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# **Research Portfolio Submitted in Part Fulfilment of the Requirements for the Degree of Doctorate in Clinical Psychology**

**Neil Alexander Carrigan**

A thesis submitted for the degree of Doctorate in Clinical Psychology

University of Bath  
Department of Psychology

May 2014

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# Abstract

## **Main Project**

*Multiple Sclerosis (MS) is an incurable disease which is commonly associated with psychological complications. Previous research by Hayter and colleagues found that in patients with MS, health anxiety (HA) can account for part the variance in quality of life (QoL) independent of any physical and cognitive impairment caused by the disease and that MS patients with health anxiety perceived their (intact) physical and cognitive performance as impaired relative to MS patients without health anxiety, attributing the impairment to MS. The findings suggest that such misperceptions might be useful targets in the treatment of health anxiety in MS using adapted cognitive behavioural therapy (CBT). The first of two studies presented here sought to replicate the findings from Hayter et al. before a second presents the findings from a brief case series of treatment for HA using CBT. In Study 1, twenty participants with Relapsing and Remitting MS were screened for HA and assigned to either a high or low HA group. Participants then completed assessment of cognitive and physical functioning before rating their performance on these tasks. Measures of QoL, mood and physical disability were then completed. Four participants in the high HA group subsequently received six sessions of CBT using a consecutive AB case series in Study 2. Study 1 replicated the main findings from the earlier study. In Study 2, three of the four patients who received treatment showed substantial improvements in HA and mood and all showed improvement in QoL. Given the high rates of HA in MS patients and its impact on QoL, this case series suggests a brief CBT intervention could significantly improve patients' wellbeing. The findings pave the way for larger, controlled studies into the effectiveness of CBT for health anxiety in MS.*

## **Service Improvement Project**

**Background:** *Early diagnosis of neurodevelopmental conditions such as Autism Spectrum Disorders (ASD) and Attention Deficit Hyperactivity Disorder (ADHD) in children are enshrined in national UK policy, as is ensuring that parents'/carers' views shape service delivery. Aim:* *The present study attempted to measure adherence to service guidelines of a neurodevelopmental disorders assessment clinic within a Child and Adolescent Mental Health Service (CAMHS) to identify service needs. It also assessed parents'/carers' satisfaction with the service and what information should be included in a patient*

information leaflet. **Method:** An audit of cases referred during 2012 -2013 plus a postal survey of parents/carers of children referred during the audit period. **Results:** The service was mostly compliant with NICE guidelines but quantifying this was difficult under its current record keeping. While satisfied with the clinic's service, the main concern of parents/carers was the length of time the assessment process took. **Conclusions:** Adoption of NICE audit tools would help document compliance with guidelines. A patient information leaflet might help manage parents' expectations about the time the assessment process takes.

### **Literature Review**

*This review considers the closely related concepts of rumination and worry; examining their role in insomnia and chronic pain. Worry has been seen for many years as a major contributor to insomnia but only recently has attention been paid to the role of rumination. Similarly, worry and rumination have both been implicated in the maintenance of distress in chronic pain. However, across these two diagnostic categories (and the wider research literature) definitions of worry and rumination vary and are often used interchangeably. This review considers the research literature on rumination/worry in relation to insomnia, chronic pain and insomnia that occurs alongside chronic pain (pain-related insomnia). The empirical findings to date suggest patterns of repetitive negative thinking characterise both worry and rumination, but the content of the thinking may be distinct, opening the way for the application of transdiagnostic approaches. It suggests cognitive behavioural approaches to treating pain-related insomnia can be improved by incorporating elements which have been successful elsewhere in allowing people to manage repetitive negative thinking. Assessment of these targeted treatments in future research should lead to a reduction in suffering for patients with chronic pain who have trouble sleeping.*

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# **A ‘malignant interaction’ or separate processes: The role of rumination and worry across insomnia and chronic pain**

**(Critical Literature Review, Dec 2013)**

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Word count (7,044)

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**Proposed Journal Submission:** *International Journal of Cognitive Therapy*. A previous review arguing for a transdiagnostic approach to worry and rumination has been published in this journal. The present review extends this work by applying it to the problem of insomnia and chronic pain.

## **1.1 ABSTRACT**

*This review considers the closely related concepts of rumination and worry; examining their role in insomnia and chronic pain. Worry has been seen for many years as a major contributor to insomnia but only recently has attention been paid to the role of rumination. Similarly, worry and rumination have both been implicated in the maintenance of distress in chronic pain. However, across these two diagnostic categories (and the wider research literature) definitions of worry and rumination vary and are often used interchangeably. This review considers the research literature on rumination/worry in relation to insomnia, chronic pain and insomnia that occurs alongside chronic pain (pain-related insomnia). The empirical findings to date suggest patterns of repetitive negative thinking characterise both worry and rumination, but the content of the thinking may be distinct, opening the way for the application of transdiagnostic approaches. It suggests cognitive behavioural approaches to treating pain-related insomnia can be improved by incorporating elements which have been successful elsewhere in allowing people to manage repetitive negative thinking. Assessment of these targeted treatments in future research should lead to a reduction in suffering for patients with chronic pain who have trouble sleeping.*

## 1.2 OVERVIEW

*“Twelve years of insomnia research led us to worry”*

(Borkovec, Robinson, Pruzinsky, & DePree, 1983, p. 9)

It almost seems self-evident that with chronic pain comes difficulty sleeping. By the same token, sleeplessness would seem likely to, at the very least, reduce the bearability of chronic pain and may even increase its perceived severity. Indeed, over the years in patients with chronic pain, sleep difficulties were labelled “secondary” to highlight the etiological role of pain. But over the last decade or so research is starting to suggest that the relationship between the two conditions may be neither linear nor unidirectional (Smith, Perlis, Smith, Giles, & Carmody, 2000; Tang, Goodchild, & Salkovskis, 2012b). This has been recognised in the Diagnostic and Statistics Manual of Mental Disorders-5<sup>th</sup> Edition (DSM 5) which removed the primary/secondary distinction in insomnia disorder so that its definition better captures the bi-directional nature of insomnia with other medical or mental health problems (APA, 2013). So rather than insomnia secondary to chronic pain, the insomnia disorder is classified as “in addition to” chronic pain. Even so, with insomnia and chronic pain it is yet to be established how these two conditions interact and the mechanisms by which one condition maintains and/or exacerbates the other. Some authors have used the term ‘pain-related insomnia’ to capture the interactive nature of these conditions and will be the term used here (Tang, Goodchild, Hester, & Salkovskis, 2012a). The present review considers chronic pain-related insomnia from the perspective of a potential common cognitive mechanism in both chronic pain and insomnia: repetitive negative thinking in the form of rumination and/or worry. While a number of cognitive processes involved in the maintenance of insomnia and chronic pain have been identified, the focus here is on rumination and worry because while they have received a lot of attention over the years, an integrative model that explains these processes in chronic pain-related insomnia remains elusive.

It has long been known that worry and rumination play a major role in insomnia (Borkovec, Ray, & Stober, 1998; Carney, Harris, Moss, & Edinger, 2010; Harvey, 2002; Harvey, Tang, & Browning, 2005) but for many years the terms were used interchangeably and only recently have researchers begun to delineate the two as potentially playing similar but distinct roles (Carney, Edinger, Meyer, Lindman, & Istre, 2006; Carney et al., 2010; Thomsen, Yung Mehlsen, Christensen, & Zachariae, 2003). Similarly, in the chronic pain

literature, worry (Eccleston & Crombez, 2007) and rumination (Sullivan, Bishop, & Pivik, 1995) have both been linked to increased distress. However, definitions of worry and rumination vary within the research on chronic pain and insomnia and across the literature more generally (Watkins, 2008). In this review, the aim is to synthesise the research literature on rumination/worry in relation to chronic pain-related insomnia. It will begin by first considering definitions of worry and rumination in the literature before considering research dating back to the 1970's that has attempted to demonstrate their role in the maintenance of insomnia. This literature came together in a cognitive model of insomnia developed by Alison Harvey (2002). While the model proposed a clear role for worry and rumination, it and the literature more generally, had not clearly specified whether they played the same or distinct roles in insomnia's maintenance. Hence the review then considers recent research that has attempted to differentiate the role of the two processes in insomnia but acknowledges that the difference between them may be one of content rather than process. While worry and rumination have been shown to be important in insomnia, it is unclear whether they have a similar function in chronic pain in general and pain-related insomnia in particular. These two questions are considered before moving towards considering worry and rumination in terms of transdiagnostic approaches and the utility of classifying them both as a process of Repetitive Negative Thinking (RNT) that differ only in the content to which they relate to. A mechanism by which RNT might then lead to the maintenance of both insomnia and pain-related insomnia is proposed within the context of Harvey's (2002) cognitive model before considering the implications of such a mechanism for the treatment of pain-related insomnia. The review concludes by suggesting that worry and rumination in insomnia and pain-related insomnia can best be conceptualised as RNT. In doing so, it aids the development of specific and targeted treatments in the future that can help reduce the distress of patients with chronic pain who also have difficulty sleeping.

### **1.3 DEFINITIONS OF WORRY AND RUMINATION**

In Response Styles theory, Nolen-Hoeksema and colleagues describe rumination as, "repetitively and passively focusing on symptoms of distress and on the possible causes and consequences of these symptoms. Rumination does not lead to active problem solving to change circumstances surrounding these symptoms." (Nolen-Hoeksema, Wisco & Lyubomirsky, (2008), p. 400). They go on to state that rumination is repeatedly thinking about problems and emotions, rather than it having any specific content. Worry on the

other hand, is defined by Borkovec et al. as “... a chain of thoughts and images, negatively affect laden and relatively uncontrollable. The worry process represents an attempt to engage in mental problem solving on an issue whose outcome is uncertain but contains the possibility of one or more negative outcomes” (1983, p. 10). Hence rumination is seen as passively focusing on what is causing the current situation or condition and its symptoms whereas worry focuses on the potential negative outcomes and actively tries to find solutions to the problem: worry is future oriented, rumination focuses on the past. Thus worry and rumination are seen as repetitive cognitive processes but vary in mood and content (Segerstrom, Tsao, Alden, & Craske, 2000). Worry is associated with anxious states; its future oriented focus means the individual is likely to attempt to anticipate future threats, often catastrophising about what will happen. So for example, they may worry that their anxiety will make it difficult for them to get to sleep later that night and lead to reduced functioning the next day. Rumination on the other hand is a response to the symptoms of low mood states and the possible causes of dysphoric mood (Nolen-Hoeksema, 1991). So the individual with insomnia may be focussing on why they are feeling tired during the day and attribute it to the poor sleep the night before. However, Martin and Tesser (1996) define rumination as a form of repetitive thought that is related to subjective goals and concerns. In this definition, rumination can be helpful or unhelpful depending on whether it allows a person to move towards their goals. Hence it does not necessarily have to be related to distress. While the authors above have attempted to differentiate worry and rumination in general terms, as will be shown, this has not always happened when studied in the context of insomnia or pain-related insomnia.

#### **1.4 THE PROBLEM OF INSOMNIA**

Insomnia is a problem for a large proportion of adults, especially for those suffering chronic pain. Between 10 – 16 percent of adults report not getting enough sleep (Ancoli-Israel & Roth, 1999; Gallup, 2002) with approximately 6 percent meeting diagnostic criteria for insomnia (Ohayon, 2002). The DSM-5 defines insomnia disorder as “difficulty initiating and maintaining sleep (experiencing frequent awakenings and difficulty returning to sleep once awake) or waking up too early and being unable to fall back asleep” (APA, 2013). In addition, to meet DSM criteria, the sleep disturbance should also cause clinically significant distress, occur on at least 3 nights per week and have lasted for over 3 months. While insomnia can occur in isolation, for the majority it occurs alongside medical and/or



psychiatric disorders (Ohayon & Roth, 2001) with rates of insomnia ranging from 16-82 percent (Katz & McHorney, 1998; Smith, Huang, & Manber, 2005; Smith et al., 2000). While it is acknowledged that a range of physiological and behavioural factors are implicated in the development and maintenance of insomnia, there has been a large body of research implicating cognitive factors.

## **1.5 COGNITIVE FACTORS IN INSOMNIA**

In a historical review covering a broad range of cognitive factors, Harvey et al. (2005) note that as early as 1970 authors were implicating worry and rumination as important elements of insomnia. Storms and Nisbett (1970) hypothesised that worry/rumination about not getting to sleep led to increased arousal and thus increased sleep onset latencies. They gave placebo tablets to patients with insomnia telling half of them that the tablets would cause arousal and the other half relaxation. The finding that those given the ‘arousal’ tablet fell asleep sooner was seen as being due to these patients attributing their arousal to the tablet and thus reducing anxiety.

In 1980, Lichstein and Rosenthal asked 296 people with insomnia whether their problems sleeping were due to somatic or cognitive arousal. Participants were 10 times more likely to state that cognitive arousal was a cause of their insomnia compared to somatic arousal. Similarly, Espie et al. (1989) administered the Sleep Disturbance Questionnaire to participants with insomnia and found they were much more likely to give higher ratings to statements such as, “My mind keeps turning things over” and, “I am unable to empty my mind”, suggesting they felt that worry was a major reason for their sleep problems (Espie, Brooks and Lindsay, 1989).

In a study that attempted to directly manipulate worry, Gross and Borkovec (1982) told a group of good sleepers that they would have to give a speech after an afternoon nap. Participants who were not told they had to give a speech fell asleep faster and this was attributed to them not worrying about having to give a speech. However, Harvey et al. (2005) note that the authors did not directly check whether having to give a speech actually increased worry in participants. While a number of studies such as the one by Gross and Borkovec have shown a relationship between cognitive factors and sleep onset latency, others have mixed findings. For example, Van Egren et al. (1983) found that while

worrying about getting to sleep did correlate positively with self-reported estimates, it did not correlate with objective estimates based on polysomnography.

In the early 1990s researchers began exploring the content of worry in insomnia. Watts, Coyle and East (1994) and Fichten et al. (1998) found that the content of thought prior to sleep focussed on sleep itself, planning as well as recent and long-term concerns. Similarly, in a study by Wicklow and Espie (2000) they found an association between cognitive factors and objective measures of sleep onset latency. In their study they gave participants a voice-activated recorder and told them to say out loud any thoughts they were having while trying to get to sleep. The authors then subjected the transcribed tapes to content analysis to reveal eight categories of pre-sleep thought. These included: rehearsal/planning/problem solving; sleep and its consequences (ease/difficulty of falling asleep, consequences of not sleeping); reflection on quality of thoughts (mind buzzing, thoughts rushing); arousal status (pre-occupation with physical tiredness); external noise; autonomic experiences (thinking about heart rate, itching, restlessness); procedural factors (relating to the research project itself) and rising from bed (thinking about getting up, turning on the light). However, even though Wicklow and Espie and others were beginning to examine the *content* of pre-sleep thought, they still make no distinction here between whether the *process* constituted a distinction between worry or rumination. It was consideration of the process by which worry and rumination maintain insomnia that led Alison Harvey to develop her cognitive model (2002).

## **1.6 A COGNITIVE MODEL OF INSOMNIA**

It was the development of robust cognitive models for a number of other psychological disorders (e.g., Ehlers and Clark (2000); Salkovskis, Clark, and Gelder (1996)) as well as the findings from the research discussed above that led Harvey (2002) to propose a cognitive model of the maintenance of insomnia (see Figure 1.1). In her model, insomnia is seen as a 24 hour a day problem where “negatively toned cognitive activity” (p.871) is focussed on not getting enough sleep and the impact this will have on the next day’s functioning such as daytime fatigue, poor concentration etc. In the model, rumination and worry trigger autonomic arousal leading to a state of anxiety. Due to their anxious state the individuals attention becomes focussed on threat related cues both internally (body sensations) and externally (the bedroom environment) that tell the person they are not

getting enough sleep and/or that during the day they are not performing well or are feeling fatigued. Because high arousal states lead to a narrowing of attention towards threat related cues, these cues are more likely to be noticed (Clark, 1999). When the individual detects such sleep-related threat it gives rise to further worry and rumination and further increases in arousal and distress. Harvey then proposes that the anxious state and attentional bias make the individual think they have had less sleep than they actually did and that daytime functioning was much worse than it really was. These distortions then feedback into worry/rumination about the potentially long term consequences of reduced sleep such as, “I’m going to get ill” or, “I will lose my job” and hence the vicious cycle continues. Erroneous beliefs about sleep, such as overestimating the actual amount of sleep adults need to survive, also exacerbate worry and rumination as do safety seeking behaviours. In Harvey’s model these safety seeking behaviours might include spending longer in bed trying to sleep, trying to control their thinking, or drinking caffeine during the day (to stay awake) and alcohol at night (to get to sleep) (see Morin & Barlow, 1993; Perlis, Giles, Mendelson, Bootzin, & Wyatt, 1997). The effects of these cognitive and behavioural processes are to “trap the individual into becoming progressively more absorbed by and anxious about the sleep problem” (Harvey, 2002, p. 873). Worry and rumination can be seen as subcomponents of negatively toned cognitive activity that plays a central role in Harvey’s model but it is still unclear the extent to which these are distinct or overlapping processes. The following section thus considers insomnia research that attempted to answer this question.

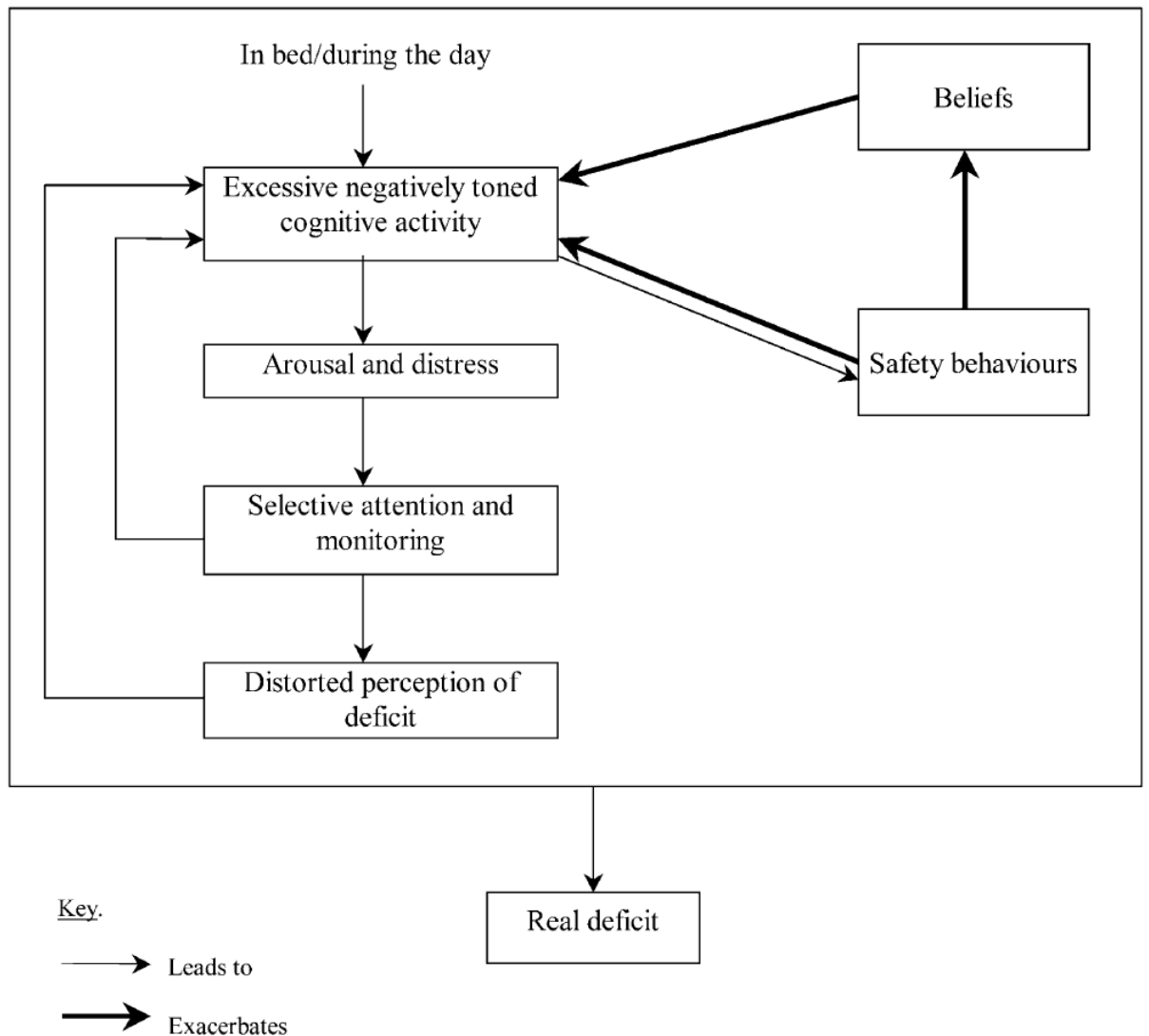


Figure 1.1: A cognitive model of the maintenance of insomnia (taken from Harvey, 2002)

## 1.7 DISTINGUISHING WORRY AND RUMINATION IN INSOMNIA

While worry has been shown to play a key role in the maintenance of insomnia, as shown in the studies reviewed above, only a handful have specifically focussed on the role played by rumination. Carney et al. (2006) argue that this is due in part to insomnia researchers generally using the terms ‘rumination’ and ‘worry’ interchangeably and in part using measures to assess worry that also include items on rumination: making it difficult to distinguish between the two. One study that did specifically focus on rumination in insomnia was Thomsen et al. (2003). They used a measure that encompassed a broader definition of rumination than those that focus on depressive symptoms (e.g., the

Rumination Response Scale, (Nolen-Hoeksema, 1991)). In doing so Thomsen et al. (2003) found that rumination was correlated with general sleep quality, sleep-onset latencies, and sleep disturbances. They took this finding to mean that worry and rumination independently contribute to sleep quality. In another study, Carney et al. (2006) used a symptom focussed scale of rumination and found that those who had trouble sleeping repetitively think about the causes of their fatigue, achiness, and concentration difficulties to a greater extent than good sleepers.

However, both the above studies were conducted on non-clinical samples which led Carney et al. (2010) to study whether rumination, separate to worry, impacts on subjective measures of sleep quality in people with clinical levels of insomnia. They administered the symptom focussed rumination subscale of the RSQ as well as the PSWQ to participants with a clinical diagnosis of insomnia. They found that worry and rumination were significantly correlated and that rumination had a significant correlation with several subjective measures of sleep quality. Furthermore, while participants high and low in rumination differed on measures of sleep onset, sleep quality and waking after sleep onset, the effect sizes were all small and the authors did not use any objective measures of sleep such as polysomnography or actigraphy. Finally, the cross-sectional design means the authors were not able to say whether rumination plays any causal role in insomnia. However, notwithstanding the limitations of the study, Carney et al. were able to highlight the importance of rumination in insomnia that is focussed on symptoms and differentiate it from worry. Given the correlation between worry and rumination in their study, the difference they found between their measures may actually be one of content rather than process.

In summary, the insomnia research suggests that both worry and rumination have an important role in the maintenance of insomnia. However, worry and rumination appear to share a repetitive thinking element but differ in content: rumination is focussed on symptoms of insomnia and their cause (Carney et al., 2006) while worry is focussed on the consequences of sleeplessness (Wicklow & Espie, 2000). However, it is not clear whether a similar distinction can be made between worry and rumination in pain-related insomnia.

## **1.8 THE PROBLEM OF CHRONIC PAIN AND RELATED INSOMNIA**

The DSM-5 is unclear about the definition of chronic pain due to the complexity of psychological and medical factors that contribute to a person's experience of it. Hence some individuals can be diagnosed with somatic symptom disorder with predominant pain, while others an adjustment disorder (APA, 2013). In patients suffering from chronic long-standing pain, between 50 and 88 percent will also suffer from insomnia (Atkinson, Ancoli-Israel, Slater, Garfin, & Gillin, 1988; Morin, Gibson, & Wade, 1998; Smith et al., 2000; Tang, Wright, & Salkovskis, 2007); and insomnia is seen by some as chronic pain's most disabling side effect (Follick, Smith, & Ahern, 1985). Insomnia used to be classified according to whether it was primary or secondary (i.e., attributable to a medical, psychiatric or environmental cause) (APA, 1994). Hence by reducing the symptoms of chronic pain, insomnia would be alleviated. However, insomnia can still continue for many patients even after adequate pain control (Ashworth, Burke, & McCracken, 2008). Furthermore, for insomnia to be "secondary" it should get worse when the pain becomes more severe. Smith et al. (2005) argue that in clinical settings, distinguishing the cause of insomnia's severity is often impossible due to it being related to multiple medical, behavioural and psychological factors.

Cross-sectional research suggests that sleep problems are linked to the severity of pain reported by patients and reductions in pain thresholds (Moldofsky & Scarisbrick, 1976; Morin et al., 1998; Smith et al., 2000; Wilson, Watson, & Currie, 1998) and pain severity negatively impacts on sleep onset, number or awakenings during sleep, sleep duration and restful sleep (Morin et al., 1998; Nicassio, Moxham, Schuman, & Gevirtz, 2002; Pilowsky, Crettenden, & Townley, 1985; Smith, Perlis, Carmody, Smith, & Giles, 2001; Wilson, Eriksson, D'Eon, Mikail, & Emery, 2002). Longitudinal studies also show similar results (Affleck, Urrows, Tennen, Higgins, & Abeles, 1996; Drewes et al., 2000). However, as stated above, insomnia can persist even when pain is controlled; leading researchers to examine cognitive-behavioural factors that affect chronic pain such as inactivity, low mood, and pre-sleep worry/rumination and their role in exacerbating the poor sleep experienced by these patients (Morin, Kowatch, & Wade, 1989; Pilowsky et al., 1985; Raymond, Nielsen, Lavigne, Manzini, & Choinière, 2001; Smith et al., 2000). While the exact relationship between sleep and chronic pain is still unclear, the research above points to a vicious cycle developing where poor sleep leads to increased pain sensitivity which

then negatively impacts on insomnia (Pigeon et al., 2012; Tang et al., 2012b). This has led to the view that in chronic pain patients, the “co-morbid” insomnia should be treated as a distinct problem to alleviate distress (NIH, 2005). Hence psychological models and treatment methods for insomnia separate from any other condition are increasingly being seen as having utility for insomnia in chronic pain. However, given the lack of clarity over the relationship between insomnia and chronic pain, treatment approaches are likely to be improved if they incorporate a more sophisticated understanding of the processes involved. Hence the review next considers the cognitive processes (including rumination and worry) that contribute to maintenance of distress first in chronic pain and then in pain-related insomnia.

## **1.9 COGNITIVE FACTORS IN THE MAINTENANCE OF CHRONIC PAIN**

According to Eccleston and Crombez (2007), “Pain is an ideal habitat for worry to flourish” (p.234). This is because pain is the body’s alarm system that alerts it to injury and to therefore take action. When the pain is brief, the person acts in an attempt to relieve the pain or escape what is causing the pain. However, when the pain is chronic, as in low back pain, the pain persists even after repeated attempts to relieve it. In this scenario, research has shown that patients worry about what has caused the pain and whether it will lead to long term disability if the cause is not treated (Moore, Von Korff, Cherkin, Saunders, & Lorig, 2000). In chronic pain, the erroneous beliefs and catastrophising that the pain is the result of physical injury can lead to fear about pain and avoidance of activity that might lead to pain - similar to forms of phobic behaviour (Leeuw et al., 2007). Based on observations that worry is a form of attempted problem solving, Eccleston and Crombez (2007) suggest that in chronic pain, problem solving is misdirected. In their cognitive model (see Figure 1.2) the individual experiencing chronic pain worries about its causes and its consequences but frames the pain as a problem caused by physical injury that needs to be solved through attempts to remove the pain. When, as in chronic pain, these attempts often fail, the model posits a ‘perseverance loop’ where the failure to solve the problem leads to further worry by the individual. Importantly, the worry increases attempts at trying to solve the problem but this increased effort only narrows and restricts their formulations of the problem, leading to repetition of the same failed attempts at pain relief. According to their model, only by reframing the problem as other than a biomedical one can the

individual head towards solutions that reduce their suffering. Hence cognitive therapeutic approaches to help the patient reassess the usefulness of worry or challenge their catastrophic thinking can help them to move away from the unachievable goal of pain relief towards living a meaningful life in the presence of pain.

Similar to the literature on insomnia, the role of rumination has not always been clearly defined in chronic pain. It is either seen as similar to worry (Moore et al., 2000) or as a subcomponent of catastrophising (Buenaver et al., 2012; Turner & Aaron, 2001). Sullivan et al. (1995) developed the Pain Catastrophizing Scale that included rumination, magnification and helplessness as subcomponents. Using this scale Sullivan, Stanish, Waite, Sullivan, and Tripp (1998) found that the rumination subscale was the strongest predictor of pain in their sample. Melanie Edwards and colleagues (Edwards, Tang, Wright, Salkovskis, & Timberlake, 2011) suggest that rumination may be triggered by catastrophic thinking and appears to be related to pain intensity and sleeplessness. However, their definition of rumination includes problem solving as a subcomponent in contradiction to more traditional definitions of rumination as a passive process of thinking about causes and symptoms (Nolen-Hoeksema et al., 2008). In an unpublished paper on their development of a new measure of rumination in chronic pain, Edwards et al. (unpublished) found that in chronic pain patients, rumination about their pain was positively correlated with pain intensity to a greater extent than in pain free controls. Furthermore their findings suggest that rumination can be distinguished not only from catastrophising but also worry (as assessed using the PSWQ) in chronic pain.

The research literature reviewed above suggests a role for both rumination and worry in the amplification of distress in chronic pain. In a similar way to insomnia, both rumination and worry can be conceptualised as a repetitive negative thought process that only differs in its content. What remains unclear in the chronic pain literature is whether worry and rumination play distinct roles in sleep disturbance. As we have already seen, worry and rumination are both implicated in cognitive arousal in insomnia disorder; hence the review now explores the evidence regarding their impact in pain related insomnia – an area that has, as yet, received little empirical investigation (Buenaver et al., 2012).



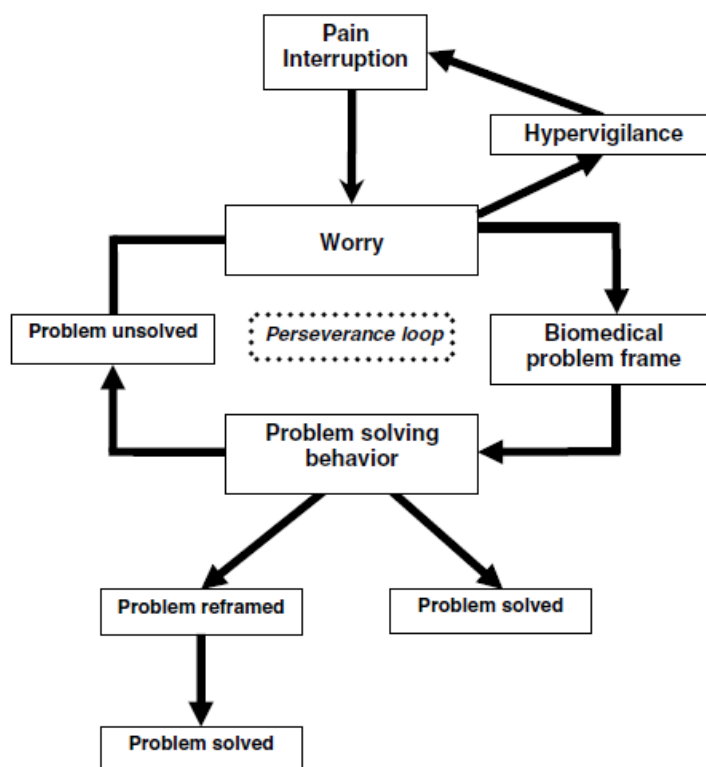


Figure 1.2: A cognitive model of chronic pain (taken from Eccleston and Crombez (2007))

### 1.10 WORRY AND RUMINATION IN PAIN-RELATED INSOMNIA

Pain has been linked to sleep difficulties (Moldofsky, Scarisbrick, England, & Smythe, 1975; Pilowsky et al., 1985; Smith & Haythornthwaite, 2004) but sleep disturbance has also been found to directly predict subsequent pain (Edwards et al., 2009; Edwards, Almeida, Klick, Haythornthwaite, & Smith, 2008; Quartana, Wickwire, Klick, Grace, & Smith, 2010). Hence it seems appropriate to focus on factors other than pain itself that contribute to pain-related insomnia. Smith et al. (2000) found that cognitive arousal best predicted sleep quality in chronic pain patients over and above somatic arousal, daily activity levels, depressive symptoms and severity of pain. In a further study Smith et al. (2001) asked chronic pain patients to tape record their pre-sleep thoughts over a seven night period. They found that participants with chronic pain had frequent catastrophic thoughts about their pain but these were not significantly more frequent than negative sleep

related thoughts or thoughts about the bedroom environment. While pain related thoughts predicted sleep onset latency, the frequency of these thoughts was not related to pain severity. They took this to confirm their hypothesis that cognitive arousal due to rumination about pain and the consequences of the pain as well as negative thoughts about sleep were contributing to their problems in getting to sleep. While they give no formal definition of rumination, their findings suggest that patients in their sample were focussing on the symptoms, causes and consequence of their pain in line with the earlier definitions of rumination (Nolen-Hoeksema, 1991). Smith et al. suggest that while rumination is implicated in both insomnia and pain-related insomnia, the content of their ruminations includes thoughts about pain and its consequences. In insomnia they ruminate about the causes and consequences of not sleeping (Van Egeren, Haynes, Franzen, & Hamilton, 1983), in chronic pain they additionally ruminate about pain and the consequences of their pain. These thoughts then increase cognitive arousal and thus impede initiation and maintenance of sleep.

Tang et al. (2012a) compared patients with insomnia and pain-related insomnia across a range of variables. They found that the insomnia group tended to worry more than the pain-related insomnia group (as assessed by the PSQW). However, even in the pain-related group, mean worry scores indicated levels of worry associated with generalised anxiety disorder. The similarities between the groups on measures known to affect insomnia (such as sleep related anxiety, somatic arousal etc.) suggest that similar cognitive behavioural processes were at work across these groups, suggesting the use of Cognitive-Behavioural Therapeutic approaches that have been successful in treating insomnia can be successfully applied to the treatment of pain-related insomnia. Unfortunately, Tang et al. did not include a measure of rumination in their study, so as yet it is still unclear whether these two groups differ in their tendency to ruminate. Also, while Tang et al. found that patients with pain-related insomnia do worry, it is not clear what the content of the worry is. However, given the finding of Smith et al. (2001) that in pain-related insomnia the content of rumination is focussed on pain, one could speculate that the content of worry in pain-related insomnia would also be focussed on pain. Further research is needed to clarify this point.

Buenaver et al. (2012) used the PCS to assess the effects of pain catastrophising and sleep disturbance on pain severity. They theorised that pain catastrophising not only has a direct effect on pain but also indirect effects on pain through disrupting sleep due to the effect of reduced sleep on pain intensity (Edwards et al., 2008). They found that only the rumination

subcomponent of the PCS predicted indirect effects on clinical pain through rumination's association with sleep difficulties. Their results are consistent with previous findings by Smith et al. (2001) that increased thinking about pain prior to sleep onset leads to reduced sleep onset latencies in chronic pain patients. These sleep difficulties then have a negative impact on pain experience.

In summary, it would appear that both worry and rumination play a role in the maintenance of pain-related insomnia via a process of repetitive negative thought. While the same processes involved in the maintenance of insomnia disorder appear to be maintaining the sleep disturbance in pain-related insomnia, the content of the thought process also includes pain and its consequences as opposed to just negative thoughts about sleep. Given these findings the review now considers whether this repetitive negative thinking process is best conceptualised in terms of a transdiagnostic approach.

### **1.11 TOWARDS A TRANSDIAGNOSTIC APPROACH IN PAIN RELATED INSOMNIA**

While theorists have tried to distinguish between rumination and worry it is clear that the two processes are overlapping in that they are repetitive in nature and lead to negative outcomes (e.g., rumination leads to depression, worry leads to anxiety). This led some to view them as a similar process but applied to different disorder specific content (Segerstrom et al., 2000). In order to overcome the domain specific definitions of these concepts, Harvey et al. (2004) proposed Recurrent/Repetitive Negative Thinking (RNT) as a transdiagnostic process. It encompasses the repetitive nature of rumination and worry about concerns from the past, people's current state and the future. Their reasoning for speculating such a transdiagnostic process was the agreement the various definitions of rumination and worry shared about the thinking process. Almost all the definitions have a repetitive element, that thinking is passive and relatively uncontrollable, and the content of the thinking is negative (Ehring & Watkins, 2008).

Evidence for the transdiagnostic view has come from studies that compared the two standardised measures of worry and rumination: the Penn State Worry Questionnaire (PSWQ) (Meyer, Miller, Metzger, & Borkovec, 1990) and the Response Styles Questionnaire (RSQ) (Nolen-Hoeksema, 1991). In reviewing the studies that have compared these two measures, Ehring and Watkins (2008) note that the findings show a

high correlation between the measures, that the measures load on common factors in structural equation models and that they both lead to anxiety and depression (Fresco, Frankel, Mennin, Turk, & Heimberg, 2002; Segerstrom et al., 2000; Siegle, Moore, & Thase, 2004). Ehring and Watkins (2008) took these findings to mean that worry and rumination share a common process. In additional research, participants had to rate the extent to which a range of characteristics related to worry or rumination (Watkins, 2004; Watkins, Moulds, & Mackintosh, 2005). The two processes were rated as very similar with only the temporal dimension being significantly different: rumination is past focussed, worry is focussed on the future. Ehring and Watkins (2008) took this as further evidence that worry and rumination share a common process (repetitive thought), but they differ in content (e.g., temporal orientation) and supports Harvey and colleagues' view (2004) that repetitive negative thinking is a transdiagnostic process.

What implication might this approach have for our understanding of insomnia and pain-related insomnia? Within Harvey's cognitive model (2002) both rumination and worry are seen as "negatively toned cognitive activity". Hence a scenario might unfold where the person with insomnia while focussing on their symptoms of fatigue might attribute them to poor sleep the night before (rumination) and thus feel low in mood. The individual might then become concerned about their performance at work and whether they will be able to sleep that evening (worry). In this scenario only the content of thought varies, whereas the repetitive thought process is the same. If this was the case, it would suggest that patients with insomnia are engaging in RNT about their sleep disruption and how it will further affect them if sleep is disrupted in the future.

In pain-related insomnia, the "negatively toned cognitive activity" is still taking place in the form of RNT (worry and rumination), but its trigger may now include pain and its focus includes the causes and consequences of pain. The model may then unfold in a similar way to insomnia disorder with patients attributing their fatigue to poor sleep the night before caused by their pain (rumination) and thus feeling low in mood. In addition, many of the behaviours that lead to the maintenance of insomnia are also apparent in the way people typically manage their chronic pain. They may engage in a number of behaviours to try and compensate for their poor sleep (staying in bed longer, using alcohol), as well as to reduce their pain (as per Eccleston and Crombez's model (2007)) leading to the bedroom becoming associated with a range of behaviours other than sleep. They are likely to hold dysfunctional beliefs not just about the impact of poor sleep on

their health generally but also on their level of pain (given the evidence that poor sleep reduces pain thresholds), leading to further RNT about the quality of their sleeping and how to cope with it (worry).

While the above mechanisms for maintaining insomnia and pain-related insomnia seem likely given the current evidence, further research is needed to consider exactly how people with insomnia and chronic pain view their sleep problem: what do they attribute its cause to; what beliefs do they hold with regards to the impact of not sleeping on their pain; are they also engaging in safety seeking behaviours related to their pain that have the unintended consequence of maintaining their insomnia? All of these questions require further empirical investigation but they suggest that cognitive behavioural factors play an important role in the maintenance of pain-related insomnia and are thus targets for its treatment.

## **1.12 TREATING PAIN-RELATED INSOMNIA**

Cognitive behavioural therapeutic approaches target the behavioural and other factors that maintain sleep problems (such as dysfunctional beliefs about sleep) either singly or in combination in what is now termed cognitive behavioural therapy for insomnia (CBT-I). CBT-I combines therapies that have demonstrated efficacy in treating insomnia such as behaviour approaches (e.g., stimulus control therapy) (Bootzin, 1973); relaxation training (Nicassio & Bootzin, 1974); and cognitive therapy (Harvey, 2005). There is now a large and growing evidence base for CBT-I that demonstrates large effect sizes on a range of measures such as sleep latency and quality across randomised controlled trials (RCTs) and meta-analyses (Edinger & Means, 2005). Only a handful of studies have so far assessed CBT-I in patients with chronic pain.

One of the earliest studies that assessed CBT-I for pain-related insomnia was Morin et al. (1989). In a case series using a multiple base-line design with three participants they showed that CBT-I that included sleep restriction and stimulus control had a positive impact not just on diary measures of sleep quality but also objective polysomnography that were maintained at six month follow up. While participants showed improvements in mood and reductions in anxiety following treatment, there was no change in their ratings of pain.

In one of the few randomised controlled trials (RCT) of CBT-I in pain-related insomnia, Currie and colleagues (Currie, Wilson, Pontefract, & deLaplante, 2000) treated 60 patients with chronic pain and insomnia using a group based format. The treatment included behavioural elements (stimulus control, sleep restriction) as well as cognitive components (challenging negative thoughts about sleep). In comparison to the wait-list control group, patients in the CBT-I group had improved sleep onset latencies, sleep quality and efficiency both on subjective (sleep diary) and objective (actigraphic) measures that were maintained on some of the measures at three month follow-up. The treatment group also showed improvements in pain severity rating over time.

Jungquist et al. (2010) assessed CBT-I in chronic pain after eight weeks of individual CBT-I that included: stimulus control, sleep restriction, sleep hygiene and a single session focussed on catastrophic thoughts about insomnia. They found that in the CBT-I group, sleep latency improved, as did sleep maintenance and efficiency but pain severity did not differ between groups. In a trial of CBT-I in patients with fibromyalgia, Edinger, Wohlgenuth, Krystal, and Rice (2005) compared patients treated with CBT, sleep hygiene or usual care. They found that patients' sleep diaries showed an almost fifty percent reduction in the time spent awake in the patients treated with CBT-I compared to a twenty percent reduction in the sleep hygiene group and only a three percent reduction in the usual care group. Vitiello, Rybarczyk, Von Korff, and Stepanski (2009) compared CBT-I with an attention control group in older patients suffering from osteoarthritis. The CBT-I was a group based intervention that included: stimulus control, sleep restriction and hygiene, relaxation training and a cognitive component focussing on unrealistic beliefs about sleep and loss of sleep. They found that the patients in the CBT-I group, but not the attention control group, showed improvements in self reported sleep measures and also pain measures that were maintained at one year follow-up.

While some of the studies show improvements in pain following CBT-I (Currie et al., 2000; Vitiello et al., 2009) not all of the studies did. Tang et al. (2012b) took this to suggest that the reciprocal link between pain and insomnia may not be bi-directional as some authors assert. They argue that this is unsurprising given the intractable nature of chronic pain. However, in line with cognitive models of chronic pain, using CBT approaches that target unhelpful beliefs about pain may lead to improvements in how patients live with intractable pain. They piloted a hybrid CBT treatment that included elements designed to address insomnia (psychoeducation, stimulus control, sleep

restriction, cognitive therapy) with additional components that tackled management of chronic pain (goal setting and behavioural activation, pain catastrophising and safety-seeking behaviour). Data from patients in the CBT group was compared with those allocated to a symptom monitoring group. Sleep improved in the CBT group post-treatment to a greater extent than the symptom monitoring group. While the groups did not differ on measures of pain intensity (as predicted), measures of pain interference, fatigue and depression all showed greater reductions in the CBT group. Both improvements in sleep and pain were maintained at six month follow-up. Interestingly this was the only study to address worry as part of the cognitive component of treatment.

While still in its early stages, the evidence from trials of CBT-I mainly supports its effectiveness in patients with chronic pain. However, given that CBT-I is a multi-component therapy it is not clear which element of the treatment is most effective and/or where the greatest clinical change is occurring. Furthermore, only one study so far has tackled RNT (in the form of worry) directly in pain-related insomnia. Cognitive models of insomnia see worry and rumination as central to its maintenance, suggesting a greater emphasis should be placed on factors such as RNT in its treatment. The evidence to date suggests this is not currently the case in the CBT-I used for pain-related insomnia, with most of the emphasis being on behavioural interventions. Harvey et al. (2004) have suggested a number of ways that RNT can be dealt with during treatment for other psychological disorders. One approach is to identify and repeatedly trigger worry or rumination while helping the patient develop alternative strategies to manage them, such as relaxation training or problem solving skills, in a similar way to treatment for generalised anxiety disorder (Borkovec & Ruscio, 2001). Use of imagery has also been shown to make thinking more concrete and solution-focussed and has been shown to reduce sleep onset latencies (Nelson & Harvey, 2003).

Another way of tackling the content of RNT is to encourage more concrete action-oriented thought. While in pain-related insomnia the content of many of these types of thoughts are likely to be 'Why' type questions, such as, "Why can't I cope with this pain", Watkins and Baracaia (2002) suggest coaching the patient to use more 'How' type questions. In pain-related insomnia this might be, "How can I manage my pain so I can sleep". Finally, Martin and Tesser (1996) conceptualised repetitive thought as an attempt to find ways to achieve personal goals. So if the goals patients set for themselves are unrealistic or conflict with other goals this is likely to increase the level of RNT. This seems especially relevant

to people with chronic pain who may have the unrealistic goal of cessation of pain (Eccleston & Crombez, 2007). Helping patients to identify and move towards more functional and realistic goals may help reduce RNT (Harvey et al., 2004). While none of the above approaches are new and have formed a part of previous cognitive interventions for insomnia (e.g., Espie, 2006) their utility in treating pain-related insomnia has not been assessed. The likelihood is, given their effectiveness in insomnia disorder, that these approaches will bring benefits to patients with chronic pain and reduce the suffering caused by disruption of sleep. Whether this is the case remains an empirical question for future research.

### **1.13 SUMMARY AND CONCLUSIONS**

Worry and rumination have formed a central part in cognitive theories of insomnia for the preceding four decades. But more recently, concerns emerged about whether these were the same or two distinct processes. This stemmed in large part from their use within the literature as interchangeable constructs and a lack of distinction made in their measurement. More recently, researchers began to consider whether these were separate processes and played different roles in the maintenance of insomnia. This review sought to address this question within the context of insomnia in patients with chronic pain.

The evidence from the research conducted so far in pain-related insomnia suggests that both worry and rumination are important maintaining factors in a similar way to insomnia disorder. These processes only appear to differ from insomnia disorder in terms of additional content: pain and its consequences. The similarities in the cognitive process (but difference in content) across these patient populations add weight to the conceptualisation of worry and rumination as forms of repetitive negative thinking (RNT). In both insomnia and pain-related insomnia, the RNT can be seen as contributing towards the sleep disruption as captured in cognitive models such as Harvey's (2002). While authors such as Carney et al. (2010) have argued for a distinction to be made between rumination and worry in insomnia, they acknowledge that the distinction is only in terms of the content of the thought process, not the process itself. As a result, worry and rumination do not appear to be distinct processes but share a repetitive element that is relatively uncontrollable with negative content. The difference between the two appears to be the one of content, with rumination focussed on the past and worry on the future. Both these forms of content have



been reported in patients with insomnia and chronic pain-related insomnia; with the pain-related insomnia patients often experiencing further RNT about their pain. In conclusion then, it would appear that worry and rumination, as a process of RNT, combine to form a 'malignant interaction' that disrupts sleep, exacerbates pain and maintains distress. As a result, therapeutic approaches that disrupt these repetitive thinking processes and replace them with more concrete, solution-focussed problem solving approaches would appear to be most likely to succeed. By highlighting the role that RNT plays in pain-related insomnia, this review suggests a more central role for this process in cognitive therapeutic treatment of insomnia that occurs in people experiencing chronic pain.

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# **Service Evaluation of the Neurodevelopmental Clinic in Swindon and Wiltshire Child and Adolescent Mental Health Service (CAMHS)**

**(Service Improvement Project, Nov 2013)**

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## 2.1 ABSTRACT

**Background:** Early diagnosis of neurodevelopmental conditions such as Autism Spectrum Disorders (ASD) and Attention Deficit Hyperactivity Disorder (ADHD) in children are enshrined in national UK policy, as is ensuring that parents'/carers' views shape service delivery. **Aim:** The present study attempted to measure adherence to service guidelines of a neurodevelopmental disorders assessment clinic within a Child and Adolescent Mental Health Service (CAMHS) to identify service needs. It also assessed parents'/carers' satisfaction with the service and what information should be included in a patient information leaflet. **Method:** An audit of cases referred during 2012 -2013 plus a postal survey of parents/carers of children referred during the audit period. **Results:** The service was mostly compliant with NICE guidelines but quantifying this was difficult under its current record keeping. While satisfied with the clinic's service, the main concern of parents/carers was the length of time the assessment process took. **Conclusions:** Adoption of NICE audit tools would help document compliance with guidelines. A patient information leaflet might help manage parents' expectations about the time the assessment process takes.

## 2.2 INTRODUCTION

Neurodevelopmental disorders are seen as arising from a child's atypical brain development and result in a range of impairments that impact on communication, cognition, behaviour and motor functioning. Within the fifth edition of the Diagnostic and Statistic Manual of Mental Disorders (DSM-5) (APA, 2013), Neurodevelopmental Disorders include: Intellectual Disability; Communication Disorders; Autism Spectrum Disorder (which now encompasses autistic disorder (autism), childhood disintegrative disorder, and pervasive developmental disorder not otherwise specified); Attention-Deficit/Hyperactivity Disorder (ADHD); Specific Learning Disorder (with reference to reading, mathematics and written expression); and Motor Disorders (that includes Tourette's disorder and tic disorders). Similar classifications exist in the International Classification of Mental and Behavioural Disorders 10th revision (ICD-10) (WHO, 1992) although it still retains the category of Pervasive Development Disorder (PDD) to refer to Autism Spectrum Disorder (ASD). In the ICD-10, ADHD is labelled hyperkinetic disorder but with more stringent criteria regarding severity of symptoms.

Clinical diagnoses of neurodevelopmental disorders are based on observations of a child's behaviour (to determine the pattern and severity of impairment) as well as gaining an understanding of the child's developmental history and context that may have a modifying influence on the presentation (Moreno-De-Luca et al., 2013). Two of the more difficult disorders to diagnose due to the complexity of their presentations are ADHD and ASD. For example, ADHD is usually characterised as "maladaptively high levels of impulsivity, hyperactivity and inattention" and associated with at least moderate impairment over multiple settings (e.g., school and home) and multiple domains (e.g., schoolwork and forming relationships with peers) (NICE, 2008, p.15). It requires differentiation from conditions that can present with similar symptoms such as conduct disorder and even autism spectrum disorder (Weinberg & Emslie, 1991). ASD is diagnosed if impairment is observed in "reciprocal social interaction and social communication, combined with restricted interests and rigid and repetitive behaviours" (NICE, 2011, p.4). However, diagnosis can become more complicated when the child has a high level of functioning and shows no delay in language or intellectual development (previously diagnosed as Asperger's Syndrome) (Gillberg, 2002). The National Institute for Health and Clinical Excellence (NICE) in the UK has developed guidelines to help Child and Adolescent

Mental Health Services (CAMHS) manage and accurately diagnose the presence of ADHD and ASD respectively (NICE, 2008, 2011).

Both guidelines recommend the assessment of children suspected of having these conditions should involve gathering information on the child's behaviour across a number of contexts (for example, school and home) and be undertaken by a multi-professional team that should include or have access to: Child and Adolescent Psychiatrists, Paediatricians, Speech and Language Therapists, Clinical Psychologists, Educational Psychologists, and Occupational Therapists. These NICE guidelines include criteria against which services can be audited (see Appendix A and Appendix B). While the criteria for ADHD cover both diagnosis and clinical management, the ASD criteria only cover diagnosis. The ASD guidelines state that children should be seen within three months of a referral to the ASD assessment team; there are no specific timescales set out in the guidelines for the assessment of ADHD.

Early recognition and diagnosis are key themes in national UK health policy such as the National Service Framework (NSF) for children and young people (Department of Health, 2004) and Every Child Matters (HM Treasury, 2003). This is especially important in ADHD which, if left undiagnosed and untreated, can have a serious impact on an individual's life (ADDIS, 2003; Young, Heptinstall, Sonuga-Barke, Chadwick, & Taylor, 2005). Early identification of ASD is also seen as vital in helping children develop the skills for independent living (as far as possible) as they move towards adulthood (Carr, 2013; Gillberg, 2002).

Another important theme in the NSF and Every Child Matters is the involvement of service users in shaping health services, with the Healthcare Commission in the UK seeing them as vital in informing how services are delivered. Hackett, Shaikh and Theodosiou (2009) surveyed through questionnaires, parent and carer perceptions of an ASD assessment service within a CAMHS in Manchester, UK. While the majority of parents (95%) were satisfied with the service a small number stated dissatisfaction with the length of time the assessment process took. One of the recommendations coming out of the survey was the development of an information leaflet to be sent to parents and carers before the assessment describing the process. The present study used a similar method to Hackett et al. to obtain the views of parents and carers of children referred to a clinic that assesses primarily for ASD and ADHD.

## **2.3 AIMS**

The present evaluation sought the views of parents and carers of children who had been through the assessment process within a Neurodevelopmental Clinic (NDC) based in a CAMHS. In addition, the clinical lead for the NDC also wanted to know from parents/carers what information they would like included in a patient information leaflet that could help improve the service the NDC provided. Alongside this, the project also evaluated the service against the criteria for diagnosis of ASD/ADHD set out in NICE guidelines (see Appendix A and Appendix B) as well as addressing specific questions set by the clinical lead for the ASD care pathway (see Appendix O). The aim here was to assess where the service was meeting NICE criteria but also highlight areas where service could be improved in relation to NICE guidance.

## **2.4 SERVICE CONTEXT**

The NDC sits within a regional tier 3 community CAMHS for children up to the age of 18 years. It serves as a specialist assessment clinic for referrals from Swindon (a mainly urban area) and Wiltshire (mostly rural) CAMHS respectively. It covers a combined population of approximately 600,000 (Swindon 200,000; Wiltshire 400,000) with around 22% being under the age of 18 years. The NDC was set up in 2010 following service reorganisation that led to a review of the diagnostic pathway in line with national guidelines for ASD and ADHD (NICE, 2008, 2011). The main change to the pathway was that a large number of first line assessments for ADHD and ASD within the trust would be carried out by paediatricians. Prior to this, all assessments were completed by a multi-disciplinary pervasive developmental difficulties assessment group (PDDAG). In the new pathway only more complex cases that require more detailed multi-disciplinary assessment are seen in the NDC. The NDC under evaluation here mainly consists of professionals from Psychiatry and Clinical Psychology with further input from the wider multi-disciplinary team within community CAMHS.

All cases referred to the NDC come internally from CAMHS clinicians following a core assessment or from the paediatrics complex case pathway. Prior to an initial appointment at the clinic, the child or young person's school is contacted to request information (including academic performance, concerns about behaviour, along with strengths and any social skills they may have observed) as well as requests to any educational psychologists or

speech and language therapists that might have been involved with the child. At the initial appointment in the NDC, all parent/carers and children (if appropriate) are asked about their concerns and why they think a referral was necessary. They are asked about the child or young person's experience at home and at school and about their medical and developmental history (including perinatal details). During these appointments, staff observe how the child or young person interacts with them and their parents in terms of their social communication, including verbal and non-verbal behaviour. The team then spend a brief period separate from the parents to discuss whether a diagnosis can be given based on the evidence observed in the room and pre-existing medical records/school reports or whether further assessment in the clinic is warranted. Further assessment may include the following: naturalistic observation of the child's behaviour in school; Autism Diagnostic Observation Schedule (Lord et al., 1989); Wechsler Intelligence Scale for Children – 4th Edition (WISC-IV) (Wechsler, 2004) or similar cognitive assessment appropriate to their age and developmental need; Test of Everyday Attention for Children (TEA-CH) (Manly, Robertson, Anderson, & Nimmo-Smith, 1999); Conners' Ratings Scale for parents (Conners, 2002a) and teachers (Conners, 2002b). Following further assessment, a feedback appointment is made with the parent/carer where the results of the assessment are presented with reasons for the team's conclusions. An opportunity is provided at this session to ask questions of the team and seek clarification as well as discuss potential treatment options; however the NDC itself does not provide treatment. A written report is given to all parents/carers that are routinely shared with their GP. All families will be offered a follow-up appointment to discuss the implications of the assessment.

## **2.5 METHOD**

The audit period for the evaluation against NICE guidelines for ASD and ADHD covered all referrals to the NDC between 1st April 2012 and 31st March 2013.

The service has recently moved to the “RiO” electronic patient records system. The system is a general electronic record system and is not currently configured to automatically capture the type of data suggested by NICE to help in the audit of services. All referrals to the NDC were also recorded on a separate Excel spreadsheet by the NDC administrator. However, while the administrator did keep a paper record of the assessment process for each patient, she expressed concerns about whether it was an accurate reflection of what had taken place or was up-to-date. For example, reports can be added to RiO by any clinician without the administrator being aware. As a result she was not always able to update the paper record. Hence data relevant to the present evaluation had to be extracted from within each individual patient record on RiO. This was then entered into a separate spreadsheet for analysis.

For the patient survey, a questionnaire was sent to the parents of every child whose data had been included in the evaluation (see Appendix E). The survey sought parents’ views about the quality of the service but also what information they would have found helpful before attending the clinic. The format for the survey was based on the standard patient satisfaction surveys used within the Trust and was provided by the Trust’s Research and Development office. This was then adapted in consultation with the clinical lead for ASD to ask patients about issues relevant to the NDC. The survey collected: basic demographic data; views about the length of time waiting for an appointment; parents’ views about the assessment process; their opinion about the diagnosis; the feedback appointment and report. The survey also asked whether they thought an information leaflet would have been helpful and what information they thought it should contain. The survey included a stamped address envelope to return to the CAMHS admin team. Two weeks after sending the surveys, a reminder letter was sent (with a further copy of the survey) to invite parents to respond if they had not already done so. Approval for the evaluation and survey was given by the Trust’s R&D office.

## 2.6 FINDINGS

Between April 2012 and March 2013 there were 62 referrals to the NDC. Of these 42 were male and 20 female. Forty four of the referrals came from Swindon with 18 coming from Wiltshire. The age ranges of the children referred to the clinic during the audit period are shown in Table 2.1. The majority were between the ages of 11-15 years old. The number of referrals from each of the different professions referring children into the NDC is shown in Figure 2.1.

Table 2.1: Age ranges of the children referred to the NDC over the audit period.

Age range:	No. of children referred
Under 5	1
5-7 yr old	7
8-10 yr old	5
11-15yr old	36
16-18 yr old	13
Total	62

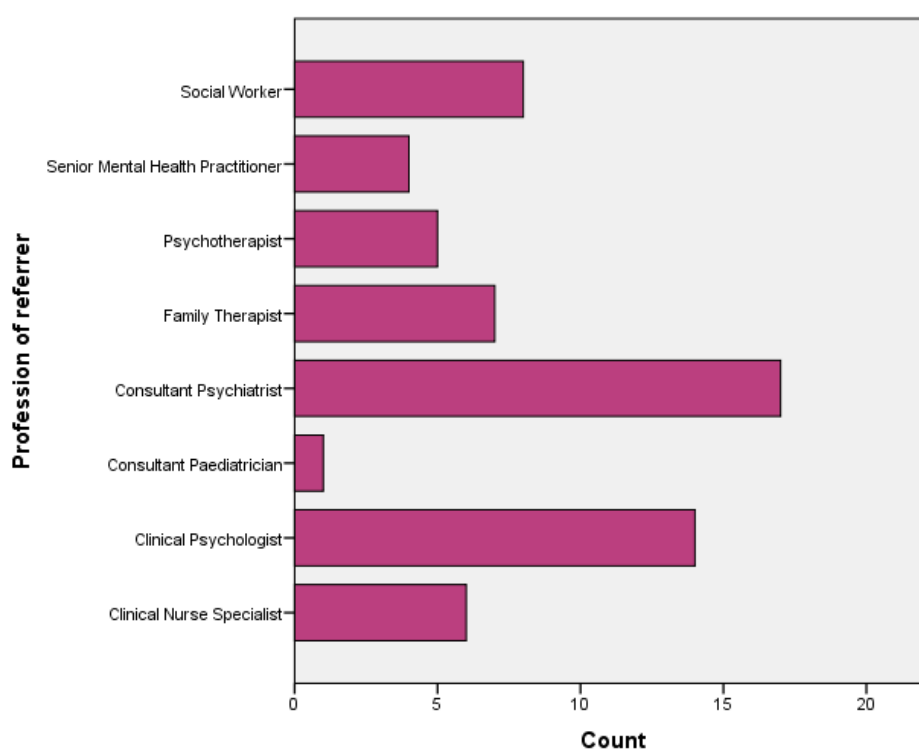


Figure 2.1: Number of referrals to the NDC over the audit period according to the profession of the referrer



The largest number of referrals to the clinic came from Psychiatrists (17, 27%) closely followed by Psychologists (14, 23%). There was only one referral during the period from a Consultant Paediatrician. However, this most likely reflects the fact than many of those referred through the paediatrics complex case pathway will have initially been seen by a CAMHS professional before that professional then refers them to the NDC.

### 2.6.1 *TIMESCALE OF THE ASSESSMENT PROCESS*

The median time to first appointment was 2.02 months with an inter-quartile range of 1 month. As shown in Figure 2.2, 86% of children were seen within 3 months of being referred.

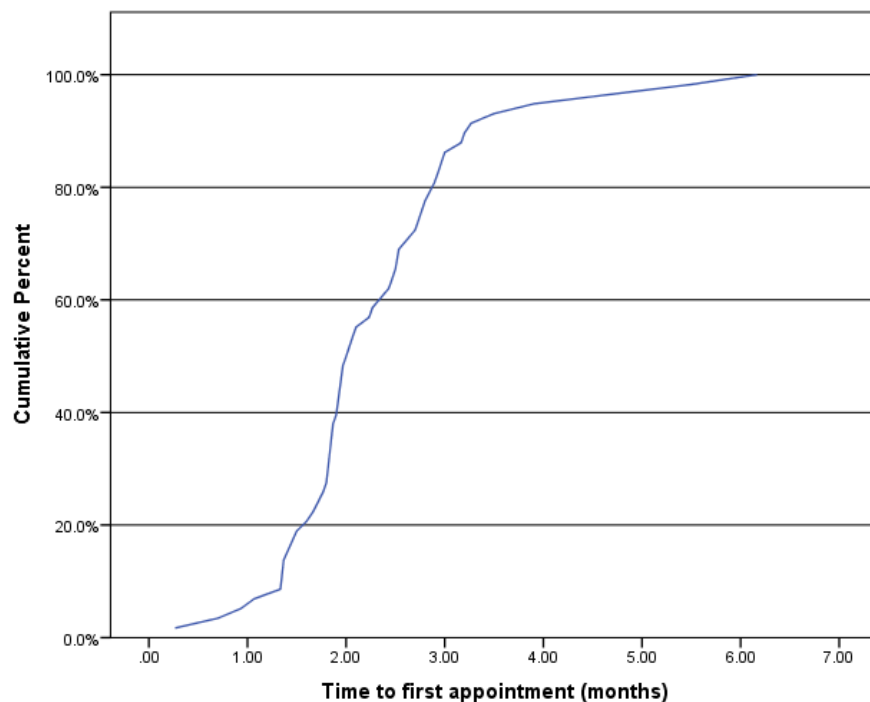


Figure 2.2: Cumulative percentage of referrals against time to first appointment (months)

In total 8 children were not seen within 3 months of referral. All of these children were referred for an assessment of ASD. The reason they were not seen within the 3 month timescale was due to either the initial appointment at the clinic not being kept by the parent/carer, or unavoidable rescheduling of appointments beyond the control of the clinic.

The parents/carers of 3 (4.8%) children referred to the clinic decided to withdraw from the assessment process. At the time of the audit, 13 (21%) children had not completed the assessment.

### 2.6.2 *ASSESSMENT & DIAGNOSIS*

All of the children in the clinic were assessed by two or more professionals from the multi-disciplinary team. Sixteen children underwent cognitive assessment as part of their assessment process; 8 using the WISC-IV and 8 using the WISC-IV plus the TEA-CH. Nineteen children (30.6%) were observed by a member of the team while at school at the time of the audit, with one child still awaiting an observation. Thirty children (48.4%) were assessed using the ADOS, all of whom were referred for ASD or ASD/ADHD assessment.

### 2.6.3 *ADHD*

Seven children were referred for an assessment of ADHD. One of the children was still awaiting an initial assessment at the time of the audit. All of the remaining 6 children were assessed using the Conners' Ratings Scale by both parents and school teachers. Three of the children were also observed by one of the NDC team while at school. Three of the children underwent cognitive assessment that comprised both the WISC-IV and the TEA-CH. All 6 children's parents were interviewed by the NDC team about their child's developmental history.

Three of the seven children referred for ADHD were still awaiting a diagnosis at the time of the audit. Of the four that were diagnosed, one was diagnosed with an attachment disorder and another was diagnosed with a learning disability. The remaining 2 children were diagnosed with ADHD and were prescribed Aripiprazole and Concerta respectively under the care of a Consultant Psychiatrist in CAMHS. One of the families of those with the ADHD diagnosis was offered a parenting intervention. The other, being over 15 years old, received individual psychological therapy within CAMHS. These two children were referred to the clinic by a Social Worker and Consultant Psychiatrist respectively (the professions of the referrers for ADHD assessment are in Table 2.2).

Table 2.2: Profession of referrers to the NDC for an ADHD assessment.

Profession of referrer:	Frequency	Percent
Clinical Psychologist	1	14.3
Consultant Psychiatrist	2	28.6
Family Therapist	2	28.6
Social Worker	2	28.6
Total	7	100.0

#### 2.6.4 ASD/ADHD

Seven children were referred for an assessment of ASD and ADHD by the referring clinicians. One of these did not continue with the assessment process. All of these children were assessed using the Conners' Ratings Scale but only three of these received ratings back from the parents. Four of these children were observed by an NDC team member while at school. Five of the children completed cognitive assessments; 3 using both the WISC-IV and the TEA-CH; one WISC-IV only and one the TEA-CH only. All six children's parents were asked about the child's developmental history.

Of the 6 children that completed the assessment process, none received a diagnosis of ASD. Only one child received a diagnosis of ADHD and was offered a parenting intervention and placed on Concerta medication under the care of a Consultant Psychiatrist in CAMHS. This child was referred to the NDC by a Consultant Psychiatrist. The profession of the referrers to the NDC for an assessment of ASD/ADHD are shown in Table 2.3. The remaining 5 children received the following diagnosis respectively: Anxiety/Low Self-esteem; Anxiety/OCD; Emotional/behavioural problems; Generalised Anxiety Disorder; Low mood.

Table 2.3: Profession of referrers to the NDC for an ASD/ ADHD assessment

Profession of referrer:	Frequency	Percent
Clinical Nurse Specialist	2	28.6
Clinical Psychologist	1	14.3
Consultant Psychiatrist	1	14.3
Social Worker	3	42.9
Total	7	100.0

#### 2.6.5 ASD

Forty-eight children were referred to the NDC for an assessment of ASD. Of these, 2 dropped out of the assessment process and did not continue and a further 10 had not completed the assessment at the time of audit. Three of the children referred were assessed using the Conners' Ratings Scale completed by their school. Twelve (25%) of the children's behaviour was observed while at school by a member of the NDC team. Eight children (18.6%) underwent a cognitive assessment; seven (16.3%) by the WISC-IV with 1 child assessed by WISC-IV and TEA-CH. At the time of the audit, one child is still awaiting an assessment of their developmental history. Table 2.4 shows the profession of those referring to the NCD for ASD assessment.

Table 2.4: Profession of referrers to the NDC for ASD assessment

Profession of referrer:	Frequency	Percent
Clinical Nurse Specialist	4	8.3
Clinical Psychologist	12	25.0
Consultant Paediatrician	1	2.1
Consultant Psychiatrist	14	29.2
Family Therapist	5	10.4
Psychotherapist	5	10.4
Senior Mental Health Practitioner	4	8.3
Social Worker	3	6.3
Total	48	100.0

Figure 2.3 shows the outcomes for the 36 children who were referred for ASD to the clinic and completed the assessment process. Sixteen children (44.4%) received a diagnosis of ASD (4 (11.1%) for ASD and 12 (33.3%) for Asperger’s Syndrome). Of those who did not receive a diagnosis of ASD, the largest percentage had an attachment disorder (19.4%) disorder. Four children (11.1%) had an existing diagnosis of ADHD and there was no change to their diagnosis from their assessment at the clinic.

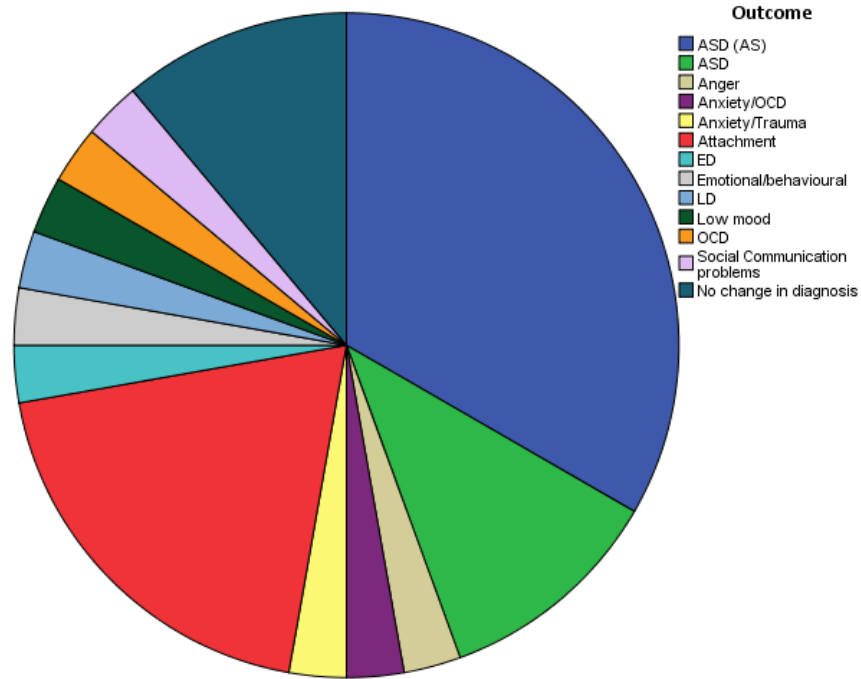


Figure 2.3: Outcomes of patients referred to the NDC for an assessment of ASD. ASD=Autism Spectrum Disorder; ASD (AS) =Asperger’s Syndrome; OCD=Obsessive Compulsive Disorder; ED=Eating Disorder; LD=Learning Disability

#### 2.6.6 TIME TO COMPLETE ASSESSMENT

Sixteen (25%) children attending the NDC were able to be given a diagnosis at their initial appointment. The median number of appointments (including their initial appointment) in the clinic was 3 with only one child having 6 appointments. The mean time from the initial appointment to being given an outcome from the clinic was 3.8 months with the range extending as far as 12 months. The inter-quartile range was 0 – 6 months. The cumulative percentage of time taken to complete the assessment process is displayed in Figure 2.4.

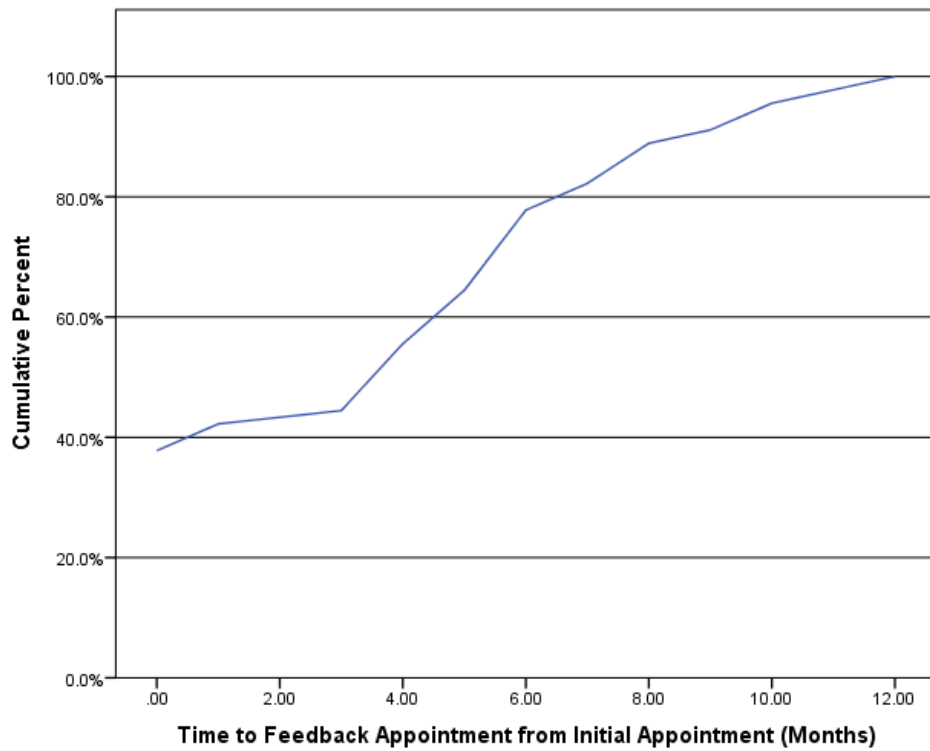


Figure 2.4: Cumulative percentage of referrals against time from initial appointment to feedback appointment in months

### 2.6.7 INTERVENTIONS

For the 46 children who had completed the assessment process in the clinic, their destination following assessment is presented in Figure 2.5. The two main destinations for children following a diagnosis in the clinic are either a psychiatric (30.4%) or psychological (19.6%) intervention within CAMHS. A number of children (10.9%) did not receive any further input from health professionals.

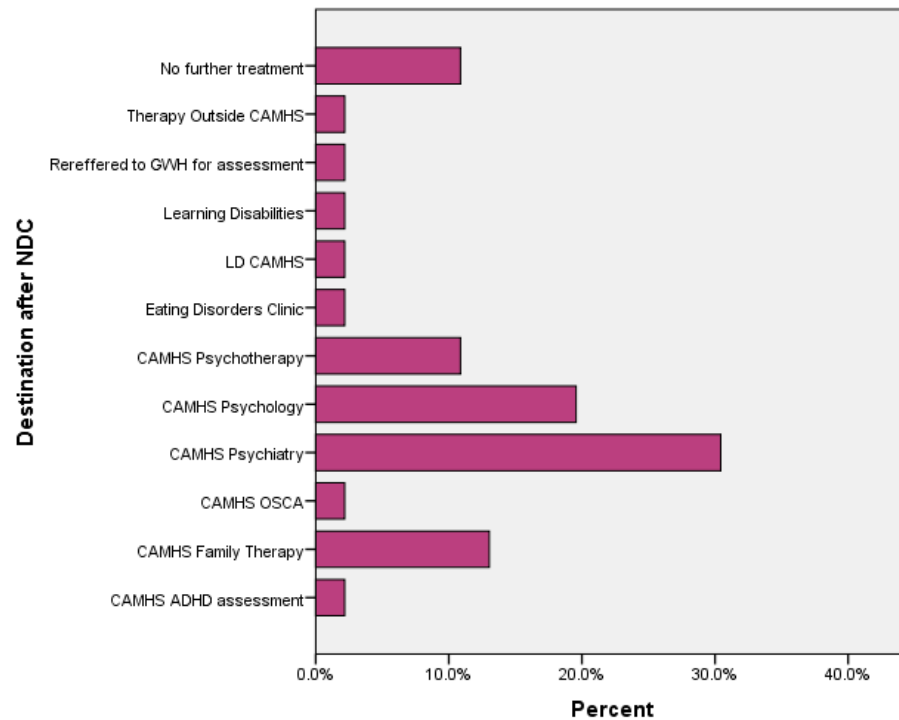


Figure 2.5: Destination of referrals following completion of assessment in NDC

### 2.6.8 SATISFACTION SURVEY

The complete data set for responses to the survey are presented in Appendix F. A total of 14 surveys were returned (22.6% of the total). The majority of those responding (57%) had children who were between 11 and 15 years old. The male to female ratio of 2:1 in overall referrals to the clinic over the audit period is roughly matched in the respondents to the satisfaction survey. Eight respondents claimed to have waited over 6 months for an appointment in the clinic with one respondent stating they had to wait over 18 months. Only 5 respondents agreed or strongly agreed that the waiting time was reasonable.

#### 2.6.8.1 The assessment process

All the respondents thought that staff explained fully why their child was being assessed in the clinic, except one who stated they did not know/remember. Only three of the respondents thought that the assessment process did not address their child's difficulties. The majority of respondents felt encouraged to participate in the assessment process and that their views were actively sought by staff, however two felt this was not the case. Of these two, one parent thought that the outcome of the assessment had already been decided



by staff before their child was even seen. The other did not feel that staff listened to their views and acted as though they were the experts on their children.

#### *2.6.8.2 The outcome of the assessment*

All of the respondents who answered had received a diagnosis of their child's condition that was fed back to them from a member of the team. Eight of the 14 respondents received a diagnosis of ASD for their child while 2 received a diagnosis of ADHD. The remainder received either no formal diagnosis or did not respond. Overwhelmingly respondents agreed with the diagnosis. However two did not agree with one of these being one of the respondents who had not felt listened to by staff. All of those who responded felt they had been given the opportunity to discuss their feelings about the diagnosis but two felt that the diagnosis had not been explained properly to them. One of these respondents stated they were unsure what the diagnosis meant in terms of getting help for their child. The other also felt that staff had not listened to them and did not agree with the diagnosis and did not think the report from the clinic was useful.

Three of the respondents did not feel they were given information about useful resources but one of these stated this was because their child had not been given a diagnosis. While six respondents stated they had been given information about useful voluntary and social support networks, seven respondents stated they had accessed them. Of those that responded, most had accessed the National Autistic Society.

#### *2.6.8.3 Satisfaction with the assessment process*

Eight of the respondents thought that the service they received from the clinic was either "Good", "Very Good" or "Excellent". Only two rated the service as not satisfactory and both of these were parents who felt they had not been listened to by staff and that the assessment process had not addressed their child's difficulties.

While five respondents thought that an information leaflet would have been helpful before attending the clinic, five felt it would not have helped but none stated why. Of those that felt it would have been helpful, five wanted to know what was going to happen at the clinic while three respondents wanted to know more about why they were attending the clinic, how long the assessment process would take and who they would be seeing at the clinic. Two respondents wanted information on what the different outcomes of the assessment might be, how it would be fed back to parents, and what will happen after the assessment process.

#### 2.6.8.4 *Comments*

Respondents were given the opportunity to provide written responses at the end of the survey on aspects of the assessment process that they found helpful, unhelpful and what could be improved.

Two respondents stated that the staff at the clinic had been friendly and approachable with their views about the process being taken seriously. Two also stated that the information provided to them was clear, jargon free and explained to them by the members of the clinic team and one stated they felt unhurried by the team and given enough time to process the information. Three respondents also mentioned the professional and positive manner of the staff. One respondent felt that appointments were made promptly and that their child's needs had been addressed.

While it has already been stated that two respondents did not feel their views were listened to, the other responses regarding what was not helpful revolved around waiting times for, and cancellation of, appointments. One respondent stated that appointments had been cancelled at short notice and that there had been a delay in providing feedback from the assessment process. This made them feel let down and demoralised. Another also stated that the long delay for an initial appointment was unhelpful, as was having to attend the clinic a number of times before a diagnosis could be given.

When asked about what could be improved, one suggested a written list of the conditions that the clinic assesses for. Another suggested speeding up the assessment process from the initial appointment to the final feedback session. Finally, one respondent felt that information about the statementing process in schools would have been helpful as well as what benefits they are entitled to as a result of their child's diagnosis.

## **2.7 DISCUSSION & IMPLICATIONS**

### *2.7.1 AUDIT*

The guidelines set out by NICE recommend that children referred for an assessment of ASD should be seen within 3 months (Criteria 1, see Appendix A). All patients referred to the clinic are given an initial appointment within three months of the date of the referral and the majority of patients (86%) were seen within that timeframe. Given that the reasons for the 8 patients who were not seen within three months were largely beyond the control of the clinic it is difficult to see what improvements could be made to make the clinic 100% compliant with this criterion.

The NICE Criterion 2 for what should be included in an ASD assessment is routinely covered during the initial appointment or from further assessment as required. All parents/carers are provided with a written report at the end of the assessment that is shared with their GP (Criteria 4 & 5) and offered a follow-up appointment within six weeks of the end of the assessment in the NDC. Only Criterion 3, a physical examination, is not conducted by the NDC. If the child or young person was referred through the paediatrics complex case pathway they would have been given a physical examination at that point. Alternatively if this was not the case and was required then the NDC would refer to paediatrics and ask them to contribute to the assessment.

In the NICE Guidelines for ADHD, only Criteria 1 and 2 relate to assessment (see Appendix B). When a child or young person is referred to the clinic for suspected ADHD, the same structure for assessment as above is followed but the emphasis is more on the diagnostic criteria in DSM-IV/5 and ICD-10 for ADHD. All of the children referred to the clinic during the audit period suspected of having ADHD were assessed in the school environment either via their school teachers using the Conners' Ratings Scale, by written reports from the school, or by direct observation in school by a member of the NDC team. Information from the school, combined with parents/carers reports about behaviour in the home environment, allows assessment across multiple settings. This ensures the NDC was compliant with Criteria 1 and 2 of the ADHD NICE Guidelines.

Criteria 3 – 7 of the NICE Guidelines relate to treatment options once a diagnosis of ADHD has been made. Only 3 patients were diagnosed with ADHD during the audit period. All of these patients were subsequently offered medication for the condition and

two were offered a parenting-training programme. Criteria 8-10 refer to young people about to transition to adult services at the time of assessment; there were no patients in that position during the audit period. All patients and their parents/carers are provided a written report about their diagnosis but they are not routinely provided with standardised written information such as the “Understanding NICE guidance” booklet as per Criteria 11 and 12.

In general, the NDC meets the majority of the Criteria set out in the NICE Guidelines but many of these are difficult to quantify due to the nature of the electronic records system adopted by the Trust within which the NDC sits. For those that could be quantified, having to access individual records and reports to obtain the data on each patient’s assessment was time and labour intensive. NICE have developed audit support tools for both of these conditions (see Appendix C and Appendix D) that allow recording of activity against the criteria. The tool is a relatively straightforward tick-box record that could be maintained in either paper or electronic form. These would allow a more rapid audit of the service in future and help provide documentation to show the NDC meets NICE guidelines.

### *2.7.2 SATISFACTION SURVEY*

In general, the majority of parents/carers who responded to the survey felt the service they received in the clinic was a good one. Respondents commented that staff were friendly, professional, listened to their concerns and explained the outcome of the assessment, giving them enough time to process and understand the diagnosis.

The main concern of those parents/carers who responded to the satisfaction survey was the length of time the assessment process took. It is interesting to note that 9 respondents stated that they had to wait over six months for an appointment at the NDC. From the audit data, only one patient had to wait over six months to be seen. The mis-match in findings may be due to a number of reasons. A simple explanation is that parents/carers perceive the time taken to be seen in the clinic as much longer than it actually is. However a more reasonable explanation is that for the parents/carers, the process of finding out what is causing their child’s difficulties starts much earlier than the time at which the referral occurs. Hence the time it takes them to find answers is much longer than is perhaps being recognised by health professionals. This was exacerbated for some respondents by the number of appointments they had to attend and the time taken to get a feedback

appointment. It is difficult to see how, when a patient requires a comprehensive assessment, the number of appointments can be reduced. Assessments such as the ADOS and WISC-IV are time intensive and cannot be combined into a single appointment. Furthermore, constraints on staff time also make it difficult to complete the assessment within a shorter timeframe. The concerns of respondents here about the length of the assessment process is a similar finding to Hackett et al. (2009) who recommended providing an information leaflet for parents/carers that should be sent with the initial appointment letter. This leaflet might explain the assessment process and timescales involved as a way of managing parents'/carers' expectations.

In the current survey, parents/carers were asked directly whether an information leaflet would have been useful. Only half of those that responded felt it would have helped, but of those that did the majority wanted information about what was going to happen at the clinic when they attended. Other concerns were how long the assessment process would take and more information about why they were attending a specialist clinic. Two respondents wanted information on the potential outcomes of the assessment and what happens after the process is completed.

The satisfaction survey reported in Hackett et al. (2009) was much more comprehensive than the one reported here and asked questions about the pre-attendance period as well as after the assessment process. Given the concerns raised by respondents about the length of time the assessment process takes, a more detailed exploration of how these could be mitigated for parents/carers given the constraints of the service is warranted. The survey reported here was made intentionally brief over concerns that parents/carers would not respond if it was too long. Given that only 22% did respond the choice seems vindicated. In future, if a more detailed survey is sent to parents/carers one option might be to follow up the initial mail survey with a telephone call. This was the strategy adopted by Hackett et al. and resulted in an 82% response rate.

## **2.8 RECOMMENDATIONS**

Based on the above discussion, the following recommendations are suggested:

- Implement the NICE audit tools for ASD and ADHD (Appendix C and Appendix D) as part of the record keeping within the clinic. This would simplify the analysis process and produce an audit trail to demonstrate the NDC is compliant with NICE guidelines.
- Develop an information leaflet to be sent to parent/carers with the initial appointment letter. The leaflet should describe the assessment process and what will happen when attending the clinic as well as managing expectations about the potential length of the assessment process.
- Development of a satisfaction survey that could routinely be provided to parents/carers to ensure that their views help to shape service delivery as per national policy (e.g. NSF and Every Child Matters).
- For clinicians and service managers to be aware that parents/carers are likely to perceive the assessment process as longer than services see them (due to having likely seen a number of health care professionals prior to referral to the NDC). While the NDC is meeting NICE guidelines, parents/carers perceive the time to be seen by a specialist as much longer than the current 3 month maximum.

## **2.9 FEEDBACK AND DISSEMINATION**

The commissioner of the project was the Trust's lead for ASD. A written copy of the report was sent and read by her and another clinical psychologist working in CAMHS. Both felt that the report was very positive about the service and would be helpful within the Trust to guide service thinking and planning. At the suggestion of the clinical lead, it was agreed that I would present the findings of the report to a review meeting of the NDC in June 2014. Attending the meeting will be the Consultant Psychiatrists and Psychologists from the NDC as well as service managers, clinical governance managers and representatives from divisional management and audit. The commissioner felt this would underline the usefulness of the work and keep the issues it raises on the wider agenda within the Trust.

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# **A targeted CBT intervention for health anxiety in Multiple Sclerosis: a replication and brief case series**

**(Main Project, May 2014)**

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**Proposed Journal Submission:** *Behavior Research and Therapy*, this journal has previously published case series of innovations in cognitive behavioural therapy.

### 3.1 ABSTRACT

*Multiple Sclerosis (MS) is an incurable disease which is commonly associated with psychological complications. Previous research by Hayter and colleagues found that in patients with MS, health anxiety (HA) can account for part the variance in quality of life (QoL) independent of any physical and cognitive impairment caused by the disease and that MS patients with health anxiety perceived their (intact) physical and cognitive performance as impaired relative to MS patients without health anxiety, attributing the impairment to MS. The findings suggest that such misperceptions might be useful targets in the treatment of health anxiety in MS using adapted cognitive behavioural therapy (CBT). The first of two studies presented here sought to replicate the findings from Hayter et al. before a second presents the findings from a brief case series of treatment for HA using CBT. In Study 1, twenty participants with Relapsing and Remitting MS were screened for HA and assigned to either a high or low HA group. Participants then completed assessment of cognitive and physical functioning before rating their performance on these tasks. Measures of QoL, mood and physical disability were then completed. Four participants in the high HA group subsequently received six sessions of CBT using a consecutive AB case series in Study 2. Study 1 replicated the main findings from the earlier study. In Study 2, three of the four patients who received treatment showed substantial improvements in HA and mood and all showed improvement in QoL. Given the high rates of HA in MS patients and its impact on QoL, this case series suggests a brief CBT intervention could significantly improve patients' wellbeing. The findings pave the way for larger, controlled studies into the effectiveness of CBT for health anxiety in MS.*

**Keywords:** Cognitive behavioural therapy; psychological therapy; Multiple Sclerosis; health anxiety; case series; quality of life.

## 3.2 INTRODUCTION

Relapsing and remitting multiple sclerosis (RRMS) is the most common form of MS affecting around 80% of MS patients. Following an initial attack that can impact both physical (e.g., fatigue, numbness, pain, blurred vision) and cognitive functioning (e.g., slowed processing speed, attentional problems) through demyelination of brain nerve fibres, patients can recover functioning for an unpredictable period before further attacks cause progressive deterioration. Given the unpredictable and fluctuating nature of RRMS it is unsurprising that many patients worry about when further attacks may occur, with rates of anxiety, in particular health anxiety (HA), high in this patient group (Chwastiak et al., 2002; Kehler & Hadjistavropoulos, 2009; Korostil & Feinstein, 2007). Although earlier work has focussed on general anxiety and depression, more recent work suggests HA may be particularly relevant to the problems experienced by MS patients. Previous research found that RRMS patients with health anxiety had lower quality of life (QoL) compared to patients without health anxiety independent of physical disability (Hayter, Salkovskis, Morris, & Silber, in process). They also found that the health anxious RRMS patients misappraised their performance on physical and cognitive tasks and suggested that these might be targets for treatment using cognitive behavioural therapy (CBT) to reduce health anxiety, and potentially improve QoL. The studies presented here first sought to replicate the earlier study but then went on to treat the health anxious RRMS patients using a brief CBT intervention; presenting the findings from a consecutive AB treatment case series.

Identifying ways of helping people with poor QoL and distress around MS is important because MS itself is, a) incurable and, b) common. Approximately 110 people per 100,000 in the UK suffer from MS (Richards, Simpson, Beard, & Tappenden, 2002). Around 85% of people with MS experience physical impairments that make the activities of daily living (such as cooking, cleaning, work and socialising) difficult (Bakshi, 2003). Cognitive difficulties, such as problems with short term and working memory, executive functioning, visuospatial abilities and reduced processing speed, affect around 65% of patients (Amato, Ponziani, Siracusa, & Sorbi, 2001; Bobholz & Rao, 2003; Rao, Leo, Bernardin, & Unverzagt, 1991a) and can disrupt employment and social relationships (Rao et al., 1991b).

While it is unsurprising that high rates of anxiety and depression exist in patients with RRMS, studies have found that emotional factors are more predictive of patients'

subjectively rated QoL than physical or cognitive impairment (Benedict et al., 2005; Dennison, Moss-Morris, & Chalder, 2009; Janssens et al., 2003). For example, Benedict et al. (2005) found that cognitive dysfunction accounted for none of the variance in a measure of health related QoL but instead was predicted by both depression and fatigue. Janssens et al. (2003) found in their study that the extent to which physical disability affects QoL in MS patients was moderated by anxiety and depression.

Cognitive accounts of anxiety and depression state that a person's symptoms are maintained through processes linked to unduly negative appraisals. Of particular relevance here is the cognitive model of health anxiety (Salkovskis & Warwick, 1986; Warwick & Salkovskis, 1990). When a person experiences ambiguous physical or cognitive symptoms (often due to "normal" bodily variations), their prior beliefs about illness lead to misinterpretation of these symptoms as signs of severe threat (i.e., a severe illness). In the model, the person remains focussed on threat relevant information through attentional, physiological and behavioural processes that lead to further misinterpretation and potential increases in anxiety. The model has recently begun to be applied to patients in physical health settings (e.g., The CHAMP trial, (Tyrer et al., 2011b)). As such, it is particularly relevant to RRMS as high levels of anxiety can lead to transient physiological symptoms that mirror that of the illness (e.g., pins and needles, dizziness, pains etc.). Hence RRMS patients vulnerable to health anxiety may experience these normal bodily variations but misappraise them as signs of MS relapse, leading to increased anxiety and thus further anxiety symptoms. This would suggest that the rates of health anxiety in RRMS are likely to be high and indeed Kehler and Hadjistavropoulos (2009) found the rate to be approximately 25% while Hayter et al. (*ibid*) found 29%.

Misappraisal in terms of exaggerated threat has been found in studies with MS patients who focus excessively on bodily sensations (Vercoulen et al., 1996) and attribute them to MS (Skerrett & Moss-Morris, 2006) with associated increases in fatigue and poor social adjustment. Catastrophising about bodily sensations has also been found to predict reduced psychological functioning even after MS related factors have been controlled for (Osborne, Jensen, Ehde, Hanley, & Kraft, 2007). MS patients who are anxious or depressed are also more likely than those not anxious or depressed to misperceive themselves as more cognitively impaired than they actually are based on objective neuropsychological test performance (Benedict et al., 2004; Julian, Merluzzi, & Mohr, 2007; Lovera et al., 2006; Maor, Olmer, & Mozes, 2001; Middleton, Denney, Lynch, & Parmenter, 2006).

In a recent study, Hayter et al. (in process) found that health anxious patients also had lower QoL compared to non health anxious RRMS patients, even after their level of physical disability was controlled for. The health anxious patients were also more likely than non health anxious patients and healthy controls to attribute their ambiguous bodily sensations to their MS. Hayter et al. asked their participants to complete short “objective” assessments of their cognitive and physical functioning as well as rate their perceived performance on these tasks. Even though there was no difference in performance, the health anxious MS patients subjectively rated their performance as worse than the non health anxious and control groups and were more likely to attribute their poor performance to their MS. These findings suggest health anxiety in patients with RRMS is leading them to perceive themselves as more physically and cognitively impaired than they really are: with a concomitant reduction in QoL.

The implication of the above findings is that potentially QoL in health anxious RRMS patients could be improved through treatment focussed on HA. Randomised controlled trials (RCTs) have shown CBT to be effective in treating health anxiety in psychiatric populations (Clark et al., 1998; Greeven et al., 2007; Seivewright et al., 2008). The approach is to help patients actively explore (through discussion and behavioural experiments) the validity of an alternative understanding of their problem as one of misinterpretation of bodily sensations that lead to safety seeking behaviours, hypervigilance, physiological arousal etc., that in turn maintain their symptoms – rather than one of having a serious illness. More recently the approach has been applied in a physical health setting in the CHAMP trial (Tyrer et al., 2013). This was a multi-centre RCT where patients with health anxiety across a range of co-morbid physical health conditions received on average six sessions of a manualised CBT intervention for health anxiety delivered by non CBT specialist health care professionals in secondary care settings. Twice as many patients in the CBT group achieved normal levels of health anxiety compared to those in the control group with no significant increase in total treatment cost. This led the authors to suggest that a brief CBT intervention was cost effective in treating health anxiety in patients with physical health conditions.

Relatively few studies have explored the effectiveness of CBT in treating co-morbid psychological problems in MS patients. A recent Cochrane review of psychological interventions in MS (Thomas, Thomas, Hillier, Galvin, & Baker, 2006) found that generic CBT lead to significant improvements in depression symptoms in two studies that

compared it to treatment as usual (Larcombe & Wilson, 1984; Mohr et al., 2000) but found no difference when compared to antidepressant medication (Mohr, Boudewyn, Goodkin, Bostrom, & Epstein, 2001). Askey-Jones, David, Silber, Shaw, and Chalder (2013) state that to date, no studies have considered the effectiveness of CBT in treating anxiety disorders in MS.

The misperception by MS patients of physical and cognitive functioning found in the Hayter et al. (*ibid*) study suggest this could be a useful target in treatment. For example, Tang and Harvey (2006) targeted misappraisals in a subgroup of insomnia patients whereby they perceived themselves as having sleep problems when in fact they displayed normal patterns of sleep. The authors developed a behavioural experiment where patients compared their self-rated sleep pattern against objective feedback from actigraphy, leading to improvements in patients' subsequent sleep ratings. Similarly, using objective data from their performance on physical and cognitive tasks might help MS patients with health anxiety reappraise their level of functioning and reduce levels of health anxiety. Hence a brief adapted CBT intervention for health anxiety (CBT-HA) may be beneficial to patients with RRMS suffering from health anxiety.

In the second study presented here, the findings of an exploratory investigation into the effectiveness of a brief six session CBT-HA intervention in RRMS patients are presented through a series of case studies. Six sessions was chosen as this was the average number of sessions needed in the CHAMP trial (Tyrer et al., 2013) to demonstrate significant improvements in health anxiety and is generally classed as a brief psychological intervention. However, before doing so, the Hayter et al. (in process) study was replicated to see if the findings are reproduced across different samples (a large proportion of Hayter et al.'s participants had university degrees (>60%) which is not representative of the UK population as a whole). In Study 1, ratings of QoL, self-rated performance on a physical and cognitive task and extent to which performance on these tasks is attributed to MS, were compared across participants with low and high levels of health anxiety. If the Hayter et al. findings generalise, then RRMS patients with health anxiety would rate their QoL and task performance as lower than RRMS patients without health anxiety, and attribute to a greater extent their performance on these tasks to MS. Replicating Hayter et al.'s findings also provides a clinical justification for treating participants using a cognitive model of health anxiety with a specific focus on misappraisals of cognitive and physical functioning and allowed the identification of targets for treatment (via behavioural experiments) during

therapy. As Hayter et al. demonstrated that health anxiety affects QoL independent of physical disability, it was expected that in Study 2 health anxious participants who went on to receive a brief CBT-HA intervention would not only show reductions in health anxiety but also improvements in QoL.

### **3.3 METHOD**

#### *3.3.1 DESIGN*

Study 1 sought to replicate the Hayter et al. study using an independent groups design with level of health anxiety (high health anxiety (HiHA) or low health anxiety (LoHA)) as a between-subject factor. Participants from Study 1 with a score of 18 or above on the Short Health Anxiety Inventory (SHAI) were invited to take part in Study 2 where they were offered six sessions of CBT-HA. The original plan was to use the same cut-off scores from the SHAI that were used by Hayter et al. to assign participants to either the HiHA group (>18) or LowHA group (<10). However to difficulty locating participants that met the inclusion criteria meant this plan had to be abandoned, as it would have meant an even smaller sample size, and instead a median-split on the SHAI was used to assign participants to groups.

Study 2 evaluated the effectiveness of a brief form of CBT-HA using a consecutive single case series A–B design (Barlow & Hersen, 1984) with follow-up. For this design, all patients were assigned to no-treatment baselines of 2 weeks. Individual baselines acted as control periods. The original plan was to control for non-specific therapy effects by counter-balancing CBT-HA with 6 sessions of Relaxation Training but time limitations meant this was not possible. CBT-HA was delivered by the study's lead author (NC) who has received doctoral level training in clinical psychology and accredited Level 2 training in CBT (British Association for Behavioural and Cognitive Psychotherapies; BABCP). One of the study authors (PS) was responsible for developing the cognitive model of health anxiety and is a recognised world authority in the field. During the delivery of treatment, NC was supervised by PS through fortnightly sessions using audio recordings from treatment to ensure adherence to the cognitive model of treatment. Follow up of patients was planned for three months after completion of treatment.

### 3.3.2 PARTICIPANTS

Participants were recruited from the caseloads of the Community Neuro & Stroke Service and MS Neurology nurse specialists in Bath, UK. All participants recruited from these caseloads had a definitive diagnosis of RRMS. Participants were contacted initially via telephone and asked if they would like to take part. The aims of the study were explained to potential participants and what they would be asked to do in the study (i.e., complete the study measures, cognitive test and handgrip measure). It was explained that their participation was completely voluntary and independent of any care they were currently being provided. If they initially agreed, an appointment was made for the researcher (NC) to visit the participants at their home where the study aims were explained to them again and they were given the Participant Information Sheet for Study 1 (see Appendix L) and asked to provide written consent to take part in the study (see Appendix M). Only three of the patients identified from the caseloads declined to take part in the study saying they were too busy with work commitments. Problems with recruitment meant that five participants were also recruited from a local MS National Therapy Centre. In total, 20 participants took part in Study 1 (17 female, 3 male). This is lower than the original plan of 24 participants (12 in each group) due to already stated problems identifying relevant participants from the various clinicians' caseloads. However, the number recruited to the study is still above that required from the power analysis ( $n=16$ ) and was done to allow for the testing of the study hypotheses via parametric data analysis. All participants were over the age of 18 years (range 21 – 54 years), were white Caucasian, and gave written informed consent to take part in the study. Ethical approval for the study was obtained from the Oxford C NHS Research Ethics Committee (ref: 13/SC/0547) and the University of Bath's Department of Psychology Ethics Committee.

Six participants who scored above 18 on the Short Health Anxiety Inventory (SHAI) were invited to take part in Study 2. It was explained that their scores on the SHAI were high and asked if they were feeling anxious about their health. It was explained that a second phase of the research was assessing a psychological therapy for health anxiety and they were asked if they would like to participate in this research. Participants were asked to look through with the researcher the Participant Information Sheet for Study 2 (see Appendix P) where a brief overview of CBT was given, stating that they would be offered up to 6 weekly sessions of CBT. If they agreed to take part they were again asked to give written informed consent to take part in the Study 2. Two of the six participants who were eligible



to take part in Study 2 declined without giving reasons, leaving four women with age ranges from 22 to 43 years to take part. The details of cases and their treatment are given below in the Results section.

### 3.3.3 MEASURES

*Health anxiety (see Appendix Q):* Health anxiety in participants was assessed with a modified version of the 14 item Short Health Anxiety Inventory (SHAI). The 14 items assess basic health-anxiety symptoms. Scores above 18 are seen as indicating clinical levels of health anxiety (Seivewright et al., 2004) and would meet DSM diagnostic criteria for hypochondriasis (APA, 2013; Salkovskis, Rimes, Warwick, & Clark, 2002b) while scores above 15 suggest the person is suffering symptoms of health anxiety. The SHAI is a reliable and valid measure in the general population (Salkovskis, Rimes, Warwick, & Clark, 2002a) and has been modified for use with patients with MS (Kehler & Hadjistavropoulos, 2009). Continuous monitoring of health anxiety in participants undergoing treatment in Study 2 was assessed using a modified version of the 6 item Health Anxiety Inventory, the Very Short Health Anxiety Inventory (VSHAI). The VSHAI has not been formally validated but in previous studies was found to correlate highly ( $r=0.8$ ) with the SHAI (Salkovskis, personal communication).

*Mood (see Appendix R):* Although not a primary measure in the study, mood was assessed using the Patient Health Questionnaire (PHQ9) (Kroenke, Spitzer, & Williams, 2001), a nine item self-report measure assessing symptoms of depression. The measure has been shown to be a reliable and valid measure of depression severity and is used routinely in NHS primary care settings.

*Disability (see Appendix S):* The level of disability in participants due to MS was assessed using the Guys Neurological Disability Scale (GNDS; Sharrack & Hughes, 1999). It is a MS related disability measure which correlates highly with objective measures of MS disability and has excellent psychometric properties (Sharrack & Hughes, 1999)

*Quality of Life (see Appendix T):* Quality of life was measured using the Quality of Life Index (QLI; Ferrans & Powers, 2007). This measures quality of life in terms of how satisfied the participant is with different areas of their life, and also how important the participant rates each of these areas. The QLI has been used in studies of various physical

health conditions (including a version tailored to MS, which was used here) demonstrating good levels of reliability and validity (Stuifbergen, 1995)

*Cognition:* The two measures of cognitive functioning used in the Hayter et al. study were also used here. These were the Brixton Spatial Anticipation Test (BSAT; Burgess & Shallice, 1997) and the Symbol Digit Modality Test (SDMT; Smith, 1982). Both are widely used, valid and reliable tests with the BSAT measuring executive functioning and the SDMT measuring processing speed and episodic memory. These tests are commonly used in the MS research literature.

*Physical functioning:* A hand grip dynamometer was used to measure physical grip strength following a similar protocol to the Hayter et al. study and developed by Rode, Salkovskis, and Jack (2001) in a study of chronic pain.

*Misperception and misattribution (see Appendix N):* Misperception of performance on the cognitive and physical tasks was assessed using a similar measure to the one developed in the Hayter et al. study. Following the physical and cognitive tasks, participants were asked to evaluate how well they felt they performed compared to other people with MS on a scale from -50 (“Extremely badly in comparison to others”) to +50 (“Extremely well in comparison to others”). They then completed a measure of how much better they felt their performance on the tasks would have been if they did not have MS, from 0 (“No better”) to 100 (“Very much better”).

### 3.3.4 PROCEDURE

In Study 1, participants initially completed the assessment of physical and cognitive functioning before completing subjective ratings of their performance. Following this, participants completed the GNDS, QLI, PHQ9, and SHAI. The sessions took approximately 1 hour.

Participants scoring below 18 on the SHAI then received feedback on their scores. Those scoring above 18 were offered the opportunity to take part in Study 2. If participants declined treatment or were not eligible then their scores on the measures were fed back to them and alternative treatment options discussed.

Participants who agreed to take part Study 2 were given a second set of baseline measures (SHAI and PHQ9) to complete one week later and bring to their initial treatment session in two weeks time. Following the individual baseline period, CBT-HA was delivered over six weekly 60 min treatment sessions delivered in the participant's home. The cognitive model of health anxiety posits that anxiety arises from the interpretation of normal bodily variations as signs of severe illness (in this case an MS relapse) leading to safety seeking behaviours, hypervigilance, physiological arousal etc., that in turn maintain their symptoms. Thus a defining element of CBT-HA is helping the patient develop a belief in an alternative explanation for their symptoms (i.e., that they are due to anxiety) rather than one of having a serious illness. This is done through behavioural experiments whereby they test out the utility of their avoidance or safety seeking behaviours in order for them to ultimately drop these behaviours and so reduce their anxiety. In Study 2 a particular treatment strategy was to use the data provided by them in Study 1 to compare their perceived performance on the cognitive and physical tasks with data from their actual performance (idiosyncratic elements of treatment are presented in the case descriptions below). In doing so it was hoped they would re-appraise their performance as well as their cognitive and physical functioning. At each treatment session participants completed the PHQ9 measure of mood and the VSHAI measure of health anxiety. At the end of treatment participants completed the SHAI, QLI and PHQ9 before being offered a follow-up session in three months time.

### 3.3.5 STATISTICAL ANALYSIS

The effect sizes in the Hayter et al. study, as measured by Cohen's  $d$  (Cohen, 1992) ranged from 1.54 (for difference in QLI between health anxious and non health anxious RRMS patients) to 1.40 (for the difference between how much health anxious patients attributed their task performance to MS compared to non health anxious patients). Given such large effects, and setting an acceptable power at 0.8, a sample of 16 participants was needed to detect a significant difference between the two groups in Study 1. Where parametric assumptions were met, parametric analysis was conducted with Bonferroni corrections where appropriate to control Type I error when multiple comparisons were made. For instances where parametric test assumptions are not met, Wilcox (2012) recommends using modern robust alternative tests that are not susceptible to violations of assumptions (see also Erceg-Hurn and Mirosevich (2008)). These include the Yuen-Welch  $t$ -test ( $T_y$ ) which

uses trimmed means and Winsorized variances that are approximated to a Student's  $t$ -distribution. Monte-Carlo simulation studies have found the test controls Type I error while still maintaining power when parametric assumptions have been violated (e.g., Keselman, Othman, Wilcox, & Fradette, 2004). The robust alternative tests were conducted with the statistical software package R using Wilcox's Robust Statistic (WRS) package.

For Study 2, visual inspection of the data was used to assess the change in measures from baseline and through treatment. Reliable and significant change index (RCI) in scores was calculated using the method developed by Jacobson and Truax (1991) whereby the difference between the pre- and post-treatment scores on the measures are divided by the standard error of the difference between the two test scores (see Appendix G). To calculate this index, the pre-treatment standard deviations of the measures from the HiHA participants in Study 1 were used as representative of MS patients suffering health anxiety.

## **3.4 RESULTS**

### *3.4.1 STUDY 1*

A median-split of SHAI scores (14.50) was used to assign participants to either HiHA or LowHA groups. Table 3.1 shows mean scores for demographic, mood and QLI measures across groups. There was no difference between groups in terms of age ( $t(18) = 1.69$ ,  $p > .05$ , two-tailed); educational level ( $T_y(13.94) = 0.10$ ,  $p > .05$ , two-tailed); physical disability (GNDS) ( $t(18) = 0.24$ ,  $p > .05$ , two-tailed); or mood (PHQ9) ( $t(18) = 1.88$ ,  $p > .05$ , two-tailed). There was a significant difference between groups on QLI scores ( $t(18) = 4.23$ ,  $p < .01$ ; Bonferroni  $p < .05$ ). This effect remained significant even when level of physical disability (GNDS) was controlled using ANCOVA ( $F(1, 17) = 18.51$ ,  $p < .001$ ). The mean (SE) scores for QLI adjusted for GNDS are also presented in Table 3.1. The effect size of the difference measured by Cohen's  $d$  was 1.89, 95% CI [0.77, 2.85] suggesting a large significant effect.

Table 3.1: Means (Sd) of demographic, mood and quality of life measures across groups.

	<u>LowHA</u>		<u>HiHA</u>	
Age	42.30	(7.27)	36.80	(7.30)
Education (no. of years)	13.20	(2.39)	13.20	(2.10)
PHQ9	7.40	(5.58)	12.80	(7.08)
GNDS	14.20	(3.08)	13.70	(5.83)
QLI	21.52	(3.63)	15.25	(2.98)*
QLI – adjusted for GNDS	21.56	(1.05)	15.20	(1.05)

\* *p* value <.05, mean difference between LowHA and HiHA

Participants' scores on the assessment of cognitive and physical abilities are presented in Table 3.2. As predicted, there was little difference between groups on any of these measures.

Table 3.2: Mean (Sd) scores for the cognitive and physical tasks across groups

	<u>Cognitive tasks</u>		<u>Physical task</u>
	<u>SDMT</u>	<u>Brixton</u>	<u>Handgrip</u>
HiHA	55.20 (13.96)	13.10 (6.01)	23.93 (13.11)
LoHA	52.10 (11.49)	13.20 (3.08)	26.38 (13.89)

Table 3.3 summarises the data from participants' subjective ratings of their performance on the physical and cognitive tasks as well as the extent to which they attributed their performance to MS. The mean scores show that LowHA participants rated their performance in comparison to others with MS as higher than those in the HiHA group on the tasks, and attributed less of their performance to MS. A MANOVA with group as a between-subjects factor and ratings of performance on the physical and cognitive tasks as dependent variables, showed an overall effect of group ( $F(2, 17) = 4.86, P < .05$ ). Subsequent univariate tests showed a significant difference in ratings of cognitive performance ( $F(1, 18) = 7.55, p < .05$ ) but no significant difference in ratings of physical performance ( $F(1, 18) = 1.20, p > .05$ ). The effect size of the difference between groups on

ratings of cognitive task performance was  $d=1.23$ , 95% CI [0.23, 2.13] suggesting a large effect of group on this measure. An independent groups t-test revealed no significant difference between groups on how much better they thought they would have performed if they did not have MS ( $t(18) = 0.86$ ,  $p>.05$ ).

Table 3.3: Participants' subjective ratings (M (Sd)) of their performance on the cognitive and physical tasks and how much better their performance would have been without MS.

	<u>Perceived performance on Handgrip task (-50 to +50)</u>		<u>Perceived performance on Cognitive tasks (-50 to +50)</u>		<u>Performance improvement if no MS (0 to 100)</u>	
HiHA	4.00	(20.11)	-5.00	(12.69)	34.30	(32.05)
LoHA	14.00	(20.66)	13.00*	(16.36)	24.00	(20.11)

\*  $p$  value  $<.05$ , mean difference between LowHA and HiHA

### 3.4.2 STUDY 2

#### 3.4.2.1 Case descriptions

See the Procedure section for common elements of treatment (that included discussion of their ratings of cognitive and physical performance).

*Patient 1:* was a 22 year old woman with a four year old daughter who suffered her first MS attack in 2013. The attack had led to paralysis down her left side and required hospital admission. While she recovered almost all her physical functioning, she continued to notice numbness and tingling in her left arm and leg. At assessment she reported spending a great deal of time worrying about the future. In particular, she had images of herself back in hospital following a relapse and permanently disabled. Her concern was that if this happened, other people would have to look after her and she would be a burden to them. The thought that frightened her the most was that she would be unable to care for her daughter. She spent long periods of time rubbing her arm to ensure she could still feel sensation in it. Whenever she noticed tingling or numbness in her arms or legs she would stand up and move around. Her belief was that if she could still move them, she was not experiencing a relapse. She would repeat this behaviour frequently during the day.

At first, Patient 1 engaged well in therapy but found talking about her fears for the future distressing, ending most of the sessions in tears. Through collaborative formulation, she recognised that while her images about the future may be accurate (physically disabled), the meanings she attributed to them may not be (being a “bad mother”/ “burden” to others). She also recognised that her checking behaviour was keeping her preoccupied with thoughts about her MS and thus maintaining her anxiety. After guided discovery around the value of rubbing her arm during the second session, she spontaneously dropped this behaviour before the third session. In Figure 3.1, Patient 1’s VSHAI score can be seen to drop following her second session, suggesting a fall in her level of health anxiety. However, at the third session a behavioural experiment was developed to help her examine what would happen if she dropped her other checking behaviours. While she stated she was happy to try the experiment, she did not attend her next scheduled sessions. When she was finally seen some weeks later, it emerged she was experiencing flashbacks to her time in hospital and being paralysed down her left side. She did not attend any further sessions so it was not possible to assess whether she was experiencing a trauma reaction that was inadvertently being triggered during treatment sessions that focussed on her MS. The implications of this for treatment are discussed below (see Discussion).

*Patient 2:* was a 40 year old woman who had been diagnosed with RRMS in 2011. Her main symptoms from her first recognised MS attack had been blurring of vision, fatigue and pain in her lower back. She had a general distrust of medical professionals; previously, when her eldest son was a young child and suffering a life threatening illness, she believed it was only through her battling to secure treatment for him that saved his life. At her initial assessment, she reported spending long periods worrying about the future. These worries were about becoming physically disabled and unable to look after her children. She remained vigilant for physical signs she was relapsing and would use the internet to check the implications of her symptoms. She would also use the internet to keep abreast of the latest research in MS and ensure that she was prepared for her next relapse in terms of being able to ask the medical professionals for the most effective treatment.

Through discussion, Patient 2 recognised that she worried less about her future when she was looking after her children and too busy to use the internet. While she did not engage in any overt checking of any physical signs of relapse, she did admit to remaining vigilant for them. Her treatment sessions focussed on differentiating the process of worry from its content and recognising it was the repetitive negative thought processes that were

maintaining her distress. Mindfulness techniques were introduced in her third session to help her recognise her thoughts when they arrived in her mind, but not to engage in the process of worry with them. In Figure 3.1, a change in trend in Patient 2's VSHAI score can be seen following this third session. While she struggled with meditation, she was very engaged with the concept and stated she wanted to continue practising following the end of treatment.

*Patient 3:* was a 43 year old woman diagnosed with RRMS in 2012. She lived with the younger of her teenage sons. She was anxious about her future and experienced intrusive images of herself in a wheelchair unable to do anything for herself. Her main concern was that she would become a burden to others who would eventually resent her. While she had discussed her condition with her new partner and he had reassured her he would not abandon her, she nevertheless remained concerned that, faced with the reality of the condition, this might happen. Most mornings when she awoke she would open her eyes and scan her bedroom to ensure that her vision was still working. During a recent appointment with a neurologist he had asked her to touch each of her fingers with her thumb. She now did this a number of times a day to check that her arms were still functioning.

Guided discovery helped Patient 3 to realise that not all her physical sensations were signs of relapse. Psycho-education on the role of adrenaline and “fight or flight” response helped her to have more helpful responses to signs of anxiety, rather than worry her disease was progressing. At her second treatment session, the value of knowing when a relapse had occurred was discussed and hence she devised with the therapist a behavioural experiment around reducing her thumb tapping. She did not engage in the behaviour at all over the subsequent week and at the fourth session she reported dropping the behaviour completely. In Figure 3.1, a change in trend in VSHAI scores can be seen following her second session after discussing her perception of physical and cognitive ability with her actual scores at assessment and development of her behavioural experiment around thumb tapping.

*Patient 4:* was a 43 year old woman who had received her initial diagnosis almost 10 years earlier. She experienced intrusive images of herself in the future being unable to care for herself. Her worry was that her young daughter would in the future have to look after her and resent her for this. Rather than inflict this on her daughter, she believed she would have to send her to live with her father and “loose” her daughter. These intrusive images



and thoughts occurred often during the day but were mainly associated with times when she was alone and had time to think.

Treatment initially involved exploration her perception of physical and cognitive abilities (see Procedure) before exploring how images can be manipulated and changed to become less distressing. Treatment then focussed on recognising how the repetitive process of worry kept her mind preoccupied on MS and was not necessarily accurate. A pie chart technique was used to help her see that she could continue to be a good mother even when physically disabled. The concept of “worry time” was presented in her third treatment session to help her gain control over her worrying. She reported that “worry time” (setting aside a specified period of the day to worry) had a profound effect on her beliefs about controlling her worry and resulted in her worrying less about her MS. This is consistent with the fall in her VSHAI score in Figure 3.1 following her third treatment session.

#### *3.4.2.2 Treatment*

The outcome of treatment in Study 2 on measures of health anxiety (SHAI, VSHAI), mood (PHQ9) and quality of life (QLI) are presented in Figure 3.1. At the start of treatment all participants had SHAI scores above threshold (18) for a diagnosis of hypochondriasis. Treatment was tracked each session using the VSHAI and PHQ9. Visual inspection of the data for each patient in Figure 3.1 reveals that Patients 2, 3 and 4 showed a level change reduction in SHAI score between baseline and the end of treatment which is confirmed by their RCI scores (4.26, 4.26 and 4.74 respectively) that were all statistically significant ( $p < .05$ ) (see Appendix G for details of formula for calculating RCI) suggesting a reliable and clinically significant reduction in SHAI scores. For Patient 2, this brought her to below the threshold for a diagnosis of hypochondriasis (18) while for Patients 3 and 4 their score fell to below 10. The RCIs of between 4.26 and 4.74, suggest large effects of treatment and but also that Patients 3 and 4 no longer suffered from health anxiety. Inspection of the VSHAI scores in Figure 3.1 suggest that the change in trend for these patients happened after the second (Patient 3) or third (Patients 2 and 4) treatment session. Patient 1’s SHAI score had increased by the end of treatment but the change was not statistically significant. The change in trend downwards of her VSHAI score also happened after the second session for Patient 1; however this was reversed by the time she attended her fourth treatment session.

There was also a change in trend and level for PHQ9 scores across all patients. Patients 1, 3 and 4 showed a reduction in PHQ9 scores by the end of therapy while Patient 2’s PHQ9 score was already low at baseline. For Patients 1, 3 and 4 the change in trend occurred following the first treatment session while for Patient 2 it was after her second session. Subjective quality of life ratings for the patients are presented in Table 3.4 with all of the patients showing improvements in QLI between baseline and end of treatment.

Table 3.4: Quality of Life Index (QLI) scores for patients at baseline and end of treatment.

	<i>Baseline</i>	<i>Post treatment</i>
<b>Patient 1</b>	11.16	12.47
<b>Patient 2</b>	15.59	17.00
<b>Patient 3</b>	14.41	23.24
<b>Patient 4</b>	18.99	22.30

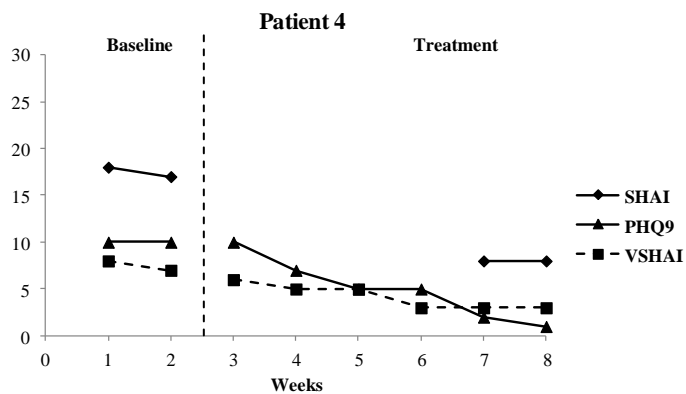
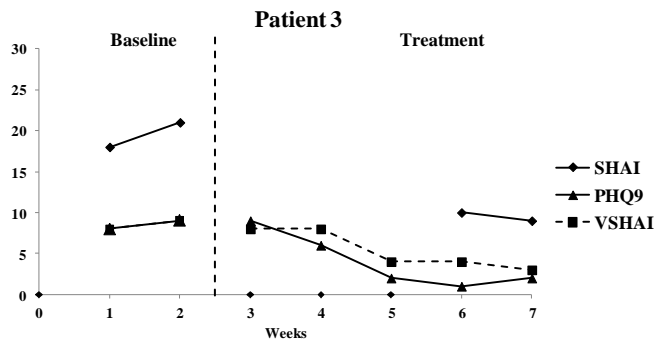
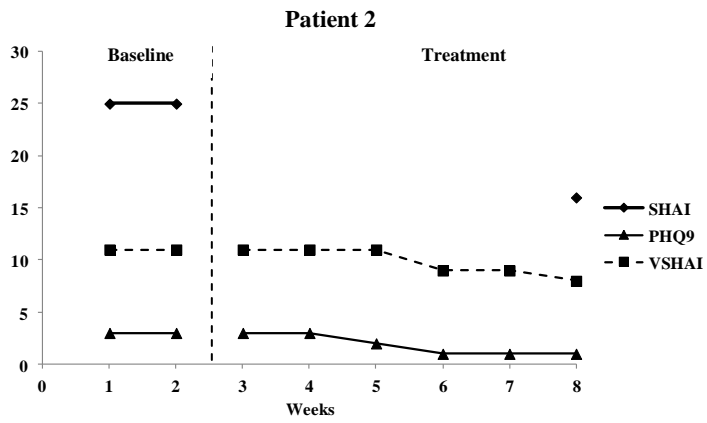
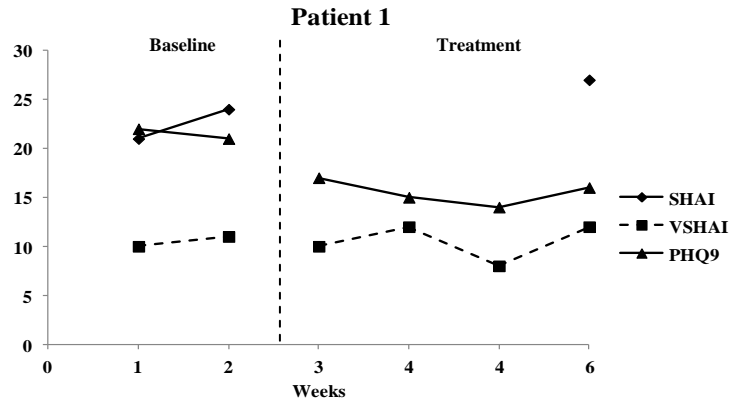


Figure 3.1: Ratings of health anxiety (SHAI, VSHAI), mood (PHQ9) and quality of life (QLI) during baseline and treatment for each patient.

## 3.5 DISCUSSION

### 3.5.1 SUMMARY OF FINDINGS AND LIMITATIONS

Study 1 was intended as a preliminary evaluation of the impact of HA on RRMS. It found that MS patients with HA rated their QoL lower than those without HA, a difference that remained significant even when physical disability was accounted for, and replicated the findings from a previous study by Hayter et al. (*in process*). While a limitation of Study 1 is its small sample size (which may account for some differences between groups being non-significant), the similar pattern of results to those found by Hayter et al. suggest these findings are likely to generalise across MS populations. Study 2 reports preliminary findings on the impact of CBT-HA for health anxiety in MS. It found that a brief course of CBT-HA led to improvements not only in health anxiety but also quality of life and mood. To our knowledge, this is the first study examining the treatment of an anxiety disorder in MS and represents a significant first step in developing effective treatments for patients with health anxiety in this population.

The findings from Study 1 are consistent with Hayter et al. (*ibid*) in that the effect-size of the difference between low and high levels of health anxiety in terms of QLI was large ( $d=1.89$ ). The same findings across these two studies is unsurprising given previous work showing that emotional factors were more predictive of subjective QoL than physical or cognitive impairment (Benedict et al., 2005; Dennison et al., 2009; Janssens et al., 2003). Given the high rates of health anxiety found in the MS population of between 25 – 30% (Hayter et al., *in process*; Kehler & Hadjistavropoulos, 2009) and the concomitant cost of health anxiety to health services (Tyrer et al., 2011a) it would suggest health anxiety should be more widely screened for and treated in MS patients.

Study 1 also found that HiHA participants rated their performance on the cognitive task as lower than those in the LowHA group. These results are in line with previous research that found anxious and depressed MS patients misperceived themselves as more cognitively impaired than their objective test results would suggest (Benedict et al., 2004; Lovera et al., 2006; Middleton et al., 2006). The findings are consistent with cognitive accounts of anxiety and depression whereby symptoms are maintained through biased appraisals. While the difference on ratings of physical performance was large, it was not statistically significant. There was also no difference between groups on their attribution of

performance to MS. A potential reason for the lack of significant differences compared to the finding from Hayter et al., and a further limitation of the study, was how participants were allocated to groups. Problems with recruitment meant a median split was used, whereas in Hayter et al. the low HA group had SHAI scores <10 and high HA group >18. Hence in the current study the difference between the groups in health anxiety was not as large, which may have meant the differences between groups on some of the measures was not large enough to be detected with the current sample size.

A limitation of Study 2 was a lack of control for non specific effects of attending therapy. The initial plan was to counterbalance the six sessions of CBT with six relaxation training sessions but time limitations meant this was not possible. However, given the theoretical rationale for the success of CBT-HA, it is not expected that the general findings would change with the inclusion of this control. The plan is for participants in Study 2 to receive a three month follow-up appointment, so as yet it is unclear whether the rapid improvements made by three of the participants remain stable long-term.

### 3.5.2 *CLINICAL IMPLICATIONS*

The case series suggests that treating health anxiety in MS is possible using an adapted CBT approach (CBT-HA) that leads not only to improvements in HA in some patients, but also mood and subjective quality of life. The replication of Hayter et al. was driven in part to identify targets for treatment during CBT-HA sessions. These were in the form of behavioural experiments that included explorations of the meanings of physical and cognitive symptoms through discussion of the participants' objective and perceived scores on the cognitive and physical tasks. The use of behavioural experiments in treating anxiety is not new (e.g., Salkovskis, Warwick, & Deale, 2003) but the present study builds on previous work by suggesting that a focus on specific targets for treatment (misappraisals of physical and cognitive functioning) can lead to significant symptom reduction in MS patients.

A large part of the treatment also focussed on participants' worries about the future; in particular what would happen if they became physically disabled. All the patients reported intrusive images of them as physically disabled in the future and unable to care of themselves. These are consistent with findings from Wells and Hackmann (1993) that images of a feared future in health anxiety are often associated with fear of abandonment

and an underestimation of coping abilities. Physical disability is a potential reality for many MS sufferers and for this reason may not represent a viable target for therapist treating health anxiety. However, the treatment here focussed on the meanings the participants attributed to this dreaded future. Across all four participants it was a concern they would become a “burden” to their families. Exploration of these meanings through use of Socratic questioning and guided discovery helped them to alter the meaning of the images such that while physical disability was a distinct possibility, their belief that they would become a “burden” (or a “bad mother”) was not. Furthermore, the direct manipulation of an intrusive image by one patient led to reductions in the negative emotions associated with it (for review see Holmes and Mathews (2010)). The present case series suggests a potential target in therapy is the unique meaning patients attribute to intrusive images in order to help them develop strategies to reduce psychological distress.

For Patient 1 in Study 2, after her third treatment session she reported other images that appeared consistent with experiencing a flash-back to her stay in hospital and suggestive of a trauma reaction to this. The reason this did not emerge until later in treatment is likely due to her avoidance of triggers of re-experiencing and arousal symptoms. When she felt more trusting of the therapist this avoidance may have decreased but the triggering of symptoms is likely to have led to her disengagement with treatment. Post-traumatic stress disorder (PTSD) can present with elements of any of the other anxiety disorders (Butler, Fennell, & Hackmann, 2008) with around sixty percent of patients with PTSD meeting criteria for at least one other disorder (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995). However, care is needed here as an emerging view in the recent literature is that intrusive images of past trauma or feared events are not confined to PTSD. Handley, Salkovskis, Scragg, and Ehlers (2009) found that the majority of patients screened for travel phobia following the London bombings in 2005 also had PTSD symptoms; with some of them reporting intrusive trauma memories and hyper-arousal. They suggest that while patients may not have met full criteria for a PTSD diagnosis, treatment should incorporate elements of PTSD treatment to help patients overcome their re-experiencing symptoms (e.g., Ehlers and Clark (2000)). This seems especially relevant to patients with RRMS as their initial attack or relapse can happen suddenly with devastating impact on physical functioning (as happened with Patient 1) and experienced as a life-threatening trauma. The experience of treating Patient 1 suggest clinicians need to be vigilant of PTSD symptoms in RRMS patients presenting with psychological complications (even if they do

not meet full criteria for a PTSD diagnosis) so they can get the most appropriate treatment. Unfortunately for Patient 1, this did not happen and her PTSD symptoms were not recognised early enough in her treatment to focus on them rather than health anxiety. If the clinician had done so, Patient 1 may have remained in therapy. .

### 3.5.3 *FUTURE RESEARCH*

The similarity of the intrusive images (and to a large part the meanings attributed to them) across all of the patients in the present case series is intriguing. Previous research by Berna et al. (2011) in patients with chronic pain revealed a wide variation in the content and meaning of intrusive of images. The similarities of images found here may have been due to the patients' similar personal circumstances (all mothers with children living at home). It remains an empirical question as to whether the similarity of intrusive images found here is reported across the MS patient population more generally. If so, future research might consider whether the similarities are accounted for by an aspect of MS or its interaction with cognitive processes involved in the development and maintenance of health anxiety (or anxiety disorders more generally). The extent to which these images are malleable through therapy is also a question for further research. Here the meanings of the negative images were successfully targeted but other approaches (such as imagery rescripting or retraining; Holmes, Arntz, and Smucker (2007)) may lead to even greater therapeutic gains.

In Study 1, QoL was lower for MS patients with HA compared to the non-HA patients and findings support an improvement following treatment (Study 2). These findings suggest that health anxiety has a direct negative impact on QoL, but it remains unclear which specific mechanisms are involved. Future research might consider whether it is behavioural (e.g., safety seeking behaviours) or cognitive (e.g., negative intrusive thoughts/images) that are most responsible for reduced QoL and help to prioritise targets for treatment.

### 3.5.4 *CONCLUSIONS*

The findings from this research partially support the findings from Hayter et al. (*in process*) where in MS patients, health anxiety reduces quality of life, over and above their level of physical or cognitive disability. Furthermore, they see their cognitive functioning as more impaired than it actually is. Psychological therapy led to improvements in HA and

QoL but without a control group it is unclear whether CBT-HA directly led to these improvements or whether some non-specific element of therapy was the cause of these improvements. Also, the small numbers of patients treated means caution is needed in generalising these findings more widely. Nevertheless, given the high prevalence rate of health anxiety in this population, and the economic burden to health care services of patients suffering health anxiety, Study 2 suggests that a brief CBT intervention that targets misappraisals of cognitive and physical performance as well as intrusive imagery about their feared future, could improve MS patients' wellbeing. The findings pave the way for larger, controlled studies to demonstrate the effectiveness of this type of intervention.

**Conflict of Interest:**

The Authors declare that there is no conflict of interest.

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# Executive Summary

Relapsing and Remitting Multiple Sclerosis (MS) is the most common form of MS. Patients have episodes of illness followed by periods of remission where symptoms fade away either partially or completely. Understandably, many patients can become anxious about when their MS will return or get worse. However, some symptoms of anxiety (problems with concentration, memory, feeling tired etc.) appear similar to those of MS and can lead to patients worrying that their MS is returning or getting worse when it is not. This worry then makes the anxiety symptoms worse which in turn makes the worry about their MS worse leading to a vicious cycle that reduces their quality of life, over and above the effects of their MS. This is important as healthcare costs increase when patients present to services believing their symptoms are signs of serious illness/relapse when in fact they are the symptoms of anxiety.

The process that maintains the anxiety can be explained by the cognitive model of health anxiety. Previous research by Hayter et al. used standardised measures to assess MS patients' mental abilities, quality of life, level of health anxiety and physical grip strength, as well as their perceptions about their performance on these measures. They found that MS patients with high levels of health anxiety perceived themselves as performing worse than MS patients with low health anxiety on the measures of physical and mental ability and attributed their perceived poor performance to their MS rather than anxiety. The high health anxious patients were also more likely to view symptoms that could have been caused by anxiety as being their MS and rated their quality of life as worse than patients with low health anxiety. These findings suggest that Cognitive Behaviour Therapy (CBT) might be helpful for patients with high levels of health anxiety by targeting their misattribution of poor performance and symptoms. This is done by getting patients to compare how poorly they thought they did with their actual performance on these tasks as a way of helping them to view their symptoms as anxiety that can be treated – rather than their MS.

This research study was in part a replication of the study by Hayter et al. in that 10 patients with high levels of health anxiety were compared with 10 low in health anxiety on standardised measures of their quality of life (QoL), cognitive and physical tasks as well as how the patients themselves viewed their performance on these tasks. Study 1 replicated the findings from the Hayter et al. study: participants with high levels of health anxiety

rated their QoL as lower than those low in health anxiety even when their level of physical disability was accounted for. The health anxious patients also thought their performance on tasks of mental ability was significantly lower; even though it was the same as those in the low health anxious group.

In Study 2, four of the participants who were in the high health anxiety group from Study 1, went on to receive six sessions of CBT. Before treatment all four had a score on the Short Health Anxiety Inventory that would indicate a diagnosis of hypochondriasis /health anxiety. Following treatment, two of the participants displayed a dramatic reduction in their level of health anxiety suggesting they were no longer anxious about their health. A third patient made a significant reduction in her level of health anxiety to below the threshold for a diagnosis. The final patient's level of health anxiety went up, but this was most likely due to undiagnosed trauma related to her first MS episode affecting her level of anxiety. Three of the patients showed significant improvements in mood, with the fourth already having a low score on a measure of mood prior to treatment. All four participants showed improvement their self-rated quality of life.

The findings from this research are consistent with the findings from previous research that showed that when MS patients suffer from health anxiety it reduces their quality of life, over and above their level of physical disability. Furthermore they see their mental abilities as more impaired than they actually are. Given the high prevalence rate of health anxiety in this population, and the economic burden to health care services of patients suffering health anxiety, Study 2 suggests services should offer brief CBT interventions that could significantly improve patients' wellbeing and reduce healthcare costs.

# Reflective Narrative

Having completed a Ph.D. over ten years ago and my entire subsequent career being involved in research (either University or Industry based), I was not intimidated at the start of training by the research component of clinical training. However, in retrospect this was probably naive as I found completion of the research projects – in particular the Service Improvement Project and Main Project – some of the most stressful research work of my career to date. The problems arose mainly from navigating the complexities and practicalities of conducting research within the NHS (something I had no experience of before) rather than struggling with any theoretical or methodological principals. However, facing these challenges and overcoming them have led to a great deal of learning on my part and leave me feeling well equipped and enthusiastic to continue with research in the NHS in whatever future role I have as a clinical psychologist. The first project I tackled was an ill-fated Service Improvement Project (SIP).

## **5.1 SERVICE IMPROVEMENT PROJECT**

My initial Service Improvement Project was chosen because I had the good fortune of being involved during my first placement (working age adults) with a bipolar group. The group had received much anecdotal evidence that it was having a major impact on the lives of those patients that attended. However, no formal evidence had been accrued that the group facilitator could take to commissioners to ensure it could continue to be funded. Hence I suggested conducting focus groups with patients who attended the bipolar group. I wrote up the proposal and developed the discussion guide for the focus group, with input from the clinical psychologist who facilitated the Bipolar group to ensure it asked the questions she wanted answered. Permission was sought from the relevant Trust's Research and Development (R&D) department and invitation letters sent out to patients. Everything had been well planned and a large amount of time and effort had been put into the project. However, when the time for the focus groups arrived, only two people turned up – even though we had received confirmations from many more.

This was a harsh lesson in the realities of working with this patient group and in the NHS more generally. The nature of bipolar disorder is unpredictable and many patient struggle to maintain consistency from day to day (helping patients to gain some semblance of



control had been a large part of the group's content). Hence my field supervisor did not express dismay when so few attended the focus group. I also wondered whether the fact we were not compensating patients for attending the group may have led to them not coming; but this view was disconfirmed later through the willingness of patients to give their time freely in my Main Project. I did consider re-arranging the focus groups and to try again with the most recent cohort of patients. However, after weighing up the risk of arranging another focus group that could fail against the time left before submission, I decided to start again with a new project.

The second SIP I embarked on was with the Neurodevelopmental clinic (NDC) based in the CAMHS team in Marlborough and Swindon. The Trust's clinical lead for ASD was my placement supervisor and she wanted an audit of the NDC to ensure it was meeting the targets set out in the NICE guidance. She also had a number of service planning questions she wanted answering from the audit that had to be incorporated into the data collection plan.

While it was felt that developing a Patient Information Leaflet (PIL) was beyond the scope of the project at this time, developing guidance for its content based on feedback from patients who had attended the clinic would be possible. The questionnaire used in the SIP was based on a previous incarnation used to survey parents when the clinic was geared towards the old care pathway. In discussion with the clinical lead, I developed further questions relevant to the new care pathway and to investigate patients' information needs.

The data collection for the audit took much longer than anticipated due to their being no mechanism in the clinic to capture the data pertinent to the audit questions. As a result, I had to interrogate individual electronic records and hand input the data into a spreadsheet. This experience directly led to one of the recommendations of the SIP: that the NDC incorporates NICE audit tools to speed up data analysis. The feedback from the Trust's clinical lead for ASD on the findings from the SIP was positive and she feels it will help with service planning. She has also asked that I present the findings to service and audit managers at the NDC review meeting in July 2014 to maximise the exposure of the findings.

The project was successful to a large extent because it answered the relevant questions. This was achieved through careful elicitation of needs from the Trust's ASD lead. This process also helped structure the data collection so that only the relevant data was extracted

from the patient record and reduced the data collection (even though this still took a considerable amount of time). Reflecting on the process, the only change I would make would be to follow up the patient survey with telephone calls as opposed to letters. This was done in a similar study published recently and their response rate was considerably higher. I was glad of the experience of conducting a service audit and testing the output against national guidelines. This is likely to increasingly form part of my role as I progress in my career. Fortunately, the service performed well. I am not sure how it would have felt to feed back poor results to a team I admired and enjoyed working with, especially given that I was a trainee. When qualified, I think that the same skills utilised in my neuropsychology placement, where I had to feed back to patients poor results from their cognitive assessment, will stand me in good stead when I have to let teams I work with and care about know that their performance needs to improve.

Having to start a new project from scratch meant that the Gantt chart for my research projects was now very much behind schedule. In the original Gantt chart, the second project I had planned to complete was my Main Project. However, given the difficulties with the process for obtaining ethical approval I had to turn my attention to my Literature review.

## **5.2 LITERATURE REVIEW**

As an intermittent sufferer, I was keen to base my literature review on insomnia: in particular the cognitive processes involved in its maintenance. I had also become intrigued by transdiagnostic approaches that posit common cognitive processes across disorders. I wondered whether it would be possible to synthesise the research literature to see if any transdiagnostic process could account for sleep problems. The most likely candidates were worry and rumination. It was through discussion with my research supervisor (Paul Salkovskis) that the topic expanded to include chronic pain with co-morbid insomnia. The original plan was to assess whether worry could be differentiated from rumination in insomnia and whether the same processes were responsible for pain-related insomnia. I have a great deal of experience writing literature reviews as a post-doctoral researcher so I did not have much problem marshalling the evidence and synthesising the findings. A metaphor I used during the writing of my Ph.D. was of a needle and thread that pulls all the pieces of the thesis together into a coherent whole. However, given the wide ranging nature

of the topics covered (insomnia, chronic pain, worry and rumination) developing a coherent narrative was difficult. This was clear after Paul read the first draft. While all the pieces needed for the review were there, it lacked coherence. While Paul suggested outlining the structure more clearly at the beginning of the review, careful thinking around the arguments I wanted to present meant a complete overhaul of the narrative arc of the review. While this did not involve any re-writing, it did mean changing the order of sections and including connecting paragraphs/sentences between them.

In most of my previous research, the literature review has been a prelude to something else (most usually data collection and analysis) rather as an end in itself. Here though, the review highlighted areas for potential new research and implications for treatment. Given the difficulties I have encountered collecting patient data in the NHS, I feel that literature reviews of this sort can compliment and provide an alternative to more empirical research work of the type embodied in my Main Project.

### **5.3 MAIN PROJECT**

As I had done many experimental and cross-sectional studies in previous research roles, I wanted my Main Project to include a treatment case series. I also thought that this might be more tractable as it would not require large numbers of participants. In the end this was irrelevant as the project incorporated both a cross-sectional and case series element. The supervisor for my main project was again Paul Salkovskis and it was at his suggestion that I replicate Amy Hayter's study as well as evaluating treatment for health anxiety in Multiple Sclerosis (MS) patients. This seemed sensible and would ensure there was a fallback position in case of delays. The project also seemed feasible as Dr Leon Dysch in the Community Neuro and Stroke Service in Bath thought (at that time in mid 2012) there would be no problem accessing sufficient numbers of patients with relapsing and remitting MS.

The original design of the project was to control for the non standard effects of attending therapy by having patients also receive six sessions of relaxation training (RT) (as well as CBT) with treatment order counterbalanced – following an ABAC alternating treatment case series design with three month follow-up. This meant that patients could potentially be in treatment for 16 weeks with a further follow-up session three months after the end of treatment. The total length of time for this part of the study would have been seven months.

To have any hope of completing this on time I needed to have ethical approval in place by the beginning of my third year of training and the start of my placement with Leon Dysch.

In retrospect, I feel I should have contacted the relevant Trust's R&D department about ethics much earlier to get their help navigating the ethics application process. However, it later transpired that even *they* gave inaccurate information about the NRES requirements.

I found completing the ethics application tortuous as it felt like I was answering the same questions over and over. Perhaps because of this it took much longer to complete than it should have done. However, now I have completed the process I feel confident it will be a much quicker process next time. As the treatment element of the research was case studies, both myself and Paul believed that ethical approval was not necessary, as it would be routine care; ethical approval would only be required for the cross-sectional part of the research. However, I thought that to place this element of the research in context and provide a rationale for replicating a previous study, the treatment element would be included in the application form. I also put the application forward for proportionate ethical review as many of my peers had done so successfully.

At the initial screen by NRES over the phone, the application was accepted for proportionate review and sent to the Brighton and South Coast Ethics Committee. I was sent a time that I should make myself available over the telephone if the committee needed to phone me to answer any questions they had. As I heard nothing on the day of the meeting I assumed there was no problem. I then received a message two days later saying they were trying to contact me. When I phoned them back they said that I had been given the wrong time and date. Their question was about the lack of a Participant Information Sheet (PIS) for the treatment phase of the study. I replied that I *did* have one but as it was routine treatment, I was not seeking ethical approval for this part of the study. I was told that this was not the case, I needed to get approval. If I had been available to send them the PIS then they did not see a problem, but as they did not have this they had sent the application back for a full committee hearing. This was in September 2013 and I was rapidly approaching the deadline for when the study needed to begin. I then had to wait for a month, unable to make any representation to NRES to clarify the matter raised at proportionate review. When my full committee meeting took place I was told that I could telephone in to the meeting to answer their questions. When I did this, I waited on hold for 45 minutes with no-one telling me whether or when I would get to speak to the committee.

It transpired that they were not aware I was using the teleconferencing facility and their main concern with my application? I did not have a PIS for the treatment phase of the study.

This was probably the lowest point in my training course and one of the most stressful periods I have ever encountered. I finally gained ethical approval two months later but now had no chance of completing the project as planned. It then became apparent that the criteria for seeing MS patients in the Community Neuro and Stroke Service had changed in the interim period since planning the project and the majority of them were no longer seen in the service. The best source of potential participants was the MS nurse specialist, but she worked for the Royal United Hospital Trust in Bath, so I had to seek further R&D approval from that Trust. All of which meant further delay to recruitment. Another avenue I pursued was contacting a local charity organisation: the MS Therapy Centre in Warminster. They were very happy to take part and in the end were able to recruit five patients to the study. I also sought help from the Bristol and Avon MS (BrAMS) centre which are part of the North Bristol NHS Trust (NBT) and thus required approval from their R&D department. At the time of writing, NBT have still not processed my request – five months after making it.

By the time I started recruitment it was December 2013 and it would be impossible for patients to receive both treatments (CBT and RT) before the deadline of May. In a meeting with Paul and Leon it was decided to titrate down the treatment to just include the CBT element while recognising the threat to validity of making such a change. Originally, all 12 of the participants in the high health anxious group would receive treatment so that the findings could be converted into an open trial. In the end only 6 participants met inclusion criteria of whom 4 agreed to take part in treatment. For the cross-sectional part of the study, recruitment went well at first with almost everyone I contacted agreeing to take part. However, by the time I had 18 participants, I had run out of people to contact. While I phoned and emailed the NBT R&D office I got nowhere with finding out what had happened to my application for clearance.

In the end, I managed to get 20 participants, four short of the total I had hoped for. While this was a small sample size, my hope was that the effect sizes I was attempting to detect were large enough that this would not be a problem. To counter problems with meeting the assumptions of parametric tests, I researched the modern robust alternatives developed by

Rand Wilcox and colleagues. In the end, only one of the measures distributions did not meet the assumptions for parametric testing, but learning about the robust alternative tests and using R (statistical software package) was a positive learning experience and has provided me with a greater range of options for sophisticated data analysis in future research.

What I have learned from this experience is that the NRES ethical clearance process is quite possibly not fit for purpose. It has become too complicated, with many people in Trusts' R&D offices not knowing what the requirements are and giving erroneous advice. However, this is the context we work in and in future I will not underestimate the time needed to steer through this process. While I feel I have learned a number of valuable lessons with regards to NHS research the main area of research methodology that I had not encountered before clinical training was the single case design.

## **5.4 CASE STUDIES**

Having little prior experience of single case experimental designs, I found this methodology slightly intimidating at first. I initially thought it required a great deal of planning. Also, many clinicians in the region do not regularly work in this way or utilise patient measures as part of routine assessments: making baseline measurement difficult. However, as I have progressed through training, I found I needed to be more assertive about this with supervisors and it now forms part of my own routine practice. This will continue in my future career. However, the greatest learning I received in this regard was through the case series I completed as part of my main project. Here I used multiple baseline measures, process measures during treatment with planned three month follow up measures. I learnt how to visually inspect data to assess changes in level and trend and also researched ways to assess reliable and significant change in these measures; it helped me develop meaningful inferences about the progress patients made following treatment. Regardless of the research I become involved with in the future, the case study is something that can always form part of my practice and can provide potential avenues to disseminate interesting findings from routine practice.

In conclusion, I have been conducting psychological research for most of the last 15 years and I hope to continue to do so as I move forward with my career. While the mainstay of this is likely to be in the first instance case studies, I hope as I settle into my role as a

clinician to continue to be involved in more large scale academic research. This could be through collaborations with University departments (either through funded research or supervising trainee research projects) and NHS research. In the past I have successfully applied for research grant money to conduct research within the NHS (even though I left the team to start the clinical training course before the project started) and I would like to continue to pursue these avenues of funding in the future – perhaps in collaboration with a University. In whatever guise it may take, I will continue to be involved in research as I move forward as a clinical psychologist – embracing the role of a scientist-practitioner.

**Appendix A NICE Criteria for Autism diagnostic assessment for children and young people**

<b>AUTISM DIAGNOSTIC ASSESSMENT FOR CHILDREN AND YOUNG PEOPLE</b>	
<b>Criterion 1</b>	The autism diagnostic assessment should be started within 3 months of the referral to the autism team.
<b>Exceptions</b>	None
<b>Guideline reference</b>	1.5.1
<b>Definitions</b>	None
<b>Criterion 2</b>	<p>Every diagnostic assessment should include:</p> <ul style="list-style-type: none"> <li>• detailed questions about parent’s or carer’s concerns and, if appropriate, the child’s or young person’s concerns</li> <li>• details of the child’s or young person’s experiences of home life, education and social care</li> <li>• a developmental history, focusing on developmental and behavioural features consistent with ICD-10 or DSM-IV criteria</li> <li>• assessment (through interaction with and observation of the child or young person) of social and communication skills and behaviours, focusing on features consistent with ICD-10 or DSM-IV criteria</li> <li>• a medical history, including prenatal, perinatal and family history, and past and current health conditions</li> <li>• a physical examination</li> <li>• consideration of the differential diagnosis</li> <li>• systematic assessment for conditions that may coexist with autism</li> <li>• development of a profile of the child’s or young person’s strengths, skills, impairments and needs that can be used to create a needs-based management plan, taking into account family and educational context</li> <li>• communication of assessment findings to the parent or carer and, if appropriate, the child or young person.</li> </ul>
<b>Exceptions</b>	None
<b>Guideline reference</b>	1.5.5
<b>Definitions</b>	DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition; ICD-10: International Statistical Classification of Diseases and



	Related Health Problems, 10th Revision.
<b>Criterion 3</b>	<p>A general physical examination should be performed, looking specifically for:</p> <ul style="list-style-type: none"> <li>• skin stigmata or neurofibromatosis or tuberous sclerosis using a Wood's light</li> <li>• signs of injury, for example self harm or child maltreatment</li> <li>• congenital anomalies and dysmorphic features including macrocephaly or microcephaly.</li> </ul>
<b>Exceptions</b>	None
<b>Guideline reference</b>	1.5.6
<b>Definitions</b>	None
<b>COMMUNICATING THE RESULTS FROM THE AUTISM DIAGNOSTIC ASSESSMENT</b>	
<b>Criterion 4</b>	Parents or carers and, if appropriate, the child or young person should be provided with a written report of the autism diagnostic assessment. This should explain the findings of the assessment and the reasons for the conclusions drawn.
<b>Exceptions</b>	None
<b>Guideline reference</b>	1.8.4
<b>Definitions</b>	None
<b>Criterion 5</b>	Information, including the written report of the diagnostic assessment, should be shared with the GP.
<b>Exceptions</b>	None
<b>Guideline reference</b>	1.8.5
<b>Definitions</b>	None
<b>Criterion 6</b>	For children and young people with a diagnosis of autism, a follow-up appointment should be offered with an appropriate member of the autism team within 6 weeks of the end of the autism assessment for further discussion.
<b>Exceptions</b>	None

<b>Guideline reference</b>	1.8.8
<b>Definitions</b>	Further discussion could be about the conclusions of the assessment and the implications for the child or young person.

## Appendix B NICE Criteria for ADHD in children and young people

<b>Criterion 1</b>	<p><b>For a diagnosis of ADHD, symptoms of hyperactivity/impulsivity and/or inattention should:</b></p> <ul style="list-style-type: none"> <li>• meet the diagnostic criteria in DSM-IV or ICD-10 (hyperkinetic disorder) and</li> <li>• be associated with at least moderate psychological, social and/or educational or occupational impairment based on interview and/or direct observation in multiple settings, and</li> <li>• be pervasive, occurring in two or more important settings including social, familial, educational and/or occupational settings.</li> </ul>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	<p>A diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD.</p> <p>See Appendix I for DSM-IV and ICD-10 diagnostic criteria.</p> <p>The ICD-10 exclusion on the basis of a pervasive developmental disorder being present, or the time of onset being uncertain, is not recommended.</p>
<b>Criterion 2</b>	<p><b>As part of the diagnostic process, include an assessment of the person's needs, coexisting conditions, social, familial and educational circumstances and physical health.</b></p> <p><b>For children and young people there should also be an assessment of their parents' or carers' mental health.</b></p>
<b>Exceptions</b>	None
<b>Standard</b>	100%

<b>Definitions</b>	None
<b>Criterion 3</b>	<b>Parents or carers of pre-school children with ADHD should be offered a referral to a parent-training/education programme</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	Parent-training/education programmes should be first-line treatment if the parents or carers have not already attended such a programme or the programme has had a limited effect.
<b>Criterion 4</b>	<b>If the child or young person with ADHD has moderate levels of impairment, the parents or carers should be offered referral to a group parent-training/education programme either:</b> <ul style="list-style-type: none"> <li>• as a standalone programme or</li> <li>• with a group treatment programme for the child or young person</li> </ul>
<b>Exceptions</b>	<b>A</b> Child is under school age
<b>Standard</b>	100%
<b>Definitions</b>	A group treatment programme would involve CBT and/or social skills training
<b>Criterion 5</b>	<b>In school-age children and young people with severe ADHD, drug treatment should be offered as the first-line treatment.</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None

<b>Criterion 6</b>	<b>Parents of school-age children and young people with severe ADHD should be offered a group-based parent-training/education programme.</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Criterion 7</b>	<b>Drug treatment for children and young people with ADHD should always form part of a comprehensive treatment plan that includes psychological, behavioural and educational advice and interventions</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Transition to adult services</b>	
<b>Criterion 8</b>	<b>A young person of school leaving age, should be reassessed to establish the need for continuing treatment into adulthood</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Criterion 8a</b>	<b>If continuing treatment is needed, arrangements should be made for a smooth transition to adult services with details of anticipated treatment and services that the young person will require</b>

<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Criterion 9</b>	<b>During the transition, full information about adult services should be provided to the young person</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Criterion 10</b>	<b>During transition, if the person is aged 16 or over, the care programme approach (CPA) should be used as an aid to transfer</b>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	None
<b>Criterion 11</b>	<p><b>Patients should be offered written information about:</b></p> <ul style="list-style-type: none"> <li>• <b>their condition</b></li> <li>• <b>the treatment and care they should be offered, including being made aware of the '<a href="#">Understanding NICE guidance</a>' booklet</b></li> <li>• <b>the service providing their treatment and care.</b></li> </ul>
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Definitions</b>	Patients should be offered written information to help them make informed decisions about their healthcare. This should cover the condition, treatments and the health service providing care.

	Information should be available in formats appropriate to the individual, taking into account language, age, and physical, sensory or learning disabilities.
<b>Criterion 12</b>	<p><b>Carers should be offered written information about:</b></p> <ul style="list-style-type: none"> <li>• the patient's condition</li> <li>• the treatment and care the patient should be offered, including being made aware of the <a href="#">'Understanding NICE guidance'</a> booklet</li> <li>• the service providing the patient's treatment and care.</li> </ul>
<b>Exceptions</b>	<p>B. Where there is no carer involved</p> <p>C. Where sharing information may compromise the patient's confidentiality or wishes</p>
<b>Standard</b>	100%
<b>Definitions</b>	Carers and relatives should have the opportunity to be involved in decisions about the patient's care and treatment, unless the patient specifically excludes them.
<b>Number of criterion replaced:</b>	<b>Local alternatives to above criteria (to be used where other data addressing the same issue are more readily available)</b>
<b>Exceptions</b>	
<b>Standard</b>	
<b>Definitions</b>	

**Appendix C Data collection tool for ‘Autism: recognition, referral and diagnosis of children and young people on the autism spectrum’**

Complete one form for each patient

<b>Patient identifier:</b>	<b>Sex:</b>	<b>Age:</b>	<b>Organisation/service:</b>
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**Ethnicity:**

White	Mixed	Asian or Asian British	Black or Black British	Other
British <input type="checkbox"/>	White and Black Caribbean <input type="checkbox"/>	Indian <input type="checkbox"/>	Caribbean <input type="checkbox"/>	Chinese <input type="checkbox"/>
Irish <input type="checkbox"/>	White and Black African <input type="checkbox"/>	Pakistani <input type="checkbox"/>	African <input type="checkbox"/>	Any other ethnic group <input type="checkbox"/>
Any other White background <input type="checkbox"/>	White and Asian <input type="checkbox"/>	Bangladeshi <input type="checkbox"/>	Any other Black background <input type="checkbox"/>	Not stated <input type="checkbox"/>
	Any other mixed background <input type="checkbox"/>	Any other Asian background <input type="checkbox"/>		

No.	Data item no.	Criteria	Yes	No	NA/ Exceptions <sup>a</sup>
<b>Autism diagnostic assessment for children and young people</b>					
1	1.1	Was the autism diagnostic assessment started within 3 months of the referral to the autism team?	<input type="checkbox"/>	<input type="checkbox"/>	
2	2.1	Did the diagnostic assessment include: <ul style="list-style-type: none"> <li>detailed questions about parent’s or carer’s concerns and, if appropriate, the child’s or young person’s concerns?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
	2.2	<ul style="list-style-type: none"> <li>details of the child’s or young person’s experiences of home life, education and social care?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	



No.	Data item no.	Criteria	Yes	No	NA/ Excep tions <sup>a</sup>	
	2.3	<ul style="list-style-type: none"> <li>a developmental history, focusing on developmental and behavioural features consistent with ICD-10 or DSM-IV criteria?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.4	<ul style="list-style-type: none"> <li>assessment (through interaction with and observation of the child or young person) of social and communication skills and behaviours, focusing on features consistent with ICD-10 or DSM-IV criteria?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.5	<ul style="list-style-type: none"> <li>a medical history, including prenatal, perinatal and family history, and past and current health conditions?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.6	<ul style="list-style-type: none"> <li>a physical examination?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.7	<ul style="list-style-type: none"> <li>consideration of the differential diagnosis?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.8	<ul style="list-style-type: none"> <li>systematic assessment for conditions that may coexist with autism?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.9	<ul style="list-style-type: none"> <li>developing a profile of the child's or young person's strengths, skills, impairments and needs that can be used to create a needs-based management plan, taking into account family and educational context?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.10	<ul style="list-style-type: none"> <li>communicating assessment findings to the parent or carer and, if appropriate, the child or young person?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	3	3.1	Was a general physical examination performed?	<input type="checkbox"/>	<input type="checkbox"/>	
		3.2	Did this look specifically for: <ul style="list-style-type: none"> <li>skin stigmata or neurofibromatosis or tuberous sclerosis using a Wood's light?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
3.3		<ul style="list-style-type: none"> <li>signs of injury, for example self harm or child maltreatment?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
3.4		<ul style="list-style-type: none"> <li>congenital anomalies and dysmorphic features including macrocephaly or microcephaly?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		

No.	Data item no.	Criteria	Yes	No	NA/ Excep tions <sup>a</sup>
<b>Communicating the results from the autism diagnostic assessment</b>					
4	4.1	Were the parents or carers provided with a written report of the autism diagnostic assessment?	<input type="checkbox"/>	<input type="checkbox"/>	
	4.2	Was the child or young person provided with a written report?	<input type="checkbox"/>	<input type="checkbox"/>	
	4.3	Did this explain the findings of the assessment and the reasons for the conclusions drawn?	<input type="checkbox"/>	<input type="checkbox"/>	
5	5.1	Was the report shared with the GP?	<input type="checkbox"/>	<input type="checkbox"/>	
6	6.1	Was the child or young person with a diagnosis of autism offered a follow-up appointment within 6 weeks of the end of the autism assessment?	<input type="checkbox"/>	<input type="checkbox"/>	

## Appendix D Data collection tool for ADHD in children and young people

<b>Patient identifier:</b>	<b>Sex:</b> M / F	<b>Age:</b>	<b>Ethnicity:</b>
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Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guide line ref.
<b>Diagnosis and assessment</b>						
1		Is there evidence that the patient's symptoms at the time of diagnosis met the diagnostic criteria in:				1.3.1.3
	1.1	<ul style="list-style-type: none"> <li>• DSM-IV</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	1.2	<ul style="list-style-type: none"> <li>• ICD-10<sup>1</sup></li> </ul> (Data source: patient record)	<input type="checkbox"/>	<input type="checkbox"/>		
	1.3	Is there evidence that the level of impairment resulting from symptoms of hyperactivity, impulsivity or inattention were: <ul style="list-style-type: none"> <li>• associated with at least moderate psychological, social and/or educational or occupational significance based on interview and/or direct observation in multiple settings</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		1.3.1.3

<sup>1</sup> The ICD-10 exclusion on the basis of a pervasive developmental disorder being present, or the time of onset being uncertain, is not recommended.

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
	1.4	<ul style="list-style-type: none"> <li>pervasive, occurring in two or more important settings including social, familial, educational and/or occupational settings.</li> </ul> (Data source: patient record)	<input type="checkbox"/>	<input type="checkbox"/>		
2		Is there evidence that diagnosis included assessments of:				1.3.1.3
	2.1	<ul style="list-style-type: none"> <li>the person's needs</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.2	<ul style="list-style-type: none"> <li>coexisting conditions</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.3	<ul style="list-style-type: none"> <li>social circumstances</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.4	<ul style="list-style-type: none"> <li>family circumstances</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.4	<ul style="list-style-type: none"> <li>educational circumstances</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	2.6	<ul style="list-style-type: none"> <li>physical health</li> </ul> (Data source: patient record)	<input type="checkbox"/>	<input type="checkbox"/>		
	2.7	Have the parents/carers had an assessment of their mental health?	<input type="checkbox"/>	<input type="checkbox"/>		1.3.1.3

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guide line ref.
<b>Treatment</b>						
3	3.1	If the child is of pre-school age, have the parents/carers been offered a referral to a parent-training/education programme?	<input type="checkbox"/>	<input type="checkbox"/>	<b>A</b>	1.5.1.3
	3.2	If yes: <ul style="list-style-type: none"> <li>• was it first-line treatment?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	3.3	<ul style="list-style-type: none"> <li>• was it the parents/carers' first referral?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	3.3.1	<ul style="list-style-type: none"> <li>○ if not, what was the reason for referral?</li> </ul>				
4	4.1	If the child/young person has moderate levels of impairment, were the parents/carers offered a referral to a group parent-training/education programme?	<input type="checkbox"/>	<input type="checkbox"/>		1.5.2.4
		If yes, was it:				

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
	4.2	<ul style="list-style-type: none"> <li>a standalone programme</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	4.3	<ul style="list-style-type: none"> <li>with a group treatment programme for the child or young person</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
		If the child/young person is of school-age and has severe ADHD,				1.5.3.1
5	5.1	<ul style="list-style-type: none"> <li>was drug treatment offered as the first-line treatment?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
6	6.1	<ul style="list-style-type: none"> <li>were the parents offered a group-based parent-training/education programme?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
7	7.1	Did/does drug treatment form part of a plan including:	<input type="checkbox"/>	<input type="checkbox"/>		1.7.1.4
	7.2	<ul style="list-style-type: none"> <li>psychological advice and interventions</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	7.3	<ul style="list-style-type: none"> <li>behavioural advice and interventions</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	7.4	<ul style="list-style-type: none"> <li>educational or occupational advice and interventions?</li> </ul> <p>(Data source: patient record)</p>	<input type="checkbox"/>	<input type="checkbox"/>		
Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
<b>Transition from CAMHS to adult services</b>						
8	8.1	Is the young person of school leaving age?	<input type="checkbox"/>	<input type="checkbox"/>		1.6.1.1
	8.2	If yes, have they been reassessed to establish the need for continuing treatment into adulthood?	<input type="checkbox"/>	<input type="checkbox"/>		
	8.3	If no to 8.2, are there plans to reassess them in the near future?	<input type="checkbox"/>	<input type="checkbox"/>		
8a	8a.1	If continuing treatment is needed, have arrangements been made for a smooth transition to adult services, including:	<input type="checkbox"/>	<input type="checkbox"/>		1.6.1.1
	8a.2	<ul style="list-style-type: none"> <li>• anticipated treatment required</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	8a.3	<ul style="list-style-type: none"> <li>• anticipated services required?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
9	9.1	If the young person is moving from CAMHS to adult services, have they been provided with full information about adult services?	<input type="checkbox"/>	<input type="checkbox"/>		1.6.1.2

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
10	10.1	If the young person is aged 16 or over, is CPA being used as an aid to transfer?	<input type="checkbox"/>	<input type="checkbox"/>		1.6.1.2
<b>Person-centred care</b>						
11		Was patient offered written information about:				Person-centred care
	11.1	<ul style="list-style-type: none"> <li>their condition</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	11.2	<ul style="list-style-type: none"> <li>the treatment and care they should be offered</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	11.3	<ul style="list-style-type: none"> <li>including being made aware of the 'Understanding NICE guidance' booklet</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	11.4	<ul style="list-style-type: none"> <li>the service providing their treatment and care.</li> </ul> <p>(Data source: patient records)</p>	<input type="checkbox"/>	<input type="checkbox"/>		
12		Was carer(s) offered written information about:				Person-centred care
	12.1	<ul style="list-style-type: none"> <li>the patient's condition</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	12.2	<ul style="list-style-type: none"> <li>the treatment and care the patient should be offered</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		



Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
	12.3	– including being made aware of the 'Understanding NICE guidance' booklet	<input type="checkbox"/>	<input type="checkbox"/>		
	12.4	<ul style="list-style-type: none"> <li>the service providing the patient's treatment and care.</li> </ul> (Data source: patient records)	<input type="checkbox"/>	<input type="checkbox"/>		

<b>Organisation/se</b>	
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Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
<b>Training</b>						
13	13.1	Is there a specialist ADHD team?	<input type="checkbox"/>	<input type="checkbox"/>		1.1.3.1
	13.2	If yes, does it run training programmes covering: <ul style="list-style-type: none"> <li>diagnosis</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.3		<ul style="list-style-type: none"> <li>management</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
	13.4	Is the training appropriate for: <ul style="list-style-type: none"> <li>mental health professionals</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		

Criterion No.	Data Item No.	Criterion	Yes	No	NA/ Exceptions	NICE guideline ref.
	13.5	<ul style="list-style-type: none"> <li>paediatric professionals</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.6	<ul style="list-style-type: none"> <li>social care professionals</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.7	<ul style="list-style-type: none"> <li>education professionals</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.8	<ul style="list-style-type: none"> <li>forensic professionals</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.9	<ul style="list-style-type: none"> <li>primary care providers</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		
	13.10	<ul style="list-style-type: none"> <li>other professionals who have contact with people with ADHD</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		

**Data collection completed**

**Appendix E The Neuro-Developmental Clinic (NDC) – Parents’ Survey**

**Q1. How old is your child?**

0 – 5 yrs

6 - 10yrs

11-15yrs

15-18yrs

**Q2. Gender of your child?**

Male

Female

**Q3. How long did you wait for the appointment?**

0-6 months

6-12 months

12-18 months

over 18 months

**Q4. Do you think the waiting time was reasonable?**

Strongly agree

Agree

Neither agree  
nor disagree

Disagree

Strongly  
disagree

**Q5. Did the staff explain the reason why you had an assessment as fully as possible?**

Yes	No	I don't know/I don't remember
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q6. Did the assessment process address all your child's difficulties?**

Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q7. As a parent and/or carer, did you feel that you were encouraged to participate in the assessment and that your views, wishes and feelings were actively sought?**

Yes	No	I don't know/I don't remember
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q8. How many times have you had to attend the Neuro-Developmental Clinic?**

**Q9. Have you had a feedback session with the clinic yet where a diagnosis for your child's condition was given?**

Yes (please go to Q10)

No (please go to Q19)

**Q10. Was the outcome of your assessment fed-back to you by one of the clinic team?**

Yes

No

I don't know/I don't  
remember

**Q11. What was your child's diagnosis?**

Autism

Speech and language disorder

Asperger's syndrome

Global developmental delay

PDD-NOS

No formal diagnosis

ADHD

**Other(s) (please specify):**

--

**Q12. Did you agree with the diagnosis?**

- Yes – this was the diagnosis I was expecting
  
- I did not have strong views regarding diagnosis
  
- No – I expected a different diagnosis

**Q13. Were you given the opportunity to discuss your feelings about the diagnosis?**

- | Yes                      | No                       | I don't know/I don't remember |
|--------------------------|--------------------------|-------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>      |

**Q14. Was the diagnosis explained properly?**

- | Yes                      | No                       | I don't know/I don't remember |
|--------------------------|--------------------------|-------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>      |

**Q15. Do you think the report from the clinic was useful?**

- | Yes                      | No                       | I don't know/I don't remember |
|--------------------------|--------------------------|-------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>      |

**Q16. Were you given information about useful resources?**

		I don't know/I don't remember
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q17. Were you told or given information about local voluntary organisations, social support networks, self-help groups and other national services relevant to your child's diagnosis?**

		I don't know/I don't remember
Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q18. Have you been able to access these resources?**

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

**Which ones:**

**Q19. How would you rate the service you and your child received from the clinic?**

Not satisfactory	Satisfactory	Good	Very good	Excellent
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q20. Would an information leaflet have been helpful before attending the clinic?**

Yes

No

Not sure

**Q21. If yes, what sort of information would you have liked to have known about before attending? (Please tick all that are appropriate)**

- Why you are attending a Neuro-Developmental Clinic
- What will happen when you attend the clinic
- How long the process of assessment will take
- Who you will be seeing in the clinic
- What the different outcomes of the assessment might be
- How the outcome of the assessment will be feedback to you
- What happens after the assessment process

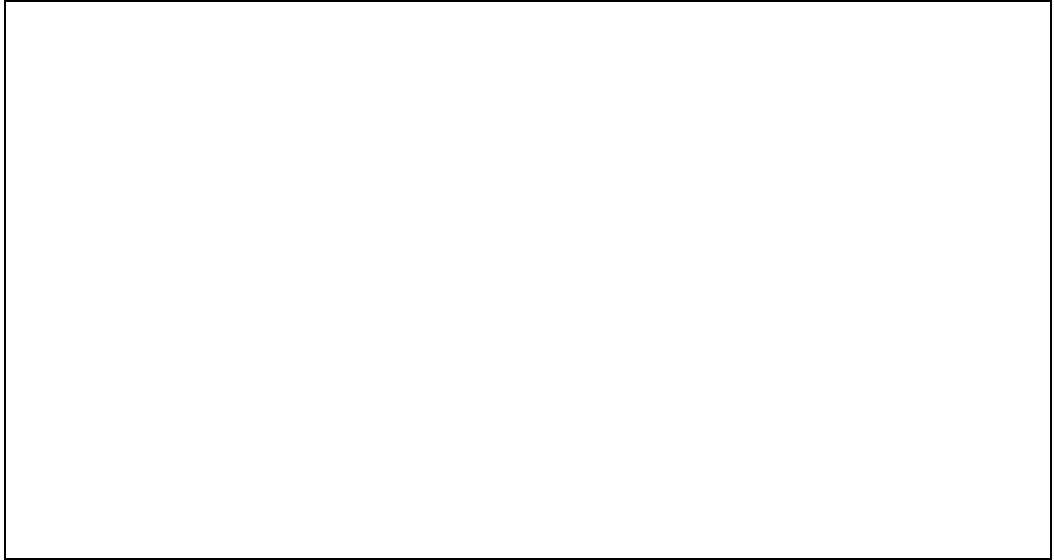
**Anything else (please specify?):**

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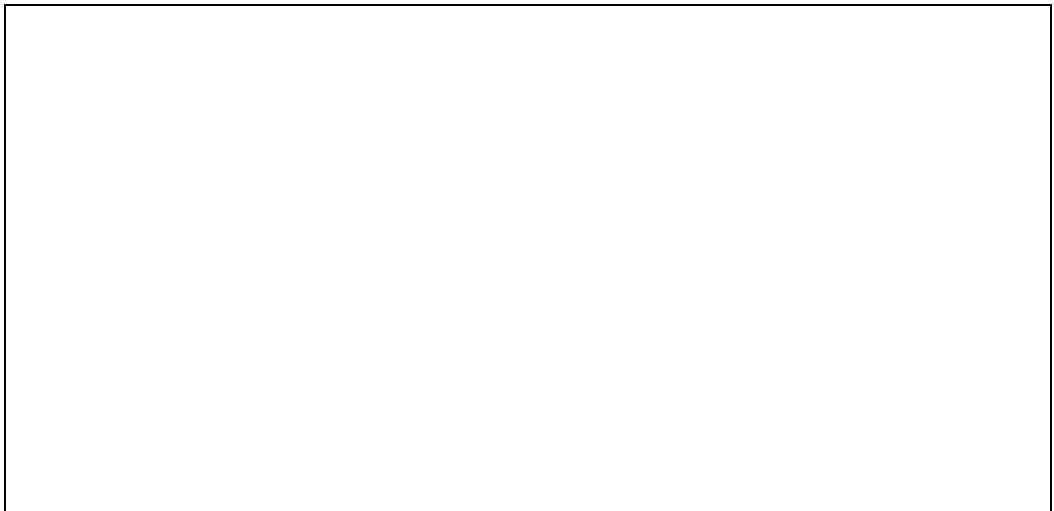


**Comments:**

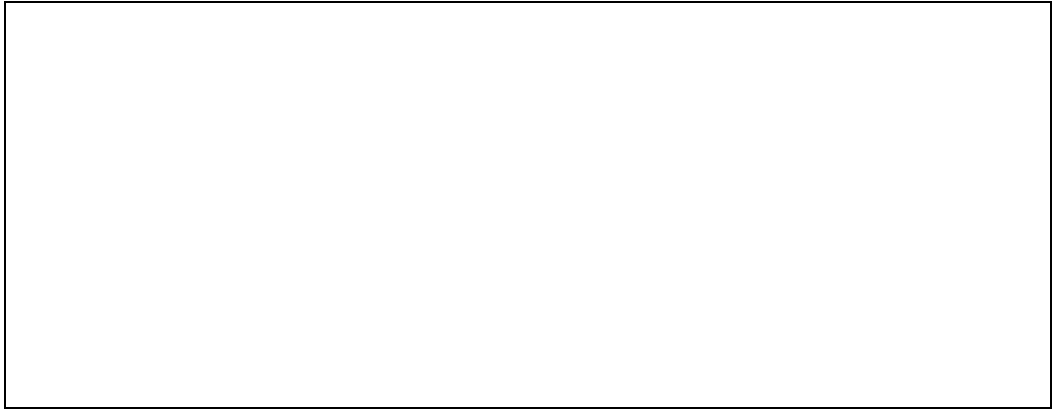
**Q22. Was there anything about your attendance at the clinic which was especially helpful?:**



**Q23. Was there anything about your attendance at the clinic which was not helpful?:**



**Q24. Any suggestions for improvement:**



**Thank you for completing this questionnaire, your feedback is very much appreciated. Please return in the stamped addressed envelope provided**

**Appendix F Results of the Satisfaction Survey sent to parents of children referred to the clinic**

<b><u>Demographics:</u></b>	
How old is your child?	2 (8-10 yrs) 8 (11-15 yrs) 4 (15-18 yrs)
Gender of your child?	9 Male 5 Female
<b><u>Prior to attending the clinic</u></b>	
How long did you wait for the appointment?	6 (0-6 months) 6 (6-12 months) 1 (12 – 18 months) 1 (Over 18 months)
Do you think the waiting time was reasonable?	2 Strongly Agree 3 Agree 3 Neither agree or disagree 5 Disagree 1 Strongly disagree
<b><u>The assessment process</u></b>	
Did the staff explain the reason why you had an assessment as fully as possible?	13 Yes 1 I don't know/don't remember
Did the assessment process address all your child's difficulties?	4 Strongly agree 4 Agree 2 Neither agree or disagree 1 Disagree 2 Strongly disagree

As a parent and/or carer, did you feel that you were encouraged to participate in the assessment and that your views, wishes and feelings were actively sought?	11 Yes 2 No 1 No response
How many times have you had to attend the Neuro-Developmental Clinic?	3 (Once) 4 (Twice) 1 (Three times) 3 (Four times) 1 (Five times) 2 No response
Have you had a feedback session with the clinic yet where a diagnosis for your child's condition was given?	13 Yes 1 No response
<b><u>The outcome of the assessment</u></b>	
Was the outcome of your assessment fed-back to you by one of the clinic team?	13 Yes 1 No response
What was your child's diagnosis?	3 Autism 5 Asperger's Syndrome 2 ADHD 3 No formal diagnosis 1 No response
Did you agree with the diagnosis?	9 Yes 2 No strong opinion 2 No – expected a different diagnosis

Were you given the opportunity to discuss your feelings about the diagnosis?	13 Yes 1 No response
Was the diagnosis explained properly?	11 Yes 2 No 1 No response
Do you think the report from the clinic was useful?	12 Yes 1 No 1 No response
Were you given information about useful resources?	8 Yes 3 No 1 Don't remember 2 No response
Were you told or given information about local voluntary organisations, social support networks, self-help groups and other national services relevant to your child's diagnosis?	6 Yes 5 No 2 Don't remember 1 No response
Have you been able to access these resources?	7 Yes 2 No 5 No response
Which ones:	4 National Autistic Society 1 Internet 1 Google
<b><u>Satisfaction with the assessment process</u></b>	
How would you rate the service you and your child received from the clinic?	3 Excellent 3 Very good 2 Good

	<p>2 Satisfactory</p> <p>2 Not satisfactory</p> <p>2 No response</p>
<p>Would an information leaflet have been helpful before attending the clinic?</p>	<p>5 Yes</p> <p>5 No</p> <p>3 Not sure</p> <p>1 No response</p>
<p>If yes, what sort of information would you have liked to have known about before attending?</p>	<p>3 Why you are attending a NDC</p> <p>5 What will happen at the clinic</p> <p>3 How long the assessment process will take</p> <p>3 Who you will be seeing in the clinic</p> <p>2 What the different outcomes might be</p> <p>2 How the outcome will be fed back to you</p> <p>2 What happens after the assessment process</p> <p>1 Timescales</p>

## Appendix G Calculation of Reliable Change Index (from Jacobson & Truax, 1991)

Let  $X_1$  = Pretest score;  $X_2$  = Posttest Score;  $r_{xx}$  = Test-retest reliability of measure;  $S_{\text{diff}}$  = standard error of difference between the two test scores;  $S_E$  = standard error of measurement;

Reliable change index (RC) is calculated by the following equation:

$$RC = \frac{X_2 - X_1}{S_{\text{diff}}}$$

Where  $S_{\text{diff}} = \sqrt{2(S_E)^2}$

And  $S_E = S_x \sqrt{(1-r_{xx})}$

An RC larger than 1.96 would be unlikely to occur ( $p < .05$ ) without actual change. When RC exceeds this level the individual can be classified as reliably changed.

The Health Anxiety Inventory has a test-retest reliability of 0.76. The standard deviation of SHAI scores in the HiHA group was 3.04. Using the above formulae,  $SE = 1.49$  and  $S_{\text{diff}} = 2.11$ .

For Patient 2  $RC = (25 - 16) / 2.11 = 4.26$

Patient 3  $RC = (18 - 9) / 2.11 = 4.26$

Patient 4  $RC = (18 - 8) / 2.11 = 4.74$

All values are above the cut-off of 1.96 and represent large and significant change ( $p < .05$ ).

## **Appendix H The International Journal of Cognitive Therapy: Instructions to Authors**

The International Journal of Cognitive Therapy is the official journal of the International Association for Cognitive Psychotherapy (IACP), a professional, scientific, interdisciplinary organization whose mission is to facilitate the utilization and growth of cognitive therapy as a professional activity and scientific discipline. The journal is devoted to advancing all scientific and clinical aspects of cognitive therapy, including rigorous research on cognitive factors and vulnerabilities in psychological disorders, mediating processes in treatment outcome, cognitive assessment and treatment, expert perspectives on specific clinical problems and populations, and critical issues in translating research to practice. We welcome articles of the following types:

1. Empirical research studies of cognitive clinical theories and applications
2. Theoretical papers and particularly innovative contributions to theory or extensions of current theory
3. Systematic case studies that either extend the current base of knowledge about applications of treatments to new clinical problems or that describe new interventions
4. Reports on new treatment manuals that describe their procedures and contributions in relation to previous ones
5. Literature reviews and meta-analyses
6. Special thematic issues

All submissions must be made electronically at <http://ijct.msubmit.net>. Only original articles will be considered. Submissions must be double-spaced. Authors should include an abstract of fewer than 150 words and must prepare manuscripts according to the format and style rules set forth in the publication manual of the American Psychological Association. Blind reviews are optional. If authors desire a blind review they should



request this in the submission letter. For blind reviews, only a separate coverage page should contain identifying information about the authors and their affiliations.

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#### Sample References

Davis, C. G., & McKearney, J. M. (2003). How do people grow from their experience with trauma or loss? *Journal of Social & Clinical Psychology, 22*(5), 477-492.

Dweck, C., & Wortman, C. (1982). Learned helplessness, anxiety and achievement. In H. Kron & L. Laux (Eds.), *Achievement, stress, and anxiety* (pp. 93-125). Washington, DC: Hemisphere Publishing Group.

Roelofs, J., Meesters, C., Ter Huurne, M., Bamelis, L., & Muris, P. (2006). On the links between attachment style, parental rearing behaviors, and internalizing and externalizing problems in nonclinical children. *Journal of Child and Family Studies, 15*, 331-344.

## Appendix I Child and Adolescent Mental Health: Instructions to Authors

### Why submit to *Child and Adolescent Mental Health*?

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The journal encourages pre-submission enquiries, which may be sent via the Managing Editor at [camh@acamh.org.uk](mailto:camh@acamh.org.uk)

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**Measurement Issues:** These are commissioned review papers that aim to evaluate evidence-based measurement issues in child mental health disorders and services.

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## Appendix J Behavior Research and Therapy: Instructions to Authors

### INTRODUCTION

*Behaviour Research and Therapy* encompasses all of what is commonly referred to as cognitive behaviour therapy (CBT). The focus is on the following: theoretical and experimental analyses of psychopathological processes with direct implications for prevention and treatment; the development and evaluation of empirically-supported interventions; predictors, moderators and mechanisms of behaviour change; and dissemination and implementation of evidence-based treatments to general clinical practice. In addition to traditional clinical disorders, the scope of the journal also includes behavioural medicine. The journal will not consider manuscripts dealing primarily with measurement, psychometric analyses, and personality assessment.

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## Appendix K NHS Research Ethics Committee Opinion



NRES Committee South Central - Oxford C

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Telephone: 01173 421383  
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12 November 2013

Dr Neil Carrigan  
Clinical Psychologist in Training  
Taunton & Somerset NHS Foundation Trust  
6 West, Department of Psychology (Clinical)  
University of Bath  
Bath  
BA2 7AY

Dear Dr Carrigan

**Study title:** The development of a targeted CBT intervention for health anxiety in recently diagnosed patients with Multiple Sclerosis: a replication and brief case series  
**REC reference:** 13/SC/0547  
**Protocol number:** N/A  
**IRAS project ID:** 130410

Thank you for your letter of 11<sup>th</sup> November 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 11<sup>th</sup> November 2013

### Documents received

The documents received were as follows:

Document	Version	Date
Participant Consent Form: Treatment Phase	2	11 November 2013
Participant Consent Form: Assessment Phase	3	11 November 2013
Participant Information Sheet: Treatment Phase	2	11 November 2013
Participant Information Sheet: Assessment Phase	3	11 November 2013

### Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity		01 August 2013
GP/Consultant Information Sheets	1	12 September 2013
Investigator CV		12 September 2013
Letter of invitation to participant	1	12 September 2013
Other: Summary CV for supervisor		12 September 2013
Participant Consent Form: Treatment Phase	2	11 November 2013
Participant Consent Form: Assessment Phase	3	11 November 2013
Participant Information Sheet: Treatment Phase	2	11 November 2013
Participant Information Sheet: Assessment Phase	3	11 November 2013
Protocol		12 September 2013
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Questionnaire: Q of L index: Multiple Sclerosis version III		
Questionnaire: Guy's Neurological Disability Scale		
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Summary/Synopsis	1	12 September 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>13/SC/0547</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

Yours sincerely



**Lauren Allen**  
**REC Manager**

E-mail: [nrescommittee.southcentral-oxfordc@nhs.net](mailto:nrescommittee.southcentral-oxfordc@nhs.net)

Copy to: *Prof Paul Salkovskis,*  
*Dr Neil Simpson, Sirona Care & Health*

## Appendix L Main Project: Participant Information Sheet – Study 1



Department of  
Psychology



### PARTICIPANT INFORMATION SHEET – ASSESSMENT PHASE

#### Effects of health anxiety in recently diagnosed Multiple Sclerosis

Chief Investigator: Dr Neil Carrigan      Supervisors:      Prof Paul Salkovskis, Dr Jo Daniels &  
Dr Leon Dysch

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.** We suggest this should take about 15 minutes.

Talk to others about the study if you wish. (**Part 1** tells you the purpose of this study and what will happen to you if you take part. **Part 2** gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear.

#### **Part 1:**

##### **What is the purpose of the study?**

I am a Clinical Psychologist in Training at the Department of Psychology, University of Bath. I am interested in the effect of anxiety on the quality of life of people recently diagnosed with MS. This research project wants to look at the effects of anxiety on physical and mental ability as well as how patients think they do on these tasks. We will also measure quality of life. This will tell us whether anxiety is affecting these abilities and its impact on patients' lives. This will hopefully point the way to better treatment for patients with MS who also suffer from anxiety.

**Why have I been invited?**

You have been invited because you have recently been diagnosed with relapsing and remitting MS. There will be 24 people in total taking part in the study.

**Do I have to take part?**

It is up to you to decide to join the study. If you decide to take part your health care professional will pass your details to the research team. We will then contact you, describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

**What will happen to me if I take part?**

We will invite you to an appointment with the researcher. There you will be asked to fill out some questionnaires about:

- Quality of life
- How anxious you are about your health
- Your physical disability due to MS.

Following the questionnaires we will take a measure of physical strength using what is called a hand grip dynamometer. This requires you to grip a lever and hold it while a measure is taken on a dial. Then we will complete a short task that measures how good your memory is, how quickly you can think and make decisions.

In total the session should take no more than 1 hour.

Following the testing session we will discuss the results with you and explain what they mean. We hope you will find the results personally interesting. If you are anxious about your health we will discuss with you the options for treatment and provide a separate information sheet to help you decide what you would like to do.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

**Part 2:**

**What will happen if I don't want to carry on with the study?**

You are free to withdraw from the study at any time and your data will then not be used in the study.

Once you have completed the study all identifiable data will be destroyed but we will retain the anonymised data. In the unlikely event that you lose the capacity to make decisions following participation in the study we will still retain the anonymised data for analysis.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (details at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this (eg NHS Complaints Procedure). Details can be obtained from the Chief Investigator.

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Bath but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**Will my taking part in this study be kept confidential?**

The paper copies of the questionnaires and physical/mental ability tasks will be shredded once they have been entered onto the secure NHS computers. Your data it will then be anonymised with access only to the researcher and the research team. We will keep this anonymous data for a period of 4 years before being disposed of securely.

### **What will happen to the results of the research study?**

Following the testing session we will discuss the results with you individually. Once we have analysed the data from all participants we will send you a summary of the main findings. This summary data may be used in publications arising from the research. None of the data used in these publications will be identifiable as you.

### **Who is funding this research?**

The research is being funded as part of the researcher's Professional Doctorate in Clinical Psychology at the University of Bath.

### **Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Oxford C Research Ethics Committee.

### **Further Information and Contact Details**

Further information about taking part in NHS research can be found on the Multiple Sclerosis Trust website here:

<http://www.mstrust.org.uk/research/gettinginvolved/clinicalstudies/patientresearch.jsp>

If you would like to speak to me further about this specific research my contact details are:

Researcher: Dr. Neil Carrigan Telephone: 0781 587 0088  
email: neil.carrigan@nhs.net

Address: Clinical Psychology, 6 West  
Department of Psychology  
University of Bath  
Bath  
BA2 7AY



## Appendix M Main Project: Consent Form



Department of  
Psychology



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Patient Identification Number:

---

### CONSENT FORM – ASSESSMENT PHASE

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Title of Project: **Effects of health anxiety in recently diagnosed Multiple Sclerosis**

Name of Researcher: **Dr Neil Carrigan**

Please initial all boxes

1. I confirm that I have read and understand the patient information sheet (assessment phase) dated 11/11/2013 (version3) 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 data collected during the study, may be looked at by individuals from University of Bath, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.
  
4. I agree that once I have completed the study, if I lose the capacity of consent, that my data will be retained by the researchers for analysis in an anonymised form
  
5. I agree to my GP being informed of my participation in the study.
  
6. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person  
taking consent.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

**Appendix N Main Project: Perception of Performance Measures**



Department of  
Psychology



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**BATH**

**Perception of Performance**

**Compared to others with a similar condition to you, how well do you feel you performed on hand grip task? (Please tick)**

Extremely badly in comparison to others											Extremely well in comparison to others
-50	-40	-30	-20	-10	0	+10	+20	+30	+40	+50	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Compared to others with a similar condition to you, how well do you feel you performed on cognitive tasks? (Please tick)**

Extremely badly in comparison to others											Extremely well in comparison to others
-50	-40	-30	-20	-10	0	+10	+20	+30	+40	+50	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**How worried were you about your performance on these tasks? (Please tick)**

Not at all worried											Extremely worried
0	10	20	30	40	50	60	70	80	90	100	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**How much better would you have performed on the tasks if you did not have MS? (Please tick)**

Not better											Very much better
0	10	20	30	40	50	60	70	80	90	100	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Appendix O Data Specification for additional questions the Trust's ASD lead wanted answers for**

**Total no of referrals**  
**Dec 2011 - Dec 2012**

	<b><u>No.</u></b>	<b><u>(%)</u></b>		<b><u>No.</u></b>	<b><u>(%)</u></b>
Sex of referrals	Male			Female	
Age Range (%)	<b><u>Under</u></b> <b><u>5</u></b>	<b><u>5-7 yr</u></b> <b><u>old</u></b>	<b><u>8-10 yr</u></b> <b><u>old</u></b>	<b><u>11-15yr</u></b> <b><u>old</u></b>	<b><u>16- 18</u></b> <b><u>yr old</u></b>
Swindon /Wiltshire (%)	Swindon =	%	Wiltshire =	%	
Profession of Referrer					
Average Time from referral to 1st appointment (weeks)	Range		9 days - 6 months	6 cases >3 months	
DNAs (%)					
<b><u>Outcome of 1st appointment (%)</u></b>					
	Diagnosis				
	Further assessment				
	Withdrew				
<b><u>Type of further assessment (%)</u></b>					
Cognitive	WISC				
	TEAcH				
	WISC & TEAcH				
School	Obs				
	Discussion				
Emotional	One-to-one				
	Self-report				
	Self-report & 1:1				
Conners'	Parent rated				
	Teacher rated				
	Self-rated				
No. Of appointments	Average				
	Range				

Time to diagnosis  
(weeks)

Average  
Range

Consider 5 longest for  
reasons

<b><u>Diagnosis (%)</u></b>	<u>Total</u>	<u>Male</u>	<u>Female</u>	<u>Under 5</u>	<u>5-7 yr old</u>	<u>8-10 yr old</u>	<u>11-15yr old</u>	<u>16- 18 yr old</u>
ASD								
ADHD								
Attachment								
Social communication								
ODD								
Other								
None								
Medications prescribed								
Destination following diagnosis								
CAMHS								
Day Unit								
LD etc								
Percentage with ADHD having parenting intervention								
% with LD								
% having Ed psych input								

## Appendix P Main Project: Participant Information Sheet – Study 2



Department of  
Psychology



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**BATH**

### PARTICIPANT INFORMATION SHEET – TREATMENT PHASE

#### Effects of health anxiety in recently diagnosed Multiple Sclerosis

Chief Investigator: Dr Neil Carrigan      Supervisors: Prof Paul Salkovskis, Dr Jo Daniels &  
Dr Leon Dysch

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.** We suggest this should take about 15 minutes.

Talk to others about the study if you wish. (**Part 1** tells you the purpose of this study and what will happen to you if you take part. **Part 2** gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear.

## **Part 1:**

### **What is the purpose of the study?**

I am a Clinical Psychologist in Training at the Department of Psychology, University of Bath. I am interested in the effect of anxiety on the quality of life of people recently diagnosed with MS. This research project wants to look at the effects of anxiety on physical and mental ability as well as on how patients think they do on these tasks. We will also measure quality of life. This will tell us whether anxiety is affecting these abilities and its impact on their lives. If anxiety is affecting the patients in this way, then treating it with psychological therapy might improve the patients' overall quality of life. This part of the study will assess how effective the psychological therapy is in doing this.

### **Why have I been invited?**

You have been invited because you recently took part in the earlier assessment phase of this study. At that point we discussed with you that your scores on the Health Anxiety Inventory questionnaire suggest you may be anxious about your health. Because you appear anxious about your health we would like to see if treating your anxiety with psychological therapy is helpful.

### **Do I have to take part?**

It is up to you to decide to join the study. We will describe the study and go through this information sheet. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

### **What will happen to me if I take part?**

If you continue in the study you will be offered up to 6 one hour sessions of psychological therapy: cognitive behaviour therapy (CBT)). This is an evidence-based treatment that has been approved by NICE (National Institute for Health and Care Excellence) for the treatment of anxiety. Every week we will ask you to complete a short set of questionnaires about your mood and level of anxiety to monitor how treatment is progressing.

The researcher will explore with you how your thoughts and the things you are doing are affecting your mood and your anxiety about your health. The researcher will work with you to explore making changes in these areas that will hopefully help you feel less anxious.

Some of these sessions will be recorded (either audio or video) to help the researcher, in discussions with his supervisor, ensure the best treatment is being delivered to you. The recordings will not be used for any other purpose. Once treatment has finished the recordings of your treatment will be destroyed. Between sessions you may be asked to complete tasks to help with your treatment and complete measures of your mood and anxiety.

When these sessions have finished we will contact you again in 3 months for a session with the researcher to see how you are doing and for you to complete a further set of questionnaires.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

**Part 2:**

**What will happen if I don't want to carry on with the study?**

You are free to withdraw from the study at any time and your data will then not be used in the study. You can then discuss with your care coordinator what treatment is most appropriate to continue with, if any. Withdrawing from the study will not affect the availability of the standard care offered to you.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (details at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this (e.g., NHS Complaints Procedure). Details can be obtained from the Chief Investigator.

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Bath but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**Will my taking part in this study be kept confidential?**

All the data recorded as part of your treatment will be kept confidential. Only your direct care team will be aware that you are taking part in the study

It is standard practice to inform your GP of any treatment you are receiving as part of your care.

**What will happen to the results of the research study?**

The data you provided from the testing session and during therapy will be discussed with you individually. Once we have analysed the data from all participants we will send you a summary of the main findings. This summary data may be used in publications arising from the research. None of the data used in these publications will be identifiable as you.

**Who is funding this research?**

The research is being funded as part of the researcher's Professional Doctorate in Clinical Psychology at the University of Bath.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Oxford C Research Ethics Committee.



## **Further Information and Contact Details**

Further information about taking part in NHS research can be found on the Multiple Sclerosis Trust website here:

<http://www.mstrust.org.uk/research/gettinginvolved/clinicalstudies/patientresearch.jsp>

If you would like to speak to me further about this specific research my contact details are:

Researcher: Dr. Neil Carrigan Telephone: 0781 587 0088  
email: neil.carrigan@nhs.net

Address: Clinical Psychology, 6 West  
Department of Psychology  
University of Bath  
Bath  
BA2 7AY

## Appendix Q Short Health Anxiety Inventory adapted for MS patients

Short Month

Ass/Wk/Sess:

—

### HAI

Each question in this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, OVER THE PAST SIX MONTHS. Identify the statement by ringing the letter next to it i.e., if you think statement (a) is correct, ring statement (a); it may be that more than one statement applies, in which case, please ring any that are applicable.

- 1      (a)    I do not worry about my health  
         (b)    I occasionally worry about my health  
         (c)    I spend much of my time worrying about my health  
         (d)    I spend most of my time worrying about my health
  
- 2      (a)    I notice aches/pains less than other people (of my age)  
         (b)    I notice aches/pains as much as most other people (of my age)  
         (c)    I notice aches/pains more than most other people (of my age)  
         (d)    I am aware of aches/pains in my body all the time
  
- 3      (a)    As a rule I am not aware of bodily sensations or changes  
         (b)    Sometimes I am aware of bodily sensations or changes  
         (c)    I am often aware of bodily sensations or changes  
         (d)    I am constantly aware of bodily sensations or changes
  
- 4      (a)    Resisting thoughts of illness is never a problem

- (b) Most of the time I can resist thoughts of illness
  - (c) I try to resist thoughts of illness but I am often unable to
  - (d) Thoughts of illness are so strong that I no longer even try to resist them
- 5
- (a) As a rule I am not afraid that I have a serious illness [other than MS]
  - (b) I am sometimes afraid that I have a serious illness [other than MS]
  - (c) I am often afraid that I have a serious illness [other than MS]
  - (d) I am always afraid that I have a serious illness [other than MS]
- 6
- (a) I do not have images (mental pictures) of myself being ill
  - (b) I occasionally have images of myself being ill
  - (c) I frequently have images of myself being ill
  - (d) I constantly have images of myself being ill
- 7
- (a) I do not have any difficulty taking my mind off thoughts about my health
  - (b) I sometimes have difficulty taking my mind off thoughts about my health
  - (c) I often have difficulty taking my mind off thoughts about my health
  - (d) Nothing can take my mind off thoughts about my health
- 8
- (a) I am lastingly relieved if my doctor tells me there is nothing wrong
  - (b) I am initially relieved but worries sometimes return later
  - (c) I am initially relieved but the worries always return later
  - (d) I am not relieved if my doctor tells me there is nothing wrong

- 9 (a) If I hear about an illness, other than MS, I never think I have it myself
- (b) If I hear about an illness, other than MS, I sometimes think I have it myself
- (c) If I hear about an illness, other than MS, I often think I have it myself
- (d) If I hear about an illness, other than MS, I always think I have it myself
- 10 (a) If I have a bodily sensation or change I rarely wonder what it means
- (b) If I have a bodily sensation or change I often wonder what it means
- (c) If I have a bodily sensation or change I always wonder what it means
- (d) If I have a bodily sensation or change I must know what it means
- 11 (a) I usually feel at very low risk for developing a serious illness [other than MS]
- (b) I usually feel at fairly low risk of developing a serious illness [other than MS]
- (c) I usually feel at moderate risk for developing a serious illness [other than MS]
- (d) I usually feel at high risk of developing a serious illness [other than MS]
- 12 (a) I never think I have a serious illness, other than MS
- (b) I sometimes think I have a serious illness, other than MS
- (c) I often think I have a serious illness, other than MS
- (d) I usually think that I am seriously ill with something other than MS

- 13 (a) If I notice an unexplained bodily sensation I never do anything to try and get rid of it
- (b) If I notice an unexplained bodily sensation I sometimes try to get rid of it
- (c) If I notice an unexplained bodily sensation I often try to get rid of it
- (d) If I notice an unexplained bodily sensation I always try to get rid of it
- 14 (a) My family/friends would say I do not worry enough about my health
- (b) My family/friends would say I have a normal attitude to my health
- (c) My family/friends would say I worry too much about my health
- (d) My family/friends would say I am a hypochondriac

**Appendix R Patient health questionnaire (PHQ9)**

Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems? <i>(Use “✓” to indicate your answer”</i>	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

**Column totals**      \_\_\_ +    \_\_\_ +    \_\_\_ +    \_\_\_

= **Total Score** \_\_\_\_\_

## Appendix S Guy's Neurological Disability Scale

### *Guy's Neurological Disability Scale*

#### *Instructions*

The scale is designed to assess disability in patients with multiple sclerosis. It has 12 separate categories each with an interview and scoring section. The total GNDS score is the sum of the 12 separate scores. The questions are directed to assess the disability in the previous one month.

#### *1. Cognitive disability:*

##### A. Interview:

Do you have any problems with your memory or your ability to concentrate and work things out?

yes       no

Do your family or friends think that you have such a problem?

yes       no

*If the answer to either question is 'yes':*

Do you need help from other people for planning your normal daily affairs, handling money or making decisions?

yes       no

*If 'yes': (To the examiner)*

Is the patient orientated in time, place and person?

yes, fully  
 yes, partially\*  
 no, totally disorientated\*

\*If the patient is not fully orientated, all their answers should be verified by the main carer(s) whose answers should take precedence.

##### B. Scoring:

0—No cognitive problems.

1—Cognitive problems not noticeable to family or friends.

2—Cognitive problems noticeable to family or friends but not requiring help from others.

3—Cognitive problems requiring help from others for normal daily affairs; patient is fully orientated in time, place and person.

4—Cognitive problems requiring help from others for normal daily affairs; patient is not fully orientated.

5—Patient is completely disorientated in time, place and person.

2. *Mood disability:*

A. Interview:

Have you been feeling anxious, irritable, depressed, or had any mood swings during the last month?

yes  no

Are you taking any medications for such problem

yes  no

*If the answer to the first question is 'yes':*

Has the problem affected your ability to do *any* of your usual daily activities such as work, housework, or normal social activity with family and friends?

yes  no

*If 'yes':*

Has this problem been severe enough to prevent you from doing *all* your usual activities?

yes  no

Have you been admitted to hospital for treatment of your mood problem during the last month?

yes  no

B. Scoring:

- 0—No mood problems
- 1—Asymptomatic on current drug treatment.
- 2—Mood problems present but not affecting the patient's ability to perform any of their usual daily activities.
- 3—Mood problems affecting the patient's ability to perform some of their usual daily activities.
- 4—Mood problems preventing the patients from doing all their usual daily activities.
- 5—Mood problems requiring inpatient management.
- X—Unknown (please score as the mean of the cognitive and fatigue disability scores rounded the nearest integer).

3. *Visual disability:*

A. Interview:

Do you have any problems with your vision that can't be corrected with ordinary glasses?

yes  no

*If 'yes':*

Can you read ordinary newspaper print (with ordinary glasses if worn, but not magnifying lenses)?

yes  no

*If 'no':*

Can you read large newspaper print?

yes  no

*If 'no':*

Can you count your fingers if you hold your hand out in front of you?

yes  no

*If 'no':*

Can you see your hand if you move it in front of you?

yes  no

B. Scoring:

- 0—No visual problems.
- 1—Visual problems (blurred vision, diplopia, scotomas) but patient is still able to read ordinary newspaper print.
- 2—Unable to read ordinary newspaper print.
- 3—Unable to read large newspaper print.
- 4—Unable to count fingers if they hold their hand out in front of them.
- 5—Unable to see hand movement if they move their hand in front of them.



4. *Speech and communication disability:*

A. Interview:

Do you have any problems with your speech?  
 yes       no

*If 'yes':*

Do you have to repeat yourself when speaking to your family or close friends?  
 yes       no

*If 'yes':*

Do you need to use sign language, or the help of your carer to make people understand you?  
 yes       no

*If 'yes': (to the examiner)*

Is the patient able to communicate effectively using these methods?  
 yes       no

B. Scoring:

- 0—No speech problems.
- 1—Speech problems which does not require the patient to repeat themselves when speaking to strangers.
- 2—Speech problems which require the patient to repeat themselves when speaking to strangers.
- 3—Speech problems which require the patient to repeat themselves when speaking to their family and close friends.
- 4—Speech problems making speech difficult to understand; patient is able to communicate effectively by using sign language or the help of their carers.
- 5—Speech problems making speech difficult to understand, patient is unable to communicate effectively by using sign language or the help of their carers.

5. *Swallowing disability:*

A. Interview:

Do you have to take care when swallowing solids or fluids?  
 yes       no

*If 'yes':*

Do you have to take care when swallowing with most meals?  
 yes       no

*If 'yes':*

Do you need a special diet such as soft or liquidated food to help with your swallowing?  
 yes       no

*If 'yes':*

Do you choke with most meals?  
 yes       no

*If 'yes':*

Do you have a feeding tube (nasogastric or gastrostomy tube)?  
 yes       no

B. Scoring:

- 0—No swallowing problems.
- 1—Needs to be careful when swallowing solids or liquids but not with most meals.
- 2—Needs to be careful when swallowing solids or liquids with most meals; patient is able to eat food of normal consistency.
- 3—Needs specially prepared food of modified consistency.
- 4—Tendency to choke with most meals.
- 5—Dysphagia requiring nasogastric or gastrostomy tube.

6. Upper limb disability:

A. Interview:

Do you have any problems with your hands or arms?  
 yes  no

If 'yes':

Do you have any difficulty in doing any of your zips or buttons?  
 yes  no

If 'yes':

Are you able to do *all* of your zips *and* buttons without help?  
 yes  no

Do you have any difficulty in tying a bow in laces or strings?  
 yes  no

If 'yes':

Are you able to tie a bow in laces or strings without help?  
 yes  no

Do you have any difficulty washing *and* brushing your hair?  
 yes  no

If 'yes':

Are you able to wash *and* brush your hair without help?  
 yes  no

Do you have any difficulty feeding yourself?  
 yes  no

If 'yes':

Are you able to feed yourself without help?  
 yes  no

If *unable to do any of the functions listed*:

Can you use your hands or arms for any other function?  
 yes  no

B. Scoring

- 0—No upper limb problem.
- 1—Problems in one or both arms, not affecting the ability to do any of the functions listed.
- 2—Problems in one or both arms, affecting some but not preventing any of the functions listed.
- 3—Problems in one or both arms, affecting all or preventing one or two of the functions listed.
- 4—Problems in one or both arms preventing three or all of the functions listed.
- 5—Unable to use either arm for any purposeful movements.

7. Lower limb disability:

A. Interview:

Do you have any problems with your walking?  
 yes  no

If 'yes':

Do you use a walking aid?  
 yes  no

If 'yes':

- A. How do you *usually* get around outdoors?
- without aid
  - or  with one stick or crutch *or* holding on to someone's arm
  - or  with two sticks or crutches *or* one stick or crutch and holding on to someone's arm
  - or  with a wheelchair

B. How do you *usually* get around indoors?

- without aid
- or  with one stick or crutch *or* holding on to someone's arm
- or  with two sticks or crutches *or* one stick or crutch and holding on to someone's arm
- or  with a wheelchair

If you use a wheelchair:

Can you stand and walk a few steps with help?  
 yes  no

B. Scoring

- 0—Walking is not affected.
- 1—Walking is affected but patient is able to walk independently.
- 2—Usually uses unilateral support (single stick or crutch, one arm) to walk outdoors, but walks independently indoors.
- 3—Usually uses bilateral support (two sticks or crutches, frame, or two arms) to walk outdoors, *or* unilateral support (single stick or crutch, or one arm) to walk indoors.
- 4—Usually uses wheelchair to travel outdoors, *or* bilateral support (two sticks or crutches, frame, or two arms) to walk indoors.
- 5—Usually uses a wheelchair indoors.

8. Bladder disability

A. Interview:

Do you have any problems with your bladder?  
 yes  no

Are you taking any medications for such problems?  
 yes  no

*If the answer to the first question is 'yes':*  
Do you have to rush to the toilet, go frequently, or have difficulty in starting to pass urine?  
 yes  no

Have you been incontinent in the last month?  
 yes  no

*If 'yes':*  
Have you been incontinent in the last week?  
 yes  no

*If 'yes':*  
Have you been incontinent every day?  
 yes  no

Do you use a catheter to empty your bladder?  
 yes  no

Do you need a permanent catheter in the bladder, or (*for men only*) do you use a sheath to collect your urine?  
 yes  no

B. Scoring:

- 0—Normal bladder problems.
- 1—Asymptomatic on current drug treatment.
- 2—Urinary frequency, urgency, or hesitancy with no incontinence.
- 3—Occasional urinary incontinence (once or more during the last month but not every week).  
or intermittent catheterisation without incontinence.
- 4—Frequent urinary incontinence (once a week or more during the last month but not daily).  
or occasional urinary incontinence despite regular intermittent catheterisation.
- 5—Daily urinary incontinence or permanent catheter (urethral/suprapubic) or penile sheath.

9. Bowel disability:

A. Interview:

Do you have any problems with your bowel movements?  
 yes  no

Are you on any medicines for such problems?  
 yes  no

*If the answer to the first question is 'yes':*  
Do you suffer with constipation?  
 yes  no

*If 'yes':*  
Do you need to take any laxatives or use suppositories for this?  
 yes  no

Do you usually use enemas?  
 yes  no

Do you usually evacuate your stools manually?  
 yes  no

Do you have to rush to the toilet to open your bowels?  
 yes  no

Have you had bowel accidents (been incontinent of faeces) in the last week?  
 yes  no

*If 'yes':*  
Have you had bowel accidents every week?  
 yes  no

B. Scoring:

- 0—No bowel problems.
- 1—Asymptomatic on current drug treatment or constipation not requiring any treatment.
- 2—Constipation requiring laxatives or suppositories or faecal urgency.
- 3—Constipation requiring the use of enemas.
- 4—Constipation requiring manual evacuation of stools or occasional faecal incontinence (once or more during the last month but not every week).
- 5—Weekly faecal incontinence.

10. Sexual disabilities:

A. Interview:

The next set of questions relates to sexual function. Do you mind if I ask you about this?

- yes  
 no  
 not applicable (Celibate)

*If the patient agrees:*

Do you have any problems in relation to your sexual function?

- yes  no

*If 'yes':*

Do you suffer with lack of sexual interest?

- yes  no

Do you have any problems satisfying yourself or your sexual partner?

- yes  no

Is your sexual function affected by any physical problem such as altered genital sensation, pain, or spasms?

- yes  no

Do you have any problems with:

(for men): erection/ejaculation?  
(for women): vaginal lubrication  
/orgasm?

- yes  no

*If physical or sexual problems are present:*

Do any of these difficulties totally prevent your sexual activities?

- yes  no

B. Scoring:

- 0—Normal sexual functions or persons who are voluntarily celibate.  
1—Reduced sexual interest.  
2—Problems satisfying oneself or sexual partner.  
3—Physical problems interfering but not preventing sexual function.  
4—Autonomic problems interfering but not preventing sexual function.  
5—Physical or autonomic problems totally preventing sexual function.  
X—Unknown (please score as the mean of the lower limb, bladder, and bowel disability scores rounded to the nearest integer).

11. Fatigue:

A. Interview:

Have you been feeling tired or getting tired easily during the last month?

- yes  no

*If 'yes':*

Have you been feeling tired most days?

- yes  no

Has this tiredness affected your ability to do any of your usual activities such as work, housework, or normal social activity with family and friends?

- yes  no

*If 'yes':*

Has this tiredness been severe enough to prevent you from doing all of your usual activities?

- yes  no

*If 'yes':*

Has the tiredness been severe enough to prevent you from doing all physical activities?

- yes  no

B. Scoring:

- 0—Absent  
1—Occasional fatigue (present some days).  
2—Frequent fatigue (present most days).  
3—Fatigue affecting the patient's ability to perform some of their usual daily activities.  
4—Fatigue preventing the patient from doing all their usual daily activities.  
5—Fatigue preventing the patient from doing all their physical activities.  
X—Unknown (please score as the mean of the cognitive and mood disability scores rounded to the nearest integer).

12. *Other disabilities:*

A. Interview:

Do you have other problems due to MS such as pain, spasms, or dizziness which have not been mentioned so far?

yes                       no

Are you taking any medicines for such problems?

yes                       no

*If the answer to either question is 'yes':*

Please name your worst problem: .....

Has this problem affected your ability to do *any* of your usual daily activities?

yes                       no

Has this problem been severe enough to prevent you from doing *all* your usual daily activities?

yes                       no

Have you been admitted to hospital for treatment of this problem?

yes                       no

B. Scoring:

0 – Absent.

1 – Asymptomatic on current drug treatment.

2 – Problems, present, but are not affecting the patient's ability to perform any of their usual daily activities.

3 – Problems affecting the patient's ability to perform some of their usual daily activities.

4 – Problems preventing the patient from doing all their usual daily activities.

5 – Problems requiring hospital admission for assessment or treatment.

## Appendix T Quality of Life Index

### Ferrans and Powers QUALITY OF LIFE INDEX® MULTIPLE SCLEROSIS VERSION III

**PART 1.** For each of the following, please choose the answer that best describes how *satisfied* you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

<b>HOW SATISFIED ARE YOU WITH:</b>	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of pain that you have?	1	2	3	4	5	6
4. The amount of energy you have for everyday activities?	1	2	3	4	5	6
5. Your ability to take care of yourself without help?	1	2	3	4	5	6
6. Your ability to get around, go places?	1	2	3	4	5	6
7. Your ability to speak?	1	2	3	4	5	6
8. The amount of control you have over your life?	1	2	3	4	5	6
9. Your chances of living as long as you would like?	1	2	3	4	5	6
10. Your family's health?	1	2	3	4	5	6
11. Your children?	1	2	3	4	5	6
12. Your family's happiness?	1	2	3	4	5	6
13. Your sex life?	1	2	3	4	5	6
14. Your spouse, lover, or partner?	1	2	3	4	5	6
15. Your friends?	1	2	3	4	5	6
16. The emotional support you get from your family?	1	2	3	4	5	6
17. The emotional support you get from people other than your family?	1	2	3	4	5	6

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<b>HOW SATISFIED ARE YOU WITH:</b>	<b>Very Dissatisfied</b>	<b>Moderately Dissatisfied</b>	<b>Slightly Dissatisfied</b>	<b>Slightly Satisfied</b>	<b>Moderately Satisfied</b>	<b>Very Satisfied</b>
18. Your ability to take care of family responsibilities?	1	2	3	4	5	6
19. How useful you are to others?	1	2	3	4	5	6
20. The amount of worries in your life?	1	2	3	4	5	6
21. Your neighborhood?	1	2	3	4	5	6
22. Your home, apartment, or place where you live?	1	2	3	4	5	6
23. Your job (if employed)?	1	2	3	4	5	6
24. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
25. Your education?	1	2	3	4	5	6
26. How well you can take care of your financial needs?	1	2	3	4	5	6
27. The things you do for fun?	1	2	3	4	5	6
28. Your chances for a happy future?	1	2	3	4	5	6
29. Your peace of mind?	1	2	3	4	5	6
30. Your faith in God?	1	2	3	4	5	6
31. Your achievement of personal goals?	1	2	3	4	5	6
32. Your happiness in general?	1	2	3	4	5	6
33. Your life in general?	1	2	3	4	5	6
34. Your personal appearance?	1	2	3	4	5	6
35. Yourself in general?	1	2	3	4	5	6

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**PART 2.** For each of the following, please choose the answer that best describes how *important* that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

<b>HOW IMPORTANT TO YOU IS:</b>	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. Having no pain?	1	2	3	4	5	6
4. Having enough energy for everyday activities?	1	2	3	4	5	6
5. Taking care of yourself without help?	1	2	3	4	5	6
6. Your ability to get around, go places?	1	2	3	4	5	6
7. Your ability to speak?	1	2	3	4	5	6
8. The amount of control you have over your life?	1	2	3	4	5	6
9. Your chances of living as long as you would like?	1	2	3	4	5	6
10. Your family's health?	1	2	3	4	5	6
11. Your children?	1	2	3	4	5	6
12. Your family's happiness?	1	2	3	4	5	6
13. Your sex life?	1	2	3	4	5	6
14. Your spouse, lover, or partner?	1	2	3	4	5	6
15. Your friends?	1	2	3	4	5	6
16. The emotional support you get from your family?	1	2	3	4	5	6
17. The emotional support you get from people other than your family?	1	2	3	4	5	6

(Please Go To Next Page)



<b>HOW IMPORTANT TO YOU IS:</b>	<b>Very Unimportant</b>	<b>Moderately Unimportant</b>	<b>Slightly Unimportant</b>	<b>Slightly Important</b>	<b>Moderately Important</b>	<b>Very Important</b>
18. Taking care of family responsibilities?	1	2	3	4	5	6
19. Being useful to others?	1	2	3	4	5	6
20. Having no worries?	1	2	3	4	5	6
21. Your neighborhood?	1	2	3	4	5	6
22. Your home, apartment, or place where you live?	1	2	3	4	5	6
23. Your job (if employed)?	1	2	3	4	5	6
24. Having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
25. Your education?	1	2	3	4	5	6
26. Being able to take care of your financial needs?	1	2	3	4	5	6
27. Doing things for fun?	1	2	3	4	5	6
28. Having a happy future?	1	2	3	4	5	6
29. Peace of mind?	1	2	3	4	5	6
30. Your faith in God?	1	2	3	4	5	6
31. Achieving your personal goals?	1	2	3	4	5	6
32. Your happiness in general?	1	2	3	4	5	6
33. Being satisfied with life?	1	2	3	4	5	6
34. Your personal appearance?	1	2	3	4	5	6
35. Are you to yourself?	1	2	3	4	5	6