Psychological Adjustment in Physical Illness

Chloe Miranda Goble B.Sc. (Hons)

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DECLARATION

This thesis has not been submitted to any other University for any other degree.

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Psychological Adjustment to Multiple Sclerosis

Abstract

Aims: Patients with Multiple Sclerosis (MS) experience higher rates of emotional disorders than comparison groups with similar levels of disability. More information is needed regarding the differences between individual reactions to conditions such as MS. The present study examined the extent to which the theory of cognitive adaptation (TCA) can explain variance in psychological adjustment among patients with MS.

Method: At time 1, 112 participants with MS completed measures of the TCA variables (i.e., meaning, mastery, self-enhancement and optimism), anxiety, depression and quality of life. Three months later, 94 participants completed measures of anxiety, depression and quality of life.

Results: Optimism explained significant amounts of variance in time 1 anxiety (ΔR^2 = .17), depression (ΔR^2 = .18) and mental well-being (ΔR^2 = .12), but failed to explain significant variance in time 2 adjustment. The situated TCA variables explained significant amounts of additional variance in time 1 anxiety (ΔR^2 = .16) and depression (ΔR^2 = .12) over and above optimism, but failed to explain significant variance in time 2 adjustment. Finally, the situated TCA variables mediated the effect of optimism on anxiety, depression and mental well-being at time 1 but not time 2.

Conclusions: Partial support was found for the TCA cross-sectionally but not prospectively. In addition, contrary to the TCA, benefit finding was found to be related to poorer psychological adjustment prospectively. Future research could investigate the role of benefit finding in adjustment to provide insight into the range of alternative explanations. The clinical implications of the study are considered.

Introduction

Multiple Sclerosis

Multiple Sclerosis (MS) is a chronic, progressive and degenerative disease, in which the body's natural defences attack the myelin sheath that surrounds nerve cells in the brain and spinal cord. The subsequent scarring blocks or delays the passage of nerve impulses and produces a unique range of symptoms for each individual. These symptoms can include: fatigue, bladder and bowel dysfunction, sexual dysfunction, pain, impaired mobility, paralysis, visual impairment, abnormal sensations and cognitive impairment (Pakenham, 2007). MS is the most common neurological condition experienced by young people in western societies and currently affects approximately 52,000 to 62,000 people in England and Wales (NICE, 2003).

Age of onset is between 20 and 50 years in 70% of cases and is 2.5 times more likely among women than men (NICE, 2003). Risk of onset is increased for individuals with a Caucasian European origin or a family history of MS (Royal College of Physicians, 2004). Most people with MS have a normal life expectancy although men have a worse prognosis than women usually experiencing higher levels of disability. The cost of MS is estimated to be 1.34 billion a year with informal care accounting for approximately 26% of this and the NHS spending approximately £3,400 a year on each patient (Kobelt et al., 2000). The psychosocial consequences of experiencing such severe multiple disabilities can be profound with individuals experiencing disruptions in their daily activity as well as family, social and occupational life (Pakenham, 2008).

The process of adjusting to MS is complicated by the experience of multiple disabilities and widespread psychosocial consequences. Research has found that individuals with MS exhibit a higher prevalence of emotional disorders than other patients with

comparable physical disability (Rao, Huber & Bornstein, 1992). Depression is experienced by approximately 27% to 47% of people with MS (Patten et al., 2003). Individuals with MS have also been found to experience high levels of anxiety, between 16% to 48% (Nicholl, Lincoln & Francis, 2001), and lower quality of life than community comparison groups (McCabe & McKern, 2002). However, not all individuals with MS experience negative psychological consequences. As a result, some research has tried to explore differences between individuals in their reactions to chronic illnesses such as MS in the hope of increasing our understanding of what factors may contribute to positive adjustment and better psychological well-being.

Theory of Cognitive Adaptation (TCA)

Taylor's (1983) theory of cognitive adaptation (TCA) proposes that positive adjustment to a health threat, such as MS, is related to an individual's ability to find meaning in the illness experience, regain mastery over the health threat and restore self-esteem. Thus, the TCA considers three themes when assessing individuals' reactions to a health threat; meaning, mastery and self-esteem. In particular, the TCA highlights the importance of forming positive beliefs in relation to these three themes, which is likely to be aided by having an optimistic outlook. Thus, according to the TCA, dispositional optimism is likely to help individuals form positive beliefs regarding meaning, mastery and self-esteem which, in turn, will be related to more positive adjustment (see Figure 1).

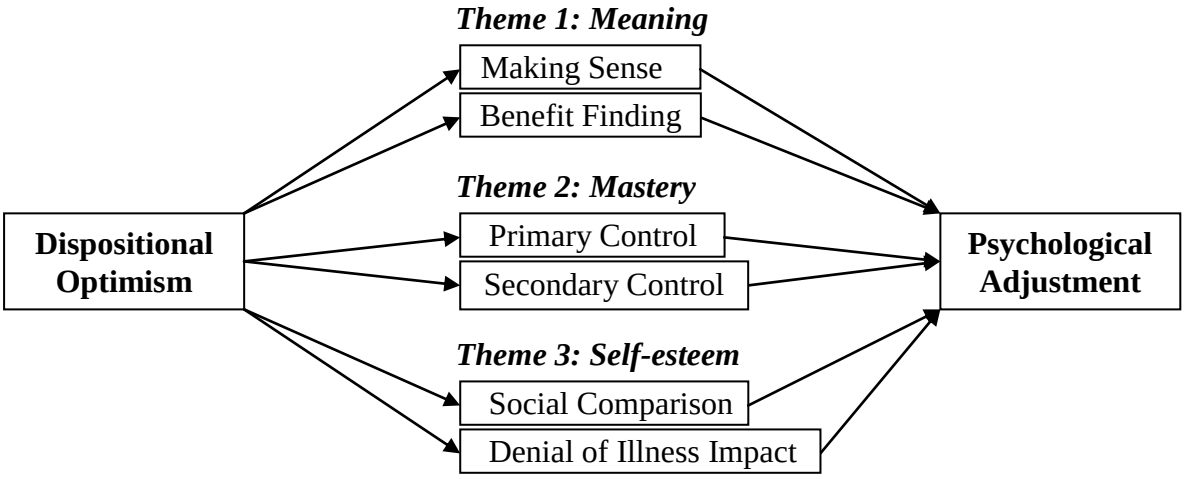

Figure 1. *Diagrammatic Representation of the Theory of Cognitive Adaptation (TCA).*

Meaning

The first theme, meaning, refers to efforts to understand what has happened. Taylor (1983) suggests that there are two pathways to finding meaning, which are making sense and benefit finding. The first pathway, making sense, refers to an individual's efforts to make sense of their situation by making causal attributions (Davis, Nolen-Hoeksema & Larson, 1998). The second pathway, benefit finding, refers to an individual's efforts to find benefits from their situation by positively reappraising their situation (Davis, Nolen-Hoeksema & Larson, 1998). Taylor (1983) proposes that higher levels of making sense and benefit finding will be related to better psychological adjustment.

Mastery

The second theme, mastery, refers to efforts to regain a sense of control over the health threat. Taylor (1983) suggest that there are two pathways to regaining a sense of mastery, which are primary control and secondary control. The first pathway, primary control, refers to an individual's efforts to increase the level of personal control they

believe they have over their illness and its management (Rothbaum, Weisz & Snyder, 1982). The second pathway, secondary control, refers to an individual's ability to accept and accommodate their illness (Rothbaum, Weisz & Snyder, 1982). Taylor (1983) proposes that higher levels of primary control and secondary control will be related to better psychological adjustment.

Self-esteem

The third theme, self-esteem, refers to efforts to regain a sense of self-esteem. Taylor (1983) suggests that there are two pathways that bolster self-esteem, which are social comparisons and denial of illness impact. The first pathway, social comparisons, refers to an individual's attempts to bolster their self-esteem by comparing themselves to others in a favourable way (Wills, 1981). The second pathway to bolstering self-esteem, denial of illness impact, refers to an individual's efforts to increase their self-esteem by minimising the true severity of their situation (Helgeson, 1999). Taylor (1983) proposes that positive social comparisons and higher levels of denial of illness impact will be related to better psychological adjustment.

Dispositional Optimism

Taylor (1983) proposes that the situated variables, meaning (i.e., benefit finding and making sense), mastery (i.e., primary and secondary control) and self-esteem (i.e., social comparisons and denial), mediate the relationship between dispositional optimism and psychological adjustment. In other words, the more optimistic an individual is the more they will be able to develop positive beliefs that give them a sense of meaning, mastery and self-esteem which, in turn, is likely to lead to positive adjustment.

The TCA and Chronic Illness

Previous research has investigated the theory of cognitive adaptation (Taylor, 1983) in relation to health threats such as cancer (Stiegelis et al., 2003; Tomich & Helgeson, 2006), heart disease (Helgeson, 1999, 2003; Helgeson & Fritz, 1999) and venous thromboelic disease (Moore, Norman, Harris & Makris, 2006). These longitudinal studies with large sample sizes, validated measures and sophisticated analyses provide strong empirical support for the TCA in health conditions other than MS as they each found the theory of cognitive adaptation was able to explain significant amounts of variance in psychological adjustment. However, no previous research has investigated the ability of the TCA to explain psychological adjustment in MS.

The TCA and Multiple Sclerosis

Although no study has investigated the components of the TCA simultaneously in MS, a small number of studies have investigated some of the individual components of the TCA in MS. However, the research in this area suffers from a range of methodological limitations. Therefore, the strength of the evidence base for the theory of cognitive adaptation with patients who have multiple sclerosis is currently poor.

Meaning and Adjustment to MS

A number of studies have examined the role of meaning in psychological adjustment to MS. In line with the TCA, greater efforts at finding meaning have been found to be related to better psychological adjustment. Considering the first pathway to meaning, higher levels of making sense have been found to be related to lower levels of depression and anxiety (Pakenham, 2007, 2008) as well as higher quality of life (Russell, White & White, 2006) in multiple sclerosis. Considering the second pathway to meaning, higher levels of benefit finding have been found to be related to higher quality

of life (Pakenham, 2005) and lower levels of depression (Hart, Vella & Mohr, 2008) in multiple sclerosis. However, although three studies were longitudinal with large samples and multivariate analyses that controlled for significant covariates (Hart el al., 2008; Pakenham, 2007, 2008), the other studies were cross-sectional, underpowered and poorly analysed (Pakenham, 2005; Russell et al., 2006).

Mastery and Adjustment to MS

Although some research has examined the role of mastery in psychological adjustment to MS, this research has only explored the first pathway to mastery, primary control, and not the second pathway, secondary control. In line with the TCA, higher levels of primary control have been found to be related to higher quality of life (Bishop, Frain & Tschopp, 2008) and lower levels of depression (Mendoza, Pittenger & Weinstein, 2001) in multiple sclerosis. However, the limited number of studies concerning primary control and the lack of research concerning secondary control are weaknesses. The available evidence is also methodologically weak as it is cross-sectional, underpowered, and poorly analysed (i.e., lack of multivariate analyses).

Self-esteem and Adjustment to MS

Research that has examined the role of self-esteem in psychological adjustment to MS, has only considered the first pathway to boosting self-esteem, social comparisons, and not the second pathway, denial of illness impact in MS. In line with the TCA, two studies found that negative downward social comparisons ("I'm going to end up as ill as them") and negative upward social comparisons ("I'll never cope as well as them") were related to poorer psychological well-being (Dewar, 2003; Russell et al., 2006). However, the limited availability of research in this area, cross-sectional designs, and small samples sizes limit this evidence base.

Dispositional Optimism and Adjustment to MS

In line with the TCA, some research has found that higher levels of dispositional optimism were related to better psychological adjustment in multiple sclerosis. Higher levels of dispositional optimism have been found to be related to lower levels of depression (Fournier, Ridder & Bensing, 1999, 2002; Gold-Spink, Sher & Theodos, 2000; Ridder, Schreurs and Bensing, 2000), lower levels of anxiety (Fournier, Ridder & Bensing, 1999, 2002) and higher quality of life (Ridder, Schreurs & Bensing, 2000) in multiple sclerosis. However, these studies have a number of methodologically limitations. They are cross-sectional and typically underpowered. In addition, they have failed to assess covariates or employ multivariate analyses.

Mediation Hypothesis

According to the TCA, beliefs about meaning, mastery and self-esteem should mediate the relationship between dispositional optimism and psychological adjustment. Only one study has explored this mediation hypothesis and this study only examined the mediating role of benefit finding. This longitudinal large scale study by Hart, Vella and Mohr (2008) found that benefit finding mediated the relationship between optimism and depression; higher levels of dispositional optimism were related to higher levels of benefit finding which, in turn, were related to lower levels of depression and mediated the effect of dispositional optimism on depression. Despite the strength of this study, there is a need for further studies to examine whether beliefs about mastery and self-esteem, as well as meaning, mediate the influence of dispositional optimism on psychological adjustment to MS.

Summary

In summary, research into multiple sclerosis has found partial support for the theory of cognitive adaptation. However, the strength of the current evidence base is weak. First, no study has investigated all of the components of the theory of cognitive adaptation simultaneously in MS preventing a thorough exploration of the hypothesised relationships. Second, only three studies were longitudinal (Hart et al., 2008; Pakenham, 2007, 2008). The other studies were cross-sectional preventing causal inferences regarding the direction of any relationships that were found. Third, sample sizes ranged from 18 participants (Gold-Spink et al., 2000) to 408 participants (Hart et al., 2008). Smaller samples were underpowered and at increased risk of making a type II error. Fourth, all of the studies relied on self-report questionnaires. Therefore, the findings are threatened by self-report bias and common method variance. Fifth, only three studies assessed potential covariates and employed multivariate statistical analyses (Hart et al., 2008; Pakenham, 2007, 2008). The findings from the other studies are threatened by a broad range of confounding variables.

Therefore, the present study aimed to overcome the limitations of the existing evidence base by 1) investigating all of the components of the theory of cognitive adaptation simultaneously, 2) in a large sample of individuals with multiple sclerosis, 3) using a longitudinal (i.e., prospective) design, 4) that assesses potential covariates, and 5) conducts multivariate statistical analyses to control for the effects of significant demographic and clinical variables.

Aims

The overall aim of the present study was to examine the extent to which the theory of cognitive adaptation explains variance in adjustment in patients with multiple sclerosis.

Hypotheses

After controlling for significant demographic and clinical variables:

1. Dispositional optimism will explain a significant amount of variance in anxiety, depression, mental well-being and physical well-being at baseline and at three month follow-up.
2. Making sense, benefit finding (i.e., meaning), primary control, secondary control (i.e., mastery), social comparisons and denial of illness impact (i.e., self-esteem) will explain a significant amount of additional variance in anxiety, depression, mental well-being and physical well-being over and above that of dispositional optimism at baseline and at three month follow-up.
3. Making sense, benefit finding (i.e., meaning), primary control, secondary control (i.e., mastery), social comparisons and denial of illness impact (i.e., self-esteem) will mediate the effect of dispositional optimism on anxiety, depression, mental well-being and physical well-being at baseline and at three month follow-up.

Method

Participants and Procedure

Ethical approval was granted by the South Yorkshire Research Ethics Committee (see Appendix B). Participants were recruited from a weekly outpatient clinic for people with Multiple Sclerosis between October 2009 and February 2010. The neurology consultant invited patients to participate if they had an existing diagnosis of Multiple Sclerosis, were aged 18 or over, spoke English, and had the physical, cognitive and language skills required to complete the questionnaire measures. Patients who did not meet these criteria were excluded from the study (n = 16). The most common reason for exclusion was the lack of a formal diagnosis of MS.

A total of 159 patients were invited to participate. Eight declined describing a lack of time or interest. The other 151 patients were interested in participating and were introduced to the researcher who provided them with an information sheet (see Appendix D), which was discussed in detail, a copy of the consent form (see Appendix D), a copy of the time 1 questionnaire (see Appendix C) and a freepost self-addressed envelope. The time 1 questionnaire measured the predictor variables and the outcome variables.

Out of the 151 patients who were invited to participate, 112 provided informed consent and returned their time 1 questionnaire (74% response rate). The 112 participants who took part at time 1 (85 females and 27 males) had a mean age of 47.4 years (*SD* = 10.35, range 22-75 years) and a mean MS duration of 11.2 years (*SD* = 8.01, range 2 months-38 years). Table 1 shows the descriptive statistics for the demographic and clinical variables at time 1. The majority of participants were married (55%), employed (35%), had a diagnosis of relapsing/remitting type MS (71%) and were currently experiencing a period of remission (56%).

Table 1. *Descriptive statistics for the demographic and clinical variables at time 1.*

Variable	Range	Mean	*SD*	Skewness (Z score)	Kurtosis (Z score)

Age (years)	22-75	47.4	10.35	1.79	-0.21
MS Duration (years)	0.2-38	11.2	8.01	5.35***	2.57
MS Severity (score)	0.0-22	17.7	2.91	-7.55***	1.45

Variable			*N*	%
Gender		Male	27	24
		Female	85	76
Marital Status		Single	26	23
		Married	62	55
		Divorced	13	12
		Separated	2	2
		Widowed	5	4
		Co-habiting	4	4
Employment		Employed	39	35
		Unemployed	24	22
		Retired	26	23
		Student	5	4
		Homemaker	18	16
Medication	Pain	No	78	70
		Yes	34	30
	Fatigue	No	102	91
		Yes	10	9
	Depression	No	93	83
		Yes	19	17
	Relapse	No	62	55
		Yes	50	45
MS Diagnosis		Relapsing/Remitting	79	71
		Secondary Progressive	19	17
		Primary Progressive	14	12
MS Status		Current Relapse	17	15
		Remitting	62	56
		Progressing	25	22
		Stable	8	7

Note: ***p<.001.

The time 2 questionnaire (see Appendix C), at three months, measured the outcome variables depression, anxiety and quality of life. A copy of the time 2 questionnaire, a free post self-addressed envelope and a copy of the information sheet were posted to participants who confirmed they still consented to taking part. All 112 participants

provided consent for this process. In total, 94 participants returned their time 2 questionnaire (84 % response rate).

To investigate the possibility of attrition biases, independent t-tests and chi-square tests were performed to identify whether any significant differences existed between participants who completed both the time 1 and time 2 questionnaires and participants who only completed the time 1 questionnaire. Differences between these two groups were investigated for each of the demographic, clinical, predictor and outcome variables. These tests found no significant differences between the two groups of participants.

Measures of Predictor Variables Assessed at Time 1

Optimism

The Revised Life Orientation Test (LOT-R; Scheier, Carver & Bridges, 1994) was used to measure dispositional optimism. The LOT-R is comprised of six items (e.g., "Overall, I expect more good things to happen to me than bad") and four filler items, which are scored on a five point scale from 0 (I disagree a lot) to 4 (I agree a lot). High scores indicate high levels of optimism. The internal reliability of the LOT-R was good for the present study ($\alpha = .87$).

Meaning

The perceived benefits subscale of the Illness Cognition Questionnaire (ICQ; Evers et al., 2001) was used to provide a situated measure of benefit finding. This subscale contains six items (e.g., "My illness has helped me realise what's important in life"), which are scored on a four point scale from 1 (not at all) to 4 (completely). High scores indicate high levels of benefit finding. The internal reliability of this subscale was good for the present study ($\alpha = .88$).

The illness coherence subscale of the Revised Illness Perception Questionnaire (IPQ-R, Moss-Morris et al., 2002) was used to provide a situated measure of making sense. This subscale has five items (e.g., "I have a clear picture or understanding of my illness"), which are scored on a five point scale from 0 (strongly disagree) to 4 (strongly agree). High scores indicate high levels of making sense. The internal reliability of this subscale was good for the present study ($\alpha = .86$).

Mastery

The personal control subscale of the Revised Illness Perception Questionnaire (IPQ-R, Moss-Morris et al., 2002) was used to provide a measure of situated primary control (personal control). This subscale has six items (e.g., "My actions will have no affect on the outcome of my illness"), which are scored on a five point scale from 0 (strongly disagree) to 4 (strongly agree). High scores indicate high levels of personal control. The internal reliability of this subscale for the present study was satisfactory ($\alpha = .73$).

The acceptance subscale of the Illness Cognition Questionnaire (ICQ; Evers et al., 2001) was used to provide a measure of situated secondary control (i.e., accommodation to the threat). This subscale has six items (e.g., "I have learned to accept the limitations imposed by my illness"), which are scored on a four point scale from 1 (not at all) to 4 (completely). High scores indicate high levels of accommodation to the threat. The internal reliability of this subscale for the present study was good ($\alpha = .87$).

Self-Enhancement

Havik and Maeland's (1986) two items for measuring denial of illness impact (e.g., "It takes more than a relapse to make me fall apart") were used to provide a situated measure of self-esteem. These items are scored on a five point scale from 0 (strongly

disagree) to 4 (strongly agree). High scores indicate high levels of self-esteem. A significant positive correlation was found between these two items, $r(110) = .47$, $p < .001$.

Four subscales from the Social Comparison in Illness Scale (SCIS; Dibb & Yardley, 2006a) were used to measure social comparisons. These were the upward positive, upward negative, downward positive, and downward negative subscales. The four subscales are comprised of 16 items (e.g., "When I hear about people with milder symptoms I feel hopeful"), which are scored on a five-point scale ranging from 1 (strongly disagree) to 5 (strongly agree). The upward positive and upward negative subscales in this study had good internal reliability ($\alpha = .94$ and .85 respectively). Correlational analyses found a significant positive relationship between the two items of the downward negative subscale ($r(110) = .42$, $p < .001$) and between the two items of the downward positive subscale ($r(110) = .79$, $p < .001$).

Measures of the Outcome Variables Assessed at Time 1 and Time 2

Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used to measure levels of anxiety and depression. The scale has 14 items and two subscales. Seven items measure depression and seven items measure anxiety. The items are scored on a four point scale to indicate the degree to which they have been experienced during the previous week. High scores indicate high levels of anxiety or depression. The depression subscale and the anxiety subscale had good internal reliability in this study at time 1 ($\alpha = .80$ and .88 respectively) and time 2 ($\alpha = .83$ and .86 respectively).

Demographic and Clinical Variables

Information regarding the age, gender, marital status and employment status was collected when participants met the researcher. The Barthel Index (BI; Mahoney & Barthel, 1965) was used to measure MS severity (functional ability). The BI has ten items that assess functional ability for 10 activities of daily living (e.g., toileting, bathing, dressing etc). Items are scored on a scale that ranges from 0 to 1, 0 to 2 or 0 to 3 depending upon the activity of daily living that is being assessed. High scores indicate high functional ability. The internal reliability of this scale for the present study was satisfactory ($\alpha = .79$). Information regarding MS diagnosis, duration, medication, and MS status was collected from medical records at the clinic, with permission from participants (see Table 1).

Statistical Analysis

Data Screening

Normality of Distributions

Skewness and kurtosis statistics were calculated to investigate whether the study variables were normally distributed. Variables that were not normally distributed were transformed to reduce their level of skewness or kurtosis to a non-significant level. These transformed variables were used for all later analyses.

Multicollinearity

The independent variables were checked for multicollinearity in two ways. First, the correlations between the independent variables were explored. Second, collinearity

statistics (i.e., tolerance, variance inflation factors) and collinearity diagnostics (i.e., condition index, variance proportions) were computed for each of the regression analyses.

Cross-sectional Analyses (Time 1)

Correlation analyses

Associations were assessed between the demographic/clinical variables (e.g., age, gender etc) and the time 1 outcome variables (anxiety, depression, mental well-being and physical well-being), using correlations, t tests and ANOVAs as appropriate, to identify significant covariates that would need to be controlled for in later regression analyses. Correlations were computed between the TCA variables (e.g., benefit finding, illness coherence etc) and the time 1 outcome variables to assess bivariate associations between the TCA and psychological adjustment in MS.

Regression Analyses

Hierarchical regression analyses were conducted to investigate the three hypotheses pertaining to this study. The independent variables were entered in 3 steps for each of the time 1 outcome variables (i.e., anxiety, depression, mental well-being and physical well-being). Step 1 controlled for covariates by entering demographic/clinical variables that were significantly associated with the time 1 outcome variables. Optimism was entered in step 2 to test the first hypothesis. The situated (i.e., MS-specific) TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons, denial of illness impact) were entered in step 3 to test the second hypothesis. Entering the situated TCA variables in step 3 after optimism in step 2 provided an initial test for mediation (hypothesis 3). Any evidence of mediation (e.g.,

reduction in the size of the beta weight for optimism from step 2 to step 3) was further analysed in line with current recommendations (Preacher & Hayes, 2008) to formally test hypothesis 3.

Prospective Analyses (Time 2)

Correlation Analyses

Associations were assessed between the demographic/clinical variables (e.g., age, gender etc) and the time 2 outcome variables (e.g., anxiety, depression etc), using correlations, t tests and ANOVAs as appropriate, to identify significant covariates that would need to be controlled for in later regression analyses. Correlations were computed between the TCA variables (e.g., benefit finding, illness coherence etc) and the time 2 outcome variables to assess bivariate associations between the TCA and psychological adjustment in MS.

Regression Analyses

Hierarchical regression analyses were conducted to investigate the three hypotheses pertaining to this study. The independent variables were entered in 4 steps for each of the time 2 outcome variables (i.e., anxiety, depression, mental well-being and physical well-being). Step 1 controlled for baseline adjustment by entering the relevant time 1 outcome score. Step 2 controlled for significant covariates by entering demographic/clinical variables that were significantly related to the time 2 outcome variables. Optimism was entered in step 3 to test the first hypothesis. The situated TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons, denial of illness impact) were entered in step 4 to test the second hypothesis. Entering the situated TCA variables in step 4 after optimism in step 3

provided an initial test for mediation (hypothesis 3). Any evidence of mediation (e.g., reduction in the size of the beta weight for optimism from step 3 to step 4) was further analysed in line with current recommendations (Preacher & Hayes, 2008) to formally test hypothesis 3.

Power Analysis

There were no previous studies that had examined relationships between all of the TCA components and anxiety or depression or quality of life in patients with MS. Therefore, a medium effect size was assumed for the present study. An initial power analysis with power set at .80 and alpha at .05 was run to determine the required sample size for the hierarchical regression analysis (Cohen, 1992). Entering three demographic or clinical variables in step 1, optimism in step 2, and the 9 TCA variables (benefit finding, making sense, primary control, secondary control, positive upward social comparison, positive downward social comparison, negative upward social comparison, negative downward social comparison and denial of illness impact) in step 3, 114 participants were required to detect a medium effect size (at step 3).

Results

Data Screening

Skewness and kurtosis statistics were calculated to investigate whether the study variables were normally distributed. Considering the demographic/clinical variables (see Table 1), the Barthel Index (i.e., MS severity) was found to have a significant negative skew (z = -7.55, p <.001). Therefore, a logarithmic transformation was performed to reduce the level of skewness to a non-significant level. The MS duration variable was found to have a significant positive skew (z = 5.35, p <.001). Therefore, a square root transformation was performed to reduce the level of skewness to a non-

significant level. These transformed variables were used for all later analyses. Considering the TCA variables and the outcome variables (e.g., anxiety, depression etc), the data for each variable was found to be normally distributed (see Table 2). There was no indications of multicollinearity.

Table 2. *Ranges, means, standard deviations, skewness and kurtosis for the main study variables at time 1 and time 2.*

	Variable	Range	Mean	*SD*	Skewness (*Z* Score)	Kurtosis (*Z* Score)
Time 1	Perceived Benefits	6-24	16.62	5.21	-1.48	-2.28
	Illness Coherence	5-25	18.24	5.46	-2.61	-1.34
	Personal Control	6-30	17.89	4.95	-0.35	-1.15
	Acceptance	6-24	16.62	4.53	-1.46	-0.91
	Impact Denial	0-8	5.36	2.08	-2.44	-1.00
	Up Positive Comparison	6-30	21.11	6.95	-2.72	-1.12
	Down Positive Comparison	2-10	7.11	2.48	-2.42	-1.40
	Up Negative Comparison	6-30	11.77	5.12	-2.54	-1.91
	Down Negative Comparison	2-10	5.00	2.21	1.21	-1.66

	Optimism	0-24	12.98	6.09	-1.04	-1.07
	Anxiety	0-21	8.05	4.44	1.50	-1.11
	Depression	0-21	6.68	3.74	1.12	-0.86
	Mental Well-being	0-100	44.90	11.04	-2.30	-1.00
	Physical Well-being	0-100	35.40	10.35	2.88	0.13
Time 2	Anxiety	0-21	7.89	4.39	1.26	-0.76
	Depression	0-21	6.99	3.71	0.73	-0.37
	Mental Well-being	0-100	43.48	11.48	0.16	2.06
	Physical Well-being	0-100	34.35	10.56	-0.88	-0.32

Cross-sectional Analyses (Time 1)

Correlational Analyses

Associations were assessed between the demographic/clinical variables (e.g., age, gender etc) and the time 1 outcome variables (e.g., anxiety, depression etc), using correlations, t tests and ANOVAs as appropriate, to identify significant covariates that would need to be controlled for in later regression analyses (See Table 3).

Age correlated significantly with anxiety ($r(110) = -.19$, $p = .04$) and mental well-being ($r(110) = .28$, $p = .003$) such that greater age was associated with lower anxiety and higher mental well-being. Females reported significantly lower levels of depression ($t(110) = 2.21$, $p = .030$) and higher physical well-being ($t(110) = 2.04$, $p = .044$) than males. Married participants had significantly lower levels of depression ($t(110) = 2.02$, $p = .046$) than single participants. Employment status was significantly related to

anxiety ($F(2, 109) = 9.55$, $p < .001$), depression ($F(2, 109) = 8.85$, $p < .001$), mental well-being ($F(2, 109) = 8.34$, $p < .001$) and physical well-being ($F(2, 109) = 8.20$, $p < .001$). Therefore, two dummy codes were created for the subsequent regression analyses to represent employment status.

Table 3. *Relationships between the demographic/clinical variables and the time 1 outcome variables.*

		Time 1 Outcome Variables			
Variable		Anxiety	Depression	Mental Well-being	Physical Well-being
Age	*r*(110)	-.19*	-.16	.28**	-.10
MS Duration	*r*(110)	-.17	-.12	.21*	-.11
MS Severity	*r*(110)	-.13	-.24*	.14	.55***

Variable		Anxiety Mean (*SD*)	Depression Mean (*SD*)	Mental Well-being Mean (*SD*)	Physical Well-being Mean (*SD*)
Gender:	Male	8.11 (3.91)	8.04 (3.81)	42.67 (11.97)	31.90 (9.53)
	Female	8.04 (4.62)	6.25 (3.63)	45.60 (10.70)	36.51 (10.41)
	t(110)	0.08	2.21*	1.20	2.04*
Marital Status:					
	Single	7.93 (4.52)	7.52 (3.60)	43.42 (11.20)	34.34 (9.61)
	Married	8.14 (4.41)	6.00 (3.74)	45.93 (10.89)	36.13 (10.85)
	t(110)	0.24	2.02*	1.18	0.90
Employment:					
Employed		7.61 (4.07)	5.09 (3.55)	46.34 (10.55)	39.50 (11.26)
Unemployed		10.02 (4.79)	8.26 (3.77)	41.18 (11.89)	34.49 (8.94)
Retired		5.62 (4.44)	6.81 (2.88)	48.44 (8.81)	29.93 (8.04)
F(2, 109)		9.55***	8.85***	8.34***	8.20***

Medication:					
Pain	No	7.85 (4.54)	6.76 (3.59)	44.55 (11.56)	36.48 (10.24)
	Yes	8.53 (4.22)	6.50 (4.11)	45.69 (9.84)	32.92 (10.31)
	t(110)	0.75	0.33	0.50	1.69
Fatigue	No	7.97 (4.44)	6.55 (3.67)	45.17 (10.98)	35.77 (10.38)
	Yes	9.50 (4.51)	9.00 (4.47)	40.02 (11.83)	28.89 (7.96)
	t(110)	0.82	1.57	1.11	1.60
Depression	No	7.85 (4.36)	6.60 (3.66)	44.84 (11.20)	35.57 (10.26)
	Yes	10.10 (5.00)	7.50 (4.55)	45.44 (9.73)	33.63 (11.65)
	t(110)	1.54	0.72	0.16	0.57
Relapse	No	8.19 (4.50)	6.52 (3.89)	44.53 (11.52)	34.36 (10.08)
	Yes	7.88 (4.41)	6.88 (3.57)	45.35 (10.51)	36.69 (10.64)
	t(110)	0.37	0.51	0.39	1.19
MS Diagnosis:					
Relapsing Type		8.01 (4.30)	6.32 (3.73)	45.93 (10.67)	37.31 (10.45)
Progressive Types		8.15 (4.84)	7.55 (3.68)	42.42 (11.69)	30.81 (8.64)
t(110)		0.15	1.60	1.54	3.15**
MS Status:					
Stable		7.49 (4.37)	5.97 (3.57)	46.88 (10.53)	38.11 (10.18)
Unstable		9.00 (4.44)	7.86 (3.75)	41.59 (11.18)	30.88 (9.08)
t(110)		1.76	2.66**	2.52*	3.79**

Note: *p<.05, **p<.01, ***p<.001.

Participants with a progressive type of MS had significantly lower physical well-being (t(110) = 3.15, p = .002) than participants with a diagnosis of relapsing/remitting type MS. Participants with a stable condition had significantly lower levels of depression (t(110) = 2.66, p = .009), higher mental well-being (t(110) = 2.52, p = .013) and higher physical well-being (t(110) = 3.79, p = .006) than participants with an unstable condition. MS severity was correlated significantly with depression (r(110) = -.24, p = .011) and physical well-being (r(110) = .55, p < .001), such that higher functional ability was associated with lower depression and higher physical well-being. MS duration correlated significantly with mental well-being (r(110) = .21, p = .025) such that a longer duration was associated with higher mental well-being.

Correlations were computed to assess bivariate relationships between the TCA variables and the time 1 outcome variables (see Table 4). Anxiety was found to correlate

significantly with acceptance ($r(110) = -.44$, $p < .001$), denial ($r(110) = -.35$, $p < .001$), upward negative comparisons ($r(110) = .40$, $p < .001$), downward negative comparisons ($r(110) = .45$, $p < .001$) and optimism ($r(110) = -.51$, $p < .001$), such that high levels of anxiety were associated with low levels of acceptance, low levels of denial, high levels of upward negative comparisons, high levels of downward negative comparisons and low levels of optimism.

Depression was found to correlate significantly with perceived benefit finding ($r(110) = -.25$, $p = .009$), illness coherence ($r(110) = -.21$, $p = .024$), acceptance ($r(110) = -.42$, $p < .001$), denial ($r(110) = -.36$, $p < .001$), upward negative comparisons ($r(110) = .49$, $p < .001$), downward negative comparisons ($r(110) = .42$, $p < .001$) and optimism ($r(110) = -.48$, $p < .001$), such that high levels of depression were associated with low levels of perceived benefits, low levels of illness coherence, low levels of acceptance, low levels of denial, high levels of upward negative comparisons, high levels of downward negative comparisons, and low levels of optimism.

Table 4. *Correlations between predictor variables and outcome variables at time 1.*

	Time 1 Outcome Variables			
Predictor Variables	Anxiety	Depression	Mental Well-being	Physical Well-being
Perceived Benefits	.03	-.25**	.12	-.09
Illness Coherence	-.15	-.21*	.13	.16
Personal Control	-.09	-.20	.09	.08
Acceptance	-.44***	-.42***	.37***	.12
Denial	-.35***	-.36***	.20*	.17
Upward Positive	.09	-.11	-.01	.01
Downward Positive	-.12	-.16	.15	-.12
Upward Negative	.40***	.49***	-.43***	-.17

Downward Negative	.45***	.42***	-.39***	-.19*
Optimism	-.51***	-.48***	.48***	-.03

Note: *p<.05, **p<.01, ***p<.001.

Mental well-being was found to correlate significantly with acceptance (r(110) = .37, p < .001), denial (r(110) = .20, p = .035), upward negative comparisons (r(110) = -.43, p < .001), downward negative comparisons (r(110) = -.39, p < .001) and optimism (r(110) = .48, p < .001), such that high levels of mental well-being were associated with high levels of acceptance, high levels of denial, low levels of upward negative comparisons, low levels of downward negative comparisons and high levels of optimism. Physical well-being was found to correlate significantly with downward negative comparisons (r(110) = -.19, p < .043), such that high levels of physical well-being were associated with lower levels of downward negative comparisons.

Regression Analyses at Time 1

Hierarchical regression analyses were conducted to investigate the three hypotheses pertaining to this study. The independent variables were entered in 3 steps for each of the time 1 outcome variables (i.e., anxiety, depression, mental well-being and physical well-being). Step 1 controlled for significant covariates (ie., demographic/clinical variables), step 2 tested the first hypothesis by entering optimism and step 3 tested the second hypothesis by entering the situated TCA variables. Any evidence of mediation (e.g., reduction in the size of the beta weight for optimism from step 2 to step 3) was further analysed in line with current recommendations (Preacher & Hayes, 2008) to formally test the third hypothesis.

Table 5 summarises the regression analysis for the variables predicting anxiety at time 1. The control variables entered in step 1 explained 15% of the variance in anxiety, ΔR^2

= .15, $F(3, 108) = 6.52$, $p < .001$, with unemployed status emerging as a significant predictor. In relation to hypothesis 1, optimism explained an additional 17% of the variance in anxiety when entered at step 2, $\Delta R^2 = .17$, $F(1, 107) = 27.56$, $p < .001$, with unemployed status and optimism emerging as significant predictors. In relation to hypothesis 2, the situated TCA variables explained a further 16% of the variance in anxiety when entered in step 3, $\Delta R^2 = .16$, $F(9, 98) = 3.51$, $p < .001$, with unemployed status, employed status, optimism, and downward negative social comparison emerging as significant predictors. The variables in the final regression equation explained 48% of the variance in anxiety, $\Delta R^2 = .48$, $F(13, 98) = 7.27$, $p < .001$.

Table 5 *Summary of the regression analysis for variables predicting anxiety at time 1*

		Anxiety Outcome Variable at Time 1		
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)
1	Age	-.07	-.02	.07
	Unemployed vs. Others	-.45***	-.34**	-.42***
	Employed vs. Others	-.18	-.14	-.22*
2	Optimism		-.44***	-.26**
3	Perceived Benefits			.10
	Illness Coherence			.08
	Personal Control			-.03
	Acceptance			-.18
	Denial			-.14
	Upward positive			.09
	Downward Positive			.00

Upward Negative			.04
Downward Negative			.22*
ΔR^2	.15***	.17***	.16***
R^2	.15***	.32***	.48***

Note: *p<.05, **p<.01, ***p<.001.

In relation to hypothesis 3, a possible mediation effect was indicated as the effect of optimism at step 2 reduced in size following the addition of the situated TCA variables at step 3. As recommended by Preacher and Hayes (2008), further analyses were conducted to test whether the situated TCA variables mediated the effect of optimism on time 1 anxiety (hypothesis 3). Optimism was entered with the potential mediators (i.e., perceived benefits, illness coherence, personal control, acceptance, denial, upward positive comparison, downward positive comparison, upward negative comparison and downward negative comparison) as well as age and employment status as covariates. The effect of optimism on time 1 anxiety, B = -.32, SE = .06, p < .001, was reduced when the situated TCA variables were controlled, B = -.19, SE = .07, p = .006, suggesting partial mediation. Using bootstrapping procedures, the total mediated effect was found to be significant, B = -.12, SE = .06, CI = -.25 to -.02. Inspection of the individual mediator variables revealed that only negative downward comparison significantly mediated the effect of optimism on time 1 anxiety, B = -.06, SE = .03, CI = -.14 to -.01.

Table 6 provides a summary of the regression analysis for variables predicting depression at time 1. The control variables entered in step 1 explained 22% of the variance in depression, ΔR^2 = .22, $F(6, 105) = 5.05$, p < .001, with unemployed status and MS status emerging as significant predictors. In relation to hypothesis 1, optimism explained an additional 18% of the variance in depression when entered in step 2, ΔR^2

= .18, $F(1, 104) = 30.29$, $p < .001$, with employed status, MS status and optimism emerging as significant predictors. In relation to hypothesis 2, the situated TCA variables explained a further 12% of the variance in depression when entered in step 3, $\Delta R^2 = .12$, $F(9, 95) = 2.68$, $p = .004$, with optimism and denial emerging as significant predictors. The variables in the final regression equation explained 52% of the variance in depression, $\Delta R^2 = .52$, $F(16, 95) = 6.45$, $p < .001$.

Table 6. *Summary of the regression analysis for variables predicting depression at time 1*

		Depression Outcome Variable at time 1		
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)
1	Gender	-.12	-.14	-.13
	Marital status	-.09	.00	-.01
	Unemployed vs. Others	-.24*	-.08	-.16
	Employed vs. Others	.13	.25*	.19
	MS severity	-.05	.01	.02
	MS status	.20*	.17*	.15
2	Optimism		-.45***	-.23*
3	Perceived Benefits			-.14
	Illness Coherence			-.02
	Personal Control			-.02
	Acceptance			-.07
	Denial			-.18*

Upward positive			.01
Downward Positive			.05
Upward Negative			.10
Downward Negative			.15
ΔR^2	.22***	.18***	.12**
R^2	.22***	.40***	.52***

Note: *p<.05, **p<.01, ***p<.001.

In relation to hypothesis 3, a possible mediation effect was indicated as the effect of optimism in step 2 reduced in size following the addition of the situated TCA variables in step 3. As recommended by Preacher and Hayes (2008), further analyses were conducted to test whether the situated TCA variables mediated the effect of optimism on time 1 depression (hypothesis 3). Optimism was entered with the potential mediators (i.e., perceived benefits, illness coherence, personal control, acceptance, denial, upward positive comparison, downward positive comparison, upward negative comparison, downward negative comparison) as well as gender, marital status, employment status, MS severity, and MS status as covariates. The effect of optimism on time 1 depression, B = -.28, SE = .05, p < .001, reduced when the situated TCA variables were controlled, B = -.14, SE = .06, p = .015, suggesting partial mediation. Using bootstrapping procedures, the total mediated effect was found to be significant, B = -.13, SE = .04, CI = -.23 to -.06. Inspection of the individual mediator variables revealed that only denial significantly mediated the effect of optimism on time 1 depression, B = -.04, SE = .03, CI = -.11 to -.01.

Table 7 provides a summary of the regression analysis for variables predicting mental well-being at time 1. The control variables entered in step 1 explained 22% of the variance in mental well-being, ΔR^2 = .22, F(5, 106) = 6.02, p < .001, with age and MS

status emerging as significant predictors. In relation to hypothesis 1, optimism explained an additional 12% of the variance in mental well-being when entered in step 2, $\Delta R^2 = .12$, $F(1, 105) = 18.20$, $p < .001$, with age, MS status and optimism emerging as significant predictors. In relation to hypothesis 2, the situated TCA variables entered in step 3, $\Delta R^2 = .08$, $F(9, 96) = 1.39$, $p = .20$, failed to produce a significant increment in the amount of variance explained in time 1 mental well-being, with only MS status and optimism emerging as significant predictors of mental well-being. The variables in the final regression equation explained 42% of the variance in mental well-being, $\Delta R^2 = .42$, $F(15, 96) = 4.50$, $p < .001$.

Table 7. *Summary of the regression analysis for variables predicting MCS at time 1*

		Mental Well-Being Outcome Variable at Time 1		
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)
1	Age	.24*	.20*	.18
	Unemployed vs. Others	.22	.13	.18
	Employed vs. Others	-.04	-.06	.02
	MS duration	.15	.03	.02
	MS status	-.27**	-.23**	-.21*
2	Optimism		.38***	.22*
3	Perceived Benefits			.07
	Illness Coherence			-.07
	Personal Control			.00
	Acceptance			.08
	Denial			-.03
	Upward positive			-.10
	Downward Positive			.07

Upward Negative			-.18
Downward Negative			-.12
ΔR^2	.22***	.12***	.08
R^2	.22***	.34***	.42***

Note: *p<.05, **p<.01, ***p<.001.

In relation to hypothesis 3, a possible mediation effect was indicated as the effect of optimism at step 2 reduced in size following the addition of the situated TCA variables in step 3. As recommended by Preacher and Hayes (2008), further analyses were conducted to test whether the situated TCA variables mediated the effect of optimism on time 1 mental well-being (hypothesis 3). Optimism was entered with the potential mediators (i.e., perceived benefits, illness coherence, personal control, acceptance, denial, upward positive comparison, downward positive comparison, upward negative comparison, downward negative comparison) as well as age, employment status, MS duration and MS status as covariates. The effect of optimism on time 1 mental well-being, B = .68, SE = .16, p < .001, reduced when the situated TCA variables were controlled, B = .41, SE = .19, p = .034, suggesting partial mediation. Using bootstrapping procedures, the total mediated effect was found to be significant, B = .26, SE = .13, CI = .05 to .58. However, inspection of the individual mediator variables revealed none of them significantly mediated the effect of optimism on time 1 mental well-being.

Table 8 provides a summary of the regression analysis for the variables predicting physical well-being at time 1. The control variables entered in step 1 explained 35% of the variance in physical well-being, ΔR^2 = .35, F(6, 105) = 9.58, p < .001, with MS severity and MS status emerging as significant predictors. In relation to hypothesis 1, optimism failed to explain additional variance in physical well-being when entered in step 2, ΔR^2 = .00, F(1, 104) = .63, p = .43. However, MS severity and MS status

emerged as significant predictors. In relation to hypothesis 2, the situated TCA variables failed to produce a significant increment in the amount of variance explained in physical well-being when entered in step 3, $\Delta R^2 = .08$, $F(9, 95) = 1.53$, $p = .15$. At step 3, only MS severity, MS status and denial emerged as significant predictors. The variables in the final regression equation explained 43% of the variance in physical well-being, $\Delta R^2 = .43$, $F(16, 95) = 4.65$, $p < .001$. In relation to hypothesis 3, no mediation analyses were performed as optimism was found to be non-significant.

Table 8. *Summary of the regression analysis for variables predicting PCS at time 1.*

		Physical Well-being Outcome Variable at Time 1		
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)
1	Gender	.02	.02	.04
	Unemployed vs. Others	-.09	-.07	-.07
	Employed vs. Others	-.17	-.15	-.16
	MS Severity	.43***	.44***	.39***
	MS Diagnosis	.04	.03	-.04
	MS status	-.22*	-.22*	-.20*
2	Optimism		-.07	-.12
3	Perceived Benefits			-.06
	Illness Coherence			.13
	Personal Control			.05
	Acceptance			.06
	Denial			.22*
	Upward positive			-.03
	Downward Positive			-.16

Upward Negative			.12
Downward Negative			-.09
ΔR^2	.35***	.00	.08
R^2	.35***	.35***	.43***

Note: *p<.05, **p<.01, ***p<.001.

Prospective Analyses (Time 2)

Correlational Analyses

Associations were assessed between the demographic/clinical variables (e.g., age, gender etc) and the time 2 outcome variables (e.g., anxiety, depression, mental well-being and physical well-being), using correlations, t tests and ANOVAs as appropriate, to identify significant covariates that would need to be controlled for in later regression analyses (See Table 9).

Age correlated significantly with anxiety ($r(92) = -.24$, $p = .02$) such that greater age was associated with lower anxiety. Females reported significantly higher physical well-being ($t(92) = 2.21$, $p = .030$) than males. Employment status was significantly related to depression ($F(2, 91) = 5.05$, $p = .008$), anxiety ($F(2, 91) = 5.71$, $p = .005$) and physical well-being ($F(2, 91) = 5.56$, $p = .005$). Therefore, two dummy codes were created for the subsequent regression analyses to represent employment status.

Participants with a progressive type of MS had significantly lower physical well-being ($t(92) = 2.68$, $p = .009$) than participants with a diagnosis of relapsing-remitting type MS. MS severity was significantly correlated with depression ($r(92) = -.38$, $p < .001$) and physical well-being ($r(92) = .51$, $p < .001$), such that higher functional ability was related to lower levels of depression and higher physical well-being. MS duration correlated significantly with mental well-being ($r(92) = .21$, $p = .047$), such that longer

duration was associated with higher mental well-being. Participants with stable conditions had significantly lower levels of depression ($t(92) = 4.03$, $p < .001$) and higher physical well-being ($t(92) = 3.57$, $p = .001$) than participants with unstable conditions.

Table 9. *Relationships between the demographic/clinical variables and the time 2 outcome variables.*

Variable		*Time 2 Outcome Variables* Anxiety	Depression	Mental Well-being	Physical Well-being
Age	*r*(92)	-.24*	-.14	.09	-.09
MS Duration	*r*(92)	-.07	-.11	.21*	-.08
MS Severity	*r*(92)	-.20	-.38***	.17	.51***

Variable		Anxiety Mean (*SD*)	Depression Mean (*SD*)	Mental Well-being Mean (*SD*)	Physical Well-being Mean (*SD*)
Gender:	Male	7.36 (3.61)	7.55 (3.83)	45.18 (12.10)	30.09 (8.14)
	Female	7.86 (4.38)	6.50 (3.39)	42.96 (11.32)	35.65 (10.92)
	t(92)	0.48	1.23	0.79	2.21*
Marital Status:					
	Single	7.49 (4.12)	7.02 (3.13)	42.86 (11.52)	32.90 (9.19)
	Married	7.91 (4.23)	6.54 (3.44)	43.87 (11.54)	35.29 (11.34)
	t(92)	0.48	1.04	0.42	1.07
Employment:					
Employed		7.59 (4.16)	5.59 (3.48)	44.20 (10.80)	37.87 (12.51)
Unemployed		9.45 (4.49)	8.16 (3.37)	40.28 (12.81)	33.91 (8.90)
Retired		5.79 (2.91)	6.79 (3.16)	46.44 (10.13)	29.18 (6.31)
F(2, 91)		5.71**	5.05**	2.13	5.56**
Medication:					
Pain	No	7.45 (4.51)	6.50 (3.44)	43.72 (12.15)	35.55 (10.75)
	Yes	8.43 (3.34)	7.32 (3.66)	42.90 (9.91)	31.51 (9.69)
	t(92)	1.03	1.04	0.31	1.71
Fatigue	No	7.58 (4.13)	6.57 (3.41)	43.64 (11.49)	34.75 (10.68)
	Yes	10.17 (4.89)	9.33 (4.23)	41.17 (12.14)	28.38 (6.75)
	t(92)	1.47	1.89	0.51	1.44

Depression	No	7.53 (4.12)	6.73 (3.43)	44.05 (11.33)	34.15 (10.75)
	Yes	9.78 (4.66)	6.89 (4.40)	38.10 (12.17)	36.25 (8.91)
	t(92)	1.53	0.13	1.49	0.57
Relapse	No	7.75 (4.11)	6.98 (3.73)	42.51 (11.95)	33.34 (9.53)
	Yes	7.74 (4.35)	6.47 (3.24)	44.62 (10.93)	35.56 (11.67)
	t(92)	0.10	0.71	0.89	1.02
MS Diagnosis:					
Relapsing Type		7.60 (4.02)	6.45 (3.38)	43.64 (11.31)	36.14 (10.96)
Progressive Types		8.11 (4.67)	7.48 (3.78)	43.08 (12.11)	29.90 (8.08)
	t(92)	0.54	1.30	0.21	2.68**
MS Status:					
Stable		7.35 (4.40)	5.77 (3.25)	44.66 (12.25)	36.98 (11.02)
Unstable		8.50 (3.73)	8.63 (3.25)	41.19 (9.60)	29.25 (7.40)
	t(92)	1.26	4.03***	1.40	3.57***

Note: *p<.05, **p<.01, ***p<.001.

Correlations were computed to assess bivariate relationships between the TCA variables and the time 2 outcome variables (see Table 10). Time 2 anxiety was found to correlate significantly with perceived benefits (r(92) = .28, p = .006), acceptance (r(92) = -.31, p = .003), denial (r(92) = -.34, p < .001), upward negative comparisons (r(92) = .29, p = .044), downward negative comparisons (r(92) = .34, p < .001), optimism (r(92) = -.38, p < .001), time 1 anxiety (r(92) = .75, p < .001), time 1 depression (r(92) = .32, p = .002), time 1 mental well-being (r(92) = -.51, p < .001) and time 1 physical well-being (r(92) = -.21, p = .039), such that high levels of anxiety were associated with high levels of perceived benefits, low levels of acceptance, low levels of denial, high levels of upward negative comparisons, high levels of downward negative comparisons, low levels of optimism, high levels anxiety at time 1, high levels of depression at time 1, low levels of mental well-being at time 1 and low levels of physical well-being at time 1.

Time 2 depression was found to correlate significantly with illness coherence (r(92) = -.28, p = .007), personal control (r(92) = -.28, p = .005), acceptance (r(92) = -.36, p < .001), denial (r(92) = -.26, p = .010), downward positive comparisons (r(92) = -.22, p = .031), upward negative comparisons (r(92) = .35, p < .001), downward negative

comparisons ($r(92) = .30$, $p = .003$), optimism ($r(92) = -.35$, $p < .001$), time 1 anxiety ($r(92) = .48$, $p < .001$), time 1 depression ($r(92) = .72$, $p < .001$), time 1 mental well-being ($r(92) = -.49$, $p < .001$) and time 1 physical well-being ($r(92) = -.59$, $p < .001$), such that high levels of depression were associated with low levels of illness coherence, low levels of personal control, low levels of acceptance, low levels of denial, low levels of downward positive comparisons, high levels of upward negative comparisons, high levels of downward negative comparisons, low levels of optimism, high levels of anxiety at time 1, high levels of depression at time 1, low levels of mental well-being at time 1 and low levels of physical well-being at time 1.

Table 10. *Correlations between time 1 predictor variables and time 2 outcome variables.*

	Time 2 Outcome Variables			
	Anxiety	Depression	Mental Well-being	Physical Well-being
Time 1 Predictor Variables				
Perceived Benefits	.28**	-.03	-.13	-.06
Illness Coherence	-.14	-.28**	.07	.12
Personal Control	-.06	-.28**	.15	.18
Acceptance	-.31**	-.36***	.21*	.12
Denial	-.34***	-.26**	.24*	.15
Upward Positive	.12	-.19	.13	.05
Downward Positive	-.06	-.22*	.18	-.06
Upward Negative	.29*	.35***	-.25*	-.08
Downward Negative	.34***	.30**	-.25**	-.19
Optimism	-.38***	-.35***	.33***	-.02
Time 1 Outcome variables				
Anxiety	.75***	.48***	-.56***	-.10
Depression	.32**	.72***	-.36***	-.33***
Mental Well-being	-.51***	-.49***	.58***	.04

Physical well-being	-.21*	-.59***	.18	.81***

Note: *p<.05, **p<.01, ***p<.001.

Time 2 mental well-being was found to correlate significantly with acceptance (r(92) = .21, p < .045), denial (r(92) = .24, p = .022), upward negative comparisons (r(92) = -.25, p = .016), downward negative comparisons (r(92) = -.25, p = .009), optimism (r(92) = .33, p < .001), time 1 anxiety (r(92) = -.56, p < .001), time 1 depression (r(92) = -.36, p < .001) and time 1 mental well-being (r(92) = .58, p < .001), such that high levels of time 2 mental well-being were associated with high levels of acceptance, high levels of denial, low levels of upward negative comparisons, low levels of downward negative comparisons, high levels of optimism, low levels of anxiety at time 1, low levels of depression at time 1 and high levels of mental well-being at time 1.

Time 2 physical well-being was found to correlate significantly with time 1 depression (r(92) = -.33, p < .001) and time 1 physical well-being (r(92) = .81, p < .001), such that high levels of physical well-being at time 2 were associated with low levels of depression at time 1 and high levels of physical well-being at time 1.

Regression Analyses at Time 2

Hierarchical regression analyses were conducted to investigate the three hypotheses pertaining to this study. The independent variables were entered in 4 steps for each of the time 2 outcome variables. Step 1 controlled for baseline adjustment, step 2 controlled for significant covariates, step 3 tested the first hypothesis by entering optimism and step 4 tested the second hypothesis by entering the situated TCA variables. Any evidence of mediation (e.g., reduction in the size of the beta weight for optimism

from step 3 to step 4) was further analysed in line with current recommendations (Preacher & Hayes, 2008) to formally test the third hypothesis.

Table 11 provides a summary of the regression analysis for variables predicting time 2 anxiety. Time 1 anxiety explained 54% of the variance in time 2 anxiety at step 1, ΔR^2 = .54, $F(1, 92) = 115.39$, $p < .001$. The addition of the control variables in step 2, ΔR^2 = .01, $F(3, 89) = .61$, $p = .61$, optimism in step 3 (hypothesis 1), ΔR^2 = .00, $F(1, 88) = .21$, $p = .65$, and the situated TCA variables in step 4 (hypothesis 2), ΔR^2 = .05, $F(9, 79) = 1.14$, $p = .35$, failed to produce significant increments in the amount of variance explained in time 2 anxiety. Time 1 anxiety emerged as a significant predictor of time 2 anxiety at each of the 4 steps. Benefit finding also emerged as a significant predictor at step 4. The variables in the final regression equation explained 60% of the variance in time 2 anxiety, ΔR^2 = .60, $F(14, 93) = 9.06$, $p < .001$. In relation to hypothesis 3, no mediation analyses were performed as optimism was found to be non-significant.

Table 11. *Summary of the regression analysis for variables predicting anxiety at time 2.*

		Anxiety Outcome Variable at Time 2			
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)	β (Step 4)
1	Time 1 Anxiety	.75***	.72***	.71***	.60***
2	Age		-.10	-.10	-.06
	Unemployed vs. Others		-.11	-.01	-.06
	Employed vs. Others		.02	.02	.02
3	Optimism			-.04	-.06
4	Perceived Benefits				.20*
	Illness Coherence				-.06
	Personal Control				.00

Acceptance				-.01
Denial				-.14
Upward positive				-.03
Downward Positive				.02
Upward Negative				-.08
Downward Negative				.07
ΔR^2	.54***	.01	.00	.05
R^2	.54***	.55***	.55***	.60***

Note: *p<.05, **p<.01, ***p<.001.

Table 12 provides a summary of the regression analysis for the variables predicting time 2 depression. Time 1 depression explained 52% of the variance in time 2 depression at step 1, ΔR^2 = .52, $F(1, 92) = 98.64$, $p < .001$. An additional 6% of the variance in time 2 depression was explained by the control variables entered in step 2, ΔR^2 = .06, $F(4, 88) = 2.87$, $p = .028$ The addition of optimism in step 3 (hypothesis 1), ΔR^2 = .00, $F(1, 87) = .53$, $p = .47$, and the situated TCA variables in step 4 (hypothesis2), ΔR^2 = .07, $F(9, 78) = 1.57$, $p = .14$, failed to produce significant increments in the amount of variance explained in time 2 depression. Time 1 depression emerged as a significant predictor of time 2 depression in all 4 steps. MS severity and MS status emerged as significant predictors of time 2 depression in steps 2 and 3. The variables in the final regression equation explained 65% of the variance in time 2 depression, ΔR^2 = .65, $F(15, 93) = 9.27$, $p < .001$. In relation to hypothesis 3, no mediation analyses were performed as optimism was found to be non-significant.

Table 12. *Summary of the regression analysis for variables predicting depression at time 2.*

		Depression Outcome Variable at Time 2			
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)	β (Step 4)
1	Time 1 Depression	.72***	.60***	.57***	.56***
2	Employed vs. Others		-.09	-.07	.00
	Unemployed vs. Others		-.12	-.11	-.12
	MS severity		-.19*	-.19*	-.17
	MS status		.16*	.16*	.14
3	Optimism			-.06	-.04
4	Perceived Benefits				.17*
	Illness Coherence				-.06
	Personal Control				-.08
	Acceptance				-.14
	Denial				.00
	Upward positive				-.04
	Downward Positive				-.13
	Upward Negative				-.12

Downward Negative				-.03
ΔR^2	.52***	.06*	.00	.07
R^2	.52***	.58***	.58***	.65***

Note: *p<.05, **p<.01, ***p<.001.

Table 13 provides a summary of the regression analysis for variables predicting mental well-being at time 2. Time 1 mental well-being explained 33% of the variance in time 2 mental well-being at step 1, ΔR^2 = .33, F(1, 92) = 46.11, p < .001. The addition of the control variable at step 2, ΔR^2 = .00, F(1, 91) = .58, p = .45, optimism at step 3 (hypothesis 1), ΔR^2 = .00, F(1, 90) = .55, p = .46, and the situated TCA variables at step 4 (hypothesis 2), ΔR^2 = .08, F(9, 81) = 1.18, p = .32, failed to produce significant increments in the amount of variance explained in time 2 mental well-being. In the first three steps, time 1 mental well-being was the only significant independent predictor of time 2 mental well-being. At step 4, time 1 mental well-being and perceived benefits emerged as significant predictors of time 2 mental well-being. The variables in the final regression equation explained 41% of the variance in time 2 mental well-being, ΔR^2 = .41, F(12, 93) = 4.85, p < .001. In relation to hypothesis 3, no mediation analyses were performed as optimism was found to be non-significant.

Table 13. *Summary of the regression analysis for variables predicting MCS at time 2*

		Mental Well-being Outcome Variable at Time 2			
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)	β (Step 4)
1	Time 1 mental well-being	.58***	.56***	.53***	.53***
2	MS duration		.07	.05	.02
3	Optimism			.07	.06
4	Perceived Benefits				-.26*
	Illness Coherence				.01
	Personal Control				.05

Acceptance				.00
Denial				.07
Upward positive				.21
Downward Positive				.02
Upward Negative				.01
Downward Negative				.00
ΔR^2	.33***	.00	.00	.08
R^2	.33***	.33***	.33***	.41***

Note: *p<.05, **p<.01, ***p<.001.

Table 14 provides a summary of the regression analysis for the variables predicting time 2 physical well-being. Time 1 physical well-being explained 65% of the variance in time 2 physical well-being at step 1, ΔR^2 = .65, F(1, 92) = 171.98, p < .001. The addition of the control variables at step 2, ΔR^2 = .01, F(6, 86) = .41, p = .87, optimism at step 3 (hypothesis 1), ΔR^2 = .00, F(1, 85) = .08, p = .78, and the situated TCA variables at step 4 (hypothesis 2), ΔR^2 = .01, F(9, 76) = .37, p = .95, failed to produce significant increments in the amount of variance explained in time 2 physical well-being. At each step, time 1 physical well-being was the only significant independent predictor of time 2 physical well-being. The variables in the final regression equation explained 67% of the variance in time 2 physical well-being, ΔR^2 = .67, F(17, 93) = 9.31, p < .001. In relation to hypothesis 3, no mediation analyses were performed as optimism was found to be non-significant.

Table 14. *Summary of the regression analysis for variables predicting PCS at time 2.*

		Physical well-Being Outcome Variable at Time 2			
Step	*Predictor Variables*	β (Step 1)	β (Step 2)	β (Step 3)	β (Step 4)
1	Time 1 physical well-being	.81***	.74***	.74***	.73***
2	Gender		.03	.04	.03
	Employed vs. Others		-.04	-.05	-.05
	Unemployed vs. Others		-.05	-.05	-.03
	MS Severity		.06	.06	.06
	MS Diagnosis		.02	.02	.00
	MS status		-.07	-.06	-.06
3	Optimism			.02	.02
4	Perceived Benefits				-.02
	Illness Coherence				-.06
	Personal Control				.07
	Acceptance				.06
	Denial				.03
	Upward positive				-.05
	Downward Positive				-.02
	Upward Negative				.10

Downward Negative				-.05
ΔR^2	.65***	.01	.00	.01
R^2	.65***	.66***	.66***	.67***

Note: *p<.05, **p<.01, ***p<.001.

Discussion

Previous research has found that the TCA explained significant and large amounts of variance in psychological adjustment in response to various health threats other than multiple sclerosis (MS) (Moore et al., 2006; Helgeson, 1999). The overall aim of the present study was to examine the extent to which the theory of cognitive adaptation could explain variance in adjustment among patients with MS.

Cross-sectional findings

In relation to the first hypothesis that dispositional optimism would explain significant amounts of variance in baseline adjustment (i.e., anxiety, depression, mental well-being and physical well-being) after significant covariates were controlled for, the regression analyses revealed that dispositional optimism explained significant amounts of variance in baseline anxiety, depression and mental well-being but not physical well-being. Higher levels of optimism predicted lower levels of anxiety, lower levels of depression and higher mental well-being. These results are consistent with previous research that has found that greater optimism was related to lower depression (Fournier, Ridder & Bensing, 1999, 2002; Gold-Spink, Sher & Theodos, 2000; Ridder, Schreurs & Bensing, 2000), lower anxiety (Fournier, Ridder & Bensing, 1999, 2002) and higher quality of life (Ridder, Schreurs & Bensing, 2000) in patients with MS.

In relation to the second hypothesis that the situated TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons and denial) would explain significant amounts of variance in baseline adjustment (i.e., anxiety, depression, mental well-being and physical well-being) over and above that of dispositional optimism, the regression analyses revealed that the situated TCA variables explained significant amounts of variance in baseline anxiety and depression but not mental well-being or physical well-being. In particular, negative downward social comparisons predicted higher levels of anxiety, while higher levels of denial predicted lower levels of depression and greater physical well-being. These findings are broadly consistent with previous research that has found that negative downward social comparisons were related to poorer adjustment (Dibb et al., 2006a, 2006b; King et al., 2009; Van der Zee et al., 1999) as well as research that has found that higher levels of denial were related to lower levels of depression and higher quality of life (Helgeson, 1999, 2003; Moore et al., 2006), although Stiegelis et al. (2003) found that denial was not related to adjustment.

In relation to the third hypothesis that the situated TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons and denial) would mediate the relationship between dispositional optimism and baseline adjustment (i.e., anxiety, depression, mental well-being and physical well-being), mediation analyses revealed that the situated TCA variables partially mediated the relationship between dispositional optimism and anxiety, dispositional optimism and depression, and dispositional optimism and mental well-being.

However, when the situated TCA variables were examined individually, only negative downward social comparisons were found to mediate the relationship between optimism and anxiety, while only denial was found to mediate the relationship between optimism and depression. The findings from the present study suggest that lower levels of optimism may make individuals more likely to engage in negative downward social comparisons, which in turn may be related to higher levels of anxiety. The findings also suggest that higher levels of optimism may make individuals more likely to engage in denial, which in turn may be related to lower levels of depression. These findings support the TCA but can be contrasted to those of previous cross-sectional studies that have found that greater optimism reduced the use of denial as a coping strategy, which in turn led to lower levels of anxiety and depression (Carver et al., 1993; Brissette, Scheier & Carver, 2002).

Overall, these results provide modest support for the TCA as only partial support was found for each of the three hypotheses in this study cross-sectionally. To date, research investigating the TCA has typically employed cross-sectional designs. However, this has made it difficult to establish the direction of any significant relationships. Therefore, the present study also assessed the ability of the TCA to explain variance in adjustment prospectively.

Prospective findings

In relation to the first hypothesis that dispositional optimism would explain significant variance in adjustment prospectively, controlling for baseline adjustment and significant covariates, the regression analyses revealed that dispositional optimism failed to explain significant additional variance in anxiety, depression, mental well-being or physical well-being. These findings are in contrast to previous research that has found that

optimism was related to lower levels of anxiety (Stiegelis et al., 2003), lower levels of depression (Karademas, 2006) and higher quality of life (Helgeson, 2003). However, it is possible the 3 month follow-up period in the present study may have been too short to test this hypothesis as there was little change in adjustment over time; thus, the time 1 adjustment scores explained large amounts of the variance in the time 2 adjustment scores.

In relation to the second hypothesis that the situated TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons and denial) would explain significant variance in adjustment prospectively over and above dispositional optimism, the regression analyses revealed that the situated TCA variables failed to explain significant additional amounts of variance in anxiety, depression, mental well-being or physical well-being prospectively. As stated earlier, it is possible the 3 month follow-up may have been too short to test this hypothesis. Despite this limitation, benefit finding emerged as a significant independent predictor of anxiety and mental well-being. However, the direction of these relationships was contrary to the predictions of the TCA as greater benefit finding was found to predict higher levels of anxiety and lower mental well-being.

Although these findings are contrary to the TCA and previous research that has found that greater benefit finding was related to lower psychological distress (Hart et al., 2008), these findings are consistent with other research that has found that greater benefit finding was related to greater psychological distress (Tomich & Helgeson, 2004), and poorer mental well-being (Tomich & Helgeson, 2002) prospectively. A number of explanations have been offered for this pattern of results (see McFarland & Alvaro, 2000; Tomich & Helgeson, 2004). In particular, benefit finding might be a coping

strategy that is employed when faced with increasing anxiety or a coping strategy that provokes anxiety when exaggerated perceptions of benefit are challenged by the reality of living with the illness.

In relation to the third hypothesis that the situated TCA variables (i.e., benefit finding, illness coherence, primary control, secondary control, social comparisons and denial) would mediate the relationship between dispositional optimism and adjustment prospectively, no mediation effects were found. This is in contrast to previous research that has found mediation effects prospectively (Carver et al., 1993; Brissette, Sheier & Carver, 2002). Again, it is possible the 3 month follow-up period may have been too short to test this hypothesis.

In summary, partial support was found for the TCA cross-sectionally but not prospectively. Contrary to the TCA, greater benefit finding was found to predict poorer psychological adjustment prospectively. However, this pattern of results provides support for research that has suggested that benefit finding might be a coping strategy that is used in response to high levels of anxiety or provokes anxiety as exaggerated perception of benefits are not matched by the reality of living with MS. Future research could explore the role of benefit finding in adjustment to provide greater insight into the range of alternative explanations that have been offered for this pattern of results.

Methodological Critique

The current study has a number of limitations that need to be considered. First, the sample was predominantly white female patients who had relapsing-remitting type MS (n = 63). Second, the small number of participants with progressive types of MS (n = 33) and the exclusion of patients with cognitive impairment (n = 1) may have resulted in a

sample that was biased towards lower levels of severity and higher levels of positive adjustment. Third, although the response rates at time 1 and time 2 were high (Punch, 2003), the overall sample size was relatively small. Together with the large number of control variables that were sometimes explored in the regression analyses, the statistical analyses for this study may have been underpowered at times, increasing the risk of a type II error (Cohen, 1988). Fourth, the short follow-up period resulted in the time 1 adjustment scores explaining large amounts of the variance in the time 2 adjustment scores, limiting the amount of variance that was available for the TCA to explain. A longer follow-up period may have negated this problem. Fifth, the measure of primary control had the lowest internal reliability in this study. Although satisfactory, this could partly account for the failure of primary control to predict adjustment as hypothesised. Sixth, it has been recommended that the TCA is assessed using both situated and dispositional measures (Dennison, Moss-Morris & Chalder, 2009; Tomich & Helgeson, 2006). This study employed situated measures for each of the TCA components and a dispositional measure for optimism. Although the use of a dispositional measure for optimism was consistent with previous research (Helgeson, 1999, 2003; Stiegelis et al., 2003), dispositional measures of optimism cannot be directly compared to situated measures of the TCA as they are measuring different constructs (Moore et al., 2006). Seventh, the present study replicated one of the limitations of previous research by relying on self-report questionnaires. Brennan and Barnett (1998) also questioned the extent to which self-report measures may reflect a common underlying dimension of negative affectivity. They recommend future research controls for negative affectivity as a confounding variable.

Future Research

New directions for future research include investigating how the influence of the TCA on adjustment changes throughout the course of an illness. Future studies could recruit participants during the pre-diagnostic assessment phase and continue to assess them across the duration of their illness. Research could also investigate the unexpected result that greater benefit finding predicted greater anxiety and lower mental well-being, over time. Tomich et al. (2004) suggested this pattern of results may represent a return to baseline anxiety at follow-up, a coping strategy that is employed when faced with increasing anxiety or a coping strategy that promotes anxiety when exaggerated perceptions of benefit are challenged by the reality of living with the illness. These theoretical debates could be empirically explored.

Clinical Implications

As discussed previously, the present findings are limited by a number of methodological issues. While acknowledging these caveats, it is still possible to draw a number of potential clinical implications from the main findings. Considering the cross-sectional results, greater optimism was related to lower anxiety, lower depression and higher mental well-being. Clinicians could consider psychological interventions that have been found to increase levels of optimism. For example, Fresco et al. (1995) suggests cognitive behaviour therapy may be able to increase optimism in patients with chronic illnesses. Second, denial predicted lower levels of depression and higher mental well-being. Clinicians may need to be aware that denial could be an adaptive coping strategy. Third, negative downward social comparisons predicted higher levels of anxiety. Clinicians could consider psychological interventions that could target negative social comparison appraisals. For example, cognitive behaviour therapy has been found to increase positive appraisals in patients with chronic illnesses (Manne & Zautra, 2004). However, clinicians may need to consider these implications with caution as none of

these findings were supported prospectively in this study and the cross-sectional nature of these findings means that the direction of these relationships can be questioned.

Prospectively, greater benefit finding predicted higher levels of anxiety and poorer mental well-being. Therefore, clinicians may need to be aware that efforts to find benefits may be related to greater psychological distress. However, more research is needed as there are a range of alternative explanations for this finding. Future research could investigate these alternative explanations to provide greater insight and clearer guidance for clinicians.

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Appendices

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03 September 2009

Miss Chloe Goble
Clinical Psychology Unit
Western Bank,
Sheffield
S10 2TP

Dear Miss Goble

Study Title: **Psychological Adjustment to Multiple Sclerosis**
REC reference number: **09/H1310/47**
Protocol number: **2**

Thank you for your letter of 17 August 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

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Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Supervisor CV - Dr Paul Norman		
Questionnaire: Validated		
Covering Letter		
Investigator CV		
REC application		03 June 2009
Peer Review		03 June 2009
Protocol	3	17 August 2009
Participant Information Sheet	3	17 August 2009
Participant Consent Form	3	17 August 2009
Covering letter addressing points set out in provisional opinion letter		17 August 2009
GP Letter	1	17 August 2009
Response to Request for Further Information		17 August 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H1310/47	**Please quote this number on all correspondence**

Yours sincerely

J Brown

Miss Jo Abbott
Chair

Enclosures: **"After ethical review – guidance for researchers"** SL-AR2

Copy to: **STH R&D Department**

Appendix C

Participant Information Sheet and Consent Form

The University Of Sheffield.

Department of Psychology
Clinical Psychology Unit
Department of Psychology
The University of Sheffield
Western Bank
Sheffield, S10 2TP

Telephone: 0114 2226650
Fax: 0114 2226610

Email: pcp07cg@sheffield.ac.uk

PATIENT INFORMATION SHEET

Version 3 (17.08.09)

Psychological adjustment to Multiple Sclerosis

You are being invited to take part in a research study.
This project is part of my training as a clinical psychologist. Before deciding whether or not you wish to take part it is important you understand why the research is being done and what it will involve. Please read the following information and discuss it with friends and relatives if you wish. Feel free to contact us by telephone or email if there is anything you are unsure of.

What is the purpose of the study?
The study aims to investigate the thoughts and beliefs people with Multiple Sclerosis have about their illness and whether these thoughts and beliefs can help us understand how well a person will cope and adjust in the future. We hope the study will provide information to improve the support provided to individuals diagnosed with MS.

Why have I been invited to participate?
You have been invited to participate because this study is interested in people who have experienced a diagnosis of Multiple Sclerosis.

What will be involved if I agree to take part in the study?
We need to record a small number of details about you, for example, current medication, type of MS, date of onset and current symptom status. We want to explore the effect these factors have upon adjustment to MS. In order to do this the named researcher may need to look at relevant sections of your medical notes. Section three on the consent form allows you to indicate whether or not you give permission for the named researcher to access your medical notes to obtain relevant information.

The main focus of the study is to explore the thoughts individuals have about their Multiple Sclerosis and how these thoughts relate to mood and quality of life. Participants will be asked to complete a questionnaire pack to collect information about their thoughts and their current mood and quality of life. Three months later participants will be asked to complete a second questionnaire that is much shorter and collects information about mood and quality of life.

Do I have to take part?
No. There is no obligation to take part. Participation is voluntary. If you do not wish to take part please discard this information sheet. This will not affect the standard of care you receive.

Benefits and disadvantages to taking part in this study
There will be no direct benefits to you taking part in this study. However, the information we obtain will help to inform future service provision for individuals with Multiple Sclerosis.

It is possible that thinking about your Multiple Sclerosis may cause you distress. If this should happen you can speak to the researcher, your GP or Claire Isaac from the MS clinic staff team on 0114 271 3770.

Can I withdraw from the study at any time?
Yes. You may withdraw at any time without giving reason. This would not affect the standard of care you receive. If so, please contact me either by phone, letter or email at the address given at the beginning of this sheet. Your consent form will then be destroyed and your details will be removed.

Will the information obtained in the study be confidential?
All the information collected in this study is confidential. Your name and any identifiable information will **not** be mentioned in any write up of the study and will **not** be passed on to other people or organisations. The information collected will be marked with a number and **not** your name, date of birth or address. Name and contact details are taken for the 3 month follow-up but they are stored separately and destroyed immediately after use.

What will happen to the results of the study?
The project is being conducted as part of my training for the Doctorate Programme in Clinical Psychology. A report of the results will be written.

Who do I contact for more information?
If you would like any further information you can contact Chloe Goble (Researcher) by leaving a message with the Research Support Officer on 0114 222 6650. The Research Support Officer will only be able to take a message but Chloe Goble will then return your call as soon as possible.

What if I wish to complain about the way in which this study has been conducted?
If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. You can access this by contacting the Patient Advice and Liaison Service (PALS) on 0114 271 2450. Or if you have any complaints or concerns about the study itself please contact Dr David Fletcher (University Registrar and Secretary) by post at Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN or by telephone on Tel 0114 222 1100. Finally, you can also contact Dr Paul Norman (Project Supervisor) and Chloe Goble (Researcher) directly to inform us of any complaints by telephoning 0114 222 6505 or by sending mail to Dr Paul Norman Reader in Health Psychology, Department of Psychology, University of Sheffield, Sheffield, S10 2TP.

Thank you for taking the time to read this information sheet.

Chloe Goble (Researcher)

The University Of Sheffield.

Department of Psychology
Clinical Psychology Unit
University of Sheffield
Western Bank
Sheffield, S10 2TP

Telephone: 0114 2226650
Fax: 0114 2226610

Email: pcp07cg@sheffield.ac.uk

Centre Number:
Study Number:
Participant ID No:

PATIENT CONSENT FORM
Version 3 (17.08.09)

Title of the Project: **Psychological adjustment to Multiple Sclerosis**
Name of Researcher: **Chloe Goble**

Please initial box

1) I confirm that I have read and understand the patient information sheet dated 17.08.09 (Version 3) for the above study and have had the opportunity to ask questions. ☐

2) I understand that my participation is voluntary and 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 sections of any of my medical notes may be looked at by the named researcher where it is relevant to my taking part in research. I give permission for this individual to have access to my medical records. ☐

4) I agree to my GP being informed of my participation in the study. ☐

5) I agree to the researcher contacting me in three months' time for completion of the second questionnaire. ☐

6) I understand that data collected during the study may be looked at by individuals from the Research Support Office in the Clinical Psychology Unit, by Regulatory authorities of 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 my records. ☐

7) I agree to take part in the above study. ☐

Name (printed)	Date	Signature