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**D.CLIN. PSYCHOL.
UNIVERSITY OF EDINBURGH / NHS (SCOTLAND)
TRAINING PROGRAMME**



**The clinical effectiveness of CBT-based self-help for symptoms of fatigue in
Multiple Sclerosis**

Kirsty Gallen

Doctorate in Clinical Psychology

The University of Edinburgh

May 2015

**D.CLIN. PSYCHOL.
UNIVERSITY OF EDINBURGH / NHS (SCOTLAND)
TRAINING PROGRAMME**



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Submitted in part fulfilment of the degree of doctorate in Clinical Psychology at the University of Edinburgh

Date Submitted: 1st May 2015

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Acknowledgements

Firstly, I would like to thank all the participants who agreed to take part in this study. I would also like to thank all members of the Fife Rehabilitation Service and the Clinical Psychology Service in NHS Fife who have supported me through this research. I would like to pay a special mention to Debbie McCallion and Ann Donaldson (specialist MS nurses) who shared their vast experience and specialist knowledge. I would also like to thank Dr Lance Sloan (Consultant in Rehabilitation Medicine) who supported the production of the self-help workbook. I would like to thank Paul Gallagher for providing the illustrations in the workbook. In addition, I would like to thank all the secretarial staff in Stratheden Hospital who supported the practicalities of gathering data.

A big thank you to the clinical psychology team in the Fife, especially the team in the Fife Rehabilitation Service for all their help. A special thanks to my clinical supervisor Debbie Pitcaithly for her support developing the idea for my thesis, as well as providing supervision and reassurance over the last 5 years. I would like to thank my academic supervisor, Dr Paul Morris for his support and valuable feedback, I have learnt a lot from your approach to research and I hope to carry this forward in my career.

I would like to thank my family and friends in Newcastle, Scotland and Ireland for their support and words of encouragement. A special thank you to my wonderful parents, you have always believed in me and enabled me to follow my dreams.

Finally, I would like to thank my amazing husband and beautiful daughter you have both helped to remind me that there is a world that exists outside of this course! Sean – I could not have done this course without you. You have been my rock throughout this journey and I appreciate all your support, love and encouragement. Olivia – you have made the end of this journey much more bearable and you never fail to make me smile.

THANK YOU ALL!

1. Thesis Abstract

Purpose: The aim of the systematic review was to address whether psychological interventions were able to reduce fatigue severity or the impact of fatigue in individuals with Multiple Sclerosis. The empirical study aimed to evaluate the effectiveness of a CBT based self-help workbook at reducing perceived impact of fatigue in a clinical sample of MS patients.

Methods: A systematic search of the literature was carried out between the years 1980 and February 2015 to review whether psychological interventions were effective for fatigue management in Multiple Sclerosis. A randomised controlled trial examined the effectiveness of a CBT-based self-help workbook for the reduction of fatigue impact in MS. Participants were randomly allocated to one of three groups treatment as usual (TAU), pure self-help (PSH) or guided self-help (GSH).

Results: Eleven studies were included in the systematic review, which indicated that CBT based interventions aiming to reduce fatigue or depression were most effective at reducing the severity of fatigue. Impact of fatigue can be reduced through mindfulness, CBT, motivational interviewing and to a lesser extent acceptance and commitment therapy. The empirical study did not find any significant differences between groups, however satisfaction with the workbook was high.

Conclusions: The review suggests that there is a clear role for psychological interventions in fatigue management in MS, although further robust research into different therapeutic modalities is needed. From the empirical study it appears that the low level CBT-based intervention for fatigue in MS was not effective at reducing the perceived impact of fatigue. This study reflects an inclusive, clinical sample, recruited from a specialist rehabilitation unit, with high levels of multidisciplinary input which may have diluted any potential effect of the workbook.

Word count – 277

2. Systematic Review

Title

Are psychological interventions effective for fatigue management in Multiple Sclerosis? –

A systematic review

Kirsty Gallen¹, Debbie Pitcaithly² & Paul Graham Morris³

This review has been written with a view to publication in the journal *Clinical Rehabilitation* and therefore follows formatting and referencing styles suggested in the journals guidelines. A copy of the guidelines can be found in Appendix 1.

Word count 3713 (not incl. Tables, references and abstract)

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2.1. Abstract

Objectives: The aim of the systematic review was to address whether psychological interventions are able to reduce fatigue severity or the impact of fatigue in individuals with Multiple Sclerosis

Data sources: A search was conducted of: Psychinfo, Medline, Embase, CINAHL between 1980 and February 2015.

Review methods: All studies were evaluated against a set of quality criteria by author (KG) with a proportion of studies being independently reviewed by author (DP) to ensure reliability of ratings.

Results: Eleven studies were included in the review. CBT based interventions with a focus on fatigue management and depression appear to significantly reduce fatigue severity with medium to large effect. Significant reductions in fatigue impact can be found from mindfulness groups, motivational interviewing and CBT. Effect sizes for CBT interventions ranged from negligible to medium. For the mindfulness and motivational interviewing interventions effect sizes were not able to be calculated. The acceptance and commitment therapy intervention did not find a significant reduction in fatigue but found a medium effect for the intervention.

Conclusions: There is a clear role for psychological interventions in the reduction of fatigue management but more high quality research needs to be carried out.

Word count - 193

Keywords

Fatigue, Tiredness, Multiple Sclerosis, MS, effectiveness, psychological interventions, Psychological therapy, CBT, systematic review

2.2 Introduction

Multiple sclerosis (MS) is a disabling neurological condition caused by inflammation of the central nervous system (CNS). The protective sheath around nerve fibres in the CNS is damaged which interferes with the transference of messages passed along the nerves. As well as physical problems such as spasticity, fatigue and muscle control, there can also be psychological complications (anxiety, depression) and cognitive deterioration. There is estimated to be 85,000 people with MS in the UK¹. Prevalence rates of MS vary across regions with between 100 and 120 per 100,000 in England² and 180 per 100,000 in Scotland³. Up to 90% of patients with Multiple Sclerosis (MS) complain of fatigue and two thirds of patients categorise fatigue as their most troubling symptom⁴. Fatigue can be defined as ‘a subjective lack of physical and/or mental energy that is perceived by the individual or caregiver to interfere with usual and desired activities’⁵. Fatigue in MS has been shown to be associated with mood problems⁶ and can have a significant impact on daily life⁷.

Interventions

Biomedical interventions consist of pharmacological treatments which have produced mixed results. Twenty to forty percent of patients with mild to moderate symptoms of MS experience a short term reduction of fatigue symptoms using Amantadine (a dopamine agonist)⁵. Minimal effects have been found for Pemoline, a central nervous system stimulant^{8, 9}. Modafinil, a drug used to treat excessive sleepiness, has been tested in MS populations with varying results^{10, 11}.

Traditional behavioural interventions for the management of fatigue in MS focus on energy conservation, increasing activity, body mechanics, ergonomics and lifestyle changes¹²⁻¹⁶. However, research suggests that biomedical interventions and behavioural therapies do not provide a complete approach to fatigue management^{17, 18}. There is some evidence that psychological approaches, particularly cognitive behavioural therapy (CBT), may be effective in the management of fatigue in Chronic Fatigue Syndrome and do not produce the unwanted side effects seen in pharmacological interventions^{19, 20}. Furthermore, some evidence has started to be reported regarding the effectiveness of CBT based interventions for fatigue in MS²¹.

Justification for current review

A general search was carried out to identify any existing reviews that incorporated elements of the current question by entering the terms multiple sclerosis and fatigue into the DARE and Cochrane library databases. At the time of searching (February 2012) two systematic reviews were found, one looking into psychological interventions for MS²² and one looking specifically at mindfulness interventions in MS, not specific to fatigue management²³.

Reference lists from these reviews were checked and four studies have been considered for inclusion in the current review²⁴⁻²⁷. Further searches via the Cochrane Multiple Sclerosis and Rare Diseases of the Central Nervous System Group found no further reviews for psychological interventions for fatigue in MS.

As the reviews discovered were either not specific to fatigue or were specific to one type of psychological therapy only, namely CBT, it was decided that a systematic review which included all psychological interventions for fatigue in MS was a relevant to this field.

Aim

To address whether psychological interventions are able to reduce fatigue severity or the impact of fatigue in individuals with Multiple Sclerosis.

2.3. Methods

The Centre for Reviews and Dissemination (CRD)²⁸, The University of York guidelines review (www.york.ac.uk/inst/crd/) and SIGN guideline 50²⁹ were followed when carrying out and reporting this current systematic review.

Inclusion and Exclusion criteria

The PICOS guidelines³⁰ were used to develop selection criteria for relevant articles, see below for full description.

Population(s)

This review included all people aged 18+ with a diagnosis of MS recognised by a suitable clinician (e.g. neurologist). All types (relapsing remitting, secondary progressive, benign, primary progressive) and all durations of multiple sclerosis (from newly diagnosed to longer term) were included.

Intervention(s)

Studies that evaluated a psychological intervention which aimed to reduce fatigue in MS as a primary or secondary outcome were included. All formats of psychological therapy were included e.g. individual, group based, guided self-help, telephone based therapy and pure self-help. Interventions needed to be derived from a psychological therapy such as cognitive behavioural therapy, psychodynamic therapy, schema therapy, acceptance and commitment therapy, mindfulness etc.

This review did not include complimentary therapy or pure relaxation therapy or generic supportive counselling/ social support (where no psychological theory could be identified). This ensured that all therapies included had an evidence base. The review omitted any interventions where a psychological therapy was combined with other physical therapies or occupational therapies such as body ergonomics, goal setting or the implementation of adaptive equipment. The rationale for this was to try and keep the review as 'pure' as possible as a combination of two different types of therapy would make it difficult to distinguish which part of the therapy was effective.

The therapists for included studies could be from any specialty as long as they were suitably qualified and/or experienced in the type of therapy they were providing and/or were supervised by a suitably qualified therapist.

Comparison(s)

Where there were control/comparator groups, all types of comparators were included e.g. waitlist, healthy controls, intervention controls etc. Where there were multiple comparators, the control groups which were as similar to other controls in the review were selected as the comparator.

Outcomes (Primary / Secondary)

Studies included measured fatigue at baseline and post intervention as a minimum. Studies which measured physical and/ or mental fatigue were included. Measures were included which focused on reduction in fatigue severity or reduction in impact of fatigue on participant's life.

Study Design

As this is a relatively new area of research the following types of studies were included in this systematic review ; randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trial, comparative studies and case series.

Only studies available in English language were included as there was no available means of translation from other languages.

Literature Search Strategies

Systematic searches were conducted in the following electronic databases: Psychinfo, Medline, Embase, CINAHL. In addition relevant studies were searched via the online database for the Journal of Multiple Sclerosis and the Journal of MS Care. Hand searches of studies cited by papers included in the current review were also considered for inclusion. The searches were conducted between the publication years of 1980 to February 2015. Search terms are listed in Appendix 2. From this search strategy 202 studies were identified. Using the PICOS criteria, firstly titles of studies were reviewed for suitability, then abstracts of relevant studies were reviewed and then the full articles of studies were reviewed to ensure they met inclusion criteria. See Figure 2.1.

Data Extraction

The following information was extracted from relevant studies; country, total number of participants (N), MS type, gender, age, intervention arms, total treatment time, type of treatment, measure of fatigue, follow up period, effect size (pre to post) recruitment method and key findings seen in Table 2.1 – Characteristics of reviewed studies.

Effect size

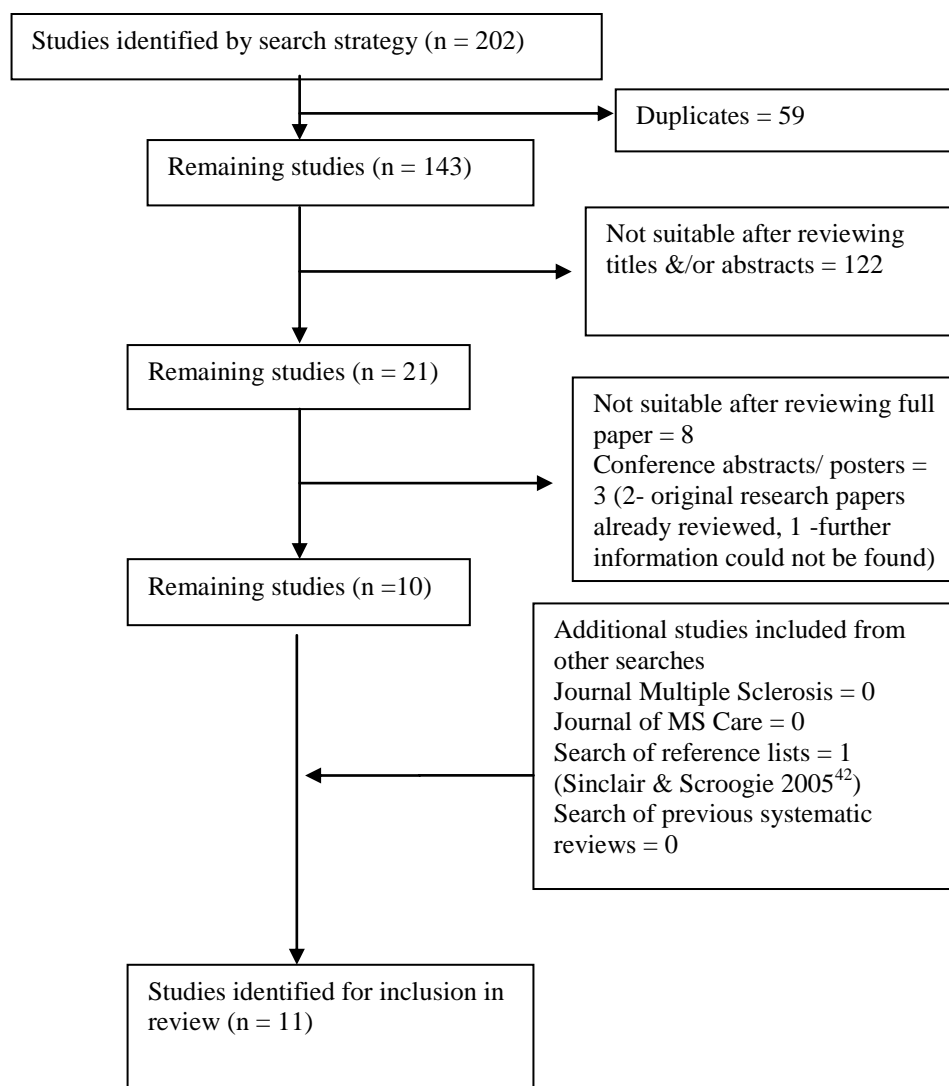
Effect sizes were calculated using Cohen's d ³¹ for pre and post fatigue measures where possible (See Table 2.1). Cohen's d allows a classification of the strength of difference between two measures (e.g. pre and post), small ($d = .20$), medium ($d = .50$) or large ($d = .80$)³⁰, this enables the reader to evaluate the magnitude of the strength of the intervention.

Assessment of quality

The quality of the selected papers were assessed using a purposely designed assessment tool based on the SIGN guidelines (prior to Feb 2013). The CRD recommendations were considered when designing the quality criteria (www.york.ac.uk/inst/crd/). A copy of the quality criteria used can be found in Appendix 3. All studies were rated by author KG. To ensure reliability of ratings, 80% of the papers were randomly selected and rated by the second author (DP). An overall agreement rating of 75% was reached. Where there were discrepancies, they were discussed until a final agreement was reached.

All criteria were given a rating either; not applicable, not reported, not addressed, poorly addressed, adequately addressed or well covered in relation to their methodological ability to address the review question. Where 100% of criteria were rated as adequate or well covered the methodological quality was rated overall as excellent. Where 70% of criteria were rated adequate or well covered the methodological quality was rated overall as very good. Where 50% of criteria were rated adequate or well covered the studies methodological quality was rated overall as good. Those studies where less than 50% of criteria were rated as adequate or well covered were classified overall as adequate. Table 2.2 shows all studies ranked in order of highest to lowest quality.

Figure 2. 1 - Flowchart Detailing Study Selection Procedure



2.4. Results

Study Characteristics

An overview of study characteristics can be found in Table 2.1. There were seven randomised controlled trials^{27, 32, 33, 35-37, 40} and three non-controlled trials^{44, 46, 47} and one repeated measures trial⁴² included in this review. Sample sizes ranged from 15-164. Mean ages ranged from 38-53. The majority of studies used patients with relapsing remitting multiple sclerosis seven studies included patients with secondary progressive multiple sclerosis^{27, 32, 33, 35-37, 44}, five reported that they included participants with primary progressive multiple sclerosis^{32, 33, 36, 37, 44}, two study reported that they included benign MS^{32, 36}, three studies did not specify the types of MS included^{40, 46, 47}. The percentage of female participants ranged from 69-100%. Four studies were undertaken in the UK, five in the USA, one in New Zealand and one in Switzerland.

Table 2.1 Characteristics of reviewed studies

Study Country	Total N	Gender (female)	Mean age (SD)	Tx arm(s) (N)	Total treatment time (in minutes)	Type of treatment	Measure of fatigue <i>Severity / Impact / both</i>	Pre mean (SD)	Post mean (SD)	Effect size pre to post (Cohen's d)	Follow-up period (N)	Recruitment method	Key findings related to fatigue
Thomas, et al 2014 ³² UK	164	CBT 73% CLP 73%	CBT 48 (10.2) CLP 50.1 (9.1)	CBT (84) CLP (80)	540+ homework	Group	Global fatigue severity subscale of FAI <i>Severity</i>	CBT 5.60 (0.98) CLP 5.61(1.09)	CBT 5.48 (0.92) CLP 5.55 (1.17)	CBT 0.12 CLP 0.05	1 mo 4 mo 12 mo	Primary and secondary care MS Society newsletter/ website	The CBT based fatigue management group did not find a significant reduction in fatigue at 2 months (post follow up) but found a significant reduction at 4 months and a close to significant reduction at 12 months. The effect size at 2 months was small which increased to a large effect size at 4 months and this was maintained at 12 months.
Van Kessel et al. 2008 ³³ New Zealand	72	CBT 80% RT 70%	CBT 42.89 (9.29) RT 47.03 (9.45)	CBT (35) RT (37) Matched healthy controls (72)	400 +homework	Individual face to face and phone	Chalder Fatigue Scale ³⁴ (CFS) <i>Severity</i>	CBT 20.94(4.25) RT 20.32 (4.28)	CBT 7.90 (4.34) RT 11.57 (5.28)	CBT 3.03 RT 1.83	2 mo 5 mo 8 mo	Hospital MS service Identified by MS nurses/ workers MS Society	CBT and relaxation therapy significantly reduced fatigue in MS patients when compared to a healthy control group. CBT was significantly more effective than relaxation therapy at post treatment. Effects were sustained at 6 month follow up.
Grossman et al. 2010 ³⁵ Switzerland	150	MBI 78% UC 81%	MBI 45.93 (10.00) Usual Care 48.68 (10.58)	Mindfulness based intervention (MBI =76) Usual care group (UC = 74)	1620 + 2240 of homework	Group	Modified Fatigue Impact Scale (MFIS) ³⁸ <i>Impact</i>	MBI 35.15 (16.68) UC 30.28 (14.98)	MBI ^a 6.19 (3.96-8.41) UC ^a 0.36 (-2.90 – 2.61)	MBI ^b 0.41 (0.09-0.73)	Post 6 mo	Self referral Recruitment via outpatient clinic, physicians or advertisements in MS bulletin	Participants who attended the Mindfulness Based Intervention (MBI) improved on fatigue measure significantly more than those in the usual care (UC) group at post and 6 month follow up. The amount of mindfulness practice correlated with improvements in fatigue.
Bombardier et al. 2008 ³⁶ USA	130	78% FEMALE	46.2	Motivational Interview (MI, N- 70) Wait List controls (60)	210-240 MI based counselling	Individual, telephone	MFIS ³⁸ <i>Impact</i>	MI 39 (16.49) W/L controls 32 (18.87)	MI 34(16.12) W/L controls 32(18.62)	MI 0.31 W/L controls 0	Post (14 weeks)	Advertisements, flyers in neurologists offices. Also recruited from a previous study	Fatigue decreased significantly in the treated group and remained unchanged among the controls. Only 7.1% of participants chose fatigue as a target area to work on with support of the MI techniques.

Moss-Morris et al. 2012 ³⁷ UK	40	Computer- rised CBT 69.63% W/L Control 94.1%	MS Invigor (CBT) 40.14 (17.76) W/L Control 41.81 (11.43)	MS Invigor (23) W/L Control group (17)	290-580 +homework	Computer and phone	Chalder Fatigue Scale(CFS) Severity MFIS ³⁸ Impact	MS Invigor 21.39 (4.30) W/L Control 21.53 (3.62) MS Invigor 13.17 (3.81) W/L Control 12.69 (3.89)	MS Invigor 12.39 (6.84) W/L Control 19.57 (5.20) MS Invigor 9.0 (3.75) W/L Control 12.88 (3.89)	CFS 1.57 MFIS 1.10	Post treatme nt (10 weeks)	Advertisement on MS Society and MS Trust website and local press release	The internet based CBT intervention for fatigue management significantly reduced both severity of fatigue and impact of fatigue on daily living. Large effect size from both fatigue measures were found compared to the control group.
Mohr, Hart & Goldberg 2003 ²⁷ USA	60 ^a	Overall 71.7% not group break- down.	44.6 overall no group break- down	CBT 22 SEGP 16 Sertraline 22	CBT – 800 SEGP - 1440	CBT – individual face to face SEGP - group	Fatigue Assessment Instrument FAI ³⁹ Severity subscale Impact subscale	CBT 58.2 (8.67) SEGP 60.7 (8.83) CBT 17.3 (2.92) SEGP 16.8 (2.61)	CBT 52.5 (12.52) SEGP 61.3 (9.89) CBT 16.4 (3.35) SEGP 17.1 (2.93)	CBT 0.53 SEGP -0.064 CBT 0.29 SEGP -0.11	Post (week 16)	Referred by neurologists, other health care professionals, the National Multiple Sclerosis Society, advertising or by other means	Treatment for depression was associated with a reduction in overall fatigue as measured by the FAI. The effect was due primarily to reductions in the global severity of fatigue subscale from the FAI. All 3 conditions reduced fatigue.CBT and medication were more effective at reducing fatigue than the supportive group.
Mohr, Hart & Vella 2007 ⁴⁰ USA	127	TCBT = 75.8% T-SEFT = 78.5%	TCBT = 48.60 (9.62) TSEFT = 7.35 (1.10)	TCBT (n-62) T-SEFT (n- 65)	800	Individual, telephone	FIS ⁴¹ Impact	Not reported	Not reported	N/A	Mid tx (8 weeks) Post (16 weeks)	Database from Medical Care facility and regional national MS Society. Offer of payment for completion of assessment	Fatigue reduced for both groups. There was a greater reduction in fatigue for the CBT group on measures of physical fatigue. Significant effects of reduction on fatigue remained when controlling for level of depression.

Sinclair & Scroggie 2005 ⁴² USA	37	100% Female	38	Participants served as own controls	600	CBT Group	FSS ⁴³ <i>Both</i>	5.67	5.59	No SD reported	Post (5 weeks) 6mo	Neurologist and local MS Society advertisement	There were no significant improvements in fatigue but there was a trend in positive direction.
Thomas et al. 2010, ⁴⁴ UK	16 ^d	69%	45.5	CBT - 16	540	Group	FAI ³⁹ <i>Severity</i>	5.8 (1.0)	5.6 (1.1)	0.19	Post (1 month)	MDT members from a hospital MS service - offered opt in	There were no significant differences in fatigue scores between pre and post measures. The satisfaction evaluation showed that the programme was relevant to those who participated.
							Brief Fatigue Inventory <i>Severity</i>	6.4 (1.6)	5.7 (2.3)	0.35			
							FAI Impact subscale	5.8 (1.0)	5.8 (1.1)	0.0			
							BFI Impact subscale <i>Impact</i>	6.0 (2.2)	5.8 (2.2)	0.09			
Sheppard et al. 2010 ⁴⁶ USA	15	80%	53.13 (7.68)	ACT group (15)	300	Group	(MFIS) ³⁸ <i>Impact</i>	51.21 (21.43)	40.00 (22.01)	0.52	Post (3 mo)	Advertisements and local neurology clinic	There was no significant change in the fatigue measure following the ACT group but results were in the correct direction i.e. showing a reduction in fatigue.
Askey-Jones et al. 2012 ⁴⁷ UK	90	73% female	43 (11.4)	Formal CBT - n=29	Mean CBT session- 11	Individual	FSS ⁴³ <i>Both</i>	36.95 (22.30)	32.63 (22.95)	0.01	Post (6 month)	MS Specialist nurses and neurologists referred in	The service provided a triage service based on stepped care model for depression where therapy in the form of CBT was one treatment option offered by nurses. There was no standardised protocol for CBT sessions with a varying number of session per patient. No significant difference were found from baseline on fatigue scores.

N = number of participants in study, SD = standard deviation, Tx = treatment/intervention, CBT = Cognitive Behavioural Therapy, RT = Relaxation Therapy, CLP = Current Local Practice ACT = Acceptance and Commitment Therapy, MBI = Mindfulness Based Intervention, SEGP = Supportive Emotional Group Psychotherapy, TCBT = Telephone Cognitive Behavioural Therapy, T-SEFT -Telephone Supportive Emotion Focused Therapy, MI = Motivational Interview,^a Comparison of CBT and SEGP only for purposes of systematic review ^a post intervention change (95% confidence interval) ^bEffect size passed on mean change at post intervention with 95% confidence interval. ^d combination from 2 iterations but no major changes to the programme were made

Quality assessment

The quality assessment (see Table 2.2) suggested that Thomas et al. 2014³² Van Kessel et al.³³ and Grossman et al.³⁵ conducted the methodologically strongest studies. Approximately half the studies had some form of comparison group, such as active therapy, usual care, waitlist controls or matched healthy controls. The studies with lower quality ratings Sheppard et al.⁴⁶, Thomas et al. 2010⁴⁴ and Askey-Jones et al.⁴⁷ did not have control groups and therefore rated lowest on this criteria and were not able to be scored on the other related criteria (randomisation to groups, matched demographic variables, matched baseline measures and matched attrition levels). Only four studies recorded follow up data beyond the immediate post intervention data collection^{32, 33, 35, 42}. The majority of studies reported low levels of attrition (less than 20%) with some of the better quality papers reporting extremely low rates of 4%³³ to 10%³⁷, suggesting good face validity of interventions.

Table 2.2 Methodological Quality Criteria Ratings

	1) Control group	2) Allocation	3) Demographic variables matched	4) Baseline measure of fatigue matched	5) Intervention Fidelity	6) Fatigue measure	7) Follow up period	8) Sample size power diff over time	9) Attrition levels	10) Attrition levels matched	11) missing data	Methodological strength score
Thomas, et al. 2015 ³²	Adequately addressed	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Adequately Addressed	Well Covered	Excellent
Van Kessel, et al. 2008 ³³	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Adequately Addressed	Adequately Addressed	Well Covered	Well Covered	Well Covered	Well Covered	Excellent
Grossman, et al. 2010 ³⁵	Adequately addressed	Well covered	Well Covered	Adequately addressed	Adequately addressed	Well Covered	Adequately Addressed	Well Covered	Well Covered	Well Covered	Well Covered	Excellent
Bombardier, et al. 2008 ³⁶	Adequately addressed	Well Covered	Well Covered	Poorly Addressed	Adequately addressed	Well Covered	Poorly Addressed	Well Covered	Well Covered	Adequately addressed	Well Covered	Very Good
Moss-Morris, et al. 2012 ³⁷	Adequately Addressed	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Poorly Addressed	Poorly Addressed	Well Covered	Well Covered	Poorly Addressed	Very Good
Mohr, Hart & Goldberg 2003 ²⁷	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Well Covered	Poorly Addressed	Poorly Addressed	Well Covered	Adequately addressed	Well Covered	Very Good
Mohr, Hart & Vella 2007 ⁴⁰	Well Covered	Well Covered	Well Covered	Not reported	Well Covered	Well Covered	Poorly Addressed	Well Covered	Well Covered	Well Covered	Well Covered	Very Good
Sinclair & Scroggie 2005 ⁴²	Poorly Addressed	Not Applicable	Well Covered	Not reported	Adequately addressed	Well Covered	Adequately addressed	Well Covered	Adequately addressed	Not Applicable	Poorly Addressed	Good
Thomas, et al. 2010 ⁴⁴	Not Addressed	Not Applicable	Not Applicable	Not Applicable	Adequately addressed	Well Covered	Poorly Addressed	Poorly Addressed	Well Covered	Not Applicable	Well Covered	Adequate
Sheppard, et al. 2010 ⁴⁶	Not Addressed	Not Applicable	Not Applicable	Not Applicable	Adequately addressed	Well Covered	Poorly Addressed	Poorly Addressed	Adequately Addressed	Not Applicable	Well Covered	Adequate
Askey-Jones, et al. 2012 ⁴⁷	Not Addressed	Not Applicable	Not Applicable	Not Applicable	Poorly Addressed	Well Covered	Poorly Addressed	Well Covered	Poorly Addressed	Not Addressed	Poorly Addressed	Adequate

To address the question of whether psychological interventions are effective for fatigue management in MS the results will be discussed in relation to the construct of fatigue measured i.e. fatigue severity, fatigue impact and those studies which reported a combination of impact and severity.

Severity of fatigue

Five studies measured the impact psychological interventions had on the severity of fatigue^{27, 32, 33, 37, 44}. The Chalder Fatigue scale (CFS), the severity subscale of the Brief Fatigue Inventory (BFI) and the severity subscale of the Fatigue Assessment Inventory (FAI) were used to measure the severity of fatigue. Although the scales were designed to be used with chronic fatigue (CFS), cancer (BFI) and general populations (FAI), they have since been used in studies with the MS population. All five interventions were based on CBT, but varied in the delivery of CBT between individual, face to face therapy²⁷ with telephone input³³, individual internet based self-help with telephone input³⁷ and group therapy^{32, 47}. Four studies focused the interventions exclusively to improve fatigue, with one study²⁷ treating depression and measuring fatigue as a secondary outcome. All recruitment from one of these studies³⁷ was taken from advertisement which does not represent a clinical sample. This suggests that the ecological validity of this intervention to be somewhat less appealing than studies where part recruitment^{27, 32, 33} and all recruitment came from a clinical sample⁴⁴.

Four of the five studies were rated as methodologically very good to excellent. They found significant reductions in fatigue and medium to large effects at post and/ or follow up time points. Evidence suggests that methodologically sound studies using CBT based interventions aimed at the reduction of fatigue severity or depression, delivered on an individual basis have the potential to significantly reduce severity of fatigue with large effects at two months³³, 2.5 months³⁷ or four months²⁷. Furthermore, Individual CBT also has the potential to produce lasting effects at eight month follow up³³. In addition, CBT delivered in a group format can significantly reduce fatigue with large effect at a follow up period of four months lasting up to one year, but not at post measure (one month)³², suggesting that a group format may take longer before a reduction in fatigue severity is found compared to some forms of individual therapy.

Impact of fatigue

Seven studies measured the effectiveness of psychological interventions on the perceived impact of fatigue^{27,35-37, 40,44,46}. The scales used in these studies were the Fatigue Impact scale (FIS)⁴¹, the Modified Fatigue Impact Scale (MFIS)³⁸ and the consequences subscale of the FAI³⁹, the former two scales were designed for use in the MS population. The methodological quality of studies ranged from adequate to excellent. The study rated as having excellent methodological quality³⁵ was a mindfulness based group intervention aimed to improve fatigue and quality of life in the MS population. The impact of fatigue was significantly reduced compared to the usual care group but there was not sufficient information to calculate effect sizes. The study found significant results on fatigue measures compared to a usual care group. This was the most time intensive intervention included in the review with a total of 2240 minutes plus homework.

Four studies were rated as methodologically very good^{27 36, 37, 40}. These studies all provided individual therapy and found significant reduction in the impact of fatigue, with large³⁷ and medium²⁷ effect sizes found. Unfortunately there was not sufficient information reported to calculate effect size for the other two studies^{36, 40}. Three studies used CBT^{27, 37, 40} and one used motivational interviewing³⁶.

One study⁴⁶ was rated as methodologically adequate. The study aimed to manage the bio psychosocial aspects of MS using a group format based on Acceptance and Commitment Therapy (ACT). Although the study did not find a significant reduction of fatigue impact they found a medium effect size. Lack of significant findings could be due to small sample size or due to the recruitment being solely from a clinical population resulting in high attrition rates.

In summarising the evidence above it appears that there is a high degree of heterogeneity amongst studies. Evidence suggests that high quality studies using psychological therapy in the form of a mindfulness group or individual CBT can reduce fatigue impact either significantly and /or have medium to large effects. This review highlights that there is more evidence for the reduction in fatigue impact using an individual therapeutic approach based on CBT compared to a group format, or individual therapy based on other modalities.

Studies which report a combination measure of fatigue impact and severity

Two studies reported the results of a measure which combined severity of fatigue as well as the impact of fatigue^{42, 47}. The measure used in both studies was the FSS⁴³ which was designed for use in the chronic health populations and has since been standardised in the MS population.

These two studies were rated amongst the lowest on the methodological quality ratings and were rated in this review, as adequate. The effect size was only able to be calculated for one paper⁴⁷ which was negligible, 0.01. Both studies used a CBT model to provide an intervention with one using a group format⁴² and the limited information reported in one study suggested that individual sessions were used⁴⁷. A moderate level of input was provided from a therapist in both studies, with the aim of the intervention also differing between studies; depression⁴⁷ and perceived control of symptoms⁴². No significant differences were found in either study and both studies recruited at least in part from a clinical population where referrals were taken from MDT members, specialist nurses and neurologists.

In summary, lower quality studies in this review which assess psychological interventions, namely CBT, by reporting a combination of both severity and impact of fatigue result in a lack of significant findings with little to no effect. Both studies had relatively small numbers of participants, no control group and for one study limited information regarding intervention⁴⁷. Although, recruitment was at least, in part, clinically relevant. The lack of significant findings may reflect the methodological design of these studies. More stringent trials need to be carried out before concrete conclusions are reached.

2.5. Discussion

The aim of this systematic review was to address whether psychological interventions were able to reduce fatigue severity or the impact of fatigue in individuals with Multiple Sclerosis. Although this review found a limited number of studies using psychological interventions for fatigue in MS, it is encouraging to see that over the last 10 years this relatively new field of research has started to develop. The majority of studies found a significant reduction of fatigue with a medium effect following a psychological intervention although intervention type, aim and methodological quality differed between studies.

The most common modality of psychological therapy was cognitive behavioural therapy, although even within these studies the method of delivery and amount of therapist input differed. This review indicates that individual and group CBT can significantly reduce fatigue severity and impact. Mindfulness therapy delivered in a group setting and Motivational Interviewing based therapy delivered individually can significantly reduce the impact of fatigue. A more tentative conclusion (due to lower methodological quality of the study) is that Acceptance and Commitment therapy may have a role in reducing the impact of fatigue, although further research is needed.

Instruments used to measure fatigue differed amongst studies. Furthermore the reliability and validity varied with some measures being employed that were not originally developed for the MS population, for example the CFS was originally developed for the chronic fatigue population and although it has good internal consistency, concurrent validity and discriminative validity in the chronic fatigue population the validity and reliability within the MS population is lacking. Some items on the CFS could be reflective of MS symptoms other than fatigue for example '*do you find it more difficult to find the right word*' and '*do you have problems starting things*' could be a symptom of executive function problems, rather than fatigue. Therefore the use of valid and reliable measures, specific to the MS population should be employed in future research, see ⁵³ for a review.

The recruitment for most of the studies included in this review was at least partially, if not fully, by advertisement. This type of recruitment is likely to attract a sub selection of MS patients who are more highly motivated and have higher self efficacy regarding changing thoughts and behaviours. Previous research into guided self-help interventions for anxiety and depression have found that interventions recruited via primary care are less effective than those recruited as self selected samples via advertisements^{48, 49, 50, 51}. Samples recruited this way may be less likely to drop out of

the study, and more likely to adhere to the requirements of the intervention, possibly leading to an exaggerated positive impact of the intervention.

This review included both psychological therapies aimed at fatigue management and psychological therapies aimed at the management of depression and anxiety within the MS population. It was seen as important to include both as there is still some clarification required regarding the cause of fatigue and whether it is a primary symptom of MS or whether it is a secondary symptom of a co-morbid illness such as depression. For example, sleep disturbance and depression were found to be the most important predictors of fatigue⁵⁴. However, not all patients with fatigue are depressed and there is evidence to suggest that fatigue and depression should be treated independently⁵⁵.

The extensive exclusion criteria used by some studies may render them less clinically applicable and therefore less effective. When reviewing the impact of psychological interventions it is important to look at both the efficacy and the effectiveness of the intervention. The efficacy of an intervention refers to the level of scientific rigor, whereas effectiveness focuses on the ability of the study to work in the 'real world'. Excluding those with co-morbid physical difficulties, psychological difficulties and those that are not ambulatory results in a sample which may not reflect the clinical population. It is evident that a high proportion of people with MS suffer from anxiety and/ or depression and as the disease progresses the physical deterioration may result in reduced mobility. It is unlikely that patients with both these aspects will be less affected by fatigue; therefore interventions that apply to the general MS population are necessary.

The studies in this review were undertaken across four different countries with the majority of research being carried out in the USA and the UK. This may impact on the findings of studies and the generalizability of these findings. For example, each country has different standards of training and requirements to be able to practice specific therapeutic modalities. Therefore what may be classified as an acceptable level of training in CBT for example, may differ between studies. This could impact on intervention fidelity, which could in turn impact on results of the studies. Furthermore, differences between public and private funding of healthcare between countries may influence the type of therapy being chosen for research purposes (depending on government guidelines, funders interests etc.) the intensity / duration of the treatment being offered (dependant on resources) and the commitment of participants in the research trials taking into account possible costs to the patient and availability of alternative treatment options etc.

Limitations of this review

This review was only carried out on English language papers. The review only included searches from four databases, possibly limiting the number of studies which could be included in the review. The review included papers where interventions were purely psychological in nature to limit the chances of any effects being due to a combination of therapeutic input. Therefore the decision was made to exclude traditional behavioural interventions as they tended to include non-psychological elements e.g. body ergonomics. Although, this strict separation of interventions does not necessarily reflect clinical practice, where multidisciplinary teams work alongside one another for the benefit of the patient.

Future research

Research into fatigue management using a psychological approach should employ less rigid exclusion criteria and more clinically relevant recruitment methods to make it more applicable to the clinical population. Future research should consider valid and reliable measures for the MS population and ensure they are measuring an appropriate effect of the intervention (e.g. a reduction in fatigue severity and/or impact). Replication of studies which have found significant results using different therapists, in different settings are required to ensure the interventions are generalisable. A longer follow up period is required to ensure that the impact of the interventions is not just achieved at post measurements but also in the longer term.

2.6. Conclusions

Although research to date is sparse, there appears to be a clear role for psychological interventions for fatigue management in MS. Furthermore, exploring different therapeutic modalities as demonstrated in this review, is important to enable a person centred approach that is suitable to patient needs and is evidence-based. At the present time it appears that CBT based interventions in the form of individual therapy or groups, individual motivational interviewing and mindfulness group therapy are able to reduce fatigue severity and /or impact.

2.7. Clinical Messages

- CBT based interventions (individual and group) can produce statistically significant reductions in fatigue severity and in some cases fatigue impact with medium to large effect sizes.

- Other psychological therapies shown to reduce fatigue impact are mindfulness based group interventions and individual motivational interviewing interventions.
- Caution should be taken when choosing a measure for fatigue to ensure it is valid and reliable in the MS population
- Evidence in this area is still sparse and more research which looks at the efficacy and effectiveness of interventions is required.

Contributors

KG initiated the study, created the design, undertook the search, participated in the appraisal and wrote the paper. DP participated in the appraisal of studies included in the review and reviewed the paper. PM supervised the design of the study, the appraisal of the studies included and reviewed the paper.

Conflicts of interest

The authors declare there is no conflict of interest.

Funding

This research was carried out by a doctoral trainee clinical psychologist based on the University of Edinburgh Doctorate of Clinical Psychology training course which is funded by NHS Education for Scotland.

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3. Development of the CBT workbook

Development and rationale for the CBT based self-help workbook for fatigue in Multiple Sclerosis

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BPS guidelines were followed for this section

Word count - 3065

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3.1. Introduction

There is estimated to be 85 000 people with Multiple Sclerosis (MS) in the UK (Compston & Coles, 2002). Prevalence rates of MS vary across regions with between 100 and 120 per 100,000 in England (Williams & McKeran, 1986) and 180 per 100,000 in Scotland (Phadke & Downie 1987) . Up to 90% of patients with MS complain of fatigue and two thirds of patients categorise it as their most troubling symptom (Branas *et al.* 2000) . Fatigue can be defined as ‘a subjective lack of physical and/or mental energy that is perceived by the individual or caregiver to interfere with usual and desired activities’(Multiple Sclerosis Council, 1998). Fatigue in MS has been shown to be associated with mood problems (Krupp,2003) and has an impact on daily life, for example it can impact on a person’s ability to remain in full-time employment (Jongbloed, 1998).

Rationale for Self-help

Due to the high numbers of people with multiple sclerosis potentially affected by fatigue it is important that the NHS has a wide range of treatment options to help patients manage this disabling symptom. Self-help and guided self-help (GSH) have been recognised in the field of mental health as a suitable first step to managing mild to moderate depression and anxiety (NICE 2009, 2011, The Matrix 2011). Implementing low intensity interventions like self-help and guided self-help can help improve access to psychological therapies using a stepped care model (DoH Delivering for mental health 2006) which can help to meet government waiting time targets (ISD Scotland 2012). Furthermore, self-help may be more appropriate for certain populations, for example those with physical health problems which would make travelling to appointments difficult. In addition, patients with fatigue may find a typical psychological therapy session lasting approximately one hour in length physically and mentally demanding. Therefore an option of self-help where the person can access the materials at their leisure or a guided self-help session which is typically shorter in length may be a more suitable intervention.

Cognitive Behavioural Therapy (CBT) based GSH introduces the patient to bibliotherapy and psychological concepts allowing short term input and support from a professional. A meta-analysis by Coull & Morris (2011) of GSH for anxiety and depression found a medium effect size (0.69) for GSH interventions compared to control conditions but further analysis found that this effect largely applied to self-selected samples rather than true clinical samples. A meta-analysis by Gellatly *et al.* (2007) of self-help (including GSH) for depression found a significantly higher effect size for GSH than pure self-help (PSH) and they also found a larger effect in self-selected patients.

Research seems to suggest that GSH may be more effective than PSH, but the majority of these studies were based on self-selected samples. The actual content of self-help materials includes both the therapeutic elements of a particular modality as well as non specific therapeutic factors. Research into an effective therapeutic relationship (Cahill *et al.* 2008) suggests that there are three stages (establishing a relationship, developing a relationship and maintaining a relationship) that need to be met to ensure an effective relationship. A number of factors between therapist and patient are involved at each stage of the therapeutic relationship such as; empathy, guidance, reflection, feedback and repair of rupture are just a few of the factors at play. Furthermore, it has been found that up to 30% of the improvement in therapy has been attributed to non-specific factors such as the therapeutic relationship, empathy and warmth (Lambert & Barley, 2001). Being able to transfer these aspects successfully into self-help materials where there is little input from a therapist (GSH) or no input from a therapist (PSH) is a challenge. Reviews of the acceptability of self-help materials written for the clinical population with depression have highlighted a number of important considerations regarding the use of common therapeutic factors in self-help materials, which if not achieved, may present as a barrier to the patient accessing the materials. These common factors include; accessibility, generating belief, empathy, goal setting, collaborative framework, guidance, developing a secure base, feedback, responsiveness, rupture prevention, repair and flexibility (Richardson *et al.* 2010), readability score and reading ease (Martinez *et al.* 2008).

Rationale for CBT

Cognitive behavioural therapy (CBT) identifies unhelpful cognitions and behaviours and introduces the patient to techniques to modify them making them more helpful. A relationship between catastrophic thoughts about fatigue and avoidance behaviours has been found (Bol *et al.* 2010). The presence of such thoughts can lead to a vicious cycle resulting in the maintenance or worsening of fatigue symptoms. Jopson & Moss-Morris (2003) and Vercoulen *et al.* (1996) further support the importance of cognitions and beliefs as a mediating factor for fatigue. For example, control beliefs have been found to be linked to an increase in fatigue (Schwartz *et al.* 1996; Jopson & Moss-Morris 2003) . In addition, patients experiencing a sense of helplessness, uncontrollability and unpredictability also leads to in an increased experience of fatigue (van der Werf *et al.* 2003). Therefore, CBT could provide an alternative to unhelpful thought and avoidance behaviours. In fact, CBT has been shown to be an effective approach to managing fatigue in MS in a number of clinical trials (Van Kessels *et al.* 2008; Moss-Morris *et al.* 2012; Mohr, Hart & Goldberg *et al.* 2003; Mohr, Hart and Vella 2007; Thomas *et al.* 2014).

Rationale for developing a new workbook

At the time of writing the workbook there were a number of general self-help books / information booklets for MS, such as 'MS and Me- A Self-management guide to living with MS' (MS Trust, 2010) and a more specific booklet for fatigue 'Living with fatigue- Fatigue management for people with MS' (MS Trust, 2006). The function of these books appeared to be more information giving, sharing of personal stories and general advice giving, and whilst some of the techniques could be argued to be behavioural in origin, such as pacing, they were lacking a specific therapeutic angle, furthermore the effectiveness of these books has not been evaluated using a randomised controlled trial. CBT has been used more specifically in the chronic fatigue population to form the basis of self-help books, for example 'Coping with Chronic Fatigue' (Chalder 1995) and 'Overcoming Chronic Fatigue - A self-help guide using Cognitive Behavioral Techniques' (Burgess & Chalder, 2005). Although some of the CBT techniques use in these books may be relevant to people with MS, there are significant differences between the chronic fatigue and MS populations which could potentially affect engagement with the materials.

3.2. Aim

The aim of the study was to create a self-help book that could be used for pure self-help as well as guided self-help in an NHS setting for the management of fatigue in MS based on CBT principles. The aim was to use CBT techniques and to include common therapeutic factors in the workbook to help people with MS engage with the workbook and find some benefit from using the strategies.

3.3. Description of the workbook

The workbook is composed of four stages. The term stage was used rather than sections or chapters to convey the message that it was a journey which could be completed by carrying out one stage at a time. To see the workbook in full refer to Appendix 4.

Stage one - Self assessment

In this stage the reader is introduced to the rationale behind choosing CBT as an evidence based therapeutic modality. They are invited to complete a self assessment of their fatigue, considering both historical factors (e.g. coping styles) and current day factors (e.g. triggers, moods, thoughts and behaviours). They are invited to complete the section by answering a series of questions and

reflecting on past experiences. At the end of the chapter the aim is for the reader to have formulated their own model of fatigue by completing the 'unlucky clover' formulation model at the end of the section. It is recommended that the reader completes this section over the course of one week.

Stage two - Thoughts

This stage is split into two parts intended to be completed over two weeks (one part per week). Firstly the rationale behind exploring unhelpful thoughts related to fatigue is discussed. Then the reader is encouraged to identify any unhelpful thoughts they may have in relation to their own fatigue. To help the reader, there is a case study taking the reader through the process of identifying thoughts. The second part of stage two aims to encourage the reader to challenge their negative thoughts. They are introduced to specific CBT techniques to achieve this and are guided through the process via a case example.

Stage three - Behaviours

This stage is broken down into three parts and readers have the choice as to whether they would like to complete all three or just two parts. The parts are titled 'over activity bust cycle', 'under activity cycle' and 'CAP activities'. Readers are encouraged to complete at least one of the first two parts and all readers are advised to complete the third part. The over activity bust cycle explains the behaviours whereby people may try to push through their fatigue which can result in an increased level of fatigue over the following days, leading to a reduction in activity. The under activity cycle explains a pattern of behaviour whereby the reader may avoid certain activities through fear that they may make their fatigue worse, but in doing so they may become less active and this may result in muscle weakness and further increase levels of fatigue. The workbook outlines particular activities to help manage both these types of behaviour including pacing or graded activity and uses specific CBT techniques such as activities diaries and self monitoring.

The final part refers to the type of activities people are doing and whether they bring a sense of Closeness, Achievement or Pleasure (CAP) to the person. The reader is encouraged to analyse their behaviours and ensure there is a balance of all these types of activities. There is also an opportunity where the reader can explore particular activities they may have stopped due to their fatigue. They are encouraged to use a problem solving approach to explore activities that may need to be adjusted to suit their physical needs.

Stage Four - Keeping on track

This stage aims to review the progress the reader has made to date by revisiting the ‘unlucky clover’ formulation model of fatigue. The aim is to see if there are any aspects of the model that have changed in a more positive way that would change the model into a 'lucky clover'. This stage also takes the reader through possible ruptures in their management of fatigue and looks at ways they can repair them. Techniques include identifying warning signs, making an emergency plan and frequently monitoring their own experience of fatigue.

3.4. The process of developing the workbook

Both non-specific therapeutic factors and specific CBT factors were considered when writing the workbook.

First impressions

Relationship building with self-help materials differs from rapport building in face to face clinical work as the therapist is not in the same room with the patient. The aim of establishing the relationship is to ensure that the reader engages with the workbook, in the same way that rapport building seeks to enable engagement with the therapist and therapeutic process. The first hurdle for self-help materials is getting the reader to open the workbook. It was important that the workbook had good face validity, looked attractive and professional to ensure that participants would open the front page. It was decided a coloured front cover, with a generic scenic picture would be the best option so not to exclude any gender, race or age by placing a specific picture on the front. Also the NHS Fife and The University of Edinburgh logos on the front cover help to portray the message that it is a credible resource. It was important to ensure that the workbook was practical therefore reinforcing the front cover with a layer of plastic sheeting ensured it would protect the contents and also helped to give it a more professional look.

Engagement

Engagement in therapy is an important factor in the overall outcome for the patient (Tetley *et al.* 2011; Dew and Bickman 2005 and Thompson *et al.* 2007) . The term engagement within the context of this self-help workbook refers to the engagement with the overall look of the workbook as well as engagement with the contents. Pictures were used to help demonstrate points in the workbook and to break up text. Colour as well as black and white pictures were used to keep the

reader engaged throughout the text. Fictional case examples were used throughout the workbook and care was taken to ensure a mix of representative ages, genders and personal circumstances with the aim of enabling as many readers as possible to identify with characters in the workbook. The characters also sought to convey a sense of empathy and normalisation of symptoms. Activities were used throughout the workbook to introduce the reader to CBT techniques. They were broken down into manageable chunks and spread throughout the workbook to ensure the participant did not feel overwhelmed.

Expectations of the workbook were outlined early in the text ensuring that the participant knew that it was not a cure for fatigue, but a toolkit to help manage fatigue on a daily basis. Furthermore, the credibility of the workbook was reinforced ensuring that readers knew CBT was an evidence based therapy and was used in several different clinical areas.

A collaborative nature was introduced where possible, highlighting that the reader owned the workbook and they could choose to annotate it. The reader was also encouraged to choose a friend or family member to support them to complete the workbook. It was highlighted early in the workbook that the more effort the reader put into the workbook the more likely it was that they would see a positive outcome from using the workbook. Advice about particular sections and information on new concepts were fully explained in both a direct manner through didactic teaching and via case examples.

Readability

The readability of the workbook was assessed by using the readability function in Microsoft WORD 2010. Twenty-eight pages (31% of the workbook) were chosen at random and all diagrams, headings and sub headings were removed. A Flesch Reading Ease score was calculated, which rates text on a 100-point scale, the higher the score the easier it is to understand the document. A score of 72.6 was achieved with a Flesch –Kicaid grade level of 7.3, indicating that the text could be understood by an average student in year 7 in the United Kingdom or a 7th grade student in the United States (11-13 years old). This score suggests that the current workbook is easier to read than those assessed by Martinez, Whitfield, Dafters, Williams (2008) who assessed the reading ease of 8 commonly used self-help books for depression in the UK. The font size (12) and type face (Arial) were chosen to be consistent with NHS brand guidelines.

CBT specific factors- Beck *et al.* (1979)

Summaries at the start of each stage were intended to replace the agenda setting element of a one-to-one CBT session. The first stage consists of a self-assessment which ultimately results in a self-formulation displayed in a simple model. The model of fatigue, titled the 'Unlucky Clover', aimed to explain both the present day impact of fatigue as well as some historical information to help the participant ground the current circumstances in their own history. Presenting a formulation helps to establish a rationale (Khan *et al.* 2007) and outlines both the onset and maintenance of the presenting problem. Beck (1995) suggested that the process of assessment and formulation should be carried out using collaborative empiricism. Although the reader is expected to complete the formulation alone using the workbook, they are guided through each stage with a rationale and examples. Needleman (1999) suggested that the process of case formulation can strengthen the therapeutic alliance. Thus by including a self-assessment and formulation in the first stage it was intended to help the reader form a therapeutic alliance with the workbook.

As well as a self-assessment and formulation in stage one, other stages covered areas of thoughts and behaviours which incorporated CBT techniques such as thought diaries, thought challenging techniques, activity diaries and activity managing techniques. The author also attempted to integrate the CBT techniques throughout the workbook, where the reader was encouraged to use thought challenging techniques if they had unhelpful thoughts about changing their behaviour.

Predicting disengagement

The workbook outlined elements which the reader may find difficult, with the aim of empathising with the reader. Reassurance was given to the reader at the more complex parts of the workbook, highlighting that the reader could take breaks and return to the activity at another time. Case examples in the clinical vignettes depicted how an individual may struggle with fatigue and how they could use the techniques in the workbook to overcome these difficulties. A conscious effort was made to show that some of the characters in the clinical examples did not have to complete the activities perfectly to gain benefits from the workbook. Participants also had the option to leave some sections of a particular stage out if they were irrelevant to their circumstances, which was intended to avoid potential triggers to disengagement.

The final stage of the workbook entitled 'Keeping on Track' outlined important relapse prevention strategies. It encouraged the reader to predict possible problems with fatigue management and to use the techniques they have learnt in the workbook to manage these times effectively.

3.5. Consultation

A clinical psychologist (DP), experienced in the physical rehabilitation service and in the MS population contributed to the workbook to ensure its clinical validity to CBT and the MS population. A health psychologist (PGM) with experience of producing guided self-help booklets also contributed to the development of the workbook. Furthermore, the workbook was reviewed by two specialist nurses in MS who made suggestions ensuring it was clinically applicable to the MS population. Finally, a patient with MS reviewed the book to ensure it was easy to engage with and was applicable to their experience of MS and fatigue. These suggestions were taken into account and changes were made to the final copy of the workbook to incorporate them.

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4. Journal Article

A randomised controlled trial of CBT based self-help for fatigue in Multiple Sclerosis

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Prepared for submission to *Multiple Sclerosis Journal* which conforms to the SAGE house style See Appendix 5 for details.

Main article word count - 3519

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4.1 Abstract

Background: Fatigue is a common disabling symptom in patients with Multiple Sclerosis (MS). Cognitive behavioural therapy (CBT) has been shown to be effective in the reduction of fatigue in MS and CBT-based self-help has been shown to be effective as a low intensity intervention for anxiety and depression in the general population.

Objectives: To evaluate the effectiveness of a CBT based self-help workbook at reducing the perceived impact of fatigue in a clinical sample of MS patients.

Methods: Participants were randomly allocated to one of three groups; treatment as usual (TAU), pure self-help (PSH) or guided self-help (GSH). Measures were taken at four time points (pre, post intervention, three and six months). The Modified Fatigue Impact Scale (MFIS) was chosen to measure fatigue.

Results: There was no significant difference between groups on measures of fatigue, anxiety, depression or quality of life. Satisfaction with the workbook was high.

Conclusions: The low level CBT-based intervention for fatigue in MS was not effective at reducing the perceived impact of fatigue. This study reflects a clinical, inclusive sample recruited from a specialist rehabilitation unit. Future studies should; include measurements of impact and severity, review level of therapist input required to produce an effect and consider the mode of therapeutic delivery, whilst remaining representative of a true clinical sample.

Word count - 214

Keywords - Multiple sclerosis, randomised controlled trial, cognitive behavioural therapy, fatigue impact, fatigue severity, self-help, guided self-help, MFIS, psychological, intervention

4.2. Introduction

Multiple sclerosis (MS) is a disabling neurological condition caused by inflammation of the central nervous system (CNS). There is estimated to be 85,000 people with MS in the UK ¹. Prevalence rates of MS vary across regions with between 100-120 per 100,000 in England ² and 180 per 100,000 in Scotland ³. Up to 90% of patients with MS complain of fatigue and two thirds of patients categorise fatigue as their most troubling symptom ⁴. Fatigue can be defined as ‘a subjective lack of physical and/or mental energy that is perceived by the individual or caregiver to interfere with usual and desired activities’⁵. Pharmacological and behavioural treatments for fatigue have produced mixed outcomes⁵⁻¹⁴ and side effects can be problematic^{5,15}.

Cognitive behavioural therapy (CBT) has been shown to be an effective approach to managing fatigue in MS¹⁶⁻²⁰. Furthermore CBT has been shown to be adaptable to short term interventions in the form of self-help²¹⁻²³. Short term, low intensity interventions such as self-help and guided self-help have been implemented in stepped care models ²⁴ to help NHS boards meet government waiting time targets²⁵. Applying this stepped care approach to management of MS fatigue may be an effective way to increase service provision and reduce the impact of fatigue. Self efficacy²⁶ has been shown to impact on health behaviour outcomes ²⁷ and will be considered in this current study.

4.3. Aims and hypotheses

Aim - To evaluate the effectiveness of a CBT based self-help workbook for MS fatigue in a clinical sample. Furthermore, variables which may impact on effectiveness of self-help interventions, such as level of input from therapist, premorbid level of fatigue and premorbid level of self-efficacy were explored. The study’s hypotheses were:

1 - Guided self-help (GSH) and pure self-help (PSH) interventions will significantly reduce fatigue and improve mood and quality of life (post intervention and follow up) in comparison with the treatment as usual (TAU) group.

2- Participants with clinically relevant fatigue scores pre-intervention will see a larger reduction in fatigue scores following PSH or GSH interventions compared with TAU.

3 - Guided self-help and pure self-help patients with higher levels of self-efficacy at baseline measurement will demonstrate greater improvements in fatigue scores following intervention compared to those with lower levels of self-efficacy.

The study also sought to determine patients' satisfaction with the self-help materials.

4.4. Methods

Design

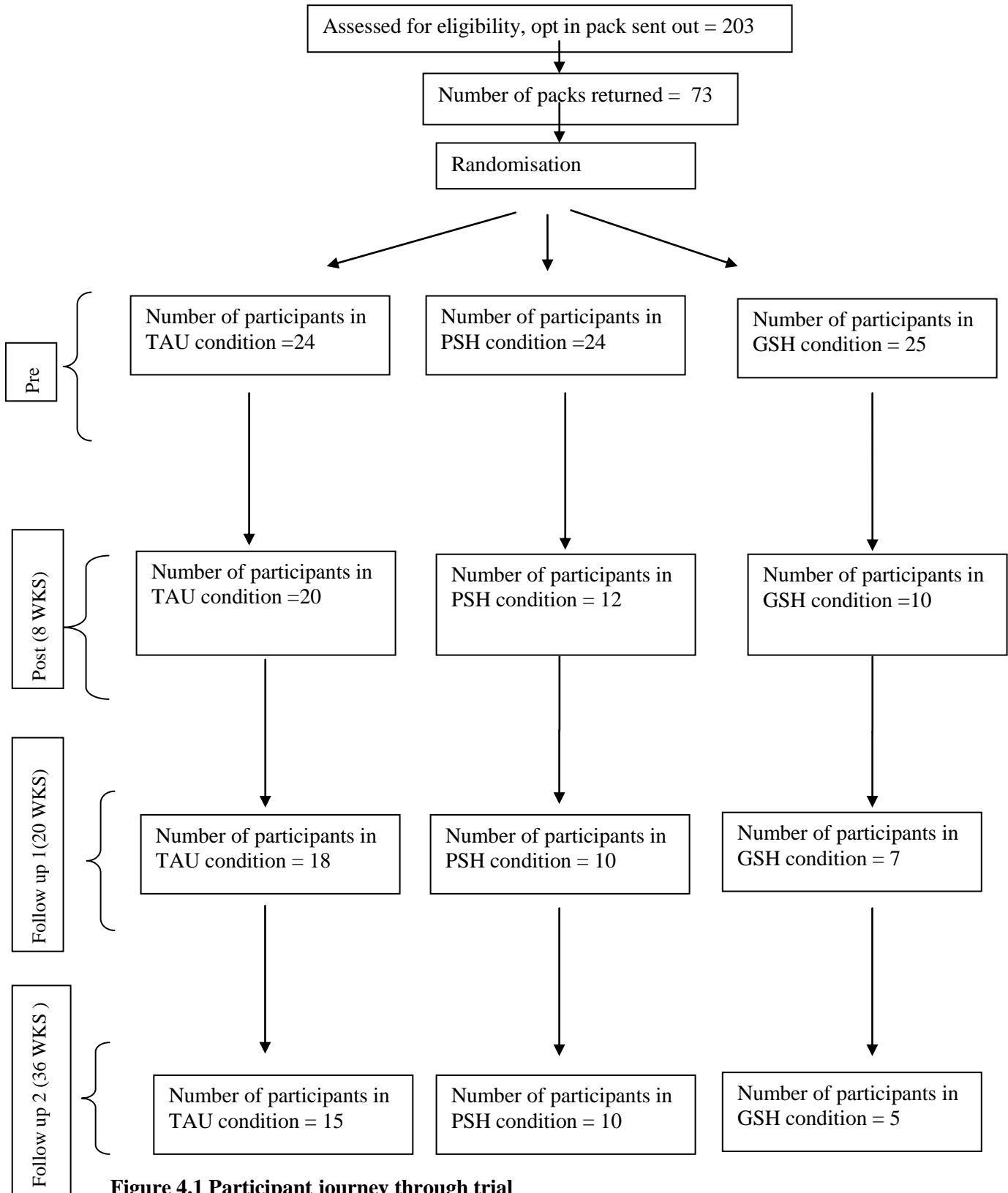
A single centre, parallel group, randomised controlled trial conducted in the Fife Rehabilitation Service in NHS Fife, Scotland. The patients were randomly allocated in equal proportion to either a treatment as usual (TAU) group, pure self-help (PSH) group or guided self-help (GSH) group. Participants in the experimental conditions (PSH & GSH) continued to receive treatment as usual in addition to either PSH or GSH throughout the trial. This trial was non-blinded, i.e. both participants and therapist knew the details of the intervention, which was unavoidable due to the transparent nature of this study.

Ethical and other approvals

Ethical approval was given by the South East Scotland Research Ethics Service (see Appendix 6). Caldicott Guardian approval was obtained from NHS Fife (Appendix 7) along with Research and Development approval (Appendix 8) to allow this study to be carried out in NHS Fife. The study was also registered with Clinical Trials.org (reference number NCT01532037).

Sample

Potential participants were identified by MS specialist nurses from the Rehabilitation Service. Participants were included if they were aged 18+, had a diagnosis of MS by a neurologist and reported fatigue as a symptom. A clinician (specialist MS nurse or clinical psychologist) screened referrals to ensure participants had the ability to give informed consent and had sufficient level of literacy understanding to ensure they could complete the standardised questionnaires and read the self-help workbook. Participants had to be willing to consent to randomisation. Participants were excluded from the study if they had a diagnosis of psychosis, personality disorders, had suicidal ideation or plans (assessed by referring clinician). See Figure 4.1 for an outline of the participant journey through the trial.



Power calculation

A previous study which measured a CBT based intervention for MS and fatigue found a large effect size at three months and a medium effect size at six months¹⁸. The computer programme G-Power²⁸ was used to calculate the sample size using an F-test, ANOVA repeated measures, within-between interaction for a medium effect of $F=0.25$, $\alpha = 0.05$, power of 0.90 for three groups (TAU, GSH & PSH) with four measurements (time points) with 0.5 correlation between repeated measures and nonsphericity correction at 1. This resulted in a total sample size of 39 (13 per group).

Attrition rate

Based on previous studies there has been a wide range of attrition rates at 6 months ranging from 4.2%¹⁸ to 28%²⁹. The more conservative rate of 28% was used to calculate required initial sample size in this current study. The equation recommended by Stewart, Jackson and Jenkins²⁹ for intention to treat (ITT) designs to account for attrition rates was employed resulting in an estimated required initial sample size of 54 (18 per group), allowing for a 28% attrition rate.

Randomisation

Once participants consented to take part in the study and returned completed questionnaires they were randomised into one of three groups: TAU, PSH or GSH. Randomisation was based on a random sequence of numbers generated via Random.org.

Study Settings

The Rehabilitation Service is an outpatient service comprising a multidisciplinary team (MDT). All participants received treatment as usual. The CBT based workbook for fatigue was provided to participants in the intervention groups only. Participants allocated to the GSH group could attend appointments in clinical locations or their own home.

Procedure

All participants received questionnaires posted at four time points; pre-intervention, post-intervention, three months follow up and six months follow up (see Figure 4.1). The TAU group received the questionnaires only. The PSH group received the CBT based self-help workbook via post with a recommended timeframe of 90 minutes to complete each stage (four stages in total) over the course of six weeks, in addition to treatment as usual. The GSH group were offered up to four,

45 minute sessions of therapist support (chief researcher, KG) alongside the CBT based self-help workbook. In addition, the GSH group were advised to spend an additional 45 minutes per stage, to complete the activities in the workbook. The first two sessions of GSH were offered weekly and the final two sessions at fortnightly intervals. The workbook contained four stages (see Box 4.1), with a copy of the workbook provided as Appendix 4. Participants in the GSH condition also received treatment as usual.

Fidelity of intervention

GSH was provided by the chief researcher (KG), a third year trainee clinical psychologist, who had received training in CBT and practised CBT as a main therapeutic modality. Furthermore, KG had one year of previous experience delivering CBT-based guided self-help to adults with anxiety and depression. Supervision for GSH cases was provided by a qualified practitioner psychologist (DP), who listened to session recordings to ensure adherence to the guided self-help protocol (see Appendix 9 for copy of the protocol).

Stage 1 Self assessment – this stage aimed to introduce the reader to information about MS, fatigue and CBT. The reader was required to complete their own self assessment of fatigue.

Stage 2 Thoughts and fatigue – this stage aimed to introduce the reader to unhelpful thoughts, as well as ways to identify and to change unhelpful thoughts.

Stage 3 Behaviours and fatigue – this stage aimed to introduce the reader to unhelpful behaviours, focusing on learning how to identify and change unhelpful behaviours. It also aimed to ensure the reader had a mix of activities including achievement activities, pleasurable activities and activities where the reader felt close to others.

Stage 4 Keeping on track – this stage aimed to review the original self assessment and identify any positive changes. It also outlined ways to manage fatigue in the future by introducing emergency plans and monitoring techniques.

Box 4.1 Brief outline of stages in the workbook

Measures

The chief researcher (KG) sent research packs to potential participants. Research packs contained a participant information sheet, consent form, demographic information sheet (Appendix 10) and a series of questionnaires which included; the Modified Fatigue Impact Scale (adapted from the longer Fatigue Impact Scale; FIS³¹), the WHOQOL-BREF³², the Hospital Anxiety and Depression Scale (HADS,³³) and the 6- item Chronic Disease Self-Efficacy Scale³⁴.

Primary outcome measure – Fatigue

The Modified Fatigue Impact Scale (MFIS) consists of 21 items selected from the Fatigue Impact Scale (FIS)³⁵. The MFIS can provide Physical, Cognitive, and Psychosocial subscales, as well as a total MFIS score with a range from 0-84. Higher scores indicate a greater perceived impact of fatigue on a patient's activities. The MFIS has good test retest reliability (correlation coefficient $>.84$), good reliability (MFIS total score $\alpha = .92$ physical score $\alpha = .88$ and cognitive score $\alpha = .92$, the psychosocial score $\alpha = .65$) and no floor or ceiling effects³⁵. Due to the low internal reliability for the psychosocial scale, results were excluded from the current study.

Secondary outcome measures

Quality of life

The WHOQOL-BREF (World Health Organisation³²) is a 26-item version of the WHOQOL100 quality of life assessment. It has four domain levels; physical health, psychological, social relationships and environment. It has good internal consistency (Cronbach's alpha values ranging from 0.66 to 0.84), good test retest reliability for domains: 0.66 for physical health, 0.72 for psychological health, 0.76 for social relationships and 0.87 for environment³⁶. Scores from the physical and psychological domains will be used to measure quality of life in the current study.

Mood

The Hospital Anxiety and Depression Scale (HADS³³) is a screening scale comprising seven anxiety items and seven depression items. It has good internal consistency ($\alpha >.75$) for both scales. Correlations between HADS and other commonly used measures of mood have been found in the range of .49 to .83³⁷. The HADS is less affected by somatic items than most other measures of anxiety or depression making it a suitable choice for those with physical health problems.

Self-efficacy

The 6-item Chronic Disease Self-Efficacy Scale³⁴ is adapted from the original 33-item scale³⁸. It covers symptom control, role function, emotional functioning and communicating with physicians. The internal consistency is reported as $>.90$ ^{38, 39} and test retest reliability is reported at 0.91 using Pearson's Correlation and 0.87 using Spearman's Correlation.

Demographic information

Gender, age, type of MS, number of years since diagnosis, use of any medication prescribed for fatigue, use of any disease modifying medication, previous fatigue management input from the Rehabilitation Service, last relapse (if applicable) and length of relapse (where applicable) were collated.

Participant satisfaction

A satisfaction questionnaire for the self-help materials was designed by the chief investigator (KG), based on a Likert scale (Appendix 11).

Statistical Analysis

Main analysis was carried out using intention to treat (ITT) analysis. As attrition rate was high in this study ITT analysis was only carried out on data at time points 1-3 (pre, post and three month follow up) as using 6 months data would be too dilute to draw any meaningful conclusions.

Exploratory analysis was carried out on completers of the intervention. Demographic information was analysed using descriptive statistics and statistical analysis evaluating the differences between demographic groups.

Analysis was carried out to ensure that data met assumptions of normality using Shapiro-Wilk test, checks of skewness and kurtosis, as well as visually inspecting histograms. Homogeneity of variance was checked using Levene's test. Where assumptions were met, parametric statistics were used and effect sizes were reported using partial eta squared (η^2). Non parametric statistics were used where significantly non-normal distributions could not be rectified via transformation of data. Where nonparametric equivalents were used medians were reported as the measurement of central tendency.

Non parametric Friedman's ANOVA was used to analyse fatigue in hypothesis one as the PSH scores were not normally distributed. The QOL physical scores at baseline met the assumptions of normality but not sphericity, therefore Greenhouse-Geisser statistic is reported. Scores for hypothesis two met normal assumptions but sphericity was not met therefore the Greenhouse-Geisser test statistic was reported.

4.5. Results

Attrition Rate

The GSH group attrition rate at post intervention, three and six months follow up was 60%, 68% and 80% respectively. The PSH group attrition rate at post intervention, three and six months was 50% and 58.3%, which remained the same at six months. For the TAU group attrition rate at post intervention, three and six months was 16.7%, 25% and 37.5% respectively. See Figure 4.1 for more detail.

Demographic and Clinical information

Demographic information is outlined in Table 4.1. All three groups were well matched on all categories apart from number of years since diagnosis where the GSH group have a significantly shorter duration of MS compared to the PSH group. See section - Exploratory Analysis for differences between completers and non completers.

Table 4.1 Demographic and Clinical information

	Guided Self-help n=25	Pure Self-help n=24	Treatment as Usual n=24	Comparison of three groups	
				Test statistic	p
Female N (%)	20 (80%)	17 (70.8%)	17 (70.8%)	$\chi^2 = 0.717$	0.753
Age - Mean, (SD) range	48.31 (10.26), 27.35-65.20	49.32 (9.05), 26.06-61.74	49.52 (10.87), 23.98-71.30	F 0.103	0.902
Number of years since MS diagnosis (mean, SD, range)	7.8 (5.7) 5.45-10.15	13.79 (10.43), 9.39-18.19	11.5 (8.47), 7.92-15.08	Welch's F 3.721	0.032 *
Type MS	RR = 19 SP=3 PP=2 Benign = 1 NOS = 0	RR = 19 SP = 3 PP = 1 Benign = 0 NOS = 1	RR = 16 SP =2 PP = 4 Benign = 1 NOS = 1	Loglinear analysis χ^2 3.861	0.869
Medication use for fatigue	Fluoxetine= 5 Interferon= 1 Modafinal= 0 Not reported=1	Fluoxetine= 2 Interferon= 0 Modafinal= 1 Not reported=1	Fluoxetine= 2 Interferon= 1 Modafinal= 2 Not reported=0	Loglinear analysis χ^2 1.927	0.926
Use of Disease Modifying Treatment N (%)	11 (44%)	11 (45.8%)	10 (41.7%)	χ^2 0.085	1.00
Median years since last relapse (range)	1 (0-7)	1 (0-7)	2 (0-5)	Kruskal-Wallis <i>H</i> 2.780	0.249
Median length of relapse in weeks (range)	6 (1-34)	6 (2-52)	3 (1-18)	Kruskal-Wallis <i>H</i> 2.553	0.279
Number of participants who had received previous Fatigue management N, (%)	11 (44%)	10 (41.7%)	9 (37.5%)	χ^2 0.219	0.955

*Significant at the .05 level. N = number of participants, SD = standard deviation, MS = Multiple Sclerosis, RR = relapsing remitting, SP = secondary Progressive, PP = primary Progressive, p = level of significance.

Main Results

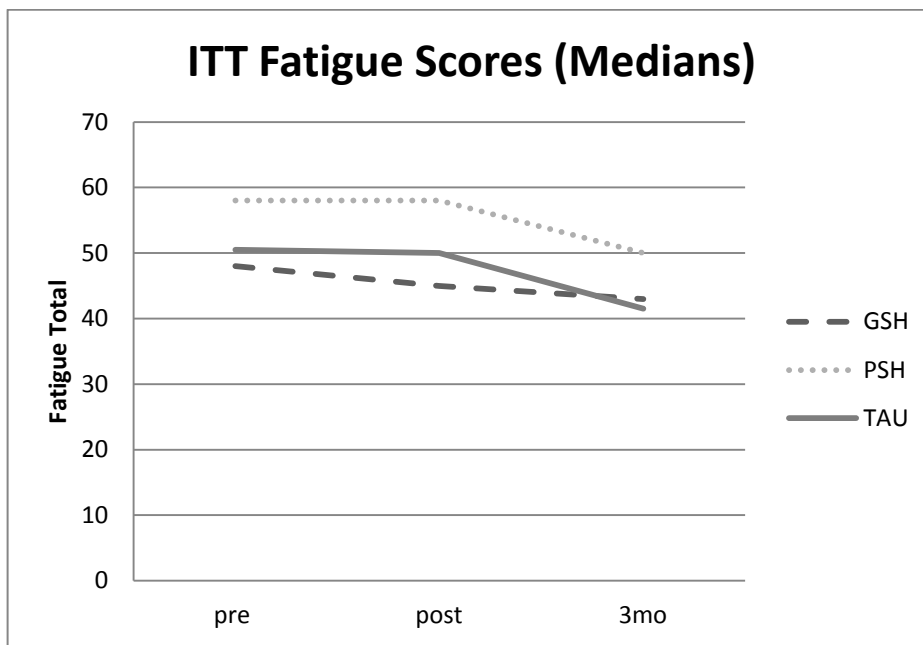
To review results for measures of central tendency and variance for all analyses see Table 4.2.

Hypothesis 1 – impact of intervention

Fatigue

The level of fatigue did not significantly change over time for GSH $\chi^2_F(2) = 0.684$, $p = 0.710$, PSH $\chi^2_F(2) = 1.286$, $p = 0.526$ or TAU $\chi^2_F(2) = 5.288$, $p = 0.071$. (see Figure 4.2).

Figure 4.2. Intention to treat (ITT) analysis of perceived impact of fatigue total score (median) across groups



Anxiety

A mixed ANOVA found no significant interaction for anxiety scores for the time by group analysis, $F(4,134) = 0.483$, $p = 0.748$, with a small effect size of $\text{Partial Eta}^2 = 0.014$.

Depression

A mixed ANOVA did not find a significant interaction for anxiety scores for the time by group analysis, $F(2,134) = 0.116$, $P = 0.891$, with a very small effect size, $\text{Partial Eta}^2 = 0.004$.

QOL Physical

Results showed a non-significant effect of the time by group interaction, $F(2,699, 91.764) = 0.588$, $p = 0.607$ with a small effect size of $\text{Partial eta}^2 = 0.017$.

QOL Psychological

A mixed ANOVA did not find a significant interaction for anxiety scores for the time by group interaction, $F(4,136) = 1.319$, $p = 0.266$, with a small effect size of $\text{Partial } \eta^2 = 0.037$.

Hypothesis 2 – Clinically relevant fatigue scores

Participants with clinically relevant level of fatigue at pre-intervention were analysed separately using the Flachnecker et al.⁴⁰ cut off score of 38 or above on the MFIS as a guide.

No significant interaction was found between time and group, $F(2,855) = 0.684$, $P = 0.558$, with a small effect size of $\text{partial } \eta^2 = 0.028$.

Hypothesis 3 – Self Efficacy

The Lorig et al.³⁸ mean of 5.17 for self efficacy was applied to the pre-intervention scores for the intervention group (GSH and PSH) to split them into groups with high (≥ 5.17) or low (< 5.17) levels of self efficacy. Fatigue scores for these groups were compared over time. No significant interaction was found for the time by group analysis, $F(6) = 0.771$, $P = 0.595$, with a small effect of $\text{partial } \eta^2 = 0.049$. This suggests that there is no difference in fatigue levels between groups over time.

Satisfaction results

Twenty one participants completed the satisfaction questionnaire (ten GSH and eleven PSH). The majority of participants found the workbook to be relevant, understandable, clear and helpful. Forty-two percent rated that their relationship with fatigue had changed following use of the workbook. Sixty-two percent reported that they would carry on using techniques they had learnt from the workbook including implementing specific CBT techniques. Ninety percent reported that they would recommend the workbook to a friend.

Table 4.2 Measures of central tendency and variance for all analysis.

Measure	Group (N)	Pre treatment (0 weeks) Medium (IQR)* Mean (SD)	Post treatment (8 weeks) Medium (IQR) Mean (SD)	3 mo follow up (20 weeks) Medium (IQR) Mean (SD)
Fatigue (Total MFIS)	GSH (25)	48 (34-63) ^a	45 (26.5-64) ^a	43 (28-64) ^a
	PSH (24)	58 (25.5-66) ^a	58 (25-68.7) ^a	50 (25.5-66) ^a
	TAU (24)	50.5 (32.25-65) ^a	50 (30.5-58.8) ^a	41.5 (28.5-60.8) ^a
Anxiety (Total HADS-A)	GSH (25)	8.72 (4.1)	8.76 (4.3)	8.48 (4.3)
	PSH (24)	8.09 (4.3)	8.70 (5.2)	8.43 (4.7)
	TAU (24)	8.09 (4.8)	8.05 (4.2)	8.27 (2.7)
Depression (Total HADS-D)	GSH (25)	6.52 (3.1)	6.56 (3.2)	6.60 (3.3)
	PSH (24)	7.22 (4.7)	7.22 (4.1)	7.13 (4.6)
	TAU(24)	6.00 (3.0)	5.73 (2.8)	5.68 (3.0)
Quality of life (Physical)	GSH (25)	21.20 (5.9)	19.84 (7.0)	20.32 (7.4)
	PSH (24)	20.42 (5.4)	19.91 (5.4)	20.63 (5.1)
	TAU (24)	22.25 (5.2)	22.42 (4.9)	22.64 (4.9)
Quality of life (psychological)	GSH (25)	18.84 (2.5)	18.88 (3.8)	18.68 (4.2)
	PSH (24)	19.63 (5.1)	18.50 (5.3)	19.33 (5.2)
	TAU (24)	20.92 (3.6)	20.58 (3.6)	21.36 (3.9)
Self Efficacy	GSH (25)	6.07 (2.2)	6.07 (2.4)	6.10 (2.3)
	PSH (24)	5.30 (2.0)	5.07 (1.9)	5.44 (2.1)
	TAU(24)	6.45 (1.9)	6.43 (1.7)	6.69 (1.9)
Total MFIS for participants with a clinical level of fatigue	GSH(18)	56.8 (12)	54.4 (19.2)	52.7 (21)
	PSH (16)	64.3 (7.6)	65.7 (8.2)	60.5 (11.1)
	TAU (16)	59.1 (9.7)	54.8 (9.5)	52.3 (15.1)
Total MFIS for participants with high self efficacy	GSH (18)	37 (20.1)	33.6 (23)	33 (20.8)
	PSH (10)	29.6 (19.1)	29.1(21.7)	29.9 (21.4)
Total MFIS for participants with low self efficacy	GSH (7)	58.2 (13.6)	58.2 (17.8)	56.2 (19.6)
	PSH (14)	59.7 (16.5)	59.9 (16.5)	56.2 (17.1)

^a Median (Interquartile range)

Exploratory analysis

Exploratory analysis were conducted with those that completed the intervention for hypotheses

1. The level of fatigue did not significantly change over time GSH $\chi^2_F(2) = 0.609$, $p = 0.738$, PSH $\chi^2_F(2) = 2.00$, $p = 0.368$ or TAU $\chi^2_F(2) = 4.229$, $p = 0.121$.

The only significant difference between completers and non-completers was that those who completed the intervention in the PSH group had a significantly greater percentage of previous fatigue management input (45%) compared to non completers (38%) $X^2\text{Chi Square} = 13.93$, $p .001$.

4.6. Discussion

This study used a randomised controlled trial to assess the impact of a CBT based self-help workbook for fatigue in MS. Results found that GSH and PSH interventions did not provide any greater benefits in terms of perceived impact of fatigue, mood or QOL than the treatment as usual group. Clinically relevant levels of fatigue and level of self-efficacy did not have any significant impact on results.

The lack of significant findings in this current study differ from previous research into CBT for fatigue management in MS^{16,17,20}. This may be due to a number of differences between the current study and previous studies. Unlike previous research where recruitment was from a mix of clinical and responders to advertisements^{16,17,20} this study recruited purely from a clinical population. Samples recruited from non clinical populations could potentially be more highly motivated to adhere to the intervention and therefore see a greater effect from the intervention. A meta-analysis of GSH for anxiety and depression found a medium effect size (0.69) for GSH interventions⁴¹ but this largely applied to self-selected samples, non clinical populations.

The control group in the current study was a treatment as usual group. Participants in all groups were able to access treatment from an MDT which could have potentially included some input on fatigue management. A previous audit assessing the services provided for fatigue from the MDT showed that all members of the team provided some level of fatigue input with Occupational therapists and Specialist MS nurses reporting that they provided input similar to CBT. Unfortunately, it was not possible to record the exact input the participants in the current study were receiving during the study period, due to time restraints. Therefore lack of effect could potentially be explained due all groups, including the comparison group, receiving possible CBT based input. It is possible that the intervention may be more effective if used in MS samples with lower levels of existing input.

Furthermore, the current study aimed to be a representative, inclusive clinical population by limiting exclusion criteria. Previous research which have found an effect of CBT used more stringent inclusion/exclusion criteria such as; a minimum level of fatigue on entering the study^{16,17,20} no previous fatigue input in the previous year²⁰, no relapse within three months²⁰, not starting on disease modifying treatment or anti depressants in past three months²⁰, a willingness to abstain from new pharmacological or psychological treatment for the duration of the study^{16,17}. Therefore, although previous research found an effect of CBT, it was for a select subgroup of the MS

population. As the current study did not use any of the above exclusions criteria it may be possible that this may account for the lack of effect.

The rationale behind this study was to explore different levels of clinical input, specifically forms of self-help as a form of stepped care, currently recommended by the Scottish government to improve access to psychological therapies. In the PSH group participants were recommended to spend a total of 360 minutes over 6 weeks, with no input from the therapist. The GSH group were offered up to 180 minutes of input from the therapist and recommended to complete a further 180 minutes of homework (total of 360 minutes over 6 weeks). This is considerably less input from a therapist compared to previous research which ranged from 290 - 800 minutes of therapist contact with the addition of homework^{16,17,20}. Gellatly et al.⁴² found a significantly higher effect size for higher intensity interventions for depression, but these results were from a self selected sample rather than a clinical population. Therefore, the lack of significant finding in this study may indicate that a higher level of input is required to improve the symptoms of fatigue in MS.

CBT is an interactive intervention where the participant is expected to take responsibility to change their thoughts and behaviours. It is time intensive and this approach may not have suited some participants. Furthermore, even though efforts were taken to produce an 'easy to use' workbook, some participants may have struggled with the level of input required and the level of reading in the workbook. It is possible that a DVD or audio tape may have been a more acceptable mode of delivery for this population, reducing some of the mental effort required to learn the CBT techniques, possibly making it more appealing.

Limitations of the current study

There was a high attrition rate in the current study (58% across all groups at 6 months) with a higher proportion in the intervention groups. This is a higher attrition rate than previous studies, possibly suggesting poorer face validity for the intervention. Although, as previously mentioned, unlike previous research, the current study was recruited from a clinical population, where participants may have been less willing to engage. In addition the higher attrition rate found in the intervention groups may reflect the level of work required in the intervention. As the majority of work in the GSH and all of the work in the PSH condition required the person to work independently it would require high levels of self motivation and self efficacy to engage with the self help materials. The therapeutic basis of the workbook was CBT. CBT require a high level of

input from the patient, firstly they need to learn and understand the constructs of CBT, become familiar with the techniques and then put them into practice before they see an effect of the therapy. This may be too demanding for some patients who struggle with low levels of self efficacy. A similarly high attrition rate (47%) at first invitation prior to any input and 53% attrition at 6 week follow up was found in a CBT self-help study for management of anxiety and depression. Participants in this study were recruited entirely from a clinical population making this similar to the current design⁴³ suggesting this high attrition rate may be more indicative of a self-help CBT based intervention. Finally, attempts were made in this study to screen for any literacy problems or cognitive impairment by asking a clinician who knows the participant whether these issues were present. This is not a thorough method of cognitive screening and it may be the case that some participants that took part in the study did have cognitive impairments, which in turn may have made engagement with the self-help materials difficult and could account for a proportion of the high attrition.

The current study measured the impact of fatigue rather than severity of fatigue. Previous research found a greater effect of CBT reducing fatigue severity over fatigue impact^{16,17,20}. Therefore it is possible that this current study may have found a reduction in severity of fatigue but failed to include appropriate measures. Future research should measure both perceived impact and severity.

Satisfaction with the workbook was high in participants who completed the intervention, suggesting good face validity for a psychological approach to fatigue management in MS. Although, these results must be treated with caution as they represent only those that completed the workbook and therefore may be biased.

4.7. Conclusion

These findings suggest that the use of the CBT self-help workbook in an inclusive clinical sample of patients with MS, recruited from a specialist rehabilitation unit does not significantly reduce their perceived impact of fatigue. The satisfaction results indicate that those who completed the workbook found it beneficial. It may be the case that a complex population with changing health needs require a higher level intervention. Future studies could explore whether increased therapist input would improve fatigue outcome in a clinical setting. Furthermore studies that explore different modes of delivery for therapeutic interventions (e.g. audio, DVD) may be beneficial for this population.

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6. Appendices

Appendix 1. Clinical Rehabilitation guidelines



Manuscript Submission Guidelines *Clinical Rehabilitation*

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Clinical Rehabilitation is a highly ranked, peer reviewed scholarly journal. It is a multi-professional journal covering the whole field of disability and rehabilitation, publishing research and discussion articles which are scientifically sound, clinically relevant and sometimes provocative.

The journal acts as a forum for the international dissemination and exchange of information amongst the large number of professionals involved in rehabilitation.

The leading journal in its field, *Clinical Rehabilitation* combines clinical application of scientific results and theoretical aspects in an ideal form. It gives high priority to articles describing effectiveness of therapeutic interventions and the evaluation of new techniques and methods.

1. Peer review policy

The journal's policy is to obtain at least two independent reviews of each article. It operates a double-blind reviewing policy in which the reviewer's name is always concealed from the submitting author; authors may choose to reveal their name but the journal otherwise leaves the article anonymous. Referees will be encouraged to provide substantive, constructive reviews that provide suggestions for improving the work and distinguish between mandatory and non-mandatory recommendations.

All manuscripts accepted for publication are subject to editing for presentation, style and grammar. Any major redrafting is agreed with the author but the Editor's decision on the text is final.

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2. Article types

The journal publishes original papers, systematic reviews, Rehabilitation in Practice articles correspondence relating to published papers and short reports. Other article types should be discussed with the editor before submission.

2.1 Summary of manuscript structure:

- A title page with names and contact details for all authors
- A **structured** abstract of **no more than 250 words** (the website checks this)
- The text (usually Introduction, Methods, Results, Discussion)
- Clinical Messages (2-4 bullet points, 50 words or less)
- Acknowledgements, author contributions, competing interests and funding support
- References (Vancouver style)
- Tables, each starting on a new page
- Figures, each starting on a new page
- Appendix (if any)

Please note that short reports follow a different format:

- The main text of a short report will usually be between **1000 and 1500 words** in length.
- A short report should have sufficient key references to cover all important points, but no more and usually there will be a **maximum of 15 references**.
- Tables and figures can be very efficient and effective ways of presenting data. A short report will usually have **no more than three tables and figures** (in total) and most will be restricted to two.

Further information on short reports can be found [here](#).

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3. How to submit your manuscript

Before submitting your manuscript, please ensure you carefully read and adhere to all the guidelines and instructions to authors provided below. Manuscripts not conforming to these guidelines may be returned. If you would like to discuss your paper prior to submission, please contact the Editor (Derick Wade) at: clinical.rehabilitation@sagepub.co.uk

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Authors are required to ensure that the following guidelines are followed, as recommended by the International Committee of Medical Journal Editors ("Uniform Requirements for Manuscripts Submitted to Biomedical Journals": http://www.icmje.org/urm_full.pdf).

Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients'

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To comply with the [guidance for Research Funders, Authors and Publishers](#) issued by the Research Information Network (RIN), *Clinical Rehabilitation* additionally requires all Authors to acknowledge their funding in a consistent fashion under a separate heading. All research articles should have a funding acknowledgement in the form of a sentence as follows, with the funding agency written out in full, followed by the grant number in square brackets:

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9. Manuscript style

9.1 File types

Only electronic files conforming to the journal's guidelines will be accepted. Preferred formats for the text and tables of your manuscript are Word DOC, and tiff or jpeg for figures (ideally figures will use journal colours). RTF, XLS and LaTeX files are also accepted. Please also refer to additional guideline on submitting artwork [and supplemental files] below.

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Clinical Rehabilitation provides the opportunity for your article to be included in OnlineFirst, a feature offered through SAGE's electronic journal platform, SAGE Journals Online. It allows final revision articles (completed articles in queue for assignment to an upcoming issue) to be hosted online prior to their inclusion in a final print and online journal issue. This significantly reduces the lead time between submission and publication. For more information please visit our [OnlineFirst Fact Sheet](#).

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11. Further information

11.1 Important 'Instructions to Authors' – from the Editor

Further specific advice on editorial aspects of the journal and of writing for the journal are also available.

[Click here for further information and advice on submitting to *Clinical Rehabilitation*.](#)

11.2 Contact SAGE

Any correspondence, queries or additional requests for information on the Manuscript Submission process should be sent to the Editorial Office as follows:

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+44 (0)20 7336 1244

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Appendix 2. Search terms used in systematic review

Search terms carried out on 02.05.2013 and re ran in February 2015

Fatigue OR Sleepiness OR Tiredness OR Hypersomnia OR Exhaustion OR Mental fatigue OR Physical fatigue

And

Multiple sclerosis OR MS OR Relapsing remitting multiple sclerosis OR Secondary progressive multiple sclerosis OR Primary Progressive multiple Sclerosis OR Benign Multiple Sclerosis

And

Behaviour therapy OR Behavior therapy OR Cognitive Behaviour therapy OR Cognitive Behavior therapy OR Emotion focused therapy OR Existential therapy OR Experiential Psychotherapy OR Gestalt therapy OR Group Psychotherapy OR Interpersonal Psychotherapy OR Psychoanalysis OR Cognitive therapy OR Online therapy OR Mindfulness OR Acceptance and Commitment Therapy OR Guided self-help OR Self-help OR Solution focused therapy OR Individual psychotherapy OR Telephone therapy OR Telephone counselling OR Telephone Counseling

Limit

1980 to current

Appendix 3. Quality criteria
Operationalisation of Quality Criteria

1 – Control group –

Well covered	Inclusion of active control
Adequately addressed	Wait list controls / Treatment as usual / Current Local Practice
Poorly addressed	Participants act as own controls
Not addressed	No control group
Not reported	
Not applicable	
Notes	

2 – Allocation to groups –

Well covered	RCT -Fully described randomisation methods. Good standard of randomisation i.e. use of database to generate random groups.
Adequately addressed	
Poorly addressed	Method of randomisation not truly random
Not addressed	
Not reported	
Not applicable	Not a controlled trial
Notes	

3 – Demographic variables matched (Sample matched for gender, age, type of MS, Duration of MS, severity of MS.)

Well covered	<p>Criteria matched (acceptable level to receive criteria)</p> <ol style="list-style-type: none"> 1. Gender (within 20%) 2. Age (mean within 10 years) 3. Types of MS (RR, SP , SP-RR, PP) within 20 %, where more than one type in study at least 2 types have to be within 20% or criteria not given) 4. Duration of MS (mean No years) within 10 years of difference 5. Severity of MS fully described (e.g. by means of EDSS, ambulatory, walking measurements, GNDS etc) with no significant difference between groups as reported in paper or small effect size of difference <0.2, or within 20% of each other. <ul style="list-style-type: none"> - To meet the well covered criteria paper must have 4-5 points above covered - OR - Use of statistical methods to control for differences (e.g. ANCOVA)
Adequately addressed	meets AA criteria if 2-3 points above covered
Poorly	If 1 points above covered

addressed	
Not addressed	
Not reported	
Not applicable	Not a controlled trial
Notes	

4 – Sample matched on baseline fatigue scores

Well covered	Criteria matched (acceptable level to receive criteria) Baseline level of fatigue measured and matched across groups (within a small effect size -Cohen's d 0-0.2) Or Any differences controlled for statistically
Adequately addressed	Baseline level of fatigue measured and matched across groups (within medium effect size - Cohen's d between 0.3-0.5)
Poorly addressed	Baseline level of fatigue measured and matched across groups (with in large effect size Cohen's d 0.6+
Not addressed	
Not reported	Baseline fatigue not measured
Not applicable	No controlled trial
Notes	When design has more than 2 groups assess criteria matched between intervention group and controlled intervention group, if no controlled intervention group use Waitlist or health controls , if no controls rate not applicable Used http://www.uccs.edu/lbecker/index.html#means and standard deviations calculator to help with effect size calculation

5– Intervention Fidelity

Well covered	<ol style="list-style-type: none"> 1. Full description of intervention given 2. Use of treatment manual/ protocol recognised as suitable for the intervention provided 3. Treatment checked to ensure meeting requirements of particular intervention e.g. CBT use of CBT checklist, recorded sessions and rated by other therapist 4. Treatment monitored by sufficiently qualified therapist /Appropriate supervision given. 5. Therapist experienced in delivering the specific therapy.
--------------	--

	Well covered if 5 points above covered
Adequately addressed	3-4 points stated above covered
Poorly addressed	1 -2 points above covered
Not addressed	None of the points above covered
Not reported	
Not applicable	
Notes	

6 –Measure of fatigue

Well covered	Suitable measure of fatigue valid & reliable in MS population. If more than one measure used - at least one measure must be valid and reliable in MS population to get this rating.
Adequately addressed	Suitable measure of fatigue standardised, valid & reliable in general population, but not MS population (ensuring there is no contraindications to using measure in MS population i.e. found to be specifically not reliable in MS population).
Poorly addressed	Measures have poor psychometrics when used with MS population or psychometrics are unknown for MS population, but are known to be poor with other populations
Not addressed	
Not reported	Psychometrics of measures not reported
Not applicable	
Notes	If psychometrics not reported reviewer will make every attempt to discover these from the literature.

7 – Follow up time points (from post intervention)

Well covered	12 month + follow up data collected of fatigue measurement
Adequately addressed	3-12 months follow up data collected
Poorly addressed	Pre and post measures only

Not addressed	
Not reported	
Not applicable	
Notes	

8 - Sample size - power to detect pre-post within-group intervention differences over time

Well covered	Adequate power based on medium effect to detect power 0.80+. Need 34+ participants
Adequately addressed	Adequate power based on medium effect to detect power 0.70-0.79. Need 28- 33 participants
Poorly addressed	Power based on medium effect would detect power <0.70. Corresponds to 27 participants or less.
Not addressed	
Not reported	No use of a priori power calculation
Not applicable	
Notes	Pre post comparison only Based on literature expecting a medium effect size (d= 0.50) comparison of differences within group - differences between 2 dependant means (matched pairs) , assuming a normal distribution with a p =0.05, use of t-test, two tailed

9 – Attrition levels of total study

Well covered	Fully described for all groups. maximum attrition rate up to <20%
Adequately addressed	Fully described for all groups, attrition rate >20% and < 40%
Poorly addressed	High attrition rates > 41%.
Not addressed	
Not reported	Attrition rates not reported
Not applicable	
Notes	pre-post attrition levels as follow-up beyond that point were too variable / patchy

10 – Attrition levels matched

Whether attrition levels were similar between groups e.g. if more participants dropped out of intervention group compared to controls lead to differences in results

Well covered	Similar dropout rates in all groups <5% difference between group OR paper reports no significant difference following statistical analysis i.e. t-tests
Adequately addressed	Dropout rate may differ slightly between groups (6-15%)
Poorly addressed	Difference in drop out between groups >16%
Not addressed	
Not reported	Attrition rates not reported
Not applicable	No control group
Notes	When design has more than 2 group assess criteria matched between intervention group and controlled intervention group, if no controlled intervention group use Waitlist or health controls , if no controls rate not applicable

11– Missing data

Well covered	Intention To Treat analysis (last measurement or baseline results carried forward) OR no dropout rate and all participants included in analysis pre and post
Adequately addressed	
Poorly addressed	Participants excluded from analysis when dropped out or when data missing
Not addressed	
Not reported	
Not applicable	
Notes	

Appendix 4. CBT workbook for fatigue in Multiple Sclerosis



THE UNIVERSITY
of EDINBURGH



Fatigue in Multiple Sclerosis

Who is this workbook for?

This workbook is for you if;

- ✓ You have a diagnosis of multiple sclerosis (MS)
- ✓ You have problems with fatigue
- ✓ You would like to learn ways to manage your fatigue more effectively

What is this workbook about?

This workbook uses cognitive behavioural therapy to help manage fatigue for people with MS. Cognitive behavioural therapy is also known as CBT. CBT is commonly used for the treatment of a number of different health concerns. CBT has been shown to be effective in treating Chronic Fatigue Syndrome and fatigue in Multiple Sclerosis. You will learn more about CBT and how it can help manage symptoms of fatigue in multiple sclerosis in the rest of this workbook.

How to use this workbook

This workbook is split into 4 stages which are designed to be completed over 6 weeks. It is estimated that it will take approximately 90 minutes to read through and complete the activities in each stage it is best to spread this out over a number of days rather than attempt to complete it in one session. Each stage is designed to be read and completed over one or two weeks as outlined below. There is guidance throughout the workbook to help you at the start of each stage.

- Stage 1 – Self assessment (1 week to complete)
- Stage 2 – Thoughts (2 weeks to complete)
- Stage 3 – Behaviours (2 weeks to complete)
- Stage 4 – Keeping on track (1 week to complete)

The total workbook should take you about 6 weeks to complete.

The workbook contains information and activities; it is recommended that you complete all the activities to get the best out of the workbook.

You may find it helpful to share the information in this workbook with a friend or family member.

If your fatigue makes it difficult to continue reading the workbook; it is fine to take a break and return when you are feeling less fatigued.

Stage One

It is estimated that it will take approximately 90 minutes to read over and complete the exercise in this stage. It is recommended that you complete stage one over 1 week.

Self assessment



In this section you will;

- Learn about multiple sclerosis
- Learn about fatigue
- Learn about cognitive behavioural therapy (CBT)
- Complete your own self-assessment

You will be asked to complete a self-assessment which will require you to answer questions about your life growing up and your life now, this is to help you understand how fatigue impacts on your life.

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Workbook page 5

Multiple Sclerosis (MS)

To understand how MS can affect the body it's useful to know a bit about how the body works. The body is made up of a lot of nerves; it's their job to pass messages throughout the body.



For example, if you had an itchy head your brain would have to realise there is an itch. It would then tell your arm to move towards your head and then tell your hand to scratch the exact place on your head that is itchy. Each message is passed on through nerves.

The nerves are protected by a covering called Myelin. Myelin protects the nerves and helps to pass the messages through the body quickly and smoothly. In MS the body's immune system gets confused. It starts to attack the protective covering around the nerves.

When this happens it makes it harder for the messages to pass between nerves. Sometimes the message can't get through at all.

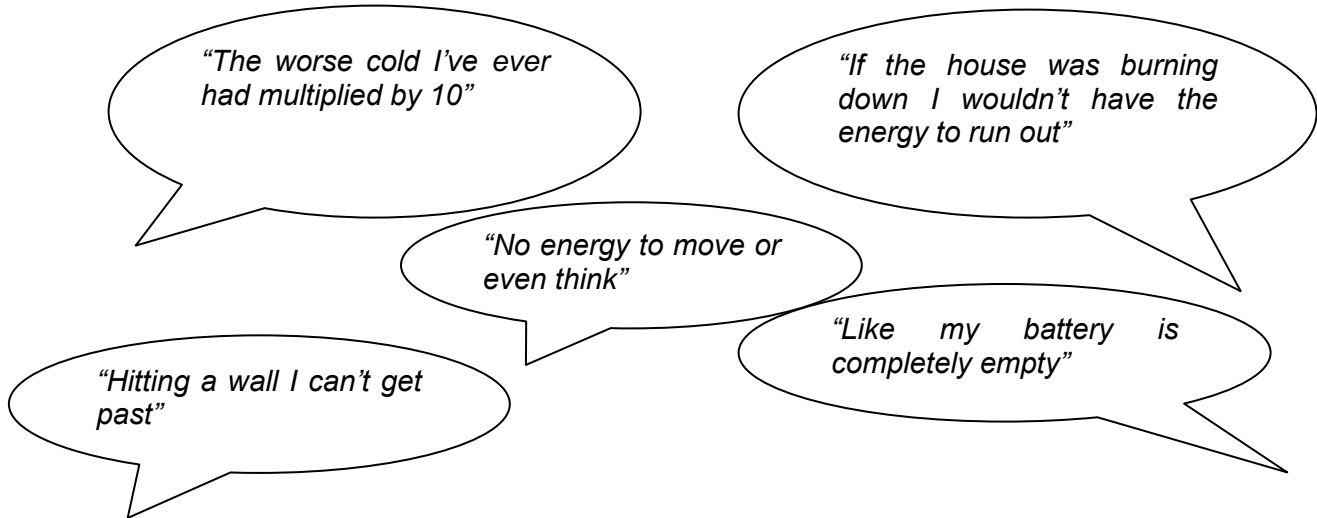


All parts of the body have nerves in them so any part of the body can be affected by MS.

Fatigue can affect all people with MS and it is important to remember that everyone's MS is personal to them. No two people are the same. It is important to understand how your symptoms affect you so you can learn the best way to manage them.

What is fatigue?

Fatigue is a lack of physical or mental energy that stops you doing things you want to do. Some people have described it as;



9 in 10 people with MS complain of fatigue and 6 in 10 people report that fatigue is their most troubling symptom.

It may be hard to recognise your own fatigue. Others might notice that you are becoming fatigued before you do. Take 5 minutes to think about your signs of fatigue. If someone was to describe you when you are fatigued what would they say? How do you look? How do you act? How do you feel?

One way to understand fatigue is to think about energy as money. Let’s imagine that before you had MS you had endless amounts of money (energy). You could use it how you wanted, spend it all day and all night and after a good sleep or periods of rest, your bank account would be topped up.

However, since MS and fatigue started to affect you, you only have a limited amount of money each day. Let’s say you now have a budget of £10 a day.

Let’s say getting up in the morning costs £1, having a shower and getting dressed costs £2, eating breakfast costs £1.

That means that you now only have £6 for the rest of the day. But hang on a minute, you haven’t tidied the house, got the paper from the shop, done the gardening, visited your friend along the road, read your book, made lunch, eaten lunch, checked the oil in the car, taken the dog for a walk, made dinner, eaten dinner, been to the pub or got ready for bed yet so what are you going to do? Remember in the past you could have done any or all of these things in one day. But now you only have £6 left.



Do you try to do it all and borrow some money from tomorrow? This may help you get more things done today but borrowing money from tomorrow means you have even less money to do what you want to do tomorrow. Also, let's not forget about interest! Whenever you borrow money you don't have, it always costs a little more (sometimes a lot more!) to pay it back. It is the same with energy. If you borrow £2 from tomorrow you may have to pay back £2.50.

Thus borrowing energy from tomorrow to use today will make it even harder to do things tomorrow. If you keep borrowing energy and do not pay it back you can become bankrupt (worsening of MS symptoms).



Like all bank accounts you can save energy. If you know you have a big event the next day it may be worth giving the house work a miss that day and putting £2's worth of energy aside for tomorrow.

Cognitive behavioural therapy for fatigue in MS – the evidence

Cognitive Behavioural Therapy (sometimes called CBT) is a widely used approach to help people improve their psychological wellbeing. It encourages you to reflect on the ways you think about things in your life and how this affects the ways you behave and feel.

Our thoughts can guide our behaviours and our behaviours can lead to certain thoughts. Our moods can also lead us to think and behave in a particular way. Furthermore, our thoughts, behaviours and moods can impact on our bodies producing physical symptoms.

For example, imagine you phoned a friend to check what time you should go to their party and they didn't answer the phone. There are many thoughts you might have about this:

..... If your thought was that they ignored your call because they didn't really want you to go to the party. This might cause your mood to be sad. Your behaviour may be to stop calling them, and not go to their party. You may experience feelings of tiredness and fatigue in your body.

.....If your thought was that you must have offended them. This might cause your mood to be anxious. Your behaviour may be to leave a message on their phone apologising. You may experience increased heart rate, muscle tension and sweating.

.....If your thought was that they must be busy getting ready for the party. This may have no effect on your mood. Your behaviour may be to call a different friend to check what time the party was, then go to the party that night. It is unlikely that you will notice physical symptoms.

The situation above was the same in the three cases but the thoughts, moods, behaviours and physical symptoms were all different.

CBT is commonly used for the treatment of a number of different health concerns. It has been shown to be effective in treating Chronic Fatigue Syndrome and fatigue in Multiple Sclerosis.

Description of CBT model

In the diagram below you can see a four leaf clover, which represents someone with MS. You will notice that there are different layers of soil labelled history and MS. The stalk is labelled trigger and each of the four leaves has a label - thoughts, moods, behaviours and body. All the leaves are connected. There are roots running from the clover through both layers of soil. This is because your history and your experience of MS affect how you think, feel and behave in different situations in the present.

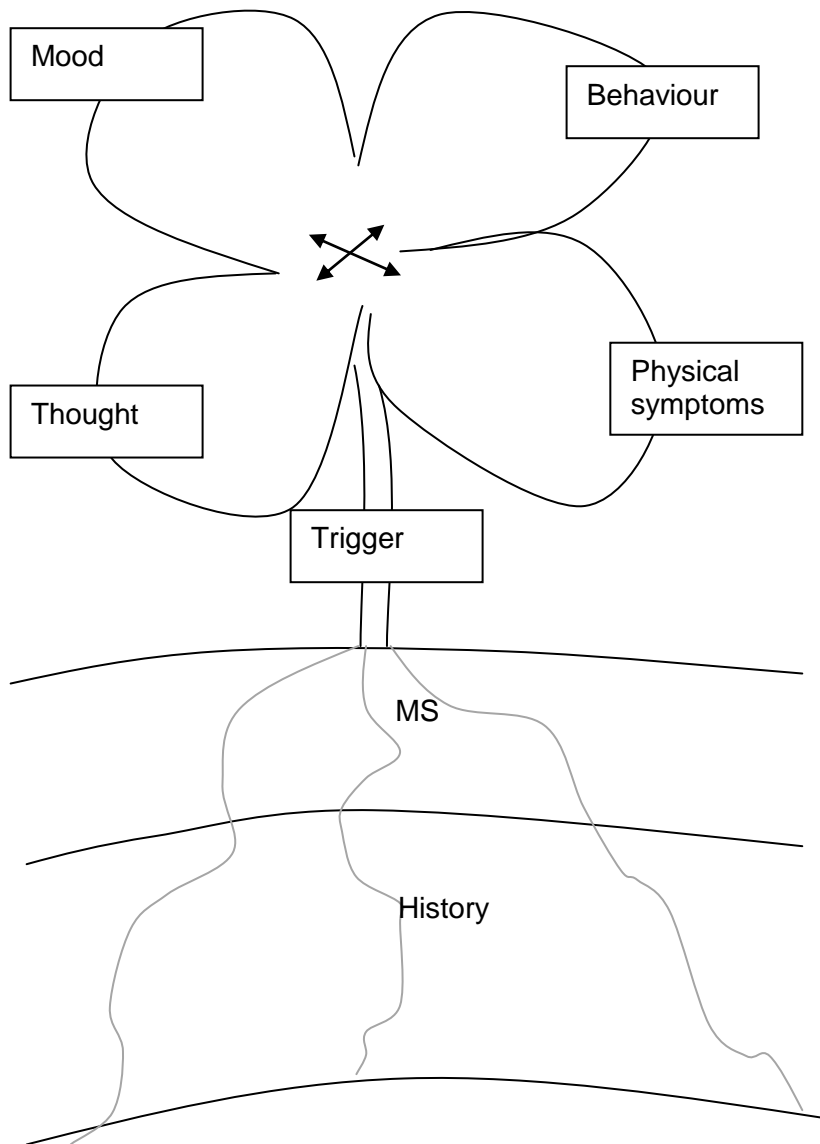


Figure 1. Four Leaf Clover

This workbook focuses on the problems we face in the 'here and now'. It is useful to understand how our history and past experiences affect how we deal with challenges in the here and now. This will be explored in more detail in the self assessment below.

There may be examples where you know what has triggered your fatigue, for example, stress at work or a hot day. Your triggers will be explored in more detail in the self assessment below.

As previously explained, our thoughts about fatigue can impact on our moods, behaviours and physical symptoms. Each leaf on the clover is connected so if you have an unhelpful thought about your fatigue such as, '*I feel useless if I cannot tidy the whole house in one attempt*', your mood will probably be low. This may result in you deciding to not bother tidying at all (thus affecting behaviour) and you may feel even more fatigued (thus affecting physical symptoms).

As you can see below, this can be an on-going negative cycle – 'an Unlucky Clover'

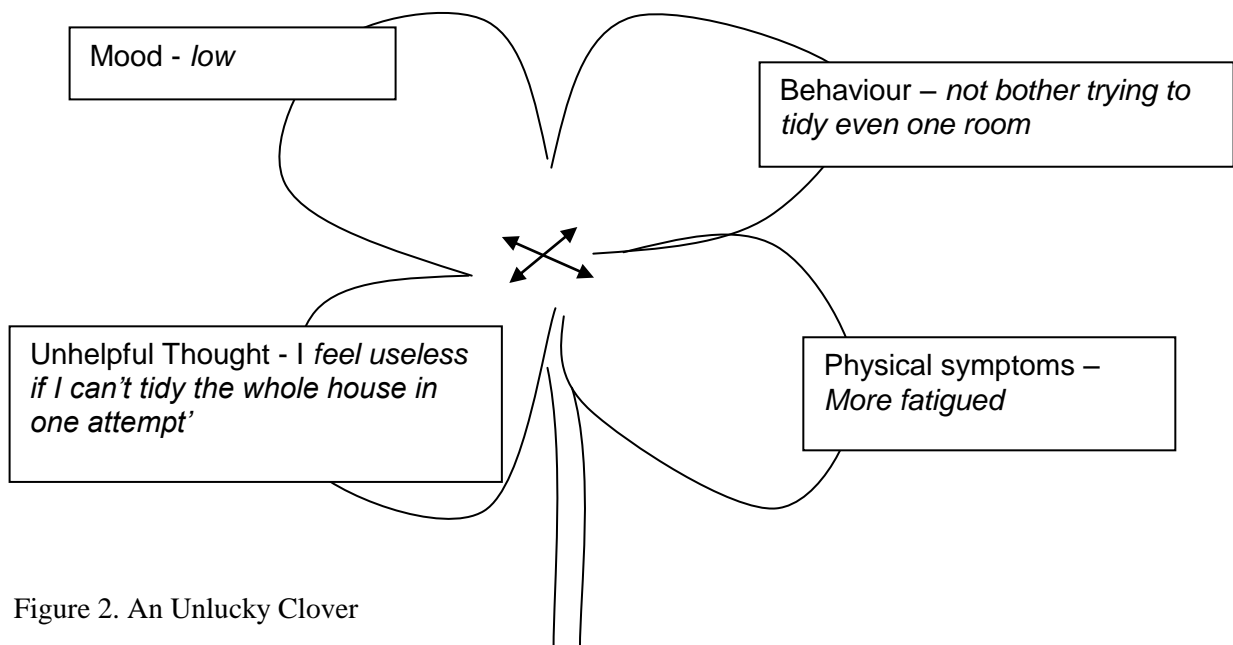


Figure 2. An Unlucky Clover

The GOOD news is that as all the leaves in the clover are connected, if you manage to change even just one leaf in a positive way all other leaves will also change in a positive way. For example, if you have a more positive thought then a) your mood may not be as low b) your behaviour may become more positive and helpful and c) your body may not feel as fatigued. So the 'unlucky clover' will change to a 'lucky clover'.

This workbook will look at each part of the clover in turn and try to identify if there are any negative cycles. Once negative cycles have been identified the workbook will show you how to replace them with more positive ones to help improve fatigue.

The first step to managing fatigue is by finding out how it is affecting you. This is done by completing the self assessment below and filling in your own personal 'unlucky clover'.

Self assessment - Completing Your Own Four Leaf Cover

The next few pages aim to help you to reflect on your own circumstances to see how these affect your fatigue by completing your own four leaf clover

Personal History

Our personal history can lead us to act in certain ways in the present. The way we have been brought up by our parents, how we were treated at school, our successes at work, our experiences of relationships etc. all shape the person we are today.

Someone may have had a supportive relationship with their parents but were bullied at school. Therefore they may find it hard to trust other people, which may mean they struggle to ask others for help when their fatigue is bad.

Other people may have achieved a lot of success in life (at school, work, relationships or friendships) which has made them feel good. If their fatigue threatens any of these areas they may feel low or angry.



Take a few minutes to think about your personal history;

- What were your experiences in childhood?
- How did your family cope with illness and injury?
- What happened when you were ill as a child?
- Were you bullied?
- How have your relationships been in adulthood?
- Have you had many successes?
- Do you find it hard to rely on other people?
- Do you find it hard to trust other people?
- Do you get a lot of your self-worth from the things you achieve in life?

Write down on page 23 in the history box anything that comes to mind that may help explain how you view yourself and other people.

Personal history continued.....

The way you have coped with challenges in the past can also impact on how you deal with fatigue in the present. For example;

- If you have always been able to face challenges head on you may see your fatigue as a challenge you need to tackle and overcome.
- If you have always ignored your problems in the past you may think that by ignoring your fatigue it will go away.
- If you have received support from your family and friends to help deal with your problems this may be a good way to manage the challenges you face with fatigue.
- If you have always worried about your problems over and over in your head you may be doing the same thing when you think about your fatigue.



Take some time to think how you have managed problems in the past; these may be problems in relationships, at work, with finances etc.

- Did you tackle the problem head on?
- Did you ignore the problem until it went away?
- Did you get support from your family or friends?
- Did you worry about your problem over and over?
- Were there other responses you had to these problems?

Write down on page 23 in the history box anything that comes to mind that may help explain how you have managed problems in the past.

Multiple Sclerosis (MS)

Everyone's experience of MS and fatigue is personal to them. For example, everyone will have a different experience of their MS diagnosis.

You may have known a lot about MS or you may not have heard anything about it before.

Maybe getting a diagnosis of MS was a relief (at least you had a name for the problems you were experiencing) or maybe it was a shock.

You may be angry about your diagnosis, you may have thoughts like why me?

You may have been in denial about your MS, trying to ignore it?

Think about the way different people in your life have reacted to your MS and fatigue for example, Are they supportive? Do they ignore it? Do they understand?



Take some time to think about how you have dealt with your MS so far.

- What did you think when you started experiencing problems?
- How did you feel about your diagnosis?
- How would you describe your fatigue and MS to a stranger?
- How has your family and friends reacted
- How did your employer react

Your experience and your thoughts about MS may impact on the way you manage fatigue, write down anything you think may be important in the MS box on page 23.

Triggers

Tick as many areas that are relevant to you and your experience of fatigue.

Are there particular times of the day where fatigue affects you the most?

- Morning
- Mid morning
- Lunchtime
- Mid afternoon
- Early evening
- Evening
- Late evening

After what activities do you feel most fatigued?

- Waking up
- Getting showered
- Getting dressed
- After eating (which meal _____)
- After work
- After house work
- After playing with the children
- After chatting to friends
- After reading a book

Any other times (write down examples)

Does pain trigger your fatigue? If so, how?

Does illness trigger your fatigue? If so, how?

Does tiredness trigger your fatigue? If so, how?

Does temperature trigger your fatigue? (Heat and cold) If so, how?

Does mood (anger, sadness, anxiety) trigger your fatigue? If so, how?



Take some time to jot down the most important triggers to your fatigue on the clover on page 23 in the trigger box. You may have some of your own examples that aren't in the workbook which are more relevant to you – jot these down too.

Mood

Fatigue can have an impact on our mood. It can be difficult to identify changes in our mood at first and it is often other people that notice a change in our mood before we do. Moods are usually described using one word. Sometimes we can notice a change in our body before we notice changes in our moods for example if our heart is beating faster and we are finding it hard to breathe our mood may be anxious, excited or scared.

Try to write down one example from your life when you have experienced the following moods.

<u>Mood</u>	<u>Example from your life</u>
e.g. Anxious	<u><i>Taking exams at school</i></u>
Anxious	_____
Excited	_____
Scared	_____
Happy	_____
Sad	_____
Angry	_____
Guilty	_____
Loving	_____
Disappointed	_____
Proud	_____

Now think your mood when you experience fatigue. Tick how often you experience each mood when you are fatigued.

	Always	Often	Sometimes	Rarely	Never
Sad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frustrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fed up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Guilty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Loved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other moods



Take some time to fill in the mood box on the unlucky clover on page 23 using the examples that are relevant to you above or your own examples.



If you ever feel very low and you have thoughts or plans about ending your own life you should contact your GP or a healthcare or phone NHS 24 Scotland on 08454 242424

Unhelpful Thoughts

We all have thoughts running through our mind throughout the day. At some times of the day you may be more aware of your thoughts than other times. Some of the thoughts we have may be unhelpful ones (i.e. they lead to feelings of low mood and unhelpful behaviours). This section of the self assessment helps you understand what unhelpful thoughts you may be having about your fatigue.

Thinking about thoughts can be hard to do at first so don't worry if you find this difficult, we will look at it in more detail later. Rather than thoughts you may have images of yourself in the future, or memories may run through your mind.

How often do you experience the following thoughts about fatigue? (please tick)

	Always	Often	Sometimes	Rarely	Never
a) I should be able to read the whole newspaper in one go	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Others will think I'm lazy when I have to rest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I think I'm lazy when I have to take a break	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My fatigue is going to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) My fatigue means in the future I will have to rely on others to do everything for me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) I don't like asking others to help	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Asking others for help makes me feel like a failure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Not being able to achieve what I want means I'm useless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) If I can't tidy the whole house I may as well not bother tidying one room	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) I have only managed some of the gardening; I used to be able to finish it all	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

When you think about your fatigue, what thoughts, memories or images run through your mind?

Workbook page 19



Take some time to fill in the thoughts box on the unlucky clover on page 23. Use the examples of unhelpful thoughts above that are relevant to you or use your own examples. We will focus on identifying and managing unhelpful thoughts in stage two of this workbook

Unhelpful behaviours

Our behaviours can have a big impact on our fatigue. It is important to understand how we act when we are fatigued so we can change any unhelpful habits.

Tick how often the statements below describe your behaviours.

	Always	Often	Sometimes	Rarely	Never
I sometimes push myself to do more, even when I need a rest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've stopped most of my activities in case it makes my fatigue worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My fatigue has stopped me doing the activities I enjoyed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've reduced seeing my friends and family as much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I can never finish anything I start so I don't bother anymore	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am no longer able to get a sense of achievement from anything because of my fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I refuse to take rests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Take some time to filling the behaviours box on the unlucky clover on page 23 using the examples that are relevant to you above or your own examples.

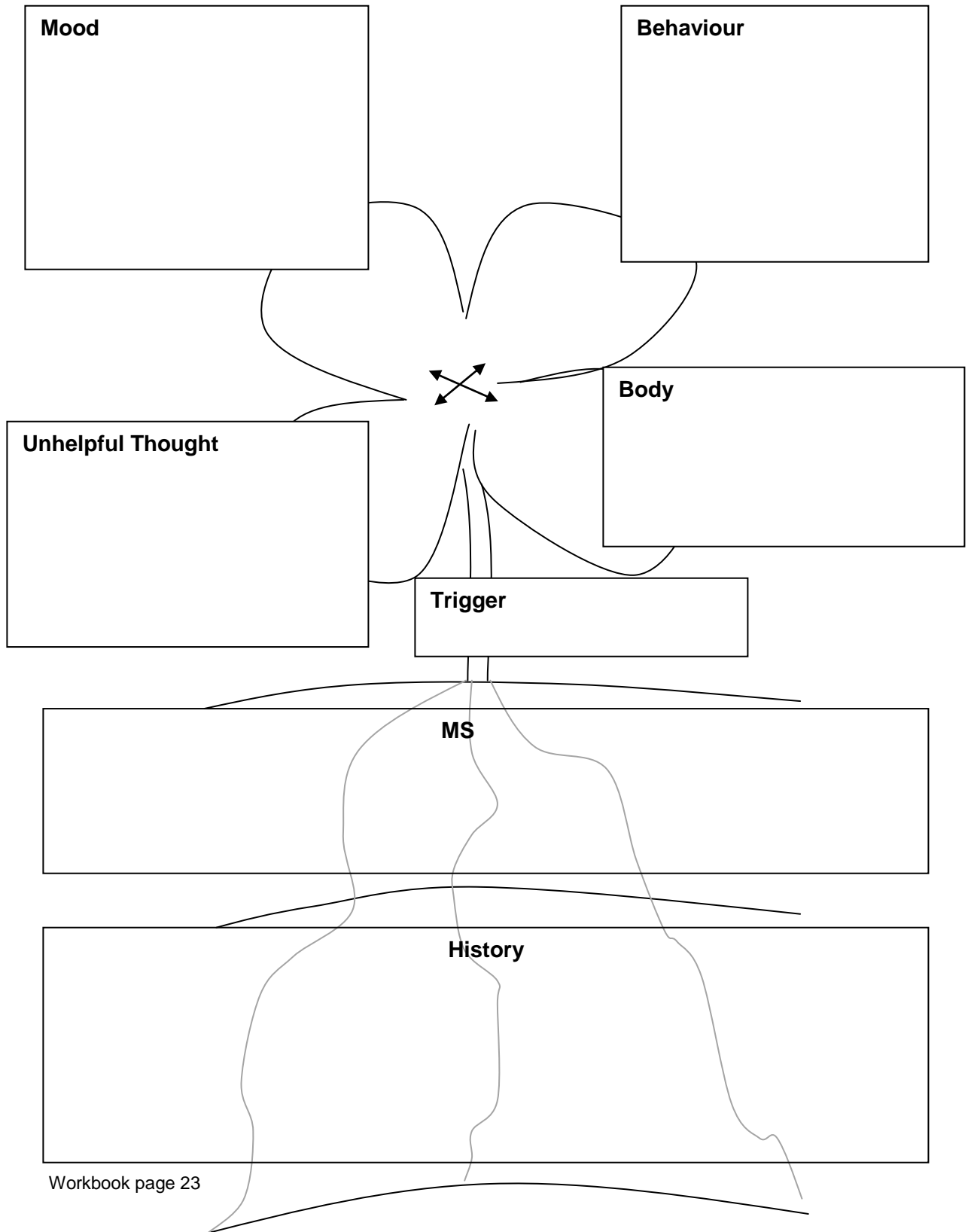
Body

Tick how often you experience the following sensations in your body when fatigue affects you.

	Always	Often	Sometimes	Rarely	Never
Pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tiredness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heavy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strange sensations (e.g. hot/cold/electric current)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Muscle tension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Weak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other _____					



Take some time to filling the body box on the unlucky clover on page 23 using the examples that are relevant to you above or your own examples.



Stage one Summary

Well done! You have now completed stage one of the workbook. You will now have a better understanding of what fatigue is and how your fatigue affects you. You will also understand how experiences in the past impact on how you manage problems in the present. You have filled in the unlucky clover and have hopefully identified some triggers, thoughts, moods, behaviours and body symptoms that are linked to your fatigue.

If you have had any problems filling in this workbook - don't worry. Give it another go in a couple of days then move on to the next section.

A better understanding of how fatigue affects you will help you to learn more useful ways manage your fatigue.

Monitoring how fatigue impacts on your life

After you have completed each stage you will be asked to assess how fatigue is impacting on your life. This will give you the opportunity to monitor your progress and reflect on what has been helpful.

On a scale of 0 – 10 how much do you feel you understand your fatigue (0= not at all 10 = completely understand).

On a scale of 0 – 10 how much do you feel you can manage your fatigue (0= not at all 10 = very confident I can manage it).

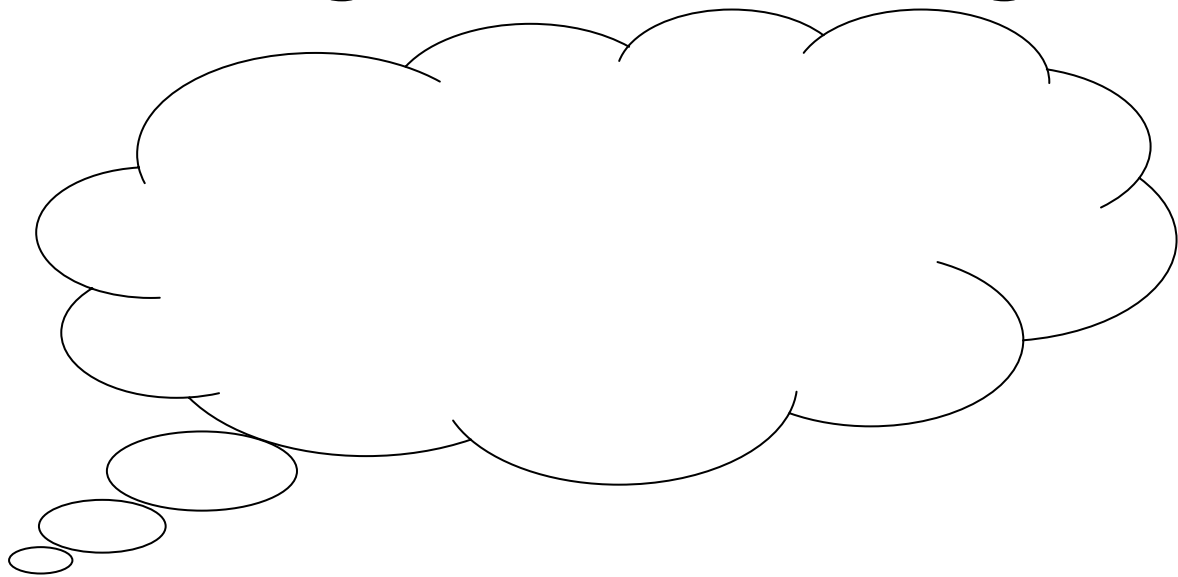
What has been most helpful in this stage of the workbook?

What has been least helpful in this stage of the workbook?

Stage Two

It is estimated that it will take approximately 90 minutes to read over and complete the exercise in this stage. It is recommended that you complete stage two over 2 weeks.

Thoughts and fatigue



Summary of previous stage

In stage 1 you started to look at the different ways your thoughts, moods, behaviour and body can impact on your fatigue. You filled out the unlucky clover worksheet with examples from your own life. Keep this sheet close as we will be looking back at it over the course of the workbook.

Introduction to stage two

Identifying any changing unhelpful thoughts is a tool used in CBT which can help to manage fatigue.

This stage aims to help you;

- learn about unhelpful thoughts
- learn how to identify unhelpful thoughts
- learn how to change unhelpful thoughts

It is suggested that you take 2 weeks to complete the exercises in this stage

Week 1 tasks are on pages 27-38

Week 2 tasks are on pages 39-49

What are unhelpful thoughts?

They are **unhelpful** – these thoughts will tend to be about yourself and your fatigue. They are often very negative.

They are **automatic** – they run through your mind so fast it can be difficult to catch them. Consequently you might not be particularly aware of these thoughts.

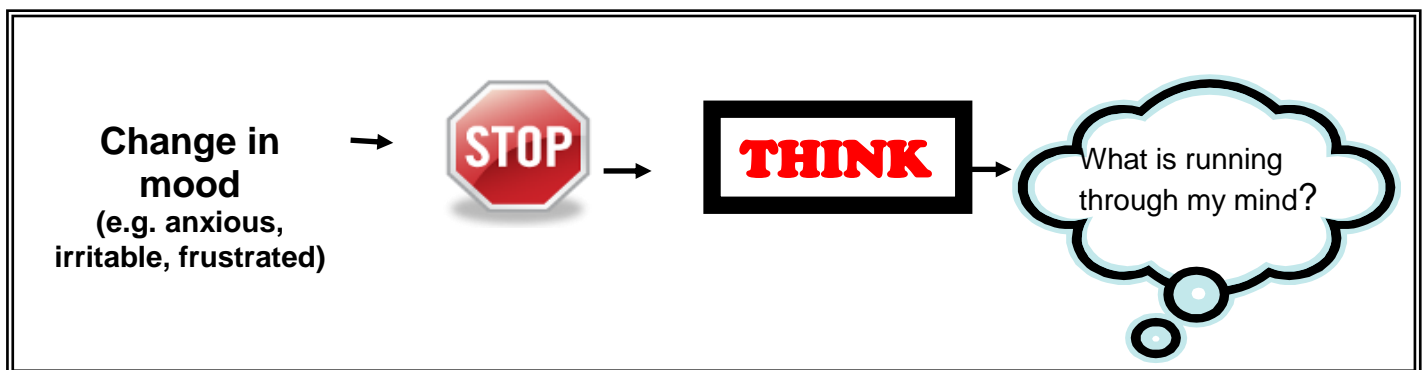
It can be **hard to get rid of** them – you may have tried to ignore them but they keep coming back.

Once you have an unhelpful thought about yourself and your fatigue it tends to lead to another unhelpful thought, then another, then another, and so on until your mind can become full of unhelpful thoughts running round and round. As we can see in the unhelpful clover your unhelpful thoughts are linked to your behaviours, mood and body creating a very negative cycle of events. It may feel like you have no control over your thoughts..... **but you do!**

Taking control of your unhelpful thoughts – step 1

The first step is to learn to recognise when you have unhelpful thoughts. This can be tricky because they can pop into your mind so quickly. You may have started to identify your unhelpful thoughts from stage one of this workbook, but if you struggled do not worry. Most people need to take a bit of time to identify all their unhelpful thoughts and we will spend some time practising in this section.

A common sign that may indicate that you are having an unhelpful thought is a change in your mood. If you start to feel down, upset, frustrated, angry or worried, it is likely that this feeling will be accompanied by an unhelpful thought. So if you notice a change in your mood, stop, and think what words, images or memories are running through my mind just now. Remember the thoughts will be negative; they will tend to be about you or about how others see you.



There are many different types of unhelpful thoughts. Below is a list of the most common types of unhelpful thoughts, you may recognise some of them. Put a tick next to any unhelpful thoughts that you recognise.



‘Shoulds’ and ‘musts’

These thoughts usually sound like ‘I should be.....’ or ‘I must’ For example, ‘I should be able to work without taking breaks’, or ‘I must get the housework finished before the children come home’. These thoughts are unhelpful as they put a lot of pressure on you to do a task or feel a particular way.





Catastrophic thoughts

These thoughts usually mean that you jump to one of the worst possible scenarios, even if there is no evidence that it is true. For example ‘If my fatigue gets worse, I won’t be able to carry on working, I’ll lose my job, I won’t be able to pay the rent and I will become homeless’.

Black and White thinking

These thoughts suggest things are one way or another, all or nothing, they don’t allow you to have shades of grey or sit on the fence. For example, ‘I either do everything on my list or I won’t do anything at all’. ‘What’s the point of starting a task and not finishing?’



Emotional reasoning



These thoughts suggest that your feelings are facts. For example, ‘I feel useless, therefore I am useless’ or ‘I feel lazy therefore I am lazy’. They are unhelpful thoughts because they are not based on evidence, they are just feelings, you would not convict a criminal because you *feel* they are guilty, you would hear the evidence, and then decide what is most likely to be true.

Predicting the future

These types of thoughts lead you to focus on what you think may happen in the future, the problem is our predictions are usually negative in nature and these negative predictions about the future can cause us to react to them in the here and now. An example of this type of thinking may be ‘My MS and fatigue will be much worse this time next year’.



Think about a time in the last week where you were feeling a strong emotion (e.g. sad, frustrated, angry, scared anxious). Think about where you were, who you were with, what was happening, when did the strong emotion start?

Unhelpful thought box

Now think about what thoughts, words, images and memories were running through your mind and fill in the box below.

What thoughts/ words were running through your mind?
.....
.....

Are these thoughts about you or about other people relating to you?
.....
.....

If these thoughts were true what would that mean about you?
.....
.....

If these thoughts were true what is the worst thing that can happen?
.....
.....

What memories does this bring up?
.....
.....

What unhelpful images are in my mind?
.....

Identifying unhelpful thoughts

It is time to start looking at the unhelpful thoughts you may have on a daily basis. Knowing your own unhelpful thoughts is important as they can lead to unhelpful moods and behaviours which all impact negatively on your fatigue. You will usually know you are having an unhelpful thought when your mood changes.

To help you identify your unhelpful thoughts its best to write them out in a thought diary (example on page 33). Before you start read through the case example (Mrs Jones) on the next page.

Common problems with filling out thought diaries

I don't have the time to fill out a diary every day

It is often difficult to dedicate time to new tasks. However, time spent now learning to manage your thoughts, moods and behaviours will improve your experience of fatigue in the long run, so it is well worth doing.

I find it hard to look at my thoughts written down on the page

Some people find it hard to look at their thoughts written down in black and white; it can somehow feel more real and can bring about strong emotions which you may not like. The fact is you are having these thoughts any way, and they are impacting on your mood but you're just not conscious of it. By writing them down you can start to take control and change them to be more helpful.

I understand what unhelpful thoughts are why do I need to write them down?

Like anything in life practice makes perfect. Even if you think you have the hang of it practise identifying your thoughts for the whole week, it will pay off in the end.

What if my family or friends see the diaries?

Like many people with MS and fatigue you may have thoughts about other people, for example how you see them or how you think they see you. If you feel comfortable doing so, show the workbook to your family member/friend and explain why it is important to write down your thoughts and they may offer their support. If you are not comfortable explaining the diaries to other people you could use initials or other terms instead of full names, and /or you could make sure the diaries are kept in a safe place.

Case example – Mrs Jones

Mrs Jones works part time in a shop. She is married and has 2 children, both in secondary school. She has recently reduced her hours as she was finding it too difficult to work full time. The extra time at home has been good for her as she has been able to spend more time with the children. Her husband works full time in a manual job and he is usually exhausted when he comes home. Mrs Jones believes it's very important to have the dinner ready for her husband and children in the evenings so they can all spend time together. Her mother always had a home cooked meal ready for her father, herself and her 2 brothers every evening and Mrs Jones believes that this is the role of a good wife and mother.

She was asked to complete the thought diary on the next page at times in the week when she felt a change in her mood. She answered the questions in the thought diary and was asked to circle her most upsetting thought.

Look at Mrs Jones' diary on the next page.

Once you have looked over Mrs Jones' diary fill out your own blank diaries on the next few pages.

To complete your own diary sheets record any unhelpful thoughts you may have over the next week. Record where you were, who you were with and what you were doing. Then write out the thought answering the questions in the thought diary. It is also helpful to record your level of fatigue when you have the thought. It is best to record the thought as soon as you have it. If it is not possible to carry this workbook with you all the time you could photocopy the extra blank sheet in the Appendix to carry with you. Try to fill out at least one unhelpful thought a day.

<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in one word Sad, angry, frustrated, upset etc</p> <p>How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <p>1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do you think the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>
<p>At home, in the kitchen By myself Trying to make dinner but feeling too fatigued</p>	<p>Angry 8 Sad 7</p>	<p>1) I'm letting my husband and children down. I'm not being a good mum He works full time, he shouldn't have to make tea when he comes home</p> <p>2) These thoughts are about me</p> <p>3) They mean I'm useless</p> <p>4) My husband will leave me</p> <p>5) All the arguments we have had</p> <p>6) Me being by myself</p>	<p>8</p>

<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in one word Sad, angry, frustrated, upset etc</p> <p>How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <ol style="list-style-type: none"> 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do you think the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? <p>Circle the most upsetting thought</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>				
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<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in one word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <p>1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do you think the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>

<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in one word Sad, angry, frustrated, upset etc</p> <p>How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <p>1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do you think the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>

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Take some time to look through your thought diaries and try to answer the following questions.

- Do you notice any similarities?

- Are there similar triggers that increase your fatigue?

- Do you have reoccurring thoughts or are they different each time?

- Is your most upsetting thought different or similar in each diary?

- Can you identify any of the unhelpful ways of thinking outlined on page 23 in your own thoughts?

- Is there a link between your moods and thoughts?

It is important to spend time reflecting on the thoughts you have and to try and understand what the triggers are as well as how they impact on your mood and your levels of fatigue.

Week 2 - Changing unhelpful thoughts

Week 2 - Changing unhelpful thoughts

Well done, you have practised identifying your unhelpful thoughts. If you feel you need more practice use the blank diary sheet in the appendix to make photocopies. Remember, it's not about being an expert in identifying unhelpful thoughts. It's about starting to notice that you are having them so you can change them.

We are now going to learn some ways to manage your unhelpful thoughts.

Before we start here are some top tips about unhelpful thoughts

- You **CAN** manage your thoughts
- Thoughts are **NOT** facts
- Just because you think it, does **NOT** mean it's true

Below are four techniques to help manage unhelpful thoughts, you may only find one or two of the techniques to be relevant to you.

1) **Fact or fiction**

Is the unhelpful thought based on fact or fiction? Sometimes our thoughts are not true, they can be based on emotions (emotional reasoning), memories from the past, fears about the future (predicting the future/mind reading) or they may be exaggerating a particular situation (catastrophising). One way to challenge these thoughts is to imagine that they have to be used as evidence in a court of law. If the thought was used as evidence in a court of law would it be enough to convict someone?

Fact – Fatigue is a symptom of my MS

Fiction – I am useless because of my fatigue

You may *feel* useless but feelings are not facts. If you had a gut feeling that someone was guilty of murder would this be enough evidence for the judge to convict them?

Fact – I have to pace myself to help manage my fatigue

Fiction – Everyone thinks I'm lazy because I have to take rests

Are you mind reading? Is there any evidence to suggest this is true? Just because you think it doesn't make it true. Thoughts don't mean facts.

2) **Evidence**

Look for evidence in favour **and** against the unhelpful thought. Be realistic, there may be some evidence to support the unhelpful thought, but there may be more evidence against it. Make sure the evidence is based on fact not fiction. Make sure your unhelpful thoughts aren't getting in the way. Be objective, considering evidence in support and evidence against the thought.

3) **What would you tell a friend**

We can often be tough on ourselves and beat ourselves up, but we would never be that tough on other people. Imagine a close friend or family member in the same situation as yourself, what would you tell them if they had your thoughts.

Would you agree that they were lazy, failures, useless, hopeless or would you be a little friendlier to them? Would you think they were being harsh on themselves? Try using this friendlier advice on yourself.

4) Advantages & Disadvantages

List the advantages and disadvantages of thinking a particular thought. Be objective. What are the advantages of calling yourself useless or beating yourself up about the things you can't do? What are the disadvantages? Does this type of thinking change your mood? Does it stop you from getting involved in activities you want to do? Does it make your fatigue worse? Is it worthwhile continuing to think this way or would it be better to change this?

Realistic conclusions

Reaching a realistic conclusion is not about pretending everything is perfect and that your problems have gone away. Realistic conclusions are about looking at the evidence and applying it to your thoughts. A realistic conclusion may be....

"My symptoms of fatigue mean I can't tidy the house in one attempt. This makes me feel useless. But feelings are not facts, therefore just because I can't tidy the whole house in one go doesn't make me useless. It just means it will take me longer to tidy the house."

On the following pages there are some more thought diaries, but this time there are extra columns to challenge thoughts and reach realistic conclusions. It's usually best to start with challenging your most upsetting thought first. Identify this by circling it on your diary – it's the thought that usually creates the strongest reaction.

Case example – Mrs Jones

You will see that Mrs Jones has used a diary on page 42 to identify her unhelpful thoughts and has started to challenge her most upsetting thought.

As before, take at least 1 week to practise identifying and challenging your thoughts. Try to fill out a diary and challenge at least one thought a day. Try to challenge the thought as soon as you notice them, remember you may notice a change in your mood first. The more you practise, the more you will be able to manage your unhelpful thoughts. There is a blank diary sheet in the appendix for you to photocopy.

Mrs Jones' thought challenging diary

<p>Trigger Where were you? Who were you with? What were you doing?</p>	<p>Mood Moods are normally described in 1 word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Challenge thoughts Start by challenging your most upsetting thought first. 1) Is it fact or fiction? 2) What is the evidence? 3) What would you tell a friend? 4) What are the advantages & disadvantages?</p>	<p>Realistic conclusion Weigh up the evidence, be realistic, how can you change this thought to be more helpful?</p>	<p>Level of fatigue (0 = not fatigued at all, 10 = most fatigued I've ever been</p>
<p>At home In the front room Children asked me to help with their home work</p>	<p>Sad (8) Frustrated (6)</p>	<p>1) I'm to fatigued to focus on their homework <i>I'm a useless parent</i> 2) About me 3) That I'm useless 4) My children will realise they don't need me 5) Reminds me of everything else I can't do</p>	<p>1) I feel like a useless parent but this may not be a fact 2) the evidence is that I can't help with the homework today 3) I'd say that they weren't a useless parent and list all the good things they do 4) there are no advantages this thought make me feel sad</p>	<p>I'm too tired to help with their homework just now this makes me feel useless but I will help tomorrow if I feel better, I do a lot of things which make me a good parent, they are always clothed, fed and warm and they are doing well at school, my husband can help them when he gets home.</p>	<p>8 – it's a bad fatigue day</p>

<p>Trigger Where were you? Who were you with? What were you doing?</p>	<p>Mood Moods are normally described in 1 word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Challenge thoughts Start by challenging your most upsetting thought first. 1) Is it fact or fiction? 2) What is the evidence? 3) What would you tell a friend? 4) What are the advantages & disadvantages?</p>	<p>Realistic conclusion Weigh up the evidence, be realistic, how can you change this thought to be more helpful?</p>	<p>Level of fatigue (0 = not fatigued at all, 10 = most fatigued I've ever been)</p>						
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<p>Trigger Where were you? Who were you with? What were you doing?</p>	<p>Mood Moods are normally described in 1 word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Challenge thoughts Start by challenging your most upsetting thought first. 1) Is it fact or fiction? 2) What is the evidence? 3) What would you tell a friend? 4) What are the advantages & disadvantages?</p>	<p>Realistic conclusion Weigh up the evidence, be realistic, how can you change this thought to be more helpful?</p>	<p>Level of fatigue (0 = not fatigued at all, 10 = most fatigued I've ever been)</p>

Stage two summary

Well done! You have completed the stage on identifying and challenging unhelpful thoughts. You have started to make positive changes by making your thoughts more realistic. This is a tricky thing to do and you may feel like you need more practice. This is normal. These unhelpful thoughts may have developed over years so it's no surprise it will take longer than 2 weeks to fully manage them. As you continue to identify and challenge unhelpful thoughts, it will become easier to do this

It's normal to have unhelpful thoughts so it's likely that they will keep popping back, but you now have the tools to manage them and stop them spinning out of control, you just need to keep practicing. Over time it will become second nature to recognise and challenge these unhelpful thoughts such that they have less effect on your mood and behaviours.

Sometimes when we start changing unhelpful thoughts things can initially seem worse. This is because you are no longer avoiding them. It can take a couple of months to break the habit of unhelpful thinking. Just like learning to drive a car you may not feel proficient in managing fatigue until you have finished the workbook and have put the techniques into practice. Remember you are learning a new skill, and this takes time.

Monitoring how fatigue impacts on your life

On a scale of 0 – 10 how much do you feel you understand your fatigue (0= not at all 10 = completely understand).

On a scale of 0 – 10 how much do you feel you can manage your fatigue (0= not at all 10 = very confident I can manage it).

What has been most helpful in this stage of the workbook?

What has been least helpful in this stage of the workbook?

Stage Three

It is estimated that it will take approximately 90 minutes to read over and complete the exercise in this stage. It is recommended that you complete stage three over 2 weeks.

Behaviours and fatigue



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Workbook page 51

Summary of stage two

In stage two you looked at your thoughts in more detail. You learned how to identify your unhelpful thoughts using diary sheets. You then learned ways to challenge your unhelpful thoughts. Identifying and challenging unhelpful thoughts is difficult, so don't worry if you need more practise. There are blank diary sheets in the appendix to photocopy.

Introduction to stage three

This stage aims to help you

- learn about unhelpful behaviours
- learn how to change unhelpful behaviours
- learn how to introduce activities that give you a sense of closeness with others, achievement and pleasure (CAP activities)

It is suggested that you take 2 weeks to complete the exercises in this stage.

Behaviours

Behaviours are the activities we do every day. Fatigue can have a big impact on the type of activities we can do. It may mean you can't carry out physical tasks in the same way as you used to. It may mean you get tired doing the day to day tasks like taking a shower, something you would have never consider as an 'activity' in the past. You may experience fatigue after non-physical tasks such as reading books or talking to a friend.

Mental tasks can impact on fatigue just as much as physical tasks. As you can see in the clover on page 23 our behaviours have an impact on our moods, thoughts, physical ability to carry out tasks and impact on our level of fatigue.

Fatigue can have an impact on our behaviour in two main ways.

1) It can cause us to push ourselves too much. This can lead to days of increased activity followed by days of not being able to do anything. This type of behaviour is called, **The over activity – bust cycle.**

or

2) It can lead to an general reduction in activity level. This is usually due to worries that any activity will trigger increased fatigue. This is called, **The under activity cycle.**

Both of these types of behaviour are included in this workbook. You should read the section most relevant to you, but you may find it useful to read through both types of behaviour. Everyone should read the section on CAP activities.

It is recommended that you take 2 weeks to complete this stage.

Week one tasks included the over activity-bust cycle (paged 54 - 65) and/or the under activity cycle (pages 66- 72).

Week 2 tasks include the CAP activities section on pages (73-79)

Week one

Behaviours
The over activity - bust cycle

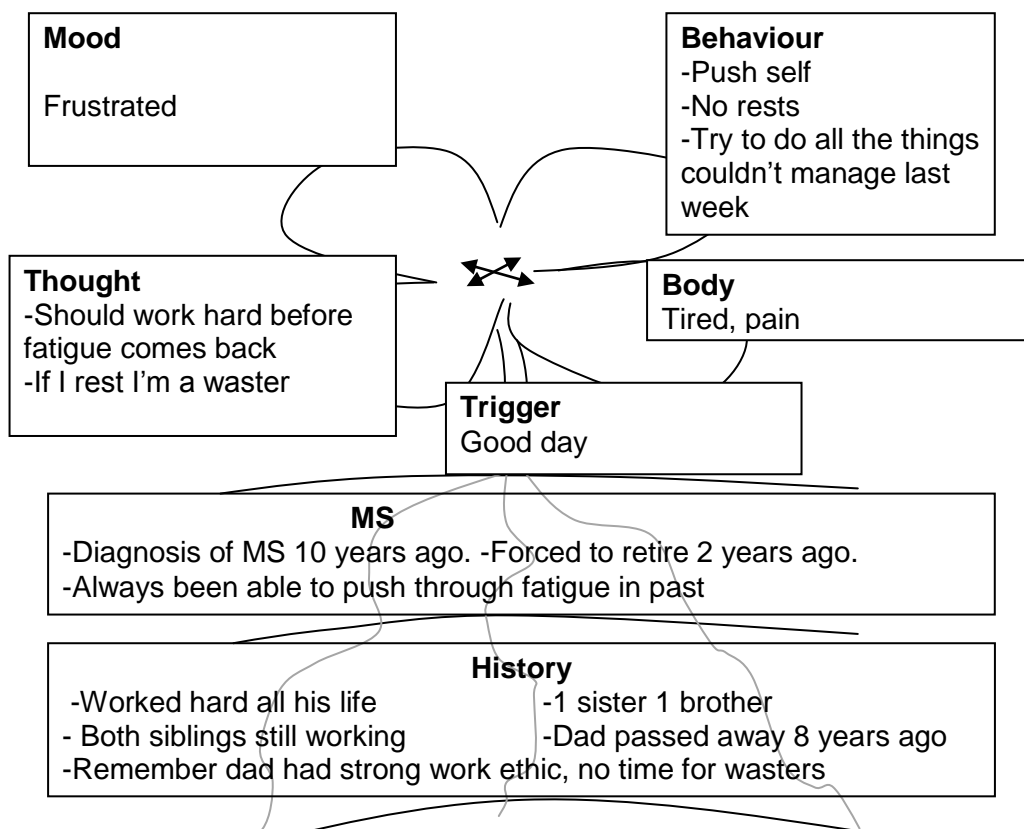
Over activity-bust cycle

Look at the example below and ask yourself what impact John's behaviours have on his mood, thoughts, and levels of fatigue.

Case example – John

John lives at home with his wife. He has been retired for 2 years due to his MS. He is a keen gardener and has always done DIY around his house. He has always worked hard and enjoys the sense of satisfaction he gets from completing a task. His fatigue is a problem for him as it gets in the way of the activities he wants to complete. He works at a task until he is exhausted. On the days he feels well, he pushes himself to do activities in the garden and around the house. He then becomes exhausted in the following days and is not able to get anything done. Recently, he has had to turn down invitations to the social club with his friends on a Thursday evening as he is too tired to go.

John's unlucky clover looks like this;



John filled out an activity diary over 1 week (below). Alongside the activity he also reported his level of fatigue from 0-10, where 0 means not fatigued at all and 10 means very fatigued. He then coloured the squares in based on the key below.

Fatigue rating	Meaning	Colour
0-4	Feeling ok	Green
5-7	Starting to feel fatigued	Amber
8-10	Very fatigued	Red

John's weekly activity sheet

	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Midnight - 6.00am	Sleep	Sleep	Wake at 5	Sleep		Sleep	Wake at 5.30
7.00-8.00am	Breakfast Shower dressed (4)	Sleep breakfast (3)	Coffee breakfast	Sleep	Sleep	sleep	Breakfast
9.00-10.00am	Read paper coffee(3)	Read paper Coffee(2)	Paint bathroom (4)	Sleep	Break- fast, TV	Shower dressed (6)	Rest in chair (7)
11.00-12.00 noon	gardening (2)	TV Snack	Lunch (6)	Up Shower (6)	Shower (8) Rest on bed	Coffee (6) snooze	Coffee (7) snooze
1.00-2.00pm	Lunch Gardening (4)	Shops (3)	Children visit (6)	Paint bathroom (8)	Lunch (7)	Lunch (6)	Lunch (8) snooze
3.00-4.00pm	House- work	Read book (5)	TV (7)	snooze	Listen to music (8)	Brother visit (6)	TV (7)
5.00-6.00pm	Eat dinner (5)	Dinner TV (4)	Dinner Read paper (7)	TV (8) Dinner	Dinner (8)	Dinner (8) snooze	TV (8) dinner
7.00-8.00pm	Grand- children visit(6)	TV(4)	Sleep	Not go to social club TV (9)	snooze Bed- sleep	TV (7) sleep	TV sleep
9.00pm- midnight	TV (5) Bed	Read (5) Sleep		sleep	Sleep		

John's activity analysis

Are there any patterns you can pick out from John's activity sheet?

Does he do most of his physical activities at the start or end of the week?

Why does he sleep in and not do much activity on Thursday?

Why do you think he is too tired to go to the social club on Thursday with his friends?

Does he have to snooze at the start or the end of the week? Why?

What do you notice about his level of fatigue throughout the day?

What do you notice about his level of fatigue throughout the week?

What do you notice about the type of activities he does at the start of the week?

Does the type of activities change by the end of the week? How?

Does anything surprise you about his activity diary?

John's week

John starts his week feeling fairly energetic. His level of fatigue starts off reasonably low staying at 5 or below at the start of the first 2 days. It steadily increases throughout the day. He benefits from coffee breaks but still feels more fatigued throughout the day as his activities build up. Note that visits from grand children and reading his book still have an impact on his fatigue even though he is not doing physical activity.

Wednesday is another busy day as he decides to paint the bathroom. He woke earlier than usual on Wednesday and his fatigue is impacting on him a little more than the previous days. He does not take a break for a coffee in the morning as he is determined to finish the bathroom but in the afternoon he is forced to leave the decorating and decides to watch TV and read – he had to go to bed earlier than usual.

On Thursday John sleeps in until 11.00am, this is very unusual for him. He is still quite fatigued after his long sleep but tries to finish off the bathroom. He ends up snoozing in the afternoon, but feels lazy. He has to turn down his weekly meeting at the social club.

John sleeps in a little on Friday and Saturday but his levels of fatigue are still quite high. He finds having a shower more tiring than usual and has to take a rest after it. John's levels of fatigue are so high, he cannot manage to get into the garden or finish the decorating. He ends up spending most of his days watching TV, sitting in his chair listening to music and snoozing but still does not get much immediate benefit from resting.

It appears that John has pushed himself so hard in the first 3 days of the week that he was unable to do much physical activity by the end of the week. Having the occasional break at the beginning of the week allowed John to keep pushing himself. But the breaks did not help much by the end of the week. John started borrowing energy from the next day. He went into his energy overdraft by Wednesday and kept spending. The energy debt and the interest kept building up until he was forced to reduce his spending and save.

John's activity diary suggests his behaviours fit the over activity-bust cycle.

You will notice that John spent a lot of time completing his activity sheet. He tried to fill it in every 2 hours but did not manage to fill them all in, this is ok. He was still able to get a good idea of how his activities impacted on his fatigue.

Your activity diary

To work out what your activity pattern is its best to complete a weekly activity sheet. An activity sheet lists days of the week and hours in the day. Your job is to fill in the activities that you have done. Then using the scale of 0-10 write how fatigued you felt at that point in the day (0 = not fatigued at all and 10 = worst fatigued I've ever felt).

It's best to complete the activity sheet at regular intervals throughout the day (for example, at lunch and before bed) to ensure you don't forget what you have done.

This a time consuming task but it will be worthwhile as it gives you a chance to really see what you do through the week. This will allow you to identify unhelpful behaviour and then make positive changes.

Sometimes patterns are clear (it helps to colour code your sheet like John did when you have finished). Sometimes it is harder to pick up on a pattern; you may want to fill out another activity sheet to see if a pattern becomes clear. There is a blank activity sheet in the appendix if you want to photocopy it.

Putting the hard work in now will pay off in the long run.

It is recommended that you use the next week to complete your own activity diary on the following page.

Your personal activity diary

	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Midnight - 6.00am							
7.00- 8.00am							
9.00- 10.00am							
11.00- 12.00 noon							
1.00- 2.00pm							
3.00- 4.00pm							
5.00- 6.00pm							
7.00- 8.00pm							
9.00- -midnight							

Your activity analysis

Do you notice any patterns in your own behaviour?

When do you do most of your physical activities?

Have you had to turn down activities because you were too fatigued?

Have you had to turn down activities you wanted to do due to your fatigue?

What do you notice about your level of fatigue throughout the day?

What do you notice about your level of fatigue throughout the week?

What do you notice about the type of activities you do at the start of the week?

Does your type of activities change by the end of the week? How?

Does anything surprise you about your activity diary?

Taking control: The over activity – bust cycle

So now you know what your typical week looks like can you recognise times of over activity? Are there days were you push yourself too much because you feel good? Are there days when you have extreme fatigue after you have pushed yourself?

The best way to manage this type of behaviour is to pace yourself. You may have been advised to do this in the past by your doctor, physiotherapist, occupational therapist or another health care provider. This is because it does work when it is done properly. The problem is that you have to stick at it for long enough to gain the benefits and it may go against the way you have done things for years.

What are your initial thoughts when you are asked to pace yourself? Are they unhelpful thoughts? If so fill out a blank thought diary, you can find a spare on in the appendix. Challenge these unhelpful thoughts as you have done previously in section 2 and try to reach a balanced conclusion.

John in the example above had been told to pace himself in the past and thought it wasn't for him. Look at his thought diary on the next page.

If you don't need to challenge your thoughts turn straight to page 64 to learn how to pace your activities.

John's thought diary

<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in 1 word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <ol style="list-style-type: none"> 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? <p>Circle the most upsetting thought</p>	<p>Challenge thoughts</p> <p><u>Start by challenging your most upsetting thought first.</u></p> <ol style="list-style-type: none"> 1) Is it fact or fiction? 2) What is the evidence? 3) What would you tell a friend? 4) What are the advantages & disadvantages? 	<p>Realistic conclusion</p> <p>Weight up the evidence, be realistic, how can you change this thought to be more helpful?</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>
<p>Asked to pace activities</p>	<p>Frustrated (7)</p>	<ol style="list-style-type: none"> 1) I've been told to do this before. <i>it won't work</i> If I'm having t good day I <i>should</i> work hard to get all my jobs done before I have a bad day. 2) me 3) If I take breaks it means I'm lazy. 5) times when I tried it in the past 	<ol style="list-style-type: none"> 2) I've tried to take breaks in the past but I only tried for a couple of days. I am having 'should' thoughts. 3) I would tell a friend to space their energy out as it makes more sense to do a little each day instead of getting exhausted. 	<p>I've never given it a real go so I will try it for a few weeks to see if it works. I'd be easier on a friend and I've challenged my unhelpful thoughts about being a waster before, I know they are not realistic. Even though It feels strange to take a break before I'm tired I will give it a go to see if it helps.</p>	<p>5</p>

Pacing activities

Taking breaks

Firstly decide how long you should work at an activity before you take a break. Remember its best to take a break before you get too exhausted. This will be different for different types of task but a good starting point may be to take a break every 20 minutes.

Length of breaks

Again this will differ depending on what activities you are doing. If its hard physical work you may want to break for 15- 30 minutes. If you're reading a book a 10 minute break may be enough. Remember the point of your breaks is to recharge your energy levels or bank some of your energy for the rest of the day so you don't end up going into your overdraft.

What is a break?

Remember that you use mental energy by concentrating hard on things such as reading a book. So for a break you need activities that use low levels of concentration, such as listening to music, watching easy going TV, having a cup of tea, looking out into the garden or street. You may even decide that there are certain times in the day when it would be best to schedule in a morning or afternoon sleep to recharge your batteries for the evening.

Plan ahead

Work out what activities you would like to do for that day/ week. What commitments do you have? Are there things you have to do every day at particular times? Write these in a blank diary (you may want to use a pencil so you can adjust the activities as you go).

How much energy will you need for these activities? Do you have to take a rest before you start them or during them to ensure you balance your energy levels? Think about leaving out physically or mentally tiring activities before-hand so you have enough energy.

Do you really need to do these activities? There may be certain commitments that you have to do but could you get help with them on some days? Can you reduce the activity in some way for example getting a friend to pick your children from school every other day, visiting parents once a week rather than 3 times?

Case example – John

John made the following changes which helped him manage his fatigue and get more enjoyment out of his week.

- He let his children and grandchildren know that he enjoyed their visits but explained that because of his fatigue he found it difficult to concentrate for more than an hour. They understood and said that they noticed he was getting a bit tired by the end of their visits and were happy he told them. They now keep their visits shorter.
- He also told his wife that 2 hours shopping and standing on his feet was too long for him. They decided to go to the local shops for a shorter length of time and agreed if they had to be out longer than an hour they would stop for a coffee somewhere.
- If he woke early in the mornings he allowed himself to have an afternoon snooze to ensure he would not get too tired the next day. He also scheduled in a snooze on afternoons before the social club. He challenged his thoughts about being lazy and realised he could actually do more if he paced himself.
- He spread out DIY and physical activities over a few days.
- He always made sure he had a rest after showering and dressing as the heat from the shower always made him more fatigued.
- Rather than doing activities that took a lot of mental concentration in the evening he chose to do these in the mornings (e.g. reading a book) and did less demanding tasks in the evening such as listening to music or watching TV.

These changes ensured that he was able to manage his fatigue better, he was able to do activities which gave him a sense of closeness such as, time spent with his children and grandchildren, visiting his mother, social club with friends, lunch out with his wife.

Try to make some changes in your own activities to help manage your fatigue. You could photocopy a blank diary sheet from the appendix or draw a diary out on paper to help you plan your week more effectively in the future.

You can now move to page 73 to work on CAP activities or you may find it helpful to read through the under activity cycle information.

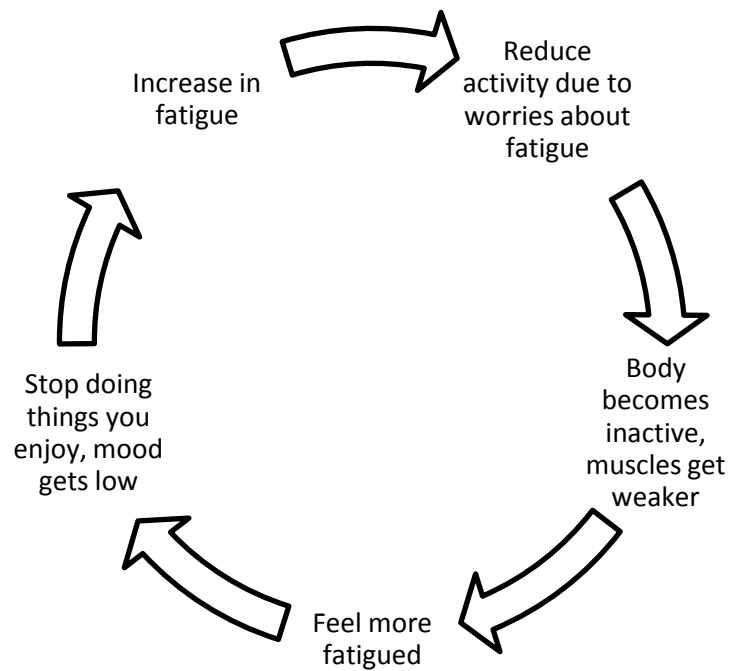
Week one activities (optional if relevant to you)

Behaviours

The under activity cycle

The under activity cycle

It may be the case that you don't do enough activity. This may be because you are scared that doing any activity at all will lead to an increase in fatigue and worsen your MS. But, not doing enough activity can actually increase your fatigue. This is because by doing too little your body becomes inactive, your muscles become weak and it becomes a struggle to do the smallest of physical jobs. Also, when we reduce the activities we used to enjoy we can start to feel low in mood and this can also lead to increased fatigue. This then turns into a vicious cycle.

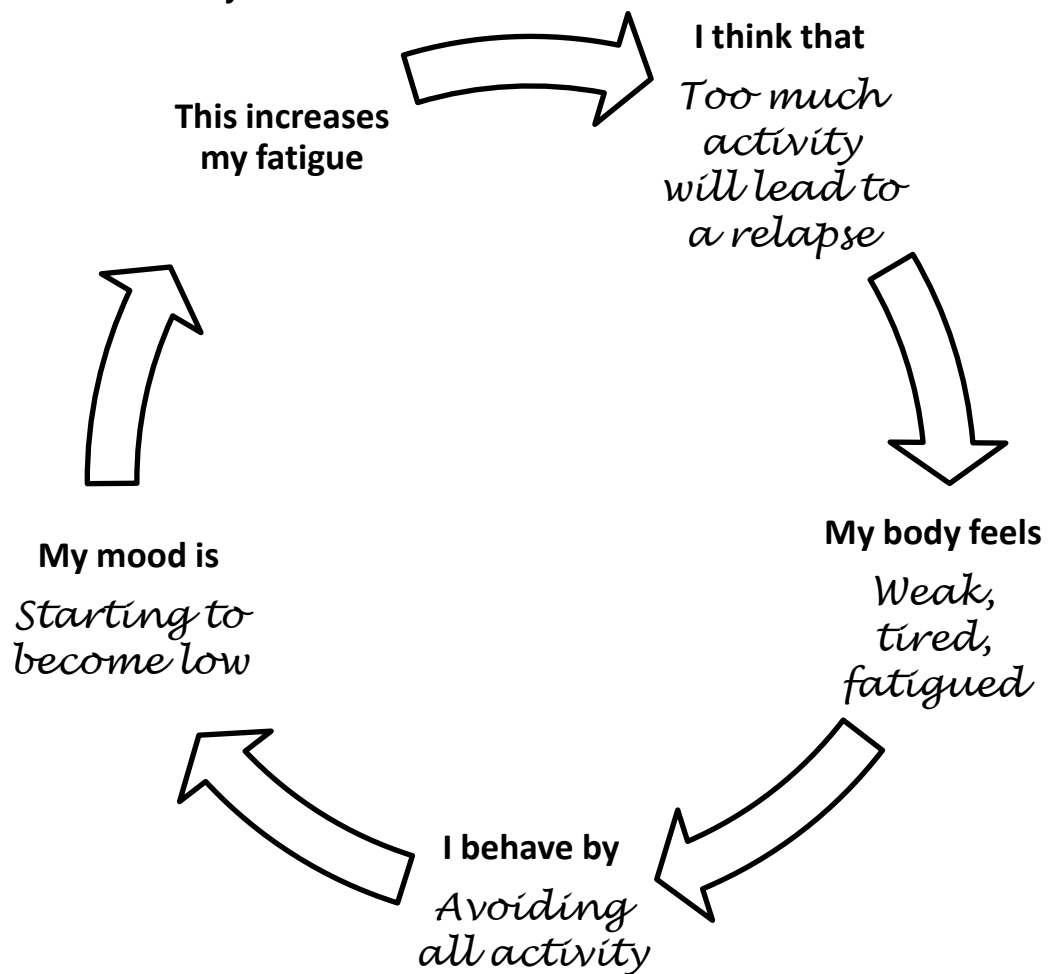


If you are doing too little it may be the case that you have unhelpful thoughts such as “I must save all my energy or I will make my fatigue worse”.

Case example – William

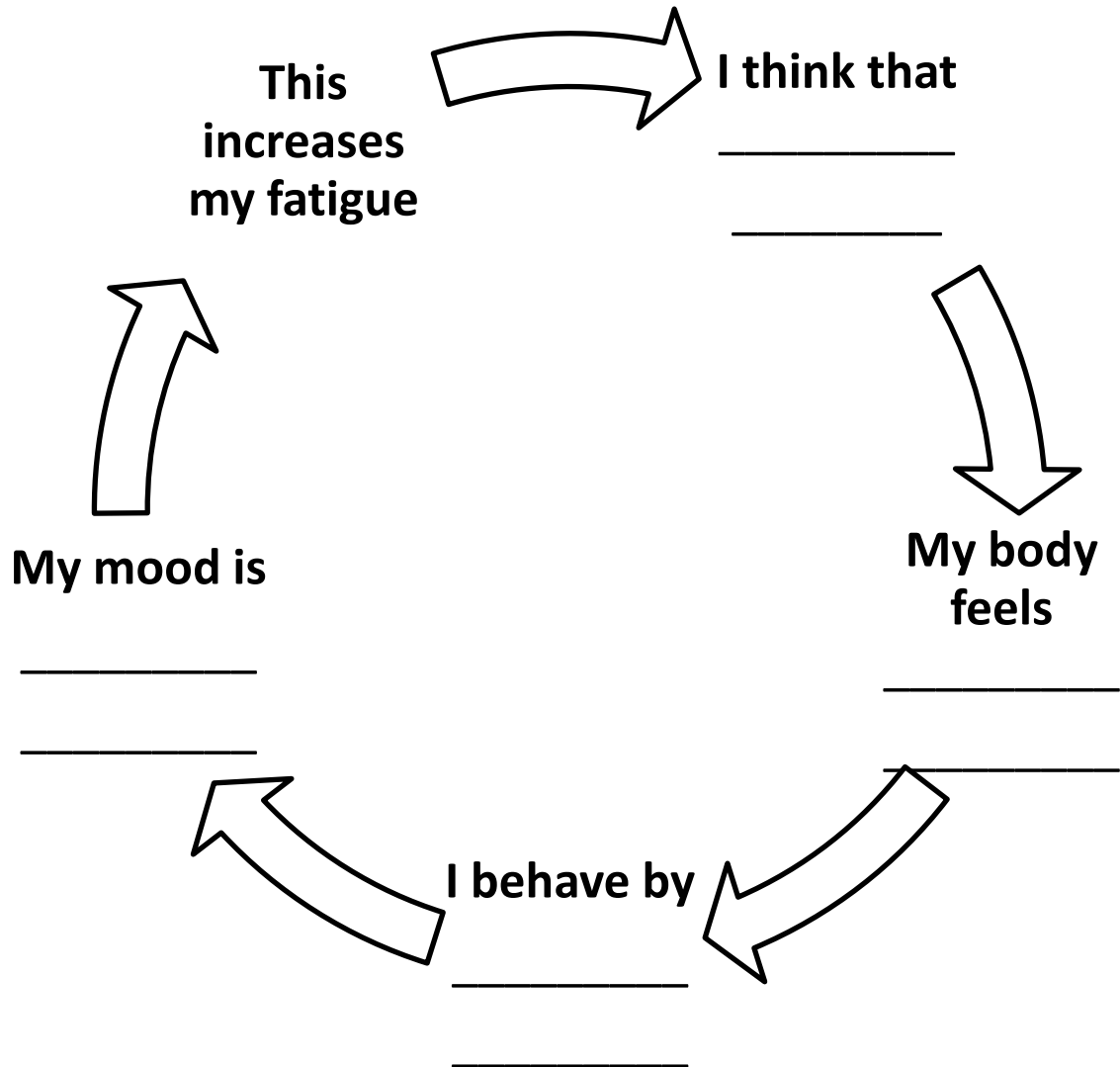
William is retired from work as MS was preventing him from carrying out his job as a mechanic. He used to be an active man with a good social life but since he retired he has reduced all of his activities. He read somewhere that pushing yourself when you have MS can lead to a relapse so he decided to stop all his activities. He no longer goes fishing, his wife cooks all the meals and looks after the house and he has stopped seeing his friends. William spends his days sitting on the sofa, watching TV and occasionally reading the paper. His thoughts are “If I do too much my fatigue will get worse”, “I feel very tired everyday and I don’t want to trigger a relapse so I will do as little as possible”, “I don’t feel as strong as I used, this means my fatigue and MS are getting worse”. William has also started to become low and mood and worries about the strain he is placing on his relationship.

William’s vicious cycle



My vicious cycle

Try filling out your unhelpful cycle below. You may want to use the unlucky clover you filled out on page 23.



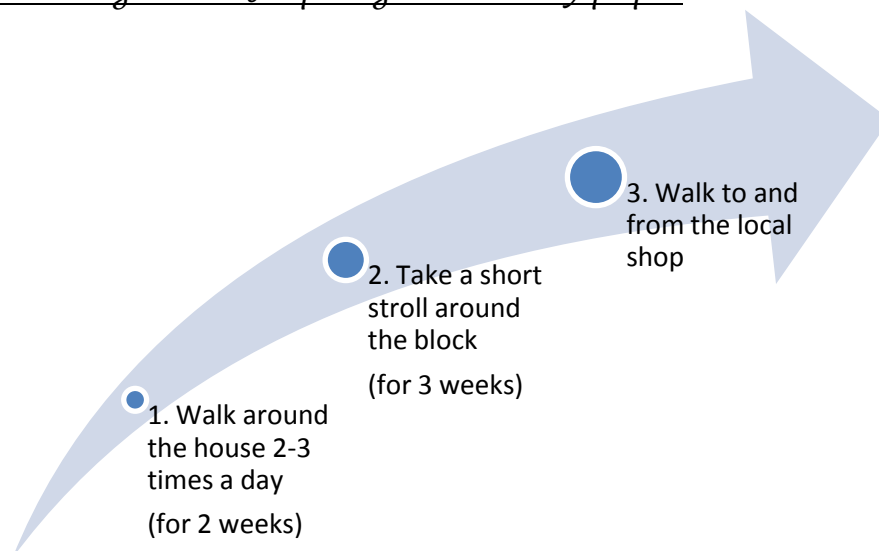
Taking control - under activity cycle

One way to break the vicious cycle of inactivity is to slowly increase your activities over a long period of time. If you have been inactive for a long time it may be helpful to speak to a healthcare professional for advice. This could be your GP, MS nurse, or anyone else, involved in your care to inform them what you are planning.

Below are the 4 techniques you will need to do to increasing your activity

1. **Set a goal** - What do you want to achieve? Be clear, write it out. But remember to be realistic, remember MS and fatigue do affect you but the fear of it shouldn't stop you from doing all activities.
2. **Break goals down** – break your goal down in to reasonable smaller steps.
3. **Time** – spend enough time on each step until you feel comfortable to move to the next step, this may take days, weeks or months.
4. **Don't move the goal posts** – once you have achieved your goal be proud of yourself and acknowledge the hard work it took you to get that far.

William used the 4 techniques above to achieve his goal
GOAL – *Walking to the shop to get the daily paper*



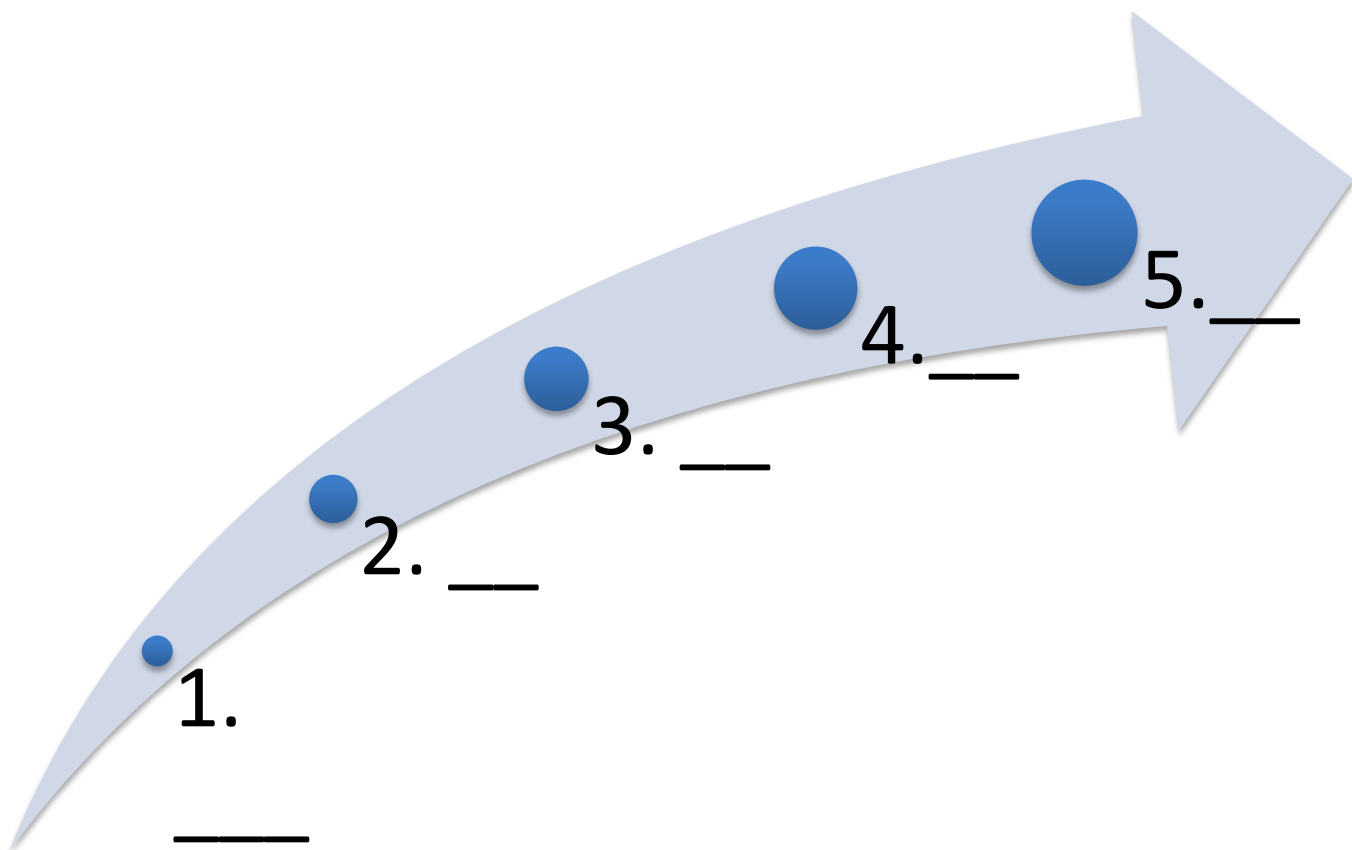
It took William 3 steps to achieve his goal and he spent 2-3 weeks on each step until he was able to move onto the next step. He started to feel like he had a little more energy and started to slowly increase other activities he had stopped.

Workbook page 70

It is important to note that there will still be some days when fatigue is worse than others and it is ok to rest on those days, it's just important to make sure you are not avoiding activity due to your fears and unhelpful thoughts. If your unhelpful thoughts are getting in the way, photocopy the black diary challenging sheet in the appendix to challenge them.

On the next page, chose a goal you want to achieve and plan the steps you need to do this. You may need to add in or take away more steps to your plan or you may want to draw out your own on a blank sheet of paper. Remember you may need to take a couple of weeks on each step before you move to the next one.

MY GOAL _____



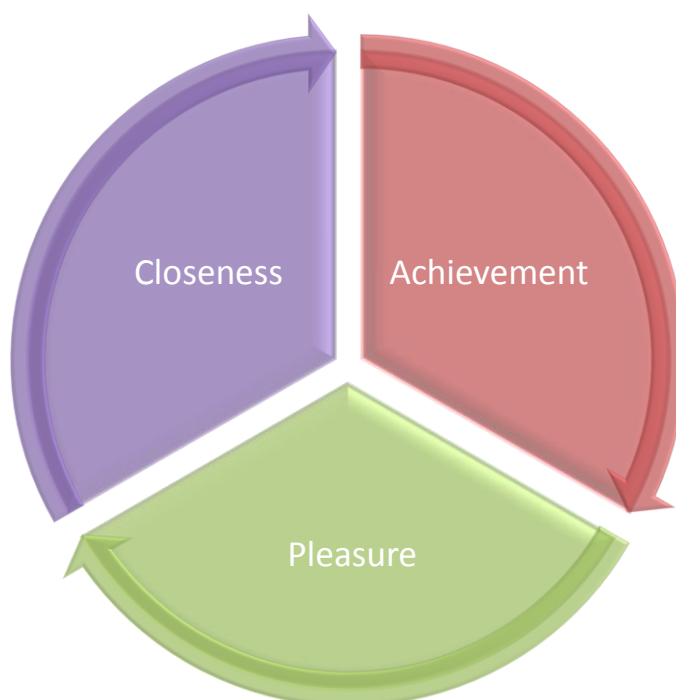
There is a blank copy of this sheet in the appendix for you to make photocopies or you can draw your own out on blank paper.

Week two actives

Behaviours - CAP activities

CAP activities

When you are planning to increase or pace your activities in your weekly diary it is important that you get a mix of different types of activities. The best mix of activities is CAP activities - **C**loseness, **A**chievement and **P**leasure activities.



Closeness activities are those where you feel close to another person. These might include coffee with a friend, going to a social club with friends, spending time with children, watching a movie with a partner etc.

Achievement activities are those where you get a sense of achievement through doing the activity. This may include finishing a book, tidying a room in your house, gardening, DIY, going to work etc.

Pleasure activities are those where you gain a sense of pleasure from doing them these may include going for a walk, listening to music, baking etc.

You may class some activities under two or three CAP activities. For example going swimming with friends may give you a sense of closeness to others, a sense of achievement for completing a physical activity and a sense of pleasure. Don't get too hung up on the different categories but make sure all your activities are not based mainly around one category.

In the table below make a list of activities you do under each heading, remember it is ok to put the same activity under different headings.

Workbook page 74

activity using the questions in the box below. It may be helpful to read the case example on the next page before filling out your own.

Workbook page 75

Activity investigation box

Name activity

What do you enjoy about it?

Is there a way it can be broken down into smaller steps?

If the activity can't be broken down, is there a different way you can get the enjoyment out of it by reducing/changing what you do? Brain storm and be creative!

Is there anyone who can help you do this activity?

Case example - Jennifer

Jennifer used to enjoy hill walking; she would go out every other weekend (weather permitting). Due to her MS and fatigue she has stopped it all together as she believes she can't get a sense of achievement from it anymore. Jennifer filled in the questions below,

Jennifer's activity investigation box

Name activity – *Hill walking*

What do you enjoy about it? *Achievement from reaching the top of a hill, Felt close to partner who came with me, took pleasure from looking at the scenery around me.*

Is there a way it can be broken down into smaller steps?

Fatigue means I could barely climb my stairs some days. So hill walking may be too much. I can probably walk a mile or two on a good day, on flat ground

Is there a different way you can get the enjoyment out of it by reducing/changing what you do?
Brainstorm and be creative!

I suppose I could get my partner to drive to national park areas and enjoy the scenery on the drive.

I could go for a short walk, maybe a mile if I'm feeling ok. It would have to be on flat ground

I enjoy watching documentaries and reading books about the Scottish landscape

There are local groups with scooters that go rambling in the hills; I may be able to do this

Is there anyone who can help you do this activity? *My partner could go on the drives with me. My son can help me find out information about local rambling groups for people with disabilities or I could use the internet*

Jennifer used her thought diaries to challenge the unhelpful thoughts she was having such as “there is no point if I can't climb a hill”, “I may as well not bother doing anything”, “and I have no enjoyment in my life anymore due to my fatigue”.

It may be true that Jennifer cannot do hill walking in the same way as before but it doesn't mean she can't get some enjoyment from altering the activities to suit her needs now. After analysing her activity she found out that there was more to it than just a sense of achievement, she enjoyed the scenery and she felt close to her

partner. She came up with different ways she could do activities so she was still enjoying them in some way. She was being realistic, she may never climb a Munro again and this is difficult to accept, but at least this way she is still getting some enjoyment from the outdoors rather than stopping the activity altogether.
Workbook page 77

Use the blank activity investigation box in the appendix; you can photocopy it if you need more sheets or draw one on blank paper.

Summary of stage 3

In stage 3 you have learnt to identify what type of unhelpful behaviours you have. You have decided whether your unhelpful behaviours fit more with the over activity-bust cycle or the under activity cycle. You have learnt to look at your behaviours more closely and started to make changes by planning ahead and making sure you have a mix of CAP activities in your week. You have also looked at ways to change the activities you may have stopped doing due to your fatigue. Do not forget to use the skills in stage 2 to challenge any unhelpful thoughts using the blank diary sheet in the appendix.

Monitoring how fatigue impacts on your life

On a scale of 0 – 10 how much do you feel you understand your fatigue (0= not at all 10 = completely understand). _____

On a scale of 0 – 10 how much do you feel you can manage your fatigue (0= not at all 10 = very confident I can manage it). _____

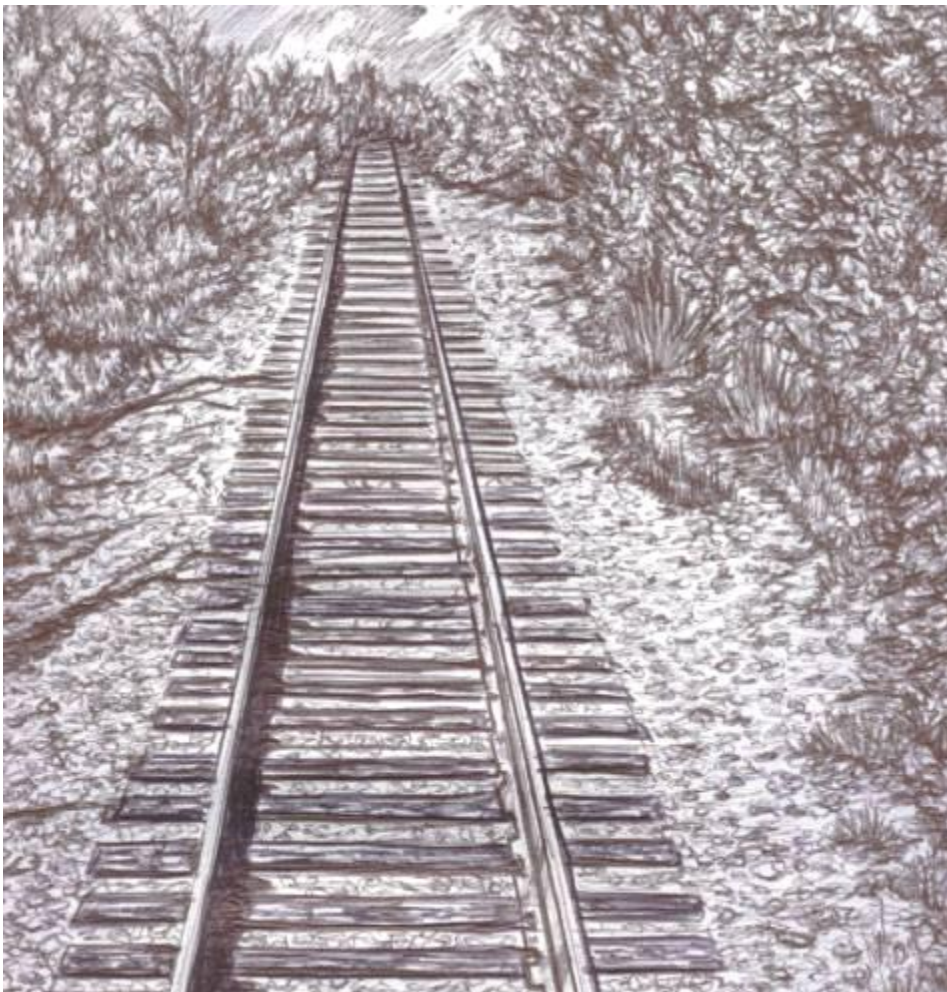
What has been most helpful in this stage of the workbook?

What has been least helpful in this stage of the workbook?

Stage four

It is estimated that it will take approximately 90 minutes to read over and complete the exercise in this stage. It is recommended that you complete stage four over 1 week.

Keeping on track



Summary so far

Well done for completing the first three stages of the workbook.

So far you have

- completed your own self assessment of fatigue
- looked at unhelpful thoughts and started to challenge them
- looked at unhelpful behaviours and started to change them
- you have started to introduce CAP activities into your week

Introduction to stage four – the final stage

This stage aims to help you

- turn your unlucky clover into a lucky clover
- learn helpful tips to stay on track
- learn how to keep monitoring your levels of fatigue

Turn to your unlucky clover on page 23. You will notice that the way you used to think and act towards your fatigue impacted on your mood and your body. You have now learnt the skills to turn your unhelpful clover in to a more helpful clover.
Workbook page 81

There will be some aspects of the clover you will be less able to change such as your past experience, but you can understand the impact it can have on your daily functioning in the here and now which is an important step.

Take some time to look at the different sections of the unlucky clover on page 23. Has anything changed?

Are your triggers the same?

Do you have more realistic thoughts?

Have you changed your behaviours?

Has your mood started to change?

Have there been any changes in your body?

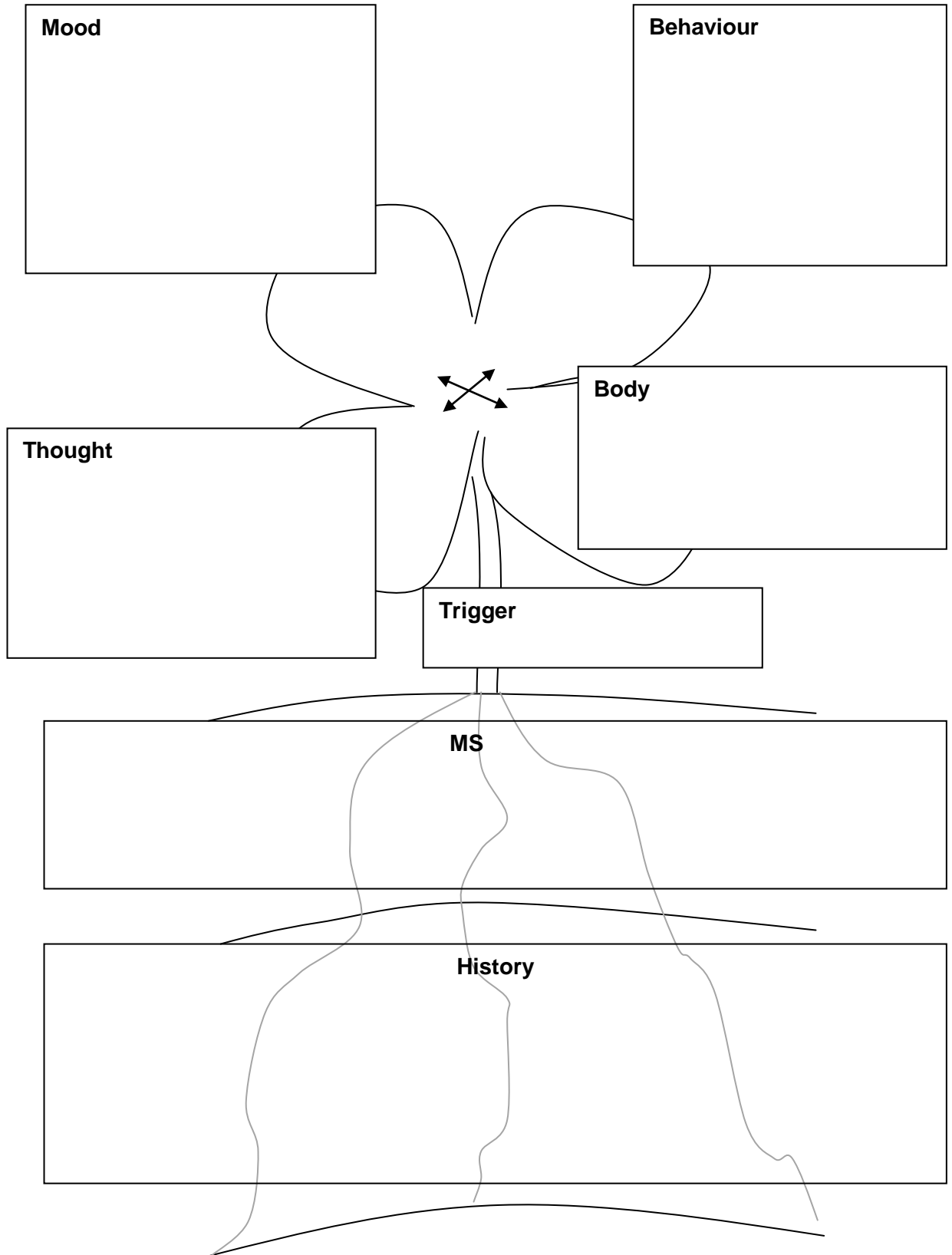


Take some time to fill out your lucky clover on the next page by answering the questions above.

Once you have completed your lucky clover keep it close by, to remind you of the changes you have made.

Workbook page 82

Lucky clover worksheet



Do not worry if you still have changes you want to make. You will be able to make further changes over the weeks and months ahead using the same techniques you have learnt in this workbook. You are living with MS on a daily basis, some days are better than others but you now understand how you can manage your fatigue better than before.

Progress monitoring

You have been monitoring your fatigue over the course of this workbook. Take some time to look over the section summaries at the end of each stage in the workbook and remind yourself of what has helped and what has been less helpful.

Look at the ratings you made about your understanding of your own fatigue and your ability to manage it.

- Has your understanding changed over the course of this workbook?
- Has the way you manage your fatigue changed over the course of this workbook?

It is important to monitor your fatigue on a regular basis to ensure you are managing it the best you can. You may wish to continue doing this by photocopying the blank diary sheets and activity sheets in the appendix.

Some people find it useful to do this by making a note in their diary, phone, or calendar once a month whereby they review how they have been managing their fatigue. Ask yourself;

- Is my fatigue better or worse than last month?
- Do I know why?
- What can I do to improve the management of my fatigue?



What if my fatigue starts to become a problem again?

It may be the case that you struggle to manage your fatigue at different points throughout your life. It is important to plan for this now, in case it happens in the future. Forward planning will ensure you are prepared.

The first step is to notice that you are struggling to manage your fatigue, this can be difficult to do. It may be helpful to think of the warning signs that mean your fatigue is becoming problematic.

Step 1 - My warning signs

Think back to times in the past when you have struggled with your fatigue. What did you notice first?

- Did work become difficult to manage?
- Did your mood change?
- Were you having unhelpful thoughts?
- Were you pushing yourself to do too much activity (similar to the over activity –bust cycle)?
- Were you avoiding activities (similar to the under activity cycle)?
- Were you just doing the daily chores and not doing any pleasurable activities?
- Were your friends or family able to recognise your fatigue in the past?

Take some time to write down your warning signs.

Step 2 – My emergency plan

Once you notice that your warning signs are occurring the next step is to put your emergency plan into action.

Emergency plan

1. First of all, **do not worry**, there will be times where all people with MS struggle with their fatigue, even if they were managing it fine previously. Take a deep breath and follow the steps below.
2. Complete a blank clover diagram to see if it is unlucky (photocopy from the appendix or draw a blank one out on paper).
3. Identify which part of your clover is most troubling to you;
 - Triggers – is there increased stress in your life at the moment?
 - Thoughts – are you having unhelpful thoughts?
 - Behaviours – are you pushing yourself or avoiding activities?There may be more than one area that you are struggling with, this is ok.
4. Read over the relevant stage(s) of the workbook. For example if you notice that your thoughts are becoming unhelpful read stage 2 of the work book. Remember to give yourself the recommended time to read over the stage and complete the activities.
5. Review your summary box, which you will fill out at the end of this section. This should help you identify what helped you in the past.
6. You may find it helpful to think about what support systems you have around you (friend, relative, MS nurse, colleague, G.P.).

The techniques you have learnt throughout this workbook are now yours to keep and you can use them whenever you need them. You can always read through the workbook in the future if you need a refresher.

Fill out your summary box on the next page which will be an important refresher of the techniques you found most helpful throughout this workbook. You can review this summary box in the future if fatigue becomes a problem for you. It may be helpful to read over the summaries of each section to jog your memory before filling out the box.

My summary box

What has helped the most?

What was least helpful?

What triggers do I need to look out for in the future?

What happens to my mood when my fatigue gets worse?

What unhelpful thoughts do I need to look out for in the future?

What unhelpful behaviours do I need to look out for in the future?

What changes do I still want to make?

How will I monitor my fatigue in the future?

What will I do if my fatigue gets worse? (e.g. read over the workbook, contact support services, talk to family or friends)

Other issues that may affect fatigue

This workbook is designed to focus on your thoughts and your behaviours to help manage your fatigue. There are other areas that you may wish to work on further, such as:

- Sleep
- Medication
- Pain
- Mood

If you would like to seek further help in these or other areas you can contact a healthcare provider for advice or look at the useful contacts below.

Useful contacts

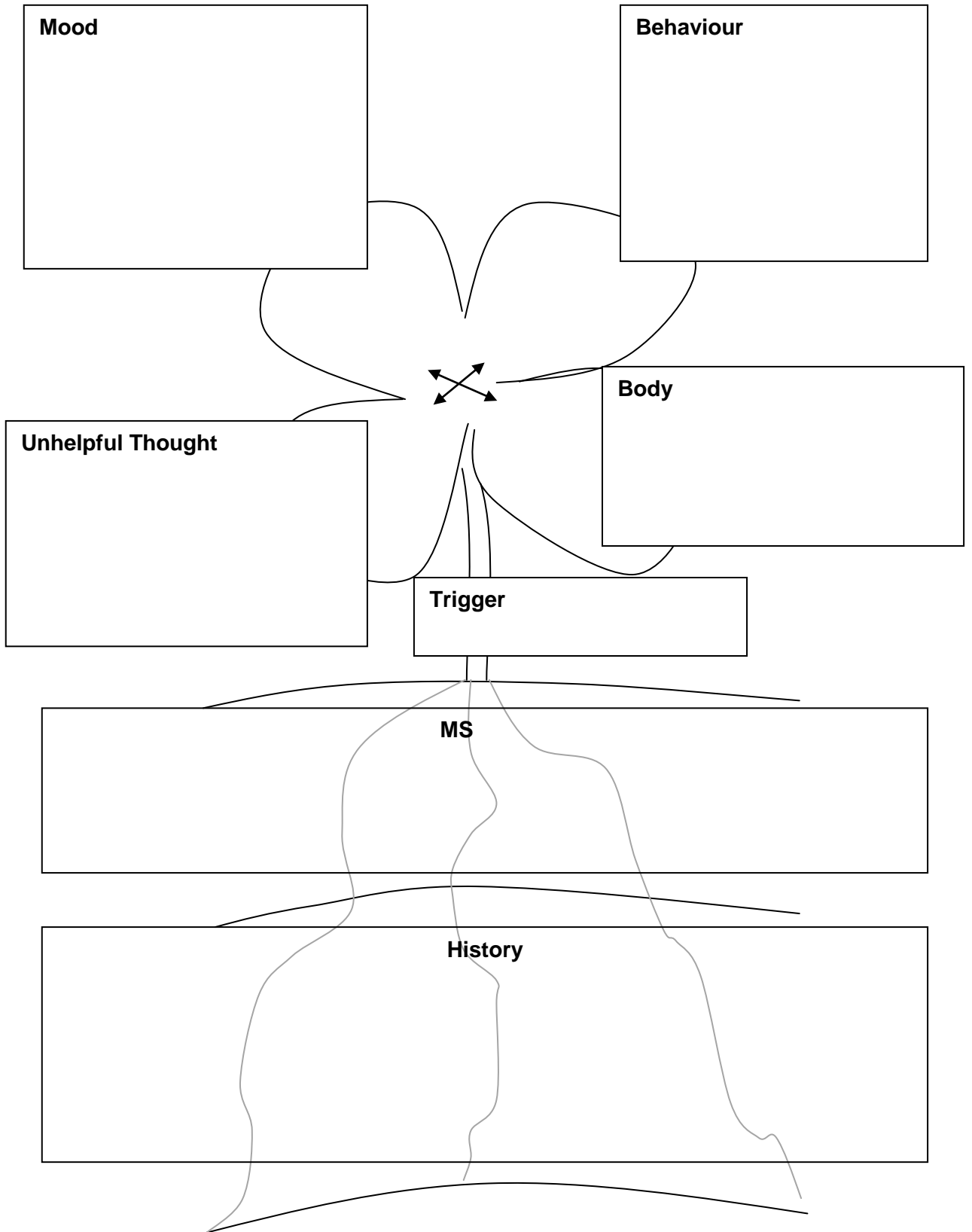
MS Society <http://www.mssociety.org.uk/>

NHS 24 Scotland - 08454 242424

Appendix

Feel free to photocopy the resources in the appendix for personal use only. Alternatively, you could draw your own versions on sheets of blank paper.

Clover Worksheet



Identifying unhelpful thoughts diary

<p>Trigger</p> <p>Where were you? Who were you with? What were you doing?</p>	<p>Mood</p> <p>Moods are normally described in one word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought</p> <p>1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do you think the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Level of fatigue</p> <p>(0 = not fatigued at all, 10 = most fatigued I've ever been</p>

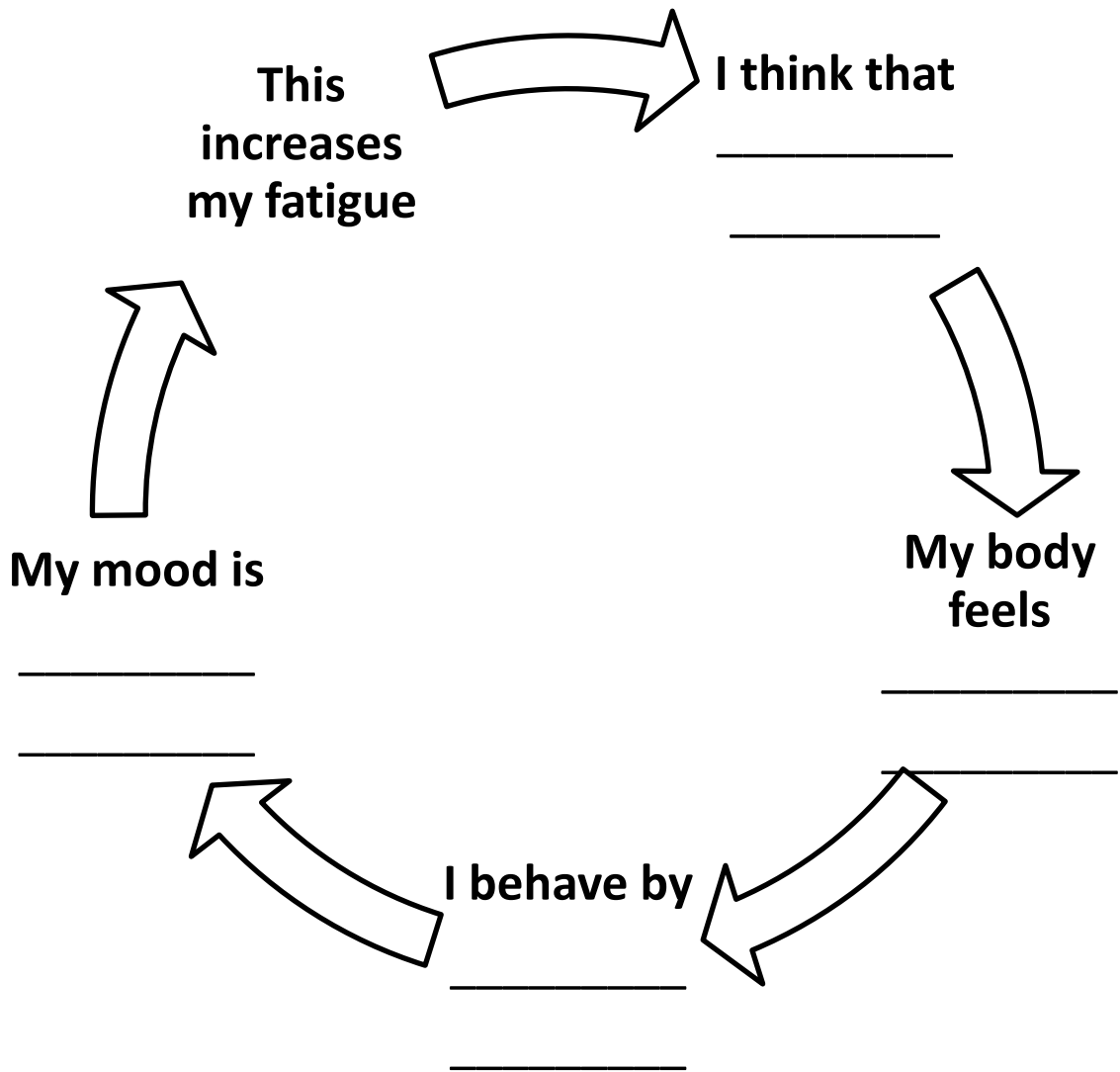
Challenging unhelpful thoughts diary

<p>Trigger Where were you? Who were you with? What were you doing?</p>	<p>Mood Moods are normally described in 1 word Sad, angry, frustrated, upset etc How strong is your mood 0 – 10 (0 = not very strong and 10 = the strongest it could be)</p>	<p>Thought 1) What's running through your mind? 2) Are these thoughts about you or about other people relating to you? 3) What do the thoughts mean about you? 4) What's the worst thing that can happen? 5) What memories does this bring up? 6) What unhelpful images are in my mind? Circle the most upsetting thought</p>	<p>Challenge thoughts Start by challenging your most upsetting thought first. 1) Is it fact or fiction? 2) What is the evidence? 3) What would you tell a friend? 4) What are the advantages & disadvantages?</p>	<p>Realistic conclusion Weight up the evidence, be realistic, how can you change this thought to be more helpful?</p>	<p>Level of fatigue (0 = not fatigued at all, 10 = most fatigued I've ever been</p>						
---	---	--	--	--	--	--	--	--	--	--	--

Activities sheet

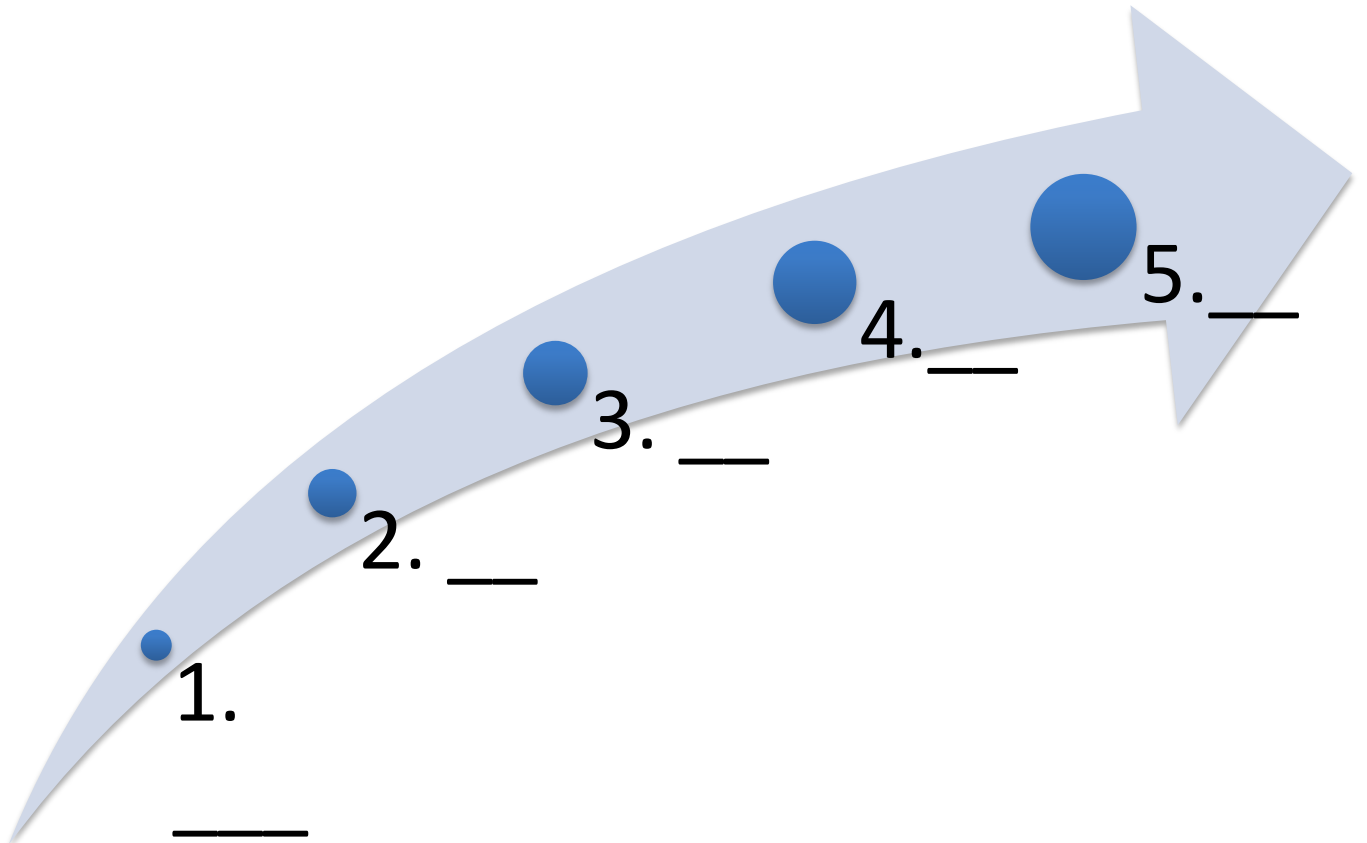
	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Midnight - 6.00am							
7.00- 8.00am							
9.00- 10.00am							
11.00- 12.00 noon							
1.00- 2.00pm							
3.00- 4.00pm							
5.00- 6.00pm							
7.00- 8.00pm							
9.00- -midnight							

My vicious cycle



Taking control - under activity cycle

MY GOAL _____



Activity investigation box

Name activity

What do you enjoy about it?

Is there a way it can be broken down into smaller steps?

If the activity can't be broken down, is there a different way you can get the enjoyment out of it by reducing/changing what you do? Brain storm and be creative!

Is there anyone who can help you do this activity?

Attributions

This booklet was developed by Kirsty Gallen, NHS Fife, with input from Debbie Pitcaithly, NHS Fife and Dr Paul Graham Morris, University of Edinburgh. Images were contributed by Paul Gallagher.

I would also like to thank Debbie Mccallion, Ann Donaldson (MS Nurses) for their help. Finally, I would like to acknowledge the Fife Rehabilitation Service for their support in the production of this workbook.

This booklet may be reproduced and used in its current format for NHS or other non-profit use. Queries regarding the booklet should be sent to Kirsty Nesbitt (kirsty.gallen@nhs.net).

The booklet could be cited as: Gallen K., Pitcaithly D. & Morris P.G. (2011) Self-help for Fatigue in Multiple Sclerosis. Unpublished manuscript



If you require this information in a community language or alternative format e.g. Braille, easy read, audio please contact the Equality and Diversity Department at: ***fife-UHB.EqualityandDiversity@nhs.net***
or phone 01383 565142

Review date May 2013

Workbook version 3 (4.05.12)

Appendix 5. Multiple Sclerosis Journal guidelines



Manuscript Submission Guidelines

Multiple Sclerosis Journal

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It is essential that you read and follow the manuscript guidelines prior to submitting your manuscript to *Multiple Sclerosis*. Failure to do so will result in your manuscript being automatically returned thus delaying the reviewing process of your submission.

Multiple Sclerosis Journal focuses on the aetiology and pathogenesis of demyelinating and inflammatory diseases of the central nervous system and on the application of such studies to scientifically-based therapy. Articles describing studies of multiple sclerosis and related diseases are particularly welcome. In addition, reports of experimental work relevant to multiple sclerosis, but based on in vivo and in vitro studies, are encouraged. Within these limits, a diversity of approach is acceptable and submissions are encouraged from those working in the following areas: clinical neurology, epidemiology, genetics, glial pathobiology and myelin repair, immunology, molecular biology, myelin chemistry, neuroimaging, pathobiology of the blood-brain barrier, pathology, therapeutics, virology.

Multiple Sclerosis Journal publishes original research articles, concise case reports and short reports, letters to the Editor, and invited reviews, editorials, topical comments, critical reviews of scientific meetings and occasional book reviews.

1. Peer review policy

Multiple Sclerosis Journal operates a conventional single-blind reviewing policy in which the reviewer's name is always concealed from the submitting author.

Papers will be sent for anonymous review by at least two reviewers who will either be members of the Editorial Board or others of similar standing in the field. In order to shorten the review process and respond quickly to authors the Editors may triage a submission and come to a decision without sending the paper for

external review.

The Editors' decision is final and no correspondence can be entered into concerning manuscripts considered unsuitable for publication in *Multiple Sclerosis Journal*. All correspondence, including notification of the Editors' decision and requests for revisions, will be sent by email.

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2. Authorship

Papers should only be submitted for consideration once the authorization of all contributing authors has been gathered. Tropical Doctor does not allow more than 6 authors to be named on each paper. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.

The list of authors should include all those who can legitimately claim authorship. This is all those who:

1. have made a substantial contribution to the concept and design, acquisition of data or analysis and interpretation of data
2. drafted the article or revised it critically for important intellectual content
3. approved the version to be published.

Authors should meet the conditions of all of the points above. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section.

Please refer to the ICMJE Authorship guidelines at <http://www.icmje.org/icmje-recommendations.pdf>.

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3. Article types

Please read the following carefully and ensure that your submission meets the requirements to avoid automatic return or delay in the consideration of your paper.

The journal no longer solicits for Traditional or Systematic Reviews.

MSJ is now requiring authors to provide the essential requirements of MRI imaging as supplementary data in order to help replication of studies. If submitting a manuscript using MRI data please use the [form](#) provide to supply the necessary data in a suitable format.

Original research papers

Original research papers should be no more than 3,000 words and contain the following sections: Title page, Abstract, Introduction, Materials (or patients or animals) and Methods, Results, Discussion, Acknowledgements, References, Tables, Figure legends, Figures (see 'Sections of the manuscript' for further details).

Case Reports, Short Reports

The Editors will consider for rapid publication Case Reports and Short Reports that illustrate important points. These must not exceed 1000 words in length, must have a title page, a short summary of no more than 100 words, up to 10 references, one figure and one table.

Letters to the Editor

Brief letters raising pertinent issues relating to recently published papers in Multiple Sclerosis Journal or

stand-alone letters on topics of interest are welcome. They will be reviewed and may be sent to the first author of the article being discussed for a possible response. They should be in letter format without an abstract.

Stand-alone letters on topics of interest will be reviewed and should be in letter format without an abstract.

Personal Viewpoints

Viewpoints which bring new ideas and stimulate discussion and debate are welcomed by the Editors, in particular those that will be of general interest, and which question or comment on new and significant MS-related studies. These will be reviewed and should be no more than 1,500 words, up to 10 references, one figure and one table (if necessary).

Topical Reviews

Topical Reviews focus on specific subjects of current interest where there have been recent and significant advances, ranging from basic neuroscience to clinical and more 'applied' areas. They are short, factual, focussed updates, comprising: Title page, an Abstract of 100-150 words, 5 or so Keywords, 2,500 words of text (excluding references), a limited number of relevant and recent references (up to 35 or so), and a figure if appropriate. See examples from the journal for more information. Topical Reviews are generally by invitation.

Controversies in Multiple Sclerosis

Controversies focus on current issues, with contrasting contributions from leading experts, and cover topics of debate from basic neuroscience to clinical and more 'applied' areas. They necessarily represent an opinion, but are founded on factual evidence. Each Controversy comprises: i) a proposal for a particular view; ii) a presentation of a contrasting view; and iii) an overview/summary. The two opposing views comprise about 1,000 words each, supported by 5-10 key references. The summary piece is written by Michael Hutchinson, based on the opposing statements, and is about 500 words in length. See examples from the journal for more information. Controversies are generally by invitation, but if you have an appropriate idea for a topic and authors to write a Proposal or Rebuttal, please contact Michael Hutchinson to discuss: mhutchin2@mac.com

Editorials

Editorials may be solicited by the Editors to address particular topics relating to one or more papers in a given issue.

Future Perspectives

Future Perspectives can provide a forum to help capture the work of groups established to improve or update areas of fundamental importance to MS such as clinical and imaging outcomes. Articles will be reviewed and ideally should be no more than 1,500 words, up to 10 references, one figure and one table (if required).

Book and Meeting Reviews

These reviews are solicited by the Editors.

Note: While Editorials, Reviews (including book and meeting reviews), and Topical Reviews will usually be solicited by the Editors, suggestions for topics or brief outlines of proposals are very welcome and can be sent to the nearest regional Editor.

Data previously published in un-reviewed format

The Editors will also consider for publication manuscripts containing data already in press elsewhere or published previously in un-reviewed format, such as abstracts or camera-ready papers for proceedings of scientific meetings. The new manuscript should differ from the one previously published and should not contain any identical tables or figures. It will be the responsibility of the senior author to bring to the Editor's attention details of previous publications and if necessary, attach relevant documents for the use of referees. The existence of such related paper(s) (published or in press) should be mentioned as a footnote to the manuscript or documented with appropriate references. The Editorial decision will take account of the originality of the work submitted for publication and the extent to which readers of *Multiple Sclerosis Journal* may be expected to have access to the book or journal in which the associated papers have appeared.

Related papers

Related papers either published or in press may be sent with the manuscript for the attention of the Editor.

Table 1. Overview of the requirements for manuscript submissions to MSJ.

Article Type	Abstract	Main Text Word limit*	References**	Figures/Tables
Original Research Paper	200	3,000	Up to 35	As necessary
Topical Review	100-150	2,500	Up to 35	As necessary
Controversies in Multiple Sclerosis (invitation)	N/A	1,000	5-10	As necessary
Case Report / Short Reports	100	1,000	10	1/2
Letter to the Editor	N/A	500	3-5	N/A
Personal Viewpoints / Future Perspective	N/A	1,500	10	1/1
Invited Editorial	N/A	1000	10	N/A

* Excludes references, tables and legends

** For reference style please see section 9.3

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4. How to submit your manuscript

Before submitting your manuscript, please ensure you carefully read and adhere to all the guidelines and instructions to authors provided below. Manuscripts not conforming to these guidelines may be returned. See [Section 9.4](#) for manuscript preparation and guidance on how to submit your files.

Online Submission

Multiple Sclerosis Journal has a fully web-based system for the submission and review of manuscripts. All submissions should be made online at the *Multiple Sclerosis Journal* SAGE track website <http://mc.manuscriptcentral.com/multiple-sclerosis>

Note: Online submission and review of manuscripts is now mandatory for all types of papers. Hard copy submissions will not be accepted.

New User Account

Please log onto the website via the link above. If you are a new user, you will first need to create an account. Follow the instructions and please ensure to enter a current and correct email address. Creating your account is a three-step process that takes a matter of minutes to set up. When you have finished, your User ID and password is sent via email immediately. Please edit your user ID and password to something more memorable by selecting 'edit account' at the top of the screen. If you have already created an account but have forgotten your details type your email address in the 'Password Help' to receive an emailed reminder. Full instructions for uploading the manuscript are provided on the submission website.

IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne [Online Help](#).

All papers must be submitted via the online system.

New Submission

A submitted manuscript will be considered for publication on the understanding that the work is original,

that it is not under consideration for publication elsewhere, it is not previously published, and that if accepted it will not be published later in the same or similar form in any language without the consent of the publisher.

It is assumed that all named authors have agreed to submission of the manuscript. Papers will be handled by the nearest of the three regional Editors.

Submissions should be made by logging in and selecting the Author Centre and the 'Click here to Submit a New Manuscript' option. Follow the instructions on each page, clicking the 'Next' button on each screen to save your work and advance to the next screen. If at any stage you have any questions or require the user guide, please use the 'Get Help Now' button at the top right of every screen. Further help is available through ScholarOne's® Manuscript Central™ customer support at +1 434 817 2040 x 167.

To upload your files, click on the 'Browse' button and locate the file on your computer. Select the designation of each file (i.e. main document, submission form, figure) in the drop down box next to the browse button. When you have selected all files you wish to upload, click the 'Upload Files' button. Review your submission (in both PDF and HTML formats) and then click the Submit button.

You may suspend a submission at any point before clicking the Submit button and save it to submit later. After submission, you will receive a confirmation e-mail. You can also log back into your author centre at any time to check the status of your manuscript.

Please ensure that you submit editable source files only. The main text should be in Microsoft Word or RTF, the tables as separate Word files, and the figures as separate EPS, JPEG or TIF files. Please ensure that your document does not include page numbers; the *Multiple Sclerosis Journal* SAGE track system will generate them for you, and then automatically convert your manuscript to PDF for peer review. All correspondence, including notification of the Editor's decision and requests for revisions, will be by email.

If you seek advice on the submission process please contact the journal administrator at the following email address: msjournal@ucl.ac.uk

Submitting a Revision

Authors submitting revised manuscripts should follow the instructions above to submit through the SAGE track system. To create a revision, go to the 'Manuscripts with Decisions' option in your Author Dashboard and select 'create a revision' in the 'Action' column. Revised text should be highlighted in the text, and authors of all revised submissions should, when prompted, provide information explaining the changes in your manuscript as this will be provided to reviewers.

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5. Journal contributor's publishing agreement

Before publication, SAGE requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. SAGE's Journal Contributor's Publishing Agreement is an exclusive licence agreement which means that the author retains copyright in the work but grants SAGE the sole and exclusive right and licence to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than SAGE. In this case copyright in the work will be assigned from the author to the institution. For more information please visit our [Frequently Asked Questions](#) on the SAGE Journal Author Gateway.

5.1 SAGE Choice

If you wish your article to be freely available online immediately upon publication (as some funding bodies now require), you can opt for it to be included in SAGE Choice subject to payment of a publication fee. The manuscript submission and peer reviewing procedure is unchanged. On acceptance of your article, you will be asked to let SAGE know directly if you are choosing SAGE Choice. For further information, please visit [SAGE Choice](#).

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6. Declaration of conflicting interests

Within your Journal Contributor's Publishing Agreement you will be required to make a certification with respect to a declaration of conflicting interests. It is the policy of *Multiple Sclerosis Journal* to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please include any declaration at the end of your manuscript after any acknowledgements and prior to the references, under a heading 'Conflict of Interest Statement'. If no declaration is made, the following will be printed under this heading in your article: 'None Declared'. Alternatively, you may wish to state that 'The Author(s) declare(s) that there is no conflict of interest'.

When making a declaration, the disclosure information must be specific and include any financial relationship that all authors of the article have with any sponsoring organization and the for-profit interests that the organisation represents, and with any for-profit product discussed or implied in the text of the article.

Any commercial or financial involvements that might represent an appearance of a conflict of interest need to be additionally disclosed in the covering letter accompanying your article to assist th

Editor in evaluating whether sufficient disclosure has been made within the Conflict of Interest statement provided in the article.

For more information please visit the [SAGE Journal Author Gateway](#).

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7. Other conventions

7.1 Medical Writers

Manuscripts submitted for publication must list all authors, including the person who drafted the original manuscript. This includes paid or unpaid medical writers.

If medical writers are to be involved in the preparation of manuscripts then they must co-author with a clinician (or other medical professional) and their name and full affiliation must appear on the article.

The work of any medical writer must not be passed off as that of a clinician or other medical professional.

The work of a ghost writer must be acknowledged clearly at the point of submission.

7.2 CONSORT & ICMJE

All randomized controlled trials submitted for publication in *Multiple Sclerosis Journal* should include a completed Consolidated Standards of Reporting Trials (CONSORT) flow chart. Please refer to the CONSORT statement website at <http://www.consort-statement.org> for more information.

Multiple Sclerosis Journal has adopted the proposal from the International Committee of Medical Journal Editors (ICMJE) which requires, as a condition of consideration for publication of clinical trials, registration in a public trials registry. Trials must register at or before the onset of patient enrolment. The clinical trial registration number should be included at the end of the abstract of the article. For this purpose, a clinical trial is defined as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g. phase I trials), would be exempt. Further information can be found at www.icmje.org.

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8. Acknowledgements

Any acknowledgements should appear first at the end of your article prior to your Declaration of Conflicting Interests (if applicable), any notes and your References.

All contributors who do not meet the criteria for authorship should be listed in an 'Acknowledgements' section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Authors should disclose whether they had any writing assistance and identify the entity that paid for this assistance.

8.1 Funding Acknowledgement

To comply with the guidance for Research Funders, Authors and Publishers issued by the Research Information Network (RIN), *Multiple Sclerosis Journal* additionally requires all Authors to acknowledge their funding in a consistent fashion under a separate heading. All research articles should have a funding acknowledgement in the form of a sentence as follows, with the funding agency written out in full, followed by the grant number in square brackets:

This work was supported by the Medical Research Council [grant number xxx].

Multiple grant numbers should be separated by comma and space. Where the research was supported by more than one agency, the different agencies should be separated by semi-colon, with "and" before the final funder. Thus:

This work was supported by the Wellcome Trust [grant numbers xxxx, yyyy]; the Natural Environment Research Council [grant number zzzz]; and the Economic and Social Research Council [grant number aaaa].

In some cases, research is not funded by a specific project grant, but rather from the block grant and other resources available to a university, college or other research institution. Where no specific funding has been provided for the research we ask that corresponding authors use the following sentence:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

For more information on the guidance for Research Funders, Authors and Publishers, please visit: <http://www.rin.ac.uk/funders-acknowledgement>

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9. Permissions

Authors are responsible for obtaining permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please visit our [Frequently Asked Questions](#) on the SAGE Journal Author Gateway.

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10. Manuscript style

10.1 File types

Only electronic files conforming to the journal's guidelines will be accepted. Preferred formats for the text and tables of your manuscript are Word DOC, and tiff or jpeg for figures (ideally figures will use journal colours). Please also refer to additional guideline on submitting artwork [and supplemental files] below.

10.2 Journal Style

Multiple Sclerosis Journal conforms to the SAGE house style. [Click here](#) to review guidelines on SAGE UK House Style

In addition to the details in the above style guide, please note the following:

Units, symbols and abbreviations

For detailed advice please refer to the guidelines in Baron, DN (1988). *Units, symbols and abbreviations*, 4th edn. (Obtainable from The Royal Society of Medicine, 1 Wimpole Street, London W1M 8AE, UK). Note that the SI system of units is preferred. Because of the multidisciplinary nature of the readership and to

avoid confusion, the number of abbreviations in the text should be kept to a minimum. Standard abbreviations acceptable without definition are limited to the following:

CNS (central nervous system); CSF (cerebrospinal fluid); DNA (deoxyribonucleic acid); HLA (human leukocyte antigen); MRI (magnetic resonance imaging); CT (computerized tomography); MS (multiple sclerosis); RNA (ribonucleic acid). Nonstandard definitions must be defined in full at their first usage in the abstract and again at their first use in the text.

10.3 Reference Style

Multiple Sclerosis Journal adheres to the SAGE Vancouver reference style. [Click here](#) to review the guidelines on SAGE Vancouver to ensure your manuscript conforms to this reference style.

If you use [EndNote](#) to manage references, download the SAGE Vancouver output file by following [this link](#) and save to the appropriate folder (normally for Windows C:\Program Files\EndNote\Styles and for Mac OS X Harddrive:Applications:EndNote:Styles). Once you've done this, open EndNote and choose "Select Another Style..." from the dropdown menu in the menu bar; locate and choose this new style from the following screen. Alternatively visit the EndNote website and search the Styles section for 'SAGE Vancouver'.

10.4. Manuscript Preparation

Submitting a new manuscript through the online system:

When making a submission, the following *separate, unpaginated* documents should be uploaded. Please do not submit one combined document. The separate files will be combined into a pdf in the online system.

1. Title page (title, names of authors, affiliations, keywords, corresponding author)
2. Main document (includes structured abstract, main text, acknowledgements, references)
3. Tables (each as a *separate* Word document)
4. Figure legends (Word document)
5. Figures (as *separate* tiff, jpg or eps files)
6. Any supplementary files

Submitting a Revision:

After review the editors may invite submission of a revised manuscript. When submitting a revision, delete the original files (as these are saved with your original submission), and upload your revised manuscript only, following the usual submission guidelines. Changes to the manuscript must be marked using highlighting or track changes, and the authors' response to the reviewers' comments should be placed in appropriate box during the submission process.

The text should be double-spaced throughout and with a minimum of 3cm for left and right hand margins and 5cm at head and foot. Text should be standard 10 or 12 point. Word counts as outlined in Table 1 re initial submissions, should still be adhered to.

Title page

The title should be concise with no abbreviations. Please provide the surname, initials, department, institution, city and country of each author, and the name, email address, full mailing address, telephone number and fax number of the corresponding author to whom proofs should be sent. List six to eight keywords (chosen from Index Medicus, Medical Subject Headings if possible).

Abstract

The second page of the manuscript must contain only the abstract, which should be of no more than 200 words and must be clearly written and comprehensive to readers before they have to read the paper. The abstract should be structured according to the following sub headings: Background, Objective, Methods, Results and Conclusion. Abbreviations should be avoided and reference citations are not permitted.

Any manuscripts submitted without a structured abstract will be returned to the author immediately without peer review, thus delaying the evaluation process of the manuscript.

Introduction

The introduction should assume that the reader is knowledgeable in the field and be as brief as possible.

Materials and Methods

Methods that have been published in detail elsewhere should not be described in detail. Avoid unnecessary detailed descriptions of widely used techniques. SI Units should be used throughout the text. Reports of experiments involving patients and healthy volunteers must describe the steps taken to obtain consent and to maintain confidentiality. Experiments involving animals must conform to accepted ethical standards.

Tables

Tables should be submitted in Word, typed on separate pages. Tables should be numbered consecutively with Arabic numerals, and cited as such in the manuscript. The preferred placing of tables in the main text should be indicated. Tables should include a brief descriptive title and be self-explanatory. Footnotes to tables indicated by lower-case superscript letters are acceptable, but they should not include extensive experimental details.

10.4.1 Your Title, Keywords and Abstracts: Helping readers find your article online

The title, keywords and abstract are key to ensuring that readers find your article online through online search engines such as Google. Please refer to the information and guidance on how best to title your article, write your abstract and select your keywords by visiting SAGE's Journal Author Gateway Guidelines on [How to Help Readers Find Your Article Online](#).

10.4.2 Corresponding Author Contact details

Provide full contact details for the corresponding author including email, mailing address and telephone numbers. Academic affiliations are required for all co-authors.

10.4.3 Guidelines for submitting artwork, figures and other graphics

For guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit SAGE's [Manuscript Submission Guidelines](#).

If, together with your accepted article, you submit usable colour figures, these figures will appear in colour online regardless of whether or not these illustrations are reproduced in colour in the printed version. If a charge applies you will be informed by your SAGE Production Editor. For specifically requested colour reproduction in print, you will receive information regarding the costs from SAGE after receipt of your accepted article.

Figure legends

Please ensure that your figure legends are included in your manuscript, saved separately to the figures. Figures will be published in black and white in the printed journal and in colour in the online version. Please ensure that your figure legends do not refer to colour in the figure (unless you are paying for your figures to appear in colour in the printed journal).

Figures

Please submit figures as jpeg, tiff or eps files with a minimum resolution of 300 dpi. All figures should be numbered using Arabic numerals and referred to in the text as Figure 1, etc. Please indicate the preferred placing of the figure in the main text. Figures are often reduced in size when appearing on the printed page. Allowance should be made for this when selecting text and symbol size. Symbols and keys should be given as a key on the figure, not in the legend. Magnification should be indicated by a scale bar on the photograph, not as a magnification factor in the legend.

10.4.4 Guidelines for submitting supplemental files

This journal is able to host approved supplemental materials online, alongside the full-text of articles. Supplemental files will be subjected to peer-review alongside the article. For more information please refer to SAGE's [Guidelines for Authors on Supplemental Files](#). For any enquiries which are not included in the above guidelines please contact the *Multiple Sclerosis Journal* editorial office at msjournal@ucl.ac.uk.

10.4.5 English Language Editing

Non-English speaking authors who would like to refine their use of language in their manuscripts might consider using a professional editing service. Visit [English Language Editing Services](#) for further information.

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11. After acceptance

11.1 Proofs

We will email a PDF of the proofs to the corresponding author. Please check for typographical errors and completeness. Extensive alterations to the submitted text incur additional production costs that will be charged to the authors. Corrected proofs must be returned to the publisher within 3 days of receipt.

11.2 E-Prints and Complimentary Copies

SAGE provides authors with access to a PDF of their final article. For further information please visit [Offprints and Reprints](#). We additionally provide the corresponding author with a complimentary copy of the print issue in which the article appears up to a maximum of 5 copies for onward supply by the corresponding author to co-authors.

11.3 SAGE Production

At SAGE we place an extremely strong emphasis on the highest production standards possible. We attach high importance to our quality service levels in copy-editing, typesetting, printing, and online publication (<http://online.sagepub.com/>). We also seek to uphold excellent author relations throughout the publication process.

We value your feedback to ensure we continue to improve our author service levels. On publication all corresponding authors will receive a brief survey questionnaire on your experience of publishing in *Multiple Sclerosis Journal* with SAGE.

11.4 OnlineFirst Publication

A large number of SAGE journals benefit from OnlineFirst, a feature offered through SAGE's electronic journal platform, SAGE Journals Online. It allows final revision articles (completed articles in queue for assignment to an upcoming issue) to be hosted online prior to their inclusion in a final print and online journal issue which significantly reduces the lead time between submission and publication. For more information please visit our [OnlineFirst Fact Sheet](#)

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12. Further information

Any correspondence, queries or additional requests for information on the Manuscript Submission process should be sent to the Editorial Office: msjournal@ucl.ac.uk

Any correspondence, queries or additional requests for information should be sent to the Publisher:

Business correspondence should be addressed to:

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Appendix 6. Ethical approval

Lothian NHS Board

South East Scotland Research
Ethics Committee 01
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 536 9088



Enquiries to Sandra Wyllie
Extension 35679
Direct Line 0131 465 5679
Email:
Sandra.Wyllie@nhslothian.scot.nhs.uk

04 April 2012

Miss Kirsty Nesbitt
Trainee Clinical Psychologist
NHS Fife
Sir George Sharp Unit
Cameron Hospital
Windygates, Fife
KY8 5RR

Dear Miss Nesbitt

Study title: A Randomised Controlled Trial of Cognitive Behavioural
Therapy based Self Help for Fatigue in Multiple Sclerosis
REC reference: 12/SS/0036
Protocol number: N/A

Thank you for your letter of 03 April 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

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

NHS 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).



Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Dr Charles J Winstanley
Chief Executive, Research and Innovation, Lothian NHS Board

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Response to Request for Further Information		03 April 2012
REC application		08 February 2012
Protocol	Version 1	15 February 2012
Protocol Diagram	Version 1	08 February 2012
Letter of invitation to participant	Version 2	26 March 2012
Participant Information Sheet	Version 3	26 March 2012
Participant Consent Form	Version 3	26 March 2012
Appointment Letter to GSH	Version 1	07 February 2012
Info Letter to PSH group	Version 1	07 February 2012
Letter to GP GSH Summary	Version 2	07 February 2012
Letter to GP pt involved in research	Version 2	07 February 2012
Letter with questionnaires	Version 1	10 February 2012
Reminder Letter to patient	Version 2	07 February 2012
Satisfaction Questionnaire	Version 2	07 February 2012

HADS		
Letter to GP High HADS	Version 2	02 April 2012
Reminder Letter	Version 3	26 March 2012
Demographic Information	Version 2	07 February 2012
Questionnaire LORIG 8-ITEM		
Questionnaire (MFIS)		
WHOQOL BREF		
Self Efficacy Questionnaire		
Workbook Stages 1- 4	Version 3	30 March 2012
CV - K Nesbitt	Version 1	07 February 2012
CV- P Morris		

Statement of compliance

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

After ethical review

Reporting requirements

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
- Notification of serious breaches of the protocol
- 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.

Feedback

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.

Further information is available at National Research Ethics Service website > After Review

12/SS/0036	Please quote this number on all correspondence
------------	--

With the Committee's best wishes for the success of this project

Yours sincerely



Dr Janet Andrews
Chair

Email: Sandra.Wyllie@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: Ms Marise Bucukoglu, University of Edinburgh
Dr Amanda Wood, NHS Fife

South East Scotland Research Ethics Committee 01

Attendance at Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Janet Andrews	Associate Specialist	Yes	
Mr Lindsay Murray	Health & Safety Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Sandra Wyllie	Committee Co-ordinator

16 April 2012

Miss Kirsty Nesbitt
Trainee Clinical Psychologist
NHS Fife
Sir George Sharp Unit
Cameron Hospital
Windygates, Fife
KY8 5RR

Dear Miss Nesbitt

Full title of study: A Randomised Controlled Trial of Cognitive Behavioural Therapy based Self Help for Fatigue in Multiple Sclerosis
REC reference number: 12/SS/0036
Protocol number: N/A
EudraCT number:

Thank you for your letter of 05 April 2012. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 04 April 2012. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

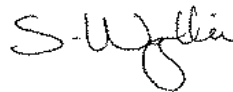
The documents received were as follows:

Document	Version	Date
Letter to GP High HADS	Version 3	05 April 2012

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.

12/SS/0036 Please quote this number on all correspondence

Yours sincerely



Mrs Sandra Wyllie
Committee Co-ordinator

E-mail: Sandra.Wyllie@nhslothian.scot.nhs.uk

Appendix 7. Caldicott approval

Fife

APPLICATION FOR CALDICOTT APPROVAL FOR USE OF PATIENT IDENTIFIABLE DATA

User Details

Name: Kirsty Nesbitt

Position: Trainee Clinical Psychologist

Organisation: NHS Fife, Psychology Department

Address: Sir George Sharp Unit, Cameron Hospital, Windygates,
Leven, Fife

Postcode: KY8 5RR

Tel. No.: 01592 226808

E-mail: kirstynesbitt@nhs.net

Name(s) of any co-user(s): Debbie Pitcaithly

You must address the 6 Caldicott Principles when submitting this request for data

1. Project/Audit title

A Randomised Controlled Trial of Cognitive Behavioural Therapy based Self Help for Fatigue in Multiple Sclerosis

2. Please provide additional background description of your project/audit to enable Caldicott Guardian to understand what outcome you trying to achieve.

This research project aims to assess the effectiveness of a cognitive behavioural therapy based self help workbook to help manage fatigue in people who have multiple sclerosis. Participants will be randomly allocated to one of three groups: treatment as usual (no intervention), pure self help (receive the workbook to complete alone) or guided self help (complete the workbook alongside the support of a therapist). If the pure self help group or the guided self help group show to significantly reduce levels of fatigue in participants, the workbook will be made free available for therapy purposes on the NHS Fife moodcafe website.

V5 -Nov 20

3. Supporting information

Please list and attach any other supporting information, e.g. Project proposal, ethics approval, data protocol, safe haven arrangements, correspondence.

The project proposal is attached.

The proposal has been reviewed by the ethics committee and given a favourable opinion (see letter attached).

The project has been sent to the Fife R&D department and is awaiting Caldicott approval.

The only database with identifiable information the chief investigator (Kirsty Nesbitt) is requiring, is a code book which can link the patient name and CHI with their anonymised reference number. The CHI is required to ensure 2 participants with the same name do not get mixed up. Furthermore the CHI number will be required to correspond with other clinicians, where necessary, a process the participants are informed of on the participant information sheet.

This database will be stored on the NHS secure network and a password will be assigned to the database. Only the chief investigator and her clinical supervisor (Debbie Pitcaithly) will have access to the database.

I am also requesting to access patient addresses via the secretary in the Fife Rehabilitation Service. I will be giving the names and CHI numbers of potential participants to the secretary to enable her to print address labels which will be required to invite potential participants to take part in the study. I will also require the patient address labels at 4-5 further times throughout the duration of the study to post out appointment letters, follow up questionnaires and a summary of the study results if they request this on the consent form.

Participants will be giving me further information i.e. date of birth and gender on the demographic information sheet but this data will be collected and stored anonymously.

4. Name of organisation receiving data (if not within NHS Fife)

NHS Fife

5. What patient identifiable information are you looking to use?
(please tick where relevant)

CHI Number	/
Forename	/
Surname	/
Initials	
Age	
Date of birth	
Gender	
Address	/
Postcode	/
Other, please specify.....	

6. Please explain how the proposal meets the following Six Caldicott

Principles. (The Caldicott Committee Report on the Review of Patient-Identifiable Information, Department of Health, December 1997)

Justify the purpose

Principle 1	Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.
Justify the purpose(s)	

The purpose of this database is to ensure the chief investigator is able to correctly identify which participants are in the study. The need for names, addresses and postcodes are to ensure the correct correspondence details are held for the research participants. The need for CHI numbers is to ensure the correct details are used when corresponding with other relevant clinicians (a process the participants are informed of on the participant information sheet). Date of birth and gender are required for demographic information purposes. This information will be collected anonymously and participants themselves will be providing this data.

Justify the requirement to use patient-identifiable data

Principle 2	Patient-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).
Don't use patient-identifiable information unless it is absolutely necessary	

Patient identifiable information will only be used as an administrative aid. No identifiable information will be written up in the study.

Justify the inclusion of each data field required

Principle 3 Use the minimum necessary patient identifiable information	Where use of patient-identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.
--	--

As stated above -

- Names, addresses and postcodes are required to ensure the correct correspondence details are held for the research participants.
- CHI numbers are required to ensure the correct details are used when corresponding with other relevant clinicians (a process the participants are informed of on the participant information sheet). CHI numbers will also ensure that participants with the same name are not wrongly contacted in this study.
- Date of birth and gender are required for demographic information purposes (participants will be anonymously providing this data themselves).

Please outline arrangements for access to information

Principle 4 Access to patient-identifiable information should be on a strict need-to-know basis	Only those individuals who need access to patient-identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.
---	---

Only myself (Kirsty Nesbitt Chief investigator) and my supervisor (Debbie Pitcaithly) will have access to the patient identifiable information in this study (code book). Both myself and my supervisor are clinicians in the Fife Rehabilitation service where the research is taking place and would usually have access to this patient information on a routine clinical basis. All correspondence for patients in the intervention groups of this study will be securely stored in their existing Fife Rehabilitation Service multidisciplinary files.

V5 -Nov 2010

Please outline action taken to ensure compliance with responsibilities and obligations to respect patient confidentiality

<p>Principle 5 Everyone with access to patient-identifiable information should be aware of their responsibilities</p>	<p>Action should be taken to ensure that those handling patient-identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.</p>
--	--

Both myself and my supervisor are contracted staff for NHS Fife and will abide by data protection obligations.

Please outline organisational compliance with legal requirements

<p>Principle 6 Understand and comply with the law</p>	<p>Every use of patient-identifiable information must be lawful. Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.</p>
--	---

The chief investigator will ensure that all patient-identifiable information is handled appropriately. They have been on the Good Clinical Practice for non-drug trials.

7. Has your application been to Research Ethics **YES**
If not, please explain why (i.e. not research)

It has been given a favourable opinion (please see attached letter)

Fife

8. Who is the data custodian for the NHS data?

Name: Susan McKenzie

Job Title: Consultant Clinical Psychologist

Return Address: Fife Rehabilitation Service, Sir George Sharp Unit, Cameron Hospital, Leven, KY8 5RR

Email Address: smckenzie1@nhs.net

Telephone Number: 01592 226808

Signature: *Susan McKenzie* Date: 17/4/12

Counter-signature by Line Manager

Name: As above

Job Title: As above

Signature: *Susan McKenzie* Date: 17/4/12

Counter-signature by Operational Division/Primary Care Caldicott Guardian

Name:

Job Title:

Signature:

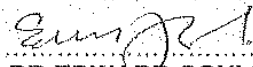
Date: 3/5/12

Please forward to:

Una Hill
 Data Protection & Caldicott Coordinator
 NHS Fife
 Information Services Department
 Lynebank Hospital
 Dunfermline KY11 8JH

I authorise access to the data as noted above:

Signature:



Date: 6/5/12

DR EDWARD COYLE
 Caldicott Guardian for NHS Fife

ADMIN USE ONLY

Applicant's Name & Project Title	
Date application received UH	
Date sent for approval to CG OD/PC	
Date received by CG OD/PC	
Date sent to Board CG for formal approval	
Date received by Board CG	
Date returned to UH	
Date received by UH	
Date applicant informed	

Appendix 8. R&D approval

Miss Kirsty Nesbitt
 Trainee Clinical Psychologist
 Sir George Sharp Unit
 Cameron Hospital
 WINDYGATES

Medical Director, Primary Care
 Room 313
 Hayfield House
 Hayfield Road
 KIRKCALDY
 Fife KY2 5AH
 Tel 01592 643355
 www.show.scot.nhs.uk/fpct

Date 2 May 2012
 Our Ref 12-020 12/SS/0036
 Enquiries to Aileen Yell
 Tel No 01383 565110
 Email aileen.yell@nhs.net

Dear Miss Nesbitt

Project Title: A randomised controlled trial of cognitive behavioural therapy based self help for fatigue in multiple sclerosis

Thank you for your application to carry out the above project. Your project documentation (detailed below) has been reviewed for resource and financial implications for NHS Fife and I am happy to inform you that NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

Document	Version	Date
Research Protocol	1	15 February 2012
REC provisional favourable opinion letter		12 March 2012
IRAS R&D Form	3.4	27 March 2012
REC final favourable opinion letter		4 April 2012
Various documents referred to in REC letters		
IRAS SSI Form	3.4	13 April 2012
Site Specific Assessment Form		19 April 2012

The terms of the approval state that you are the Principal Investigator authorised to undertake this study within NHS Fife.

I note that separate Site Specific Review has been undertaken for this study by the R&D Office, based on the Site Specific Information Form provided and that no objections were raised.

The sponsors for this study are Edinburgh University.

Details of our participation in studies will be included in annual returns we are expected to complete as part of our agreement with the Chief Scientist Office. Regular reports of the study require to be submitted. Your first report should be submitted to Dr A Wood, R&D Manager, R&D Resource Centre, Lynebank Hospital, Halbeath Rd, Dunfermline, KY11 4UW (Amanda.wood3@nhs.net) in 12 months time and subsequently at yearly intervals until the work is completed. A Lay Summary will also be required upon completion of the project.

In addition, approval is granted subject to the following conditions:-

- All research activity must comply with the standards detailed in the Research Governance Framework for Health & Community Care (<http://www.cso.scot.nhs.uk/publications/resgov/resgov.htm>), health &

safety regulations, data protection principles, other appropriate statutory legislation and in accordance with Good Clinical Practice (GCP).

- Any amendments which may subsequently be made to the study should also be notified to Aileen Yell, Research Governance Officer (aileen.yell@nhs.net), as well as the appropriate regulatory authorities. Notification should also be given of any new research team members post approval and/or any changes to the status of the project.
- This organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research. You will be required to assist with and provide information in regard to monitoring and study outcomes (including providing recruitment figures to the R&D office as and when required).
- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until the destruction of this data.
- Permission is only granted for the activities for which a favourable opinion has been given by the REC (and which have been authorised by the MHRA where appropriate).
- The research sponsor or the Chief Investigator or local Principal Investigator at a research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D office (aileen.yell@nhs.net) should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

I would like to wish you every success with your study and look forward to receiving a summary of the findings for dissemination once the project is complete.

Yours sincerely



DR STELLA CLARK
Medical Director, Primary Care
NHS Fife

Cc : Aileen Yell, Research Governance Officer, NHS Fife, Lynebank Hospital, Dunfermline

Appendix 9. Protocol of guided self-help sessions

Guided self-help protocol

Session 1, stage 1 self assessment and intro to GSH

30-45 mins

Intro to GSH/aim of sessions

- To work through workbooks together in sessions and alone at home to complete tasks, revise info.
- Workbook split into 4 stages
- Stage 1 – Self assessment
- Stage 2- Thoughts
- Stage 3 – Behaviours
- Stage 4 – keeping on track
- Cover stages over 6 weeks 90 mins per session which includes 40-45 mins in this appointment.

Sense that the workbook is their property

- Important to bring workbook to each session
- It belongs to you, so you can write on it, make notes and best to complete the exercises in the
- workbook so it's all kept together.

Sense that they take ownership of the work

- We will read some parts of the booklet together and leave some for you to do in own time.
- Important to read over even if covered in sessions to consolidate knowledge.

Consideration of privacy vs sharing info

- May write sensitive info in workbook so may want to think about privacy.
- Some people find it helpful to share info with friends or family members

General understanding of fatigue and a sense of their own experience of fatigue

- Book examples/ definitions
- Physical and mental impact
- How would you describe your fatigue
- Go over energy money example

CBT intro

- CBT evidence.
- Link of thoughts, behaviours, mood, fatigue
- CBT MODEL
- Clover diagram

Introduction to self monitoring

- Important to complete section summary

Sense of manageability , graded approach

- Not to move on to next section before next week
- One thing at a time
- Try not to overwhelm with too much info.

Check understanding

- Questions

Arrange following appointments

Session 2 Stage 2, thoughts

Summary of last session and how they coped with using workbook alone

- Review how found using workbook at home?
- Go over clover model - check understanding
- Summary of section 1 review
- Any questions

Didactic info giving, whilst checking out understanding

- Intro to section 2
- Link to clover thoughts page 23
- Split in 2 parts, 2 weeks
- Challenging
- Identifying
- Go over unhelpful thought types
- Case example
- own example in thought diary if have time/ not understand book example

Understanding of CBT principles re thoughts and ability to use techniques in workbook

Sense of manageable contained approach

- Importance to spend 1 week identifying before challenging
- Week 2 challenging thoughts

Didactic info giving, whilst checking out understanding

- Review techniques for challenging
- Go over case example

Own self monitoring

- Summary and progress monitoring at end

Stage 3, session 3 behaviours

Summary of last session and how they coped with using workbook alone

- spend time reviewing section 2
- Look over thought diary examples identifying and challenging. Found it difficult/easy?
- Review section summary
- Any questions – use of appendix – keep practicing

Didactic info giving, whilst checking out understanding

- Intro to stage 3
- Link to unlucky clover page 23
- 2 types of behaviour over activity –bust / under activity can do both but focus on 1 in session.
- Must do CAP activity section

- Case example activity analysis
- Week 1 own activity diary (at home)
- Or
- Under activity Cycle in book
- Own cycle
- Use of thought challenging if need be
- week 2 CAP - List own CAP activities, Activity investigation box

Own self monitoring

- Summary and progress monitoring at end

Stage 4, session 4 – keeping on track

Summary of last session and how they coped with using workbook alone

How found working on behaviours

Questions/problems

Review summary of stage 3

Didactic info giving, whilst checking out understanding

- Stage 4 intro
- Review unlucky clover
- Start to fill out lucky clover in own time
- Importance of Progress monitoring
- review over workbooks
- Warning signs
- Emergency plan

Use of appendix

Attempt to sum up role of workbook in managing fatigue

- Living with fatigue, good and bad days, no quick fix but by understanding own fatigue, doing things differently, managing thoughts, behaviours it can help with mood and fatigue. May have known techniques before looked through booklet but this is a refresher can be used at any time in future

Sense of ownership

- Tools to keep and use in future

Troubleshooting in future / supports

MS nurses, GP – contacts

Appendix 10. Research pack

Kirkcaldy & Levenmouth
Clinical Psychology Department
Community Health Partnership
Sir George Sharp Unit
Cameron Hospital
Cameron Bridge
Direct Tel No: 01592 226808
Fax: 01592 715851
Date__

Dear

____(name of clinician, title)____ from the Fife Rehabilitation Service has identified you as someone who may be appropriate to take part in a study in to fatigue in multiple sclerosis.

Please find enclosed an information sheet which will explain the study. There is also a consent form to complete and return along with the questionnaires in the freepost envelope if you are happy to take part in the study.

If you have any questions about the study please do not hesitate to contact me on 01592 226808.

Yours Sincerely

Kirsty Nesbitt
Trainee Clinical Psychologist
(lead researcher)

Debbie Pitcaithly C.Psychol
Clinical Supervisor

Dr Paul Morris C.Psychol
Academic Supervisor

Participant information Sheet - Fatigue and Multiple Sclerosis

You are being invited to take part in a research project. Before you decide if you would like to take part please read this information very carefully. It tells you about the study and what you will need to do if you decide to take part. This study is being conducted as part of an academic qualification (Doctorate in Clinical Psychology).

What is the purpose of this study?

This study will explore whether self-help materials can help people with multiple sclerosis (MS) manage their symptoms of fatigue.

Fatigue is a common symptom in MS and research has shown that cognitive behavioural therapy (a type of therapy that looks at a person's thoughts, behaviours and feelings) can be beneficial for managing symptoms of fatigue in MS. The self-help materials in this study will be based on cognitive behavioural therapy.

The study is also part of an educational project.

Why have I been invited?

You have been identified from a staff member in the Fife Rehabilitation Service, Cameron Hospital as someone who has a diagnosis of MS and has symptoms of fatigue.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you are interested in the study you will be given this information sheet to read over in your own time. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive now, or in the future.

What will happen to me if I take part?

If you decide to take part you will complete and return the consent form and the questionnaires in this pack using the pre-paid envelope. You will then be randomly put into one of three groups.

Group 1 is the treatment as usual group – in this group you will receive your usual care from the Fife Rehabilitation Service and you will be posted questionnaires on 4 more occasions over the next year and 2 months. The questionnaires will be sent to you at 2, 5, 8, 14 months after you have completed and returned the questionnaires in this pack. The questionnaires will always include a pre-paid envelope so you will never have to pay for stamps.

Group 2 is the self-help group. In this group you will receive your usual care from the Fife Rehabilitation Service and you will also be sent a self-help workbook for fatigue and MS to complete over the next 2 months by yourself. You will then be posted questionnaires on 4 occasions over the next year

and 2 months. The questionnaires will be sent to you at 2, 5, 8, 14 months after you have completed and returned the questionnaires in this pack. The questionnaires will always include a pre-paid envelope so you will never have to pay for stamps.

Group 3 is the Guided self-help group. In this group you will receive your usual care from the Fife Rehabilitation Service and you will also be sent an appointment to attend 4, 45 minute sessions where a trainee clinical psychologist will support you to complete a self-help workbook for fatigue and MS over a 2 month period. The sessions will either be at a clinic located in Fife. If you do not have transport, home visits will be offered. After the guided self-help sessions you will be posted questionnaires on 4 occasions over the next year and 2 months. The questionnaires will be sent to you at 2, 5, 8, 14 months after you have completed and returned the questionnaires in this pack. The questionnaires will always include a pre-paid envelope so you will never have to pay for stamps.

By consenting to take part in this study you are agreeing to be randomly placed in one of the three groups described above. By randomly allocating you to one of the three groups we will get a more accurate and therefore useful measurement of the impact of the self-help workbook for symptoms of fatigue in MS.

What are the possible disadvantages of taking part?

The questionnaires will take between 20-30 minutes to complete each time you are sent them. If you are in the self-help or guided self-help group it will take time for you to complete the workbook and the recommended tasks.

What are the possible advantages of taking part?

Being part of a study to help further understanding and management about the symptom of fatigue in MS. If the workbooks are found to be effective they will be used more widely throughout NHS Fife either to be used alone or with help from a healthcare professional.

What if I have a relapse during the study?

You can choose to stay in the study or opt out of the study if you are having a relapse. Your usual care will not be affected in any way.

What happens if I don't want to carry on with the study?

You can leave the study at any time without giving reason; this will not affect the usual care you receive. Information already collected would be retained and used in the study, your personal details will be removed from it.

What if you have questions or concerns about the study?

If you have a concern about any aspect of this study, you should speak to the researcher(Kirsty Nesbitt) who will do their best to answer your questions .

Contact details – Kirsty Nesbitt (Trainee Clinical Psychologist). Sir George Sharp Unit, Cameron Hospital, Windygates, Leven, Fife KY8 5RR . Tel – 01592 226808.

Will my taking part in this study be kept confidential?

Yes, all information which is collected about you during the course of the research will be kept strictly confidential and any information which could identify you will be replaced with a participant information number to anonymise it for the purpose of the research. Personal data such as the consent forms will be stored securely for 6 months after the study has finished, they will then be destroyed. Your G.P. will be informed that you are taking part in this study. If you report severe levels of anxiety and/or depression on any of the questionnaires you return the lead researcher has a duty to inform your G.P. whom will decide if further follow up is needed. If you are in the guided self-help group a summary letter will be sent to your G.P. and a copy kept in your Fife Rehabilitation Service notes detailing the number of sessions you attended and your questionnaire results before and after the sessions of guided self-help.

What will happen to the results of the research study?

All data collected from the questionnaires will be stored securely, anonymised and used for the study. The anonymised results of the study will be written up as part of an academic project and submitted as part of the University of Edinburgh Doctorate of Clinical Psychology training course. It may also be published in an academic journal. You will not be identified in any report or publication.

Who is organising and funding the research?

This is a Doctorate or Clinical Psychology student project and is organised by the University of Edinburgh and NHS Fife.

Who has approved the study?

The NHS South East Scotland Ethics Committee has reviewed and given a favourable opinion on the study.

If you have a complaint

If at any time you wish to make a complaint about any aspect of the study please contact NHS Fife Headquarters, Hayfield House, Hayfield Road, Kirkcaldy, Fife, KY2 5AH and follow the standard NHS complaints procedure. Thank you for taking the time to read this information sheet and for considering to take part in this study. If you would like to take part please complete the attached consent form and the enclosed questionnaires and return it in the pre-paid envelope provided.

Thank you

Consent Form

A Randomised controlled trial of self-help for fatigue in multiple sclerosis

Chief Investigator – Kirsty Nesbitt

Please place your initials in the boxes below

1) I confirm that I have read and understood the information sheet dated 6.3.12 (version 3) 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 and my usual care will not be affected in anyway.

3) I understand that consenting to take part in this study means agreeing to be randomly allocated to one of the three groups (usual care, self-help or guided self-help).

4) I understand that my G.P. will be informed that I am taking part in this study.

5) I understand that my G.P. will be contacted if the questionnaires I complete indicate that I have high levels of anxiety and/or depression.

6) I agree to take part in the above study.

7) I would like a summary of the findings posted to me once the study is complete

Name of patient

Date

Signature

Researcher
Ref No (Admin purposes only) _____

Date

Signature

Demographic information - Please fill in the following questions below

1. Male / Female (delete as appropriate)

2. Date of birth _____

3. Approximate year of multiple sclerosis diagnosis _____

4. Are you taking any medication for fatigue?

Yes / No (delete as appropriate)

If yes, what type

Modafinil

Amantadine

Fluoxetine

Other _____

5. Are you taking Disease Modifying Treatments (DMT)?

6. Have you ever received psychological help for fatigue?

Yes / No (delete as appropriate)

If yes, in what year (approximate)? _____

7. Have you ever had contact with any member of the Fife Rehabilitation Service at Cameron Hospital for fatigue management? Yes / No (delete as appropriate)

If yes, which team did you see (e.g. nursing, physiotherapy, occupational therapy?)

If yes, approximately what year did you see them in? _____

8. If applicable, approximately when was your last relapse? _____

9. If applicable, approximately how long did it last? _____

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Appendix 11. Satisfaction questionnaire

Self Help Satisfaction Questionnaire

As you have been using the Self-help for fatigue in Multiple Sclerosis workbook it would be useful to get your opinion on your experience of using the workbook. Please take some time to read through then answer the questions below. It would be helpful if you could be as honest as possible. Thank you.

1) How often did you use the workbook (Please circle one response)	Once a Week	Once a Fortnight	Once a month	I did not use the workbook	
2) How relevant was the workbook to you? (Please circle one response)	Very relevant	A little bit relevant	Not sure	Not relevant	Totally irrelevant
3) Was the workbook clear? (Please circle one response)	Very clear	Mostly clear	Not sure	Mostly not clear	Totally unclear
4) Did you understand the workbook? (Please circle one response)	No	Mostly no	Not sure	Mostly yes	Yes
5) Did you find the workbook helpful? (Please circle one response)	No	Mostly no	Not sure	Mostly yes	Yes
6) Did your understanding of your relationship with fatigue change after using the workbook? If Yes, please state how	Yes	Not sure	No		
<hr/>					
7) Will you be using any of the techniques in the workbook to help manage your fatigue? If Yes, please state which techniques you will use	No	Not sure	Yes		
<hr/>					
8) Would you recommend this workbook to someone else with MS and fatigue?	No	Not sure	Yes		
9) Would you change anything about this workbook? If Yes, please state what you would change	Yes	Not sure	No		
<hr/>					
<hr/>					

Thank you for taking the time to complete this questionnaire