greenberg et al, 1996).

[142] This additional information is presented here rather than where some of the studies were initially reported in chapter two because an emphasis on the negative effects of WED was not appropriate at that point; positive effects were anticipated.

Where WED derives negative effects in both distressed and unselected student samples there is additionally some evidence of a short-term, disproportionate and superficial increase in positive affect which may be taken to reflect a failure to fully confront stressors/denial, a 'cheerful facade' and sugar-coating, for example greater use of positive emotion words (Batten, Follette, Hall & Palm, 2002; Holmes, Alpers, Ismailji, Classen, Wales, Cheasty, Miller & Koopman, 2007) an increase in positive emotion words (Pennebaker et al, 1997), increases in positive affect post-writing (Gallagher & MacLachlan, 2002), and a prefabricated and superficial positive conclusion at the close of writing (Honos-Webb et al, 2000).

As described in chapter two, the initial increase in negative mood in WED should dissipate quickly. In distressed, depressed and LTPC samples, negative WED effects have also been demonstrated to be associated with an apparent over involvement in negative emotion without resolution, manifested as a higher use of negative emotion words overall (Fernàndez & Pàez, 2008; Holmes et al, 2007; Lee & Cohn, 2010; Pennebaker et al, 1997; Smith, Anderson-Hanley, Langrock & Compas, 2005). Indeed, as noted in chapter two, it seems that only a moderate reference to negative emotion words may be preferable. Emotional expression with a focus on negative emotion without cognitive processing has also demonstrated a negative effect on outcomes (Ullrich & Lutgendorf, 2002).

Moreover, increases in cognitive processing words have occasionally been shown to be related to negative effects of WED in distressed samples (Baikie et al, 2006; Batten et al, 2002; Pennebaker et al, 1997), where this is taken to reflect initiation but not completion of cognitive processing (Baikie et al, 2006). Should this be the case it is noteworthy that these maladaptive processes may be operating when intervention fidelity (Rogers et al, 2007) and the anticipated mechanisms of change

are apparently observed (Honos-Webb et al, 2000). Indeed, as argued in chapter two, it is possible that the linguistic changes observed in WED could reflect processes other than E&CP.

It is also speculated that WED derives negative effects for distressed samples because they topic switch; staying focussed on the traumatic event may be difficult whereas topic switching would presumably relive this distress (Sloan & Marx, 2006). As described in chapter two, topic switching prohibits EA&H in these samples (i.e. exposure approach). Indeed, in a detailed case study Sloan and Marx (2006) observed topic switching to apparently be associated with an absence of resolution of disclosed distress for a participant with significant problems. However, the exposure approach (i.e. EA&H) and the inherent assumption that topic switching has a detrimental effect upon outcomes (i.e. as it interferes with EA&H) has not been consistently supported in WED studies, at least in non-traumatised samples (discussed in chapter two).

Evidence for the processes purported to underpin negative effects in WED

Intervention fidelity and mechanisms of change

In the present study two mechanisms of change were investigated; E&CP of stressors, specifically an increase in words reflecting cognitive processing and positive emotion, and a decrease in words reflecting negative emotion, across writing sessions (i.e. cognitive processing and self-regulatory approaches) and EA&H, specifically a reduction in post-writing negative affect across writing sessions (i.e. exposure and self-regulatory approaches). As described in chapter six, no conclusions can be drawn from the exploratory explanatory analyses owing to the sample obtained, yet they were proceeded with in a hypothesis generating way and because this may additionally aid interpretation of any main effect.

Indeed, the changes observed provided some information that could be used in endeavouring to interpret the main effect. It seems that ED and initial EA was achieved as intervention fidelity was confirmed; there was greater use of positive and negative emotion and cognitive processing words, and more post-writing negative affect, for the WED group compared to the control group overall. However, while the E&CP changes were in the right direction they were somewhat incomplete, and there was no reduction in post-writing negative affect across sessions. It should be pointed out that these findings did not necessarily discern the initial hypotheses, though. This is because again no conclusive inferences can be drawn from these analyses, but additionally because the failure to confirm the anticipated mechanisms of change was somewhat unsurprising given that this was expected in the event of a positive not negative effect.

While tentative, the intervention fidelity and pattern of change in LIWC variables that was observed may be interpreted as being somewhat consistent with the aforementioned maladaptive processes reflecting evocation yet avoidance and an absence of resolution. Intervention fidelity was greatest for the positive emotion word category (yet closely followed by negative emotion word use), and in fact within the WED group for each session participants used more positive emotion words than any other category. Indeed, many participants wrote about positive issues in addition to stressors within their essays, seemingly because they were generally well-adjusted. In fact, again a number of the participants that reported not being stressed and unsure what to write about additionally wrote about positive issues (see chapter eight).

Across writing sessions, there was a small increase in positive emotion word use which then plateaued, and increases in insight and causal word use, albeit this later plateaued for insight and was followed by a notable decrease in causal word use.

There was no change in negative emotion word use, only a slight reduction towards the last writing session, and again a slight increase in post-writing negative affect was observed. In sum, it seems that there was clear consideration of negative emotion yet a definite, somewhat increasing focus on positive emotion, with a concurrent increase in post-writing negative affect. There was also an apparent initial increase in cognitive processing, yet this dissipated in particular with respect to finding meaning in the event.

Additional observations from post-hoc exploratory analyses

There were some additional related observations that potentially supported the assertion that the aforementioned maladaptive processes may have been operating in the present study. Exploratory correlations identified that a change in the direction of an increase in depressive symptom severity was possibly associated with a higher use of negative emotion words and changes in the direction of an increase in insight words yet a decrease in causal words across writing sessions. Correlations between the linguistic features of WED and the secondary outcome variables generally concurred with this pattern of associations, including those for the outcomes for which it seems that WED may have had a negative effect, albeit there were limited associations between negative emotion word use and change in these outcomes. Interestingly more use of and an increasing focus on positive emotion words was generally associated with a change in the direction of an improvement in outcomes, yet this was typically not the case for those outcomes for which it seems that WED may have had a negative effect. There was also clear, consistent evidence of excessive topic switching, with issues rarely discussed more than once in WED participants writing.

Whilst again speculative, these findings may be taken to suggest that perhaps stressful issues were evoked, yet participants felt they had no significant stressors

to discuss in depth and thus did not attempt this. Alternatively, perhaps when participants thought about stressful issues not previously considered they realised they were unhappy about them, felt uncomfortable with the emotions evoked and then avoided discussing them. Consequently, many wrote about positive topics and emotions, and displayed little continuity in the content of their disclosures. For those that additionally engaged in notable disclosure of negative emotions and endeavoured to some degree to understand the events disclosed and ultimately derive meaning from them yet did not succeed in this, perhaps as a result of this avoidance, current stressors that were previously not acknowledged may have been evoked and not resolved. Indeed, one WED participant commented that they felt they had not achieved anything by the close of writing. It should be pointed out that, as described in chapter two, writing about positive aspects of stressors and positive issues/experiences has demonstrated benefits. However, in none of these studies did participants elect to additionally write about such positive issues when instructed to disclose stressors.

Additional potential explanations

Sampling bias

The sample comprised more males than females. It could be argued that perhaps males experienced difficulties with processing and resolving the evoked stressors. Most of the participants that exhibited a potentially clinically important increase in depressive symptom severity were men (71%). Moreover, some participants, predominantly males, explained that they did not complete the intervention, or had difficulty completing it, because they did not wish to/found it too difficult discussing emotions. While the systematic review described in chapter three indicated a possible beneficial effect of WED upon negative affect, there was a bias to female participants. Indeed, as also described in chapter three, some research has identified a superior effect of WED for women, yet the evidence is again inconsistent

and others suggest men benefit more or no moderating effect. Again, the relationship between gender and WED is likely complex and requires further study. Nonetheless, while clinicians report WED is acceptable to men in practice (Baikie & Wilheim, 2005), finding WED difficult and subjectively reporting no benefit has been observed for male research participants with arthritis (Byrne-Davis et al, 2006). This explanation is also consistent with the literature, and tentative preliminary observation in the present study, that suggest WED may increase depressive symptom severity particularly for people with lower emotional processing ability (i.e. high alexithymia).

Protocol deviations

Again WED was not consistently implemented exactly as intended, however. Perhaps this somehow prohibited proper processing, and explains the negative effects. WED has evidenced improvement when the number, spacing and length of sessions have deviated significantly from the original paradigm, for example three sessions spaced out over an hour (Chung & Pennebaker, 2008). Indeed spacing is reportedly not important (Sheese et al, 2004), hence one week was allowed in the present study. However, no studies have examined WED with the deviations observed in the present study. Such severe deviations were, however, relatively infrequent, which weakens this assertion.

Constrained disclosure

As mentioned earlier, participants were additionally aware their writing would be read, and this was very much evident in their essays. Some assert the greater the presumed audience the more constrained the disclosure (Baikie & Wilheim, 2005; Frattaroli, 2006; Smyth & Helm, 2003). Others argue, though, that WEDs effects are not related to the presumed audience (Czajka, 1987; Pennebaker, 2000) and even

more positive when writing is submitted (Radcliffe, Lumley, Kendall, Stevenson & Beltran, 2007).

Factors external to WED

However, the observed effect may not be the result of WED again given the proportion of enrolled participants returning a writing pack was low. In fact, of those that exhibited a clinically important increase in depressive symptom severity, 43% did write at all (see chapter eight). It should be noted that it may be that some participants who did not return the intervention actually started or even completed it, in which case they may have been affected as those that completed it were. Indeed, some reasons for non-return of writing were finding it too difficult discussing feelings. Otherwise, simply receiving WED and considering it may have evoked negative emotion that was not resolved, and thus been harmful to generally well-adjusted participants whether it was completed or not. Indeed, one participant explained that they had not returned their writing as they found it too stressful trying to think of something to write about.

Alternatively though, there could be some other reason altogether for the increase in depressive symptom severity in only the WED group, which was unrelated to the intervention. Indeed, the finding of an increase in negative affect related to WED is perplexing, and this finding should be interpreted with caution given the small number of participants in the intervention group (i.e. again no conclusions can be drawn from the exploratory analyses in the present study). In fact, a number of WED participants reported experiencing events that may have impacted upon negative affect during the study, whereas this was generally not observed for controls. As mentioned earlier, two WED participants became quite seriously ill between writing and three month follow up (i.e. heart failure and double bypass operation) and even noted that this may explain their answers/why these have changed from the

previous questionnaire (see chapters six and eight). Other potentially confounding issues reported by WED participants during the trial included new stressful events (i.e. as noted earlier one participant's friend was diagnosed with cancer during their writing period, another participant's sister-in-law died during their writing period and another avid church goer noted in their three month questionnaire that there may be a small negative change in their responses owing to the recent loss of their parish's church building).

To identify whether the observed effects were robust to the responses of these participants, sensitivity analyses were performed excluding these five WED participants and a control participant that reported experiencing potentially confounding events during the study[143] from the preliminary effectiveness analysis for depressive symptom severity. However, once these participants were excluded, the effects observed from the ITT and complete case analyses became slightly more significant and the mean differences and effect sizes became slightly larger (and as with the original analyses, the 95% CIs associated with the means for the WED and control group did not or at most marginally overlapped). The conclusions derived were generally unchanged, though.[144] The original mean differences, p values and effects size estimates and those derived in the sensitivity analysis are reported in Table 55.

[143] This was the participant that reported not feeling well at baseline and in their writing (see chapters six and eight), and they also reported being frustrated by their current diabetes control in their three month questionnaire.

[144] Assumption checks for both the ITT and complete case analysis indicated homogeneity of regression slopes for the covariates, namely age, gender and baseline depressive symptom severity ($p>.05$). However, the assumption of homogeneity of variance was apparently violated for the untransformed data for both the ITT and complete case analysis ($p<.05$), yet this was not the case for the transformed data. Analyses with the transformed and untransformed data generally derived the same conclusions with one exception; ω^2 for the complete case analysis with the untransformed data just met the cut-point for a large effect (see chapter five) (.14), whereas ω^2 for the transformed indicated a medium-sized effect (.12). For ease of interpretation the untransformed data is reported, yet the magnitude of the effects for both analyses were presumed not to have changed with the exclusion of these participants.

It should be noted, however, that given their age and that poor health was discussed within the WED essays relatively frequently (see chapter eight), a number of participants may have experienced yet did not report potentially confounding events, which may have systematically affected the WED group.

Table 55 Mean differences, p values and effect size estimates for the original ITT and complete case analyses and the sensitivity analyses excluding participants reporting potentially confounding events during the study

Analysis	Mean difference	P value	ω^2
Sensitivity analysis			
ITT	5.8	.004	.12
Complete case	6.8	.008	.14
Original analysis			
ITT	4.8	.006	.09
Complete case	5.5	.012	.10

Additional attempts to understand the observed effect

There was no evidence of mediation in the present study; the anticipated mediating processes did not offer any further understanding of the observed effect. It should be noted that as with the mechanisms of change investigated, these findings did not necessarily discern the initial hypotheses though. This is because again no conclusive inferences can be drawn from these analyses, but also because these findings were somewhat unsurprising in that mediation of a positive not negative intervention effect was anticipated. These mediating processes had not been confidentially established (as reported in chapter four), thus it may be that they are not as important in explaining WEDs effects as was initially anticipated. Such assertions are speculative, however, as again no conclusions can be drawn from these analyses.

Sub-group (moderator) analyses

As explained in chapter six, these analyses were particularly limited and as such were considered only very briefly in a hypothesis generating way. To this end, it was notable that the findings were consistent with the literature in chapter two; for alexithymics WED may have evoked stressors without resolution increasing awareness of distress and symptom perception, and pessimists undertaking WED may have ruminated on the negative aspects of an issue without resolution and derived negative expectations about the impact of WED resulting in increased symptom perception. It may be worth investigating these moderators in future studies.

Potentially meaningful effects: health-related QoL and diet

As described in chapter four, SMBs and health-related QoL were included as outcomes as it was unclear whether or anticipated respectively that WED may influence them. Additionally, the diabetes literature suggested that even lower-level depression adversely influences these outcomes, and that depression treatment can improve them concurrently, albeit whether these changes are related to change in depression is unclear. In the present study, WED additionally produced trends for poorer specific diet behaviour, possibly reflecting comfort eating, and poorer health-related QoL. A possible explanation for these effects, should they be genuine, is that WED evoked rather than resolved current stressors, which adversely affected depressive symptom severity but also these outcomes. Indeed, the baseline EQ-5D scores also indicated participants were generally well-adjusted; the average utility (i.e. .89) and VAS (i.e. 80) scores were above the average reported for UK adults with Type 2 diabetes (i.e. .75 and 68.8 respectively) (Matza et al, 2007). Whether these trends were associated with the increase in depressive symptom severity is unknown yet as such remains a possibility. The systematic review reported in

chapter three did not suggest any adverse effect on WED on health-related QoL, yet again these studies were associated with an unacceptable risk of bias. Nonetheless, none of the included studies included participants selected for not experiencing any significant depressive symptoms.

It is notable that no effect on general diet behaviour was observed. However, a number of participants noted that they experienced difficulty answering items in this sub-scale as they ask about following an eating plan which they did not have (as noted in chapter eight), yet they answered them nonetheless. These data are therefore ambiguous. Additionally, should it be the case that WED evoked rather than resolved current stressors and thus exacerbated comfort eating, directly or indirectly by increasing depressive symptom severity, questions asking specifically about these behaviours may be considered to be more sensitive to this change than more generic questions about healthy eating. There was also no effect on the EQ-5D utility outcome. However, it is acknowledged that this measure is prone to ceiling effects; not all health problems, especially those unrelated to the domains assessed, are detected (i.e. some variation in the independent variable is not captured). Its responsiveness to change in clinical trials may therefore be limited and is yet to be established (Matza et al, 2007). Indeed, a substantial proportion of people with Type 2 diabetes indicate perfect health on this measure (i.e. a score of 1) (Matza et al, 2007), as was observed in the present study.

Other SMBs

As described in chapter two, there is limited evidence that WED influences health behaviours, which is seemingly limited to effects upon addictive behaviours only for some populations (e.g. psychologically stressed/problematic populations). There is equivocal evidence regarding SMBs in LTPCs but this is underdeveloped. Chapter

one reported that the depression intervention literature in diabetes suggests some, albeit few, SMBs may be influenced, namely diet and exercise. Incidentally the present study identified a potential effect for diet yet not exercise, and the aforementioned unpublished study of WED in Type 1 diabetes identified the opposite pattern of effects. In the present study, participants often commented that the questions about exercise were not applicable to them owing their age and associated health problems (again noted in chapter eight). Moreover, individuals with Type 2 diabetes are more prone to weight problems than those with Type 1, and indeed the average BMI in the present study was 30. The absence of an effect on exercise in the present study is therefore unsurprising. Whilst speculative, the study in Type 1 diabetes may have similarly omitted an effect on diet, given that the sample was small (n=22) and effects were considered in terms of significance suggesting a risk for a Type 2 error. However, the effect on diet in the present study was negative, possibly owing to the sample obtained. Moreover, and most importantly, as noted earlier as a result of the small sample obtained no conclusions can be drawn from the exploratory analyses in the present study.

DSED

DSED was included as an outcome because as highlighted in chapters one to four, WED was anticipated to be specifically effective in diabetes. This was because WED targets emotional aspects of stressors and presumably DSED, which are associated with depression. Consequently, improvement in depression may be optimised. However, the systematic review reported in chapter three suggested an effect of WED on negative affect yet not distress, which has additionally been observed in some non-LTPC samples. It was therefore advocated that whether WED might target distress and improve depression via a concurrent reduction in this

in LTPCs should be clarified. Consistent with the systematic review, the present findings do not support this presumption.

There are a number of potential explanations for the apparent adverse effect of WED on depressive symptom severity yet not DSED. Diabetes-related stressors were infrequently discussed, and where they were evoked, given the data presented below, it seems that these may have already been in people's minds. Thus an exacerbation of DSED could be considered to have been unlikely whereas writing about diabetes-related stressors may have stirred depressive feelings. As described in chapter four, in diabetes general stressors/stress are associated with both DSED and depression, thus evocation rather than resolution of this might reasonably be expected to adversely influence both of these outcomes. However, it seems logical that depressive symptom severity might be more readily influenced. There may have also been a ceiling effect such that there was less room for worsening in DSED. Furthermore, a number of the factors external to WED that may have increased depressive symptom severity for WED participants, for example serious illness and new general life stresses during the trial, are again arguably more likely to have influenced depressive symptom severity than DSED.

It should additionally be pointed out that the apparent adverse effect of WED on depressive symptom severity but not DSED may be taken to suggest that perhaps DSED and depressive symptoms are not as closely related as is anticipated; changes in depressive symptom severity may not necessarily equate to a change in DSED. Indeed, chapter four noted that it is generally agreed these are related yet independent constructs. While speculative perhaps the association is less evident for certain sub-groups. This is consistent with clinical observation that people with diabetes and depression typically do not discuss diabetes as the main cause rather it can be a contributory factor (JS). Indeed, the study identified that it is possible to

have DSED in the absence of notable depressive symptoms. The average baseline PAID scores indicated moderate DSED (i.e. 36), and the mean was close to the lower bound indicating most participants exhibited this level and some even scored 74. In a general outpatient diabetes population a screened sample scores between 20-30 (Papathanasiou, Shea, Koutsovasilis, Melidonis, Papavasiliou & Lionis, 2008; Polonsky et al, 1995; Welch et al, 1997), and scores of 30-50 are observed in secondary care diabetes samples (Hermanns et al, 2006; Papathanasiou et al, 2008). In fact, scores of ≥33 and ≥38 are also reported to have adequate sensitivity and specificity for detecting elevated depressive symptoms and MDD according to diagnostic clinical interview in diabetes (Hermanns et al, 2006).

Comparison with previous reviews

To facilitate comparison with the effects observed in the previous WED systematic reviews and the effects from the systematic review reported in chapter three, for the potentially important effects observed in the exploratory RCT η^2 was converted to r, by taking the square root, and then d was computed (see chapter three for formula). These are reported for the ITT analysis in Table 56 below.

Table 56 Potentially important effects converted to r and d (ITT analysis)

Outcome	ITT analysis	
	R	**D**
Depressive symptoms	.32	.67
Specific diet SMBs	.20	.41
Health-related QoL (EQ-5D VAS)	.14	.28

The effects observed were generally larger than the positive effects derived for psychological health outcomes in previous WED reviews that included many samples including those with an LTPC; d=.07 (non-sig.) (psychological health) (Frisina et al, 2004), d=.12 (sig.) (psychological health) and d=.15 (sig.) (depressive

symptoms) (Frattaroli, 2006)[145], and the potentially important positive effects derived in the systematic review; d=.13 (negative affect) and d=.31 (health-related QoL). However, they were of a similar magnitude to the larger positive effect reported for healthy samples in Smyth's (1998) review (d=.66). Interestingly, in Meads et al's (2003) review, there was actually a slight trend for more negative mood for people with pre-existing physical conditions. However, this was seemingly attributable to a single study which caused effect heterogeneity amongst studies; a trial of WED in cancer (Walker et al, 1999). This was the only study in the systematic review presented in chapter three that reported a non-significant trend for a medium-sized effect indicating more negative affect for WED participants (d=.47) (i.e. before meta-analysis). Together with the present findings, this may be taken to suggest that WED might occasionally produce negative effects that are of a relatively large magnitude perhaps owing to sample-specific quirks. It should be noted, however, that the Walker et al (1999) study comprised a similarly small sample (n=35), and was assessed as having a high risk of bias such that other factors may explain the observed effects.

Study strengths

Before discussing the study limitations, it is important to additionally consider the strengths of the present endeavour. This was one of only a very small number of studies to investigate therapeutic writing for use in general practice in the UK, and the only one to consider the feasibility and preliminary effectiveness of WED for LTPCs and specifically Type 2 diabetes in primary care in the UK. This is important given the clinical issue of unmet lower-level E&P need in LTPCs, and specifically in Type 2 diabetes, which requires management in primary care. The study

[145] Frattaroli (2006) reported r=.06 (psychological health) and r=.07 (depression), which can be converted to d (again see chapter three for formula).

endeavoured to obtain and report on thorough process data, albeit it was not possible to compile as much information as would have been liked (i.e. qualitative interviews had to be dropped from the protocol as reported in chapter four). This identified a wealth of invaluable information to inform future endeavours. For example, the study highlighted some key recruitment issues particularly for primary care practices, derived some valuable insights into the challenges to be addressed when undertaking research into WED, and potentially identified some conditions under which WED may not be safe to implement.

The study also initially attempted to enhance the informative potential of the trial and obtain a more accurate estimate of the anticipated effectiveness of WED by addressing issues not normally considered within MRC phase two exploratory trials (e.g. internal validity and bias). Conclusive inferences were, however, prohibited by the sample obtained. The study was also designed on the basis of a rigorous systematic review of effectiveness, and a thorough consultation process was implemented in which advice from users and a range of relevant experts was sought and proceeded with.

Study limitations: research design and methods

Problems associated with the recruitment strategies employed

As reported in chapter four, recruitment in primary care was initially sought yet extended to secondary care and then support groups owing to the recruitment problems experienced. This was argued to be justified in terms of enhancing the external validity and applied relevance of the trial, and because WED has also been successfully implemented in these contexts. Ultimately, though, the samples derived were not representative of the intended primary care population. There is also a threat to ecological validity in that the setting of the study should approximate the

real-life situation that is under investigation. Furthermore, by opening recruitment to online support groups it was possible that international participants may have been enrolled when ideally UK participants were required (consistent with the recommendations reported in chapters three and four). Indeed, research into the feasibility of recruiting GP practices has indicated that often there is a need to balance scientific rigor against the reality of clinical practice and practical application (Graham et al, 2007).

Moreover, the decision to combine data from primary care and the online support groups was considered the most appropriate approach because this would increase statistical power and precision, it was anticipated that any bias would be equally distributed and diluted and analyses based on the small number of support group participants recruited would be of limited utility. However, there was some evidence of a difference at baseline that seemed to reflect involvement in the forums (i.e. support seeking), and it was acknowledged that there are many reasons why these samples should not be combined; support group participants represent support seeking individuals, which introduces further selection bias and constitutes a non-representative sample. Indeed, some additionally argue that use of online support groups may dilute WEDs effects (Atkinson, Hare, Merriman & Vogel, 2009; Murray, 2009; Smyth & Pennebaker, 2008).

The feasibility of multiple questionnaires: participant burden

Multiple questionnaires were employed as the initial objectives of the thesis were to provide a comprehensive preliminary exploratory investigation of WEDs effects. The WDREUG were consulted about the acceptability of the study materials and the burden associated with the questionnaires so that participants could be informed about this prior to providing consent. Nonetheless, participant burden was noted to

explain some missing data (as reported in chapter eight), and may explain the participation rates observed (i.e. the third of the eligible participants that did not return the baseline questionnaire in primary care and losses to follow up). Indeed, one participant reported that they found completing the questionnaires to be repetitive.

Issues associated with the data collection schedule

Perhaps three months was insufficient to observe the full trajectory of WEDs effects (Nezu & Nezu, 2008). A six month follow up was intended but removed due to the delay in acquiring ethical approval and recruitment; should it be genuine, whether the negative effect observed would have been maintained or changed at a longer follow up is of interest. Indeed, follow up at any other interval may not have evidenced the same effect. It is advocated studies should contain multiple follow ups to identify at exactly which points WED is effective and whether the effects are fleeting (Sloan & Marx, 2004a). Moreover, whilst again speculative, the tentative evidence of negative associations between some mediator variables measured at three months[146] and depressive symptom severity may be taken to suggest that perhaps two weeks to one month is an insufficient follow up for mediators, and that three months may be insufficient to then observe the influence of mediating processes.

[146] Self-efficacy for diabetes SMBs and perceived satisfaction with emotional support.

Study limitations: preliminary effectiveness analysis and further exploration of the observed effect

Statistical conclusion validity

Sample size

As described in chapter six, the sample size obtained was much less than that required to ensure adequate statistical power to detect a potentially clinically important difference on the CES-D as statistically significant at $p<.05$ (i.e. as there being less than 5% risk the effect is a Type 1 error (i.e. due to sampling error/random fluctuations). Smaller samples give rise to more sampling error (i.e. nosier data sets with more variation and thus random fluctuations), whereas in larger samples these fluctuations cancel one another out; the average value better reflects the population value (Ellis, 2010). It is therefore more difficult to detect a potentially clinically important effect as not likely due to sampling error with a smaller sample; the power to detect it as significant is reduced increasing the risk of a Type 2 error. The effect for depressive symptom severity was detected as not likely due to sampling error, however, as the effect size was large; the anticipated difference between the group means was observed yet their SDs were smaller[147] and indeed the associated 95% CIs barely overlapped. There was evidence, however, of small yet potentially important effects, which were not detected as significant. It should be acknowledged, however, that these effects were still associated with an unacceptable risk that they reflect random fluctuations/the null hypothesis is true, and should be interpreted as inconclusive warranting investigation in a larger trial.

Effects that were detected as statistically significant may additionally not be genuine; while the null hypothesis is 'probably' false there is still up to a 5% (1 in 20)

[147] 5.2 rather than 8.5.

risk of a Type 1 error (i.e. that random fluctuations were detected as significant) (Ellis, 2010). In fact, the risk of Type 1 error was substantially inflated owing to the multiple exploratory tests performed on the same dataset. For example, the ITT preliminary effectiveness analysis alone entailed 10 tests, thus the probability of no Type 1 error decreased from .95 to .60 (i.e. $.95^{10}$) and the accepted risk of making a Type 1 error increased from 5% to 40% (Field, 2005). All of the statistical analyses performed were pre-specified and thus do not reflect finishing for effects. Nonetheless, the significant effects may not have been observed had only one test been performed. Ultimately, the only means of determining whether an effect is genuine is to repeat it in a different sample (Ellis, 2010).

Owing to the small sample size achieved, the effects whether detected as significant or not were also very much imprecise and thus likely not representative of the population effect; the 95% CIs associated with the regression parameters for the effect of group in the preliminary effectiveness analysis were wide indicating a range of possible effect estimates and thus conclusions.[148] For the non-significant effects, 95% CIs suggested positive or negative effects, or indeed a null effect (i.e. the intervals crossed 0 hence it could not be assured that there was only a 5% risk that the null hypothesis was true consistent with the significance test). For the significant effects, the negative effect could have been larger than observed but importantly also trivial. Similar if not greater imprecision likely applied to the other statistical analyses, which included even smaller samples and indeed evidenced uncertainly around the means and medians derived.

[148] As expected, the ITT analysis consistently derived slightly narrower confidence intervals than the complete case analysis, probably owing to the slightly larger sample included in analyses.

Internal reliability

Interestingly, the Cronbach's alpha for the CES-D scale was slightly below the lower bound of acceptability. Moreover, this was not calculated for the EQ-5D measures and SDSCA sub-scales as they comprised too few items. Indeed, internal reliability is typically reduced for scales comprising less than three items (Peterson, 1994), and the SDSCA authors acknowledge this problem for the diet sub-scales (Toobert et al, 2000). As such, the items in the measures for which potentially important effects were observed may not have been measuring the same thing; the intended construct. Measurement error typically underestimates the association between variables and thus effect sizes, and introduces additional noise (i.e. random fluctuations) into a dataset making it more difficult to detect effects (i.e. reducing statistical power) (Ellis, 2010; Nezu & Nezu, 2008). This might not explain the effect on depressive symptom severity, but it may be taken to suggest that the non-significant trends observed could reflect Type 2 errors.

Validity

The acceptability and interpretative issues reported in chapter eight suggest that the validity of some of the measures employed may have been compromised; some data were ambiguous and or may not have reflected the intended construct. Problems were reported for the SDSCA, DMSES UK, SSQ6 and IIRS (i.e. certain items within these scales were reported to be difficult to answer as they were not explicitly applicable yet they were answered nonetheless (i.e. typically with no option indicting inapplicability within the response format), the items were answered ambiguously owing to a complex response format, or the items were explicitly answered with respect to a different construct from that intended).

Furthermore, whilst it was ensured that validated tools were employed there are some potential issues associated with the measures employed. No problems were

observed with the PAID in the present study, but this scale has been criticised with respect to content validity (i.e. covering some areas of interest too briefly or not at all) and ambiguity in the meaning of some items (Polonsky et al, 2005). At the time that the protocol was developed the PAID had been subject to more extensive psychometric testing than alternatives, for example the Diabetes Distress Scale; a revision of the PAID recently developed by the same research group (Polonsky et al, 2005). However, this scale addresses these issues and may perhaps now be a preferable alternative. Furthermore, the DMSES UK is a revised version of the original DMSES measure validated for use in the USA and Netherlands; face and content validity were assessed, and redundant items removed. However, the UK version has not been subject to extensive psychometric testing. Indeed, internal reliability was not demonstrated for support group participants.

In fact, that missing and ambiguous responses were often related to items within the SDSCA and DMSES UK asking about management of diabetes that were not applicable suggests that perhaps alternatives should be employed to measure these constructs. The SDSCA and DMSES UK were employed, however, as no plausible alternative were available; The Self-Care Inventory - Revised (Weinger, Welch, Butler & La Greca, 2005) has been validated for use in Type 2 diabetes, however it was initially developed to assess the treatment regimen for Type 1 diabetes thus many items are not appropriate for Type 2. Similarly, the Diabetes Empowerment Scale (Anderson, Fitzgerald, Funnell & Marrero, 2000) assesses empowerment in relation to diabetes generally, including the managing psychosocial aspects rather than only SMBs, and the Confidence in Diabetes Scale (van der Ven, Ader, Weinger, van der Ploeg, Yi, Snoek & Pouwer, 2003) is for use in Type 1 diabetes. Should perceived emotional support be re-examined as a mediator, a measure with a less complex response format is absolutely required. The SSQ6 was employed as typically other scales had not been validated in diabetes, whilst the SSQ is a core

EDID measure. Nonetheless, a plethora of general perceived emotional support measures were available.

It is additionally unclear whether the PANAS was the right measure to tap EA&H. Such self-report measures should have been developed to assess fear activation and responding and must be validated (i.e. demonstrated to co-vary with physiological responses to emotion) (Sloan & Marx, 2004b). Indeed, WED studies that have additionally failed to observe EA&H have employed state anxiety measures (Kloss & Lisman, 2002) and the PANAS (D'Souza et al, 2008; Gillis et al, 2006; Norman et al, 2004).

Finally, self-report measures are potentially inaccurate and reliance on them introduces mono-method bias hence they should be accompanied by objective measures, although it is encouraging that the self-report and objectively determined clinical data obtained in the present study did apparently corroborate.

Internal validity

Randomisation and allocation concealment

Again, there were no substantial systematic differences on prognostic variables apparent at baseline that could explain effects (i.e. no selection bias was apparent).

Blinding[149]

However, blinding was again apparently compromised for a number of primary care patients, some of who it seems may have merely guessed theirs was an active or inert task. Again, this may explain the observed effects. Demand characteristics may be implicated; some participants may have unconsciously responded in a way

[149] It should be noted that with respect to the withholding information about the study to protect blinding, no participants reported concerns about this at debriefing.

that discerned, rather than confirmed, the study hypothesis (i.e. adopting the negative participant role; Weber & Cook, 1972). Indeed, there was some evidence of cynicism and negative expectations about the intervention and study. Compensatory rivalry may have additionally come into play had controls worked extra hard to see that the expected superiority of the intervention group was not demonstrated. Moreover, controls may have sought treatment from their GP. Incidentally, the IAPT programme (see chapter one) was initiated in Coventry and Warwickshire while participants were still being recruited to and participating in the trial (i.e. October 2009). However, such treatment diffusion is unlikely given the sample was relatively well adjusted at baseline.

Attrition

There was some evidence of self-selection at follow up; approximately 20% of participants were lost at each follow up. Consistent with the majority of the studies included in the systematic review (chapter three) though, this was acceptable and not indicative of substantial attrition bias (i.e. selection bias caused by attrition). Nonetheless, those who stayed in may have differed systematically from the sample initially recruited, and had attrition been related to a negative experience of the intervention the negative effect associated with WED may have been underestimated. There was no notable evidence of imbalance in attrition at two weeks (WED 22%; control 17%) or three months (WED 22%; control 22%), or reasons for attrition (i.e. whether theses were related to the task) at two weeks (WED 33%; control 33%) and three months (WED 25%; control 25%), albeit reasons could not be obtained for all dropouts. There was therefore little evidence of selective attrition bias; systematic group differences in attrition that are potentially related to some aspect of the study (e.g. treatment response) and may have influenced the observed effect.

Problems associated with the analytical approach

Strict ITT analysis was not possible as some participants did not complete the intervention as intended, but also because attrition and missing data meant that some observations were imputed. Additionally, data could not be imputed for some albeit few participants for the EQ-5D VAS and SDSCA blood glucose testing sub-scale; selective attrition bias cannot be ruled out. Moreover, the extent of missing data and thus imputation was notable for the blood glucose testing measure; particular caution must be exercised in interpretation of these analyses.

The approach to imputation was additionally not ideal; no change was presumed as a conservative approach. The natural course of depression in diabetes is unknown yet the evidence suggests it is probably unstable (see chapter four). However, imputation is always an estimate, and a sensitivity analysis was performed to identify the impact. As expected the effect of WED was slightly underestimated. Importantly though, given that the observed effect was negative assuming no change was not a conservative approach. The ideal approach would have been multiple imputation (i.e. generating possible values for missing values and thus estimating several complete sets of data, then using the pooled output from analyses), yet this is difficult to perform.

The contamination, and again the mechanisms of change, analyses must additionally be interpreted with caution. The extent of missing data for the PANAS negative affect sub-scale was substantial, and indeed the numbers included in these and also the LIWC analyses were very small; it is highly likely these analyses were underpowered and the effects derived imprecise (i.e. not representative of the population effect). The PANAS variables were notably influenced by high scoring outliers, which introduced ambiguity in the mechanisms of change analyses (reported in chapter eight). Moreover, the non-parametric analyses employed

disposed of valuable information resulting in a loss of power; only the order of the data was retained (Ellis, 2010). Nonetheless, these were considered more accurate than parametric analyses with severely skewed data.

Again, caution must additionally be exercised in interpreting the mediation analyses. The regression analyses included almost 15 participants per variable as typically recommended, yet as mentioned in chapter four many more are actually required to reliably gauge the effect estimate (R^2 and thus ΔR^2) and achieve adequate statistical power when effects are small. Indeed, adjusted R^2 consistently overestimated the population effect indicating shrinkage. There was also some limited evidence of non-significant trends (mentioned above), although these may be inaccurate and in fact could be explained by external variables correlated with the predictors (Field, 2005).

Finally, the correlations investigating whether the linguistic features of WED presumed to reflect E&CP were related to changes in outcomes were not pre-specified or formal mediation analyses (again as described in chapter five). While this provided interesting information to aid interpretation of the pre-specified analyses, mediation cannot be presumed and again no conclusions can be drawn from these exploratory analyses.

External validity

The small sample size also reduces the external validity and thus generalizability of the findings. The sample was also highly self-selected; of those invited to participate only 10% of the primary care patients and 4% of support group participants expressed an interest. This suggests sampling bias; participant's decisions about whether to participate may have been related to motivations or traits that derived an unrepresentative sample. Participant feedback indicated that the motivation for

taking part for some was curiosity and an interest in furthering understanding and management of diabetes.[150] Indeed, again it seemed that most participants were generally well-adjusted. However, interest in the study may reflect treatment seeking, and indeed some people were excluded owing to high depressive symptom severity (as described in chapter six). Moreover, PAID levels were notable, and one participant commented that they were frustrated by their current diabetes control (as reported earlier). However, few patients choose to write about diabetes as a stressor. While speculative, perhaps those excluded in the eligibility check were motivated by treatment seeking, whereas the sample obtained acknowledged diabetes-related problems yet was predominantly motivated by curiosity and a desire to further understanding and management of the condition. There may also have been an element of treatment seeking for some participants though. In sum, should this be the case, the sample would only be representative of individuals exhibiting these motivations. Interestingly, others report WED is less effective where individuals are not motivated by a desire to disclose, for example those responding to a researchers request (Lumley, 2004).

The results can also only be generalised within the selection criteria employed, for example only to individuals with Type 2 diabetes experiencing nothing more than minimal depressive symptoms. Individuals recently diagnosed with Type 2 diabetes were also not represented, and indeed there is preliminary evidence that WED may be less effective and even contraindicated when LTPC patients have been diagnosed for a longer period (Low et al, 2010). The sample was also biased to older participants, although this is unlikely to explain the negative effect observed given that there is preliminary evidence of positive effects of WED in seniors with

[150] One patient commented that they hoped their writing would be useful and that they would like to think they had done something to rid others of the dreadful complaint (WED, primary care). Another patient commented that they hoped the study would shine some light onto coping with the condition (WED, primary care). In threads on the online support group forums some people stated that their motivation to take part was because they were curious to see how writing could possibly help people manage and cope with diabetes/wanted to know the outcome of the research.

Type 2 diabetes (as described in chapter four) (Taylor, 2001). It is noteworthy however that some WED participants reported problems with writing and either did not return their writing pack for this reason or found the task to be difficult. Hence, as anticipated WED may not be pragmatically appropriate for some older individuals with Type 2 diabetes.

Moreover, as no patients were recruited in secondary care individuals with more serious diabetes complications were not represented. Moreover, only the socio-demographic characteristics of the PCTs from which practices, and then patients, were recruited are represented. This and the English writing ability and literacy requirements of the present study meant that lower socio-economic groups, ethnic minorities and less educated individuals were under/not represented. WED has demonstrated effectiveness across samples that are heterogeneous on these characteristics (Frattaroli, 2006; Pennebaker, 1997; Pennebaker & Graybeal, 2001; Smyth & Helm, 2003; Yogo & Fujihara, 2008), however there is some evidence WED is differentially effective with respect to ethnicity (Lu & Stanton, 2010); the privacy of WED may again offer an acceptable means of disclosure for Asian patients, and education (Junghaenal, Schwartz & Broderick, 2008); expressing thoughts and feelings by writing may be less suitable for individuals with lower education.

The implications for service delivery and research, effective strategies, potential means of addressing the limitations observed and the conclusions derived from the exploratory RCT are considered in the following chapters in the context of the thesis findings as a whole.

Chapter 10 Overall conclusions

Chapter overview

This chapter presents the broader implications for service delivery and research, drawing on the findings and conclusions from the previous chapters. The current position regarding the implementation of WED in Type 2 diabetes and LTPCs generally is therefore clarified, and the overarching recommendations for further research into WED in LTPCs are specified. A discussion of how the limitations associated with the present endeavour could be addressed follows, and some further recommendations for future research born out of the present trial are then mentioned. The chapter closes with a summary of the findings and recommendations from the thesis as a whole, with consideration of what was learnt and the potential contribution to knowledge.

Broader implications for service delivery

The findings from the exploratory RCT suggested that WED may be acceptably and feasibly implemented as part of general practice in the UK and for use with LTPCs in this context, specifically Type 2 diabetes. The systematic review suggested that, should the observed effects be genuine, in adults with LTPCs WED may produce slight improvements in depressive symptoms that could have a large, favourable impact on the range of important clinical and service level outcomes adversely impact by depression at the population level (discussed in chapter one). Indeed, as mentioned in chapter three, when produced for a number of people even small and seemingly unimportant effects can accumulate to large effects that have a substantial impact on outcomes at the population level (Ellis, 2010). The U_3 statistics that were derived indicated WED may produce improvements in depressive symptoms, and some associated outcomes namely health-related QoL, such that 5

to 10% of the population may do better than would be expected by chance. This effect may additionally be more prominent for certain LTPCs. The effect sizes were consistent with the previous albeit limited systematic reviews, and may be taken to support the assertion that WED can be expected to deliver small yet clinically important beneficial effects in LTPCs (Baikie & Wilheim, 2005). Smyth and Pennebaker (2008) argue that for such a brief and inexpensive intervention to have any effect is impressive, thus again should they be genuine these effects are encouraging.

The preliminary effectiveness analysis in the exploratory RCT suggested that, should the observed effects be genuine, delivering WED as it was implemented in the present exploratory trial to patients with Type 2 diabetes may promote an increase in depressive symptom severity and a slight worsening in health-related QoL and dietary behaviour. As described in chapter three, while Cohen's conventions for interpreting effects sizes are grounded in logic, reflect observable effects and are important for comparing effect sizes across studies, their use is controversial and it is crucial to further interpret effects in terms of clinical importance, and additionally their contribution to knowledge (Ellis, 2010).

Investigation of whether a clinically important effect on depressive symptom severity was observed in the exploratory trial was thus pre-specified. Again, the clinical importance of effects based on SMDs is difficult to interpret as the difference is expressed in SD units rather than the measurement scale employed. A five point difference on the CES-D was therefore considered potentially clinically important given that a score of 16 is taken to indicate significant symptoms (i.e. this discriminates between important levels of severity and is potentially clinically meaningful). This difference was observed. However, as also mentioned in chapter three, the change in a person's actual depressive state that corresponds with a unit

change on such self-report symptom measures is not known. Certainly, no sensible inferences could be made about the clinical significance of a five to eight point difference on the EQ-5D VAS. The effect for specific diet was, however, more easily interpreted; the group difference equated to half a day per week spent eating more high fat foods and less fruit and vegetables for the WED group compared to the control group.

Regardless though, as above should they be genuine the effects observed in the present study could have a substantial impact at the population level, for example in terms of the health service implications of unhealthy eating in diabetes. That WED may additionally produce a comparatively large and potentially clinically important increase in depressive symptom severity is especially concerning given the aforementioned impact of depressive symptoms in adults with LTPCs and specifically diabetes (see chapters one and four). As in chapter three, to illustrate that the effects observed in the exploratory trial could have a substantial impact at the population level, SMDs can be expressed as the U_3 statistic. For the ITT analysis, the SMDs of .67 for depressive symptom severity, .41 for specific diet behaviour and .28 for health-related QoL are equivalent to 75%, 66% and 61% of WED participants having greater depressive symptom severity, poorer specific diet behaviour and lower health-related QoL respectively than the average control participant. Put another way, 25%, 16% and 11% respectively of the population may do worse than would be expected by chance alone (i.e. U_3=.75, .66 & .61 respectively).

Importantly, though, there were a number of methodological issues which substantially undermine the findings and necessitate that the observed effects are interpreted with caution; again no conclusions can be drawn from this analysis. The effects may not be genuine and cannot be confidently accepted without replication,

although given that effects were negative this presents an ethical dilemma (Lilienfeld, 2007). Indeed, some statisticians have referred to statistically significant findings in the opposite direction to that anticipated as Type 3 errors (Lilienfeld, 2007).

In sum, it is not justified to dismiss WED as a potentially valuable intervention for adults with Type 2 diabetes on the strength of this analysis alone. Further research addressing the pitfalls associated with the present endeavour is clearly required. Until then, however, caution must be exercised in considering WED for Type 2 diabetes. In fact, given the substantial risk of bias identified for the studies included in the systematic review, which suggested that the effects may have been overestimated, and the present findings it seems that WED should not be widely disseminated for LTPCs at all outside further high quality research. It should also be noted that the present study identified that while there seems to be is a sub-group of individuals for whom WED may be a welcome source of support, patient acceptability is mixed. Indeed, the compliance that was observed echoed that in previous WED trials in LTPCs suggesting that patients' acceptability may be mixed in LTPCs generally. Evidently, it must be acknowledged that WED may not be acceptable to all patients with LTPCs.

Broader implications for research

Future trials must therefore address the limitations identified in the systematic review and the present endeavour. In fact, the exploratory trial attempted to address the limitations observed in this evidence base, yet despite concerted efforts did identify with some of them (i.e. initial sample size, difficultly implementing participant blinding and completion of the intervention). Obviously, future trials must secure external funding and thus adoption onto the research portfolio/assistance from the

Research Networks, so that WED can be properly investigated. The acceptability and feasibility information and this presence of an unmet need documented in the present study suggest that this is a worthy endeavour. Indeed, interest in WED for LTPCs is still evident. Many ongoing trials were identified in the systematic review, and in fact two more published studies in patients with chronic lung disease (Sharifabad, Hurewitz, Spiegler, Bernstein, Feuerman & Smyth, 2010) and psoriasis (Paradisi, Abeni, Finore, Di Pietro, Sampogna, Mazzanti, Pilla & Tabolli, 2010) that would have met the criteria for the review were identified after the cut off for inclusion. In fact, there is also a large scale, ongoing trial of WED for diabetes by an established research group yet this is in the USA (Smyth et al.).

An important issue identified in the present endeavour is that WED must be tested with a more appropriate sample of adults with Type 2 diabetes; should the observed effects be genuine WED may be differently effective in a more appropriate sample. Indeed, as above, the systematic review suggested that WED derives positive, and no negative effects, on depressive symptoms, and some associated outcomes, across unselected samples of adults with LTPCs. There is additionally preliminary research that has suggested the same in diabetes (reported in chapter four). However, these studies are again limited and the effects may have been overestimated.

Nonetheless, the findings from the present study may be taken to support the assertion made in the systematic review that WED should be administered to patients with at least some, albeit not significant, depressive symptoms. Consequently, the research priorities specified in the systematic review still hold; trials should investigate the effectiveness of WED for reducing negative affect, for example depressive symptoms, and associated outcomes such as health-related QoL, for LTPCs that are associated with negative affect and in which negative affect

has a significant impact, perhaps still diabetes. Patients should be experiencing lower-level negative affect. This is consistent with the appropriate clinical application of WED and would enhance the applied relevance of trials whilst importantly protecting patient safety. It would also potentially optimise effectiveness.

Such trials should again be exploratory, informed by the invaluable data acquired in the present exploratory trial, this time delineating the conditions under which WED should rather than should not be implemented. Indeed, the issues encountered in the present exploratory RCT underscore the importance of feasibility trials. Indeed, it seems important to examine acceptability and feasibility again given that much of the negative patient feedback about WED may have related to the sample obtained. Further qualitative investigation into acceptability and feasibility would also be fruitful, for example the planned interviews that were not possible in the present endeavour. Importantly, the anticipated effectiveness of WED should also be re-assessed but in a larger, more appropriate sample.

How the limitations associated with the present endeavour could be addressed

What worked well

The recruitment strategy employed in primary care was actually relatively effective rather it was circumstantial factors and study design flaws that apparently created problems. For example, eight GP practices were recruited as required, yet three were lost owing to swine flu related workload and the QoF inclusion criterion employed. Of the remaining five practices, three actually identified many patients, typically more than that anticipated for a practice, and for one of those that identified few patients this was again owing to the QoF inclusion criterion and swine flu related workload. The patient recruitment rate was lower than anticipated, but

should a means of covering resource costs to practices be acquired recruitment of more practices would potentially overcome this. In fact, resource costs to practices were proven to be minimal, which dispels some of the initial concerns expressed about the study by practices. Indeed, this strategy was apparently more effective than the strategy tested in secondary care.

Having GPs offer WED in consultation would offer greater ecological validity (i.e. ascertaining whether WED can feasibly and effectively be implemented as part of routine general practice). However, this activity would require significant reimbursement and there may be a risk of compromising participant blinding. The pace of recruitment would additionally almost certainly be slower (i.e. as suggested by the previous feasibility trial of WED based interventions in primary care including in the UK; reported in chapter four).

Unsurprisingly, recruitment, albeit not retention, was seemingly better when practices were visited and GPs (and to a lesser extent nurses) were spoken to. This should therefore be fervently sought. Other observations were that having participants write at home, which afforded greater ecological validity, was relatively successful given the limited experimental control (i.e. the instructions were typically adhered to). Typing disclosure was also well accepted and executed by support group participants, hence there does not seem to be any reason why this could not be offered to those requesting it in primary care. Email administration in support groups resulted in speedier return of materials, although to offset formatting problems that may deter participants and introduce interpretative problems an encrypted online resource would be required for administration of materials electronically. Finally, reminders were generally effective in obtaining materials. In fact, participants seemed to engage more with the study when spoken and value the opportunity to speak with the researcher, with some even requesting this; personal

contact with the researcher seems to be helpful. However, as reported in chapter four, caution must be exercised as personal contact and extensive discourse with the researcher risks additional intervention, influences from experimenter expectancies/bias, compromised blinding, treatment diffusion and pre−disclosure priming. It was also an ethical requirement that the researcher avoided situations in which clinical support was being sought.

What worked less well and what would be done differently knowing what is now known

Recruitment and sample size

The most notable caveat related to practice and patient recruitment and ultimately the small sample size, statistical power and imprecision observed. In primary care, practices were apparently unable to participate owing to practice workload, resource costs and occasionally payment; the imposition to practices whilst at the minimum possible was still considered too great. Some means of reimbursing primary care practices for the resource costs associated with the study must be implemented (i.e. further limiting the imposition to practices). Assistance for the research networks, in particular having an appropriate person introduce the study to practices and be available to go into practices to support searches would be ideal. Indeed, previous research suggesting means of encouraging GPs to participate in research has indicated that they must be encouraged to see value in research participation (as noted in chapter six), an effective strategy for which may be to confer value by payment for participation (Graham et al, 2007; Johnston et al, 2010; Salmon et al, 2007). This is consistent with the economic drivers inherent within the QoF (Salmon et al, 2007).

Even when funding and assistance from the research networks are secured, however, recruiting practices can still be challenging. As noted in chapter six, the aforementioned studies suggest that emphasising the relevance and potential benefits of the study is crucial. Furthermore, they advocate that as a means of recognising and rewarding GPs for their time in studies additional indirect and personal incentives may maximise participation, for example providing feedback on patient health outcomes and practices processes, and incorporating an element of continued professional development (CPD) into the study (Johnston et al, 2010). Perhaps, then, it could be emphasised that whilst this was perceived to be barrier to recruitment amongst practices in the present study, pro-actively screening and identifying patients with potentially significant depressive symptoms is actually consistent with NICE guidelines (see chapter one) and may provide useful information for audit (NIHR PCRN, 2010). It could then be enthused that having been identified in the eligibility check patients beyond the study may additionally derive benefit, and that the study would provide early access to novel treatments and additional time and monitoring for patients (NIHR PCRN, 2010). Other potentially useful approaches advocated by these studies are recruiting a GP champion to the research team who could champion the study to colleagues (Johnston et al, 2010).

In online support groups, the most notable barriers to patient recruitment specifically in this context were limited exposure to the study information owing to posting in research sub-forums. Posting within Type 2 diabetes sub-forums is apparently important. Recruitment in local support groups could also be pursued. In secondary care, clinical support was much less available than anticipated thus the ideal recruitment strategy had to be changed considerably. Clinician agreement that they will at least mention the study to patients initially as was initially intended may be important. However, the limited availability of clinical support and the many other

barriers to recruitment in secondary care suggest that perhaps recruitment in this context should not be pursued. In fact, to promote ecological validity and consistency with the anticipated implementation of WED, and to avoid the inappropriate combination of data from different sources, recruitment should ideally be constrained to primary care.

Finally, across recruitment contexts, the eligibility questions and or the DSQ seemed to deter participants. Such measures are unavoidable, yet participants should be assured that this is merely a check required to satisfy relatively standard ethical requirements and is not intended to select only individuals experiencing problems.

Eligibility check

The eligibility check in place to ensure the exclusion of participants potentially at risk may have excluded some who could have actually taken place. With regards to identifying a more appropriate sample, the only workable and acceptable option may be for appropriately qualified clinicians to test WED in Type 2 diabetes, such that ethical requirements can be satisfied without the need to exclude people for who WED may be suitable and include those for whom it may not. This is not, however, consistent with the anticipated application of WED as a self-administered, low-intensity psychological intervention. Perhaps another option then is the exclusion of individuals scoring above a threshold for significant symptoms on a symptom measure derived from DSM-V diagnostic criteria. As described in chapter four, other WED trials have sought to identify patients with elevated but not significant depressive symptoms using a similar approach with different measures to exclude at risk participants, for example the BDI (Stice et al, 2006). These studies report improvement in depressive symptoms and no negative effect. In fact, the BDI has demonstrated predictive efficacy in Type 2 diabetes, specifically a superior

positive predictive value whilst maintaining sensitivity (Lustman, Clouse, Griffith, Carney & Freedland, 1997). The gold standard is again the diagnostic clinical interview and should be conducted where feasible.

Ensuring inclusion of participants with lower-level depression

The present study initially sought patients with at least some lower-level depressive symptoms, yet identified that this cannot be achieved by enforcing the QoF depression-screening questions employed in primary care as an inclusion criteria. Some alternative means of identifying such individuals is thus warranted. Perhaps an alternative worthy of investigation is the inclusion of individuals scoring above a threshold for mild symptoms yet below that for significant symptoms on a symptom measure derived from DSM-V diagnostic criteria. This has been employed in some other WED studies reporting benefits and no negative effects (discussed in chapter nine).

Participant burden

In order to reduce the participant burden that was apparently associated with the use of multiple questionnaires, issues such as moderators, mediators and mechanisms of change should perhaps be shelved and examined in the context of a full effectiveness trial. When this is re-examined, though, more appropriate measures of EA&H should be sought, it may be advisable to measure mediators later than two weeks post-intervention, and in view of the limited support for the mediators tested exploration of alternative mediators may be more productive.

The data collection schedule

The follow up employed was insufficient to observe the full trajectory of WEDs effects. Consequently, follow ups that extend beyond three months are advocated.

Reliability and validity of study measures

Estimation of effects with more reliable measures, especially in relation to diet behaviour, is important. The validity of some of the measures employed was additionally uncertain, and owing to acceptability issues for certain measures missing data were problematic. Alternative measures should be considered where they exist (as discussed in chapter nine), and instructions to complete all questions including those which are not applicable indicating (i.e. this within the required format where this is possible) are required. Assessment beyond self-report measures is also indicated (e.g. depressive symptoms by clinician ratings).

Acceptability of writing

Some participants reported that they found it difficult to fit writing in with life. In view of this and the observed effect, it may be prudent to allow people write as and when they need to. Whilst non-return of writing packs may reflect patient acceptability, strategies to promote completion of WED/return of writing packs should be identified. Perhaps assistance in getting people started with WED would be helpful. Contact with the researcher may help but again should be implemented with caution. In fact, many, albeit not all participants, reported a dislike for handwriting/preference for typing. Perhaps offering the opportunity to type if preferred would be advisable. Indeed, this is advocated (Baikie & Wilheim, 2005).

Blinding

Again, blinding was apparently compromised for a number of primary care patients, some of who it seems may have merely guessed theirs was an active or inert task. Given the requirement to involve them in relation to patient safety, practice staff/GPs should be specifically advised not to disclose the study purpose to patients. However, provision of even less information to participants is not ethically

justifiable, and caution must be exercised in using a more engaging writing task which is less noticeably a placebo yet risks intervention. Exactly how participant blinding can be improved is thus unclear and must be explored.

Control group comparison

Again, where WED was associated with a worsening in outcomes, this was consistently partly explained by an improvement for controls. Additional inclusion of a usual care control group is thus also warranted, to establish whether any improvement for controls is due to the time management task or external factors, and thus whether an alternative inert control writing task is required. Should this be the case, a task that may further compromise blinding should be avoided.

Further recommendations for future research born out of the present trial

Further recommendations for future research born out of the present trial are presented in Table 57.

Conclusions: what was learnt

The thesis suggested that WED may be acceptably and feasibly implemented as part of general practice in the UK and for use with LTPCs in this context, specifically Type 2 diabetes, and provided a wealth of invaluable process data to inform future endeavours. Given that this has not previously been investigated, the present study may be considered to offer a notable addition to the evidence base.

Table 57 Further recommendations for future research

- Enhance the external validity of the findings by seeking to ensure the inclusion of the full age range of adults with Type 2 diabetes and adapting WED for ethnic minorities , for example South Asians. The latter may also serve to boost participant recruitment. For this group diabetes is particularly prevalent (as reported in chapter four), depression in diabetes is particularly under diagnosed and treated (Ali, Davies, Taub, Stone & Khunti, 2009), and WED may be culturally acceptable and particularly effective (as discussed in chapters four and nine). It is asserted that translating stressful experiences into language is beneficial regardless of the language employed (Smyth & Pennebaker, 2008).
- The exploratory trial suggested men may require some additional assistance with WED. There is some evidence that additional instruction facilitating cognitive processing can derive further improvement from WED (see chapter two). Perhaps this could be helpful.
- Explore whether and reasons why WED does not seem to target distress and produce improvement via a concurrent reduction in this in LTPCs.
- WED could be used to obtain a valuable insight into the emotional factors impinging upon life for patients with Type 2 diabetes, which would inform future intervention efforts.
- Address the impact of recent changes in regulations relating to health service research on institutionally or self-funded PhD research, which suggests that primary care research training experiences may be limited.
- Explore further the finding that a substantial number of adults including primary care patients with Type 2 diabetes may be seeking support for unmet E&P need, many of whom are experiencing significant depressive symptoms and that there may also be an element of dissatisfaction where treatment is currently provided.
- Clarify the precise nature and magnitude of the relationship between depressive symptoms and DSED, and explore the finding that some people with diabetes apparently experience DSED in the absence of depressive symptoms given that DSED additionally warrants intervention yet is less likely identified and treated than depression in diabetes (see chapter 4).

The feasibility demonstrated and, should they be genuine, the findings of a generally positive effect of WED for negative affect and associated outcomes in the systematic review are encouraging. The effects observed in the present exploratory

RCTs also potentially serve as a notable addition to the existing evidence base, though. Should they be genuine, they suggest that while the systematic review indicated that positive effects of WED are generally observed in LTPCs there may be instances in which WED may not be safe to implement; WED may cause iatrogenic harm perhaps owing to sample-specific quirks. Thus identification of such predisposing factors could be a priority. Specifically, when implemented for individuals with Type 2 diabetes selected for not having any significant depressive symptoms and without ensuring at least some symptoms, writing about current stressors may evoke rather than resolve previously unacknowledged issues. The effect may also extend beyond depressive symptoms, for example to diet behaviour potentially reflective of comfort eating and health-related QoL.

However, methodological problems that are common to WED trials and are difficult to resolve mean that no conclusions can be drawn from this or indeed previous studies in LTPCs. In sum, there is as yet insufficient evidence on a whole to suggest that WED should be implemented in primary care for LTPCs including Type 2 diabetes. Further research addressing the pitfalls associated with previous endeavours is necessary, specifically feasibility trials initially. However, this will require significant investment in and efforts to advance on existing attempts to prevent the succession of inconclusive trials that is currently apparent. Indeed, a principal learning from this thesis was that research into WED and recruitment of primary care practices without access to the research networks was more difficult than was initially anticipated. The issues experienced and reported within this thesis must now be overcome.

Publication strategy

The following papers will be written up and submitted for peer reviewed publication:

- The systematic review.
- The findings from the exploratory RCT; feasibility and preliminary effectiveness.
- The ethical difficulties in undertaking research into WED and the impact of changes necessitated by ethical review and the measures taken to address them.
- What adults with Type 2 diabetes talk about when asked to emotionally disclose.

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Appendices

WED evidence base

Appendix A: Data extraction for previous WED systematic reviews

Review	Evidence (RCTs)	Intervention, Comparisons & Follow up Included	Comprehensive Search Strategy?	Formal quality Assessment?	Duplication in review processes	Approach to unreported outcome data	Heterogeneity beyond outcome & population	Outcomes assessed & effects
Smyth (1998)	13	Original WED paradigm only. Neutral writing. >1 month post intervention.	X Electronic database (but limited & key one's missing e.g. Medline). Search terms limited. Author contact. Bibliographies of reviews & primary studies. Author contact.	X	Data extraction (all studies).	Studies were required to provide sufficient statistical information to calculate effects then for included studies, effects reported as non-significant/not reported presumed to be 0). No indication authors contacted for missing data.	✓	Overall effect d=0.47 (p<.0001), reported health d=.42 (p<.0001), **psychological well-being d=.66 (p<.0001)**, physiological functioning d=.68 (p<.0001) & health behaviours d=.029 (p>.05).

Frisina et al (2004)	9	Original WED paradigm only. Comparison not reported – assumed any. >1 month post intervention.	X Electronic database search (limited but dissertation database included). Search terms limited (& key terms omitted e.g. disclosure). Author contact. Bibliographies of reviews & primary studies. Author contact.	X	X	Studies were required to provide sufficient statistical information to calculate effects. No indication authors contacted for missing data.	X	Overall effect d=.19 (p<.05), physical health d=.21 (p=.01) & **psychological health d=.07 (p>.05)**. **Trend for positive effects in depressive symptoms, mood & anxiety.** **Writing generally less effective for psychiatric than physically ill samples (individual effects not reported).**
Meads et al (2003); Meads & Nouwen (2005)	61	Any variant of written emotional disclosure or private verbal emotional disclosure (but preference for original WED paradigm). Written or private verbal neutral activity, no activity, or waiting list (preference for writing). >1 week post intervention.	✔ Electronic database search (including dissertation/abstract databases). Search terms relatively comprehensive. Citation search. Internet search (including J.W. Pennebaker website). Bibliographies of reviews & primary studies. Journal & conference proceedings hand searching. Author contact.	✔ Jadad score & qualitative discussion of range of potential sources of bias (e.g. randomisation, blinding, allocation concealment and attrition) & reporting inadequacies.	Extraction of effectiveness data (subset of studies) (& data extraction conducted twice on subset of studies at 6 month interval & repeated prior to publication).	No attempt to impute data from statistics such as p or Cohen's d. Unreported outcome data vote counted if possible or recorded as unreported. Authors contacted for missing data for studies identified early in the review process.	X	Range of outcomes within the broad categories of physical health & **psychological health**. Mixture of positive, negative null & negative effects; outcomes showed some positive intervention effects however these were offset by null and or unreported effects (a third of all outcomes measured were unreported), **for example for depressive symptoms. There was a slight trend for worse psychological outcomes for people with pre-existing physical conditions (i.e. more negative mood and intrusions).**

Mogk et al (2006)	30	Original WED paradigm (but if more than 1 disclosure group averaged). Neutral writing. >1 month post intervention.	X Electronic database search (but limited). Author contact. Search terms relatively comprehensive. Bibliographies of reviews. Journal hand searching. Author contact.	X (collected data about 'biasing characteristics' e.g. randomisation but not used in interpretation of evidence).	Data extraction (subset of studies).	Calculated effects if studies reported means/SDs, F-scores, t-tests, significance levels & number if participants. If odds ratios provided effects presumed to be 0. Attempts to obtain missing data from authors reported.	X	Overall effect g=.04 (95%CI -.8 to .15), **psychological health g=.01 (95%CI -.17 to .19) (PTSD symptoms g=.10 (95%CI .25 to .46)**, somatic health g=.07 (95%CI -.06 to .19) & health behaviours g=.02 (95%CI .04 to .36). **Clinical samples g=-.08 (95%CI -.15 to .31)**, high risk samples g=-.03 (95%CI -.06 to .20), healthy g=.07 (95%CI -.03 to .22).
Harris (2006)	30	Original WED paradigm only. Neutral writing or no writing. >1 month post intervention.	✓ Electronic database search (including dissertation databases). Search terms relatively comprehensive. Bibliographies of theoretical articles, reviews, primary studies. Conference proceedings hand searching. Author contact.	✓ (but only examined whether method of randomisation stated & evidence of blinding as moderators of effects).	X	Studies were required to provide an estimate of effect size or data that permitted calculation of Hedges g. Attempts to obtain missing data from authors reported.	✓	Health care use: healthy samples g=.16 (95%CI .02 to .31 (exc. 1 outlier), medical samples g=.21 (95%CI -.03 to .43), **psychological samples g=.06 (95%CI -.12 to .24).**

Frattaroli (2006)	146	Any variant of emotional disclosure (e.g. written or verbal, real or imagined & negative or positive). Neutral writing or no activity. >1 day post intervention.	✔ Electronic database search (including dissertation databases). Search terms comprehensive. Citation search. Bibliographies of books, reviews & primary studies. Conference proceedings hand searching. Author contact.	✔ (but examined whether attrition, delivery of instructions (proxy for experimenter blinding) and overall quality score were moderators of effects).	Extraction of moderator variables & effect size estimates (subset of studies).	Studies were required to provide sufficient statistical information to calculate effects and then for included studies effect sizes were calculated if significant p values reported or effects presumed to be zero if non-significant p values reported. If only F tests reported or it outcomes only stated as significant or not, outcomes coded as unreported. Attempts to obtain missing data from authors reported.	✔	Overall effect r=.075 (95%CI .051 to .98), reported health r=.072 (95%CI .36 to .107), **psychological health r=.056 (95%CI .026 to .086) (anger r=.183 (95%CI -.70 to .84), bereavement/grief r=.137 (95%CI -.40 to .60), distress r=.102 (95%CI .04 to .16), depressive symptoms r=.073 (95%CI -.01 to .16), anxiety r=.051 (95% -.09 to .19), positive functioning r=.045 (95% CI .01 to .08), stress r=.029 (95%CI -.02 to .08), coping r=.002 (95%CI -.08 to .08), cognitive schemas/core beliefs r=-.005 (95%CI -.04 to .04), post-traumatic growth r=-.009 (95%CI -.15 to .14), eating disorder problems r=-.020 (95%CI -.07 to .03), dissociative experiences r=--.041 (one study), post-traumatic stress symptoms r= .032, (p=.130) & self-regulation r=-.077 (p=.124)**, physiological functioning r=.060 (95%CI .013 to .106), health behaviours r=.007 (95%CI -.091 to .104. Larger effect if physically ill (r=.131) than if not (r=.054) on reported health (r=.188; p=.034) but not other outcomes (i.e. psychological health, r=.075; p=.21).

Appendix B: Search strategies

Original search strategies[151]

Downloaded to Endnote

Medline (MeSH terms focussed/not exploded)

1. Writing/
2. Disclosure/
3. Self disclosure/
4. Expressed emotion/
5. Catharsis/
6. pennebaker.tw
7. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
8. (emotional adj (express$ or disclos$)).tw
9. (written emotional adj (express$ or disclos$)).tw
10. (emotional disclosure adj2 writing).tw
11. (emotional expression adj2 writing).tw
12. ((stressful life events or critical life events) adj2 writing).tw
13. or/1-12
14. health.tw
15. 13 and 14
16. limit 15 to yr="1986 - 2007"

PsychINFO (MeSH terms focussed/not exploded)

1. Expressed emotion/
2. Catharsis/
3. Self disclosure/
4. Emotional content/
5. Narrative therapy/
6. pennebaker.tw
7. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
8. (emotional adj (express$ or disclos$)).tw
9. (written emotional adj (express$ or disclos$)).tw
10. (emotional disclosure adj2 writing).tw
11. (emotional expression adj2 writing).tw
12. ((stressful life events or critical life events) adj2 writing).tw
13. or/1-12
14. health.tw
15. 13 and 14
16. limit 15 to yr="1986 - 2007"

[151] Where possible terms were focussed and not exploded, terms indexing relevant trials and reviews in each database were included in strategies, and where searches restricted the number of text words that could be searched the most comprehensive were selected.

Cinahl and Embase (MeSH terms focussed/not exploded)

1. Writing/
2. Self disclosure/
3. pennebaker.tw
4. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
5. (emotional adj (express$ or disclos$)).tw
6. (written emotional adj (express$ or disclos$)).tw
7. (emotional disclosure adj2 writing).tw
8. (emotional expression adj2 writing).tw
9. ((stressful life events or critical life events) adj2 writing).tw
10. or/1-9
11. health.tw
12. 13 and 14
13. limit 12 to yr="1986 - 2007"

PsychARTICLES (MeSH terms focussed/not exploded)

1. Pennebaker.tw
2. limit 1 to psycharticles
3. catharsis.tw
4. limit 3 to psycharticles
5. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
6. limit 5 to psycharticles
7. (emotional adj (express$ or disclos$)).tw
8. limit 7 to psycharticles
9. (written emotional adj (express$ or disclos$)).tw
10. limit 9 to psycharticles
11. (emotional disclosure adj2 writing).tw
12. limit 11 to psycharticles
13. (emotional expression adj2 writing).tw
14. limit 13 to psycharticles
15. ((stressful life events or critical life events) adj2 writing).tw
16. limit 15 to psycharticles
17. or/ 2, 4, 6, 8, 10, 12, 14, 16
18. health.tw.
19. limit 10 to psycharticles
20. 18 and 20
21. limit 20 to yr="1986 - 2007"

CCRCT (clinical trials only, 2007 Issue 2) (‘search this term only’ for Index terms)

1. Narration/
2. Writing/
3. Expressed emotion/
4. Disclosure/
5. ((emotive or affective or therapeutic or express* or disclos*) NEAR/2 writ*):ti,ab,kw, from 1986 to 2007 in clinical trials
6. (emotional NEXT (express* or disclos*)):ti,ab,kw, from 1986 to 2007 in clinical trials
7. (“written emotional” NEXT (express* or disclos*)):ti,ab,kw, from 1986 to 2007 in clinical trials
8. (“emotional disclosure” NEAR/2 writing):ti,ab,kw, from 1986 to 2007 in clinical trials
9. (“emotional expression” NEAR/2 writing):ti,ab,kw, from 1986 to 2007 in clinical trials
10. (“stressful life events” or “critical life events”) NEAR/2 writing:ti,ab,kw, from 1986 to 2007 in clinical trials
11. or/1-10 limit
12. limit 11 to 1986-2007

SCI, SSCI, and ISI Proceedings

1. TS=(Pennebaker)
2. TS=((emotive or affective or therapeutic or express* or disclos*) SAME writ*)
3. TS=(("stressful life events" or "critical life events") SAME writing)
4. TS=(emotional SAME (express* or disclos*))
5. TS=("written emotional" SAME (express* or disclos*))
6. TS=("emotional disclosure" SAME writing)
7. TS=("emotional expression" SAME writing)
8. or/1-7
9. TS=Health
10. 8 and 9
11. limit 10 to 1986-2007

Francis and Eric

1. kw: Pennebaker
2. kw: emotive w writing
3. kw: affective w writing
4. kw: therapeutic w writing
5. kw: disclos* n writ*
6. kw: express* n writ*
7. kw: emotional w express*
8. kw: emotional w disclos*
9. kw: written w emotional w express*
10. kw: written w emotional w disclos*
11. kw: emotional w disclosure n1 writing
12. kw: emotional w expression n1 writing
13. kw: stressful w life w events n1 writing
14. kw: critical w life w events n1 writing or
15. or/1-14
16. limit 15 to 1986-2009

Proceedings First and Papers First

1. kw: Pennebaker
2. kw: emotive w writing
3. kw: affective w writing
4. kw: therapeutic w writing
5. kw: disclos* n writ*
6. kw: express* n writ*
7. kw: emotional w express*
8. kw: emotional w disclos*
9. kw: written w emotional w express*
10. kw: written w emotional w disclos*
11. kw: emotional w disclosure n1 writing
12. kw: emotional w expression n1 writing
13. kw: stressful w life w events n1 writing
14. kw: critical w life w events n1 writing or
15. or/1-14
16. limit 15 to 1993-2009

Sociological Abstracts (could not be date limited –left as earliest to latest)

1. DE=Emotional expression
2. DE=Disclosure (individuals)
3. DE=Self disclosure
4. KW=Pennebaker
5. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
6. KW=emotional (disclos* or express*)
7. KW=written emotional (disclos* or express*)
8. KW=emotional expression WITHIN2 writing
9. KW=emotional disclosure WITHIN2 writing
10. KW=(stressful life events or critical life events) WITHIN2 writing
11. or/1-10

Conference Papers Index

1. KW=Pennebaker
2. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
3. KW=emotional (disclos* or express*)
4. KW=written emotional (disclos* or express*)
5. KW=emotional expression WITHIN2 writing
6. KW=emotional disclosure WITHIN2 writing
7. KW=(stressful life events or critical life events) WITHIN2 writing
8. or/1-7
9. limit 8 to 1986-2007

Citation search
Performed for J.W. Pennebaker, M.A. Lumley, J.M. Smyth and S.J. Lepore (performed via Science Citation Index, Social Science Citation Index databases).

ProQuest (limited to Interdisciplinary dissertations and theses/index terms and key words)

1. IF(Pennebaker)
2. IF(emotive or affective or therapeutic or express* or disclos* w/2 writ*)
3. IF(emotional w/1 express* or disclos*)
4. IF(written emotional w/1 express* or disclos*)
5. IF(emotional expression w/2 writing)
6. IF(emotional disclosure w/2 writing)
7. IF("stressful life events" or "critical life events" w/2 writing)
8. or/1-7
9. PDN(>1/1/1986) and PDN(<31/12/2007)
10. 8 and 9

Hand Searching (electronically)
The British Library Integrated Catalogue (catalogue subset search/document supply (all) (any word/not exact phrases)

1. writ? disclos?
2. express? writ?
3. emotional? disclos?
4. or/1-3
5. limit 4 to 1986-2007

Index to Theses (standard search/any field)

1. Pennebaker
2. (emotive or affective or therapeutic or express* or disclos*) w/2 writ*
3. emotional w/1 (express* or disclos*)
4. "written emotional" w/1 (express* or disclos*)
5. "emotional expression" w/2 writing
6. "emotional disclosure" w/2 writing
7. ("stressful life events" or "critical life events") w/2 writing
8. or/1-7

NDLTD (all subject areas/complete document/exact phrase)

1. "emotional disclosure"
2. "expressive writing"
3. "written disclosure"
4. or/1-3
5. limit 4 to 1986-2007

Google
The first 100 references of each individual search for the terms 'emotional disclosure', 'expressive writing' and 'written disclosure' (all exact phrases and latter two searched within results for 'health' as the links retrieved initially were not generally related to health).

HSRproj

1. “Truth disclosure” [mh]
2. Writing [mh]
3. Emotions [mh]
4. personal log/diary [kw]
5. “emotional disclosure” [kw]
6. “expressive writing” [kw]
7. “written disclosure” [kw]
8. or/1-7

MRC Research Register (full text searched for text words)

1. Writing (Mesh Term)
2. Evaluation w/1 studies (Mesh Term)
3. Clinical w/1 trials (Mesh Term)
4. Stress (Mesh Term)
5. Stress w/1 psychological (Mesh Term)
6. emotion* w/1 disclos*
7. express* w/2 writ*
8. writ* w/2 disclos*
9. or/1-8

NRR

1. WRITING (MeSH)
2. EXPRESSED EMOTION (MeSH)
3. SELF DISCLOSURE (MeSH)
4. DISCLOSURE (MeSH)
5. EMOTIONS (MeSH)
6. emotive next writing
7. affective next writing
8. therapeutic next writing
9. express* next writ*
10. disclos* next writ*
11. emotional next disclos*
12. emotional next express*
13. written next emotional next disclos*
14. written next emotional next express*
15. emotional next expression next writing
16. emotional next disclosure next writing
17. stressful next life next events next writing
18. critical next life next events next writing
19. or/1-18

mRCT (all active registers searched). Individual searches for:

1. Pennebaker
2. “affective writing”
3. “emotive writing”
4. “therapeutic writing”
5. “expressive writing”
6. “disclosive writing”
7. writing therap%
8. written expression
9. written expression
10. written disclosure
11. disclos% in writing
12. express% in writing
13. written emotional expression
14. written emotional disclosure
15. “emotional express%”
16. “emotional disclosure in writing”
17. “emotional expression in writing”
18. “stressful life events and writing”
19. “critical life events and writing”

CRISP Individual searches for:

1. PERSONAL LOG/DIARY (MeSH term)
2. emotional & disclos%
3. express% and writ%
4. writ% & disclos%

Updated search strategies[152]

Downloaded to Endnote

Medline (MeSH terms focussed/not exploded)

1. Writing/
2. Disclosure/
3. Self disclosure/
4. Expressed emotion/
5. Catharsis/
6. pennebaker.tw
7. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
8. (emotional adj (express$ or disclos$)).tw
9. (written emotional adj (express$ or disclos$)).tw
10. (emotional disclosure adj2 writing).tw
11. (emotional expression adj2 writing).tw
12. ((stressful life events or critical life events) adj2 writing).tw
13. or/1-12
14. health.tw
15. 13 and 14
16. limit 15 to yr="2007-2009"

[152] Where possible terms were focussed and not exploded, terms indexing relevant trials and reviews in each database were included in strategies, and where searches restricted the number of text words that could be searched the most comprehensive were selected.

PsychINFO (now CSA)

1. DE=Expressed emotion
2. DE=Catharsis
3. DE=Self disclosure
4. DE=Emotional content
5. DE=Narrative therapy
6. KW=Pennebaker
7. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
8. KW=emotional (disclos* or express*)
9. KW=written emotional (disclos* or express*)
10. KW=emotional expression WITHIN2 writing
11. KW=emotional disclosure WITHIN2 writing
12. KW=(stressful life events or critical life events) WITHIN2 writing
13. or/1-12
14. KW=health.tw
15. 13 and 14
16. limit 15 to 2007-2009

Embase (MeSH terms focussed/not exploded)

1. Writing/
2. Self disclosure/
3. pennebaker.tw
4. ((emotive or affective or therapeutic or express$ or disclos$) adj2 writ$).tw
5. (emotional adj (express$ or disclos$)).tw
6. (written emotional adj (express$ or disclos$)).tw
7. (emotional disclosure adj2 writing).tw
8. (emotional expression adj2 writing).tw
9. ((stressful life events or critical life events) adj2 writing).tw
10. or/1-9
11. health.tw
12. 13 and 14
13. limit 12 to yr="2007-2009"

Cinahl (now EBSCO Host) (boolean/phrase search mode)

1. MM Writing
2. MM Self Disclosure
3. TX emotive writ*
4. TX affective writ*
5. TX therapeutic writ*
6. TX express* N2 writ*
7. TX disclos* N2 writ*
8. TX emotional express*
9. TX emotional disclos*
10. TX written emotional express*
11. TX written emotional disclos*
12. TX emotional expression W2 writing
13. TX emotional disclosure W2 writing
14. TX stressful life events and TX writing
15. TX critical life events and TX writing
16. or/1-8
17. TX health
18. 9 and 10
19. limit 18 to January 2008–May 2009

PsychARTICLES (now CSA)

1. KW=Pennebaker
2. KW=Catharsis
3. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
4. KW=emotional (disclos* or express*)
5. KW=written emotional (disclos* or express*)
6. KW=emotional expression WITHIN2 writing
7. KW=emotional disclosure WITHIN2 writing
8. KW=(stressful life events or critical life events) WITHIN2 writing
9. or/1-12
10. KW=health
11. 9 and 10
12. limit 11 to 2007–2009

CCRCT (clinical trials only, 2009 Issue 3) (‘search this term only’ for Index terms)

1. Narration/
2. Writing/
3. Expressed emotion/
4. Disclosure/
5. ((emotive or affective or therapeutic or express* or disclos*) NEAR/2 writ*):ti,ab,kw, from 2007 to 2009 in clinical trials
6. (emotional NEXT (express* or disclos*)):ti,ab,kw, from 2007 to 2009 in clinical trials
7. (“written emotional” NEXT (express* or disclos*)):ti,ab,kw, from 2007 to 2009 in clinical trials
8. (“emotional disclosure” NEAR/2 writing):ti,ab,kw, from 2007 to 2009 in clinical trials
9. (“emotional expression” NEAR/2 writing):ti,ab,kw, from 2007 to 2009 in clinical trials
10. (“stressful life events” or “critical life events”) NEAR/2 writing:ti,ab,kw, from 2007 to 2009 in clinical trials
11. or/1-10
12. limit 11 to 2007–2009

SCI, SSCI, and Conference Proceedings Citation Index- Science

1. TS=(Pennebaker)
2. TS=((emotive or affective or therapeutic or express* or disclos*) SAME writ*)
3. TS=(("stressful life events" or "critical life events") SAME writing)
4. TS=(emotional SAME (express* or disclos*))
5. TS=("written emotional" SAME (express* or disclos*))
6. TS=("emotional disclosure" SAME writing)
7. TS=("emotional expression" SAME writing)
8. or/1-7
9. TS=Health
10. 8 and 9
11. limit 10 to 2007–2009

Francis, Eric, and Proceedings First, and Papers First

1. kw: Pennebaker
2. kw: emotive w writing
3. kw: affective w writing
4. kw: therapeutic w writing
5. kw: disclos* n writ*
6. kw: express* n writ*
7. kw: emotional w express*
8. kw: emotional w disclos*
9. kw: written w emotional w express*
10. kw: written w emotional w disclos*
11. kw: emotional w disclosure n1 writing
12. kw: emotional w expression n1 writing
13. kw: stressful w life w events n1 writing
14. kw: critical w life w events n1 writing or
15. or/1-14
16. limit 15 to 2007-2009

Sociological Abstracts

12. DE=Emotional expression
13. DE=Disclosure (individuals)
14. DE=Self disclosure
15. KW=Pennebaker
16. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
17. KW=emotional (disclos* or express*)
18. KW=written emotional (disclos* or express*)
19. KW=emotional expression WITHIN2 writing
20. KW=emotional disclosure WITHIN2 writing
21. KW=(stressful life events or critical life events) WITHIN2 writing
22. or/1-10
23. limit 11 to 2007-2009

Conference Papers Index

1. KW=Pennebaker
2. KW=(emotive or affective or therapeutic or express* or disclos*) WITHIN2 writ*
3. KW=emotional (disclos* or express*)
4. KW=written emotional (disclos* or express*)
5. KW=emotional expression WITHIN2 writing
6. KW=emotional disclosure WITHIN2 writing
7. KW=(stressful life events or critical life events) WITHIN2 writing
8. or/1-7
9. limit 8 to 2007-2009

Citation search
Limited to 2007-2009.

ProQuest (limited to Interdisciplinary dissertations and theses/index terms and key words)

1. IF(Pennebaker)
2. IF(emotive or affective or therapeutic or express* or disclos* w/2 writ*)
3. IF(emotional w/1 express* or disclos*)
4. IF(written emotional w/1 express* or disclos*)
5. IF(emotional expression w/2 writing)
6. IF(emotional disclosure w/2 writing)
7. IF("stressful life events" or "critical life events" w/2 writing)
8. or/1-7
9. PDN(>31/12/2007) and PDN(<31/5/2009)
10. 8 and 9

Hand Searching (electronically) – cross checked and removed duplicates from original search initially (except Google as original results not available in detail but did exclude known duplicates of original search –can't guarantee all duplicates removed).

The British Library Integrated Catalogue (catalogue subset search/document supply (all) (any word/not exact phrases)

1. writ? disclos?
2. express? writ?
3. emotional? disclos?
4. or/1-3
5. limit 4 to 2007-2009

Index to Theses (standard search/any field). Individual searches for (unable to combine using OR?):

1. Pennebaker
2. (emotive or affective or therapeutic or express* or disclos*) w/2 writ*
3. emotional w/1 (express* or disclos*)
4. "written emotional" w/1 (express* or disclos*)
5. "emotional expression" w/2 writing
6. "emotional disclosure" w/2 writing
7. ("stressful life events" or "critical life events") w/2 writing

NDLTD (all subject areas/complete document/exact phrases)

1. "emotional disclosure"
2. "expressive writing"
3. "written disclosure"
4. or/1-3
5. limit 4 to 2007-2009

Google

The first 100 references of each individual search for the terms 'emotional disclosure', 'expressive writing' and 'written disclosure' (all exact phrases and latter two searched within results for 'health' as the links retrieved initially were not generally related to health). Limited to previous 24 months (i.e. May 2008 to May 2009 –small gap as last search undertaken Jan 2008).

HSRproj

1. "Truth disclosure" [mh]
2. Writing [mh]
3. Emotions [mh]
4. personal log/diary [kw]
5. "emotional disclosure" [kw]
6. "expressive writing" [kw]
7. "written disclosure" [kw]
8. or/1-7
9. limit 8 to 2007-2009

MRC Research Register (full text searched for text words)

1. Writing (Mesh Term)
2. Evaluation w/1 studies (Mesh Term)
3. Clinical w/1 trials (Mesh Term)
4. Stress (Mesh Term)
5. Stress w/1 psychological (Mesh Term)
6. emotion* w/1 disclos*
7. express* w/2 writ*
8. writ* w/2 disclos*
9. or/1-8
10. limit 9 to 01 December 2007-31 May 2009

NIHR portfolio (research summary field) (exact phrases). Individual searches for:

1. emotive writing
2. affective writing
3. therapeutic writing
4. expressive writing
5. disclosive writing
6. emotional disclosure
7. emotional expression
8. written emotional disclosure
9. written emotional expression
10. emotional expression in writing
11. emotional disclosure in writing
12. stressful life events in writing
13. critical life events in writing

No date restriction function (and no truncation, proximity or index terms available) – NRR database terminated in 2007 now NIHR (UKCRN) portfolio database (some existing data not fully updated yet and trials added in last 30 days not included in this search –thus take search as undertaken Start of May 2009).

mRCT (all active registers searched). Individual searches for:

20. Pennebaker
21. “affective writing”
22. “emotive writing”
23. “therapeutic writing”
24. “expressive writing”
25. “disclosive writing”
26. writing therap%
27. written expression
28. written disclosure
29. disclos% in writing
30. express% in writing
31. written emotional expression
32. written emotional disclosure
33. “emotional express%”
34. “emotional disclosure in writing”
35. “emotional expression in writing”
36. “stressful life events and writing”
37. “critical life events and writing”

No date restriction function

CRISP. Individual searches for:

5. PERSONAL LOG/DIARY (MeSH term)
6. emotional & disclos%
7. express% and writ%
8. writ% & disclos%

No date restriction function –each restricted to fiscal years 2008-2009 (year research funding awarded)

Appendix C: Identified but unobtainable studies

Potentially eligible but unobtainable conference proceedings

Arden-Close, Gidron, Y., Moss-Morris, R. & Bayne, L. Effects of guided written disclosure on wellbeing in ovarian cancer patients and their partners. Division of Health Psychology and European Health Psychology Society (abstract) 2008.

Gidron, Y., Duncan, E., Jenkins, E. & Arden-Close. Effects of a written guided disclosure protocol on various health outcomes in four studies (inc. effect on infectious symptoms): Rational & Evidence. International Congress of Behavioural Medicine (abstract) 2004.

Ironson, G., Leserman, J, O'Clerigh, C., Schniederman, N. Patient evaluations including self-reported symptom burden in a randomised placebo controlled emotional disclosure intervention in HIV. International Congress of Behavioural Medicine (abstract) 2006.

Jessen, I.B., Johansen, M.B., Christensen, S., Zachariae, R., Jensen, A.B., Valdimarsdottir, H., Bovjerg, D, Zakowski, S. Disclosure of negative and positive emotions and changes in mood following expressive writing intervention (EWI) in a group of breast cancer patients. International Congress of Behavioural Medicine (abstract) 2006.

Johansen, M.B., Zachariae, R., Christensen, S., Jessen, I.B., Jensen, A.B., Valdimarsdottir, H., Bovjerg, D, Zakowski, S. Expressive writing intervention, depression, and health related quality of life of breast cancer patients –results from a pilot study. International Congress of Behavioural Medicine (abstract) 2006.

Dissertations

Unobtainable
Adams, J.H. (2001). Effects of written disclosure and problem solving in women with breast cancer. University of Houston, MA.

Anderson, S.S. (2008). The effect of written emotional expression on depression following mild traumatic brain injury : a pilot study. Drexel University, PhD.

Balderson, B.H.K. (2000). The effects of written disclosure on physical and mental health in individuals with asthma. Oklahoma State University, PhD.

Davidson, K. (2003). The effect of emotional disclosure on symptom reporting in repressive coping style. Ohio State University, Hons.

Horgan, M.G. (2004). The effects of written emotional disclosure on disease activity in patients with psoriasis. University of Auckland, MSc.

Khin, N.R. (1996). The influence of thought suppression, writing and emotional disclosure on headache and migraine frequency, duration and severity. University of Auckland, MA.

Lynch, T.J. (2004). The effects of a modified written disclosure protocol on individual bone marrow transplant recipients: psychological and behavioral functioning. Eastern Michigan University, MS.

Macklem, D.J. (2008). Exploration of emotion regulation styles as potential moderators of emotional disclosure in patients with rheumatoid arthritis: Testing a model of emotional expression. Wayne State University, PhD.

Metzger, A. (1991. A comparison of verbal and written expression in early Alzheimer's disease. University of Cincinnati, MA.

Stout, R.A. (2008). An analysis of writing content in a web-based guided writing intervention for migraine headaches. Wayne State University, PhD.

McLaughlin, M.S. (2000). The impact of written disclosure on hypertension. Oklahoma State University, MSc.

Wilson, K. Effect of emotional disclosure on cardiac rehabilitation. Ohio State University, MSc thesis, ongoing research (2002).

Hughes, K.N. (2006). Expressive writing and breast cancer: outcomes and linguistic analyses. Utah State University, PhD.

Marston, C.B. (2003). Written emotional expression, and its relation to psychological and physical health variables among people with HIV disease. Alliant International University, PhD.

McElligott, M.D. (2006). Expressive writing as an intervention for adolescents with sickle cell disease. Virginia Consortium for Professional Psychology –Old Dominion University, PhD.

McKenna, M.H. (1997). Symptom as a story teller: migraine headaches and journal writing. Pacifica Graduate Institute, PhD.

Siegel, K.M. (2003). The effects of emotional disclosure on the physical symptoms, healthcare utilization, and psychosocial adjustment in patients with irritable bowel syndrome. Alliant International University -California School of Professional Psychology, San Diego, PhD.

Stark, H.G. (2009). Expressive writing as an adjunct to multidisciplinary pain treatment in chronic pain patients. Alliant International University, PhD.

Obtainable and eligible yet excluded

Averill, A. J. (2007). Emotional disclosure in patients with amyotrophic lateral sclerosis: A randomized, controlled trial. University of Kentucky, PhD.

Bodor, N. Z. (2002). The health effects of emotional disclosure for individuals with type 1 diabetes. The University of Texas at Austin, PhD.

Craft, M. (2006) Expressive writing in newly diagnosed breast cancer patients. Texas Woman's University, PhD.

Gadler, D. (2005). The effects of written emotional expression on health-related quality of life and cognitive processing in early-stage breast cancer patients: an exploratory study. Alliant International University, PhD.

Possemato, K. A. 2007 An Internet-based expressive writing intervention for kidney transplant recipients Drexel University, Ph.D.

Taylor, E. (2001). Improving the perceived psychological well-being of seniors with Type 2 diabetes through participation in two innovative programs. California School of Professional Psychology - Fresno, Psy.D.

Woods, K. (2010). The effects of written and verbal emotional expression on cancer patients' health. Indiana University of Pennsylvania. Psy.D.

Appendix D: Screening decision check tables

Original search: Spotcheck of references for which no clear decision could be made

Study	**Search Type** (article type)	**Obtained** (Title or abstract?)	**Reviewer 1** (I=include/ obtain further info E=exclude)		**Reviewer 2** (I=include/ obtain further info E=exclude)		**Agreement** A=agreed D=disagreed	**Consensus (if initially D)**
Anonymous (1999)	Endnote (published article).	Title	E	News article unlikely writing intervention trial.	E	News article unlikely writing intervention trial.	A	
Agee et al (2003)	Google (conference proceeding –Association for Behavioural and Cognitive Therapies).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	
Agee et al (2006)	Google (conference proceeding – association for the Advancement of Behavior Therapy).	Title	E	No indication physically ill sample and unlikely experimental design.	E	No indication physically ill sample.	A	
Allen, RK (1993)	Google (published article).	Title	E	No indication physically ill sample or experimental study.	E	No indication physically ill sample or experimental study.	A	
Anderson et al (2006)	Endnote (conference proceeding).	Title	E	Theoretical article –not an intervention study.	E	Theoretical article –not an intervention study.	A	
Antoni, MH (1995)	Endnote (APS conference proceeding).	Title	E	Nothing in title to indicate sample physically ill.	E	Unlikely sample physically ill.	A	
Baker & Guttfreund (1993)	Endnote (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Bolton, et al (2000)	Endnote (published article).	Title	E	More likely literature review as 2 pages and title doesn't suggest intervention study.	E	Not likely intervention study.	A	
Bower, et al	Endnote (published paper).	Title	E	Bereavement – unlikely	E	Bereavement – unlikely	A	

(2003)				sample physically ill.		sample physically ill.		
Burshteyn, D (2006)	Hand searching (APS 2006 conference poster).	Abstract	E	No indication physically ill sample from abstract so unlikely.	E	No indication physically ill sample from abstract so unlikely.	A	
Burt, CDB (1994)	Endnote (published article).	Abstract	E	Anxious/stressed sample –unlikely physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Caplan et al (2005)	Endnote (published article).	Abstract	E	Loss in later life – sample unlikely physically ill if not mentioned in abstract.	E	Loss in later life – sample unlikely physically ill if not mentioned in abstract.	A	
Carey, L (2005)	Endnote (published article).	Abstract	E	Not an experimental design.	E	Not an experimental design.	A	
Danoff-Burg et al (2001)	Google (APA conference proceeding).	Title	E	No indication writing intervention and benefit finding.	E	No indication writing intervention.	A	
da Vicente et al (2004)	Google (published article).	Abstract	E	Homeless people –not physically ill.	E	Homeless people –not physically ill.	A	
Davison & Pennebaker (1992)	Google (published article).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	
Dellasega, CA (2001)	Endnote (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Dickerhoof (2004)	Hand searching (APA conference proceeding).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Donnelly & Murray (1991)	Endnote (published article).	Title	E	Unlikely intervention trial or physically ill.	E	Unlikely intervention trial or physically ill.	A	
Esterling et al (1995)	Google (APS conference proceeding).	Title	I	Latent herpes virus infection –could possibly be considered a physical condition (i.e. is a chronic infection that flares up occasionally).	E	Not a physically ill sample.	D	E Possibly chronically physically ill sample but title does not suggest writing

								or experimental design, and is conference proceeding from 1995. Likely study not published as not picked up by search. Not worth attempting to find.
Evers et al (1999)	Endnote (published article).	Title	I	Although not explicit from title likely experimental study with health outcomes.	I	May meet criteria.	A	E Got conference abstract - not an intervention in which participants write (receive written information)
Francis & Pennebaker (1992)	Google (published article).	Title	E	Illness prevention -no indication physically ill sample.	E	Illness prevention -no indication physically ill sample.	A	
Frattaroli, J (2004)	Hand searching (APA conference proceeding).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Gallagher & MacLachlan (2002)	Endnote (published article)	Abstract	I	Include for now –lower limb amputees physically ill?	E	Not an experimental design?	D	I Not clear obtain further information
Gidron et al (2002)	Endnote (published paper).	Abstract	E	Frequent clinic attenders –don't have a physical condition?	I	Physically ill sample – may meet criteria.	D	I Include for now as could have somatic illness
Gidron et al (2004)	Hand searching (ICBM 2004 conference	Abstract	I	Refers to a study of written guided	I	Refers to a study of written guided	A	

	proceeding).			disclosure on infectious symptoms –physically ill sample? Also experimental design / writing and talking?		disclosure on infectious symptoms –physically ill sample?		
Greenberg et al (1996)	Pennebaker ref (published article).	Title	E	No indication physically ill sample from title – unlikely.	E	No indication physically ill sample from title – unlikely.	A	
Greenberg & Stone (1990)	Endnote (published article).	Title	E	No indication from title sample physically ill – esp. given date.	E	No indication from title sample physically ill.	A	
Hannay & Gillie (1999)	Hand searching (published article).	Title	I	May meet criteria.	I	May meet criteria.	A	
Harvey & Farrrell (2003)	Endnote (published article).	Title	I	Poor sleepers - counting this as a physical condition for now.	I	Poor sleepers -counting this as a physical condition for now.	A	
Heffner et al (2006)	Hand searching (APS conference poster).	Abstract	E	Older adults -unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Hockemeyer & Smith (2002)	Endnote (published article).	Abstract	I	For now – may meet criteria.	I	For now – may meet criteria.	A	
Horowitz, S (2000)	Endnote (published article).	Title	E	No indication writing intervention trial or sample physically ill from title.	E	No indication writing intervention trial or sample physically ill from title.	A	
Junghaenel et al (2008)	Hand searching (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Kalb, C (1999)	Endnote (published article).	Title	E	Likely literature overview rather than intervention trial and unlikely sample is physically ill.	E	Likely literature overview rather than intervention trial and unlikely sample is physically ill.	A	
Kellogg, RT (2006)	Hand searching (APS 2006 conference poster).	Abstract	E	No indication physically ill sample from abstract so unlikely.	E	No indication physically ill sample from abstract so unlikely.	A	
Klapow et al	Endnote (published article).	Title	E	Physical symptoms not	I	Older primary care	A	E

(2001)				used as selection criteria –included both healthy and with somatic symptoms…but don't know whether this means they had physical conditions just assuming this is likely given their age?		patients.		Sample not physically ill – whole sample required to be defined by illness –if some healthy people included do not include.
Kraft et al (2008)	Hand searching (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Kroner-Herwig et al (2004)	Endnote (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Kroner-Herwig et al (2004)	Translated title/hand searching (published article).	Title	E	Same as reference below -unlikely sample physically ill.	E	Unlikely sample physically ill.	A	
L'Abate et al (in press)	Hand searching (article in press).	Title	E	Unlikely physically ill participants and experimental design.	E	Unlikely physically ill participants and experimental design.	A	
Laccetti, M (2007)	Endnote (published article).	Abstract	E	Correlational study –not experimental design.	E	Correlational study –not experimental design.	A	
Lammerts van Bueren, N (2007)	Endnote (published article).	Abstract	E	Patients with anxiety disorder –unlikely physically ill if not mentioned in abstract.	E	Patients with anxiety disorder –unlikely physically ill if not mentioned in abstract.	A	
Lanceley, A (1995)	Endnote (conference proceeding).	Title	E	Unlikely a writing intervention –disclosure between people.	E	Unlikely a writing intervention.	A	
Landhuis, E (2004)	Hand searching (ICBM 2004 conference proceeding).	Abstract	E	No indication of sample used – unlikely physically ill if not mentioned in abstract.	E	No indication of sample used – unlikely physically ill if not mentioned in abstract.	A	
Lowe et al (2003)	Google (published article).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	
Low et al (2006)	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	

Lumley et al (1999)	Hand searching (APS conference proceeding).	Abstract	E	College students with high physical symptoms –not physical condition.	E	College students with high physical symptoms –not physical condition.	A	
Lumley & Provenzano (2003)	Endnote (published article).	Abstract	E	College students with physical symptoms – not physical condition.	E	College students with physical symptoms – not physical condition.	A	
MacDuff & West (2002)	Google (published article).	Title	E	No indication physically ill sample or experimental study.	E	No indication physically ill sample or experimental study.	A	
Mackenzie et al (2007)	Pennebaker ref (published article).	Title	E	Family caregivers of older adults –not physically ill.	E	Family caregivers of older adults –not physically ill.	A	
Manier & Olivares (2005)	Pennebaker ref (published article).	Title	E	No indication physically ill sample from title – unlikely.	E	No indication physically ill sample from title – unlikely.	A	
Marston, CB (2004)	Hand searching (APA conference proceeding).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Martinez-Sanchez	Translated title/hand searching (published article).	Title	E	No indication physically ill or writing intervention.	E	No indication physically ill or writing intervention.	A	
Mastel-Smith (2004)	Endnote (published article?).	Abstract	E	People over 60 years – unlikely sample physically ill if not mentioned in abstract.	E	People over 60 years – unlikely sample physically ill if not mentioned in abstract.	A	
Mastel-Smith et al (2007)	Endnote (published article?).	Abstract	E	People over 60 years – unlikely sample physically ill if not mentioned in abstract.	E	People over 60 years – unlikely sample physically ill if not mentioned in abstract.	A	
McGihon, NN (1996)	Endnote (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Mosher et al (2004)	Google (APA conference proceeding).	Title	E	No indication physically ill sample, and although 1 author has done WED research with cancer patients unlikely this is a separate trial.	E	No indication physically ill sample.	A	

Murray et al (1989)	Endnote (published article).	Title	E	No indication physically ill sample from title esp. given the date- unlikely.	E	No indication physically ill sample from title – unlikely.	A	
Nazarian et al (2006)	Endnote (APS conference proceeding).	Abstract	E	Community adults – unlikely physically ill if not mentioned in abstract.	E	Community adults – unlikely physically ill if not mentioned in abstract.	A	
O'Cleirigh, C (2000)	Endnote (published article).	Abstract	I	Not possible to identify whether experimental trial or correlational study.	I	Not possible to identify whether experimental trial or correlational study.	A	
O'Cleirigh et al (2002)	Hand searching (conference proceeding).	Title	I	Not possible to identify whether experimental trial or correlational study.	I	Not possible to identify whether experimental trial or correlational study.	A	
O'Cleirigh et al (2008)	Handsearch (published article).	Abstract	I	Not possible to identify whether experimental trial or correlational study.	I	Not possible to identify whether experimental trial or correlational study.	A	
O'Connor (2006)	Google (conference proceeding).	Title	E	No indication physically ill sample from title – unlikely.	E	No indication physically ill sample from title – unlikely.	A	
O'Connor & Ashley (2007)	Google (published article).	Abstract	E	No indication of sample used – unlikely physically ill if not mentioned in abstract.	E	No indication of sample used – unlikely physically ill if not mentioned in abstract.	A	
O'Heeron, RC (1992)	Hand searching (APA conference proceeding).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Pace, BJ (2002)	Endnote (thesis).	Abstract	E	Smokers -unlikely physically ill if not mentioned in abstract.	E	Smokers –unlikely physically ill if not mentioned in abstract.	A	
Palmer & Braud (2002)	Pennebaker ref (published article).	Title	E	No indication physically ill sample from title – unlikely. Unlikely writing intervention of experimental design.	E	No indication physically ill sample from title – unlikely.	A	
Pennebaker, JW (1991)	Google (published article).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	

Pennebaker, JW (1998)	Endnote (published article).	Title	E	2 pages –more likely literature overview.	E	Unlikely writing intervention trial.	A	
Pennebaker, JW (1999)	Translated title/hand searching (published article).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Pennebaker, JW (2001)	Google (published article).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	
Pennebaker & Campbell (2000)	Google (published article).	Title	E	No indication physically ill sample.	E	No indication physically ill sample.	A	
Pizarro, J (2004)	Endnote (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Ritz et al (1995)	Hand searching (conference proceeding).	Title	I	Not possible to identify whether experimental trial or correlational study.	I	Not possible to identify whether experimental trial or correlational study.	A	E Got abstract – not a writing intervention.
Rivkin & Stanton (1998)	Endnote (APS conference proceeding).	Title	E	Nothing to indicate physically ill sample from title.	E	Unlikely physically ill sample.	A	
Sangsue, J (1999)	Translated title/ hand searching (thesis).	Title	E	No indication physically ill.	E	No indication physically ill.	A	
Schilte et al (2001)	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Schoutrop et al (1999)	Hand searching (conference proceeding).	Abstract	E	Traumatised persons unlikely physically ill if not mentioned in abstract.	E	Traumatised people.	A	
Schoutroup et al (2002)	Hand searching (published article).	Abstract	E	Unlikely sample physically ill if not mentioned in abstract.	E	Unlikely sample physically ill if not mentioned in abstract.	A	
Schwartz & Kline (1994)	Endnote (APA conference proceeding).	Title	E	More likely a literature review than intervention trial.	E	More likely a literature review than an intervention trial.	A	
Segal et al (1999)	Pennebaker ref (published article).	Title	E	Spousal loss among older adults –unlikely physically ill.	E	Spousal loss among older adults –unlikely physically ill.	A	
Segal et al	Pennebaker ref (published	Title	E	Bereaved older adults –	E	Bereaved older adults –	A	

(2001)	article).			unlikely physically ill.		unlikely physically ill.		
Sloan & Marx (2006)	Google (published article).	Abstract	E	Trauma related psychopathology –not physically ill.	E	Trauma related psychopathology –not physically ill.	A	
Sloan et al (2002)	Hand searching (published article).	Title	E	Unlikely physically ill sample.	E	Unlikely physically ill sample.	A	
Smith et al (2005)	Endnote (published article).	Abstract	E	Not an experimental design.	E	Realised not an experimental design.	A	
Smyth & Nazarian (2006)	Endnote (published article).	Title	I	Title meets criteria.	I	Title meets criteria.	A	
Smyth et al (2002)	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Solano et al (2003)	Endnote (published article).	Abstract	I	Urology inpatients waiting to undergo papilloma resection – physically ill?	I	Urology inpatients waiting to undergo papilloma resection – physically ill?	A	
Stanton, AL (2005)	Google (APS 2005 conference poster).	Abstract	I	No indication of sample used – but author known to conduct WED studies with cancer patients.	E	No indication of sample used – unlikely physically ill if not mentioned in abstract.	D	E Unlikely physically ill if not mentioned in abstract.
Stanton et al (1997)	Hand searching (conference proceeding).	Title	I	Not possible to identify whether experimental trial or correlational study.	I	Not possible to identify whether experimental trial or correlational study.	A	
Stanton et al (1999)	Had already (conference proceeding).	Title	I	Possibly experimental intervention or correlational study.	I	Possibly experimental intervention or correlational study.	A	
Stone et al (2000	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Taylor, DN (1995)	Hand searching (published paper).	Title	I	Title indicates could meet criteria obtain further info.	I	Title indicates could meet criteria obtain further info.	A	
Uhlmann et al (1995)	Translated title/google (published article).	Title	E	No indication physically ill and possibly verbal disclosure.	E	No indication physically ill and possibly verbal disclosure.		A
Ullrich &	Pennebaker ref (published	Title	E	No indication physically	E	No indication physically	A	

Lutendorf (2002)	article).			ill sample from title – unlikely.		ill sample from title – unlikely.		
Van Middendorp et al (2007)	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Vance, T (1999)	Endnote (published article).	Title	E	More likely literature review –unlikely experimental study with physically ill sample.	E	More likely literature review –unlikely experimental study with physically ill sample.	A	
Vedhara, K (2004)	Hand searching (?).	Title	E	No indication sample likely physically ill from title and even if it was unlikely to be a different trial to later psoriasis trial (2007) by same author.	E	Unlikely sample physically ill.	A	
Wetherell, MA et al (2005)	Endnote (published article).	Abstract	I	May meet criteria.	I	May meet criteria.	A	
Wolf, M (1999)	Endnote (published article).	Title	E	Nothing to indicate likely physically ill sample from title.	E	Nothing to indicate likely physically ill sample from title.	A	
Woods et al (1999)	Endnote (Annual Congress of the Oncology Nursing Society 1999 conference proceeding).	Title	E	Title doesn't suggest this is an intervention.	E	Title doesn't suggest this is an intervention.	A	

Original search: Full papers obtained

Study	**Search Type** (article type)	**Obtained** (Title or abstract?)	**Reviewer 1** (I=include/ obtain further info E=exclude)		**Reviewer 2** (I=include/ obtain further info E=exclude)		**Agreement** A=agreed D=disagreed	**Consensus (if initially D)**
Broderick et al (2004)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Broderick et al (2005)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Bruera et al (2008)	Cited ref search alert post download to Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	E Decided at data extraction to impose at least 1 week post int. follow up restriction.
Cameron, LD (1998)	Hand searching (EHPS conference proceeding).	Abstract (detailed)	E	Intervention is WED plus other aspects of self regulation.	E	Self regulation intervention.	A	
Cepeda et al (in press)	Ongoing Research Database –now completed (in press, published article obtained in search update).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Cohen et al (in preparation)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Creswell et al (2007)	Endnote (published article).	Full paper	I	Meets all criteria (length of writing sessions not reported but says same as Pennebaker & Beall).	I	Meets all criteria.	A	E Later realised secondary analysis for Stanton 2002 paper.
Danoff-Burg et al (2006)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
DeMoor et al (2002)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	

D'Souza et al (under review)	Endnote (under review, published article obtained in search update).	Full paper	E	Meets all criteria –but no psychological health/QoL outcome.	E	Meets all criteria –but no psychological health/QoL outcome.	A	
Freyd et al (2005)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	E Later decision to exclude as the comparison and results presented do not allow for isolating the effects of WED (i.e. 2 WED & 2 CTL groups –different treatment within WED and control groups so cannot combine -but results presented for overall WED and control groups only)
Gallagher & MacLachlan (2002)	Endnote (published article).	Full paper	E	Intended to be an experimental design but both groups emotionally disclosed so treated writing as one continuous variable.	E	Intended to be an experimental design but both groups emotionally disclosed so treated writing as one continuous variable.	A	
Gidron et al (2002)	Endnote (published paper).	Full paper	E	Frequent clinic attenders with no known chronic physical illness –whole sample not defined by a	E	Whole sample not defined by a chronic physical condition.	A	

				chronic physical condition.				
Gillis et al (2006)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Graham, JE (2004)	Endnote (dissertation –later received draft article, obtained published paper in search update).	Full paper	E	Don't write for at least 3 days –only 2 and directed letter format/anger expression component.	E	Don't write for at least 3 days –only 2 and directed letter format/anger expression component.	A	
Hamilton-West & Quine (2007)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Hannay & Gillie (1999)	Hand searching (published article).	Full paper	E	Anxious depressed sample –no mention physically ill.	E	Anxious depressed sample –no mention physically ill.	A	
Hartke et al (2007)	Hand searching (published article).	Full paper	E	No indication whole trial RCT –just initial phase that is barely described –paper describes the second phase and writing groups.	E	No indication whole trial RCT –just initial phase that is barely described –paper describes the second phase and writing groups.	A	
Harris et al (2005)	Endnote (published article).	Full paper	E	Meets all criteria –but no psychological health/QoL outcome.	E	Meets all criteria –but no psychological health/QoL outcome.	A	
Harvey & Farrell (2003)	Endnote (published article).	Full paper	I	Include for now – meets all criteria.	I	Include for now - meets all criteria.	A	E Later decision to exclude as unclear whether poor sleep is chronic physical condition – may be acute (i.e. exam stress) so otherwise health sample (& no psychological

								outcome).
Hockemeyer & Smyth (2002)	Endnote (published article).	Full paper	E	Emotional disclosure writing included as part of CBT intervention.	I	Meets all criteria.	D	E Later decision to exclude as effect of WED cannot be isolated from relaxation/CBT intervention – groups received different treatment other than WED
Junghaenel et al (2008)	Hand searching (published article).	Full paper	E	Secondary analysis of a trial already received.	E	Secondary analysis of a trial already received.	A	
Kraft et al (2008)	Hand searching (published article).	Full paper	E	Secondary analysis of a trial already received.	E	Secondary analysis of a trial already received.	A	
Low et al (2006)	Endnote (published article).	Full paper	E	Secondary analysis of a trial already received.	E	Secondary analysis of a trial already received.	A	
Mann, T (2001)	Endnote (published article).	Full paper	E	Writing about a positive future not disclosing emotions about a traumatic event.	E	Writing about a positive future not disclosing emotions about a traumatic event.	A	
McGuire et al (2005)	Endnote (published article).	Full paper	E	High to moderately elevated blood pressure –not a chronic physical illness.	E	Not a chronic physical illness.	A	
Norman et al (2004)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
O'Cleirigh, C (2000)	Endnote (published article).	Full paper	E	Not an experimental design –2 different groups compared – relationship between level of emotional disclosure and health status.	E	Not an experimental design –2 different groups compared – relationship between level of emotional disclosure and health status.	A	
O'Clerigh et al	Hand searching	Full paper	E	Not an experimental	E	Not an experimental	A	

(2002)	(conference proceeding).			study of writing intervention –case control.		study of writing intervention –case control.		
O'Cleirigh et al (2008)	Handsearch (published article).	Full paper	E	Not an experimental design –2 different groups compared – relationship between level of emotional disclosure and health status.	E	Not an experimental design –2 different groups compared – relationship between level of emotional disclosure and health status.	A	
Panagopoulou et al (in preparation)	Hand searching (ICBM conference proceeding).	Powerpoint presentation –study not yet written up?	I	Meets all criteria –info limited author offered to provide more.	E	IVF is a chronic condition but not physical illness – sample not physically ill.	D	E IVF is a chronic condition but not physical illness
Petrie et al (2004)	Endnote (published article).	Full paper	E	Meets all criteria –but no psychological health/QoL outcome.	E	Meets all criteria –but no psychological health/QoL outcome.	A	
Rivkin et al (2006)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Rosenberg et al (2002)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Schilte et al (2001)	Endnote (published article).	Full paper	E	Not a writing intervention –verbal disclosure in meetings with Dr and diary keeping in between. Frequent clinic attendees with somatisation symptoms not explained by organic disease and serious physical conditions excluded.	E	Not a writing intervention –verbal disclosure in meetings with Dr and diary keeping in between. Frequent clinic attendees with somatisation symptoms not explained by organic disease and serious physical conditions excluded.	A	
Smyth et al (1999)	Endnote (published article).	Full paper	E	Meets all criteria –but no psychological health/QoL outcome.	E	Meets all criteria –but no psychological health/QoL outcome.	A	
Smyth et al	Endnote (published article).	Full paper	E	Secondary analysis of	E	Secondary analysis of	A	

(2002)				a trial already received		a trial already received.		
Smyth & Nazarian (2006)	Endnote (published article).	Full paper	E	Not a RCT –case control (2 trauma writing and 2 neutral writing).	E	Not a RCT.	A	
Solano et al (2003)	Endnote (published article).	Full paper	E	Urology patients waiting to undergo papilloma resection – but exclusion criteria was total absence of any chronic disease that may influence post operative course.	E	Authors specifically chose to investigate the effect of writing on surgical course rather than chronic conditions.	A	
Solano et al (2007)	Endnote (published article).	Full paper	E	Sample undergoing endoscopic operation TURP for benign prostatic hypertrophy – not cancerous –not chronic physical illness.	E	Not a chronic physical illness.	A	
Stanton et al (1997)	Hand searching (conference proceeding).	Full paper	E	Preliminary report of later published trial (Stanton et al).	E	Preliminary report of later published trial (Stanton et al).	A	
Stanton et al (1999)	Had already (conference proceeding).	Neither	E	Author contacted for full paper and confirmed longitudinal design.	E	Author contacted for full paper and confirmed longitudinal design.	A	
Stanton et al (2002)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Stone et al (2000	Endnote (published article).	Full paper	E	Secondary analysis of a trial already received.	E	Secondary analysis of a trial already received.	A	
Taylor, DN (1995)	Hand searching (published paper).	Full paper	E	Not a writing intervention.	E	Not a writing intervention.	A	
Taylor et al (2003)	Endnote (published article).	Full paper	E	Meets all criteria but NB 1/3 of participants aged 15 and above.	I	Meets all criteria.	D	I
Van Middendorp et al (2007)	Endnote (published article).	Full paper	E	Verbal disclosure intervention.	E	Verbal disclosure intervention.	A	

Vedhara et al (2007)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Walker et al (1999)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Warner et al (2006)	Endnote (published article).	Full paper	E	Sample aged 12-17 – not adults over 18.	E	Sample not adults over 18.	A	
Wetherell et al (2005)	Endnote (published article).	Full paper	I	Meets all criteria (some participants verbally disclosed but very few and only as could not write).	I	Meets all criteria.	A	
Zakowski et al (2004)	Endnote (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	

Search update: Spotcheck of references for which no clear decision could be made

Study	**Search Type** (article type)	**Obtained** (Title or abstract?)	**Reviewer 1** (I=include/ obtain further info E=exclude)		**Reviewer 2** (I=include/ obtain further info E=exclude)		**Agreement** A=agreed D=disagreed	**Consensus (if initially D)**
? Girl Talk	Endnote (published article).	Title	E	Title does not indicate this is a writing intervention with experimental design and health outcome assessed.	E	Title does not indicate this is a writing intervention with experimental design and health outcome assessed.	A	
NAMI (2008)	Endnote (published article).	Title	E	Nothing in title to indicate sample physically ill.	E	Nothing in title to indicate sample physically ill.	A	
Ames et al (2007)	Endnote (published article).	Title	E	Nothing in abstract to indicate sample physically ill.	E	Nothing in abstract to indicate sample physically ill.	A	
Ames et al (2008)	Endnote (published article).	Abstract	E	Nothing in abstract to indicate sample physically ill.	E	Nothing in abstract to indicate sample physically ill.	A	
Andersen et al (2007)	Journal hand searching (published article).	Abstract	I	May meet criteria – can't tell if writing intervention?	E	Not likely writing intervention.	D	E Not likely writing intervention
Arden-Close et al (2008)	Conference proceedings hand searching (DHP/EHPS conference abstract).	Abstract	I	May meet criteria.	E	Couples write rather than one person.	D	I May meet criteria
Austenfeld & Stanton (2008)	Endnote (published article).	Title	E	Not physically ill.	E	Not physically ill.	A	
Baikie (2008)	Endnote (published article).	Title	E	Not physically ill.	E	Not physically ill.	A	
Baker & Berenbaum (2008)	Endnote (published article).	Title	E	Not physically ill and not clear whether writing intervention.	E	Not physically ill.	A	
Bantum &	Endnote (published article).	Abstract	E	Unlikely experimental	E	Unlikely experimental	A	

Owen (2009)				design or health outcome assessed.		design or health outcome assessed.		
Barak et al (2008)	Endnote (published article).	Abstract	E	Review –and not physically ill / unlikely experimental design.	E	Review –and not physically ill / unlikely experimental design.	A	
Barrowclough et al (2008)	Endnote (published article).	Abstract	E	Not physically ill, not writing intervention and not experimental design.	E	Not physically ill, not writing intervention and not experimental design.	A	
Barton & Jackson (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Basso & Peach(2008)	Endnote (published article).	Abstract	E	Not writing intervention or experimental design.	E	Not writing intervention or experimental design.	A	
Bingley et al (2008)	Endnote (published article).	Abstract	E	Review –and not experimental design.	E	Review.	A	
Blank & Adams-Blodnieks (2007)	Endnote (published article).	Abstract	E	Not an experimental design and no health outcome assessed.	E	Not an experimental design and no health outcome assessed.	A	
Brown et al (2010)	Search Alert POST UPDATE (published article).	Abstract	I	Not clear whether a RCT –get further information.	I	Not clear whether a RCT –get further information.	A	
Brun, A (2008)	Endnote (published article).	Abstract	E	Nothing in the title to indicate physically ill, experimental design and no health outcome assessed.	E	Nothing in the title to indicate physically ill, experimental design and no health outcome assessed.	A	
Bonanno et al (2007)	Endnote (published article).	Abstract	E	Not physically ill, experimental design or writing intervention.	E	Not physically ill, experimental design or writing intervention.	A	
Butcher, H (2008)	Endnote (published article).	Abstract	E	Nothing in title to indicate physically ill or experimental design.	E	Nothing in title to indicate physically ill or experimental design.	A	
Cameron & Jago (2008)	Endnote (published article).	Abstract	E	Review.	E	Review.	A	
Carlson & Bultz (2008)	Endnote (published article).	Abstract	E	Review –and not physically ill or writing	E	Review.	A	

				intervention.				
Chung & Pennebaker (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Cohen et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Crogan at al (2008)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Cushen, N (?)	Contacting authors re: potentially completed ongoing trial found in hand searching for update (i.e. now completed) (NRR document).	Title	E	Unlikely experimental design.	E	Unlikely experimental design.	A	
Dalton & Glenwick (2009)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Dean & Rotenberg (2008)	Endnote (conference abstract?).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
De Ridder et al (2008)	Endnote (published article).	Abstract	E	Review –and not experimental design or writing intervention.	E	Review.	A	
Dennis et al (2008)	Endnote (published article).	Abstract	E	Not writing intervention, experimental design and no health outcome assessed.	E	Not writing intervention, experimental design and no health outcome assessed.	A	
Dorr et al (2007)	Endnote (published article).	Abstract	E	Not writing intervention or experimental design.	E	Not writing intervention or experimental design.	A	
Ehrenreich et al (2007)	Endnote (published article).	Abstract	E	Not experimental design and no health outcome assessed.	E	Not experimental design and no health outcome assessed.	A	
Evans et al (2008)	Endnote (published article).	Abstract	E	Not writing intervention and no health outcome assessed.	E	Not writing intervention and no health outcome assessed.	A	
Finset, A (2007)	Endnote (World Congress on Psychosomatic Medicine conference abstract).	Title	E	Not writing intervention, experimental design and no health outcome	E	Not writing intervention, experimental design and no health outcome	A	

				assessed.		assessed.		
Fraas & Balz (2008)	Endnote (published article).	Abstract	E	Unlikely experimental design.	E	Unlikely experimental design.	A	
Garlock M (2008)	Endnote (published article).	Title	E	Nothing in title to say sample physically ill or health outcome assessed.	E	Nothing in title to say sample physically ill or health outcome assessed.	A	
Giese-Davis et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention or experimental design.	E	Not a writing intervention or experimental design.	A	
Gillanders et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention or experimental design.	E	Not a writing intervention or experimental design.	A	
Gordon JS (2008)	Endnote (published article).	Abstract	E	Review –and not a writing intervention.	E	Review.	A	
Gortner, et al (2005)	Endnote (Conference on Clinical Cognition conference abstract).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Greenberg MA (2008)	Endnote (published article).	Abstract	E	Book - not physically ill.	E	Book.	A	
Guastella & Dadds (2008)	Endnote (published article).	Abstract	E	Not physically ill and no health outcome assessed.	E	Not physically ill and no health outcome assessed.	A	
Hamill et al (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Harrison, & Barlow (2009)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Hathaway et al (2008)	Conference proceedings hand searching (Association for Psychological Science conference abstract).	Abstract	E	Unlikely physically ill if not mentioned in abstract and unlikely health outcome assessed.	E	Unlikely physically ill if not mentioned in abstract and unlikely health outcome assessed.	A	
Haug et al (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome	E	Not physically ill, experimental design and no health outcome	A	

				assessed.		assessed.		
Hauwel-Fantini & Pedinielli (2008)	Endnote (published article).	Title	E	Nothing in the title to indicate sample physically ill, writing intervention, experimental design and health outcome assessed.	E	Nothing in the title to indicate sample physically ill, writing intervention, experimental design and health outcome assessed.	A	
Henry et al (2009)	Endnote (published article).	Abstract	E	Not writing intervention and no health outcome assessed.	E	Not writing intervention and no health outcome assessed.	A	
Holtslander & Duggleby (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Horn et al (2007)	Endnote (conference abstract?).	Title	I	May meet criteria – can't tell if sample physically ill, experimental design or health outcome assessed?	E	Unlikely sample physically ill, experimental design or health outcome assessed.	D	E Unlikely sample physically ill, experimental design or health outcome assessed
Horneffer & Chen (2009)	Endnote (published article).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Horowitz, S (2008)	Endnote (published article).	Title	E	Review.	E	Review.	A	
Kay-raining Bird et al (2008)	Endnote (published article).	Abstract	E	Not physically ill and no health outcome assessed.	E	Not physically ill and no health outcome assessed.	A	
Keefe et al (2008)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Kerner & Fitzpatrick (2007)	Endnote (published article).	Abstract	E	Review –and not physically ill, experimental design and no health outcome assessed.	E	Review.	A	

Kim, Y (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Kloos & Daly (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Ko & Kuo (2009)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Krantz & Pennebaker (2007)	Endnote (published article).	Abstract	E	Book - not physically ill.	E	Book.	A	
Kusumi et al (2008)	Endnote (International Symposium on Universal Communication conference abstract).	Abstract	E	Not experimental design.	E	Not experimental design.	A	
Lieberman, M (2007)	Endnote (published article).	Abstract	E	Not experimental design and no health outcome assessed.	E	Not experimental design and no health outcome assessed.	A	
Lieberman, MA (2008)	Endnote (published article).	Abstract	E	Not experimental design.	E	Not experimental design.	A	
Lieberman, MA (2008)	Endnote (published article).	Abstract	E	Not experimental design.	E	Not experimental design.	A	
Liess et al (2008)	Endnote (published article).	Abstract	E	Not experimental design and no health outcome assessed.	E	Not experimental design and no health outcome assessed.	A	
Litt et al (2009)	Contacting authors re: potentially completed ongoing trial found in hand searching for update (i.e. now completed) (published article).	Abstract	E	This paper reports the process of rather than final outcomes of the ongoing trial that was requested (i.e. final outcomes not available yet). However, not a writing intervention.	E	This paper reports the process of rather than final outcomes of the ongoing trial that was requested (i.e. final outcomes not available yet). However, not a writing intervention.	A	
Lonardi, C (2007)	Endnote (published article).	Abstract	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Lumley et al (2008)	Google (published article).	Abstract	I	May meet criteria – can't tell if writing intervention/experiment	E	Not likely writing intervention.	D	E Not likely writing

				al design.				intervention.
Mackenzie et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Magai et al (2009)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Mainous et al (2009)	Endnote (published article).	Title	E	Nothing in the title to indicate sample physically ill, writing intervention, experimental design and health outcome assessed.	E	Nothing in the title to indicate sample physically ill, writing intervention, experimental design and health outcome assessed.	A	
Manna et al (2007)	Endnote (published article).	Title	E	Book – and not clear whether writing intervention or experimental design.	E	Book.	A	
Manne et al (2007)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Manne et al (2008)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Mantel, H (2009)	Endnote (published article).	Title	E	Nothing in the title to indicate experimental design and health outcome assessed.	E	Nothing in the title to indicate experimental design and health outcome assessed.	A	
Mathews, P (2008)	Endnote (published article).	Title	E	Nothing in the title to indicate sample physically ill, experimental design and health outcome assessed.	E	Nothing in the title to indicate sample physically ill, experimental design and health outcome assessed.	A	
McGuire, B (2009)	Google (Cochrane review protocol).	Abstract	E	Review.	E	Review.	A	
McNess, A (2008)	Endnote (published article).	Abstract	E	Not a writing intervention, physically ill, experimental design and no health outcome assessed.	E	Not a writing intervention, physically ill, experimental design and no health outcome assessed.	A	
Mehl-	Endnote (published article).	Abstract	E	Not writing intervention	E	Not writing intervention	A	

Madrona, L (2007)				or experimental design.		or experimental design.		
Meier et al (2007)	Endnote (published article).	Abstract	E	Not experimental design and no health outcome assessed.	E	Not experimental design and no health outcome assessed.	A	
Mills et al (2007)	Endnote (Society of Neuroscience conference abstract).	Title	E	Not writing intervention.	E	Not writing intervention.	A	
Moreira et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention, physically ill or experimental design.	E	Not a writing intervention, physically ill or experimental design.	A	
Morgan et al (2008)	Endnote (published article).	Abstract	E	Not experimental design.	E	Not experimental design.	A	
Murray et al (2008)	Endnote (published article).	Abstract	E	Review –and not physically ill.	E	Review.	A	
Neidtfield et al (2008)	Endnote (published article).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Nicholls, S (2009)	Endnote (published article).	Abstract	E	Review –and not physically ill.	E	Review.	A	
O'Clerigh & Safren (2008)	Endnote (published article).	Abstract	E	Review –and not writing intervention.	E	Review.	A	
O'Connor & Ashley (2008)	Endnote (published article).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Page & Fletcher (2008)	Endnote (published article).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Pakenham, KI (2008)	Journal hand searching (published article).	Abstract	I	May meet criteria – can't tell if writing intervention/experimental design?	E	Not likely writing intervention or experimental design.	D	E Not likely writing intervention or experimental design.
Panton & Marshall (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome	E	Not physically ill, experimental design and no health outcome	A	

				assessed.		assessed.		
Papousek & Schulter (2008)	Endnote (published article).	Abstract	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Park, CL (2008)	Endnote (published article).	Abstract	E	Not physically ill, writing intervention and no health outcome assessed.	E	Not physically ill, writing intervention and no health outcome assessed.	A	
Patterson et al (2007)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Perry, N (2008)	Endnote (published article).	Title	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Preau et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Provine et al (2007)	Endnote (published article).	Abstract	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Ravert & Crowell (2008)	Endnote (published article).	Abstract	E	Not an experimental design and no health outcome assessed.	E	Not an experimental design and no health outcome assessed.	A	
Reinhold-Hurley & Kroner-Herwig (2007)	Endnote (published article).	Title	E	Not physically ill.	E	Not physically ill.	A	
Resick et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Robinson & Serfaty (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	

Roy, EC (2008)	Endnote (published article).	Title	E	Not physically ill.	E	Not physically ill.	A	
Rubin et al (2008)	Google (published article).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Rullkoetter et al (2009)	Endnote (published article).	Abstract	E	Not experimental design and no health outcome assessed.	E	Not experimental design and no health outcome assessed.	A	
Sandgren & McCaul (2007)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Schneider et al (2008)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Schuler et al (2008)	Endnote (International congress of psychology conference abstract).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Seery et al (2008)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Seih et al (2008)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Shaw et al (2008)	Endnote (published article).	Abstract	E	Not experimental design.	E	Not experimental design.	A	
Sierpina et al (2007)	Endnote (published article).	Title	E	Review –and not experimental design or writing intervention.	E	Review.	A	
Sloan et al (2007)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Sloan, DM (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Smith et al (2007)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Smith, B (2007)	Endnote (published article).	Title	E	Nothing in the title to indicate sample physically ill, experimental design and health outcome assessed.	E	Nothing in the title to indicate sample physically ill, experimental design and health outcome assessed.	A	

Smyth & Arigo (2009)	Endnote (published article).	Abstract	E	Review.	E	Review.	A	
Smyth et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Smyth & Pennebaker (2008)	Endnote (published article).	Title	E	Review -and not physically ill.	E	Review.	A	
Solano et al (2008)	Endnote (published article).	Abstract	E	Book.	E	Book.	A	
Steinhauser et al (2008)	Endnote (published article).	Abstract	E	Not writing intervention.	E	Not writing intervention.	A	
Stice et al (2007)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Stice et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Stice et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Swanbon et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Tabibnia et al (2008)	Endnote (published article).	Abstract	E	Not physically ill or writing intervention.	E	Not physically ill or writing intervention.	A	
Talusan, G (2008)	Endnote (published article).	Title	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Tan, L (2008)	Endnote (published article).	Abstract	E	Not physically ill or experimental design.	E	Not physically ill or experimental design.	A	
Tanis, M (2007)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Tanis, M (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Tannenbaum, J (2007)	Endnote (published article).	Title	E	Not a writing intervention, physically ill, experimental design and no health outcome	E	Not a writing intervention, physically ill, experimental design and no health outcome	A	

				assessed.		assessed.		
Theadom et al (2009)	Google (Cochrane review protocol).	Abstract	E	Review.	E	Review.	A	
Thomsen & Jensen (2007)	Endnote (published article).	Abstract	E	Not a writing intervention or experimental design.	E	Not a writing intervention or experimental design.	A	
Tsao et al (2008)	Conference proceedings hand searching (Association for Psychological Science conference abstract).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
van Emmerick et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Van Middendorp et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention or experimental design.	E	Not a writing intervention or experimental design.	A	
Van Middendorp et al (2009)	Endnote (published article).	Abstract	E	Not a writing intervention.	E	Not a writing intervention.	A	
Ward et al (2008)	Journal hand searching (published article).	Abstract	I	May meet criteria – can't tell if writing intervention?	E	Not likely writing intervention.	D	E Not likely writing intervention
Watine, P (2007)	Endnote (published article).	Title	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Watkins et al (2008)	Conference proceedings hand searching (Association for Psychological Science conference abstract).	Abstract	E	Unlikely physically ill if not mentioned in abstract.	E	Unlikely physically ill if not mentioned in abstract.	A	
Watkins et al (2008)	Conference proceedings hand searching (Association for Psychological Science conference abstract).	Abstract	E	Secondary analysis of the above trial.	E	Secondary analysis of the above trial.	A	
Weber & Solomon (2008)	Endnote (published article).	Abstract	E	Not an experimental design and no health outcome assessed.	E	Not an experimental design and no health outcome assessed.	A	

Weinman et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Weinstein & Hodgins (2009)	Endnote (published article).	Abstract	E	Unlikely physically ill or experimental design.	E	Unlikely physically ill or experimental design.	A	
Westling et al (2007)	Endnote (published article).	Title	E	Not an experimental design.	E	Not an experimental design.	A	
Willig et al (2007)	Endnote (published article).	Abstract	E	Not an experimental design and no health outcome assessed.	E	Not an experimental design and no health outcome assessed.	A	
Wise et al (2008)	Endnote (published article).	Abstract	E	Not a writing intervention or experimental design.	E	Not a writing intervention or experimental design.	A	
Wolf et al (2008)	Endnote (published article).	Abstract	E	Not physically ill, experimental design and no health outcome assessed.	E	Not physically ill, experimental design and no health outcome assessed.	A	
Wray et al (2007)	Endnote (published article).	Abstract	E	Not a writing intervention, experimental design and no health outcome assessed.	E	Not a writing intervention, experimental design and no health outcome assessed.	A	
Yamaski et al (2008)	Endnote (published article).	Abstract	E	Not physically ill.	E	Not physically ill.	A	
Yeh et al (2008)	Endnote (published article).	Title	E	Book –and not a writing intervention, physically ill, experimental design and no health outcome assessed.	E	Book.	A	
Yogo & Fujihara (2008)	Endnote (published article).	Abstract	E	Not physically ill and no health outcome assessed.	E	Not physically ill and no health outcome assessed.	A	
Yukawa, S (2008)	Endnote (published article).	Abstract	E	Not a writing intervention, physically ill, experimental design and no health outcome assessed.	E	Not a writing intervention, physically ill, experimental design and no health outcome assessed.	A	

Zolowere et al (2008)	Endnote (published article).	Abstract	E	Not physically ill, writing intervention or experimental design.	E	Not physically ill, writing intervention or experimental design.	A	

Search update: Full papers obtained

Study	**Search Type** (article type)	**Obtained** (Title or abstract?)	**Reviewer 1** (I=include/ obtain further info E=exclude)		**Reviewer 2** (I=include/ obtain further info E=exclude)		**Agreement** A=agreed D=disagreed	**Consensus (if initially D)**
Brown et al (2010)	Search Alert POST UPDATE (published article).	Full paper	E	Not a RCT, no relevant psychological outcome and intervention content not entirely consistent with WED?	E	Not a RCT, no relevant psychological outcome and intervention content not entirely consistent with WED?	A	
Bugg et al (2009)	Endnote (published article).	Full paper	E	Sample not chronically ill.	E	Sample not chronically ill.	A	
Gellaitry et al (2010)	Contacting authors re: potentially completed ongoing trial found in hand searching for update (i.e. now completed)/conference proceeding from original search that was unobtainable (published article).	Full paper	I	Meets all criteria.	E	Women not chronically ill –completed treatment?	D	I Does meet all criteria –not necessarily cured
Jones et al (2008)	Google (conference proceeding).	Abstract	E	Contacted author –still ongoing.	E	Contacted author –still ongoing.	A	
Low et al (2010)	Search Alert POST UPDATE (published article).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	
Mallett, K (2009)	Endnote (published article).	Full paper	E	Description of trial -but not experimental design.	E	Description of trial -but not experimental design.	A	
Theadom et al (2009)	Conference proceedings hand searching (i.e. looking for more details about a relevant abstract and came across this).	Full paper	E	No psychological health outcome assessed.	E	No psychological health outcome assessed.	A	
Wagner et al (2008)	Google/dissertation from original search that was	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	

	unobtainable (published article).							
Willmott et al (under review)	Contacting authors re: conference proceeding (found via bibliographies of included trials in search in update)/potentially completed ongoing trial/manuscript in prep from original search that was unobtainable (paper under review).	Full paper	I	Meets all criteria.	I	Meets all criteria.	A	

Appendix E: Data extraction table

Study design and participant characteristics

(Some studies included more than the two intervention groups that were included in the present review, thus sample sizes are additionally presented for only the included groups. Where studies did not present it by group demographic data are presented for the full sample)

Author (year)	Country	Follow up	No. randomised	Condition	Mean age & Time since diagnosis (SD)	Gender, Ethnicity, Education & Marital Status	Method of recruitment
de Moor et al (2002)	USA.	10 weeks.	42 (WED=21, NEUTRAL WRITING=21).	Metastatic renal cell carcinoma.	Average age: 56.4yrs. Time since diagnosis NOT REPORTED (but cancer advanced).	Gender: 14% Female. Ethnicity NOT REPORTED. Education NOT REPORTED. Marital status NOT REPORTED.	Already enrolled in RCT of vaccine therapy.
Gellaitry et al (2010)	UK.	6 months.	93 (WED=45, CONTROL=48).	Breast cancer.	Mean age: 58 (10)yrs. All diagnosed within previous 12 months (stage I or II).	Gender: 100% Female Ethnicity NOT REPORTED Education NOT REPORTED Marital status NOT REPORTED	Patients attending last radiotherapy appointment at out-patient clinic (i.e. penultimate week of therapy) –provided with study information by consultant.
Low et al (2010)	USA.	3 months.	76 (38 WED; 38 NEUTRAL WRITING).	Metastatic breast cancer.	Mean age: 53.8 (10.3)yrs First diagnosed with cancer 7.9 years ago (67 months); first diagnosed with Stage IV 3.3 years ago (SD 28.1 months).	Gender: 100% Female. Ethnicity: 87% White. Education: 74% college educated. Marital status: 71% married or living as married.	Patients that took part in a previous study if consented to be contacted about future studies; flyers posted in oncology clinics and community breast cancer practice; advertisement posted on online resource for people with metastatic breast cancer.

Rosenberg et al (2002)	USA.	6 months.	30 -implied 15 per group. **But when obtained data from authors seems WED=16; CONTROL=14.**	Prostate cancer.	Mean age: 70.5(5.4)yrs. Time since diagnosis NOT REPORTED (but not acute phase).	Gender: 0% Female. Ethnicity: 97% Caucasian. Education: 97% 12+ yrs. Marital Status: 90% married.	Registered hospital outpatients under observation– researcher approached at appointments.
Walker et al (1999)	USA.	28 weeks.	50 (total sample). **For included groups: 35 (WED=19, CONTROL=16).**	Breast cancer.	**For total sample:** Mean age: 53.6 (29-76)yrs. Time since diagnosis NOT REPORTED (but stage I or II).	**For total sample:** Gender 100% Women. Ethnicity: 95% Caucasian. Education: 79% beyond high school. Marital status: 71% married.	Approached during scheduled visits to university based treatment centres.
Zakowski et al (2004)	USA.	6 months.	127 (WED=74, NEUTRAL WRITING=53).	Gynaecological / prostate cancer.	Mean age: 59.8 (11.1)yrs. Mean time since diagnosis: 1.4 (1.2)yrs (stage I-IV).	Gender: 52% Female. Ethnicity: 95% Caucasian. Education: 46% at least college education. Marital Status: 80% married.	Referred by treating physician at clinics – those interested then contacted by a member of the research group.
Gillis et al (2006)	USA.	3 months.	83 (WED=45, NEUTRAL WRITING=38).	Fibromyalgia.	Mean age: 50.3 (23-72)yrs. Time since diagnosis: 5.9(1-20)yrs.	Gender: 97% Female. Ethnicity: 93% White. Mean education: 2.6 yrs college (all 10th grade ed.). Marital status: 72% married.	Flyers in Rheumatology clinic, announcements at FM support groups and advertisements in AF newsletter.
Norman et al (2004)	USA.	2 months.	60 (WED=32, PW=28).	Chronic pelvic pain.	Mean age: 38.2(11.5)yrs. Duration of CPP 12.7(2.3) yrs.	Gender: 100% Female. Ethnicity: 83% European American. Education: 14.7(2.1)yrs.	Brochures at gynaecology/ pain clinics, mass media advertisements, EA announcements.

						Marital status NOT REPORTED.	
Cohen et al (in prep)	USA.	6 months.	150 (total sample). **For included groups: 113 (WED: 74 (written=37; verbal=37), CONTROL: 39 (written=19; verbal=20).**	Rheumatoid arthritis.	**For total sample:** Mean age: 54.1(11.2)yrs. Mean duration of time with RA: 12(10.6)yrs.	**For total sample:** Gender:87% Females. Ethnicity: 59% Caucasian. Mean education: 13.5(2.7)yrs. Marital status: 59% married/living together.	Directly recruited from 5 local clinics.
Danoff-Burg et al (2006)	USA.	3 months.	75 (total sample). **For included groups: 48 (WED=24, NEUTRAL WRITING=24).**	Systemic lupus erythematosus or Rheumatoid Arthritis.	**For total sample:** Mean age: 51.2(13.3)yrs. Time since diagnosis: 15yrs/modal time <10yrs.	**For total sample:** Gender: 83% Female. Ethnicity: 87% White. Mean education: 15.2(yrs). Marital status: 68% married/long term relationship.	Brochures posted in rheumatologist's offices/sent to mailing lists of local chapters of AF/LFA.
Hamilton-West & Quine (2007)	UK.	3 months.	107 (WED=71, NEUTRAL WRITING=36).	Ankylosing Spondylitis.	Mean age: 52(22-78)yrs. Mean time since diagnosis: 16(0-46)yrs.	Gender: 32% Female. Ethnicity: 97% White. Education NOT REPORTED. Marital status: 72% married.	Charitable organisation (NASS) –newsletter advertisement/ information sent to support groups.
Wetherell et al (2005)	UK.	10 weeks.	Unclear -42 assessed at baseline -no. per group NOT REPORTED.	Rheumatoid arthritis.	Mean age: 60.7 yrs. Mean disease duration: 14.7 yrs.	Gender: 83% Female. Ethnicity NOT REPORTED. Education NOT REPORTED. Marital status: 67% married.	Identified by consultant rheumatologist and approached by researcher.
Vedhara et al	UK.	12	69 –no. per group	Psoriasis.	Mean age: 50(+/-13)yrs.	Gender: 37% Female.	Recruited from

(2007)		weeks.	NOT REPORTED.		Mean length of diagnosis: 22(+-15)yrs.	Ethnicity: 88% White European. Marital status: 73% married. Education: 42% up to university diploma or degree.	dermatology clinics/psoriasis patient groups/advert in local newspaper.
Taylor et al (2003)	USA.	3 months.	70 –no. per group NOT REPORTED.	Cystic fibrosis.	15-18yrs (31%) & 19->37yrs (69%). Time since diagnosis NOT REPORTED.	Gender NR. Ethnicity: 90% Caucasian. Education NR. Marital status: 38% married.	Information mailed to eligible patients and approached during routine clinic visits – 2 cystic fibrosis centres in children's hospitals.
Willmott et al (under review)	UK.	5 months.	179 (WED=88, NEUTRAL WRITING=91).	Post 1st MI.	Mean age: 62.3 (10.9)yrs. Time since diagnosis NOT REPORTED.	Gender: 16% Female. Ethnicity: 98% White. Education NOT REPORTED. Relationship status: 79% currently in relationship.	National Health Service Trust (2 acute clinics) – patients approached by cardiac rehabilitation service or cardiac research nurse on day 5 of admission to hospital –given written invitation then approached the following day.

Intervention, comparison exposure, outcome and results

(Some studies included more than the two intervention groups that were included in the present review, thus completion of the intervention, intervention fidelity, numbers of participants included in analyses and effects are presented for only the included groups)

Author (year)	**Writing topic / Number, length & spacing of sessions**	**Comparison**	**Completion of intervention / Fidelity of intervention**	**No. analysed (% of no. randomised)**	**Outcomes measured / Effect(s) (reported in paper/final end point data)**	**Author Conclusions / Commentary (for entire study)**
de Moor et al (2002)	Cancer. Instructions consistent with original WED paradigm. 4 sessions/ over 4-6 weeks –length NOT REPORTED but state followed Pennebaker & Beall (1986) model.	Neutral writing –different health behaviour per session (NEUTRAL WRITING).	Of the no. randomised WED=3 (14%), NEUTRAL WRITING=4 (19%) did not complete all 4 sessions (all completed at least 1 writing session –average no. WED=3.7(.8) NEUTRAL WRITING=3.8 (.5). LIWC for both groups –confirmed: sig. difference in 24/32 word categories inc. affective/cognitive/social processing, time, and meta-physical.	WED=19 (90%), NEUTRAL WRITING=18 (86%).	**Perceived stress (PS); Perceived Stress Scale (PSS).** **Mood disturbance (MD); Profile Of Mood States (POMS).** ~~**Psychological distress (PD); Impact of Events Scale (IES).**~~ No sig. effects on main outcomes. Effect sizes based on means across all follow ups adjusted for baseline values (and SEs): **PS:** **WED=19.8(.9)** **NEUTRAL WRITING=20.5(.9)** **MD:** **WED=15.7(4.7)** **NEUTRAL WRITING=19.8(5.2)**	WED may have some sleep related health benefits in terminally ill patients (but not other outcomes).
Gellaitry et al (2009)	Experience of cancer. Instructions consistent with original WED paradigm BUT guided instructions - day 1	Usual care control (CONTROL).	Of the no. randomised - WED: 3 did not return any writing and 1 completed 2/4 writing days. Therefore – 4 (9%) did not report writing according to the protocol.	WED=38 (84%); CONTROL=42 (87.5%).	**Mood disturbance (MD); Profile of Mood States (POMS).** **Disease specific QoL (DSQoL); Functional Assessment of Cancer Therapy –Breast (FACT-B).**	WED was associated with higher levels of perceptions of social support (emotional) for women recently completing treatment for early stage breast

	emotional disclosure (deepest thoughts and feelings), day 2 cognitive appraisal (making sense of cancer), day 3 benefit finding (perceived benefits of cancer experience) & day 4 looking to the future (coping strategies). 20 minutes/4 consecutive days.		Patient self-report (but re: the impact of WED post-writing) -4 categories easy/no adverse effects, apprehensive but +ve effects, difficult and challenging but beneficial effects, difficult not helpful and no benefit –but –ve effects not prolonged & benefits realised later. At follow up –valued being able to express feelings not previously acknowledged, process/ deal with cancer experience, positive effect on relationships and perception of social support –no neutral writing condition to compare to.		No sig. main effect on outcomes (all p>.05). Effect sizes based on adjusted means at final follow up (and SDs): **MD:** **WED=20.63(32.28)** **CONTROL= 24.21(36.97)** **DSQoL:** **WED=109.56(19.81)** **CONTROL=108.03(21.36)**	cancer....but there was no main effect of the intervention on women's overall QoL or psychological well-being.
Low et al (2010)	Cancer related emotions. Specific instructions not reported at all (just advises instructions adapted from Pennebaker & Beall (1986) and Stanton et al (2002). 4 sessions over 3 week interval – 20 minute sessions.	Neutral writing –facts about condition and it's treatment (NEUTRAL WRITING).	All but one participant did not complete writing within the intended time frame (i.e. 3 weeks) and so was dropped from the study (not clear whether completed all, some or none of the sessions though); implied all others completed all sessions as required. Review of essay content; independent rater read essays and recorded which instructions they most reflected (fidelity confirmed -94% of essays correctly classified) and participant testimony; extent to which participants had thought about what they wrote, talked to others about what they wrote, felt the research project had positive or negative long lasting effects and felt the study had increased their understanding of their experience (fidelity only partially confirmed –no significant group differences but higher mean ratings	WED=31 (82%), NEUTRAL WRITING=31 (82%).	**Depressive symptoms (DS); Centre for Epidemiological Studies –Depression (CES-D) scale.** ~~**Cancer related intrusive thoughts (CRIT); Impact of Events Scale (IES).**~~ No significant main effect of experimental condition for any outcome. Effect sizes based on adjusted means at final follow up (and SEs): **DS:** **WED=12.8 (1.48)** **NEUTRAL** **WRITING= 13.2 (1.48)**	Although there was no main effect of WED on health among the current metastatic breast cancer sample, WED may be beneficial for a subset of patients including women with low levels of emotional support and who have been more recently diagnosed. WED may be contraindicated for others (i.e. those who have been living with the diagnosis for years). Significant proportion of the sample had experience journaling about their cancer experience (two thirds), had talked to a mental health care professional

			for 'thought about' and 'understanding' items for WED group relative to NEUTRAL WRITING group).			about cancer (two thirds) and had attended a cancer support group (three quarters); authors acknowledge this may explain lack of effect. Neutral writing control was facts of diagnosis and treatment – potentially not inert. Mean CES-D 12.4 (34% ≥16).
Rosenberg et al (2002)	Cancer/treatment and any traumatic event. Instructions consistent with original WED paradigm. 20-30 minutes/4 sessions –spacing NOT REPORTED.	Non-writing control (CONTROL).	Implied of the no. randomised all completed writing assignments (unclear whether all completed *all* sessions as required but presume they did). None reported –no neutral writing condition to compare to anyway.	Implied WED=16 (100%), CONTROL=14 (100%).	**Psychological symptoms (PS); Symptom Checklist 90 –Revised.** **Mood (M); The Brief Profile Of Mood States (Brief POMS).** **Health related QoL (HRQoL); Short Form-36 (SF-36) - mental health component (MHC) & physical health component (PHC).** **Disease specific QoL (DSQ OL); Functional Assessment of Cancer Therapy –P (FACT-P).** PS, M, HRQoL and DSQoL no data reported at all; just stated no significant group effect (no data reported at all). *Requested data from authors & obtained for some outcomes.*	Results support the feasibility of expressive disclosure for men with prostate cancer but limited support for its positive impact on health and quality of life outcomes.

					Effect sizes based on adjusted means at final follow up (and SDs): **M:** **WED=2.38 (12.60)** **CONTROL=6.21 (7.41)** **DSQoL:** **WED=130.16 (12.60)** **CONTROL=107.92 (69.03)** *Still missing for PS & HRQoL: authors did not provide data for PS at all & provided group means/SDs for SF-36 but only for 8 separate sub-scales (& health transition score)....decided that is it not ok just to sum these within study to derive mental/physical health component scores): if they all had same SD10 then perhaps could have combined but they do not (when they are combined means & SDs for two main sub-scales are similar to the other trial that included the SF-36 but made the decision that this is not worth it).*	
Walker et al (1999)	Cancer. Instructions consistent with original WED paradigm. 30 minutes/3 sessions spaced over 3-4 days	Usual care control (CONTROL).	**For included groups:** Of no. randomised WED= 3 (16%) did not complete all 3 writing sessions. LIWC for 3WED –no neutral writing condition to compare to.	**For included groups:** WED=14 (74%), CONTROL=14 (87.5%).	**Positive Affect (PA); (Positive And Negative Affect Schedule (PANAS) +ve sub-scale).** **Negative Affect (NA); (Positive And Negative Affect Schedule (PANAS) -ve sub-scale).**	Emotional expression is feasible for patients with cancer, but the efficacy of the intervention in improving mood was not supported.

	for 1st 8 participants - then spaced over 5 days.				**~~Cancer related intrusive thoughts and avoidance (CRIT&A); Impact of Events Scale (IES).~~** No sig. group effect across all follow ups or for each individual follow up for any outcome. Effects sizes based on adjusted means at final follow up (and SEs): **PA:** **WED=36.4(1.6)** **CONTROL=34.8(1.8)** **NA:** **WED=17.1(1.6)** **CONTROL=14.1(1.7)**	
Zakowski et al (2004)	Cancer. Instructions consistent with original WED paradigm. 20 minutes/3 consecutive days (within 1 week if not possible).	Neutral writing –time management (NEUTRAL WRITING).	Of the no. randomised WED=9 (12%), NEUTRAL WRITING=8 (15%) dropped out after baseline assessment/before writing (& WED=3 (4%); NEUTRAL WRITING=3 (6%) dropped out after completing writing) – unclear whether those staying in after baseline (regardless of whether they dropped out after writing or not) completed all writing sessions as planned? Participant self-report –confirmed: WED rated essays as sig. more personal and revealing emotions compared to NEUTRAL WRITING.	Implied WED=62 (84%), NEUTRAL WRITING=42 (79%).	**Distress (D); Brief Symptom Inventory (BSI) –global severity index. Clinically significant cases defined as 1 SD above the t score norm for female and male adult non-patients, scores of .62 and .42 respectively.** **~~Cancer related intrusive thoughts and avoidance (CRIT&A); Impact of Events Scale (IES) (more as a mediator but final end point data provided for follow up).~~** No sig. group effect on distress (F(1,100)=.98, p>.1), or cases of clinically sig. D at 6	WED was not effective for reducing distress for all cancer patients instead it may be helpful in aiding patients in their psychological adjustment if they are lacking opportunities in their social environment.

					months (latter not reported alone as data not provided). Effect size based on unadjusted means at final follow up (and SDs): **D:** **WED=.35(.4)** **NEUTRAL WRITING=.34(.4)**	
Gillis et al (2006)	Any stressful experience. Instructions consistent with original WED paradigm BUT instructions for selecting bothersome stressor/disclosing e.g. how condition affected by stressor/resolve each stressor one at a time. 15-20 minutes/4 consecutive days.	Neutral writing –time management (NEUTRAL WRITING).	Of those randomised (WED=7(16%), NEUTRAL WRITING=4(11%)) did not complete any follow up (& stated those not completing a follow up 'typically did not write'...presume they didn't complete all sessions as required?) & of those who provided some follow up1 WED (3%) and 1 NEUTRAL WRITING (3%) did not complete writing. Thus (WED=8(18%), NEUTRAL WRITING=5(16%)) did not complete writing as required. LIWC both groups and review of essay content –all 38 WED wrote about a stressful topic but only 5/34 (15%) NEUTRAL WRITING did not write about time management and mentioned something stressful. WED contained substantially more affect, cognitive, bodily related words than NEUTRAL WRITING.	~~ITT: WED=45 (100%), NEUTRAL WRITING=38 (100%).~~ **WED=36 (80%), NEUTRAL WRITING=32 (84%) included in completer analysis.**	**Negative Affect (NA); (Positive And Negative Affect Schedule (PANAS) -ve sub-scale).** **Global health status (GHS); Fibromyalgia Impact Questionnaire (FIQ) –global health status.** From baseline to 3 month follow up more improvement for WED compared to NEUTRAL WRITING in GHS ($F(1,81)=4.23$, $p=.04$) (improvement for WED/no change for NEUTRAL WRITING). Positive effect. No sig. effect on NA ($p=.64$). Inadequate data to calculate SMD for ITT so effect sizes based on unadjusted means at final follow up for completer sample (and SDs) (all still sig.): **GHS:** **WED=52.70(20.35)** **NEUTRAL**	At home WED leads to a greater degree of improvement on various health indexes 3 months after writing than does emotionally neutral writing for individuals with FM. Baseline group differences in health may have confounded effects –greater improvement for WED as poorer health at baseline–3 month scores similar in both groups suggests effect of limited clinical significance.

					WRITING=53.79(18.13) **NA:** **WED=1.91(.71)** **NEUTRAL** **WRITING=2.14(.78)**	
Norman et al (2004)	Negative emotional experiences related to pain. Instructions consistent with original WED paradigm. 20 minutes/3 consecutive days.	Neutral writing but writing about positive life events unrelated to pain (i.e. positive thoughts and feelings) - described as a superior control task compared to trivial/time management topics; provides a control for writing about an emotionally engaging topic, has face validity for reducing stress/being meaningful and will not create a negative response (NEUTRAL WRITING).	Of the no. randomised 10 (17%) (WED=2 (6%), PW=8 (29%)) dropped out before finishing writing and of those completing writing and follow up 48 (WED=28, PW=20) all but WED 1/32 did not complete writing as required –thus WED=3(9%) and NEUTRAL WRITING=8(29%) did not complete writing as required –(but unclear whether the additional 2 patients who dropped out after writing but before follow up completed all sessions as required....CB/KD decision assume they did thus WED=3(9%) and NEUTRAL WRITING=8(29%) did not complete writing as required). Participant self-report and review of essay content. WED reported previously holding back more than NEUTRAL WRITING yet both perceived writing to be meaningful (i.e. control was to write about pleasant events). All but 1 patient classified correctly re: group assignment.	WED=28 (87.5%), PW=20 (71%). .	**Positive Affect (PA); (Positive And Negative Affect Schedule (PANAS) +ve sub-scale).** **Negative Affect (NA); (Positive And Negative Affect Schedule (PANAS) -ve sub-scale).** No sig. effects for main outcomes. Effects based on unadjusted means at final follow up (and SDs): **PA:** **WED=2.43(.84)** **NEUTRAL** **WRITING=2.89(.84)** **NA:** **WED=2.09(.59)** **NEUTRAL** **WRITING=2.11(.80)**	Writing about stressful effects of CPP leads to limited reductions in pain compared with writing about positive experiences, and mood/functioning appear to improve for women who are ambivalent over emotional expression or have elevated negative affect. Generalizability limited to primarily depressed sample of women with CPP; mental health: 75% history of depression & 64.6% previous mental health treatment.
Cohen et al (in prep)	*Data not available.*	Neutral writing –time	**For included groups:**	**For included groups:**	**Perceived stress (PS); Perceived Stress Scale**	Despite sufficient power, multiple assessment

		management (NEUTRAL WRITING).	*Data not available.*	*Data not available (presumed no. randomised; (WED: 74 (written=37; verbal=37), CONTROL: 39 (written=19; verbal=20).*	**(PSS).** **Positive Affect (PA); (Positive And Negative Affect Schedule (PANAS) +ve sub-scale).** **Negative Affect (NA); (Positive And Negative Affect Schedule (PANAS) -ve sub-scale).** No sig. group effects on main outcomes (PS F=.162, p=.851; PA F=.316, p=.730, NA F=.783, p=.459). Effects based on unadjusted means at final follow up (and SDs): **PA:** **WED=2.83(.78)** **NEUTRAL WRITING=2.98(.71)** **NA:** **WED=1.92(.72)** **NEUTRAL WRITING=1.83(.59)** **PS:** **WED=1.73(.68)** **NEUTRAL WRITING=1.66(.59)**	points, a range of measures, failed to find consistent evidence for the benefits of disclosure –may be disclosure conducted in the field has weaker effects than found in more highly controlled supervised environments. Both intervention and control condition contained both written and verbal tasks –found no differences in effect between the 2 methods across the follow ups/outcomes thus collapsed the categories.
Danoff-Burg et al (2006)	Experience with rheumatic disease. Instructions consistent with original WED paradigm. 20 minutes/4 sessions	Neutral writing –facts about condition (non-emotional) (NEUTRAL WRITING).	**For included groups:** No. per group NOT REPORTED (for total sample off the no. randomised 2 (3%) dropped out having completed less than 3 of the 4 writing sessions (unclear whether those staying in completed all sessions as required -	**For included groups:** No. per group for included groups NOT REPORTED (total sample	**Depressive symptoms (DS); Centre for Epidemiological Studies –Depression (CES-D) scale.** ~~**Positive mood (PM); Profile Of Mood States (POMS) –vigor sub-scale.**~~	Reduction in fatigue three months following the intervention was evident among patients assigned to standard WED and people with lower levels of trait anxiety may be more

	20 minutes/within 3 weeks.		implied some completed only 3)? No. per group NOT REPORTED (for total sample review of essay content (essays ordered randomly and raters blind to group assignment) -86.9% essays correctly classified); 2 people in NEUTRAL WRITING revealed emotions despite being instructed to focus only on the facts).	implied 64 completing final follow up). **No. included in analyses for DS (WED=20 (83%), NEUTRAL WRITING=20 (83%) ~~& PM (WED=21(88%); NEUTRAL WRITING=20 (83%)~~ provided by author when final endpoint data provided.**	No sig. main effects. Inadequate data to calculate SMD; stated no significant difference, statistical test reported and means/SDs reported but not by group. *Requested data from authors and obtained.* Effects based on unadjusted means at final follow up (and SEs): **DS: WED=12.53 (2.42) NEUTRAL WRITING=15.08 (2.57)**	comfortable processing and expressing emotion in the context of a WED intervention than those with high trait anxiety. Did not test for differences between disease groups due to small no. with SLE –may have influenced main effects found.
Hamilton-West & Quine (2007)	Any stressful experience. 20 minutes/3 consecutive days.	Neutral writing – time management (NEUTRAL WRITING).	Of the no. randomised 39 (WED=27 (38%), NEUTRAL WRITING=12 (33%)) did not complete baseline measures/writing (unclear whether the remaining participants completed all writing sessions as required?)....but CB/KD decision that as the authors said these participants 'completed baseline measures and diary writing exercise' take this to mean that they did complete all sessions as required. None reported.	~~ITT/LOCF so presumed WED=71 (100%); NEUTRAL WRITING=36 (100%)~~ **BUT when obtained data from author no. included in 3 month follow up was WED=43 & NEUTRAL WRITING=24.**	**Depression (D); Hospital Anxiety and Depression Scale (HADS).** **Global health (GH); Bath Ankylosing Spondylitis – Global Score (BAS-G).** **Clinically important change defined as change of 2.6 points on BAS-G (GH).** (GH alone not reported as based on only 2 items & data NOT REPORTED). No sig. changes. Inadequate data to calculate SMD; stated no significant group effect.	The results do not provide support for the use of emotional disclosure intervention for all patients with AS, although it may be useful for some patients on some outcomes (i.e. functional limitations).

					Requested data from authors and obtained. Effects based on unadjusted means at final follow up (and SDs): **D:** **WED=5.33 (3.57)** **NEUTRAL WRITING=6.46 (3.49)** **GH:** **WED=4.82 (1.94)** **NEUTRAL WRITING=5.77 (2.47)**	
Wetherell et al (2005)	Most upsetting experience in life. Instructions consistent with original WED paradigm. 20 minutes/4 consecutive days – breaks during writing sessions allowed.	Neutral writing – time management (NEUTRAL WRITING).	Of the 42 randomised and assessed at baseline, implied 8 (19%) (but not completely clear/could be 9 (21%)) dropped out during intervention (but unclear whether those staying in completed writing sessions as required...implied they did?). Patient self-report and checklist (i.e. stress/arousal) –WED rated disclosure as more personal, emotional and stressful than NEUTRAL WRITING and a greater wish to share their information yet they had actively held back from doing this (all sig.).	Implied WED=19, NEUTRAL WRITING=15 (81% of total sample – proportion per group not known).	**Mood disturbance (MD); Short Form Profile Of Mood States (POMS-SF).** Sig. trend for improvement for WED compared to NEUTRAL WRITING at 10 weeks for MD $F(1,28)=4.56$, $p=.04$, $\varepsilon=.14$). Effects based on unadjusted means at final follow up (and SDs): **MD:** **WED=33.9(26.1)** **NEUTRAL WRITING=43.5(19.9)**	The study provides preliminary evidence for a beneficial effect of emotional disclosure on mood outcomes in RA, but not on clinical and physiological measures of disease status. 7/34 (21%) verbal not written disclosure.
Vedhara et al (2007)	Most traumatic experience of life. Instructions consistent with original WED paradigm.	Neutral writing –time management (NEUTRAL WRITING).	4 (6%) dropped out after baseline –the remaining participants 'completed the study' but unclear whether they completed any or all writing sessions as required.	WED=31, NEUTRAL WRITING=28 (86% of total sample – proportion per	**Disease specific QoL (DSQoL); Dermatology Life Quality Index (DLQI).** **Mood; HADS and POMS (not described as an outcome in**	Disease severity and quality of life in patients with psoriasis improved in both the intervention and control patients over the follow up period and

	20 minutes/4 consecutive days.		LIWC both groups and patient self-report. WED rated writing as more personal, emotionally revealing, meaningful, and more likely to report having wanted to tell another person about the topic, having engaged in some disclosure of the topic previously but having held back re: what they had disclosed. WED used sig. more affective (overall), -ve affect, cognitive/insight words and pronouns than NEUTRAL WRITING (and NEUTRAL WRITING used more words re: time management).	group not known).	**the paper but group end point data for final follow up reported).** No sig. group difference at 12 weeks for DS or DSQoL. Effects based on unadjusted means at final follow up (and SDs): **DSQoL:** **WED=5.39(4.59)** **NEUTRAL WRITING=4.82(3.82)** **POMS** **WED=38.20(26.83)** **NEUTRAL WRITING =40.27(21.05)** **HADS depression** **WED=4.38(4.44)** **NEUTRAL WRITING =3.68(3.36)** **HADS anxiety** **WED=5.81(3.14)** **NEUTRAL WRITING =6.54(3.66)**	the magnitude of improvement was comparable between the groups –ED did result in improvements in these outcomes but these did not exceed those observed in the control group.
Taylor et al (2003)	Most distressing experience of life. Instructions consistent with original WED paradigm. 20 minutes/3 sessions/5 day period.	Usual care (CONTROL).	Of the no. randomised 5 (7%) didn't complete all writing sessions and unclear whether 9 dropping out (some dropped because they didn't complete follow up) completed the intervention....CB/KD decision authors say all 14 did not complete the intervention so take this (i.e. 20% of those randomised did not complete	WED=18, CONTROL=21 (56% of total sample – proportion per group not known).	**Depression (D); Patient Health Questionnaire (PHQ) –depression sub-scale. Anxiety (A); Patient Health Questionnaire (PHQ) - anxiety sub-scale. Psychological distress (PD); Patient Health Questionnaire (PHQ) –stressful life events**	The findings demonstrate an effect of written-self-disclosure on health care utilization. 12(31%) completers aged 15-18yrs –sample had wide age span (i.e.

			the intervention). Patient self-report (but re: feasibility and acceptability) –WED rated level of comfort while writing as very good and rated value for mental, physic al and overall health as fair –no neutral writing condition to compare to.		**sub-scale.** **Health related QoL (HRQoL); Short Form-12 (SF-12) - mental health component (MHC) & physical health component (PHC).** No sig. effects for main outcomes. Effects based on unadjusted means at final follow up (and SDs): **D:** **WED=12.4(4.1)** **CONTROL=13.9(4.2)** **A:** **WED=15.3(1.4)** **CONTROL=16.1(3.1)** **PD:** **WED=14.8(6.9)** **CONTROL=14.3(3.1)** **MHC:** **WED=53.7(7.5)** **CONTROL=49.5(9.1)** **PHC:** **WED=43.8(10.3)** **CONTROL=43.3(10.0)**	adults and adolescents).
Willmott et al (under review)	Experience of having a heart attack. Instructions consistent with original WED paradigm BUT instructions to write about any emotions +ve or –ve, thoughts about how	Neutral writing –time management (NEUTRAL WRITING).	Stated most attrition occurred before writing (implied WED=8(9%); NEUTRAL WRITING=14(15%) (but no indication whether those who stayed in/started writing completed all writing sessions as required?). Participant self-report –WED reported writing sig more personal, secret, emotionally expressive and	WED=79 (90%), NEUTRAL WRITING=77 (85%).	**Health related QoL (HRQoL) –Short Form-36 (SF-36); mental health component (MHC) & physical health component (PHC).** Group difference in change over time was non-sig. for PHC (F(2, 2258)=.17, P>.01) and marginal for MHC	Findings suggest that written emotional disclosure is a beneficial strategy which could be incorporated into existing rehabilitation programs to help individuals adjust after first MI.

	they might cope, and in last session encouraged to try and wrap things up (i.e. think about the future). Minimum 10 minutes–maximum 20 minutes/3 consecutive days.		meaningful/valuable than NEUTRAL WRITING. LIWC both groups –WED more +ve emotion, -ve emotion, insight, and causal words than NEUTRAL WRITING (all p<.001).		(F(2,258)=2.94, p=.055) –inc in WED but dec. in NEUTRAL WRITING at 5 months but no sig. group difference in MHC at 5 months (F(1,137)=3.40, p>.05). Effects based on adjusted means at final follow up (and SDs): **MHC:** **WED=71.28(20.50)** **NEUTRAL WRITING=63.12(22.01)** **PHC:** **WED=67.91(22.61)** **NEUTRAL WRITING=62.48(23.17)**	

Appendix F: Risk of bias decisions table

(Some studies included more than the two intervention groups that were included in the present review, thus attrition and numbers of participants included in analyses are presented for only the included groups)

Study	Randomisation	Score	Allocation concealment	Score	Blinding	Score	Completeness of outcome data	Score
de Moor et al (2002)	Randomisation stated and sequence generated by minimisation.	Y	Method of randomly allocating participants not described thus not known whether concealed.	N	Neutral writing control but no indication information received at enrolment sufficiently vague to ensure blinding. Participants also outcome assessors thus possibly not blind.	N	Attrition: 5 (12%) (WED=2(10%), NEUTRAL WRITING=3(14%)) did not provide data for at least 1 follow up –attrition for final follow up not reported. Thus, number providing data for at least 1 follow up reported per group: (88%) (EW=90%, NW=86%) - but number not completing final follow up not known. Average number of follow ups completed also reported: EW=3.4 (*SD*1.7) and NW=3.1 (*SD* 2.1). Included in analyses: 37 (88%) WED=19 (90%), NEUTRAL WRITING=18 (86%). Implied data partially included where available. The number included in analyses was the number providing data for at least 1 follow up & 'correlations among observations were modelled thus the group effect represented the average intervention effect across all time points.	?
Gellaitry et al (2009)	Computer generated random number table used.	Y	No mention of whether allocation concealed.	N	No neutral writing control and no indication information at enrolment sufficiently vague to ensure participant blinding: stated participants informed	N	Attrition: 13 (14%) (WED=7(16%), CONTROL=6(12.5%)) did not provide complete data - attrition for final follow up not reported but can be somewhat inferred:	Y

					they would be randomised to a writing or non-writing group. Participants also outcome assessors thus possibly not blind. Not reported whether interviewer 'monitoring' telephone calls post intervention was blind.		Only 3 of the lost patients were excluded for incomplete data rather than dropped out (i.e. and thus likely did not complete final follow up) -unclear which follow up these patients did not complete (i.e. whether final follow up was completed) but this number is conservative and presumes they did not complete the final follow up (i.e. if these 3 patients did complete final follow up attrition would be less than is reported here). Thus, number providing complete follow up data (& likely the final follow up) reported by group: 86% (EW=84%, NW=87%) Included in analyses: 80 (86%) WED=38 (84%); CONTROL=42 (87.5%). Implied complete case analysis.	
Low et al (2010)	Computerised random numbers generator.	Y	Sealed sequentially numbered envelopes used to conceal allocation (& implied that different person generated randomisation schedule to the person enrolling patients).	Y	Neutral writing but no indication information received at enrolment sufficiently vague to ensure blinding. Participants also outcome assessors thus possibly not blind.	N	Attrition: 14 (18%) (WED=7 (18%), NEUTRAL WRITING=7 (18%) did not complete follow up (11 died, 2 did not return follow up no reason provided & 1 dropped from the study as did not complete writing within the time interval allowed) (& only one follow up) . Thus, number providing complete follow up reported by group (& only one follow up): 82% (EW 82%; NW 82%).	Y

							Included in analyses: 62 (82%) WED=31 (82%), NEUTRAL WRITING=31 (82%). Implied complete case & per protocol analysis (i.e. included in analysis if completed intervention and follow up).	
Rosenberg et al (2002)	Randomisation stated but method not described.	?	Interviewers enrolling participants blind until writing but no indication of how this was achieved.	?	No attempt to blind participants (usual care control/no indication information at enrolment vague). Participants also outcome assessors thus possibly not blind.	N	Attrition: No attrition/all randomised completed study thus implied completed final follow up; complete data for most outcomes. Thus, number providing complete follow up reported: 30 (100%) (EW 100%; NW 100%). Included in analyses: Implied 30 (100%) (number per group provided by authors: WED=16 (100%), CONTROL=14 (100%).	Y
Walker et al (1999)	Randomised but method not appropriate – assigned sequentially to groups.	N	No indication those enrolling/allocating participants to conditions were unaware of randomisation schedule.	N	No neutral writing control and no indication information at enrolment sufficiently vague to ensure participant blinding. Outcome assessors conducting follow up telephone interviews blind but outcomes subjective thus possibly not blind.	N	**For included groups** Attrition: 7(20%) WED=5(26%), CONTROL=2(13%) dropped as they did not complete the intervention as required/did not provide data at all follow ups –- attrition for final follow up not reported but can be somewhat inferred: The lost patients were excluded for not completing the intervention/incomplete follow up data -unclear whether final follow up was completed but this number is conservative and presumes they did not complete	Y

							the final follow up (i.e. if these patients did complete final follow up attrition would be less than is reported here). Thus, number completing the intervention/all follow ups reported by group: 80% (WED=74%, CONTROL=87%) - but number not completing final follow up not reported. Group differences in attrition apparent (CTL greater than 20%) –but not know for final follow up. Included in analyses: 28 (80%) WED=14 (74%), CONTROL=14 (87.5%). Implied complete case & per protocol analysis.	
Zakowski et al (2004)	Randomisation stated but method not described.	?	No description of the method of random allocation thus no indication of whether concealed.	N	Neutral writing control but no indication information at enrolment sufficiently vague to ensure participant blinding. Participants were outcome assessors except for telephone reminders from interviewer who administered intervention thus possibly not blind.	N	Attrition: 23 (18%) (WED=12(16%), NEUTRAL WRITING=11(21%) dropped out after baseline/the intervention & so did not provide data for final follow up. Thus, number completing final follow up reported by group: 82% (EW=84%, NW=79%). Very slight group differences in attrition (NW great than 20%). Included in analyses: Implied 104 (82%) WED=62 (84%), NEUTRAL WRITING=42 (79%). Implied data partially included were available.	Y

Gillis et al (2006)	Random numbers table – stratified by gender.	Y	Packs given ID, randomised, and experimenter enrolling/allocating participants/mailing packs blind (but unclear whether this is because separate person to the one enrolling generated randomisation schedule). Also unclear whether packs sealed?	Y	Neutral writing control and information at enrolment designed to ensure participant blinding: the study was described generically (to ensure blinding) as designed to see how writing about different aspects of a person's life might influence their health and adjustment. Not informed of allocation to EW/NW group. Participants also outcome assessors thus blind.	Y	Attrition: 15 (18%) (WED=9(20%), NEUTRAL WRITING=6(16%)). Thus, number completing final follow up reported by group: 82% (EW=80%, NW=84%). Group differences in attrition formally assessed –no significant difference and appears to be true. Included in analyses: ~~ITT: WED=45 (100%), NEUTRAL WRITING=38 (100%).~~ 68 (82%) WED=36 (80%), NEUTRAL WRITING=32 (84%) included in completer analysis for which group final end-point data were available. Implied data partially included where available.	Y
Norman et al (2004)	Randomisation stated – restricted by blocking but method of deriving random allocation within blocks not described.	?	Sealed packets numbered, randomised and interviewer enrolling/allocating participants blind (but unclear whether this is because separate person to the one enrolling generated randomisation schedule). But –block size only 2 thus person enrolling may have inferred some group assignment if deciphered box size (i.e. unclear whether researcher enrolling blind after	Y	Neutral writing control designed to have face validity for reducing stress/being meaningful, and information at enrolment sufficiently vague to ensure participant blinding; the study was described as designed to get a better understanding of the experience of pelvic pain and to explore the effects of a writing exercise on pain, mood, and functioning (NW involved writing about positive experiences/not pelvic pain – slight risk of compromised blinding but not great).	Y	Attrition: 12 (20%) (WED=4(12.5%), PW=8(29%) did not provide data for final follow up. Thus, number not completing final follow up reported by group: 80% (EW=88%, NW=71%) Slight imbalance in attrition (NW less than 80%). Included in analyses: 48 (80%) WED=28 (88%), NW=20 (71%). Implied data partially included where available.	Y

			allocation concealment).		Not informed of allocation to EW/NW group. Participants also outcome assessors thus blind.			
Danoff-Burg et al (2006)	Randomisation stated in abstract but method not described.	***?***	Stated experimenter blind and handed instructions to participants in envelope – but not clear whether envelopes were sealed/serially numbered? Also unclear whether blind because separate person to the one enrolling generated randomisation schedule.	?	Neutral writing control and information at enrolment sufficiently vague to ensure participant blinding: participants were informed that the study would involve completing questionnaires and writing about rheumatic disease (& both groups them wrote about the condition). Not informed of allocation to EW/NW group. Participant's also outcome assessors thus blind.	Y	**For included groups** Attrition: Number per group for included groups NOT REPORTED (for total sample 11(15%). Thus, number completing final follow up provided for total sample 85% -but not by group or for included groups. Group differences in attrition somewhat assessed i.e. stated completion of follow up did not vary as a function of group assignment. No. included in analyses: Number per group for included groups NOT REPORTED (total sample implied 64 (85%) completing final follow up). No. included in analyses for depressive symptoms 40 (83%) (WED=20 (83%), NEUTRAL WRITING=20 (83%) provided by group by author when final end point data provided (i.e. 8 of the lost participants were to these groups, 4 (16%) per group). Implied data partially included where available.	Y

Hamilton-West & Quine (2007)	Computer generated list – restricted by blocking.	Y	Only one researcher who had no contact with participants knew randomisation schedule and does state person allocating participant's blind but no indication of how this was achieved (& researcher that knew the schedule might have enrolled -don't have to meet participants to do this). Also blocking (size unreported) –person enrolling may have inferred future allocations had they inferred block size (as don't know whether researcher enrolling was blind after AC).	?	Neutral writing control and information at enrolment sufficiently vague to ensure participant blinding: participants were informed that that they would be asked to keep a detailed diary which would involve writing about their experiences (& control group wrote about plans for the following day). Not informed of allocation to EW/NW group. Participants also outcome assessors thus blind.	Y	Attrition: 62 (58%) (WED=41 (58%); NEUTRAL WRITING=21 (58%). Thus, number completing final follow up as planned reported by group: 42% (EW=42% NW=42%). Group differences in attrition formally assessed -no group differences and seems to be true. Included in analyses: ~~ITT/LOCF so presumed WED=71 (100%); NEUTRAL WRITING=36 (100%).~~ BUT when obtained data from authors no. included in 3 month follow up was WED=43 & NEUTRAL WRITING=24 (not the number competing follow up (i.e. WED=30 (42%), NEUTRAL WRITING=15 (42%). Implied missing data imputed for those completing baseline assessment NOT RANDOMISED (i.e. number randomised was 107 (WED=71, NEUTRAL WRITING=36) & number completing baseline assessment was WED=44 & NEUTRAL WRITING=24) minus one intervention participant excluded for some outcomes (i.e. must have been missing data for one participant on these outcomes).	N
Wetherell et al (2005)	Randomisation stated but method not	?	Stated researcher enrolling participant's blind to subsequent group	?	Neutral writing control and information at enrolment sufficiently vague to ensure	Y	Attrition: 8 (19%) (but not completely clear/could be 9 (21%) did not complete intervention or	?

	described.		allocation but no description of how this was achieved.		participant blinding: participants were informed it was a study to assess the effects of writing or talking about particular topics on the symptoms of RA and that of particular interest was how the topics make you feel and what effect this has on the symptoms of your RA. No information regarding individual topics was given but patients were informed that it was possible that they could find some of the topics upsetting –risk of pre-disclosure priming but unlikely to have inferred group assignment. Not informed of allocation to EW/NW group. Participants also outcome assessors thus blind.		provide data at final follow up - number per group not reported. Thus, exact number completing follow up 81% (but possibly 9 dropped out, not 8, if so this would be 79%) - number per group not reported. Included in analyses: Implied 34 (81%) (WED=19, NEUTRAL WRITING=15 –proportion per group not known). Implied data partially included where available.	
Vedhara et al (2007)	Randomisation stated – restricted by blocking/stratified by gender but method of generating random allocation within each block not described.	?	Method of random allocation not described thus no indication of whether concealed. NB blocks of 20 -some future allocations may have been inferred if block size deduced (i.e. don't know whether researcher enrolling was blind after allocation concealment...unlikely as	N	Neutral writing control and implied information at enrolment sufficiently vague to ensure participant blinding: stated no information regarding individual topics was given patients were only informed that it was possible that they could find some of the topics upsetting –risk of pre-disclosure priming but unlikely to have inferred group assignment.	Y	Attrition: 4 (6%) dropped out after baseline/did not 'complete the study' & then 6 (9%) did 'complete the study' but did not provide complete follow up data (& were excluded from analyses) –number per group not reported & number providing data at final follow up not known but can be somewhat inferred: Only 6 of the lost patients were excluded for incomplete data	Y

			patients were called with writing instructions –but don't know whether this is the same as the person enrolling).		Participants also outcome assessors thus blind.		rather than dropped out (i.e. and thus likely did not complete final follow up) -unclear which follow up these patients did not complete (i.e. whether final follow up was completed) but this number is conservative and presumes they did not complete the final follow up (i.e. if these 6 patients did complete final follow up attrition would be less than is reported here). Thus, number 'completing study' or providing complete follow up data reported (& likely the final follow up): 59 (85%) but not by group. Included in analyses: 59 (85%) WED=31, NEUTRAL WRITING=28 –proportion per group not known). Implied complete case analysis.	
Taylor et al (2003)	Randomisation stated but method not described.	?	Method of randomly allocating not described thus no indication of whether concealed.	N	No neutral writing control and information at enrolment not sufficiently vague to ensure participant blinding: told study about relationship between feelings and physical health. Participants also outcome assessors thus possibly not blind.	N	14 (20%) 'did not complete the intervention/study' (5 did not complete writing as required, 6 did not return for follow up (& only one follow up) & 2 lung transplant (implied dropped out) –number per group not reported & number providing data at final follow up not known but can be somewhat inferred: Only 5 of the lost patients were excluded for incomplete data rather than dropped out (i.e. and thus likely did not complete final	Y

							follow up) -unclear which follow up these patients did not complete (i.e. whether final follow up was completed) but this number is conservative and presumes they did not complete the final follow up (i.e. if these 5 patients did complete final follow up attrition would be less than is reported here). Thus. number completing follow up reported (& only one follow up): 80%. BUT additional 17 (24%) participants with unusually high or low health care use excluded from analysis to test the effect of WED for patients with typical utilization patterns (not known whether they completed follow up –implied they did). Included in analysis: 39 (56%) WED=18, CONTROL=21– proportion per group not known). Implied per protocol analysis/data partially included where available.	
Willmott et al (under review)	Randomisation stated but method not described.	?	No mention of whether allocation concealed & stated researchers not blind.	N	Neutral writing control and implied information at enrolment sufficiently vague to ensure participant blinding: stated participants informed they would be writing about potentially different topics. Not informed of allocation to EW/NW group.	Y	Attrition: 23 (13%) (WED=9(10%), CONTROL=14(15%)) did not complete follow up –attrition at final follow up can be somewhat inferred: Only 1 of the lost patients were lost to follow up (most were lost before writing) thus implied only 1 patient did not complete all follow	Y

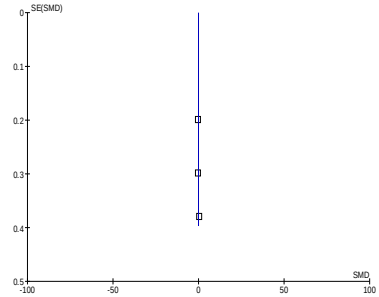
					Participants also outcome assessors thus blind.		ups - unclear which follow up this was lost to (i.e. whether final follow up was completed) but this number is conservative and presumes this patient did not complete the final follow up (i.e. if this patient did complete final follow up attrition would be less than is reported here). Thus, number completing follow up reported by group 87% (EW=90%, NW=85%). Included in analyses: 156 (87%) WED=79 (90%), NEUTRAL WRITING=77 (85%). Implied complete case analysis (if one patient lost to follow up after writing provided some data) or data partially included as available (if this patient did not provide any data).	

Appendix G: Within study data

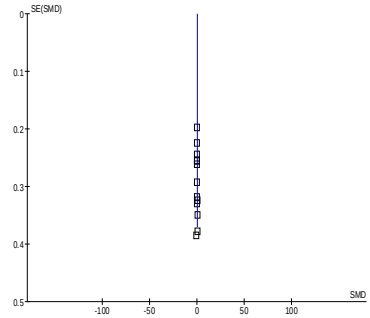
Trial/outcome	Summary Data						Individual Effects (SMD (95% CIs)
	WED			Control			
	Mean	SD	N	Mean	SD	N	
Taylor - negative affect							
Taylor et al (2003): PHQ depression	-12.4	4,1	18	-13.9	4.2	21	.35 (-.28 to .99)
Taylor et al (2003): PHQ anxiety	-15.3	1.4		-16.1	3.1		.32 (-.32 to .95)
Vedhara – negative affect							
Vedhara et al (2007): POMS	-38.2	26.83	31	-40.27	21.05	28	.08 (-.43 to .60)
Vedhara et al (2007): HADS depression	-4.38	4.44		-3.68	3.36		-.17 (-.69 to .34)
Vedhara et al (2007): HADS anxiety	-5.81	3.14		-6.54	3.66		.21 (-.30 to .72)
Taylor - health-related SoI							
Taylor et al (2003): physical	43.8	10.3	18	43.3	10	21	.05 (-.58 to .68)
Taylor et al (2003): mental	53.7	7.5		49.5	9.1		.49 (-.15 to 1.13)
Willmott - health-related SoI							
Willmott et al (under review): physical	67.91	22.61	79	62.48	23.17	77	.24 (-.08 to .55)
Willmott et al (under review): mental	71.28	20.50		63.12	22.01		.38 (.07 to .70)*

Appendix H: Funnel plots

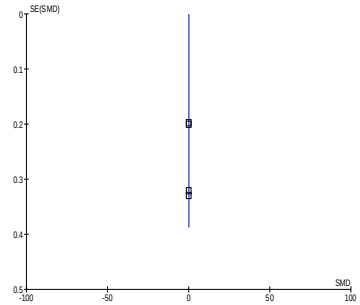
Positive affect



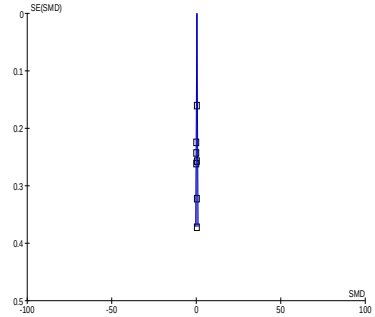
Negative affect



Distress



QoL



Appendix I: Sensitivity analyses

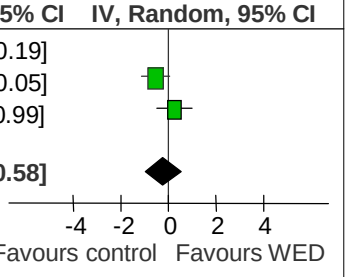
Running meta-analysis without Cohen et al (in prep)

Positive affect without Cohen: no change (non-significant trend for a small negative effect).

Study	WED Mean	WED SD	WED Total	Control Mean	Control SD	Control Total	SMD IV, Random, 95% CI
Cohen	2.83	0.78	74	2.98	0.71	39	-0.20 [-0.59, 0.19]
Norman	2.43	0.84	28	2.89	0.84	20	-0.54 [-1.12, 0.05]
Walker	36.4	5.99	14	34.8	6.73	14	0.24 [-0.50, 0.99]
Total (95% CI)			**42**			**34**	**-0.18 [-0.95, 0.58]**

Heterogeneity: Tau² = 0.19; Chi² = 2.63, df = 1 (P = 0.11); I² = 62%

Test for overall effect: Z = 0.47 (P = 0.64)

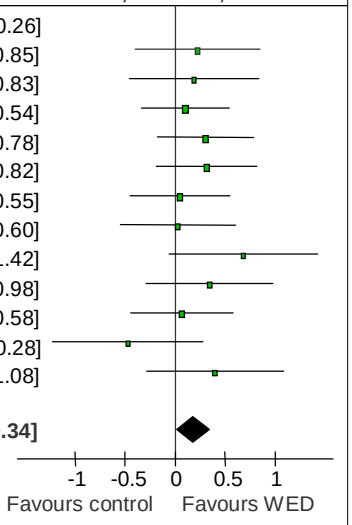


Negative affect without Cohen: change from trend for a positive effect that was small and marginally inconclusive yet approaching significance to a small positive and significant effect.

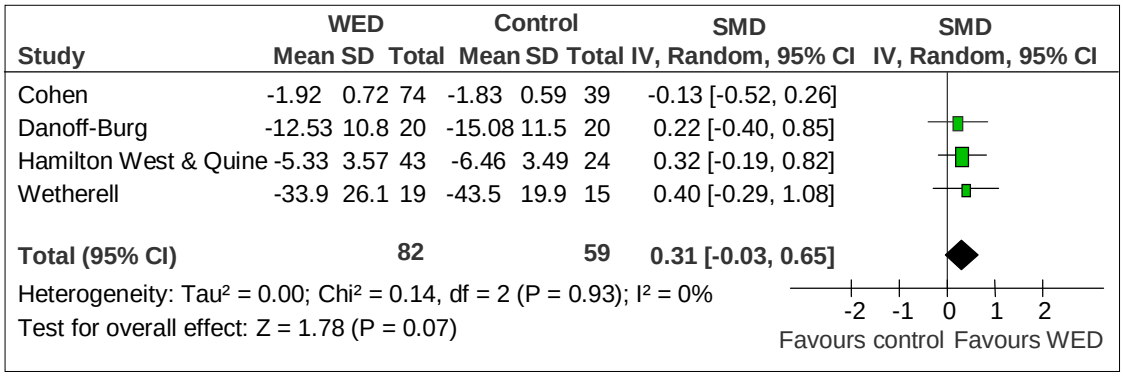
Study	WED Mean	WED SD	WED Total	Control Mean	Control SD	Control Total	SMD IV, Random, 95% CI
Cohen	-1.92	0.72	74	-1.83	0.59	39	-0.13 [-0.52, 0.26]
Danoff-Burg	-12.53	10.8	20	-15.08	11.5	20	0.22 [-0.40, 0.85]
deMoor	-15.7	20.49	19	-19.8	22.06	18	0.19 [-0.46, 0.83]
Gellaitry	-20.63	32.28	38	-24.21	36.97	42	0.10 [-0.34, 0.54]
Gillis	-1.91	0.71	36	-2.14	0.78	32	0.31 [-0.17, 0.78]
Hamilton West & Quine	-5.33	3.57	43	-6.46	3.49	24	0.32 [-0.19, 0.82]
Low	-12.8	8.24	31	-13.2	8.24	31	0.05 [-0.45, 0.55]
Norman	-2.09	0.59	28	-2.11	0.8	20	0.03 [-0.55, 0.60]
Rosenberg	-2.38	2.83	16	-6.21	7.41	14	0.68 [-0.06, 1.42]
Taylor	-13.85	2.75	18	-15	3.65	21	0.34 [-0.29, 0.98]
Vedhara	-16.13	11.47	31	-16.83	9.35	28	0.07 [-0.45, 0.58]
Walker	-17.1	5.99	14	-14.1	6.36	14	-0.47 [-1.22, 0.28]
Wetherell	-33.9	26.1	19	-43.5	19.9	15	0.40 [-0.29, 1.08]
Total (95% CI)			**313**			**279**	**0.18 [0.02, 0.34]**

Heterogeneity: Tau² = 0.00; Chi² = 6.71, df = 11 (P = 0.82); I² = 0%

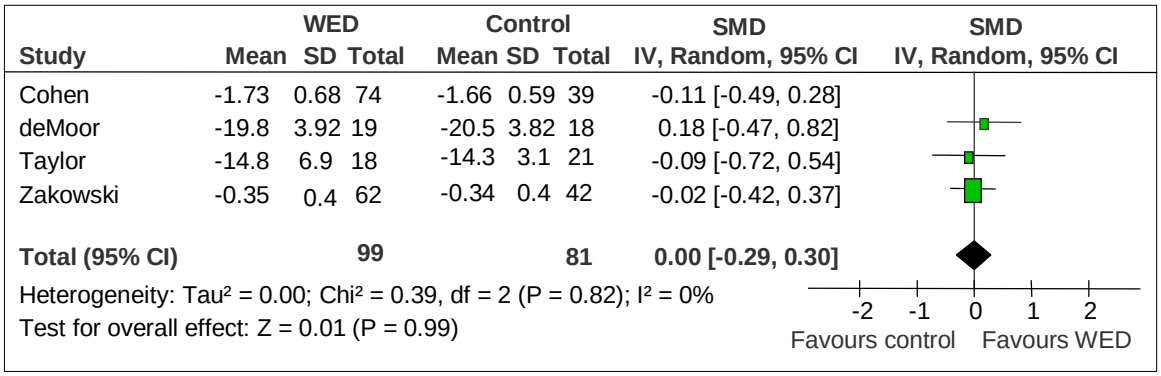
Test for overall effect: Z = 2.17 (P = 0.03)



Negative affect in rheumatic conditions without Cohen: changes from a non-significant and inconclusive effect to a small positive effect that was approaching significance.

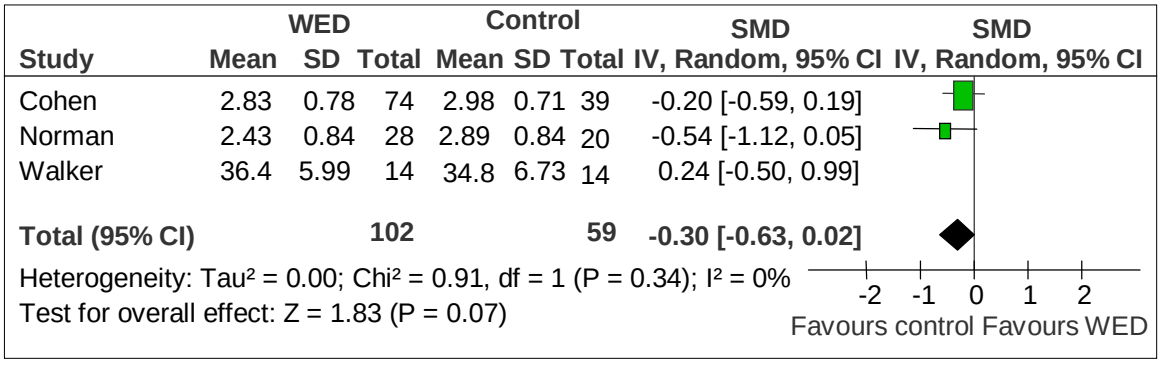


Distress without Cohen: no change (non-significant trend for a small negative effect).

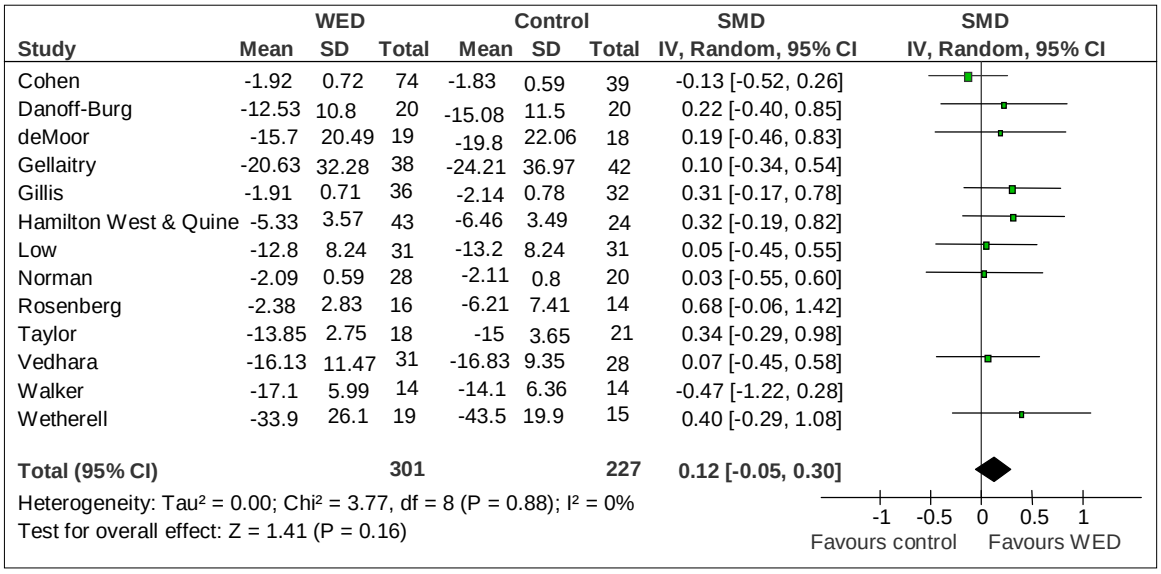


Running meta-analysis with only neutral writing comparison (i.e. usual care removed)

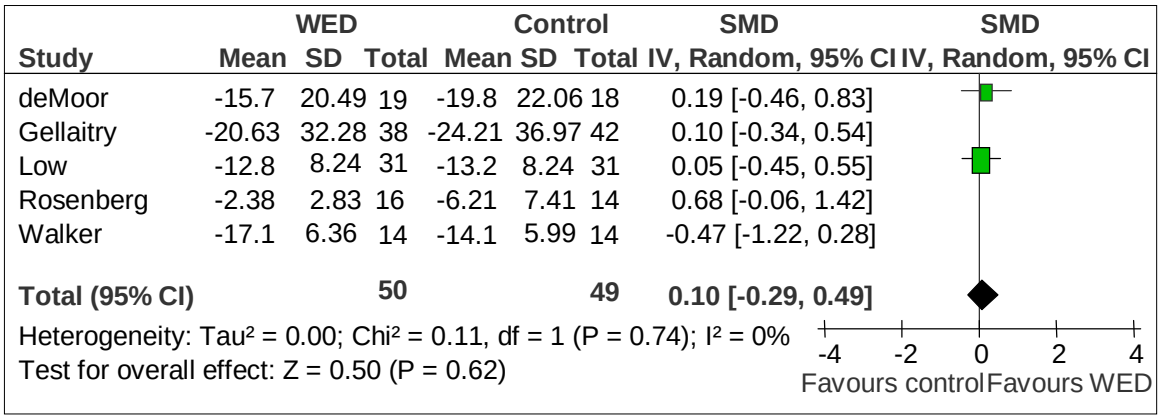
Positive affect without Walker: no change (a non-significant trend for a small negative effect).



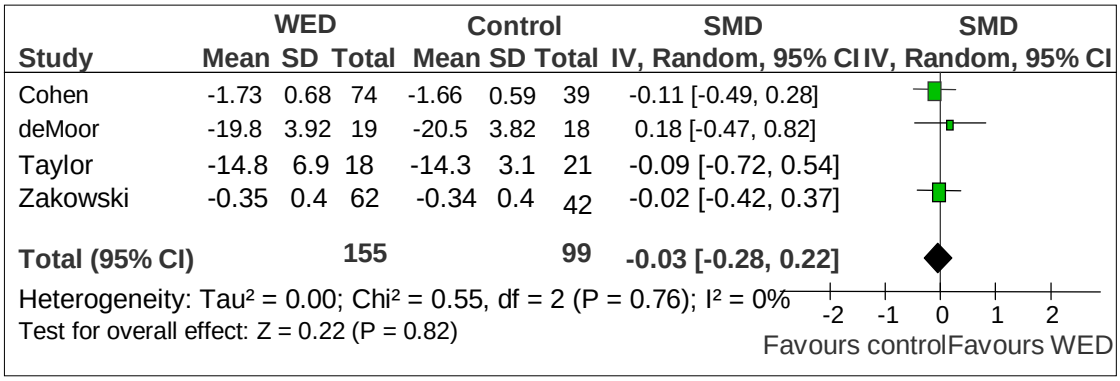
Negative affect without Gellaitry, Rosenberg, Walker & Taylor: no change (a trend for a positive effect that was small and marginally inconclusive yet approaching significance; slightly less notable though).



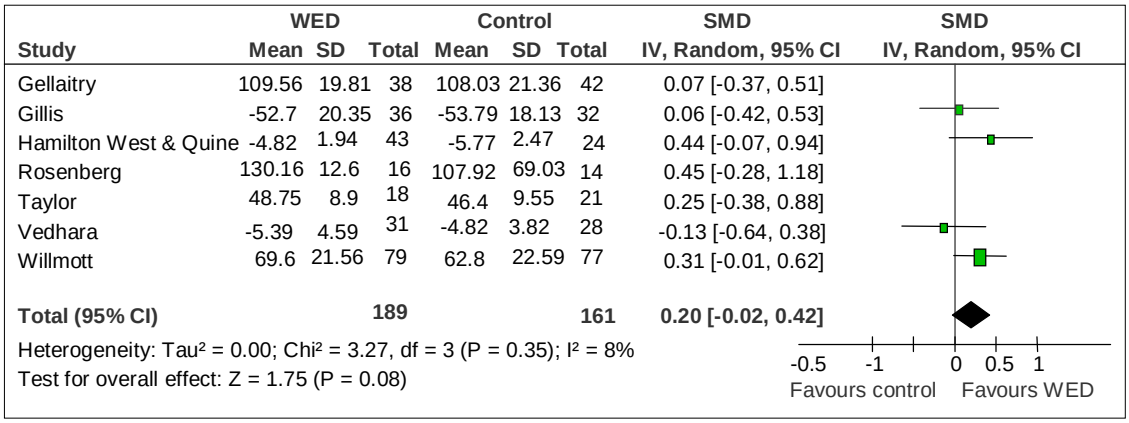
Negative affect in cancer without Gellaitry, Rosenberg & Walker: no change (non-significant and inconclusive effect).



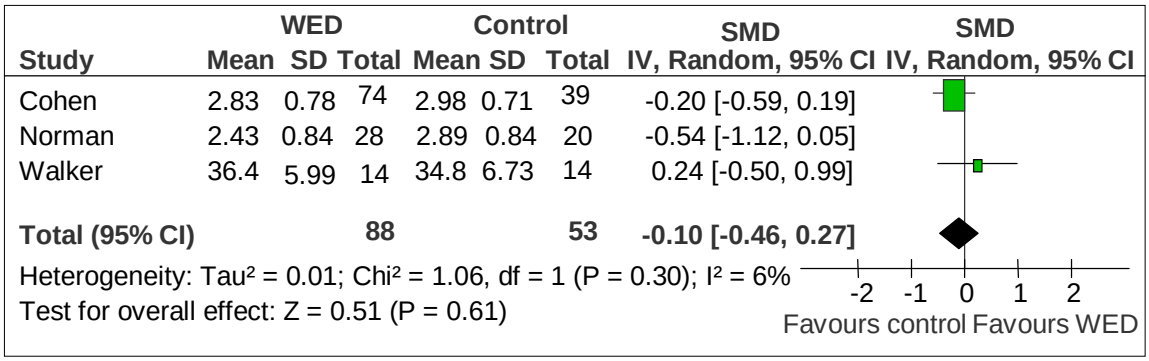
Distress without Taylor: no change (non-significant and inconclusive effect).



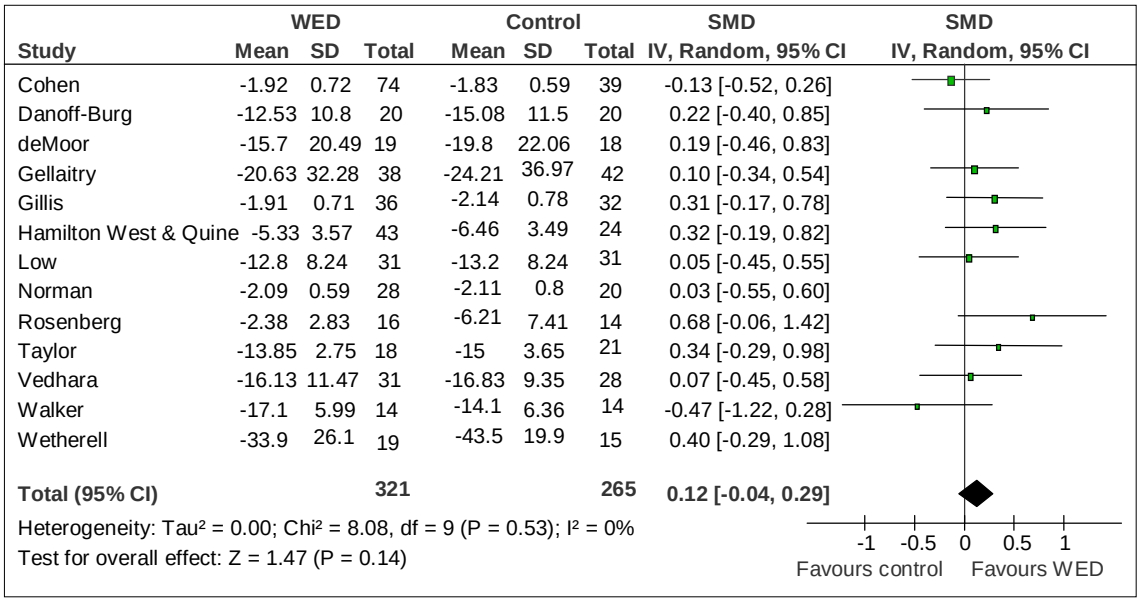
Quality of life without Gellaitry, Rosenberg & Taylor: a small positive effect that changed from being significant to approaching significance.



Running meta-analysis with only follow up ≥3 months (i.e. <3 month removed)
Positive affect without Norman: change from a non-significant trend for a small negative effect to a non-significant and inconclusive effect.



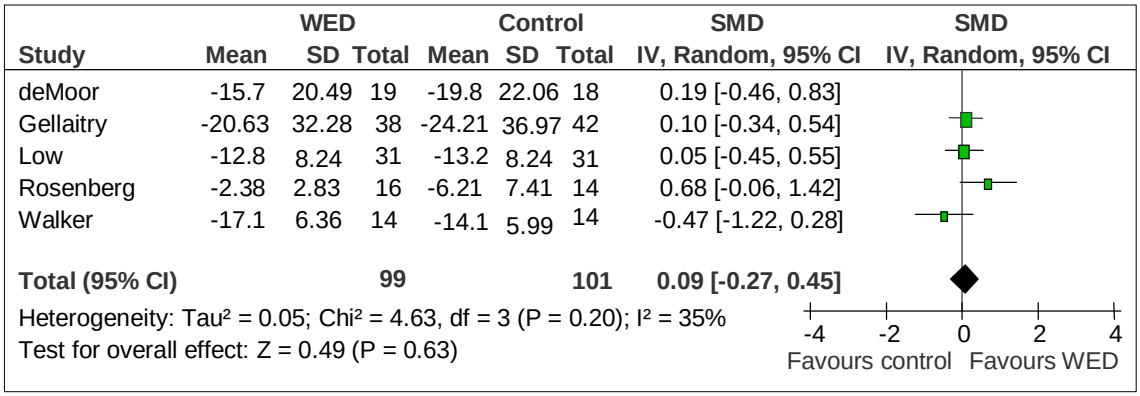
Negative affect without de Moor, Norman & Wetherell: no change (a trend for a positive effect that was small and marginally inconclusive yet approaching significance; slightly less notable though).



Study	WED Mean	WED SD	WED Total	Control Mean	Control SD	Control Total	SMD IV, Random, 95% CI
Cohen	-1.92	0.72	74	-1.83	0.59	39	-0.13 [-0.52, 0.26]
Danoff-Burg	-12.53	10.8	20	-15.08	11.5	20	0.22 [-0.40, 0.85]
deMoor	-15.7	20.49	19	-19.8	22.06	18	0.19 [-0.46, 0.83]
Gellaitry	-20.63	32.28	38	-24.21	36.97	42	0.10 [-0.34, 0.54]
Gillis	-1.91	0.71	36	-2.14	0.78	32	0.31 [-0.17, 0.78]
Hamilton West & Quine	-5.33	3.57	43	-6.46	3.49	24	0.32 [-0.19, 0.82]
Low	-12.8	8.24	31	-13.2	8.24	31	0.05 [-0.45, 0.55]
Norman	-2.09	0.59	28	-2.11	0.8	20	0.03 [-0.55, 0.60]
Rosenberg	-2.38	2.83	16	-6.21	7.41	14	0.68 [-0.06, 1.42]
Taylor	-13.85	2.75	18	-15	3.65	21	0.34 [-0.29, 0.98]
Vedhara	-16.13	11.47	31	-16.83	9.35	28	0.07 [-0.45, 0.58]
Walker	-17.1	5.99	14	-14.1	6.36	14	-0.47 [-1.22, 0.28]
Wetherell	-33.9	26.1	19	-43.5	19.9	15	0.40 [-0.29, 1.08]
Total (95% CI)			**321**			**265**	**0.12 [-0.04, 0.29]**

Heterogeneity: Tau² = 0.00; Chi² = 8.08, df = 9 (P = 0.53); I² = 0%
Test for overall effect: Z = 1.47 (P = 0.14)

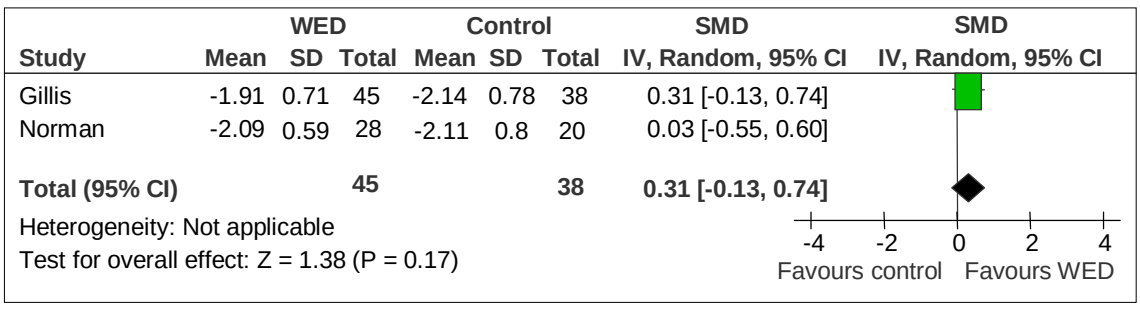
Negative affect in cancer without de Moor: no change (a non-significant and inconclusive effect).



Study	WED Mean	WED SD	WED Total	Control Mean	Control SD	Control Total	SMD IV, Random, 95% CI
deMoor	-15.7	20.49	19	-19.8	22.06	18	0.19 [-0.46, 0.83]
Gellaitry	-20.63	32.28	38	-24.21	36.97	42	0.10 [-0.34, 0.54]
Low	-12.8	8.24	31	-13.2	8.24	31	0.05 [-0.45, 0.55]
Rosenberg	-2.38	2.83	16	-6.21	7.41	14	0.68 [-0.06, 1.42]
Walker	-17.1	6.36	14	-14.1	5.99	14	-0.47 [-1.22, 0.28]
Total (95% CI)			**99**			**101**	**0.09 [-0.27, 0.45]**

Heterogeneity: Tau² = 0.05; Chi² = 4.63, df = 3 (P = 0.20); I² = 35%
Test for overall effect: Z = 0.49 (P = 0.63)

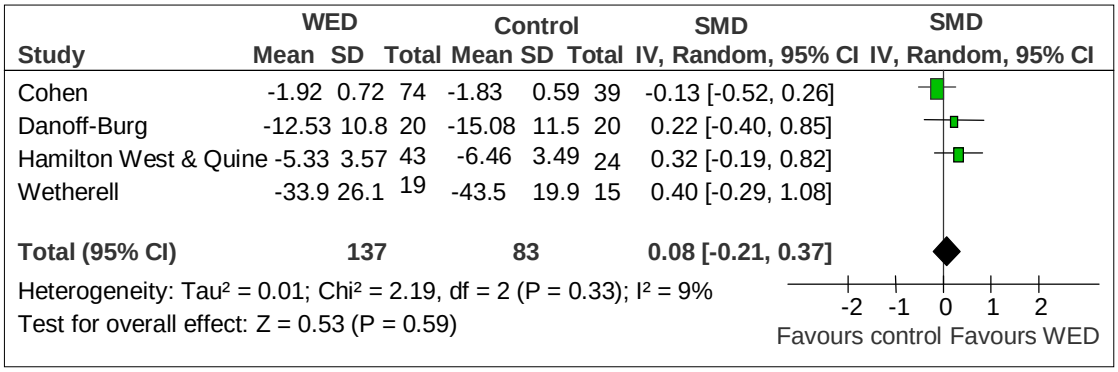
Negative affect in chronic pain without Norman: no change (a non-significant trend for a small positive affect).



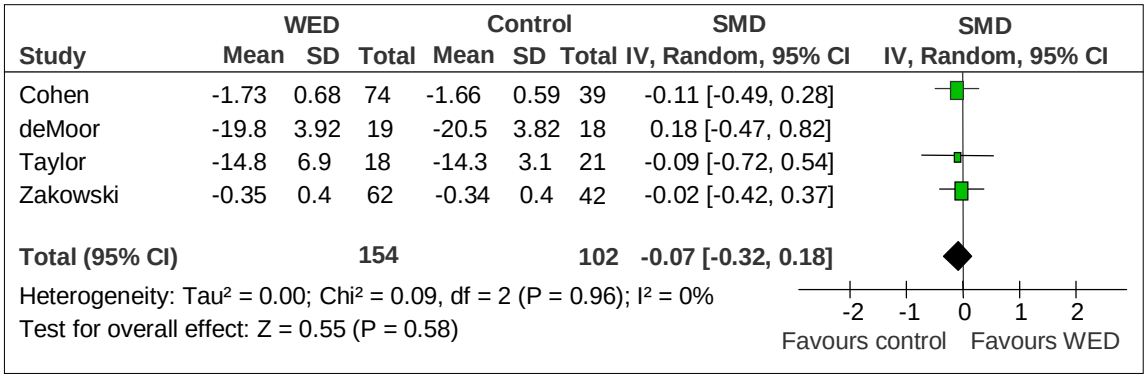
Study	WED Mean	WED SD	WED Total	Control Mean	Control SD	Control Total	SMD IV, Random, 95% CI
Gillis	-1.91	0.71	45	-2.14	0.78	38	0.31 [-0.13, 0.74]
Norman	-2.09	0.59	28	-2.11	0.8	20	0.03 [-0.55, 0.60]
Total (95% CI)			**45**			**38**	**0.31 [-0.13, 0.74]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.38 (P = 0.17)

Negative affect in rheumatic conditions without Wetherell: no change (a non-significant trend and inconclusive effect).



Distress without de Moor: no change (a non-significant and inconclusive effect).



Appendix J: Ethical approval letters

National Research Ethics Service NHS

03 October 2008

Dr Chris Bridle
Associate Professor in Health Psychology
The University of Warwick
Warwick Medical School
Gibbet Hill Road
Coventry
CV4 7AL

Warwickshire Research Ethics Committee

Lewes House
George Eliot Hospital
College Street
Nuneaton
Warwickshire
CV10 7DJ

Tel: 02476 865244
Fax: 02476 865264
pat.horwell@geh.nhs.uk

Dear Dr Bridle

Full title of study: **Written Emotional Disclosure for Adults with Type 2 Diabetes and Symptoms of Depression.**

REC reference number: **08/H1211/129**

The Research Ethics Committee reviewed the above application at the meeting held on 24 September 2008. I would like to thank Dr Jackie Sturt and Kathryn Dennick for attending.

The committee expressed their approval that the supervisor had attended with the student.

Ethical opinion

The members of the Committee present decided they were unable to give a favourable ethical opinion of the research.

The Committee asked questions about the following issues:

- The committee wanted to know that it would be safe for the intended client group to participate in the study and the attendees explained that those practices that routinely screened these patients would be asked to approach potential participants, and that they might include people currently not receiving support for mental ill-health or clinical depression
- The committee wanted know how participants who were unwell would be supported and the attendees stated that some studies had indicated that participants had felt lower at the end of the three days and in this study they would be dealt with on a case by case basis. The committee were also informed that there was a Project Steering Committee where these cases would be referred
- The attendees agreed that the PIS would have to be rewritten to explain the limits to confidentiality for those participants at serious risk of harming themselves or others
- The attendees explained that they had suggested in the PIS that distressed participants contact the Citizens Advice Bureau in order not to alarm the control group

Warwickshire Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within

- The attendees reassured the committee that the cost benefit analysis would not be carried out until the necessary knowledge at a training course had been acquired

The attendees left the room at 5.10 pm having chosen to wait to receive a summary of the committee's decision.

The attendees re entered the room at 5.20 pm to receive a summary of the committee's decision.

Decision

The committee gave an unfavourable opinion for the following reasons:

- **The committee commended the applicant for wishing to undertake the study as it addressed an important question but had concerns about participant safety**
- **There was little evidence that the applicant had the skill to evaluate participants at potential risk**
- **The committee did not feel the screening process was sufficiently robust to exclude patients potentially at risk of, for example, re traumatisation**
- **The committee were concerned at the applicant's lack of understanding of the issues surrounding previously undisclosed trauma and the limits to confidentiality where participants and/or others may be at serious risk of harm**

I regret to inform you therefore that the application is not approved.

The committee suggested that the applicant's colleague, Professor Scott Weich, at the University of Warwick, might be approached for advice regarding these aspects of the study before making a revised application

Options for further ethical review

You may submit a new application for ethical review, taking into account the Committee's concerns. You should enter details of this application on the application form and include a copy of this letter, together with a covering letter explaining what changes have been made from the previous application. We recommend that the application is submitted again to this Committee, but you may opt to submit to another Research Ethics Committee within this domain.

Alternatively, you may appeal against the decision of the Committee by seeking a second opinion on this application from another Research Ethics Committee. The appeal would be based on the application form and supporting documentation reviewed by this Committee, without amendment. If you wish to appeal, you should notify the relevant Research Ethics Service manager (see below) in writing within 90

days of the date of this letter. If the appeal is allowed, another REC will be appointed to give a second opinion within 60 days and the second REC will be provided with a copy of the application, together with this letter and other relevant correspondence on the application. You will be notified of the arrangements for the meeting of the second REC and will be able to attend and/or make written representations if you wish to do so.

The contact point for appeals is:

Joan Kirkbride
Head of Operations, The North, Midlands & East of England
National Research Ethics Service (NRES)
National Patient Safety Agency
c/o Darlington Primary Care Trust
Dr Piper House
King Street
Darlington
Co Durham
DL3 6JL
joan.kirkbride@nres.npsa.nhs.uk

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Applicant checklist		
Covering Letter		28 August 2008
Application	1.1	27 August 2008
Debriefing Sheet	1	28 August 2008
CV Kathryn Dennick		
CV Dr J.A. Sturt		
Participant Consent Form: Patient	1	28 August 2008
Participant Information Sheet: Patient	1	28 August 2008
Letter of invitation to participant	1	28 August 2008
Protocol	1	28 September 2008
Investigator CV		19 August 2008
GP Letter	1	28 August 2008
Practice letter	1	28 August 2008
Participant Information Sheet: Practice	1	28 August 2008
Questionnaire: Booklet 3	1	28 August 2008
Questionnaire: Booklet 2	1	28 August 2008
Questionnaire: Booklet 1	1	28 August 2008
Questionnaire: Study Writing Pack	1	28 August 2008
Questionnaire: Study Writing Pack	1	28 August 2008
Peer Review	1	26 April 2006
Evidence of Insurance/indemnity		31 July 2008

Questionnaire: Booklet 4	1	28 August 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

a) Providing feedback. You are invited to give your view of the service you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
b) Re-submission/Appeal.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk .

08/H1211/129 correspondence	Please quote this number on all

Yours sincerely

Mr Matthew Dunn
Chair

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

Copy to: *Dr Nicola Owen*
R&D Office

National Research Ethics Service NHS

17 December 2008

Dr Chris Bridle
Associate Professor in Health Psychology
The University of Warwick
Warwick Medical School
Gibbet Hill Road
Coventry
CV4 7AL

Warwickshire Research Ethics Committee

Lewes House
George Eliot Hospital
College Street
Nuneaton
Warwickshire
CV10 7DJ

Tel: 02476 865244
Fax: 02476 865264
pat.horwell@geh.nhs.uk

Dear Dr Bridle

Full title of study: **Written Emotional Disclosure for Adults With Type 2 Diabetes and Sub-clinical Symptoms of Depression.**

REC reference number: **08/H1211/165**

The Research Ethics Committee reviewed the above application at the meeting held on 10 December 2008. Thank you for attending to discuss the study.

Ethical opinion

This study had previously received an unfavourable opinion by this committee in September 2008

After discussion the committee came to view that all the issues raised previously had now been addressed and there were no further issues

The committee commended the applicant for addressing the issues and for re submitting to this committee

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Unfavourable opinion letter		03 October 2008
Covering Letter		17 November 2008
Application	1.1	19 November 2008
Issues addressed to unfavourable opinion	1	
Applicant checklist	1.1	24 November 2008
Protocol	2	01 December 2008
Investigator CV		17 November 2008
CV Jackie Sturt		18 August 2008
CV Kathryn Dennick		19 August 2008
Participant Information Sheet		
Expression of interest form	1	01 December 2008
Participant Information Sheet: Patient	2	01 December 2008
Participant Consent Form: Patient	2	01 December 2008
Debriefing sheet	2	01 December 2008
Letter of invitation to participant	1	01 September 2008
Participant Information Sheet: Practice	2	01 December 2008
GP/Consultant Information Sheets	2	01 December 2008
Summary/Synopsis		
GP Letter	1	01 September 2008
Insurance letters x 2		31 July 2008
Peer Review	1	24 April 2006
Study writing pack	2	01 December 2008
Study Flow Diagram	2	
Questionnaire: Screening booklet 1	2	01 December 2008
Questionnaire: Screening	1	01 December 2008
2nd Study Writing pack	2	01 December 2008
Self Harm checklist	1	01 December 2008
Questionnaire: Booklet 4	1	01 September 2008
Questionnaire: Booklet 3	1	01 September 2008
Questionnaire: Booklet 2	1	01 September 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H1211/165	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

per Rathwell

Mr Matthew Dunn
Chair

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Dr Peter Hedges*
R&D office

Appendix K: Practice recruitment materials

Practice letter

Warwick Medical School

THE UNIVERSITY OF WARWICK

Enter Date
Practice Name & Address

Dear [Enter Practice Name]

Writing for People Living with Type 2 diabetes Study

Practice Letter

I am writing to invite you to participate in a research study. This study is being undertaken by me, Kathryn Dennick, a postgraduate researcher, supervised by Dr Chris Bridle and Dr Jackie Sturt, at Warwick Medical School. At Warwick Medical School, one of our research interests relates to innovative ways to help people living with diabetes cope with the consequences of the condition and manage their own care well.

Having Type 2 diabetes often means considerable changes to lifestyle and can have a negative effect on psychological well-being. We know that many patients experience distress, which can have an adverse effect on their condition. This study is investigating whether a writing intervention can influence the health of individuals with Type 2 diabetes. I have enclosed full details.

I do hope that you will agree to help with this important study, which necessitates minimal practice involvement. Under the quality framework set up by the Department of Health the project would provide an alternative for responding to individuals who have indicated that they are experiencing some distress.

If you have any further questions relating to the research please do not hesitate to contact the Project Researcher, Kathryn Dennick on 02476575132, or Project Supervisor, Chris Bridle, on 02476150222. Thank you in anticipation of your help with this study. I will be contacting you shortly about your decision to participate.

Yours sincerely

Kathryn Dennick
Postgraduate Researcher
University of Warwick, Coventry CV4 7AL
E-mail: K.J.Dennick@warwick.ac.uk

Practice information sheet

Writing for People Living with Type 2 diabetes Study

Practice Information Sheet

Background

Having Type 2 diabetes often means considerable changes to lifestyle and can have a negative effect on psychological well-being. We know that many patients experience distress, which can have an adverse effect on their condition. Research suggests that writing about thoughts and feelings about a stressful topic, an intervention termed Written Emotional Disclosure (WED), can have a positive effect on health for many people including those with a long term physical condition and experiencing psychological distress.

Aim

To investigate whether WED influences the health of individuals with Type 2 diabetes.

Design

Randomised controlled trial of WED with 6 month follow up.

Selection Criteria

Type 2 diabetes patients who have been diagnosed for at least 6 months, are aged 18 years or over. Patients who have been diagnosed with a psychotic or bipolar disorder, are currently receiving treatment for depression or any psychological therapy as part of routine care or another research study, have any history of self harm, suicidal ideation or suicide attempts**,** or who you feel would be unsuitable (e.g. if they have past or present psychological vulnerabilities) will be excluded. In the interest of patient safety, patients will undergo a further eligibility check in which those displaying significant depressive symptoms will be excluded.

Intervention

Participants in the intervention group will write at home about the emotional topic, while participants in a control group will write a fact based description of their day, for 20 minutes a day for 3 days over the course of one week. Usual care will continue throughout the study and will not be restricted in any way.

Follow up

Postal questionnaire at 2 weeks, 3 months and 6 months after completion of the intervention. The longest questionnaire takes approximately 20 minutes to complete. With your co-operation, BMI and HbA1c will be collected from existing patient notes at baseline.

Practice Involvement

This study requires minimal practice involvement, limited to help with identifying participants that will not significantly add to your practice workload. All we ask is that you:

a) Search practice registers to identify patients to participate in the study.

b) Mail letters of invitation, patient information sheets, expression of interest forms and a depression-screening questionnaire, provided by the university, to potentially eligible patients.

c) Allow research staff to promptly and anonymously score returned screening questionnaires to identify whether patients are eligible to take part. Alternatively, this can be undertaken by practice staff should that be preferred.

d) Either mail participants consent forms and a baseline questionnaire booklet, or deal accordingly with patients who screen as experiencing significant depressive symptoms and are excluded from the trial.

e) Agree that patient's who screen as experiencing significant depression, or those who experience concerns arising from completing our depression screening questionnaire or the writing task, can be signposted back to their GP.

f) Provide the screening questionnaires/some clinical data for consented participants at the start and or end of the study. You would be required to retain screening questionnaires for a couple of weeks for this purpose.

Feedback to the practice

With participants consent, GPs will be informed of their enrolment into the trial.

Additional Information

a) Patient Complaints and Indemnity:

Patients will be informed that any complaint relating to their participation should be initially directed to the research team where it will be dealt with accordingly. Should they remain unhappy and wish to complain formally please contact Ken Sloan, Deputy Registrar, on 02476524768, Ken.Sloan@warwick.ac.uk. The University of Warwick will provide indemnification.

b) Procedure for serious concern

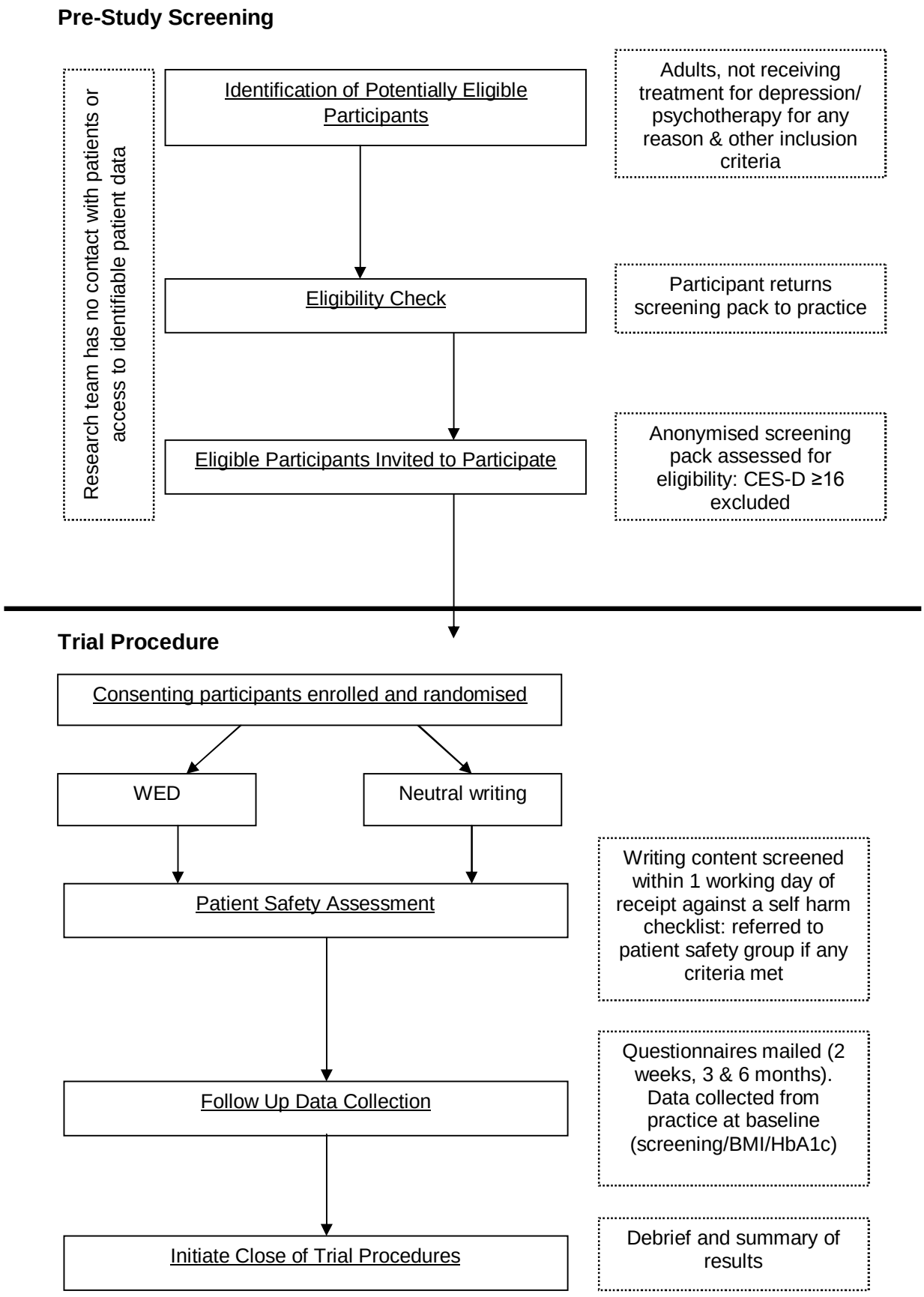
If at any point the research team obtains information that suggests a risk of serious harm to participants or others, they will follow a formal process referring this to a patient safety group. Members of this group include a community psychiatrist, a GP and expert in clinical ethics, a clinical trialist and a lay member of the Warwick University Diabetes User Group.

c) *Access to Study Findings:*
Once the study is completed we will analyse the results and make participants aware of any benefits from writing. Each practice and participant involved in the study will be provided with a summary of findings. It is anticipated the study will also be published.

d) *Study Review*:
The study has been internally peer reviewed within Warwick Medical School, and also reviewed by the Warwick Diabetes Care User Group. This group provides patient perspectives on the validity of diabetes research. The study has additionally been reviewed and approved by the Warwickshire Research Ethics Committee.

Please contact Kathryn Dennick on 02476575132, or Project Supervisor, Dr Chris Bridle, on 02476150222 if you wish to discuss any aspect of the study.

Study Flow Diagram



Appendix L: Patient recruitment materials

Patient letter

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Warwick Medical School

THE UNIVERSITY OF WARWICK

Dear Patient,

Writing for People Living with Type 2 diabetes Study

Patient Letter

I am a researcher at Warwick Medical School (WMS). I would like to invite you to take part in a study. A lot of our research looks at ways to help people cope with having diabetes. We are looking at whether writing affects the health of people with Type 2 diabetes.

We would be grateful if you would think about taking part in this study. Full details are included with this letter.

If you have any questions please do contact the Project Researcher, Kathryn Dennick on 02476575132, or Project Supervisor, Dr Chris Bridle, on 02476150222. Thank you for thinking about taking part.

Yours sincerely

Kathryn Dennick
Postgraduate Researcher
University of Warwick, Coventry CV4 7AL
02476575132
E-mail: K.J.Dennick@warwick.ac.uk

Patient information sheet

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Patient Information Sheet

Before you decide whether you would like to take part in this study, you may want to understand why the research is being done and what it would involve for you. Please take time to read the information below carefully. This tells you about the purpose of the study and what will happen if you take part. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information. Contact details for the research team are provided below. Take time to decide whether or not you would like to take part.

What is the purpose of the study?

The study is looking at different ways of improving the health of people with Type 2 diabetes. Research suggests that writing can affect health for many people including those with a long term condition. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. This study will look at whether and how writing about different topics affects the health of people with Type 2 diabetes.

Why have I been chosen?

You have been selected by staff at your GP practice because you are an adult who has been diagnosed with Type 2 diabetes for at least 6 months. About 150 similar adults with Type 2 diabetes are being asked to take part.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. If you do, you will be asked to sign a consent form. You are free to withdraw at any time without giving a reason, even after you have signed the consent form. This would not affect the standard of care you receive. Information you have already provided may still be used. If you choose to withdraw from writing or not complete some documents once you have consented to take part in the study, we will continue to attempt to obtain information about you as described below, unless you ask us not to. We would appreciate it if you would continue to let us know about your progress.

What will happen to me if I take part?
This study will run for 6 months. You will be asked to complete an intervention and questionnaires at different times. We will give you prepaid envelopes to return anything you are sent.

1. You will first be asked to complete the form showing that you are interested in taking part and screening questionnaire to assess your current well-being, which will take about 3 minutes, which you received with this information sheet. You would then return this to your GP practice. At this point, no information that can be traced back to you will be seen by anyone outside the practice, including the research team. Your eligibility will be determined from your response, and if you are able to take part your practice will mail you a formal consent form and questionnaire booklet to complete, which will take about 20 minutes. As we are not able to discuss individual screening scores we suggest you contact your GP if you would like to discuss this.

2. You will then return this booklet with a copy of the signed consent form to the research team, and we will mail you a writing pack. If you consent to take part in the study we will then contact your practice for your screening information. The writing pack will include instructions to write about some aspect of your life for 20 minutes each day for 3 days over the course of one week. There will also be some short questions about how you found the task. It is really important that you do the writing task as requested. This study is not concerned with your writing ability. In fact you will be asked not to pay attention to spelling and grammar etc. Once you have completed the task you will return the pack.

3. To see whether writing has affected your health, you will then receive a questionnaire at 2 weeks, 3 months, and 6 months after you return the writing pack. The 3 month one will also take about 20 minutes to complete while the other 2 will take about 15 minutes each. You may receive a reminder letter or telephone call if you do not return some documents. With your permission your health care records will also be looked at by practice staff at the start of the study. They will then give us your height, weight and blood results, but if you do not want us to have this information you can record this on the consent form.

What is the procedure being tested?
We will ask you to write about different aspects of your life.

Who will know that I am taking part?
The only people who will know that you are taking part are the research team, and with your consent, your GP.

What will you do with the findings?
A summary of the results will be given to you at the end of the study. In addition the results of the study may be published, which we will let you know about. We will not use any details that could identify you in any report or publication.

What are the possible risks of taking part?
We do not foresee any risks to your health in taking part. You will be asked to take time out of your daily routine to write for 20 minutes on three days and complete five questionnaires. However, you can stop at any time.

What are the side effects of any treatment received whilst taking part?
Most people will not experience any side-effects. If you feel that the screening questionnaire has raised some issues that you would like to discuss we advise that you contact your GP on..... Some people, depending on the topic they write about, may also experience a slightly lower mood than usual, like watching a sad film, but this would be temporary and pass very quickly. If you are worried about how you feel, you are free to stop writing at any time and talk to someone about this if you wish, including your GP on..... Potentially helpful contacts include:

Citizens Advice Bureau 08451202920 (Coventry) 01926457900 (Warwick Districts)
Mind 08457660163
NHS Direct 08454647
Samaritans 08457 90 90 90

What are the possible benefits of taking part?
We cannot promise the study will help you but you may experience some benefit from writing. The findings from the study will help us understand how to improve the treatment of people with Type 2 diabetes.

Will my details be kept confidential?
Yes. Any information you provide to the research team will be kept strictly confidential. Paper records will only have your participant number on so that you cannot be recognised from them except by the research team. Any information about you from your health care records that leaves your practice will have your name and address removed so that you cannot be recognised from it. It is possible, however, that if you reveal information of a certain nature once you have consented to take part in the study, for example if your writing includes information that suggests a risk to yourselves or others, we may need to break our confidentiality agreement and tell an appropriate party**.**

How will records from the study be stored?
All paper records will be stored in a locked filing cabinet in a locked office and will not leave the university premises. Information stored on a computer can only be viewed with a password. Only the research team will have access to information. Your information will only be used for this study and will be retained for 5 years once the study has finished. After this it will be securely destroyed.

What will happen to the writing I do?
This will be stored securely with the other paper records as described above.

What happens if there is a problem?
Any complaint about the way you have been dealt with during the study will be addressed.

1. You are first encouraged to speak to the research team who will do their best to answer your questions.
2. If you are still unhappy and wish to complain formally please contact Ken Sloan, Deputy Registrar, on 02476524768, Ken.Sloan@warwick.ac.uk. The University of Warwick will provide indemnification.

What if relevant new information becomes available?
It is not expected that we will get new information about this writing intervention. However, if this happens, we will tell you and discuss whether you should continue in the study. If you decide to continue you may be asked to sign an updated consent form.

What happens when the research stops?
Once the study has finished we will analyse the data and let you know if we find any benefits from writing.

Who has reviewed the study?
All research involving the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). This is to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by the Warwickshire REC.

Who is paying for this study?
The University of Warwick is sponsoring and funding the research.

Contact Details
For further information about the study please contact the researcher, Kathryn Dennick, on 02476575132, or Project Supervisor, Dr Chris Bridle, on 02476150222 who will be happy to answer any questions.
Our address for correspondence is Kathryn Dennick
Warwick Medical School
The University of Warwick
Gibbet Hill Road
Coventry CV4 7AL

This is your information sheet to keep. Thank you for taking time to read it.

Expression of interest form

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Writing for People Living with Type 2 diabetes Study

Expression of Interest Form

Thank you again for considering taking part in this research. If you are interested please RETURN THIS FORM TO YOUR PRACTICE in the pre-paid envelope provided.

I _____(name) would like to express an interest in taking part in this study.

Screening questionnaire

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Warwick Medical School

THE UNIVERSITY OF WARWICK

Participant Identification Number _____

Writing for People Living with Type 2 diabetes Study

Screening Questionnaire

Thank you again for considering taking part in this research. If you are interested please RETURN THIS QUESTIONNAIRE TO YOUR PRACTICE in the pre-paid envelope provided.

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week by circling the appropriate number

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or All of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	1	2	3	4
2. I did not feel like eating; my appetite was poor.	1	2	3	4
3. I felt that I could not shake off the blues even with help from my family or friends.	1	2	3	4
4. I felt that I was as good as other people.	1	2	3	4
5. I had trouble keeping my mind on what I was doing.	1	2	3	4
6. I felt depressed.	1	2	3	4
7. I felt that everything I did was an effort.	1	2	3	4
8. I felt hopeful about the future.	1	2	3	4
9. I thought my life had been a failure.	1	2	3	4
10. I felt fearful.	1	2	3	4
11. My sleep was restless.	1	2	3	4
12. I was happy.	1	2	3	4
13. I talked less than usual.	1	2	3	4
14. I felt lonely.	1	2	3	4
15. People were unfriendly.	1	2	3	4
16. I enjoyed life.	1	2	3	4
17. I had crying spells.	1	2	3	4
18. I felt sad.	1	2	3	4
19. I felt that people disliked me.	1	2	3	4
20. I could not get "going".	1	2	3	4

Appendix M: Consent forms

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Consent Form

PLEASE KEEP THIS COPY

Please Initial Box

1. I confirm that I have read and understand the information sheet dated Dec 08 (version 2) for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of my medical notes and data collected during the study may be looked at by individuals from the University of Warwick, from regulatory authorities, or from the NHS trust, where this is relevant to me taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

GP SURGERY LETTER HEAD TO BE INSERTED HERE

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Consent Form

PLEASE RETURN THIS COPY TO THE RESEARCHER in the pre-paid envelope provided

Please Initial Box

1. I confirm that I have read and understand the information sheet dated Dec 08 (version 2) for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of my medical notes and data collected during the study may be looked at by individuals from the University of Warwick, from regulatory authorities, or from the NHS trust, where this is relevant to me taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

We would be grateful if you would provide the following contact details so that we can collect the information we need as described in the patient information sheet.

Address _____

_____

Telephone _____

Name of GP practice _____

Appendix N: Debrief sheet

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Debriefing Sheet

Thank you for taking part in this study. Without your support it would not have been possible. The study looked at whether writing about aspects of life affects the health of people with Type 2 diabetes.

Research shows writing about feelings of a stressful event can improve physical and mental health for people with long term conditions. The aim was to find out whether this procedure has the same effect for people with Type 2 diabetes. We looked at people with Type 2 diabetes as research shows they are at risk of depression.

You were either in a group where you wrote about your feelings of a stressful event or in a group where you wrote about your daily routine with no feelings. These groups will be compared to see whether writing about feelings improves health more than just writing. Hence, the 'no feelings' writing task was crucial so that we can find out whether writing about feelings does improve health.

We are sorry that we could not tell you about this until now. The decision was not taken likely. We spoke with people with Type 2 diabetes and experts in clinical ethics when designing our study. We also obtained NHS ethical approval. We withheld this from you to protect you and the quality of the research.

So that we can analyse our results we would be grateful if you would answer the questions on the next page.

If you have any problems talk to someone about this if you wish, including your GP on..... Potentially helpful contacts include:

Citizens Advice Bureau 08451202920 (Coventry) 01926457900 (Warwick Districts)
Mind 08457660163
NHS Direct 08454647
Samaritans 08457 90 90 90

If you have any queries or concerns about the study please contact the researcher, Kathryn Dennick, on 02476575132, or Project Supervisor, Dr Chris Bridle, on 02476150222.

Thank you again.

PLEASE COMPLETE THE FOLLOWING QUESTIONS

1. Were you aware that there were 2 different groups?

Yes ❑ No ❑

2. Having read this debriefing sheet had you guessed what the other group was writing about?

Yes ❑ No ❑

3. Having read this debriefing sheet and now knowing what group you were in, had you already guessed the purpose of your writing task?

Yes ❑ No ❑

May I take this opportunity to thank you for taking the time to help with this research.

As you already know, we need to be able to compare your answers on each questionnaire you complete. However, to protect your anonymity, we do not want your name to appear on any questionnaire you complete. For this reason everyone is provided with a unique identification code, which you can create yourself by using the following formula:

In the space provided please write …

1) … the first 2 letters of your **mother's** first name, e.g. 'SU' for Susan ☐☐

2) … the **month** you were born, e.g. '07' for July ☐☐

3) … the first 2 letters of **your own** first name, e.g. 'JO' for John. ☐☐

Once again, thank you very much for your help with this research.
Please return this form in the pre-paid envelope provided.

Appendix O: Baseline questionnaire

THE UNIVERSITY OF WARWICK

Warwick Medical School

Writing for People Living with Type 2 diabetes Study

Questionnaire Booklet 1

Please complete the following sections

Section 1

Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you . Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?	1	2	3	4	5
2. Feeling discouraged with your diabetes treatment plan?	1	2	3	4	5
3. Feeling scared when you think about living with diabetes?	1	2	3	4	5
4. Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat?)	1	2	3	4	5
5. Feelings of deprivation regarding food and meals?	1	2	3	4	5
6. Feeling depressed when you think about living with diabetes?	1	2	3	4	5
7. Not knowing if your mood or feelings are related to your diabetes?	1	2	3	4	5
8. Feeling overwhelmed by your diabetes?	1	2	3	4	5
9. Worrying about low blood sugar reaction?	1	2	3	4	5
10. Feeling angry when you think about living with diabetes?	1	2	3	4	5
11. Feeling constantly concerned about food and eating?	1	2	3	4	5
12. Worrying about the future and the possibility of serious complications?	1	2	3	4	5
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	1	2	3	4	5
14. Not "accepting" your diabetes?	1	2	3	4	5
15. Feeling unsatisfied with your diabetes doctor?	1	2	3	4	5
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	1	2	3	4	5
17. Feeling alone with your diabetes?	1	2	3	4	5
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	1	2	3	4	5
19. Coping with complications of diabetes?	1	2	3	4	5
20. Feeling "burned out" by the constant effort needed to manage diabetes?	1	2	3	4	5

Section 2
By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

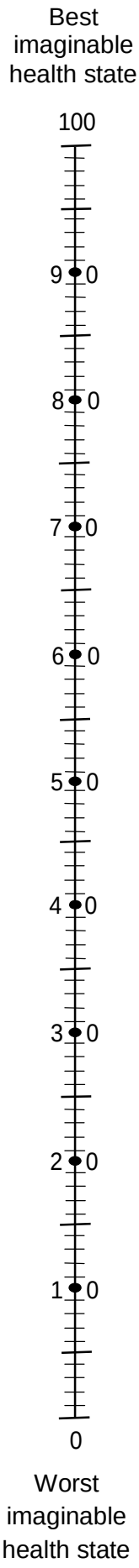
Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



Section 3

The questions below ask you about your diabetes self care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1. How many of the last SEVEN DAYS have you followed a eating plan?	0	1	2	3	4	5	6	7
2. On average, over the past month, how many days per week have you followed your eating plan?	0	1	2	3	4	5	6	7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?	0	1	2	3	4	5	6	7
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (total minutes of continuous activity including walking).	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?	0	1	2	3	4	5	6	7
9. On how many of the last SEVEN DAYS did you check your feet?	0	1	2	3	4	5	6	7
10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	0	1	2	3	4	5	6	7

11. Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?
    0. No
    1. Yes.

If yes, how many cigarettes did you smoke on an average day? Number of cigarettes.....

Section 4

1. **In the past 6 months**, how many times did you visit a doctor? Do **NOT** include visits while in the hospital or the hospital emergency room.....visits

2. **In the past 6 months**, how many times did you go to a **hospital** emergency room?.....times

3. How many total NIGHTS did you spend in the hospital **in the past 6 months**? .....nights

4. When was the last time you had your eyes examined? (example: for glaucoma or any other problem).....month/yr

5. How many **times** did the doctor or nurse examine your feet in the last 6 months?.....times

Section 5
The following items ask about how much your illness and/or its treatment interferes with your life. **Please circle the one number that best describes your current life situation.** If an item is not applicable, please check the box to indicate that this aspect of your life is not affected. Please do not leave any item unanswered.

How much does your illness and/or its treatment interfere with:

1. Your feeling of being healthy?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
2. The things you eat and drink?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
3. Your work, including job, house work, chores, or errands?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
4. Playing sports, gardening, or other physical recreation or hobbies?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
5. Quiet recreation or hobbies such as reading, TV, music, knitting, etc.?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
6. Your financial situation?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
7. Your relationship with your spouse or domestic partner?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
8. Your sex life?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
9. Your relationship and social activities with your family?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
10. Social activities with your friends, neighbours, or groups?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
11. Your religious or spiritual activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
12. Your involvement in community or civic activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
13. Your self-improvement or self-expression activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑

Section 6

Below is a list of activities you have to perform to manage your diabetes. Please read each one and then circle the number which best describes how **confident** you usually are that you could carry out that activity. For example, if you are completely confident that you are able to check your blood sugar levels when nessessary, circle 10. If you feel that most of the time you could not do it, circle 1 or 2.

I am confident that……..

	Cannot do At all			**Maybe yes maybe no**						**Certain can do**
1	I am able to check my blood sugar if necessary									
	0	1	2	3	4	5	6	7	8	9	10
2	I am able to correct my blood sugar when the sugar level is too high.									
	0	1	2	3	4	5	6	7	8	9	10
3	I am able to correct my blood sugar when the blood sugar level is too low.									
	0	1	2	3	4	5	6	7	8	9	10
4	I am able to choose the correct foods.									
	0	1	2	3	4	5	6	7	8	9	10
5	I am able to keep my weight under control.									
	0	1	2	3	4	5	6	7	8	9	10
6	I am able to examine my feet for cuts.									
	0	1	2	3	4	5	6	7	8	9	10
7	I am able to adjust my eating plan when ill.									
	0	1	2	3	4	5	6	7	8	9	10
8	I am able to follow a healthy eating pattern most of the time.									
	0	1	2	3	4	5	6	7	8	9	10
9	I am able to take more exercise if the doctor advises me to.									
	0	1	2	3	4	5	6	7	8	9	10
10	When taking more exercise I am able to adjust my eating plan.									
	0	1	2	3	4	5	6	7	8	9	10
11	I am able to follow a healthy eating pattern when I am away from home.									
	0	1	2	3	4	5	6	7	8	9	10
12	I am able to follow a healthy eating pattern when I am eating out or at a party.									
	0	1	2	3	4	5	6	7	8	9	10
13	I am able to adjust my eating plan when I am feeling stressed or anxious.									
	0	1	2	3	4	5	6	7	8	9	10
14	I am able to take my medication as prescribed.									
	0	1	2	3	4	5	6	7	8	9	10
15	I am able to adjust my medication when I am ill.									
	0	1	2	3	4	5	6	7	8	9	10

Section 7

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help and support in the manner described. Give the persons' initials, their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have.

If you have had no support for a question, check the words "No one", but still rate your level of satisfaction.

Do not list more than nine persons per question.

Please answer all the questions as best you can.

EXAMPLE:

Who do you know whom you can trust with information that could get you in trouble?

No one	1) T.N. (brother)	4) T.N. (father)	7)
	2) L.M. (friend)	5) L.M. (employer)	8)
	3) R.S. (friend)	6)	9)

How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

1. Whom can you really count on to be dependable when you need help?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

2. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

3. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

4. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

5. Who accepts you totally, including both your worst and best points?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

6. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

7. Whom can you really count on to care about you, regardless of what is happening to you?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

8. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

9. Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

10. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

11. Who can you count on to console you when you are very upset?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

12. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

Section 8

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers. Answer according to your own feelings, rather than how you think "most people" would answer. Circle the number that gives the best answer for you.

	1 I agree a lot	2 I agree a little	3 I neither agree nor disagree	4 I disagree	5 I disagree a lot
1. In uncertain times, I usually expect the best.	1	2	3	4	5
2. It's easy for me to relax	1	2	3	4	5
3. If something can go wrong for me, it will.	1	2	3	4	5
4. I'm always optimistic about my future.	1	2	3	4	5
5. I enjoy my friends a lot.	1	2	3	4	5
6. It's important for me to keep busy.	1	2	3	4	5
7. I hardly ever expect things to go my way.	1	2	3	4	5
8. I don't get upset too easily.	1	2	3	4	5
9. I rarely count on good things happening to me.	1	2	3	4	5
10. Overall, I expect more good things to happen to me than bad.	1	2	3	4	5

Section 9

Using the scale provided as a guide, indicate how much you agree or disagree with each of the following statements by circling the corresponding number. Give only one answer for each statement.

Circle 1 if you STRONGLY DISAGREE
Circle 2 if you MODERATELY DISAGREE
Circle 3 if you NEITHER DISAGREE NOR AGREE
Circle 4 if you MODERATELY AGREE
Circle 5 if you STRONGLY AGREE

	Strongly Disagree	Moderately Disagree	Neither Disagree Nor Agree	Moderately Agree	Strongly Agree
1. I am often confused about what emotion I am feeling.	1	2	3	4	5
2. It is difficult for me to find the right words for my feelings.	1	2	3	4	5
3. I have physical sensations that even doctors don't understand.	1	2	3	4	5
4. I am able to describe my feelings easily.	1	2	3	4	5
5. I prefer to analyze problems rather than just describe them.	1	2	3	4	5
6. When I am upset, I don't know if I am sad, frightened, or angry.	1	2	3	4	5
7. I am often puzzled by sensations in my body.	1	2	3	4	5
8. I prefer to just let things happen rather than to understand why they turned out that way.	1	2	3	4	5
9. I have feelings that I can't quite identify.	1	2	3	4	5
10. Being in touch with emotions is essential.	1	2	3	4	5
11. I find it hard to describe how I feel about people.	1	2	3	4	5
12. People tell me to describe my feelings more.	1	2	3	4	5
13. I don't know what's going on inside me.	1	2	3	4	5
14. I often don't know why I am angry.	1	2	3	4	5
15. I prefer talking to people about their daily activities rather than their feelings.	1	2	3	4	5
16. I prefer to watch "light" entertainment shows rather than psychological dramas	1	2	3	4	5
17. It is difficult for me to reveal my innermost feelings, even to close friends.	1	2	3	4	5
18. I can feel close to someone, even in moments of silence.	1	2	3	4	5
19. I find examination of my feelings useful in solving personal problems.	1	2	3	4	5
20. Looking for hidden meanings in movies or plays distracts from their enjoyment.	1	2	3	4	5

Section 10
Please provide the following information about yourself (tick boxes as appropriate):

Age: …….yrs

Gender: Male ☐ Female ☐

Ethnicity: *White*

British ☐
Irish ☐
Other ☐ (please specify…….....)

Asian or Asian British

Indian ☐
Pakistani ☐
Bangladeshi ☐
Other ☐ (please specify……..)

Black or Black British

Caribbean ☐
African ☐
Other ☐ (please specify……..……)

Mixed

White and Black Caribbean ☐
White and Black African ☐
White and Asian ☐
Other ☐ (please specify……)

Chinese or other ethnic group

Chinese ☐
Other ☐ (please specify……)

Education:

Level 1 ☐
(1 to 4 O level passes, 1 to 4 CSE/ GCSE any grades, NVQ level 1 or Foundation GNVQ)

Level 2 ☐
(5 or more O level passes, 5 or more CSEs (grade 1), 5 or more GCSEs (grades A-C), School Certificate, 1 A level, 1 to 3 AS levels, NVQ level 2, Intermediate GNVQ)

Level 3 ☐
(2 or more A levels, 4 or more AS levels, Higher School Certificate, NVQ level 3, Advanced GNVQ)

Level 4/5 ☐
(First degree, higher degree, NVQ levels 4 and 5, HNC, HND, Qualified Teacher Status, Qualified Medical Doctor, Qualified Dentist, Qualified Nurse, Midwife, Health Visitor)

Relationship Status: Single ☐ (including separated/ divorced and widowed) Co-habiting ☐ Married/Remarried ☐

Time since diabetes diagnosis: …….yrs/months

Diabetes complications:

Heart disease/stroke ☐ Neuropathies (nerve damage) ☐

Retinopathy (eye disease) ☐ Kidney disease/failure ☐

Hypoglycemia (low blood glucose) ☐ Sexual/urologic Problems ☐

Other ☐ (please specify……..)

Diabetes medication: Diet/exercise only ☐ Tablets ☐

Tablets and insulin ☐ Insulin ☐

Are you currently involved in any other research projects? Yes ☐ No ☐

You have now completed the questionnaire.

May I take this opportunity to thank you for taking the time to help with this research.

As you know, we will ask you to complete more questionnaires over the next few months, and we need to be able to compare your answers on each questionnaire you complete. However, to protect your anonymity, we do not want your name to appear on any questionnaire you complete. For this reason everyone is provided with a unique identification code, which you can create yourself by using the following formula:

In the space provided please write …

1) … the first 2 letters of your **mother's** first name, e.g. 'SU' for Susan ☐☐

2) … the **month** you were born, e.g. '07' for July ☐☐

3) … the first 2 letters of **your own** first name, e.g. 'JO' for John. ☐☐

Once again, thank you very much for your help with this research.
Please return this booklet with the researcher's copy of your signed consent form in the pre-paid envelope provided.

Appendix P: Two week questionnaire

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Questionnaire Booklet 2

Please complete the following sections

Section 1

The following items ask about how much your illness and/or its treatment interferes with your life. **Please circle the one number that best describes your current life situation.** If an item is not applicable, please check the box to indicate that this aspect of your life is not affected. Please do not leave any item unanswered.

How much does your illness and/or its treatment interfere with:

1. Your feeling of being healthy?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
2. The things you eat and drink?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
3. Your work, including job, house work, chores, or errands?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
4. Playing sports, gardening, or other physical recreation or hobbies?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
5. Quiet recreation or hobbies such as reading, TV, music, knitting, etc.?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
6. Your financial situation?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
7. Your relationship with your spouse or domestic partner?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
8. Your sex life?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
9. Your relationship and social activities with your family?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
10. Social activities with your friends, neighbours, or groups?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
11. Your religious or spiritual activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
12. Your involvement in community or civic activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
13. Your self-improvement or self-expression activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑

Section 2

Below is a list of activities you have to perform to manage your diabetes. Please read each one and then circle the number which best describes how **confident** you usually are that you could carry out that activity. For example, if you are completely confident that you are able to check your blood sugar levels when nessessary, circle 10. If you feel that most of the time you could not do it, circle 1 or 2.

I am confident that……..

	Cannot do At all			**Maybe yes maybe no**						**Certain can do**
1	I am able to check my blood sugar if necessary									
	0	1	2	3	4	5	6	7	8	9	10
2	I am able to correct my blood sugar when the sugar level is too high.									
	0	1	2	3	4	5	6	7	8	9	10
3	I am able to correct my blood sugar when the blood sugar level is too low.									
	0	1	2	3	4	5	6	7	8	9	10
4	I am able to choose the correct foods.									
	0	1	2	3	4	5	6	7	8	9	10
5	I am able to keep my weight under control.									
	0	1	2	3	4	5	6	7	8	9	10
6	I am able to examine my feet for cuts.									
	0	1	2	3	4	5	6	7	8	9	10
7	I am able to adjust my eating plan when ill.									
	0	1	2	3	4	5	6	7	8	9	10
8	I am able to follow a healthy eating pattern most of the time.									
	0	1	2	3	4	5	6	7	8	9	10
9	I am able to take more exercise if the doctor advises me to.									
	0	1	2	3	4	5	6	7	8	9	10
10	When taking more exercise I am able to adjust my eating plan.									
	0	1	2	3	4	5	6	7	8	9	10
11	I am able to follow a healthy eating pattern when I am away from home.									
	0	1	2	3	4	5	6	7	8	9	10
12	I am able to follow a healthy eating pattern when I am eating out or at a party.									
	0	1	2	3	4	5	6	7	8	9	10
13	I am able to adjust my eating plan when I am feeling stressed or anxious.									
	0	1	2	3	4	5	6	7	8	9	10
14	I am able to take my medication as prescribed.									
	0	1	2	3	4	5	6	7	8	9	10
15	I am able to adjust my medication when I am ill.									
	0	1	2	3	4	5	6	7	8	9	10

Section 3

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help and support in the manner described. Give the persons' initials, their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have.

If you have had no support for a question, check the words "No one", but still rate your level of satisfaction.

Do not list more than nine persons per question.

Please answer all the questions as best you can.

EXAMPLE:

Who do you know whom you can trust with information that could get you in trouble?

No one	1) T.N. (brother)	4) T.N. (father)	7)
	2) L.M. (friend)	5) L.M. (employer)	8)
	3) R.S. (friend)	6)	9)

How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

1. Whom can you really count on to be dependable when you need help?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

2. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

3. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

4. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

5. Who accepts you totally, including both your worst and best points?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

6. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

7. Whom can you really count on to care about you, regardless of what is happening to you?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

8. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

9. Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

10. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

11. Who can you count on to console you when you are very upset?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

12. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

You have now completed the questionnaire.

May I take this opportunity to thank you for taking the time to help with this research.

As you know, we will ask you to complete more questionnaires over the next few months, and we need to be able to compare your answers on each questionnaire you complete. However, to protect your anonymity, we do not want your name to appear on any questionnaire you complete. For this reason everyone is provided with a unique identification code, which you can create yourself by using the following formula:

In the space provided please write …

1) … the first 2 letters of your **mother's** first name, e.g. 'SU' for Susan ☐☐

2) … the **month** you were born, e.g. '07' for July ☐☐

3) … the first 2 letters of **your own** first name, e.g. 'JO' for John. ☐☐

Once again, thank you very much for your help with this research.
Please return this booklet in the pre-paid envelope provided.

Appendix Q: Three month questionnaire

Warwick Medical School

THE UNIVERSITY OF WARWICK

Writing for People Living with Type 2 diabetes Study

Questionnaire Booklet 3

Please complete the following sections

Section 1

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week by circling the appropriate number

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or All of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	1	2	3	4
2. I did not feel like eating; my appetite was poor.	1	2	3	4
3. I felt that I could not shake off the blues even with help from my family or friends.	1	2	3	4
4. I felt that I was as good as other people.	1	2	3	4
5. I had trouble keeping my mind on what I was doing.	1	2	3	4
6. I felt depressed.	1	2	3	4
7. I felt that everything I did was an effort.	1	2	3	4
8. I felt hopeful about the future.	1	2	3	4
9. I thought my life had been a failure.	1	2	3	4
10. I felt fearful.	1	2	3	4
11. My sleep was restless.	1	2	3	4
12. I was happy.	1	2	3	4
13. I talked less than usual.	1	2	3	4
14. I felt lonely.	1	2	3	4
15. People were unfriendly.	1	2	3	4
16. I enjoyed life.	1	2	3	4
17. I had crying spells.	1	2	3	4
18. I felt sad.	1	2	3	4
19. I felt that people disliked me.	1	2	3	4
20. I could not get "going".	1	2	3	4

Section 2

Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you . Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?	1	2	3	4	5
2. Feeling discouraged with your diabetes treatment plan?	1	2	3	4	5
3. Feeling scared when you think about living with diabetes?	1	2	3	4	5
4. Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat?)	1	2	3	4	5
5. Feelings of deprivation regarding food and meals?	1	2	3	4	5
6. Feeling depressed when you think about living with diabetes?	1	2	3	4	5
7. Not knowing if your mood or feelings are related to your diabetes?	1	2	3	4	5
8. Feeling overwhelmed by your diabetes?	1	2	3	4	5
9. Worrying about low blood sugar reaction?	1	2	3	4	5
10. Feeling angry when you think about living with diabetes?	1	2	3	4	5
11. Feeling constantly concerned about food and eating?	1	2	3	4	5
12. Worrying about the future and the possibility of serious complications?	1	2	3	4	5
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	1	2	3	4	5
14. Not "accepting" your diabetes?	1	2	3	4	5
15. Feeling unsatisfied with your diabetes doctor?	1	2	3	4	5
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	1	2	3	4	5
17. Feeling alone with your diabetes?	1	2	3	4	5
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	1	2	3	4	5
19. Coping with complications of diabetes?	1	2	3	4	5
20. Feeling "burned out" by the constant effort needed to manage diabetes?	1	2	3	4	5

Section 3
By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

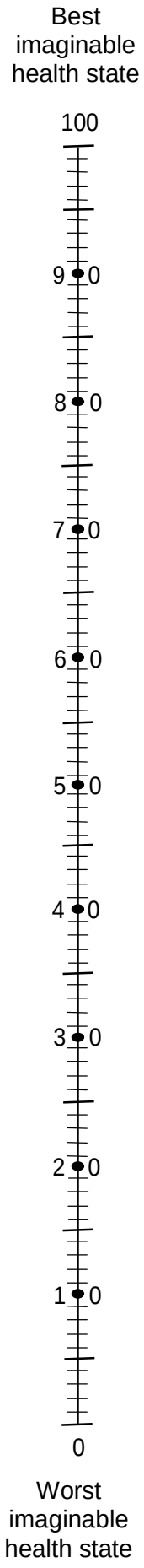
Pain/Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



Section 4

The questions below ask you about your diabetes self care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1. How many of the last SEVEN DAYS have you followed a eating plan?	0	1	2	3	4	5	6	7
2. On average, over the past month, how many days per week have you followed your eating plan?	0	1	2	3	4	5	6	7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?	0	1	2	3	4	5	6	7
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (total minutes of continuous activity including walking).	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?	0	1	2	3	4	5	6	7
9. On how many of the last SEVEN DAYS did you check your feet?	0	1	2	3	4	5	6	7
10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	0	1	2	3	4	5	6	7

11. Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?
    0. No
    1. Yes.

If yes, how many cigarettes did you smoke on an average day? Number of cigarettes.....

Section 5
The following items ask about how much your illness and/or its treatment interferes with your life. **Please circle the one number that best describes your current life situation.** If an item is not applicable, please check the box to indicate that this aspect of your life is not affected. Please do not leave any item unanswered.

How much does your illness and/or its treatment interfere with:

1. Your feeling of being healthy?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
2. The things you eat and drink?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
3. Your work, including job, house work, chores, or errands?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
4. Playing sports, gardening, or other physical recreation or hobbies?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
5. Quiet recreation or hobbies such as reading, TV, music, knitting, etc.?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
6. Your financial situation?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
7. Your relationship with your spouse or domestic partner?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
8. Your sex life?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
9. Your relationship and social activities with your family?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
10. Social activities with your friends, neighbours, or groups?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
11. Your religious or spiritual activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
12. Your involvement in community or civic activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑
13. Your self-improvement or self-expression activities?	Not very much► 1 2 3 4 5 6 7 ◄Very much	Not applicable ❑

Section 6

Below is a list of activities you have to perform to manage your diabetes. Please read each one and then circle the number which best describes how confident you usually are that you could carry out that activity. For example, if you are completely confident that you are able to check your blood sugar levels when necessary, circle 10. If you feel that most of the time you could not do it, circle 1 or 2.

I am confident that……..

	Cannot do At all			**Maybe yes maybe no**						**Certain can do**
1	I am able to check my blood sugar if necessary									
	0	1	2	3	4	5	6	7	8	9	10
2	I am able to correct my blood sugar when the sugar level is too high.									
	0	1	2	3	4	5	6	7	8	9	10
3	I am able to correct my blood sugar when the blood sugar level is too low.									
	0	1	2	3	4	5	6	7	8	9	10
4	I am able to choose the correct foods.									
	0	1	2	3	4	5	6	7	8	9	10
5	I am able to keep my weight under control.									
	0	1	2	3	4	5	6	7	8	9	10
6	I am able to examine my feet for cuts.									
	0	1	2	3	4	5	6	7	8	9	10
7	I am able to adjust my eating plan when ill.									
	0	1	2	3	4	5	6	7	8	9	10
8	I am able to follow a healthy eating pattern most of the time.									
	0	1	2	3	4	5	6	7	8	9	10
9	I am able to take more exercise if the doctor advises me to.									
	0	1	2	3	4	5	6	7	8	9	10
10	When taking more exercise I am able to adjust my eating plan.									
	0	1	2	3	4	5	6	7	8	9	10
11	I am able to follow a healthy eating pattern when I am away from home.									
	0	1	2	3	4	5	6	7	8	9	10
12	I am able to follow a healthy eating pattern when I am eating out or at a party.									
	0	1	2	3	4	5	6	7	8	9	10
13	I am able to adjust my eating plan when I am feeling stressed or anxious.									
	0	1	2	3	4	5	6	7	8	9	10
14	I am able to take my medication as prescribed.									
	0	1	2	3	4	5	6	7	8	9	10
15	I am able to adjust my medication when I am ill.									
	0	1	2	3	4	5	6	7	8	9	10

Section 7

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help and support in the manner described. Give the persons' initials, their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have.

If you have had no support for a question, check the words "No one", but still rate your level of satisfaction.
Do not list more than nine persons per question.

Please answer all the questions as best you can.

EXAMPLE:

Who do you know whom you can trust with information that could get you in trouble?

No one	1) T.N. (brother)	4) T.N. (father)	7)
	2) L.M. (friend)	5) L.M. (employer)	8)
	3) R.S. (friend)	6)	9)

How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

1. Whom can you really count on to be dependable when you need help?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

2. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

3. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

4. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

5. Who accepts you totally, including both your worst and best points?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

6. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

7. Whom can you really count on to care about you, regardless of what is happening to you?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

8. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

9. Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

10. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

11. Who can you count on to console you when you are very upset?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

12. How satisfied?

6-very satisfied	5-fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied

Section 8

Have you carried on writing since completing the writing task we assigned?

Yes ❑ No ❑

You have now completed the questionnaire.

May I take this opportunity to thank you for taking the time to help with this research.

As you know, we will ask you to complete more questionnaires over the next few months, and we need to be able to compare your answers on each questionnaire you complete. However, to protect your anonymity, we do not want your name to appear on any questionnaire you complete. For this reason everyone is provided with a unique identification code, which you can create yourself by using the following formula:

In the space provided please write …

1) … the first 2 letters of your **mother's** first name, e.g. 'SU' for Susan ☐☐

2) … the **month** you were born, e.g. '07' for July ☐☐

3) … the first 2 letters of **your own** first name, e.g. 'JO' for John. ☐☐

Once again, thank you very much for your help with this research.
Please return this booklet in the pre-paid envelope provided.

Appendix R: Intervention

WED

Writing for People Living with Type 2 diabetes Study

Study Writing Pack

Please read the following instructions and complete the writing task for 20 minutes each day for three days over the course of one week. Please record the time at which you started and finished writing in the spaces provided for each day. After each day's writing please also complete the questions at the end of the space provided for writing for that day.

I would like you to write about your deepest thoughts and feelings about any stressful experience you have encountered over the last month, or any worries or concerns that are currently troubling you.

In your writing, I'd like you to really let go and explore your very deepest emotions and thoughts. You might link your topic to your relationships with others, including parents, lovers, friends, or relatives. You might also like to link your experience to the present and future, who you are or who you would like to be. You may write about the same general issues or different experiences each day.

Find a time and place where you won't be disturbed. Ideally, pick a time at the end of your workday or before you go to bed. Once you begin writing, write continuously. Don't worry about spelling or grammar –that is not important. If you run out of things to write about, just repeat what you have already written.

Please turn over to begin writing

Control

Writing for People Living with Type 2 diabetes Study

Study Writing Pack

Please read the following instructions and complete the writing task for 20 minutes each day for three days over the course of one week. Please record the time at which you started and finished writing in the spaces provided for each day. After each day's writing please also complete the questions at the end of the space provided for writing for that day.

I want you to write about how you use your time. In your writing, please go into as much detail as possible about how you have spent your days and managed your time. Please be as objective as possible. The most important thing is that you describe your activities in detail without discussing any of your thoughts or feelings related to the topic.

In today's writing I want you to describe what you did yesterday from the time you got up until the time you went to bed. You might include where you went and the tasks you had to complete.

Find a time and place where you won't be disturbed. Ideally, pick a time at the end of your workday or before you go to bed. Once you begin writing, write continuously. Don't worry about spelling or grammar –that is not important. If you run out of things to write about, just repeat what you have already written.

Please turn over to begin writing

Within writing packs

Repeated for each writing session.

Day X

Time you started writing: _____am / pm

(blank pages for writing)

Time you finished writing: _____am / pm

How do you feel right now?

It is important for us to know how you feel immediately after completing the writing task. To help us achieve this, below we have provided a list of words that describe different feelings and emotions, which you may be experiencing. For each word, we would like you to consider the extent to which you currently feel the way described, using the following scale to select the answer that best describes how you feel right now:

1	**2**	**3**	**4**	**5**
(very slightly or not at all)	(a little)	(moderately)	(quite a bit)	(extremely)

For example, if you currently feel *a little bit irritable*, you should write **2** in the space provided next to the word *irritable*. Remember, your answer should reflect how you feel right now, that is, at the present moment. Please complete this task now.

Right now I feel …

…….interested	…….irritable	…….hostile	…….distressed
…….alert	…….enthusiastic	…….excited	…….ashamed
…….jittery	…….upset	…….inspired	…….active
…….strong	…….nervous	…….proud	…….guilty
…….determined	…….afraid	…….scared	…….attentive

You have now completed Day X.
Thank you.

Day 3 only

How many days did you write for? ……..days

If you were not able to write for the required time each day and number of days, so that we can evaluate our study we would appreciate it if you would tell us why

_____

_____

_____

_____

You have now completed the task.

May I take this opportunity to thank you for taking the time to help with this research.

As you know, we will ask you to complete questionnaires over the next few months, and we need to be able to compare your writing to the questionnaires you complete. However, to protect your anonymity, we do not want your name to appear on anything you complete. For this reason everyone is provided with a unique identification code, which you can create yourself by using the following formula:

In the space provided please write …

1) … the first 2 letters of your **mother's** first name, e.g. 'SU' for Susan ☐☐

2) … the **month** you were born, e.g. '07' for July ☐☐

3) … the first 2 letters of **your own** first name, e.g. 'JO' for John. ☐☐

Once again, thank you very much for your help with this research.
Please return this booklet in the pre-paid envelope provided.

Appendix S: Self-harm checklist

Date writing received _____

Date writing screened _____

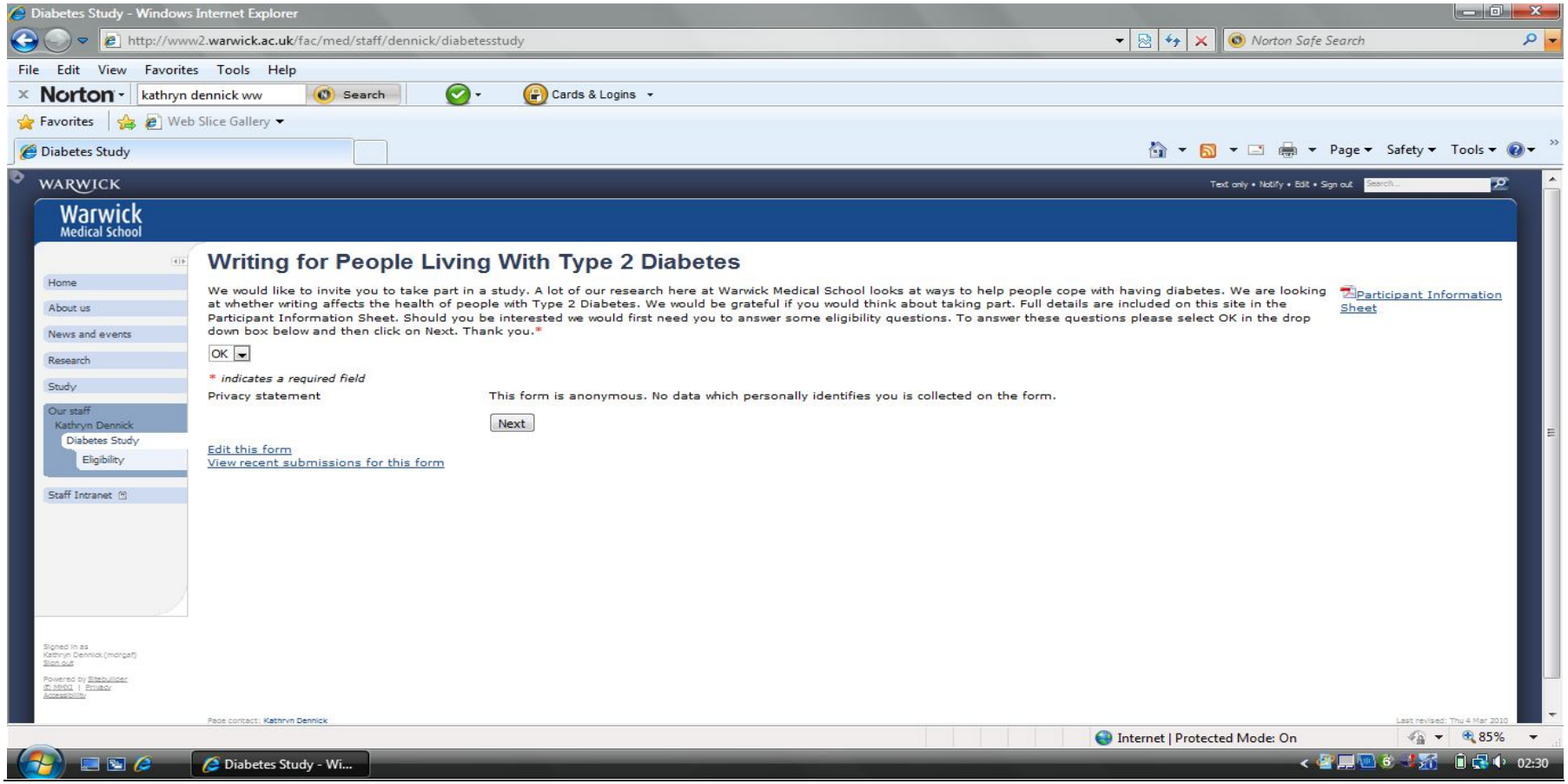
Patient Identification Number: _____

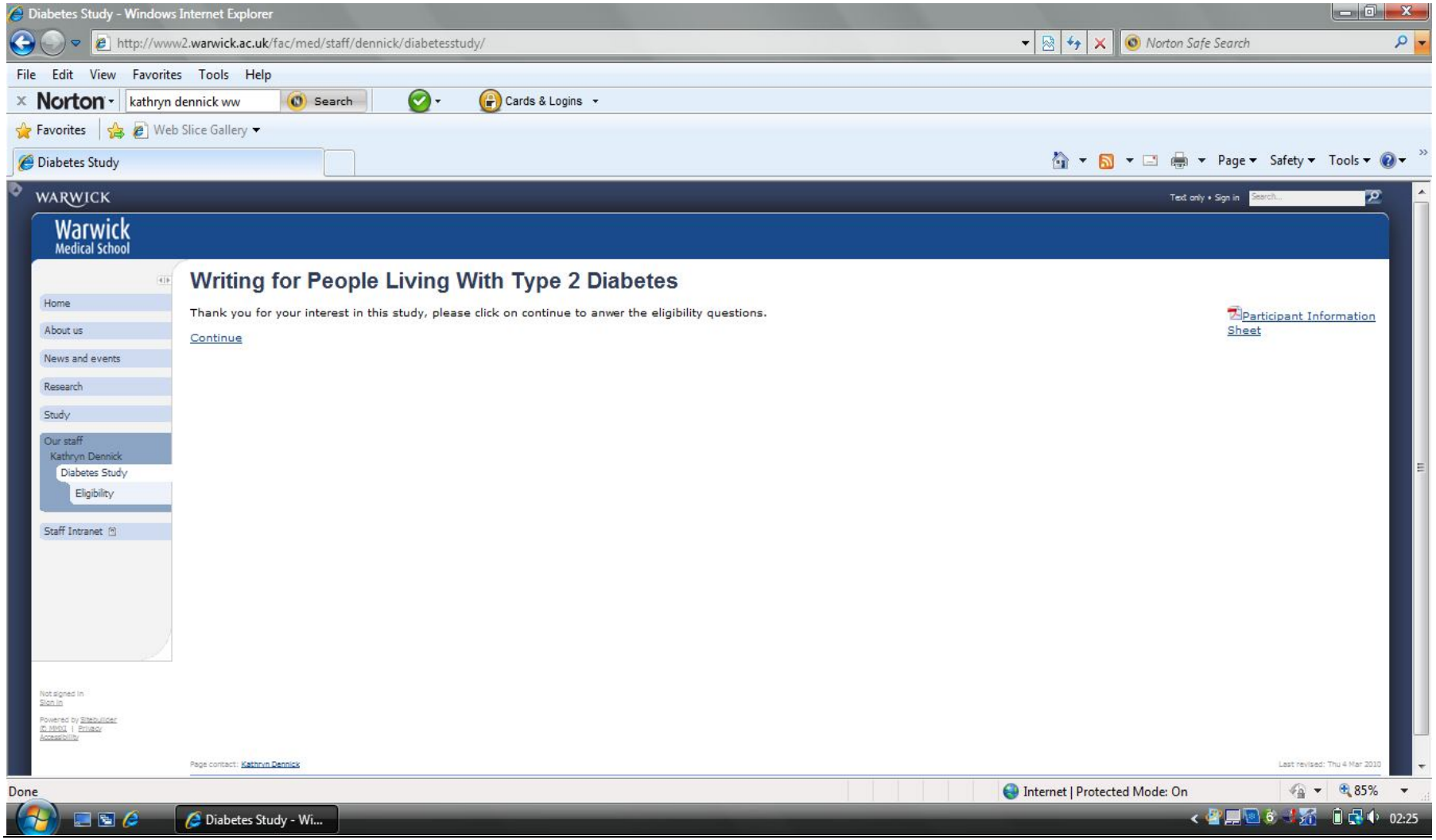
Direct statement of suicidal intent	Yes ❑	No ❑
Previous undocumented self-harm or suicide attempts	Yes ❑	No ❑
Marked hopelessness	Yes ❑	No ❑
Images of death of self or others including bereavement	Yes ❑	No ❑
Alcohol and drug dependency	Yes ❑	No ❑
Insomnia	Yes ❑	No ❑
Social isolation	Yes ❑	No ❑
Chronic painful illness	Yes ❑	No ❑
Inability to concentrate	Yes ❑	No ❑
Feeling generally stressed/overwhelmed	Yes ❑	No ❑

Decision to refer? Yes ❑ No ❑

If yes
Date of referral _____

Appendix T: Study website




Diabetes Study - Windows Internet Explorer
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Norton Safe Search
File Edit View Favorites Tools Help
Norton
kathryn dennick ww
Search
Cards & Logins
Favorites
Web Slice Gallery
Diabetes Study
Page
Safety
Tools
WARWICK
Text only • Sign in
Warwick Medical School
Home
About us
News and events
Research
Study
Our staff
Kathryn Dennick
Diabetes Study
Eligibility
Staff Intranet
Writing for People Living With Type 2 Diabetes
Thank you for your interest in this study, please click on continue to anwer the eligibility questions.
Continue
Participant Information Sheet
Not signed in
Sign in
Page contact: Kathryn Dennick
Done
Internet | Protected Mode: On
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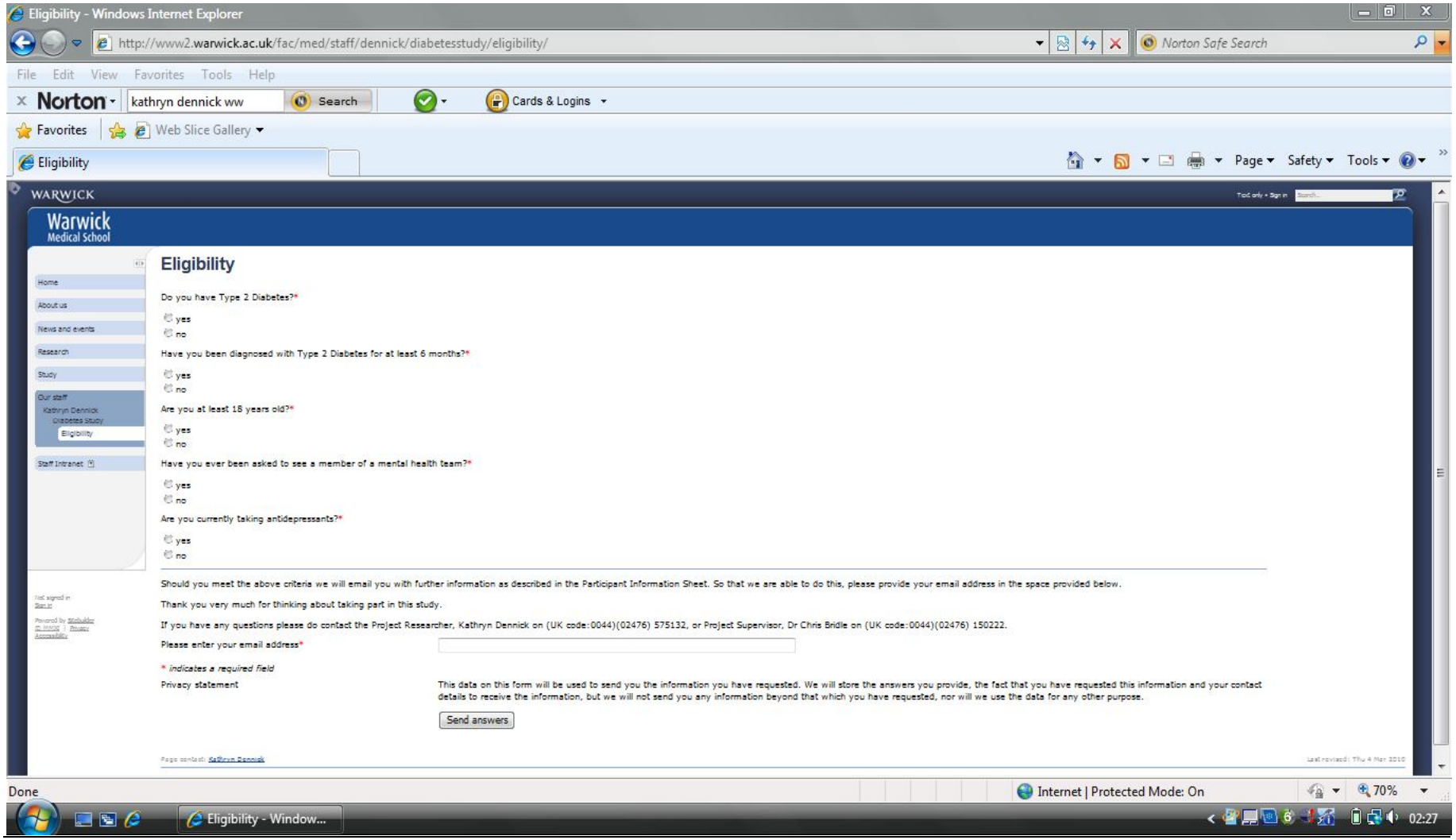
Diabetes Study - Wi...
02:25


Eligibility - Windows Internet Explorer
http://www2.warwick.ac.uk/fac/med/staff/dennick/diabetesstudy/eligibility/
Norton Safe Search
File Edit View Favorites Tools Help
Norton
kathryn dennick ww
Search
Cards & Logins
Favorites
Web Slice Gallery
Eligibility
Page
Safety
Tools
WARWICK
Warwick
Medical School
Eligibility
Home
About us
News and events
Research
Study
Our staff
Kathryn Dennick
Diabetes Study
Eligibility
Staff Intranet
Do you have Type 2 Diabetes?*
yes
no
Have you been diagnosed with Type 2 Diabetes for at least 6 months?*
yes
no
Are you at least 18 years old?*
yes
no
Have you ever been asked to see a member of a mental health team?*
yes
no
Are you currently taking antidepressants?*
yes
no
Should you meet the above criteria we will email you with further information as described in the Participant Information Sheet. So that we are able to do this, please provide your email address in the space provided below.
Thank you very much for thinking about taking part in this study.
If you have any questions please do contact the Project Researcher, Kathryn Dennick on (UK code:0044)(02476) 575132, or Project Supervisor, Dr Chris Bridle on (UK code:0044)(02476) 150222.
Please enter your email address*
* indicates a required field
Privacy statement
This data on this form will be used to send you the information you have requested. We will store the answers you provide, the fact that you have requested this information and your contact details to receive the information, but we will not send you any information beyond that which you have requested, nor will we use the data for any other purpose.
Send answers
Done
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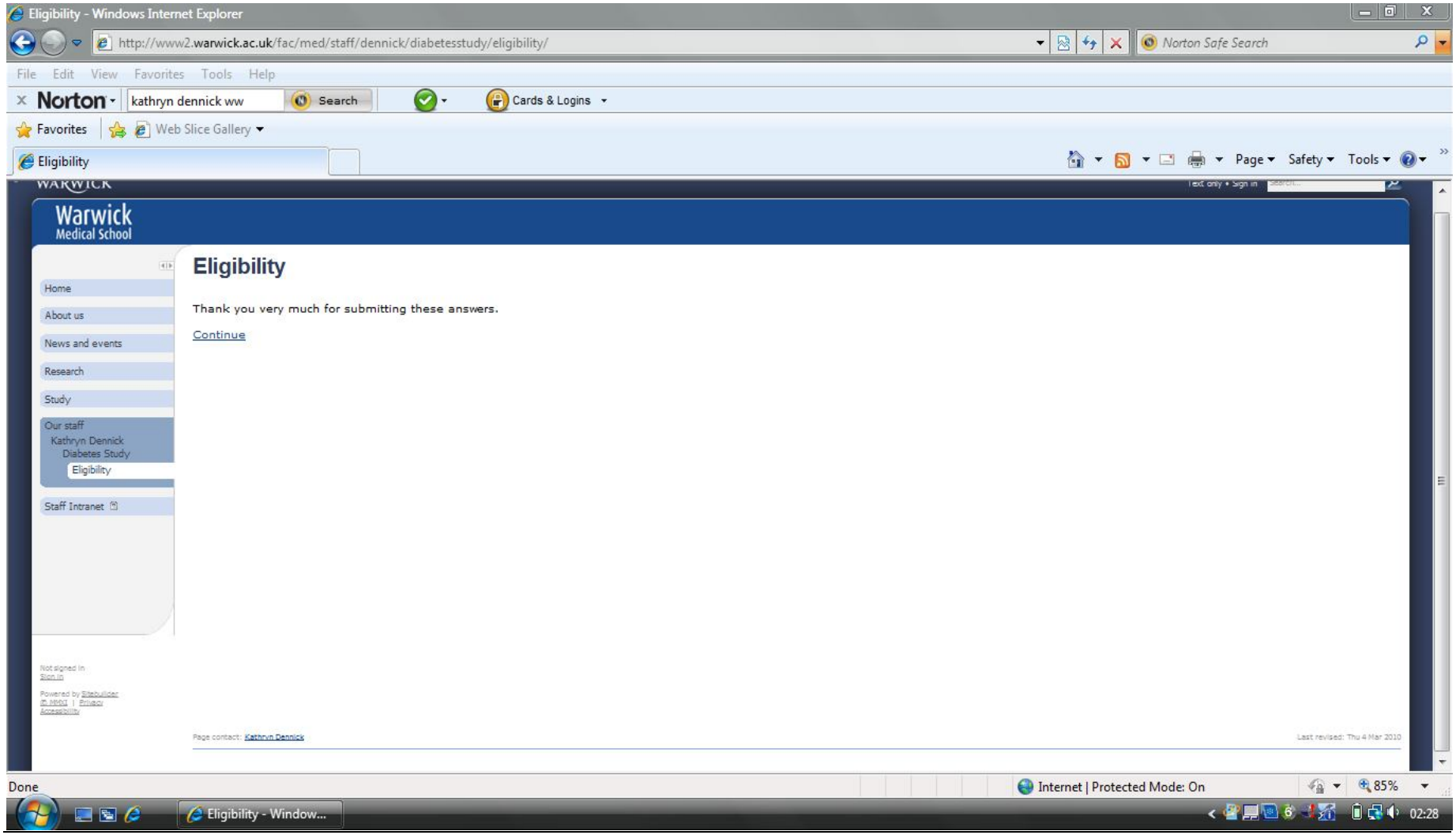
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Norton
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Search
Cards & Logins
Favorites
Web Slice Gallery
Eligibility
Page
Safety
Tools
Warwick
Medical School
Eligibility
Home
About us
News and events
Research
Study
Our staff
Kathryn Dennick
Diabetes Study
Eligibility
Staff Intranet
Thank you very much for submitting these answers.
Continue
Page contact: Kathryn Dennick
Done
Internet | Protected Mode: On
85%
Eligibility - Window...
02:28

Appendix U: Transformation

Types of transformation performed for each continuous variable included in analyses

Analysis	Continuous variables included in analyses	Transformation performed
Effectiveness analyses		
Depressive symptom severity	CES-D (baseline & follow up) & Age	SQRT+1
DSED	PAID (baseline & follow up) & Age	LOG
Health-related QoL	EQ-5D utility (baseline & follow up) & Age	SQRT+1
Health-related QoL	EQ-5D VAS (baseline & follow up)	Reversed & then SQRT+1
	Age	SQRT+1
Diabetes SMBs: general diet	SDSCA: general diet (baseline & follow up)	Reversed & then LOG+1
	Age	LOG+1
Diabetes SMBs: specific diet	SDSCA: specific diet (baseline & follow up)	Reversed & then LOG+1
	Age	LOG+1
Diabetes SMBs: exercise	SDSCA: exercise (baseline & follow up)	Reversed & then SQRT+1
	Age	SQRT+1
Diabetes SMBs: blood glucose testing	SDSCA: BG testing (baseline & follow up) & Age	LOG+1
Diabetes SMBs: foot care	SDSCA: Foot care (baseline & follow up) & Age	LOG+1
Sub-group (moderator) analyses		
Alexithymia	TAS-20 & CES-D (baseline & follow up)	SQRT + 1
Optimism	LOT-R & CES-D (baseline & follow up)	SQRT + 1
Mediator analyses (same for 2 weeks & 3 months)		
Self-efficacy for diabetes SMBs	DMSES UK	Reversed & then SQRT+1
	CES-D (baseline & follow up)	SQRT+1
Perceived illness interference	Perceived illness interference	LOG
	CES-D (baseline & follow up)	SQRT+1
Perceived emotional support (number)	SSQ6 (number)	LOG+1
	CES-D (baseline & follow up)	SQRT+1
Perceived emotional support (satisfaction)	SSQ6 (satisfaction) & CES-D (baseline & follow up)	SQRT+1
Mechanisms of change		
PANAS (negative affect) session 1, 2 & 3		LOG+1
LIWC positive emotion session 1, 2 & 3		LOG+1
LIWC negative emotion session 1, 2 & 3		LOG+1
LIWC insight session 1, 2 & 3		LOG+1
LIWC cause session 1, 2 & 3		LOG+1
Contamination analyses		
PANAS(negative affect) average		LOG
LIWC positive emotion, negative emotion, insight and cause averages		LOG

Initial and post-transformation assumption checks

	Before transformation	**Best transformation**	**Post transformation**
	Normality		Normality
Effectiveness			
CES-D baseline	Shapiro-Wilk: CTL D(18)=.937, p=.262 WED D(23)=.921, p=.072 Boxplots: ok Histograms: ok Skewness: CTL .241/.536 = .45 WED -.124/.481 = -.26 Kurtosis: CTL -1.079/1.039 = -1.04 WED -1.319/.935 = -1.41	SQRT + 1	Shapiro-Wilk: CTL D(18)=.932, p=.210 WED D(23)=.889, **p=.015** Boxplots: -ve skew (WED only) Histograms: +ve skew Skewness: CTL -.282/.536 = -.53 WED -.535/.481 = -1.11 Kurtosis: CTL -1.109/1.038 = -1.07 WED -1.117/.935 = -1.19
CES-D follow up	Shapiro-Wilk: CTL D(14)=.790, **p=.004** WED D(18)=.932, p=.212 Boxplots: +ve skew Histograms: +ve skew (esp. CTL) Skewness: CTL 1.193/.597 = 1.99 WED .615/.536 = 1.15 Kurtosis: CTL -.018/1.154 = -.02 WED .467/1.038 = -.45	SQRT + 1	Shapiro-Wilk: CTL D(14)=.881, p=.060 WED D(18)=.953, p=.475 Boxplots: +ve skew (CTL only) Histograms: +ve skew (CTL only) Skewness: CTL .763/.597 = -1.28 WED -.114/.536 = -.21 Kurtosis: CTL -.604/1.154 = -.52 WED -.842/1.038 = -.811
PAID baseline	Shapiro-Wilk: CTL D(17)=.831, **p=.006** WED D(22)=.876, **p=.010** Boxplots: +ve skew (esp. WED) Histograms: +ve skew (esp. WED) Skewness: CTL 1.452/.550 = **2.64** WED 1.350/.491 = **2.75** Kurtosis:	LOG	Shapiro-Wilk: CTL D(17)=.888, **p=.043** WED D(22)=.930, p=.124 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 1.071/.550 = 1.95 WED .514/.491 = 1.05 Kurtosis:

	CTL 1.522/1.063 = 1.43 WED 2.684/.953 = **2.82**		CTL .417/1.063 = .39 WED .017/.953 = .02
PAID follow up	Shapiro-Wilk: CTL D(14)=.869, **p=.041** WED D(18)=.760, **p=.000** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .980/.597 = 1.64 WED 1.450/.536 = **2.70** Kurtosis: CTL -.005/1.154 = -.004 WED .924/1.038 = .89	LOG	Shapiro-Wilk: CTL D(14)=.904, p=.128 WED D(18)=.808, **p=.002** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .624/.597 = 1.04 WED 1.190/.536 = 2.22 Kurtosis: CTL -.677/1.154 = -.59 WED .162/1.038 = .16
EQ-5D utility baseline	Shapiro-Wilk: CTL D(16)=.701, **p=.000** WED D(22)=.821, **p=.001** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -.869/.594 = - 1.54 WED -.226/.491 = -.46 Kurtosis: CTL -1.138/1.091 = -1.04 WED -1.584/.953 = -1.66	SQRT + 1	Shapiro-Wilk: CTL D(16)=.702, **p=.000** WED D(22)=.824, **p=.001** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -.881/.564 = -1.56 WED -.253/.491 = -.52 Kurtosis: CTL -1.104/1.091 = -1.01 WED -1.532/.953 = -1.62
EQ-5D utility follow up	Shapiro-Wilk: CTL D(14)=.638, **p=000.** WED D(18)=.839, **p=.006** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -2.214/.597 = **-3.71** WED .028/.536 = .05 Kurtosis: CTL 5.358/1.154 = **4.64** WED -1.730/1.038 = -1.67	SQRT + 1	Shapiro-Wilk: CTL D(14)=.622, **p=.000** WED D(18)=.843, **p=.007** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -2.372/.597 = -.25 WED .000/.536 = 0 Kurtosis: CTL 6.236/1.154 = **5.40** WED -1.702/1.038 = -1.6
EQ-5D VAS baseline	Shapiro-Wilk: CTL D(16)=.899, p=.078 WED D(22)=.844, **p=.003** Boxplots: -ve skew	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(16)=.965, p=.750 WED D(22)=.956, p=.420 Boxplots: ok

	Histograms: -ve skew Skewness: CTL -.897/.564 = -1.59 WED -1.118/.491 = -2.28 Kurtosis: CTL -.088/1.091 = -.08 WED .155/.953 = .16		Histograms: ok Skewness: CTL .160/.564 = .28 WED .253/.491 = .52 Kurtosis: CTL -.800/.564 = -1.42 WED -.689/.953 = -.72
EQ-5D VAS follow up	Shapiro-Wilk: CTL D(14)=.943, p=.459 WED D(18)=.802, **p=.002** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -.721/.597 = -1.21 WED -1.783/.536 = **-3.33** Kurtosis: CTL .582/1.154 = .50 WED 3.251/1.038 = **3.13**	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(14)=.973, p=.911 WED D(18)=.933 , p=.217 Boxplots: ok Histograms: ok Skewness: CTL -.244/.597 = -.41 WED .851/.536 = 1.59 Kurtosis: CTL -.031/1.154 = -.03 WED .551/1.038 = .53
SDSCA general diet baseline	Shapiro-Wilk: CTL D(17)=.776, **p=.001** WED D(23)=.748, **p=.000** Boxplots: -ve skew Histograms: -ve skew (esp. WED) Skewness: CTL -1.314/.550 = -2.39 WED -2.356/.481 = **-4.90** Kurtosis: CTL .959/1.063 = .902 WED 7.766/.935 = **8.30**	REVERSED & LOG + 1	Shapiro-Wilk: CTL D(17)=.821, **p=.004** WED D(23)=.897, **p=.022** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .541/.550 = .98 WED .444/.481 = .92 Kurtosis: CTL -1.083/1.063 = -1.02 WED =.065/.935 = -.07
SDSCA general diet follow up	Shapiro-Wilk: CTL D(14)=.817, **p=.008** WED D(18)=.908 , p=.081 Boxplots: -ve skew Histograms: -ve skew (esp. CTL) Skewness: CTL -1.299/.597 = -2.18 WED -.363/.536 = -.68 Kurtosis: CTL .924/1.154 = .80	REVERSED & LOG + 1	Shapiro-Wilk: CTL D(14)=.885, p=.069 WED D(18)=.883, **p=.029** Boxplots: +ve skew Histograms: +ve skew (esp. CTL) Skewness: CTL .415/.597 = .695 WED -.267/.536 = -.498 Kurtosis: CTL -.982/1.154 = -.85

	WED -.881/1.038 = -.85		WED -1.328/1.038 = -1.28
SDSCA specific diet baseline	Shapiro-Wilk: CTL D(17)=.977, p=.922 WED D(22)=.843, **p=.003** Boxplots: ok Histograms: -ve skew (WED only) Skewness: CTL -.171/.550 = -.31 WED -1.534/.491 = **-3.12** Kurtosis: CTL -.261/1.063 = -.25 WED 2.437/.953 = 2.56	REVERSED & LOG + 1	Shapiro-Wilk: CTL D(17)=.945, p=.377 WED D(22)=.922, p=.085 Boxplots: ok Histograms: +ve skew WED only Skewness: CTL -.806/.550 = -1.47 WED .829/.491 = 1.69 Kurtosis: CTL .538/1.063 = .51 WED .551/.953 = .58
SDSCA specific diet follow up	Shapiro-Wilk: CTL D(14)=.945, p=.493 WED D(18)=.908, p=.080 Boxplots: ok Histograms: -ve skew (WED only) Skewness: CTL -.443/.597 = -.74 WED -.726 /.536 = -1.35 Kurtosis: CTL -.558/1.154 = -.48 WED .132 /1.038 = .13	REVERSED & LOG + 1	Shapiro-Wilk: CTL D(14)=.940 , p=.415 WED D(18)=.923 , p=.146 Boxplots: ok Histograms: ok Skewness: CTL -.436/.597 = -.73 WED .130/.536 = .24 Kurtosis: CTL -.638/1.154 = -.55 WED -.571/1.038 = -.55
SDSCA exercise baseline	Shapiro-Wilk: CTL D(17)=.897, p=.060 WED D(23)=919, p=.063 Boxplots: +ve skew for CTL & -ve skew for WED Histograms: +ve skew Skewness: CTL .201/.550 = .37 WED -.130/.481 = -.27 Kurtosis: CTL -1.333/1.063 = -1.25 WED 1.255 / .935 = -1.34	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(17)=.899, p=.065 WED D(23)=.914, **p=.050** Boxplots: -ve skew (CTL only) Histograms: -ve skew (CTL only) Skewness: CTL -.592/.550 = -1.08 WED -.253/.481 = -.53 Kurtosis: CTL -.522/1.063 = -.49 WED -1.199/.935 = -1.28
SDSCA exercise follow up	Shapiro-Wilk: CTL D(14)=.924, p=.255 WED D(18)=.858, **p=.011** Boxplots: -ve skew (WED only) Histograms: -ve skew (WED only)	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(14)=.927, p=.281 WED D(18)=.854, **p=.010** Boxplots: -ve skew for CTL & +ve skew for WED

	Skewness: CTL .051/.597 = .09 WED -.208/.536 = -.39 Kurtosis: CTL -1.337/1.154 = -1.16 WED -1.672/1.038 = -1.61		Histograms: -ve skew for CTL & +ve skew for WED Skewness: CTL -.422/.597 = -.71 WED -.014/.536 = -.03 Kurtosis: CTL -.915/1.154 = -.79 WED -1.796/1.038 = -1.7
SDSCA blood glucose testing baseline	Shapiro-Wilk: CTL D(15)=.772, **p=.002** WED D(20)=.765, **p=.000** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .929/.580 = 1.60 WED 1.307/.512 = 2.55 Kurtosis: CTL -.727/1.121 = -.65 WED .597/.992 = .60	LOG +1	Shapiro-Wilk: CTL D(15)=.789, **p=.003** WED D(20)=.849, **p=.005** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .473/.580 = .86 WED .437/.512 = .85 Kurtosis: CTL -1.669/1.121 = -1.49 WED -1.146/.992 = -1.16
SDSCA blood glucose testing follow up	Shapiro-Wilk: CTL D(13)=.806, **p=.008** WED D(15)=.768, **p=.001** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .568/.616 = .90 WED .354/.580 = .61 Kurtosis: CTL -1.340/1.191 = -1.125 WED -1.827/1.121 = -1.63	LOG +1	Shapiro-Wilk: CTL D(15)=.746, **p=.001** WED D(13)=.781, **p=.004** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .090/.616 = .15 WED .076/.580 = .13 Kurtosis: CTL -2.032/1.191 = 1.71 WED -2.121/1.121 = -1.89
SDSCA foot care baseline	Shapiro-Wilk: CTL D(17)=.910, p=.102 WED D(23)=.853, **p=.003** Boxplots: +ve skew (CTL only) Histograms: +ve skew (CTL only) Skewness: CTL .867/.550 = 1.58 WED .249/.481 = .52 Kurtosis:	LOG +1	Shapiro-Wilk: CTL D(17)=.935, p=.265 WED D(23)=.883, **p=.011** Boxplots: +ve skew for CTL & -ve skew for WED Histograms: ok Skewness: CTL -.193/.550 = -.35 WED -.201/.481 = -.42

	CTL .581/1.063 = .55 WED -1.727/.935 = 1.85		Kurtosis: CTL -1.044/1.063 = -.98 WED -1.531/.935 = -1.64
SDSCA foot care follow up	Shapiro-Wilk: CTL D(14)=.880, p=.059 WED D(18)=.918, p=.120 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .641/.597 = -1.25 WED .248/.536 = .46 Kurtosis: CTL -.904/1.154 = -.78 WED -1.169/1.038 = -1.13	LOG +1	Shapiro-Wilk: CTL D(14)=.906 , p=.136 WED D(18)=.891, **p=.040** Boxplots: ok Histograms: +ve skew Skewness: CTL -.064/.597 = -.12 WED -.370/.536 = -.69 Kurtosis: CTL -1.558/1.154 = -1.35 WED -1.342/1.038 = -1.29
Covariates			
Age for CES-D/EQ-5D/SDSCA exercise	Shapiro-Wilk: CTL D(18)=.925, p=.157 WED D(23)=.977, p=.858 Boxplots: ok Histograms: ok Skewness: CTL .204/.536 = .38 WED -.520/.481 = 1.08 Kurtosis: CTL -1.329/1.038 = 1.28 WED .574/.935 = .61	SQRT + 1	Shapiro-Wilk: CTL D(18)=.930, p=.192 WED D(23)=.962, p=.514 Boxplots: ok Histograms: ok Skewness: CTL .120/.536 = .22 WED -.762/.481 = -1.58 Kurtosis: CTL -1.323/1.038 = -1.27 WED 1.060/.935 = 1.13
Age for PAID		LOG	Shapiro-Wilk: CTL D(18)=.934, p=.224 WED D(23)=.941, p=.187 Boxplots: -ve skew (CTL only) Histograms: ok Skewness: CTL .030/.536 = .056 WED -1.027/.481 = -2.14 Kurtosis: CTL -1.300/1.038 = -1.25 WED 1.738/.935 = 1.86
Age for SDSCA general diet,		LOG + 1	Shapiro-Wilk:

specific diet, blood glucose testing & foot care			CTL D(18)=.933, p=.223 WED D(23)=.942, p=.195 Boxplots: ok Histograms: ok Skewness: CTL .033/.536 = .06 WED -1.018/.481 = -2.12 Kurtosis: CTL -1.301/1.038 = -.80 WED 1.712/.935 = 1.83
Moderators			
TAS-20 (to match CES-D)	Shapiro-Wilk: CTL D(17)=.923, p=.165 WED D(23)=.958 , p=.427 Boxplots: ok Histograms: ok Skewness: CTL .623/.550 = 1.15 WED -.460/.481 = -.96 Kurtosis: CTL -.565/1.063 = -.53 WED -.506/.935 = -.54	SQRT + 1	Shapiro-Wilk: CTL D(17)=.937, p=.285 WED D(23)=.935, p=.142 Boxplots: ok Histograms: ok Skewness: CTL .447/.550 = .81 WED -.750/.481 = -1.56 Kurtosis: CTL -.824/1.063 = -.76 WED -.099/.935 = -.11
LOT-R (to match CES-D)	Shapiro-Wilk: CTL D(15)=.952, p=.559 WED D(23)=.932 , p=.120 Boxplots: ok Histograms: ok Skewness: CTL -.096/.580 = -.17 WED .477/.481 = .99 Kurtosis: CTL -.787/1.121 = -.70 WED -.735/.935 = -.79	SQRT + 1	Shapiro-Wilk: CTL D(15)=.947, p=.480 WED D(23)=.942, p=.200 Boxplots: ok Histograms: ok Skewness: CTL -.251/.580 = -.43 WED .324/.481 = .67 Kurtosis: CTL -.753/1.121 = -.67 WED -.724/.935 = -.77
Mediators			
IIRS 2 weeks	Shapiro-Wilk: CTL D(15)=.797, **p=.003** WED D(18)=.857, **p=.011** Boxplots: +ve skew	LOG	Shapiro-Wilk: CTL D(15)=.922, p=.205 WED D(18)=.905, p=.071 Boxplots: +ve skew

	Histograms: +ve skew Skewness: CTL 1.878/.580 = **3.24** WED .769/.536 = 1.43 Kurtosis: CTL 3.716/1.121 = **3.31** WED -.851/1.038 = -.82		Histograms: +ve skew Skewness: CTL 1.028/.580 = 1.77 WED .317/.536 = .59 Kurtosis: CTL .855/1.121 = .76 WED -1.353/1.038 = -1.30
IIRS 3 months	Shapiro-Wilk: CTL D(11)=.805, **p=.011** WED D(16)=.845, **p=.011** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 1.450/.661 = 2.19 WED 1.212/.564 = 2.15 Kurtosis: CTL 1.812/1.279 = 1.42 WED .797/1.091 = .73	LOG	Shapiro-Wilk: CTL D(11)=.870, p=.078 WED D(16)=.907, p=.106 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL .835/.661 = 1.26 WED .483/.564 = .86 Kurtosis: CTL -.440/1.279 = -.34 WED -1.048/1.091 = -.96
DMSES UK 2 weeks	Shapiro-Wilk: CTL D(15)=.937, p=.351 WED D(18)=.904, p=.067 Boxplots: -ve skew Histograms: ok Skewness: CTL -.757/.580 = -1.31 WED -.821/.536 = -1.53 Kurtosis: CTL .123/1.121 = .11 WED -.007/1.038 = .007	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(15)=.981, p=.978 WED D(18)=.939, p=.283 Boxplots: ok Histograms: ok Skewness: CTL -.072/.580 = -.12 WED .074/.536 = .14 Kurtosis: CTL -.750/1.121 = -.67 WED -1.131/1.038 = -1.09
DMSES UK 3 months	Shapiro-Wilk: CTL D(11)=.901, p=.190 WED D(16)=.891, p=.058 Boxplots: -ve skew (esp. WED) Histograms: -ve skew Skewness: CTL .034/.661 = .05 WED -.817/.564 = -1.45 Kurtosis: CTL -1.665/1.279 = -1.30	REVERSED & SQRT + 1	Shapiro-Wilk: CTL D(11)=.879, p=.100 WED D(16)=.926, p=.213 Boxplots: ok +ve skew (WED only) Histograms: ok +ve skew for WED & –ve skew for CTL Skewness: CTL -.474/.661 = -.72 WED .088/.564 = .16 Kurtosis:

	WED -.043/1.09 = -.04		CTL -1.521/1.279 = -.08 WED -1.265/1.091 = -1.16
SSQ6 (number) 2 weeks	Shapiro-Wilk: CTL D14)=.829, **p=.012** WED D(15)=.729, **p=.001** Boxplots: +ve skew (esp. CTL) Histograms: +ve skew Skewness: CTL 1.351/.597 = -2.26 WED 2.335/.580 = 4.03 Kurtosis: CTL 1.280/1.154 = 1.11 WED 6.454/1.121 = **5.76**	LOG + 1	Shapiro-Wilk: CTL D(14)=.908, p=.149 WED D(15)=.869, **p=.032** Boxplots: +ve skew (WED only) Histograms: +ve skew (esp. WED) Skewness: CTL .588/.597 = .98 WED 1.324/.580 = 2.28 Kurtosis: CTL -.201/1.154 = -.17 WED 1.839/1.121 = 1.64
SSQ6 (number) 3 months	Shapiro-Wilk: CTL D(11)=.889, p=.125 WED D(15)=.716, **p=.000** Boxplots: ok Histograms: +ve skew (WED only) Skewness: CTL .208/.661 = .31 WED 2.533/.580 = **4.37** Kurtosis: CTL -1.590/1.279 = -1.24 WED 8.022/1.121 = **7.16**	LOG + 1	Shapiro-Wilk: CTL D(11)=.902, p=.195 WED D(15)=.877, **p=.043** Boxplots: -ve skew (CTL only) Histograms: +ve skew (WED only) Skewness: CTL -.222/.661 = -.34 WED 1.203/.580 = 2.07 Kurtosis: CTL -.995/1.279 = -.78 WED -2.571/1.121 = -.44
SSQ6 (satisfaction) 2 weeks	Shapiro-Wilk: CTL D(14)=.689, **p=.000** WED D(15)=.544, **p=.000** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -.973/.597 = -1.63 WED -2.940/.580 = **-5.07** Kurtosis: CTL -1.032/1.154 = -.89 WED 9.342/1.121 = **8.33**	SQRT + 1	Shapiro-Wilk: CTL D(11)=.688, **p=.000** WED D(15)=.523, **p=.000** Boxplots: -ve skew Histograms: -ve skew Skewness: CTL -.982/.597 = -1.64 WED -3.081/.580 = **-5.31** Kurtosis: CTL -1.012/1.154 = -.88 WED 10.211/1.121 = **9.11**
SSQ6 (satisfaction) 3 months	Shapiro-Wilk: CTL D(10)=.623, **p=.000** WED D(15)=.425, **p=.000** Boxplots: -ve skew	SQRT + 1	Shapiro-Wilk: CTL D(10)=.617, **p=.000** WED D(15)=.425, **p=.000** Boxplots: -ve skew

	Histograms: -ve skew Skewness: CTL -2.076/.687 = **-3.02** WED -2.447/.580 = **-4.22** Kurtosis: CTL 4.059/1.334 = **3.04** WED 4.690/1.121 = **4.18**		Histograms: -ve skew Skewness: CTL -2.140/.087 = **-3.11** WED -2.450/.580 = **-4.22** Kurtosis: CTL 4.418/1.334 = **3.31** WED 4.775/1.121 = **4.26**
Mechanisms of change			
PANAS negative affect session 1	Shapiro-Wilk: CTL D(7)=.560, **p=.000** WED D(10)=.860, p=.076 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 2.447/.794 = **3.08** WED 1.497/.687 = 2.18 Kurtosis: CTL 6.081/1.587 = **3.83** WED 2.654/1.334 = 1.99	LOG	Shapiro-Wilk: CTL D(7)=.576, **p=.000** WED D(10)=.943, p=.592 Boxplots: ok Histograms: ok Skewness: CTL 2.378/.794 = **2.99** WED .638/.687 = .93 Kurtosis: CTL 5.739/1.587 = **3.62** WED .107/1.334 = .08
PANAS negative affect session 2	Shapiro-Wilk: CTL D(7)=.671, **p=.002** WED D(10)=.792, **p=.012** Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 2.122/.794 = **2.67** WED 1.298/.687 = 1.89 Kurtosis: CTL 4.735/1.587 = **2.98** WED .408/1.334 = .31	LOG	Shapiro-Wilk: CTL D(7)=.963, **p=.003** WED D(10)=.875, p=.115 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 1.991/.794 = 2.51 WED .780/.687 = 1.14 Kurtosis: CTL 4.155/1.587 = **2.62** WED -.600/1.334 = -.45
PANAS negative affect session 3	Shapiro-Wilk: CTL D(7)=.582, **p=.000** WED D(10)=.868, **p=.094** Boxplots:+ve skew Histograms: +ve skew Skewness: CTL 2.347/.794 = **2.96** WED .924/.687 = 1.35 Kurtosis:	LOG	Shapiro-Wilk: CTL D(7)=.595, **p=.000** WED D(10)=.892, p=.179 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 2.273/.794 = **2.86** WED .294/.687 = .43 Kurtosis:

	CTL 5.580/1.587 = **3.52** WED .107/1.334 = .08		CTL 5.202/1.587 = **3.28** WED -1.467/1.334 = -1.10
LIWC positive emotion session 1	Shapiro-Wilk: CTL D(13)= .926, p=.298 WED D(14)=.961 , p=.739 Boxplots: +ve skew (CTL only) Histograms: +ve skew Skewness: CTL .465/.616 = .75 WED .089/.597 = .15 Kurtosis: CTL -.440/1.191 = -.37 WED -1.027/1.154 = -.89	LOG + 1	Shapiro-Wilk: CTL D(13)=.912, p=.195 WED D(14)=.909, p=.195 Boxplots: +ve skew Histograms: +ve skew (CTL only) Skewness: CTL 1.019/.616 = 1.65 WED .665/.597 = 1.11 Kurtosis: CTL .704/1.191 = .59 WED -.603/1.154 = -.52
LIWC positive emotion session 2	Shapiro-Wilk: CTL D(12)=.989 , p=.999 WED D(13)=.771, **p=.003** Boxplots: +ve skew (WED only) Histograms: +ve skew (WED only) Skewness: CTL .199/.637 = .31 WED 2.062/.616 = **3.35** Kurtosis: CTL -.082/1.232 = -.07 WED 4.899/1.191 = **4.1**	LOG + 1	Shapiro-Wilk: CTL D(12)=.812, **p=.013** WED D(13)=.936, p=.407 Boxplots: +ve skew (CTL only) Histograms: +ve skew (CTL only) Skewness: CTL 1.570/.637 = 2.46 WED .061/.616 = .10 Kurtosis: CTL 1.975/1.232 = 1.60 WED -1.394/1.191 = -1.17
LIWC positive emotion session 3	Shapiro-Wilk: CTL D(12)=.940, p=.494 WED D(12)=.974, p=.948 Boxplots: +ve skew Histograms: +ve skew (CTL only) Skewness: CTL .993/.637 = 1.56 WED .303/.637 = .48 Kurtosis: CTL 1.391/1.232 = 1.13 WED .129/1.232 = .10	LOG + 1	Shapiro-Wilk: CTL D(12)=.945, p=.567 WED D(12)=.939, p=.482 Boxplots: +ve skew (WED only) Histograms: +ve skew (esp. WED) Skewness: CTL .798/.637 = 1.25 WED .731/.637 = 1.15 Kurtosis: CTL 1.396 /1.232 = 1.13 WED .109/1.232 = .09
LIWC negative emotion session 1	Shapiro-Wilk: CTL D(13)=.816, **p=.011** WED D(14)=.976, p=.949 Boxplots: +ve skew (CTL only)	LOG + 1	Shapiro-Wilk: CTL D(13)=.915, p=.213 WED D(14)=.954, p=.631 Boxplots: +ve skew (WED only)

	Histograms: +ve skew (CTL only) Skewness: CTL 1.487/.616 = 2.41 WED -.082/.597 = -.14 Kurtosis: CTL 1.623/1.191 = 1.36 WED -.512/1.154 = -.44		Histograms: ok Skewness: CTL -.329/.616 = -.53 WED -.322/.597 = -.54 Kurtosis: CTL -1.048/1.191 = -.88 WED -.907/1.154 = -.79
LIWC negative emotion session 2	Shapiro-Wilk: CTL D(12)=.766, **p=.004** WED D(13)=.908, p=.172 Boxplots: +ve skew (WED only) Histograms: +ve skew (esp. CTL) Skewness: CTL 2.219/.637 = **3.48** WED .817/.616 = 1.33 Kurtosis: CTL 6.1 81/1.232 = **5.02** WED -.363/1.191 = -.30	LOG + 1	Shapiro-Wilk: CTL D(12)=.972, p=.950 WED D(13)=.921, p=.263 Boxplots: ok Histograms: +ve skew (WED only) Skewness: CTL -.629/.637 = -.99 WED .860/.616 = 1.40 Kurtosis: CTL .714/1.232 = 1.73 WED .704/1.191 = -.59
LIWC negative emotion session 3	Shapiro-Wilk: CTL D(12)=.884, p=.100 WED D(12)=.954, p=.701 Boxplots: +ve skew (CTL only) Histograms: +ve skew (CTL only) Skewness: CTL 1.249/.637 = 1.96 WED -.491/.637 = -.77 Kurtosis: CTL 1.256/1.232 = 1.02 WED .375/1.232 = .30	LOG + 1	Shapiro-Wilk: CTL D(12)=.99, p=1.0 WED D(12)= .951, p=.646 Boxplots: ok Histograms: ok Skewness: CTL -.152/.637 = -.24 WED -.747/.637 = -1.17 Kurtosis: CTL .094/1.232 = .08 WED .862/1.232 = .67
LIWC insight session 1	Shapiro-Wilk: CTL D(13)=.869, **p=.050** WED D(14)=.882, p=.063 Boxplots: +ve skew (esp. WED) Histograms: +ve skew Skewness: CTL 1.362/.616 = 2.21 WED .886/.397 = 1.48 Kurtosis: CTL 1.637/1.191 = 1.4	LOG + 1	Shapiro-Wilk: CTL D(13)=.910, p=.186 WED D(14)=.950, p=.562 Boxplots:+ve skew for CTL & -ve skew for WED Histograms: +ve skew for CTL & -ve skew for WED Skewness: CTL .749/.616 = 1.22 WED -.724/.597 = -1.21

	WED -.297/ 1.154 = -.26		Kurtosis: CTL -.331/1.191 = -.28 WED .163/1.154 = .14
LIWC insight session 2	Shapiro-Wilk: CTL D(12)=.742, **p=.002** WED D(13)=925, p=.294 Boxplots: +ve skew (esp. CTL) Histograms: +ve skew (esp. CTL) Skewness: CTL 1.933/.637 = **3.03** WED .294/.616 = .48 Kurtosis: CTL 3.524/1.232 = **2.86** WED -1.364/1.191 = -1.15	LOG + 1	Shapiro-Wilk: CTL D(12)=.915, p=.245 WED D(13)=.953, p=.641 Boxplots: -ve skew (CTL only) Histograms: +ve skew (CTL only) Skewness: CTL 1.041/.637 = 1.63 WED .259/.616 = .42 Kurtosis: CTL 2.126/1.232 = 1.73 WED -.969/1.191 = -.81
LIWC insight session 3	Shapiro-Wilk: CTL D(12)=.894, p=.132 WED D(12)=.906 , p=.189 Boxplots: +ve skew (WED) Histograms: +ve skew Skewness: CTL 1.349/.637 = 2.12 WED 1.087/.637 = 1.71 Kurtosis: CTL 2.712/1.232 = 2.2 WED 1.058/1.232 = .86	LOG + 1	Shapiro-Wilk: CTL D(12)=.939, p=.487 WED D(12)=.851, p=.038 Boxplots: + skew (CTL only) Histograms: -ve skew (WED only) Skewness: CTL .759/.637 = 1.19 WED -1.576/.637 = -2.47 Kurtosis: CTL -.103/1.232 = -.08 WED 2.909/1.232 = 2.36
LIWC cause session 1	Shapiro-Wilk: CTL D(13)=.935, p=.392 WED D(14)=.906, p=.137 Boxplots: ok Histograms: +ve skew (esp. CTL) Skewness: CTL .177/.616 = .29 WED .570/.597 = .95 Kurtosis: CTL -1.154/1.191 = -.97 WED -1.130/1.154 = -.98	LOG + 1	Shapiro-Wilk: CTL D(13)=.937, p=.414 WED D(14)=.933, p=.334 Boxplots: ok Histograms: ok Skewness: CTL -.143/.616 = -.23 WED .316/.597 = .53 Kurtosis: CTL -1.278/1.191 = -1.07 WED -1.212/1.154 = -1.05
LIWC cause session 2	Shapiro-Wilk: CTL D(12)=.945, p=.564 WED D(13)=.964, p=.813	LOG + 1	Shapiro-Wilk: CTL D(12)=.945 , p=.566 WED D(13)=.964, p=.813

	Boxplots: ok Histograms: -ve skew (CTL only) Skewness: CTL .492/.637 = .77 WED .325/.616 = .53 Kurtosis: CTL -.125/1.232 = -.10 WED -.384/1.191 = -.32		Boxplots: ok Histograms: ok Skewness: CTL -.320/.637 = -.50 WED -.281/.616 = -.46 Kurtosis: CTL -.210/1.232 = -.17 WED -.611/1.191 = .51
LIWC cause session 3	Shapiro-Wilk: CTL D(12)=.870, p=.066 WED D(12)=.932, p=.406 Boxplots: ok Histograms: +ve skew Skewness: CTL 1.178/.637 = 1.85 WED .623/.637 = .98 Kurtosis: CTL 2.614/1.232 = 2.12 WED .064/1.232 = .05	LOG + 1	Shapiro-Wilk: CTL D(12)=.908, p=.201 WED D(12)=.951, p=.657 Boxplots: +ve skew (CTL only) Histograms: +ve skew (WED only) Skewness: CTL .077/.637 = .11 WED -.264/.637 = -.41 Kurtosis: CTL .088/1.232 = .07 WED .736/1.232 = .60
Contamination			
LIWC positive emotion (average)	Shapiro-Wilk: CTL D(13)=.938, p=.427 WED D(14)=.898, p=.107 Boxplots: +ve skew (WED only) Histograms: +ve skew (WED only) Skewness: CTL -.033/.616 = -.05 WED 1.364/.597 = 2.28 Kurtosis: CTL -1.324/1.191 = -1.11 WED 2.737/1.154 = 2.37	LOG	Shapiro-Wilk: CTL D(13)= .923, p=.272 WED D(14)=.976, p=.943 Boxplots: ok Histograms: ok Skewness: CTL -.411/.616 = -.667 WED .309/.597 = .518 Kurtosis: CTL -1.185/1.191 = -.99 WED .526/1.154 = .456
LIWC negative emotion (average)	Shapiro-Wilk: CTL D(13)=.911, p=.188 WED D(14)=.920, p=.218 Boxplots: -ve skew (WED only) Histograms: +ve skew (CTL only) Skewness: CTL .619/.616 = 1.00 WED .670/.597 = 1.12	LOG	Shapiro-Wilk: CTL D(13)=.949, p=.590 WED D(14)=.947, p=.522 Boxplots: ok Histograms: ok Skewness: CTL .164/.616 = .266 WED -.026/.597 = -.04

	Kurtosis: CTL -.836/1.191 = -.70 WED .100/1,154 = .09		Kurtosis: CTL -.852/1.191 = -.72 WED .115/1.154 = .10
LIWC insight (average)	Shapiro-Wilk: CTL D(13)=.871, **p=.054** WED D(14)=.922, p=.235 Boxplots: ok Histograms: +ve skew (CLT only) Skewness: CTL 1.422/.616 = 2.31 WED .187/.597 = .31 Kurtosis: CTL 1.875/1.191 = 1.57 WED -1.496/1.154 = -1.30	LOG	Shapiro-Wilk: CTL D(13)=.960, p=.760 WED D(14)=.929, p=.292 Boxplots: +ve skew (CTL only) Histograms: +ve skew for CTL & -ve skew for WED Skewness: CTL .688/.616 = 1.117 WED -.149/.597 = -.25 Kurtosis: CTL .200/1.191 = .168 WED -1.384/1.154 = -1.199
LIWC cause (average)	Shapiro-Wilk: CTL D(13)=.925, p=.293 WED D(14)=.942, p=.440 Boxplots: -ve skew Histograms: -ve skew for WED & +ve skew for CTL Skewness: CTL -.510/.616 = -.83 WED -.507/.597 = -.85 Kurtosis: CTL 1.006/1.191 = .84 WED -.442/1.154 = -.38	LOG	Shapiro-Wilk: CTL D(13)=.897, p=.121 WED D(14)=.914, p=.179 Boxplots: -ve skew (esp. CTL) Histograms: -ve skew (WED only) Skewness: CTL -.843/.616 = -1.37 WED -.849/.597= -1.42 Kurtosis: CTL -.409/1.191 = -.34 WED .051/1.154 = .04
PANAS negative affect (average)	Shapiro-Wilk: CTL D(7)=.608, **p=.000** WED D(10)=.852, p=.061 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 2.380/.794 = **3.00** WED 1.410/.687 = 2.05 Kurtosis: CTL 5.790/1.587 = **3.65** WED 1.697/1.334 = 1.27	LOG	Shapiro-Wilk: CTL D(7)=.629, **p=.001** WED D(10)=.934, p=.492 Boxplots: +ve skew Histograms: +ve skew Skewness: CTL 2.301/.794 = **2.56** WED .648/.687 = .94 Kurtosis: CTL 5.416/1.587 = **3.41** WED -.221/1.334 = -.16
Exploratory correlations			

CES-D (change)	Shapiro-Wilk: WED D(12)=.948, p=.602 Boxplots: ok Histograms: ok Skewness: WED .837/.637 = 1.31 Kurtosis: WED .564/1.232 = .46		
PAID (change)	Shapiro-Wilk: WED D(11)=.973, p=.915 Boxplots: Histograms: ok Skewness: ok WED .122/.661 = .18 Kurtosis: WED -.441/1.279 = -.34		
EQ-5D utility (change)	Shapiro-Wilk: WED D(11)=.644, **p=.000** Boxplots: -ve skew Histograms: -ve skew Skewness: WED -2.544/.661 = **-3.84** Kurtosis: WED 6.997/1.279 = **5.47**		
EQ-5D VAS (change)	Shapiro-Wilk: WED D(12)=.686, **p=.001** Boxplots: -ve skew Histograms: -ve skew Skewness: WED -2.427/.637 = **-3.81** Kurtosis: WED 7.736/1.232 = **6.28**		

SDSCA general diet (change)	Shapiro-Wilk: WED D(12)=.772, **p=.005** Boxplots: +ve skew Histograms: +ve skew Skewness: WED 2.105/.637 = **3.30** Kurtosis: WED 6.085/1.232 = **4.94**		
SDSCA specific diet (change)	Shapiro-Wilk: WED D(11)=.756, **p=.002** Boxplots: -ve skew Histograms: -ve skew Skewness: WED -1.220/.661 = -1.85 Kurtosis: WED .027/1.279 = .02		
SDSCA exercise (change)	Shapiro-Wilk: WED D(12)=.820, **p=.016** Boxplots: -ve skew Histograms: -ve skew Skewness: WED -1.854/.637 = **-2.91** Kurtosis: WED 5.069/1.232 = **4.11**		
SDSCA blood glucose testing (change)	Shapiro-Wilk: WED D(9)=.703, **p=.002** Boxplots: +ve skew Histograms: +ve skew Skewness: WED 1.804/.717 = 2.52 Kurtosis: WED 2.717/1.400 = 1.94		

SDSCA foot care (change)	Shapiro-Wilk: WED D(12)=.920, p=.289 Boxplots: ok Histograms: ok Skewness: WED.054/.637 = .08 Kurtosis: WED 1.367/1.232 = 1.11		
LIWC insight (change)	Shapiro-Wilk: WED D(12)=.886, p=.106 Boxplots: +ve skew Histograms: +ve skew Skewness: WED 1.257/.637 = 1.97 Kurtosis: WED 2.782/1.232 = 2.26		
LIWC cause (change)	Shapiro-Wilk: WED D(12)=.905, p=.182 Boxplots: +ve skew Histograms: ok Skewness: WED .059/.637 = .09 Kurtosis: WED -1.222/1.232 = -.99		
LIWC positive emotion (change)	Shapiro-Wilk: WED D(12)=.930, p=.383 Boxplots: ok Histograms: ok Skewness: WED .148/.637 = .23 Kurtosis: WED -1.026/1.232 = .83		

LIWC negative emotion (change)	Shapiro-Wilk: WED D(12)=.911, p=.221 Boxplots: ok Histograms: ok Skewness: WED -.871/.637 = 1.37 Kurtosis: WED -.087/1.232 = -.07		

Appendix V: Effect size estimates for effectiveness analyses[153]

Outcome	WED		n	Control		n	Untransformed data			Transformed data		
	Mean	SE		Mean	SE		ω^2 (small =.01; medium=.06; large =.14)	η^2 (small =.01; medium=.06; large =.14)	η_p^2 (small =.01; medium=.06; large =.14)	ω^2 (small =.01; medium=.06; large =.14)	η^2 (small =.01; medium=.06; large =.14)	η_p^2 (small =.01; medium=.06; large =.14)
ITT analysis												
CES-D	9.90	1.08	23	5.12	1.22	18	.09 M	.10 M	.19 L	.08 M	.10 M	.19 L
PAID	35.33	1.41	23	34.37	1.60	18	-.01 X	.00 X	.01 S	-.01 X	.00 X	.00 X
EQ-5D: utility	.86	.03	23	.87	.03	18	-.01 X	.00 X	.00 X	-.01 X	.00 X	.00 X
EQ-5D VAS	77.43	2.75	22	82.09	3.04	18	.01 S	.02 S	.04 S	.01 S	.02 S	.05 S
SDSCA: general diet	5.76	.24	23	5.84	.27	18	-.02 X	.00 X	.00 X	-.01 X	.01 S	.01 S
SDSCA: specific diet	4.50	.19	23	5.06	.21	18	.03 S	.04 S	.10 M	.04 S	.05 S	.14 L
SDSCA: exercise	3.46	.28	23	3.96	.31	18	.00 X	.01 S	.04 S	.00 X	.01 S	.02 S
SDSCA: blood glucose testing	2.54	.39	22	2.48	.46	16	-.01 X	.00 X	.00 X	-.01 X	.00 X	.00 X
SDSCA: foot care	3.15	.24	23	3.03	.27	18	-.00 X	.00 X	.00 X	.01 S	.01 S	.04 S
Complete case analysis												
CES-D	10.63	1.36	18	5.12	1.54	14	.10 M	.12 M	.21 L	.10 M	.12 M	.20 L
PAID	33.45	1.82	17	32.80	2.08	13	-.02 X	.00 X	.00 X	-.02 X	.00 X	.00 X
EQ-5D: utility	.83	.03	17	.84	.04	12	-.02 X	.00 X	.00 X	-.02 X	.00 X	.00 X
EQ-5D VAS	74.75	3.46	18	82.22	4.25	12	.02 S	.03 S	.07 M	.02 S	.04 S	.10 L
SDSCA: general diet	5.63	.31	18	5.63	.36	13	-.03 X	.00 X	.00 X	-.01 X	.01 S	.02 S
SDSCA: specific diet	4.15	.25	17	4.96	.28	13	.07 M	.08 M	.16 L	.08 M	.10 M	.20 L
SDSCA: exercise	3.55	.36	18	4.02	.43	13	-.00 X	.01 S	.03 S	-.01 X	.00 X	.02 S
SDSCA: blood glucose testing	3.22	.60	13	2.72	.62	12	-.01 X	.01 S	.02 S	-.02 X	.00 X	.01 S
SDSCA: foot care	2.94	.31	18	2.70	.37	13	-.01 X	.01 S	.01 S	.01 S	.02 S	.06 M

[153] The adjusted means/SEs relate to analyses with the untransformed data.