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A clinical replication series to investigate if EMDR has the potential to treat clients with long term depression, its acceptability to them and possible mechanisms of change.

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Abstract

Depression is one of the world's leading causes of disability. Current methods used to treat it, both medication and psychotherapy, are effective for some but not all; new approaches need to be developed to complement the ones already available. This need is particularly acute for chronic and recurrent depression.

A single case experimental design with replications was implemented for a preparatory investigation into the potential of Eye Movement Desensitisation and Reprocessing (EMDR) to treat long term depression. Ten people with recurrent and/or chronic depression were recruited from primary care mental health services and received Standard Protocol EMDR for a maximum of 20 sessions. Levels of depression and social functioning were measured before and after treatment and at follow up, clients also rated their mood each day. Before and after treatment the participants recorded their target memories whilst recording psychophysiological parameters and after treatment they were interviewed about their experience of EMDR.

Eight people engaged with the treatment, seven of these had clinically significant and statistically reliable improvement on the Hamilton Rating Scale for Depression and this improvement was linked to the progress of treatment. Heart rate variability was significantly reduced indicating a less withdrawn parasympathetic nervous system. Interviews elicited a highly favourable opinion of EMDR from the participants including all participants saying they would recommend it to others.

EMDR has shown potential to be an effective treatment for depression. This phase I study has provided a platform for a phase II pilot trial and phase III randomised controlled trials to gauge efficacy and effect size in a larger sample. This study's results are consistent with the working memory taxation theory of mechanism of change in EMDR.

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Acronyms

Psychotherapies

CBASP- Cognitive behavioural analysis system of psychotherapy

CBT- Cognitive behavioural therapy

EMDR – Eye Movement Desensitisation and Reprocessing

PE - Prolonged exposure

SC- Standard care

TAU – Treatment as usual

WL – Waiting list

Rating scales

BDI (or BDI-II) - Beck depression inventory (version 2)

GAF – Global assessment of functioning

HAT – Helpful aspects of therapy

HRSD – Hamilton rating scale for depression

IES-r – Impact of event scale - revised

MINI – Mini-international neuropsychiatric interview

PHQ-9 – Patient Health Questionnaire (9 items)

SASS - Social Adaption Self-Evaluation Scale

Other acronyms

AIP – Adaptive Information Processing Model

APA – American Psychiatric Association

BLS – Bilateral stimulation

C-reps – contextual representations

CASP - Critical Appraisal Skills Programme

CMHT – Community Mental Health Team

DSM – Diagnostic and statistical manual (versions 4 – text revision and 5)

EMDRIA – EMDR International Association

EMDR UK & I – EMDR Association for the UK and Ireland

HRV – Heart rate variability

IAPT – Improving Access to Psychological Therapies NHS service

ICD-10 – International Classification of Disease version 10

MDD – Major depressive disorder

N – number of participants in a study

NHS- National Health Service

NICE – National Institute for Health and Clinical Excellence

OCEBM – Oxford Centre for Evidenced Based Medicine

PDD – Persistent Depressive Disorder

PhD – Doctor of Philosophy

PTSD – Post Traumatic Stress Disorder

RCT – Randomised Control Trial
REM – Rapid eye movement
OR – Orientating response
S-reps – sensory representations
SCR – Skin conductance response
SCED – single case experimental design
SD- Standard deviation
SEDI – Sheffield EMDR and depression investigation
SSRI – Selective serotonin reuptake inhibitor
UK – United Kingdom
USA – United States of America
WM – working memory
WHO – World Health Organisation

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Introduction

Levels of depression are reaching pandemic proportions. The World Health Organisation predicts depression will be the second leading cause of disability by 2020 (Üstün et al., 2004). At any one time approximately 10% of people have depression (Singleton et al., 2003) and 20% will be diagnosed in their lifetime (Kessler et al., 2005). As well as the personal and social costs, depression is estimated to have an economic cost of \$36bn a year in the United States of America alone (Monroe and Harkness, 2011).

For a diagnosis of Major Depressive Disorder (MDD) the Diagnostic and Statistical Manual (DSM version IV – text revision) produced by the American Psychiatric association (APA) requires that the client reports at least five of the following symptoms during the same two week period and that at least one symptom is (1) depressed mood or (2) loss of interest:

- (1) Depressed mood
- (2) Markedly diminished interest or pleasure
- (3) Significant weight loss (not dieting) or weight gain or marked change in appetite
- (4) Insomnia or hypersomnia nearly everyday
- (5) Psychomotor retardation or agitation nearly everyday
- (6) Fatigue nearly everyday
- (7) Feelings of worthlessness or excessive or inappropriate guilt
- (8) Diminished ability to think/ concentrate nearly everyday
- (9) Recurrent thoughts of death, suicidal thoughts (with or without plan), suicide attempt

Long term depression refers to either chronic depression (when the episode of depression has lasted at least two years without remission) or recurrent depression (when the client has had two or more episodes of depression in their lifetime) (APA, 2003). Although only around 10% of cases last longer than one year (Keller et al., 1997) approximately 60% of clients will go on to have a second episode (Solomon et al., 2000).

The DSM fifth edition included the diagnosis of Persistent Depressive Disorder (PDD) (APA, 2013), where low mood is experienced on most days for at least two years along with at least two of the other symptoms listed above. Chapter one will give more detail on these different definitions.

Current recommended treatments for depression include antidepressant medication, Cognitive Behavioural Therapy (CBT), Counselling, and Interpersonal Therapy (NCCMH, 2010) however,

despite the efficacy of these interventions (Olfson et al., 2006, Butler et al., 2006) they do have limitations.

A review of pharmaceutical trials (including unpublished data) suggested an overall efficacy of antidepressants of only 32% (Turner et al., 2008). In chronic depression typical response rates to both medication and psychotherapy may be less than 50% (Torpey and Klein, 2008). This is compounded by the findings that in practice as few as 21% of clients seeking treatment for depression are actually receiving adequate treatment (i.e. minimal concordance with the published guideline) (Kessler et al., 2003). Cuijpers and colleagues also found that psychotherapy (CBT, interpersonal therapy, and cognitive behavioural analysis system of psychotherapy) may be less effective for chronic depression than for acute phase depression (Cuijpers et al., 2010).

Although current treatments are very helpful for some people, they are not for everyone. There are several hundred documented psychotherapies (Roth and Fonagy, 2005) but one which has generated interest recently is Eye Movement Desensitisation and Reprocessing (EMDR) (Shapiro, 1995). Despite much enthusiasm, reviews of early research on EMDR found that much of it did not meet rigorous research standards (Foa and Meadows, 1997, Lohr et al., 1998). More recently improvements in the research quality and a growing body of evidence led the Cochrane Collaboration review of treatments for post-traumatic stress disorder (PTSD) to recommend only EMDR and trauma focussed CBT (Bisson and Andrew, 2007). Most of the research into EMDR has been done on PTSD, it was after all developed to treat trauma, but recently interest has spread to using EMDR with other diagnoses. The theoretical model behind EMDR, the Adaptive Information Processing model (AIP), is clear that problematic memories are the cause of pathology and this is not limited to PTSD. Equally, several randomised controlled trials into EMDR for PTSD also noticed significant improvements in comorbid depression (van der Kolk et al., 2007, Arabia et al., 2011, Lee et al., 2002, Ironson et al., 2002). Despite this the research into using EMDR with clients with a primary diagnosis of depression amounts to only a few case studies and clinical reports (Wood and Ricketts, 2013).

Major Depressive Disorder and Post Traumatic Stress Disorder are independent but related conditions (Blanchard et al., 1998). These disorders have three diagnostic symptoms in common (sleep disturbance, lack of concentration and anhedonia) (APA, 2003) and share other characteristics such as guilt and overgeneral memories (Reynolds and Brewin, 1999) and they are associated with high levels of comorbidity (Nixon et al., 2004, Campbell et al., 2007). Crucially both

conditions are also characterised by intrusive memories of negative life events (Holmes and Mathews, 2010), and it has been suggested that distress in both conditions is due to the inability to correctly process the memories formed during these events (Brewin et al., 2010, Shapiro, 1995).

Depression is often associated with negative life events (Lenze et al., 2008) and people with chronic depression tend to report greater levels of early life adversity (Riso and Newman, 2003). Childhood trauma is a direct and strong risk factor for developing depression later in life (Heim et al., 2008). Given the accumulating evidence of common characteristics between depression and PTSD in terms of aetiology, symptoms, memory processing, and intrusive negative memories, there is a case for exploring the possibility of improving therapeutic outcomes in depression, by adapting methods known to be effective in PTSD. EMDR was designed to treat problematic memories stemming from traumatic incidents. Therefore this research intended to investigate if EMDR has the potential to be a treatment for long term depression. By using 20 sessions, and by working with people who have already not responded to a NICE recommended course of therapy, I aimed to investigate if EMDR has the potential to be another 'step' in the stepped care model utilised by UK primary care mental health services. The rationale for using EMDR as a therapeutic method in depression is developed in depth in Chapters 1 and 2.

The intent of this two-phase sequential mixed methods study was to investigate the claims that EMDR can improve peoples' mental health symptoms and does so by altering their autobiographical memories. In the first quantitative phase, a single case experimental design investigated the efficacy of EMDR to treat long term depression. Thirteen participants were recruited from the primary care Improving Access to Psychological Therapies service and treated at Sheffield Health and Social Care NHS Foundation Trust's Focussed Depression Team in Psychological Services. Information from this first phase was explored further in the qualitative second phase. Here all of the participants from phase one were interviewed to explore aspects of therapy experience. The reason for following up with qualitative research in the second phase is to improve the understanding of the use of EMDR to treat depression far better than either method could do alone. This is because by mixing methods this study offers a more comprehensive account of what has occurred by including process questions and client views to whether or not it was effective, the different approaches will also offset the weaknesses and draw on the strengths of both methods. It can answer more questions and unexpected findings in one area may be

illuminated by findings in another and the diversity of views may improve the practical usefulness of the findings by helping to understand which parts of the EMDR method are helpful in depression treatment.

Chapter 1 will provide an overview of the current knowledge on depression and define long term depression.

Chapter 2 introduces EMDR, including the controversy surrounding it, a review of the current literature on EMDR and depression and an overview of the competing theories around the mechanism of action behind EMDR.

Chapter 3 discusses research design and is split into two parts. Chapter 3.1 discusses some of the methodological issues surrounding research paradigms, single case experimental design, mixed methods and using skin conductance response and heart rate variability. Chapter 3.2 describes the methods used in the Sheffield EMDR and Depression Investigation.

The results are described in chapters 4, 5 and 6. Chapter 4 details the impact of EMDR on the depression of the participants and includes details on the quality of the data in the study. Chapter 5 is concerned with the mechanism of change in EMDR and details the outcome from the memory investigations. Chapter 6 focuses on the acceptability of EMDR, what the participants thought of it.

Chapter 7 then reviews the results in a mixed methods analysis. It combines the purely quantitative chapter 4 and 5 with the purely qualitative interview data from chapter 6.

Chapter 8 discusses all the results both separately and then combined. It also considers the limitations of the study and what recommendations for research and implications for clinical practice come from it.

Chapter 1 - Depression

1.1 Classification and prevalence

Depression is a common mental health disorder, at any one time approximately 10% of people in the United Kingdom (UK) meet the criteria for a depressive episode (Singleton et al., 2003) and approximately 20% of Americans will have at least one episode in their lifetime (Kessler et al, 2005). Human despondency was described as early as the fifth century BC by Hippocrates who called it melancholia as he believed it to be caused by an imbalance of black bile (Leventhal and Rehm, 2005). It is now thought by the World Health Organisation to be the fourth leading cause of disease burden in the world (Üstün et al., 2004). These are two main systems for classifying mental health problems, the International Classification of Disease (ICD-10) from the World Health Organisation (WHO) and the Diagnostic and Statistical Manual revised fourth edition (DSM-IV-TR)¹ from the American Psychiatric Association (APA) (APA, 2003). The two systems are slightly different. For a diagnosis of Major Depressive Disorder (MDD) the APA requires that the client reports at least five of the following symptoms during the same two week period and that at least one symptom is (1) depressed mood or (2) loss of interest:

1. Depressed mood
2. Markedly diminished interest or pleasure
3. Significant weight loss (not dieting) or weight gain or marked change in appetite
4. Insomnia or hypersomnia nearly everyday
5. Psychomotor retardation or agitation nearly everyday
6. Fatigue nearly everyday
7. Feelings of worthlessness or excessive or inappropriate guilt
8. Diminished ability to think/ concentrate nearly everyday
9. Recurrent thoughts of death, suicidal thoughts (with or without plan), suicide attempt

Whereas the ICD-10 specifies that the client must have two of three key symptoms, depressed mood, lack of interest and lack of energy (symptom 6) (WHO, 1993). Both systems use an increasing number of symptoms along with increasing disability to define the severity of the episode.

¹ Although the DSM-5 was published in 2013 it came out after ethics and research and development applications had been made so the decision was made to continue with the DSM-IV-TR definitions. Comparisons between the two systems are made later in Chapter 1.

Both systems also assume that 'depression' is one homogenous illness. Although they do allow for different specifiers to be attached to the diagnosis, these are more to describe the length or severity of the illness rather than the existence of different disorders. The validity of this is contested, not only by those who look at mental health from a social perspective (Moncrieff and Timimi, 2013) but also those from biological psychiatry (Bosch et al., 2012). There is some evidence to suggest 'depression' may actually be made of several subtypes, including but not limited to, melancholic and non-melancholic depression (Parker et al., 2013) and mixed depression (Azorin et al., 2012). There also appears to be significant differences between acute and long term depression (Klein et al., 2006), recurrent and chronic depression (Klein and Santiago, 2003) and dysthymia (long term subclinical depression) remains a contentious diagnosis (Rhebergen et al., 2012). This lack of clarity has led some to call for more research into the subtypes of depression especially concerning the way the different types respond to different therapies available (Maj, 2012, Torpey and Klein, 2008).

1.2 Determinates of depression

Major Depressive Disorder, as defined by the APA and WHO, is a common disorder, but it is twice as common in women as in men (Levinson, 2009) and those from lower socio-economic backgrounds are also more susceptible (Monroe et al., 2009). There is a strong relationship between experiencing a major life stress and developing depression (Monroe et al., 2009); there is evidence that there are significantly more 'life events' immediately before the onset of depression than in a control population (Tyrer and Steinberg, 2006). Life events describe any stressful occurrence in a person's life, these can be positive such as moving house or getting married, or negative such as getting ill or being assaulted. Depression is often associated with negative life events (Lenze et al., 2008) and people with chronic depression tend to report greater levels of early life adversity (Riso and Newman, 2003). Childhood trauma is a direct and strong risk factor for developing depression later in life (Heim et al., 2008). There is a strong dose-response relationship between adverse childhood experiences and lifetime depressive illness (Chapman et al., 2004) and it can be considered a determinate for chronicity (Wiersma et al., 2009), earlier onset (Bernet and Stein, 1999), more lifetime episodes (Bernet and Stein, 1999) and treatment resistance (Kaplan and Klinetob, 2000).

Not all depression is linked to childhood trauma (Heim et al., 2008), it would appear to have biological as well as social risk factors. Researchers have found smaller hippocampal volumes in

depressed clients, that this has been found even in people in a first episode suggests the depression itself is not the cause (Frodl et al., 2002). Others have found neuropsychological impairment, suggesting dysfunction in the prefrontal cortex/ anterior cingulate, in elderly depressed clients, although it was unclear whether this was a cause or effect of the depressed state (Lockwood et al., 2002). Another potential biological risk factor, which may be linked to the previous two, is excessive cortisol activity (Schatzberg, 2002). These abnormalities in the different brain regions are more associated with chronic and long term depression than with a single short episode (APA, 2013).

It would seem likely that a number of different factors increase the risk of depression in certain individuals and they have been classified as stressful life events, biological/genetic vulnerability, and psychological factors (personality, cognitive and interpersonal vulnerabilities) (Hankin, 2006). The DSM-5 lists risk factors as neuroticism, adverse childhood experiences, stressful life events, first degree family members with MDD, chronic or disabling medical conditions and a diagnosis of all major non-mood mental disorders (APA, 2013).

1.3 Models of depression

Biological – The biological or disease model of mental health problems suggests that an abnormality of the mind must have its origins in a malfunction of the nervous system (Tyrer and Steinberg, 2006). The biomedical model is concerned with the relationship between psychopathology and physiological processes (Davies and Bhugra, 2004). This raises questions about the mind and the brain and the relationship between the two, but the term mental ‘illness’ implies ‘disease’ (Tyrer and Steinberg, 2006). As the illness is caused by physiological problems, the treatment should be to address this. The client is a passive recipient of this treatment and failure to improve is a failure of the treatment not the client (Tyrer and Steinberg, 2006). In depression the malfunction is thought to be associated with the monoamine neurotransmitters (especially serotonin and noradrenaline) and cortisol, a glucocorticoid hormone (Thase, 2009). It has been suggested that sustained stress can dysregulate noradrenaline neurotransmission and serotonin receptors, susceptibility of the serotonin receptors to stress also appears to be genetic (Thase, 2009). So genetics can also be thought to play some role in depression, up to 50% of the susceptibility to it may be caused by our genetic makeup but it is a complex interaction and depression does not appear to be directly inheritable (Levinson, 2009).

Cognitive – The cognitive theories of mental illness argue that it is a person's thoughts, interpretations, attitudes and inferences about events and the way in which they attend to and remember them that determines their emotional response (Joormann et al., 2009). Most involve a stress-vulnerability model where some kind of stressor (e.g. a life event) occurs and interacts with our psychological vulnerability to the stress (e.g. the way we process information) (Joormann et al., 2009). Beck's cognitive theory comprises three such vulnerabilities or components of emotional disorders, 'negative automatic thoughts, systemic logical errors and depressogenic schemas' (Williams, 1995). The cognitive model differs from the other models of mental illness because it sees the symptoms (e.g. negative thoughts) as the heart of the illness, i.e. 'the negative thought is the 'neurosis' it is not caused by it' (Tyrer and Steinberg, 2006).

Social – Our social environment can affect us in many different ways, on large scale level our culture or socioeconomic status may affect our ability to access help in a crisis or on a more personal level it may reflect individual differences in the negative life events (e.g. bullying, accident or illness) that we experience (Monroe et al., 2009). The social model states that mental illness is caused by life events which appear to be independent of one's health, social forces such as class, occupation and social role can not only lead to but also maintain mental disorder. This has led some to argue that much of what is labelled as illness should actually be regarded as a temporary maladjustment (Tyrer and Steinberg, 2006).

In practice many clinicians will refer the 'biopsychosocial' model. This multifactorial approach reflects the idea that depression, and mental ill-health in general, is caused and maintained by a complex interaction of biological, psychological and social factors (Gilbert, 2000).

1.4 Onset

Surveys of depressive symptoms (rather than diagnoses) in relation to age show a U shaped curve; the highest reports of symptoms occur among the young and the old (Kessler et al., 1992). Primarily however, depression is an illness which begins in young adults, between 20-50% of adolescents report significant, but subdromal, symptoms (Hankin, 2006), many will recover and not go back to being depressed but it may persist throughout adulthood and ten percent of all first onsets of depression occur after the age of 55 years (Kessler et al., 2005).

1.5 Long term depression

Long term depression has, until recently, been poorly studied but it is a common, often a lifelong, condition and can be broken down into several classifications. In the DSM-IV-R it is not one diagnosis but comprises four types: dysthymia (subclinical depressive symptoms lasting over 2 years), chronic major depressive disorder (MDD) (fitting the criteria for MDD for more than 2 years), double depression (dysthymia as a baseline with episodes of MDD) and recurrent MDD with incomplete recovery between episodes (APA, 2003). However, there is little evidence that these types are different significantly from each other (McCullough Jr et al., 2003). Also under the nomenclature of long term depression is recurrent MDD, this is defined as two or more episodes of MDD (APA, 2003), and it is considered to be different to chronic depression (Klein and Santiago, 2003).

To clarify this position the DSM-5 attempted to reorganise these classifications into two broad categories, major depressive disorder and persistent depressive disorder (PDD). The clear aim being to separate recurrent depression from chronic depression. MDD then, includes different specifiers so it may be single episode or recurrent, in full or partial remission and of any severity (APA, 2013). PDD is any long lasting none-remitting depressive illness rather than the four previous ones i.e. any depressive illness that has lasted for over two years; even if it doesn't always meet the criteria for a full major depressive episode (APA, 2013). However these diagnoses do still overlap. It is difficult to judge from the DSM-5 whether a client who is currently not meeting the criteria for a full major depressive episode, but has in the past and is displaying some depressive symptoms would be classified as having major depressive disorder in partial remission or persistent depressive disorder with intermittent major depressive episodes, without current episode (APA, 2013). However, as the treatment guidelines in the United Kingdom (see section 1.8) are based on the ICD classifications, these overlaps are only really of importance to research.

Some of those who relapse may take a long time to achieve a subsequent remission (Boland and Keller, 2009). Once someone has suffered a recurrence then the chances of further episodes increase, the risk of a new episode increases by 16% with each recurrence (Solomon et al., 2000) and reoccurrences are more common in women than in men (Williams, 1995).

Thus when referring to long term depression this study encompasses those with depression that has lasted at least two years or those who have had two or more episodes of MDD.

1.6 Prognosis

Although depression is often considered an acute illness, that will last four months or longer untreated (APA, 2003), around 60% of people suffering a first episode of depression will go on to have a second (Solomon et al., 2000). The vast majority (90%) of all depression cases are expected to recover within one year (Keller et al., 1997) but this is not a predictor of recurrence. Despite differing studies having differing definitions for key terms such as 'depression' and 'early onset' it does appear that child/adolescent onset depression is associated with poorer outcomes including longer time to remission and lower likelihood of remission (Greden, 2001). Studies tend to disagree on whether or not early onset depression increases the risk of multiple episodes (Boland and Keller, 2009). Certain clusters of symptoms may also be predictive of chronic courses of depression, including severe fatigue, insomnia, suicidal ideation, loss of interest and social withdrawal (Moos and Cronkite, 1999, Gilchrist and Gunn, 2007). Comorbid illnesses can also have an effect on the course of depression. Panic disorder, anxiety, personality disorder, substance abuse and medical illnesses occurring with the depression can lead to longer recovery times for depressive illness (Boland and Keller, 2009). Depression has been reported to be of comparable strength to smoking as a risk factor for mortality (Mykletun et al., 2009).

1.7 Economics

The economic and personal costs of chronic depression are high (Robinson et al., 1990). Clients with chronic depression use up to twice as many medical services as non-depressed clients, and have higher rates of suicide and hospital admission than acutely depressed clients (Arnou and Constantino, 2003). Up to 20% of all depressed clients have a chronic course (Klein and Santiago, 2003), which translates to around 3% of the adult population of Western countries (Cuijpers et al., 2010b), and it accounts for 12% of the total years lived with disability (Üstün et al., 2004). By 2020 depression is expected to have become the world's second leading cause of disability and is estimated to cost \$36bn a year in the United States of America (USA) alone (Monroe and Harkness, 2011). It also points to poorer educational outcomes for adolescents; early onset depression predicts high school and college dropout and increased rates of teen pregnancy (Kessler et al., 1995). Major Depressive Disorder is associated with high mortality (APA, 2013), depressive symptoms may be a factor in predicting early mortality in otherwise healthy individuals (Takeshita et al., 2002) and it appears to adversely affect the course of other diseases such as breast cancer and cardiovascular disease (Greden, 2001).

1.8 Treatment

In the UK, the National Institute for Health and Clinical Excellence (NICE) recommends those with moderate or severe depression should be treated with a combination of antidepressant medication and Cognitive Behavioural Therapy (CBT) (NCCMH, 2010). Despite the efficacy of these approaches (Olfson et al., 2006, Butler et al., 2006) both do have limitations. A review of medication for treatment resistant depression found that after initial treatment failure on a selective serotonin reuptake inhibitor (SSRI) switching to another SSRI gave remission rates of 27-70% and combining a SSRI with a tricyclic antidepressant saw remission in 54-71% (Shelton et al., 2010). However this leaves 29-73% of clients still not responding to medication and it may be optimistic, a review of unpublished medicine trials suggested an overall efficacy of antidepressants of only 32% (Turner et al., 2008). In chronic depression typical response rates to both medication and psychotherapy may be less than 50% (Torpey and Klein, 2008). This is compounded by the findings that in practice as few as 21% of clients seeking treatment for depression are actually receiving adequate treatment (i.e. minimal concordance with the published guideline) (Kessler et al., 2003). Cuijpers et al, (2010) also found that psychotherapy (CBT, interpersonal therapy, and cognitive behavioural analysis system of psychotherapy (CBASP)) may be less effective for chronic depression than for acute phase depression.

Even in the studies where the CBT approaches had an effect on the depressive symptoms reported by clients they did not improve in social functioning and did not appear to be doing well at follow up (Schramm et al, 2011, Kocsis et al, 2009). As long term depression is a relapsing – remitting illness then the need for long term follow up is paramount in assessing the effectiveness of a treatment. Due to the significant impairment in social functioning that is seen in long term and chronic depression (Klein and Santiago, 2003) then a treatment that does not affect any improvement in this aspect cannot be said to be a truly effective one. The UK NICE guidance on depression recommends differing treatments for depression based on severity but not on chronicity (NCCMH, 2010). Considering the evidence that acute and chronic depression are different illnesses (Klein and Santiago, 2003) that respond differently to treatments including psychological treatments (Cuijpers et al., 2010b) this could be a mistake. Although Interpersonal Psychotherapy was developed specifically to treat depression it may not be as helpful in chronic depression as it is in acute depression (Cuijpers et al., 2010b, Schramm et al., 2011) but NICE recommend that it is offered to those who have not responded to initial treatment (CBT, computerised CBT and medication). CBASP, which was specifically developed to treat chronic

depression, does not yet feature in the recommendations despite initial positive results due to a lack of good quality, randomised controlled trial based evidence (Schramm et al., 2011, Kocsis et al., 2009). NICE does consider long term depression differently when it comes to relapse prevention, here CBT or mindfulness should be offered to people with a history of recurrent depression. This advice could be questioned because, in common with other NICE guidance, it does not take account of the lack of evidence on other approaches: although mindfulness does appear to be better than medication (Kuyken et al., 2008) and General Practitioner standard care (Bondolfi et al., 2010) at reducing relapse, it has not been compared to any other active psychological therapy.

1.9 Summary and the need for new treatments

Depression is a common and devastating illness. It has high costs for both the individual and society. Despite this the best treatments we have available can only hope to achieve a 50-60% success rate. It is of paramount importance that we continue to research treatments for depression. Although it is unlikely that any one treatment will be found that is suitable for all suffers the more approaches we have the more likely it is that we will be able to treat more people and help get them to a state of remission.

Chapter 2 – Eye Movement Desensitisation and Reprocessing (EMDR)

2.1 Background

Eye Movement Desensitization and Reprocessing (EMDR) is said by its developers to be a comprehensive psychotherapy approach (Shapiro and Liliotis, 2011). It was developed by Francine Shapiro (1995) to treat the victims of trauma. It uses bilateral stimulation, e.g. taps, tones or eye movements, aiming to stimulate information processing systems of the brain in addition to employing other psychotherapeutic methods of known effectiveness. It consists of a structured eight-phase protocol and is usually delivered in weekly 90-minute sessions (Shapiro, 1995). A typical session begins with the therapist evaluating the imagery, cognition, emotion and body sensations related to a traumatic memory. The client and therapist also decide upon a positive cognition that may be substituted for the negative one and then check the scores of the Subjective Units of Disturbance Scale and the Validity of Cognition scale. After this, clients are instructed to attend to their memories of the traumatic event and simultaneously follow the bilateral stimulation (usually eye movements). This process of attending to both internal and external stimuli is called dual attention. If new material comes up after 28-30 eye movements, clients are asked again to attend to the event and move their eyes. This dual attention and association are repeated until the memory of the traumatic event is no longer stressful (Shapiro, 1995).

The theoretical model behind EMDR is the Adaptive Information Processing (AIP) model; this was developed alongside the EMDR treatment model for Post-Traumatic Stress Disorder (PTSD). The AIP model claims that mental pathology is caused by incorrectly processed memories getting 'stuck' in an emotional and vivid state. It is suggested that EMDR alleviates pathology by helping the client to reprocess these memories so they are no longer traumatic (Shapiro, 1995).

Research evidence for the effectiveness of EMDR treatment is mixed. Many of the early studies were not rigorously carried out. When Foa and Meadows reviewed all treatments for Post-Traumatic Stress Disorder (PTSD) in 1997 EMDR got a footnote only. They said "the picture emerging from the studies reviewed here is mixed, some found improvement but methodological flaws rendered most, though not all, of these findings uninterpretable" (Foa and Meadows, 1997). A year later another review identified 16 studies and although they concluded that the treatment effects of EMDR were not measurement artefacts only two of the studies they found met full methodological rigour (Lohr et al., 1998). More recently the quality has improved and a series of

systematic reviews and meta-analyses including one by the Cochrane Collaboration have found that EMDR is significantly better at treating PTSD than no treatment and not significantly different from trauma focussed CBT (Van Etten and Taylor, 1998, Shepherd et al., 2000, Davidson and Parker, 2001, Bisson and Andrew, 2007, Ho and Lee, 2012). As a result of the improved quality and quantity of research evidence, EMDR is now a recommended treatment for Post-Traumatic Stress Disorder (PTSD) in clinical guidelines (NICE, 2005). One review of treating PTSD in children found that EMDR was significantly better than CBT (Rodenburg et al., 2009) although it only had a very small number of studies to analyse.

The quality of the research is not the only criticism levelled against EMDR. Several authors have been concerned about the pseudoscientific nature of the AIP, chiefly its lack of falsifiable predictions (Herbert et al., 2000) and that it makes no reference to other cognitive science theories or experimental data (Lohr et al., 1998). There has also been plenty of controversy over the use of eye movements or other types of bilateral stimulation most potently whether they are of any use what so ever (Lohr et al., 1998) or actually whether they are doing more harm than good by causing a distraction during imaginal exposure (Deville et al., 2013). The AIP model and theories around mechanism of change will be examined more closely in part 2.3. Finally questions have been raised about aggressive marketing tactics by EMDR providers and trainers in the USA and about the way that the EMDR International Association (EMDRIA) runs training programmes (Herbert et al., 2000). These issues have led to one comparison being made between EMDR and Mesmerism (McNally, 1999). In reply to this article Ricky Greenwald wrote “Mesmer’s theory [was exposed] as invalid however the eminent scientists apparently failed to consider that the method itself might have been valid regardless” (Greenwald, 1999). Whilst Greenwald was talking about the development of hypnosis from Mesmerism his argument could equally relate to EMDR. There are concerns about the AIP model, leading members of the UK & Ireland and European EMDR Associations have publically stated that the way training is run needs to be changed urgently (Farrell, 2013) and the mechanism of change is not established. However this does not preclude EMDR being helpful for many people with trauma issues. Many of the authors who express concerns about EMDR state that EMDR is no more effective than CBT so argue that it is not worth using in preference to CBT (Davidson and Parker, 2001). It could equally be argued that although meta-analysis may indicate EMDR is no more effective than CBT, they do not demonstrate the superiority of CBT either. As chapter one discussed CBT, although it is the first choice treatment, does not work for everyone and it is unlikely that EMDR or any other psychotherapy will work for

every person in all circumstances. This is why it is important to have a range of treatments available and to undertake research to find out what works for whom and when.

Major Depressive Disorder and Post Traumatic Stress Disorder are independent but correlated conditions (Blanchard et al., 1998). These disorders have three diagnostic symptoms in common (sleep disturbance, lack of concentration and anhedonia) (APA, 2003) but also share other characteristics such as guilt and overgeneral memories (Reynolds and Brewin, 1999) and they are both associated with high levels of mutual comorbidity. Up to 50% of PTSD clients have depression (Nixon et al., 2004) and around 36% of clients with MDD also have PTSD (Campbell et al., 2007). Crucially both conditions are also characterised by intrusive memories of negative life events (Holmes and Mathews, 2010), and it has been suggested that distress in both conditions is due to the inability to optimally process the memories formed during these events (Brewin et al., 2010, Shapiro, 1995).

EMDR was developed to help people process traumatic memories usually associated with one or two major events but also with numerous small incidents that have been traumatising if not life threatening. It may therefore be an effective treatment for depression which is often closely associated with negative life events (Lenze et al., 2008). It can be hypothesized that using EMDR to process the stressful memories preceding the onset of depression may reduce symptoms (Bae et al., 2008). There is some support for this from studies using EMDR with PTSD and phantom limb pain sufferers, which have noticed improvements in comorbid depression scores during treatment (Maxfield and Hyer, 2002, van der Kolk et al., 2007, Korn and Leeds, 2002, Schneider et al., 2008). However this does not tell us if EMDR is directly responsible for the reduction in depression or if it is merely a by-product of the reduction in PTSD. Very little research on EMDR with clients with a primary diagnosis of depression is available. The studies that have been undertaken suggest that EMDR is a promising but as yet unproven treatment for depression (Hofmann, 2012). Section 2.2 systematically reviews the evidence on EMDR and depression.

There is also a lack of explanation to link the AIP model to the treatment of depression. The AIP considers negative behaviours and characteristics to be the result of dysfunctionally held information (Solomon and Shapiro, 2008). This is consistent with cognitive theories of depression but much of the language of the AIP is centred around the pathology of PTSD, as AIP was developed alongside EMDR by EMDR practitioners and this meant it initially developed as theory on the cause of and treatment to traumatic stress.

The two main competing theoretical models used to explain the change mechanisms in EMDR, are AIP and Emotional Processing, the conditioning theory that suggests EMDR is little more than exposure. Although both models are cognitive theories they have different explanations for the causes of pathology. Emotional Processing and the CBT model assert that it is the cognitions that it is the way you think about a situation, that causes pathology. AIP posits that it is dysfunctionally stored memories that led to problem symptoms that include the negative thoughts (Solomon and Shapiro, 2008). This also leads to a differing approach in the practical application of the therapies; in CBT the goal is to change the way the client thinks about a situation (Brewin, 2006) and in EMDR the goal is to change the memory. Once the memory is properly processed and linked with adaptive information about how to cope in stressful situations then it is posited that the pathology will subside (Solomon and Shapiro, 2008). Recent developments in imagery rescripting have found clinically important improvements in some depressive clients by working through the visual imagination alone with no challenging of negative beliefs (Brewin et al., 2009); this may work by allowing a new more elaborate contextualised representation which blends the negative experience with novel positive elements to be created and then compete with the original memory in stressful situations (Brewin et al., 2010). Section 2.3 aims to summarise and explain some of the main theories on the workings of EMDR.

Finally, although a detailed review of the neuropsychology of memory is beyond the scope of this thesis, section 2.4 reviews and summarises relevant memory research studies and theories, aiming to understand if it is possible for EMDR to change problematic memories and how that might happen.

2.2 A systematic review of EMDR as a treatment for depression

Introduction

A scoping review (Wood and Ricketts, 2013) revealed little research on the subject of using EMDR to treat depression. Much of what does exist is case studies or clinical anecdotes and cannot demonstrate the efficacy of the approach. For this reason a systematic review of the research literature with systematic search strategy, data extraction and quality appraisal was undertaken to look for randomised trials to investigate if the question of efficacy has been addressed.

Background

- Description of the population

The review is focussed on adults (over 18 years old) with Major Depressive Disorder. Depression is a common mental health problem, at any one time approximately 10% of people in the UK meet the criteria for a depressive episode (Singleton et al., 2003). It is now thought by the World Health Organisation (WHO) to be the fourth leading cause of disease burden in the world (Üstün et al., 2004). For a diagnosis of Major Depressive Disorder (MDD) the Diagnostic and Statistical Manual (DSM-IV-TR) (APA, 2003) states that the client must report at least five of the following symptoms during the same two week period of which at least one symptom is (1) depressed mood or (2) loss of interest:

1. Depressed mood
2. Markedly diminished interest or pleasure
3. Significant weight loss (not dieting) or weight gain or marked change in appetite
4. Insomnia or hypersomnia nearly everyday
5. Psychomotor retardation or agitation nearly everyday
6. Fatigue nearly everyday
7. Feelings of worthlessness or excessive or inappropriate guilt
8. Diminished ability to think/ concentrate nearly everyday
9. Recurrent thoughts of death, suicidal thoughts (with or without plan), suicide attempt

Current treatment guidelines in the UK recommend that MDD is treated at step three with cognitive behavioural therapy, interpersonal therapy, behavioural activation, or behavioural couple therapy. If that is declined counselling and psychodynamic therapy should be considered, as well as the use of antidepressants or a combination of medication and talking therapy (NICE, 2009). However, a review of pharmaceutical trials (including unpublished data) suggested an overall efficacy of antidepressants of only 32% (Turner et al., 2008). In chronic depression typical response rates to both medication and psychotherapy may be less than 50% (Torpey and Klein, 2008). In addition, Cuijpers and colleagues found that psychotherapy (CBT, interpersonal therapy, and cognitive behavioural analysis system of psychotherapy) may be less effective for chronic depression than for acute phase depression (Cuijpers et al., 2010).

- Description of the intervention

Eye Movement Desensitization and Reprocessing (EMDR) was developed by Francine Shapiro (1989) to treat the victims of trauma. It uses bilateral stimulation, e.g. taps, tones or eye

movements, aiming to stimulate information processing systems of the brain in addition to employing other psychotherapeutic methods of known effectiveness. It consists of a structured eight-phase protocol and is usually delivered in weekly 90-minute sessions (Shapiro, 1989). A typical session begins with the therapist evaluating the imagery, cognition, emotion and body sensations related to a traumatic memory. The client and therapist also decide upon a positive cognition that may be substituted for the negative one and then check the scores of the Subjective Units of Disturbance Scale (SUDS) and the Validity of Cognition scale (VoC) (Shapiro, 1995). After this, clients are instructed to attend to their memories of the traumatic event and simultaneously follow the bilateral stimulation (usually eye movements). This process of attending to both internal and external stimuli is called dual attention. If new material comes up after 28-30 eye movements, clients are asked again to attend to the event and move their eyes. This dual attention and association are repeated until the memory of the traumatic event is no longer distressing (Shapiro, 1995).

EMDR is now a recommended treatment for Post-Traumatic Stress Disorder (PTSD) based on meta-analytic evidence for its efficacy in treating this condition (Bisson and Andrew, 2007).

- Description of the comparisons

Cognitive Behavioural Therapy (CBT) for depression

Cognitive behaviour therapy (CBT) refers to the pragmatic combination of concepts and techniques from cognitive and behaviour therapies, common in clinical practice. *Cognitive therapy* is a structured treatment approach derived from cognitive theories. Cognitive techniques (such as challenging negative automatic thoughts) and behavioural techniques (such as activity scheduling and behavioural experiments) are used with the main aim of relieving symptoms by changing maladaptive thoughts and beliefs. *Behaviour therapy* is a structured therapy originally derived from learning theory, which seeks to solve problems and relieve symptoms by changing behaviour and the environmental factors which control behaviour. Graded exposure to feared situations is one of the commonest behavioural treatment methods and is used in a range of anxiety disorders (DH, 2001).

Meta-analysis of CBT suggests that it is a successful treatment for depression and at least as successful in treating depression as other psychotherapies or medication (Butler et al., 2006). However, there is some suggestion that publication bias and researcher allegiance could have led

to an overestimate of the effectiveness of CBT and psychotherapy in general (Cuijpers et al., 2010a).

Other therapies

There are numerous types of antidepressants available to treat depression. Many have been the subject of Cochrane collaboration reviews, for example Fluoxetine (Magni et al., 2013), Citalopram (Cipriani et al., 2012) and Sertraline (Cipriani et al., 2010). There appears to be little to separate the different medications in terms of clinical effectiveness (Cipriani et al., 2012) and may be more a degree of tolerability of side effects for the patient. Guidelines recommend the first choice of antidepressants should be from the Selective Serotonin Reuptake Inhibitors as they have a greater risk-benefit ratio (NCCMH, 2010). For this reason any comparison of EMDR to medication will be to the class of antidepressants rather than individual medications.

- Why is it important to do this review?

There are several references to depression in the EMDR literature including those that claim EMDR is an effective treatment for depression (Shapiro, 2009a). However, much of this is based on randomised controlled trials of EMDR as a treatment for PTSD which include depression as a secondary outcome (van der Kolk et al., 2007) or clinical case studies that report EMDR as a treatment for depression (Grey, 2011, Bae et al., 2008). Many RCTs of EMDR for PTSD include depression scales as a secondary outcome measure and the majority report significant improvements in depression (Wood and Ricketts, 2013); however, this improvement in depression occurs at the same time as the PTSD is treated. This does not show that EMDR is treating the depression directly. It is possible that as the PTSD symptoms improve so do the co-morbid depression symptoms for no other reason than the PTSD has improved. This is therefore not evidence that EMDR treats depression but that it treats depression when it occurs co-morbidly with PTSD.

There are several case studies and clinical anecdotes reporting EMDR treating people with a primary diagnosis of depression. The clinical anecdotes rarely include any reported outcome measures and therefore one cannot be sure that any change in depression genuinely occurred (Shapiro, 2009a). The case studies are often only on one or two participants, without randomisation or control for the effect of time (Grey, 2011, Bae et al., 2008) and as such are not able to answer questions of efficacy.

- Research Question

Is there any evidence in the peer reviewed literature that examines the effectiveness or efficacy of EMDR as a treatment for depression compared to other treatments or no treatment?

- Objectives

To review systematically the evidence for the effectiveness of EMDR compared with other psychotherapy or antidepressant medication interventions or no intervention in the treatment of depression.

Methods

- Types of studies

To be included papers must describe a randomised controlled trial investigating the use of EMDR. Randomisation was determined to have occurred if the authors have used terms such as random or randomised to describe the way participants have been allocated to each group. The quality of the randomisation was part of the quality assessment.

The full text of studies had to be available in English. No date limit was applied nor country of origin excluded, if it is in English.

- Types of participants

Participants were men or women, over the age of 18 (no upper age limit) with a diagnosis of depression using DSM diagnoses, ICD diagnoses or clinically assessed not otherwise specified. All types and subtypes of depression will be included. Other diagnoses may have been present but the primary diagnosis and the condition being targeted by the intervention must have been depression.

- Types of intervention (experimental and comparator)

The intervention was EMDR; this may be as a stand-alone treatment or as an adjunct to another treatment.

The comparators included were another form of psychotherapy, anti-depressant medication, waiting list, no treatment group or a non-active control condition. Electroconvulsive therapy, magnetic resonance or other physical treatments were excluded.

- Types of outcomes (primary and secondary)

The primary outcome was any continuously distributed measure of depression measured before and after the intervention. Common measures are the Beck Depression Inventory and the Hamilton Rating Scale for Depression. When more than one scale is used the main outcome measure will be determined as the one identified by the trial authors as the primary outcome measure or the first one reported in the results.

- Search methods for identification of studies (electronic and other)

Medline, Embase, CINAHL, the Cochrane Library and PsycINFO were searched using the following terms:

Eye movement desensitisation and reprocessing OR EMDR

AND depression (MESH)

Multiple spellings were used to include the UK English (desensitisation) and the American English (desensitization) spellings as well as 're-processing' and 'reprocessing'. The full search strategy used in OVID (Embase, Medline and PsycINFO) can be found in the appendix (p213).

Following the electronic database searches the grey literature was searched via the Francine Shapiro library for the term 'depression' to ensure a comprehensive search as a scoping review revealed very few publications in this area. The Francine Shapiro library is a repository of EMDR literature held at the EMDR International Association and available to the public via the internet. The Library aims to keep an up to date repository of all EMDR literature. Whilst citations of all forms of publications appear in the Library, only the journal articles were searched (total 1687).

The reference lists of included trials were searched to look for any further studies missed by the other searches.

- Exclusion criteria

Studies investigating intervention for PTSD as the primary diagnosis were excluded. Meta-analysis has demonstrated the efficacy of EMDR in treating PTSD (Bisson and Andrew, 2007).

Data collection and analysis

- Selection of studies

One author (EW) screened the citations to decide which full texts should be retrieved. The inclusion criteria were then applied to the studies.

- Data extraction

Data extracted were the intervention and comparator (including dosage), primary and secondary outcomes at the end of the intervention and where available at follow up, length of follow up, drop out, number of people screened, randomised, allocated to each group and completing treatment, adverse events and main conclusions

- Main comparisons

EMDR v control (no treatment, waiting list or other control)

EMDR v other psychotherapies

EMDR v anti-depressant medication

- Assessment of risk of bias

The Cochrane risk of bias tool was used to assess the risk of bias of each of the included studies (Higgins et al., 2011). There are six domains within the tool, each are assessed separately:

1. Sequence generation: Was the allocation sequence adequately generated?
2. Allocation concealment: Was allocation adequately concealed?
3. Blinding: Was knowledge of the allocated intervention adequately prevented during the study?
4. Incomplete outcome data: Were incomplete outcome data adequately addressed?
5. Selective outcome reporting: Are reports free of suggestion of selective reporting?
6. Other sources of bias: Was the study free of problems that could put it at high risk of bias?
In psychotherapy research this can include the allegiance of the researchers to the therapy under investigation.

Each of these domains was graded as low risk of bias, unclear risk of bias or high risk of bias by the researcher. A list of quality criteria designed specifically for psychological interventions was used to inform section 6 of the Cochrane tool (Lackner et al., 2004).

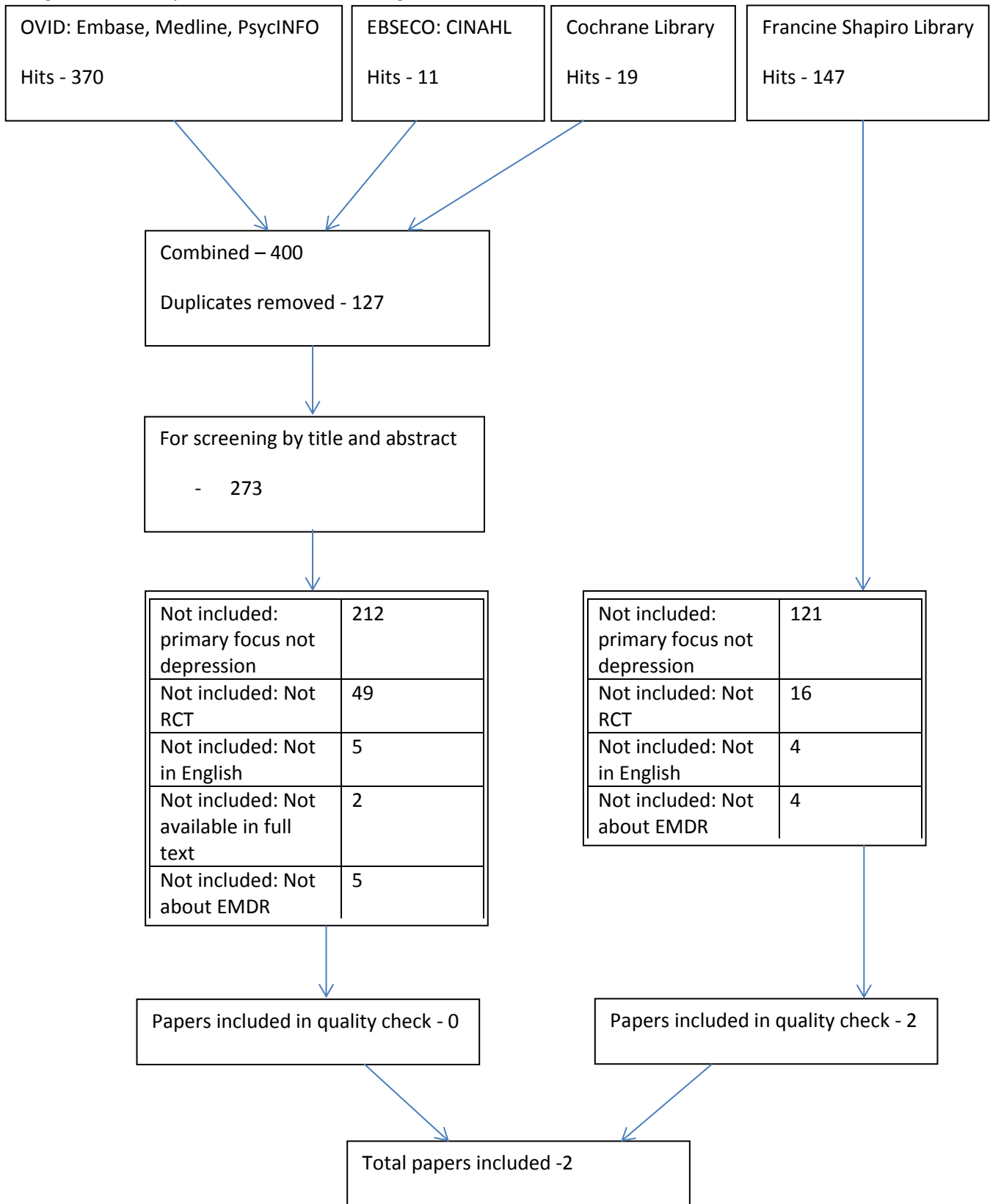
Results

Description of studies

- Results of the search

The search of the research data bases uncovered 400 hits, of which 127 were duplicates leaving 273 for screening. The Francine Shapiro library yielded 147 hits. Some of these overlapped with the other databases but it was not possible to export the findings from this library so they were screened separately. The screening process is outlined in figure 2.1. No additional papers were found from the reference lists.

Figure 2.1: The systematic review flow diagram



- Included studies

Two studies by the same research group (Behnammoghadam et al., 2015a, Behnammoghadam et al., 2015b) were found in the Francine Shapiro library. These two papers did not appear in the other searches, this is likely to be due to the Journals that they were in, the Global Journal of Health Science and the Iranian Journal of Critical Care Nursing. The second paper describes the same trial as the first but also includes 12 month follow up data on the intervention group.

- Study designs, participants, interventions and outcomes

Both Behnammoghadam papers describe the same randomised controlled trial. The 60 participants were all cardiovascular patients with a diagnosis of depression and were split equally between the intervention group (EMDR) and the control group (not described). The primary outcome was the Beck Depression Inventory. The paper describing the follow up also reports a 'mental distress scale' which is unnamed but from the description could be the Subjective Units of Distress Scale (SUDS) which is used routinely in EMDR.

- Excluded studies

Studies were excluded because the primary focus was not on depression or EMDR was not used as a treatment. Other studies were excluded as the full text was not available in English or it was not a randomised controlled trial (see figure 2.1).

- Risk of bias in included studies

Risk of bias in the papers was judged using the Cochrane tool. The primary findings are displayed in Table 2.1 and then considered in more detail below.

Table 2.1: Outcomes from the assessment of risk of bias

Study	Sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Behnammoghadam et al 2015a	unclear	unclear	low	high	high	high
Behnammoghadam et al 2015b	unclear	unclear	low	high	high	high

Sequence generation

In Behnammoghadam et al 2015a, the groups are described as randomly assigned but the method by which the randomisation occurred is not described further. Behnammoghadam et al 2015b does not add anything to make this clearer.

Allocation concealment

As no method for randomisation and allocation to groups is described it is not possible to judge if allocation could have been foreseen in advance of or during enrolment.

Blinding

It is not possible to blind the participants or therapists in psychological therapy trials leading to a high risk of bias (Churchill et al., 2013). This can be mitigated to a certain extent by having blind researchers collecting the outcome data. In the study the primary outcome measure (BDI) is self-rated so bias of the researcher is less of a factor.

Incomplete outcome data

Exclusion criteria are listed but numbers excluded and whether exclusion happened before or after randomisation are not reported. There is no reporting of attrition at any stage.

Selective outcome reporting

The trial registration number is reported but no protocol is available. The trial register entry is for a study on anxiety and reports the primary outcome as the Beck Anxiety Inventory but the paper is on depression and reports the Beck Depression Inventory as the primary outcome. It is unclear whether this is a language confusion (the study is Iranian), a different study or if the focus of the study was changed or why that may have occurred. The second paper does reference an unpublished Master's thesis by the first author looking at EMDR to treat anxiety in patients who have had a Myocardial Infarction (MI). However, it is unclear what the researchers initially intended to measure with the patient group.

The researchers have reported the difference between the two groups and between before and after measures using t tests which is appropriate but it falls short of what they could have done. They do not include intention to treat analysis or calculate an effect size for EMDR. As there is no sample size calculation and fairly small numbers in each group this study should be considered a pilot study and as such a key aim should have been to calculate effect size. The groups are also significantly different on smoker status before the study began. Although this should not be directly related to the efficacy of EMDR it may be indirectly related. The participants in this study have all had MI and as such smoker status is important for their physical health outcomes. It would have been helpful to undertake additional analysis to control for smoker status.

Other sources of bias

As with all psychotherapy research the allegiance of the researchers is a potential source of bias in EMDR research (Luborsky et al., 1999). Levels of training in EMDR or numbers of therapists involved are not reported. No assessment of treatment fidelity is reported, although they do report the use of the standardised protocol. The treatment received by the control group is not reported nor are any medications for either group, either for MI or depression.

Experimental group was significantly more depressed at start than the control group. No sample size calculation is reported. Details of side effects or adverse events are not reported. The primary outcome measure was the BDI which is a well-recognised scale, well validated in many situations; however, it is old and has been replaced by the more rigorous BDI-ii. There is no stated funding source for the study and no declaration of interests.

- Effect of the intervention

Over the course of the study the participants in the EMDR group went from an average BDI score indicating moderately severe depression (range is not reported), to a score indicating mild depression. This reduced further to subclinical levels at the 12 month follow up period. For the pre and post measurements standard deviations were reported and the change score was significant. Standard deviations and significance are not reported for the follow up data.

The control group went from an average BDI score indicating moderate depression to one indicating severe depression from the pre to post measurements. This was also statistically significant. No follow up for the control group is reported.

Discussion

- Summary of main results

Only one comparison is possible due to a lack of evidence, that is EMDR v control or no treatment group to treat depression. Only one study is reported (twice) investigating the use of EMDR to treat depression in a randomised controlled trial. The study is of low quality and can be considered to be at high risk of bias. However, in this one study EMDR did lead to a significant reduction in depression and the control group saw a significant increase over the same period.

- Uncertainties

Many uncertainties remain about the efficacy of EMDR in treating depression. No studies were found comparing EMDR to recognised treatments and no studies were found in patients without physical health co-morbidities. No high quality studies were found.

- Overall applicability of the evidence

The only study found investigates depression in MI patients so it is unclear whether this can be related to depression patients in general. Having a MI is a life threatening experience which can lead to PTSD in as many as 30% of patients (Chung et al., 2006). It could be that these patients had PTSD or were traumatised by their experience, as EMDR can be expected to treat trauma with a degree of efficacy these patients may not be comparable to the wider depressed population.

- Quality of the evidence

The quality of the evidence is low, so no firm conclusions can be based on this limited data.

- Potential biases in the review process

This review only included papers published in English due to lack of funds to pay for translations from other languages. It may be that there are studies in other languages that could add to the evidence.

- Agreements/disagreements with other studies/reviews

This review concurs with a previous scoping review which concluded that there is insufficient evidence to claim EMDR was an evidenced based treatment for depression and that further research is required (Wood and Ricketts, 2013).

Author's conclusions

Due to the current lack of good quality evidence EMDR cannot be considered an evidenced based treatment for depression. However, there are indications from a low quality RCT and from other research methods that EMDR has the potential to treat depression.

- Implications for practice

EMDR should not be used as a first line treatment for depression as other evidenced based treatments are available.

- Implications for research

High quality feasibility and pilot studies are required to investigate the possibility of using EMDR to treat depression. Factors such as the acceptability of the treatment have not been established.

High quality randomised controlled trials are needed to investigate the efficacy of EMDR to treat depression.

If patients have received the recommended first line treatments but not responded there is justification for offering EMDR in a research setting as long as the patient is aware that it remains an experimental option at this point (WMA, 2001).

2.3 Theories regarding EMDR's mechanism of action

Although much Health Service Research is pragmatically focussed on the outcomes of treatment, to test which treatments yield greatest benefit, one of the criticisms levelled at EMDR is the lack of a coherent theoretical underpinning and no agreed mechanism of action. Therefore although it is not the goal of this research to undertake pure cognitive science research, to evaluate an effective treatment for depression it is important to understand some of the cognitive theory. There is no comprehensive and definitive explanation of the mechanism of action in EMDR but there are many theories. The Adaptive Information Processing Model was developed to try to explain in psychological terms how EMDR works. There are also many theories regarding specific biological and psychological memory processes that have been seen in clinical practice and in research laboratories. This is a summary and critique of these theories in relation to the processing of trauma memory.

Adaptive Information Processing

The Adaptive Information Processing (AIP) model was developed by Francine Shapiro alongside the development of EMDR. AIP is a cognitive learning theory and consistent with that, it posits an 'information processing system that assimilates new experiences into already existing memory networks. These memory networks are the basis of perception, attitudes and behaviour' (Solomon and Shapiro, 2008). Current experiences are linked with their associated memory networks, useful information is integrated into the networks and is then available as part of our learned experience in the future (Shapiro, 1995). Pathology occurs when a distressing incident is unable to connect with the memory networks that hold the adaptive information required to deal with the situation, the memory is 'frozen in time' and stored in a state- specific form (Solomon and Shapiro, 2008). Therefore AIP views negative behaviours, thoughts and personality characteristics to be a result of incorrectly stored information, and negative cognitions are symptoms of a dysfunctionally stored memory. Successful treatment with EMDR leads to a memory which is no longer isolated and has been integrated within the larger memory network (Solomon and Shapiro, 2008). This is consistent with the process of assimilation and accommodation, rather than habituation (Rogers and Silver, 2002). This isolated memory theory is consistent with other theories of PTSD but it is when AIP is translated to other illnesses it becomes more complicated. AIP suggests that all mental health issues are caused by these isolated, unprocessed memories but it has been argued that in

depression the problem with the traumatic memory is that it is too well processed and fixed within the client's schema not that it does not connect at all (Brewin, 2012). AIP has come under further criticism for not generating falsifiable hypotheses and therefore not being a true scientific theory (Deville, 2002).

Conditioning/ exposure

The Emotional Processing Model, proposed by Foa and Kozak (1986), offers a mechanism of action to explain the success of behavioural therapy, specifically exposure therapy, to treat pathological fear such as Post Traumatic Stress Disorder (PTSD) and phobias. Fear is represented in memory networks that incorporate information about the fear stimulus, behavioural responses to it and the meaning of the stimulus. We all experience fear throughout our lives and these networks are adapted (positively and negatively) through new experiences (Foa and Kozak, 1986). Pathological fears involve excessive response elements and resistance to modification; this persistence is, in part, down to 'impairments in mechanisms for processing the fear-relevant information'. Treatment of these pathological fears requires the activation of the fear memory (exposure to fear stimuli), noticeable reduction in anxiety by remaining with the stimulus rather than fleeing/avoiding (habituation) and longer term 'unlearning' of the fear reaction to the initial stimuli (extinction) (Foa and Kozak, 1986). The emotional processing model has its roots in operant conditioning and is backed up by countless experimental and theoretical papers, the model itself is not under question. However, there is a question as to whether or not it is applicable to EMDR.

It has been argued that EMDR is a form of exposure therapy; this is due to the fact that in part four of the standard eight-stage protocol for EMDR the client is asked to bring up an image of the distressing memory and hold it in mind. Then, as processing occurs the relaxation or orientating response (see below) that follows is a form of habituation and hence emotional processing. However, others would argue that there are some problems with this explanation of EMDR. Habituation is a slow and gradual process taking between 20-100 minutes per exposure (Rogers and Silver, 2002). This is because when a fear response is generated the body releases adrenaline, as this wears off the body relaxes again and fear decreases. In EMDR, the 'exposures' are very short, often only 20-30 seconds which should not be enough time for the physiological responses to occur and because the client is splitting his or her attention between the memory and the bilateral stimulation (BLS) this should slow down any habituation response not speed it up (Rogers and Silver, 2002). In fact, Foa and Kozak (1986) are clear that distraction during exposure will

reduce its effectiveness and can lead to the failure of between-session habituation, which in turn will inhibit long term habituation. In other words, the emotional processing model suggests that due to short exposure periods and bilateral stimulation during the act of bringing the memory to mind EMDR will not be very successful at reducing distress. Likewise, exposure therapy involves 'reliving' the event whereas in EMDR psychological distancing is encouraged (see below) (Lee, 2008). EMDR also contains an element of free association, during processing clients are encouraged to just 'see what comes up', which is actively discouraged in exposure where the object is to concentrate on the distressing situation and not avoid it by thinking of other things (Rogers and Silver, 2002).

The Neural Systems model

Brewin and colleagues' 2010 revision of the Dual Representation Theory suggests a different explanation for the mechanisms underlying EMDR. They suggest that memory and imagery rely on common networks and that both utilise flexible, contextualised representations (C-reps) and inflexible sensory bound representations (S-reps). In healthy individuals who experience an extreme event the S-rep is associated with a corresponding C-rep allowing it to be contextualised semantically and autobiographically. Pathology occurs when the sensory representation is not linked to context. This means the feelings of fear can occur even the context does not warrant it and this can manifest as intrusive thoughts, images and feelings. This model suggests that EMDR works via extinction, forming a new C- rep memory containing not only the traumatic image but also identifying with the safe present (rather than the dangerous past) and containing the distracted or disambiguating information from the bilateral stimulation phase. This would then compete effectively with the original traumatic S-rep when the individual encounters reminders of trauma (Brewin et al., 2010). Thus EMDR is one way of creating new, contextual C-reps to compete with out-of-context sensory representations of distress. Other methods include exposure therapy and imagery rescripting (the client focuses on their intrusive image/ memory and concentrates on creating a new more positive outcome which they then rehearse with the therapist). However the neural systems model is a model of PTSD not psychotherapy and so although it may explain EMDR in PTSD clients it does not transfer to depression clients (Brewin, 2012).

As well as the cognitive model explanations of change processes there are also other psychological and physiological explanations for some of the effects seen in EMDR.

Orientating response

The orientating response (OR) is a physiological process, it involves paying attention to significant and new stimuli. It is geared towards information processing as it compares novel incoming information with that which is already familiar (Bergmann, 2010). It is different from the startle response and defensive response as they direct us to action. As such they are associated with a sympathetic response in the nervous system whereas the OR is generally regarded as parasympathetic in nature (Bergmann, 2010) and therefore a relaxation response (Gunter and Bodner, 2009). Some have expressed the belief that the BLS in EMDR triggers an OR; however this is not without controversy (Gunter and Bodner, 2009). OR is characterised by a decreased pulse and breathing rate and skin temperature and an increase in skin conductance (Sondergaard and Elofsson, 2008) but there have been inconsistencies in the psychophysiological research on EMDR, including increases in finger temperature (Sondergaard and Elofsson, 2008). Bergman (2010) does argue however that in the literature, OR has often failed to be adequately differentiated from startle and defensive responses and therefore conflicting results are a distinct possibility.

Working memory disruption

Gunter and Bodner (2008) cast some doubt on the OR and theories of relaxation as a mechanism of action for EMDR and emphasise the importance of dual attention to the trauma memory and to the BLS. Their findings suggest that the benefits of eye movements are only significant when they correspond to the traumatic memory being held in mind. They also found that during eye movements their participants showed a decrease in arousal (Gunter and Bodner, 2008). They argue these findings would be consistent with the working memory account. The working memory account of EMDR asserts that when the image of the traumatic memory is called to mind it is held in the visuospatial sketchpad part of the working memory, BLS is then a divided attention task and leads to a reduction in vividness and emotionality of the image by taxing the capacity of the working memory (Gunter and Bodner, 2008). In this model the eye movements are a useful distracter task but otherwise not special in themselves (Gunter and Bodner, 2009). This model has not been tested in a clinical population. Although it has been shown that dual attention leads to a reduction in emotionality during BLS (Andrade et al., 1997, Kavanagh et al., 2001, van den Hout et al., 2001, Barrowcliff et al., 2004, Kemps and Tiggemann, 2007, Lee and Drummond, 2008, Maxfield et al., 2008), it is not known if this change lasts outside the therapy session (Lilley et al., 2009). In 2001, Kavanagh and colleagues found that this reduction in emotionality was not maintained. However, it could be argued that as their participants only received a total of 64

seconds of eye movements this was long enough to produce an initial reduction but not to maintain it. It is possible that a longer 'dose' may have maintained the effect. The role of eye movements remains one of the controversial aspects of EMDR with some saying they are unnecessary at best and at worst interfere with exposure (Deville, 2002). However, the weight of current research is tipping in favour of the need for bilateral stimulation (Jeffries and Davis, 2013). Jeffries and Davis performed a systematic review of the literature concerning eye movements and other tasks from the clinical and non-clinical research. Although there is contradictory evidence from some clinical studies they found no evidence to suggest that eye movements should be removed from the protocol. The authors conclude that it remains unclear whether eye movements are superior to other distraction tasks and call for more thorough research into the subject. A theoretical rationale for why bilateral eye movements may be a specific requirement is reviewed below.

Psychological distancing

Distancing refers to the detached observation of the traumatic memory and is one of the major arguments against EMDR being considered to be an exposure therapy (Gunter and Bodner, 2009). In prolonged exposure treatment for PTSD the client is expected to attend to the memory in as much detail as possible, reliving the experience, EMDR however, instructs the client to be an 'observer' (Shapiro, 1995) and remember that their experiences are transient (Lee, 2008). Lee and colleagues have focused on this and in clinical and analogue studies on university students they investigated the levels of distancing and changes in emotion and vividness associated with distressing memories. The degree of distancing has been found to be significantly associated with improvement and the distancing process was more likely to have been due to eye movements than therapist instructions (Lee, 2008). These studies did not have control groups, instead of measuring the same outcomes in an exposure treatment group and comparing them to the eye movement group they measured what occurred during the eye movements and compared that to the theoretical principles of exposure.

Increased inter-hemispheric communication

It has been postulated that saccadic horizontal eye movements have a specific influence on inter-hemispheric interaction and episodic memory (Propper and Christman, 2008). Propper and Christman (2008) reviewed the evidence that saccadic horizontal eye movements improve episodic memory in non-pathological populations and found that the benefits are seen at the retrieval stage. They do not state whether this relationship is inhibitory or excitatory in nature

simply that leftward-rightward eye movements may equalise the activation of both hemispheres and as one side is usually more active than the other by equalising them then communication between the two may be enhanced (Propper and Christman, 2008). Gunter and Bodner (2009) have asserted that inter-hemispheric communication cannot be the whole story in the mechanism of EMDR as vertical eye movements have been shown to decrease emotionality as much as horizontal ones despite this approach not having an effect on the two hemispheres.

REM like states

As the horizontal eye movements induced during EMDR resemble the eye movements seen during Rapid Eye Movement (REM) sleep, Stickgold has proposed that EMDR produces a brain state similar to that of REM sleep which allows for improved facilitation of memories as seen in both processes (Stickgold, 2008). Some aspects of the physiological changes seen during EMDR fit well with this hypothesis, for example increased skin temperature is seen in EMDR and REM (Sondergaard and Eloffson, 2008). The model suggests that EMDR induces an REM like state that is able to support 'cortical integration of the traumatic memories into general semantic networks' this will lead to a reduction in the strength of the episodic memory and negative affect associated with it (Stickgold, 2002). It has not been directly tested.

Integrated approach

As no single mechanism has been shown to explain EMDR, Gunter and Bodner (2009) have suggested an integrated model. They suggest that the dual attention task of keeping the memory in mind and focussing on the BLS leads to a disruption in working memory, this aids psychological distancing. This may lead to beneficial memory reprocessing leading to the reported psychophysiological effects similar to the orientating response and relaxation phenomenon. Memory reprocessing and psychophysiological changes then work together to reduce the symptoms of PTSD (and potentially other pathologies) (Gunter and Bodner, 2009).

There are many possibilities to explain the effectiveness of EMDR but all are poorly researched, they have only been studied on subjects with PTSD or non-clinical populations if they have been studied directly at all. This reduces their explanatory power in understanding the potential for EMDR to be useful in depression. Most of these explanations are not mutually exclusive but some are; EMDR cannot be AIP *and* emotional processing. AIP posits that the underlying cause of pathology is unprocessed memories and that by resolving this, the pathology can come to an adaptive resolution. Emotional processing on the other hand states that it is the cognition around

the memory that causes the pathology and by learning a new response to fearful stimuli, fear can be reduced. The AIP does allow for the model to be transferred to pathologies other than PTSD for which it was developed. In the case of depression, unprocessed memories may be linked with low mood, sadness and loss which remain at the forefront of consciousness until the memories are correctly processed with the aid of EMDR. Gunter and Bodner's (2009) integrated model has not been directly tested although its individual components have some merit. It has been suggested that EMDR is analogous to the processes occurring in REM sleep has some logical and theoretical support but again has not been directly empirically validated (Stickgold, 2002). Brain imaging with a few nonclinical and PTSD case studies has found interesting activations in the ventral medial Prefrontal Cortex and hippocampus but this has not been seen in enough people to be categorically the result of the EMDR process. The increase in hippocampal volume is of interest to the treatment of long term depression as clients with 3 or more episodes of depression have a decreased recruitment of the right hippocampal and left parahippocampal gyrus leading to impairments in memory performance (Milne et al., 2012) and a reduction in hippocampal volume both of which appears to be caused by repeated depressive episodes (McKinnon et al., 2009).

Although much of this theory and neuroscience does not appear directly relevant to clinical practice it can be. By understanding how a treatment works it can be made more effective, more cost-efficient and more acceptable to the client by removing parts of the treatment that are unnecessary or even counter-productive. For example, we can consider the EMDR technique known as the 'butterfly hug' (Artigas and Jarero, 2009). This is a method of bilateral stimulation which the participant does on themselves. It was developed by a disaster relief worker who had a classroom full of traumatised children and did not have time to give them all one to one therapy. He taught the children to tap themselves on the shoulders by 'hugging' themselves then tapping with alternate hands as fast as they could. Whilst it is still primarily used in disaster zones it has growing popularity for people offering therapy over the phone or internet and for group therapy. The butterfly hug appears to cause a relaxation response like some of the other methods but it should not really be called bilateral stimulation. Yes, the participant taps alternate shoulders but they tap it with their opposite hand, therefore getting simultaneous left and right stimulation. Whilst this is no problem for the working memory models of EMDR, as it is just another method of distraction, it is a problem for the models which state that alternate bilateral stimulation is essential to the process. This demonstrates that the theory is important: is the butterfly hug EMDR if it is not bilateral stimulation? Does it work at all, should it be stopped, should it be encouraged

and theories surrounding left brain / right brain stimulation thrown out? At present these questions cannot be answered but they remain important.

2.4 Memory, Depression and the AIP

In summary then, although there is plenty of evidence that EMDR can help at least some people with PTSD, there is little to assume it can be used equally as well with depression. However, this is due to a lack of any studies rather than disconfirming research. There is poor understanding as to the mechanism of action behind EMDR which makes it difficult to state definitively that EMDR should be considered a treatment for long term depression. However, few of the posited mechanisms rule out the possibility of benefit in reducing the influence of negative depressive memories on mood. As mentioned previously (section 2.1) PTSD and depression have many symptoms in common but more than that they often have a trauma history in common too (chapter 1.2). All three cognitive science theories mentioned in part 2.3 (AIP, emotional processing and neural systems model) refer to problems with the memory of the traumatic event. So however EMDR works in people with PTSD it is working on that traumatic memory and if a large proportion of people with long term depression also have problematic traumatic memories it is possible that EMDR would benefit such clients too.

Exactly how the brain stores memories is not known but Baddeley's multi-component model allows all the components of the short term memory to interact and connect with both perception and the long term memory (Baddeley, 2009). Several theories have been developed to try to explain how the different components of our memories are stored and retrieved including the Interacting Cognitive Subsystems (Barnard and Teasdale, 1991) and the Neural Systems Model (Brewin et al., 2010). These models suggest different elements such as emotions and contexts of situations are stored separately and then are retrieved either as a whole memory or as fragments of feelings or perceptions which can be the basis for pathological memories such as sadness, anxiety or fear. The key then would be to realign these disconnected fragments and change the memory.

The process of memory consolidation allows a temporary memory trace to become stabilised and established in the long term memory, once consolidated the learnt memory is resistant to change (Walker et al., 2003). However it can be destabilised again. There are two ways to change learnt

information: reconsolidation and extinction. 'Reactivation of an apparently stable, long term memory can render it fragile and dependant on a restabilisation process referred to as reconsolidation' (Hupbach et al., 2009). During this process memories can be either reinforced or altered (Suzuki et al., 2004). Animal studies have shown that fear memories can change during this process (Kindt et al., 2009). During reconsolidation the memory is activated, this makes it labile and vulnerable to disruption, when it is restabilised it may contain new information (Taylor et al., 2009), this may have impaired or enhanced the memory trace (Dudai, 2006). Few studies have looked at reconsolidation of memories in humans as the main methods used in rats (protein synthesis inhibitors) are highly toxic (Schiller and Phelps, 2011), even fewer have looked at clinical populations. Only two appear to have looked at the pathological thoughts of mental health clients, however they do suggest that it is possible (Rubin, 1976, Brunet et al., 2008).

In extinction, a new memory is formed to compete with the old one (Taylor et al., 2009). The Emotional Processing model of CBT and exposure therapy and neural systems theory would come under extinction (Brewin, 2006). During exposure therapy the client is placed in a stressful situation but encouraged to remain rather than avoiding it. As nothing bad happens and the stress subsides through habituation to the stimulus and a new memory is formed of this stress free situation. Research suggests that CBT works via the retrieval competition account - new learning deactivates problematic memories, rather than changing them, by strengthening the competing positive representations (Brewin, 2006). Brewin and colleagues have also hypothesised that this may be the mechanism behind EMDR, as the bilateral stimulation reduces emotion this becomes associated with a new safe, contextualised representation of the memory (Brewin et al., 2010).

The AIP model of EMDR states that when the memory is brought to mind it can then be altered and restored in a more stable and adaptive manner (Shapiro, 1995). This would be coherent with the idea of reconsolidation (Solomon and Shapiro, 2008). Logically then, if EMDR works by reconsolidating the memory, after therapy it should be less distressing and contain adaptive and non-traumatic information that was not present before. Schiller and Phelps (2011) have shown how it is possible to update memories in humans during reconsolidation in a nonclinical population. During EMDR the memory is reactivated when the client is asked to bring to mind the disturbing memory. They consider the thoughts, emotions and somatic experiences that are associated with it, they are then asked to identify a key image and negative thought and these then cue the memory repeatedly during the bilateral stimulation phase. This does fit the criteria

needed for reconsolidation to be possible (Schiller and Phelps, 2011). These targeted memories could then be retested after therapy to see if their content and impact has changed.

The theories of change for EMDR rely heavily on the idea of pathological memories. EMDR was developed to tackle the vivid emotional trauma memories in PTSD but negative intrusive imagery related to autobiographical memories are also a feature of depression (Holmes and Mathews, 2010). Images can evoke powerful emotional states, both positive and negative and this impact on emotion can cause distress and contribute to the maintenance of various disorders but can also be harnessed in treatment (Holmes and Mathews, 2010). This is seen in imaginal exposure but can also be done by other methods such as imagery rescripting, imagery reduction via competition and EMDR. Several studies have shown that it is difficult to hold a negative image in mind and perform a task which uses related cognitive resources (Holmes and Mathews, 2010), doing this appears to reduce the impact of the negative intrusive image (Holmes and Mathews, 2010) this working memory disruption has been proposed by Gunter and Bodner (2008) to be at least part of the mechanism behind the success of EMDR to treat negative images.

The biggest problem for the AIP model when it comes to depression is that it claims that problematic memories are isolated and 'frozen in time' and that EMDR will process them and help them integrate with the rest of the memory network (Solomon and Shapiro, 2008). However, negative memories, which are very salient in depression, could be described as overprocessed and incorporated into the self-schemata. They are certainly not isolated. A childhood memory that teaches a girl she is worthless is not separate, in depression it has become how she defines herself. However, there is a contradiction here as well. When you ask the adult to remember that event from childhood the memory is raw, vivid and emotional and she will avoid it if possible. This is exactly what the AIP predicts. The mix of both overprocessed elements and underprocessed elements of the same memory suggest a more complicated memory processing system than the AIP describes. Models like Interacting Cognitive Subsystems (Barnard and Teasdale, 1991), allow different elements of a memory to be overprocessed in one subsystem and underprocessed in another.

The memory research does then indicate that it is possible for memories to be stored in a way that means the emotion and context are split. There are many similarities between onset and symptoms of long term depression and PTSD, including childhood trauma, negative and overgeneral autobiographical recall as well as sleep disturbance, anhedonia, disproportionate guilt

and poor concentration. Although the theories are divided as to how EMDR may be able to affect change in these problematic memories from childhood they are not divided on the key concept, that it is possible.

2.6 Formulating the research questions

As chapters one and two have shown, research looking at EMDR as a treatment for people with a primary diagnosis of long term depression is no more rigorous than a single case study; even in acute depression, studies are lacking. There have been conference reports of some unpublished work in Germany (Hofmann, 2012). However the EMDR community often cites studies that look at PTSD with comorbid depression as proof of success in treating depression (Shapiro, 2009a). Despite this, the collected case studies do suggest that EMDR as a treatment for depression is worth investigation. Theoretically this should be the case. Shapiro's AIP model does state that the cause of mental distress is the inadequate processing of traumatic events (Solomon and Shapiro, 2008) and a large number of cases of depression appear to be linked to early traumatic events and common to both depression and PTSD are the intrusive memories of these events (Holmes and Mathews, 2010).

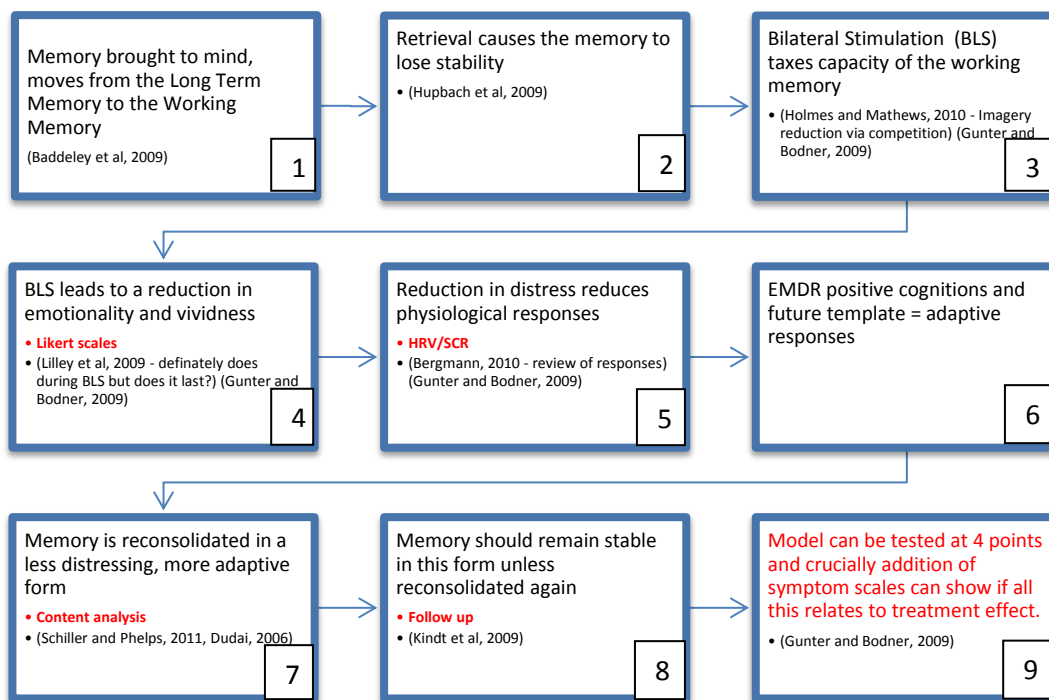
This led to the development of the first research questions and the main objective of this project; is there an improvement in depressive symptoms following a course of EMDR? As social functioning is an important factor in the quality of life for people with long term depression (Schramm et al., 2011) this was also included, as was a follow up period to see if any improvements were maintained. No form of psychotherapy is suitable or helpful to all people in all circumstances. Investigating who may benefit from an individual therapy is an important part of being able to target the correct type of therapy to the correct client. It is useful, when developing a treatment, to look into those who did not respond in as much detail as those who did. By looking for patterns in these two groups, health services can begin to treat people more effectively by treating them with the therapy that is more suited to them (Hunt, 2012). This can also reveal information about the processes involved, who may be likely to benefit from the new treatment and potentially improve the treatment (Craig et al., 2008). This forms the rationale and research questions for study 1.2 which will look for differences between the responders and non-responders to EMDR to see if this can reveal any information about process, types of people who may benefit more than others and potential opportunities to improve the treatment protocol.

The research questions for study two are based on the theoretical basis for EMDR, the AIP model. It is important to know how treatments work and there is some argument in the literature as to whether AIP (rather than EMDR) has actually been tested (Greenwald, 2010, Shapiro, 2010). To develop questions that inquire into the processes of EMDR, how it may work and what is happening to the client, the advice of colleagues with expertise in the field was sought. Meetings took place with Professor Chris Brewin, University College London, who has developed some key theories in the field of imagery in PTSD and depression including the Neural Systems Model (Chapter 2.3) and Imagery Rescripting for depression, and Dr David Blore, head of EMDR Yorkshire and researcher on the subject of EMDR and positive psychology. Discussions were focussed on ensuring a good understanding of the theories and psychology behind the AIP, neural systems model and emotional processing. The initial aim was to test direct predictions from these models to see which best fit the clients experience however, it became clear that it would not be possible as identifying consistent predictions across the models is not straightforward. One of the few areas where all three models are explicit is how they affect the client's memories, with emotional processing and the neural systems model asserting habituation whereas the AIP claims EMDR uses reconsolidation.

The integrated model of EMDR proposed by Gunter and Bodner, (2009) and discussed in chapter two (2.3) combines some of the observed clinical changes that occur during EMDR however their model seems incomplete. They assert that the chain of events, working memory disruption, psychological distancing and physiological responses then allow PTSD symptoms to decrease. They do not describe how this occurs however. Reconsolidation of memory has been linked with EMDR theory too but not in a form that allows for testable predictions (Solomon and Shapiro, 2008). An extended version of Gunter and Bodner's model is proposed here that incorporates theories of memory retrieval and reconsolidation as the processes by which EMDR effects long term change in pathological symptoms (Figure 2.2). This model offers an explanation for the processes that occur during EMDR and how that improves pathology in mental health clients. Investigators of working memory have shown that the first three stages (activation and destabilisation of the memory trace and imagery reduction via competition in the working memory) of the model occur under laboratory conditions (Baddeley, 2009, Hupbach et al., 2009, Holmes and Mathews, 2010, Lilley et al., 2009). Numerous studies have shown that physiological stress responses are affected by the EMDR process during the therapy session (Bergmann, 2010). This model proposes that the pathological memory is reactivated when the memory is targeted in EMDR, destabilised and then

the dual attention (bilateral stimulation) taxes the working memory. This allows the emotionality of the memory to reduce, likewise the physiological responses also reduce, and the installation of the positive cognition and future template during the EMDR process allow the memory trace to access adaptive material. The original memory is then reconsolidated as less distressing, less emotional, with a reduced physiological response and adaptive material incorporated. This reconsolidated memory should then remain stable and adaptive unless a new situation occurs that reconsolidates it again. This model links current work on working memory with the results of observational studies on the effect of bilateral stimulation to promote a more comprehensive theory on the working of EMDR.

Figure 2.2: An extended integrated model of memory retrieval and reconsolidation as a mechanism of change in EMDR – The reconsolidation model of EMDR.



Previous research has looked at memory retrieval mechanisms but later stages of the model (boxes 4, 5, 7 and 8) which are specific to EMDR have not been fully tested (Gunter and Bodner, 2009). Lilley et al (2009) have shown that bilateral stimulation leads to a reduction in emotionality and vividness during dual attention (box 4) but the lasting effect of this can be measured by continuing the ratings after therapy and at follow up, the same is true of the physiological effects

(box 8). If the original memory is reconsolidated then analysing the content of the memory before and after therapy should allow researchers to evaluate if this has changed, the model predicts that the memory will have changed and it will contain positive and adaptive information that was not present before therapy (box 7). As a reconsolidated memory is a stable one then this content should remain consistent at follow up (box 8), unless the memory has been reactivated by a new event. If it has this may have led to another reconsolidation event which may be positive or negative. Directly testing reconsolidation of existing memories in humans is very difficult, most studies look at cue/response test/retest methods (Schiller and Phelps, 2011). So other stages of the model in Figure 2.2 must be the focus of this study. The model in figure 2.2 predicts that bilateral stimulation during EMDR will lead to the reduction of the emotional response triggered by the memory and the vividness of the memory experienced by the client (box 4). This study will test this by using Likert rating scales before and after treatment. It also predicts that there will be a corresponding reduction in physiological arousal triggered by the target memory (box 5), this study will also measure heart rate variability and skin conductance response before and after treatment. The model predicts that when the memory is recalled by the participant after treatment it will be less distressing and contain adaptive material that was not present before (box 7). This study will test this using content analysis of the participant's descriptions of their memories. Finally this should all be stable at a follow up period if reconsolidation has occurred (box 8). This study will therefore repeat the post therapy tests at a follow up period some months after treatment has finished. As these tests could be run in conjunction with a standard course of therapy they could also be compared to psychometric tests of pathological symptoms and social functioning. This series of tests would not only investigate the effects and processes involved in EMDR but also whether any changes in memories are linked to changes in pathology which is, after all, the goal of psychotherapy.

During EMDR, the AIP model tells us, the traumatic memory that has caused the mental distress is accessed and 'reprocessed' so that it becomes integrated with the wider memory network and able to link to adaptive knowledge (Solomon and Shapiro, 2008). Transcripts of EMDR sessions where clients are describing how these memories change are common in books written by EMDR professionals (Shapiro, 1995, Shapiro, 2009a) however, this does not show what happens to these memories in the long term, outside of the therapy session. By asking participants to describe their memories and rate their distress in a standardised way before reprocessing, after it and after a follow up period it may be possible to assess what EMDR is doing to the client's memory content

on a longer term basis. An important issue here is whether it can be considered stable enough to research over a six month period. Earlier work has shown that the central features of autobiographical memory are accurate and stable over time and despite the memory difficulties which characterise depression recall of significant past events does not appear to be affected by mood state (Brewin et al., 1993).

Several studies have investigated the psychophysiological responses within the EMDR session that appear to accompany the decreasing subjective distress of the participant (Gunter and Bodner, 2009, Bergmann, 2010). Again these measurements have been done during the session and do not show what happens outside the therapist's office and over a longer time period. Nor have these studies performed correlation analyses to see if these observed changes in psychophysiological response, distress ratings and memory content are related to changes in symptomatology. Without these correlations there are too many questions we cannot answer. If EMDR changes memories but not symptoms then it is interesting but not a treatment and if it changes symptoms but not memories then it is a treatment but it does not work in the way the theory says it does. If these correlations do exist then it should be possible to attribute this change to EMDR and would be consistent with, at least in part some of the AIP's assertions about the mechanism of change during therapy.

Finally, but importantly, many studies comparing EMDR with other treatments have commented on the fact that clients find EMDR more acceptable than the comparisons. Several papers claim clients find that EMDR more acceptable than CBT for treating PTSD but these seem to comment without much information about how they came to this conclusion (Hogan, 2001), or infer this from lower dropout rates in the EMDR group (Ironson et al., 2002). However, there is a paucity of literature utilising qualitative methods to ask clients about their experiences of EMDR. Study three has a primarily evaluative aim. To identify the factors that contribute to the intervention (EMDR) being successful (or unsuccessful). For the purposes of study three the intervention is judged successful if the participant says it is regardless of the scores from the quantitative studies. Any treatment must be acceptable to clients; if someone receives a treatment that is so unpleasant they immediately drop out of therapy they have not been helped. Nor is it helpful if their symptoms ease but their quality of life remains poor as they still cannot function in society. The qualitative and quantitative data will then be reanalysed as a mixed methods analysis to attempt to provide further evaluation. The aim here is to provide a summative evaluation of the

intervention – did it work? And a formative evaluation – how can it be made more effective/more acceptable?

2.6 Summary

EMDR's efficacy to treat PTSD has been shown in several trials but so far research on other pathologies is lacking. The collection of practice based evidence suggests that EMDR has the potential to be a new treatment for depression but further research is necessary. Despite many theories and investigations into the workings of EMDR, the mechanism of action is still unknown. This may be partly because the way we store and retrieve memories is also not well understood. As well as investigating if EMDR can treat depression it will also be helpful to contribute to knowledge about how it does this.

Chapter 3 Part 1 - Discussion of the methodology

3.1.1 Study rationale

Despite the growing suggestion from case studies and comorbidity literature that EMDR may be a suitable treatment for long term depression there are no English language papers published of trials investigating this. Conversations with other European researchers have revealed two unpublished pilots but both involved adding a small number of sessions of EMDR into other therapeutic approaches (Hofmann, 2012). As far as the published literature is concerned, no investigation has looked at EMDR as a therapy in its own right in a national healthcare setting for treating a primary diagnosis of depression. This is a gap in knowledge that needs addressing. EMDR claims to be a comprehensive psychotherapy (Solomon and Shapiro, 2008) but has not been investigated as a treatment for one of the world's most common and costly mental health problems. The most effective approaches reviewed by the literature so far have included elements of cognitive, behavioural and interpersonal work but the AIP model claims that these problem areas are all symptoms of dysfunctional memories (Solomon and Shapiro, 2008). Preliminary work is needed to address whether or not EMDR has potential to be used in an NHS setting to treat long term depression and this requires a full course of treatment comparable to that which is provided by the NHS already.

3.1.2 An introduction to mixed method research

Before undertaking research that attempts to understand someone else's view of the world and their experiences of it, it is important to have an understanding of how you view the world. This worldview (or paradigm) is usually defined in terms of a researcher's beliefs about ontology (what is the nature of reality?) and epistemology (theory of knowledge: what is the relationship between researcher and knowledge? – can we know the 'truth'?) (Denzin and Lincoln, 2011). This author believes in a substantial, objective reality, a world that exists 'out there' regardless of human knowledge of it or interaction with it and that with carefully designed and well conducted measurement and experiment it should be possible to describe this world. The author does acknowledge that there are significant limits on that, due to human intelligence, comprehension, unavoidable *a priori* assumptions and biases and the ability to build the precision instruments for measurement, that inevitably mean that the absolute 'truth' is frequently and maybe always outside of our ability to capture it, but it is nonetheless something that should be continually striven for. It is also important to remember that the object being measured in health service

research is not always the same as in the natural sciences. In the natural sciences the aim is to measure an event or a thing, a tangible item with an objective reality. Although health service research is interested in events it is also interested in human responses to these events and the way that a person perceives an event, both contemporaneously and later when recalling the memory, maybe be very different to the objective occurrence.

As with all things, placing an individual's beliefs into predefined boxes is never straight forward but these stated attitudes place the researcher in broad agreement with post-positivism and critical realism. Although it has been suggested that critical realism is a form of post-positivism (Lincoln et al., 2011) it is unclear from his writing that Roy Bhaskar agrees with this summation of his theory (Bhaskar, 1975) as he sees critical realism as distinct from positivism but neither he nor more modern writings on the subject compare it to post-positivism. Both theories maintain that an external reality exists and that it is not dependant on human perceptions however that scientific observations of this reality are flawed (McEvoy and Richards, 2003, Collier, 1994). Critical realism is distinguished by its position that the world is composed of events, physical and psychological, and underlying structures, powers and tendencies. It is the latter that than provide the conditions for the possibility of actual events and understanding them should be the ultimate aim of research (Patomaki and Wight, 2000). Both post-positivism and critical realism move away from the 'naïve' realism of positivism, where there is a true reality and a suitably objective researcher will be able to find this truth (Lincoln et al., 2011). Positivism is usually associated with quantitative research and theory testing typically using numerical data and statistical analysis (Creswell, 2009). Qualitative research, typically used to explore and understand meaning for individuals and groups, is associated with a constructivist/interpretivist approach (Creswell, 2009). Constructivists, at their most extreme, consider that reality is entirely subjective and socially constructed (McEvoy and Richards, 2006). For critical realism, it is not reality which is socially constructed but our theories of reality therefore 'we can, and should, make attempts at investigating reality in itself, but do so cautiously and critically' (Pilgrim and Bentall, 1999).

Mixed methods research is research in which a researcher combines elements of quantitative and qualitative approaches to improve the breadth and depth of understanding and corroboration (Johnson et al., 2007). The increasing use of mixed methods approaches (O'Cathain et al., 2007) has seen the debate surrounding paradigms extend to include issues surrounding the mixing of approaches (Morgan, 2007). Some have argued that the two approaches are mutually exclusive

and contradictory and are therefore incommensurable (Lincoln et al., 2011), a mixing of methods is not only undesirable, it is not possible. However this author is in agreement with Bryman (2012) that this position confuses the difference between philosophical worldviews and research methods. Whilst it is true that constructivist and realist positions are contradictory and so it is not possible to hold both beliefs, it is not necessary to believe that all reality is a social construct in order to analyse the data produced in an interview. The differing research methods are tools to enable a researcher to answer the research question and a tool can be put to a variety of uses (Bryman, 2012).

There are many reasons to want to mix methods to create a more robust research strategy, these include but are not limited to, offsetting the weaknesses and utilising the strengths of both approaches and developing a more comprehensive account of the phenomenon by getting different points of view. The researcher may wish to answer different research questions within the project that are suited to different approaches. Findings from one part of the investigation may be helpful in illuminating unexpected findings from the other. A mixed methods approach may help to improve the utility of the findings, by not just looking at whether an intervention works but also how people have reacted to it and experienced it, the findings may be more useful to the practical application of the intervention in the real world (Bryman, 2006, O'Cathain et al., 2007). In light of the controversy regarding paradigms, there are different theoretical arguments to justify mixed methods research.

Pragmatism is a fairly new philosophy of research and has developed with mixed methods research; it is not concerned with the arguments of epistemology and ontology and advocates purely that a researcher uses the method which best suits the research question he or she is trying to answer (Creswell, 2009). Pragmatism can be considered as a set of conceptual tools to solve problems rather than a philosophical position (Teddlie and Tashakkori, 2011). Critical realism is logically in favour of mixed methods; it claims there are three overlapping domains in the world, the 'empirical', which is those aspects of reality that we can experience directly or indirectly, the 'actual', aspects of reality that occur but may not be experienced and the 'real' which is the underlying structures and mechanisms that generate phenomena (Bhaskar, 1975, McEvoy and Richards, 2006). Quantitative methods investigate the 'empirical', qualitative, the 'actual' and by combining the two the researcher can begin to develop an understanding of the 'real' (McEvoy and Richards, 2006). Post-positivist thinking also welcomes mixed methods as a way of capturing

as much of reality as possible (Denzin and Lincoln, 2011), especially when the mixed method design has the quantitative section occurring first and given priority (Creswell et al., 2003), but also because post-positivists are open to the idea of aspects of society being social constructions (Onwuegbuzie, 2000). The extent and importance of these arguments varies in different disciplines, within the social sciences there is still a 'quant-qual divide' but in health service research mixed methods approaches are increasingly used and accepted with a view that they complement each other and the discipline's aims (Pope and Mays, 2006).

3.1.3 Single Case Experimental Design

There remains some controversy over the best way to investigate a psychotherapeutic approach. The NICE guidelines are based heavily on the results from randomised controlled trials (RCTs). This has been heavily criticised by the UK Council for Psychotherapy, who consider that this approach has led to the favouritism of CBT. RCTs are very expensive to run and as such there are not many to be found which investigate the psychotherapies which last for years rather than weeks. As there are no RCTs to show their effectiveness then they are not recommended. This does not mean, however, that they are not effective at reducing symptoms (Guy et al., 2010). Other criticisms of RCT come from practiced based evidence and that RCTs are not actually as representative as they claim to be because of the strict exclusion criteria usually associated with them. In the real world most clients have multiple problems (comorbidities) so what we actually need to know is whether the treatment is effective in these circumstances (Parry, 2000). RCTs have very good 'internal validity' but we cannot be sure of their 'external validity' (Hunt, 2012). This is the rationale for conducting RCTs in clinical practice. This still has the problem however, that a client who agrees to be randomised may not be a typical client.

The hourglass model (Salkovskis, 1995) and also the current Medical Research Council's (MRC) guidelines (Craig et al., 2008) on developing and evaluating complex interventions, consider the RCT to be one step in the process. There is much to be done before we can conduct an RCT effectively and there is much to be done after it to confirm and refine our knowledge. The MRC guidelines state that there are five key stages to the process; develop an intervention, piloting and feasibility, evaluating the intervention, reporting and implementation. The guidance states that at this stage there are two questions that need answering, does the intervention work in everyday practice and how does it work (Craig et al., 2008)? Many would argue that in the case of EMDR there is sufficient evidence to be confident it works in everyday practice for many people with

PTSD. How it works has been less convincingly argued, and there is scant evidence at all that it is an acceptable treatment for depression (Chapter 2). The design of this study has then started at the beginning of this process. The intervention has already been developed but little more than that is known about it.

For this reason alone it would then be difficult to justify an RCT at this stage. The MRC warn against forgetting about the piloting and feasibility part of the process (Craig et al., 2008). This is essential to lay the groundwork if future RCTs will be worth the expenditure, resource and burden to the clients. The other question raised from the idea of doing an RCT is what will the comparison arms of the trial be. In mental health this is commonly medication or the usual psychotherapy treatment. Without access to pharmacological support a medication comparison was unlikely in this study and to compare with a different type of psychotherapy would require a very large number of therapists to be dedicated to the research. To get funding for these types of comparisons it is vital to show that the new intervention is able to compete with these established treatments. As chapter two has demonstrated there is little evidence to suggest EMDR may be as successful at treating depression as CBT. One option is to compare EMDR to no treatment. A pilot RCT like this was considered as this design could be a test to find out if there is any reason to do a large RCT however this means denying therapy to depressed clients and the potential unnecessary distress it may cause in the control group was considered unacceptable. There were also concerns about moving to a trial prematurely without first conducting a feasibility study to develop a safe, acceptable and potentially effective intervention. After consulting with the local NHS ethics committee it was clear that this would not be supported. Using a single case design was considered so that a control group was not necessary.

Single Case Experimental Designs (SCED) are common at this stage of developing a psychological intervention. They are more robust than an anecdotal case study and attempt to show effectiveness in the individual (Barker et al., 1994). Although this can cause a problem for the generalisability of the results, undertaking a clinical replication series, preferable on a heterogeneous client group, can help (Kazdin, 1998). SCED or 'N of 1' studies are not new they have been around since the 1950's and when done properly can be considered among the highest levels of evidence, higher for some purposes than an RCT (Glasziou, 2011). The Oxford Centre for Evidence Based Medicine recently suggested that the SCED trial (along with the systematic review of randomised trials) was the best way to answer the questions, 'does this intervention help?',

‘what are the common harms?’ and ‘what are the rare harms?’ (OCEBM, 2011). They are particularly suited to research questions that investigate causal relations by examining the effects that introducing or manipulating an independent variable (for example psychotherapy) has on a dependant variable (such as depression and social functioning) (Horner et al., 2005).

How the method will provide rigorous data

Single case experimental designs address individual uniqueness and complexity (Barker et al., 1994); they have been used extensively in the history of psychotherapy research especially in Behaviour Therapy and clinical psychology. In SCED, data are collected throughout the research period not just at the start and end of treatment. This continuous or repeated measure is begun before treatment starts. This baseline phase is designed to show the stability (or lack thereof) of the participant’s symptoms prior to the onset of treatment and is often called a predictive baseline as it is predictive of a person’s symptoms if the treatment had not been administered. In this way the participant acts as their own control by providing data showing how their symptoms change with and without treatment, these can then be compared (Barlow and Hersen, 1984). By studying one person in detail the design seeks to exclude other explanations for any effect seen during the treatment period. The standard design for demonstrating change during a SCED study is to use an ABAB design where a baseline period (A) precedes treatment (B); the treatment is stopped (A) and then reinstated (B). However this raises two serious issues, firstly that if a treatment is helping to address a serious or life threatening condition then removing it is unethical (Turpin, 2001) and secondly, not all treatments are reversible, indeed many are intended to have sustained effects after the treatment is completed, so removing it may not actually lead to a relapse of symptoms even if the therapy is highly effective (Barker et al., 1994). In this case EMDR is not considered to be reversible. The current presiding theory supporting EMDR, the AIP, predicts that once change has occurred in the problem memory then it will not revert back to causing distress without a new distressing incident occurring. Although using an ABAB design could test this theory this is not the aim of this research. Before we can test the theory that memory change caused by EMDR is irreversible we must first be sure there is memory change. One of the aims of this research is to investigate this. As it is not clear what the mechanism of change is in EMDR, at this point we must assume that whatever it is, it is irreversible. It is also not appropriate to test the predication that the effects of EMDR are non-reversible in a novel population.

Due to this an ABAB design is not appropriate in this research. An AB design will therefore be used. This will see a baseline period, of at least one week, followed by a treatment period, up to 20 twice weekly sessions. The problem with the AB design is that it is weaker at demonstrating the causal influence of treatment than the ABAB design (Barker et al., 1994). However, this disadvantage can be offset with additions to the research process. Firstly it is necessary to demonstrate that change actually occurred. A repeated (daily) measure, based on the DSM-IV-R criteria for depression (APA, 2003), will show how the participant's depressive symptoms have changed over time and will reveal trends over the research period, such as a difference between the baseline phase and the treatment phase (Kazdin, 1998). Additional standardised measures before and after therapy and at follow up will allow differing aspects of the participant's symptoms to be analysed. The additional assessment point at follow up should show if any improvement during the therapy period has been maintained. By repeating the SCED design on multiple participants it is possible to improve the generalisability of the findings, especially if the participants are heterogeneous in areas such as gender, social class, severity of symptoms and other demographics (Kazdin, 1998).

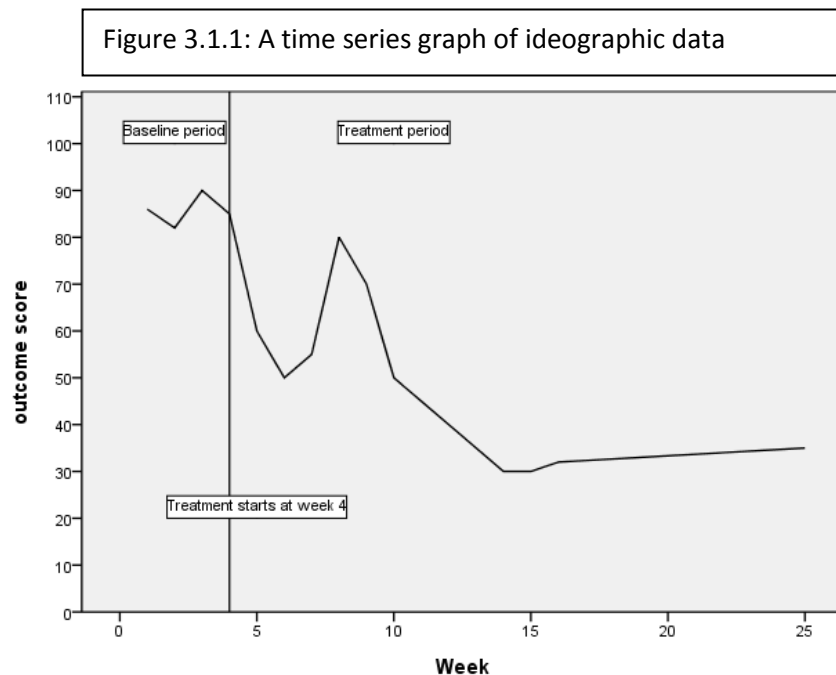
It is also necessary to link any change to the therapy provided (Barker et al., 1994). It is unlikely that any one measure can definitively answer this point but by taking several measures and linking this evidence it improves validity of the conclusions. However, if a participant has change in a chronic or stable condition it is likely that change is due to the intervention. Another method is to ask the participant for their view of what has caused change to occur. It is also possible to look for correlation between symptom change and therapy events. It is also important to rule out alternative explanations for change, these can be that change did not actually occur (participant shows no improvement or deterioration, reported improvement is due to statistical or relational artefacts) or that change did occur but it was not due to the specific therapy (participant engages in self-correction due to improved self-awareness, extra therapy factors such as positive life events occurred, psychobiological factors or the reactive effects of research caused change) (Barker et al., 1994).

SCED designs also allow for an examination of the therapy process. By using a self-report session measure, such as the Helpful Aspects of Therapy (HAT) form, it is possible to get the participant's view on which parts of the therapy process they are finding helpful and which are not and why. This is often very different from the therapist's view which is more usually reported. Here the HAT

will inform the interview schedule which will allow the participant to explore their experiences and give their views on the therapy process.

Analysis of the SCED data

The data from SCED studies are typically analysed by visual inspection of a graphical representation of the changes recorded by the ideographic measure. In the visual analysis a graph of the ideographic data are plotted in a time series analysis and the reader judges the immediacy of the effect, the proportion of overlap between baseline and intervention and the magnitude and consistency of change (Horner et al., 2005). An example of this type of graph is displayed in Figure



3.1.1.

There are several advantages to this method; it is quick to make graphs and draw conclusions from them, graphed messages are immediate and accessible to the reader, minimal transformation of the data is required and the theoretical premises underlying graphs are minimal, well known and well understood (Parsonson and Baer, 1992). In the example in figure 3.1.1, a higher outcome score indicates worse symptoms so we have a client with a stable but severe baseline who initially responds well to treatment, there is a reversal in her symptoms which then responds again and remains stable over the follow up period. However there are serious problems with relying on visual inspection alone; outliers can skew results, results may be autocorrelated (client A's mood today is linked to his mood yesterday) and cyclicity in biological rhythms may appear as treatment

effects and even experienced researchers can have difficulty recognising and interpreting such data (Franklin et al., 1996). Integrating the visual analysis with a statistical approach is advisable when a stable baseline cannot be established, a new treatment is being evaluated or findings are to be shared with other professionals (Franklin et al., 1996). This is because the visual display is descriptive and the statistical analysis is inferential and predictive and so by combining the two it may increase the validity of the findings (Franklin et al., 1996).

Autocorrelation (or serial dependency) is a problem for SCED studies because it means there are non-random processes in the time series and this can affect both visual and statistical analyses leading to an increased risk of a type one error (Busk and Marascuilo, 1992). Autocorrelation is the extent to which values at time $t(Y_t)$ are correlated with values at time $t-i(Y_{t-i})$ (Matyas and Greenwood, 1996). There are different types of non-random patterns that can be present in the data, trends (also referred to in the literature as maturation - systematic increases or decreases in observed values over time), periodicity (regular, rhythmic or cyclic fluctuations of values over time) and variability (deviations around a mean level) (Gorman and Allison, 1996). AB designs are particularly susceptible to maturation and ABA or ABAB designs are more vulnerable to cyclicity (Beasley et al., 1996). The presence of autocorrelation does not mean the data from a SCED is not useful, but it does mean that it will require a more complex statistical analysis. Although there is some disagreement about the extent of autocorrelation and its effect, it is wise to assume that observations are not independent; however this invalidates the assumptions of many parametric tests (Busk and Marascuilo, 1992). By using time series methods or randomisation tests the data can be transformed to remove the effect of the autocorrelation and then standard statistical tests can be performed (Busk and Marascuilo, 1992, Beasley et al., 1996).

One of the criticisms of SCEDs is that an intensive study of one case cannot be generalised to the larger population. This can be mitigated through replication. If it does matter it is possible to perform a meta-analysis on a collection of case studies (Manolov and Solanas, 2008). By combining the results from many case studies the meta-analysis can be used to provide a point estimate of effect size, confidence intervals around the effect size and search for variables that mediate the effect size (Faith et al., 1996). Meta-analysis of SCED studies allows comparison across individuals, systematically investigates effect size and allows objective and systematic review of large numbers of replications (Busk and Serlin, 1992). As this study will include several SCED

studies that will all have been carried out under near identical conditions they will be suited to meta-analysis as they will be very homogenous and equally weighted.

Skin conductance response

The link between treatment outcomes and theoretical explanation is remarkably weak in psychotherapy in general (Salkovskis, 2002) and in EMDR in particular. When Ricky Greenwald challenged the AIP as untested, Francine Shapiro's response was that because EMDR had been shown to be successful in over 20 RCTs this also showed the accuracy of the AIP model (Greenwald, 2010, Shapiro, 2010). This is an unjustified assertion. It is possible for treatment trials to inform theory but only if the correct mechanisms are built into the experimental design.

As was highlighted in chapter 2.3 there are many theories as to the mechanism of action in EMDR but one with slightly more empirical evidence behind it is the working memory model. To recap, several working memory researchers have shown that a memory stored in the long term memory but brought to mind in the working memory is changeable and a distressing memory can lose its emotionality and vividness in the presence of eye movements (Andrade et al., 1997, Kavanagh et al., 2001, Gunter and Bodner, 2009). There are two main ways to measure this change in response, by asking the participant to mark scores on a Likert scale or to measure physiological indicator of arousal. This is why this research will also consider the client's psychophysiological response to their target memory. Heart rate variability (HRV) is recognised to be generally lower in depression clients than non-depressed controls (Rechlin et al., 1994, Carney et al., 1995, Agelink et al., 2002, Licht et al., 2008) and has been used in several studies to look at the change in arousal levels after EMDR (Sack et al., 2008, Sondergaard and Elofsson, 2008, Gunter and Bodner, 2008). Skin conductance response (SCR) is frequently used in anxiety and distress research. Numerous studies have used SCR to look at the effect of EMDR on a participant's stress levels. However, in anxious or stressful situations SCR is high. Several studies have shown that skin conductance in depressed clients is often lower than controls (Argyle, 1991, Ward et al., 1983). The common usage of these two measures in the depression and EMDR literature and the ease of data collection without the need for large scanners or high investment mean this study will also use SCR and HRV.

Conductance is the degree to which an object conducts electricity (Oxford dictionary). Electrical conductance is measured in Siemens and is equivalent to electrical current (Amperes) divided by electric potential difference (Volts) and it is the inverse of electric resistance (Ohms) (Thompson and Taylor, 2008). Skin conductance response is therefore a change in the electrical properties of

the skin in response to a given stimulus (Tarvainen et al., 2000). In the literature skin conductance response (SCR) is often used interchangeably with galvanic skin response (GSR), sympathetic skin response (SSR), skin conductance orientating response (SCOR) and skin conductance level (SCL). However, there appears to be some confusion over what is actually being measured in these five different responses. For example, galvanic skin response has been described as a measure of skin resistance and sympathetic skin response is a measure of potential difference (Arunodaya and Taly, 1995). As resistance should be measured in ohms and conductance in μ Siemens it is then odd that Tarvainen et al (2000) then report their GSR in microSiemens (μ Siemens).

There is also an issue with exactly what is being measured as the response, SSR, which is described by Kanzato et al (1997) as a transient change in the electrical potential of skin, is demonstrated in their paper to be a biphasic response with negative wave followed by a positive wave before the voltage returns to normal. This gives three possible ways of measuring sympathetic skin response the amplitude of the negative peak, the amplitude of the positive peak or the peak to peak amplitude. Tarvainen et al (2000) also describe GSR as a biphasic response. Those who describe which one they have used describe the peak to peak amplitude (Kanzato et al., 1997, Kucera et al., 2004) but there is a huge range of 'normal' values for SSR in the literature and this may indicate that not everybody is using the same measure. In Raines et al's (1991) investigation of skin conductance orientating response four different measures are quoted, all measured in μ Siemens but all with markedly different values with no explanation as to why they are different. These are SCOR, SCR at rest, SCL and amplitude of SCR. This is important because to compare (Kucera et al., 2004) results with the literature it is imperative to know what is being compared. For example Guinjoan et al (1995) found that depressed clients had a significantly larger SSR than controls however Ward et al (1983), who was looking at skin conductance level, found the exact opposite. In fact this paper found the skin conductance level for clients with major depressive disorder was significantly lower than controls consistently enough to recommend this as a biological test for depression with a sensitivity of 87% and specificity of 89%.

From the different language used in the names of these measures and the way they are used across the literature it could be assumed that skin conductance level should refer to the resting level of conductance of the skin measured in μ Siemens. The skin conductance response should be to change in that level of conductance following a given stimulus and would be the peak to peak amplitude measured in μ Siemens. Sympathetic skin response would be the same thing but

measured as a change of potential rather than conductance. No definition was found for the skin conductance orientating response and galvanic skin response is either exactly the same as skin conductance response or may be a measure of resistance as opposed to conductance. Due to this confusion this study will focus on skin conductance response (using the definition above) and does not consider that these five terms are necessarily interchangeable; although they are all clearly related.

However whatever name, these skin conductance responses are measures of electro-dermal activity and as such reflect activity in the sympathetic nervous system (Vetrugno et al., 2003). The sympathetic nervous system (SNS) is the part of the autonomic nervous system which mobilises our fight and flight response as opposed to our parasympathetic nervous system which maintains rest and digestion states. The SNS also has a large role in maintaining homeostasis and as such, it is nerve impulses from the SNS which trigger sweating. There are two types of sweating, thermoregulatory and emotional (Vetrugno et al., 2003). Whilst thermoregulatory sweating is a response to being too warm and occurs all over the body emotional sweating is a component of the orientating response and occurs when our attention is directed to a novel significant stimulus. As sweat contains salts, as we sweat we increase the conductive properties of the skin and this is what skin conductance response measures. As the SNS causes us to sweat when we are emotionally aroused we can therefore use electro-dermal response as a measure of sympathetic arousal. Brain mechanisms underlying the generation of the SCR are also those implicated in emotional processing (Critchley et al., 2000). By measuring skin conductance response whilst recording target memories identified during the EMDR process, this research is testing the hypothesis that before therapy these target memories are causing the client distress and therefore increasing sympathetic arousal. The AIP model then claims that after therapy the EMDR process will have reduced the distress associated with these memories and as a consequence reduce the level of arousal that occurs when these memories are brought to mind.

There have been five studies which look into electro-dermal activity and EMDR or eye movements specifically. Barrowcliffe et al (2004) investigated eye movements in nonclinical settings and with a nonclinical population, skin conductance response was reported as the square root of μ Siemens; this was to reduce skewedness. Their results showed that eye movements did reduce the level of arousal. Sondergaard and Elofsson (2008) measured skin conductance response in PTSD clients and found that there had been a significant decrease by the end of the session this was again

measured in μ Siemens. Wilson et al (1996) investigated GSR in clients with anxiety phobia and PTSD they found a significant reduction in GSR during the session of EMDR. GSR here was measured and reported in polygraph chart units (Wilson et al., 1996). Dunn et al (1996) investigated EMDR on nonclinical university students and found a decrease in skin conductance response measured in microvolts (further indication of the confusion surrounding SCR), however this was not significant (Dunn et al., 1996). Aubert-Khalifa et al (2008) measured skin conductance response of PTSD clients before and after an EMDR session they measured this in two states, one a relaxed state and then one when they were visualising their own traumatic event. There was a significant decrease in the difference between these two readings after therapy and this reduction in physiological state was correlated with a reduction in symptoms (Aubert-Khalifa et al., 2008).

These results would appear to support the AIP claim that the EMDR process reduces the emotionality of past disturbing memories and as such reduces the negative effect that these memories have on mood, stress levels and general emotional state. However when we are looking at anxiety disorders, we would expect a decrease in electro-dermal activity to correlate with a decrease in severity of symptoms. This is because anxiety is an over activation of the SNS leading to heightened levels of arousal in unnecessary circumstances. Depression however generally sees a dulling of affect and depressed clients regularly record lower than normal levels of electro-dermal activity. This then makes it difficult to predict how skin conductance response will alter following EMDR treatment for depression.

Heart rate variability

Heart rate variability (HRV) is another marker of autonomic activity. HRV however is more associated with the influence of the parasympathetic nervous system. The parasympathetic nervous system's influence is mediated by the vagus nerve releasing acetylcholine. HRV, especially high-frequency HRV, is associated with this parasympathetic input. HRV is in fact not the variability of the heart rate but the variability of the interval between consecutive beats; it measures fluctuations in autonomic inputs to the heart rather than the mean level of autonomic inputs. Therefore both autonomic withdrawal and saturation lead to diminished HRV (Camm et al., 1996).

Like skin conductance response there are numerous different ways with which to refer to heart rate variability. However unlike skin conductance response these are well defined and can be split in the time domain methods and frequency domain methods. The heart rate variability guideline (1996) covers the main measurements in each of these areas and has recommendations for

researchers to use in different circumstances. Of the time domain methods, the recommendation is to use the RMSSD, which is the root mean square difference of successive NN intervals. This is considered to have better statistical properties than other methods of measuring the NN ratio. Frequency domain methods, for example the ratio between high and low frequencies generated, are recommended by the guide as preferable however they also say that the results from 'frequency domain analysis were equivalent to those of time domain analysis and that the latter are easier to perform' (Camm et al., 1996). HRV is frequently found to be significantly lower in depressed clients than in healthy controls, this is also found in clients with stress and anxiety disorders. The general consensus of the literature appears to be that the heart rate variability of anxious clients increases following session of EMDR.

The literature reveals three studies that have looked into the use of heart rate variability as an indicator of arousal when using EMDR. Sack et al looked at the HRV readings taken during reading of a trauma memory script and a neutral script before and after an EMDR session on the trauma memory. They found whilst the change in heart rate data significantly decrease after therapy there was no significant increase in HRV. Sondergaard and Elofsson (2008), in the study mentioned before with PTSD clients also considered heart rate and heart rate variability. This team did find an increase in HRV as measured using the frequency domain method. Gunter and Bodner (2008) also used the natural log of the high-frequency power spectrum in their investigations. They also found an increase in HRV during processing. Their conclusion was that this meant there was an increase in arousal and that this is then a problem for the theory which claims eye movements cause 'de-arousal'; but as HRV is reduced in depressed and anxious clients and increased HRV is a the goal of treatment and signifies a reduction in arousal, so it is unclear what Gunter and Bodner mean by this.

We can utilise these physiological markers of arousal within this study. As part of the normal process of EMDR clients identify at least one traumatic memory to desensitise. Once this memory was identified by the participants, the memory narrative was recorded. Whilst this memory was vocalised the participant had the SCR and HRV measures taken. This happened before processing, at the end of therapy and at the follow up period. If the predictions of the AIP are correct then the HRV will increase, it is not clear what the SCR will do but it should be consistent across all participants. Any psychophysiological response should be correlated with any change in subjective rates of distress and with changes in the memory narrative.

Comparing responders and non-responders

Non-responders to treatment can tell us about the different groups that may or may not benefit from different types of therapy. By comparing the responders and non-responders we may be able to discover who will be most effectively treated by EMDR for depression. It may be that non-responders have not fully processed their memories, or that it was not the memories that were the problem in the first place. This forms the rationale and research questions for study 1.2 of this study which will look for differences between the responders and non-responders to EMDR to see if this can reveal any information about process, types of people who may benefit more than others and potential places to improve the treatment protocol.

It is important to define non-response before the study begins. This definition will differ between studies depending on the conditions being studied and the treatment offered. Here remission was defined as a score of eight or lower on the 24 item Hamilton Rating Scale for Depression (HRSD), response was defined as at least a 50% reduction from baseline and a final score of 15 or less on the HRSD this definition was used by Schramm et al (2011) and the ReVAMP trial (Kocsis et al., 2009). By defining both response and remission the study can look into groups of clients who, by the end of the treatment no longer meet the criteria for depression, but also those who are improving but are still depressed. This second group is important; their existence can mean several things. EMDR may be efficacious but need more than 20 sessions for most people or it may be that EMDR is only part of what is needed so although it can reduce symptoms it cannot remove them completely. Unless we look at response as well as remission we cannot begin to answer these questions.

Some studies have tried to identify non-responders to treatment, to classify them and to treat those whose conditions are 'treatment resistant'. The idea of treatment resistance is common but not well defined. Thase and Rush have attempted to classify non-response in depression, and described a five stage model of treatment resistance. However, this is primarily based on the use and failure of medication (and electroconvulsive therapy) and makes nothing but a passing mention of psychotherapy, which the authors consider offers little more than a supportive role (Thase and Rush, 1997). Likewise, the World Federation of Societies of Biological Psychiatry regard treatment resistance to be the failure of two or more antidepressants from different drug classes (Bauer et al., 2007). In much of the literature treatment failure and treatment resistance is assumed for chronic and long term depression although it is rarely defined. It is assumed that if

someone has been depressed for several years, they will have received at least one, probably more treatment and this has failed (Schramm et al., 2011, Cuijpers et al., 2010b).

Other authors have tried to identify the characteristics of non-response to treatment and non-response appears more likely in some presenting symptoms (Taylor and Abrams, 1975). Saxon et al (2008) found that one of the factors that was most associated with non-response was a diagnosis of long term depression. However they were looking at brief counselling and suggested that long term depression requires more than six sessions to treat (Saxon et al., 2008). Other factors that have been identified include economic inactivity (i.e. unemployment) and being male (Saxon et al., 2008, Shepherd et al., 2005), age at onset and number of problem episodes (Roth and Fonagy, 2005) and chronicity (Thase and Howland, 1994). Although there were significant differences between those who responded to treatment and those who did not these differences were not large enough to be predictive (Saxon et al., 2008). Due to the small number of participants in this study and that randomisation of these characteristics was not possible this study will not be able to claim it can predict response but it will be able to systematically explore the data generated (Shepherd et al., 2005) to see if these factors are also important here.

3.1.4 Semi Structured Interviews

The qualitative data were collected from semi structured interviews. Interviews were chosen to provide total focus on the individual and investigate their perspective (Ritchie, 2003). They were semi structured because although the aim was to uncover the attitudes and experiences of the clients, the study required some specific information from them (Bowling, 2009); it also allowed the interviewer leeway to respond to the answers given and topics do not need to be covered in a predefined structure. The semi structured format allowed the interview to be flexible and in depth (Bryman, 2012). Some of the questions were derived from the Helpful Aspects of Therapy forms and therapy events, this was because one aim of the interview was to offer the opportunity to clarify unexpected findings during therapy (Ritchie, 2003).

A badly designed topic guide or interview schedule would be confusing and could restrict the usefulness of the collected data (Arthur and Nazroo, 2003). When undertaking to write an interview schedule (or to evaluate one) there are several key questions to consider to ensure a high quality interview. Why did you ask this specific question, why did you formulate it in this way and why did you position it at this point of the schedule (Flick, 2006)? Questions should always avoid use of leading language, bias, double negatives and having two questions in one (Bowling,

2009). They should use language which is comprehensible and relevant to the participant (Bryman, 2012). A suggested structure for the guide includes beginning with objectives and instructions, introducing the topics, section one – demographic questions, section two – the first main topic area, several subtopics and important bits to remember, section three - the second main topic area, several subtopics and important bits to remember, and then how to end the interview (Arthur and Nazroo, 2003). Suggested questions should include ‘content mapping’ questions, ones designed to encourage the participant to open up, ‘content mining’ questions, ones designed to explore, explain and clarify answers and ideas for probes achieve more depth (Arthur and Nazroo, 2003). To improve the quality of the interview and the data collected from it a safe and sensitive atmosphere must be maintained (Bowling, 2009). To aid with this the interviewer should be prepared to be asked questions by the participant and to answer carefully, maintain control of the interview and critically appraise his/her own interviewing skills (Britten, 2006).

To analyse the data collected from the interviews a technique called framework analysis was used. This is a series of interconnected stages which explicitly guide the systematic analysis of data from initial management to the development of explanatory accounts (Smith and Firth, 2011). Framework consists of three main stages, data management, descriptive accounts and explanatory accounts. Data management involves identifying initial themes from the data, sorting, labelling and tagging and beginning to assign meaning to portions of data. In the descriptive accounts, the data are summarised and synthesised, typologies are established and themes are refined to more abstract concepts. Finally explanatory accounts detect patterns and develop explanations from the data, concepts portray meaning and applications to wider theory are sought (Spencer et al., 2003). This analytic process is not a linear one. It may be necessary to keep going back a few steps or even to the raw data to check that your themes and concepts fit (Spencer et al., 2003). Framework is a versatile and useful technique as it allows for both *a priori* themes and also emergent ones to be handled side by side (Srivastava and Thomson, 2009). This allowed study three to investigate predictions from the theory behind EMDR but also deal with the unexpected results and previously unresearched concepts surrounding client experience.

3.1.5 Combining Data – How to mix methods

Although mixed methods maybe considered to yield more than the sum of their parts (O’Cathain and Thomas, 2006) consideration must be given to when and how to combine them. Creswell et al (2003) have suggested that the researcher should state the implementation order of a mixed

methods study, the priority given to each method and when the intended integration will occur. Figure 3.1.3 shows a representation of a classical sequential explanatory design for mixing methods (Creswell et al., 2003) and Figure 3.1.4 shows the modification of that design that better describes the research and analysis process.

Figure 3.1.2: Sequential evaluation design for mixed methods (Creswell et al., 2003)



Figure 3.1.3: Adapted sequential evaluation design for mixed methods (after Creswell et al., 2003)



This research considers both the quantitative and qualitative parts of this study to be of importance. Both are covering new ground and will provide a contribution to knowledge. When evaluating a new treatment it is imperative that the primary outcome be whether or not the clients have improved because of the intervention. The accepted and most straight forward methods for this are quantitative. However, the views of clients are of fundamental importance when it comes to implementing an intervention. Further, by combining the two sets of results (Figure 3.1.4 box 5) the aim is to achieve greater illumination as to why some people responded to the treatment when others did not. This was achieved using the Framework analysis method because the chart structure means that Framework analysis leads itself very easily to both qualitative and quantitative data can be analysed together in a mixed methods matrix (O’Cathain, 2013). Although the question of the impact of an intervention is traditionally a purely quantitative investigation, the views of the participants are also important here. If the measures suggest people have improved but the participants disagree, or vice versa, then this is important, both for the implementation of the intervention and it raises questions about the suitability of the measures in this subgroup of clients. This is of core significance in mental health where one of our most used diagnostic tools is the report of the client.

This is a necessarily sequential design. The quantitative data collection was done as before and after therapy assessments of the clients' symptoms, the qualitative data came from interviews which attempted to understand the client experience of therapy. As such they had to be done after the therapy, and therefore after the quantitative data collection, took place. This study has an evaluation type of design as it attempted to explain how and why the results of the impact questions (does the EMDR intervention have an effect on depression symptoms?) occurred. It is hoped this will enable the treatment to be improved and targeted to clients who will respond to it.

Chapter 3 Part 2 Method

3.2.1 Aim

To investigate if EMDR has an impact on long term depression and if the mechanism of change is by changing distressing autobiographical memories

3.2.2 Research questions

Following a course of therapy comparable to ones delivered in the NHS:

1. Is there an improvement in depressive symptoms and social functioning, and if so is it stable at follow-up?
2. Are there any significant differences between the responder group and non-responder group of clients which might be able to predict response in others?
3. Has the content of the target memory become less distressing and more adaptive, and if so is it stable at follow-up?
4. Has the impact of the target memory and the psychophysiological response to it decreased?
5. Is there a relationship between changes in symptoms and changes in memories?
6. Do clients find EMDR to be an acceptable treatment for long term depression?

3.2.3 Objectives

To study the impact of standard protocol EMDR on depression and functioning symptoms, memory content, heart rate variability (HRV), skin conductance response (SCR) and psychological responses to distressing autobiographical memories of clients with long term depression over a 20 session period. There were two primary outcomes for the study, Hamilton Rating Scale for Depression (HRSD-24) scores to measure symptom change and content analysis of memories to investigate the processes behind EMDR's effect. The HRSD-24 was chosen as it is a comprehensive scale which is sensitive to change and as it is rated by the researcher it is less likely to be biased by the client or therapists involved. Other quantitative outcomes were used to measure interactions and correlations to answer the subsidiary research questions. Qualitative interviews were used to understand the therapy from a client's perspective.

3.2.4 Null Hypotheses

There will be no significant change in symptom or functioning scores after the therapeutic intervention.

There will be no differences between the groups of responders and non-responders to treatment that may be predictive of who will be most likely to benefit from EMDR for long term depression.

There will be no change in the way that distressing autobiographical memories are remembered after the therapeutic intervention.

There will be no psychological change to the target memories, with respect to emotionality, vividness, completeness and psychological distance, following the therapeutic intervention.

There will be no change in the physiological responses, HRV and SCR, to the stress of the target memory following the therapeutic intervention.

There will be no correlation between the psychometric symptom/social functioning scores and psychological/physiological scores.

3.2.5 Study design

The investigations took the form of three studies. The first investigated the impact of EMDR on depressive symptoms. It utilised quantitative methods and relied on standardised measurements and compared the responders to non-responders to attempt to draw predictions regarding who may benefit most from EMDR therapy for depression. The single case experimental design allowed the comparison of before treatment and during treatment symptoms for each participant using the repeated measure. It also used information from the interviews to assess what the participant view of impact was, as it can be argued that no matter what the outcome of the questionnaires, unless the clients' report feeling better, then it is not truly successful. The two methods were brought together in a mixed methods matrix. Study two investigated possible mechanisms of change in EMDR. This involved testing the predictions of the adaptive information processing model and what, if anything happened to the targeted memory at different points. In the third study, semi structured interviews of the participants gathered information about their experience

of the therapeutic process and whether the participants found EMDR an acceptable treatment for long term depression.

A feasibility study is justified at this point, as the literature does not contain any pilot studies or memory tests of clients with long term depression who have been treated with EMDR. A mixed methods approach will allow the study to investigate complementary research questions, as suggested by the Medical Research Council (MRC) guidelines for developing complex interventions. By providing a process evaluation we can investigate discrepancies between expected and observed outcomes in an attempt to provide insights that may aid implementation (Craig et al., 2008). By providing data on a small number of clients treated by numerous clinicians the results should show, with reasonable reliability but low power, what may be expected in a larger trial (Craig et al., 2008). To achieve this aim a series of single case experimental design (SCED) studies (Barlow and Hersen, 1984) was conducted, a range of measures was taken before and after the course of therapy to answer the research questions. The participants identified key autobiographical memories and then completed a range of measures to test the content, impact of and physiological responses to these memories. They also had a range of depression symptom scales and social functioning scales to measure changes in their mental health. All tests were completed before and after therapy and three months post therapy. As with all SCED studies a repeated measure was completed daily by the participants to look for trends in the data, sudden therapy gains and to be used with the interviews to help understand therapy events.

3.2.6 Ethical considerations

Four key concepts inform health care research and clinical practice; beneficence, non-maleficence, autonomy and justice. Beneficence is the ethical obligation to maximise benefit and non-maleficence is its obverse - the obligation to do no harm. The World Health Organisation (WHO) follows the Belmont report (Ryan et al., 1978) and assumes these are two sides of the same coin and refers to both as beneficence (WHO, 2005). Autonomy means that potential research participants should be regarded as autonomous agents; they are capable of and should be given the opportunity to choose what shall or shall not happen to them. The WHO good clinical practice guidelines incorporate this into the category of 'respect for persons' and include the concept that the vulnerable should be protected (WHO, 2005). Justice refers to the moral principle of fairness.

To ensure fairness or justice entry to the study was conducted on a sequentially. No one was given preferential entry to the study and everyone who fulfilled the inclusion and exclusion criteria and consented to join the study was included. As recruitment was via the primary care mental health service - Improving Access to Psychological Therapies (IAPT) - then only people living in the area served by Sheffield South East and Sheffield South West IAPTs could join the scheme. However, as this was a feasibility study, restricting the number of recruitment sites was necessary. Had we recruited more widely it would possibly have meant that people were offered the research clinic but then later had to be refused due to the limited capacity of the clinicians. The NHS England Research and Development Strategy 2013-18 'Research is everyone's business' has the vision of, where possible, every patient has the option to participate in research (p7) (Minogue, 2013).

Following the guidance of the Helsinki Declaration in order to maximise benefit and minimise harm, a thorough analysis of possible risks and benefits was undertaken (WMA, 2001). The suggested plan was discussed with a service user researcher and taken to the Sheffield NHS Research Ethics Committee and local NHS Research and Development service (paperwork in the appendix) for scrutiny and permission to proceed. Their suggestions lead to modifications of the protocol. Although adverse events in psychotherapy are rare and rarely reported they do occur (Duggan et al., 2014). For this reason adverse events were monitored, although none occurred that was attributable to the treatment or research. Theoretically, there is reason to believe EMDR may be a useful treatment for people with long term depression, however, the research evidence is lacking (see chapter 2). Each of the participants in this study had received at least one course of psychotherapy and failed to respond, they were given the opportunity to try something different (WMA, 2001).

Autonomy and respect for the individual were of paramount importance. In accordance with the aforementioned guidance, the potential participants were all given the opportunity to make informed decisions about their own care (a choice between treatment as usual (CBT or counselling within the IAPT service) or EMDR within the research clinic). Choice, opportunity and informed decision making is the essence of patient centred care and a key strategic aim of the NHS (DoH, 2010). Informed consent has been defined as 'a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate' (NIHR, 2011).

Each part of the study had different ethical issues associated with it. To implement EMDR in a manner that allowed it to be researched it had to be the only psychotherapy that the participants were receiving. This meant withholding a NICE recommended treatment from the participants. When the research clinic was first offered by the Psychological Well-being Practitioner (PWP), the potential participant was given a patient information sheet; if they remained interested they met with the researcher to discuss the study at a venue and time that was convenient to them. Potential participants were given the option to make an informed choice to decide their own treatment. They were given the option of remaining in IAPT or joining the research clinic. The differences between the treatments were explained along with the differences between being a research participant and being a patient. They were clearly told they could withdraw from the research or from EMDR at any time and return to IAPT with no penalty in their care. The decision was then left to them. Those who chose to join the research were asked to sign two identical copies of the consent form, one for the researcher and one for their own records. The recording of memories and responses to them was highly unusual for an NHS therapy. The purpose and procedure was explained and the participants were able to ask any questions they had. The service user researcher commented that measuring skin conductance may imply a small electrical shock would be given. This was not the case and this was explained and the researcher demonstrated the safety of the equipment on herself where required with anxious participants. As stated above, informed consent is a process not a single act (NIHR, 2011), each time the participants met with the researcher they were reminded that they did not have to complete any measures if they did not wish to and could withdraw consent at any time.

All those who engaged with EMDR were invited for interview after therapy had finished. They were told at the start that this interview would be offered and that they could choose whether or not to participate. Two of those who were offered an interview did not respond to the letter. A second letter was sent to ensure they had received one but no further contact was made as failure to respond was considered to be a refusal to take part. The interviews were about the experience of receiving EMDR therefore those who did not receive EMDR were not invited for interview. Interviews about therapy have the potential to be distressing, these interviews focused on the experience of receiving EMDR rather than the subjects targeted during treatment. The interviewer was an experienced mental health nurse who did not ask questions about the targets of treatment

however, if they came up the participant was given time and support as required. All participants requested a summary of the results and this was sent after all the data had been collected.

The study in its entirety was put before the Research Ethics Committee in December 2012. The Committee was keen for a non-inferiority randomised controlled trial to be conducted but as stated in Chapter 3.1 this was not considered appropriate at this point in developing a complex intervention. After some changes to the protocol, ethical approval for all parts of the study was given in January 2013, the local NHS Trust Research and Development department did not request any changes and gave permission for the study to be conducted within their organisation shortly after.

3.2.7 Symptom scales

To assess the impact that EMDR has on depression, standardised scales allow the study to assess symptom change in a recognised and reliable way that can be compared to other research. In long term depression social functioning is considered to be a serious problem so ratings of this were also done. The combination of clinician and self-report symptom scales should improve the validity of the results (Roth and Fonagy, 1996). EMDR has been shown to reduce depressive symptoms in PTSD clients (van der Kolk et al., 2007). It is possible that improvement in depression could be related to improvement in a comorbid but undiagnosed PTSD, so a PTSD scale was also completed with the clients (the impact of event scale). Symptom scales have been chosen as they have been used by other similar studies into long term depression and its response to psychotherapy (Schramm et al., 2011). These measures were done at the start and end of therapy and at follow up. Following screening, eligible participants signed a consent form and completed the symptom questionnaires.

Hamilton Rating Scale for Depression (HRSD)

The HRSD is a 24 item clinician rated scale for depression symptoms. It has been shown to have good reliability between raters (Hamilton, 1960) and is sensitive to change over time and treatment (Miller et al., 1985). This is the primary outcome for the indicators of symptoms change. Scores range from 0-75 and 8 or less = no symptoms, 9-18 = mild, 19-26 = moderate, 27-34 = severe, 35+ (max score 75) = very severe

HRSD was chosen as the primary outcome measure as this is a validated and recognised scale worldwide. It has been the gold standard in depression rating scales for 40 years (Bagby et al.,

2014). It enables the research to be compared to other research. However, EMDR research is a controversial area and some research shows significant bias. As the researcher was not blind to the treatment there is a possibility that only using a clinician rated scale leaves the study open to allegations of bias. As any change on HRSD was down to the researcher to record it would be possible to allege that any improvement has been exaggerated. Participant rated scales for depression were also included as an independent measure to triangulate with the HRSD. Even without the controversy around EMDR, a single outcome measure can be argued to be insufficient. The HRSD is heavily biological in its design whereas the Beck Depression Inventory (BDI) is more responsive to the cognitive aspects of depression. It is advisable to have more than one scale covering differing perspectives and symptom domains (Roth and Fonagy, 2005). The HRSD and the BDI-ii are considered two of the best tested and reliable rating scales available for depression (Cusin et al., 2010) but are not commonly used in clinical practice in the UK. The BDI-ii is regularly used in American studies but less so in the UK. The PHQ-9 is a standard measure used in IAPT in the UK so allows the results to be comparable to the IAPT data set should that be appropriate.

The Patient Health Questionnaire - 9 items (PHQ-9)

The PHQ-9 (Kroenke and Spitzer, 2002) is a self-rated depression measure routinely used in IAPT services that takes about two minutes to complete and it is validated in a UK population (Gilbody et al., 2007). The IAPT handbook recommends the following interpretation of PHQ-9 scores, 1-4 Minimal depression, 5-9 Mild depression, 10-14 Moderate depression, 15-19 Moderately severe depression, 20-27 Severe depression (DoH, 2011).

Beck Depression Inventory (v.2) (BDI-II)

The BDI is a 21 item self-report rating scale for depression (Beck et al., 1961), it was replaced by the BDI-II (Beck et al., 1996) which has been found to be a stronger instrument than the BDI, as it covers all nine of the DSM diagnostic criteria rather than the six of the BDI and it includes increases as well as decreases in somatic symptoms (Dozois et al., 1998). It is used in many research studies into depression and is the primary depression tool in the USA (Sharp and Lipsky, 2002), it has good validity when compared with other self-rate scales and clinician rated measures for depression (Steer et al., 1997), the interpretation of the score should follow the table 3.2.1 (Beck et al., 1988).

Table 3.2.1 Classification for BDI-ii scores

Classification	Total Score	Level of Depression
Low	1-10	Normal ups and downs
	11-16	Mild mood disturbance
Moderate	17-20	Borderline clinical depression
	21-30	Moderate depression
Significant	31-40	Severe depression
	Over 40	Extreme depression

The repeated measure

As is usual in an SCED study a repeated measure is required. By using this repeated measure it is possible to track fluctuations in mood in between the sessions, this can add insight to the before and after measures and enable the research to be placed in context of the natural changes in depressive symptoms over time (Turpin, 2001). As has been used in other time series evaluations the repeated measure was based on the DSM-IV-R criteria for the disorder of interest (Kellett, 2007), in this case major depressive disorder. However in order to keep the measure short and simple not all of the nine criteria were included. Included were questions about low mood and lack of interest in activities, which are required for a diagnosis. In the DSM-IV-R criteria a client must have at least one of the first two. These two criteria also form the basis for the screening questionnaire the PHQ-2; which GPs use when screening for depression which says that if neither 'low mood' or 'lack of interest or pleasure' is present then the screening must be stopped and a different diagnosis sought (NCCMH, 2010). The third question regarding a lack of energy or feelings of tiredness is one of the essential criteria from the ICD-10 criteria for depression. Although this is not validated, as is common for repeated measures, it has been piloted and the wording has been borrowed from the PHQ-9 which has been validated for British adults with depression (Gilbody et al., 2007). The participants were given a paper copy of the scale to complete every day, figure 3.2.1 shows what each day's questions looked like. The questions were set out in the standard visual analogue form and the participant made a mark on the line representing their mood at that time. Completed forms were brought to the therapy session where they collected the next week's diary. It was possible to set up a text message alert to act as a reminder to the participants to complete the diary, if necessary. Afterwards, the mark was measured from the right-hand side to give a decreasing number as the symptoms improved.

Figure 3.2.1: An example of one day of the repeated questions

Date			
Low mood/ depression	'I am extremely low or depressed'	_____	'I don't have low mood'
Interest or pleasure in activities	'I have no interest in doing things'	_____	'I get involved'
Energy levels	'I have no energy'	_____	'I have enough energy'

Social Adaptation Self-evaluation Scale (SASS)

The SASS is a 21 item self-report scale developed specifically for the evaluation of social motivation and behaviour in depression (Bosc et al., 1997). It has been shown to be valid, reliable and sensitive to change (Bosc et al., 1997) and has been used in other studies looking at treatments for chronic depression (Schramm et al, 2011). Scores range from 0-60 and higher scores indicate greater adaptation to the social environment. Using this scale, “normal” social functioning was determined to be a score of 35–52; therefore, impaired functioning is any score below 35. (McNamara et al)

Global Assessment of Functioning (GAF)

The GAF is a clinician rated scale of psychological, social and occupational functioning assuming a continuum of mental health – illness. It is provided by the DSM-VI for assessing psychological disturbance (APA, 2003). The GAF has been shown to be a reliable measure of psychological disturbance within a severely mentally ill population (Jones et al., 1995). As the total GAF (GAFT) is based on symptom severity or functional disability (whichever is worst) (APA, 2003), two additional scores can be used splitting symptoms (GAFSYM) and disability (GAFDIS) (Jones et al., 1995).

Impact of Event Scale – revised (IES-r)

The IES-r is a self-report scale measuring traumatic stress; it was developed to improve the IES scale which did not include persistent hyper-arousal (Creamer et al., 2003). It is a useful

instrument for measuring traumatic stress and a score of 33 or more gives optimal diagnostic accuracy for PTSD (Creamer et al., 2003).

Sessional measures

Two brief questionnaires were given to the clients every session as repeated measures are important to understand the trajectory of change and as an insurance against attrition in final stage measures. These are Patient Health Questionnaire (9 item) (PHQ-9) and the Helpful Aspects of Therapy (HAT) form. The HAT was developed to enable researchers to gain an insight into which parts of therapy were considered helpful and unhelpful by therapists and clients (Llewelyn, 1984). This was done at the end of each session and informed the semi structured interview schedule in study two.

Mechanism of change measures

Often in EMDR several target memories will be identified for attention during therapy. These may include several different incidents that may or may not be related. For the research the memory that was identified as the 'earliest' will be the one for which responses are tested as this is the one that EMDR always aims to target first as it should be the key to the pathology. Once the target memories have been identified all participants were asked to complete a range of tests and scales to assess different aspects of the identified 'earliest' memory. All participants were asked to recall and describe in detail the memory that they have identified. This was described verbally and recorded for transcription later. During the recall the client's heart rate variability (HRV) and skin conductance response (SCR) were measured.

The memory narrative was a modification of the one used by Foa and colleagues. They concentrated only on memories of rape so their script had to be adjusted to be applicable to all traumatic memories – 'I'm going to ask you to recall the memory we have identified as vividly as possible. I don't want you to tell a story about the incident in the past tense. Rather I would like you to describe the incident in the present tense, as if it were happening now, right here. I'd like you to close your eyes and tell me what happened during the incident in as much detail as you can remember. This includes details about the surroundings, your activities, the activities of others, how you felt and what your thoughts were during the incident.' modified from (Foa et al., 1995).

Once they finished the memory narrative they were asked to complete four Likert scales to assess the emotionality, vividness, completeness and psychological distance of the memory (after Gunter and Bodner, 2008).

0 – 10

No emotion – overwhelmingly emotional

Not clear at all – extremely vivid

Not at all complete – extremely complete

Very distant – extremely close

As the participants finished therapy, they were invited back for a repeat of all the tests completed prior to the therapy. All tests were done focussing on the same memory as before i.e. the target memory of EMDR treatment. By using the same memory the HRV/SCR, Likert tests and recall descriptions will assess if the reaction to this memory has changed over the test period. Psychometric scales showed whether or not clinical symptoms changed too and were tested to see if this correlated with changes in memories.

3.2.8 Participants and recruitment

Thirteen clients with a primary diagnosis of long term depression (defined as at least two years in duration or two or more episodes over the lifetime) and referred to the Improving Access to Psychological Therapy (IAPT) team for treatment for depression were recruited for the treatment phase. Although they did not need to be native English speakers they did need sufficient English to be able to understand the testing and fully describe their memories.

Inclusion criteria – People 18 and over, with depression, confirmed through structured interview to ensure they met the DSM-IV-R criteria for long term depression. Participants must meet the criteria for a current major depressive episode AND had at least two episodes (i.e. it is recurrent depression) OR the current episode lasted two years or more (chronic major depressive disorder or dysthymia were accepted). Clients had to be able to give informed consent. They were screened using the Mini International Neuropsychiatric Interview (MINI) - The MINI is a short structured diagnostic interview designed to allow rapid but accurate neuropsychiatric interview for clinical trials, epidemiology studies and clinical settings (Sheehan et al., 1998). The MINI was developed for both the DSM-IV and ICD-10 psychiatric diagnoses and is validated against the much longer

Structured Clinical Interview for DSM criteria (Sheehan et al., 1997) and the Composite International Diagnostic Interview for ICD-10 criteria (Lecrubier et al., 1997).

Exclusions – those under 18, those unable to give informed consent, those with current suicidal intent or behaviour, psychosis, bipolar disorder, PTSD, dementia, brain injury, current drug/alcohol dependence, epilepsy, pregnancy, current opiate analgesic use, electro-convulsive therapy in the last six months or anyone whose primary mental health diagnosis is not long term depression.

Data collection – age, gender, age at onset of depression, number of episodes, length of current episode, medication history, psychotherapy history, risk history, medical conditions.

The project requested volunteers from the IAPT caseload. IAPT clinicians were informed of the study and requested to offer the opportunity to join the study to anyone on their caseload that appeared to have long term depression and did not have PTSD. Potential participants were informed about the study by their clinician within the IAPT service. They were given participant information sheets about EMDR and about the proposed research. If they wished to be referred their contact details were passed to the researcher and a meeting was arranged at a place and time convenient for the potential participant. At the meeting the research and EMDR were again explained, the participants were told what would occur and how that would differ from usual treatment. They were informed that they could leave the research at any time and this would not affect the care they received, they would go back to the IAPT service and receive the usual treatment with no penalty. Potential participants were offered the chance to ask questions of the researcher. If they were happy to continue they were asked to sign a consent form and then they were screened for the inclusion and exclusion criteria and informed immediately of whether or not they were eligible for the study or not, and if not why not. The referrer was informed of the outcome. Referrals and screening took place from August to December 2013. All participants who began the treatment were invited for interview. Figure 3.2.2 shows the flow of participants through the study, table 3.2.2 details participant demographics.

Figure 3.2.2 Flowchart of participant recruitment and retention

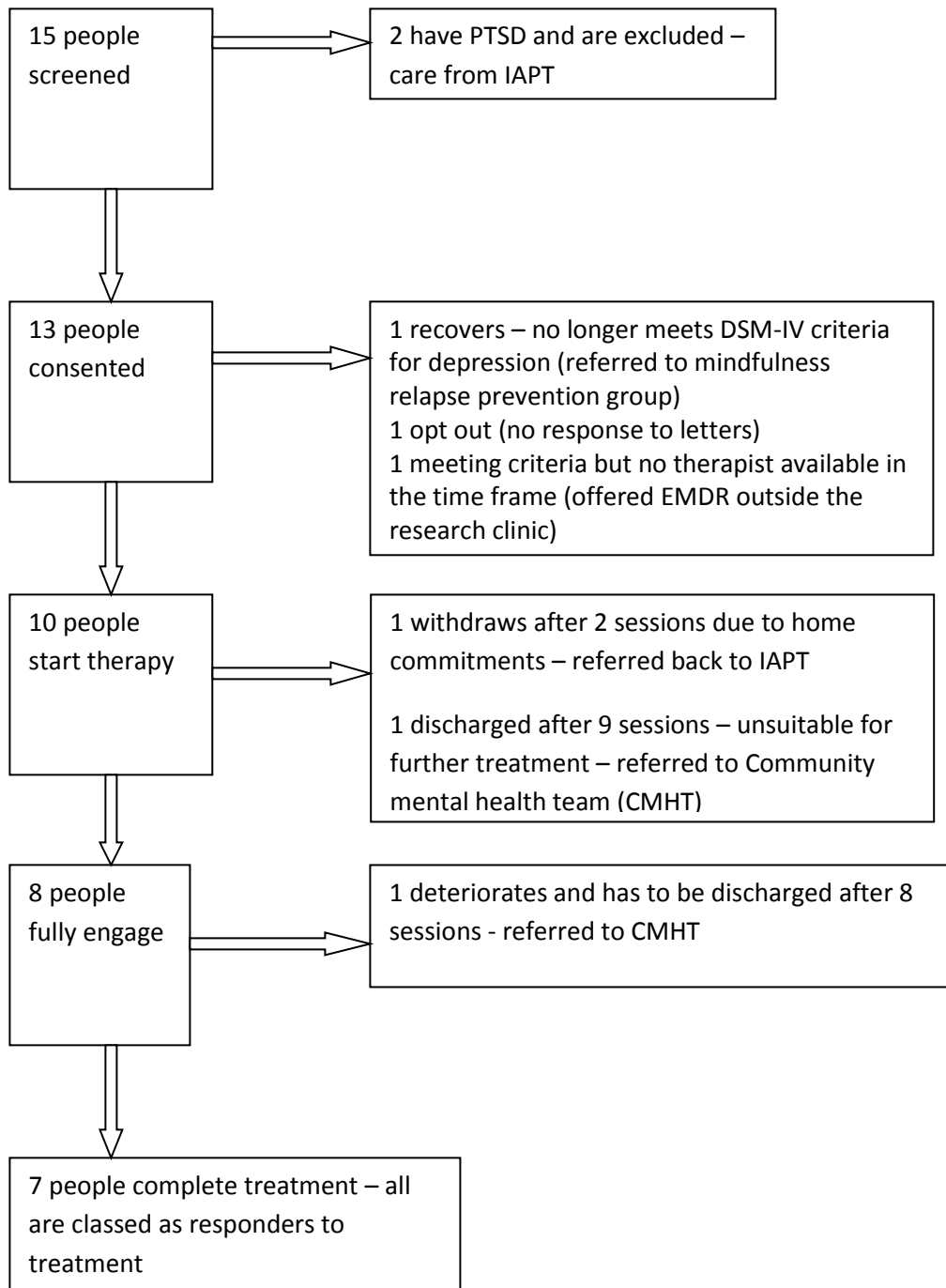


Table 3.2.2 Participant demographics

Age range	29-65
Age mean	46
Female	8/13
In employment	8/13
Age at first onset of depression - range	9-43
Those under 18 at first onset of depression	7/13
Number of episodes of depression - range	2-15
Length of Current Episode of depression	1 month – 10 years
Taking antidepressants at start of study	12/13
History of antidepressant use	13/13
History of at least 1 trial of a talking therapy	13/13
Number of trials of talking therapies - range	1-6
Previous talking therapies attended	Cognitive behavioural therapy, computerised CBT, cognitive analytical therapy, counselling, bereavement counselling, workplace wellbeing, psychodynamic therapy, hypnotherapy, pain-team psychology
Diagnoses identified by the MINI:	
Major depressive disorder	13/13
Recurrent MDD	11/13
Melancholic MDD	5/13
Dysthymia	7/13
Panic disorder	4/13
Agoraphobia	8/13
Social phobia	8/13
Generalised anxiety disorder	11/13

Of the 13 participants 12 are white British and one is white European. Although this may seem to be unrepresentative it is not. All these clients were recruited from the south of Sheffield. Sheffield in its entirety is not a particularly diverse city, it is 80.8% white British according to the City Council's website. However in the south of the city, in the electoral wards where these participants were recruited from, that rises to 92% white British. So to have one person in the

sample who is not white British is representative for the area studied. Table 3.2.3 shows the pre-treatment outcome measure scores for the participants.

Table: 3.2.3 Participant scores on the validated measures at the pre therapy screening appointment

Participant	HRSD	BDI-ii	PHQ-9	SASS	GAF	IES-r
1	17	33	17	31	65	13
2	27	50	24	24	40	52
3	13	21	10	47	61	11
4	25	48	24	31	68	50
5	26	43	19	30	35	54
6	13	26	10	44	62	19
7	21	34	18	29	52	45
8	22	28	17	26	38	33
9	-	-	-	-	-	-
10	23	23	13	29	68	25
11	10	24	10	43	65	15
12	26	37	17	30	42	35
14	19	21	9	24	55	54

Participant 001, hereafter given the pseudonym 'Alice', was a healthcare professional. She had been suffering with recurrent depression of the melancholic type since the age of 15. She recalls at least five episodes of depression and was prescribed antidepressant medication for most of them including the current episode which is five months long at the start of treatment. She had taken several different antidepressants before and she had also had three years of psychodynamic therapy a few years ago. As well as depression she also screened positively for social phobia and generalized anxiety disorder. On the daily measure her energy levels are substantially worse than her low mood and level of interest because she also suffers from a chronic physical health problem. At screening she scored mild to moderate depression on the HRSD but on the BDI-ii her score indicated a severe depression and her PHQ-9 score indicated moderately severe depression. Her SASS score indicated impaired social functioning, the IES-r did not indicate that she was traumatised.

Participant 002, 'Pauline', had to give up work due to a physical health problem. She met the criteria for double depression (current major depressive episode and long term dysthymia). Her depression had begun when she was 40 and she had experienced two chronic episodes of depression since that time. She was prescribed medication and had received two types of counselling in the past. The current episode had lasted for 18 months when she was screened and had not responded to counselling or antidepressant medication. She had several anxiety comorbidities including panic disorder, agoraphobia and social phobia. Her HRSD and PHQ-9 scores indicated severe depression and her BDI-ii score, extreme depression. Her SASS score indicated impaired social functioning, the IES-r indicated that she was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 003, 'Sophie', was a healthcare professional. She met the criteria for double depression. She had experienced her first depressive episode at the age of 15 and had two episodes in total. She described her current episode as having lasted for 'years', she was prescribed antidepressant medication and had received counselling and two courses of CBT without remission. She did not screen for any comorbidities. Her HRSD score only indicated mild depression but her BDI-ii and PHQ-9 scores both suggested moderate depression. Her social functioning scores did not indicate any clinically significant impairment; the IES-r did not indicate that she was traumatised.

Participant 004, 'Robbie', was a civil servant. He screened positive for double depression, He reported two very long episodes of depression beginning at the age of 10. He reported the current episode lasting for nine years. Robbie had also received three separate courses of CBT, he had been prescribed anti-depressants but stopped taking them as he didn't think they helped. He also screened for social phobia and generalized anxiety disorder. His HRSD score suggested moderate depression, his PHQ-9 score, severe depression and the BDI-ii indicated extreme depression. His SASS score indicated impaired social functioning, the IES-r indicated that he was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 005, 'Maxine', was retired. She met the criteria for current and recurring melancholic type depression. She first experienced depression at the age of 23 and reported that she had been depressed six times in total. She said the current episode had lasted for three years. She was

taking antidepressant tablets and had received CBT at the start of this episode but although she found it of some help she remained depressed. She also screened positive for generalized anxiety disorder. Her HRSD and PHQ-9 scores indicated moderate to severe depression, the BDI-ii indicated extreme depression. Her SASS score indicated some impairment in social functioning, the IES-r indicated that she was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 006, 'Martin', was self-employed. He met the criteria for recurrent and chronic major depressive disorder. His first experience of depression was at the age of 43 and he had been chronically depressed for at least six years at the point of screening. He was prescribed antidepressant medication and had been given CBT and Cognitive Analytic Therapy in the past. He also screened for agoraphobia, social phobia and generalized anxiety disorder. He also expressed some obsessive thoughts that had the potential to be subclinical obsessive compulsive disorder. His HRSD and PHQ-9 scores indicated a moderate depression, although the BDI-ii suggested moderately severe. The SASS did not indicate any social functioning impairment; the IES-r did not indicate that he was traumatised.

Participant 007, 'Lewis', ran his own business. He met the criteria for a current and recurrent melancholic depressive disorder. He had a six year history of depression and had suffered two episodes of depression. The current one had lasted for seven months at the time of screening. He was currently taking antidepressants. He had previously tried hypnotherapy and counselling for his depression. He met the criteria for panic disorder, agoraphobia, social anxiety and generalized anxiety disorder. Lewis also had a history of cannabis use but he stopped using six months before the study began. The HRSD indicated moderate depression, the PHQ-9, moderately severe depression and the BDI-ii severe depression. His SASS score suggested impaired social functioning, the IES-r indicated that he was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 008, 'Andrew', was an unemployed man with melancholic, recurrent and chronic depression. Andrew reported that his first episode of depression was at the age of 42 and he had three episodes. He reported the current episode had lasted one month but under the screening

assessment he met the criteria for dysthymia. He had tried counselling in the past with limited success. He was currently prescribed Mirtazapine but was determined to stop this against medical advice due to the side effects he was experiencing. He also screened for generalised anxiety disorder. Andrew's depression rating scales scores all indicated moderately severe depression with impaired social functioning, the IES-r indicated that he was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 009, 'Rebecca' was an admin worker. She reported that her depression began in primary school but she could not remember more exactly than that. Primary school in the UK is from the ages of 5-11. 'Rebecca' was included in error at this stage as she met the criteria for dysthymia but not MDD. She never received EMDR and was referred to a mindfulness relapse prevention programme.

Participant 010, 'Sandy', was a mature student. She met the criteria for current and recurrent depressive disorder and dysthymia. She first became depressed at the age of 17. She had since had four or five episodes but she was not able to be exact. She felt the current episode had lasted for about a year and had been on at least two different antidepressants and tried a course of counselling in 2000. Sandy reported that this counselling required her to record dream diaries which she did not find helpful. She also screened for agoraphobia, social anxiety and generalised anxiety disorder. Sandy's depression scale scores all indicate a moderate depression with impaired social functioning, the IES-r did not indicate that she was traumatised.

Participant 011, 'Julie', was a health care professional. She had current, recurrent and melancholic type depressive disorder. She reported that she had first become depressed as a teenager, around the age of 15, and she had been depressed on around 15 separate occasions since then. This episode had lasted approximately four months at the time of screening. She had tried several antidepressants in the past and previously received counselling. She also suggested a possible agoraphobia and reported a history of bulimia when she was much younger. This was no longer an issue. The HRSD indicated a mild level of depression whilst the PHQ-9 and BDI-ii both indicated moderate depression. The SASS score suggested no impairment of social functioning, the IES-r did not indicate that she was traumatised.

Participant 012, 'Laura', was a woman who was currently on sick leave from her admin job due to the depression. Laura screened positive for current and recurrent major depressive disorder. She states that she first became depressed at the age of 26 and has had four episodes of depression. The current episode is three months long and she is taking antidepressants for that. She has also accessed counselling and workplace wellbeing. She displayed a large amount of anxiety screening for panic disorder, agoraphobia, social phobia and generalised anxiety disorder. Laura's depression rating scale scores all indicate a moderately to severe level of depression with impaired social functioning shown on the SASS scale, the IES-r indicated that she was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

Participant 014, 'Daniel' was a man who was currently unemployed due to ill health. He screened positive for major depressive disorder and recurrent MDD. He reported having first become depressed at the age of 15 and had rarely been well since then. He thought his current episode had lasted 10 years. He was currently taking antidepressants and had taken at least three different types in the past. He had also had four different periods of talking therapy including counselling and psychology from the pain-team. He also had been to two other therapists but he was unsure what type of therapy it was. He also had an interest in Neurolinguistic Programming (NLP), around which he had done a lot of reading. He was also an anxious person screening positive for panic, agoraphobia, obsessive-compulsive disorder and generalised anxiety disorder. Daniel's depression rating scale scores indicate moderate depression on the HRSD and BDI-ii and mild depression on the PHQ-9 and the SASS indicated impaired social functioning, the IES-r indicated that he was traumatised but did not have a criterion A event needed for a PTSD diagnosis.

3.2.9 Treatment

After screening and the completion of the symptom questionnaires, participants were assigned to a therapist. EMDR was delivered twice weekly by therapists trained in EMDR by the EMDR International Association institute approved trainers. Although the Improving Access to Psychological Therapy (IAPT) team agreed to help recruit participants to the study they did not have sufficient numbers of EMDR therapists working for them for the study to use that service to deliver the treatment as well. Therapists were recruited through the Sheffield Health and Social Care NHS Foundation Trust. The Royal College of Nursing Foundation granted the researcher a

bursary of £2500. The School of Health and Related Research at The University of Sheffield also provided a data collection grant of £2000 to cover the cost of the therapists' wages.

The EMDR adhered to the manualised 8 stage protocol design by Francine Shapiro and approved by the EMDR International Association institute. To ensure the therapists were working to the standard EMDR eight stage protocol they were asked to complete a therapy process record. Although the Medical Research Council guidelines (Craig et al., 2008) recommend that treatments are modified to meet the needs of different populations the original EMDR 'Standard Protocol' was used. The protocol was designed for PTSD but it has been claimed (Shapiro, 2009a) to also be useful for treating depression. There are many varied protocols for EMDR but there is no depression protocol. Before making changes to the Standard Protocol it is necessary to discover its deficits in this population.

After stage three of the protocol (identification of the traumatic memory), therapy was briefly interrupted so that this memory could be recorded and reaction to it tested using the memory narrative, SCR/HRV and Likert scales for distress. This testing took 15 minutes to one hour and was usually able to be done between sessions so the client did not have to wait to begin therapy again. Once this was done they returned to the therapist and completed the therapy and worked through the protocol. This was the only interference in the normal structure of the therapy process.

The therapists had no other involvement with the research. The principal investigator did not treat the participants. Participants were offered up to 20 sessions as this is comparable to a course of CBT currently offered in the UK for depression, but also because Cuijpers et al (2010) found that for psychotherapy to be effective in chronically depressed clients at least 18 sessions are required. The actual number received was the decision of the therapist and based on clinical need. Therapy was delivered twice a week. Case studies have suggested EMDR may be successfully delivered in this way (Grey, 2011), partly because it does not have the homework component of CBT so the participant does not need time to complete it. It has also been reported that by increasing therapy from once to twice a week the effect size can be dramatically increased even when keeping the total number of sessions constant (Cuijpers et al., 2013).

Participants could continue with any other medical input they normally received, as this could have changed over time and increased and decreased according to client need, including discharge

if this was appropriate, this continued with the only restriction being that they cannot begin any other psychological therapy during the experimental period. It was also necessary that the participants did not change their anti-depressant medication during the therapy period as this may have affected testing. It was decided beforehand that any participants that did require a change of medication would be removed from the study but none required this.

3.2.10 Concealment and priming

All the assessments (BDI-II, HRSD, SASS, GAF, IES-r, PHQ-9, Likert scales, HRV/SCR and content of memory) were done with or by the researcher and the therapists were not involved in the testing.

There are two reasons for conducting a follow up session after three months. Firstly the therapist may inadvertently or deliberately prime the participant to report changes in memory when none have occurred. Priming is only really considered to be relevant for a few weeks after therapy has (Brewin, 2012) concluded, so if it did occur repeating the tests several months later would show a reversal to pretreatment test results. The second reason is to test the idea of reconsolidation. If the memory has changed and this is via reconsolidation it should remain stable. If it is not stable at three months then this suggests that the memory either did not change in the first place or it did but not via reconsolidation.

3.2.11 Study 1 – The clinical impact of the intervention

Aim: To investigate the clinical impact of EMDR upon long term depression

RQ - 1 Is there an improvement in depressive symptoms and social functioning, and if so is it stable at follow up?

RQ - 2 Are there any identifiable differences between the responders and non-responders which might be able to predict response in others?

Participants underwent a range of symptom and functioning testing before and after therapy and at a follow up period of three months. The symptom and social functioning scales are a good indication of what has happened to the participant's depressive symptoms.

Non-responders to treatment can tell us about the different groups that may or may not benefit from different types of therapy. By comparing the responders and non-responders we may be able to discover who will be most effectively treated by EMDR for depression. It may be that non-

responders have not fully processed their memories, or that it was not the memories that were the problem in the first place.

Study 1 analysis

The primary outcome for measuring impact was the Hamilton Rating Scale for Depression. To assess whether participants had made clinically significant and statistically significant changes the Reliable Change Index was used. Reliable change is a way of determining if the change you see is likely to be real or simply an artefact due to the unreliability of the instrument (Jacobson and Truax, 1991). A reliable change index (RCI) can be determined for each measure. If the client's score on the measure changes between the initial and end of therapy reading by more than the RCI, then we can be confident that in 95% of cases this change will be real and not due to error in the measure (i.e. it is statistically significant). The RCI was calculated for all of the scales. Due to the small sample size in this study, previously published means, standard deviations and internal consistency scores derived from larger samples were used to calculate the RCIs as they may be considered more reliable (see table 3.2.3).

For all scales the literature was searched for published means and standard deviations. Where more than one population was found the one most like this study was used. Also found were published measures of internal consistency of the measure (Cronbach's Alpha). These figures were then put into the Reliable Change criterion calculator (www.psych.org/stats/rcsc1.htm accessed 30.10.13 15.25). Where more than one Alpha score was found the lowest score was used this should make the RCI increase and thereby giving the most stringent criteria. Although test-retest reliability is considered preferable to Cronbach's Alpha it could not be found for every measure and so Alpha was used throughout to have a consistent result.

The formula for the standard error of change is:

$$SD1 * \sqrt{2} * \sqrt{1 - rel}$$

where SD1 is the initial standard deviation

sqrt indicates the square root

rel indicates the reliability

The formula for criterion level, based on change that would happen less than 5% of the time by unreliability of measurement alone (i.e. the reliable change index), is:

$$1.96 * SD1 * \sqrt{2} * \sqrt{1 - \text{rel}}$$

This gives you a RCI which is the number of points on the measure to signify reliable change. Change can occur in either direction so change can be deterioration or improvement. Increasing SD or decreasing internal consistence will increase the RCI meaning more change is necessary to be sure it is reliable.

Table 3.2.4 Reliable change

Measure	Published mean	Published SD	SEDI pretherapy mean	Published α	SE of change	Reliable Change
HRSD (Miller et al., 1985, Cusin et al., 2010)	21.2	6.2	20.3	0.88	3.04	5.95
PHQ-9 (Smarr and Keefer, 2011, Kroenke et al., 2001)	17.1	6.1	16.3	0.86	3.23	6.33
BDI-ii (Brouwer et al., 2013)	16.6	10.2	33.4	0.90	4.56	8.94
IES-r (Coffey et al., 2006)	39.5	17.2	32.0	0.86	9.10	17.84
SASS (Bosc et al., 1997)	29.65	8.73	33.1	0.74	6.30	12.34
GAF (Jones et al., 1995, Söderberg et al., 2005)	52.4	14.6	54.2	0.74	10.53	20.64

Clinically significant change

Although it is important to know that change is reliable it must be meaningful to the clinicians as well and therefore needs to be related to caseness and severity of illness. The RCI tells us if the change is statistically significant, it doesn't necessarily tell us if it is clinically meaningful (Barkham and Mellor - Clark, 2003). Many articles reporting a clinical measure will assign a cutoff level to

determine what levels of symptoms are clinically significant enough to be given a diagnosis. Sometimes they also suggest levels of change that can be considered clinically significant or an adequate response to treatment. This acknowledges that although a client's symptoms may not disappear entirely this does not mean that a treatment has not made a major improvement to their life.

Table 3.2.5 Clinically significant response

Measure	Caseness cutoff	Clin sig response
HRSD (Schramm et al., 2011, Hamilton, 1960)	<8 is nonclinical	At least 50% reduction in score and score is now less than 15
PHQ-9 (Kroenke et al., 2001, Smarr and Keefer, 2011)	<10 is nonclinical	At least a 5 point reduction
BDI-ii (Smarr and Keefer, 2011)	No official level of caseness but some have suggested at least 16 points is required for diagnosis	5 point decrease = minimal improvement 10-19 = moderate 20+ = large
IES-r (Creamer et al., 2003)	33 or more indicates PTSD	
SASS (Bosc et al., 1997)	35 or less indicates impaired social functioning	
GAF	No official level of caseness	

The other way to look at clinically significant change is to calculate if a client has moved from the clinical distribution to a normative population distribution. There are three different ways to calculate this (Evans et al, 1998) but what is required is to know the clinical and normative distributions and that the measure is reliable enough that two standard deviations from the mean for both distributions do not overlap. Unfortunately this study had such a small sample that a reliable distribution is not possible and the published distributions for the GAF and IES-r have very large standard deviations. This makes using this method almost meaningless for this study with the measures chosen. For this reason the standard cut off points used in previous studies and highlighted in table 3.2.4 will be used as a clinically significant benchmark. Using the RCI and clinical significance as a guide the pre and post therapy HRSD scores for each participant were plotted on a Jacobson Plot (Jacobson and Truax, 1991).

The progress of the participants as measured by the repeated assessment measure was plotted graphically for visual analysis, as is standard in a SCED study (McLeod, 2003). Often in a single case

design such as this the data from the repeated measurement is autocorrelated, i.e. your mood score today is likely to be related to your mood yesterday. This phenomenon is widely accepted although its significance is not (Parker and Vannest, 2009). To avoid the possibility that autocorrelation could affect the analysis of the data it can be tested for (Manolov and Solanas, 2008). Although quantifying SCED data in this way is not always necessary it is needed when attempting to provide support for evidence based practice and clinical effectiveness (Parker and Vannest, 2009). For each participant the autocorrelation was calculated. As the autocorrelation for each participant showed widely differing patterns, no obvious correction could be made as each would have needed different ones. However, as this data are looking at outcome rather than attempting to make a prediction it does not need to be subjected to a time series analysis (Campbell, 2012) and therefore the autocorrelation is less of a problem.

A correlation analysis was done on the different daily measures to see if they were all measuring related concepts, their means were also examined. The raw data from the low mood measure was plotted, with raw data and a smoothed version to enable seeing the trends and levels more easily. The median of seven days of data was taken and the moved on one day and take the median of the next seven days etc. (Franklin et al., 1996). This helped remove some, although not all, of the variability. However an autoregressive moving average model (ARIMA) was not used as there were less than 50 time points in the baseline phase and ARIMA is more appropriate to predictive time series rather than outcome time series like this one. Despite this a time domain rather than frequency domain was still considered the most appropriate as it is necessary to know if the levels of low mood changed over time during the treatment rather than just how frequently the participant was feeling low (Huitema and McKean, 1991). The differences between the baseline phase and the treatment phase were analysed with a Mann-Whitney U test as they were not normally distributed. The Mann-Whitney U test looks for the difference between the means of the whole of the two phases. One method for analysing SCED graphs to look for change is to see if there is a difference between them at different stages. The treatment phase was split in two to see if there were more treatment phase data points below the baseline mean at the end of the treatment phase rather than the beginning. If there are, this would indicate that even for those whose mean score was not different towards the end of treatment they became more consistently lower scoring. This corresponds to constantly lower mood. Finally, the number of points in the treatment phase that were below the baseline phase mean was calculated (Ma, 2006). This is another indication of a downward trend to lower levels of depression.

Jacobson plots were also completed for the secondary measures (BDI-II, HRSD, GAF, SASS, IES-r.). Paired t tests were used (as long as all assumptions are met) to see if there are any significant differences between the participants' scores before and after the intervention. This was done on all measures (BDI-II, HRSD, GAF, SASS, IES-r.) although the HRSD is the primary outcome and the others are to support the primary outcome or provide possible explanations for unexpected results. This was done twice, once combining all results and once using only the responders. Correlations were carried out to see if the different measurements changed in relation to each other. Over the three studies this research will make use of several t tests as long as the assumptions are met. The assumptions for a two sample t test are that the data are continuous, the data are normally distributed, the variances of the two populations are equal, the two samples are independent and both are random samples from their population (O'Rourke et al., 2005). The assumption that is likely to pose a problem for this data is the normal distribution; this is because it is a very small sample size. Where necessary a non-parametric test was used instead.

As these tests require data to have been gathered at the start and end of treatment, consideration must be given to those who drop out at various stages and are not able to provide end point data. Any participants who initially agree to join the study but then change their minds and do not start EMDR sessions with a clinician will be counted as a failure of research not a failure of the treatment and will be excluded from the analysis. Participants who begin but then drop out will be considered a failure of treatment and will be included.

Following therapy, participants were classified into responders and non-responders. Remission was defined as a score of eight or lower on the 24 item HRSD, response was defined as at least a 50% reduction from baseline and a final score of 15 or less on the HRSD (as used by Schramm et al and the ReVAMP trial). Responders to treatment had either a clinically important improvement in symptoms or a remission of their depression. Comparisons were made between the two groups to see if there were any significant differences between them at the pre-treatment phase in demographic data such as age range, mean age, gender, socio-demographics, age at onset of depression, number of previous episodes of depression, length of current episode and IES-r score pre-therapy. These data were specifically chosen because they have been identified by previous researchers as likely to impact upon response to psychological therapy (Saxon et al., 2008, Roth and Fonagy, 2005, Thase and Howland, 1994). The exception here was the IES-r. Although it has

not been identified previously, the importance of PTSD or at least traumatisation in the treatment of EMDR makes this an outcome of importance.

Independent t tests were used (assuming test assumptions are met) to compare the differences in the before/after scores and the initial data in the responder and non-responder groups for change in HRSD, age, age at onset, number of previous episodes of depression, length of current episode and IES-r score. A chi square test was used to test to see if the gender makeup of the two groups was different. Due to the low numbers involved in this research it may be that the numbers in each group are too low to undertake meaningful statistical analysis. In this case the outcome will be descriptive instead.

Outcomes were also grouped according to which therapist participants saw. These two groups were then compared using t tests (assuming test assumptions are met) to see if there was any significant difference between them. If there is this would indicate that therapist effect was key in determining who responded and who did not.

Data quality is also reported in several ways. The amount of missing data for each participant for the daily measure is listed. Correlations of the ranked standardised measures were calculated at the start and end of treatment. This is to indicate if they are reporting the same relative severity for each participant. The PHQ-9 was also taken at several points during treatment. This was correlated with the daily low mood measure for those days for each participant to see if they are related.

With the exception of the Reliable Change Index, calculations for all quantitative analysis utilised Microsoft Excel (Microsoft Office 2010) and SPSS 21 (IBM).

3.2.12 Study 2 - Investigating possible mechanisms of action

Aim: To investigate predictions of the AIP and previous EMDR research

RQ - 3 Has the content of the target memory become less distressing and more adaptive, and if so is it stable at follow up?

RQ - 4 Has the emotional impact of the target memory and the psycho-physiological response to it decreased?

RQ - 5 Is there a relationship between the changes in symptoms and the changes in memories?

As was described in chapter two, there remains much discussion around possible mechanisms of action in EMDR. One of the key predictions from the AIP model is that in EMDR the client accesses a distressing memory and reprocesses it with more adaptive information so that in the future this memory is less distressing. The AIP also claims that this is the key way in which EMDR affects mental health problems as the memory of the distressing event is the trigger for the current difficulties and by changing the memory, the trigger is removed. These research questions aim to test these predictions.

Study 2 analysis

The memory descriptions were analysed by content analysis. The AIP model behind EMDR predicts that after treatment memories will be less distressing, less negative and more adaptive. Content analysis required the transcriptions to be coded for distressing, positive/adaptive and miscellaneous themes. As deciding what is a positive or negative theme could be subjective this was done by the researcher but also cross checked the scoring with someone else to ensure reliability of the coding. The ratios of the different themes were then compared before and after EMDR therapy to see if the EMDR has led to an increase in the amount of positive/adaptive themes being expressed. This was done using the Mann Whitney U test. Although a narrative description such as this could be analysed qualitatively in much more detail this is not necessary to answer the research question. The predictions of the model are clear that there should be a quantitative difference between before and after memories.

Before and after comparisons of 4 Likert readings, HR, HRV and SCR were undertaken. Paired t tests (assuming test assumptions are met) were done to look for significant differences before and after treatment. The AIP predicts the response to the memory will be less emotional, less vivid, and more distant after treatment.

Correlation analysis between before and after HRSD score, content analysis and HRV/SCR will show if these measures are changing in the same way. The AIP model predicts that as the depression (measured by HRSD) decreases then the content of the memory will become more positive and the heart rate variability will increase. Predictions of the direction of change in skin conductance response are debatable however, whatever the change direction, it should be consistent and correlate with the HRV, content analysis and HRSD if the model originally proposed by Gunter and Bodner (chapter 2) and expanded here (chapter 3) is correct.

In the interviews the participants were asked about the helpful aspects of EMDR and what happened to them during the Bilateral Stimulation. Where this elicited relevant information it was included again using a mixed methods matrix to introduce the comparisons and then expanded with quotes and explanation from the interviews. This will be helpful to answer questions about mechanism because the model is clear the bilateral stimulation is the key. Participants may be able to describe what did or did not happen to their memory during the bilateral stimulation.

3.2.13 Study 3 - Acceptability

Aim: To develop a framework to analyse EMDR therapy from a client viewpoint.

RQ - 6 Do clients find EMDR to be an acceptable treatment for long term depression?

Although we can tell how well EMDR affects the participant's symptoms from the standardised scales, it is less straight forward to tell how it affected them. To try to understand EMDR from the point of view of the client interviews will be conducted two months after therapy has finished.

Between the end of therapy and follow up the participants were invited back for a semi structured interview to discuss their experience of therapy, the interviews were conducted by an independent assessor. The interview topic guide was agreed in advance, it was based on the information gained from the HAT questionnaires, questions were on three main themes:

1/ the participant experience of therapy – how did it compare to other interventions they have had?

2/ experience of memories – did they report that they have changed with regard to content or impact? (It is possible that the memory will remain as it was but be less dominating – similar to pain in pain management therapy)

3/ experience of depression – do they feel better? Have symptoms / functioning changed in a way that they recognise?

By basing the questions on the HAT questionnaires, the interviewer can be more certain of covering the subjects that are most pertinent to the therapy experience without having to rely on the client's memory of a therapy session that may have taken place many months earlier. A topic guide for the interviews is in the appendix.

Study 3 analysis

A framework analysis approach was used to analyse the interview data. This involved five steps: familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Srivastava and Thomson, 2009).

Familiarisation: getting to know the transcripts of the data, becoming immersed in it.

Identifying a thematic framework: key to the framework analysis is the concept that although the research questions were designed around *a priori* issues, and these may form some of the key themes, it is also possible for unexpected themes to emerge from the data.

Indexing: identifying portions of data that correspond to certain themes and coding these appropriately.

Charting: indexed data are now removed from the transcript and placed in charts of corresponding themes linking key portions of data.

Mapping and interpretation: Analysing key characteristics of the data set.

This process has been described by Spencer, Ritchie and O'Connor (2003) and Bazeley and Jackson (2013) and contains eight steps to manage, describe and analyse the data.

Data management:

Step one - Go through each transcript, marking concepts and themes as you go through

Draw up a framework or index of these themes

Step two - Apply the index to each transcript (use Nvivo)

Step three - Redo each transcript, ensure the coding is consistent

Step four - Use Nvivo to create thematic charts and compare each subtheme for each client

Descriptive analysis

Step five - Detection - Review chart to find range of views across themes

Step six - Categories – interpretation of themes, attempt to form categories that can incorporate and discriminate between different manifestations

Step seven - Classifications – take categories to a higher level of abstract interpretation (consider if typologies are appropriate)

Explanatory analysis

Step eight – look for patterns and clustering of subgroups (for mixed methods this includes subgroups based on quantitative data)

Predictions here are likely to be based on how well the person does in the therapy. Someone who does well will probably be more favourable towards the treatment than someone who remains depressed. Most reports of EMDR in PTSD give descriptions of change in the visual image of the target memory. It is therefore predicted that this will also occur when used with depression. The interviews were transcribed, then analysed on the latest version of Nvivo.

3.2.14 Mixed Methods Analysis

After the qualitative and quantitative data have been analysed separately they will be combined and reanalysed in a mixed methods format. This aim of this is to look for patterns and clusters of subgroups that were not apparent when the data was scrutinised separately. The primary method for this will be to use a mixed method matrix (O’Cathain et al., 2010), taking the tables created for the Framework analysis and adding in quantitative data to it. This allows data for each participant to be compared side by side, this is integration done at the level of analysis and is sometimes called integration through joint display (Fetters et al., 2013).

Another method is triangulation; here the themes from the different methods are compared. This is done at the level of interpretation and looks specifically for areas of convergence, complementarity (expansion) and divergence in the datasets (O’Cathain et al., 2010, Fetters et al., 2013).

3.2.15 Procedure

1. Clients referred to step three in IAPT (individual therapy) had an assessment with a therapist (CBT or counselling). This therapist identified clients who met the research entry requirements (require step 3 care, aged 18 or over with primary diagnosis of long term depression) and told them about the study. If client was interested in participating they completed the contact form which was returned to the research team. The client was given two information sheets. One specifically about EMDR and one about the research itself.
2. The researcher contacted those who expressed an interest in participation and invited them for screening
3. Screening with MINI, if volunteer met criteria following screen then they were given detailed explanation of the study. If they still wished to be a participant they signed the consent form and completed the battery of symptom scales (HRSD, BDI-ii, GAF, SASS, IES-r, PHQ-9). The

HAT scale and the daily scale were explained to them as was the importance of completing these. Any questions they had regarding the scales, testing, EMDR or anything else to do with the research was answered.

4. Volunteers who meet the criteria and who signed consent form were assigned to an EMDR therapist (first 12 will be included). The therapists were bank workers brought in under the Sheffield Health and Social Care NHS FT (SHSC) governance procedures to deliver EMDR. The EMDR sessions took place at St George's community health centre. Any volunteers who did not meet the criteria or decided not to participate were diverted back into the normal IAPT channels. The referring IAPT therapist was informed by email of the outcome to ensure that no one went untreated.
5. Prior to beginning EMDR they had at least seven days of baseline period in which they completed the repeated measure every day. If there is a problem and the daily measures were not completed for the baseline period then the start of therapy was deferred for a week to allow time to collect the data. The participant met with the researcher and therapist to ensure they have understood the need to complete the research tools and if they needed any help in doing so. For example it was possible to send prompts by text message if people had difficulty in remembering to fill it in.
6. EMDR followed the manualised standard protocol and therapists were asked to complete the 'therapy process record' to check adherence.
7. After parts one to three of the protocol the participant returned to the University (or other arranged location) for pre-therapy testing. The memory narrative was recorded and the Likert scales and HRV/SCR readings taken.
8. Client returned to EMDR therapist, two x 50 minute sessions per week. Up to 20 sessions in total as determined by clinical need and the client continued to complete the daily measure of symptoms.
9. At each treatment session the client was asked to complete the PHQ-9 and HAT forms.
10. At discharge or after 20 sessions, whichever came first, the client again met the University researcher to do the post-therapy testing and interviews (over at least two sessions). At the end of the treatment period they stopped the daily measure.
11. At three months post-therapy the client was asked to do the follow up set of tests.

Chapter 4 – The clinical impact of the intervention

4.1 RQ - 1 Is there an improvement in depressive symptoms and social functioning following EMDR for long term depression, and if so is it stable at follow up?

Of the 13 participants recruited, three did not begin treatment (002, 009 and 014). The reasons for this are in the flow chart in Chapter 3.2. As they did not have any EMDR sessions they cannot be considered treatment failures and therefore their before therapy figures will not be included in the outcome data. Only one other participant did not provide after therapy outcome data, participant 008. He did begin therapy but he was discharged as the therapist deemed him unsuitable for treatment at the present time. After his discharge he did not respond to the researcher's requests to meet for end measures. This was then treated as a drop out. As this is a failure of treatment his scores are included in the analyses. Table 4.1 shows the number of sessions received by all the participants who had at least one session with a clinician and how many of those sessions contained bilateral stimulation – the technique that separates EMDR from other therapies.

Table 4.1: The number of sessions received by each participant and how many of those sessions contain bilateral stimulation (BLS)

Participant	Number of sessions	Number of sessions using BLS
1	17	12
3	20	17
4	20	16
5	16	9
6	9	1
7	19	15
8	9	0
10	2	0
11	20	10
12	20	12

4.1.1 Response on the primary outcome measure, the Hamilton Rating Scale for Depression

The HRSD was administered at the screening, after the final session and after a three month follow up. The figure (4.1) shows a Jacobson plot which shows the before and after scores and if any change is reliable, as measured on the reliable change index (RCI), and if it is clinically significant.

Any point on the plot that is below the central diagonal line (red) is a participant who improved during the course of therapy. If that point is outside the tramlines (blue) then the change is reliable and if it is below the horizontal line (green) then the participant is now in remission. On the HRSD change can be clinically significant but not reach the point of remission, i.e. the participant has shown a major improvement in his or her symptoms but they are not yet well enough to be considered in remission, table 4.2 shows this in more detail.

Figure 4.1: Jacobson plot for the HRSD

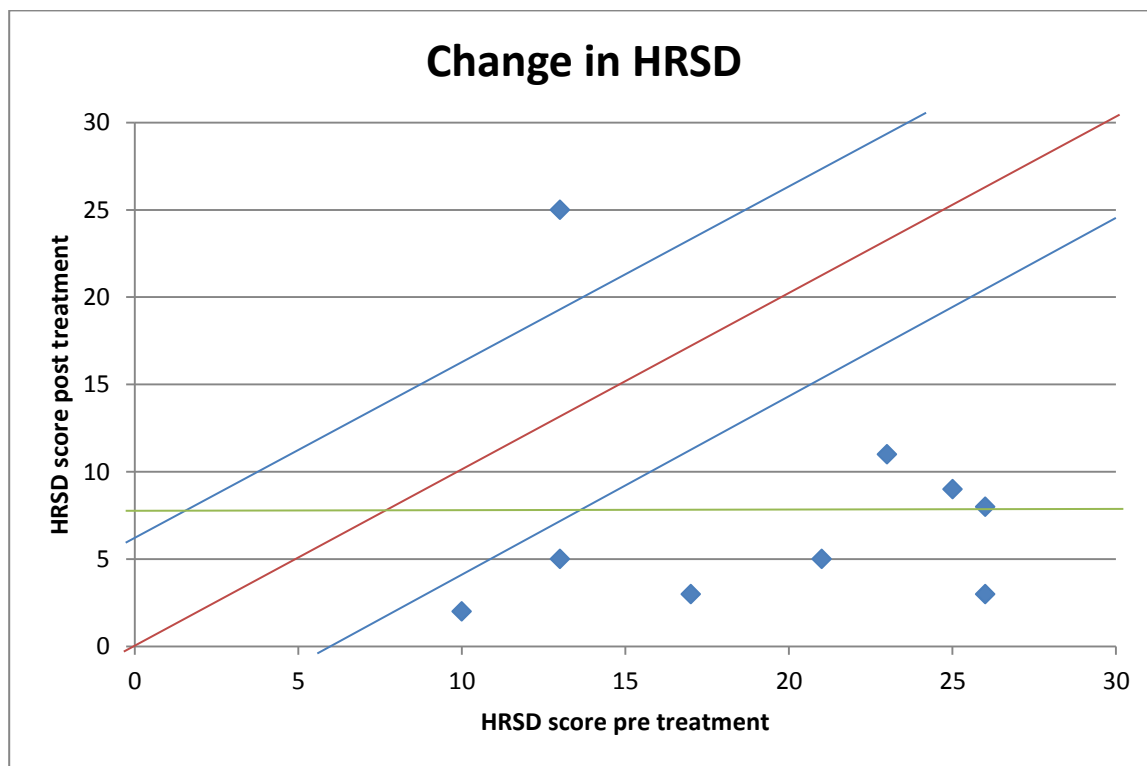


Table 4.2: the change in HRSD and if that change was reliable and clinically significant

Participant	HRSD Pre	HRSD Post	Change	Reliable?	Clinically sig?
1	17	3	14	Yes	Yes – remission
3	13	5	8	Yes	Yes – remission
4	25	9	16	Yes	Yes - response
5	26	3	23	Yes	Yes – remission
6	13	25	-12	Yes	Yes but deteriorated
7	21	5	16	Yes	Yes – remission
8	22	-	-	-	Drop out
10	23	11	12	Yes	Yes - response
11	10	2	8	Yes	Yes - remission
12	26	8	18	Yes	Yes - response
mean	20.3	7.89	11.4		

*a 6 point change is required for change to be considered reliable on the HRSD, for change to be clinically significant the participants post-score must be below 8 or have dropped by at least 50% and now be below 15.

The table and Jacobson plot show that of the nine people to have before and after measures only one of those deteriorated and all the others meet the criteria for response. Of these five are in remission (001, 003, 005, 007 and 011) and three responded to treatment with at least a 50% reduction in HRSD score and are now rated as having mild depression (004, 010 and 012). The one person to have deteriorated (006) went from mild to moderate depression with an almost 50% increase in his score. Table 4.3 shows if participants maintained their gains over a three month follow up period.

Table 4.3: HRSD score before and after the intervention and after the 3 month follow up

Participant	HRSD Pre	HRSD Post	HRSD F/U	Are benefits maintained?
1	17	3	4	Yes
3	13	5	6	Yes
4	25	9	7	Yes
5	26	3	7	Yes
6	13	25	5	Improved
7	21	5	4	Yes
8	22	-	-	
10	23	11	-	
11	10	2	5	Yes
12	26	8	-	
mean	20.3	7.89	4.9	

4.1.2 Repeated measures for individual participants

As well as the standardised scales the participants completed a visual analogue daily measure on levels of low mood, energy levels and levels of interest in activities. Levels of low mood and interest were very similar as one may expect and correlated across each participant, see table 4.4 in the appendix for details. However there were problems with the energy levels measure for this study. One of the clients had ME and one had an underactive thyroid, for this reason the energy levels questions were often marked as much worse than the low mood and lack of interest but may have not be associated with the depression. So even though the energy still correlates with the other measures its mean was generally much higher (table 4.5, also in the appendix). Therefore for the sake of consistency and to avoid the risk that physical health problems will confound the graphs the visual analysis has been provided for low mood only.

Figures 4.2 to 4.10 show the change in daily low mood for each participant. The top half of the figure shows raw data, the lower half shows a seven day median smoothed data. In both instances the red vertical line shows when the treatment phase began and the green one shows when stage 4 of the protocol began. The reason for this is that many people consider stage four, which is when the bilateral stimulation takes place, to be the key part of EMDR, it is certainly the part that makes it unique. Many early studies did not consider treatment to have begun until the eye movements started. Whereas for this study, any contact with the therapist is considered treatment as the therapeutic alliance (Klein et al., 2003) and the importance of non specific factors like treatment rationale and coping strategies (stage 2) (Ilardi and Craighead, 1994) are not to be underestimated, especially in depressed clients. However, by adding this second cutoff point on the visual analysis is allows the reader to compare these results with those of other researchers and to draw conclusions about the importance of the bilateral stimulation. Client 008 has no green line as he never started stage four. As can be seen in the upper portions of the figures there was very large variability in the mood ratings from day to day. For this reason the moving average (median) was calculated and also graphed. This shows a much smoother, although still highly variable, representation and makes it esier to see trends in the data. Although previous studies have suggested three day median smoothed data, this did not offer any visible smoothing so seven days was used instead (Franklin et al., 1996). On all these graphs a higher number on the y axis equals lower mood so a downward trend will show improvement in mood. The horizontal blue line shows the mean score in the baseline period.

Figure 4.2: low mood repeated data for participant 001 (Alice).

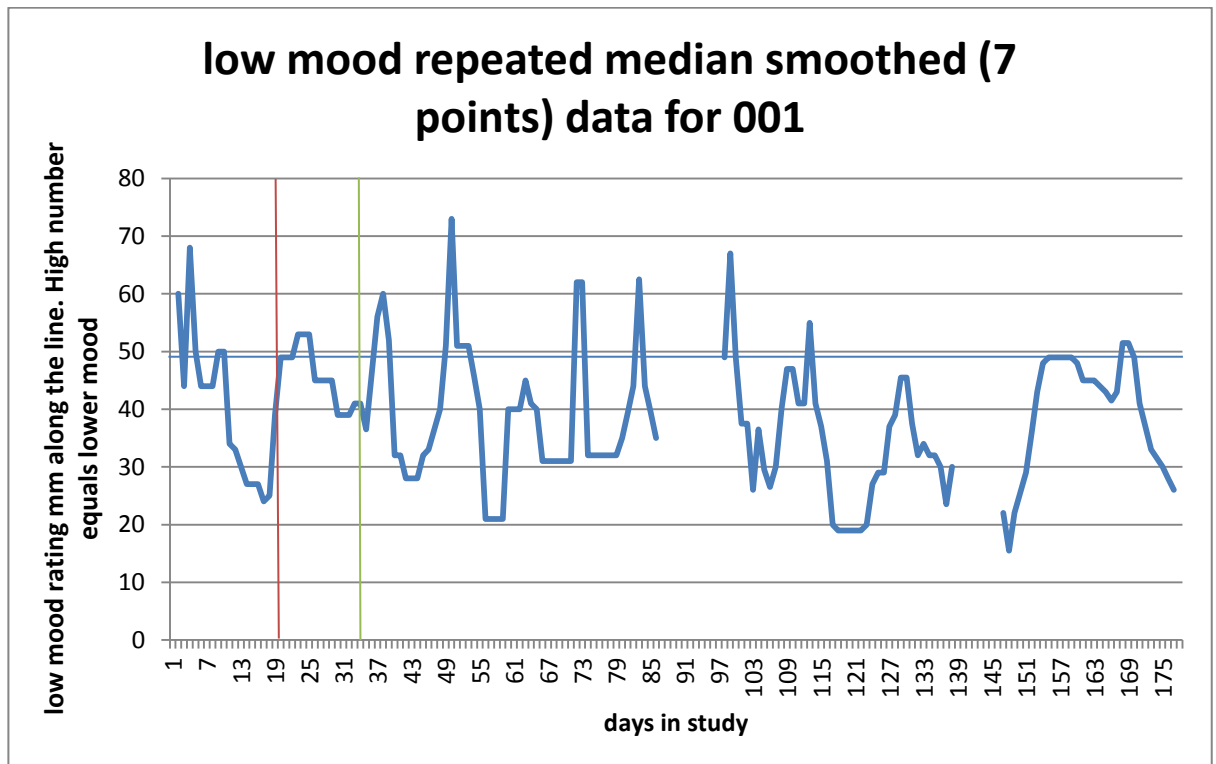
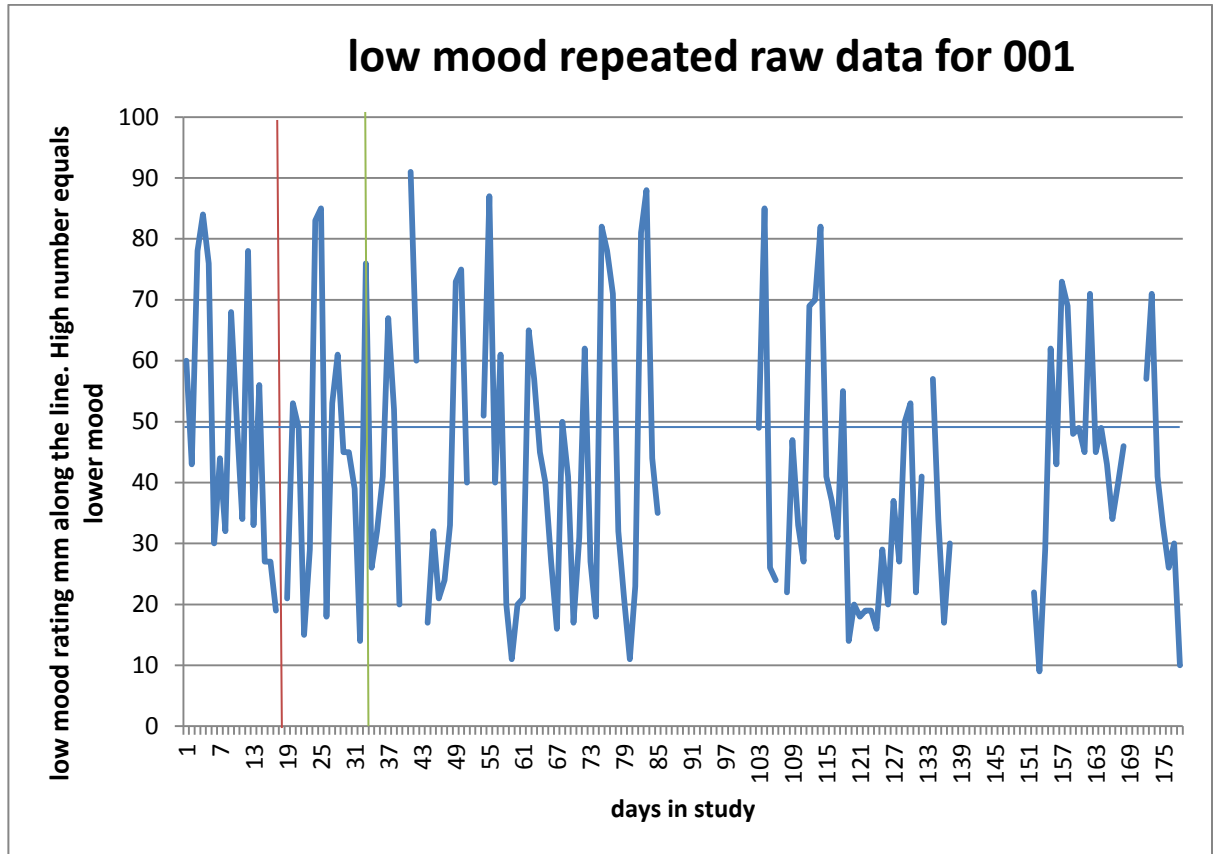


Figure 4.3: low mood repeated data for participant 003 (Sophie)

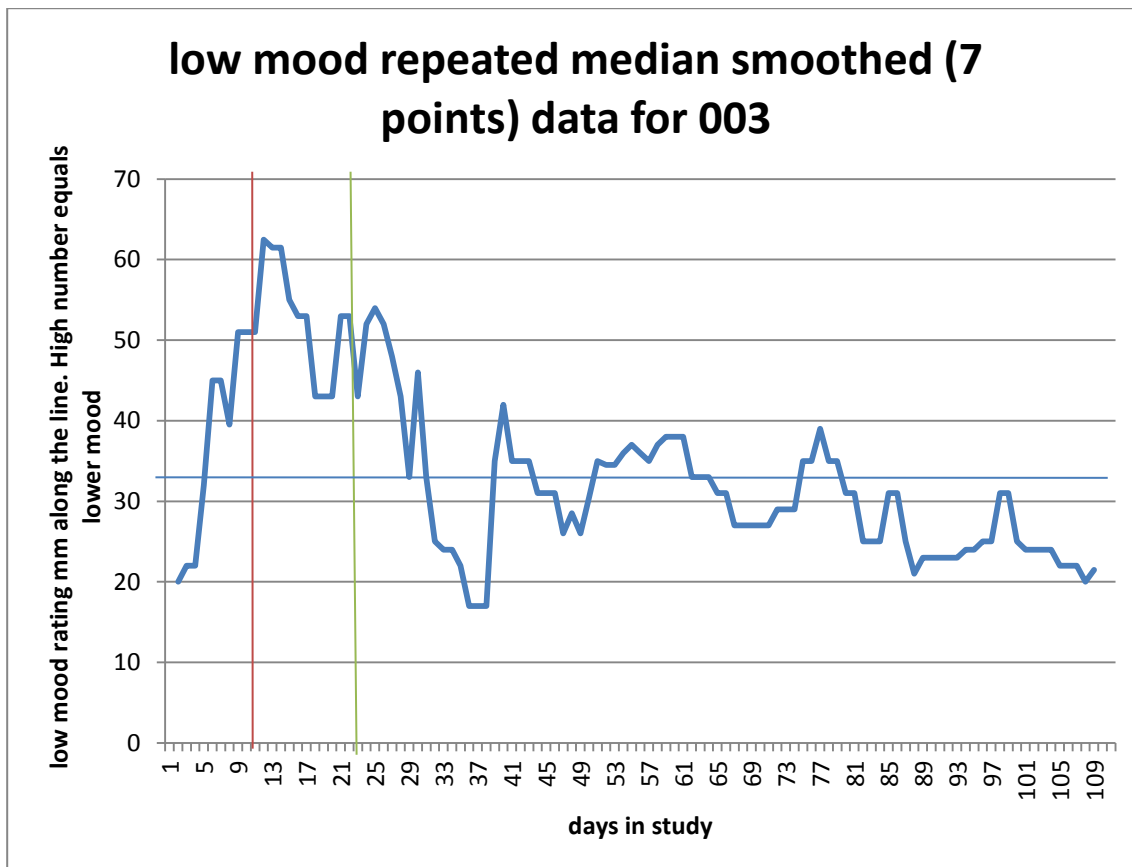
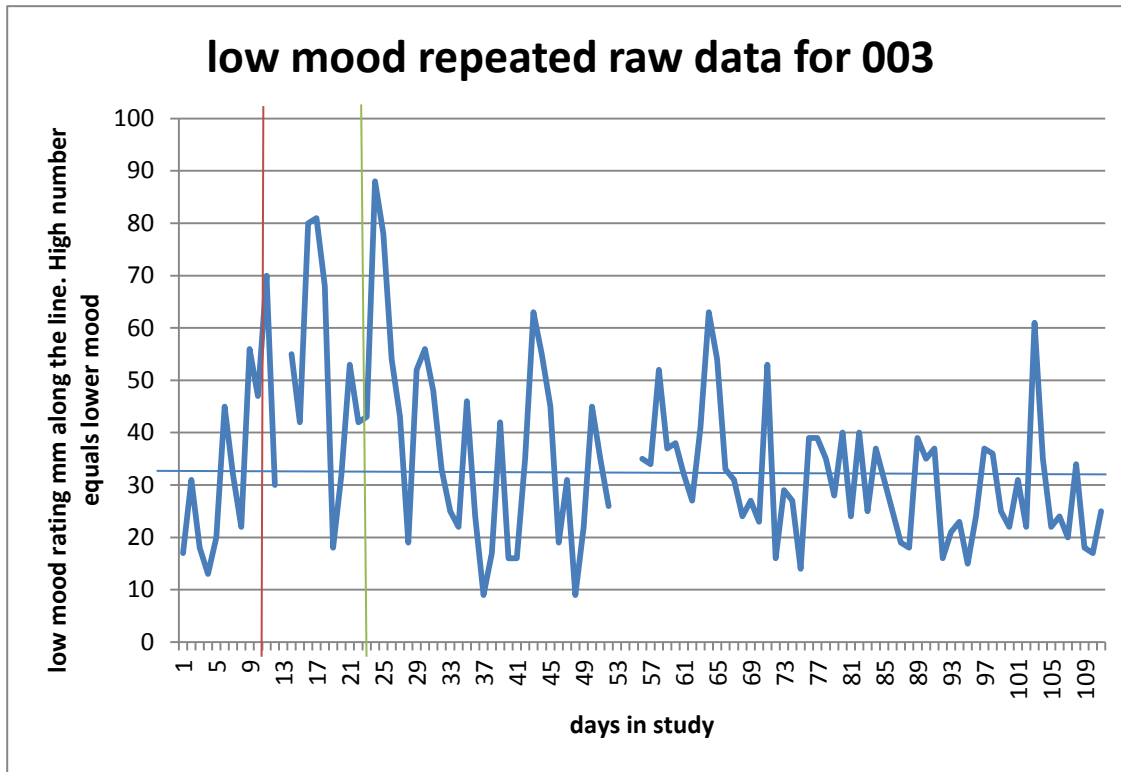


Figure 4.4: low mood repeated data for participant 004 (Robbie)

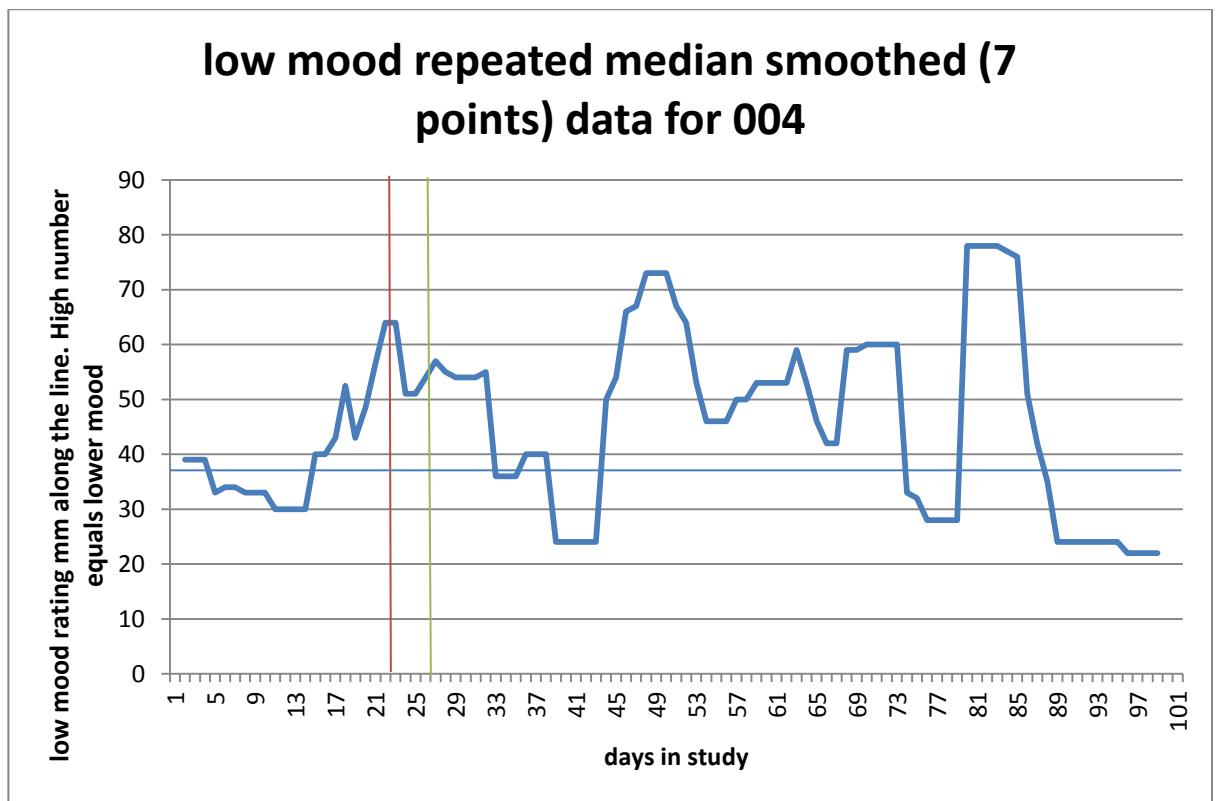
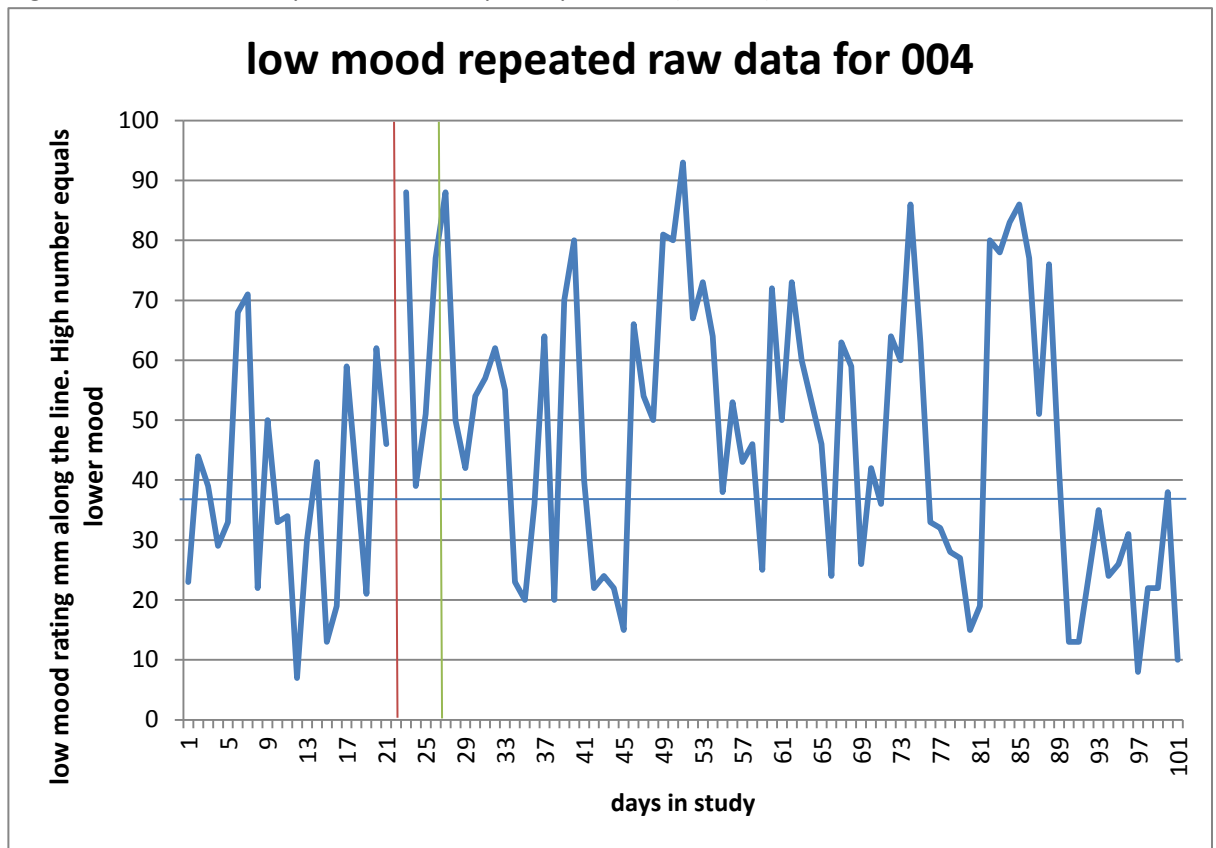


Figure 4.5: low mood repeated data for participant 005 (Maxine)

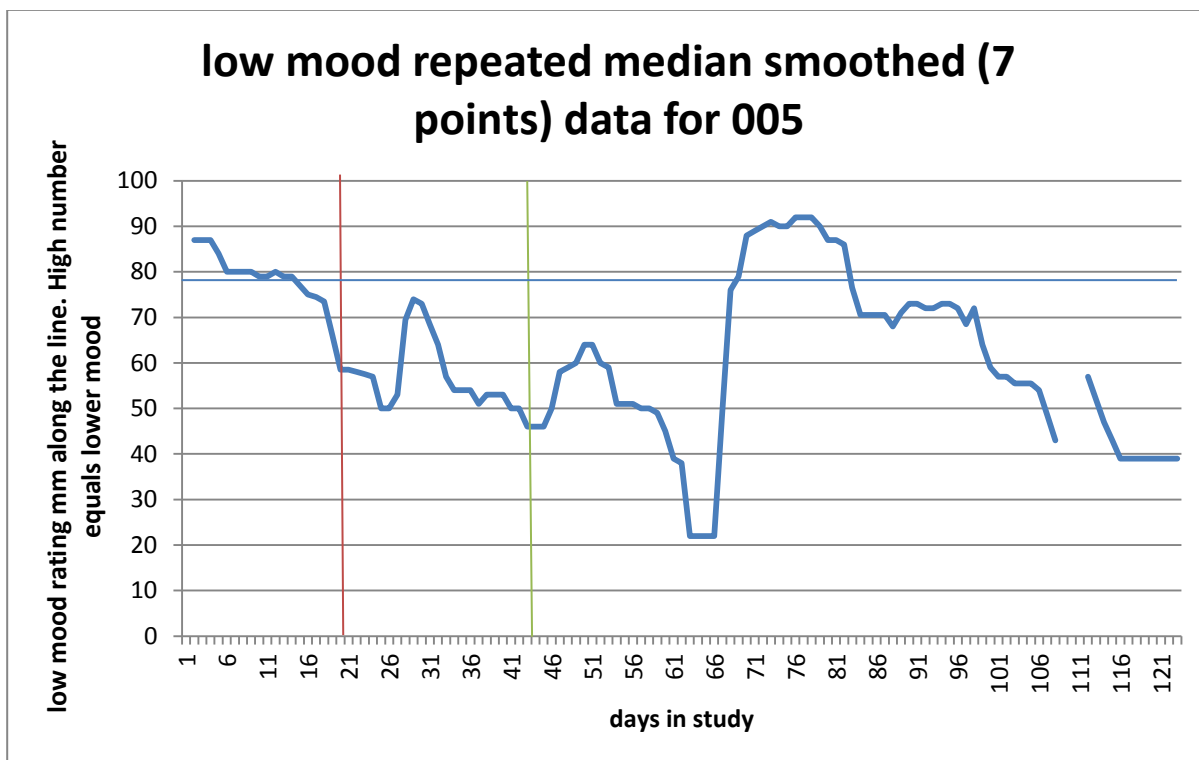
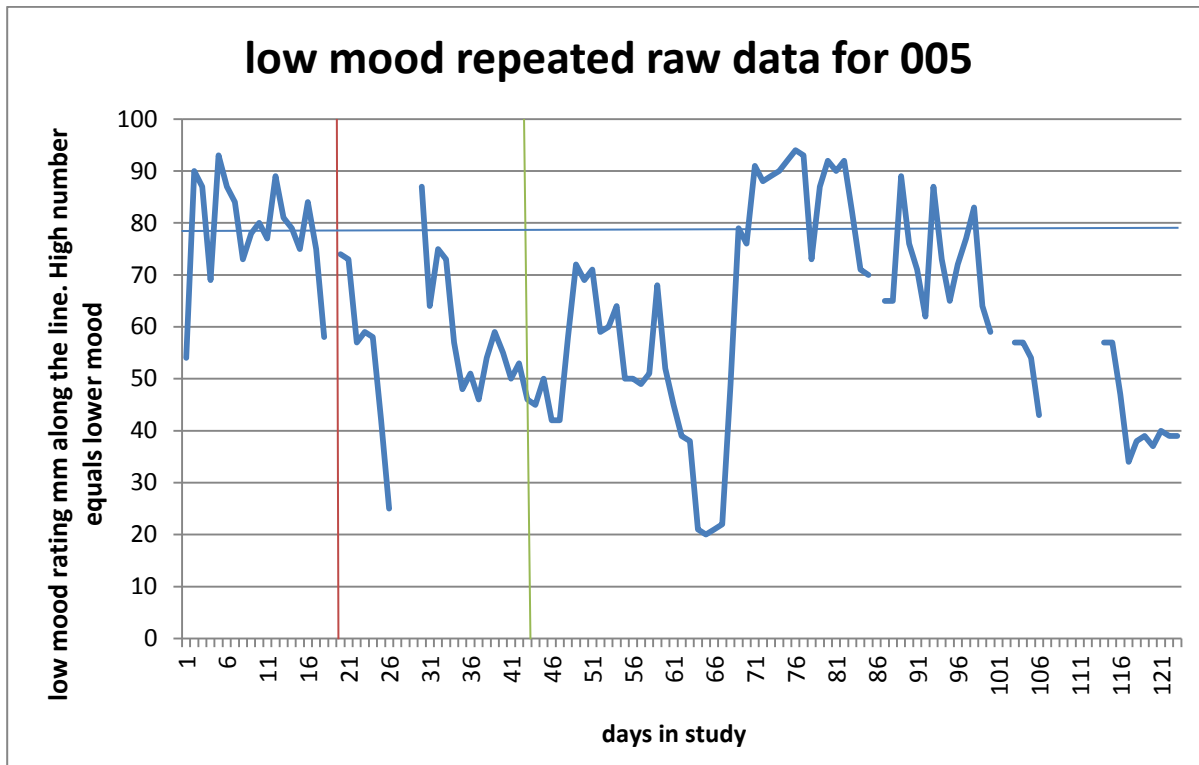


Figure 4.6: low mood repeated data for participant 006 (Martin)

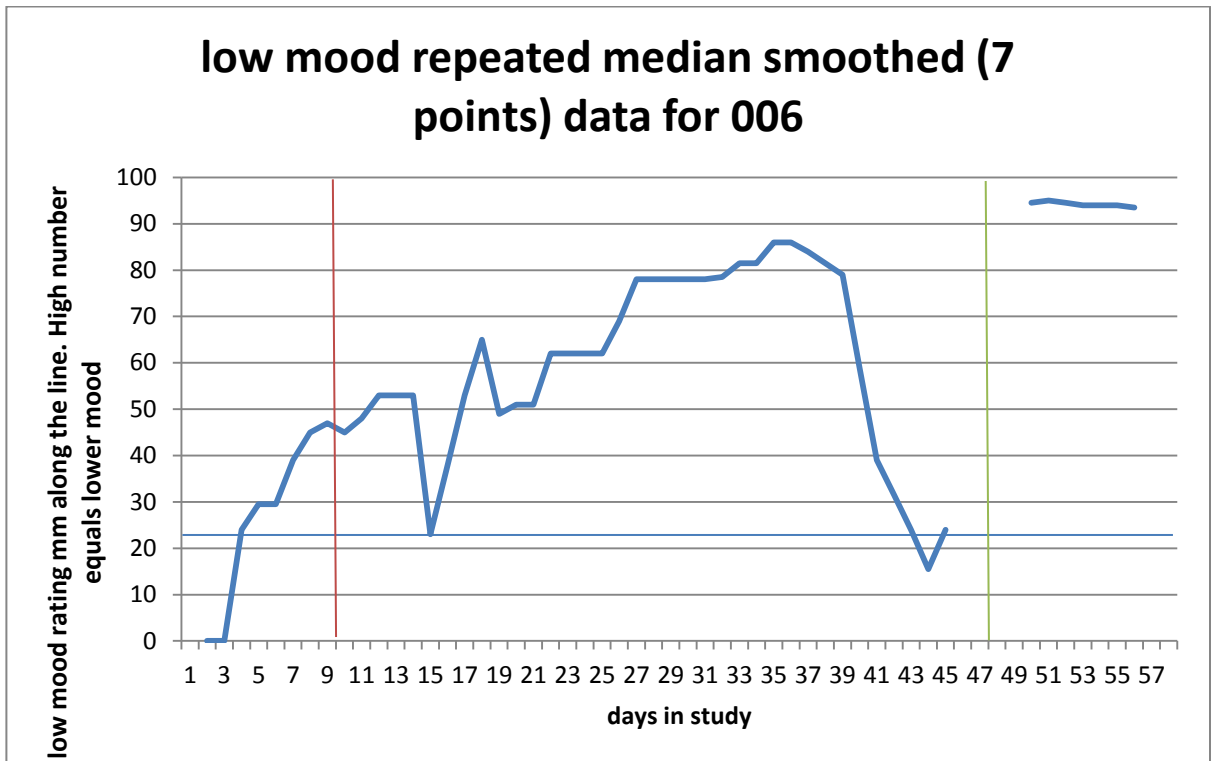
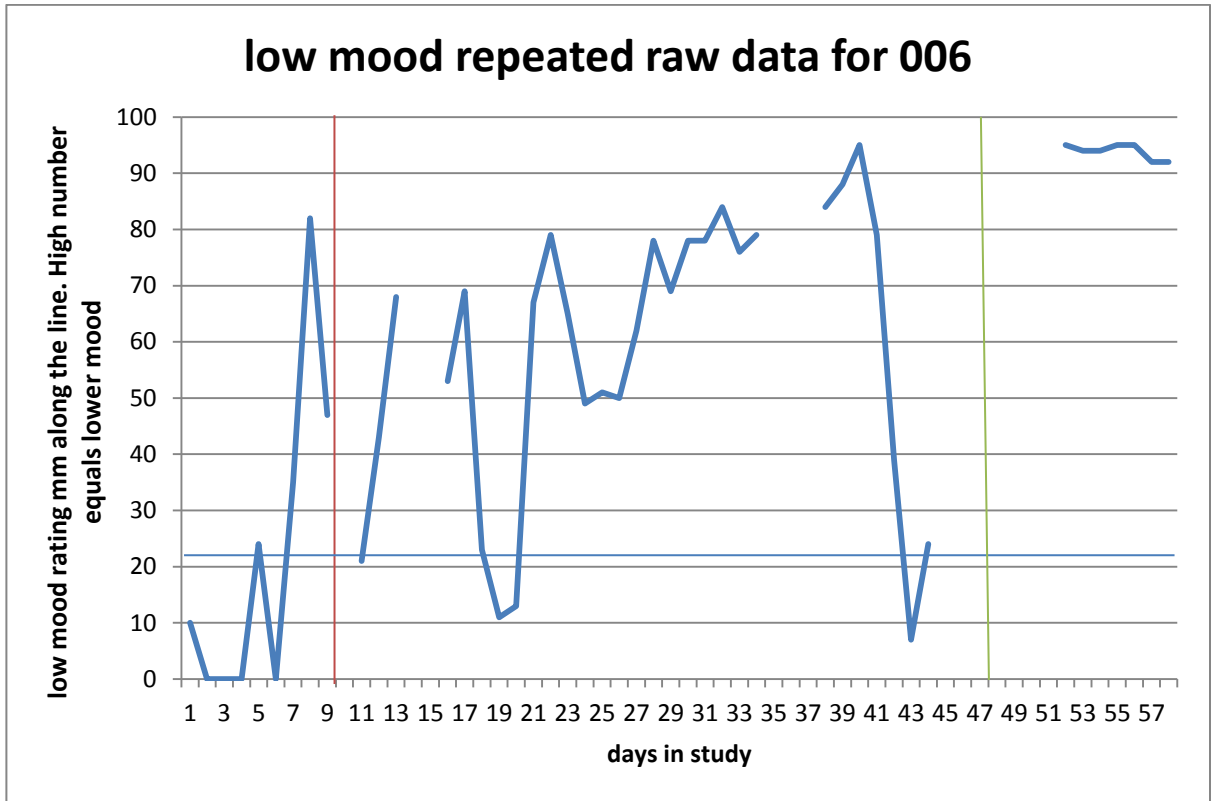


Figure 4.7: low mood repeated data for participant 007 (Lewis)

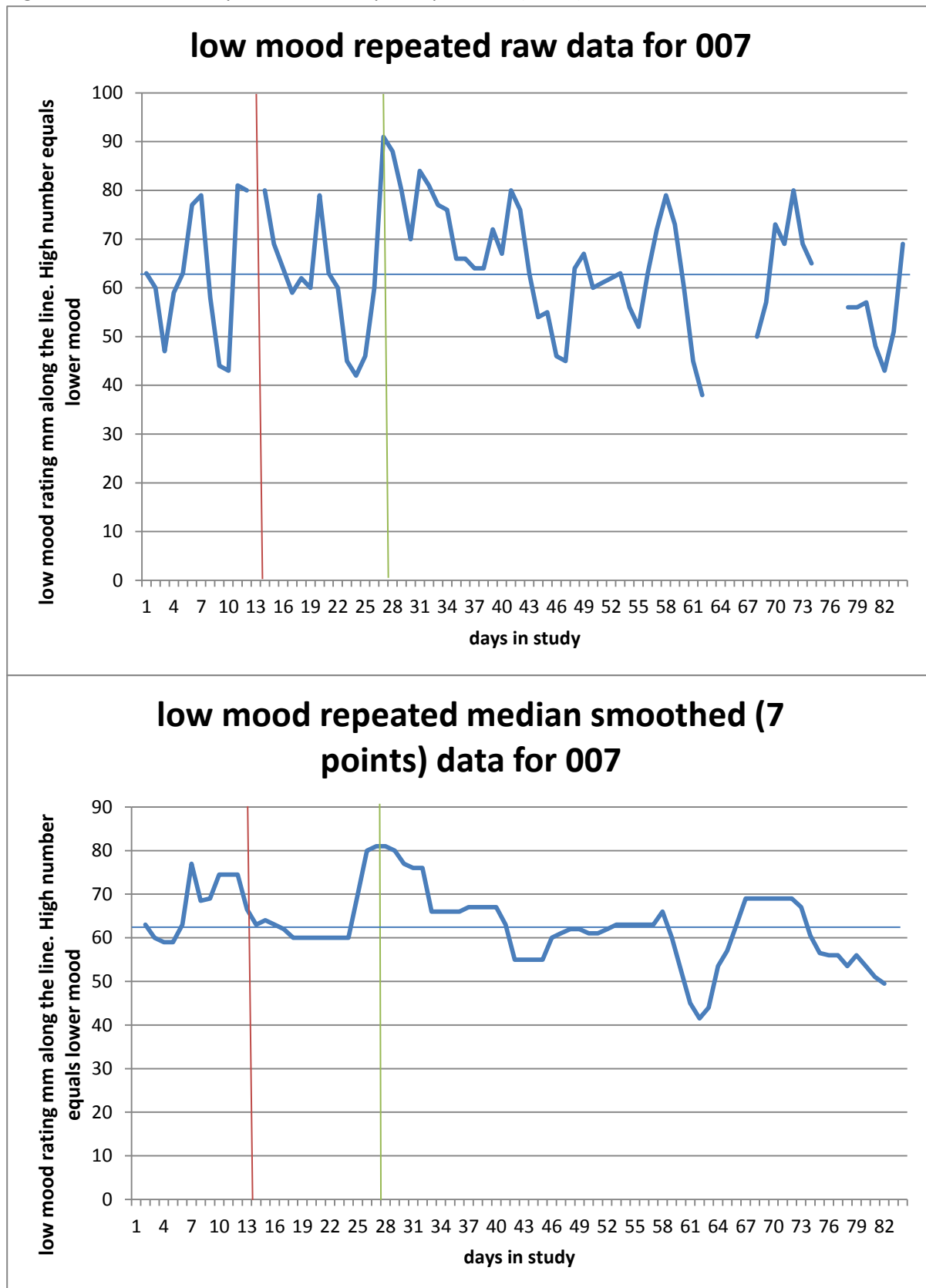


Figure 4.8: low mood repeated data for participant 008 (Andrew)

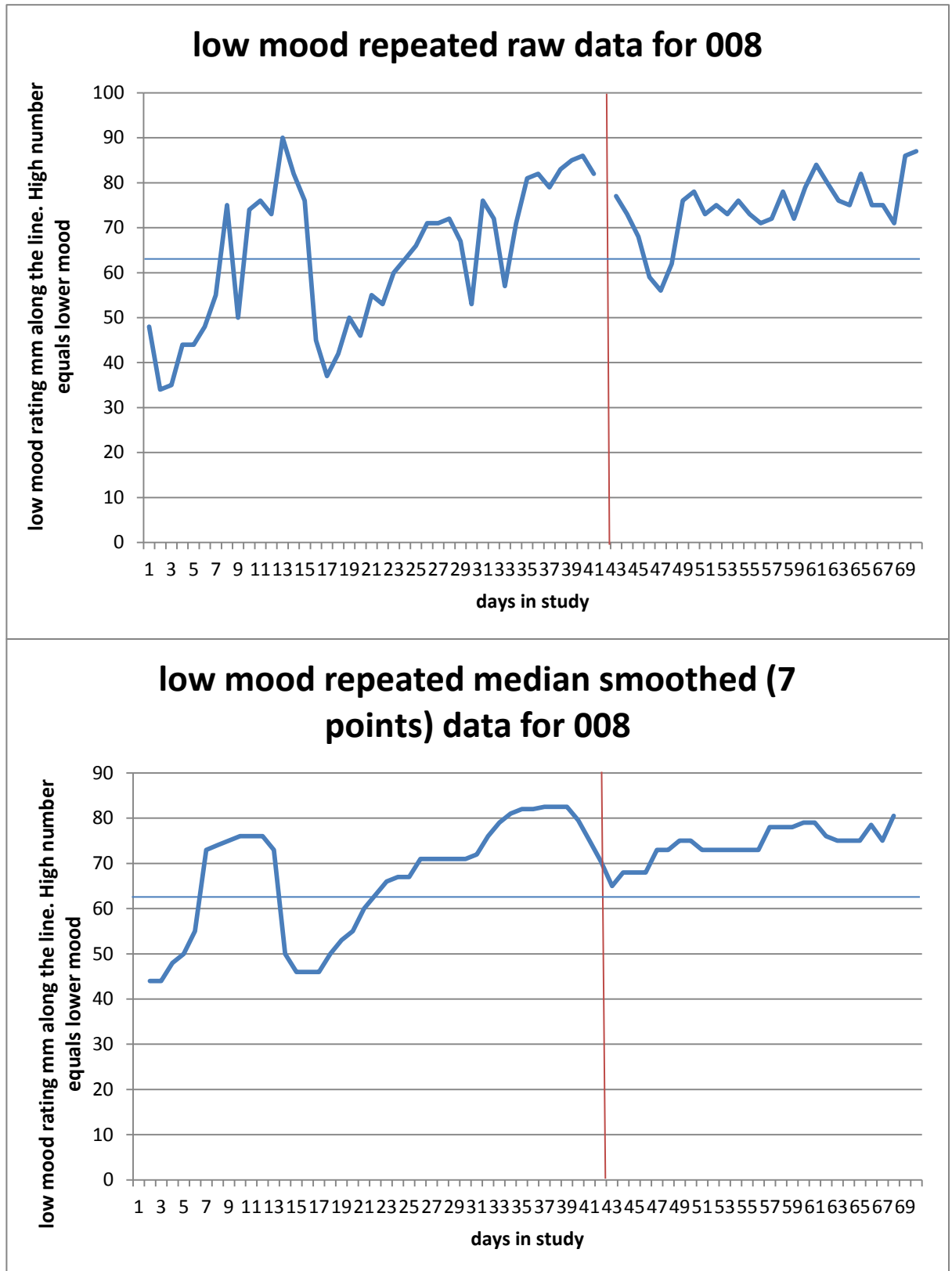


Figure 4.9: low mood repeated data for participant 011 (Julie)

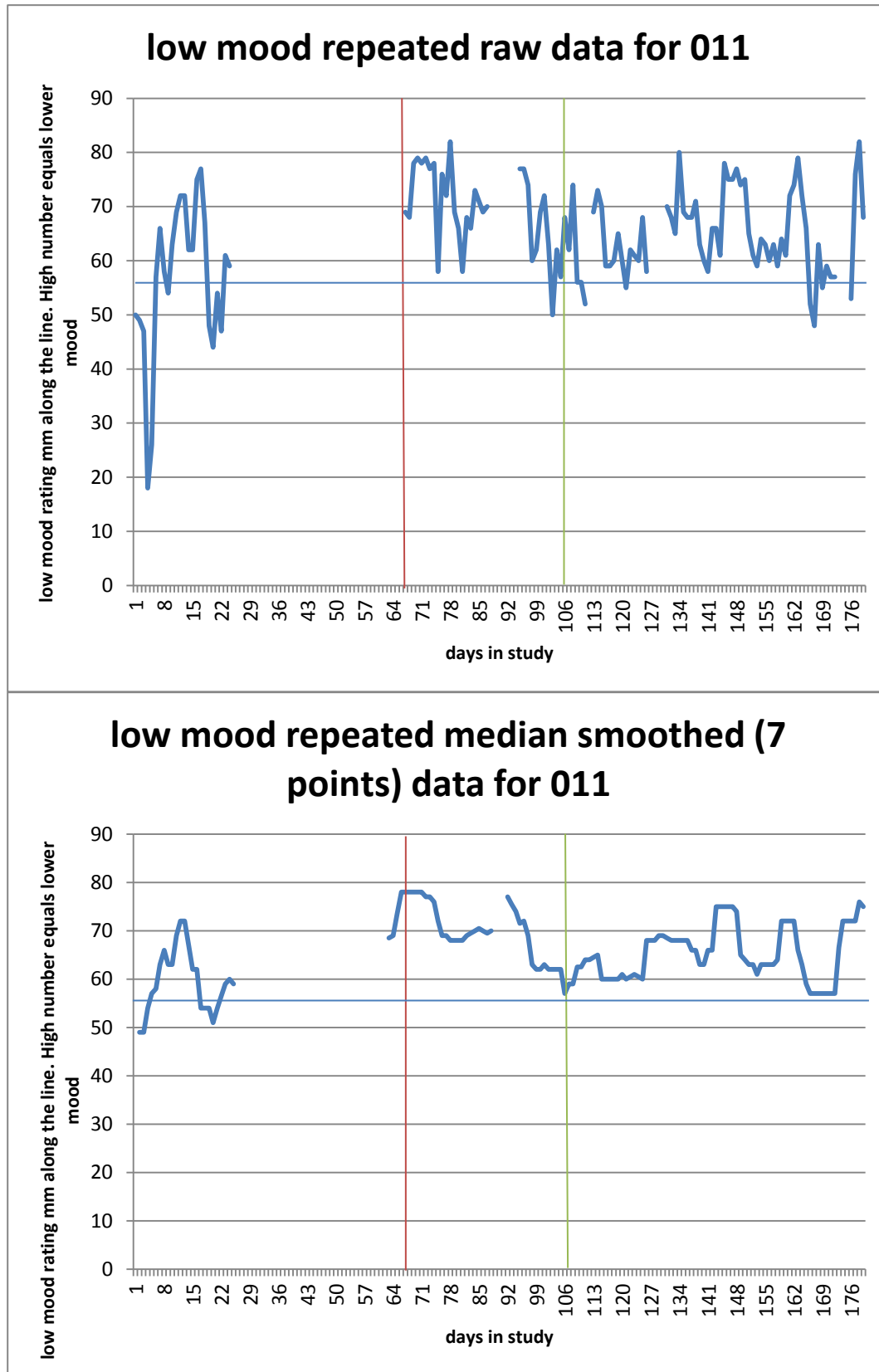
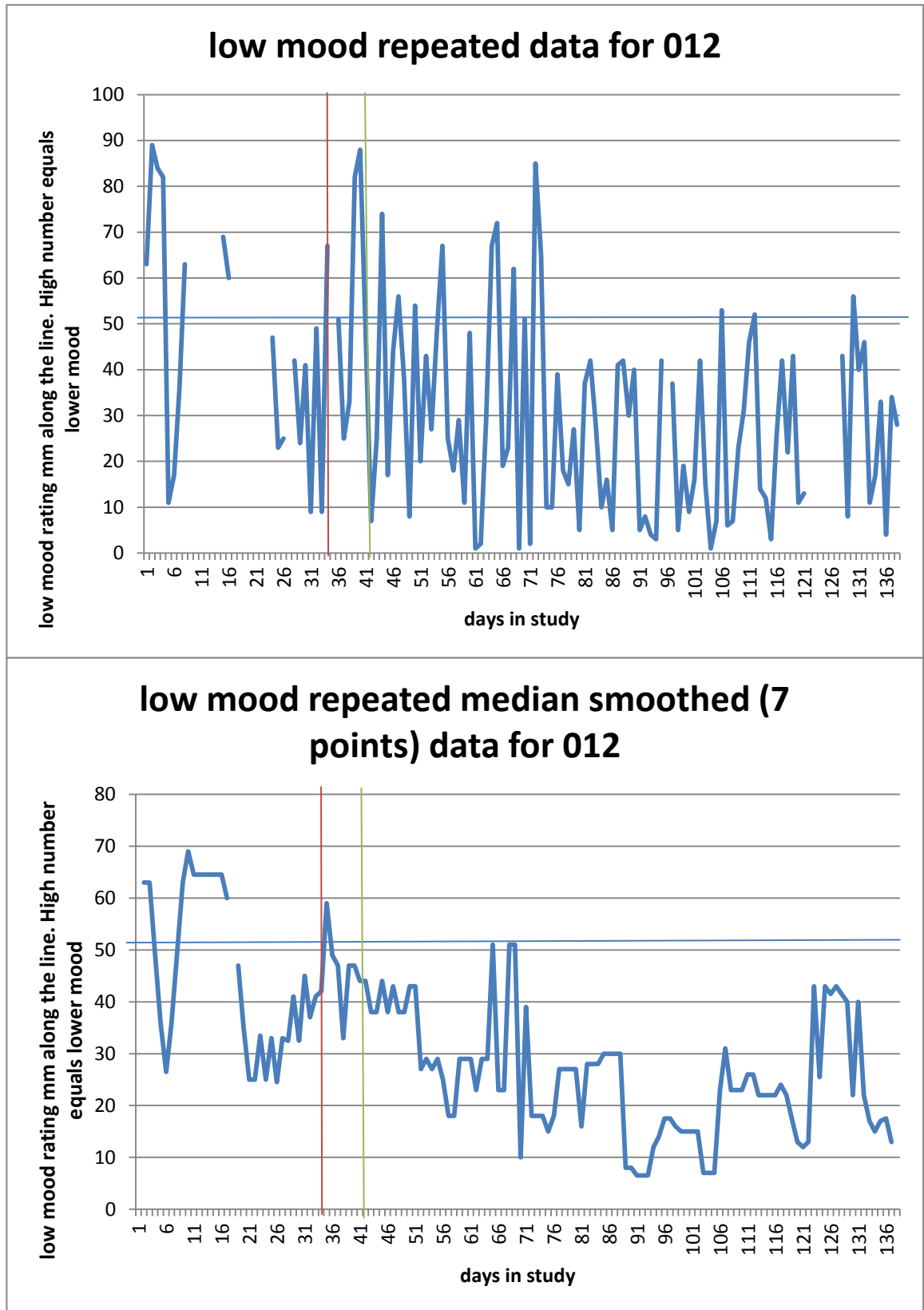


Figure 4.10: low mood repeated data for participant 012 (Laura)



There is clear downward trend during the treatment phase for all but participants 011, 008 and 006. Participants 006 and 008 showed significant worsening during the baseline phase and did not reverse that trend in the treatment phase. In both cases the clinician made a judgement that they should be discharged from the research and required referral to the CMHT. Participant 011 appears to improve on the standardised measures but deteriorate on the daily score. This will be discussed in more detail below.

The question of importance, and the reason for taking the repeated measurement, is can the improvement seen in the HRSD and the graphs be attributed to the intervention. Even in the smoothed data, some participants have extreme variability in their daily scores. Whilst this will not be a surprise to clinicians or researchers of depression it does make interpretation of the graphs more complex. Depression is a naturally fluctuating illness and over a period of three or four months such as in the research project, some people will improve regardless of any input. Traditionally in SCED visual analysis improvement in the baseline phase is considered to be part of natural variation and to be considered a sign that the participant would have improved anyway. However, in depression it is not quite as straight forward. The knowledge that the participant now has, that they are about to start treatment, the hope and expectation that this treatment may bring and the knowledge that their experiences are of interest and importance to someone (in this case the researcher) can improve mood. So although this is quite separate from the intended intervention it is not the same as natural variability.

It is also not unusual for talking therapies to cause deterioration in a client's mood before it starts to help them improve. In general people will avoid situations, experiences or memories that upset or distress them but in therapy that material is unavoidable. As a result mood scores often worsen at the start of a talking therapy (Castonguay et al., 2006) but it is how quickly that is reversed and how well as client is doing at the end that is of greater importance. Table 4.6 shows the percentage of treatment phase data points which are below the baseline mean for the whole period and the split into the first and second half of the phase.

To investigate if the baseline and treatment phases were different an independent Mann-Whitney U test was conducted for each sample. The samples were not normally distributed so a nonparametric test was chosen instead of a t test, table 4.7 shows the results of these tests.

Table 4.6: Treatment phase data points below the baseline mean

	Points below BL mean - total	Total %	First half	1 st ½ %	Second half	2 nd ½ %
001	85/159	53	39/79	49	46/80	58
003	48/95	51	16/47	34	32/48	67
004	31/78	40	10/39	26	21/39	54
005	74/103	72	46/51	90	28/52	54
006	4/47	9	3/23	13	1/24	4
007	19/70	27	4/35	11	15/35	43
008	3/27	11	3/13	23	0/14	0
011	9/112	8	5/56	9	4/56	7
012	82/101	81	39/50	78	43/51	84

Table 4.7: Comparison of the baseline and treatment phases

	BL mean	BL SD	Treat mean	Treat SD
001	49.35	21.25	41.91	21.29
003	33.42	17.64	34.91	16.40
004	37.43	17.61	48.13	23.13
005	78.50	10.39	60.53*	18.90
006	22.00	28.46	64.97*	27.05
007	62.82	13.93	63.68	12.09
008	63.63	16.03	74.36*	7.07
011	56.54	14.24	66.46*	7.96
012	51.46	26.84	29.89*	21.67

*treatment mean is significantly different from the baseline mean at the 5% level. BL=baseline phase, Treat= treatment phase, SD= standard deviation of the mean

Of those who improved on the HRSD, two had highly significant lowering of daily mood scores after the intervention, one decreased but not significantly, two stayed about the same and one's mood score got significantly worse despite reported feeling better on every other scale (011). The two participants who deteriorated during the intervention had significantly higher mood score at the end of the treatment period, concurring with other estimates of their mood.

Client 001 shows improvement in her low mood during the baseline phase, however, she was very keen to be in the research clinic and had emailed the researcher before she had been referred to discuss the project and asked to be referred rather than it being suggested by her health professional. The high variability in her data makes it hard to be sure of definite trends in the data even after smoothing. Her situation was further compounded by poor physical health that relapsed during the treatment period and she had to take several months of work.

Participant 003 shows consistent deterioration during the baseline phase which is followed by high variability during the treatment phase. As the treatment continues however, the variability becomes less and the median is consistently lower, indicating and more consistently improved mood.

Participant 004 shows a similar pattern of consistent deterioration in baseline and then a variable treatment period. It does take this client longer to show the improvement of 003 but by the end of the treatment period he is reporting a more consistent mood.

Client 005 had a highly variable but generally improving mood during the baseline period. This improvement continued during the treatment, to the extent that the client was considering finishing the treatment early. She took a couple of weeks off to go on holiday and said she would make up her mind when she got back and agreed to continue filling in the daily measures during this period. This was day 66. During the holiday she had what the therapist reported as a severe relapse, she returned early and asked to come straight back into the clinic. This was day 76. Following a return to treatment she once again improved consistently and reported that she thought the 'relapse' on holiday had actually helped her see she was not as well as she had thought she was and she was able to work on this in the coming sessions. What is interesting with client 005 is that she imposed this gap in treatment. Just before the break her low mood scores were very low indicating, as she reported, that she was feeling good. Within less than a week of treatment being withdrawn her mood scores become very high, higher even than the initial baseline at times. Then once she resumed treatment she followed a similar pattern as before of steady improvement. This could be seen as controlling for the effect of the intervention as she was reporting low depression scores in treatment and then very rapidly reported high scores once the treatment was removed.

Client 006 showed substantial deterioration during the baseline phase. This in general continues during the treatment phase. Although he attempts to begin stage four and onwards he is judged by the clinician as not stable enough to continue. Client 006 was able to express in the interview afterwards that his deterioration was due to several external factors and he wished he had been able to continue with EMDR because he actually found it very helpful.

Participant 007's baseline period has a lot of variability around a stable median, the first part of the treatment shows initial moderate improvement followed by deterioration as stage four is about to start. This is quickly reversed and the client is doing well by the end of the treatment phase.

Participant 008 deteriorates severely during the baseline phase, going from less than 10 to nearly 80 in the 6 week period. He does show some stabilisation during the start of treatment but unfortunately not enough for him to be suitable for treatment to continue and he had to be discharged.

Client 011 has a large amount of missing data in her baseline period. Once the treatment starts she is much better at completing the daily measures. Client 011 is quite curious, she appears to be gradually deteriorating during the start of the baseline period, the only part that we have data for, during the treatment period this stabilises but does not improve on this measure. Despite this she does improve on the all other measures. This lady's distress, although starting in childhood, was exacerbated by an unsupportive family. It could be that although she was developing a better understanding of her problems and no longer feeling guilty or abandoned her mood was still low due to also having a better understanding about how unhelpful her family had been and the pressures she is under.

Client 012 also has a large amount of missing data during her baseline phase which makes it difficult to be sure about her mood during that period. However, her mood during the start of therapy is reasonably stable followed by a clear improving trend. Towards the end of treatment this appears to reverse slightly. However, the client reported a fear of endings. Right from the start of therapy she had been concerned about what would happen at the end. Once she reached the last few sessions, despite the fact that she had been feeling better on every scale she required large amounts of reassurance and work on dealing with ending the relationship with the therapist.

When the huge variability in daily scores was first seen the possibility that this was a feature of depression was considered. If this is the case then the variability should reduce over time as the participants start to recover. Therefore means of the low mood measure and the associated standard deviations were calculated for each week of the research. A Spearman's rho correlational analysis was run on the standard deviations versus time, the results of which are in table 4.8.

Table 4.8: Correlations of standard deviation of the daily measure over time for each participant

			SD001	SD003	SD004	SD005	SD006	SD007	SD008	SD011	SD012
Spearman's rho	week	Correlation	-.534**	-.474	.050	-.191	-.733*	-.063	-.661*	-.266	-.324
		Coefficient									
		Sig. (2-tailed)	.009	.064	.860	.448	.025	.846	.038	.257	.205
		N	23	16	15	18	9	12	10	20	17

*. Correlation is significant at the 0.05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed).

As the table shows, with the exception of participant 001, the only participants whose variability significantly decreases are those whose mood actually deteriorated over time. Therefore this does not suggest that the variability was a symptom of worse depression or if it was it was not affected by the EMDR. The variability, especially in the baselines, did mean however, that the sample was not as homogenous as had been expected and therefore a meta-analysis was not completed.

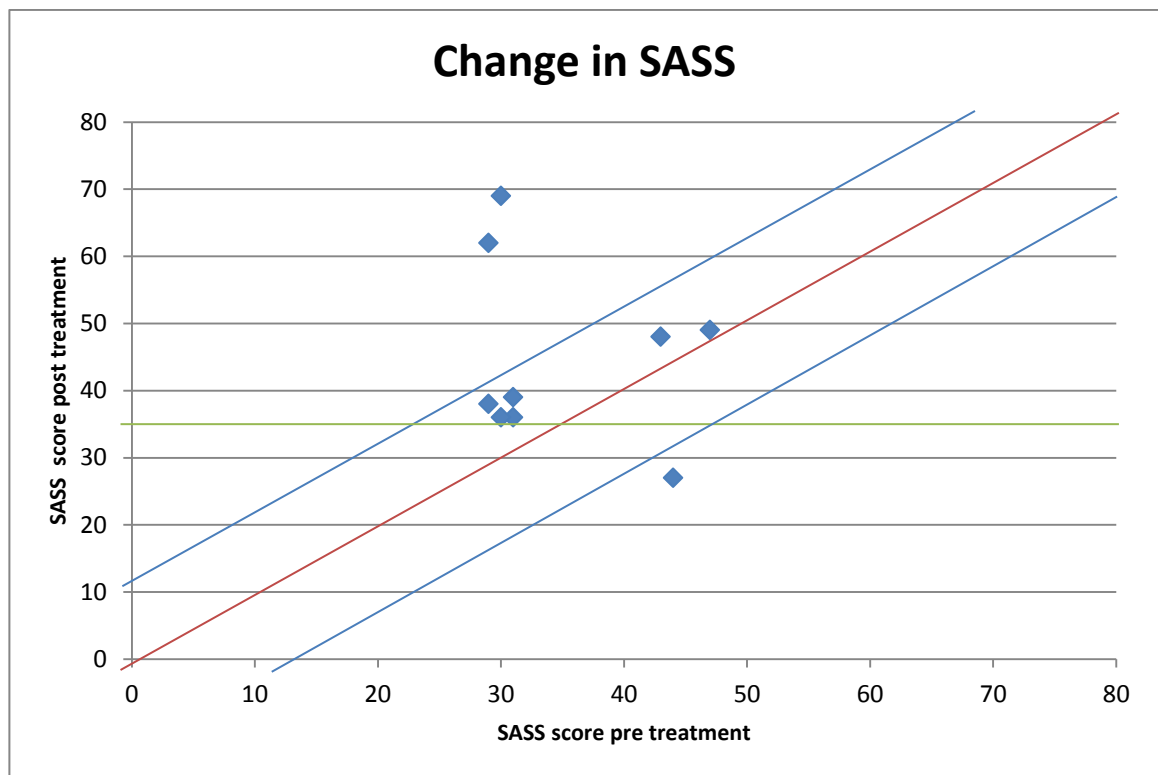
As is common in time series data the daily mood ratings are highly autocorrelated for all participants. For all the participants the first lag is positively autocorrelated but for some the later lags are negatively autocorrelated. This gives rise to the up and down nature of many of the graphs and suggests a pattern of a day or two of low mood will be quickly reversed and vice versa. It was also hypothesised that the intervention may help to reduce the amount of autocorrelation. Therefore the data for each client were split into separate columns, at least 50 data points in each column and the test run again. Participant 003 had significant autocorrelation in the first two lags for the first half of her data but no significant autocorrelation in the second half. For participants 001 and 004 the first half did not have significant autocorrelation but the second half did. For participants 005 and 007 the autocorrelation was significant in both halves. For participant 012 once the data was split it no longer had enough power to identify any autocorrelation. Participant 011 had enough data to split into three parts. The first and last were highly autocorrelated but the middle section was not. There does not appear to be any pattern within the data to suggest any change or otherwise in autocorrelation during the treatment phase.

4.1.3 Outcomes on each of the secondary standardised measures

Social Functioning

To investigate if there was also any improvement in social functioning, which is also a serious problem for people with long term depression, the Social Adaptation Self-evaluation Scale (SASS) and Global Assessment of Functioning (GAF) were used. Figure 4.11 shows the Jacobson plot for the SASS and GAF. Unlike the previous plot, improvement on the SASS and GAF is shown by a higher score. Therefore any point on the plot that is ABOVE the central diagonal line (red) is a participant who improved during the course of therapy. If that point is outside the tramlines (blue) then the change is reliable and if it is ABOVE the horizontal line (green) then the participant is now in remission. There is no cut off point on the GAF indicating 'caseness'. Table 4.9 details the data in the graphs.

Figure 4.11: Jacobson plots for SASS and GAF



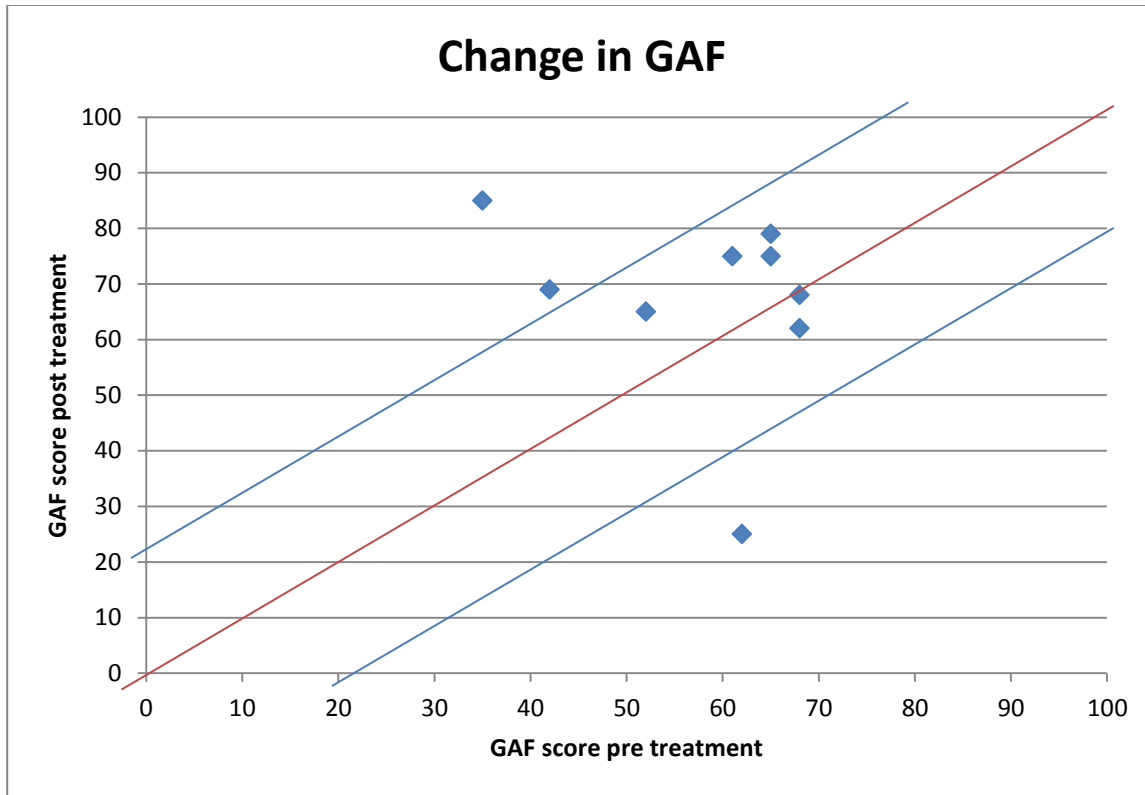


Table 4.9: The change in SASS and GAF and if that change was reliable and clinically significant

Participant	SASS pre	SASS post	Change	Reliable	Clin sig	GAF pre	GAF post	Change	Reliable
1	31	39	8	N	Y	65	75	10	N
3	47	49	2	N	N	61	75	14	N
4	31	36	5	N	Y	68	68	0	N
5	30	36	6	N	Y	35	85	50	Y
6	44	27	-17	Y	Y	62	25	-37	Y
7	29	38	9	N	Y	52	65	13	N
8	26	-				38	-		Drop out
10	29	62	33	Y	Y	68	62	-6	N
11	43	48	5	N	N	65	79	14	N
12	30	69	39	Y	Y	42	69	27	Y
mean	33.1	38.1	10.0			54.2	67	9.4	

Reliable change on SASS = 12 and on GAF =21 and clinically significant change on the SASS= a score above 35.

Of the nine people with before and after scores, six of these had impaired social functioning on the SASS before treatment began. All of these six improved their scores so that it was now above the SASS's threshold of 35, however only two improved by such a margin that the improvement can be considered reliable and only one of those engaged with the treatment programme. The

GAF does not have a green line because it does not have a cut-off point for caseness nor does it have a published definition of clinically significant change. Its RCI is so large (see the blue tramlines on the graph) that even an improvement of 20 points cannot be said to be reliable. This raises questions about how meaningful the GAF is and how useful it is in a clinical situation. However, of the eight people who improved on the HRSD five improved on the GAF, only two of these can be considered reliable change due to the very large reliable change index (RCI) for the GAF. Table 4.10 shows if any gains in social functioning were maintained after three months.

Table 4.10: SASS and GAF scores before and after the intervention and after the 3 month follow up period

Participant	SASS Pre	SASS Post	SASS F/U	Are benefits maintained?	GAF Pre	GAF Post	GAF F/U	Are benefits maintained?
1	31	39	41	Yes	65	75	85	Yes
3	47	49	48	Yes	61	75	68	No
4	31	36	32	No	68	68	68	No improvt
5	30	36	40	Yes	35	85	82	Yes
6	44	27	41	Improved	62	25	75	Improved
7	29	38	52	Improved	52	65	78	Improved
8	26	-	-		38	-	-	
10	29	62	-		68	62	-	
11	43	48	44	No	65	79	75	Yes
12	30	69	-		42	69	-	
mean	33.1	38.1	42.6		54.2	67	75.9	

Traumatic Stress

The revised version of the impact of event scale is a validated self-report measure to measure traumatic stress. As EMDR is an efficacious treatment for post-traumatic stress disorder the participants were screened to ensure they did not have this diagnosis. None of the participants had witnessed a 'Criterion A' event, or if they had they had not responded with fear and helplessness. Despite this, seven of the 13 participants (four of those who started treatment) scored 33 or above on the IES-r indicating traumatic stress; they were traumatised by their past experiences. It was key for the research to ensure that EMDR was capable of treating depression not just trauma. Figure 4.12 shows the Jacobson plot for the IES-r and table 4.11 details this data. The Jacobson plot for IES-r once again shows improvement as a decreasing score just as the HRSD did.

Figure 4.12: Jacobson plot for IES-r

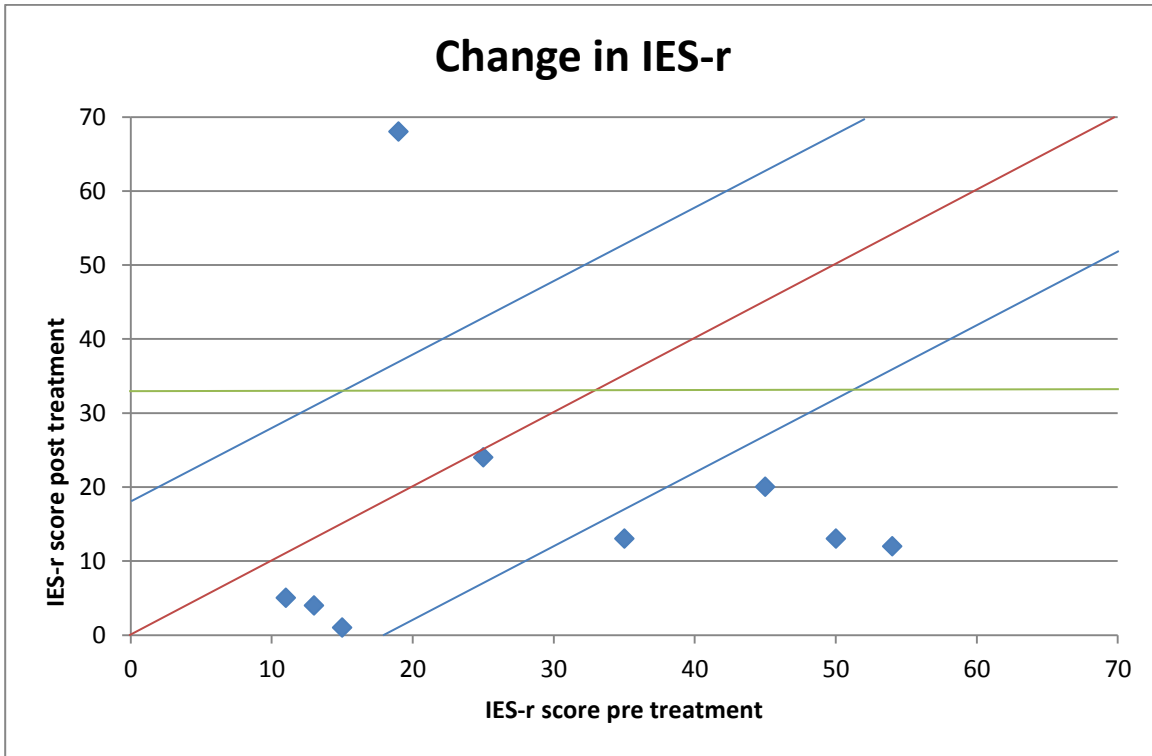


Table 4.11: The change in IES-r and if that change was reliable and clinically significant

Participant	IES pre	IES post	Change	Reliable?	Clinically sig?
1	13	4	9	N	N
3	11	5	6	N	N
4	50	13	37	Y	Y
5	54	12	42	Y	Y
6	19	68	-49	Y	Y
7	45	20	35	Y	Y
8	33	-			Drop out
10	25	24	1	N	N
11	15	1	14	N	N
12	35	13	22	Y	Y
mean	32	17.8	13.0		

Reliable change on IES= 18 and clinically significant change = a score dropping below 33

Four of the nine people with before and after scores had scores on the IES-r indicative of traumatic stress before they started EMDR. All of these four improved so they can no longer be described as such, this change was reliable and clinically significant. The one participant who deteriorated did not have traumatic stress when he started but his scores indicate he was traumatised afterwards. Three participants showed a decrease in their IES-r score but it cannot be categorised as clinically

significant because their starting score was under the threshold for trauma or reliable change as their starting score was lower than the tramlines are wide. The tramlines representing the RCI are almost as wide for the IES-r as they are for the GAF. Change is only reliable if it is more than 18 points but these three participants had a starting score of less than 18 so they cannot improve reliably. Table 4.12 shows if any of the gains from the treatment phase were maintained by the end of the three month follow up period.

Table 4.12: IES-r score before and after the intervention and after the 3 month follow up

Participant	IES-r Pre	IES-r Post	IES-r F/U	Are benefits maintained?
1	13	4	8	No
3	11	5	12	No
4	50	13	15	Yes
5	54	12	0	Improved
6	19	68	28	Improved
7	45	20	22	Yes
8	33	-	-	
10	25	24	-	
11	15	1	20	No
12	35	13	-	
mean	32	17.8	15	

Self-rated Depression Scales

The primary outcome for this section was the Hamilton Rating Scale for depression; this is a clinician rating scale. There has been some debate about the use of this scale when the clinician is not blind to the research aims. To counteract that claim two participant rated scales, the BDI-ii and the PHQ-9 were also completed. Figure 4.13 shows the Jacobson plots for these scales and table 4.13 details the data. As with the HRSD and IES-r, on both the PHQ-9 and BDI-ii an improvement is shown by a decreasing score which will be BELOW the diagonal red line.

Figure 4.13: Jacobson plots for BDI-ii and PHQ-9

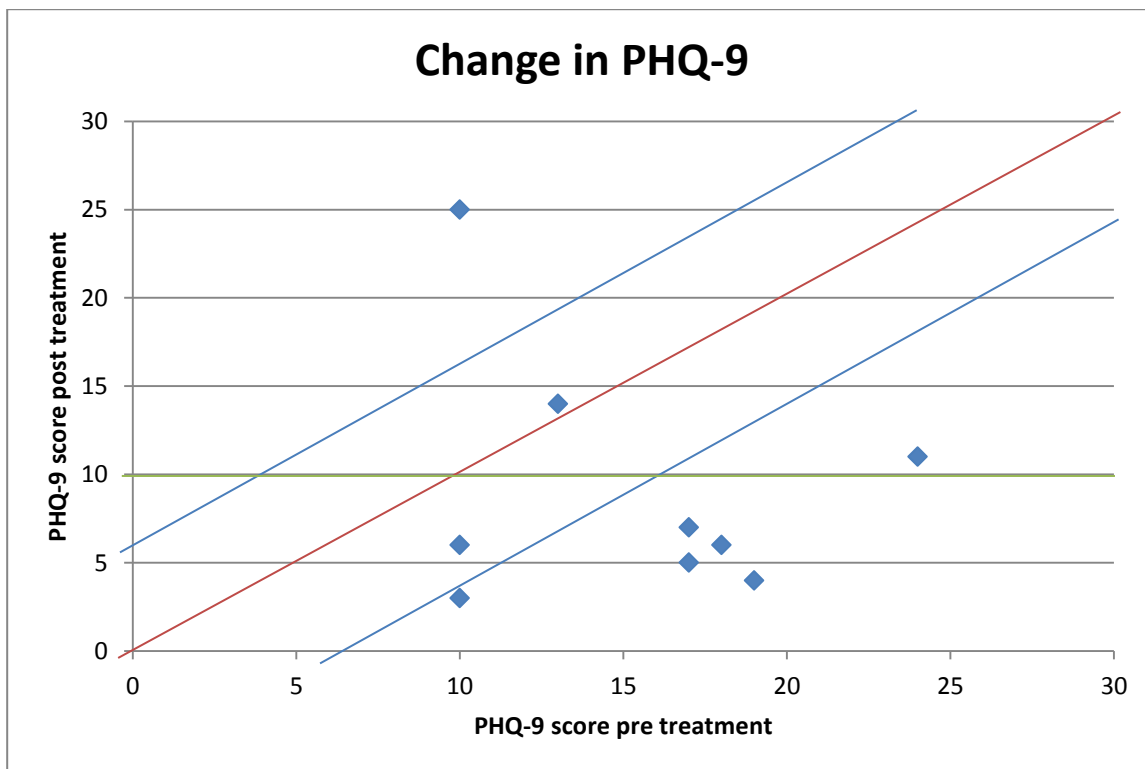
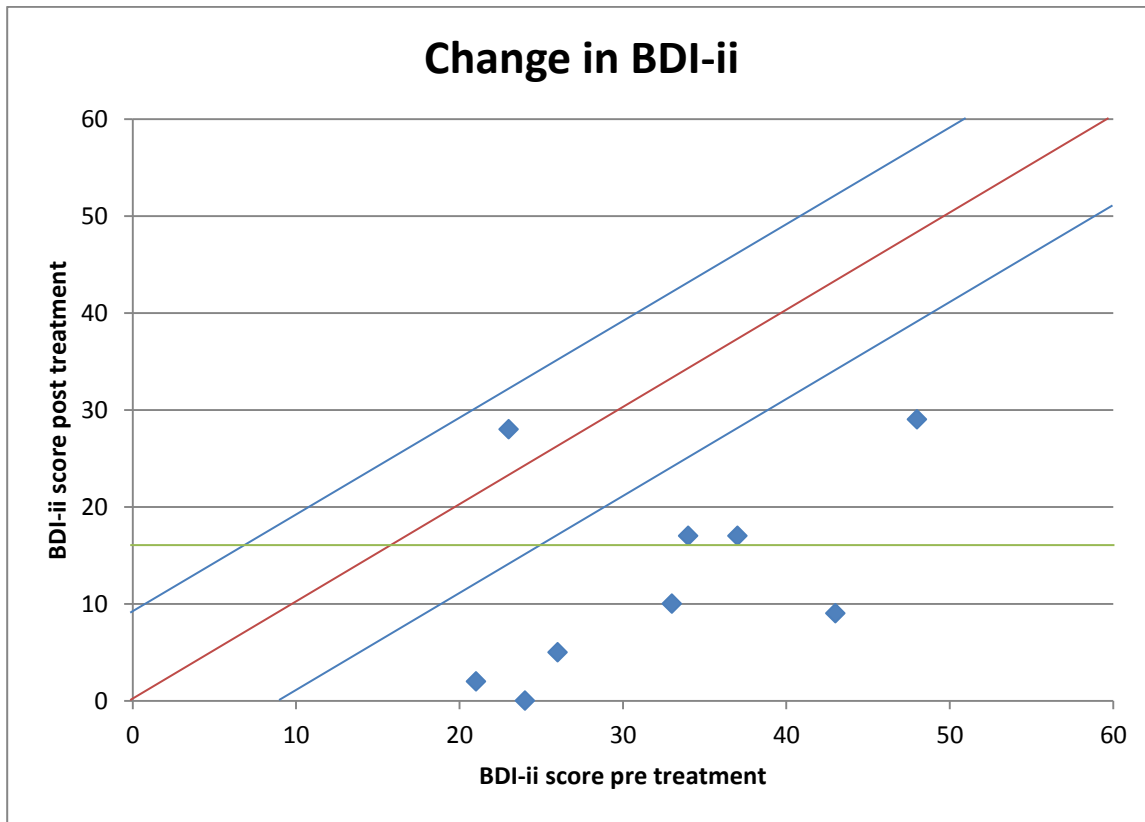


Table 4.13: Change in BDI-ii and PHQ-9 and if that change was reliable and clinically significant

Participant	BDI Pre	BDI post	Change	Reliable	Clin sig	PHQ pre	PHQ post	Change	Reliable	Clin sig
1	33	10	23	Y	Y	17	7	10	Y	Y
3	21	2	19	Y	Y	10	3	7	Y	Y
4	48	29	19	Y	Y	24	11	13	Y	Y
5	43	9	34	Y	Y	19	4	15	Y	Y
6	26	5	24	Y	Y	10	25	-15	Y	Y
7	34	17	17	Y	Y	18	6	12	Y	Y
8	28	-				17	-			dropout
10	23	28	-5	N	N	13	14	-1	N	N
11	24	0	24	Y	Y	10	6	4	N	N
12	37	17	20	Y	Y	17	5	12	Y	Y
mean	33.3	18	19.4			16.3	9	6.3		

Reliable change on the BDI-ii=9 and on the PHQ-9=6 and clinically significant change on the BDI-ii =a 10 improvement and the PHQ-9= a 5 point improvement

Of the eight participants that showed improvement on the HRSD, seven also showed reliable and clinically significant improvement on the BDI-ii and PHQ-9. The only one that did not was the participant who left the programme after two sessions and therefore cannot be considered to have received EMDR. The one participant who deteriorated on the HRSD also had reliable and clinically significant deterioration on the BDI-ii and PHQ-9 as well. Table 4.14 shows if any gains from the treatment phase were maintained through to the end of the follow up period. Benefits have been described as still maintained if the client is still non-clinical in their score.

Table 4.14: BDI-ii and PHQ-9 scores before and after the intervention and after the 3 month follow up period

Participant	BDI Pre	BDI Post	BDI F/U	Are benefits maintained?	PHQ Pre	PHQ Post	PHQ F/U	Are benefits maintained?
1	33	10	6	Improved	17	7	4	Improved
3	21	2	8	Yes	10	3	6	Yes
4	48	29	27	Yes	24	11	7	Improved
5	43	9	2	Improved	19	4	5	Yes
6	26	5	25	No	10	25	13	Improved
7	34	17	8	Improved	18	6	7	Yes
8	28	-	-		17	-	-	
10	23	28	-		13	14	-	
11	24	0	12	Yes	10	6	4	Improved
12	37	17	-		17	5	-	
mean	33.3	18	12.6		16.3	9	6.6	

4.2 RQ - 2 Are there any identifiable differences between the responders and non-responders which might be able to predict response in other?

4.2.1 Participant effects

Of the nine participants who received more than two sessions of treatment there were only two negative outcomes. The two groups of responder and non-responders are therefore not powered to be able to answer the question statistically. Therefore, the differences between the participants who achieved remission will be compared to those who only achieved a response and those who did not respond is described in key demographics before a description of the non-responders is given.

At the end of treatment 001, 003, 005, 007 and 011 were in remission, 004, 010 and 012 responded to treatment but did not see a remission in their symptoms. 010 left after two sessions and did not receive anything that could be described as EMDR so will not be included in the rest of this section. As there are so few participants in the each group formal statistical analysis could not be completed but table 4.15 shows the spread of data in the key demographic areas highlighted in chapter 3.2.

It is difficult to see any clear pattern in the data in table 4.15 to help understand who may benefit from EMDR for long term depression and crucially who would not. From the median data it appears that the remission group have much lower initial IES-r scores than the other groups. This is interesting because an initial concern was that EMDR would only treat depressed clients who had a high IES-r score meaning they were highly traumatised. The average scores suggest that the opposite is true although when the spread of the raw data is taken into account it does not appear to be too important. The remission group contains the clients with both the highest and lowest initial IES-r score.

The clearest difference between the remission group and the responder group is the initial HRSD score. The responder group has a much higher score at the start indicating a much more severe depression. However, this does not mean that EMDR was not suitable; they still show a clinically significant response. However, it may be that they needed a longer treatment period to go into remission.

Table 4.15: The demographic characteristics of each group

		remission	response	non-response
N		5	3	2
Initial HRSD	raw	17, 13, 26, 21, 10	25, 23, 26	12, 22
	mean	17.4	24.7	17
	median	17	25	17
Change in HRSD	raw	14, 8, 23, 16, 8	16, 12, 18	12
	mean	13.8	15.33	12
	median	14	16	12
Age range		31-65	29-34	41-44
Current age	raw	32, 31, 65, 44, 64	29, 43, 39	58,55
	mean	47.2	42	43
	median	44	39	42.5
Gender mix		4 f, 1 m	2 f, 1 m	0 f, 2 m
Sociodemographics		4 C1, 1 retired	2 C1, 1 student	1 C1, 1 E
Age at onset	raw	15, 15, 23, 38, 15	10, 17, 26	43, 42
	mean	21.2	17.67	42.5
	median	15	17	42.5
Number of previous episodes	raw	5, 2, 6, 2, 15	2, 4, 4	1, 3
	mean	6	3	1.5
	median	5	4	1.5
Length of current episode (months)	raw	5, 75, 36, 7, 4	108, 12, 36	72, 1
	mean	24.8	52	36.5
	median	7	36	36.5
IES-r score pre-therapy	raw	13, 11, 54, 45, 15	50, 25, 35	19, 33
	mean	28	37	26
	median	15	35	26

The three participants with the highest number of previous episodes all achieved remission and the next two highest achieved a response. However with the longest length of the current episode was split between the groups. Of the four people who reported their current episode had lasted less than one year, three were in the group that achieved remission. As chronic and recurrent depression are considered to be different conditions (Klein and Santiago, 2003) this is important to investigate in a larger sample as it could be that recurrent depression is more responsive to EMDR than chronic depression.

Responders v non-responders

Participant 006 relapsed and had to be referred to the community mental health team (CMHT) for home visits as he could not leave the house. Whether or not this was a serious adverse effect of the treatment was considered in some detail. It was decided it was not, as this pattern of agoraphobia in relapse is typical for this participant and was not unexpected in a relapse situation.

The participant was also clear that the relapse was caused by factors external not the treatment programme, which he found helpful and wished he could have continued.

The other negative outcome was participant 008. He attended nine sessions, almost half of those on offer, but had difficulty engaging with the treatment programme. He never got as far as stage four (processing) in the standard protocol of EMDR. His mental state was becoming more unstable throughout the sessions and again it was decided that the CMHT was a more appropriate intervention for him at that time.

Both were middle aged men who had developed depression in their early 40's. Both had current and recurrent Major Depressive Disorder and dysthymia. Although one had melancholic type, the other did not. One scored highly for anxiety, the other did not. One was long term unemployed, the other was self-employed. Both relapsed substantially during the baseline phase and both seemed to have problems relating back to their relationship with their mothers, although one's mother was abusive, the other's was smothering. Both had markedly differing starting scores on the HRSD, PHQ-9, IES-r, SASS and GAF.

In comparison to the rest of the participants, these men were of average age for the group. At the start of the study there were four men and eight women, however, although only male participants had poor outcomes this is of the ten who actually started treatment. Two women did not start and another stopped after two sessions. Not only that, but the other two men in the study did very well, so it is unlikely that gender is a key factor here.

As mentioned above, the scores of the non-responders on the standardised measures were so different that it is not possible to group them and compare them to the other participants. One link the non-responders have is their age, however, older, younger and similar aged participants responded well to the treatment.

It is more likely that this was a time in their lives when talking therapy was not appropriate due to external factors and their lack of support. Talking therapies require significant input from the participant and as 010 discovered, when there is a lot going on in your world that is not always possible. This may also have been the reason behind the failure of 002 to start. She was offered several appointments to begin treatment but refused them saying, 'I'll take the next one'. Maybe it just was not the right time for her either.

No assessment was considered at screening to discover if the potential participants had the resources available to undertake therapy. It was assumed that as they had been seen by at least one IAPT worker and that 1:1 therapy had been recommended that was an indication that therapy was suitable at this time. This assumption may not have been correct. IAPT has a high dropout rate (Griffiths and Steen, 2013) and here several participants either did not start treatment at all or dropped out quickly. Even the ones who did remain in treatment commented on the logistical difficulties of attending. A wider roll out of EMDR would need to consider elements such as when and where people can attend, how often and if they need other support as well.

4.2.2 Therapist effects

There were three therapists in the research clinic. Therapist 1 saw participants 001, 005, 006, 011 and 012. Therapist 2 saw 003, 004 and 007 and therapist 3 saw 008 and 010. The two participants with negative outcomes, 006 and 008, had different therapists. Therapist 3 will be excluded from this analysis as 008 has no end of therapy data and 010 only completed two sessions of treatment. This does raise the question of why this therapist was not able to engage these two participants in the treatment programme but the sample size is so small it is difficult to offer robust explanations. The change in HRSD for each client was grouped by therapist and the two groups showed no significant difference at the 5% level using a Mann-Whitney U test.

The two therapists who saw participants to the end of treatment and have before and after measures were compared. There was no significant difference between the two groups ($p=0.79$). The one outlying score (for participant 006) was removed and the analysis conducted again, there was still no significant difference between the two ($p=0.63$). From this it can be concluded that there is no significant difference between the therapists in terms of the outcomes of their clients on the HRSD.

4.3 Data quality

- correlation between PHQ9 and repeated measure
- Correlations between standardised measures
- Missing data from repeated measure

4.3.1 Correlation between PHQ9 and repeated measure

The PHQ-9 and low mood repeated measure were both repeated during the treatment phase and both are attempting to measure the participants' low mood. If they are both truly measuring the same phenomenon over the same time period, they should be highly correlated.

Figure 4.14 shows a scatter plot of PHQ-9 scores and the corresponding daily low mood score.

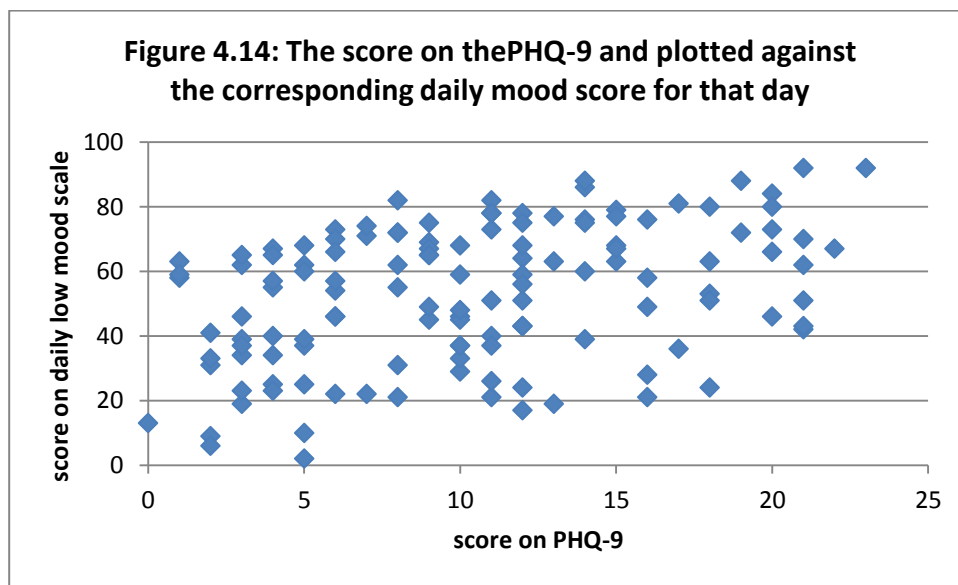


Figure 4.14 shows the data from all participants and it suggests an upward gradient meaning that a higher PHQ-9 score corresponded with a higher daily low mood score which is what one would expect if the two the measures were truly measuring the same thing. However, there is a large amount of scatter in the graph so correlation analysis was undertaken for each client and for the group (table 4.16).

Table 4.16: Correlations (Spearman's) between each participant's low mood repeated score and their PHQ-9 score. Both taken only on the day of the treatment session for comparison

Participant		PHQ-9 and low mood repeated measure score for each session
001	Correlation coefficient Sig (2 tailed) N	-.187 .523 14
003	Correlation coefficient Sig (2 tailed) N	.491* .033 19
004	Correlation coefficient Sig (2 tailed) N	.300 .211 19
005	Correlation coefficient Sig (2 tailed) N	.433 .122 14
006	Correlation coefficient Sig (2 tailed) N	.943** <0.01 6
007	Correlation coefficient Sig (2 tailed) N	.369 .194 14
008	Correlation coefficient Sig (2 tailed) N	.280 .542 7
011	Correlation coefficient Sig (2 tailed) N	.599* .014 16
012	Correlation coefficient Sig (2 tailed) N	.697** <0.01 19
Meta of all clients	Correlation coefficient Sig (2 tailed) N	.490** <0.01 112

*Correlation is significant at the 0.05 level (2-tailed)

**Correlation is significant at the 0.01 level (2-tailed)

The meaning of this is difficult to determine. For some people there is a clear link between the two measures for others there is not. It could simple be that the sample sizes are too small for the majority of individuals for the analysis to be confident of a pattern. It could be that the PHQ-9 is not as reliable for this complex client group as it is for general primary care clients. It was remarked by the therapists that even when the clients were scoring very low on the PHQ-9 and indicating remission that they felt this was not accurate and they still needed a lot more input.

It could be that the repeated measure was flawed. It could be something much more subtle. Clients with depression and especially long term depression are known to have selective memory for negative experiences. It could be that the repeated measure, because it only looked at low mood, continued to show this negative outlook even as other symptoms improved.

It is suspected that these two scales are measuring different things. The PHQ-9 scale asks clients to rate items based on the last two weeks. The repeated measure was only asking for how the client felt at the moment of completing the measure. This makes it likely that the two will get different scores for two reasons. Firstly, it is quite plausible that a person’s mood this instant is not necessarily related to their mood over a two week period. Secondly, the PHQ-9, to be accurate, requires that the client can remember accurately how they have felt for the last two weeks and be able to average that into one reading. As is clear from the repeated data that the participants in this study have quite labile mood and there is a wealth of literature documenting the memory biases and general poor memory of people with depression (Brewin et al., 1999, Watkins, 2002, Barry et al., 2006).

4.3.2 Correlations between standardised measures

Table 4.17: showing the rank orders of severity of symptoms on the pre therapy measures

	best symptoms										worst
HRSD	11	3	6	1	7	8	10	4	5	12	2
BDI-ii	3	10	11	6	8	1	7	12	5	4	2
GAF	10	4	11	1	6	3	7	12	2	8	5
PHQ-9	3	6	11	10	1	8	12	7	5	4	2
SASS	3	6	11	1	4	5	12	7	10	8	2
IES-r	3	1	11	6	10	8	12	7	4	2	5

Table 4.17 shows the rank orders of the different scales; with the exception of participants 10 and 4 most people’s scores are consistent. Correlations on these data (table 4.18, appendix) show that the depression rating scales (HRSD, BDI-ii and PHQ-9) were, as expected, highly correlated as was the IES-r to all three depression scales (HRSD, BDI-ii and PHQ-9). Surprisingly the GAF showed no correlation to any other scale. The other social functioning scale (SASS) however, was correlated with HRSD, PHQ-9 and IES-r. This is a very small data set so it cannot be assumed that the GAF truly does not bare any relation to the other measure but it may in this group it is not an accurate measure of distress.

The BDI-ii shows higher severity of depression symptoms than the other depression measures at the end of treatment. This seems to be that the different emphasis of the different questionnaires. The HRSD only asks about two negative thought styles, low mood and guilt, and the rest are about physical symptoms whereas the BDI-ii asks 16 questions about thought pattern and mood and only 5 about physical symptoms. There were a couple of participants who clearly still have negative thought patterns that remain untreated although other areas of their depression have improved.

4.3.3 Missing data from repeated measure

Table 4.22 shows the amount of missing data for each participant across both phases of the study

Participant	Length of baseline (days)	Number of data points	% missing data BL	Length of treatment (days)	Number of data points	% missing data T
001	17	17	0	159	120	25
002	-	-	-	-	-	-
003	12	12	0	98	95	3
004	21	21	0	85	85	0
005	18	18	0	107	94	12
006	9	9	0	48	36	25
007	12	12	0	78	52	33
008	41	41	0	28	28	0
009	-	-	-	-	-	-
010	12	0	100	47	0	100
011	66	25	62	112	97	13
012	34	20	41	101	94	7
014	-	-	-	-	-	-

Participants 002, 009 and 014 never started and therefore do not have a baseline period or a treatment period and no data, missing or otherwise.

Participant 010 had her first session just before the Christmas holiday and as she had not done the recordings during the baseline phase it was decided that she could start them over the holidays and start with treatment when she got back. At the second treatment in January she had not completed them again and then cancelled several sessions. A joint meeting was arranged with the participant, researcher and therapist to discuss the issue. As it transpired 010's home life was so turbulent that she was not in a position to take part in therapy and definitely not the extra work required by the research. She was discharged by the clinic and referred back to IAPT for treatment when things became more stable. For the other participants much of the missing data comes from towards the end of the treatment period.

Chapter 5 – Investigating possible mechanisms of action

5.1 RQ - 3 Has the content of the target memory become less distressing and more adaptive, and if so is it stable at follow up?

The Adaptive Information Processing model states that EMDR activates and changes the target memory taking it from distressing to adaptive through the use of bilateral stimulation. To determine if any changes actually occurred in the target memories the participants described their first target in detail before and after therapy. Content analysis was used to analyse the level of positive and negative statements in the memory descriptions, this is described in table 5.1. Counted were the total number of statements (pre total, post total), the number of negative statements (pre neg, post neg), the number of positive statements (pre pos, post pos) and the word count for both before and after the intervention. The negative and positive numbers were also converted to a percentage of the total.

Table 5.1: Content analysis of the memory descriptions by participant

	pre total	pre neg (%)	pre pos (%)	word count	post total	post neg (%)	post pos (%)	word count
1	63	27 (42.9)	3 (4.8)	1221	29	5 (17.2)	0 (0.0)	336
3	29	9 (31.0)	1 (3.5)	403	25	4 (16)	2 (8.0)	336
4	265	38 (14.3)	12 (4.5)	4329	70	23 (32.9)	9 (12.9)	976
5	36	11 (30.6)	1 (2.8)	365	23	5 (21.7)	2 (8.7)	205
6	24	7 (29.2)	0 (0.0)	191	11	3 (27.3)	0 (0.0)	108
7	58	15 (25.9)	3 (5.2)	1030	28	2 (7.1)	3 (10.7)	255
11	32	3 (9.4)	1 (3.1)	475	41	2 (4.9)	2 (4.9)	422
12	73	22 (30.1)	2 (2.7)	911	35	7 (20.0)	0 (0.0)	342
mean	72.5	16.5 (26.7)	2.88 (4.0)	1115.6	32.75	6.37 (18.39)	2.25 (6.9)	372.5

From the table it appears that there are some differences between the pre and post treatment time periods so a comparison of the groups was undertaken. As these are very small samples and not normally distributed nonparametric analyses were used throughout the chapter. Mann-

Whitney U tests revealed there was no significant difference in the percentage of negative statements, the percentage of positive statements, the number of positive statements or the total number of statements across the two time points. There was a significant reduction in word count and in the number of negative statements.

Surprisingly the number of total statements is not significantly different despite a large difference in the means. Closer examination of Table 5.1 suggests that this is because although some participants had very large changes many did not. Word count is significantly lower suggesting that the statements get shorter after the treatment rather than there being fewer of them. The situation with the negative statements is more complicated. The number of statements is significantly fewer as the word count goes down which may be expected. However, as the total number of statements has not reduced this suggests that the number of negative statements has changed in relation to the total number. However, the percentage of negative statements has not changed significantly. It is likely that this study does not have enough power to properly unpick this.

The AIP model states that the number of negative statements should go down and the number of positive statements should go up. This is only partly supported by the findings. The working memory model says the statements should become more neutral; this was supported by the findings. This relates closely to some of the statements made in the interviews and will be looked at further in chapter 7.2.

5.2 RQ - 4 Has the emotional impact of the target memory and the psychophysiological response to it decreased?

As detailed in Chapter two, some researchers have shown a decrease in psychophysiological responses during the EMDR session. However, whether or not this relaxed state lasts outside the session has not been measured. Research suggests that clients with depression have decreased heart rate variability so it can be expected that an improvement in depression should lead to an increase in HRV. Previous research on EMDR in PTSD clients has seen skin conductance response decrease. SCR is lower in depressed clients than in healthy controls, unlike anxiety which raises SCR. Again it can then be expected that successful reduction in depression symptoms should be accompanied by an increase in SCR. These readings are taken at the same time as asking them to describe the distressing target memory; this can be expected to be distressing, at least at first, so it should raise the heart rate. If the AIP is correct then after treatment the memory will no longer be

distressing and therefore will not raise the heart rate so the reading after the intervention should be lower than the one taken before. Table 5.2 shows the before and after psychophysiological responses and if there was a change.

The AIP also makes predictions about other effects of the treatment on the target memory. Previous research on PTSD clients and health participants has suggested the bilateral stimulation reduces the strength of emotion produced by the memory. It also reduces the vividness of it, makes the memory more complete and increases the distance of it. Table 5.3 displays the findings from the SEDI participants. If the AIP is correct the after memories will be higher on the completeness score but lower on the emotionality, vividness and distance scores.

Table 5.2: The psychophysiological response generated by the target memory, before and after therapy and if there was a change

	Pre SCR uSiemens (SD)	Post SCR uSiemens (SD)	Diff	Pre HRV RMSSD (SD)	Post HRV RMSSD (SD)	Diff	Pre HR bpm (SD)	Post HR bpm (SD)	Diff
1	496.75 (75.46)	271.13 (40.75)	-225.62	29.58 (45.28)	61.25 (117.9)	31.67	82.67 (9.97)	73.97 (22.26)	-8.7
3	494.52 (33.36)	2786.08 (178.73)	2291.56	36.13 (64.32)	48.24 (124.7)	12.11	73.57 (12.28)	59.28 (21.9)	- 14.4
4	396.55 (53.16)	1722.88 (184.61)	1326.33	40.56 (57.05)	37.29 (91.2)	-3.27	72.28 (18.85)	61.88 (17.79)	- 10.4
5	109.75 (10.98)	334.66 (25.44)	224.91	22.68 (54.95)	56.58 (123.0)	34.05	68.92 (10.08)	73.27 (24.31)	4.35
6	366.28 (13.02)	274.93 (6.02)	-91.35	23.53 (87.98)	54.39 (125.1)	30.86	83.84 (16.76)	65.53 (20.36)	- 18.3
7	349.05 (9.22)	378.34 (16.16)	29.29	35.65 (49.33)	50.86 (86.7)	15.21	66.93 (7.35)	75.96 (26.97)	9.03
11^	267.19 (42.2)	-	-	43.36 (86.38)	-	-	67.46 (17.18)	-	-
12	401.98 (66.97)	405.28 (96.33)	3.3	31.43 (41.27)	37.5 (66.5)	6.07	73.46 (8.62)	67.71 (11.65)	- 5.75
mean	360.26 (38.05)	881.9 (78.29)	521.64	32.87 (60.82)	49.44 (105.0)	16.57**	73.64 (12.64)	68.23 (20.75)	- 5.41

SCR=skin conductance response measured in uSiemens, HRV= heart rate variability measured in the root mean square difference of successive NN intervals (RMSSD), HR = heart rate measured in beats per minute, SD= standard deviation, Diff= change from pre to post therapy.

**significant difference at the 1% level (2 tailed t test)

^Client 011 does not have any post therapy measures due to equipment failure

Table 5.3: The emotional reaction generated by the target memory, before and after therapy and if there was a change

	Emotion Pre	Emotion post	diff	Vividness pre	Vividness post	diff	Completeness pre	Completeness post	diff	Distance pre	Distance post	diff
1	51	-		87	-		115	-		65	-	
3	32	51	-19	32	35	-3	15	19	-4	49	33	16
4	167	35	132	84	64	20	4	55	-51	149	106	43
5	86	16	70	151	103	48	151	33	118	151	16	135
6	117	101	16	135	134	1	102	67	35	156	134	22
7	51	17	34	135	135	0	118	120	-2	68	18	50
11	136	18	118	136	35	101	137	35	102	137	38	99
12	153	120	33	134	62	72	100	76	24	116	54	62
mean	99.1	51.1	48.0	111.8	81.1	30.6	92.8	57.9	34.9	111.4	57	54.4*

^All scores are mm along a visual analogue scale, measured from the left so a lower number indicates less extreme emotion, vividness, completeness or closeness of the image.

*significant difference at the 5% level (2 tailed t test)

Mann Whitney U tests were performed to determine if the skin conductance response, heart rate variability and heart rate were different after the treatment. As expected the heart rate variability of the participants significantly increased following the intervention. This suggests that the autonomic withdrawal associated with depression has been lessened during the research period. Despite the very large mean increase in skin conductance response this was not significant. This is likely to be due to the large variations in the small sample size. At the post treatment recording clients 003 and 004 had very high skin conductance response readings. As they did not have unusual readings at the pre-therapy time point it could be a machine error in the reading. However, they were not done at the same time and client 007 actually had his end of therapy recording done in the middle of the other two. A lengthy consultation was undertaken with the makers of the equipment (Vilistus) to try to find an explanation for the unusual readings. Despite several attempts to replicate the effects of short circuits and other possible artefacts that could cause an unexpected reading, no score as high as this was reached by the researcher or Vilistus. The team at Vilistus reported never having seen such a high reading. This remains unexplained. The equipment failure that occurred in the case of 011 was different. In this case only 3 seconds were recorded before the equipment failed. As expected the heart rate decreased following treatment, however this was not large enough to be significant.

The Likert scales covering emotionality, vividness, completeness and distance were attempting to test the AIP predictions that following EMDR the target memories will provoke less emotion, appear less vivid, be more complete and appear further away. The Likert scales for emotion, vividness and distance moved in the direction predicted by the AIP but only distance was significant. The memories got less complete following the intervention but this was not significant.

Client 006 is the only participant who deteriorated during the study to also have before and after scores for the psychophysiological responses and the Likert scales. Although he barely changes his scores on the Likert scales which is to be expected. He surprisingly improved on the psychophysiological measures. He has the highest reduction in heart rate, he is one of three with a very large increase in heart rate variability and has a substantial decrease in skin conductance response suggesting a reduction in distress. This may however, be a reflection of the fact that SCR is not a suitable measure when working with depression rather than suggesting that at some biological level he was improving.

5.3 RQ - 5 Is there a relationship between the changes in symptoms and the changes in memories?

The AIP claims that the way in which EMDR reduces pathology, whether that is depression, PTSD or any other mental health problem, is by reducing the distress associated with the target memories. It is clear from chapter four that the participants in the study have in general seen a reduction in their depressive symptoms over the course of the research period. We have also seen pulse rate go down, and heart rate variability and skin conductance response go up. For most people the memories are now less emotional, less vivid and more distant.

This is all consistent with the AIP; however, have they changed in relation to each other, have they changed in any consistent way. Table 5.4 shows a correlational analysis between the change in HRSD, the content analysis (word count and number of negative statements) and HRV. These measures were chosen as the HRSD and content analysis were the primary outcome measure for research questions 1 and 2. Word count and number of negative statements were both found to have changed significantly. There was also substantial change in the HRSD as can be seen in the Jacobson plots. Heart rate variability is a key indicator of the psychophysiology and as this was also found to be significantly changed following treatment it was decided to include this as well.

Surprisingly, although all the outcome measures in table 5.4 changed significantly and in the direction that was predicted they have not changed in a consistent pattern over the different measures. The exception is word count and change in the number of negative statements in the memory description but this is likely to be the case, if the number of words decreases the number of negative words also decreases. It would be interesting to see this repeated with a larger sample size to see if this is a genuine phenomenon or just a lack of power.

Table 5.4: Correlations between the change in HRSD, heart rate variability, word count and number of negative statements in the memory report.

		Change HRSD	Change wordcount	Change HRV	Change numneg
Spearman's rho	Change HRSD	1.000			
	Correlation Coefficient				
	Sig. (2-tailed)	.			
	N	8			
Change word count	Change word count	.566	1.000		
	Correlation Coefficient				
	Sig. (2-tailed)	.143	.		
	N	8	8		
Change HRV	Change HRV	.090	-.250	1.000	
	Correlation Coefficient				
	Sig. (2-tailed)	.848	.589	.	
	N	7	7	7	
Change numneg	Change numneg	.552	.898**	-.198	1.000
	Correlation Coefficient				
	Sig. (2-tailed)	.156	.002	.670	.
	N	8	8	7	8

** . Correlation is significant at the 0.01 level (2-tailed).

Chapter 6 - Client views on the acceptability of EMDR for long term depression

RQ - 6 Do clients find EMDR to be an acceptable treatment for long term depression?

The interviews took place around 2 months after the end of therapy. This was deliberate to ensure that real life had a chance to become normal and not revolving around therapy and to reduce the chance of being primed by therapists. The interviews lasted approximately 45 minutes and were undertaken with seven participants, five of whom achieved remission at the end of therapy, one was a responder and finally one who had deteriorated during EMDR. Ten people had started EMDR, one only had two sessions and never got past the assessment stage so was not interviewed as she had not truly experienced EMDR. One did not respond to letters and answer machine messages to meet up for the interview. Finally the other participant who deteriorated could not be interviewed. Although it would have been very helpful to get his views his mental state was such that it was agreed that he would not be contacted without the permission of his care coordinator and this was not forthcoming. The interviews focussed on three subject areas, the participant experience of therapy, their experience of memories and their experience of depression, the topic guide is in the appendix. Within the area of participant experience of therapy there were five themes, helpful aspects of EMDR, unhelpful aspects of EMDR, comparing EMDR to other therapies, the relationship with the therapist and the friends and family test. Within participant experience of memories two themes emerged, identification of the target memory and the experience of processing. The experience of depression contained two themes covering their current feelings of depression and whether or not other people had noticed change. There were three emerging themes to have come from the interviews and these covered the motivation to attend therapy, the stigma of depression and post traumatic growth.

6.1 Participant experience of therapy

Among those who were contactable and agreed to be interviewed, the overall consensus was that EMDR was very helpful.

'I think it was really helpful' (001)

'It was brilliant really' (005)

All seven participants made similar comments, all denied it had been unhelpful or damaging, however they were not necessarily convinced by some of EMDR's more unique aspects.

'The person who came in and the person who came out is different. That's fact. There's no disputing that. Now you can dispute the how's and which's and where's in between but the fact is I came out better than I went in, a lot better and it's continued on from there.' (007)

'The therapy that I had worked, which of the bits of it it was it's been useful whatever, even if that is just having therapy twice a week, who knows' (003)

6.1.1 Helpful aspects of EMDR

Both when asked in the interview about what was most helpful and also on the HAT forms it was frequently the preparation and relaxation exercises that were well thought of by the participants.

'that light stream was brilliant' (005)

'(therapist) did quite a lot of stuff with me around like having like a team of people. At the time I found it really annoying. When she first did it I just thought oh no, I can't be doing with this. (Laughter) I'm not doing all this imaginary nonsense but I think actually it did make me kind of more open to being kind of aware of who is in my life that I can rely on and people that I trust and being more open with people.' (001)

It was universally considered to be very helpful to have got to the root of the problem.

'You know and I was able to understand a lot of my, you know my background and everything, why I am as I am I suppose.' (005)

'this [EMDR] is the sort of thing that is going to tackle my deep-seated problems' (006)

Whilst the participants talked about understanding the things that had happened in their past they also talked about accepting there was a problem at all.

'it has made me aware that they were problems and that in itself has been quite helpful.' (001)

It was also helpful to get emotional at times and access the feeling that had been suppressed.

'For me it was really really good because it located the feelings in a big way, in a way I'm not, well I just don't think I have probably ever done it before' (011)

6.1.2 Unhelpful aspects of EMDR

One theme that ran through the interviews was one of individuality and the need for a person centred approach. Although everyone was pleased with EMDR in general there were some aspects that divided the group, they were mostly logistical, and could be accommodated if services were able to be a bit more flexible. This included the location of the therapy, most did

not mind where it was, some preferred St George's to their GPs, others would have preferred their GP's, but one participant found that St George's sparked severe anxiety that impacted on several sessions. This would have been avoided if therapy could have been offered somewhere else.

'I liked it being away from the GP. Yeah GP's would have felt too busy or something too much, not the right atmosphere. It was a nice atmosphere it was quiet.' (011)

'it would have been more convenient at (GP surgery name)' (005)

'it probably wasn't very helpful me having to go to that place, just because I just found the whole experience really stressful so I think and it got better because (therapist name) bless her, let me go in the back door. But I think that sometimes I would get myself so wound up about having to sit there and potentially see somebody I knew that that's probably kind of got in the way a bit' (001)

The number and length of sessions also came up. Most people had achieved remission by the end of 20 sessions but not everyone. An ability to alter the range of sessions to suit the needs of the client would be helpful. For many people the 50 minute session was long enough, some mentioned how tiring EMDR can be and did not want a longer session. For others the sessions were so emotionally difficult that they would have preferred a longer session so they had more time to calm down before leaving.

'Therapy sessions ought to be a little bit longer may be an hour rather than 50 minutes, I mean we always went over. I think it needs to be a longer session if it's a deep-seated problem like mine it needs to be longer.' (006)

'I would say I would need more than 20 yes. Yeah because I think it was just getting to it' (011)

Most of the participants really like this format of two sessions a week; however it was difficult for some to get the time off work.

'yeah it is more frequent than you would normally get but I suppose that focuses you better for and I mean if you had that many sessions once a week it would be a very protracted process. Although it might have been easier to get the time off work, but you might not feel you got the results the same way. The difficulty is how draining it is.' (003)

'I'm glad it was twice a week. I think once a week wouldn't have been enough and I would have felt that the progress was too slow. Whereas twice a week you could pick up on something quite quickly' (007)

'I think I would have preferred it once week so it would have gone on longer' (011)

6.1.3 Comparison with other treatments

All the participants in this study had received at least one type of psychotherapy before joining the research. In the main this was either CBT or counselling as these are the ones typically offered by the health service for depression. It is clear that most people did get something out of their previous therapy experiences, validation of their issues, coping strategies and recognising unhelpful thinking styles were all listed as beneficial.

'it was like errm like psychodynamic therapy so I suppose it was a lot less structured and went on for a lot longer errm yeah it wasn't as focused but yeah the same themes were definitely there. It was less focused and more just going with what is on your mind at the moment rather than having any kind of plan. Errm whereas, I guess there was more of an intention with the EMDR. That we are going to do this and that and you knew that you were following the process. I think they have probably both got their, I don't know, yeah there's good things to both of them.' (001)

'trying to challenge some of the negative thoughts well it was more when I realised that the kind of negative thoughts I was having I wouldn't even say out loud, and that's when I realised quite how, I hadn't even noticed how unpleasant I was to myself and I thought about some of the things I was saying to myself.' (003)

'it's good to recognise unhelpful thinking styles but don't think they go into enough to teach you how to deal with it. And to do things with it so it's very surface. I think it's very good for you know things that have occurred recently that aren't too in-depth.' (004)

'I had the hypnotherapy before and that has helped me to errm give me the tools to try and calm down in anxiety attacks or try and calm myself, little things too like the breathing thing.' (007)

However, there were problems. CBT is highlighted for not recognising the client's past as an important factor, many participants here described it as *'for surface things'* or *'fine if you have mild depression but not if it's deep seated'*. There is a definite view that long term problems cannot be solved without getting to the bottom of the issue. Which was one of the reasons participants liked EMDR. The other issue with CBT is that although the strategies and thinking styles are valued by participants trying to put them into practice when you are severely depressed they considered almost impossible. CBT was not the only therapy to have been unhelpful to the participants here. CAT and psychiatry also raise ire from 006 and 011 highlights the problem with some private therapy keeping client for far longer than they want to be there.

'the problem with CBT it's almost feels like you're, you've got to be responsible for everything and I think if you don't get a good therapist it can almost feel like you are being blamed for what's happening all the time and was I'd never had before was something that looked at underlying reasons because CBT is all here and now stuff.' (003)

'that (CBT) didn't really address the fundamentals of errm my personality and why I am like I am. Errm it's gave you strategies for managing it but they were very hard strategies if you are really depressed which is what I was. Very very hard but I did do, I really tried' (005)

'I've had most therapies, the worst one was psychoanalysis, CAT, the therapist doesn't say anything really. I had a very good one to start with who would look at me and look saddened or disappointed or happy or, but the next one I had, she left and then the next one I had sat there at an oblique angle so I could barely see her. And just didn't say anything ever and that was just awful.' (006)

'psychiatry doesn't work and psychiatrists don't know what they're doing. My experience of psychiatrists is completely negative, they just say try this comeback three months, try this one oh it doesn't work try this one. Hopeless.' (006)

'she could have had me going there for five years and I didn't want that.' (011)

Despite deteriorating during EMDR, 006 still preferred it to the numerous other treatments he had received in the past.

'if I was to meet a person in a similar position to me, the one I would go for rather than psychiatry or CBT or CAT or any of the other therapies that is the one I would go for, or medication, including medication I would go for EMDR first.' (006)

6.1.4 The relationship with the therapist

All the participants emphasised the importance of a good relationship with the therapist. They all felt the therapists they saw for EMDR made them feel comfortable and that this was essential for EMDR to progress smoothly. This was demonstrated in different ways, some spoke of 'validation' or feeling able to 'open up'. One explained that tapping was very intimate so whilst she felt fine with her therapist she is not sure how she would have found the same situation with a male worker (003).

6.1.5 The friends and family test

Ultimately the research question was to discover if the participants consider EMDR to be an acceptable form of therapy for long term depression and they certainly indicated that they do. They have given a lot of detail about what happened to them during therapy, what they think has been helpful and the parts of the treatment that were very difficult to go through. This is valuable information for clinicians and researchers alike. Crucially EMDR passed the 'Friends and Family test'. Increasingly, NHS services are asking their clients 'would you recommend this service to your friends and family?' All seven interviewees, including the one who deteriorated during treatment, said they would definitely recommend EMDR. Some acknowledged that other therapies had given them some tools but no therapy invited as much praise as EMDR did.

6.2 Participant experience of target memories

6.2.1 Identifying target memories

Initially the idea of identifying target memories was very difficult for the participants either because they did not have any obvious targets or that they did but were not sure they could talk about them.

'that was hard because I have no obvious negative things.' (003)

'yeah very difficult. Having to speak about something that had only ever gone on in my own mind from being quite a young age, something that is quite a sensitive issue' (004)

'Having to recall those memories was painful errm and they of course sparked off other memories that were equally painful.' (006)

'I was worried at the beginning that my trauma wasn't going to be the right trauma. Partly because it was, I had perhaps not seen it as trauma before in the way that you would as if you had had a car accident. So I wasn't quite sure whether I would fit the bill errm but that, it did.' (011)

6.2.2 Experience of processing

The participants preferred to have their eyes closed to help them to bring up the memory. This meant that they could not use the eye movements during processing but usually used tapping instead.

'so initially we tried to do it with me following eye movements but errm I couldn't think and have my eyes open at the same time (laughter) errm so we used the buzzers which worked like loads better for me.' (001)

'with the eye following you can't close your eyes' (007)

During the interview it became apparent that 004 had an extremely vivid visual experience during processing.

'I could feel something changing it was like my eyes were following the tap in some kind of way, like bouncing side to side while it was happening. I was thinking I could feel the physical sense that something was happening. How that would work I don't know. But it has.' (004)

'it was almost as though I could feel my mind searching (laugh). I almost felt like I was in a big room filing cabinets, I'm like (makes noise like flicking through papers), like a machine just rattling through, oh that's significant, oh that pops up, oh I didn't realise that. And it's almost as if these things were misfiled. I'm reading through things and I didn't expect to see this just lying around, it's almost as though, okay what's that doing here. Why is that out? Not with everything else it's almost like it's out of place or not put away properly.' (004)

'I was becoming aware of things, some of the things have never even come up in CBT. Some of the things I didn't even think with that big a deal and they turned out to probably be the

most significant thing there. Errm, the realisation from that was quite profound for me really. (004)

it would bring the emotion to the forefront' (004)

Although he was the most vivid in his descriptions he was not the only one to “see” changes in his target memories.

'I would be thinking of a picture of something but then it would move onto yeah yeah. That's it.' (005)

'yes and when the eye movements were being done it was (daughter's) face who was constantly popping up, reassuring not saying anything but, just reassuring.' (006)

Not everyone is quite so visual in their imaginations however and not all the participants had this reaction.

'yeah like it felt different, it seemed different but I don't know exactly how.' (001)

'nothing I can put my finger it's difficult because over time eventually your body tires itself out so, eventually you're probably going to stop or at the least do something different.' (003)

'That is a different image. It's like I'm not, what keeps coming in, it doesn't matter.' (007)

'I can't say no I've never thought about that, I think that it was I was listening more to what (therapist name) was saying.' (011)

Several participants mentioned that the bilateral stimulation seemed to cause a change of state in their mind.

'when you had actually been doing the processing, sometimes I felt quite weird. A bit kind of sickie or spaced out or something' (001)

'trance like' (007)

Participant 011 described that most of the time she lived in her *'intellectual head'* and that during EMDR she was able to get into her *'emotional head'* which was something she had never done before. Interestingly these are the same participants who did not have a very visual image change in their memories but have clearly had a profound experience.

These experiences were not confined to the therapy session.

'weirdly some of the things that happened not necessarily in the session, kind of after the sessions at night and stuff like I would have quite vivid dreams errm and also I would start to remember things. But not like bad things, quite nice things that I had may be not given any, that hadn't popped up before. Just like nice memories from being a child and that was really

nice to, I felt like it's given me access to those again all something but may be because I had I don't know gone to memories that were nearby or whatever I don't know' (001)

She said this was incredibly helpful because during the session they would focus on something negative that happened at a particular age, and then later she would access these positive memories. She felt that it 'restored balance' to her childhood, reminding her that although there were unhappy incidents, there were some really good ones too.

During processing these target memories changed, each person appears to have experienced this differently but the end result is the same, the memories have gone from being incredibly traumatising to not mattering.

'I've controlled it subconsciously I've not sort of got any physical strategies for doing it, it has somehow not happened. It's up here (taps head), it's switched it.' (005)

'but errm so the memories don't bother me now. Errm I mean they weren't memories until I did this, they were my childhood really. So they are just there now and I can understand it.' (005)

'That is a different image. It's like I'm not, what keeps coming in, it doesn't matter.' (007)

6.3 Participant experience of depression

6.3.1 Do they feel better?

According to the participants EMDR was in parts very difficult, but generally a very positive experience. However, the aim of all therapy is to ensure lasting changes, to reduce the symptoms of depression and have a positive impact in the wider lives of the clients. The other key point is that the Hamilton rating scale of depression indicated that the participants did very well in therapy and most are in remission, however, do they agree with that assessment?

'I feel like different to how I felt before I started the EMDR.' (001)

'a huge ball and chain has been loosened, it's not completely gone but I don't feel like I've got the weight of it any more. I feel like it's still there I've still got marks, scars but don't feel like I'm dragging around this weight.' (004)

'taking me before the course and me after the course it's almost like a different person.' (007)

Clearly the participants feel that things have moved in a very positive way, they were also very clear about what specific parts of their lives have changed. Again this is expressed by the

participants in different ways, some talk about how the memory no longer has such an effect on them, others talk more about reducing day to day stress in their lives.

'I certainly think depressive memories can sometimes have a traumatic effect on you, they certainly did in my case. I was almost visually traumatised. Every night I was having intrusions. I can't remember having one for a while, I might have had one in a few weeks' (004)

'there were two, two really big things for me I have always felt that everything that has happened has always been my fault, I'm the one that is caused it, it's been my fault, on the other really big thing was that nobody ever really liked me and why did people want to be friends with me. Both of those really went straight back down to my childhood and that was how I was made to feel right from being little. So my whole and you know you're not a nice person, your own self-image and those things that I actually know now were weren't true. So they actually helped me to look at people and myself very differently.' (005)

'I was always highly stressed, quite wound tight in a way. Like a coiled spring you know the compressed spring. Errm whereas I don't feel as compressed these days.' (004)

'I try not to rush in so much, I try not to let things build up and get me down I try to slow things down much more, I think about things in a different way.' (007)

The AIP model differs from CBT in that it considers negative thoughts to be a symptom of the pathology (caused by the unresolved memory), rather than the cause. 005 had previously had a failed course of CBT but here managed to change her thinking style even though this was not worked on directly during the treatment.

For others it's about resolving issues in the past and moving on or how they cope better when a crisis does strike.

'if you don't believe in yourself then you are not being fair to yourself as you going to experiences in your life. You are going to be critical all that time, rather than think well actually I did that quite well considering' (011)

'To leave me feeling better, I'm at work having a laugh with people. I don't think, I do take things to heart sometimes, I do start to self-criticise and to beat myself up but I'm able to sort of bounce back quickly from it, like within the half-hour or hour not be affected for weeks. So again a massive significance. I think personally I've seen some significant changes.' (004)

As well as being better able to cope with the memories that were the target of therapy, or reduce stress and depression in their daily lives there were statements that appeared to go beyond healing and into positive growth. Participants began talking of acceptance, insight into themselves and their relationships with others and a need to look after yourself if you are to remain healthy.

'I'm trying to be more accepting of yeah emotional responses.' (003)

'you forget that you've got to maintain yourself like you're a car, if you don't it's going to let you down. Errm and I think that I had neglected to give myself time and I think this therapy helped me realise that.' (004)

'you know you're not a nice person, your own self-image and those things that I actually know now were weren't true. So they actually helped me to look at people and myself very differently. Errm and one of the really big things has been the relationship with my eldest daughter, that was really really helped me understand my relationship with her.' (005)

'I don't have to forgive her actually. She was horrible and I have to accept that' (006)

'I'm actually going through some sort of challenge in my life at the moment which is about saying what your needs are, what your wants are.' (011)

Like many people with long term depression these participants had difficulty with many of their relationships, whether it was with family, existing friends or making new ones. Again everyone commented on how their view of relationships has changed and the tangible effect that is having on their interactions with others.

'it was like I was more willing to errm connect with people or something and I think that has kind of continued I have been less avoidant of sort of my relationships I suppose. I think it makes me feel more like more kind of optimistic about the possibility of kind of making new relationships.' (001)

'I do feel as if I am in control a lot more of my emotional feelings really and I understand why I have been like this all my life. It's had a massive impact on the way I view friendships.' (005)

'My relationship with my daughter is so much better because I laugh and I joke with her now.' (007)

'you've got a lot of people expecting things from you... but internally I think it's about that asking for what you want which is really quite fundamental.' (011)

6.3.2 Have others noticed?

Several people commented on how others had noticed change in their mood and behaviour.

'I had supervision and I was just like I've got my last session like the review thing today and she [manager] was asking about do I know the results from other people or anything, had everybody else had such a positive response and that kind of thing' (003)

'In fact my friend said 'how do you get this?.' (005)

'All I could do is say what other people see in me now how much better they all see me.' (005)

'even people who know me just say I look different, just the way I will smile more, or my eyes are different' (007)

'I'm not saying that I'm completely cured, my wife would say 'I don't know any change', but I feel a change.' (004)

Although 004's wife did not think he had made much improvement he disagreed. He put this disagreement down to the fact that *'she didn't know the half of it'*.

6.4 Emerging themes

6.4.1 Motivation

All talking therapies ask for a significant investment from clients, it can be hard work and different people will find the motivation to continue in different places.

'I think the thing that was really useful for me was that it was the research project. And so I was much more willing to accept this was kind of weird (laughter) like what's going on here oh well just go with it because there is almost like a higher purpose to it and if it was just for my benefit I don't know if I do have err. I think I would have been more, what is this all about, why am I doing this, is this a good use of my time, it's a big use of my time etc etc. Whereas if there was going to be something practical that came out of it whether it worked for me or not than was more useful I think than, yeah having the additional reason to do it was helpful for me.' (003)

6.4.2 Stigma

The issue of getting time off work also linked to the issue of mental health stigma and about talking about depression to employers and colleagues. Despite initial fears the participants their employers were very supportive, allowing them time off work, not only for the therapy but also for the research appointments as well, some people's colleagues were not as open minded.

'I've not had that much choice, I've had to tell them what was going on eventually, but I feel able to talk about and I've got a really good support network at work.' (003)

'very fortunately (employer) were very very good. They let me have the time to do it' (004)

'one of the hardest bits was tiptoeing round colleagues. Trying to bat off questions, I just told them it was physio linked to research. Because when something is physical it's easier to talk about, people understand it. I sit next to somebody who you mentioned owt about depression or anxiety and he screws his face up and that is his first reaction, 'people, what's that about blah blah blah', really negative about it. So to be sat next to somebody like that who is fishing for information about where you have been, what you've been doing, blah blah blah, who has that opinion, was quite a difficult experience,' (004)

Unfortunately it's not just members of the public who have difficulty understanding depression.

'I honestly hope that GPs get more awareness of these things' (004)

Here 004 is not just talking about depression but also about getting the right treatment. Despite not responding well to CBT and actively asking for something else, he was given CBT on three occasions.

'I've always known that the therapies I've had in the past errm, through IAPT have been CBT based. I've known very early on into that it wasn't for me. errm, yet trying to get other people of the power to refer you to these things to understand that you have got a bit of an idea about what you are, where you are, you've studied a little bit of something, and you've got all bit more awareness than a lot, and you know something is not right for you but you don't know what it is. Trying to get that across and trying to get that has been something that took the best part of seven or eight years.' (004)

This clearly frustrating experience only came to an end when his latest CBT therapist heard about this research programme and asked him if he would like to try something different. Service managers in the NHS are currently claiming to respect clients as experts by experience, that they know their condition better than anyone else, but because there is very little flexibility in the system this expertise has little chance to be expressed.

6.4.3 Positive growth

There is a field of study around post therapeutic gains sometimes referred to as positive psychology or post traumatic growth. This refers to the benefits of treatment over and above 'getting back to normal'. The participants made several references to areas that were not directly worked on the therapy but nonetheless have seen behavioural or attitudinal change. They talked about being more accepting of themselves, their emotions and their histories. They also mentioned having a new found confidence to apply for a promotion (004) or to ring friends (001,005) which they would not have considered doing before.

There was also a recognition that it is important to look after yourself. Whether that is eating properly (005), building in some relaxation time (004) or leaving stress at work and not taking it home with you (007).

'you forget that you've got to maintain yourself like you're a car, if you don't it's going to let you down. Errm and I think that I had neglected to give myself time and I think this therapy helped me realise that.' (004)

6.5 Interlinking themes

The separation into themes for qualitative analysis runs the risk that interactions between themes are missed. The themes here are clearly interlinked. The relationship with the therapist relates to the identification of the memory and feeling comfortable enough for that to be possible. A good relationship with the therapist was highlighted many times as important and allowed them to feel secure and validated. They felt comfortable enough to explore parts of their pasts they had not revealed to anyone else, even previous therapists. They also felt comfortable enough to use tapping for processing. This requires the client and therapist to be in closer proximity than in most therapy and to have physical contact.

The processing also linked to the themes of helpful and unhelpful aspects of the therapy because although it was considered helpful overall, there were some difficult aspects to overcome. Not just identifying the memory but also processing it. All the participants found the eye movements difficult and tapping could have caused issues if the participant had not had such a good relationship with their therapist.

There are links between identifying the memory, thoughts on their depression and positive growth. Getting to the bottom of the reason for their depression was universally considered helpful. By developing an understanding of their pasts and feeling that there was a good reason for their depression, helped them to feel validated and more accepting of self. This allowed them to move past the depression and adopt behaviours and attitudes more likely to lead to a healthier outlook such as being more engaged with friends and family, accepting emotions, making time for relaxation and leaving stress at work.

The friends and family test linked to the things other people had said about their depression. There were cases of friends asking to be part of the research or asking about how it was going for the others as they had seen such a change in their friend. This is a level of endorsement that cannot be underestimated.

Chapter 7 Integration Chapter – Mixed methods

Although the quantitative and qualitative methods have provided interesting results a true mixed methods study recombines this data and reanalyses it to discover if there is more to be learnt. The three main questions of the study remain, did EMDR have an impact on depressive symptoms, does the data support predictions of mechanism of change and did the participants find the treatment acceptable? However, this chapter will draw on mixed methods to answer these questions. The quantitative and qualitative data can be combined at different stages. The data for the three key research questions will be combined at the stage of analysis using a mixed methods matrix (O'Cathain et al., 2007). This will look at the data on an individual level. Data can also be combined at the group level at the interpretation stage using the triangulation protocol (O'Cathain et al., 2007). This will take the different types of data and look for convergence, divergence and expansion of understanding between them.

7.1 Impact

In depression diagnosis is heavily based on the subjective reports from the clients themselves, it is important that the clients agree with the assertion that they have improved over the course of treatment. In a client focussed service, with an emphasis on recovery, if the client is not satisfied that they have improved then they cannot be said to have improved sufficiently. Table 7.1 is a mixed methods matrix allowing close comparison of how much the participants changed on the primary outcome measure of the research (the Hamilton rating scale of depression - HRSD) and the views the clients expressed during the interviews.

006 recognises issues but also benefits that EMDR had for him

'I know now something that I knew then but didn't realise it had had such a spectacular effect and that is the use of triggers that set me off on a train of negative thought and I wasn't sure whether errm and I'm still not sure whether me recounting all of these experiences from my history was errm useful.' (006)

004 acknowledges that he is 'not cured' but had a 'ball and chain lifted'. He thinks his wife hasn't seen much difference because she 'didn't know the half of it'. He was very candid about the changes he has seen and the ones he hasn't. He did not reach remission during the 20 sessions of therapy but he had one of the highest scores on the HRSD at the start and he did make very large gains, he had the third largest improvement on that scale.

Table 7.1: views of clients and their change on the HRSD

	HRSD change	Views of change	Views of others
001	14 (remission)	'at the moment like I feel like things feel clearer or they feel bit more hopeful definitely'	
003	8 (remission)	'I'm trying to be more accepting of yeah emotional responses'	'my boss commented on it today you see... I had supervision and I was just like I've got my last session like the review thing today and she was asking about do I know the results from other people or anything, had everybody else had such a positive response '
004	16 (response)	'I'm not saying that I'm completely cured, ... but I feel a change'	'my wife would say 'I don't know any change''
005	23 (remission)	'there has been a massive shift in how I am'	'my friend said 'how do you get this' 'All I could do is say what other people see in me now how much better they all see me'
006	12 (deteriorate)		
007	16 (remission)	'I felt a lot more relaxed or like a weight off my shoulders kind of thing. I definitely came out of the sessions feeling better than when I went in.' 'it's like a new beginning'	'people who know me just say I look different, just the way I will smile more, or my eyes are different'
011	8 (remission)	'Its acceptance really its acceptance that something happened'	

011 is probably the largest discrepancy. According to the HRSD she moved into remission during treatment. However, during the course of treatment she realised how much pressure her family put on her and how little support she received in return. This is obviously very distressing and means she is going *'though a difficult period'* right now. She may not be clinically depressed but it could be argued she is not psychologically balanced. She was also lacking in confidence during the interview. At times she reverted to talking about herself in the third person and when she was asked if she thought she needed more sessions she skirted around the issue until the interviewer gave her permission to say yes. She also said she thought getting EMDR was a *'treat'* implying it was a luxury rather than a treatment for her mental health.

This lack of confidence was also seen in 006, who deteriorated during treatment, he felt that he should not be contributing to the development of EMDR for depression because he was not important. He referred to the recurring image of his mother's disapproving face and her voice telling him that it was *'not his place'*.

005 and 007 were the most enthusiastic about EMDR using phrases like *'brilliant'* (005) and *'it's like a new beginning'* (007). 005's only negative comment was that she was saddened by finding EMDR so late in her life and wondered how things would have been different if she had received it as a young woman, a view echoed by 011.

001 and 003 are both young healthcare professionals. Although both did well in treatment, and acknowledged that, they were not as enthusiastic as 005 and 007. This is possibly in part due to very high expectations from the start *'I wanted there to be one thing from the past that was stopping me from being happy and that I could go and fix that memory and then be happy'* (001). This is not likely to be the case especially when suffering from a chronic health condition. 003 has clearly made impressive progress but some potential issues remain. 003 has difficulty expressing emotion and views crying as being wrong and something that should be fought, whilst she now admits to *'trying to be more compassionate toward my emotions'* she still keeps a diary noting all the times she is *'not coping'*.

With the notable exception of 011, the HRSD matches remarkably well with the views of the clients. The participants also had views on issues that might affect improvement during EMDR. It is clear that when dealing with complex cases a large number of sessions might be necessary. 004 made impressive improvements and given more sessions he may have moved into remission as well. 011 eventually admitted that she would like more sessions, although she would have been happy to have 20 but more spread out rather than having the twice a week. Other issues that were mentioned were not spending enough time in preparation so you could not cope with the strong emotions brought up in the session. This was brought up by 006 who admitted that he *'thought he could cope but couldn't'*. The effect of outside factors was acknowledged by several people, 004 noted that if you were stressed by work it was hard to get into a session as you spend most of it relaxing.

7.2 Mechanism

The EMDR grey literature contains very vivid descriptions of processing when the image of the memory the client is holding in their head changes dramatically and helps them to take out the emotion so they can put the incident behind them (Shapiro, 1995, Shapiro, 2005, Shapiro,

2009a). However, the peer-reviewed literature is sparse when it comes to client descriptions of what is happening to them during processing.

Here 004's interviews were full of metaphors and similes and his descriptions of EMDR are no different.

'the tapping? I could feel something changing it was like my eyes were following the tap in some kind of way, like bouncing side to side while it was happening. I was thinking I could feel the physical sense that something was happening. How that would work I don't know. But it has.' (004)

'it was almost as though I could feel my mind searching (laugh). I almost felt like I was in a big room filing cabinets, I'm like (makes noise like flicking through papers), like a machine just rattling through, oh that's significant, oh that pops up, oh I didn't realise that. And it's almost as if these things were misfiled. I'm reading through things and I didn't expect to see this just lying around, it's almost as though, okay what's that doing here. Why is that out? Not with everything else it's almost like it's out of place or not put away properly. And I think that's what EMDR is about isn't it, it's about trying to find stuff that you've not processed or filed away in storage correctly that's bothering you. Errm, because it's not been dealt with, it's like unfinished business type stuff. Errm, and so I'd thought that was helpful' (004)

'It has a buffering effect. So when I was tackling XY and Z it felt like it buffered things around those things. So it kind of had a wider impact. I think it kind of had a ripple effect really' (004)

'I feel like burden has been lifted the vividness of the image is not anywhere near, it's very greyed down, sort of like lacking colour really. At the time, it wasn't like fluorescent vivid you know some kind of wappy crazy thing, it was just like a very clear, crystal clear I'm there its happening right under my nose kind of situation where as now it's like I'm further back from it, sometimes I can barely see it, it's not like I'm right distant instead of being in the room sometimes I maybe stood outside the room through the window but the window is steamy. It's a bit like that sometimes. So and the emotional sort of errm value attached to it is, it's much less damaging, it's much less, it doesn't really, it's not got that fire it had before it's very sort of tame. I hope it stays like that' (004)

He has clearly benefited from the EMDR and the effect on his particular target memory has been quite profound. These descriptions could be out of one of the training books but are not from any of the verbal or written material that he was given during the research. This does not stop him from having done his own research but he did deny this in the interview. When talking about lots of different themes 004's language remains metaphorical and full of vivid description. It seems likely that he is a very visual type of person in the way he imagines and describes his world.

However, as Chapter six described not everyone had the same vividly visual experience. There seemed to be a split in the group, three had a visual experience and three had a 'trance like' experience, one had a more abstract experience where she was convinced there had been

change but had no words to describe what that change was.

Table 7.2 contrasts the type of experience described by the participants with the key changes in the content analysis to unravel if there is a difference in the way EMDR has affected the target memories and the responses that they induce or it is just that some people have very visual imaginations and some people do not.

003 doesn't even mention the target memory in the interview, even when asked about it, it seems to have so little importance there is no need. She rationalises that the memory, which was from when she was a teenager, is linked to an ego state response and that she is now *'trying to connect with that person'* rather than *'fighting it all the time'*.

Table 7.2: Content analysis v descriptions in interviews

	Change in total word count	Change in neg statements	Change in pos statements	Experience type	Reports of change
001	-885	-22	-3	Trance	'it seemed different but I don't know exactly how'
003	-67	-5	+1	Abstract	'Nothing I can put my finger on'
004	-3353	-15	-3	Visual	'the vividness of the image is not anywhere near, it's very greyed down, sort of like lacking colour really'
005	-160	-6	+1	Visual	'I would be thinking of a picture of something but then it would move on'
006	-83	-4	0	Visual	'when the eye movements were being done it was (daughters)'s face who was constantly popping up, reassuring not saying anything but, just reassuring'
007	-775	-13	0	Trance	'It's like I'm not, what keeps coming in, it doesn't matter'
011	-53	-15	-2	Trance	'definitely the feelings changed'

Those describing 'trance-like' experiences appear to have generally larger reductions in negative statements, but there does not appear to be any pattern in the changes of word count or positive statements. Indeed the change in positive statements did not occur as expected at all. The AIP model states that the memory should become positive or adaptive (Solomon and Shapiro, 2008). In most cases here this did not happen. The memory became

irrelevant. The memory remains, it is still there and most people acknowledged that it was an unpleasant thing but it is no longer of importance (*It's a different image...it doesn't matter – 007*). It is in the past and that is where it belongs. The AIP clearly predicts the number of positive statements in the memory narrative to increase and it has not. Despite this the participants report having generally benefited from the EMDR treatment. They express many positive statements in regards to their lives and their futures but not towards the memory.

'the memories are there, I don't think they will ever go, because that's memories..... it wasn't nice but then it wasn't very clear, it was like looking through steamed glass.....I don't think it'll ever go but I don't think it had the impact it did.' (004)

In this respect these interviews raised more questions than they answered.

Table 7.3 reports each participant's HRV and Likert responses and the reported levels of stress and impact of the memory in comparison with the type of experience they had during processing to investigate any links here.

Table 7.3: Mixed methods matrix of changes in emotional response to the memories on different measures

	HRV change	Likert scale change				Exp type	Reports of change
		Emotion	Vividness	Completeness	Closeness		
001	+++					Trance	'it seemed different but I don't know exactly how'
003	++	More	No change	No change	Less	Abstract	'Nothing I can put my finger on'
004	-	Much less	Less	Much more	Much less	Visual	'the vividness of the image is not anywhere near, it's very greyed down, sort of like lacking colour really'
005	+++	Much less	Less	Much less	Less	Visual	'I would be thinking of a picture of something but then it would move on'
006	+++	Less	No change	Less	Much less	Visual	'when the eye movements were being done it was (daughters)'s

							face who was constantly popping up, reassuring not saying anything but, just reassuring'
007	++	Less	No change	No change	Less	Trance	'It's like I'm not, what keeps coming in, it doesn't matter'
011		Much less	Much less	Much less	Less	Trance	'definitely the feelings changed'

HRV change – slight decrease (less than 10 μ S), + slight increase (less than 10 μ S), moderate increase (10-30 μ S), +++ large increase (more than 30 μ S) Likert change – no change - difference is +/- 10mm, less – difference is 11-50mm, much less – difference is over 51mm. Empty cells denote missing data.

Those describing a visual type experience appear to have experienced a greater distancing effect but it is impossible to be sure as the numbers of participants involved are so small. The changes in the other descriptors of the memories do not appear to have any relationship to experience type. This is perhaps surprising as it would be logical to hypothesise that those with the visual type of experience would be more likely to notice changes in descriptors like vividness as this is a very visual term.

The key response here is that something has changed, what it is is not really that important because the memory does not matter anymore. Only 004 has the flowing, vivid descriptions that are considered to exemplify EMDR in the text books, most of the other participants did at least as well as 004, both on the HRSD and by their own reports and yet did not describe their experiences in such a way. As EMDR has made attempts to distance itself from hypnosis it (Shapiro, 1993) could be that there has been selective reporting and this trance like state is common but not discussed.

7.3 Acceptability

Of the 10 people who began EMDR as part of the research project, three were discharged early (i.e. before the clinician felt they had made sufficient improvement to end treatment). All three were discharged on the advice of the clinician, one was unable to manage the research commitments rather than the EMDR and two had deteriorating mental health and needed community mental health team care. Therefore no one left the treatment programme because they did not want to continue receiving EMDR once they had started it.

One participant dropped out between the end of treatment and the interview / follow up sessions (012). This participant did not respond to any attempts to contact her so it is unclear why this was. However, at the end of the treatment period she requested details of how to receive EMDR outside the research project, so it would appear that it was the research appointments, not the EMDR appointments, which she did not want to be a part of.

During the interviews the participants were asked some direct questions to discover their attitude to possible issues with EMDR:

- Would you recommend EMDR to family or friends in a similar position to you? (The friends and family test)
- Was there anything unhelpful or damaging in the EMDR?

Table 7.4 shows a comparison between what participants said about unhelpful aspects of the treatment and whether they would recommend EMDR to their friends and family.

Table 7.4 shows that all participants said they would recommend EMDR to friends and family, in fact two actually did, they asked if there was any space left in the research clinic as they knew someone who wanted to be involved. This is a clear endorsement of the participant's view of EMDR as an acceptable treatment and also that at least some of them improved so much that this was visible to family and friends who then wanted to do the same.

Table 7.4: Interview responses to the Friends and family test and questions about unhelpful aspects of EMDR

	F&F	Unhelpful
001	'yeah definitely yeah'	'only thing in terms of the actual sitting in the room... I just found the whole experience really stressful'
003	'yes, in fact I have a friend who wants to do it'	'only that it was exhausting'
004	'definitely, all the way.'	'sometimes depending what was happening outside of here with me and I be stressed out I might be tired, ...on the occasions where I found it hard to relax for no reason really, it wasn't anybody's fault, it wasn't anything I was doing I don't think it certainly wasn't anything (therapist) did'
005	'oh I would yes, yes definitely. In fact my friend said 'how do you get this'.'	'There was nothing that was unhelpful'
006	'yes I would given the option.'	'I was doing quite well in the therapy, in the sense that I understood it, just the fact that I was doing well may have contributed to my downfall'
007	'yes definitely. I have, yes. I mean that course that I did	'no I have no memory of anything unhelpful.'

	really did sort of change me, well changed my life really.'	
011	'yeah I would, I would recommend it'	'Nothing'

The biggest complaint about EMDR was that it was so tiring it was difficult to do anything afterwards. It was also mentioned that it was hard to get into a session if you were stressed; it meant spending a long time in the session relaxing so you were in the right frame of mind to continue. Only two participants deteriorated during the project. One of these could not be interviewed due to his mental state. The other was interviewed and despite not doing well he held EMDR in high regard and made it clear that he would use it again in the future if he got the chance.

'if I was to meet a person in a similar position to me that is the one I would go for rather than psychiatry or CBT or CAT or any of the other therapies that is the one I would go for, or medication, including medication I would go for EMDR first.' (006)

7.4 Triangulation of interpretation

Triangulation aims to use the different information coming from different sources of data to look for convergence, divergence and expansion in understanding. A triangulation protocol (O’Cathain et al., 2010) looked at the group data from the quantitative and qualitative methods, this is summarised in table 7.5.

Although there was some divergence at the individual level there is little to be found at the group level. The qualitative and quantitative data regularly converge and help to expand our understanding of the findings from the individual methods.

7.5 Conclusions

Although there were very small numbers in this project there are still some important findings. Of the nine participants that had more than two sessions of therapy seven had statistically reliable and clinically significant improvements in their depression symptoms. This is highlighted both on the HRSD results but also in the comments made by the participants in the interviews. Improvements were so marked in certain cases that family and friends of the participants wanted to join the project. For the majority the gains seen at end of treatment were maintained (or even better) at follow up.

Some, although not all, of the predictions of the AIP model were seen. However there were significant discrepancies in certain areas. Not least the trance like experience of three of the participants. The reason for this remains unexplained as it was so unexpected the questions required to investigate the phenomenon further were not asked at the start of treatment.

The value of using mixed methods in this study has been to use data from different sources to expand on the understanding of using EMDR with depressed clients.

Table 7.5: A triangulation protocol matrix for the Sheffield EMDR and Depression Investigation

Quantitative data	Qualitative data	Convergence/Divergence/Expansion
Impact of EMDR		
Clin sig & Stat rel* improvement in HRSD	Report feeling better but with qualifications	Convergence and expansion
Improvement on IES	Memory no longer matters	Convergence
Improvement on social functioning	Report improved relationships	Convergence
Consistent improvement seen from about halfway through treatment	Reported that EMDR helped but mentioned phase 2 interventions more than phase 4	Convergence and expansion
Mechanism of change		
Increased distance from the memory	Memory reported as no longer important	Convergence
Decreased vividness/ completeness/ emotionality		
Increased heart rate variability		
Decreased heart rate and skin conductance response		
	Visual and trance like experiences	Expansion
Acceptability of EMDR		
No drop out from therapy	Friends and family recommendations	Convergence
Only two did not engage	EMDR reported favourably in comparison to other therapies	Expansion

*Clinically significant and statistically reliable improvement in Hamilton Rating Scale for Depression Score

Chapter 8 Discussion

This thesis has described a feasibility study to investigate if EMDR has the potential to be a treatment for long term depression. Eight of the nine participants with before and after treatment data points showed clinically significant improvement and statistically reliable change on the primary outcome measure (Hamilton Rating Scale for Depression); this was reflected in the secondary depression measures with eight on the BDI-ii and six on the PHQ-9 showing clinically significant improvement and statistically reliable change. Five of them had non-clinical levels of depression after treatment. Of the ten who began the intervention three did not receive a full course of EMDR. One dropped out as she did not have the time to attend therapy twice a week, one participant was discharged by the therapist as she was concerned the participant was not engaging with the treatment and proceeding could be detrimental to him. One participant dropped out due to a relapse in agoraphobia and could not leave the house to attend therapy. The first went back to IAPT; the other two were referred to the local community mental health team.

This indicates that it is feasible to design and implement an EMDR intervention for depression which is acceptable to service users and potentially effective. This would need to be investigated further in larger studies with more diverse populations and compared to the effects of CBT. This study used 20 sessions of EMDR. With CBT or counselling in IAPT a course of treatment can be between five and twenty sessions for depression (BABCP, 2012). It would also be possible to investigate whether EMDR can be successful at a lower dosage. If EMDR requires 20 sessions it could be considered as a treatment for those who have previously not responded to shorter treatments of CBT and counselling. All the participants in this study had previously received at least one and up to six courses of psychotherapy but remained symptomatic, which indicates EMDR may be suitable for this hard to treat client group.

Encouragingly the participants were enthusiastic about EMDR at the interview and all would recommend it to family or friends in a similar situation. Despite being a small study some of the data investigating mechanism of change was very interesting. The study data supports the theory that EMDR works via taxing the capacity of the working memory. It also suggests that although the AIP assertion that EMDR can be used to treat more than just PTSD may be correct, the AIP itself may not be complex or nuanced enough to explain how EMDR works in depression.

8.1 Strengths and limitations of the Sheffield EMDR and Depression Investigation

Despite being a small study it has several strengths: it addressed the research questions that it set out to investigate. The quality of the data collected was good, it included a good number of replications giving it greater validity and there was very little drop out between the end of the study and the follow up.

Whilst all efforts were made to make the study as rigorous as possible it has some limitations. As with any PhD study there was a lack of resources in terms of finance, duration and manpower. In fact additional funds had to be secured from the Royal College of Nursing Foundation and the University of Sheffield's School of Health and Related Research to be able to pay for the therapists to deliver the treatment. Without these generous grants the research would not have gone ahead. Duration was also a problem; the time limited nature of PhD courses and a delay in receiving NHS R&D approvals resulted in a follow up period of three months. At least six months, preferably a year or more would have been more appropriate when working with long term depression but this was just not possible. A PhD is also a solo project, ideally it would be better to have at least two people deciding inclusions and extracting data for the systematic reviews and cross checking the coding for the content analysis. However, there was no one available to complete this task so it was done by the author alone. Arguably this is also an issue for the framework analysis on the interview data. On the other hand, one could also argue that as any identification of themes necessarily incorporates the researchers own feelings and beliefs as well as those of the interviewees, this cannot be replicated in the same way as quantitative coding, nor should it be attempted (Bazeley and Jackson, 2013). This is a feasibility study and as such is small in size and did not have the power required for some of the secondary analyses. However, the primary questions were answered within the remit of a feasibility study.

Another limitation of the study is the potential for bias from the allegiance of the researcher. The author is an EMDR therapist and despite all attempts to achieve equipoise there remains the potential that this study is influenced by the researcher's allegiance (Luborsky et al., 1999). Although, both critical and subtle realism and post-positivism recognise that true objective measurement is impossible, it should nonetheless be strived for and methodological rigour can reduce the chance of bias (Maxfield and Hyer, 2002). Even when the researcher takes all possible measures to achieve this they are not the only people involved in the data collection. There are also the participants. Once again due to a lack of resources the data collection and

analysis was done by the lone PhD student. So not only did the researcher know the participants, the participants knew her. The participants were of course aware of the aims of the research, they had all received a client information sheet and had the chance to ask questions, and they as much as anyone wanted the EMDR to be successful. It could be assumed that this was purely selfish, they wanted to get well, and who could blame them? However, it was soon discovered that there might be another motivation behind the dedication to data collection that many of the participants showed. The therapists started reporting that at the end of a session the participants would start filling in the Helpful Aspects of Therapy forms and they would start asking questions such as 'Is this enough?' or 'Is this what Emily needs?' It was also noted at the memory recordings they would describe their memories and then say 'Is that ok?', this especially occurred at the end when the recordings were much shorter. There are numerous recordings of the researcher saying 'It is your memory, if that is how you see it that is great'. It began to appear that a desire to help the researcher was a powerful motivator for the participants. This was confirmed by some of the interviews when the idea of helping someone else was mentioned again. This is not entirely unexpected when working with people with long term depression, many had issues around worthlessness and that they should not do things for themselves. Thus some may have started or stayed in therapy for the researcher. As almost everyone improved significantly it is not a concern that they were unintentionally coerced into something harmful but it could mean that the data quality is better than it would have been and that there may have been more dropouts if the participants had only been in therapy to help themselves. It is difficult to see how this could have been approached differently, the participants needed to be aware this was a research study, they needed to meet the researcher to be screened so a relationship was formed from the beginning and as previously mentioned there was no one else to do these jobs.

In 2005 Horner and colleagues published a paper on using single case designs to identify evidence based practice. Within that paper they listed 21 quality indicators for single subject research under the headings of description of participant and settings, dependant variable, independent variable, baseline, experimental control and internal validity, external validity and social validity. The main issue where this study does not reach the standards set by Horner and colleagues is for the independent variable to be 'systematically controlled and under the control of the experimenter' (Horner et al., 2005). In this study the baseline period was decided by how quickly a therapist became available and not formally randomised. Although

this means it is not a true experimental design, it was clinically more appropriate as randomisation could lead to impossible situations such as a baseline being specified as too short and a therapist not being available or it being too long and a therapist was available but was waiting for the computer allotted baseline period to be up, this would entail preventing a participant from accessing treatment unnecessarily and was considered unacceptable. This was mediated slightly in that a one week baseline was mandatory; however in the end everyone's baseline was longer than this.

Although under ideal circumstances SCED can make causal inferences this study did not meet those ideal conditions. Weaknesses here involved non-random, unstable baselines and using an AB (rather than ABAB) design due to the time restraints mentioned above and crucially the irreversible nature of the intervention.

The baselines all contained at least nine data points, some as many as 41. The key use of a baseline in single case experimental design is to offer a prediction of how the long term illness would progress over time if no intervention occurred. For this to be of most use the baseline needs to be stable. Unfortunately in this study the measure of daily low mood varied widely from day to day and for many of the participants there were indications of trend either in worsening or improving low mood during the baseline phase. For this reason conclusions of cause and effect are not possible as the baselines were unable to predict with confidence how low mood may or may not change without the intervention. This is also an issue for the mechanism of change questions. For the data to be able to relate to mechanism of change it must be assumed that any change occurred due to the intervention. Despite this weakness, the design is sufficient to answer the primary research question, because this was a feasibility study and it did not aim to investigate efficacy.

The conclusions of this study must be that the results indicate change occurred, but it cannot be certain that this was due to the intervention. Larger, randomised and controlled studies will be able to confirm or disprove any preliminary conclusions from this study.

Although this thesis contains a systematic research review in its second chapter, I was unable to perform a meta-analysis because only one randomised controlled trial investigating EMDR and depression was discovered. This trial looked at a subpopulation of those with depression who also had had a myocardial infarction. The study was of low quality had no active

comparison group. No conclusions about the efficacy of EMDR to treat depression can be concluded from this review. The review highlights the need for high quality studies of EMDR to treat depression including feasibility studies, RCTs and dismantling studies.

When it comes to mixing methods, the way to assess quality is still being discussed (Creswell et al., 2011), however O’Cathain and colleagues have suggested the GRAMMS approach to good reporting in mixed methods studies (O’Cathain et al., 2008):

Good Reporting of a Mixed Methods Study (GRAMMS)

- (1) Describe the justification for using a mixed methods approach to the research question
- (2) Describe the design in terms of the purpose, priority and sequence of methods
- (3) Describe each method in terms of sampling, data collection and analysis
- (4) Describe where integration has occurred, how it has occurred and who has participated in it
- (5) Describe any limitation of one method associated with the presence of the other method
- (6) Describe any insights gained from mixing or integrating methods

Items (1), (5) and (6) are very clearly interrelated. The justification for using mixed methods is that by mixing and integrating quantitative and qualitative methods, the limitations of each can be mitigated and far more can be learnt than by using one method alone. For example in this study although standardised scales like the HRSD, BDI-ii and PHQ-9 are essential for comparison to other studies and to add to the research evidence on the impact of psychotherapy approaches, in a client centred health service can we truly say that a client is better unless they agree? The scales measure what symptoms the client reports but only by talking to them can we know if this actually translated into some noticeable difference in their lives. It can therefore be argued that the limitations of quantitative and qualitative methods and the insights that can be gained by combining them are the justification for mixed methods approaches.

Despite these limitations this PhD has been a tremendous learning experience and has produced some interesting results. Lessons learnt include a better understanding of how long and potentially problematic the bureaucratic side of research can be and not underestimating the need to leave plenty of time for ethics and research and development permissions, recruiting staff and recruiting participants. This took almost a year and meant that the follow up had to be truncated which was not ideal. This study’s findings could have been more

informative if participants had been asked in more detail about their experiences of their traumatic memories, the memory recording only contained the visual image but they could also be asked about what they heard, smelt, and felt. This may have been able to give better insight into the differences between the trance and visual change experiences reported by the participants. Although the EMDR Standard Protocol worked reasonably well there were some issues and modifications could be made to improve its use in treating depression (see section 8.6), including a Delphi consensus on what constitutes good practice in the preparation phase. More systematic recording of the therapists' experiences during the intervention could also bring insights into which parts of the protocol work for people with depression.

8.2 The impact of EMDR on long term depression

Many EMDR proponents claim it can be used for far more than just PTSD (Shapiro, 2005, Shapiro, 2009a). The primary aim of this research (research question 1, chapter 3.2) was to investigate if it had potential to be a treatment for long term depression. These results indicate that it does indeed have potential. Eight out of ten starters improved on the Hamilton rating scale for depression, that improvement was clinically significant and statistically reliable. The average scores on all scales continued to show improvement between the end of treatment and follow up. It is impossible to know from this data if this is due to time or treatment but is nonetheless encouraging. On the social functioning scales, nine improved on the SASS and eight improved on the GAF however, these were not statistically reliable due to the very large reliable change index for those scales.

The clinician rated, self-rated and daily measures of depression all show the same pattern of the majority of clients improving over the research period, usually by substantial amounts. However, there are some discrepancies. The clinician rated scale (the HRSD) is heavily weighted to questions on biological symptoms such as sleep patterns and eating behaviours, the self-rated scales (PHQ-9 and especially the BDI-ii) are more focussed on thinking styles. All of these ask for an answer representative of the last two weeks. Whereas from the daily low mood score we can see that this fluctuates a lot over that period. This raises questions over the best way to measure symptoms of depression, self-rated or clinician rated, focus on biology or cognition and rating today or the last two weeks. These different measures, all claim to be valid scales for clinical depression (Dozois et al., 1998, Miller et al., 1985, Kroenke and Spitzer, 2002), but they are all asking different things. Can they really be measuring the same illness? The DSM-IV and the PHQ-9 (which is essentially a list of diagnostic criteria) are heavily

reliant on the medical model (see chapter 1) whereas Beck who wrote the BDI is focussed on the cognitive model of depression, Hamilton's rating scale gives more weight to somatic symptoms (Cheung and Power, 2012). The two week requirement for many of the scales is based on the diagnostic criteria for depression (APA, 2003), considering the daily fluctuations in mood seen here it seems reasonable to attempt to base a diagnosis on a longer time period. Although factor analyses comparing the BDI with the HRSD show that both scales appear to be measuring the same underlying concept (Brown et al., 1995, Hotopf et al., 1997) more recent research has cast doubt on that (Cameron et al., 2011). Although the BDI-ii and the PHQ-9 have good convergence (Titov et al., 2011), this is less good with the HRSD and the BDI-ii appears to consistently rate severity much higher than other scales (Cameron et al., 2011, Titov et al., 2011).

The impact of event scale results show that those who were classified as traumatised before the treatment were no longer traumatised at the end and this remained true at follow up. Although it could be predicted that EMDR would be successful at treating trauma (van der Kolk et al., 2007), it was more surprising that so many participants scored so highly for trauma when they screened for not having PTSD. This may highlight the difference between PTSD criterion A events (those events sometimes referred to as 'big T trauma' in the EMDR literature) and negative life events (also called 'small t trauma' in the EMDR literature). Negative life events may not be life threatening but they can still have a profoundly damaging effect on a person's mental state. The AIP states that the memory of these events can fail to be fully processed regardless of whether or not the event is life threatening (Shapiro, 1995). It also predicts that it is these memories that cause negative thinking styles and that by processing the memory, the negative thinking style can be altered. This was reported by several of the participants here.

The reason for using a single case experimental design was to follow the participant closely and then to be able to plot their progress over the course of the baseline and treatment periods. None of the graphs shows an immediate obvious effect at the onset of EMDR but three (003, 005 and 012) show a strong reduction in low mood from about half way through the sessions, another shows a moderate relationship (001). Two graphs show no real change over the time period (004 and 007) and three show low mood getting worse, however two of these (006 and 008) are the two participants who were referred to the CMHT. The final one was the participant (011) who continued to struggle with family issues right to the end and

requested details of how to access EMDR privately once the follow up period was complete. Even the participants who showed a marked change on their daily low mood scores do not show that until at least half way through the treatment phase. Once improvements are made they are fairly consistent but there is no immediate effect. Although 20 sessions over a three month period does not make EMDR a long term treatment it is also not the rapid acting treatment it claims to be for PTSD (Van Etten and Taylor, 1998). However, long term depression is not likely to be as rapidly treated as a single trauma, adult onset PTSD due to the likelihood of complex and multiple childhood traumas and the nature of depression to be incorporated into self-schemata (see chapter 1).

This research also hoped to identify people who may not be likely to benefit from EMDR (research question 2, chapter 3.2). However, as only two participants failed to improve this was not possible. When looking at the differences between those who responded to treatment but failed to reach remission it is clear that they started treatment with a much higher score on the Hamilton rating scale for depression. Although they achieved among the highest reductions in symptom score on this scale it was not enough to reach remission. This would indicate that they may have just required more sessions due to the initial severity of their illness rather than that they did not respond well to EMDR. This observation and the two clients who asked how to access EMDR outside the NHS after the research was complete indicate that EMDR may need a longer intervention period for long standing and severe depression. There are mixed reports about the effectiveness of an increased number of sessions in psychotherapy. A recent meta-analysis that looked at psychotherapy for depression concluded that there was little evidence for increasingly the number of sessions past 15 or 16 (Cuijpers et al., 2013), however when the same research group focussed purely on psychotherapy for chronic depression they did find a need for more sessions (Cuijpers et al., 2010b). Neither of these studies included EMDR as one of the psychotherapies. As EMDR focusses on past traumatic events rather than current thinking styles it is possible to argue that a person with many traumas will need more sessions than someone with few to achieve the same effect. One thing the Dutch analyses did show is that increasing the intensity of the therapy (more sessions per week) was an important factor in improving effectiveness (Cuijpers et al., 2013). In this study sessions were, as often as possible, twice a week. Many of the clients said they found this helpful as it 'carried on the momentum'.

This adds to a growing body of literature that EMDR has distinct potential to treat depression (Hofmann et al., 2014, Grey, 2011, Bae et al., 2008). It also shows that EMDR does not necessarily need to be an adjunct to another therapy but can be used as the standard protocol describes. Further research will be needed to see if that is the best way to treat depression but it is certainly possible. In Hofmann's work in Germany (2014) the participants received an average of seven sessions (range 3-16) of EMDR along with around 38 sessions of CBT. As the start of the standard protocol involves history taking and preparation and stabilisation it can be assumed that this was done, at least in part during the CBT sessions before the therapist moved on to the more experimental EMDR. Although it is not clear from the paper, seven sessions of EMDR probably means seven sessions of bilateral stimulation. In the Sheffield study bilateral stimulation was given in 10-16 of the sessions, the other 4-10 sessions involving other aspects of the protocol such as history taking, stabilisation and reviews. As these other aspects are not unique to EMDR and stabilisation techniques may include cognitive, behavioural or mindfulness techniques they are comparable to CBT sessions. This study questions the need for so many additional sessions. By using only standard protocol EMDR this study appears to have seen results equivalent to the German study but in half the number of sessions.

8.3 Indications of the mechanism of change

Research questions 3 and 4 (chapter 3.2) aimed to investigate some of the specific predictions of the AIP model about the mechanism of change in EMDR. The descriptions given of the target memories do change over the study period but not in the ways described in the literature. Firstly, the AIP model (Solomon and Shapiro, 2008) expects the number of negative statements in the memory description to decrease after treatment which makes sense if the aim of the treatment is to remove the distress from the memory. This was seen here. The AIP also states that the number of positive or adaptive statements should increase. This is because the client can now see the positive in the situation. This did not occur. What was seen was that the sentences became shorter and more matter of fact. There was little emotion at all in the final descriptions. They did not go from being distressing to being adaptive, they went from being distressing to unimportant. Again this discrepancy could be due to the differences between PTSD and depression. The AIP model is heavily based on PTSD and has developed alongside EMDR as it has developed as a treatment for PTSD. As these memories were of negative life events not life threatening terror, perhaps a more adaptive response to them is to say 'actually that situation seemed important when I was 8 but it isn't' rather than to try to invoke some inspirational message from it.

The AIP model also predicts that these adaptive changes can lead to positive psychological growth. There is an argument that this was seen in many of the participants here. Although they did not refer to their pasts in a positive light they did start to look more positively on their futures. This was manifested in different ways but included having the confidence to apply for jobs or take the initiative in interacting with friends and family.

The emotional and neurological response to the memories was more in line with predictions from the AIP. Heart rate variability significantly increased, skin conductance response increased and heart rate reduced although not significantly. The emotionality of the memory, its vividness and completeness all decreased (not significant) and the closeness of the memory significantly decreased (i.e. it felt further away). The only one of these that contradicts the previous literature is the completeness of the memory. Previous explanations would have expected that to increase. However, as with the length of the memory narrative this could be due to the difference between the way memories are recalled in PTSD and depression. It has previously been shown that these physiological changes occurred during processing but until now there was no evidence that EMDR had a lasting effect on these memories as well.

The reduction in word count is opposite to what was found by Foa et al (1995). Foa and colleagues did work specifically with rape victims who had developed PTSD (Foa et al., 1995), a very different population from this study. Here there were no criterion A events reported. It could be that there is something specific about rape memories or even criterion A memories that makes them different. It could also be the difference between PTSD and depression. In PTSD there is a desire on behalf of the client to suppress the disturbing memory due to its horrific nature and what it says about the world (Dalgleish, 2004). In depression, on the other hand, the client is more likely to ruminate on the memory and what it says about them (Nolen-Hoeksema, 2000). It is possible that the rumination in depression has made the memory long and detailed and as it becomes less important it loses those details, whereas in PTSD the avoided memory becomes less distressing so the client is able to describe it in full.

For research question 5, the study had investigated if there were any correlations between the way symptoms changed and the way memories, or responses to memories, changed. No significant relationships were found although most measures did move consistently in the expected direction. The lack of significance in these relationships and in changes to memories

and responses to memories could be due to a lack of power in this study. This was always likely to be a problem with such a small sample size but as these were secondary research questions the number of participants was not changed for them.

8.4 The acceptability of EMDR as a treatment for depression

The final research question (research question 6, chapter 3.2) aimed to investigate if the clients thought EMDR was an acceptable treatment for depression. All the interview participants said that they would recommend EMDR to their family or friends if they were in a similar situation to themselves. Two actually did ask if there were any spaces left in the research programme as they knew someone who wanted to join and two participants how to get EMDR outside of the study so that they could continue to receive EMDR after the follow up period was complete. Only one participant had difficulty engaging with the treatment programme and ultimately had to be referred elsewhere. No one dropped out of the treatment programme. This indicates that EMDR had a high level of acceptability among participants in this study.

It is difficult to compare this to other research as acceptability and client views of EMDR are rarely reported. If they are they are usually reported as dropout rate rather than interview data. The Cochrane review of treatment for PTSD found that there were no differences between dropout rates in EMDR or tfCBT/exposure treatment arms (Bisson and Andrew, 2007). However, tfCBT for PTSD is a different treatment to CBT for depression.

The clients were also asked about what they thought had been helpful and unhelpful during the treatment. Many of the techniques used during the stabilisation phase were noted as helpful, the light stream, safe place and supportive figures. Most people also said they found it helpful to get to the root of their problems and resolve their issues. Although no explicit thought challenging occurs in EMDR it is clear that the participants' negative thinking styles had changed anyway. Some described this as 'like a switch in my head'. This supports the AIP assertions that the problem memory is the cause of the negative thinking style and is the key to changing it (Solomon and Shapiro, 2008).

Some of the unhelpful aspects were purely logistical, such as difficulties having time off work or the location of the therapy sessions. Others were more directly related to the treatment modality, such as the tiring nature of the therapy and the difficulty using eye movements.

Ironically, if the working memory model of EMDR is correct then the tiredness shows that it is working (Van Den Hout et al., 2011). Identifying the target memories was also identified as difficult. Some found it demoralising as they had hoped to find one distinct memory that they could work on and then 'be happy'. When finding the memories was hard or did not appear to be immediately relevant this was distressing. This highlights the need for sensitivity on behalf of the therapist but also sufficient education in the earlier parts of the protocol to try to ensure the client has realistic expectations.

The response to the treatment in the interviews was very positive. This raises the question of bias in the sample. Generally people are likely to think favourably on something which has helped them, so the fact that most of the participants responded well to treatment could be a factor. One of the two people who deteriorated during treatment was also interviewed and he also liked EMDR (006). One possibility is that the researcher had formed a relationship with the participants and they knew that she had a vested interest in the project. This could mean that participants were more positive than they would have been to someone they did not know. However, they were able to identify some aspects they did not like suggesting they were able to express negative opinions during the interviews if they had them.

8.5 Integration of the data

Trance v visual change

Just as the key qualitative themes are linked, so are the key mixed methods themes. The impact EMDR had on depression is caused by its mechanism and both lead to whether or not it would be considered as acceptable by the participants. Almost all these participants saw a clinically significant and statistically reliable improvement in their depression. This alone makes it likely that they would feel favourably towards the intervention, especially as they had all received failed therapy before. However, the manner of the treatment also matters. Many found it hard going in places, whether it was coming up with the target memory or the exhaustion that followed processing. The interviews revealed some interesting descriptions of the way EMDR works and what participants think of it. Eye movements, generally thought of as key to EMDR and taught to trainees as the stimulation of choice, were universally disliked. Despite this it still had a positive impact on symptoms.

One interesting aspect that was uncovered by the interviews was the two distinct modalities of experience during the processing. For some of the participants this was the vivid visual change in the memory image that is commonly seen in EMDR textbooks (Shapiro, 1995). However, for the others there was a trance like experience. This was wholly unexpected and has not been commonly described in the EMDR literature. When comparing the two groups there is no obvious difference in their other data. Both groups preferred tapping to eye movements, both did equally well when it came to symptom reduction and changes in response to the memories. It could be that these participants were particularly unusual in this respect. It could be that it is specific to the treatment of depression and thus has not been seen in PTSD studies. It could be that it is a common phenomenon but that it remains unreported. This could be because no one is asking clients what happens to them during processing. Or it could be because they are asked but when the response does not fit the model answer the therapists do not raise it as they lack the confidence to challenge the orthodoxy. It is likely that the numbers involved here are too small to be able to discern any difference between the groups and that further study on larger numbers is required, which takes into account a range of measures and interview data including the primary mode of memory (visual, somatic, auditory). If the primary mode of the memory is not visual then it is arguable that the change that occurs in it will not be visual, especially if the working memory model is considered. For a visual change the memory must be held in the visuospatial sketchpad but a memory could be primarily reliant on the phonological loop, this could be expected to change the experience of sound during processing but not the visual image (Baddeley, 2009). The mode of the memory was not investigated in depth before the EMDR treatment in this case.

EMDR has been linked to hypnosis before (Lilienfeld, 1996). The similarity of moving a hand in front of the client's face and for example the moving pocket watch used to induce a hypnotic state has been made. So it could be theorised that the trance like state is in fact a hypnotic state induced by the eye movements. However, these participants did not use eye movements, they used tapping and that draws fewer parallels with the hypnotic procedure. Also there has been a study which looked at the brain scans of those undergoing EMDR and they were different from those undergoing hypnosis (Nicosia, 1995). In 2001 the American Journal of Clinical Hypnosis published a special issue on the ways EMDR and hypnosis could be combined, they were clear in their introduction to the issue that although these approaches have similarities they also have several differences (Frischholz et al., 2001). These differences include hypnosis begins by inducing relaxation, whereas EMDR deliberately attempts to

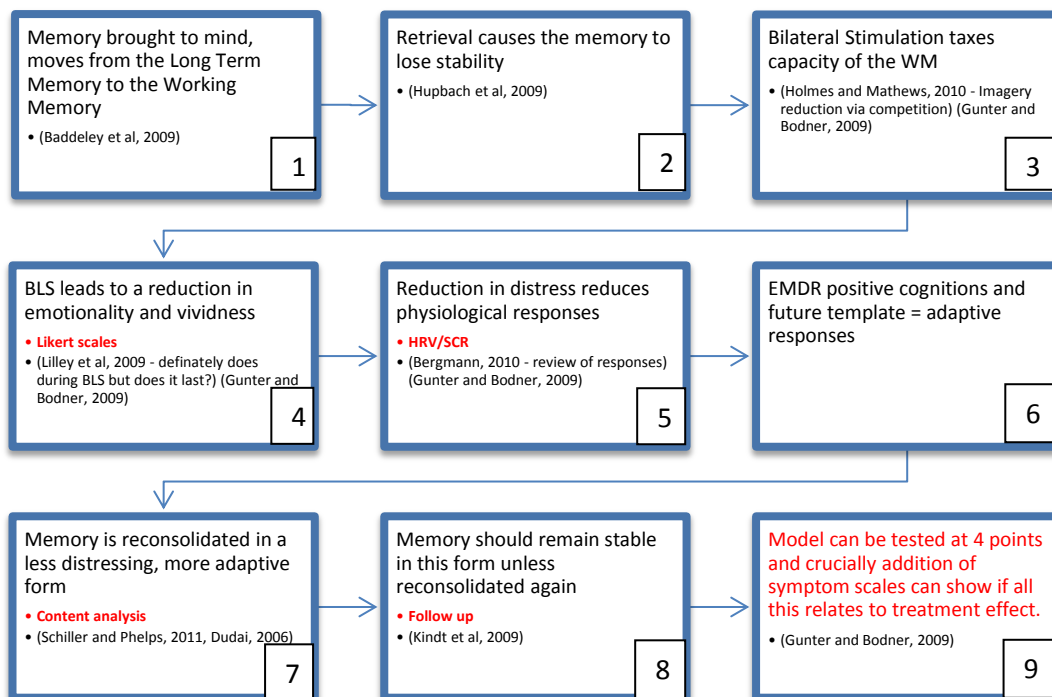
connect to the anxiety, hypnosis attempts to create a single highly focussed state whereas EMDR maintains duality of focus between the negative and positive and hypnosis promotes a state of fantasy and imagination whereas EMDR attempts to keep the client grounded by coming back to the room and the body's physical sensations (Frischholz et al., 2001). Despite their differences they are regularly used together and this special issue contained seven papers discussing how they could be combined.

One technique that links EMDR and hypnosis is ego state therapy. Ego state therapy can be done in two ways, working with the conscious mind and helping the client to understand why what happened as a child can relate to how they respond to situations in the present. This is commonly used in the preparation phase of EMDR (Forgash and Knipe, 2008). The second way is by using hypnosis to regress the client to repressed ego states (Wade and Wade, 2001). This is not done as a matter of routine in EMDR as EMDR training does not include hypnosis but some of the literature reporting a combination of EMDR and hypnosis uses ego state therapy in this way. It could be that when including ego state work in EMDR it promotes a state where the client moves between ego states and the processing happens to a child ego state causing a trance like experience for the adult in therapy. However, this can be viewed as a type of dissociation and a dissociating client is expected to do less well in EMDR but that does not appear to be the case here.

The reconsolidation model of EMDR

An integrated model of EMDR was suggested in chapter 2 (figure 8.1), along with suggestions to test the model.

Figure 8.1: An extended integrated model of memory retrieval and reconsolidation as a mechanism of change in EMDR – The reconsolidation model of EMDR.



This working memory model of EMDR assumes that boxes 1 and 2 are true, that old memories can be brought from the long term memory into the working memory and that in doing so this causes the memory to lose stability. Box 3 states the crux of the theory, that bilateral stimulation is a task that taxes the capacity of the working memory at the crucial moment when the distressing memory is held within.

As a method of therapy it is then expected that this taxing of the working memory will produce a reduction in the emotionality and vividness of the image (Figure 8.1 box 4, research question 4). Lilley and colleagues (2009) showed that this was the case in people with PTSD but only during the task. This research found that the emotionality and vividness of the memories did decrease and stay decreased but not significantly. This could be due to low numbers or that there is no significant reduction. Other work on the neurophysiology of EMDR has shown that we should also expect changes in the biological responses to these memories (Figure 8.1 box 5, research question 4). Here heart rate variability increased significantly and remained improved, indicating the participant's parasympathetic system is less withdrawn (Camm et al., 1996). The skin conductance response of the participants is difficult to interpret. On average there was an increase but this was not significant due to high variability within the sample. This included two very unusual readings, removing these gives a very slight reduction in SCR. As the expected change in SCR was unclear (people with depression have lower SCR so a reduction in

depression should increase SCR however, anxiety when recalling trauma leads to a higher SCR so reduced anxiety provoked by the memory should lead to lower SCR), it is likely that the variability of the readings are due to the complexity of the situation. As many of the participants had anxiety as well as depression it is possible that SCR is not a suitable measure in this population and concentrating on HRV (which moves in the same direction regardless of anxiety or depression) may be a more suitable measure.

The addition of positive and adaptive messages into the memories is where these results most differ from what was expected (Figure 8.1 box 6/7, research question 3) (Solomon and Shapiro, 2008). Although the memories definitely became less distressing there is little evidence to support a more adaptive view of them. Short of 'they are no longer important' the participants did not have anything more to say of them. There are two theories as to why this is. Firstly, as depression memories differ from PTSD memories it could be that the AIP model of positive adaptation is not relevant in this case. Nothing more than 'letting go' may be necessary for non-life threatening memories. A key adaptive scenario would be for a client to acknowledge that they did live through the car crash and they are now safe. This is just not necessary in the sorts of memories targeted here. A second view is that standard protocol EMDR is not very good at installing positive and adaptive thoughts.

If EMDR does indeed work using working memory taxation as a mechanism then there is a problem in the EMDR Standard Protocol. According to working memory disruption by holding the image in mind at the same time as the distraction task, the capacity of the working memory is overstretched and the image becomes less disturbing, less emotional (van den Hout et al., 2012). The problem with the EMDR protocol is that it also tells therapists to use the bilateral stimulation to install the positive cognition. This would then mean the client holds the positive image in mind and taxes the working memory. This would have the effect of reducing the emotion associated with the positive not enhancing it (van den Hout et al., 2012).

There is increasing support for the working memory account of EMDR in the literature (Jeffries and Davis, 2013, Altink et al., 2012, Hornsveld et al., 2011, van den Hout et al., 2012) . There is also more evidence that the interhemispheric interaction account of EMDR may be incorrect (Hornsveld et al., 2011, Samara et al., 2011). This is important as the interhemispheric account is the one usually taught in training for EMDR but is not supported by the evidence. By using bilateral stimulation with positive images EMDR may even be damaging results. It is also important when it comes to the type of bilateral stimulation provided and if it actually needs

to be bilateral. Some researchers have found that vertical eye movements have the same effect as horizontal ones (Gunter and Bodner, 2008). EMDR training states that eye movements, taps or tones can be used but eye movements are preferred (Shapiro, 2009b). As taps and tones are passive they are less taxing to the working memory and therefore less likely to have an effect as eye movements (de Jongh et al., 2013), although as van den Hout and colleagues (2012) discovered the level of complexity must be tailored to the client.

Another technique used in EMDR is the 'butterfly hug', originally developed to work with groups of traumatised children; it is now being used to deliver EMDR via online video call and in group therapy. In the butterfly hug position the client crosses their arms over their chest and uses opposite hands to tap their shoulders alternately (Artigas and Jarero, 2009). This is not bilateral stimulation as you tap your left shoulder with your right hand so both sides of the body are stimulated simultaneously. However, it has still had some success (Jarero et al., 2006) and is now recommended as an acceptable technique by EMDRIA. Although the butterfly hug is not bilateral stimulation, it is a task which would tax the working memory, more so than being tapped by the therapist or electronic tappers. The latter is a passive task like listening to tones but the butterfly hug requires more concentration. Many EMDR therapists are using a technique that does not support the interhemispheric interaction model but does support the working memory model.

If vertical eye movements and the butterfly hug are as successful as horizontal eye movements then it becomes less likely that the inter-hemispheric account can be true. But if it is working memory taxation that is behind EMDR then there are potentially other tasks that can be added to the techniques used in EMDR. Memory researchers have shown that counting and arithmetic tasks can also disrupt the working memory. Van den Hout and colleagues (2012) also found that mindful breathing, a component of Mindfulness-Based Cognitive Therapy, also taxes the working memory. Another recently developed therapy with links to working memory may be Emotional Freedom Technique (EFT) (Craig, 1995). Although EFT bases its current theory of mechanism of change on 'Qi lines', it may be much less mystical. In EFT the client is expected to bring to mind the issue they wish to deal with and then tap their hand or head in a certain pattern. The pattern is based on pseudoscientific notions of acupuncture and Qi but the pattern is unlikely to be what is important (Waite and Holder, 2003). By bringing to mind the distressing event and completing a complex tapping sequence the client is taxing their working memory. It may be that these third wave therapies are based, not on habituation to

distress and realisation that the situation is not as bad as imagined, but on an entirely different neurological process, taxing the capacity of the working memory. This gives these therapies that have been accused of pseudoscience a sound theoretical base and also a different mode of working which may help those who do not respond well to the traditional cognitive behavioural model of therapy.

8.6 The EMDR Standard Protocol as a treatment for depression

The EMDR Standard Protocol is more flexible than its name implies. It is a list of stages, some more prescriptively described than others (Shapiro, 1995). There is no guidance on how long each section should take relative to others. In one sense this is helpful as it means the therapist can adapt their approach to the needs of the client, however it also makes it difficult to be sure a standardised procedure has been used in the research environment. The Standard Protocol contains eight stages: (1) history taking, (2) preparation, (3) assessment of the memory, (4) desensitisation, (5) installation, (6) body scan, (7) closure and (8) re-evaluation. The idea is to move in a generally linear pattern through the phases but this is not a requirement and going back to do more history or preparation is permissible. Phases 1, 7 and 8 are not unique to EMDR, discovering the reason why a client has come to therapy, closing down a session before the issue is completely resolved and then re-evaluating the situation at the next session are common to all approaches. Phase 2 is where the client is prepared for the memory processing to occur. EMDR can bring up some intense emotions, quite fast and so it is recommended that adequate resourcing is done beforehand to help the client cope. Phases 3-7 are the ones most commonly associated with EMDR as a technique, rather than EMDR as a therapy, because this is the build up to and then use of bilateral stimulation, first with the trauma memory, then with the positive cognition and finally with body sensations.

Most of the participants in this study did very well which would suggest the Standard Protocol is adequate for treating depression. However, the interviews with the participants and numerous conversations with the therapists during the intervention did reveal some problems. For the clients this was primarily around three areas, anxiety about not having a memory of a traumatic event and therefore the treatment would not work for them, anxiety about knowing what the memory was and being reticent to talk about it and finally the fact that the sessions were physically and emotionally draining (chapter 6). Although the AIP states that everyone who has psychological issues must have a trauma memory that can be uncovered and can be treated (Solomon and Shapiro, 2008), it was not known at the start of this study if that would apply to depression. In the end everyone did find something to work on and this was generally

very helpful. Integrating this finding into information for future participants may help set their minds at ease.

The therapists were most concerned with phase two, the preparation and resourcing phase. This phase has little guidance about appropriate techniques. Two suggested approaches are the safe place and the light stream (Shapiro, 1995) but what is actually done is left to the therapist's judgement about what the client needs. This is where most of the differences between therapists occur. All EMDR therapists are qualified mental health professionals before they undertake their EMDR training. However, this qualification could be in social work, psychiatry, psychology, CBT, nursing or pretty much any other accredited profession. This leads to a wide range of backgrounds, skills and preferred techniques learnt from other roles. An EMDR therapist may take a very different view of resourcing if their background is social work to another therapist trained in psychodynamic psychotherapy. The therapists in this study were concerned about how much they could or could not do in phase two and still be adhering to the protocol. Although the light stream and safe place were helpful, they were never sufficient. The methods employed varied from client to client but included, light stream, safe place (including the addition of nurturing, protective and inner wisdom figures where necessary (Parnell, 2013)), ego state strengthening, compassionate mind, psycho-education, relaxation (including simple breathing meditations). It was agreed that anything that involved key concepts from other therapies (such as behavioural activation or hypnosis) should not be used in the research although may be used in clinical practice.

This experience suggests that if EMDR for depression is to be taken further, then clearer guidance on helpful resources is necessary. Research is needed into what resources are better for depressed as opposed to PTSD clients, or if, in fact, it makes a difference. Despite the growing evidence base for EMDR there is still a paucity of dismantling studies that help therapists make decisions about which techniques they should or should not be using (Leeds, 2009) and whether or not they should be using bilateral stimulation to install them (van den Hout et al., 2012). At the very least some consensus across the discipline would be helpful to guide therapists until the research is done.

8.7 Recommendations for research

This small feasibility study has shown that EMDR has potential to be able to treat long term depression. Larger studies, preferably randomised controlled trials where EMDR is compared to an equal number of CBT sessions, are required to fully investigate its clinical use.

Medical research council guidelines (Craig et al., 2008) recommend building on knowledge. The next step should be a pilot RCT to check randomisation, dropout rates and effect size before moving on to a larger trial.

Close attention should be paid to identifying those who do not respond to EMDR and trying to discover why.

The mechanism behind EMDR is still not fully understood. Further investigations into client experience during bilateral stimulation may help here. These should include brain imaging where possible and further investigation of the trance v visual image experience during processing.

To ensure the acceptability of EMDR, client views should be sought during clinical trials. Clients here were pleased with EMDR but they were few in number and their views need to be replicated in a larger population.

A dismantling study to understand the efficacy of different resources in phase two and how to install them is needed.

This research showed some support for the theory that EMDR does change the emotional content of traumatic memories; however similar studies are needed to see if this also happens in CBT and counselling when depression is successfully treated.

8.8 Implications for practice

Although this study has indicated that EMDR has the potential to be a treatment for long term depression it was not an adequate test of the efficacy or effectiveness of the therapy. As such EMDR should not yet be considered a first line, evidenced based treatment for depression. However, if a client has already received the first line treatments and not improved, EMDR could be considered. The client must be informed that EMDR is not a proven treatment for depression but does have potential.

Where possible, sessions should be available twice a week if the client is able to attend.

During training novice EMDR therapists should not be taught that EMDR works via interhemispheric interaction when evidence increasingly points away from that theory and towards working memory as a mechanism of action.

The use of bilateral stimulation with the positive cognition and resourcing is not supported.

This study has raised some interesting questions about trauma in depression and the beneficial use of the IES-r with clients who do not have PTSD.

8.9 Conclusions

This small study has shown that EMDR has the potential to be a treatment for long term depression with seven of the eight participants who received EMDR to at least the

reprocessing stage achieving clinically significant and statistically reliable change on the Hamilton rating scale for depression. When interviewed participants spoke favourably of EMDR and although it seemed strange to them to do some of the imaginal work and bilateral stimulation they found it helpful. One key message that was repeated was that it was helpful to look into their past at why they were depressed not just using coping strategies to deal with the depression.

Due to the size of the study it was not able to provide conclusive results on any potential mechanism of change but it did add support to the growing body of research suggesting that the taxing of the working memory as the mechanism behind EMDR. A new phenomenon was described, that of the bilateral stimulation causing a trance like state. This has not been previously noted in the EMDR literature and warrants further investigation.

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Appendices

Ovid Search strategy for the systematic review

Contact form

Consent form

Information sheets (x2 for participants, x1 for GPs)

Invitation to interview letter

Interview guide

REC favourable opinion letter

R&D permission letter

Tables from chapter 4

Outcome measures (HRSD, BDI-ii, PHQ-9, GAF, SASS, IES-r, HAT, MINI, Likert scales for psychological impact and repeated measure)

EMDR Standard Protocol

The Therapy Process Record

Ovid Search strategy for the systematic review

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1	EMDR.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	2031	Advanced	Display More >
2	(eye movement desensitisation and reprocessing).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	131	Advanced	Display More >
3	(eye movement desensitization and reprocessing).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	1831	Advanced	Display More >
4	(eye movement desensitisation and re-processing).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	3	Advanced	Display More >
5	(eye movement desensitization and re-processing).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	2	Advanced	Display More >
6	1 or 2 or 3 or 4 or 5	2375	Advanced	Display More >
7	depress*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	1223659	Advanced	Display More >
8	dysthymi*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	14343	Advanced	Display More >
9	MDD.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui, tc, id, tm]	24240	Advanced	Display More >
10	7 or 8 or 9	1227383	Advanced	Display More >
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Contact Form

SEDI contact form, v2, 22/03/2013

Sheffield EMDR and Depression Investigation (SEDI)

Contact form for potential participants

I am willing to be contacted by the research team for consideration in the SEDI project, my details are:

Name _____

Address _____

Daytime Telephone Number _____

Email _____

Preferred Method of Contact: Telephone Email

Name of referring IAPT therapist _____

Email address of IAPT therapist _____

Please return the form to:

Emily Wood
EMDR research (SEDI)
FDT, Specialist Psychotherapy Service
St George's Community Health Centre
Sheffield Health and Social Care
Winter Street
Sheffield S3 7ND

NIHR CLAHRC
for South Yorkshire

Sheffield Health and Social Care 
NHS Foundation Trust



The National Institute for Health Research Collaborators for Leadership in Applied Health Research and Care for South Yorkshire (NIHR CLAHRC SY) is a five year partnership between Sheffield Health and Social Care, The University Of Sheffield and other NHS and Higher Education partners.

Consent form

SEDI Consent form for research, v5, 31/01/2013

Sheffield EMDR and Depression Investigation (SEDI)

Consent form

Please initial
boxes:

Name of Researcher:

1. I confirm that I have read and understand the information sheet dated 23.01.2013 (Version 5) 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 any reason, without my medical care or legal rights being affected.
3. I understand that my GP will be informed that I am participating in the study.
4. I understand that relevant sections of data collected during the study, may be looked at by individuals from the University of Sheffield or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. I understand that all information will be confidential, except if I disclose that I am at risk of serious harm to myself or to others. In this instance the interviewer will discuss the situation with your NHS worker.
6. I give permission for my Sheffield Health and Social Care care record to be reviewed by the study team.
7. I agree to take part in the research study.

Name of participant

Date

Signature

Name of person taking
consent

Date

Signature

1 copy for participant, 1 for person taking consent

NIHR CLAHRC
for South Yorkshire

Sheffield Health and Social Care 
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The National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care for South Yorkshire (NIHR CLAHRC SY) is a five year partnership between Sheffield Health and Social Care, The University of Sheffield and other NHS and Higher Education partners.

Participant information sheet

Sheffield EMDR and Depression Investigation (SEDI)

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

We are researchers from the University of Sheffield and the NHS. We are carrying out this research to investigate new ways of treating longer term depression with psychotherapy. Eye Movement Desensitisation and Reprocessing (EMDR) is a therapy that has been used extensively with people suffering from Post-Traumatic Stress Disorder (PTSD). It is said to work by helping people manage their distressing memories. People with depression often have memories of distressing events from their past and we hope to find out if EMDR can help them and if it works in the same way as in people with PTSD. There is information about what EMDR is on the additional information sheet.

Usually people with depression will be offered Cognitive Behavioural Therapy (CBT). CBT has been shown to work for a lot of people with depression but not everyone which is why we are looking for a new treatment. Although EMDR is recommended for people with PTSD it is currently an unproven experimental therapy for depression. The purpose of this research is to see if it may help people with depression too.

Why have I been invited to take part?

You are being invited to take part because you have experience of longer term depression. We are asking all people with longer term depression who have just been referred to Sheffield Health and Social Care NHS FT's Improving Access to Psychological Therapies (IAPT) South East Team and assessed as suitable for one to one therapy to consider taking part.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will ask you to sign a consent form for this part of the study to show you have agreed to take part in it. You are free to withdraw at any time, without giving a reason. This would not affect any regular services you receive.

What will happen to me if I take part?

Initially we will ask you to meet a researcher to determine whether you can be included in the study by asking you some questions about your mental health. If we can include you and you agree, you will be placed in the study.

By agreeing to take part in this study you will be choosing to have this experimental treatment INSTEAD of CBT.

You will be asked to complete some questionnaires and talk about some specific unpleasant memories before the research project begins, at the end and 3 months after. These questionnaires should take no longer than one hour to complete. We would like to record your recollections of your memories to see if they change over time and therapy. These recordings will be transcribed and analysed by the researcher.

After the questionnaires there will be a short wait, so that we can measure your symptoms before the start of therapy then you will receive up to 20 sessions of EMDR depending on how many you need. You will be asked to complete a quick rating scale every day. This is so we can see how you are progressing. We may also need to review your medical notes (held by Sheffield Health and Social Care NHS FT).

What are the possible disadvantages, risks or benefits of taking part?

We do not think that the psychotherapy or completing the questionnaires will cause you harm. However you may experience strong thoughts or feelings. This often happens in therapy but sometimes it can be unpleasant. For some people these may be remembering past events or new feelings or thoughts about the person asking you questions. If you do feel uncomfortable about completing any of the questionnaires or during therapy we will stop what we are doing and ask you what you need to feel comfortable.

We hope that your participation will help you to manage your depression more effectively in the future. However as this is an experimental treatment, it may not help you; if this is the case then you will be able to return to IAPTs for CBT after the research is complete. The results of your involvement will also help us design and provide services to people with long term depression in the future.

What if there is a problem?

If you have a concern about any aspect of this study, you should contact the research supervisor, Glensy Parry. Her contact details are at the end of this Information Sheet.

In the unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, then you can contact the Principal Investigator for this research study, Emily Wood. Her contact details are: Telephone: 0114 2222975; email: e.f.wood@sheffield.ac.uk; postal address: University of Sheffield, ScHARR, Regent Court, 30 Regent Street, Sheffield, S1 4DA.

Alternatively, if you would like to speak to someone independent of the research you can contact the local Patient Advice and Liaison Service (PALS). They can be contacted on 0114 271 8768 or email: faye.mellors@shsc.nhs.uk.

Will my taking part in the study be kept confidential?

Your therapist will continue to communicate with other members of the mental health team and your general practitioner about your care as usual.

All additional information you give the researchers will be confidential, kept safe and later destroyed. A transcriber will be used to type up the audio-tapes or notes and they will sign a statement to ensure confidentiality. No one else apart from the researchers in the study will see your information, for example your doctor or anyone from any other health services will not see the information. The only exception is if you tell the researcher that you are at risk of serious harm to yourself or others. In this situation, the researcher would discuss this with your NHS worker to ensure you get any help that you require. If needed, immediate action will be taken, but you would be told about this first.

Regulatory authorities may look at your consent form to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the research office.

All research information will be kept in a locked cupboard in a locked office and then destroyed 5 years after the study ends. This is in case the University wants to monitor the quality of the research.

What will happen to the results of the research study?

The results will be analysed by the researcher and a report will be written about the research study. No information which could identify you or anyone else would be contained in the report. Please let us know if you would like to be sent a summary of the findings of the study, and we will send one to you.

Who is organising and funding the research?

The study is being organised by a PhD Student the University of Sheffield and the NHS. It will form part of her PhD thesis. It is part of a larger programme of research that is taking place, called CLAHRC (Collaboration for Leadership in Applied Health Research and Care) and it is funded by the National Institute of Health Research (NIHR). See <http://clahrc-sy.nihr.ac.uk/> for more information. This particular part of the study is focusing only on longer term depression (see <http://clahrc-sy.nihr.ac.uk/theme-iquests.html>).

Who has reviewed the study?

Before any research goes ahead it has to be checked by an independent group of people (a Research Ethics Committee). They make sure that the research is fair and that people's safety, rights, wellbeing and dignity are protected.

Further information and contact details

If you want to talk to someone about the study please contact Emily Wood, PhD student. She can be contacted at SchARR, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA; email: e.f.wood@sheffield.ac.uk

Telephone: 0114 2222975. Emily can direct you to Glenys Parry, who is supervising this part of the study, if necessary.

EMDR Information Sheet

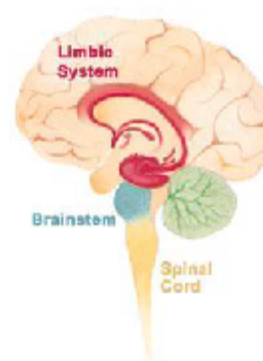
EMDR – Client Handout

What is EMDR?

The mind can often heal itself naturally, in the same way as the body does. Much of this natural coping mechanism occurs during sleep, particularly during rapid eye movement (REM) sleep. Francine Shapiro developed Eye Movement Desensitisation and Reprocessing (EMDR) in 1987, utilising this natural process in order to successfully treat Post-traumatic Stress Disorder (PTSD). Since then, EMDR has been used to effectively treat a wide range of mental health problems.

What happens when you are traumatised?

Most of the time your body routinely manages new information and experiences without you being aware of it. However, when something out of the ordinary occurs and you are traumatised by an overwhelming event (e.g. a car accident) or by being repeatedly subjected to distress (e.g. childhood neglect), your natural coping mechanism can become overloaded. This overloading can result in disturbing experiences remaining frozen in your brain or being "unprocessed". Such unprocessed memories and feelings are stored in the limbic system of your brain in a "raw" and emotional form, rather than in a verbal "story" mode. This limbic system maintains traumatic memories in an isolated memory network that is associated with emotions and physical sensations, and which are disconnected from the brain's cortex where we use language to store memories. The limbic system's traumatic memories can be continually triggered when you experience events similar to the difficult experiences you have been through. Often the memory itself is long forgotten, but the painful feelings such as anxiety, panic, anger or despair are continually triggered in the present. Your ability to live in the present and learn from new experiences can therefore become inhibited. EMDR helps create the connections between your brain's memory networks, enabling your brain to process the traumatic memory in a very natural way.



What is an EMDR session like?

EMDR utilises the natural healing ability of your body. After a thorough assessment, you will be asked specific questions about a particular disturbing memory. Eye movements, similar to those during REM sleep, will be recreated simply by asking you to watch the therapist's finger moving backwards and forwards across your visual field. Sometimes, a bar of moving lights or headphones is used instead. The eye movements will last for a short while and then stop. You will then be asked to report back on the experiences you have had during each of these sets of eye movements. Experiences during a session may include changes in thoughts, images and feelings.

With repeated sets of eye movements, the memory tends to change in such a way that it loses its painful intensity and simply becomes a neutral memory of an event in the past. Other associated memories may also heal at the same time. This linking of related memories can lead to a dramatic and rapid improvement in many aspects of your life.

www.getselfhelp.co.uk

www.get.gg

What can EMDR be used for?

In addition to its use for the treatment of Post-traumatic Stress Disorder, EMDR has been successfully used to treat:

- anxiety and panic attacks
- depression
- stress
- phobias
- sleep problems
- complicated grief
- addictions
- pain relief, phantom limb pain
- self-esteem and performance anxiety

Can anyone benefit from EMDR?

EMDR can accelerate therapy by resolving the impact of your past traumas and allowing you to live more fully in the present. It is not, however, appropriate for everyone. The process is rapid, and any disturbing experiences, if they occur at all, last for a comparatively short period of time. Nevertheless, you need to be aware of, and willing to experience, the strong feelings and disturbing thoughts, which sometimes occur during sessions.

How long does treatment take?

EMDR can be brief focused treatment or part of a longer psychotherapy programme. EMDR sessions can be for 60 to 90 minutes.

Will I will remain in control and empowered?

During EMDR treatment, you will remain in control, fully alert and wide-awake. This is not a form of hypnosis and you can stop the process at any time. Throughout the session, the therapist will support and facilitate your own self-healing and intervene as little as possible. Reprocessing is usually experienced as something that happens spontaneously, and new connections and insights are felt to arise quite naturally from within. As a result, most people experience EMDR as being a natural and very empowering therapy.

What evidence is there that EMDR is a successful treatment?

EMDR is an innovative clinical treatment which has successfully helped over a million individuals. The validity and reliability of EMDR has been established by rigorous research. There are now nineteen controlled studies into EMDR making it the most thoroughly researched method used in the treatment of trauma, (Details on www.emdr-europe.org and www.emdr.org) and is recommended by the National Institute for Health and Clinical Excellence (NICE) as an effective treatment for PTSD.

Adapted from www.thetraumacentre.com

www.getselfhelp.co.uk

www.get.gg

GP information letter

Emily Wood MMedSci RMN
PhD Student in Psychological Therapies
Mental Health Group, Health Services Research
School of Health and Related Research (SchARR)
University of Sheffield
Regent Court, 30 Regent Street
Sheffield S1 4DA

Tel: (+44) (0) 114 2222975
Fax: (+44) (0)114 2724095
Email: e.f.wood@sheffield.ac.uk

Dear Dr

Please be advised that your client, Mr/Ms _____, is involved in the Sheffield EMDR and Depression Investigation (SEDI).

Your client has a history of depression and was assessed as suitable for step 3 care with the IAPTs service. They have opted to enter this research programme and receive EMDR instead of receiving CBT or counselling.

We are researchers from the University of Sheffield and the NHS. We are carrying out this research to investigate new ways of treating longer term depression with psychotherapy. Eye Movement Desensitisation and Reprocessing (EMDR) is a therapy that has been used extensively with people suffering from Post Traumatic Stress Disorder (PTSD). It is said to work by helping people manage their distressing memories. People with depression often have memories of distressing events from their past and we hope to find out if EMDR can help them and if it works in the same way as in people with PTSD.

The Principal Investigator for this research study, Emily Wood. Her contact details are: Telephone: 0114 2222975; email: e.f.wood@sheffield.ac.uk; postal address: University of Sheffield, SchARR, Regent Court, 30 Regent Street, Sheffield, S1 4DA.

It is anticipated that your client will remain in the study for around six months, up to three months of EMDR and a three month follow up period.

Yours sincerely

Emily Wood

SEDI GP information letter version 1.0 15 October 2012

NIHR CLAHRC
for South Yorkshire

Sheffield Health and Social Care 
NHS Foundation Trust



The National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care for South Yorkshire (NIHR CLAHRC SY) is a five year partnership between Sheffield Health and Social Care, The University Of Sheffield and other NHS and Higher Education partners.

Invitation to interview letter

Emily Wood MMedSci RMN
PhD Student in Psychological Therapies
Mental Health Group, Health Services Research
School of Health and Related Research (SchARR)
University of Sheffield
Regent Court, 30 Regent Street
Sheffield S1 4DA

Tel: (+44) (0) 114 2222975
Fax: (+44) (0)114 2724095
Email: e.f.wood@sheffield.ac.uk

Date

Dear -----

Thank you for taking part in the research so far, investigating the use of EMDR to treat long term depression.

As we spoke about before I wish to interview you to find out your views on EMDR, what it was like to receive EMDR and if you think it has been a helpful treatment. I anticipate that the interview will take around 1 hour.

You do not have to take part in the interview however, if you would be willing to answer my questions or you have any questions about what the interview will include then please contact me on the above details and we can arrange a time and place that is convenient to you.

Kind Regards

Emily Wood

Sheffield EMDR and Depression Investigation Interview Guide

Context

As you are aware the EMDR therapy that you received a couple of months ago is experimental. Although it has been approved for post-traumatic stress disorder, it has not been fully investigated for use with depression.

As well as finding out how the EMDR did by using the questionnaires I asked you to complete at the start and end of the therapy I am also really interested in finding out what you thought about the treatment.

You may remember that after each session you completed a form listing helpful or unhelpful parts of the sessions. I have made a summary of those forms and may refer to that today if it is related to our discussion.

If at any point you want a break, want to stop or just don't want to answer a particular question then that is fine, just say.

Everything you say will be analysed as part of the research project, so it will be recorded. I will also take notes. I will anonymise anything you say that may be able to identify you.

I want to ask you some questions to get an idea of how the EMDR has affected you.

This is all about your experience so there are no right answers here I just want to know how you feel. If you say something I am interested in I will ask you some follow up questions so I can fully understand.

Are you happy to continue?

SEDI Topic guide

How was the EMDR for you?

How have things changed since EMDR?

- How do you feel now?
- Do you feel 'better'?

What was it like going to St George's?

- What was it like going twice a week?

Thinking about the actual EMDR, can you tell me about any **helpful bits**?

- Compare answer to HAT form summary

Can you tell me about any **unhelpful bits**?

Can you tell me about other treatments you have had?

- **How does EMDR compare to them?**

What was it like to have to pick out the upsetting memories?

What was it like to use the eye movements/tapping?

Do you think that memory has changed in any way?

- What are your thoughts about this?

How do you now feel about your experience of depression?

Do you feel more confident about the future?

Would you recommend EMDR to someone you know in your position?

What have you learnt from this experience?

Is there anything else you would like to say?

REC Favourable Opinion Letter



Health Research Authority
NRES Committee Yorkshire & The Humber - Sheffield
Yorkshire and the Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 3050128

01 February 2013

Miss Emily Wood
PhD student
University of Sheffield
School of Health and Related Research
30 Regent Street, Sheffield
S1 4DA

Dear Miss Wood

Study title: Does Eye Movement Desensitisation and Reprocessing (EMDR) change traumatic autobiographical memories to reduce their emotional impact and thus reduce the pathology associated with them in patients with long term depression?
REC reference: 12/YH/0523
Protocol number: URMS132149
IRAS project ID: 116376

Thank you for your letter of 10 January 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Rachel Bell, nrescommittee.yorkandhumber-sheffield@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Copy of Full IRAS data set for REC submission

Full Project Data Set for 12.YH0523

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)

Sheffield EMDR and Depression Investigation (SEDI)

1. Is your project research?

Yes No

2. Select one category from the list below:

If your work does not fit any of these categories, select the option below:

Clinical trial of an investigational medicinal product

Clinical investigation or other study of a medical device

Combined trial of an investigational medicinal product and an investigational medical device

Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

Basic science study involving procedures with human participants

Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

Study involving qualitative methods only

Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

Study limited to working with data (specific project only)

Research tissue bank

Research database

Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

Yes No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? Yes **No**

b) Will you be taking new human tissue samples (or other human biological samples)? Yes **No**

c) Will you be using existing human tissue samples (or other human biological samples)? Yes

No

3. In which countries of the UK will the research sites be located?(Tick all that apply)

England

Scotland

Wales

Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

3. In which countries of the UK will the research sites be located?(Tick all that apply)

England

Scotland

Wales

Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

England

Scotland

Wales

Northern Ireland

This study does not involve the NHS

4. Which review bodies are you applying to?

HRA Approval

NHS/HSC Research and Development offices

Social Care Research Ethics Committee

Research Ethics Committee

Confidentiality Advisory Group (CAG)

National Offender Management Service (NOMS) (Prisons & Probation)

5. Will any research sites in this study be NHS organisations?

Yes No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

Yes No

6. Do you plan to include any participants who are children?

Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

Yes No

9. Is the study or any part of it being undertaken as an educational project?

Yes No

Please describe briefly the involvement of the student(s):

The research is a PhD project. The research run by the PhD student, the intervention will be given by therapists not involved in the research part of the project.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

Integrated Research Application System

Application Form for Other clinical trial or investigation

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters this will be inserted as header on all forms)

Sheffield EMDR and Depression Investigation (SEDI)

A1. Full title of the research:

Does Eye Movement Desensitisation and Reprocessing (EMDR) change traumatic autobiographical memories to reduce their emotional impact and thus reduce the pathology associated with them in patients with long term depression?

A21.

Educational projects

Name and contact details of student(s):

Student 1

Title Forename/Initials Surname

Miss Emily Wood

Address University of Sheffield

School of Health and Related Research

30 Regent Street, Sheffield

Post Code S1 4DA

Email

Telephone

Fax

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:

PhD in Health Service Research

Name of educational establishment:

University of Sheffield

Name and contact details of academic supervisor(s):

Academic supervisor 1

Title Forename/Initials Surname

Prof Glenys Parry

Address University of Sheffield

School of Health and Related Research

30 Regent Street, Sheffield

Post Code S1 4DA

Email

Academic supervisor 2

Title Forename/Initials Surname

Dr Tom Ricketts

Address Sheffield Health and Social Care NHS FT

75 Osborne Road

Sheffield

Post Code S11 9BF

Email

Student(s) Academic supervisor(s)

Student 1 Miss Emily Wood

Prof Glenys Parry

Dr Tom Ricketts

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A22. Who will act as Chief Investigator for this study?

Student

Academic supervisor

Other

A31. Chief Investigator:

Title Forename/Initials Surname

Miss Emily Wood

Post PhD student

Qualifications MMedSci, RNMH

Employer University of Sheffield

Work Address University of Sheffield

School of Health and Related Research

30 Regent Street, Sheffield

Post Code S1 4DA

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

Title Forename/Initials Surname

Miss Emily Wood

Address University of Sheffield

School of Health and Related Research

30 Regent Street, Sheffield

Post Code S1 4DA

Email

A51. Research reference numbers. Please give any relevant references for your study:

Additional reference number(s):

Applicant's/organisation's own reference number, e.g. R & D (if available):

ZP57

Sponsor's/protocol number: URMS132149

Protocol Version: Version 1

Protocol Date: 04/10/2012

Funder's reference number: X/00197722

Project website: <http://clahrscy.nih.ac.uk/themeiquestsintroduction.html>

A52. Is this application linked to a previous study or another current application?

Yes No

A61. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.* Long term depression is a common but not well treated illness with a high social and economic cost. Eye Movement Desensitisation and Reprocessing (EMDR) has been shown to successfully treat Post Traumatic Stress Disorder (PTSD) and in theory should be able to be used for other mental health problems, however there is limited research to back this claim. The aim of this study is to investigate if EMDR can be a viable treatment option for people with long term depression.

It will also investigate if the theory behind EMDR applies to depression in the way it applies to PTSD. Patients will be recruited from IAPTs and if they meet the entry criteria and would like to try a different therapeutic approach they will be given up to 20 sessions of EMDR. Before and after therapy, symptom and functioning scales will monitor clinical change. As EMDR claims to promote clinical change by allowing patients to access and reprocess memories of significant life events this study will also ask the patients to describe in depth their memory before and after treatment so the content can be analysed for changes. Interviews with patients after therapy will discuss the lived experience and ask them to compare EMDR with other treatments they may have had. Finally the pretreatment characteristics of patients who do respond well to EMDR will be compared with those who do not to see if there is the potential to target EMDR to those who are most likely to respond well.

A62. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them. Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.*

This research will involve implementing treatment which is not currently recommended for long term depression on chronically ill patients. Some people do experience adverse effects from psychological therapies. Patients will not be able to switch their antidepressant during the therapy. The therapist and researcher will be required to have access to the patient's medical history and to add to their mental health notes where appropriate. During therapy some issues maybe disclosed that have not been shared with health service workers before, such as past events and current risk. They will also have to undergo testing which is not routine for depression care, during the tests all participants will be asked to concentrate on distressing memories which could affect their mood and wellbeing after the testing is complete. The unusual nature of the testing and the intrinsic problems in motivating people with chronic depression could lead to problems for recruitment and retention.

In an attempt to negate these problems or control them where possible, prior to the commencement of the therapy informed consent will be sought from the patients. They will be informed that the intervention will adhere to the same policies as the Sheffield Health and Social Care NHS FT (from which they already receive care) and that policies about sharing information on history and risk will therefore be the same (notes are accessible by other members of the patient's care team). They will also be informed about specific confidentiality issues around research (the researcher will be able to access their notes and will write up their case for the thesis and journal articles but under a false name and other identifiable information will either be left out or changed). All patients will be fully informed of the scope and aims of the study, no nondisclosure is necessary. Risks from the therapy process will be controlled according to Trust policy, if the patient has an extended care team they will be informed of risk issues if and when they arise. Patients will be able to leave therapy at any point without penalty. Patients who withdraw from the study will return to receiving treatment as usual from their IAPTs provider.

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

Case series/ case note review

Case control

Cohort observation
Controlled trial without randomisation
Cross sectional study
Database analysis
Epidemiology
Feasibility/ pilot study
Laboratory study
Meta-analysis
Qualitative research
Questionnaire, interview or observation study
Randomised controlled trial
Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Is there an improvement in depressive symptoms and social functioning following a course of EMDR for long term depression?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

- If there is a change, is it stable at follow up?
- Has the content of the target memory become less distressing and more adaptive, and if so it is stable at follow up?
- Has the impact of the target memory and the psychophysiological (heart rate variability and skin conductance response) response to it decreased?
- Is there a relationship between changes in symptoms and changes in memories?
- Do patients find EMDR to be an acceptable treatment for long term depression?
- Are there any significant differences between the responder group and non-responder group of patients which might be able to predict response in others?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Depression is a common but debilitating mental health condition, it affects an estimated 121 million people worldwide (WHO, 2009). For many people depression is a recurrent condition which requires long term management to minimise the impact of the disorder on their quality of life. Although the evidence for the recommended treatments, antidepressant medication and cognitive behavioural therapy, is good, most of the research focusses on single episode rather than longer term depression. There is significant potential to develop our understanding of the treatment of long term depression.

EMDR was initially developed to treat Post Traumatic Stress Disorder (PTSD) and focusses on the client's memories of distressing incidents. Randomised controlled trials using EMDR with PTSD clients has shown it reduces comorbid depression along with PTSD symptoms. They have found this despite some underpowered studies. However this does not tell us if EMDR is directly responsible for the reduction in depression or if it is merely a by-product of the reduction in PTSD. Studies on the use of EMDR with patients with a primary diagnosis of depression are lacking.

There is to date no full RCT published in English although case studies abound in the peer reviewed and grey literature that suggest it may be a useful tool to add to standard treatments for depression. There is also a lack of explanation to link the adaptive information processing model to the treatment of depression.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Planned protocol

1. Upon referral to IAPTs clients are assessed by a wellbeing practitioner. WBP to identify clients who meet the research entry requirements (require step 3 care, aged 18 or over with primary diagnosis of long term depression) and tell them about the study, including giving them the two information sheets. If client is interested in participating they sign consent form 1 (consent for contact by research team).
2. Researcher contacts those who have expressed an interest in participation and invites them for screening
3. Screening with MINI (and asked if they meet any of the exclusion criteria not covered by the MINI), if volunteer still meets criteria following screening then they will be given an explanation of the study, however they will not be given any new information other than having any questions they may have answered. If they still wish to be a participant they will sign the consent forms.
4. Volunteers who meet the criteria and who have signed consent forms will be assigned to an EMDR therapist (first 12 will be included, there will be no randomisation or matching at this stage). These will, mostly, be private practitioners brought in under the Sheffield Health and Social Care NHS FT (SHSC) governance procedures to deliver EMDR. Ideally the EMDR will take place in one of SHSC's buildings. Any volunteers who don't meet the criteria or decide not to participate will go back into the normal IAPTs channels.
5. EMDR will follow the manualised protocol and some sessions will be taped to check therapist adherence.
6. After parts 13 of the protocol the participant will return to the University (or other arranged location) for pretherapy testing and will complete a range of pre intervention measures such as the HRSD24, BDIII, SASS, GAF, IESr, PHQ9, describe and rate a distressing memory which will be targeted during therapy and have readings taken of heart rate variability and skin conductance response.
7. Client returns to EMDR therapist, 2x 1 hour session per week. Up to 20 sessions as determined by client need.
8. After each session the client will be asked to complete the PHQ9 and HAT forms. These will not be seen by the therapist but will inform the research questions and analysis.
9. At discharge or after 20 sessions, whichever comes first, the client will again meet the University researcher to do the posttherapy testing and interviews (over at least 2 sessions)
10. At 3 months posttherapy the client will be asked to do the follow up set of tests. The client will not be able to have CBT or other psychotherapy during the research period. They will also be asked not to change their antidepressant medication. If there is a medical need to do this they will not be included in the final analysis.
11. If the results from the treatment group do not support the null hypothesis (i.e. it would appear that EMDR has had a positive effect on the participants), then a control group will be recruited from the South Yorkshire cohort (a group of service users who have registered an interest in assisting in research).
12. This control group will go through the same testing procedures over the same time period as the treatment group but will receive no therapy.

A141. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

Design of the research

Management of the research

Undertaking the research

Analysis of results

Dissemination of findings

None of the above

Give details of involvement, or if none please justify the absence of involvement.

The University department includes service user researchers as integral members of the team.

One of these was consulted to discuss this project and highlight any possible areas for concern.

Their suggestion of a robust plan in the event of negative outcomes was incorporated into the study design.

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

Blood

Cancer

Cardiovascular

Congenital Disorders

Dementias and Neurodegenerative Diseases

Diabetes

Ear

Blood

Cancer

Cardiovascular

Congenital Disorders

Dementias and Neurodegenerative Diseases

Diabetes

Ear

Eye

Generic Health Relevance

Infection

Inflammatory and Immune System

Injuries and Accidents

Mental Health

Metabolic and Endocrine

Musculoskeletal

Neurological

Oral and Gastrointestinal

Paediatrics

Renal and Urogenital

Reproductive Health and Childbirth

Respiratory

Skin

Stroke

Gender: Male and female participants

Lower age limit: 18 Years

Upper age limit: No upper age limit

A171. Please list the principal inclusion criteria (list the most important, max 5000 characters).

People who have been referred to IAPTs for treatment for depression, are 18 and over, with depression, confirmed through structural interview (e.g. the MINI). The depression is long term

i.e. it is recurrent (2 or more episodes) or the current episode has a duration of 2 years or more. Patients must be able to give informed consent.

A172. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Those under 18, those unable to give informed consent, those with a first episode of depression, psychosis, bipolar disorder, PTSD, dementia, brain injury, current drug/alcohol dependence, epilepsy, pregnancy, current opiate analgesic use, ECT in the last 6 months or anyone whose primary mental health diagnosis is not long term depression.

A18. Give details of all nonclinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, nonclinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure 1 2 3 4

As part of their assessment for IAPTs clients who have long term depression will be given information about the research and asked if they consent to their details

1 1 1 hour

Assessment will be done by a Wellbeing Practitioner from their local IAPTs service at their usual site.

Research associate contacts client to explain the research and arrange a MINI diagnostic interview if the client still wants to take part.

1 0 30 mins

Conversation will take place by phone (or letter/email if the client prefers) MINI diagnostic interview including giving consent for the interview.

1 0 1 hour

Research clinician will conduct the MINI at a place convenient for both client and assessor eg at an NHS site, University of Sheffield site or participants home if that is their preference. Those who meet the inclusion criteria, will meet a research clinician, give consent for the research and complete baseline measures, describe their memories and undergo psychophysiological tests

1 0 90 mins

The measures will be collected by a research clinician at a location suitable for the client, probably an NHS or University site.

After every session of EMDR the client will complete PHQ9 and Helpful aspects of therapy (HAT) forms

20 0 20mins

The forms will be given to the client at the end of each session with an envelope to seal them in.

Once the intervention is complete the client will be asked to complete the same measures as at the pretreatment phase.

1 0 90 mins

The measures will be collected by a research clinician at a location suitable for the client, probably an NHS or University site.

After completion the client will be interviewed about their views of the intervention questions will be informed by the HAT responses

1 0 1 hour

The interview will be done by a researcher at a location convenient to the participant and researcher. 3 months after completion the clients will be asked to complete the pre and post measures again.

1 0 90 mins

The measures will be collected by a research clinician at a location suitable for the client, probably an NHS or University site.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure 1 2 3 4

Eye Movement Desensitisation and Reprocessing 20 0 1hour EMDR will be carried out by a qualified EMDR therapist at an NHS site.

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

Yes No

If Yes, please give details, explain the risks and justify the need to withhold the intervention or procedure:

Clients referred to IAPTs with depression would normally receive cognitive behavioural therapy. However CBT only has around a 50% efficacy rate with long term depression. This study wishes to look at an alternative to CBT so clients will not be able to have both at the same time, it would be impossible to tell which was having an effect. It is also generally inadvisable to have 2 forms of psychotherapy at the same time.

We will also request that clients do not change their medication during the intervention period. This is so we can be clear about what has affected the clients mood. Clients who require a change in medication will not be included in the final analysis.

Many clients with long term depression will have had medication or some form of therapy prior to this study. As they have relapsed it is not anticipated that trying a different form of therapy will be detrimental to their mental health, in fact by trying a different approach they may benefit greatly.

A21. How long do you expect each participant to be in the study in total?

Up to 6 months. It is not anticipated that the intervention will last longer than 3 months, there will also be a 3 month follow period.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Any psychological therapy carries a risk of causing temporary distress for the participants. To minimise this risk the participants and therapists are being monitored during the course of the therapy. If there is concern then action can be taken quickly to minimise harm. People may find participating in the research a burden because they will be assessed regularly using intervention measures such as HRSD and asked to participate in an interview. To minimise the impact of this all participants will be fully informed about the process before starting and informed consent will be sought continually throughout the process rather than just once. The burden will be minimised by consulting with the participant about how the process can be made easier for them such as arranging an interview at a time and place to suit them. The memory recall part of the testing procedure is the part that may cause most distress for the participants. Having to explain a distressing memory several times can be upsetting. However, the memory would be identified as part of the EMDR process anyway and the client would have to think about it in detail several times during desensitisation. The additional ask here would be that they would have to verbalise their memory which they don't have to do (although many people do) during therapy. However this is an unusual aspect of EMDR. In many other therapies the client would have to explain in detail the incident that was the focus of the session, and in some cases analyse it as well. If the intervention study finds that EMDR appears to be making a difference to client's mood and memories a control study will be undertaken. One of the reasons for the control group is that the repeated description of the distressing event may in fact be therapeutic. It resembles 'reliving' and may lead to habituation. To ensure that any distress is limited the control group will be taken from a less severely ill population (they will still have long term depression but not requiring treatment) and the control group will only be used if the treatment group appear to respond to the new treatment.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

If Yes, please give details of procedures in place to deal with these issues:

The majority of the outcome measures used will be quantitative of closed questions and it is not thought that this will lead to people discussing issues that are upsetting or lead to criminal disclosures.

The qualitative interviews and memory test will be done by a clinician researcher who is experienced in discussing sensitive topics and managing the issue such as allowing people breaks in the interview if they become distressed. The interviews will focus on the client's experience of EMDR rather than the issues that were the focus of the therapy.

The consent form clearly states that if participants disclose that they are a risk to themselves or others or disclose specific criminal incidents then the researcher, therapist or supervisor will if necessary inform the appropriate services, breaking confidentiality if required. The interview questions will be based on the responses given to the HAT questionnaires so will be relevant to the patient experience.

A24. What is the potential for benefit to research participants?

The purpose of the investigation is to discover if this type of therapy has potential as a treatment for long term depression. Participants may benefit from having this form of therapy.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

Continued provision will remain limited initially as this research will form a pilot study and IAPTs have limited resources to offer nonstandard therapies.

A26. What are the potential risks for the researchers themselves? (if any)

Researchers may experience distress from listening to the potentially distressing experiences of service users. The line management system in place will ensure the opportunity to seek support where necessary.

The safety researchers travelling in public places and interviewing people in their homes has been given consideration. A policy on lone working is held by the University of Sheffield and will be adhered to. This includes tracking visits and procedures for alerting emergency services.

A271.

How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).

Clients will be told of the research as part of their assessment interview for IAPTs. Any client who has been referred, has had 2 or more episodes of depression and is suitable for step 3 (individual psychotherapy) care will be told about the research. If they are interested in finding out more they will be asked to sign the 'consent for contact' form and a University researcher will contact them with more information and invite them for a screening interview. The 'consent to contact' form is for that purpose alone and the client will be required to consent again for the screening interview and again to receive the intervention. They will also be given 2 participant information sheets which will explain the research and what will happen to the client in laymen's terms.

The researcher from the University of Sheffield will have an honorary contract with the Sheffield Health and Social Care NHS FT.

A272. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

Initially the Wellbeing practitioner who conducted the client's assessment at the IAPTs team will identify those they wish to inform about the research and with the client's permission, advise the researcher to send them the study information. No one outside the client's care team will have access to their details until the client consents to this.

A273. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.

Clients will be told of the research by a Wellbeing Practitioner whom they would have seen anyway. Unless they consent their details will not be passed on to the research team. They will be asked to sign a 'consent to contact' form (they will keep a copy and one will go to the research team).

A274. Will researchers or individuals other than the direct care team have access to identifiable personal information patients, service users or any other person in the process of identifying potential participants.

Yes No

A275.

Has prior consent been obtained or will it be obtained for access to identifiable personal information?

Yes No

If Yes, please give details below.

Clients will be told of the research by a Wellbeing Practitioner whom they would have seen anyway. Unless they consent their details will not be passed on to the research team. They will be asked to sign a 'consent to contact' form (they will keep a copy and one will go to the research team). This will be used to allow the diagnostic screening interview to be held.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

A29. How and by whom will potential participants first be approached?

Potential participants will be approached by the Wellbeing Practitioner (WP) conducting their assessment at the IAPTs team. The WP will explain about the research at the end of their assessment session and given them the information sheets and permission form for having a researcher contact them. The assessor will inform the client about the research.

A301. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7. If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

During their assessment at IAPTs clients will be asked if they wish to be contacted by a researcher about the research and will give permission for their details to be given to the researcher for this purpose.

For those that do wish to proceed, a screening interview will be arranged. At this stage the researcher will send the potential participant the information sheets again if they want them. The participant will not receive any new information as all the information about EMDR and SEDI will have been included in the leaflets given out by the WP but the researcher will be able to answer any questions they have or give them another leaflet if they wish. The EMDR information sheet has been developed by clinicians for patients receiving this intervention and is designed to be comprehensive yet accessible. At the screening interview the client will consent to have this without further commitment at this stage.

Those who progress to the intervention stage will sign a consent form for the intervention when they meet with a researcher to complete the baseline measures.

Potential participants will be provided with contact details for the researcher whom they can contact if they have any queries regarding the research or wish to withdraw. At each stage they will be asked if they still consent to taking part.

Those who do not wish to participate or drop out will proceed through the IAPT service as usual.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A302. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

A minimum of 24 hours

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

Yes

No

Not Known

A331. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

People with no spoken English will have difficulty in completing the outcome measures as psychometrically valid

measures are not always available in languages other than English, they would also have difficulty in describing their memories, this would make it difficult for them to participate.

If someone has other needs such as literacy problems the research team will support them.

For example a researcher could read out the questions on the outcome questions and record their response for them rather than leaving the person to complete it themselves

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

The nature of the information will effect what action is taken.

If it is urgent information, such as discovering that EMDR is harmful to people with long term depression then relevant participants will be contacted by telephone to explain the new information in laymen's terms.

If the information is nonurgent then a report will be written in laymen's terms and sent to the relevant participants along with the researcher's contact details if they wish to discuss the issue further.

In all cases the participants, rather than the research, will be prioritised.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

The participant would continue to be included in the study.

Not applicable – informed consent will not be sought from any participants in this research.

Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)

Access to medical records by those outside the direct healthcare team

Access to social care records by those outside the direct social care team

Electronic transfer by magnetic or optical media, email or computer networks

Sharing of personal data with other organisations

Export of personal data outside the EEA

Use of personal addresses, postcodes, faxes, emails or telephone numbers

Publication of direct quotations from respondents

Publication of data that might allow identification of individuals

Use of audio/visual recording devices

Storage of personal data on any of the following:

Manual files (includes paper or film)

NHS computers

Social Care Service computers

Home or other personal computers

University computers

Private company computers

Laptop computers

Further details:

As the participants will have been recruited to the study from an NHS service, NHS computers will have their personal details. Access to personal information will only occur after the research project has been explained to the participant and they have consented.

Personal addresses and phone numbers will be used by a researcher to arrange meetings for screening, outcome measures and interviews. Paper files will be kept in a locked filing cabinet. Recordings will be made of some of the therapy sessions this is to ensure the therapists are adhering to the manualised process correctly. They will be viewed by another, highly experienced therapist and they destroyed. The recordings will be concerned with the therapist not the client.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Any personal data on paper will be stored in a locked filing cabinet. Electronic data will be password protected.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

No personal details will be passed outside of the direct care team until the client consents to this occurring. Even then they will be seen by the fewest number of people possible.

Any data used in the thesis or papers that come from the research will be anonymised.

Pseudonyms will be used for the reporting of the interviews.

Data is stored for 5 years in compliance with the University of Sheffield's data management policies. Personal identifiable information will be stored securely at NHS sites. Audio-visual recordings will be destroyed once they have been transcribed and analysed.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

As the participants will have been recruited to the study from an NHS service, NHS computers will have their personal details. Access to personal information will only occur after the research project has been explained to the participant and they have consented. Personal addresses and phone numbers will be used by a researcher to arrange meetings for screening, outcome measures and interviews.

A41. Where will the data generated by the study be analysed and by whom?

Data collected will be analysed by Emily Wood at the University of Sheffield.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title Forename/Initials Surname

Mr David Saxon

Post Research Associate/Data Manager

Qualifications MSc in Health Service Research
Work Address ScHARR, Regent Court
30 Regent Street
Sheffield
Post Code S1 4DA

A43. How long will personal data be stored or accessed after the study has ended?

Less than 3 months

3 – 6 months

6 – 12 months

12 months – 3 years

Over 3 years

If longer than 12 months, please justify:

Data is stored for 5 years in compliance with the University of Sheffield's data management policies. Personal identifiable information will be stored securely at NHS sites. Audiovisual recordings will be destroyed once they have been transcribed and analysed.

A44. For how long will you store research data generated by the study?

Years: 5

Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

Long term storage will follow the University of Sheffield's archive protocol.

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

Yes No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.

Therapists will be paid to deliver therapy at a rate similar to normal local levels.

Participants will receive travel expenses for attending the screening and outcome measure appointments but will not be paid to attend therapy sessions, unless they would normally be able to claim travel expenses due to the state benefits they receive.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

A491. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A492.

Will you seek permission from the research participants to inform their GP or other health/care professional?

Yes No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

A501.

Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials.

Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

Yes **No**

Please give details, or justify if not registering the research.

As this is not a standard clinical trial there is no appropriate database in which to register it.

Please ensure that you have entered registry reference number(s) in question A51.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

PhD thesis

Peer reviewed scientific journals

Internal report

Conference presentation

Publication on website

Other publication

Submission to regulatory authorities

Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee

on behalf of all investigators

No plans to report or disseminate the results

Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

All identifiable information will be removed prior to publication; pseudonyms will be used where necessary.

A53. Will you inform participants of the results?

Yes **No**

Please give details of how you will inform participants or justify if not doing so.

Participants will be asked if they want to be informed of the results. If they do a short report written in laymen's terms will be sent to them at the end of the research.

A541.

How has the scientific quality of the research been assessed? Tick as appropriate:

Independent external review

Review within a company

Review within a multi-centre research group

Review within the Chief Investigator's institution or host organisation

Review within the research team

Review by educational supervisor

Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

A research proposal was produced by the chief investigator in consultation with educational supervisors.

This was reviewed by as part of the Mphil to PhD 'Upgrade' by 2 experts in the subject field from the University of Sheffield.

It is noted that no major changes were necessary following the reviewers comments.

For all studies except nondoctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For nondoctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? Tick as appropriate:

Review by independent statistician commissioned by funder or sponsor

Other review by independent statistician

Review by company statistician

Review by a statistician within the Chief Investigator's institution

Review by a statistician within the research team or multi-centre group

Review by educational supervisor

Other review by individual with relevant statistical expertise

No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Mr David Saxon

Department School of Health and Related Research

Institution University of Sheffield

Work Address 30 Regent Street

Sheffield

Post Code S1 4DA

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Hamilton rating scale for depression

A58. What are the secondary outcome measures?(if any)

BDIII, IESr, SASS, GAF, PHQ9psychophysiological measures and memory impact scales.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 24

Total international sample size (including UK): 24

Total in European Economic Area: 24

Further details:

12 participants will be given the EMDR intervention, if the null hypothesis is NOT confirmed and it appears that EMDR has made a difference on the outcome measures then a second group of 12 participants will be given the outcome measure tests over the same time period as the intervention group but with no EMDR (or any other intervention).

A60. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

A formal sample size calculation was not done. As this is a pilot, we do not know what the expected effect size will be. We have included as many people as we can realistically treat within the timescale and budget.

A611. Will participants be allocated to groups at random?

Yes No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Study 1

Paired t tests can be used (assuming test assumptions are met – data are normally distributed) to see if there are any significant differences between the participants scores before and after the intervention. This will be done on all measures (Likert scales, BDIII, HRSD, GAF, SASS, IESr, HRV and SCR) although the HRSD is the primary outcome and the others are to support the primary outcome or provide possible explanations for unexpected results.

An ANCOVA test can be used (assuming test assumptions are met) to compare the differences in the before/after scores in the treatment and control groups. Here the outcome will be the change in the measures before and after therapy and the test will be able to control for baseline differences between the two groups. The ANCOVA will be able to generate confidence intervals for the data.

Correlations can be carried out to see if the different measurements change in relation to each other. As the memory content data is categorical this data can be transformed into those who showed a change towards more positive emotions and those who did not. This can then be analysed using ANCOVA to look for correlations.

The memory descriptions will be analysed by content analysis. Content analysis will require the transcriptions to be coded for distressing, positive/adaptive and miscellaneous themes. As deciding what is a positive or negative theme could be subjective this will be done by the researcher but will also cross check the scoring with someone else to ensure reliability of the coding. The ratios of the different themes can then be compared before and after EMDR therapy and also between the treatment and control groups to see if the EMDR has led to an increase in the amount of positive/adaptive themes being expressed. This will be done using chi-squared tests. As this research involves small numbers of patients it is possible that an expected count may be below 5, in this case a Yates's correction can be used. SPSS will be used for the statistical analysis and when undertaking a chisquared analysis it will automatically do additional tests when expected counts of less than 5 occur.

The chisquared table for the treatment group will compare time 1 and time 2 (before and after therapy) with the proportion of positive and negative content. To compare the control group to the treatment group will look at the proportions of each group who got more positive and those that didn't.

Study 2

The interviews will be transcribed and analysed on the latest version of Nvivo. A framework analysis approach will be used. This involves five steps: familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Srivastava and Thomson, 2009).

Familiarisation: getting to know the transcripts of the data, becoming immersed in it.

Identifying a thematic framework: key to the framework analysis is the concept that although the research questions were designed around a priori issues, and these may form some of the key themes, it is also possible for unexpected themes to emerge from the data.

Indexing: identifying portions of data that correspond to certain themes and coding these appropriately.

Charting: indexed data is now removed from the transcript and placed in charts of corresponding themes linking key portions of data.

Mapping and interpretation: Analysing key characteristics of the data set.

Study 3

Independent t tests can be used (assuming test assumptions are met) to compare the differences in the before/after scores and the initial data in the responder and non responder groups. Due to the low numbers involved in this research it may be that the numbers in each group are too low to undertake meaningful statistical analysis. In this case the outcome will be descriptive instead. Identifying a thematic framework: key to the framework analysis is the concept that although the research questions were designed around a priori issues, and these may form some of the key themes, it is also possible for unexpected themes to emerge from the data.

Indexing: identifying portions of data that correspond to certain themes and coding these appropriately.

Charting: indexed data is now removed from the transcript and placed in charts of corresponding themes linking key portions of data.

Mapping and interpretation: Analysing key characteristics of the data set.

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including nondoctoral student researchers.*

Title Forename/Initials Surname

Post

Qualifications

Employer

Work Address

Post Code

Telephone

Fax

Mobile

Work Email

A641. Sponsor Lead Sponsor Contact person

Status: NHS or HSC care organisation

Academic

Pharmaceutical industry

Medical device industry

Other

If Other, please specify:

Commercial status: NonCommercial

Name of organisation The University of Sheffield

Given name Kirsty

Family name Woodhead

Address Scharr, Regent Court, 30 Regent Street

Town/city Sheffield

Post code S1 4DA

Country UNITED KINGDOM

Is the sponsor based outside the UK?

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

Yes **No**

A65. Has external funding for the research been secured?

Funding secured from one or more funders
External funding application to one or more funders in progress
No application for external funding will be made

What type of research project is this?

Standalone project

Project that is part of a programme grant

Project that is part of a Centre grant

Project that is part of a fellowship/ personal award/ research training award

Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a cosponsor listed in A641)? *Please give details of subcontractors if applicable.*

Yes **No**

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes **No**

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A62

how the reasons for the unfavourable opinion have been addressed in this application.

A681. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname

Ms Yiwei Harland

Organisation Sheffield Health and Social Care NHS FT

Address R&D office

Fulwood House, Old Fulwood Road

Sheffield

Post Code S10 3TH

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A682. Select Local Clinical Research Network for NHS Organisation identified in A681:

Not Selected *For more information, please refer to the question specific guidance.*

A691. How long do you expect the study to last in the UK?

Planned start date: 01/01/2013

Planned end date: 29/08/2014

Total duration:

Years: 1 Months: 8 Days:

A711. Is this study?

Single centre

Multicentre

A712. Where will the research take place? (Tick as appropriate)

Total UK sites in study 1

Does this trial involve countries outside the EU?

England

Scotland

Wales

Northern Ireland

Other countries in European Economic Area

Yes **No**

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

NHS organisations in England 1

NHS organisations in Wales

NHS organisations in Scotland

HSC organisations in Northern Ireland

GP practices in England

GP practices in Wales

GP practices in Scotland

GP practices in Northern Ireland

Joint health and social care agencies (eg community mental health teams)

Local authorities

Phase 1 trial units

HSC organisations in Northern Ireland

GP practices in England

GP practices in Wales

GP practices in Scotland

GP practices in Northern Ireland

Joint health and social care agencies (eg community mental health teams)

Local authorities

Phase 1 trial units

Prison establishments

Probation areas

Independent (private or voluntary sector) organisations

Educational establishments

Independent research units

Other (give details)

Total UK sites in study: 1

A731. Will potential participants be identified through any organisations other than the research sites listed above?

Yes **No**

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

University of Sheffield educational supervisory team and Sheffield Health and Social Care NHS FT research governance protocol.

A751. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

University of Sheffield educational supervisory team and Sheffield Health and Social Care NHS FT research governance protocol. Regular meetings with the supervisory team rather than a separate formal body.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A752. What are the criteria for electively stopping the trial or other research prematurely?

If information from outside the study suggests EMDR may be harmful to people with depression:

The nature of the information will effect what action is taken.

If it is urgent information, such as discovering that EMDR is harmful to people with long term depression then relevant participants will be contacted by telephone to explain the new information in laymen's terms.

If the information is non-urgent then a report will be written in laymen's terms and sent to the relevant participants along with the researcher's contact details if they wish to discuss the issue further.

If information arises within the study that suggests EMDR may be harmful to people with depression:

No new treatment will be started until the issue has been resolved, if this is not possible no new treatment will be started at all.

Those currently receiving therapy will be contacted immediately by telephone to explain the new information in laymen's terms. This contact will be made by a clinical researcher with many years experience in working with people with mental health problems. The participant will be assisted to decide if they wish to continue.

In the case of severe risk, the option to continue with EMDR will be removed and the participants will be assisted to access other treatment options.

Any participants who have finished treatment will be contacted to explain the new information in laymen's terms. They may be advised to consult their healthcare provider about further support or treatment.

In all cases the participants, rather than the research, will be prioritised.

In psychological therapy it is not unusual for some people to deteriorate slightly before they start to improve. However sustained and/or dramatic deterioration will be cause for concern.

If 3 (25%) of the participants suffer sustained deterioration that cannot be attributed to external factors than the research will be stopped.

A761. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or cosponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

NHS indemnity scheme will apply (NHS sponsors only)

Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A762. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

NHS indemnity scheme will apply (protocol authors with NHS contracts only)

Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A763. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where nonNHS sites are to be included in the research,

including private practices, please describe the arrangements which will be made at these sites and provide evidence.

NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

Research includes nonNHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

Yes **No**

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

Yes **No** Not sure

Please enclose a copy of relevant documents.

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site in the departmental row.*

Investigator identifier

Research site Investigator Name

IN1

NHS site

NonNHS

site

Country: England

Organisation

name

SHEFFIELD HEALTH AND SOCIAL CARE

NHS FOUNDATION TRUST

Address FULWOOD HOUSE

OLD FULWOOD ROAD

SHEFFIELD SOUTH YORKSHIRE

Post Code S10 3TH

Forename Emily

Middle name

Family name Wood

Email

Qualification: MMedSci, RNMH

Country UNITED KINGDOM

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

I Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.

I May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.

I May be seen by auditors appointed to undertake accreditation of RECs (where applicable).

I Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

I May be sent by email to REC members.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

Chief Investigator

Sponsor

Study coordinator

Student

Other – please give details

None

Access to application for training purposes (Not applicable for R&D Forms)

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Print Name: Emily Wood

Date: 23/10/2012 (dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A641.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research. Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

Signature:

Print Name: John Brazier

Post: Director of Research

Organisation: The University of Sheffield

Date: 23/10/2012 (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature:

Print Name: Glenys Parry

Post: Professor of Applied Psychological Therapies

Organisation: The University of Sheffield

Date: 23/10/2012 (dd/mm/yyyy)

Academic supervisor 2

Signature:

Print Name: Tom Ricketts

Post: Honorary Research Fellow

Organisation: The University of Sheffield

Date: 23/10/2012 (dd/mm/yyyy)

NHS R&D permission letter



Sheffield Health and Social Care

NHS Foundation Trust

Medical Directorate
Research Development Unit
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 2718804
Fax: 0114 2718736

E-mail: rd@shsc.nhs.uk
www.shsc.nhs.uk

30th May 2013

Miss Emily Wood
School of Health and Related Research
University of Sheffield
30 Regent Street
Sheffield
S1 4DA

Dear Miss Wood

RDU ID: ZP57
Full Project Title: The Sheffield EMDR and Depression Investigation (SEDI)
REC No: 12/YH/0623

I can confirm on behalf of Sheffield Health and Social Care NHS Foundation Trust that you now have **NHS Permission to start research within that Trust.**

We also advise you of the following conditions and guidance:

- Please Inform us of the actual project start date immediately you do start and at that time inform us also of the expected end date.**
- The study is to be conducted in accordance with the Research Governance Framework.
- A favourable opinion must have been given by the REC
- All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS. Please also notify us of any changes to the status of your project.
- Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by selected audit of research, usually chosen randomly.
- We recommend the enclosed documents for maintenance of your project site file to ensure all documentation is readily accessible for our audit.
- Permission has been granted based on the following documentation:
 - 12.YH.0523 FIFO 01.02.13.pdf
 - 12.YH.0523 Response not complete 23.01.13.pdf
 - 2013.04.04DLA ZP57 R&D Form.pdf 116376/361851/14/153
 - 2013.04.08DLA ZP57 SSI Form.pdf 116376/433063/6/281/178797/268996
 - 2013.04.08DLb ZP57 SEDI protocol v2 20.12.12.docx
 - Consent_form_for_researchv5 31.01.2013.docx
 - Covering letter for response to Sheffield REC provisional opinion.docx
 - Explanation of Minor amendment of PIS from v4 to v5.msg
 - GP info letter.docx
 - Other - 2012.10.23Yb ZP57 R&D peer review letter.pdf
 - Other - CLARHC ISR sign off.docx
 - Other - contact form v1 17.12.2012.docx
 - Other - EMDR client handout.pdf

Tables from chapter 4

Table 4.3: Correlations between the different repeated measures for each participant

		interest	energy
001 low mood	Person correlation	.873**	.614**
	Sig (2 tailed)	.000	.000
	N	137	137
003 low mood	Person correlation	.811**	.648**
	Sig (2 tailed)	.000	.000
	N	107	107
004 low mood	Person correlation	.968**	.938**
	Sig (2 tailed)	.000	.000
	N	100	100
005 low mood	Person correlation	.943**	.742**
	Sig (2 tailed)	.000	.000
	N	109	109
006 low mood	Person correlation	.934**	.986**
	Sig (2 tailed)	.000	.000
	N	45	45
007 low mood	Person correlation	.922**	.917**
	Sig (2 tailed)	.000	.000
	N	75	75
008 low mood	Person correlation	.953**	.918**
	Sig (2 tailed)	.000	.000
	N	69	69
011 low mood	Person correlation	.773**	.723**
	Sig (2 tailed)	.000	.000
	N	118	118
012 low mood	Person correlation	.702**	.718**
	Sig (2 tailed)	.000	.000
	N	111	111

** Correlation is significant at the 0.01 level (2 tailed)

Table 4.4: Means for the repeated measures

	low mood	interest	energy
001	42.83	42.19	55.34*
003	34.74	33.02	39.74*
004	45.88^	47.81^	50.87*
005	63.50^	65.02^	73.82*
006	56.38	53.78	57.78*
007	63.55	63.16	62.56*
008	67.99^	58.59^	53.99*
011	64.51^	58.06^	55.92*
012	32.39	32.25	39.97*

*Paired t test shows energy is significantly different from at least one other at the 5% level

^Paired t test shows low mood and interest are significantly different from one another at the 5% level

Table 4.18: Correlations of the ranked pre-therapy outcome measures

	rank HRSD score	rank BDI score	rank GAF score	rank PHQ-9 score	rank SASS score	rank IES-r score
Spearman's rho	1.000					
rank HRSD score						
Correlation Coefficient	.782**	1.000				
Sig. (2-tailed)	.004	.				
N	11	11				
rank BDI score						
Correlation Coefficient	.418	.418	1.000			
Sig. (2-tailed)	.201	.201	.			
N	11	11	11			
rank GAF score						
Correlation Coefficient	.827**	.945**	.391	1.000		
Sig. (2-tailed)	.002	.000	.235	.		
N	11	11	11	11		
rank PHQ-9 score						
Correlation Coefficient	.718*	.464	.373	.655*	1.000	
Sig. (2-tailed)	.013	.151	.259	.029	.	
N	11	11	11	11	11	
rank SASS score						
Correlation Coefficient	.779**	.861**	.497	.875**	.528	1.000
Sig. (2-tailed)	.005	.001	.120	.000	.095	.
N	11	11	11	11	11	11

** . Correlation is significant at the 0.01 level (2-tailed). * . Correlation is significant at the 0.05 level (2-tailed).

Table 4.19: The rank orders of severity of symptoms on the post therapy measures

	best symptoms								worst
HRSD	11	1	5	3	7	12	4	10	6
BDI-ii	11	3	3	5	1	6	12	10	4
GAF	5	11	1	3	12	4	7	10	6
PHQ-9	3	5	12	7	11	1	4	10	6
SASS	12	10	3	11	1	7	4	5	6
IES-r	11	1	3	5	4	12	7	10	6

Table 4.20: Correlations of the ranked post-therapy outcome measures

	Rank final HRSD	Rank final SASS	Rank final GAF	Rank final IES	Rank final BDI	Rank final PHQ
Spearman's rho	1.000					
Rank final						
Correlation Coefficient	.					
Sig. (2-tailed)						

HRSD	N		9					
Rank final SASS	Correlation Coefficient		.117	1.000				
	Sig. (2-tailed)		.765	.				
	N		9	9				
Rank final GAF	Correlation Coefficient		.900**	.067	1.000			
	Sig. (2-tailed)		.001	.865	.			
	N		9	9	9			
Rank final IES	Correlation Coefficient		.917**	.167	.883**	1.000		
	Sig. (2-tailed)		.001	.668	.002	.		
	N		9	9	9	9		
Rank final BDI	Correlation Coefficient		.533	-.150	.433	.467	1.000	
	Sig. (2-tailed)		.139	.700	.244	.205	.	
	N		9	9	9	9	9	
Rank final PHQ	Correlation Coefficient		.567	.283	.650	.483	.317	1.000
	Sig. (2-tailed)		.112	.460	.058	.187	.406	.
	N		9	9	9	9	9	9

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Table 4.21: Correlations of the changes among the different standardised measures

		Change in HRSD score	Change in SASS score	Change in GAF score	Change in IES-r score	Change in BDI-ii score	Change in PHQ-9 score
Spearman's rho	Change in HRSD score	1.000					
	Correlation Coefficient						
	Sig. (2-tailed)	.					
	N	9					
	Change in SASS score	.356	1.000				
	Correlation Coefficient						
	Sig. (2-tailed)	.347	.				
	N	9	9				
	Change in GAF score	.186	.113	1.000			
	Correlation Coefficient						
	Sig. (2-tailed)	.631	.771	.			
	N	9	9	9			
Change in IES-r score	.515	.059	.485	1.000			
Correlation Coefficient							
Sig. (2-tailed)	.156	.881	.185	.			
N	9	9	9	9			
Change in BDI-ii score	.136	-.177	.726*	.538	1.000		
Correlation Coefficient							
Sig. (2-tailed)	.727	.648	.027	.135	.		
N	9	9	9	9	9		
Change in PHQ-9 score	.638	.076	.481	.941**	.487	1.000	
Correlation Coefficient							
Sig. (2-tailed)	.064	.846	.190	.000	.183	.	
N	9	9	9	9	9	9	

* . Correlation is significant at the 0.05 level (2-tailed).

** . Correlation is significant at the 0.01 level (2-tailed).

Outcome measures

(HRSD, BDI-ii, PHQ-9, GAF, SASS, IES-r, HAT, Likert scales for psychological impact and repeated measure)

HAMILTON DEPRESSION RATING SCALE

Page 1 of 4

HAMILTON DEPRESSION RATING SCALE - 24 item

(to be completed by a trained clinician)

DATE: 6/22/2012

TIME (24hr): 13:29

1. Depressed Mood

0 = Absent.

1 = These feeling states indicated only on questioning.

2 = These feeling states spontaneously reported verbally.

3 = Communicates feeling states non-verbally

- i.e., through facial expression, posture, voice, and tendency to weep.

4 = Patient reports virtually only these feeling states in his spontaneous verbal and non-verbal communication.

2. Work and Activities

0 = No difficulty.

1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies.

2 = Loss of interest in activities; hobbies or work - either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities).

3 = Decrease in actual time spent in activities or decrease in productivity. In hospital rate 3 if patient does not spend at least three hours a day in activities (hospital job or hobbies) exclusive of ward chores.

4 = Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted.

3. Social Withdrawal

0 = Interacts with other people as usual.

1 = Less interested in socializing with others but continues to do so.

2 = Interacting less with other people in social (optional) situations.

3 = Interacting less with other people in work or family situations (i.e. where this is necessary).

4 = Marked withdrawal from others in family or work situations.

4. Genital Symptoms

0 = Absent.

1 = Mild.

2 = Severe.

5. Somatic Symptoms - GI

0 = None.

1 = Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.

2 = Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms.

6. Loss of Weight

0 = No weight loss.

1 = Probable weight loss associated with present illness.

2 = Definite (according to patient) weight loss.

7. Weight Gain

- 0 = No weight gain.
- 1 = Probable weight gain due to current depression.
- 2 = Definite (according to patient) weight gain due to depression.

8. Appetite Increase

- 0 = No increase in appetite.
- 1 = Wants to eat a little more than usual.
- 2 = Wants to eat somewhat more than normal.
- 3 = Wants to eat much more than usual.

9. Increased Eating

- 0 = Is not eating more than usual.
- 1 = Is eating a little more than usual.
- 2 = Is eating somewhat more than usual.
- 3 = Is eating much more than normal.

10. Carbohydrate Craving

- 0 = No change in food preference or consumption.
- 1 = Craving or eating more carbohydrates (starches or sugars) than before.
- 2 = Craving or eating much more carbohydrates than before.
- 3 = Irresistible craving or eating of sweets or starches.

11. Insomnia - Early

- 0 = No difficulty falling asleep.
- 1 = Complains or occasional difficulty falling asleep - i.e., more than 1/2 hour.
- 2 = Complains of nightly difficulty falling asleep.

12. Insomnia - Middle

- 0 = No difficulty.
- 1 = Patient complains of being restless and disturbed during the night.
- 2 = Waking during the night - any getting out of bed rates 2 (except for purposes of voiding).

13. Insomnia - late

- 0 = No difficulty.
- 1 = Waking in early hours of the morning but goes back to sleep.
- 2 = Unable to fall asleep again if he gets out of bed.

14. Hypersomnia

- 0 = No increase in sleep length.
- 1 = At least 1 hour increase in sleep length.
- 2 = 2+ hour increase.
- 3 = 3+ hour increase.
- 4 = 4+ hour increase.

2

15. Somatic Symptoms - General

- 0 = None.
- 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- 2 = Any clear-cut symptom rates 2.

16. Fatigability

- 0 = Does not feel more fatigued than usual.

1 = Feels more fatigued than usual but this has not impaired function significantly; less frequent than in (2).

2 = More fatigued than usual; at least one hour a day; at least three days a week.

3 = Fatigued much of the time most days.

4 = Fatigued almost all the time.

17. Feelings of Guilt

0 = Absent.

1 = Self reproach, feels he has let people down.

2 = Ideas of guilt or rumination over past errors or sinful deeds.

3 = Present illness is a punishment. Delusions of guilt.

4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

18. Suicide

0 = Absent.

1 = Feels life is not worth living.

2 = Wishes he were dead or any thoughts of possible death to self.

3 = Suicide ideas or gestures.

4 = Attempts at suicide (any serious attempt rates 4).

19. Anxiety - Psychic

0 = No difficulty.

1 = Subjective tension and irritability.

2 = Worrying about minor matters.

3 = Apprehensive attitude apparent in face or speech.

4 = Fears expressed without questioning.

20. Anxiety - Somatic

0 = Absent.

1 = Mild.

2 = Moderate.

3 = Severe.

4 = Incapacitating.

21. Hypochondriasis

0 = Not present

1 = Self-absorption (bodily)

2 = Preoccupation with health.

3 = Frequent complaints, requests for help, etc.

4 = Hypochondriacal delusions.

22. Insight

0 = Acknowledges being depressed and ill.

1 = Acknowledges illness but attributes cause to bad food, climate, over work, virus, need for rest, etc.

2 = Denies being ill at all.

23. Motor Retardation

0 = Normal speech and thought.

1 = Slight retardation at interview.

2 = Obvious retardation at interview.

3 = Interview difficult.

4 = Complete stupor.

24. Agitation

0 = None.

1 = Fidgetiness.

2 = Playing with hands, hair, etc.

3 = Moving about can't sit still.

4 = Hand wringing, nail biting, hair pulling, biting of lips.

TOTAL HDR:

(HDR maximum score = 15)

0 - 4 normal, depending on age, education, complaints

5 - 8 mild

8 - 11 moderate

12 - 15 severe

TEXT FOR YOUR RECORDS - [click here](#):

Electronic form developed at the Palo Alto Veterans Affairs Hospital
by Wes Ashford, M.D., Ph.D.
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There is no individual or agency that takes responsibility for the results obtained
with this test or this form.


**Beck Depression
Inventory**
Baseline

VC477

CRTN: _____ CRF number: _____

Page 14

patient initials: _____

BDI-II

Date: _____

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

- 0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism

- 0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

- 0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

- 0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

- 0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

- 0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

- 0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

- 0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

- 0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

- 0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

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Subtotal Page :

Continued on Back

 0154010392
NR15845



11. Agitation

- 0 I am no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I am so restless or agitated that it's hard to stay still.
- 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people or activities.
- 1 I am less interested in other people or things than before.
- 2 I have lost most of my interest in other people or things.
- 3 It's hard to get interested in anything.

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- 0 I have not experienced any change in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 I have not experienced any change in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19. Concentration Difficulty

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page 2

Subtotal Page 1

Total Score

NR15645

8456789 10 11 12 ABCDE

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?
(Use **✓** to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + + +
=Total Score:

If you checked off **any** problems, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Global Assessment of Functioning (GAF) Scale

Consider psychological, social, and occupational functioning on a hypothetical continuum of mental health-illness. Do not include impairment in functioning due to physical (or environmental) limitations.

Code (Note: Use intermediate codes when appropriate, e.g., 45, 68, 72.)

100	Superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. No symptoms.	Ex0 Axis
91	Absent or minimal symptoms (e.g., mild anxiety before an exam), good functioning in all areas, interested and involved in a wide range of activities, socially effective, generally satisfied with life, no more than everyday problems or concerns (e.g., an occasional argument with family members).	Axis
81	If symptoms are present, they are transient and expectable reactions to psychosocial stressors (e.g., difficulty concentrating after family argument); no more than slight impairment in social, occupational, or school functioning (e.g., temporarily falling behind in schoolwork).	Axis Axis Axis
71	Some mild symptoms (e.g., depressed mood and mild insomnia) OR some difficulty in social, occupational, or school functioning (e.g., occasional truancy, or theft within the household), but generally functioning pretty well, has some meaningful interpersonal relationships.	Ex0 Axis
61	Moderate symptoms (e.g., flat affect and circumstantial speech, occasional panic attacks) OR moderate difficulty in social, occupational, or school functioning (e.g., few friends, conflicts with peers or co-workers).	Axis Axis Axis
51	Serious symptoms (e.g., suicidal ideation, severe obsessional rituals, frequent shoplifting) OR any serious impairment in social, occupational, or school functioning (e.g., no friends, unable to keep a job).	Ex0 Axis
41	Some impairment in reality testing or communication (e.g., speech is at times illogical, obscure, or irrelevant) OR major impairment in several areas, such as work or school, family relations, judgment, thinking, or mood (e.g., depressed man avoids friends, neglects family, and is unable to work; child frequently bears up younger children, is defiant at home, and is failing at school).	Axis Axis
31	Behavior is considerably influenced by delusions or hallucinations OR serious impairment in communication or judgment (e.g., sometimes incoherent, acts grossly inappropriately, suicidal preoccupation) OR inability to function in almost all areas (e.g., stays in bed all day; no job, home, or friends).	Axis Axis
21	Some danger of hurting self or others (e.g., suicide attempts without clear expectation of death, frequently violent; mania, excitement) OR occasionally fails to maintain minimal personal hygiene (e.g., smears feces) OR gross impairment in communication (e.g., largely incoherent or mute).	Ex0 Axis
11	Persistent danger of severely hurting self or others (e.g., recurrent violence) OR persistent inability to maintain minimal personal hygiene OR serious suicidal act with clear expectation of death.	Axis Axis Axis
1	Inadequate information.	Axis Axis

The rating of overall psychological functioning on a scale of 0-100 was operationalized by Luborsky in the Health-Sickness Rating Scale (Luborsky L. "Clinicians' Judgments of Mental Health." *Archives of General Psychiatry* 7:407-411, 1962). Spitzer and colleagues developed a revision of the Health-Sickness Rating Scale called the Global Assessment Scale (GAS) (Endicott J, Spitzer RL, Hais JL, Cohen J. "The Global Assessment Scale: A Procedure for Measuring Overall Severity of Psychiatric Disturbance." *Archives of General Psychiatry* 33:765-771, 1976). A modified version of the GAS was included in DSM-IV-R as the Global Assessment of Functioning (GAF) Scale.

Social Adaptation Self Evaluation Scale (SASS)

You are asked to answer some simple questions, stating what your opinion is at this moment.

Please answer all questions and circle ONE answer for each question.

1 Do you have an occupation Yes No

If yes- How interested are you in your occupation?

3 – very 2 – moderately 1 – a little 0 – not at all

If no – How interested are you in your home activities?

3 – very 2 – moderately 1 – a little 0 – not at all

2 Do you pursue this occupation/these activities with:

3- a lot of enjoyment 2 – some enjoyment 1- only a little enjoyment 0 – no enjoyment at all?

3 Are you interested in hobbies/leisure?

3 – very 2 – moderately 1 – a little 0 – not at all

4 Is the quality of your spare time

3- very good 2 – good 1 – fair 0 – unsatisfactory?

5 How frequently do you seek contacts with your family members (e.g. spouse, children, parents)?

3 – very frequently 2 – frequently 1 – rarely 0 – never

6 Is the state of relations in your family:

3- very good 2 – good 1 – fair 0 – unsatisfactory?

7 Outside your family, do you have relationships with:

3 – many people 2 – some people 1 – only a few people 0 – nobody?

8 Do you try to form relationships with others?

3 – very actively 2 – actively 1 – moderately actively 0 – in no active way

9 How – in general – do you rate your relationships with other people?

3- very good 2 – good 1 – fair 0 – unsatisfactory?

10 What value do you attach to your relationship with others?

3 – great value at all 2 – some value 1 – only a little value 0 – no value

11 How often do people in your social circle seek contact with you?

3 – very often 2 – often 1 – rarely 0 – never

12 Do you observe the social rules, good manners, politeness etc?

3 – always 2 – most of the time 1- rarely 0 – never

13 To what extent are you involved in community life (e.g. clubs, church etc)?

3 – fully 2 – moderately 1 – slightly 0 – not at all

14 Do you like searching for information about things, situations and people to improve your understanding of them?

3 – very much 2 – moderately 1 – not much 0 – not at all

15 Are you interested in scientific, technical or cultural information?

3 – very 2- moderately 1 – only slightly 0 – not at all

16 How often do you find it difficult to express your opinions to people?

0 – always 1 – often 2 – sometimes 3 – never

17 How often do you feel rejected, excluded from you circle?

0 – always 1 – often 2 – sometimes 3 – never

18 How important do you consider your physical appearance?

3 – very 2 – moderately 1 – not very much 0 – not at all

19 To what extent do you have difficulties managing your resources and income?

0 – always 1 – often 2 – sometimes 3 – never

20 Do you feel able to organise your environment according to your wishes and needs?

3 – very much so 2 – moderately 1 – not very 0 – not at all

Thank you

Appendix D10 - Post Traumatic Stress Disorder

Impacts of Events Scale - Revised

Name..... Date.....

Below is a list of comments made by people after stressful life events. Please check each item, indicating how frequently these comments were true for you **DURING THE PAST SEVEN DAYS.**

	STATEMENTS				
	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it.	0	1	2	3	4
2. I had trouble staying asleep.	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry.	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
6. I thought about it when I didn't mean to.	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders about it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Total Score - sum of all 22 items.
 If a client omits any items, calculate the mean of the non-missing items and then multiply by 22 to arrive at the total score, i.e. pro-rata.

(Data Item 17 in the IAPT Data Standard).

HELPFUL ASPECTS OF THERAPY FORM (H.A.T.) (10/93)

1. Of the events which occurred in this session, which one do you feel was the most **helpful** or **important** for you personally? (By "event" we mean something that happened in the session. It might be something you said or did, or something your therapist said or did.)

2. Please describe what made this event helpful/important and what you got out of it.

3. How helpful was this particular event? Rate it on the following scale. (Put an "X" at the appropriate point; half-point ratings are OK; e.g., 7.5.)

HINDERING <-----				Neutral	----->				HELPFUL
1	2	3	4	5	6	7	8	9	
----- ----- ----- ----- ----- ----- ----- -----									
E	G	M	S		S	M	G	E	
X	R	O	L		L	O	R	X	
T	E	D	I		I	D	E	T	
R	A	E	G		G	E	A	R	
E	T	R	H		H	R	T	E	
M	L	A	T		T	A	L	M	
E	Y	T	L		L	T	Y	E	
L		E	Y		Y	E		L	
Y		L				L		Y	
		Y				Y			

4. About where in the session did this event occur?

5. About how long did the event last?

6. Did anything else particularly **helpful** happen during this session?

YES NO

(a. If yes, please rate how helpful this event was: _____ 6. Slightly helpful
_____ 7. Moderately helpful
_____ 8. Greatly helpful
_____ 9. Extremely helpful

(b. Please describe the event briefly:

7. Did anything happen during the session which might have been **hindering**?

YES NO

(a. If yes, please rate how hindering the event was: _____ 1. Extremely hindering
_____ 2. Greatly hindering
_____ 3. Moderately hindering
_____ 4. Slightly hindering

(b. Please describe this event briefly:

Participant number

Insight number

Date

Pre / Post / Follow up

Likert scales for impact of memory

When you are thinking about the unpleasant memory please rate how intense the impact of it is. Please mark on the line to show the memories impact in terms of emotional response (does it make you have strong feelings?), vividness (how bright or detailed it is), completeness (is it a logical story or are bits missing?) and how distant it feels on a scale of 0-10 where 0= no impact and 10=extreme impact.

		0	1	2	3	4	5	6	7	8	9	10	
Emotionality	No emotion	_____											Extremely emotional
Vividness	Not at all clear	_____											Extremely vivid
Completeness	Not at all complete	_____											Extremely complete
Distance	Very distant	_____											Extremely close

Thank you

Daily measure

Daily mood rating

Participant code number

When you think about your mood today please rate how severe your symptoms feel to you. Please **mark a cross** on the line to show where you feel you are today, where the left hand side indicates that you have severe problems and the right hand side indicates that you do not have any problem in this area. Please do this **every day**. It is not necessary to do it at the same time each day.

For example:

Low mood/ depression	'I am extremely low or depressed'	_____X_____	'I don't have low mood'
-------------------------	--	-------------	----------------------------

Date			
Low mood/ depression	'I am extremely low or depressed'	_____	'I don't have low mood'
Interest or pleasure in activities	'I have no interest in doing things'	_____	'I get involved'
Energy levels	'I have no energy'	_____	'I have enough energy'

Date			
Low mood/ depression	'I am extremely low or depressed'	_____	'I don't have low mood'
Interest or pleasure in activities	'I have no interest in doing things'	_____	'I get involved'
Energy levels	'I have no energy'	_____	'I have enough energy'

Date			
Low mood/ depression	'I am extremely low or depressed'	_____	'I don't have low mood'
Interest or pleasure in activities	'I have no interest in doing things'	_____	'I get involved'
Energy levels	'I have no energy'	_____	'I have enough energy'

Daily mood rating scale v1 10.01.13

PHASE TWO: PREPARATION CHECKLIST

Check when completed:

EMDR Seating Position

- Seating arrangement (ships passing)

Eye Movements

- Comfortable distance from client's face
- Comfortable speed (horizontal EMs)
- Alternative directions (- / \)

Alternative Bilateral Stimulation (to be used only if necessary)

- Tapping
- Auditory

Explanation of EMDR

- AIP/REM
"When a disturbing event occurs, it can get locked in the brain with the original picture, sounds, thoughts, feelings and body sensations. EMDR seems to stimulate the information and allows the brain to reprocess the experience. That may be what is happening in REM or dream sleep--the eye movements (tonics, tactile) may help to reprocess the unconscious material. It is your own brain that will be doing the healing and you are the one in control."

Client Stability/Coping Strategies

- Metaphor (train/video)
"in order to help you 'just notice' the experience, imagine riding on a train or watching a video and the images, feelings, thoughts, etc., are just going by."
- Stop signal

DEVELOPING AND ENHANCING A CALM/SAFE PLACE

Use other coping skills if more appropriate (container, focus, courage, etc.)

IMAGE

"I'd like you to think about some place you have been or imagine being that feels very calm or safe. Perhaps being on the beach or sitting by a mountain stream. What image represents your place?"

EMOTIONS AND SENSATIONS

"As you think of that calm/safe place, notice what you see, hear, and feel right now. What do you notice?"

ENHANCEMENT

"Focus on your calm/safe place--its sights, sounds, smells, and body sensations. Tell me more about what you are noticing."

EYE MOVEMENTS

"Bring up the image of that place. Concentrate on where you feel the pleasant sensations in your body and allow yourself to enjoy them. Concentrate on those sensations and follow my fingers. (6-8 slow BLS) How do you feel now?"

If positive

"Focus on that. (BLS) What do you notice now?"

If negative

Redirect to identify another calm place or consider some other self-soothing strategy such as a container, mindfulness, or a breathing exercise.

CUE WORD

"Is there a word or phrase that represents your safe place? Think of _____ and notice the positive feelings you have when you think of that word. Concentrate on those sensations and the word _____ and follow my fingers. (6-8 BLS) How do you feel now?" Repeat and enhance positive feelings with BLS several times.

SELF-CUING

"Now I'd like you to say that word _____ and notice how you feel."

CUING WITH DISTURBANCE

"Now imagine a minor annoyance (SUDS 1-2) and how you feel. Bring up that word _____ and notice any shifts in your body. What did you notice?"

SELF-CUING WITH DISTURBANCE

"I'd like you to think of another mildly annoying incident (SUDS 2-3), notice how you feel, then bring up that word _____ by yourself, especially noticing any changes in your body when you focus on your cue word."

PHASE THREE: ASSESSMENT WORKSHEET

REMINDER: The target incident selected for reprocessing (referred to during reprocessing as the "original target") represents the presenting complaint and the image represents a picture of the selected incident.

Please **write down the answers** your client gives to the following questions.

Specific Instructions:

"Often we will be doing a simple check on what you are experiencing. I need to know from you exactly what is going on with as clear feedback as possible. Sometimes things will change and sometimes they won't. There are no "supposed to's" in this process. So just give as accurate feedback as you can as to what is happening without judging whether it should be happening or not. Just let whatever happens, happen." (Remember to tell the client about the SUD hand signal.)

TARGET (Incident chosen to be the focus of reprocessing, during reprocessing referred to as **"The Original Target"**)

Image:

Most disturbing: "What picture represents the worst part of the incident?"
 If no picture: "When you think of the incident, what do you get?"

Negative Cognition:

"What words go best with that picture that expresses your negative belief about yourself now?"

Positive Cognition:

"When you bring up that picture, what would you like to believe about yourself now?"

Validity of Cognition (VOC):

"When you think of that picture, how true do those words (repeat the positive cognition above) feel to you now on a scale of 1 to 7, where 1 feels completely false and 7 feels completely true?"

1	2	3	4	5	6	7
completely false						completely true

Emotions:

"When you bring up that picture and those words (negative cognition above), what emotion(s) do you feel now?"

SUDs:

"On a scale of 0 to 10, where 0 is no disturbance or neutral and 10 is the highest disturbance you can imagine, how disturbing does the incident feel to you now?"

0	1	2	3	4	5	6	7	8	9	10
(no disturbance/neutral)										(highest disturbance)

Location of Body Sensation:

"Where do you feel it in your body?"

Go to next page for Reprocessing Procedures Phases 4-7

PHASE FOUR: DESENSITIZATION: Processing and checking for new channels:

"To like you to bring up that picture, those negative words (repeat the negative cognition), and notice where you are feeling it in your body—and follow my fingers." (BLS 25-35)

- A. **REPROCESS:** *"Take a breath, let it go, what do you notice now? Go with that."* (BLS 25-35 passes)
Repeat: *"Take a breath, let it go, what do you notice now? Go with that."* (BLS 25-35 passes)
as long as client reports change or new information (as many sets of BLS as necessary)
until the client stops reporting change for two consecutive sets of BLS, then ask (B).
- B. **BACK TO TARGET:** *"When you go back to the original incident, what do you get now? Go with that."*
(BLS 25-35 passes)
Repeat: *"Take a breath, let it go, what do you notice now? Go with that."* (BLS 25-35 passes)
as long as client reports change or new information (as many sets of BLS as necessary)
When the client goes back to target for two consecutive sets of BLS and still reports no change
check SUDs (see C below).
- C. **CHECK SUDs:**
*"When you bring up the incident, on a scale of 0 to 10, where 0 is no disturbance and 10 is the highest
disturbance you can imagine, how disturbing does it feel to you now? Go with that."* (BLS 25-35 passes)
REPEAT Steps A, B, and C until SUDs is 0 (or ecologically sound).

PHASE FIVE: Installation:

Linking the dashed positive cognition with the original memory/incident or picture:

1. *"Do the words (repeat the PC) still fit, or is there another positive statement you feel would be more suitable?"*
2. *"Think about the incident and those words (repeat the selected PC). From 1 (completely false) to 7 (completely true), how true do they feel?"*
3. *"Hold them together." Do BLS.*
4. *"On a scale of 1 to 7, how true do those words (PC) _____ feel to you now?"*
5. Continue installation as long as the material is becoming more adaptive. Continue sets of BLS until the VOC no longer strengthens. Once the VOC=7 (or ecological), go to Phase 6: Body Scan.
6. If client reports a 6 or less, check appropriateness and address blocking belief (if necessary) with additional reprocessing.

PHASE SIX: Body Scan:

"Close your eyes and keep in mind the original incident and the (repeat the selected positive cognition). Then bring your attention to the different parts of your body, starting with your head and working downward. Any place you find any tension, tightness or unusual sensation, tell me." If any sensation is reported, do BLS. If a positive/comfortable sensation, do BLS to strengthen the positive feeling. If a sensation of discomfort is reported—reprocess until discomfort subsides.

PHASE SEVEN: Closure: Procedure for closing unfinished sessions:

An unfinished session is one in which a client's material is still unresolved, i.e., s/he is still obviously upset or the SUDs has not gone down to 0 or the VOC has not gone up to 7, or you have not had time to complete the Body Scan. The following is a procedure for closing down an unfinished session. The purpose is to acknowledge clients for what they have accomplished and to leave them well grounded before they leave the office.

Steps:

1. Give the client the reason for stopping. *"We are almost out of time and we will need to stop soon."* Give encouragement and support for the effort made. *"You have done some very good work and I appreciate the effort you have made. How are you feeling?"*
2. Do containment exercise? *"I would like to suggest we do a relaxation exercise before we stop. I suggest we do _____"* (clinician suggests a form of relaxation, e.g., Imagery, Safe Place, Light Stream, etc.).
3. Read the Closure/Debriefing the Experience section to the client.

Closure: Debrief the experience

"The processing we have done today may continue after the session. You may or may not notice new insights, thoughts, memories, or dreams. If so, just notice what you are experiencing, take a snapshot of it in a log (what you are seeing, feeling, thinking, and the trigger on the TICRS grid). Use the Safe Place exercise to rid yourself of any disturbance. Remember to use a relaxation technique daily. We can work on this new material next time, if you feel it is necessary, call me."

PHASE EIGHT: REEVALUATION

TREATMENT PLAN (Global)

"Tell me what you have noticed that is different in your life since our last session."

Ask questions such as:

"Any changes in how you respond to the issue we have been working on?"

"Any new insights?"

"Any dreams?"

"Changes in behavior?"

"Changes in your symptoms?"

TARGET (Target Specific)

"Now as you think about the incident (target) we focused on during our last session, what are you noticing now?"

Additional questions to consider:

"What has changed or is different about the incident now?"

"Any new insights or thoughts?"

"Any new connections?"

"When you think of the incident now, on a scale from 0-10, how disturbing is it now?"

Therapy Process Record

Participant ID

SEDI - Therapy Process Record

Client INSIGHT number

Actual session number.....

Date.....

Suggested session to include intervention action	Intervention action	Tick when you have done an action
1	Check client has completed baseline phase daily measures	
	Offer client EMDR information sheet	
	Phase 1 History taking	
	Give out new daily measures sheet, PHQ- 9 and HAT	
2	Phase 2 Preparation/stabilisation	
	Phase 3 Assessment of target memories	
	Give out new daily measures sheet, PHQ- 9 and HAT	
	Refer client back to researcher for memory testing	
3 to 20 inclusive	Phase 4 Desensitisation	
	Phase 5 Installation	
	Phase 6 Body Scan	
	Phase 7 Closure	
	Phase 8 Re-evaluation	
	Give out new daily measures sheet, PHQ- 9 and HAT at end of every session	
20/end of therapy	Review therapy	
	Let researcher know therapy has ended	