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# THE ROLE OF SELF-EFFICACY IN MULTIPLE SCLEROSIS

Laura Spencer

The North Wales Clinical Psychology Programme, Bangor University

Thesis submitted in partial fulfilment of the degree of Doctor of Clinical Psychology

June 2017

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## **Acknowledgements**

Conducting this research project would not have been possible without the incredible support I have received along the way.

Firstly, I would like to thank each and every research participant for voluntarily giving up their time and for welcoming me into their lives. I would also like to thank the committee members of the North Wales Multiple Sclerosis Society branches who kindly invited me to attend their business and social events, enabling me to speak to a wider audience of people with Multiple Sclerosis. You selflessly all hoped that by supporting the project, you would help other people with Multiple Sclerosis. I share this aspiration with you all.

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Last but not least, I would like to thank my family and friends. Not only have you supported me throughout this research project, you have consistently supported me throughout the entirety of my career to date. A sincere thank you, to you all.

## Table of Contents

Thesis abstract .....	V
<b>Chapter 1 – Literature Review .....</b>	<b>1</b>
Journal guidelines .....	3
List of abbreviations .....	8
Abstract .....	10
Introduction .....	12
Method .....	16
Results .....	19
Discussion .....	27
Conclusions .....	30
References .....	31
<b>Chapter 2 – Empirical Paper .....</b>	<b>38</b>
Journal Guidelines .....	40
List of abbreviations .....	46
Abstract .....	47
Introduction .....	49
Method .....	51
Results .....	57
Discussion .....	61
Conclusions .....	63
References .....	64
<b>Chapter 3 – Contributions to Theory and Clinical Practice .....</b>	<b>69</b>
Contributions to theory and clinical practice .....	70
Research implications .....	75
Reflective commentary .....	80
References .....	83
<b>Appendices .....</b>	<b>86</b>
<b>Word Counts .....</b>	<b>144</b>

## **Thesis Abstract**

### *The role of self-efficacy in Multiple Sclerosis*

This thesis aimed to explore the role of self-efficacy in Multiple Sclerosis. The thesis begins with a systematic literature review and meta-analysis to examine whether fatigue management interventions, based upon energy conservation strategies, increase self-efficacy in people with Multiple Sclerosis experiencing fatigue. Three databases were searched, and a total of nine articles were identified as meeting the inclusion criteria. Meta-analysis revealed a medium effect of energy conservation interventions in reducing fatigue, and a large effect of energy conservation interventions in increasing self-efficacy. The findings from this systematic review suggest that energy conservation interventions are effective at increasing self-efficacy in people with Multiple Sclerosis, as well as reducing the impact of fatigue.

The literature review is followed by an empirical paper, which aimed to investigate whether self-efficacy remains predictive of perceived cognitive impairment after controlling for objective cognitive functioning. This empirical paper also aimed to further explore the relationship between self-efficacy and cognitive domains (i.e., attention, processing speed, memory, and executive functioning), as measured objectively. A convenience sample of 25 adults with Multiple Sclerosis was recruited from a semi-rural part of North Wales. All participants completed a series of questionnaires and undertook a battery of neuropsychological assessments. Using hierarchical regression analyses, self-efficacy was found to significantly predict perceived cognitive impairment, even after controlling for objective cognitive functioning. Correlational analyses also revealed a significant relationship between self-efficacy and processing speed, and self-efficacy and

executive function. The paper concludes that self-efficacy is associated with perceived cognitive impairment in people with Multiple Sclerosis, and therefore may be an important aspect of self-management programmes.

The third chapter of this thesis addresses the implications for theory development and clinical practice, and future research. A reflective commentary is also enclosed.

# **Chapter 1 – Literature Review**



**Do energy conservation interventions increase self-efficacy in people with Multiple Sclerosis experiencing fatigue? A Systematic Review and Meta-Analysis.**

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**Disclosures:** None

**Acknowledgements:** This paper is submitted in partial fulfilment of the requirements for Doctorate in Clinical Psychology

**Word Count:** 3040

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This paper will be submitted to *Archives of Physical Medicine and Rehabilitation*, and has therefore being formatted in accordance with this journal's guidelines. The submission guidelines are listed at the beginning of this chapter.

## Types of papers

**Original Research:** Present new and important basic and clinical information, extend existing studies, or provide a new approach to a traditional subject. Manuscripts should be limited to 3000 words of text (Introduction through Conclusions). Figures, tables, and references should be limited to the number needed to clarify, amplify, or document the text.

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For any further information please visit our customer support site at <http://support.elsevier.com>.

## List of Abbreviations

**A:** Adequate

**C:** Control group

**CI:** Confidence interval

**E:** Experimental group

**f:** female

**FACETS:** Fatigue: Applying Cognitive behavioural and Energy effectiveness  
Techniques to Lifestyle

**FIS:** Fatigue Impact Scale

**GFS:** Global fatigue severity

**ITT:** Intention-to-treat

**LOCF:** Last-observation-carried-forward

**m:** male

**M:** Mean

**MFIS:** Modified Fatigue Impact Scale

**MS:** Multiple Sclerosis

**MSFSES:** Multiple Sclerosis Fatigue Self-Efficacy Scale

**MSSS:** Multiple Sclerosis Self-efficacy Scale

**n:** Number of participants

**RCT:** Randomised controlled trial

**S:** Strong

**SD:** Standard deviation

**SE:** Standard error

**SEG:** Self-Efficacy Gauge

**SEQ:** Self-Efficacy Questionnaire

**SEPECS:** Self-Efficacy for Performing Energy Conservation Strategies Assessment

**W:** Weak



## Abstract

**Objective:** To investigate whether fatigue management interventions, based upon energy conservation strategies, increase self-efficacy in people with Multiple Sclerosis experiencing fatigue.

**Data Sources:** The Web of Science, PubMed, and PsycInfo databases were searched to identify relevant randomised controlled trials and single group design studies. The search was filtered to include English language articles only, and restricted to publications post-1950. An ancestral search was also conducted. The search identified a total of 75 articles.

**Study Selection:** Inclusion criteria included quantitative experimental designs assessing both fatigue and self-efficacy pre- and post- a non-pharmacological intervention based upon energy conservation strategies. The first author reviewed the article's title and abstract to determine whether the criteria for inclusion were met.

**Data Extraction:** The first author extracted the relevant data and assessed the methodological quality of the studies, included in the meta-analysis, using the Evaluative method.

**Data Synthesis:** Of the initial 75 studies, 9 were included in the review ( $n = 587$ ). Two studies were assessed to have weak quality, five studies demonstrated adequate quality, and two studies were of strong quality. Meta-analyses revealed a medium effect of energy conservation interventions in reducing fatigue; pooled effect size of  $-0.39$  (95% CI,  $-0.54$  to  $-0.25$ ,  $p = .001$ ), and a large effect of energy conservation interventions in enhancing self-efficacy; with a pooled effect size of  $0.53$  (95% CI,

0.15 to 0.9,  $p = .01$ ).

**Conclusions:** The findings from this systematic review suggest that energy conservation interventions are effective at increasing self-efficacy in people with Multiple Sclerosis, as well as reducing the impact of fatigue. Future research may wish to examine whether increased self-efficacy is maintained at follow-up.

**Key Words:** Meta-analysis, self-efficacy, fatigue, Multiple Sclerosis.

Multiple Sclerosis (MS) is a disease of the central nervous system causing inflammation, demyelination and destruction of axons within the brain and spinal cord. It is the most common neurological condition affecting young adults, with a typical onset between 20-40 years of age<sup>1</sup>. The disease presents as either relapsing-remitting or progressive in nature; however often involves an accumulation of neurological deficits over time, resulting in cognitive and behavioural difficulties<sup>2</sup>. Symptomology varies depending upon the lesion site affected; yet common symptoms include weakness, stiffness, alterations in sensation(s), visual problems, difficulties with co-ordination, bladder and bowel difficulties, sexual dysfunction, and cognitive changes<sup>2</sup>. One of the most common complaints is fatigue, with studies indicating that fatigue is experienced by 75-95% of people with Multiple Sclerosis<sup>3</sup>. The Multiple Sclerosis Council Clinical Practice Guidelines<sup>3</sup> (1998) defines fatigue 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'.*

The cause of fatigue in Multiple Sclerosis is often characterised into primary and secondary disease processes. Primary fatigue refers to changes in the brain which are hypothesised to directly cause fatigue such as demyelination and axonal loss, functional changes, and immunological factors during an 'attack' or relapse<sup>4</sup>. Secondary fatigue however, refers to non-direct processes. For example, fatigue due to sleep disturbance, reduced physical activity, depression, pain, medication side effects, and psychological processes such as self-efficacy<sup>4</sup>.

Fatigue in Multiple Sclerosis, 1) inhibits sustained physical functioning, 2) is exacerbated by heat, 3) impacts upon physical functioning, 4) ‘comes on easily’, 5) impacts upon the individuals ability to meet their everyday responsibilities, and 6) results in ‘problems’ for the individual on a regular basis<sup>5</sup>. Research has demonstrated that fatigue in Multiple Sclerosis is associated with quality of life; Individuals who experience fatigue are more likely to experience depression and to report a lower quality of life<sup>6</sup>, even when levels of depression and disability are controlled for<sup>7</sup>.

Clinical guidelines for the management of fatigue in adults with Multiple Sclerosis include both pharmacological and non-pharmacological intervention<sup>8</sup>. With regard to pharmacological treatment, the National Institute for Clinical Excellence<sup>8</sup> (2014) recommends the use of Amantadine. A recent meta-analysis included seven pharmacological trials (including the use of Amantadine and Modafinil), and reported a pooled effect size in treating fatigue to be 0.07 (95% CI, -0.22 - 0.37,  $p = .63$ )<sup>9</sup>. Non-pharmacological interventions are also recommended within clinical practice guidelines, and include mindfulness based training, Cognitive-Behavioural Therapy, and fatigue management<sup>8</sup>. Aerobic, balance, and stretching exercises may also be advised<sup>8</sup>. Comparable with pharmacological treatments, research reports non-pharmacological treatments (i.e., exercise and educational interventions) to be more effective at treating fatigue<sup>9</sup>.

Fatigue management interventions have been delivered via individual telephone sessions<sup>10</sup>, group based teleconference<sup>11,12</sup>, group-format community settings<sup>1,13-19</sup>, and via online groups<sup>20</sup>.

One of the most common non-pharmacological fatigue management treatments includes energy effectiveness or energy conservation strategies, defined as: ‘the identification and development of activity modifications to reduce fatigue through a systematic analysis of daily work, home, and leisure activities in all relevant environments’<sup>3</sup>. Energy conservation strategies may include reorganising the individual’s environment, using aids and assistive technologies, revisiting and re-prioritising activities, asserting one’s own needs with others and re-distributing activities and tasks accordingly, altering activities to reduce energy consumption, and ensuring adequate rest<sup>21</sup>.

A meta-analysis published in 2013 found energy conservation treatments were more effective than no treatment (i.e., waiting list controls) in reducing the impact of fatigue (as assessed via self-report), and in improving quality of life for people with Multiple Sclerosis<sup>21</sup>. Furthermore, immediate benefits of participation in energy conservation treatments, including reduced impact of fatigue and an improved quality of life, are maintained at 12 months post intervention<sup>22</sup>.

Engaging in any new behaviours, including energy conservation behaviours, is related to cognitive and psychological processes. One of the processes theorised to be involved in the initiation and maintenance of new behaviours is self-efficacy. Grounded in social-cognitive theory, self-efficacy refers to the degree to which an individual believes that they are able to perform a task in order to produce a desired outcome<sup>23</sup>. It determines whether an individual engages in coping behaviours, the amount of effort that they will apply, and the length of time that the individual will continue to apply this effort when they experience difficulties or problems<sup>23</sup>. The

stronger the individual's self-efficacy expectation, the more active are their coping efforts<sup>24</sup>.

Self-efficacy has been associated with other treatments in Multiple Sclerosis. For example, previous research found that pre-treatment self-efficacy was associated with adherence to self-administered intramuscular injections at six-month follow up<sup>25</sup>, and adherence to an exercise programme<sup>26</sup>. Further research has also found that self-efficacy is associated with physical activity, i.e., individuals with high self-efficacy for exercise are more likely to engage in physical activity<sup>27</sup>.

Self-efficacy is also an important concept in fatigue management treatments such as energy conservation, as an individual can be 'taught' self-management strategies, but if the individual is unsure about whether they have the ability to perform such strategies, then they are unlikely to apply the strategies that they have learnt<sup>23</sup>.

Increased self-efficacy following energy conservation treatments therefore may account for changes in energy conservation behaviours post intervention<sup>18</sup>. However, no studies to date have systematically reviewed the current evidence base to determine whether non-pharmacological interventions based on energy conservation strategies increase self-efficacy in people with Multiple Sclerosis.

The aims of this study are two-fold: Firstly, to re-examine the current evidence base to determine whether energy conservation strategies reduce negative fatigue outcomes (i.e., fatigue impact or severity) in people with Multiple Sclerosis. Secondly, to investigate whether interventions, based upon energy conservation principles, increase self-efficacy for individuals with Multiple Sclerosis experiencing fatigue. Both aims

will be addressed by using meta-analyses to produce an overall effect size for both fatigue and self-efficacy following energy conservation treatments.

## **Methods**

### **Search Strategy**

A systematic search of the literature was conducted in April 2017. The Web of Science, PubMed, and PsycInfo databases were searched using the following search terms: (“energy manag\*” OR “energy conserv\*” OR “energy sav\*” OR “fatigue manag\*” OR “managing fatigue”) AND “multiple sclerosis” AND (“self efficacy” OR “self-efficacy”). The search was filtered to include English language articles only, and restricted to publications post-1950. An ancestral search was also conducted.

### **Inclusion and eligibility criteria**

The criteria for inclusion in the meta-analysis included:

*Study design:* Experimental, quantitative designs. Qualitative designed studies were excluded.

*Participants:* Adults (aged  $\geq 18$  years) with a diagnosis of Multiple Sclerosis, with no restrictions as to gender, diagnostic subtype, or duration of the disease. Studies that included other neurological conditions met inclusion criteria if they reported separate data for the Multiple Sclerosis sample.

*Intervention:* Studies must have included a non-pharmacological intervention based upon energy conservation principles. Studies were required to meet the following definition of energy conservation strategies as described by the Multiple Sclerosis Clinical Council: ‘the identification and development of activity modifications to

reduce fatigue through a systematic analysis of daily work, home, and leisure activities in all relevant environments<sup>3</sup>. Fatigue management interventions based upon cognitive behavioural therapy were excluded. Studies including pharmacological treatments only were excluded.

*Outcome measures:* Studies were required to have used pre- and post- intervention measures to assess both fatigue, such as the Fatigue Impact Scale<sup>28</sup>, and self-efficacy, such as the Multiple Sclerosis Self-Efficacy Scale<sup>29</sup>.

### **Study selection**

The first author initially screened article abstracts, and articles were excluded if the topic was not relevant to the meta-analysis. Full text articles were then assessed for eligibility.

### **Data extraction**

Information detailing the demographics of the sample, the intervention, the control condition (if present), and outcome measures were obtained from each of the studies. As the length of follow-up varied greatly between studies, we used the data for the time period immediately post intervention. To ensure consistency, where data from both intention-to-treat (ITT) and compliers analyses were reported, data from the ITT analyses were used. Where articles did not report the mean and standard deviation for the total Fatigue Impact Scale<sup>28</sup>, an average score was taken from the three subscales and incorporated into the analysis. In instances where the published article did not report raw data, the first author was contacted via e-mail to request this information.



## **Measurement of research quality**

The methodological quality of the studies included in the meta-analysis was assessed using the Evaluative method for evaluating and determining evidence-based practices<sup>30, 31</sup>. This method has demonstrated good psychometric properties<sup>31</sup> and has been deemed a suitable instrument for the appraisal of experimental research designs<sup>32</sup>.

Each study was initially reviewed and evaluated against a set of primary quality indicators, e.g., description of the independent variable (intervention) provided with ‘replicable precision’. Studies were awarded a quality rating of high (H), acceptable (A), or unacceptable (U). Secondly, each study was reviewed against a set of secondary quality indicators, e.g., treatment fidelity and attrition. These secondary quality indicators were rated dichotomously as either the study demonstrated or did not demonstrate evidence of each of the indicators. Finally, the overall strength of the research article was determined by synthesising the ratings from the appraisal of both the primary and secondary quality indicators. Each study was awarded an overall strength of strong (S), adequate (A), or weak (W).

## **Data analysis**

The Metafor package<sup>33</sup> for R<sup>34</sup> was used to conduct all statistical analyses. Initially, the effect size for each study was calculated using the mean and standard deviation. For studies that reported the mean and standard error only, the standard error was transformed into the standard deviation using the equation:  $SD = SE \times (\sqrt{n})$ , allowing

for an effect size to be calculated. Where no raw data was available, the effect size stated in the article was added to the model in Metafor.

Once an effect size had been calculated for each study, an overall effect size was calculated using a random-effects model. Using Cohen's (1988)<sup>35</sup> guidelines, effect sizes were interpreted as either small ( $r = 0.10$ ), medium ( $r = 0.30$ ), or large ( $r = 0.50$ ).

## **Results**

### **Included studies**

Of the initial 75 articles identified, the first author reviewed the article's title and abstract to determine whether the criteria for inclusion were met. Ten articles were removed at this stage, as the topic was not relevant to the meta-analysis. Sixty-five full text-articles were then reviewed, and 10 were assessed as meeting the criteria for inclusion in the meta-analysis. One article did not provide either the raw data or effect sizes, and these were unable to be obtained from the corresponding author of the study. This article was therefore excluded. Figure 1. provides a diagrammatic summary of the study selection process.

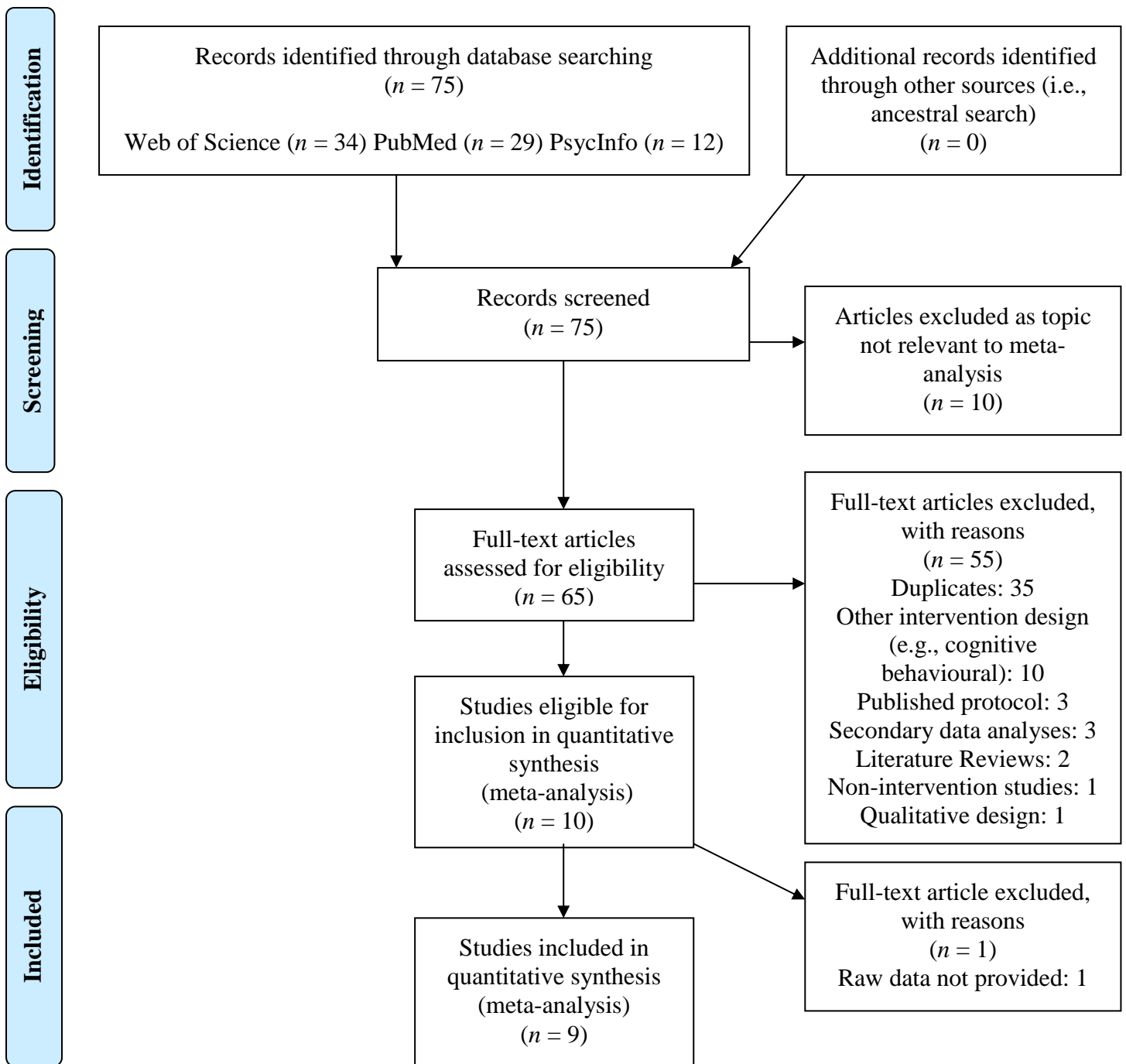


Figure 1. PRISMA (2009) flow diagram of the literature search process

A total of nine studies ( $n = 587$ ) published between 2001 and 2016 were identified as meeting the criteria for inclusion in the meta-analysis. Three studies employed a single group design<sup>11,17,18</sup>, and five studies were randomised controlled trials (RCT)<sup>13-16,19,36</sup>. One article, Lamb et al. (2007)<sup>36</sup>, was a secondary data analysis from a previous RCT. Six studies included a comparison condition, these ranged from

waiting list control<sup>14</sup> and delayed treatment control<sup>15</sup>, to peer support groups<sup>13,18</sup>, current local practice<sup>19</sup>, and a placebo intervention which included the provision of general information such as car adaptations<sup>16</sup>. For five studies<sup>11,13,15,18,36</sup>, the original or a modified version of the “Managing Fatigue” energy conservation course developed by Packer et al. (1995)<sup>37</sup> was administered during the intervention phase. This was the most common treatment approach.

*Outcome measures.* The most commonly used measure of fatigue was the Fatigue Impact Scale<sup>28</sup> ( $n = 6/9$  studies, 67%), followed by the Modified Fatigue Impact Scale<sup>3</sup> ( $n = 2/9$ , 22%), and the Global Fatigue Severity subscale of the Fatigue Assessment Instrument<sup>38</sup> ( $n = 1/9$ , 11%). Where both the impact and severity of fatigue were measured, data from the Fatigue Impact Scale<sup>28</sup> or the Modified Fatigue Impact Scale<sup>3</sup> were used in an attempt to maintain consistency across studies.

Self-efficacy was assessed using four different measures. The Multiple Sclerosis Self-Efficacy Scale<sup>29</sup> ( $n = 4/9$  studies, 45%) and the Self-Efficacy for Performing Energy Conservation Strategies Scale<sup>39</sup> ( $n=3/9$ , 33%) were the most commonly used. Other measures included the Self-efficacy Gauge<sup>40</sup> ( $n = 1/9$ , 11%) and the Multiple Sclerosis Fatigue Self Efficacy Scale<sup>41</sup> ( $n = 1/9$ , 11%).

Table 1. provides a summary description of the studies included in the meta-analysis.

Table 1. Summary descriptions of the studies included in the meta-analysis

First Author (Year)	Design	n	Follow-up	Age	Gender	Intervention	Control	Outcomes (Pre-Post)	Research Report Strength
Finlayson (2005) <sup>11</sup>	Single group	29	0	47 (9.6)	5m, 24f	Modified “Managing Fatigue” by Packer (delivered via teleconference)	-	SEQ: 7.46(1.11) – 7.81 (1.37) FIS Total: 124.83 (27.1) – 112.1 (29.78)	W
García Jalón (2012) <sup>13</sup>	RCT	E: 13 C: 10	3m	E: 45.9 (9.9) C: 52 (7)	E: 3m, 10f C: 4m, 6f	Energy conservation programme by Packer	Peer support group	Energy conservation group: MSSS: 46(8.5) - 43.31(8.74) FIS: 83.31(16.26) - 59.62(23.14) Support Group: MSSS: 49.9(7.5) - 43.5(8.44) FIS: 80.9(21.73) - 63.3(26.03)	A
Hugos (2010) <sup>14</sup>	RCT	E: 15 C: 15	13w	E: 58.4 (7.7) C: 55.4 (9.1)	E: 4m, 11f C: 2m, 13f	“Take control” programme	Wait-list control	Week 1 to Week 5+ ‘Take control’ group: MSSS:1362.67(61.3) - 1391(61.3) MFIS: 44(3.46) - 39.79(6.44) Wait-list control group: MSSS:1284.67(61.3)- 1318.57(63.45) MFIS: 44.4(3.35) - 40.43(3.46)	A
Kos (2007) <sup>16</sup>	RCT	E: 28 C: 23	6m	E: 42.9 (9.1) C: 44.5 (9.9)	E: 8m, 20f C: 8m, 15f	Multi-disciplinary fatigue management programme	Placebo intervention	Baseline to Week 35 (ITT group) Fatigue management: MFIS: 46.69(10.80) - 42.03(11.96) MSSS (function subscale):	A

								694.31(155.37) - 689.4(135.95) MSSS (control subscale): 516.08(185.18) - 577.57(165.98)	
Lamb (2005) <sup>36</sup>	RCT	43	0	48.4 (10)	7m, 36f	“Managing fatigue” programme by Packer	-	FIS: 115.2(28.4) - 102.86(30.06) SEPECSA: 7(2.06) - 8.11(1.27)	A
Mathiowetz (2005) <sup>15</sup>	RCT	169	6w	48.34 (8.44)	29m, 140f	Energy conservation course by Packer	Delayed treatment control	(ITT LOCF Effect size) FIS Cognitive subscale: 0.52 FIS Physical subscale: 0.74 FIS Social subscale: 0.69 SEPECSA: 1.82	S
Mathiowetz (2001) <sup>18</sup>	Single group	54	6w	50 (31-74 <sup>#</sup> )	18m, 36f	Energy conservation course by Packer	Support group	Energy conservation (week 7-13): FIS: 66.4(26.5) - 55.8(29.7) SEG: 206.1(40.4) - 214(35.8) Support group (week 1-7): FIS: 68.9(26.2) - 66.4(26.5) SEG: 201.5(36.3) - 206.1(40.4)	A
Mulligan (2016) <sup>17</sup>	Single group	24	0	49.29 (8.12)	0m, 24f	“Minimise Fatigue, Maximise Life: Creating balance with Multiple Sclerosis” (MFML)	-	Time 2 - Time 3: MFIS: 11.25(4.12) - 9.17(3.57) MSSS: 34.75(12.79) - 43.3(11.85)	W
Thomas (2013) <sup>19</sup>	RCT	E: 84 C: 80	4m	E: 48.0 (10.2) C: 50.1 (9.1)	E: 23m, 61f C: 22m, 58f	“Fatigue: Applying cognitive behavioural and energy effectiveness techniques to lifestyle (FACETS)”	Current local practice (CLP)	FACETS group: GFS: 5.6(.98) - 5.48(.92) MSFSE: 45(17) - 57(17) CLP group: GFS: 5.61(1.09) - 5.55(1.17) MSFSE: 49(16) - 50(17)	S

Note. All values are  $M$  ( $SD$ ) unless otherwise stated, <sup>+</sup> = Values in brackets are standard error, <sup>#</sup> = range.

Abbreviations: A, adequate; C, control group; E, experimental group; f, female; FIS, Fatigue Impact Scale; GFS, Global Fatigue Severity subscale of the Fatigue Assessment Inventory; m, male; MFIS, Modified Fatigue Impact Scale; MSFSES, MS Fatigue Self-efficacy Scale; MSSS, MS Self-efficacy Scale; RCT, Randomised Controlled Trial; S, Strong; SEG, Self-efficacy gauge; SEPECSA, Self-efficacy for performing energy conservation strategies assessment; SEQ, Self-efficacy Questionnaire; W, Weak.

### **Data extraction**

One study, by Mathiowetz et al. (2005)<sup>15</sup> reported ITT data using both the method of last-observation-carried-forward (LOCF) and using the maximum likelihood method. In this case, data from the LOCF method was used.

### **Measurement of research quality**

Using the Evaluative method<sup>30,31</sup>, two studies were assessed to be of weak quality, five were of adequate quality, and two studies were of strong quality. The research report strength for each study is detailed in Table 1.

### **Publication bias**

Although it was not possible to thoroughly assess for publication bias due to the limited number of studies included in the analysis, a visual review of the funnel plots did not reveal any obvious positive bias (see appendix).

### **Effectiveness of energy conservation treatments**

Effect sizes for fatigue outcomes post-intervention ranged from -0.01 to -0.65. The pooled effect size was -0.39 (95% CI, -0.54 to -0.25,  $p = .001$ ), which equates to a medium effect size. The test for heterogeneity was significant ( $Q = 24.09$ ,  $p < .01$ ,  $I^2 = 62.25\%$ ). Figure 2. demonstrates the effect size for each individual study and the overall effect size for fatigue.



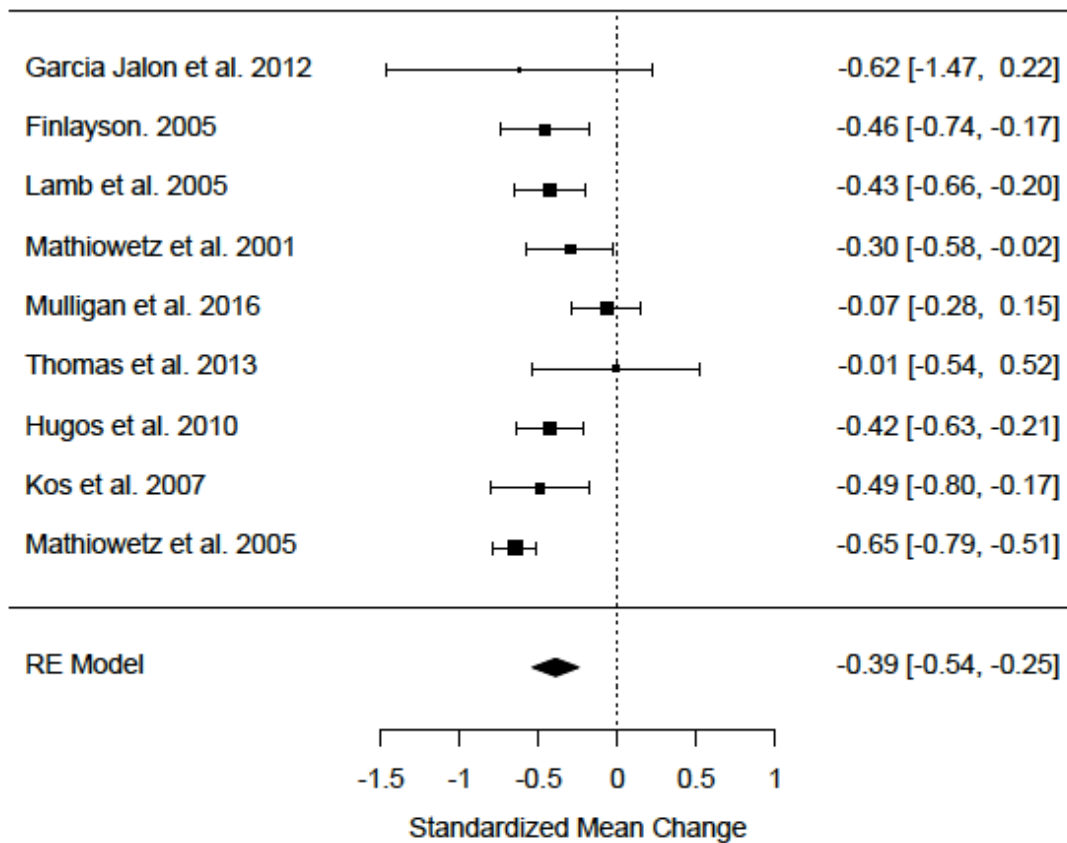


Figure 2. Forest plot for fatigue outcomes.

### Self-efficacy

Effect sizes for self-efficacy outcomes post-intervention ranged from -0.02 to 1.82.

The pooled effect size was 0.53 (95% CI, 0.15 to 0.9,  $p = .01$ ), equating to a large effect size. The test for heterogeneity was significant ( $Q = 347.61$ ,  $p < .01$ ,  $I^2 = 95.41\%$ ). Figure 3. details the effect size for each study and the overall effect size for self-efficacy.

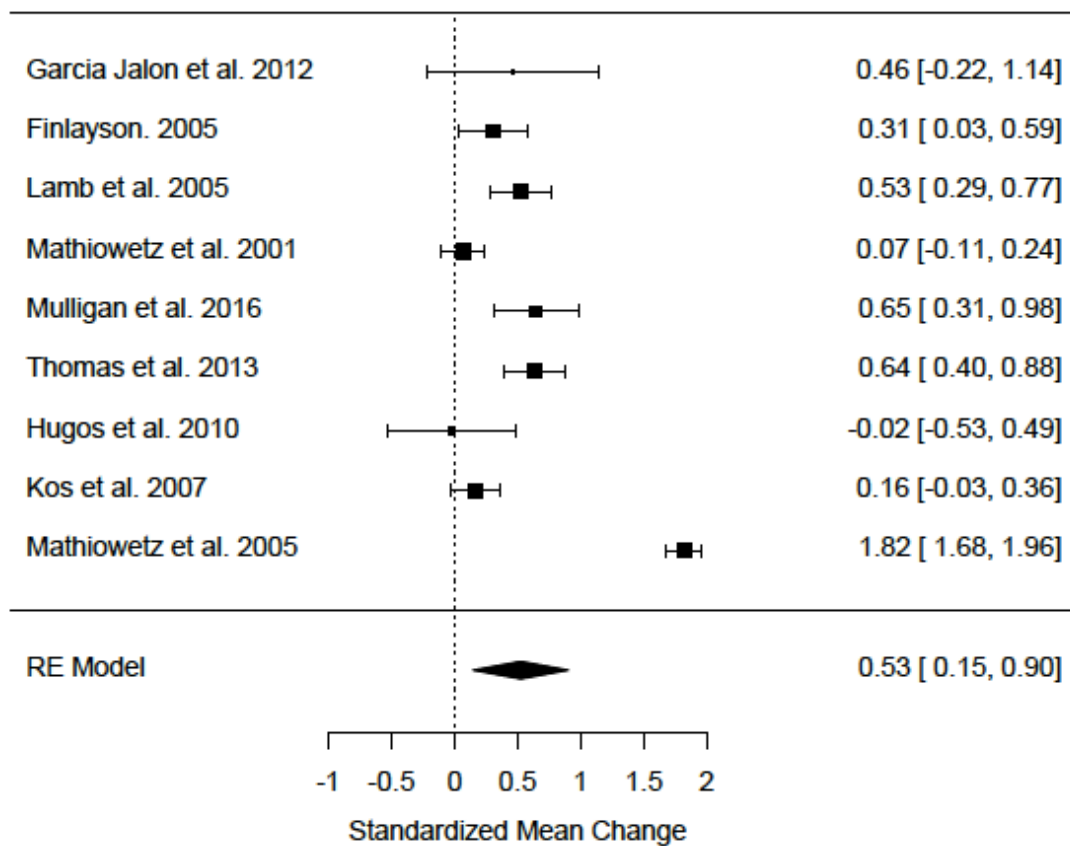


Figure 3. Forest plot for self-efficacy outcomes.

## Discussion

The aim of this study was to systematically review the effectiveness of energy conservation interventions in reducing fatigue and increasing self-efficacy in people with Multiple Sclerosis, and to use meta-analysis to produce an overall effect size for both fatigue and self-efficacy.

### *Effectiveness on fatigue*

With regard to fatigue, the meta-analysis revealed that fatigue management interventions which incorporate energy conservation strategies, are moderately effective at reducing the impact or severity of fatigue when compared to no treatment

(i.e., wait-list control), a placebo intervention, or alternative support. These findings support previous research that also reported energy conservation strategies to be effective at reducing fatigue <sup>21</sup>.

### *Effectiveness on Self-Efficacy*

The main aim of this study however was to determine whether energy conservation strategies are effective at enhancing self-efficacy in people with Multiple Sclerosis experiencing fatigue. Results from the meta-analysis showed that energy conservation interventions do increase self-efficacy, with a large effect.

The current literature base suggests that self-efficacy is an important psychological construct in Multiple Sclerosis. Although self-efficacy is unlikely to be the sole determinant of engagement in energy conservation strategies, it is highly likely to influence the initiation of such behaviours, and the quantity of both time and effort an individual will expend in these behaviours<sup>23</sup>. Interventions that increase self-efficacy may therefore increase the likelihood than an individual will utilise energy conservation strategies. Furthermore, an increased self-efficacy for fatigue management may generalise to other behaviours that were previously limited due to the individual's lack of efficacy expectations<sup>23</sup>. Fatigue management strategies that increase self-efficacy may therefore have positive consequences on other health outcomes in addition to reducing the impact of fatigue.

### *Study limitations*

This meta-analysis included a relatively small sample of 9 studies, including 587 people with Multiple Sclerosis, and therefore the findings should be interpreted with

some caution. There was also some variation in the methodological quality of the studies included in this meta-analysis. Whilst, the majority of studies were assessed as being of adequate or strong quality, some studies were of weak methodological quality. This was typically due to the lack of an appropriate control condition. Some caution may be required in interpreting the findings of this study due to the overall quality of the studies included in the meta-analysis. The literature base would therefore also benefit from future high quality randomised controlled clinical trials.

In this study, the effectiveness of energy conservation strategies in reducing fatigue and increasing self-efficacy was assessed using data collected immediately post-intervention. The findings from this paper therefore are limited to the short-term effects of energy conservation interventions, and it is not possible to conclude whether these findings would be maintained over time. Although, previous studies have found a reduction in fatigue, following participation in energy conservation treatments, to be maintained one year post-intervention<sup>22</sup>. It is possible that reductions in fatigue impact may be due to a sustained increase in self-efficacy for performing energy conservation strategies; however further research is required to investigate this hypothesis.

#### *Future research*

This study found energy conservation interventions reduce fatigue impact and increase self-efficacy. However, it is not clear as to the relationship between these two variables. Future research may wish to incorporate a mediational analysis to determine whether the increase in self-efficacy indirectly accounts for the reduction in fatigue impact, by increasing the uptake of energy conservation strategies.

This meta-analysis incorporated studies in which energy conservation interventions were delivered via a number of different modalities including community groups and teleconference. In addition, there was some variation in the fatigue management approaches used, including programmes based on Packer<sup>37</sup> and the group-based fatigue management programme (FACETS). In this study, the test for heterogeneity was significant for fatigue and self-efficacy outcomes, indicating varying effectiveness across studies. This may be due to differences in treatment modality, treatment approaches, or other variables. Therefore an interesting focus of future research may be in examining what variables account for differences in effectiveness. This may guide future service development and clinical work to ensure people with Multiple Sclerosis experiencing fatigue are offered the most effective treatment.

Finally, the number of studies included in the meta-analysis was limited, as some studies examining the effectiveness of energy conservation treatments did not include a measure of self-efficacy. Future research studies should therefore incorporate a measure of self-efficacy.

### **Conclusions**

This study is the first to systematically review the literature and to use meta-analysis to determine whether energy conservations interventions increase self-efficacy in people with Multiple Sclerosis. The results suggest that energy conservations interventions may be more effective than either no treatment or general support in increasing self-efficacy in the short-term. Future research may wish to consider whether the increase in self-efficacy is maintained over time.

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## **Chapter 2 – Empirical Paper**

**Investigating the role of objective cognitive functioning in the relationship between self-efficacy and perceived cognitive impairment in people with Multiple Sclerosis**

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**Word Count:** 2974

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This paper will be submitted to *Archives of Physical Medicine and Rehabilitation*, and has therefore being formatted in accordance with this journal's guidelines. The submission guidelines are listed at the beginning of this chapter.

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**Original Research:** Present new and important basic and clinical information, extend existing studies, or provide a new approach to a traditional subject. Manuscripts should be limited to 3000 words of text (Introduction through Conclusions). Figures, tables, and references should be limited to the number needed to clarify, amplify, or document the text.

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## List of Abbreviations

**BADS:** Behavioural Assessment of the Dysexecutive Syndrome

***M:*** Mean

**MS:** Multiple Sclerosis

***n:*** Number of participants

**NeuroQol:** Quality of Life in Neurological Disorders Measure

**NHS:** National Health Service

**OCF:** Objective cognitive functioning

**PASAT:** Paced Auditory Serial Additions Test

**PHQ-9:** Patient Health Questionnaire - 9

**PROMIS:** Patient Reported Outcomes Measurement Information System

***SD:*** Standard Deviation

**WAIS:** Wechsler Adult Intelligence Scale

**WMS:** Wechsler Memory Scale

## Abstract

**Objective:** To investigate whether self-efficacy remains predictive of perceived cognitive impairment after controlling for objective cognitive functioning, and to further examine the relationship between self-efficacy and cognitive domains, as measured objectively.

**Design:** A cross-sectional design was employed.

**Setting:** General community setting within a semi-rural part of the United Kingdom.

**Participants:** A convenience sample of twenty-five participants with a diagnosis of Multiple Sclerosis. Participants were recruited via National Health Service clinics and the Multiple Sclerosis Society. Eligible participants were those with a diagnosis of Multiple Sclerosis (any subtype), aged  $\geq 18$  years, of fluent English language, and with sufficient cognitive and motor ability to complete neuropsychological assessment.

**Intervention(s):** Not applicable.

**Main Outcome Measure(s):** The main outcome measures included the Liverpool Self-efficacy Scale<sup>1</sup> as a measure of self-efficacy, and the Cognitive Function (v.2) questionnaire of the Quality of Life in Neurological Disorders (Neuro-QOL) Measures<sup>2</sup> to assess perceived cognitive impairment. Objective cognitive functioning, i.e., attention, processing speed, memory, and executive functioning, was assessed using a variety of neuropsychological measures.

**Results:** Using regression analyses, self-efficacy was found to significantly predict perceived cognitive impairment, even after controlling for objective cognitive functioning. Self-efficacy accounted for 45% of the variance in perceived cognitive impairment ( $F_{(1,22)} = 8.92, p = .001$ ). Correlational analyses revealed a significant

relationship between self-efficacy and processing speed, and self-efficacy and executive function.

**Conclusion(s):** Self-efficacy is associated with the perception of cognitive impairment in people with Multiple Sclerosis, and therefore may be an important aspect of self-management programmes.

**Key words:** Self-efficacy, cognition, Multiple Sclerosis.

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system causing inflammation, demyelination and axonal loss within the brain and spinal cord<sup>3</sup>. A review of the General Practice Research Database estimated the prevalence of MS in the U.K to be 203.4 per 100,000 population in 2010, with women accounting for 72% of the prevalence rates<sup>4</sup>. Clinical symptoms vary dependent upon the lesion site affected, and the subsequent disease course of either relapsing-remitting or progressive MS. However, symptoms can include motor, cognitive, and behavioural deficits<sup>5</sup>, and neuropsychiatric complications such as depression and anxiety<sup>6</sup>.

The research literature refers to a number of different psychological processes that may impact upon an individual's ability to adjust to life with a physical health condition, such as MS<sup>7</sup>. One of these psychological processes, grounded in social-cognitive theory, is self-efficacy. Differentiated from outcome expectancies, i.e., the understanding that performing a behaviour will lead to a specific outcome<sup>8</sup>, self-efficacy expectations refers to the degree to which an individual believes that they are able to perform a task in order to produce a desired outcome<sup>9</sup>. Self-efficacy is one of the major determinants of peoples choice of activities, how much effort they expend in a task, and how long they persist in the face of difficulties<sup>9,10</sup>. Yet, possibly due to the unpredictable nature of the disease, people with MS experience lower levels of self-efficacy than people with other physical health conditions, including spinal cord injury<sup>11</sup>.

Research suggests that self-efficacy is associated with health-related quality of life, depression, and social functioning<sup>12</sup>, as well as physical activity in people with MS<sup>13</sup>.



However, only three studies to date have investigated the relationship between self-efficacy and cognition in people with MS. Initial research examined self-efficacy in the context of perceived cognitive impairment i.e., impairment as measured by patient self-report. Research by Schmitt and colleagues in 2014 found self-efficacy to be predictive of perceived cognitive impairment in a sample of individuals with a range diagnostic subtypes<sup>12</sup>. Expanding these initial findings, longitudinal research found self-efficacy to remain predictive of perceived cognitive impairment over a three-year period<sup>14</sup>. Although depression and fatigue are associated with perceived cognitive impairment in MS<sup>15</sup>, self-efficacy continues to be predictive of perceived cognitive impairment even when these variables are controlled for<sup>14</sup>.

More recent research has begun to consider the relationship between self-efficacy and objective cognitive functioning, i.e., cognitive ability as measured using computer or clinician administered neuropsychological assessments. Using a sample of participants with clinically isolated syndrome or early relapsing-remitting MS, Jongen and colleagues (2015) found self-efficacy to be associated with power of attention, reaction time variability, and speed of memory, using a computerised battery of cognitive tests<sup>16</sup>. The findings suggest that self-efficacy positively affects performance on cognitive tests, particularly in the cognitive domains most typically affected by MS<sup>16</sup>. The authors also hypothesised that cognitive ability may impact upon self-efficacy, in that individuals with greater cognitive capacity may feel better able to manage their symptoms as compared to individuals with impaired cognition<sup>16</sup>.

Cognitive impairments are reported to occur in approximately 45-65% of people with MS, and commonly include deficits in attention, memory, and executive functioning<sup>17</sup>. The impact of cognitive impairment is wide spread, and includes a greater risk of unemployment, reduced engagement in social activities, and increased difficulties undertaking activities of everyday living<sup>18</sup>. Therefore, understanding psychological variables associated with cognition is essential in order to continue to develop self-management interventions that are grounded in the evidence base.

The primary aim of this study was to address the current gaps in the research literature by investigating whether self-efficacy remains predictive of perceived cognitive impairment, even when objective cognitive functioning has been controlled for. Secondly, this study aimed to add to the currently limited literature base by examining the relationship between self-efficacy and objective cognitive functioning using ecologically valid measurement tools.

## **Methods**

### ***Participants***

The participant sample ( $n = 25$ ) was recruited from National Health Service clinics and from local branches of the MS Society, based within a semi-rural area in North Wales, United Kingdom. Eligible participants were those with a diagnosis of MS, aged  $\geq 18$  years, of fluent English language, and with sufficient cognitive and motor ability to complete neuropsychological assessment. Exclusion criteria included co-morbid

neurological diagnoses (including diagnosis of a dementia syndrome), current substance misuse, and significant current mental health difficulties that would impact upon capacity to provide informed consent.

## ***Measures***

***Clinical Measures.*** Participants completed five questionnaire measures.

*Self-efficacy.* Self-efficacy was measured using the Liverpool Self-efficacy Scale<sup>1</sup>. This is an 11-item Likert-type scale, consisting of two domains of control and personal agency. The scale has been validated using a sample of people with MS; the authors report good internal consistency ( $\alpha = 0.81$ ) and acceptable test-retest reliability (intraclass correlation coefficient of 0.79)<sup>1</sup>. Low scores on this scale are associated with low self-efficacy.

*Perceived cognitive impairment.* The Cognitive Function questionnaire of the Quality of Life in Neurological Disorders<sup>2</sup> (Neuro-QOL) short-form measure (version 2) assesses both executive function and general concerns (e.g., attention, memory, planning, and organising), and consists of 8 items scored on a 5-point Likert scale. This short-form measure allows for raw scores to be converted into standardised T scores ( $M = 50$ ,  $SD = 10$ ). Higher scores denote less perceived cognitive difficulty.

*Multiple Sclerosis subtype and neurological impairment.* MS subtype was assessed using self-report. Where participants were unsure as to their diagnosis, their MS specialist nurse was consulted (with written consent) to obtain this information. Neurological impairment was assessed using the Multiple Sclerosis Questionnaire<sup>19</sup>. This 17-item questionnaire has been demonstrated to be highly cross-correlated with other measures of impairment in MS and is therefore recommended as a valid and accurate measure<sup>19</sup>.

*Fatigue.* The Patient-Reported Outcomes Measurement Information System (PROMIS) Fatigue short form for MS was administered to assess fatigue<sup>20</sup>. This measure includes 8 items scored using a 5-point Likert scale. Raw scores are converted to standardised T scores ( $M = 50$ ,  $SD = 10$ ). The PROMIS measures have been shown to be valid for use with people with MS<sup>21</sup>. Higher scores on this measure are associated with greater levels of fatigue.

*Depression.* Symptoms associated with depression were assessed using the Patient Health Questionnaire (PHQ-9)<sup>22</sup>. This 9-item measure is scored using a 4-point Likert-type scale. The PHQ-9 has been validated for use in a MS sample<sup>23</sup>. Higher scores are associated with greater symptoms of depression.

***Neuropsychological measures.*** Participants completed a series of neuropsychological assessments, covering a breadth of cognitive domains.

*Attention.* The Paced Auditory Serial Additions Test (PASAT)<sup>24</sup> was initially developed as a measure of information processing speed and flexibility. It has since been adapted<sup>25</sup>, and subsequently has been extensively used within the MS population as a measure of attention. Participants are presented with a series of single-digit numbers using a pre-recorded tape, and are required to add the most recent number to the one presented immediately before it. Participants are not required to keep a running total, but to provide the sum of the last two numbers heard. There are two subtests, and the numbers are presented at a rate of every three seconds on the first subtest and every two seconds on the following subtest. On each subtest, participants are presented with a total of 60

numbers. The PASAT has demonstrated good internal consistency<sup>26</sup>. High scores represent greater attentional abilities.

*Processing Speed.* The symbol search and coding subtests of the Wechsler Adult Intelligence Scale fourth edition (WAIS-IV)<sup>26</sup> were administered as a measure of speed of information processing. The symbol search subtest assesses both processing speed and visual perception. On the symbol search subtest, participants are required to scan a series of symbols presented sequentially in a row, and identify whether they match a target symbol. On the coding subtest, participants are required to translate symbols, each uniquely associated with a number, into boxes. Both the symbol search and coding subtests are timed tasks of two minutes each, and therefore participants are encouraged to work as quickly and accurately as possible. Scores on the symbol search and coding subtests are converted into a processing speed index score ( $M = 100$ ,  $SD = 15$ ). Higher scores reflect a quicker processing speed.

*Memory.* The Logical Memory subtests of the Wechsler Memory Scale fourth edition (WMS-IV)<sup>28</sup> were administered as a measure of immediate and delayed verbal memory. The researcher read two short stories, which participants were required to recall both immediately and after a 30-minute delay. There are two versions available, one for adults (16-69 years) and one for older adults (aged 65-90 years). These were administered accordingly given the participant's age. Higher scores indicate greater recall.

*Executive Function.* Executive functioning was measured using the 6 Elements Test of the Behavioural Assessment of the Dysexecutive Syndrome (BADS)<sup>29</sup>. This is a set task of ten minutes in which participants are instructed to undertake three different types of tasks, a dictation task, a picture-naming task, and an arithmetic task. Participants are

advised to adhere to specific rules throughout the task, with points deducted if the rules are not observed. Low scores represent executive dysfunction.

## **Procedure**

Ethical approval was obtained from the School of Psychology, Bangor University, and from the Research and Ethics Committee of local Health Board. Participants were recruited via three methods: Potential participants who met the eligibility criteria were approached during their routine National Health Service (NHS) MS nurse appointment, and the third author approached potential participants at their NHS clinical psychology appointment. The first author also contacted the local branches of the MS Society and presented details about the research study at Society meetings. Potential participants were provided with a bilingual (English and Welsh) information pack, containing an information sheet and an initial contact form. Interested participants were advised to return the initial contact form to the first author using a freepost envelope provided in the information pack. Upon receipt of the initial contact form, participants were contacted via telephone and a research appointment was arranged. Appointments took place within NHS premises or within the participants' own home. Written consent was obtained at the start of the appointment, and subsequently, the questionnaire and neuropsychological measures were administered. Measures were completed over 1-3 appointments as requested by the research participant to accommodate for participant fatigue. Recruitment and testing took place between September 2016 and March 2017.

## Data analyses

The Statistical Package for the Social Sciences (SPSS) version 23 was used to perform all analyses. In order to create a single measure of objective cognitive functioning, tests measuring the four individual cognitive domains (i.e., attention, processing speed, memory, executive function) were standardised and averaged, before the four cognitive domain scores were averaged to create a single measure. Specifically, the raw scores for each neuropsychological assessment were converted into standardised scores using normative data. The WMS-IV Logical Memory subtest raw scores were converted into scaled scores using normative data based upon age ( $M = 10, SD = 3$ ). These two scaled scores were each transformed into z scores. An average of the two z scores was then calculated to produce an overall z score for verbal memory. For the WAIS-IV symbol search and coding subtests, again, each raw score was converted into a scaled score using normative data based upon age ( $M = 10, SD = 3$ ). The sum of the two scaled scores were then transformed into a processing speed composite score ( $M = 100, SD = 15$ ). A final z score for processing speed was then calculated from the composite score. Scores on the PASAT and the BADS 6 Elements Test were converted into z scores to generate a total score for attention and executive functioning respectively. Finally, the z scores for each cognitive domain were averaged, using the mean, to create a unified measure of objective cognitive functioning ( $M = 0, SD = 1$ ).

The primary aim of this study was to determine whether self-efficacy remains predictive of perceived cognitive impairment, even when objective cognitive functioning has been controlled for. This aim was addressed using hierarchical regression analyses, with

perceived cognitive impairment as the outcome variable, and objective cognitive functioning and self-efficacy as the predictor variables. Objective cognitive functioning was entered into the regression model at stage 1 (Model 1), and self-efficacy was entered into the model at stage 2 (Model 2). This study also aimed to further examine the relationship between self-efficacy and objective cognitive functioning. Therefore correlational analyses were performed between self-efficacy and the cognitive domains of attention, processing speed, memory, and executive functioning. The data were initially examined to determine whether the assumptions for parametric analyses were met, and either Pearson's product or Spearman's rho analyses were performed, dependent upon whether the data were normally distributed.

## **Results**

### **Participants**

Descriptive statistics for demographic variables, self-efficacy, fatigue, perceived cognitive impairment, and depression are presented in Table 1. The majority of participants were female ( $n = 18$ ), and all participants were aged between 31 and 78 ( $M = 52.92$ ,  $SD = 12.96$ ). Ten participants had a diagnosis of relapsing-remitting MS (40%), nine participants had a diagnosis of secondary progressive MS (36%), and six participants had a diagnosis of primary progressive MS (24%). Participants had experienced symptoms of MS for between 33 and 480 months ( $M = 185.68$ ,  $SD = 111.28$ ), and had received a diagnosis of MS between 22 and 300 months prior to undertaking the research project ( $M = 132.16$ ,  $SD = 91.30$ ).



Table 1.

*Descriptive statistics for demographic and disease-related variables, fatigue, depression, self-efficacy, and perceived cognitive impairment*

	<u>Values (n = 25)</u>
<i>Education level</i>	
School or less	8 (32)
College course or equivalent	7 (28)
University degree or higher	10 (40)
<i>Employment Status</i>	
Employed full time	7 (28)
Unemployed	3 (12)
Retired/retired on ill-health grounds	15 (60)
<i>Ethnicity</i>	
White British	21 (84)
Welsh	1 (4)
Other ethnicity	3 (12)
<i>PROMIS-Fatigue</i>	58.85 ± 10.52 (34.7, 81.3)
<i>PHQ-9</i>	9.6 ± 7.14 (0, 26)
<i>Liverpool Self-efficacy Scale</i>	
Control subscale	15.76 ± 4.42 (7, 24)
Personal agency subscale	13 ± 3.01 (6, 20)
Total score	28.76 ± 6.95 (14, 44)
<i>NeuroQOL-Cognitive Function</i>	42.72 ± 7.72 (25.9, 56.3)

Note. Values are mean ± SD (minimum, maximum) or n (%).

Details regarding neurological impairment for the sample are provided in Table 2. Based upon the mean score on the PHQ-9, the sample was experiencing a mild to moderate level of depression. Perceived cognitive impairment and fatigue fell within one standard deviation of the population mean. Group means and standard deviations for performance on neuropsychological assessments are displayed in the appendix.

Table 2.

*Neurological impairment (MS Questionnaire<sup>19</sup>)*

	<u>(%)</u>
Require an aid to walk	48
Uses a wheelchair for almost all activities	16
Mild weakness	12
Moderate or severe weakness	64
Mildly impaired sensation	28
Moderately or severely impaired sensation	56
Mildly impaired visual acuity	4
Moderately or severely impaired visual acuity	12
Mildly uncoordinated	32
Moderately or severely uncoordinated	24
Mild difficulties with speech	12
Moderate or severe difficulties with speech	12
Mild difficulty with balance	16
Moderate or severe difficulty with balance	68
Mild spasticity and/or spasms	40
Moderate or severe spasticity and/or spasms	48
Mild difficulty with swallowing	32
Moderate or severe difficulty with swallowing	4
Difficulties with bowel or bladder function	76
Mild dizziness or vertigo	32
Moderate to severe dizziness or vertigo	12

**Regression analysis**

A hierarchical regression analysis revealed that objective cognitive functioning only explained 12% of the variance in perceived cognitive impairment, and this model (Model 1) was not significantly better than chance ( $F_{(1,23)} = 3.15, p = .089$ ). When both objective cognitive functioning and self-efficacy were entered at stage 2 (Model 2), they explained 45% of the variance and significantly contributed to the model ( $F_{(1,22)} = 8.92, p = .001$ ).

The regression analysis is detailed in Table 3.

Table 3.

*Regression analyses*

Variable	Model 1			Model 2		
	B	SE B	$\beta$	B	SE B	$\beta$
Constant	44.46	1.78	-	19.90	6.95	-
OCF	2.67	1.50	.35	-0.48	1.49	-.06
Self-efficacy	-	-	-	0.78	0.22	.70**
Adjusted R <sup>2</sup>	-	.08	-	-	.40	-
R <sup>2</sup> Change	-	.12	-	-	.33	-
F Change	-	3.15	-	-	13.05	-

Note. OCF, objective cognitive functioning; \*\* $p = .002$

**Correlational analyses**

*Correlational analysis between self-efficacy and cognitive domains*

A significant relationship between self-efficacy and processing speed was found on both the personal agency subscale and the total self-efficacy score. A significant relationship between executive function and both the control subscale and self-efficacy total score was also found. No other significant relationships were found between self-efficacy and cognitive domains. All correlational analyses are demonstrated in Table 4.

Table 4.

*Correlational analyses between self-efficacy and cognitive domains*

	Cognitive Domain			
	Attention	Processing Speed <sup>a</sup>	Memory	Executive Function
Control	.11	.33	.31	.49*
Personal agency	.31	.51**	.34	.26
Total self-efficacy	.15	.43*	.33	.42*

Note. \*\*p<. 01, \*p<. 05 (2-tailed)

All values are Spearman's rho, unless otherwise stated

<sup>a</sup> =Pearson's r

### Discussion

Extending previous research <sup>12,14</sup>, this study found self-efficacy significantly predicts perceived cognitive impairment in individuals MS, even when controlling for objective cognitive functioning. In this sample, objective cognitive functioning was not a significant predictor of perceived cognitive impairment. This may be due to discrepancy between perceived and objective cognitive impairment found in individuals with MS<sup>30</sup>. The relationship between self-efficacy and specific cognitive domains was also investigated. Unlike previous research by Jongen and colleague (2015)<sup>16</sup>, there was not a significant relationship between attention and self-efficacy, although this may be due to differences in measurement. However, this study found a significant relationship between processing speed and self-efficacy, and executive functioning and self-efficacy. One of the strengths of this study was the use of ecologically valid measures of objective cognitive functioning. Furthermore, this study adds to the current literature on self-

efficacy and objective cognitive functioning by including people with a wider variety of diagnostic subtypes.

The findings from this study have both clinical and research implications. With regard to research implications, this study was the first to examine whether self-efficacy remains predictive of perceived cognitive impairment, whilst controlling for objective cognitive functioning. This study may therefore benefit from replication to ensure the findings are robust. With regard to clinical practice, clinicians may wish to consider whether self-management interventions, aimed at enhancing self-efficacy, reduce perceived cognitive impairment. Such studies would need to be carefully evaluated to determine their effectiveness. However, this is a meaningful area of rehabilitative work that has the potential to improve health outcomes for people with MS.

#### *Study limitations*

Previous research has found perceived cognitive impairment to be associated with depression and fatigue in individuals with MS<sup>15</sup>. However, due to the relatively small sample size and therefore limited statistical power of this study, depression and fatigue were not entered into the regression analysis. In addition, no demographic or disease-related variables were entered in to the regression model. However, previous research has not found a relationship between demographic variables (including age and diagnostic subtype) and self-efficacy in a sample of people with MS<sup>1</sup>. It is therefore possible that these variables would not have significantly contributed to the regression model.

Due to the cross-sectional design of this study, it is not possible to infer the direction of causality between self-efficacy and perceived cognitive impairment. Indeed, some authors have proposed that cognitive ability may affect self-efficacy, as opposed to self-efficacy affecting cognition<sup>16</sup>. Longitudinal research would be required to address this question. This study also assessed self-efficacy for MS in terms of sense of control and personal agency, as opposed to self-efficacy specifically in regard to cognition. However, participants were aware that they had consented to take part in a study on self-efficacy and cognition, and so it is reasonable to infer that they completed the self-efficacy measure with cognition in mind. Finally, due to the relatively small sample size included in this study, one should interpret the findings with some cautiousness.

### **Conclusion**

The present study was the first to examine the role of objective cognitive functioning in the relationship between self-efficacy and perceived cognitive impairment in people with MS. This study found that self-efficacy was predictive of perceived cognitive impairment, and remained so after controlling for objective cognitive functioning. There was a significant relationship between processing speed and self-efficacy, and executive functioning and self-efficacy; this study did not find a significant relationship between attention and self-efficacy, or verbal memory and self-efficacy.

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## **Chapter 2 – Empirical Paper**

**Investigating the role of objective cognitive functioning in the relationship between self-efficacy and perceived cognitive impairment in people with Multiple Sclerosis**

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This paper will be submitted to *Archives of Physical Medicine and Rehabilitation*, and has therefore being formatted in accordance with this journal's guidelines. The submission guidelines are listed at the beginning of this chapter.

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## List of Abbreviations

**BADS:** Behavioural Assessment of the Dysexecutive Syndrome

***M:*** Mean

**MS:** Multiple Sclerosis

***n:*** Number of participants

**NeuroQol:** Quality of Life in Neurological Disorders Measure

**NHS:** National Health Service

**OCF:** Objective cognitive functioning

**PASAT:** Paced Auditory Serial Additions Test

**PHQ-9:** Patient Health Questionnaire - 9

**PROMIS:** Patient Reported Outcomes Measurement Information System

***SD:*** Standard Deviation

**WAIS:** Wechsler Adult Intelligence Scale

**WMS:** Wechsler Memory Scale

## Abstract

**Objective:** To investigate whether self-efficacy remains predictive of perceived cognitive impairment after controlling for objective cognitive functioning, and to further examine the relationship between self-efficacy and cognitive domains, as measured objectively.

**Design:** A cross-sectional design was employed.

**Setting:** General community setting within a semi-rural part of the United Kingdom.

**Participants:** A convenience sample of twenty-five participants with a diagnosis of Multiple Sclerosis. Participants were recruited via National Health Service clinics and the Multiple Sclerosis Society. Eligible participants were those with a diagnosis of Multiple Sclerosis (any subtype), aged  $\geq 18$  years, of fluent English language, and with sufficient cognitive and motor ability to complete neuropsychological assessment.

**Intervention(s):** Not applicable.

**Main Outcome Measure(s):** The main outcome measures included the Liverpool Self-efficacy Scale<sup>1</sup> as a measure of self-efficacy, and the Cognitive Function (v.2) questionnaire of the Quality of Life in Neurological Disorders (Neuro-QOL) Measures<sup>2</sup> to assess perceived cognitive impairment. Objective cognitive functioning, i.e., attention, processing speed, memory, and executive functioning, was assessed using a variety of neuropsychological measures.

**Results:** Using regression analyses, self-efficacy was found to significantly predict perceived cognitive impairment, even after controlling for objective cognitive functioning. Self-efficacy accounted for 45% of the variance in perceived cognitive impairment ( $F_{(1,22)} = 8.92, p = .001$ ). Correlational analyses revealed a significant

relationship between self-efficacy and processing speed, and self-efficacy and executive function.

**Conclusion(s):** Self-efficacy is associated with the perception of cognitive impairment in people with Multiple Sclerosis, and therefore may be an important aspect of self-management programmes.

**Key words:** Self-efficacy, cognition, Multiple Sclerosis.

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system causing inflammation, demyelination and axonal loss within the brain and spinal cord<sup>3</sup>. A review of the General Practice Research Database estimated the prevalence of MS in the U.K to be 203.4 per 100,000 population in 2010, with women accounting for 72% of the prevalence rates<sup>4</sup>. Clinical symptoms vary dependent upon the lesion site affected, and the subsequent disease course of either relapsing-remitting or progressive MS. However, symptoms can include motor, cognitive, and behavioural deficits<sup>5</sup>, and neuropsychiatric complications such as depression and anxiety<sup>6</sup>.

The research literature refers to a number of different psychological processes that may impact upon an individual's ability to adjust to life with a physical health condition, such as MS<sup>7</sup>. One of these psychological processes, grounded in social-cognitive theory, is self-efficacy. Differentiated from outcome expectancies, i.e., the understanding that performing a behaviour will lead to a specific outcome<sup>8</sup>, self-efficacy expectations refers to the degree to which an individual believes that they are able to perform a task in order to produce a desired outcome<sup>9</sup>. Self-efficacy is one of the major determinants of peoples choice of activities, how much effort they expend in a task, and how long they persist in the face of difficulties<sup>9,10</sup>. Yet, possibly due to the unpredictable nature of the disease, people with MS experience lower levels of self-efficacy than people with other physical health conditions, including spinal cord injury<sup>11</sup>.

Research suggests that self-efficacy is associated with health-related quality of life, depression, and social functioning<sup>12</sup>, as well as physical activity in people with MS<sup>13</sup>.

However, only three studies to date have investigated the relationship between self-efficacy and cognition in people with MS. Initial research examined self-efficacy in the context of perceived cognitive impairment i.e., impairment as measured by patient self-report. Research by Schmitt and colleagues in 2014 found self-efficacy to be predictive of perceived cognitive impairment in a sample of individuals with a range diagnostic subtypes<sup>12</sup>. Expanding these initial findings, longitudinal research found self-efficacy to remain predictive of perceived cognitive impairment over a three-year period<sup>14</sup>. Although depression and fatigue are associated with perceived cognitive impairment in MS<sup>15</sup>, self-efficacy continues to be predictive of perceived cognitive impairment even when these variables are controlled for<sup>14</sup>.

More recent research has begun to consider the relationship between self-efficacy and objective cognitive functioning, i.e., cognitive ability as measured using computer or clinician administered neuropsychological assessments. Using a sample of participants with clinically isolated syndrome or early relapsing-remitting MS, Jongen and colleagues (2015) found self-efficacy to be associated with power of attention, reaction time variability, and speed of memory, using a computerised battery of cognitive tests<sup>16</sup>. The findings suggest that self-efficacy positively affects performance on cognitive tests, particularly in the cognitive domains most typically affected by MS<sup>16</sup>. The authors also hypothesised that cognitive ability may impact upon self-efficacy, in that individuals with greater cognitive capacity may feel better able to manage their symptoms as compared to individuals with impaired cognition<sup>16</sup>.



Cognitive impairments are reported to occur in approximately 45-65% of people with MS, and commonly include deficits in attention, memory, and executive functioning<sup>17</sup>. The impact of cognitive impairment is wide spread, and includes a greater risk of unemployment, reduced engagement in social activities, and increased difficulties undertaking activities of everyday living<sup>18</sup>. Therefore, understanding psychological variables associated with cognition is essential in order to continue to develop self-management interventions that are grounded in the evidence base.

The primary aim of this study was to address the current gaps in the research literature by investigating whether self-efficacy remains predictive of perceived cognitive impairment, even when objective cognitive functioning has been controlled for. Secondly, this study aimed to add to the currently limited literature base by examining the relationship between self-efficacy and objective cognitive functioning using ecologically valid measurement tools.

## **Methods**

### ***Participants***

The participant sample ( $n = 25$ ) was recruited from National Health Service clinics and from local branches of the MS Society, based within a semi-rural area in North Wales, United Kingdom. Eligible participants were those with a diagnosis of MS, aged  $\geq 18$  years, of fluent English language, and with sufficient cognitive and motor ability to complete neuropsychological assessment. Exclusion criteria included co-morbid

neurological diagnoses (including diagnosis of a dementia syndrome), current substance misuse, and significant current mental health difficulties that would impact upon capacity to provide informed consent.

## ***Measures***

***Clinical Measures.*** Participants completed five questionnaire measures.

*Self-efficacy.* Self-efficacy was measured using the Liverpool Self-efficacy Scale<sup>1</sup>. This is an 11-item Likert-type scale, consisting of two domains of control and personal agency. The scale has been validated using a sample of people with MS; the authors report good internal consistency ( $\alpha = 0.81$ ) and acceptable test-retest reliability (intraclass correlation coefficient of 0.79)<sup>1</sup>. Low scores on this scale are associated with low self-efficacy.

*Perceived cognitive impairment.* The Cognitive Function questionnaire of the Quality of Life in Neurological Disorders<sup>2</sup> (Neuro-QOL) short-form measure (version 2) assesses both executive function and general concerns (e.g., attention, memory, planning, and organising), and consists of 8 items scored on a 5-point Likert scale. This short-form measure allows for raw scores to be converted into standardised T scores ( $M = 50$ ,  $SD = 10$ ). Higher scores denote less perceived cognitive difficulty.

*Multiple Sclerosis subtype and neurological impairment.* MS subtype was assessed using self-report. Where participants were unsure as to their diagnosis, their MS specialist nurse was consulted (with written consent) to obtain this information. Neurological impairment was assessed using the Multiple Sclerosis Questionnaire<sup>19</sup>. This 17-item questionnaire has been demonstrated to be highly cross-correlated with other measures of impairment in MS and is therefore recommended as a valid and accurate measure<sup>19</sup>.

*Fatigue.* The Patient-Reported Outcomes Measurement Information System (PROMIS) Fatigue short form for MS was administered to assess fatigue<sup>20</sup>. This measure includes 8 items scored using a 5-point Likert scale. Raw scores are converted to standardised T scores ( $M = 50$ ,  $SD = 10$ ). The PROMIS measures have been shown to be valid for use with people with MS<sup>21</sup>. Higher scores on this measure are associated with greater levels of fatigue.

*Depression.* Symptoms associated with depression were assessed using the Patient Health Questionnaire (PHQ-9)<sup>22</sup>. This 9-item measure is scored using a 4-point Likert-type scale. The PHQ-9 has been validated for use in a MS sample<sup>23</sup>. Higher scores are associated with greater symptoms of depression.

***Neuropsychological measures.*** Participants completed a series of neuropsychological assessments, covering a breadth of cognitive domains.

*Attention.* The Paced Auditory Serial Additions Test (PASAT)<sup>24</sup> was initially developed as a measure of information processing speed and flexibility. It has since been adapted<sup>25</sup>, and subsequently has been extensively used within the MS population as a measure of attention. Participants are presented with a series of single-digit numbers using a pre-recorded tape, and are required to add the most recent number to the one presented immediately before it. Participants are not required to keep a running total, but to provide the sum of the last two numbers heard. There are two subtests, and the numbers are presented at a rate of every three seconds on the first subtest and every two seconds on the following subtest. On each subtest, participants are presented with a total of 60

numbers. The PASAT has demonstrated good internal consistency<sup>26</sup>. High scores represent greater attentional abilities.

*Processing Speed.* The symbol search and coding subtests of the Wechsler Adult Intelligence Scale fourth edition (WAIS-IV)<sup>26</sup> were administered as a measure of speed of information processing. The symbol search subtest assesses both processing speed and visual perception. On the symbol search subtest, participants are required to scan a series of symbols presented sequentially in a row, and identify whether they match a target symbol. On the coding subtest, participants are required to translate symbols, each uniquely associated with a number, into boxes. Both the symbol search and coding subtests are timed tasks of two minutes each, and therefore participants are encouraged to work as quickly and accurately as possible. Scores on the symbol search and coding subtests are converted into a processing speed index score ( $M = 100$ ,  $SD = 15$ ). Higher scores reflect a quicker processing speed.

*Memory.* The Logical Memory subtests of the Wechsler Memory Scale fourth edition (WMS-IV)<sup>28</sup> were administered as a measure of immediate and delayed verbal memory. The researcher read two short stories, which participants were required to recall both immediately and after a 30-minute delay. There are two versions available, one for adults (16-69 years) and one for older adults (aged 65-90 years). These were administered accordingly given the participant's age. Higher scores indicate greater recall.

*Executive Function.* Executive functioning was measured using the 6 Elements Test of the Behavioural Assessment of the Dysexecutive Syndrome (BADS)<sup>29</sup>. This is a set task of ten minutes in which participants are instructed to undertake three different types of tasks, a dictation task, a picture-naming task, and an arithmetic task. Participants are

advised to adhere to specific rules throughout the task, with points deducted if the rules are not observed. Low scores represent executive dysfunction.

## **Procedure**

Ethical approval was obtained from the School of Psychology, Bangor University, and from the Research and Ethics Committee of local Health Board. Participants were recruited via three methods: Potential participants who met the eligibility criteria were approached during their routine National Health Service (NHS) MS nurse appointment, and the third author approached potential participants at their NHS clinical psychology appointment. The first author also contacted the local branches of the MS Society and presented details about the research study at Society meetings. Potential participants were provided with a bilingual (English and Welsh) information pack, containing an information sheet and an initial contact form. Interested participants were advised to return the initial contact form to the first author using a freepost envelope provided in the information pack. Upon receipt of the initial contact form, participants were contacted via telephone and a research appointment was arranged. Appointments took place within NHS premises or within the participants' own home. Written consent was obtained at the start of the appointment, and subsequently, the questionnaire and neuropsychological measures were administered. Measures were completed over 1-3 appointments as requested by the research participant to accommodate for participant fatigue. Recruitment and testing took place between September 2016 and March 2017.

## Data analyses

The Statistical Package for the Social Sciences (SPSS) version 23 was used to perform all analyses. In order to create a single measure of objective cognitive functioning, tests measuring the four individual cognitive domains (i.e., attention, processing speed, memory, executive function) were standardised and averaged, before the four cognitive domain scores were averaged to create a single measure. Specifically, the raw scores for each neuropsychological assessment were converted into standardised scores using normative data. The WMS-IV Logical Memory subtest raw scores were converted into scaled scores using normative data based upon age ( $M = 10, SD = 3$ ). These two scaled scores were each transformed into z scores. An average of the two z scores was then calculated to produce an overall z score for verbal memory. For the WAIS-IV symbol search and coding subtests, again, each raw score was converted into a scaled score using normative data based upon age ( $M = 10, SD = 3$ ). The sum of the two scaled scores were then transformed into a processing speed composite score ( $M = 100, SD = 15$ ). A final z score for processing speed was then calculated from the composite score. Scores on the PASAT and the BADS 6 Elements Test were converted into z scores to generate a total score for attention and executive functioning respectively. Finally, the z scores for each cognitive domain were averaged, using the mean, to create a unified measure of objective cognitive functioning ( $M = 0, SD = 1$ ).

The primary aim of this study was to determine whether self-efficacy remains predictive of perceived cognitive impairment, even when objective cognitive functioning has been controlled for. This aim was addressed using hierarchical regression analyses, with

perceived cognitive impairment as the outcome variable, and objective cognitive functioning and self-efficacy as the predictor variables. Objective cognitive functioning was entered into the regression model at stage 1 (Model 1), and self-efficacy was entered into the model at stage 2 (Model 2). This study also aimed to further examine the relationship between self-efficacy and objective cognitive functioning. Therefore correlational analyses were performed between self-efficacy and the cognitive domains of attention, processing speed, memory, and executive functioning. The data were initially examined to determine whether the assumptions for parametric analyses were met, and either Pearson's product or Spearman's rho analyses were performed, dependent upon whether the data were normally distributed.

## **Results**

### **Participants**

Descriptive statistics for demographic variables, self-efficacy, fatigue, perceived cognitive impairment, and depression are presented in Table 1. The majority of participants were female ( $n = 18$ ), and all participants were aged between 31 and 78 ( $M = 52.92$ ,  $SD = 12.96$ ). Ten participants had a diagnosis of relapsing-remitting MS (40%), nine participants had a diagnosis of secondary progressive MS (36%), and six participants had a diagnosis of primary progressive MS (24%). Participants had experienced symptoms of MS for between 33 and 480 months ( $M = 185.68$ ,  $SD = 111.28$ ), and had received a diagnosis of MS between 22 and 300 months prior to undertaking the research project ( $M = 132.16$ ,  $SD = 91.30$ ).

Table 1.

*Descriptive statistics for demographic and disease-related variables, fatigue, depression, self-efficacy, and perceived cognitive impairment*

	<u>Values (n = 25)</u>
<i>Education level</i>	
School or less	8 (32)
College course or equivalent	7 (28)
University degree or higher	10 (40)
<i>Employment Status</i>	
Employed full time	7 (28)
Unemployed	3 (12)
Retired/retired on ill-health grounds	15 (60)
<i>Ethnicity</i>	
White British	21 (84)
Welsh	1 (4)
Other ethnicity	3 (12)
<i>PROMIS-Fatigue</i>	58.85 ± 10.52 (34.7, 81.3)
<i>PHQ-9</i>	9.6 ± 7.14 (0, 26)
<i>Liverpool Self-efficacy Scale</i>	
Control subscale	15.76 ± 4.42 (7, 24)
Personal agency subscale	13 ± 3.01 (6, 20)
Total score	28.76 ± 6.95 (14, 44)
<i>NeuroQOL-Cognitive Function</i>	42.72 ± 7.72 (25.9, 56.3)

Note. Values are mean ± SD (minimum, maximum) or n (%).

Details regarding neurological impairment for the sample are provided in Table 2. Based upon the mean score on the PHQ-9, the sample was experiencing a mild to moderate level of depression. Perceived cognitive impairment and fatigue fell within one standard deviation of the population mean. Group means and standard deviations for performance on neuropsychological assessments are displayed in the appendix.



Table 2.

*Neurological impairment (MS Questionnaire<sup>19</sup>)*

	(%)
Require an aid to walk	48
Uses a wheelchair for almost all activities	16
Mild weakness	12
Moderate or severe weakness	64
Mildly impaired sensation	28
Moderately or severely impaired sensation	56
Mildly impaired visual acuity	4
Moderately or severely impaired visual acuity	12
Mildly uncoordinated	32
Moderately or severely uncoordinated	24
Mild difficulties with speech	12
Moderate or severe difficulties with speech	12
Mild difficulty with balance	16
Moderate or severe difficulty with balance	68
Mild spasticity and/or spasms	40
Moderate or severe spasticity and/or spasms	48
Mild difficulty with swallowing	32
Moderate or severe difficulty with swallowing	4
Difficulties with bowel or bladder function	76
Mild dizziness or vertigo	32
Moderate to severe dizziness or vertigo	12

**Regression analysis**

A hierarchical regression analysis revealed that objective cognitive functioning only explained 12% of the variance in perceived cognitive impairment, and this model (Model 1) was not significantly better than chance ( $F_{(1,23)} = 3.15, p = .089$ ). When both objective cognitive functioning and self-efficacy were entered at stage 2 (Model 2), they explained 45% of the variance and significantly contributed to the model ( $F_{(1,22)} = 8.92, p = .001$ ).

The regression analysis is detailed in Table 3.

Table 3.

*Regression analyses*

Variable	Model 1			Model 2		
	B	SE B	$\beta$	B	SE B	$\beta$
Constant	44.46	1.78	-	19.90	6.95	-
OCF	2.67	1.50	.35	-0.48	1.49	-.06
Self-efficacy	-	-	-	0.78	0.22	.70**
Adjusted R <sup>2</sup>	-	.08	-	-	.40	-
R <sup>2</sup> Change	-	.12	-	-	.33	-
F Change	-	3.15	-	-	13.05	-

Note. OCF, objective cognitive functioning; \*\* $p = .002$

**Correlational analyses**

*Correlational analysis between self-efficacy and cognitive domains*

A significant relationship between self-efficacy and processing speed was found on both the personal agency subscale and the total self-efficacy score. A significant relationship between executive function and both the control subscale and self-efficacy total score was also found. No other significant relationships were found between self-efficacy and cognitive domains. All correlational analyses are demonstrated in Table 4.

Table 4.

*Correlational analyses between self-efficacy and cognitive domains*

	Cognitive Domain			
	Attention	Processing Speed <sup>a</sup>	Memory	Executive Function
Control	.11	.33	.31	.49*
Personal agency	.31	.51**	.34	.26
Total self-efficacy	.15	.43*	.33	.42*

Note. \*\*p<. 01, \*p<. 05 (2-tailed)

All values are Spearman's rho, unless otherwise stated

<sup>a</sup> =Pearson's r

### Discussion

Extending previous research <sup>12,14</sup>, this study found self-efficacy significantly predicts perceived cognitive impairment in individuals MS, even when controlling for objective cognitive functioning. In this sample, objective cognitive functioning was not a significant predictor of perceived cognitive impairment. This may be due to discrepancy between perceived and objective cognitive impairment found in individuals with MS<sup>30</sup>. The relationship between self-efficacy and specific cognitive domains was also investigated. Unlike previous research by Jongen and colleague (2015)<sup>16</sup>, there was not a significant relationship between attention and self-efficacy, although this may be due to differences in measurement. However, this study found a significant relationship between processing speed and self-efficacy, and executive functioning and self-efficacy. One of the strengths of this study was the use of ecologically valid measures of objective cognitive functioning. Furthermore, this study adds to the current literature on self-

efficacy and objective cognitive functioning by including people with a wider variety of diagnostic subtypes.

The findings from this study have both clinical and research implications. With regard to research implications, this study was the first to examine whether self-efficacy remains predictive of perceived cognitive impairment, whilst controlling for objective cognitive functioning. This study may therefore benefit from replication to ensure the findings are robust. With regard to clinical practice, clinicians may wish to consider whether self-management interventions, aimed at enhancing self-efficacy, reduce perceived cognitive impairment. Such studies would need to be carefully evaluated to determine their effectiveness. However, this is a meaningful area of rehabilitative work that has the potential to improve health outcomes for people with MS.

#### *Study limitations*

Previous research has found perceived cognitive impairment to be associated with depression and fatigue in individuals with MS<sup>15</sup>. However, due to the relatively small sample size and therefore limited statistical power of this study, depression and fatigue were not entered into the regression analysis. In addition, no demographic or disease-related variables were entered in to the regression model. However, previous research has not found a relationship between demographic variables (including age and diagnostic subtype) and self-efficacy in a sample of people with MS<sup>1</sup>. It is therefore possible that these variables would not have significantly contributed to the regression model.

Due to the cross-sectional design of this study, it is not possible to infer the direction of causality between self-efficacy and perceived cognitive impairment. Indeed, some authors have proposed that cognitive ability may affect self-efficacy, as opposed to self-efficacy affecting cognition<sup>16</sup>. Longitudinal research would be required to address this question. This study also assessed self-efficacy for MS in terms of sense of control and personal agency, as opposed to self-efficacy specifically in regard to cognition. However, participants were aware that they had consented to take part in a study on self-efficacy and cognition, and so it is reasonable to infer that they completed the self-efficacy measure with cognition in mind. Finally, due to the relatively small sample size included in this study, one should interpret the findings with some cautiousness.

### **Conclusion**

The present study was the first to examine the role of objective cognitive functioning in the relationship between self-efficacy and perceived cognitive impairment in people with MS. This study found that self-efficacy was predictive of perceived cognitive impairment, and remained so after controlling for objective cognitive functioning. There was a significant relationship between processing speed and self-efficacy, and executive functioning and self-efficacy; this study did not find a significant relationship between attention and self-efficacy, or verbal memory and self-efficacy.

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## Appendices

1. Funnel plot for publication bias (fatigue)
2. Funnel plot for publication bias (self-efficacy)
3. Empirical paper – Cognitive profile of research participants
4. Bangor University, School of Psychology Ethics Committee Approval
5. NHS IRAS Research Ethics Committee Form
6. Initial Research Ethics Committee Approval Letter
7. Research and Development Approval Letter
8. Notification of non-substantial amendments and corresponding Research Ethics Committee approval letters
9. Initial contact form – English
10. Initial contact form - Welsh
11. Participant information sheet – English
12. Participant information sheet – Welsh
13. Participant consent form – English
14. Participant consent form – Welsh
15. Demographic questionnaire
16. MS questionnaire
17. Liverpool self-efficacy scale
18. PROMIS-Fatigue
19. Patient Health Questionnaire – 9
20. NeuroQol - Cognitive Function
21. Word counts

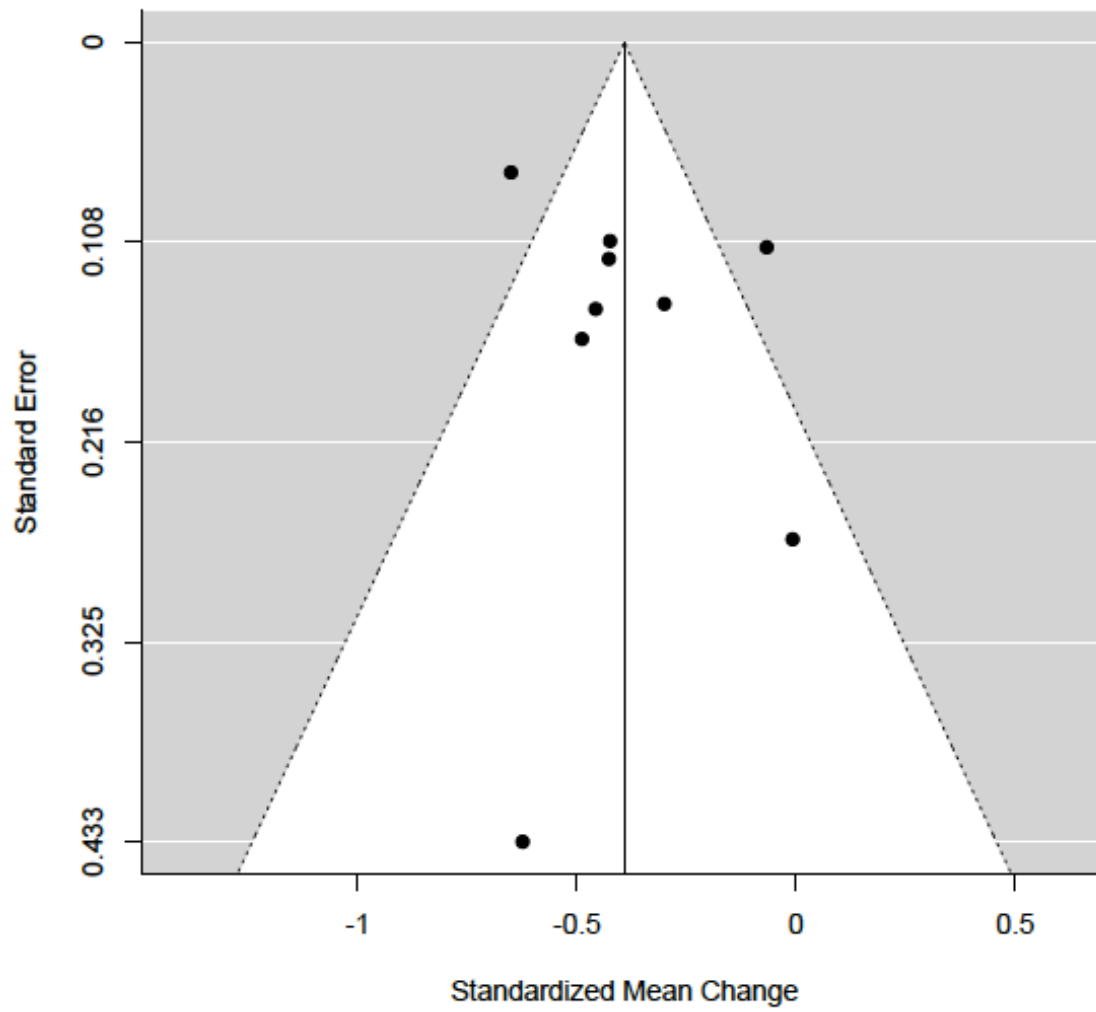


Figure 1. Funnel plot for fatigue

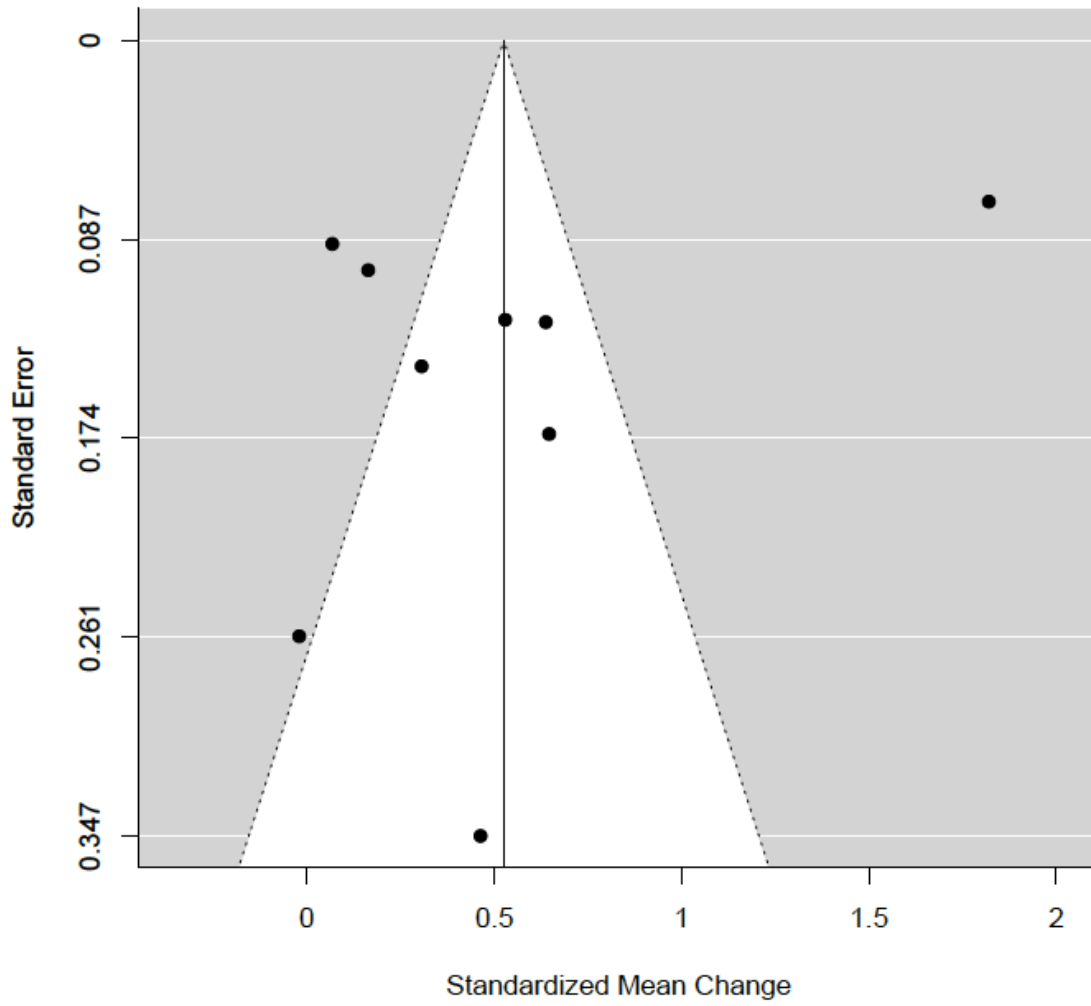


Figure 2. Funnel plot for self-efficacy

Table 1.

*Means and standard deviations for neuropsychological assessment scores (non transformed)*

<i>Measure</i>	<i>M ± SD</i>	<i>Range</i>
PASAT A 3" Total Correct Raw Score	35.83 ± 12.57	16 - 60
PASAT A 2" Total Correct Raw Score	28.38 ± 9.65	10 - 50
WAIS-IV Symbol Search	25.44 ± 7.32	9 - 38
WAIS-IV Coding	56.75 ± 18.11	32 - 101
WMS-IV Logical Memory 1 (Adults)	24.55 ± 6.91	13 - 36
WMS-IV Logical Memory 1 (Older adults)	34.25 ± 10.15	22 - 44
WMS-IV Logical Memory 2 (Adults)	19.65 ± 8.06	5 - 34
WMS-IV Logical Memory 2 (Older adults)	18.50 ± 8.10	11 - 26
BADS 6 Elements Profile Score	3.08 ± 1.32	0 - 4

Note. BADS, Behavioural Assessment of the Dysexecutive Syndrome; PASAT, Paced Auditory Serial Additions Test; WAIS, Wechsler Adult Intelligence Scale; WMS, Wechsler Memory Scale.

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)  
Self-efficacy and cognition in Multiple Sclerosis

1. Is your project research?

Yes  No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation?  Yes  No
- b) Will you be taking new human tissue samples (or other human biological samples)?  Yes  No
- c) Will you be using existing human tissue samples (or other human biological samples)?  Yes  No

3. In which countries of the UK will the research sites be located?(Tick all that apply)

- England
- Scotland

- Wales  
 Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England  
 Scotland  
 Wales  
 Northern Ireland  
 This study does not involve the NHS

4. Which applications do you require?

**IMPORTANT:** If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- IRAS Form  
 NHS/HSC Research and Development offices  
 Social Care Research Ethics Committee  
 Research Ethics Committee  
 Confidentiality Advisory Group (CAG)  
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

5. Will any research sites in this study be NHS organisations?

- Yes  No

6. Do you plan to include any participants who are children?

- Yes  No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes  No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes  No



<b>8. Is the study or any part of it being undertaken as an educational project?</b> <input checked="" type="radio"/> Yes <input type="radio"/> No  Please describe briefly the involvement of the student(s): The student will be involved in all aspects of the project.
<b>8a. Is the project being undertaken in part fulfillment of a PhD or other doctorate?</b> <input checked="" type="radio"/> Yes <input type="radio"/> No
<b>10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?</b> <input type="radio"/> Yes <input checked="" type="radio"/> No
<b>11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?</b> <input type="radio"/> Yes <input checked="" type="radio"/> No

## Site-Specific Information Form (NHS sites)

**Is the site hosting this research a NHS site or a non-NHS site?** NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.

- NHS site  
 Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:  
Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.

Short title: Self-efficacy and cognition in Multiple Sclerosis

Chief Investigator:      Title Forename/Initials Surname  
Mrs Laura E                      Spencer

Name of NHS Research Ethics Committee to which application for ethical review is being made:  
WalesRECS

Project reference number from above REC:                      15/WA/0186

1-1. Give the name of the NHS organisation responsible for this research site

Betsi Cadwaladr University Health Board

1-3. In which country is the research site located?

- England  
 Wales  
 Scotland  
 Northern Ireland

1-4. Is the research site a GP practice or other Primary Care Organisation?

- Yes     No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title:  Principal Investigator  
 Local Collaborator

Title Forename/Initials Surname  
Mrs Laura E Spencer

Post Trainee Clinical Psychologist

Qualifications BSc Psychology with Clinical and Health Psychology, University of Wales, 2010  
MSc Foundations of Clinical Psychology, Bangor University, 2011

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Work Telephone 07972763722

Mobile

Fax

a) Approximately how much time will this person allocate to conducting this research? Please provide your response in terms of Whole Time Equivalents (WTE).  
0.2WTE

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation?  Yes  No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

Location	Activity/facilities
1 The North Wales Brain Injury Service, Hesketh Road, Colwyn Bay, LL29 8AY	All participant testing will take place within the premises including the administration of neuropsychological measures and questionnaires.
2 Should participants be unable to attend the North Wales Brain Injury Service, or prefer to be seen at home, then a home visit will be conducted.	All participant testing will take place within the participants home, including the administration of neuropsychological measures and questionnaires.
3 Other NHS site	Where participants are unable to attend the North Wales Brain Injury Service, and would not like to be seen at home, an appointment in another NHS location within Betsi Cadwaladr University Health Board may be arranged depending upon room availability, eg., within the participants local GP surgery.

6. Please give details of all other members of the research team at this site.

1	
	Title Forename/Initials Surname Dr Craig Roberts
Work E-mail	Craig.Roberts@Wales.nhs.uk
Employing organisation	Betsi Cadwaladr University Health Board
Post	Consultant Neuropsychologist
Qualifications	2005 Doctorate In Clinical Psychology University of Wales, Bangor 2000 MA in Clinical Psychology (Cum Laude) University of Stellenbosch 1996 Hon. BA in Psychology (Cum Laude) University of Stellenbosch 1993 B. Economic Sciences University of Stellenbosch
Role in research team:	other (please specify) Academic Supervisor
a) Approximately how much time (approximately) will this person allocate to conducting this research? Please provide your response in terms of Whole Time Equivalents (WTE). 0.2WTE	
b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? <input checked="" type="radio"/> Yes <input type="radio"/> No	

8. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes  No

7. What is the proposed local start and end date for the research at this site?

Start date: 04/07/2016  
End date: 04/07/2017  
Duration (Months): 12

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. (These include seeking consent, interviews, non-clinical observations and use of questionnaires.)

Columns 1-4 have been completed with information from A10 as below:

- Total number of interventions/procedures to be received by each participant as part of the research protocol.
- If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?
- Average time taken per intervention (minutes, hours or days)
- Details of who will conduct the procedure, and where it will take place

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Participant approached to	1	0	2	MS clinicians will approach	MS Clinicians at the MS clinics,

potentially be included in the research study	minutes	participants with details regarding the study and will provide an envelope containing the study information sheet(in English and Welsh), the initial contact form, and a free post envelope. This stage will take place in the MS clinic.	i.e., MS nurse, occupational therapist, physiotherapist, consultant neurologist.
Telephone conversation to determine consent to participate.	1 0 5 minutes	CI will telephone potential participants and answer any questions they may have, and determine consent. A convenient date, time, and location will be arranged to undertake the assessment.	Laura Spencer
Questionnaire measures	8 0 40 minutes	The participant will provide written consent, and will complete the demographic questionnaire, the NeuroQOL, Patient Health Questionnaire-9, PROMIS-FatigueMS, MS Questionnaire, Liverpool Self-efficacy scale, and the BADS Dysexecutive Questionnaire. This will take place at the North Wales Brain Injury Service, other BCUHB premises, or at the participants own home.	Laura Spencer
Neuropsychological measures	6 0 50 minutes	The CI will administer the DKEFS-Verbal Fluency and Trail Making Tests, Paced Auditory Serial Additions Test, The WMS-IV List Learning and Logical Memory tests, WAIS-IV Coding and Symbol Search tests, and the BADS Modified 6 Elements test.This will take place at the North Wales Brain Injury Service, other BCUHB premises, or at the participants own home.	Laura Spencer
Debrief	1 0 5 minutes	The CI will verbally debrief the participant. This will take place at the North Wales Brain Injury Service, other BCUHB premises, or at the participants own home.	Laura Spencer
Participant will be asked to complete the initial contact form	1 0 5 mins	Potential participants who are interested in the study will be advised to return the initial contact form to the CI using the free post envelope provided.This will take place at the patient's own home.	Laura Spencer

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

Yes  No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/complexes is it expected will be recruited/obtained from this site?

It is hoped that 33 participants will be recruited.

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

The CI will present the research project to the multi-disciplinary team at the MS clinic at Ysbyty Glan Gilyd. Clinicians will be asked to identify participants who meet the inclusion criteria for the study from their current caseloads. Potential participants will be approached initially by their clinician to: 1) Determine whether they are interested in the study, 2) Determine whether they would be happy to receive a study information sheet (either in English or Welsh) which may be provided immediately during the appointment, 3) Determine whether they would be happy to be contacted by the CI approximately one week later to discuss the project. This contact will also be an opportunity for potential participants to ask any questions regarding the project and a brief discussion of the research process. Before participating in the project, participants will provide written consent.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Mrs Laura Spencer (CI)	The CI has previous experience of obtaining consent for research purposes during involvement in two previous research projects as part of her BSc and MSc in clinical psychology. The CI is fully informed about the nature of the study, and is aware of the process of taking consent.

16-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Yes, Involving People, through Health & Care Research Wales:

(Tel: 02920 230457  
research-involvement@wales.nhs.uk  
Health and Care Research Wales Support Centre, Castlebridge 4, 15 – 19 Cowbridge Road East, Cardiff, CF11 9AB)

16-2. Is there a contact point where potential participants can seek further details about this specific research project?

Yes, The CI (Mrs Laura Spencer) and Dr. Craig Roberts can be approached should potential participants wish to seek further details about the study. Both contacts are members of the research team.

18. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

Participants deemed not able to provide informed consent will not be approached to take part in the study. Capacity to consent will be determined by the patients treating clinician at the MS clinic. All study information will be available in both English and Welsh. Participants who are not fluent in English will not be approached to participate as the neuropsychological measures are only available for use in the English language.

**18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?**

Participants GP and MS Nurse (Mrs Yvonne Copleland) will be informed via writing that the participant has consented to take part in the research. Informed written consent to do so will be obtained from all participants prior to their involvement. Should any participants experience any distress as a result of taking part in the research, their GP and MS Nurse may be contacted again, with the participants consent, to ensure the well being of the participant.

**18. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?**

No direct risks are anticipated to participants or staff.

As participants will be asked to complete a series of questionnaires about their symptoms of MS, this has the potential to cause some distress. Furthermore, completion of neuropsychological assessments has the potential to cause some distress. As the CI is a trainee clinical psychologist, it is anticipated that any distress may be resolved immediately within the testing session. However, all participants will also be advised that they should contact their GP and/or MS clinician should they experience any distress. Furthermore, participants GP and MS Nurse (Mrs Yvonne Copleland) will be informed via writing that the participant has consented to take part in the research.

As participants are required to complete neuropsychological assessments, they may request feedback upon their scores. Participants will be provided with this feedback by the CI and/or academic supervisor.

Once the testing session has finished participant's will receive a full debrief regarding the study and it's aims. Participants who consent to do so will also receive a newsletter outlining the main results of the study.

Possible risks to the research team include those associated with lone working. Where possible, the testing session will take place at the North Wales Brain Injury Service in Colwyn Bay or other NHS premises. Where testing occurs within the participants own homes, the BCUHB Lone Worker Policy will be adhered to.

The research team have been trained in basic life support.

No additional staffing will be required.

**20. What are the arrangements for the supervision of the conduct of the research at this site? Please give the name and contact details of any supervisor not already listed in the application.**

The CI will be supervised by Dr. Craig Roberts. The North Wales Clinical Psychology Programme (NWCPP) has a monitoring role regarding the study. The CI is required to submit 6-monthly reports to the NWCPP until completion of the study in June 2017.

**21. What external funding will be provided for the research at this site?**

- Funded by commercial sponsor  
 Other funding  
 No external funding

How will the costs of the research be covered?

The costs of the research will be covered by the North Wales Clinical Psychology Programme. The CI is a trainee clinical psychologist undertaking a doctorate in clinical psychology with the programme.

**23. Authorisations required prior to R&D approval**

The local research team are responsible for contacting the local NHS R&D office about the research project. Where the research project is proposed to be coordinated centrally and therefore there is no local research team, it is the

responsibility of the central research team to instigate this contact with local R&D.

NHS R&D offices can offer advice and support on the set-up of a research project at their organisation, including information on local arrangements for support services relevant to the project. These support services may include clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers depending on the nature of the research.

Obtaining the necessary support service authorisations is not a pre-requisite to submission of an application for NHS research permission, but all appropriate authorisations must be in place before NHS research permission will be granted. Processes for obtaining authorisations will be subject to local arrangements, but the minimum expectation is that the local R&D office has been contacted to notify it of the proposed research project and to discuss the project's needs prior to submission of the application for NHS research permission via IRAS.

Failure to engage with local NHS R&D offices prior to submission may lead to unnecessary delays in the process of this application for NHS research permissions.

**Declaration:**

I confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services. I understand that failure to engage with the local NHS R&D office before submission of this application may result in unnecessary delays in obtaining NHS research permission for this project.

Please give the name and contact details for the NHS R&D office staff member you have discussed this application with:

Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

	Title	Forename/Initials	Surname
	Ms	Debra	Slater
Work E-mail	Debra.Slater@Wales.nhs.uk		
Work Telephone	01248384877		

**Declaration by Principal Investigator or Local Collaborator**

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.



8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by Mrs Laura Spencer on 08/07/2016 09:46.

Job Title/Post: Trainee Clinical Psychologist  
Organisation: Betsi Cadwaladr University health Board  
Email: psp4eb@bangor.ac.uk

## Ethical approval granted for 2016-15686 Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis



ethics@bangor.ac.uk

Thu 02/06/2016, 10:23

Laura Elizabeth Spencer ▾



Reply all | ▾

Inbox

Dear Laura,

2016-15686 Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis

Your research proposal number 2016-15686 has been reviewed by the Psychology Ethics and Research Committee and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.



Ymchwil Iechyd  
a Gofal Cymru  
Health and Care  
Research Wales

Gwasanaeth Moezeg Ymchwil  
Research Ethics Service



**Pwyllgor Moezeg Ymchwil Cymru 5**  
**Wales Research Ethics Committee 5**  
**Bangor**

Clinical Academic Office  
Ysbyty Gwynedd Hospital  
Betsi Cadwaladr University Health Board  
Bangor, Gwynedd  
LL57 2PW  
Telephone/ Facsimile: 01248 - 384.877  
Email: [Rossela.Roberts@wales.nhs.uk](mailto:Rossela.Roberts@wales.nhs.uk)

24 June 2016

Mrs Laura E Spencer  
Trainee Clinical Psychologist  
Betsi Cadwaladr University Health Board  
Clinical Psychology Programme  
School of Psychology  
Bangor University, Bangor, Gwynedd  
LL57 2AS [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Dear Mrs Spencer,

**Study title:** Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
**REC reference:** 16/WA/0186  
**IRAS project ID:** 196799

Thank you for your letter of 20 June 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Dr Rossela Roberts, [rossela.roberts@wales.nhs.uk](mailto:rossela.roberts@wales.nhs.uk)

#### **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.

### **Conditions of the favourable opinion**

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, [www.hra.nhs.uk](http://www.hra.nhs.uk) or at <http://www.rforum.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 management permissions from host organisations

### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**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).**

### **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" above).

## 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>
REC Application Form [REC_Form_03062016]	-	03 June 2016
Research protocol or project proposal [Research protocol]	3	20 June 2016
Response to Request for Further Information [Response to request for further information]	-	20 June 2016
GP/consultant information sheets or letters	2	26 May 2016
Other [Letter to G.P and other healthcare professionals]	1	20 June 2016
Other [Participant G.P details]	1	20 June 2016
Other [Initial contact form]	3	20 June 2016
Participant consent form [Participant consent form]	3	20 June 2016
Participant information sheet [Participant Information Sheet]	3	20 June 2016
Validated questionnaire [Patient Health Questionnaire]	1	26 May 2016
Validated questionnaire [PROMIS Fatigue MS]	1	26 May 2016
Validated questionnaire [MS Questionnaire]	1	26 May 2016
Validated questionnaire [Liverpool Self-efficacy scale]	1	26 May 2016
Validated questionnaire [NeuroQol Cognitive function]	1	26 May 2016
Non-validated questionnaire [Demographic Questionnaire]	2	26 May 2016
Summary CV for Chief Investigator (CI) [Laura Spencer]	1	26 May 2016
Summary CV for supervisor [Craig Roberts]	1	26 May 2016
Evidence of Sponsor insurance or indemnity [Insurance certificate]	-	20 July 2015

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

### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

### HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>16/WA/0186</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project.

Yours sincerely



**Dr Philip Wayman White, MBChB, MRSM**  
**Chair**  
E-mail: [rossela.roberts@wales.nhs.uk](mailto:rossela.roberts@wales.nhs.uk)

*Enclosures:* "After ethical review – guidance for researchers"

Copy: Sponsor: Hefin Francis  
School of Psychology  
Adeilad Brigantia, Penrallt Road  
Bangor University, Bangor  
LL57 2GD [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk)

R&D Office: Miss Debra Slater  
R&D Office  
Betsi Cadwaladr University Health Board  
Ysbyty Gwynedd,  
Bangor, LL57 2PW [debra.slater@wales.nhs.uk](mailto:debra.slater@wales.nhs.uk)



Betsi Cadwaladr University Health Board  
Ysbyty Gwynedd  
Clinical Academic Office  
Bangor, Gwynedd  
LL57 2PW

Mrs Laura Spencer  
Clinical Psychology Programme#  
School of Psychology  
Bangor University  
Bangor  
LL57 2AS

[psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Chairman/Cadeirydd – Dr Nefyn Williams PhD, FRCGP  
Email: [rossela.roberts@wales.nhs.uk](mailto:rossela.roberts@wales.nhs.uk)  
[debra.slater@wales.nhs.uk](mailto:debra.slater@wales.nhs.uk)  
[sion.lewis@wales.nhs.uk](mailto:sion.lewis@wales.nhs.uk)  
Tel/Fax: 01248 384 877

09<sup>th</sup> August 2016

Dear Mrs Laura Spencer

Re: Confirmation that R&D governance checks are complete / R&D approval granted

Study Title            Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
IRAS reference        196799  
REC reference         16/WA/0186

The above research project was reviewed at the meeting of the BCUHB R&D Internal Review Panel

Thank you for responding to the Panel's request for further information. The R&D office considered the response on behalf of the Panel and is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the revised application.

The Internal Review Panel is pleased to confirm that all governance checks are now complete and to grant approval to proceed at Betsi Cadwaladr University Health Board sites as described in the application.

The documents reviewed and approved are listed below:

Document:	Version:	Date:
R&D Form	V5.3.1	04/07/2016
SSI Form	V5.3.1	08/07/2016
Protocol	V3	20/06/2016
Information sheet	V4	08/08/2016
Consent Form	V4	08/08/2016
Initial contact form	V4	08/08/2016
Letter to Clinicians	V2	26/05/2016
Letter to GP and other Healthcare Professionals	V1	20/06/2016
Summary CV: Roberts		26/05/2016
Summary CV: Spencer		20/02/2016
Evidence of Insurance (UMAL)		Expires 31/07/2016
REC Favourable Opinion		24/06/2016

The study should not commence until the Ethics Committee reviewing the research has confirmed final ethical approval ('favourable opinion').

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (2009). An electronic link to this document is provided on the BCUHB R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the Betsi Cadwaladr University Health Board.

If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that the Chief Investigator will be required to regularly upload recruitment data onto the portfolio database. To apply for adoption onto the NISCHR CRP, please go to: <http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979>. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at: <http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571> and/or from your NHS R&D office colleagues.

To upload recruitment data, please follow this link: [http://www.crnc.nihr.ac.uk/about\\_us/processes/portfolio/p\\_recruitment](http://www.crnc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment). Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office.

If you need any support in uploading this data, please contact [debra.slater@wales.nhs.uk](mailto:debra.slater@wales.nhs.uk) or [sion.lewis@wales.nhs.uk](mailto:sion.lewis@wales.nhs.uk)

If you would like further information on any other points covered by this letter please do not hesitate to contact me.

On behalf of the Panel, I would like to take this opportunity to wish you every success with your research.

Yours sincerely,



Dr. Rossela Roberts, MICR, CSci  
Clinical Governance Officer (R&D/Ethics)

Copy to:

Academic Supervisor: Dr Craig Roberts  
The North Wales Brain Injury Service  
Hesketh road  
Colwyn Bay  
Conwy  
LL29 8AY [craig.roberts@wales.nhs.uk](mailto:craig.roberts@wales.nhs.uk)

Sponsor: Hefin Francis  
School of Psychology#Brigantia Buildings  
Bangor University  
Bangor  
LL57 2AS [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk)



**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**Notification of Non-Substantial/Minor Amendments(s) for NHS Studies**

This template must only be used to notify NHS/HSC R&D office(s) of amendments, which are NOT categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

**Instructions for using this template**

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

**1. Study Information**

Full title of study:	Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis
IRAS Project ID:	196799
Sponsor Amendment Notification number:	1
Sponsor Amendment Notification date:	18.08.2016
<b>Details of Chief Investigator:</b>	
Name (first name and surname)	Laura Spencer
Address:	3 South Street, Llanfairfechan, Conwy
Postcode:	LL33 0RF
Contact telephone number:	07972763722
Email address:	psp4eb@bangor.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	Mr. Hefin Francis
Contact email address:	h.francis@bangor.ac.uk
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	Wales
If England led is the study going through CSP? <i>delete as appropriate</i>	N/A
Name of lead R&D office:	Debra Slater Research Governance Officer

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

	BCUHB Ysbyty Gwynedd Penrhos Gamedd Bangor LL57 2PW
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Gwasanaeth Moeleg Ymchwil  
Research Ethics Service



Pwyllgor Moeleg Ymchwil Cymru 5  
Wales Research Ethics Committee 5  
Bangor

Clinical Academic Office  
Ysbyty Gwynedd Hospital  
Betsi Cadwaladr University Health Board  
Bangor, Gwynedd  
LL57 2PW  
Telephone/ Facsimile: 01248 - 384.877  
Email: [Rosalea.Roberts@wales.nhs.uk](mailto:Rosalea.Roberts@wales.nhs.uk)

18 August 2016

Mrs Laura E Spencer  
Trainee Clinical Psychologist  
Betsi Cadwaladr University Health Board  
Clinical Psychology Programme  
School of Psychology  
Bangor University,  
Bangor, Gwynedd  
LL57 2AS [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Dear Mrs Spencer

**Study title:** Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
**REC reference:** 16/WA/0186  
**Amendment number:** 01  
**Amendment date:** 18 August 2016  
**IRAS project ID:** 196799

Thank you for your letter of 18 August 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

#### Documents received

The documents received were as follows:

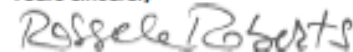
Document	Version	Date
Notice of Minor Amendment	01	18 August 2016
Other [Initial contact form ]	4	08 August 2016
Participant consent form	4	08 August 2016
Participant information sheet (PIS)	4	08 August 2016

**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.

<b>16/WA/0186:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely

  
**Dr Rossela Roberts**  
**Research Ethics Service Manager**

Email: [Rossela.Roberts@wales.nhs.uk](mailto:Rossela.Roberts@wales.nhs.uk)

Copy:	Sponsor:	Hefin Francis School of Psychology Adeliad Brigantia Penrallt Road Bangor University Bangor Gwynedd LL57 2GD <a href="mailto:h.francis@bangor.ac.uk">h.francis@bangor.ac.uk</a>
	R&D Office:	Miss Debra Slater R&D Office Betsi Cadwaladr University Health Board Ysbyty Gwynedd Bangor Gwynedd LL57 2PW <a href="mailto:debra.slater@wales.nhs.uk">debra.slater@wales.nhs.uk</a>

**Partner Organisations:**  
 Health Research Authority, England  
 NHS Research Scotland  
 HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England  
 NISCHR Permissions Co-ordinating Unit, Wales

### Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template must only be used to notify NHS/HSC R&D office(s) of amendments, which are NOT categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

#### Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

#### 1. Study Information

Full title of study:	Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis
IRAS Project ID:	196799
Sponsor Amendment Notification number:	2
Sponsor Amendment Notification date:	19.09.2016
<b>Details of Chief Investigator:</b>	
Name (first name and surname)	Laura Spencer
Address:	3 South Street, Llanfairfechan, Conwy
Postcode:	LL33 0RF
Contact telephone number:	07972763722
Email address:	psp4eb@bangor.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	Mr. Hefin Francis
Contact email address:	h.francis@bangor.ac.uk
<b>Details of Lead Nation:</b>	
Name of lead nation delete as appropriate	Wales
If England led is the study going through CSP? delete as appropriate	N/A
Name of lead R&D office:	Debra Slater Research Governance Officer

**Partner Organisations:**

Health Research Authority, England

NIHR Clinical Research Network, England

NHS Research Scotland

NISCHR Permissions Co-ordinating Unit, Wales

HSC Research & Development, Public Health Agency, Northern Ireland

	BCUHB Ysbyty Gwynedd Penrhos Garnedd Bangor LL57 2PW
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**Gwasanaeth Moeseg Ymchwil  
Research Ethics Service**



**Pwyllgor Moeseg Ymchwil Cymru 5  
Wales Research Ethics Committee 5  
Bangor**

Clinical Academic Office  
Ysbyty Gwynedd Hospital  
Betsi Cadwaladr University Health Board  
Bangor, Gwynedd  
LL57 2PW  
Telephone/ Facsimile: 01248 - 384.877  
Email: [Rossela.Roberts@wales.nhs.uk](mailto:Rossela.Roberts@wales.nhs.uk)

20 September 2016

Mrs Laura E Spencer  
Trainee Clinical Psychologist  
Betsi Cadwaladr University Health Board  
Clinical Psychology Programme  
School of Psychology  
Bangor University  
Bangor  
Gwynedd  
LL57 2AS

[psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Dear Mrs Spencer

**Study title:** Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
**REC reference:** 16/WA/0186  
**Amendment number:** 02  
**Amendment date:** 19 September 2016  
**IRAS project ID:** 196799

Thank you for your letter of 19 September 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

Document	Version	Date
Interview schedules or topic guides for participants [Rey Auditory Verbal Learning Test]	1	19 September 2016
Notice of Minor Amendment	02	19 September 2016
Research protocol or project proposal [Protocol V4]	4	19 September 2016

**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.

**18/WA/0186: Please quote this number on all correspondence**

Yours sincerely

  
Dr Rosalea Roberts  
Research Ethics Service Manager

Email: [Rosalea.Roberts@wales.nhs.uk](mailto:Rosalea.Roberts@wales.nhs.uk)

Copy: Sponsor: Heffn Francis  
School of Psychology  
Adelard Brigantia, Penrill Road  
Bangor University  
Bangor  
Gwynedd  
LL57 2GD [h.francois@bangor.ac.uk](mailto:h.francois@bangor.ac.uk)

R&D Office: Miss Debra Slater  
Clinical Academic Office  
Betsi Cadwaladr University Health Board  
Ysbyty Gwynedd  
Bangor  
Gwynedd  
LL57 2PW [debra.slater@wales.nhs.uk](mailto:debra.slater@wales.nhs.uk)



**Partner Organisations:**

Health Research Authority, England  
 NHS Research Scotland

NIHR Clinical Research Network, England  
 NISCHR Permissions Co-ordinating Unit, Wales  
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**1. Study Information**

Full title of study:	Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis
IRAS Project ID:	196799
Sponsor Amendment Notification number:	3
Sponsor Amendment Notification date:	11.10.2016
<b>Details of Chief Investigator:</b>	
Name (first name and surname)	Laura Spencer
Address:	3 South Street, Llanfairfechan, Conwy
Postcode:	LL33 0RF
Contact telephone number:	07972763722
Email address:	psp4eb@bangor.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	Mr. Hefin Francis
Contact email address:	h.francis@bangor.ac.uk
<b>Details of Lead Nation:</b>	
Name of lead nation delete as appropriate	Wales
If England led is the study going through CSP? delete as appropriate	N/A
Name of lead R&D office:	Debra Slater Research Governance Officer

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

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Ymchwil Iechyd  
a Gofal Cymru  
Health and Care  
Research Wales

Gwasanaeth Moeleg Ymchwil  
Research Ethics Service



Pwyllgor Moeleg Ymchwil Cymru 5  
Wales Research Ethics Committee 5  
Bangor

Clinical Academic Office  
Ysbyty Gwynedd Hospital  
Betsi Cadwaladr University Health Board  
Bangor, Gwynedd  
LL57 2PW  
Telephone/ Facsimile: 01248 - 384.877  
Email: [Roszela.Roberts@wales.nhs.uk](mailto:Roszela.Roberts@wales.nhs.uk)

24 October 2016

Mrs Laura E Spencer  
Trainee Clinical Psychologist  
Betsi Cadwaladr University Health Board  
Clinical Psychology Programme  
School of Psychology  
Bangor University,  
Bangor,  
Gwynedd  
LL57 2AS [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Dear Mrs Spencer

**Study title:** Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
**REC reference:** 16/WA/0186  
**Amendment number:** 03  
**Amendment date:** 11 October 2016  
**IRAS project ID:** 196799

Thank you for your letter of 11 October 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees.

The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

#### Documents received

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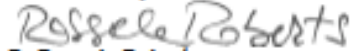
Document	Version	Date
Notice of Minor Amendment	03	11 October 2016
Research protocol or project proposal	5	11 October 2016

**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.

<b>16/WA/0186:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely



**Dr Rossella Roberts**  
**Research Ethics Service Manager**

Email: [Rossella.Roberts@wales.nhs.uk](mailto:Rossella.Roberts@wales.nhs.uk)

Copy: Sponsor: Hefin Francis  
School of Psychology  
Adeliad Brigantia, Penrallt Road  
Bangor University, Bangor  
LL57 2GD [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk)

R&D Office: Miss Debra Slater  
R&D Office  
Betsi Cadwaladr University Health Board  
Ysbyty Gwynedd,  
Bangor  
LL57 2PW [debra.slater@wales.nhs.uk](mailto:debra.slater@wales.nhs.uk)

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#### 1. Study Information

Full title of study:	Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis
IRAS Project ID:	196799
Sponsor Amendment Notification number:	4
Sponsor Amendment Notification date:	26.10.2016
<b>Details of Chief Investigator:</b>	
Name [first name and surname]	Laura Spencer
Address:	3 South Street, Llanfairfechan, Conwy
Postcode:	LL33 0RF
Contact telephone number:	07972763722
Email address:	psp4eb@bangor.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	Mr. Hefin Francis
Contact email address:	h.francis@bangor.ac.uk
<b>Details of Lead Nation:</b>	
Name of lead nation delete as appropriate	Wales
If England led is the study going through CSP? delete as appropriate	N/A
Name of lead R&D office:	Debra Slater Research Governance Officer

**Partner organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

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**Gwasanaeth Moeseg Ymchwil  
Research Ethics Service**



**Pwyllgor Moeseg Ymchwil Cymru 5  
Wales Research Ethics Committee 5  
Bangor**

Clinical Academic Office  
Ysbyty Gwynedd Hospital  
Betsi Cadwaladr University Health Board  
Bangor, Gwynedd  
LL57 2PW  
Telephone/ Facsimile: 01248 - 384.877  
Email: [Rosalea.Roberts@wales.nhs.uk](mailto:Rosalea.Roberts@wales.nhs.uk)

26 October 2016

Mrs Laura E Spencer  
Trainee Clinical Psychologist  
Betsi Cadwaladr University Health Board  
Clinical Psychology Programme  
School of Psychology  
Bangor University,  
Bangor,  
Gwynedd  
LL57 2AS [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk)

Dear Mrs Spencer

**Study title:** Self-efficacy and cognition in people with a diagnosis of Multiple Sclerosis.  
**REC reference:** 16/WA/0186  
**Amendment number:** 04  
**Amendment date:** 26 October 2016  
**IRAS project ID:** 196799

Thank you for your letter of 26 October 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees.

The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:


Document	Version	Date
Notice of Minor Amendment	04	26 October 2016
Research protocol or project proposal	6	26 October 2016

**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.

16/WA/0186:	Please quote this number on all correspondence
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Yours sincerely



**Dr Rossela Roberts**  
Research Ethics Service Manager

Email: [Rossela.Roberts@wales.nhs.uk](mailto:Rossela.Roberts@wales.nhs.uk)

Copy:	Sponsor:	Hefin Francis School of Psychology Adeilad Brigantia Penrallt Road Bangor University Bangor Gwynedd LL57 2GD <a href="mailto:h.francis@bangor.ac.uk">h.francis@bangor.ac.uk</a>
	R&D Office:	Miss Debra Slater R&D Office Betsi Cadwaladr University Health Board Ysbyty Gwynedd Bangor Gwynedd LL57 2PW <a href="mailto:debra.slater@wales.nhs.uk">debra.slater@wales.nhs.uk</a>



COLEG IECHYD A GWYDDORAU YMDDYGIAD  
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG  
SCHOOL OF PSYCHOLOGY



NWCPP-RSCGC

**RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU  
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME**

**Initial Contact Form**



PRIFYSGOL  
**BANGOR**  
UNIVERSITY

**Study title:** Self-efficacy and cognition in people with Multiple Sclerosis  
**Name of researcher:** Laura Spencer, Trainee Clinical Psychologist  
**Supervised by:** Dr Craig Roberts, Clinical Neuropsychologist

If you are interested in participating in our research, please read and complete the following, and return to Laura Spencer using the stamped addressed envelope provided within one month of receipt. Thank you.

Please initial  
box

I agree to be contacted to discuss the research study

**Name (please print):** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Contact Address & postcode:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Contact Telephone Number:**

\_\_\_\_\_

Thank you for considering participating in this research study. I will look forward to speaking with you in the near future. Laura Spencer.

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COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG  
SCHOOL OF PSYCHOLOGY



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RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU  
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME



PRIFYSGOL  
**BANGOR**  
UNIVERSITY

### Ffurflen Cyswilt Cyntaf

**Teitl yr astudiaeth:** Hunaneffeithlonrwydd a gwybyddiaeth mewn pobl â Sglerosis Ymledol

**Euw'r ymchwilydd:** Laura Spencer, Seicolegydd Clinigol dan Hyfforddiant

**Dan oruchwyliaeth:** Dr Craig Roberts, Niwroseicolegydd Clinigol

Os oes gennych ddi-ddordeb mewn cymryd rhan yn ein hymchwil, darllenwch y wybodaeth a llenwch y darn isod, a dychwelyd y ffurflen i Laura Spencer yn yr amlen barod o fewn mis o'i derbyn. Diolch.

Llofnodwch  
y bocs

Rwy'n cytuno y gellwch gysylltu â mi i drafod yr astudiaeth ymchwil

**Euw** (*wedi'i brintio*) \_\_\_\_\_

**Llofnod:** \_\_\_\_\_

**Cyfeiriad cyswilt a'r cod post:**

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**Rhif ffôn:**

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Diolch am ystyried cymryd rhan yn yr astudiaeth ymchwil hon. Edrychaf ymlaen at siarad â chi yn y dyfodol agos. Laura Spencer.

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YSGOL SEICOLEG  
SCHOOL OF PSYCHOLOGY



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**RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU  
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME**



PRIFYSGOL  
**BANGOR**  
UNIVERSITY

### **Participant Information Sheet**

**Study title:** Self-efficacy and cognition in people with Multiple Sclerosis

**Name of researcher:** Laura Spencer, Trainee Clinical Psychologist

**Supervised by:** Dr Craig Roberts, Clinical Neuropsychologist

We would like to invite you to take part in our research. Before you decide, please take time to read the following information about what this would involve for you. Thank you.

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

We are interested in how people's thinking skills (e.g., memory and problem solving) may be affected by self-efficacy, or how well one believes that they are able to perform a task. We are also interested in understanding how people's thinking skills may be affected by fatigue and mood, and by the severity of their symptoms of multiple sclerosis. We hope this research will help us to support people with multiple sclerosis more effectively in the future.

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

You have been invited to participate because you have a diagnosis of multiple sclerosis, and you have attended an appointment at one of the multiple sclerosis clinics.

#### **What would taking part involve?**

If you decide that you may be interested in taking part our research, please complete the initial contact form enclosed, and return using the stamped addressed envelope provided. If you return the initial contact form, Laura will contact you by telephone approximately one week later to discuss the study further and answer any questions you may have. At the end of the conversation, Laura will ask if you would like to participate in the study.

If you are still interested in taking part, Laura will arrange to meet with you in person at a convenient time and date. This may be at your own home, at the North Wales Brain Injury Service in Colwyn Bay, or at another NHS building (whichever is preferable to you).

In the appointment you will be asked to complete a series of short questionnaires about self-efficacy, your mood, levels of fatigue, symptoms of multiple sclerosis, and your thinking skills. You will also be asked to complete some tasks to look at your thinking skills, e.g., we may ask you to remember a short story. The appointment will last no longer than two hours, but could be split over two shorter appointments if you would prefer.

#### **What are the possible benefits of taking part?**

There is no direct benefit to yourself from taking part however your participation will have the potential of benefitting people with multiple sclerosis in the future.

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COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG  
SCHOOL OF PSYCHOLOGY

**What are the possible disadvantages and risks of taking part?**

It is anticipated that the study will take no longer two hours of your time. Sometimes people can find it difficult to complete some of the tasks, which could be frustrating or upsetting. You will also be asked to complete a questionnaire about your mood and symptoms of multiple sclerosis, which might raise some difficult emotions. If you find this is the case for you then we would encourage you to speak to your clinician at the multiple sclerosis clinic or your GP. If you find you are becoming upset then we can stop at any time. You can also choose to withdraw from the study should you wish.

**Will taking part in the study affect the care I receive in the NHS?**

Taking part in the study will not affect the care that you receive in the NHS. If you agree to take part in this research, I will notify your G.P. and Mrs. Yvonne Copeland, MS specialist nurse. This is to ensure your safety and well-being. With your permission, I may collect information about your symptoms of multiple sclerosis from your medical records.

**Who is organising and funding this study?**

This study is organised and funded by the North Wales Clinical Psychology Programme at Bangor University.

**Who has reviewed this study?**

The study has been reviewed and approved by an independent panel of people from the School of Psychology at Bangor University, and from the NHS Research Ethics Committee.

**What if something goes wrong?**

If you have any concerns about the research study, you may contact Laura Spencer via telephone on 07972763722 or via e-mail at [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk). You may also wish to contact Dr. Craig Roberts, Clinical Neuropsychologist, at the North Wales Brain Injury Service via telephone on 01492 807770 or via e-mail at [Craig.Roberts@Wales.nhs.uk](mailto:Craig.Roberts@Wales.nhs.uk)

If neither Laura nor Dr. Roberts are able to address your concerns satisfactorily and/or you wish to raise a complaint about the study, please contact Mr. Hefin Francis, School of Psychology Manager:

Mr. Hefin Francis  
School of Psychology Manager  
Bangor University,  
School of Psychology,  
Brigantia Building,  
Penrallt Road,  
Gwynedd,  
LL57 2DG.

Tel: 01248 388339  
E-mail: [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk)

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COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG  
SCHOOL OF PSYCHOLOGY

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

You may withdraw from the study at any time, without giving any reason, and without your care in the NHS being affected in any way. Should you wish to withdraw, you can also ask for your data to be removed from the study.

**How will my information be kept confidential?**

All information collected will be kept confidentially. The only exceptions to confidentiality are where there are concerns about your safety, or that of somebody else's, then Laura will have a duty to share this information with other professionals. Where incidental disclosures are made, it may also be necessary to share this information with other professionals. In these circumstances, Laura will make every effort to inform you about this first. The data collected will be stored securely and separately from your personal details. Only Laura and Dr. Craig Roberts will have access to the data, and data will be destroyed upon completion of the project in accordance with NHS guidelines.

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

The results of the study will be used to write a report for Bangor University as part of the Doctoral training programme. Laura Spencer may also write a report for publication in a scientific journal. If you wish, you will be able to receive a letter detailing the results of the study in the post. All information about participants will be anonymous, so you will not be identifiable in any written documentation.

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

Yours Sincerely,

Laura Spencer  
Trainee Clinical Psychologist

Supervised by Dr. Craig Roberts  
Clinical Neuropsychologist



### Taflen wybodaeth i gyfranogwyr

**Teitl yr astudiaeth:** Hunaneffeithlonrwydd a gwybyddiaeth mewn pobl â Sglerosis Ymledol

**Enw'r ymchwilydd:** Laura Spencer, Seicolegydd Clinigol dan Hyfforddiant

**Dan oruchwyliaeth:** Dr Craig Roberts, Niwroseicolegydd Clinigol

Hoffem eich gwahodd i gymryd rhan yn ein hymchwil. Cyn i chi benderfynu, cymerwch amser i ddarllen y wybodaeth isod ynglŷn â'r hyn y byddai'n ei olygu i chi. Diolch.

#### **Beth yw diben yr astudiaeth hon?**

Mae gennym ddiddordeb yn y ffordd y gall sgiliau meddwl pobl (e.e. cof a datrys problemau) gael eu heffeithio gan hunaneffeithlonrwydd, neu ba mor dda y mae rhywun yn credu y gallant wneud tasg. Mae gennyf ddiddordeb hefyd mewn deall sut y gall sgiliau meddwl pobl gael eu heffeithio gan flinder a thymor, a chan ba mor ddifrifol yw eu symptomau o sglerosis ymledol. Rydym yn gobeithio y bydd yr ymchwil hwn yn ein helpu i gefnogi pobl sydd â sglerosis ymledol yn fwy effeithiol yn y dyfodol.

#### **Pam y gofynnwyd imi gymryd rhan?**

Rydych wedi cael gwahoddiad i gymryd rhan oherwydd eich bod wedi cael diagnosis o sglerosis ymledol.

#### **Beth y byddai cymryd rhan yn ei olygu?**

Os penderfynwch y byddai gennych ddiddordeb cymryd rhan yn yr ymchwil, llenwch y ffurflen cyswllt cyntaf amgaeedig, a'i dychwelyd yn yr amlen barod a ddarperir. Os byddwch yn dychwelyd y ffurflen cyswllt cyntaf, bydd Laura yn cysylltu â chi drwy eich ffonio tua wythnos yn ddiweddarach i drafod yr astudiaeth ymhellach ac ateb unrhyw gwestiynau sydd gennych. Ar ddiwedd y sgwrs, bydd Laura yn gofyn a hoffech gymryd rhan yn yr astudiaeth.

Os bydd dal gennych chi ddiddordeb mewn cymryd rhan, bydd Laura yn trefnu i'ch cyfarfod yn bersonol ar adeg ac mewn lle cyfleus. Gall hyn fod yn eich cartref eich hun, yng Ngwasanaeth Anaf i'r Ymennydd Gogledd Cymru ym Mae Colwyn, neu adeilad GIG arall (pa un bynnag sydd orau gennych chi).

Yn yr apwyntiad gofynnir i chi lenwi cyfres o holiaduron byr ynglŷn â'ch hunaneffeithlonrwydd, eich tymor, lefelau blinder, symptomau o sglerosis ymledol a'ch sgiliau meddwl. Gofynnir i chi hefyd wneud ychydig o dasgau er mwyn gweld eich sgiliau meddwl, e.e. gallwn ofyn i chi gofio stori fer. Ni fydd yr apwyntiad yn para mwy na dwy awr, ond gellir ei rannu i ddau apwyntiad byrrach os byddai'n well gennych.

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**Beth yw'r manteision posibl o gymryd rhan?**

Nid oes unrhyw fudd uniongyrchol i chi o gymryd rhan ond mae'n bosibl y bydd eich cyfranogiad o fudd i bobl gyda sglerosis ymledol yn y dyfodol.

**Beth yw'r anfanteision a'r risgiau posib o gymryd rhan?**

Rhagwelir na fydd yr astudiaeth yn cymryd mwy na dwy awr o'ch amser. Weithiau gall fod yn anodd i bobl gyflawni rhai o'r tasgau, a gall hyn fod yn rhwystredig neu'n achosi gofid. Gofynnir i chi hefyd lenwi holiadur am eich tymer a symptomau sglerosis ymledol, a all ysgogi rhai emosiynau anodd. Os bydd hyn yn wir i chi, yna byddem yn eich annog i siarad â'ch clinigwr yn y clinig sglerosis ymledol neu â'ch meddyg teulu. Os bydd yn achosi gofid i chi, gallwn roi'r gorau iddi ar unrhyw adeg. Gallwch hefyd dynnu'n ôl o'r astudiaeth os dymunwch.

**Fydd cymryd rhan yn yr astudiaeth yn effeithio ar y gofal a dderbyniad yn y GIG?**

Ni fydd cymryd rhan yn yr astudiaeth yn effeithio ar y gofal a dderbyniwch yn y GIG. Os ydych yn cytuno i gymryd rhan yn yr ymchwil hwn, byddaf yn rhoi gwybod i'ch meddyg teulu a Mrs. Yvonne Copeland, nyrs arbenigol MS. Mae hyn er mwyn sicrhau eich diogelwch a'ch lles. Gyda'ch caniatâd, gallaf gasglu gwybodaeth am eich symptomau o sglerosis ymledol o'ch cofnodion meddygol.

**Pwy sy'n trefnu ac yn cyllido'r astudiaeth hon?**

Trefnir ac ariannir yr astudiaeth hon gan Raglen Seicoleg Glinigol Gogledd Cymru, ym Mhrifysgol Bangor.

**Pwy sydd wedi adolygu'r astudiaeth hon?**

Mae'r astudiaeth wedi'i hadolygu a'i chymeradwyo gan banel annibynnol o bobl yn yr Ysgol Seicoleg ym Mhrifysgol Bangor, ac o Bwyllgor Moeseg Ymchwil y GIG.

**Beth os aiff rhywbeth o'i le?**

Os oes gennych unrhyw bryderon ynglŷn â'r astudiaeth ymchwil, gellwch gysylltu â Laura Spencer drwy ffonio 07972763722 neu anfon e-bost at [psp4eb@bangor.ac.uk](mailto:psp4eb@bangor.ac.uk). Gallwch hefyd gysylltu â Dr. Craig Roberts, Niwroseicolegydd Clinigol, yng Ngwasanaeth Anaf i'r Ymennydd Gogledd Cymru drwy ffonio 01492 807770 neu anfon e-bost at [Craig.Roberts@Wales.nhs.uk](mailto:Craig.Roberts@Wales.nhs.uk)

Os na fydd Laura na Dr. Roberts yn gallu rhoi sylw boddhaol i'ch pryderon ac/neu rydych eisiau gwneud cwyn am yr astudiaeth, cysylltwch â Mr Hefin Francis, Rheolwr yr Ysgol Seicoleg:

Mr. Hefin Francis  
Rheolwr yr Ysgol Seicoleg  
Prifysgol Bangor,  
Ysgol Seicoleg,  
Adeilad Brigantia,  
Ffordd Penrallt,  
Gwynedd,  
LL57 2DG.

Ffôn: 01248 388339  
E-bost: [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk)

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**Beth fydd yn digwydd os na fyddaf yn dymuno parhau â'r astudiaeth?**

Gellwch dynnu'n ôl o'r astudiaeth ar unrhyw adeg heb roi rheswm, ac ni fydd eich gofal yn y GIG yn cael ei effeithio mewn unrhyw ffordd. Os byddwch yn dymuno tynnu'n ôl, gallwch ofyn i'ch data gael ei dynnu o'r astudiaeth hefyd.

**Sut fydd fy ngwybodaeth yn cael ei chadw'n gyfrinachol?**

Bydd yr holl wybodaeth a gesglir yn cael ei chadw'n hollol gyfrinachol. Yr unig eithriad i gyfrinachedd yw os oes pryderon am eich diogelwch, neu ddiogelwch rhywun arall, yna bydd yn ddyletswydd ar Laura i rannu'r wybodaeth honno gyda gweithwyr proffesiynol eraill. Os datgelir rhywbeth yn ddamweiniol, efallai bydd rhaid rhannu'r wybodaeth hon gyda gweithwyr proffesiynol eraill hefyd. Yn yr amgylchiadau hyn, bydd Laura yn gwneud pob ymdrech i roi gwybod i chi yn gyntaf. Cedwir yr holl ddata a gesglir yn ddiogel ac ar wahân oddi wrth unrhyw fanylion personol amdanoch. Dim ond Laura a Dr. Craig Roberts fydd yn cael gweld y data, a chaiff y data eu dinistrio ar ôl cwblhau'r project yn unol â chanllawiau'r GIG.

**Beth fydd yn digwydd i ganlyniadau'r astudiaeth hon?**

Defnyddir canlyniadau'r astudiaeth i ysgrifennu adroddiad i Brifysgol Bangor fel rhan o'r rhaglen hyfforddi ddoethurol. Efallai y bydd Laura Spencer hefyd yn ysgrifennu adroddiad i'w gyhoeddi mewn cylchgrawn gwyddonol. Os dymunwch, cewch lythyr drwy'r post yn rhoi manylion am ganlyniadau'r astudiaeth. Bydd yr holl wybodaeth am gyfranogwyr yn ddiennw, ac ni fydd modd eich adnabod mewn unrhyw ddogfennaeth ysgrifenedig.

**Diolch i chi am roi o'ch amser i ddarllen y daflen wybodaeth hon.**

Yn gywir,

Laura Spencer  
Seicolegydd Clinigol dan Hyfforddiant

Dan oruchwyliaeth Dr. Craig Roberts  
Niwroseicolegydd Clinigol



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SCHOOL OF PSYCHOLOGY



NWCPP-RSCGC

**RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU  
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME**



PRIFYSGOL  
**BANGOR**  
UNIVERSITY

Participant Identification Number:

### Participant Consent Form

**Study title:** Self-efficacy and cognition in people with Multiple Sclerosis

**Name of researcher:** Laura Spencer, Trainee Clinical Psychologist

**Supervised by:** Dr Craig Roberts, Clinical Neuropsychologist

Please initial  
box

1. I confirm that I have read the Participant Information Sheet dated 08/08/2016 for the above study.
2. I have had the opportunity to consider the information and ask questions, and I have had any questions answered satisfactorily.
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my care anywhere in the NHS being affected.
4. I understand that the information collected about me may be used to support other research in the future at the North Wales Brain Injury Service.
5. I understand that information may be shared with other professionals where there are concerns regarding my safety and/or the safety of other people, and where incidental disclosures are made.
6. I give my consent for my General Practitioner to be informed that I have agreed to participate in this research.
7. I give my consent for Mrs. Yvonne Copeland, MS Specialist Nurse, to be informed that I have agreed to participate in this research.
8. I give my consent for Laura to access my medical records.
9. I agree to take part in the above study.

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Name of Participant

---

Date

---

Signature

---

Name of Person  
Taking Consent

---

Date

---

Signature



NWCPP - RSCGC

Rhif Adnabod y Cyfranogwr:

**RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU**  
**NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME**



PRIFYSGOL  
**BANGOR**  
UNIVERSITY

### Ffurflen Gydsynio i Rai sy'n Cymryd Rhan

**Teitl yr astudiaeth:** Hunaneffeithlonrwydd a gwybyddiaeth mewn pobl â Sglerosis Ymledol

**Enw'r ymchwilydd:** Laura Spencer, Seicolegydd Clinigol dan Hyfforddiant

**Dan oruchwyliaeth:** Dr Craig Roberts, Niwroseicolegydd Clinigol

1. Cadarnhaf fy mod wedi darllen y daflen wybodaeth i gyfranogwyr dyddiedig 20/06/2016 ar gyfer yr astudiaeth uchod.
2. Rwyf wedi cael cyfle i ystyried y wybodaeth a gofyn cwestiynau, ac wedi cael atebion boddhaol i unrhyw gwestiynau oedd gennyf.
3. Deallaf fy mod yn cymryd rhan o'm gwirfodd, a bod gennyf hawl i dynnu'n ôl ar unrhyw adeg, heb roi unrhyw reswm, a heb i hynny effeithio ar fy ngofal mewn unrhyw ran o'r GIG.
4. Deallaf y bydd y wybodaeth a gesglir amdanaf yn cael ei defnyddio i gefnogi ymchwil arall yn y dyfodol yng Ngwasanaeth Anaf i'r Ymennydd Gogledd Cymru.
5. Deallaf y gellir rhannu gwybodaeth gyda gweithwyr proffesiynol eraill lle bo pryderon ynghylch fy niogelwch fy hun a/neu ddiogelwch pobl eraill, a phan ddatgelir rhywbeth yn ddamweiniol.
6. Rwy'n cytuno i'm Meddyg Teulu gael gwybod fy mod wedi cytuno i gymryd rhan yn yr ymchwil hon.
7. Rwy'n cytuno Mrs Yvonne Copeland, Nyrs Arbenigol MS, gael gwybod fy mod wedi cytuno i gymryd rhan yn yr ymchwil hon.
8. Rwy'n caniatáu i Laura weld fy nghofnodion meddygol.
9. Rwy'n cytuno i gymryd rhan yn yr astudiaeth uchod.

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Enw'r cyfranogwr

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Dyddiad

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Llofnod

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Enw'r Unigolyn  
yn cymryd cydsyniad

---

Dyddiad

---

Llofnod



Participant Identification Number:

### Demographic Questionnaire

*The following questions are designed to collect information regarding your background. Please tick the appropriate boxes, or write in the spaces provided. Thank you.*

**1. Please specify your gender**

Male  Female  Other

**2. What was your age in years on your last birthday?** \_\_\_\_\_

**3. What is your current marital status?**

Married/Civil Partnership  Cohabiting/Living with partner   
In a relationship but living separately  Single   
Divorced/Separated  Widowed

**4. How would you describe your ethnicity?** *(Please choose one option that best describes your ethnic group or background)*

White:  
Welsh/English/Scottish/Northern Irish/British  Black/African/Caribbean/Black British:  
Irish  African   
Gypsy or Irish Traveller  Caribbean   
Asian/Asian British:  
Indian  Mixed/Multiple ethnic groups   
Pakistani  White and Black Caribbean   
Bangladeshi  White and Black African   
Chinese  White and Asian

Other ethnic group  
Arab   
Any other ethnic group, please describe \_\_\_\_\_

**5. What is your first language?**

Welsh  English   
Other, please specify \_\_\_\_\_

**6. What age did you start school?** \_\_\_\_\_

**7. What age did you leave school?** \_\_\_\_\_

**8. Do you hold any formal qualifications?** *(Please specify, e.g., O Level, A Level, Degree, NVQ etc)*

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**9. Please specify your current employment status**

Employed (full time)

Employed (part time)

Retired

Unemployed

Please specify your main occupation (current or previous):

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**10. What subtype of Multiple Sclerosis have you been diagnosed with?**

Clinically isolated syndrome

Relapsing and remitting multiple sclerosis

Benign multiple sclerosis

Secondary progressive multiple sclerosis

Primary progressive multiple sclerosis

Not known

**11. When do you feel your symptoms of multiple sclerosis first started? (Please specify how many months or years)**

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**12. How long ago were you diagnosed with multiple sclerosis? (Please specify how many months or years)**

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**13. Other than multiple sclerosis, do you have any long-term illnesses, health problems, or disabilities?**

(Please specify)

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MS Questionnaire  
Participant Identification Number:

Appendix 1.

Multiple Sclerosis (MS) Information: Patient Scoring

1. Which of the following three descriptions best characterizes your disease? (circle one)

1. I have attacks where I am worse for a period of time (lasting longer than 24 hours) followed by an improvement in my condition (although not necessarily back to where I was before the attack). In between attacks I am stable.
2. My disease began as indicated above but subsequently it changed so that now I have been getting progressively worse, even when I am not having an attack.

How long ago did this change take place? \_\_\_\_\_

3. From the beginning, my disease has gotten steadily and progressively worse, even when I am not having an attack.

2. Which of the following best describes your ability to walk? (circle one)

1. I can walk without any problem.
2. I have some difficulties with walking but I can walk without aid for 500 meters or more (i.e., approximately the length of five football fields or one third of a mile).
3. I have some difficulties with walking but I can walk without aid for about 300 meters (i.e., approximately the length of three football fields or one fifth of a mile).
4. I have some difficulties with walking but I can walk without aid for about 200 meters (i.e., approximately the length of two football fields or one tenth of a mile).
5. I have some difficulties with walking but I can walk without aid for about 100 meters (i.e., approximately the length of one football field or 300 feet).
6. I require an aid (e.g. cane, crutch, walker or another person) to walk 100 meters (300 feet).
7. I require an aid (e.g. cane, crutch, walker or another person) to walk 20 meters (60 feet).
8. I require an aid (e.g. cane, crutch, walker or another person) to walk 8 meters (25 feet).
9. I use a wheelchair for almost all activities.
10. I am confined to bed most of the time.

3. When you move about, what percentage of the time do you:

1. walk without aid? \_\_\_\_\_
2. use a cane, a single crutch, or hold onto another person? \_\_\_\_\_
3. use a walker or other bilateral support? \_\_\_\_\_
4. use a wheel chair? \_\_\_\_\_

Total=100%

4. Which of the following best describes your functional abilities? (circle one)

1. I am able to carry out my usual daily activities without limitation.
2. I have limitations but can carry out most of my usual daily activities, even if I may require some special provisions such as altered work hours or naps.
3. I am able to carry out about only half of my usual daily activities even with special provisions.
4. I am severely limited in my ability to carry out my usual daily activities.
5. I require assistance with even my basic self care activities such as dressing, bathing, transferring and going to the bathroom.

5. Which of the following best describes your strength (power)? (circle each location only once)

1. My strength (power) is normal in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
2. I am mildly weak in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
3. I am moderately weak in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
4. I am severely weak in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)

6. Which of the following best describes your sensation (feeling)? (circle each location only once)

1. My sensation (feeling) is normal in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
2. My sensation (feeling) is mildly impaired in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
3. My sensation (feeling) is moderately impaired in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)
4. My sensation (feeling) is severely impaired in the following locations:  
(Right arm, Left arm, Right leg, Left leg, Face)

7. Which of the following best describes your corrected visual acuity (i.e., using glasses if necessary)? (circle each eye only once)

1. My corrected vision is normal in the following locations:  
(Right eye, Left eye)
2. My corrected vision is mildly impaired in the following locations:  
(Right eye, Left eye)
3. My corrected vision is moderately impaired in the following locations:  
(Right eye, Left eye)
4. My corrected vision is severely impaired in the following locations:  
(Right eye, Left eye)

MS Questionnaire

Participant Identification Number:

8. Which of the following best describes your double vision? (circle one)

1. I don't experience double vision.
2. I experience double vision only occasionally.
3. I experience double vision moderately often.
4. I experience double vision most of the time.

9. Which of the following best describes your coordination? (circle each location only once)

1. My coordination is normal in the following areas:  
(Right arm, Left arm, Right leg, Left leg)
2. I am mildly uncoordinated in the following areas:  
(Right arm, Left arm, Right leg, Left leg)
3. I am moderately uncoordinated in the following areas:  
(Right arm, Left arm, Right leg, Left leg)
4. I am severely uncoordinated in the following areas:  
(Right arm, Left arm, Right leg, Left leg)

10. Do you have dif/fulty speaking or with your speech? \_\_\_\_\_; If yes, is this dif/fulty mild, moderate or severe? \_\_\_\_\_

11. Which of the following best describes your balance? (circle one)

1. I have no dif/fulty with my balance
2. I have mild dif/fulty with my balance
3. I have moderate dif/fulty with my balance
4. I have severe dif/fulty with my balance

12. Which of the following best describes the spasticity (stiffness) and/or spasms (brief involuntary contraction) of your muscles? (circle each location once)

1. I have no spasticity and/or spasms in the following locations:  
(Right arm, Left arm, Right leg, Left leg)
2. I have mild spasticity and/or spasms in the following locations:  
(Right arm, Left arm, Right leg, Left leg)
3. I have moderate spasticity and/or spasms in the following locations:  
(Right arm, Left arm, Right leg, Left leg)
4. I have severe spasticity and/or spasms in the following locations:  
(Right arm, Left arm, Right leg, Left leg)

13. Which of the following best describes your cognitive (thinking) ability? (circle one)

1. I have had no change in my cognitive (thinking) abilities.

2. I have had a mild impairment of my cognitive (thinking) abilities.

3. I have had a moderate impairment of my cognitive (thinking) abilities.

4. I have had a severe impairment of my cognitive (thinking) abilities.

5. I am unable to handle my affairs because of my severe cognitive problems.

14. Which of the following best describes your mood since getting MS? (circle one)

1. My mood has been unchanged since getting MS.
2. I have become depressed or more depressed since getting MS.
3. Although I am not pleased to have MS, I have become a more cheerful person since getting it.

15. Do you have dif/fulty swallowing? \_\_\_\_\_; If yes, is the dif/fulty mild, moderate, or severe? \_\_\_\_\_

16. Which of the following best describes your bowel and bladder function? (circle all that are appropriate but circle the bowel and bladder at least once)

1. I have normal function of my:  
(Bladder, Bowel)
2. I have urgency (i.e., I have to go quickly when I feel the urge) of my:  
(Bladder, Bowel)
3. I have frequency (i.e., I go unusually often) of my:  
(Bladder, Bowel)
4. I have hesitancy (i.e., I have dif/fulty getting started) of my:  
(Bladder, Bowel)
5. I am occasionally incontinent (less than once a week) of my:  
(Bladder, Bowel)
6. I am frequently incontinent (weekly or more often but less than daily) of my:  
(Bladder, Bowel)
7. I am frequently incontinent (daily or more often) of my:  
(Bladder, Bowel)
8. I require intermittent catheterization
9. I require an indwelling catheter.
10. I have constipation.

17. Do you experience vertigo or dizziness (i.e. a sense or a feeling of motion)? \_\_\_\_\_; If yes, is your dizziness mild, moderate, or severe?  
\_\_\_\_\_



Liverpool Self Efficacy Questionnaire

Think about how you have been feeling over the last week. Please read the following statements and indicate the extent to which you agree or disagree with them by circling one answer to each question.

		<b>Strongly agree</b>	<b>Agree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
1.	Since my diagnosis was confirmed, my life has been beset with difficulties over which I have no control	1	2	3	4
2.	I feel in control of my life	4	3	2	1
3.	I rely on others to help me make decisions	1	2	3	4
4.	Sometimes I feel that my MS controls my life	1	2	3	4
5.	I often feel helpless when dealing with my difficulties	1	2	3	4
6.	The way my MS affects me in the future mostly depends on me	4	3	2	1
7.	I worry about how I will cope in the future	1	2	3	4
8.	Despite my difficulties, I still manage to cope with daily life	4	3	2	1
9.	There is really no way I can solve some of the problems I have with my MS	1	2	3	4
10.	Despite my MS, I can do anything I set my mind to	4	3	2	1
11.	I am confident I can overcome my difficulties	4	3	2	1

PROMIS Fatigue MS  
 Participant Identification Number:

**PROMIS-Fatigue<sub>MS</sub>**

<i>In the past 7 days...</i>	<b>Never</b>	<b>Rarely</b>	<b>Some- times</b>	<b>Often</b>	<b>Always</b>
How often were you too tired to think clearly?	1	2	3	4	5
How often were you too tired to enjoy life?	1	2	3	4	5
How often did you find yourself getting tired easily?	1	2	3	4	5
How often did you feel tired even when you hadn't done anything?	1	2	3	4	5
How often did you have trouble finishing things because of your fatigue?	1	2	3	4	5
How often did you have to push yourself to get things done because of your fatigue?	1	2	3	4	5
How often did your fatigue interfere with your social activities?	1	2	3	4	5
<i>In the past 7 days...</i>	<b>Not at all</b>	<b>A little bit</b>	<b>Some- what</b>	<b>Quite a bit</b>	<b>Very Much</b>
To what degree did your fatigue interfere with your physical functioning?	1	2	3	4	5

Patient Health Questionnaire  
 Participant Identification Number:

**PATIENT HEALTH QUESTIONNAIRE-9  
 (PHQ-9)**

Over the **last 2 weeks**, how often have you been bothered  
 by any of the following problems?  
 (Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + \_\_\_\_\_ + \_\_\_\_\_ + \_\_\_\_\_  
 =Total Score: \_\_\_\_\_

If you checked off **any** problems, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NeuroQOL-CF  
Participant Identification Number:

**Cognition Function– Short Form**

Please respond to each question or statement by marking one box per row.

In the past 7 days...		Never	Rarely (once)	Sometimes (2-3 times)	Often (once a day)	Very often (several times a day)
		5	4	3	2	1
NQCCG641	I had to read something several times to understand it.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG751	My thinking was slow.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG771	I had to work really hard to pay attention or I would make a mistake.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG801	I had trouble concentrating.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**How much DIFFICULTY do you currently have...**

		None	A little	Somewhat	A lot	Cannot do
		5	4	3	2	1
NQCCG221	reading and following complex instructions (e.g., directions for a new medication)?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG241	planning for and keeping appointments that are not part of your weekly routine, (e.g., a therapy or doctor appointment, or a social gathering with friends and family)?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG251	managing your time to do most of your daily activities?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NQCCG401	learning new tasks or instructions?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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## **Word counts**

**Thesis Abstract:** 292

**Chapter 1 – Meta analysis and Literature review:** 3,548 (including title page, footnotes, list of abbreviations, and abstract, but excluding tables, figures, and references)

**Chapter 2 – Empirical Paper:** 3,437 (including title page, footnotes, list of abbreviations, and abstract, but excluding tables, figures, and references)

**Chapter 3 – Contributions to Theory & Clinical Practice:** 3,135 (excluding references)

**Total Word Count:** 10,120 (excluding tables, figures and reference lists)

**Appendices Word Count:** 9,443 (including all tables, all figures, and all references, and the list of appendices. Excluding the ethics appendices)