

# **Intervention for Cognitive Difficulties in Functional Neurological Disorder**

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## **Thesis Overview**

Functional neurological disorders (FND) are conditions that present as neurobehavioural functional alterations in the central nervous system despite no known organic cause. Cognitive difficulties are one of many varied presentations of the condition, collectively termed functional cognitive disorders (FCD). These may present as difficulties with attention, memory, processing speed and executive functioning, without evidence of brain injury or neurodegeneration.

The purpose of the systematic literature review was to a) understand the context around FND presentations and the neuropsychosocial mechanisms behind FCD, and b) formulate hypotheses of the most effective treatment components for managing symptoms of FCD. A systematic search of empirical literature revealed that interventions are in their infancy, meaning that no conclusions could be established. Nevertheless, the review provided a framework for future research.

The empirical research paper investigated the efficacy of a mindfulness-based intervention for managing the experiences of FCD, designed to address the emotion regulation, behavioural activation, metacognitive evaluations, and executive control elements underpinning FCD, as hypothesised from the systematic literature review. The mindful awareness, psychological wellbeing, and cognitive performance of thirteen people with FCD were measured before and after mindfulness training. Statistical analyses showed that trait-mindful abilities improved, as well as correlational associations between mindful awareness and psychological wellbeing and attentional performance. These findings support the hypothesised treatment components as well as the use of mindfulness-based interventions in the management of FCD, supporting both clinical application in healthcare settings and the empirical literature. Future research should focus on the development of treatment guidelines.

## **Dedication**

To Stella-Rose and Isabelle,

For your patience

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## **1. Systematic Literature Review:**

### **Cognitive difficulties in Functional Neurological Disorder: a conceptual review of the phenomena and a systematic review of available treatment**

#### **1.1. Abstract**

##### **1.1.1. Introduction**

This systematic literature review investigated the range and efficacy of interventions for cognitive difficulties associated with functional neurological disorders (FND). These experiences are not yet included in DSM-5 classification and there are no guidelines provided for symptom management. The neuropsychosocial mechanisms of functional cognitive difficulties were explored to discern the appropriate intervention needs.

##### **1.1.2. Research Aims**

This review aimed to identify the available literature reporting interventions for cognitive difficulties in FND, describe their components and review their efficacy in meeting expected standards inferred from the literature.

##### **1.1.3. Method**

A search of electronic databases took place using search criteria provided in the literature. The application of inclusion and exclusion criteria screened the search results in several stages to narrow down those included for review. Five controlled trials were identified and analysed for risk of bias. All studies were deemed to have high credibility yet lacked generalisability due to small sample sizes.

#### **1.1.4. Findings from Review Studies**

Available interventions included transcranial magnetic stimulation, a cognitive remediation approach, a psychosocial group intervention and an exercise programme. The impact of these interventions on cognitive functioning was described, along with whether the intervention components would meet the neuropsychosocial needs of those with FND.

#### **1.1.5. Future Implications**

The lack of empirical research has implications for patients and healthcare providers. Interventions that aim to improve functional cognitive difficulties may have parallels with treatments used for other functional conditions, making future research in this area highly valuable.

## **1.2. Introduction**

This systematic literature review investigates the cognitive difficulties experienced by people with functional neurological disorders (FND), and more specifically, the range and efficacy of interventions applicable to address these difficulties. Interventions that aim to improve functional cognitive difficulties may have parallels with treatments used for other conditions that come under the collective term of FND. Thus, some exploration into the nature of FND, the phenotypic expressions and common underpinnings with other functional conditions such as dissociative seizures, fibromyalgia, and chronic fatigue syndrome, may assist in the identification of intervention needs. The focus of current psychological approaches for those with FND typically target the manifestations of mental health distress and lower quality of life brought about by the condition. There is less empirical research studying the treatment components needed for effective management of symptoms of cognitive dysfunction associated with FND.

### **1.2.1. Classification of Functional Neurological Disorder**

Functional neurological disorders, which overlap the fields of neurology and clinical psychology, are believed to be neurobehavioural conditions with alterations in the central nervous system despite no known organic disease or identifiable physical explanation (Reuber et al., 2007; Perez, 2015; Hallet, 2016). The term ‘conversion disorder’ has previously been used to describe these conditions, with contemporary understandings of how nervous system signals sent to and from the body are disrupted, leading to functional difficulties. This label has connotations with historical depictions of ‘conversion hysteria’ (Hurst, 1983; Trimble & Reynolds, 2016) and there remains a stigma around the experiences of FND being feigned or purely psychological in nature, with academics and healthcare clinicians continuing to use varied terminology or taxonomic labels such as psychogenic, non-organic, and ‘worried well’ (Berrios, Marková & Giralá, 2000; Metternich, Schmidtke & Hüll, 2009; Kanaan, Armstrong & Wessely, 2011; Stone et al., 2011; Perez et al., 2012; Edwards, Yogarajah & Stone, 2023; Mason, 2023; McLoughlin et al., 2023).

The reclassification of FND came about with the revision of the Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> Edition (DSM-5; American Psychiatric Association, 2018), whereby diagnosis is now based on a positive identification of symptoms under the ‘Somatic Symptoms and Related Disorders’ category. Functional difficulties are diagnosed if the person reports difficulties that are incongruent or inconsistent with the person’s observable performance, whereby individuals describe obvious motor, sensory and cognitive difficulties, but when being observed or tested, they appear to function well. This is termed ‘internal inconsistencies.’ Diagnosis of FND no longer relies on previous trauma, a recent psychological stressor, or the idea of feigning for classification (Lehn et al., 2016). Included is the distinctive characteristic of how individuals interpret their subjective experiences, leading to differing degrees of disability (Stone et al., 2005; Carson & Lehn, 2016; Lehn et al., 2016). Dissociation is believed to be an underlying contributing factor to FND and somatoform presentations, with evidence found cross-culturally (Brown & Lewis-Fernández, 2011; Pick, Rojas-Aguiluz, et al., 2020), to the extent that the International Classification of Diseases, Version 11 (6B60, ICD-11, World Health Organisation, 2022) have labelled the condition as ‘dissociative neurological symptom disorder.’ Here, the condition is described as an involuntary disruption or discontinuity of integration of mental processes, mediating attentional capacity to experiences and somatic control, thereby altering awareness and control of memory, identity, movement, sensation, and affect. In this review, the term FND is used to reflect the transdiagnostic processes of involuntary disruption or discontinuity of integration of mental processes into action, resulting in variation of functional neurological presentations.

### **1.2.2. FND Phenotype Presentations**

The varied presentations of FND are often expressed in the literature as ‘phenotypes’ of FND, adopting the term used for gene expressions to describe how symptom clusters represent variants of similar, or potentially the same, underlying mechanisms that are expressed differentially (Perez et al., 2012). Nicholson et al. (2020) reviewed the ‘core’ FND presentations, commonly seen as functional weakness or paralysis, dissociative seizures and sensory dysfunction. When including the associated biopsychological symptom clusters and influencing factors, they concluded that FND conditions can present as a wide range of conditions that resemble other neurological, physiological, psychiatric, and functional complaints. The common FND phenotypes and their specific presentations described in the

literature are summarised in Table 1 (Mayou & Farmer, 2002; Carson & Lehn, 2016; Metternich, Schmidtke & Hüll, 2009; Ganslev et al, 2020; Nicholson et al., 2020; Stone, Burton and Carson, 2020; McLoughlin et al., 2023, Edwards, Yogarajah & Stone, 2023). The presence of additional comorbidities alongside FND phenotypes have also been included in this summary as it is plausible that other somatic or medically unexplained conditions could come under a classification umbrella of FND. For example, functional somatic syndromes, like fibromyalgia, chronic pain syndrome, chronic fatigue syndrome or irritable bowel syndrome, are likely to present alongside other FND presentations (Dixit et al., 2013). Additionally, the presence of psychiatric comorbidities of depression, anxiety or post-traumatic responses may help to distinguish diagnoses of FND from their organic condition counterparts (Diseth & Christie, 2005; Reuber et al., 2007; Carson & Lehn, 2016; Keynejad et al., 2019; Van der Feltz-Cornelis, Allen and Van Eck van der Sluijs, 2020; Menon, 2021).

**Table 1:** List of documented symptoms of FND, including their phenotypic diagnostic terms and presentation definitions as described in the literature.

<b>FND Symptom Clusters</b>	<b>Phenotypic Expression</b>	<b>Presentation</b>
<b>Functional movement disorders</b>	Functional tremor	Uncontrollable shaking, usually in a limb, that can be sporadic and may disappear if the person is distracted.
	Functional tics	Involuntary rapid and repetitive movement and sound, look similar to a tic in Tourette's syndrome
	Functional myoclonus	Sudden involuntary movements such as jerks and jumps without being startled
	Functional dystonia	Uncontrollable muscle spasms in an unusually fixed position, like a clenched fist or inverted ankle
	Functional facial dystonia	Episodic facial spasms, with contraction of platysma or orbicularis with jaw deviation to one side
	Functional dysphagia	Difficulties with swallow function including weakened mastication, restricted swallow, sensations of choking and fear of swallowing
	Functional muscle weakness	Inconsistent weakness in muscles or lack of muscle control Can affect bladder and bowel control
	Functional limb weakness	Inconsistent weakness of arm or leg and feels unable to bear weight Heaviness down one side, feeling like a limb isn't part of the body Hoover's and hip abductor signs, including weakness of hip extension and/or abduction which returns to normal against resistance
	Functional gait disorder	Difficulties walking, such as dragging a leg, sudden knee buckling uneven steps, unsteadiness, excessive movements, or lack of leg coordination.
	Functional drop attacks	Sudden falling to the ground without losing consciousness
	Functional paralysis	An inability to move a part of the body Can last for varied durations, e.g., hours or days, before returning to full function Can affect one side of the body, specific limb, both legs together and full body paralysis
	Functional speech symptoms	Disturbances to speech including dysphonia, slurred speech, stutter, word finding difficulties, word substitutions of mixing up
<b>Functional seizures</b>	Dissociative seizures, psychogenic epileptic seizures, non-epileptic seizures, non-epileptic attack disorder	Episodes that look and feel like epileptic seizures or faints Uncontrolled shaking, motionless or unresponsive, staring, not responding to surroundings Include autonomic arousal such as palpitations, warmth or sweating Dissociative experiences with or without fear Present with tightly closed eyes, tearfulness, hyperventilation and side to side head shaking Typical duration more than 5 minutes May coexist with epileptic seizures



<b>FND Symptom Clusters</b>	<b>Phenotypic Expression</b>	<b>Presentation</b>
<b>Functional sensory symptoms</b>	Functional sensory symptoms	Disturbances to sensory processing, including visual, olfactory or hearing disturbances, numbness, pins and needles, feeling that a limb is not part of the body
	Functional visual loss	Blurred vision, double vision, sensitivity to light, reduced vision such as tubular vision (rather than conical), visual field spiralling Longer duration of test constricts visual field further
	Functional sensory loss	Deprivation of sensory processing Anaesthesia
	Hypersensitivity	Over sensitive to light sound, smell, touch, or taste
	Fleeting sensations	Feeling like the skin is crawling, electric shocks or twitching
<b>Functional cognitive disorders</b>	Functional cognitive difficulties	Poor concentration or focus, going blank, slower processing speed, working memory difficulties with losing track of task or conversations, misplaced items
	Functional memory disorder Dissociative amnesia	Memory loss and word finding difficulty that looks similar to dementia
	<b>Functional somatic syndromes</b>	Chronic pain syndromes
	Fibromyalgia	Muscle, joint and soft tissue pain, increased sensitivity to pain, and muscle stiffness
	Chronic pelvic pain	Pain in pelvic area of lower abdomen, including heavy ache, pressure, twisted or knotted feeling, cramping, throbbing, pain after exercise, sex, urinating or defecating
	Fatigue Chronic fatigue syndrome Myalgic encephalomyelitis	Chronic tiredness despite resting or sleeping, taking a long time to recover after physical exertion
	Functional dizziness Persistent postural-perceptual dizziness Functional vertigo	Continuous feeling of dizziness, light-headedness, unsteadiness, vertigo, non-spinning vertigo, swaying or floating sensations, which worsen with an upright posture, when walking or in environments with moving visual stimuli, e.g., crowds, patterned carpets, supermarket aisles
	Irritable bowel syndrome	Disturbances in the digestive system including pain, cramps, bloating, constipation, or diarrhoea
	Functional dyspepsia Non-ulcer dyspepsia	Feelings of an upset stomach, pain, burning sensation and discomfort in the upper abdomen, bloating, belching, nausea, and early satiety signals

### **1.2.3. Prevalence**

Studies of the prevalence of FND are scarce (see Aybek & Perez (2022) for an authoritative review) but a reported rate of around 50/100,000 was found for FND in the community, depending on the definition of FND and timeframe of sampling. FND is one of the most common causes of neurological disability (Stone et al., 2009; Carson et al., 2000; 2011; Espay et al., 2018; McWhirter et al., 2020), with a peak incidence between the ages of 35 and 50 years (Carson & Lehn, 2016). This has implications for frequent healthcare attendance across physical and mental health settings, including emergency and rehabilitation services, with direct and indirect costs (Carson et al., 2011; Pareés et al., 2014; Williams et al., 2016; Anderson et al., 2019; Hardin & Carson, 2019; Stone, Burton & Carson, 2020; Stephen et al., 2021; Edwards, Yogarajah & Stone, 2023). There is evidence of between double and triple the number of women diagnosed with functional neurological disorders compared to men (Duncan et al., 2006; Goldstein et al., 2019; Baizabel-Carvalho & Jankovic, 2020; Edwards & Aybek, 2020; Lidstone et al., 2022; Pennington, Hayre et al., 2015; McLoughlin et al., 2023). This is likely due to interactions of biopsychosocial factors in the experience and reporting of somatic symptoms (Barsky, Peekna & Borus, 2001; Morgante et al., 2012; Carson & Lehn, 2016; Quinter, 2020; McLoughlin et al., 2023). There is evidence of cross-cultural similarities in the experiences of FND, including international studies based in Europe, Africa, Middle East, East Asia and North America (Cubo et al., 2005; Asadi-Pooya et al., 2019; Osman, Alsharief, & Siddig, 2020; Muthusamy et al., 2022). Accuracy of reporting and comparison of symptom rates are hindered by a lack of standardised objective measures for assessing the severity and extent of functional symptomatology (Nicholson et al., 2020; Pick, Anderson, et al., 2020) and socioeconomic factors involved in the availability of assessment and diagnosis facilities (Dekker et al., 2018, Hingray et al., 2018; Osman, Alsharief & Siddig, 2020). It appears that the prevalence of FND is associated with significant investment of health care resources; appropriate assessment and management of FND is needed to relieve experiential distress as well as unnecessary diagnostic procedures or hospital admissions.

### **1.3. Cognitive Dysfunction in FND**

Functional cognitive symptoms have been recognised as a phenotypic expression of FND and similar neurocognitive profiles have been found across FND phenotypes (Stone et al., 2011; Teodoro et al., 2018). However, cognitive phenotypes are not yet included in the DSM-5 classification for FND, with little information available to conceptualise these experiences (Ball et al., 2020). Evidence suggests that there are overlapping subtypes of functional cognitive difficulties with dissociative seizures, functional movement disorders, fibromyalgia, chronic fatigue syndrome, fugue state and Ganser syndrome (McWhirter et al., 2020; Orum and Atmaca, 2022; McWhirter & Carson, 2023). For example, those with functional movement disorders and dissociative seizures report more cognitive complaints than controls (Heintz et al., 2013; Myers et al., 2014; Orum and Atmaca; 2022). It is hypothesised that functional cognitive symptoms are almost always present in FND conditions (McWhirter & Carson, 2023).

There are differences in the way that functional cognitive symptoms are experienced in relation to the scope of the difficulties. For instance, a broad presentation of fatigue or “brain fog” would indicate a more generalised cognitive dysfunction across brain modalities. They may also present as difficulties within a particular cognitive domain, for example, in memory retrieval, which may be given a particular diagnostic classification, such as functional memory disorder or dissociative amnesia (see Table 1). The diagnosis of functional cognitive disorder can be used to describe the broad spectrum of cognitive dysfunction in FND. Evidence suggests that functional cognitive difficulties are present in between 25-50% of those attending specialised cognitive disorder clinics, making it one of the leading causes of cognitive dysfunction complaints (Pennington, Newson et al, 2015; Bharambe & Lerner, 2018b; Bhome, McWilliams et al., 2019; McWhirter et al., 2020). Exploring the nature and mechanisms underpinning these experiences will help to formulate the intervention needs.

### 1.3.1. Clinical Features

The symptoms associated with functional cognitive disorder include absent-mindedness, concentration difficulties, forgetfulness, and prospective memory lapses (Schmidtke, Pohlmann & Metternich, 2008; Pennington, Newson et al., 2015; Stone et al., 2015; Bhome, McWilliams et al., 2019). A review by McWhirter and colleagues (2020) suggest cognitive failures may be associated with other medical conditions, use of medication, or functional disturbances to cognitive and introspective processes. As training programmes and curriculums very rarely include information about FND presentations, there are concerns within the literature about the potential for functional cognitive difficulties to go undiagnosed, be misdiagnosed as neurodegeneration, or that clinicians will make inaccurate predictions of future decline, with the authors claiming this goes as far as iatrogenic harm (McWhirter et al., 2020). Some examples in the literature include the misattribution of the term pseudodementia to be given in clinical judgements, which specifically relates to the set of cognitive symptoms found in depression and mimic those of dementia (Bhome, McWilliams et al., 2019; McWhirter & Carson, 2023). Memory dysfunction in the absence of a recognisable cause is a differential diagnosis to prodromal dementia (Schmidtke & Metternich, 2009), and functional memory symptoms are not synonymous with the diagnoses of subjective cognitive impairment or mild cognitive impairment, although these diagnoses are often used interchangeably (Stone et al., 2015). It is important to inform those responsible for making clinical decisions about the features distinguishing functional cognitive difficulties from neurodegeneration.

Stone and colleagues (2015) described presentational features that help to distinguish functional cognitive symptoms from those caused by neurological disease include:

- a younger population
- greater awareness of the difficulties
- attending appointments alone
- ability to recall healthcare screening and medication use
- dissociative lapses
- variability in experiences that do not fluctuate out of an individual's natural ability.

Additionally, there is evidence that those with functional cognitive disorders tend to perform within the normative range on neuropsychological tests of memory and attention which is incongruent with reports of their everyday cognitive failures (Schmidtke, Pohlmann, & Metternich, 2008). This phenomenon is reflected in the concept of internal inconsistency, where those complaining of memory disturbances are able to retain the ability to give detailed descriptions of the memory failures. These include a) relaying personal information or reflections; b) displaying working memory in conversations and in compound questions; and c) faster response rates and the elaboration of detail when discussing memory failures (Stone et al., 2015; Jones et al., 2016). The phenomenon of internal inconsistency is believed to be caused by the switching from automatic unconscious processing to more effortful conscious control of cognitive functions (Ball et al., 2020; McWhirter & Carson, 2023). For example, when attention is directed towards memory functions, the tasks of memory encoding, storage and retrieval are brought into conscious awareness. Monitoring these functions causes an additional drain on cognitive energy, encoding of irrelevant contextual information, and making memory slips more frequent and more noticeable. The types of cognitive slips experienced in functional cognitive difficulties can occur quite naturally within the general population and increase across the lifespan (McCaffrey et al., 2006; Stone et al., 2015). However, there appears to be a fundamental difference in the way that those with FND interpret their subjective experiences of cognitive failures, particularly leading to a higher level of distress and disability.

McWhirter et al. (2020) helpfully compiled the following criteria to holistically define functional cognitive disorders:

- One or more symptoms of impaired cognition
- Clinical findings show evidence of internal inconsistency between objective measures of cognitive performance and self-report, or varying abilities in different situations
- Symptoms of impairment are not better explained by another medical disorder, although may be comorbid
- Symptoms or impairment cause clinically substantial distress or impairment in social, occupational, or other important areas of function, or warrant medical evaluation.

### **1.3.2. Mechanisms of Cognitive Dysfunction in FND**

To understand the intervention needs of those with functional cognitive difficulties, the biopsychosocial mechanisms and cognitive domains implicated in the cognitive dysfunction of FND are formulated.

#### **1.3.2.1. Biopsychosocial Mechanisms**

The biological factors influencing functional cognitive difficulties appear to be higher levels of fatigue, pain, and sleep disruption when compared to healthy controls, implications of medication use and heightened autonomic nervous system response, whereby researchers have suggested that symptom burden impacts on available attentional resources (Dick et al., 2008; Moriarty, McGuire & Finn, 2011; Pennington, Hayre, et al., 2015; Elhadd, Bharambe & Larner, 2018; Bhome, Huntley et al., 2019; McWhirter & Carson, 2023; Teodoro et al., 2023).

Similarly, the psychological experience of functional cognitive disorder often coincides with anxiety and affective symptoms, with depression being the most common comorbidity (McWhirter et al., 2020; McWhirter & Carson, 2023). Chronic dysfunction in attention, memory, and executive control have been found to remain when depression symptoms are accounted for (Christley et al., 2013; Stone et al., 2015), suggesting that negative self-evaluation and illness perceptions persist, specifically related to health anxiety. Perceptions of cognitive deficit as part of anxiety or depression also crossover with other somatoform conditions (Stone et al., 2015; McWhirter et al., 2020; Teodoro et al., 2023). Low memory self-efficacy and high memory-related achievement motivation, or perfectionism, also seem to be key psychological features of functional cognitive disorder, in that higher expectations of one's own memory performance can lead to pathologising of everyday forgetfulness or natural cognitive decline with age (Metternich, Schmidtke & Hüll, 2009; Pennington, Newson et al., 2015). Those with functional memory difficulties often present with all or nothing thinking styles, reporting perfect memory abilities before the onset of symptoms and describe their current difficulties in terms of absolute failure or disability (McWhirter and Carson 2023). These negative appraisals can manifest as withdrawal from memory activities for fear of failure, leading to deconditioning and lower cognitive reserve, prolonging the difficulties and worries about them (Moss-Morri & Chalder, 2003; McWhirter & Carson, 2023). This suggests that biological and psychological stress could be both a precursor and a consequence of cognitive failures in FND.

Social and occupational difficulties are also common for those with functional cognitive symptoms (Michiels & Cluydts, 2001; Schmidtke, Pohlmann, & Metternich, 2008; Stone et al., 2015). Recent onset and persistent medically unexplained symptoms have been found to have a significant impact on those rejecting promotions, retiring early, receiving disability related financial benefits, and depending on carers (Berrios, Marková & Giralá, 2000; Reuber et al., 2003; Rask et al., 2015). More than half of those with functional cognitive disorder reported that they were unemployed because of the condition (Bhome, Huntley et al., 2019).

Therefore, the mechanisms of functional cognitive disorders appear to be underpinned by reciprocal relationships between the experience of natural cognitive failures, cognitive dysfunction due to drains on attentional resources, negative illness perceptions, health anxiety, reduced self-efficacy, and underperformance in social, work and home settings.

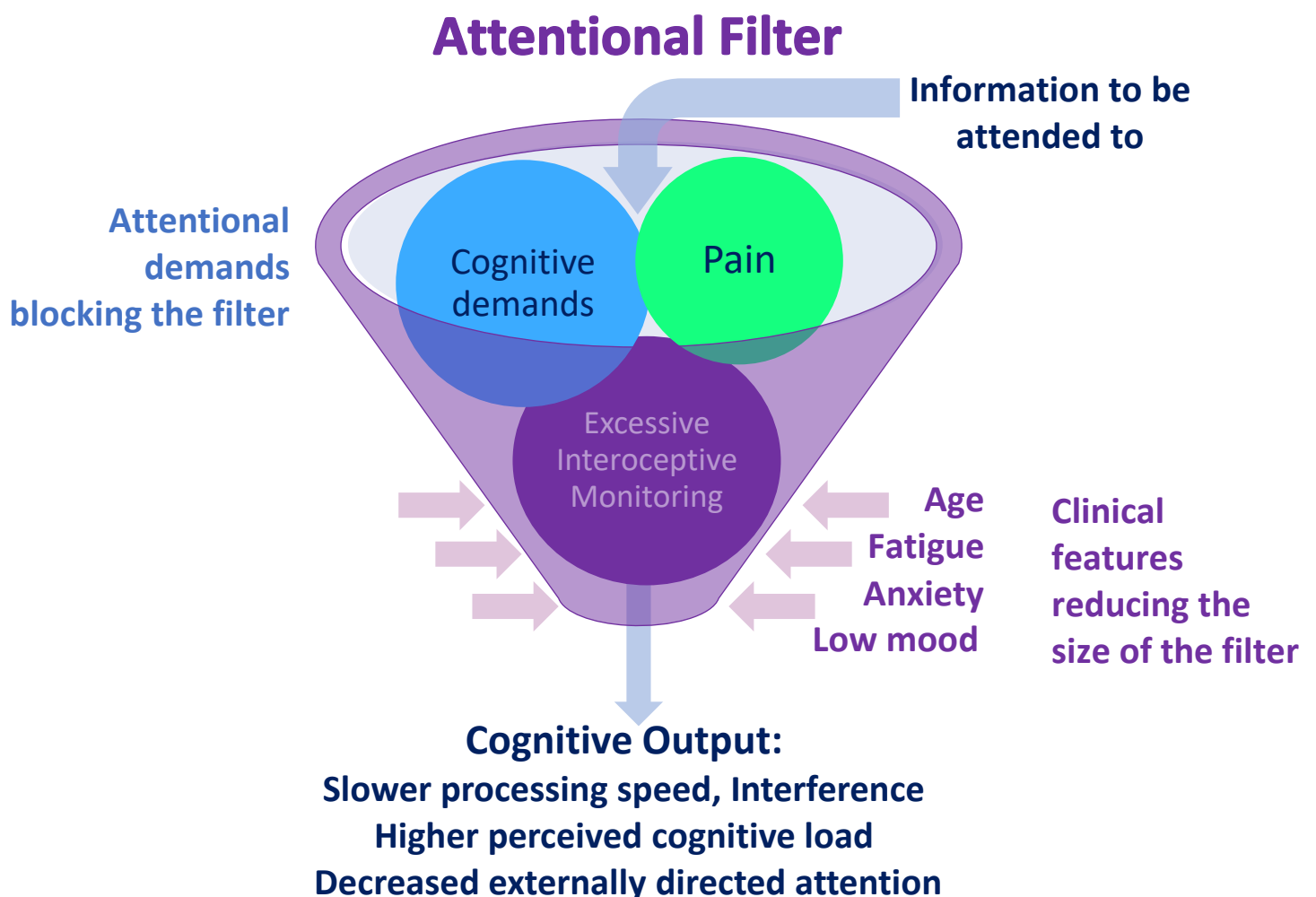
### **1.3.2.2. Cognitive Domains**

#### **1.3.2.2.1. Attention**

Attentional processes form the fundamental foundations for other cognitive functions; only once information has been attended to can it be processed by other cognitive modalities. Attentional difficulties can cause disruption to memory and reaction time tasks and have been noted in the FND presentations of fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome and functional cognitive disorders (Dick et al., 2008; Christley et al., 2013; Stone et al., 2015; Teodoro, Edwards & Isaacs, 2018; Keynejad et al., 2019; 2020).

It is hypothesised that pain and excessive interoceptive monitoring have implications for distractibility, reduced attentional awareness, impaired selective attention, and divided attention in FND (Teodoro, Edwards & Isaacs, 2018; Teodoro et al., 2023). In accordance with Broadbent's (1958) filter theory of selective attention, these functions may limit how much information can be processed at one time, essentially blocking the attentional filter. Other clinical features such as fatigue, age, mood, and autonomic nervous response may limit the filter's capacity further. This process is described in the filter theory of FND attentional difficulties (Teodoro, Edwards, & Isaacs, 2018) as depicted in Figure 1.

Evidence of this mechanism has been found in functional movement disorders, whereby impaired motor control is seen following attentional exhaustion from sustained and divided attention demands (Pareés et al., 2013; Teodoro et al., 2023). Similarly, prolonged periods of concentration can cause disruptions to working memory in chronic fatigue syndrome (Caseras et al., 2006; Christley et al., 2013). Functional neuroimaging studies of those with functional somatosensory deficits have been found to exhibit similar dysfunction in attentional regions, suggesting that impaired interoception, attentional neglect, dissociation, and emotional unawareness are implicated with the corresponding brain region activity (Perez et al., 2012). Perez et al (2012) described the ‘functional unawareness’ construct, a helpful neurobiological framework that conceptualises the brain-behaviour relationships in functionality with FND.



**Figure 1.** Bottle neck effect of attention, as theorised by Broadbent (1958), whereby symptoms of functional neurological disorder are implicated in outcomes described by Teodoro, Edwards & Isaacs (2018).



### **1.3.2.2.2. Memory**

As one of the distinctive features of functional cognitive disorder is the phenomenon of internal inconsistency, there are incongruences found in memory processing. Ball et al. (2021) found that those with functional cognitive disorder tended to display impaired immediate recall and recognition yet spared delayed recall and retention. This suggests that access to memory stores has been disrupted for immediate retrieval of information but is encoded as it can be retrieved after a delay. This supports the theory that subjective memory complaints are incongruent with objective memory performance. Accordingly, the frequently reported incongruence between subjective impairment and objective measurements may present challenges to the psychometric assessment of cognitive dysfunction in FND (Larner, 2020), with approximately 50% of FND patients continuing to give invalid neuropsychological results after measuring and accounting for effort. Additionally, with longer task duration, increased confidence in ability can improve memory performance (Pennington, Hayre et al., 2015; Pennington et al., 2021), supporting the influence of memory self-efficacy on performance (Metternich, Schmidtke & Hüll, 2009).

Ten categories of memory dysfunction in FND have been postulated (Schmidtke, Pohlmann & Metternich, 2008; Stone et al, 2015) as follows:

- Memory symptoms as part of anxiety or depression
- Natural memory symptoms that become the focus of attention
- Natural memory symptoms that are not explained by anxiety
- Health anxiety about dementia
- Memory symptoms as part of another functional disorder
- Dissociative amnesia
- Memory symptoms secondary to prescribed medication or substance misuse
- Memory symptoms from neurological disorders other than dementia
- Memory symptoms that develop into dementia or another neurological disease
- Exaggeration or malingering

The authors hypothesised that these typologies may overlap but differ in causation or outcome and so need differential treatments. Presentational examples include difficulties encoding information from conversations, amnesic blocks where information used every day like names

or PIN numbers cannot be retrieved, and prospective memory failures of forgetting appointments (Berrios, Marková & Giralá, 2000; Metternich, Schmidtke & Hüll, 2009).

#### **1.3.2.2.3. Processing Speed and Cognitive Fatigue**

Both processing speed difficulties and cognitive fatigue are consistently associated with functional cognitive disorder. Teodoro et al. (2023) found significantly slower reaction times in incongruent Stroop test conditions that induced interference compared to congruent conditions, as well as when compared to healthy controls. Whereas, in more challenging tasks where attention was divided between visual and auditory stimuli, no significant differences in reaction times or errors were found between groups. This suggests that slower reaction times are a trait of FND and not a function of task difficulty, corroborating subjective reports of greater mental workload. Other studies have supported this with evidence of reduced motor speed, slower reaction times and poorer performance on time limited tasks or those that require rapid manipulation of information when compared to controls (Deluca et al, 2004; Christley et al., 2013). This would be consistent with a greater emphasis on effortful, conscious processing. Differential abilities in processing speed may be due to deficits in decision speed, being the time to respond to moderately complex tasks, compared to perceptual speed, being the time taken to respond to simple tasks with no errors (Salthouse, 2000). Deluca et al (2014) found that those with chronic fatigue syndrome showed impairment in complex information processing, which may mirror other findings across FND phenotypes. They hypothesised that there may be at least two independent constructs of information processing influencing this finding, one being responsible for simple information processing and slowed performance, and another responsible for complex information processing where speed deficits would only be present in cognitively challenging tasks. This supports the notion that slower processing speed and cognitive fatigue associated with FND is consistent regardless of attentional demand.

#### **1.3.2.2.4. Executive Functioning**

It is theorised that the top-down processing aspects of cognitive control, which provide decisions to direct executive functioning to other cognitive domains, may be compromised in functional cognitive disorder (Perez et al., 2012; Keynejad et al., 2019). As such, higher order cortical control may bring some attentional processes into conscious awareness more prominently, or unhelpfully remove them from online conscious control when needed. This

may be due to impaired connectivity between the supplementary motor area, implicated in self-awareness and motor control, and inhibitory areas of the prefrontal cortex (Keynejad et al., 2019). For instance, those with functional tremors were found to perceive 65% higher rates of tremors than were objectively measured, compared to a 28% over estimation by those with organic tremors (Pareés et al., 2012). The increase in reporting of stimuli perception was hypothesised to occur through an inference process, whereby the expected frequency of tremors overwhelmed the capacity to monitor actual sensory input, resulting in a biased and counterfactual impression of the symptom. The implications of this may be a top-down controlled attentional spotlight, where the relationships between sensory evidence and prior expectations is mediated by bodily attention, expectations of symptoms, emotional experiences, and illness beliefs (Edwards et al., 2012; Keynejad et al., 2019). Hallett (2016) described studies with other relevant examples. Inhibition of the motor cortex in functional weakness or paralysis occurred with overactivation of frontal cortical areas when shown motor imagery, which would usually increase motor evoked potentials from the motor cortex to spinal cord to muscle function. Contradictory results have been found with reduced anaesthetising effects of the somatosensory cortex with the addition of anaesthesia. It is believed that there is a switch from automatic processing to more effortful cognitive control in FND, which leads to slower processing speed, greater interference, higher perceived cognitive load and decreased externally directed attention (Teodoro, Edwards & Isaacs, 2018), as shown in Figure 1.

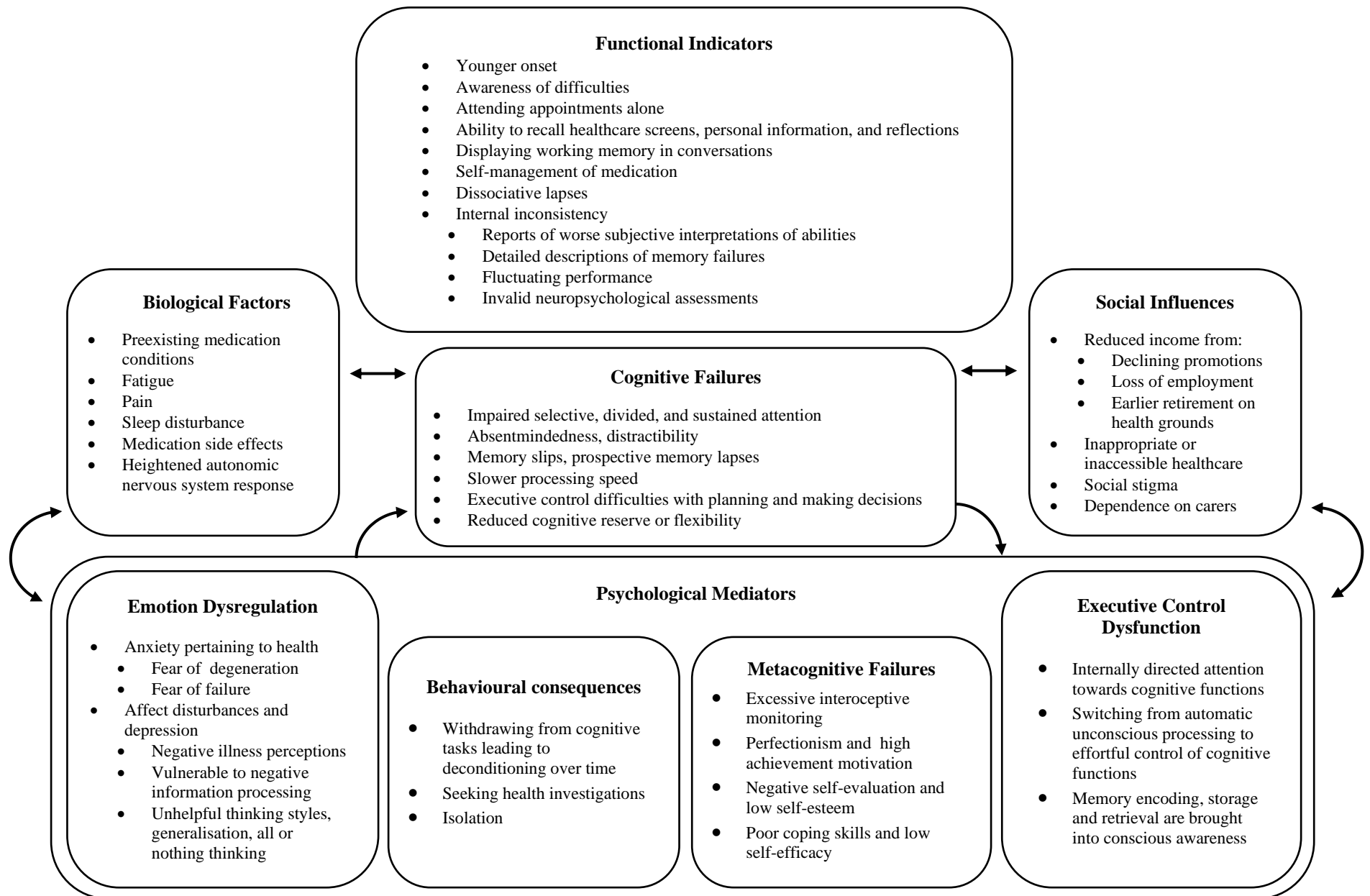
Those with functional cognitive difficulties frequently underestimate their own cognitive abilities, implying difficulties with error monitoring and confidence in decision making as part of wider executive control (Pennington, Newson et al., 2015). Metacognition is believed to play a large role in functional cognitive disorder, considering the ability to reflect, monitor and evaluate cognitive processing (Ball et al., 2020; Larner, 2020; Bhome, McWilliams et al., 2019, Teodoro et al., 2023). Metacognitive failures manifest as impaired self-awareness of one's own cognitive abilities, experiencing disproportionate concern about cognitive decline (Bhome, McWilliams et al., 2019; McWhirter & Carson, 2023; Teodoro et al., 2023). When attention is directed towards monitoring one's own cognitive performance, this leads to exhausted cognitive reserve, reducing the amount of attention paid to the environment and increasing the likelihood of cognitive failures, with a greater amount of mental effort needed for cognitive clarity. However, reviews of the literature have suggested that there is limited evidence of local

metacognitive deficits (Bhome, McWilliams et al., 2019). More evidence is needed before this hypothesis can be accepted.

### **1.3.3. Summary of Cognitive Dysfunction in FND**

Discrepancies between the subjective perception and objective measurement of cognitive dysfunction has been observed with respect to attention, memory, processing speed, cognitive fatigue and executive functioning. The consistent finding of an incongruence between the subjective perception and objective measurement of cognitive dysfunction would suggest that those with FND misinterpret the perception of cognitive dysfunction or even benign variation in natural cognitive performance. This misinterpretation serves to reinforce the perception of cognitive dysfunction and amplify the subjective estimate of its frequency and severity, encouraging further interoceptive monitoring which may itself cause further deterioration of cognitive performance due to the blocking of other cognitive processing. It may also be speculated that the increased perception of cognitive dysfunction and interoceptive monitoring may initiate negative emotional reactions to the perception of cognitive dysfunction which overtime may lead to avoidance situations that place demands on cognitive abilities, leading to further exacerbation of disability.

The formulation in Figure 2 summaries the biopsychosocial interactions and the functional indicators that distinguish cognitive dysfunction as a phenotype of FND. In particular, the framework of psychological mediators can be formulated as the impact of emotion dysregulation, executive control dysfunction, metacognitive failures, and the behavioural consequences, each of which result in perpetuating cycles of distress and disability.



**Figure 2.** Formulation of biopsychosocial mechanisms of cognitive dysfunction in FND.

### **1.3.4. Implications for the Treatment of Cognitive Dysfunction in FND**

It is evident that the needs of those with functional cognitive disorders would require interventions that target the neuropsychosocial mechanisms of FND to address the disabling and distressing effects of the disruptions to several cognitive domains. It is unknown what interventions are available, or most efficacious, due to a lack of sound empirical support for treatment specific models (Williams et al., 2016; Ganslev et al., 2020; Larner, 2020; Gutkin et al., 2021; McLoughlin et al., 2023).

It may be inferred from the current literature that successful interventions would need to account for and address the multitude of neurological, psychological, and social needs of those experiencing functional cognitive difficulties. It would be expected for interventions to specifically include treatment components of:

1. emotion regulation: the ability to manage and respond to emotional experiences in a balanced way
2. behavioural activation: deliberately performing behaviours and prioritising activities that improve wellbeing management
3. metacognitive adjustments: reflecting, monitoring, and evaluating cognitive processing more accurately
4. executive control remediation: increased externally directed attention through emphasis on bottom-up sensory processing

Similarly, to assess whether an intervention was effective in the rehabilitation of cognitive difficulties in FND, interventions would also be expected to:

5. measure the impact on cognitive performance: neuropsychological assessment of cognitive domains whilst accounting for internal inconsistencies

## **1.4. Aims of the current review**

This systematic review aims to identify the conclusions that can be derived from the existent literature and learn from practice-based evidence towards recommendations for the next wave of outcome studies. This is going to be achieved by:

- identifying the literature that reports interventions for cognitive difficulties in those with FND
- describing the components of the interventions and what specific outcomes were measured
- reviewing the efficacy of the interventions and whether they meet the hypothesised treatment components.

## **1.5. Method**

The procedures used to explore the evidence-based literature are described, in relation to identifying studies which evaluate available interventions for cognitive difficulties in FND and their study characteristics, to be used for comparison with the expected treatment components. Studies were identified by searching literature databases and applying inclusion and exclusion criteria to specify those relevant to the review.

### **1.5.1. Search of Electronic Databases**

A systematic search of the literature was initially undertaken in October 2022 using the OVID electronic gateway to search Medline, APA PsychInfo and Embase databases. The aim of the search was to obtain a comprehensive overview of the literature investigating interventions for the cognitive symptoms of FND. The limiters of English language and human research were used to filter the search data. The search terms were categorised into constructs of ‘FND phenotype,’ ‘cognitive symptoms’ and ‘trial type.’ Search terms for ‘FND phenotype’ and ‘trial type’ were adopted from the review completed by Ganslev et al. (2020), investigating psychosocial interventions for FND. The terms ‘functional cognitive disorder’ and ‘functional memory disorder’ were added to include the cognitive experiences of FND. A construct of ‘cognitive symptoms’ was used to include studies that specifically measured ‘memory,’ ‘attention,’ or ‘cognition’ more broadly. The search terms are outlined in Table 2.

**Table 2: Search Criteria**

<b>Construct</b>	<b>Search Terms</b>	<b>Method of Search</b>	<b>Limits</b>
<b>FND phenotype</b>	<ul style="list-style-type: none"> <li>• conversion disorder/</li> <li>• (conversion disorder* or conversion reaction* or conversion hysteria* or functional neurological disorder*).mp.</li> <li>• dissociative disorder/</li> <li>• (dissociative possession* or dissociative disorder* or possession disorder* or trance disorder* or fugue* or dissociative amnesia* or dissociative stupor* or dissociative convulsion* or dissociative symptom* or dissociative identit*).mp.</li> <li>• hysteri*.mp.</li> <li>• multiple personality disorder*.mp.</li> <li>• (non-epileptic or nonepileptic or pseudo-seizure* or pseudoseizure* or psychogenic non-epileptic seizure* or psychogenic nonepileptic seizure* or psychogenic non epileptic seizure* or PNES).mp.</li> <li>• ganser*.mp.</li> <li>• fibromyalgia*.mp</li> <li>• (chronic fatigue syndrome* OR CFS OR ME OR myalgic encephalomyelitis*).mp.</li> <li>• functional cognitive disorder*.mp</li> <li>• functional memory disorder*.mp</li> </ul>	<ul style="list-style-type: none"> <li>• Free search terms</li> <li>• All search terms per construct combined with <i>OR</i></li> <li>• Combination search terms for each construct combined with <i>AND</i></li> </ul>	<ul style="list-style-type: none"> <li>• English Language</li> <li>• Humans</li> </ul>
<b>Cognitive symptoms</b>	<ul style="list-style-type: none"> <li>• memory.m_titl.</li> <li>• attention.m_titl.</li> <li>• cognition.m_titl.</li> </ul>		
<b>Trial type</b>	<ul style="list-style-type: none"> <li>• randomized controlled trial/</li> <li>• randomised controlled trial*.mp.</li> <li>• controlled clinical trial*.mp.</li> <li>• random*.mp.</li> <li>• trial*.mp.</li> <li>• (treatment as usual or waitlist or waiting list).mp.</li> </ul>		



### **1.5.2. Inclusion and Exclusion criteria**

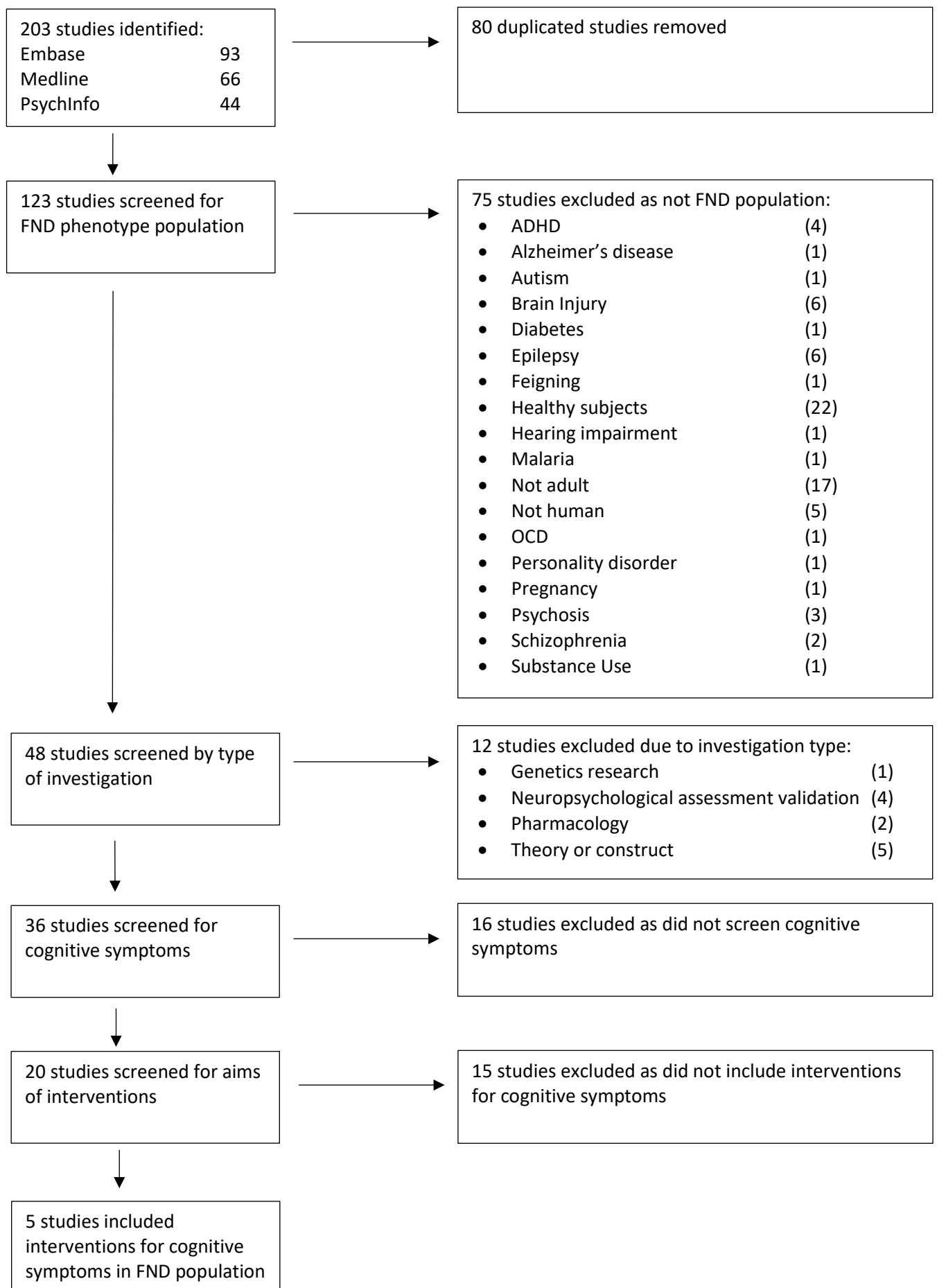
Full inclusion and exclusion criteria are described in Table 3, broken down into the respective criteria. The focus of the criterion of ‘study population’ was to include those experiencing a phenotypic expression of FND. Studies using participants who did not experience FND symptoms were excluded from the review. The criterion of ‘investigation type’ was limited to a treatment intervention to retrieve primary research outcomes. Studies needed to measure cognitive performance before and after the intervention to be included in the ‘outcome data’ criterion. The criterion for ‘nature of the intervention’ needed to include a treatment looking at non-pharmacological interventions for relieving the measured cognitive symptoms. Finally, the criterion for ‘study design’ needed to show robust evidence-based support of the knowledge base for it to be included, thus only controlled, such as randomised controlled trials, non-randomised control comparisons or before and after studies, were included in reviewing the efficacy of the intervention.

**Table 3: Inclusion and Exclusion Criteria.**

<b>Criterion</b>	<b>Inclusion Criteria</b>	<b>Exclusion Criteria</b>	<b>Justification</b>
<b>Study population</b>	<ul style="list-style-type: none"> <li>• Participants who have FND, a phenotypic expression of FND or symptoms of FND</li> <li>• Control subjects included in the study may also have FND, a phenotypic expression of FND, symptoms of FND, or be identified as healthy controls</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that exclusively include participants without FND symptoms</li> <li>• Studies that include university or college populations</li> </ul>	This is to ensure that studies included in the search only investigate the experiences of those with FND, and to also capture those who experience symptoms of FND but have not been given a diagnosis. The University population is an idiosyncratic population and so, these studies will be excluded to reduce this bias.
<b>Type of investigation</b>	<ul style="list-style-type: none"> <li>• Studies that report on interventions targeted towards those who have FND, or a phenotypic expression linked with FND</li> </ul>	<p>The following article types were excluded:</p> <ul style="list-style-type: none"> <li>• theoretical papers</li> <li>• reviews</li> <li>• commentaries</li> <li>• clinical guidance</li> <li>• non-outcome focused studies i.e., longitudinal/association studies</li> <li>• case studies</li> <li>• validation of psychometric scales</li> <li>• qualitative papers</li> <li>• meta-analysis</li> </ul>	This review is solely focussed on intervention studies through primary research to provide objective outcome data. Other types of articles may include biased narratives.
<b>Outcome Data</b>	<ul style="list-style-type: none"> <li>• Studies that have included measures of cognitive performance before and after the intervention</li> <li>• Studies that present group data</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that present individual scores</li> </ul>	This is to evaluate the efficacy of the intervention at targeting cognitive symptoms.
<b>Nature of intervention</b>	<ul style="list-style-type: none"> <li>• Studies that include interventions aimed at relieving the cognitive symptoms associated with FND, a phenotypic expression of FND or symptoms of FND</li> <li>• To reflect the broad landscape of the literature, the intervention may incorporate any therapeutic elements other than pharmacological or medication.</li> <li>• Studies that include group interventions and individual interventions</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that do not include interventions aimed at relieving cognitive symptoms</li> </ul>	This is to ensure the specificity of the intervention towards the aims of the review.
<b>Study Design</b>	<ul style="list-style-type: none"> <li>• Studies that include any controlled study, such as randomised controlled trials, non-randomised controlled trials and before and after studies</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that include single cases or case series</li> </ul>	This is to ensure robust empirical data as part of the knowledge base is being reviewed.

### **1.5.3. Application of Inclusion Criteria**

The results of the systematic literature search are presented in Figure 3. The search yielded a total of 203 articles, leaving 123 once duplicates were removed. The study titles and abstracts were screened according to the exclusion criteria. Firstly, 78 articles were excluded because the population being studied did not conform to the criteria for FND, with the most common reasons for exclusion as having only healthy control participants such as university students (n = 22) or directed towards the experiences of children or adolescents (n = 17). Forty-eight articles were screened by type of investigation, with 12 studies being excluded for only including genetics research (n = 1), neuropsychological assessment validation (n = 4), pharmacology treatments (n = 2), or validating a theory or a construct (n = 5). The full text of the remaining 36 studies were reviewed, 16 of which were excluded as they did not measure cognitive symptoms. Out of the 20 studies remaining, 15 studies did not include an intervention specifically targeting the phenomenon or experience of cognitive symptoms in FND and so were excluded. Each of the remaining five studies met the criteria for study design, with four including randomised controlled trials and one including a non-randomised controlled trial. Thus, the remaining five studies included investigations into the efficacy of interventions for cognitive symptoms in an FND population, meeting the full inclusion criteria for this review.



**Figure 3.** Prisma diagram showing the selection process for review

#### **1.5.4. Study Characteristics**

The characteristics of the five studies included for review (Baudic et al., 2013; Maroti et al., 2015; Metternich et al., 2008; Norouzi et al., 2020; Santos et al., 2018) are summarised in Table 4, which outlines the study design, population and sample size, the treatment aims and measures used. The populations used as study participants included those with fibromyalgia (Baudic et al., 2013; Norouzi et al., 2020; Santos et al., 2018), chronic fatigue syndrome (Maroti et al., 2015) and functional memory disorder (Metternich et al., 2008). Each of the studies assessed cognitive performance both before and after the intervention, on a range of different cognitive domains.

**Table 4:** Characteristics of the reviewed studies

Study	Design	Population	Sample size	Intervention	Aims	Cognitive and Other Outcome Measures
<b>Baudic et al. (2013)</b>	Randomised controlled trial	Fibromyalgia	Experimental Group: N = 20 (gender not reported) mean age 51.8 yrs Control Group: N = 18 (gender not reported) mean age 49.7 yrs	Repetitive transcranial magnetic stimulation (rTMS) for pain management	Assess cognitive functions in those with fibromyalgia whilst undergoing rTMS	<i>Immediate memory and verbal learning</i> - The Rey Auditory Verbal Learning Test <i>Sustained attention, concentration and directed shifting</i> - The Symbol Digit Modalities Test - The Trail Making Test - The Stroop Colour Word Test
<b>Maroti et al. (2015)</b>	Non-randomised controlled trial	Chronic Fatigue Syndrome	Experiment Group: N = 9 (5 women, 4 men) mean age 39 yrs Control Group: N = 12 (10 women, 2 men) mean age 42 yrs	Computerised training programme for working memory	Evaluate computerised training on working memory	<i>Working Memory</i> - Digit Span of Wechsler Adult Intelligence Scale
<b>Metternich et al. (2008)</b>	Randomised controlled trial	Functional Memory Disorder	Experimental Group: N = 15 (5 women, 10 men) mean age 57.4 yrs Waiting List Control Group: N = 16 (6 women, 10 men) mean age 53.5 yrs	Stress management group, including education, cognitive behavioural formulations, relaxation techniques	- Increase memory self-efficacy - Reduce achievement motivation of perfectionism in memory performance - Reduce perceived stress or psychiatric complaints	<i>Memory</i> - Verbaler Lern- und Merkfähigkeitstest (VLMT): German Version of the Auditory Verbal Learning Test <i>Cognitive Speed</i> - Zahlenverbindungstest (ZVT): German version of the Trail-Making-Test-A <i>Premorbid intelligence</i> - Mehrfachwahlwortschatztest Version B (MWT-B): German version of the National Adult Reading Test <i>Attention Deficit Hyperactivity Disorder</i> - Wender Utah Rating Scale (WURS-k) in German <i>Depression and other relevant "Axis-I" disorders</i> - Beck Depression Inventory (BDI) - Structured Clinical Interview for DSM-IV, Axis I: Psychological disorders <i>Memory self-efficacy</i> - Metamemory in Adulthood Questionnaire (MIA). A German version was obtained from the original authors. <i>Achievement motivation pertaining to memory</i> - "Achievement" subscale of the MIA (see above) - Perceived Stress Psychiatric symptoms - Perceived Stress Questionnaire (PSQ) - Symptom Checklist (SCL-90-R) <i>Direct measurement of therapy effects</i> - Unidentified <i>Client satisfaction</i> - Zürcher Fragebogen zur Patientenzufriedenheit (ZUF-8). German version of the CSQ-8

Study	Design	Population	Sample size	Intervention	Aims	Cognitive and Other Outcome Measures
Norouzi et al. (2020)	Randomised controlled trial	Fibromyalgia	Experimental Group 1: N = 20 women mean age 35.5 yrs Experimental Group 2: N = 20 women mean age 35.5 yrs Control Group: N = 20 women mean age 35.4 yrs	Aerobic exercise and Zumba dancing for fibromyalgia	Compares impact of aerobic exercise training and Zumba dancing on working memory, motor function and depressive symptoms	<i>Working Memory</i> - N-back computerised test <i>Motor Function</i> - Timed Up and Go test (TUG) <i>Depressive Symptoms</i> - Persian version of Beck Depression Inventory (BDI-II)
Santos et al. (2018)	Randomised controlled trial	Fibromyalgia	Experimental Group: N = 20 women mean age 49.2 yrs Control Group: N = 20 women mean age 50.1 yrs	Transcranial direct current stimulation (tDCS) for cognitive dysfunction	Compare impact of tDCS and working memory training on immediate and delayed memory, verbal fluency and working memory	<i>Sleep Quality</i> - Pittsburgh Sleep Quality Index <i>Depressive Symptoms</i> - Beck Depression Inventory (BDI-II) <i>Quality of Life</i> - Fibromyalgia Impact Questionnaire (FIQ): Brazilian validated version <i>Catastrophic Thinking</i> - Brazilian Portuguese version of Pain Catastrophising Scale (BP-PCS) <i>Anxiety</i> - State Trait Anxiety Inventory (STAI) <i>Pain</i> - Brazilian Profile of Chronic Pain: Screen (B-PCP:S) - Visual Analogue Scale (VAS) - Heat pain threshold and tolerance <i>Psychiatric Disorder</i> - Mini-International Neuropsychiatric Interview (MINI) <i>Memory</i> - Rey Auditory-Verbal Learning Test (RAVLT) <i>Fluency</i> - Controlled Oral Word Association Test <i>Attention</i> - Forward and Backward Digit Span - Paced Auditory Serial Addition Test (PASAT)

## 1.6. Risk of Bias Analysis

### 1.6.1. Study Design Hierarchy

The various study designs reported in the literature were evaluated using a hierarchy (see Table 5), where methodological flaws and biases to the data were considered whilst weighting with a quality score to reflect the evidence carrying capacity of each of the studies. Only studies that included randomised controlled trials, non-randomised controlled trials or before and after studies were included in this literature review, being given a quality score of 30, 20 and 10 respectively, to reflect the quality of evidence that would be provided by the design.

**Table 5:** Study Design Hierarchy

<b>Study Design</b>	<b>Quality Score</b>	<b>Description</b>
<b>Randomised controlled trial/experiment</b>	30	These are experimental studies comparing groups (usually two) to establish the effectiveness of specific interventions. The most common design is to compare a new intervention against normal practice (treatment as usual). Participants in the trials are randomly assigned to the treatment/control groups to minimise bias.
<b>Non-randomised controlled trial/experiment</b>	20	These trials are run when it is not possible to incorporate randomisation into the design. There is an increased risk of biases being introduced into the research and this should be considered carefully when analysis is reported.
<b>Before and after study</b>	10	Before and After Study is a study in which within-subject observations are made before (pre) and after (post) the implementation of an intervention/exposure.



### **1.6.2. Risk of Bias Framework**

The risk of study level bias was assessed using criteria developed specifically for this review, which are in line with the recommendations by Higgins et al. (2011) for risk of bias analysis in systematic reviews and metaanalyses.

The risk of bias criteria were adapted from existing risk of bias frameworks, including The Cochrane Collaboration Risk of Bias Tool (Higgins et al., 2011) and the Risk of Bias Assessment Tool for Nonrandomised Studies (Kim et al., 2013). The current framework assesses risk of bias in seven domains: selection bias, performance bias, treatment fidelity, detection bias, statistical bias, reporting bias and generalisation. For each of the included studies, the risk of bias in the seven domains was rated as either 'low', 'unclear' or 'high risk.' The criteria for these risk categories are described in Table 6 and the application of these criteria are reported in Table 7.

**Table 6: Quality Criteria Framework**

Domain	Description	Risk of Bias		
		Low Risk	Unclear Risk	High Risk
<b>Selection Bias</b>	<p>If using randomisation, has the study clearly described the method of allocation? Has this allowed for comparable groups?</p> <p>Was convenience sampling used? If so, studies should be penalised.</p>	<ul style="list-style-type: none"> <li>- The characteristics of the study group are clearly described.</li> <li>- Sampling method used is good (i.e., some form of random sampling taken from representative population).</li> </ul>	<ul style="list-style-type: none"> <li>- The characteristics of the study group are not clearly defined.</li> <li>- It is not clear how the researchers sampled the study group.</li> <li>- Selection method is not ideal (e.g., quasi randomised), although characteristics of the study group are representative of the target population.</li> <li>- Limited details on method of allocation to conditions</li> </ul>	<ul style="list-style-type: none"> <li>- The study has used opportunistic or non-random sampling to select participants.</li> <li>- The characteristics of the study group are not representative of the target population.</li> <li>- No randomisation to conditions has occurred</li> </ul>
<b>Performance Bias</b>	<p>Differences in the levels/type of effort or motivation between the groups.</p>	<ul style="list-style-type: none"> <li>- Steps have been put in place to prevent participant lack of effort or motivation affecting performance across conditions.</li> </ul>	<ul style="list-style-type: none"> <li>- Not reported upon.</li> </ul>	<ul style="list-style-type: none"> <li>- No steps have been put in place to prevent lack of participant effort or motivation affecting performance</li> </ul>
<b>Intervention Fidelity</b>	<p>Were procedures in place to assess the fidelity of the administered interventions? How did the researchers ensure this occurred?</p>	<ul style="list-style-type: none"> <li>- Intervention clearly described.</li> </ul>	<ul style="list-style-type: none"> <li>- Little mention of the processes used to ensure intervention fidelity, limited details on what the conditions involved.</li> </ul>	<ul style="list-style-type: none"> <li>- No mention of processes used to ensure intervention fidelity.</li> </ul>
<b>Detection Bias</b>	<p>Are the outcome assessors blind to participant allocation?</p>	<ul style="list-style-type: none"> <li>- Outcome assessor is blind to participant allocation.</li> </ul>	<ul style="list-style-type: none"> <li>- Not reported on.</li> </ul>	<ul style="list-style-type: none"> <li>- No blinding of outcome assessment has taken place.</li> </ul>

Domain	Details	Risk of Bias		
		Low Risk	Unclear Risk	High Risk
<b>Statistical Bias</b>	<p>Have appropriate statistical methods been used?</p> <p>Is there incomplete data due to attrition?</p>	<ul style="list-style-type: none"> <li>- Appropriate statistical methods used</li> <li>- Less than 20% attrition.</li> </ul>	<ul style="list-style-type: none"> <li>- No information on attrition rates.</li> </ul>	<ul style="list-style-type: none"> <li>- Inappropriate statistical methods used</li> <li>- Greater than 20% attrition.</li> </ul>
<b>Reporting Bias</b>	<p>Is there evidence of selective outcome reporting? i.e., only significant results reported.</p> <p>Are there measures that have not been reported in the results that have been mentioned in the method section?</p> <p>Does the study provide reasons for attrition or exclusions of participants?</p>	<ul style="list-style-type: none"> <li>- Reported all results of measures as outlined in the method</li> <li>- All exclusions/attrition described.</li> </ul>	<ul style="list-style-type: none"> <li>- Not all descriptive and/or summary statistics are presented.</li> </ul>	<ul style="list-style-type: none"> <li>- Not reported full outcome measures that are stated in the method section/reported only a subsample of results/only significant results.</li> <li>- No reasons provided for exclusion or attrition.</li> </ul>
<b>Generalisation</b>	<p>Can the research findings be applied to settings other than that in which they were originally tested?</p> <p>Is there a sufficient number of participants for the study to be meaningful?</p>	<ul style="list-style-type: none"> <li>- Sufficient sample for generalisation and representative of target population (&gt;20 per group).</li> </ul>	<ul style="list-style-type: none"> <li>- Sufficient sample for generalisation but some idiosyncratic features evident (&gt;20 per group).</li> </ul>	<ul style="list-style-type: none"> <li>- Small sample with or without idiosyncratic features (&lt;20 per group).</li> </ul>

### **1.6.3. Overall Quality Index**

A scoring system was applied to each risk category from the quality criteria framework, whereby domains evaluated as low risk of bias scored two points, those ranked as having an unclear risk scored one point, and those ranked as having a high risk scored zero points. Summing the scores for each domain would give a total risk of bias score, which would vary between 0 and 14 points. The study design quality score and the study design hierarchy score were summed and the overall quality index for each study was expressed as a percentage of the maximum possible score, being a randomised controlled trial without risks of bias.

### **1.6.4. Risk of Bias Outcomes**

The risk of bias outcomes for each study are presented in Table 7 with descriptions explaining where each study meets the standards of the quality criteria framework in relation to each bias domain.

**Table 7:** Risk of Bias Outcomes

Study	Study Design	Selection Bias	Performance Bias	Intervention Fidelity	Detection Bias	Statistical Bias	Reporting Bias	Generalisability	Study Design Quality Score	Total Risk of Bias Score	Overall Quality Index
<b>Baudic et al. (2013)</b>	Randomised controlled trial/experiment	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk	High risk	30	9	88.6%
<b>Maroti et al. (2015)</b>	Non-randomised controlled trial/experiment	Low risk	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	High risk	20	8	82.4%
<b>Metternich et al. (2008)</b>	Randomised controlled trial/experiment	Low risk	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	High risk	30	10	90.9%
<b>Norouzi et al. (2020)</b>	Randomised controlled trial/experiment	Low risk	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	High risk	30	10	90.9%
<b>Santos et al. (2018)</b>	Randomised controlled trial/experiment	Low risk	Unclear risk	Low risk	Low risk	Low risk	Low risk	High risk	30	11	93.2%

#### **1.6.4.1. Selection Bias**

With regard to selection bias, all of the five studies included in the review (Baudic et al., 2013; Maroti et al., 2015; Metternich et al., 2008; Norouzi et al., 2020; Santos et al., 2018) were rated as low risk due to adequate descriptions of participant recruitment, sampling demographics and randomisation to experimental and control groups.

#### **1.6.4.2. Performance Bias**

All the included studies were rated as having unclear risk for performance bias, by omitting whether there were incentives provided to participants for completing the study or whether effort was assessed. It is therefore difficult to detect whether behaviours were influenced by internal or external motivators.

#### **1.6.4.3. Intervention Fidelity**

All the included studies were rated as low risk of intervention fidelity due to adequate descriptions of the procedures taking place during the assessments and interventions, allowing replicability for further application or study.

#### **1.6.4.4. Detection Bias**

Two of the studies were rated as having low risk of detection bias, with descriptions of replicable double-blind procedures for transcranial magnetic stimulation interventions (Baudic et al., 2013; Santos et al., 2018). In contrast, three studies were rated as having an unclear risk of detection bias. Maroti et al. (2015) and Norouzi et al. (2020) did not report whether assessments or interventions were conducted with a blind experimental approach. Metternich et al. (2008) stated that participants were not blind to their group membership and omitted information about blind assessor procedures. This may have led to confounding influences on the assessors' and participants' behaviour if the hypotheses of these studies could be assumed.

#### **1.6.4.5. Statistical Bias**

Four of the five studies were rated as having low risk of statistical bias as they used appropriate statistical analyses and reported less than 20% attrition (Maroti et al., 2015; Metternich et al., 2008; Norouzi et al., 2020; Santos et al., 2018). Specifically, Norouzi et al (2020) reported 0% attrition from the study. One study was rated as having an unclear risk of statistical bias as they did not provide information about attrition (Baudic et al., 2013).

#### **1.6.4.6. Reporting Bias**

Each of the five studies reported outcomes that were outlined in the study methodology and gave justification for the exclusion of any participants, suggesting low risk of reporting bias.

#### **1.6.4.7. Generalisability**

All studies in the review had small sample sizes, meaning that the statistical analyses lacked power and subtle treatment effects may be obfuscated. Additionally, there appeared to be unequal distribution of gender in some sample groups (Maroti et al., 2015; Metternich et al., 2008), some only reported female participants (Norouzi et al., 2020; Santos et al., 2018) and gender differences were not reported in one study (Baudic et al., 2013). Thus, all studies were rated as having a potentially high risk of bias if outcomes were to be generalised to the populations being studied.

### **1.6.5. Summary Conclusions of Study Level Bias**

The five included studies reported data from four randomised controlled trials and one non-randomised controlled trial. The risk of bias analysis shows that adequate recruitment procedures took place through randomisation and matched groups for each study. Unfortunately, it appears that by the nature of opportunistic sampling, it is unclear if the samples represent the general FND population due to limited gender variation. The literature shows that women are more likely to experience FND symptoms as well as having a higher propensity to seek out healthcare sources, which may explain the gender differences in sampling in these studies (Carson & Lehn, 2016). However, without descriptive statistics of the total referral population from which the participants were recruited, it is unhelpful to assume that the studies provide generalisable results to all those experiencing FND. Similarly, without information

about motivators to participate, it is difficult to objectively apply the efficacy of interventions in different healthcare pathways. For example, participation in a study may have improved the quality or frequency of contact with healthcare providers, which the studies did not account for and so are not comparable across the literature.

Nevertheless, the studies provided detailed and replicable descriptions of procedures for assessment, intervention, and statistical analyses, meaning that replication was possible for future study. Additionally, the overall quality index scores of the risk of bias analysis ranged from 82.4% to 93.2% across the five studies, suggesting a reasonably high level of credibility within this research evidence. Nonetheless, these studies would be strengthened by larger sample sizes and introducing double-blind data-collection procedures.

## **1.7. Findings from Review Studies**

The components of the studies summarised in Table 4 were investigated further to assess the treatment components, measurements, outcomes, efficacy, and potential application.

### **1.7.1. Intervention Components and Measures**

#### **1.7.1.1. Transcranial Stimulation**

Two of the studies investigated the effect of deep brain stimulation on the cognitive performance of those with fibromyalgia, through transcranial magnetic stimulation (TMS), being a safe and non-invasive way of stimulating the cerebral cortex. Baudic et al. (2013) investigated the impact of repetitive TMS over the left primary motor cortex on cognition, a technique that was being used therapeutically for its analgesic effects for those with fibromyalgia, over the span of 21 weeks. Participants completed neuropsychological screening at three intervals throughout the intervention. These included: the Rey Auditory Learning Test, measuring immediate memory and verbal learning; the Symbol Digit Modalities Test, involving sustained attention, focussed concentration and directed visual shifting; the Trail-Making Test measuring attentional shift and working memory; and finally, the Stroop Colour Word Test, measuring processing speed and executive control of inhibition.



Similarly, Santos et al. (2018) investigated the effect of direct TMS over the left dorsolateral prefrontal cortex compared to sham stimulation for women with fibromyalgia over eight days. This was combined with working memory training which consisted of an online Dual N-Back task, where participants were to respond with a button press when visual stimuli of green squares presented in eight positions, and auditory stimuli presented binaurally through headphones, had already been presented. The training was predicted to improve immediate recall, working memory capacity through task monitoring, and executive control through inhibition of inaccurate responding.

### **1.7.1.2. Cognitive Remediation**

Another study using cognitive remediation was by Maroti et al. (2015), recruiting those with chronic fatigue syndrome who experienced working memory deficits, and compared their immediate memory, sustained attention and working memory performance following five weeks of cognitive training. This consisted of computerised video game exercises involving verbal and spatial short term and working memory exercises. The participants were to remember the correct forward serial order of letters and digits or locations in a 2- or 3-dimensional grid. Participant performance was compared to the performance of those with chronic fatigue syndrome but without working memory deficits. Cognitive performance was measured with the digit span subtest from the Wechsler Adult Intelligence Scale III.

### **1.7.1.3. Psychosocial Intervention**

Metternich et al. (2008) evaluated a psychosocial intervention targeting memory self-efficacy in those with functional memory disorder. The psychoeducational group therapy included stress-management and cognitive restructuring, with peer support as an additional treatment factor, with the aim of reducing experiences of stress and memory-related anxiety to break the cycle of memory complaint and stress. Memory-self efficacy, memory-related anxiety and memory perfectionism were measured with the Metamemory in Adulthood Questionnaire, hypothesising that increased self-efficacy would lead to improvements in wellbeing and better memory performance. Secondary outcomes for wellbeing were measured through the Perceived Stress Questionnaire and Symptom Checklist, and cognitive screening was conducted for memory through the auditory verbal learning test and cognitive speed with the Trail-Making Test.

#### **1.7.1.4. Exercise**

An intervention using behavioural activation and physical therapy was studied by Norouzi et al. (2020), who investigated the impact of dance and aerobic exercise on the working memory of women with fibromyalgia. The first condition of Zumba dancing consisted of a 12-week programme of three-weekly sessions with a professional coach. The aerobic exercise training took place over the same duration using a treadmill. The control group met for group meetings at the clinic to account for social interaction effects. A measurement of verbal working memory was tested with the Dual N-Back task, with participants responding when letter stimuli matched a previous trial. Motor function was tested through mobility skills with the Timed Up and Go Test, and measures of depressive symptom severity were obtained with the Beck Depression Inventory II.

#### **1.7.2. Intervention Outcomes**

##### **1.7.2.1. Transcranial Stimulation**

At baseline, Baudic et al. (2013) found that poorer cognitive performance in fibromyalgia was associated with increased pain intensity, specifically for immediate memory, processing speed and inhibitory control, yet this did not improve as pain reduced. Likewise, those with greater cognitive impairments did not show change over time. No deleterious effects of repeated TMS on cognitive functioning were found which was the primary aim of the study. Interestingly, small but significant improvements in sustained attention and switching attention were found in the experimental group over time, without cognitive training being introduced.

Santos et al (2018) found a higher increase in immediate memory capacity and verbal fluency when both TMS and computerised working memory training were combined, compared to cognitive training alone. Therefore, combining the two interventions increased the functioning of the inhibitory system, the neurobiological mechanism of which is found to be imbalanced in fibromyalgia. These findings suggest that TMS is deemed to be a safe intervention to support pain management in fibromyalgia, as well as supporting memory, attention, and executive functions.

### **1.7.2.1. Cognitive Remediation**

Maroti et al (2015) found no changes in the cognitive performances of the control group compared to normative data at baseline or after training, whereas those with chronic fatigue syndrome showed increased performance in global attention and working memory and a trend towards improvement in immediate memory. Additionally, working memory performance had improved to be on par with norms in the reference population. The authors suggested that this study was the first of its kind to offer cognitive remediation to those with chronic fatigue syndrome.

### **1.7.2.2. Psychosocial Intervention**

In the study by Metternich et al. (2008), those with functional memory disorder showed significant improvements to memory related self-efficacy after six months compared to controls, without changes in depression. They suggested the shift towards significance happened towards the end of the test period as cognitive restructuring and integrating stress management strategies takes time and practice, in turn, influencing one's own perceived change in memory related anxiety. Improvements in cognitive speed and learning were found but could not be attributed to treatment effects as they were not compared to control group outcomes.

### **1.7.2.3. Exercise**

Norouzi et al. (2020) found significant improvements in working memory, motor function and depressive symptoms with aerobic exercise, and observed greater effects in the Zumba dancing group, without changes in the control group. This suggested that the attentional resources required for learning and monitoring complex motor patterns involved in Zumba dancing were strengthened for those with fibromyalgia through the exercise programme.

## **1.7.3. Intervention Efficacy**

Despite the small number of studies to review, the evidence showed that interventions aimed at cognitive rehabilitation, psychosocial interventions targeting self-efficacy or interventions based around behavioural activation and exercise improved the experiences of those with cognitive symptoms in FND. Benefits were observed for sustained attention and switching

attention (Baudic et al., 2013), immediate memory capacity and verbal fluency from TMS (Santos et al., 2018), global attention and working memory with cognitive remediation (Maroti et al., 2015), memory related self-efficacy from psychosocial intervention targeting self-efficacy (Metternich et al., 2008) and working memory, motor function and depressive symptoms with interventions based around behavioural activation and exercise (Norouzi et al., 2020). To evaluate whether these studies matched hypothesised expectations, Table 8 shows which treatment components and measurements were included in each study.

### **1.7.3.1. Emotion Regulation**

The study by Metternich et al. (2008) was the only study to use emotion regulation strategies, included within the psychosocial intervention. Norouzi et al. (2020) found an indirect effect of improved mood with exercise, yet it appears that participants did not make any new learning of emotion regulation techniques.

### **1.7.3.2. Behavioural Activation**

Studies that included behavioural activation towards wellbeing management were Metternich et al. (2008) with their use of stress management strategies, Maroti et al. (2015) for adapting a computerised cognitive training programme to be used at home, and Norouzi et al. (2020) through dance and exercise programmes.

### **1.7.3.3. Metacognitive Adjustments**

The study by Metternich et al. (2008) was the only study to include metacognitive adjustments, through cognitive restructuring of attitudes towards achievement motivation and self-efficacy.

### **1.7.3.4. Executive Control Remediation**

The cognitive remediation studied by Maroti et al. (2015) included bottom-up processing of visual and spatial stimuli for improved executive control. Likewise, Norouzi et al. (2020) were successful at including movement exercises that improved externally directed attention and sensory proprioception through spatial awareness. The cognitive remediation task provided by Santos et al (2018) included executive control elements yet lacked ecological validity as the computer tasks would not be replicable in everyday situations.

### **1.7.3.5. Measurements of Cognitive Performance**

Each of the five included studies, as was outlined in the inclusion criteria, measured cognitive performance. This was the only score given to Baudic et al. (2013), with the research specifically aiming to measure cognitive performance without the intention of improving it. Metternich et al. (2008) did not include neuropsychological assessments as part of their primary outcome measures so no conclusions can be drawn from them.

### **1.7.3.6. Summary of Expected Treatment Components and Measurements**

Overall, the findings showed that neither of the reviewed studies met all the expected neuropsychosocial treatment components and measurements as hypothesised in the aims of the review. The study that showed the greatest efficacy in the five areas was that of Metternich et al. (2008), suggesting that psychosocial interventions including emotional regulation techniques, behavioural activation with wellbeing strategies, and cognitive restructuring towards self-efficacy are the most effective interventions for management of FCD symptoms that have been evaluated in the literature.

**Table 8:** Comparison of reviewed studies against expected treatment components for effective interventions for functional cognitive disorder, as outlined in Section 1.3.4. Key:   component met   component included but not met   component not included

Study	Emotion Regulation	Behavioural Activation	Metacognitive Adjustments	Executive Control Remediation	Measuring Cognitive Performance
<b>Baudic et al. (2013)</b>	Not included	Not included	Not included	Not included	Measured immediate memory, verbal learning, sustained attention, directed visual shifting, attentional shift, working memory, processing speed and executive control of inhibition as primary measures
<b>Maroti et al. (2015)</b>	Not included	Cognitive training included as part of rehabilitation programme and used at home	Not included	Included bottom-up processing of verbal and spatial stimuli	Measured immediate memory, sustained attention and working memory as primary measures
<b>Metternich et al. (2008)</b>	Information sharing and formulation around symptoms and stress management	Use of stress management and relaxation techniques	Cognitive restructuring of attitudes towards achievement motivation and self-efficacy	Not included	Measured baseline memory and cognitive speed but did not include as part of primary outcomes
<b>Norouzi et al. (2020)</b>	Exercise activities aimed at improving depressive symptoms yet not emotional regulation	Psychical exercise tasks in ecologically valid settings	Not included	Increasing bottom-up processing for new learning and spatial awareness through movement	Measured working memory and spatial awareness as primary outcomes
<b>Santos et al. (2018)</b>	Not included	Specific computerised training task, not ecologically valid	Not included	Included inhibition of actions through working memory tasks, not ecologically valid	Measured immediate and delayed memory as primary outcomes, measured verbal fluency and working memory as secondary outcomes

## **1.8. Discussion**

### **1.8.1. Evaluation of the Current Review**

Firstly, it should be noted how few studies were identified as investigating interventions for cognitive difficulties in FND, reflecting the nascent nature of literature in this area despite a high level of healthcare costs. The review fulfilled its aims of identifying the empirical studies reporting interventions for cognitive dysfunction in those with FND and explored their components and measurements. The efficacy of each intervention was analysed in relation to the nature and mechanisms of the condition and found that research studies currently available do not yet cover the necessary neuropsychosocial components.

The search process as part of this review demonstrated that academic interest in cognitive dysfunction in FND is difficult to track due to a lack of standardised terminology, which makes it difficult to generate accurate and inclusive searches. A further limitation of the review was to assume credibility in the studies reporting effectiveness of an intervention by measuring cognitive performance with neuropsychological measures, due to the impact of internal inconsistencies (Larner, 2020). This emphasises the need for self-report measures to be developed that can assess the experiences of functional cognitive difficulties without relying on invalid objective outcomes, as suggested by Nicholson et al. (2020).

### **1.8.2. Implications for Future Research**

The existing aetiological and theoretical literature providing experiential understanding about the impact of cognitive dysfunction in FND appears to be from a small number of active research clinicians, yet there has been collaboration across global communities for FND in general (Pick et al., 2015; Pick, Anderson, et al., 2020; Goldstein et al., 2019; Lidstone et al., 2022; McLoughlin et al., 2023). Interventions for functional cognitive disorder are in their infancy, with literature limited to early investigations. Subsequently, this review has allowed for few firm conclusions to be drawn.

There are possible explanations for the discrepancy between the prevalence of functional cognitive symptoms and underrepresentation in research. Functional symptoms have historically been identified by the lack of organic pathology and so less was understood about their origins. Placing emphasis on psychological distress often leads to judgements of symptoms being unexplainable, and relying on lone symptoms misses the combinations of

features to form the wider formulation (Stone, Burton & Carson, 2020). A lack of training in curriculums and perpetual cycles of misinformation about FND has maintained a bias that the symptoms are less valid, with a pervasive stigma of feigning, and so less important for study despite the high prevalence rates (Kanaan et al., 2009; McLoughlin et al., 2023).

There needs to be an appropriate level of attention paid by clinic and research sites to the effects of cognitive dysfunction in FND, considering its heterogeneous nature and impact on the variability of disability experienced. There are future proposed studies including psychoeducational groups for FND also measuring attention and concentration ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), 31-03-23). This review offers a conceptual framework for future research with an important and contemporary question as to why this research is not yet taking place. Further research ought to develop multisite studies based on the neurological and psychological underpinnings of functional cognitive symptoms, as well as the intervention components described in this review to offer more holistic care to those experiencing the difficulties.

### **1.8.3. Implications for Practitioners, Patients and Service Purchasers**

It is concerning that those diagnosed with a functional cognitive disorder without an organic cause are found to have poorer prognoses, more psychological distress, more social isolation, higher dependency on carers and are less likely to be employed compared to those with organic dysfunction (Crimlisk et al., 1998; Moss-Morri & Chalder, 2003; Reuber et al, 2003; Stone et al., 2003; McKenzie et al, 2010; Sharpe et al, 2010; Carson et al., 2011). Psychological distress can affect more than half of those with FND, with symptoms of anxiety, panic, depression, and shame worsening the manifestation into disability (Crimlisk et al., 1998; Carson et al., 2000; Stone et al., 2003; Reuber et al., 2007; McKenzie et al., 2010; Brown & Reuber, 2016; Robson & Lian, 2017; Gelauff et al., 2019; Stone, Burton and Carson, 2020). The lived experience of those diagnosed with FND consists of very little support beyond the clinical judgement of them not having a neurological disorder, with recommendations to seek mental health support being relied on (Tolchin et al., 2021). Due to the multitude of needs and presentations, there are calls for evidence-based guidelines to be developed to support those with FND and the systems around them (LaFaver et al., 2021). It is wholly more compassionate to assume that measuring devices are not yet sensitive or powerful enough to understand the experiences of those with FND, rather than base assumptions on prior knowledge of conscious instrumental behaviours.



Without appropriate symptom management of cognitive difficulties being prioritised in FND, there is reduced potential for recovery for all FND phenotypes (McWhirter & Carson, 2023). Due to similar underpinning mechanisms with other functional conditions, there is scope that interventions for functional cognitive difficulties could be transferrable across the breadth of experiences in FND, making this area of research more valuable. This review has shown that the application of a broad range of interventions could assist with differential formulations of needs and choices in healthcare pathways. It would be interesting to evaluate the acceptability of these approaches with differing FND presentations, as done by Metternich et al. (2008), as well as discussing the invasiveness of the procedures and impact on worsening other symptoms of FND, as suggested by Maroti et al. (2015). Overall, funding investigations into helpful interventions will bridge the gap between physical and mental health services frequented by those with functional cognitive difficulties, streamlining the resources available to patients and allowing for greater feasibility for commissioning.

## **2. Empirical Research Report:**

### **Investigating the efficacy of a mindfulness-based intervention for improving mindful awareness, psychological wellbeing, and cognitive performance in Functional Cognitive Disorder**

#### **2.1. Abstract**

##### **2.1.1. Introduction**

Functional cognitive disorder (FCD) is the experience of cognitive processing difficulties due to multisystem and higher order control dysfunction, not explained by central nervous system pathology. There is little evidence of effective treatments for FCD, meaning that there are no current treatment guidelines. Literature describing the effectiveness of mindfulness-based interventions led to the offering of mindfulness training for rehabilitation of FCD, as a novel area of research.

##### **2.1.2. Methodology**

Thirteen people with FCD attended a mindfulness-based training programme and completed outcome measures before and after the intervention to investigate the impact of improvements in trait-mindfulness abilities on psychological wellbeing and cognitive performance in FCD.

Measures used included:

- Five Facet Mindfulness Questionnaire
- Depression, Anxiety, Stress Scale
- Addenbrooke's Cognitive Exam-III
- Questionnaire for Assessing Blocking Beliefs

### **2.1.3. Findings**

Statistical analyses of reliable change found clinically meaningful improvements in observational awareness and statistically significant changes for non-reactivity, suggesting that mindfulness training does improve trait-mindfulness abilities in FCD. Correlational findings showed consistent negative associations between improved mindfulness abilities and fewer symptoms of psychological distress, and positive correlations between improved mindfulness abilities and attentional task performance. Measurable benefits were found for more than half of the sample.

### **2.1.4. Conclusion**

This study supported predictions that mindfulness-based interventions assist with emotion regulation, behavioural activation towards wellbeing management, metacognitive adjustments, and act as cognitive remediation, meeting the neuropsychosocial needs of those with FCD with the potential for effective symptom management. The theoretical and clinical applications of the findings are discussed.

## **2.2. Introduction**

### **2.2.1. Functional Cognitive Disorders**

#### **2.2.1.1. Conceptualisation**

Functional cognitive disorder (FCD) is the experience of difficulties with attention, memory, executive control, or other cognitive processes that are not the result of brain injury or disease, but instead a multisystem, higher order control dysfunction that is not explained by central nervous system pathology. Stone, Burton and Carson (2020) likened FCD to an analogy of how brain systems function, whereby there is an impairment to the software of the brain, meaning that the electrical signalling and functioning between brain locations is disrupted, when the hardware which represents the white and grey matter, remains intact. FCD is recognised as one of many phenotypic expressions of symptoms relating to functional neurological disorder, a transdiagnostic range of conditions that are characterised by involuntary disruptions to neurological processes (Perez et al., 2012).

FCD manifests as attentional neglect, impairments in interoception, dissociation and emotional dysregulation. The experiences of FCD can include absent-mindedness, poor concentration, forgetfulness, and prospective memory lapses (Schmidtke, Pohlmann & Metternich, 2008; Pennington, Newson et al., 2015; Stone et al., 2015; Bhome, McWilliams et al., 2019). It is hypothesised that pain, fatigue and excessive interoceptive monitoring have implications for slower processing speed, susceptibility to distractions, interferences with multitasking, and higher perceived cognitive load, resulting in a decrease in externally directed attention (Stone et al., 2011; Teodoro, Edwards & Isaacs, 2018). Theoretically, those with FCD could be experiencing a switch from automatic processing to a less efficient cognitive control, making routine cognitive processes additionally effortful. This results in the phenomenon of ‘internal inconsistency,’ referring to the differences in objective measures of cognitive performance compared to ability, or varying performance in cognitive tasks across time or situations (Stone et al., 2015; Jones et al., 2016; Ball et al., 2020; Lerner, 2020; McWhirter et al., 2020). Thus, it is suggested that cognitive difficulties are present in all functional neurological conditions and are thought to be more disabling and distressing than organic neurological conditions (McWhirter et al., 2020; McWhirter & Carson, 2023).

Recent publications have explored how metacognitive errors appear to provide a theoretical understanding of increased self-directed attention alongside negative and inaccurate appraisal of one's own cognitive abilities (Bhome, McWilliams et al., 2019, 2022; McWhirter et al., 2020; Pennington, Ball, et al., 2021; McWhirter & Carson, 2023; Teodoro et al., 2023). Metacognitive errors may lead to overestimation of cognitive failures which overrides sensory processing, whereby sensory feedback fails to alter previous assumptions. Further cognitive errors occur due to a lack of cognitive reserve, being the cognitive agility to improvise and adapt to challenges, leading to reduced attentiveness to the environment. This perpetuating cycle of metacognitive error, health anxiety, negative self-perception and low cognitive reserve maintains the disabling effects of functional cognitive disorder.

Metternich et al. (2008) suggested that the symptoms of FCD can lead to psychosocial disruptions such as embarrassment, anxiety, occupational shortcomings and the fear of neurodegeneration and mortality. Depressive symptoms are the most common comorbid experience with FCD, with health anxiety, negative self-beliefs and increased interoception being associated with more frequent and severe cognitive complaints (McWhirter et al., 2020). Rehabilitation of these processes could enable better management of the neuropsychosocial implications of the condition through relevant compensation strategies.

#### **2.2.1.2. Interventions**

There is little evidence of effective treatments for FCD, comparative to other functional neurological disorder phenotypes, such as functional motor disorders and dissociative seizures, meaning that there are no current treatment guidelines (Bhome, Huntley et al., 2019; Bhome, McWilliams et al., 2019; McWhirter & Carson, 2023). Due to the perpetuation of experiences being rooted in higher order cognitive and psychological attributions, it was deemed necessary to explore the evidence base for psychological treatments offered for FCD. Some treatments have been evaluated as ineffective in FCD populations due to low levels of engagement or poor retention of coping skills, linked to the nature of the cognitive dysfunction (Howlett et al., 2007). Advising those with FCD to simplify tasks, minimise distractions, chunk information or write checklists is not effective at undoing the person's perception of their ability and exacerbates excessive monitoring (Teodoro et al., 2023). Additionally, there may be a reluctance for someone to rely on their memory for fear of failure, leading to an increased dependency on others and implicating the need to involve carers in interventions (Stone et al., 2015).

As described in a recent review of the conceptualisation and treatment of cognitive symptoms in FND (Wolstencroft, 2023, Chapter 1 of this volume), effective interventions that would address the multitude of needs of those with functional cognitive difficulties would need to include treatment components of emotion regulation, behavioural activation towards wellbeing management, metacognitive adjustments for evaluating cognitive processes more accurately and increasing externally directed attention through executive control. There is only one study to date that evaluated a psychosocial therapy targeting memory self-efficacy in those with FCD (Metternich et al., 2008). This included psychoeducation of stress-management and cognitive restructuring in group therapy, with peer support as an additional treatment factor. Subjective memory performance was measured as a primary outcome, with perfectionism pertaining to memory, perceived stress and psychiatric symptoms as secondary measures. Significant improvements to memory related self-efficacy were found. However, they did not directly target executive control with a cognitive remediation strategy, limiting the potential for redirected attentional focus.

It appears that psychological interventions used to support functional neurological conditions in general have mainly aimed at improving the secondary effects on wellbeing, including anxiety, depression, low quality of life and low motivation, which in turn may improve psychosomatic symptomatology (Zaroff et al, 2004; Bullock et al, 2015; Cope et al, 2017; Ganslev et al., 2020; O'Connell et al, 2020). Some therapies effectively combined psychological approaches with physiotherapy programmes for more effective management of symptoms (Dallochio et al, 2016; Lehn et al, 2016). Motivational interviewing alongside mindfulness-based treatments (Tolchin et al, 2019) seemed to have greater efficacy when compared to behavioural therapy, psychodynamic therapy, CBT and hypnosis, by reframing patient outlook in therapy and allowing those with dissociate seizures to open up to a broad awareness around their disorder (Ganslev et al, 2020). The mindfulness-based protocol evaluated by Tolchin et al. (2019) was developed by Baslet and colleagues (Baslet et al., 2015; Baslet & Oser, 2016; Baslet et al., 2020) and found to be effective in managing the symptoms of dissociative seizures and comorbid mental health experiences.

### **2.2.2. Trait-Mindful Awareness**

It was necessary to ascertain whether a mindfulness-based intervention would meet the expected neuropsychological factors implicated in FCD. Mindfulness-based treatments target poor recognition or acceptance of emotional states (Baslet et al., 2015) and mindfulness skills

have been associated with emotion regulation strategies such as reappraisal, problem-solving and reacting flexibly (Iani et al., 2019). This would suggest that mindfulness techniques could assist with emotion regulation difficulties associated with FCD. Similarly, there is evidence of fewer psychiatric symptoms in those who meditate and practice mindfulness regularly (Baer et al., 2008; Carmody & Baer, 2008), suggesting that mindfulness techniques could be a helpful behavioural activation tool targeting wellbeing management. Improving trait mindfulness has also been found to increase meta-awareness through disidentification from thoughts and emotions. The mindfulness-to-meaning theory posited by Garland et al. (2015) suggested that negative appraisals are more likely to occur in chronically stressful contexts, whereby a narrowing of attention occurs due to suppression of the viscerosensory brain circuits, which increases negativity bias in evaluations. The theory suggests that mindful reappraisal can be a process of positive therapeutic change through the neural principle of ‘interoceptive recovery.’ This occurs through decentering; when focus is internalised towards monitoring and evaluation, shifting the perspective towards sensations and perceptions of external stimuli broadens the attentional spotlight and allows for balanced metacognitive adjustments. In support of this theory, studies have shown that improving trait mindfulness protects against rumination in healthy controls, those with major depressive disorder, and those facing health inequalities (Keune et al., 2011; Shallcross & Spruill, 2018; Iani et al., 2019). Strengthening focussing abilities reduces mind wandering and its associated cycle of negative emotions (Levinson et al., 2014). Therefore, it may be possible that mindfulness training could address the metacognitive disruptions in FCD. To take this a step further, mindfulness training could also serve as cognitive remediation. A meta-analysis by Sumantry and Stewart (2021) found that generalised attention, accuracy, and the alerting and inhibition aspects of executive control, have been improved through meditation. Thus, mindfulness could address more effortful cognitive control in FCD and help to strengthen sensory processing pathways. The evidence presented suggests that offering the use of mindfulness-based training for rehabilitation of FCD is a novel area of research worth pursuing, as it involves the neuropsychosocial treatment components needed to manage the debilitating effects of the condition.

### **2.2.3. Rationale**

The aim of the intervention in this study was to adapt a mindfulness-based psychotherapy developed by Baslet & Oser (2016) towards rehabilitation of FCD and to be delivered in a group setting. Therapeutic advantages to group treatments include increased and consistent

contact with care teams, an emotionally safe place for healing, goal focus, reduced hospitalisation and combatting disorder related isolation (Libbon, 2019). It was hoped that there would be additional benefits of peer support in normalising minor cognitive errors to help attendees recognise them as a common part of the human experience (Metternich et al., 2008; Pennington, Newson et al., 2015). Moreover, developing the protocol into a group therapy enabled pooling of NHS resources across a division that was not yet commissioned to provide treatments for those with FCD. Clinically relevant findings could inform the existing knowledge base around effective treatments for FCD where alternative attempts are scarce. Clinical applications of this research would provide a foundation for healthcare systems and other disciplinary modalities to support the holistic needs of those with functional neurological disorders more generally.

#### **2.2.4. Research Aims**

The primary aim was to investigate whether:

- a) Mindfulness-based training will improve trait mindful awareness

Secondary aims were to investigate whether:

- b) Increased mindful ability will be associated with improved psychological wellbeing
- c) Increased mindful ability will be associated with improvements in self-perception.
- d) Increased mindful ability will be associated with improved cognitive performance

### **2.3. Methodology**

The following accounts describe participant eligibility, recruitment and study sample, the intervention procedure, and data analysis.

#### **2.3.1. Participants**

##### **2.3.1.1. Eligibility Criteria**

Signposting to the intervention included the positive identification of symptoms of FCD and associated comorbid mental health difficulties, for adults aged 18 to 99 years old with any gender identification. Interpreter support was offered to those whose first language was different to English. The training was designed to be completed as a group cohort, yet those with access needs were offered the training in individual sessions. Eligibility for participation



in the study included those who had completed: a) assessment with the memory clinic; b) baseline and repeated outcome measures; and c) attended at least 87.5% of the training, being seven out of eight training sessions.

#### **2.3.1.1.1. Inclusion criteria**

Those with functional cognitive difficulties, including:

- memory difficulties, e.g., long term, short term, encoding, retrieval, working memory
- attention difficulties, e.g., focus, concentration, sustained attention
- other cognitive difficulties, e.g., language, word finding, visuospatial function
- executive dysfunction, e.g., coordinating, planning, sequencing

Alongside comorbid mental health difficulties, such as:

- anxiety, e.g., generalised anxiety disorder, fear, specific phobias
- depression, e.g., chronic and acute onset
- trauma, e.g., post-traumatic stress disorder, somatisation
- dissociation, e.g., blackouts, out of body experiences, depersonalisation
- fatigue, e.g., low energy and motivation
- apathy, e.g., loss of enjoyment, feeling numb
- low quality of life, e.g., lack of satisfaction, barriers to activities of daily living

#### **2.3.1.1.2. Exclusion criteria**

Those who had received a diagnosis of neurodegeneration, like subcortical vascular dementias or a cortical dementia such as Alzheimer's, frontotemporal, or Lewy body dementia, were excluded from the study as their needs were not met by the intervention. Those who experienced unstable mental health symptoms due to enduring conditions, such as psychotic disorders or personality disorders, were excluded from the study due to the potential for cognitive symptoms to occur from an organic basis.

#### **2.3.1.2. Recruitment**

Those who experienced symptoms associated with FCD were offered a recruitment leaflet by members of their care team. Those interested in completing the training were put forward for telephone screening by facilitators of the intervention. Telephone screening included

discussing the eligibility criteria and access needs. The demographics of the 19 people signposted to the intervention are shown in Table 9. All of those who were screened met the eligibility criteria and were invited to an appointment to discuss the training further, as well as completing baseline outcome measures.

### 2.3.1.3. Attrition

Due to the neuropsychosocial difficulties associated with FCD, attrition was anticipated at several stages of the intervention, at recruitment, commencement, or during the intervention. Nineteen people completed baseline measures, two did not commence training due to poor health or moving out of area and four people attended two sessions or less. Thirteen people went on to complete the training and repeated outcome measures, giving an attrition rate of 31.6%. In a physical health context, behavioural modification programs typically have attrition rates that range from 10% to 80% within the first few days of treatment (Farley et al., 2003).

### 2.3.1.4. Sample

The participant sample included eleven women and two men who had been diagnosed with FCD within the last year, sample demographics are shown in Table 9. The sample included three group cohorts and two people who completed the training in individual sessions, one of whom needed support from an interpreter and the other experiencing distress around meeting new people.

**Table 9:** Participant Demographics

		Screened	Completing Intervention
<b>Participants</b>	N	19	13
<b>Gender</b>	Women:	17	11
	Men:	2	2
<b>Age Mean and Range</b>	Women:	$\bar{x}$ : 64.4 yrs	$\bar{x}$ : 63.9 yrs
		SD: 8.43 yrs	SD: 8.57 yrs
	Men:	Range: 50 yrs – 79 yrs	Range: 50 yrs – 79 yrs
		$\bar{x}$ : 70.0 yrs	$\bar{x}$ : 70.0 yrs
		SD: 11.31 yrs	SD: 11.31 yrs
		Range: 62 yrs – 78 yrs	Range: 62 yrs – 78 yrs
<b>Ethnicity</b>	Black British:	3	1
	White British:	15	11
	Other white background:	1	1

## **2.3.2. Procedure**

### **2.3.2.1. Study Design**

The study used a within subjects AB experimental design, with all participants being part of the treatment condition and each completing baseline and repeated outcome measures.

### **2.3.2.2. Study Setting**

The intervention took place between November 2022 and May 2023 at NHS clinic sites. Data analysis took place at the University of Birmingham and all data were stored through the University of Birmingham Research Data Store for data protection.

### **2.3.2.3. Intervention Protocol**

The mindfulness training intervention was adapted from a previously used protocol developed by Baslet & Oser (2016). Permission was granted by Dr Gaston Baslet for the protocol to be adapted to suit the needs of a population with functional cognitive disorders (Baslet et al., 2015; 2020). The previous training consisted of twelve sessions divided into five modules:

- 1) Understanding your condition and your treatment
- 2) Stress Management Strategies
- 3) Mindfulness
- 4) Emotion Management
- 5) Reworking cognitions

Common themes across sessions were combined to reduce the intervention from twelve sessions to eight. Group activities and interactive demonstrations using sensory stimulation, physical sculpts, and educational videos, were used to assist engagement in the discussion topics. Home practice packs were provided with the aim of supporting memory retention. The resources from Professor Jon Stone and his team at the University of Edinburgh, freely available from [neurosymptoms.org](http://neurosymptoms.org), were included to provide information about attentional and memory processes in FCD. Additional information about self-compassion from the work of Dr Kristin Neff, available at [self-compassion.org](http://self-compassion.org), was also included to realign negative self-perceptions. Personal exploration through home practice was discussed during a coaching phone call between sessions and as a check in at the start of each training session to explore

progress and barriers. This was with the aim of assisting in memory prompts whilst participants established a new routine with mindfulness techniques.

### **2.3.3. Outcome Measures**

The primary outcome was to measure the efficacy of the intervention on improving trait-mindful awareness. As secondary outcomes, a measure of comorbid psychopathology, self-perception and cognitive performance were used to assess the impact of improved trait-mindful awareness. To our knowledge, there has been no research to validate any outcome measures for use with those with functional cognitive difficulties (Nicholson et al., 2020). The following outcome measures were used as a best fit for the purpose of this investigation.

#### **2.3.3.1. Trait Mindful Awareness**

The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006; 2008; 2012) was designed to measure enduring changes in mindfulness ability. It assesses five domains of mindful awareness, including:

- Observing: observation of sensory awareness and selective focus of the internal and external world
- Describe: descriptions of experiences using language to label and express them to ourselves and others
- Acting with Awareness: awareness of actions through choice, self-awareness, and information from the present moment
- Non-judging: non-judgemental evaluations through compassionate self-acceptance and fact checking
- Non-reactivity: detaching from thoughts and emotions, accepting their existence, and choosing behavioural responses that improve emotional resilience.

The FFMQ was shown to be valid in those with recurrent depression and is a predictor of positive thinking, uplifted mood, and subjective feelings of wellbeing (Baer et al; 2006; Bohlmeijer et al., 2011; Gu et al, 2016). This measure has also been validated in other languages (Radon, 2014; Radon & Ryzewska, 2018). It was deemed the most suitable measure of change in mindful awareness for this intervention, appropriately matching the aims of the treatment content. The brief FFMQ questionnaire consists of 15 items, with ratings given

for how true the respondent believes the statement is to their experiences on a 5-point Likert scale, with scores summed out of 15 for each mindfulness domain.

Unfortunately, the FFMQ does not provide test-retest reliability statistics in the original description of its psychometric properties (Baer et al., 2008). Test-retest reliability has been subsequently reported in three independent articles as depicted in Table 10 (Watson-Singleton et al., 2018; Truong et al., 2020; Okafor et al., 2023). To calculate the reliable change index, the test-retest reliability coefficients found in these studies were averaged using the harmonic mean. The mean and standard deviation values were also averaged, using the arithmetic mean.

**Table 10:** Test-retest reliability, mean and standard deviation for the FFMQ subscales

	Watson-Singleton et al. (2018)			Truong et al. (2020)			Okafor et al. (2023)			Average Parameters		
	R <sub>1,2</sub>	$\bar{x}$	SD	R <sub>1,2</sub>	$\bar{x}$	SD	R <sub>1,2</sub>	$\bar{x}$	SD	R <sub>1,2</sub>	$\bar{x}$	SD
<b>Observe</b>	0.54	14.11	3.71	0.74	25.4	5.71	0.7	11.08	2.42	0.67	16.86	3.95
<b>Describe</b>	0.22	16.17	4.66	0.9	26.33	6.61	0.71	10.84	2.61	0.70	17.78	4.63
<b>Awareness</b>	0.48	10.19	4.44	0.87	25.11	6.17	0.7	10.65	2.49	0.72	15.32	4.37
<b>Non-judgement</b>	0.32	10.87	3.45	0.81	26.74	7.15	0.71	10.57	2.74	0.61	16.06	4.45
<b>Non-reactivity</b>	0.24	8.13	2.61	0.75	19.74	4.37	0.52	10.2	2.5	0.54	12.69	3.16

R<sub>1,2</sub> = subscale test-retest reliability coefficient

$\bar{x}$  = subscale mean

SD = subscale standard deviation

### 2.3.3.2. Psychological Wellbeing

To address the comorbid mental health difficulties associated with FCD, it was important to include a measure of psychological wellbeing. The Depression Anxiety Stress Scale (DASS; Lovibond & Lovibond, 1995) has been shown as a reliable measure for symptoms of depression and anxiety, as well as non-specific symptoms of arousal categorised as a stress scale, with adequate convergent and discriminant validity for each domain (Ball et al., 2021; Crawford & Henry, 2003). The psychometric properties of the DASS subscales are shown in Table 11 (Brown et al., 1997). The brief version of the DASS includes a 21-item questionnaire, rating the frequency of somatic symptoms of depression, anxiety and stress over the week prior on a 4-point Likert scale. Scores out of 42 are given for each subscale. This questionnaire is also available in multiple languages ([www.psy.unsw.edu.au/dass](http://www.psy.unsw.edu.au/dass)).

**Table 11:** Test-retest reliability, mean and standard deviation for the DASS subscales

	<b>Brown et al. (1997)</b>		
	$R_{1,2}$	$\bar{x}$	SD
<b>Depression</b>	0.713	10.65	9.3
<b>Anxiety</b>	0.785	10.9	8.12
<b>Stress</b>	0.813	21.1	11.15

$R_{1,2}$  = test-retest reliability coefficient

$\bar{x}$  = subscale mean

SD = standard deviation

### **2.3.3.3. Self-Perception**

The impact of self-perception on those with functional cognitive difficulties has been covered in studies investigating metacognition (e.g., Bhome, McWilliams et al., 2019) and memory self-efficacy (e.g., Metternich, Schmidtke & Hüll, 2009). Therefore, it was deemed important to find a measure that incorporated more reflective aspects of interoception, including health beliefs, self-perception and self-efficacy. The Questionnaire for Assessing Blocking Beliefs (QABB; Knipe, 1998a; cited in Knipe, 2015) is an in-therapy qualitative scale used by therapists to assess beliefs that may be blocking recovery in post-traumatic stress disorder and dissociation. The items help to identify psychological defences that pertain to separate states of self, so that higher-ranking beliefs can be reframed towards integrating the person's identity. There is evidence supporting its use in those with negative self-perceptions (Draganović, 2021). To administer this questionnaire, participants were asked to choose an area of their life that they felt needed improvement, which could become a treatment target during the intervention. Some participants felt that social circumstances were more pertinent to focus on, meaning that outcomes did not reflect their health beliefs. Additionally, there does not appear to be psychometric properties for this measure in the literature, meaning that outcomes could not be analysed in a meaningful way. Therefore, the outcomes of this measure are not reported on in the findings.

### **2.3.3.4. Cognitive Performance**

The Addenbrooke's Cognitive Examination III (ACE-III; Noone, 2015) is a brief neuropsychological assessment of cognitive performance used as part of routine cognitive screenings. The assessment tests five cognitive domains, including performance in attention,

memory, verbal fluency, language, and visuospatial tasks, and is an efficacious tool in diagnosing and discerning neurodegenerative conditions (Potts et al., 2022). A repeated cognitive screen was conducted following the intervention to compare to baseline data, ensuring at least six months had passed. An alternative version of the ACE-III was used to minimise practice effects, e.g., Version A at baseline and Version B as repeat measure. The ACE-III has been validated as a measure in multiple languages and readily available (Dementia test - Brain and Mind Centre (sydney.edu.au)). Psychometric properties are shown in Table 12 (Alilou et al., 2017). Scores are summed for attention (out of 18), memory (out of 26), fluency (out of 14), language (out of 26) and visuospatial performance (out of 16).

**Table 12:** Test-retest reliability, mean and standard deviation for the ACE-III subscales

	<b>Alilou et al. (2017)</b>		
	$R_{1,2}$	$\bar{x}$	SD
<b>Attention</b>	0.91	14.65	4.32
<b>Memory</b>	0.89	22.41	3.87
<b>Fluency</b>	0.93	12.20	2.09
<b>Language</b>	0.92	23.50	4.32
<b>Visuospatial</b>	0.90	14.29	2.55

$R_{1,2}$  = test-retest reliability coefficient

$\bar{x}$  = subscale mean

SD = standard deviation

### 2.3.4. Statistical Analyses

Due to the small sample size, any frequentist descriptive or inferential statistics were likely to lack power. Reliable change index (RCI) analyses were used to compare the observed differences in outcomes to the expected variability within the reference groups, the test-retest correlation, and the variability of the measure in the appropriate reference population. The RCI value and corresponding confidence interval were calculated using the procedure described by Jacobson and colleagues (Jacobson and Truax, 1991; Jacobson et al., 1999).

### **2.3.4.1. Group Level Analyses**

- a. **Primary Outcomes:** the magnitude of change in FFMQ scores from baseline to repeated assessment, and whether the changes were clinically meaningful or statistically relevant. Increases in scores would infer a benefit to mindful awareness.
- b. **Secondary Outcomes:** the magnitude of change in scores for the DASS and ACE-III from baseline to repeated measures, and whether the changes were clinically meaningful or statistically relevant. Decreases in DASS scores indicate fewer symptoms of depression, anxiety, and stress and thus improvements in psychological wellbeing. Increases in ACE-III scores indicate an improvement in cognitive performance.
- c. **Association Outcomes:** Correlational analyses of the RCI values found for the FFMQ compared with those of the DASS and ACE-III measures. Negative correlations found for the FFMQ and DASS would indicate an association between improved mindful awareness and reduced psychological distress. Positive correlations between the FFMQ and DASS would indicate an association between improved mindful awareness and improved cognitive performance.

### **2.3.4.2. Participant Level Change:**

- d. **Measurable Benefits:** Individual profiles detailing the magnitude of change in all subscales whereby changes to mindful awareness, psychological wellbeing and cognitive performance meet the research aims.
- e. **Ambiguous Profiles:** Individual profiles detailing the magnitude of change whereby only some outcomes show benefits.
- f. **Absence of Benefits:** Individual profiles which showed no change or deterioration in measured outcomes following the intervention.



## **2.4. Results**

### **2.4.1. Group Level Analyses**

#### **2.4.1.1. Reliability of Change**

Baseline and repeated scores for each participant were plotted as scatterplot graphs for each subscale. Where no change occurred, scores were plotted along the line of no change, depicted as a continuous black line on the graph. Jacobson and Traux (1991) recommend that the 66% confidence interval is used as the boundary for clinically meaningful change, shown as the blue dashed line on the graph. The 95% confidence interval is used as the boundary for statistically significant change, shown as the red dashed line on the graph. Therefore, participant outcomes that are plotted in the area between the black line of no change and blue line of clinically meaningful change can be deemed as showing no meaningful change in outcome scores and due to measurement error. Participant outcomes that are plotted between the blue line of clinically meaningful change and the red line for statistically significant change can be deemed to show a clinically meaningful improvement or deterioration, depending on the direction of change away from the line of no change. Finally, participant outcomes that are plotted beyond the red line for statistically significant change and thus further away from the line of no change, are considered to show statistically significant improvement or deterioration depending on the direction of the change.

##### **2.4.1.1.1. Five Facet Mindfulness Questionnaire (FFMQ)**

The reliable change outcomes for the five subscales of the FFMQ are depicted in the scatterplots in Figure 4.

###### **2.4.1.1.1.1. Observing Subscale**

For the observe domain, four participant outcomes (31%) likely occurred by measurement error. Two participants (15%) showed clinically meaningful decreases in observation scores. Conversely, six outcomes (46%) showed clinically meaningful improvements, and one outcome (8%) showed a statistically significant increase in scores from baseline ( $RCI = 2.18$ ,  $p = 0.029$ ), with an increase of 47% to fulfil a full score after the intervention.

#### **2.4.1.1.1.2. Describe Subscale**

For the describe domain, nine outcomes (69%) likely occurred by measurement error. Four outcomes (31%) showed clinically meaningful improvements.

#### **2.4.1.1.1.3. Acting with Awareness Subscale**

The scores for acting with awareness showed ten outcomes (77%) were likely found by measurement error. One outcome (8%) was scored as a clinically meaningful decrease. Nonetheless, one outcome (8%) showed a clinically meaningful improvement in mindful actions, and the remaining outcome (8%) showed a statistically significant improvement within 95% confidence ( $RCI = 2.45$ ,  $p = 0.014$ ), with an increase of 53% in total score.

#### **2.4.1.1.1.4. Non-judging Subscale**

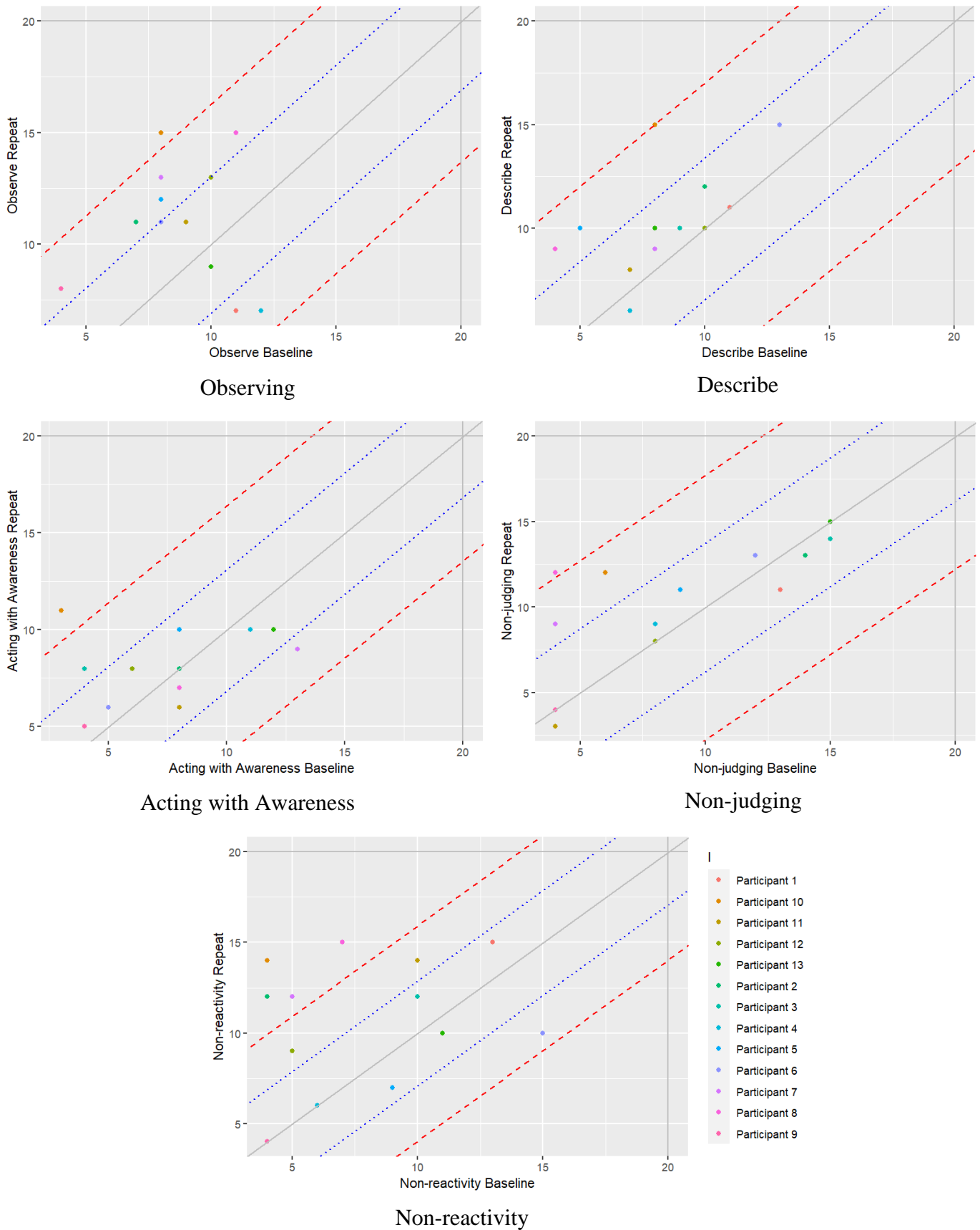
For the non-judging domain, ten outcomes (77%) were likely found by measurement error. Two outcomes (15%) showed clinically meaningful improvements and a further outcome (8%) indicated a statistically significant improvement in balanced evaluations ( $RCI = 2.02$ ,  $p = 0.043$ ) with an increase of 53% in total score.

#### **2.4.1.1.1.5. Non-reactivity Subscale**

The non-reactivity domain showed six outcomes (46%) were likely due to measurement error. There was a clinically meaningful decrease in one outcome (8%). Two outcomes (15%) showed clinically meaningful change and four outcomes (31%) showed statistically significant changes of between 33% and 67% increases in total score from baseline, within 95% confidence ( $RCI = 2.62$ ,  $p = 0.009$ ;  $RCI = 2.30$ ,  $p = 0.021$ ;  $RCI = 2.62$ ,  $p = 0.009$ ;  $RCI = 3.28$ ,  $p = 0.001$ ).

#### **2.4.1.1.1.6. Summary or FFMQ Outcomes**

The findings suggest that seven participants showed improved perception of their internal and external experiences, three were better able to label their experiences, two were found to be more aware of their actions, three were able to monitor their judgemental thoughts, and six were able to actively detach from their thoughts and choose how to react to them. The greatest meaningful changes in mindful ability occurred in observational awareness, whereas the greatest statistical changes occurred for non-reactivity.



**Figure 4.** Scatterplot of outcome scores for baseline and repeated outcome measures of the FFMQ. Continuous black line = line of no effect; blue dashed line = cut off for clinically meaningful change; red dashed line = cut off for statistically significant change.

#### **2.4.1.1.2. Depression, Anxiety and Stress Scale (DASS)**

The analyses of the DASS questionnaire were completed for twelve participants in the sample, with one participant being unable to complete the baseline measure due to low levels of reflective ability and concentration levels. This participant went onto complete the questionnaire after the intervention, inferring that either their reflective abilities or level of concentration had improved following the training. The scatterplots depicting the reliable change outcomes for the remaining twelve participants are depicted in Figure 5.

##### **2.4.1.1.2.1. Depression Subscale**

Scores for reporting symptoms of depression showed nine outcomes (75%) were likely due to measurement error. Three participants (25%) reported statistically significant decreases in depressive symptoms following the training (RCI = -2.70,  $p = 0.001$ ; RCI = -5.68,  $p < 0.001$ ; RCI = -3.97,  $p < 0.001$ ), with score decreases of between 45% and 95% of the total score.

##### **2.4.1.1.2.2. Anxiety Subscale**

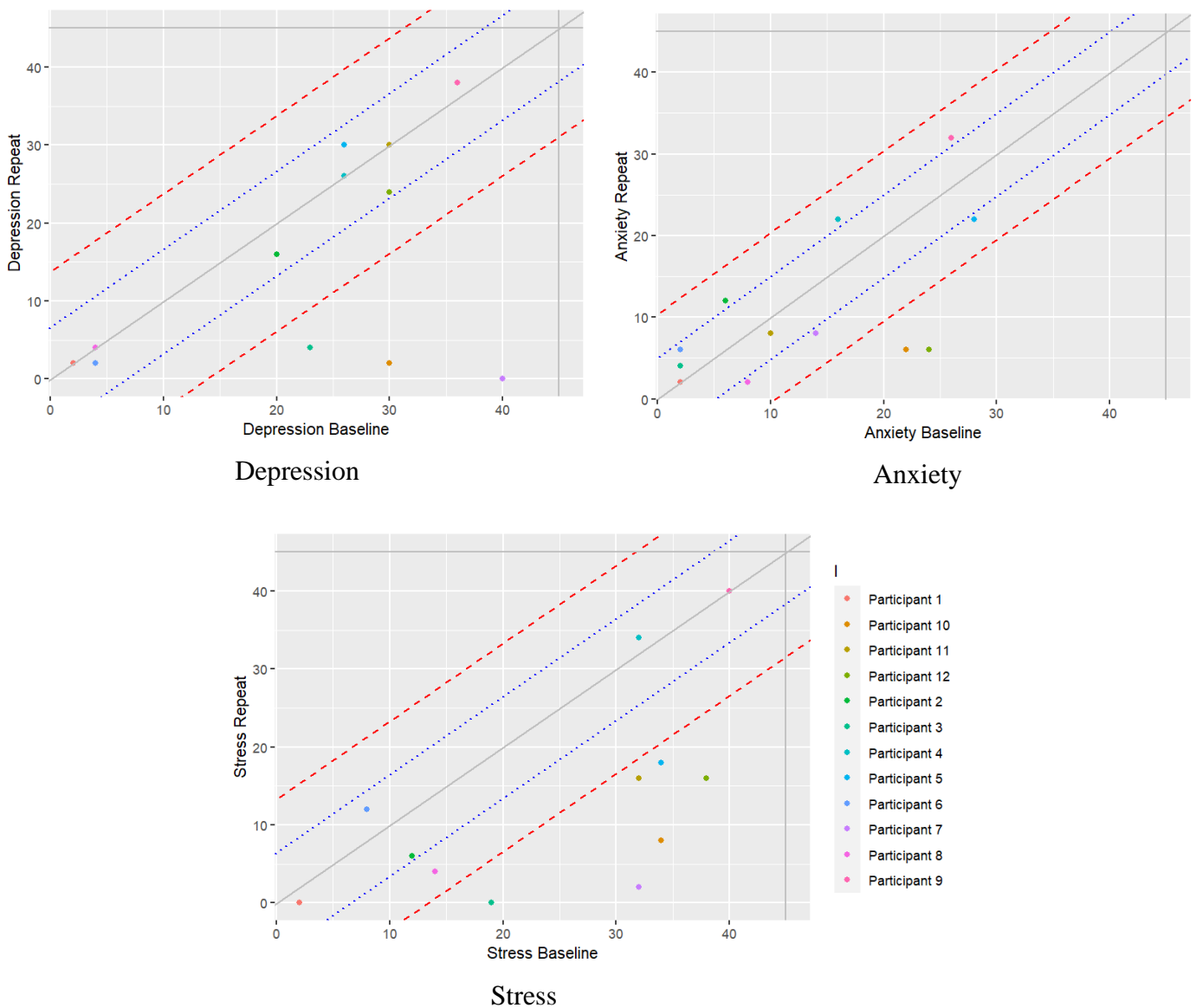
Scores for reporting symptoms of anxiety showed four outcomes (33%) were likely due to measurement error. Three participants (25%) reported an increase in anxiety symptoms above the threshold for clinically meaningful change. Nevertheless, three participants (25%) reported a clinically meaningful decrease in anxiety symptoms and two participants (17%) showed statistically significant reductions in levels of anxiety by 38% and 43% (RCI = -3.00,  $p = 0.003$ ; RCI = -3.38,  $p = 0.001$ ).

##### **2.4.1.1.2.3. Stress Subscale**

Scores for reporting symptoms of stress showed five outcomes (42%) were likely due to measurement error. One participant (8%) reported a clinically meaningful reduction in levels of stress and six participants (50%) reported statistically significant reductions of between 38% to 71% fewer experiences of stress following the training (RCI = -2.79,  $p = 0.005$ ; RCI = -2.35,  $p = 0.019$ ; RCI = -4.40,  $p < 0.001$ ; RCI = -3.81,  $p < 0.001$ ; RCI = -2.35,  $p = 0.019$ ; RCI = -3.23,  $p = 0.001$ ).

### 2.4.1.1.2.4. Summary of DASS Outcomes

The data for psychological wellbeing shows that three participants experienced fewer symptoms of depression, five participants reported fewer symptoms of anxiety and seven participants reported fewer symptoms of stress following the mindfulness training. It appears that the intervention had the greatest impact on reducing levels of stress for this sample.



**Figure 5.** Scatterplot of outcome scores for baseline and repeated outcome measures of the DASS. Continuous black line = line of no effect; blue dashed line = cut off for clinically meaningful change; red dashed line = cut off for statistically significant change.

### **2.4.1.1.3. Addenbrooke's Cognitive Examination-III (ACE-III)**

The reliable change outcomes for the five cognitive domains assessed by the ACE-III are shown in the scatterplots in Figure 6.

#### **2.4.1.1.3.1. Attention Subscale**

For the attentional subscale, nine outcomes (69%) were likely due to measurement error. Four outcomes were found to have clinically meaningful changes, whereby one participant (8%) showed an increase in attentional abilities and three participants (23%) showed a decrease in attentional abilities following the training.

#### **2.4.1.1.3.2. Memory Subscale**

For the memory subscale, six outcomes (46%) were likely due to measurement error. Two outcomes (15%) showed a clinically meaningful decrease in memory performance and one outcome (8%) showed a statistically significant decrease ( $RCI = -2.20$ ,  $p = 0.028$ ), with a decrease in total score by 15%. Two participants (15%) showed a clinically meaningful improvement in memory performance, and two participants (15%) showed a statistically significant improvement ( $RCI = 2.20$ ,  $p = 0.028$ ;  $RCI = 4.41$ ,  $p < 0.001$ ) with an increase of 15% and 30% of the total score.

#### **2.4.1.1.3.3. Fluency Subscale**

For the fluency subscale, two outcomes (15%) showed no change in scores. One outcome (8%) showed a statistically significant deterioration in fluency ( $RCI = -3.84$ ,  $p < 0.001$ ) with a score reduction of 22%. However, five outcomes (38%) showed clinically meaningful improvements in scores and five participants (38%) showed statistically significant improvements in fluency following the intervention ( $RCI = 2.56$ ,  $p = 0.011$ ;  $RCI = 5.12$ ,  $p < 0.01$ ;  $RCI = 5.12$ ,  $p < 0.01$ ;  $RCI = 5.12$ ,  $p < 0.01$ ;  $RCI = 2.56$ ,  $p = 0.011$ ) with between 14% and 29% increases in total score.

#### **2.4.1.1.3.4. Language Subscale**

For the language subscale, eight outcomes (62%) were likely due to measurement error. Three outcomes (23%) showed a clinically meaningful deterioration whereas two outcomes (15%) showed clinically meaningful improvements in language outcomes.

#### **2.4.1.1.3.5. Visuospatial Subscale**

For the visuospatial subscale, eleven outcomes (85%) were likely due to measurement error. One outcome score (8%) showed clinically meaningful improvements in visuospatial performance and one outcome score (8%) showed a statistically significant improvement (RCI = 2.63,  $p = 0.009$ ) with a 19% increase of the total score.

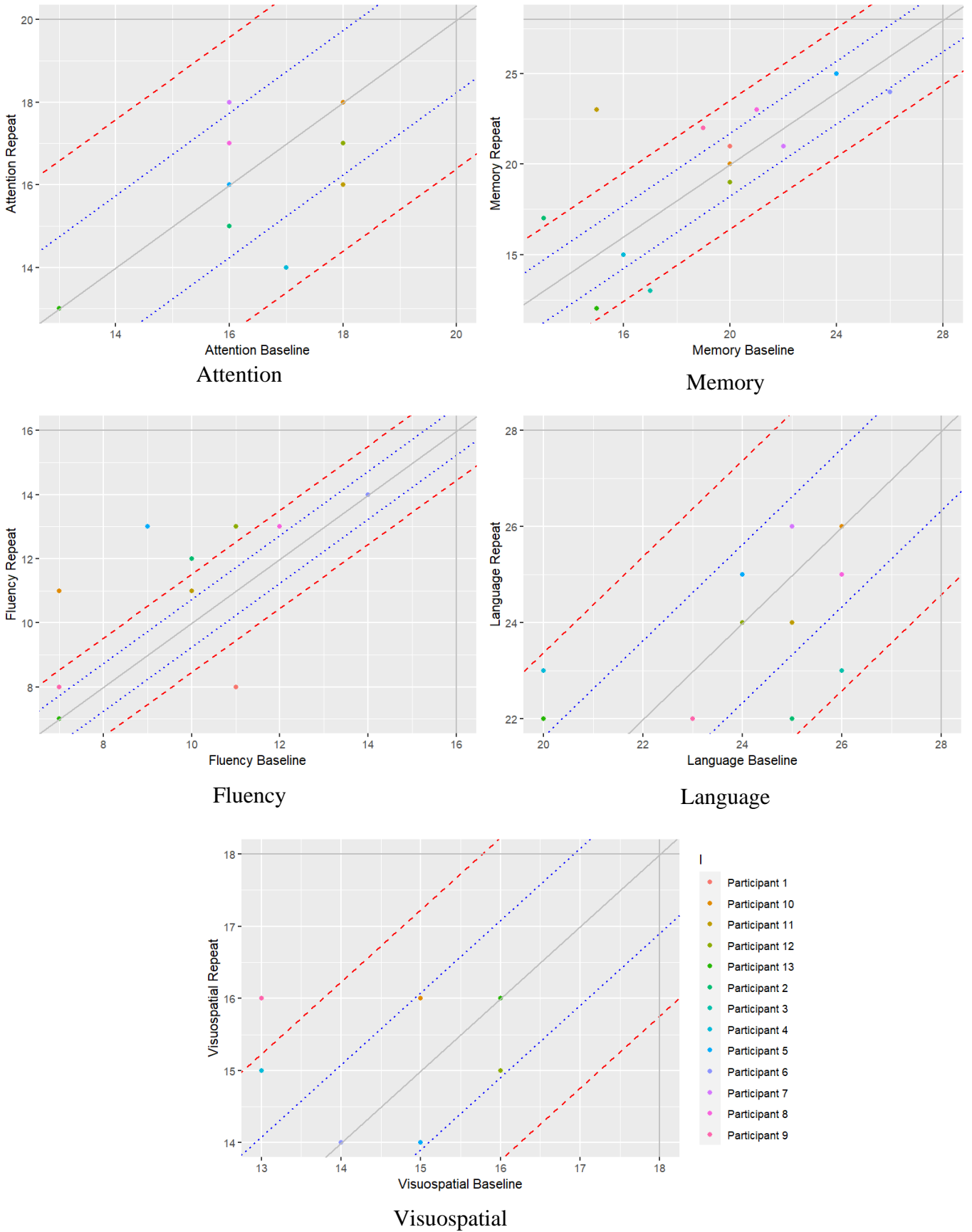
#### **2.4.1.1.3.6. Summary of ACE-III outcomes**

For the cognitive screening assessment, one participant showed improved performance on attentional tasks, four improved memory performance, ten improved agility in verbal fluency, and two participants improved performance on language and visuospatial tasks. Therefore, the greatest improvement outcome following the mindfulness training was for verbal fluency.

#### **2.4.1.1.4. Summary of Reliable Change Analyses**

The RCI analyses showed some treatment effects for the mindfulness training intervention, including improved mindful awareness, improved psychological wellbeing and cognitive performance, with some treatment effects being stronger than others.

To understand the distribution of participants showing improvements in mindfulness outcomes alongside improvements in psychological wellbeing and cognitive performance, Table 13 summarises the findings of the RCI analyses. There appear to be strong relationships between positive outcomes on the FFMQ and positive outcomes on the DASS and ACE-II, which were further investigated using correlational analyses.



**Figure 6.** Scatterplot of outcome scores for baseline and repeated outcome measures of the ACE-III. Continuous black line = line of no effect; blue dashed line = cut off for clinically meaningful change; red dashed line = cut off for statistically significant change.



**Table 13:** Distribution of participants showing improvements in FFMQ outcomes, compared to improvements in DASS and ACE-III outcomes

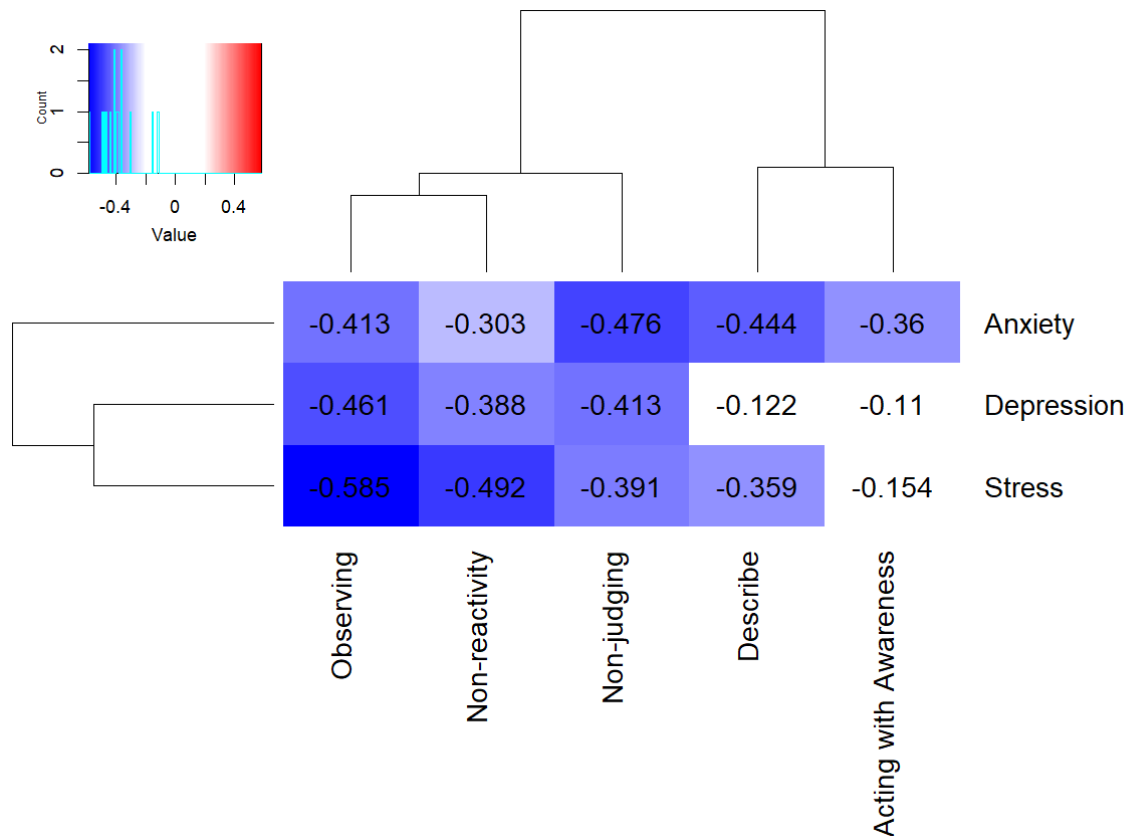
Number of participants showing clinical or significant improvement on the FFMQ (N = 13)		The distribution of participants showing improvements in the FFMQ domains in terms of associated improvements on the DASS and ACE-III subscales																
		DASS (N = 12)						ACE-III (N = 13)										
		Depression		Anxiety		Stress		Attention		Memory		Fluency		Language		Visuospatial		
<b>Observing</b>	7 (54%)	3 (43%)	5 (71%)	6 (86%)	1 (14%)	3 (43%)	7 (100%)	0 (0%)	1 (14%)	3 (43%)	7 (100%)	0 (0%)	1 (14%)	3 (43%)	7 (100%)	0 (0%)	1 (14%)	
<b>Describe</b>	3 (23%)	1 (33%)	3 (100%)	3 (100%)	0 (0%)	1 (33%)	3 (100%)	0 (0%)	1 (33%)	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
<b>Acting with Awareness</b>	2 (15%)	2 (100%)	1 (50%)	2 (100%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
<b>Non-judging</b>	3 (23%)	2 (67%)	3 (100%)	3 (100%)	1 (33%)	1 (33%)	3 (100%)	0 (0%)	0 (0%)	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
<b>Non-reactivity</b>	6 (46%)	2 (33%)	4 (67%)	5 (83%)	1 (17%)	3 (50%)	6 (100%)	0 (0%)	0 (0%)	6 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
<b>Total</b>		10	16	19	3	8	20	0	1									

### **2.4.1.2. Correlation Between Therapeutic Process Variables and Therapeutic Outcome Variables**

Correlations of the RCI values for each outcome measure were analysed, presented as correlation matrices in the form of heatmaps. The strength of association between two outcome measures is represented by a colour at the intersection of the row and column, with the intensity and hue of the colour representing the strength and character of the association. Negative correlations are depicted as an increasingly dark blue hue, whereas positive correlations are depicted as an increasingly bright red hue. Null or near zero correlations up to a magnitude of +/- 0.2 are depicted in white. The direction and magnitude of the correlation is given with Pearson's *r* correlation coefficient and classification interpretations are given for the strength of the associations (Dancey & Reidy, 2004; Akoglu, 2018). To aid the interpretability of the heatmap, the order of the row and column variables are determined by hierarchical agglomerative clustering. A dendrogram for each of the cluster analyses is provided, with the outcomes of the FFMQ presented in rows, and to the left side of the map for either the DASS or ACE-III outcome measures.

#### **2.4.1.2.1. Correlation of Mindful Awareness and Psychological Wellbeing**

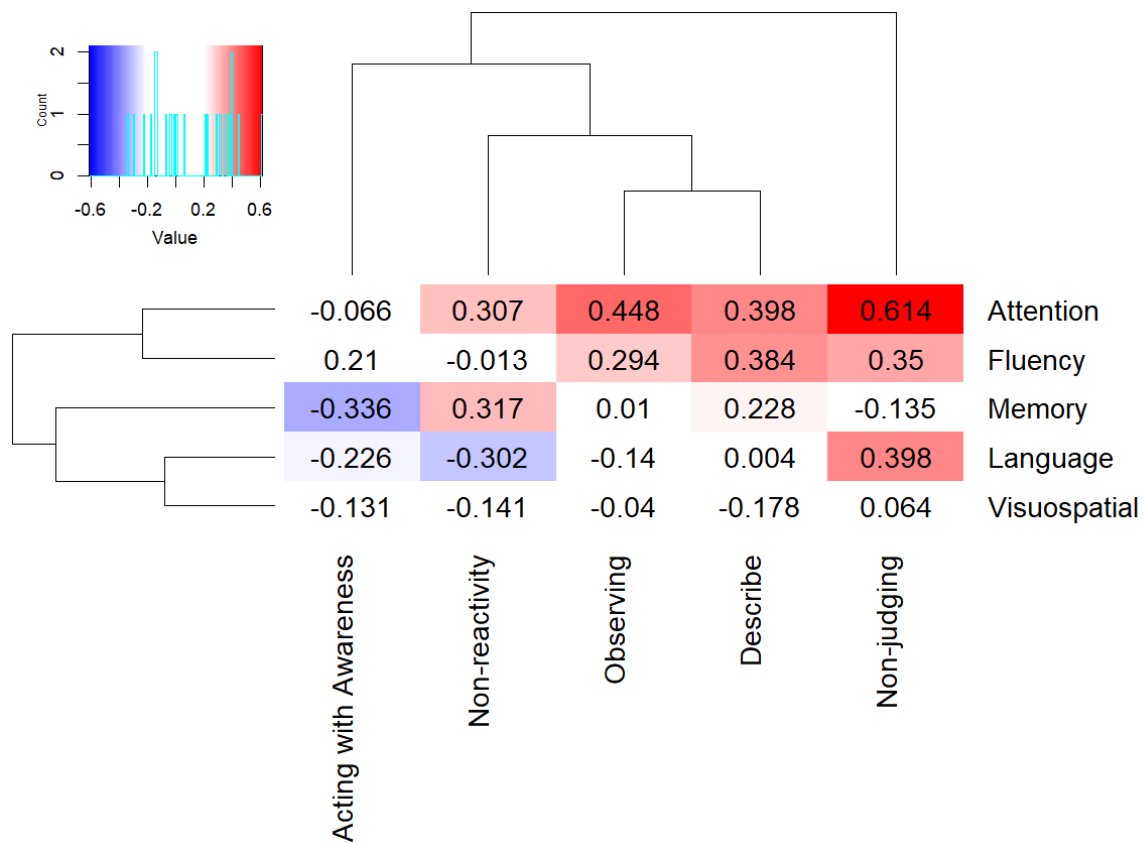
The correlational heatmap of the RCI values for the FFMQ and DASS is presented in Figure 7 and shows that all associations between mindful ability and symptoms of depression, anxiety and stress were found to be negatively correlated, as depicted in blue. The dendrogram for the correlations of RCI values for the FFMQ with the DASS shows clustering in the FFMQ domains of observing and non-reactivity, then with the non-judging domain. The correlations for the describe domain and acting with awareness had a separate cluster, less similar when compared to the other domains. The dendrogram for the DASS subscales shows a cluster of correlations for depression and stress outcomes being most alike, with symptoms of anxiety being less similar. The strongest association was found between the observing and stress subscales, with a moderate negative correlation that was found to be statistically reliable ( $r = -0.585$ ,  $p = 0.046$ ), suggesting that an increased score on observational ability was associated with fewer symptoms of stress and accounted for nearly 60% of the variance in both subscales. Correlations with changes in other DASS subscales were found to be weak or non-significant.



**Figure 7.** Heatmap depicting correlations of RCI values found for FFMQ (x-axis) and DASS (y-axis). Blue = negative correlations; White = near zero correlations; Red = positive correlations

#### 2.4.1.2.2. Correlation of Mindful Awareness and Cognitive Performance

The correlational heatmap of the RCI values for the FFMQ and ACE-III is presented in Figure 8 showing a wider spread of both negative and positive correlations and more ambiguity in the relationships between mindfulness and cognitive performance. The dendrogram for the FFMQ shows clustering in domains of observing and describe, then non-reactivity, then acting with awareness. The clustering of non-judging with the other domains was shown as less similar. The dendrogram for the ACE-III subscales shows a cluster between language and visuospatial performance, then memory, which are separate from the cluster formed for attention and fluency. Changes in non-judgemental reasoning and attentional performance were found to have mostly positive correlations, with a moderate positive association between the two subscales found to be statistically reliable ( $r = 0.614$ ,  $p = 0.034$ ), suggesting that 61% of the variance in scores on attentional tasks can be accounted for by variance in scores in non-judgemental awareness. All other correlations were found to be weak or non-significant.



**Figure 8.** Heatmap depicting correlations of RCI values found for FFMQ (x-axis) and ACE-III (y-axis). Blue = negative correlations; White = near zero correlations; Red = positive correlations

### 2.4.1.2.3. Summary of Correlational Analyses

Overall, the correlational analyses of reliable change indices suggested that there were associations between increased mindful ability and decreased symptoms of psychological distress, affirming the research aims that improvements in mindful awareness following the intervention will relate to improvements in psychological wellbeing. There were also associations found for increased scores in mindful awareness and increased scores in cognitive performance, specifically for attentional tasks. This suggests that predictions of improved mindful awareness being related to improved cognitive performance was true for some cognitive domains.

## **2.4.2. Participant Level Change**

### **2.4.2.1. Individual Profiles**

The RCI values for each subscale were collated as performance profiles for each participant, to ascertain individual responses to the intervention. The bar graphs represent the RCI values for the difference between baseline and repeated outcome scores. The black line, indicated by 0 on the x-axis, represents no change. RCI values shown to the left of the line of no effect indicate a decrease in scores and are depicted by a negative value, whereas RCI values shown to the right of the line of no effect reflect an increase in outcome scores. Clinically meaningful changes are marked with an asterisk and statistically significant changes are marked with two asterisks. For a change to be considered a benefit, there must be at least one clinically meaningful or statistically significant improvement in subscale outcomes. The profiles were categorised based on response to the intervention, being those showing measurable benefits, those showing ambiguous results, and those showing no change or deterioration.

#### **2.4.2.1.1. Measurable Benefits**

The participant profiles that showed measurable benefits from the intervention are shown in Figures 9 to 13.

##### **2.4.2.1.1.1. Mindful Awareness**

Clinically meaningful increases in observational ability were reported by Participants 5, 7, 8 and 12, and statistically significant increases were reported by Participant 10 (RCI = 2.18,  $p = 0.029$ ). Clinically meaningful increases in describing experiences were reported by Participants 5, 8 and 10. Statistically significant increases in acting with awareness were reported by Participant 10 (RCI = 2.45,  $p = 0.014$ ). Clinically meaningful increases in non-judgemental evaluations were reported by Participants 7 and 10, and statistically significant increases were reported by Participant 8 (RCI = 2.02,  $p = 0.043$ ). Clinically meaningful increases in non-reactivity were reported by Participant 12, and statistically significant increases were reported by Participant 7 (RCI = 2.30,  $p = 0.021$ ), Participant 8 (RCI = 2.62,  $p = 0.009$ ), and Participant 10 (RCI = 3.29,  $p = 0.001$ ).

#### **2.4.2.1.1.2. Psychological Wellbeing**

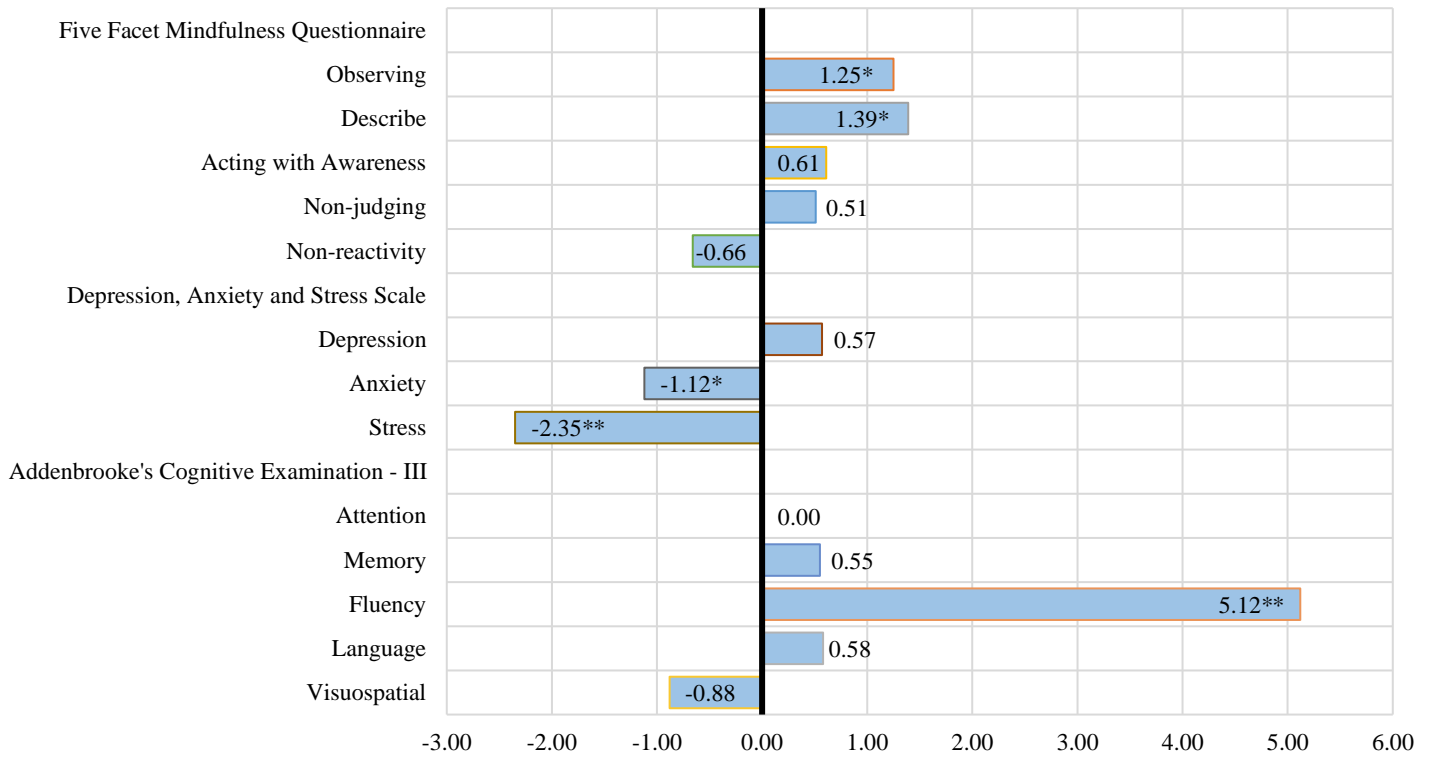
Statistically significant decreases in symptoms of depression were reported by Participant 7 (RCI = -5.68,  $p < 0.001$ ) and Participant 10 (RCI = -3.97,  $p < 0.001$ ). Clinically meaningful decreases in symptoms of anxiety were reported by Participants 5, 7 and 8, with statistically significant decreases reported by Participant 10 (RCI = -3.00,  $p = 0.003$ ) and Participant 12 (RCI = -3.38,  $p < 0.001$ ). Clinically meaningful decreases in symptoms of stress were reported by Participant 8, and statistically significant decreases were reported by Participant 5 (RCI = -2.35,  $p = 0.019$ ), Participant 7 (RCI = -4.40,  $p < 0.001$ ), Participant 10 (RCI = -3.81,  $p < 0.001$ ) and Participant 12 (RCI = -3.23,  $p = 0.001$ ).

#### **2.4.2.1.1.3. Cognitive Performance**

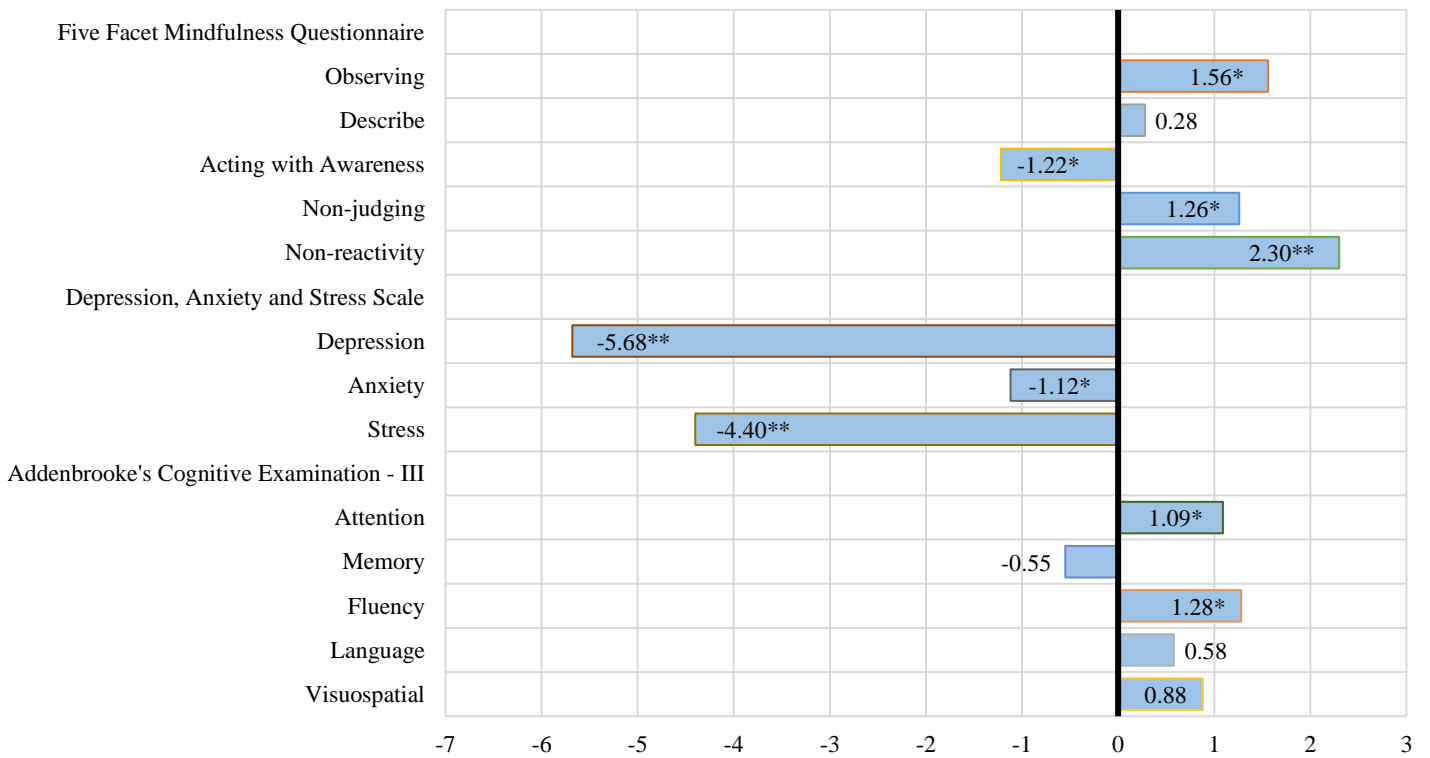
There were clinically meaningful increases in attentional performance by Participant 7, in memory performance by Participant 8, and in verbal fluency by Participants 7 and 8. There were statistically significant increases in verbal fluency by Participant 5 (RCI = 5.12,  $p < 0.001$ ), Participant 10 (RCI = 5.12,  $p < 0.001$ ), and Participant 12 (RCI = 2.56,  $p = 0.011$ ).

#### **2.4.2.1.1.4. Summary of Measurable Benefits**

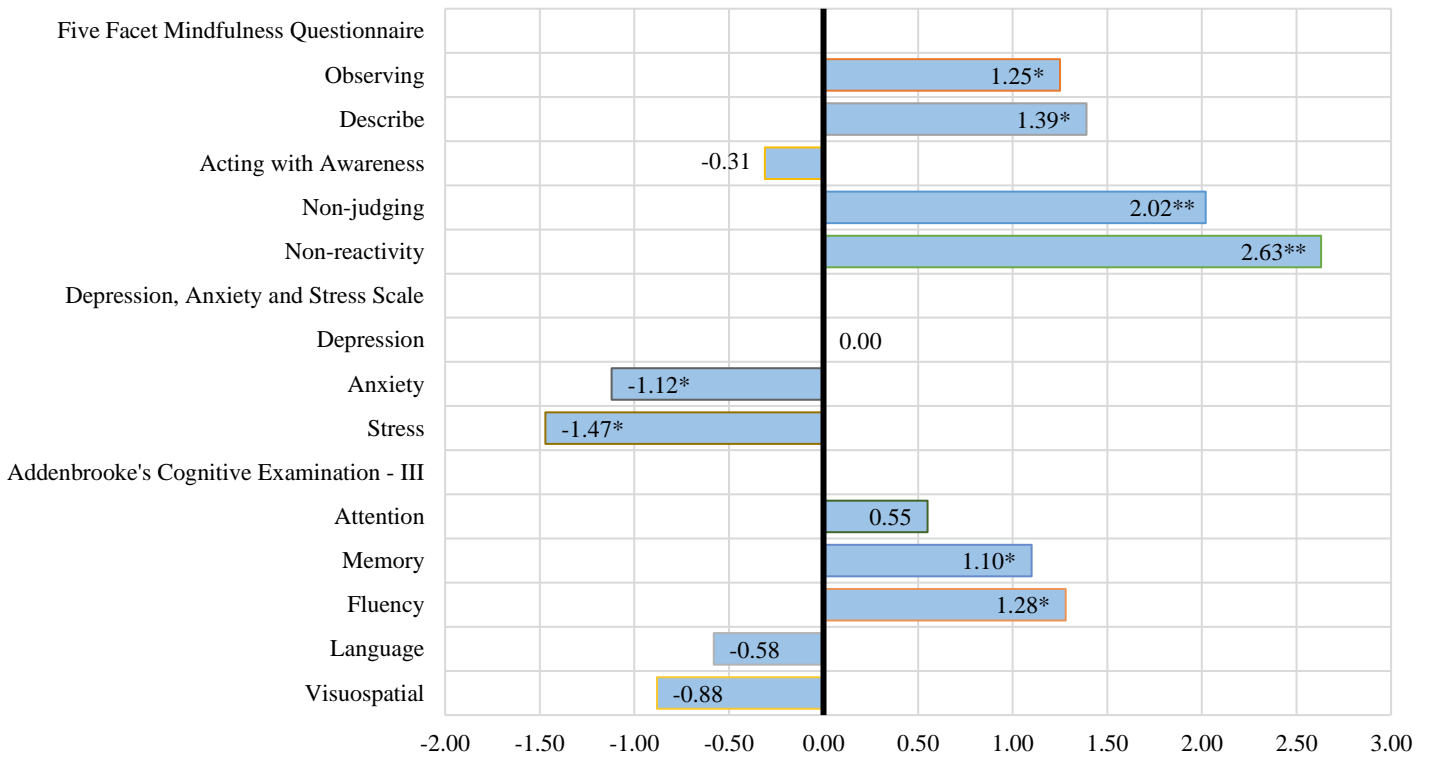
Five participant profiles found improved mindful awareness also reflecting in improved psychological wellbeing and cognitive performance. All domains of mindfulness ability showed improvements, with observational ability showing the most improvements and acting with awareness showing the least. The non-reactivity domain showed the highest frequency of statistically significant improvements. For psychological wellbeing, all subscales found improvements in symptoms, with symptoms of stress showing the highest frequency of statistically significant improvements. The cognitive domains that showed improvements in this category included attentional performance, memory performance and verbal fluency, with verbal fluency showing the highest frequency of statistically significant improvements.



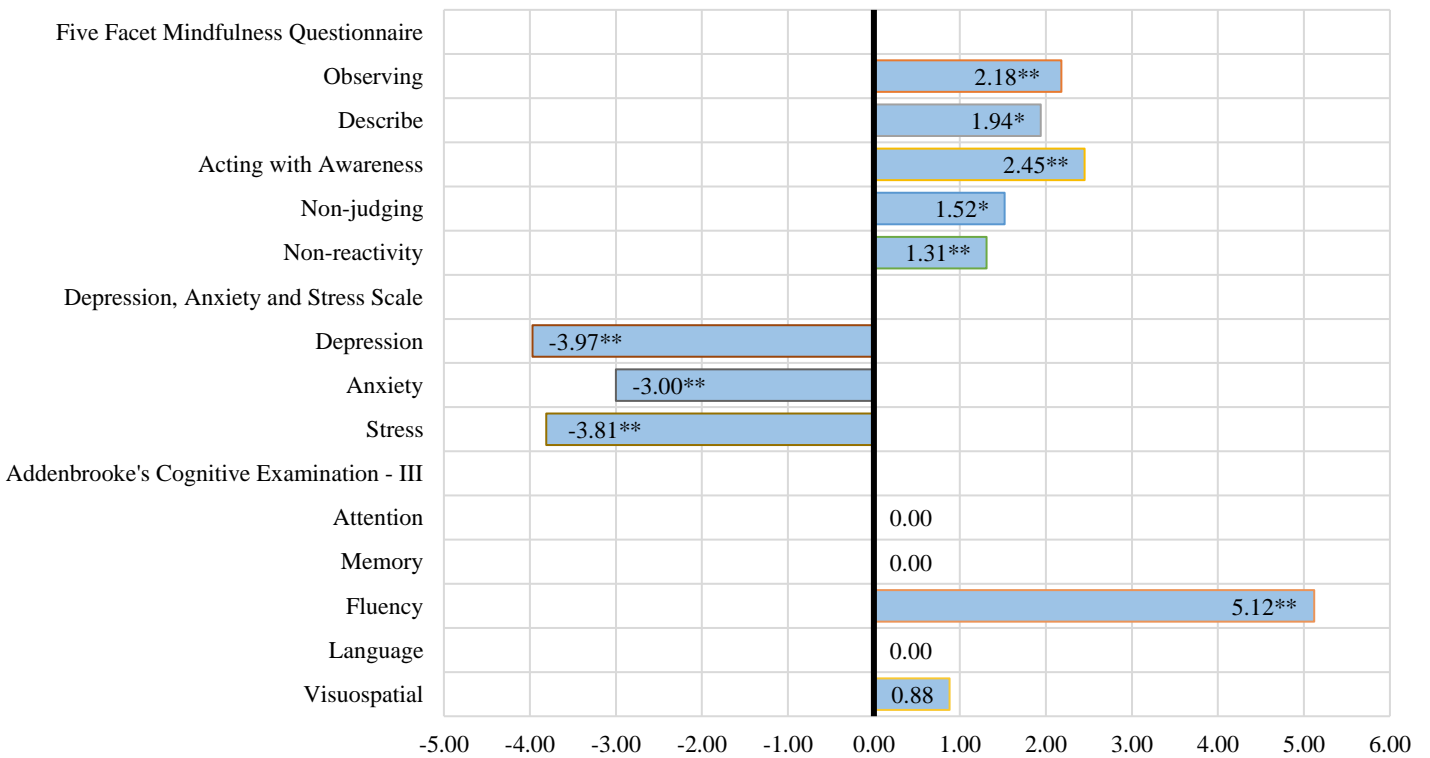
**Figure 9.** Reliable change indices profile for Participant 5.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 10.** Reliable change indices profile for Participant 7.  
 \*= clinically meaningful change; \*\* = statistically significant change

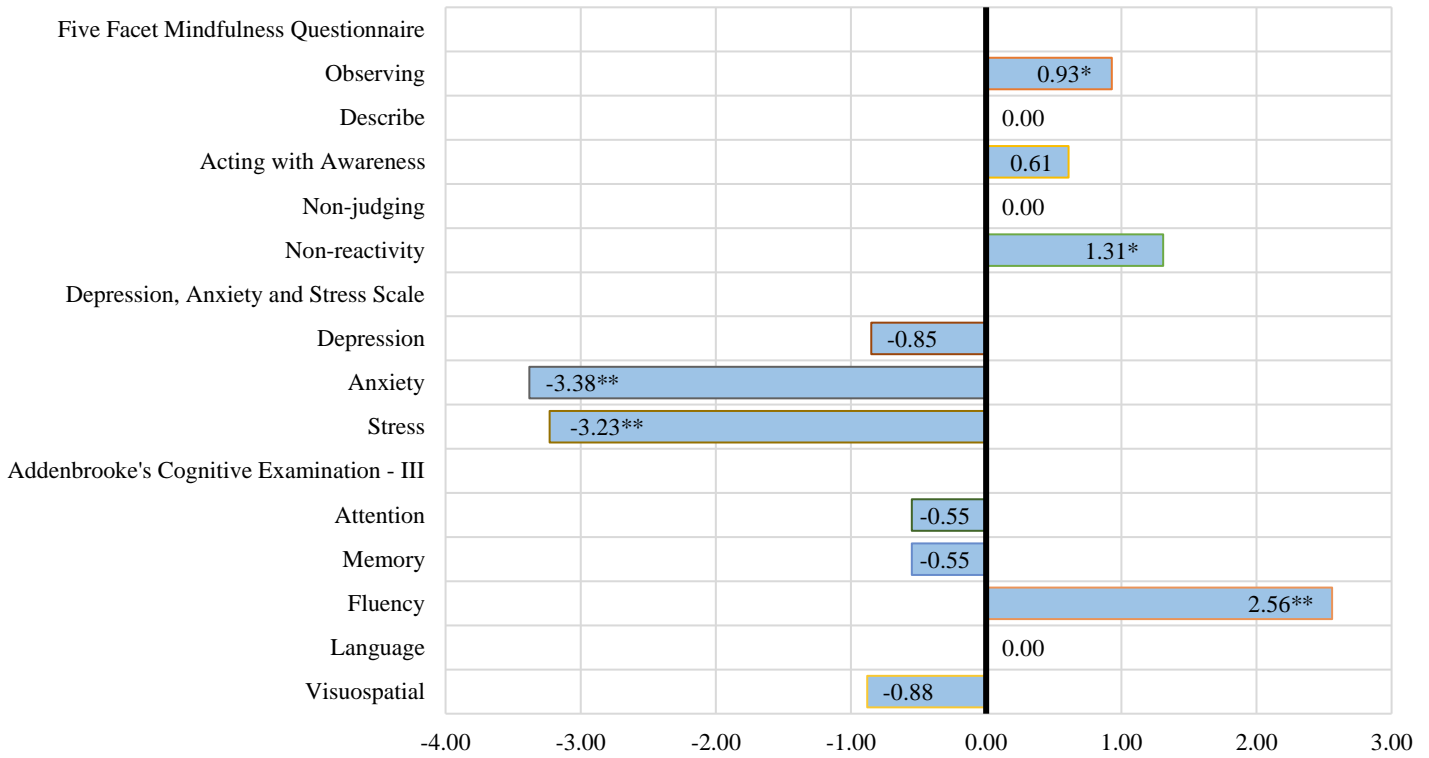


**Figure 11.** Reliable change indices profile for Participant 8.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 12.** Reliable change indices profile for Participant 10.  
 \*= clinically meaningful change; \*\* = statistically significant change





**Figure 13.** Reliable change indices profile for Participant 12.  
 \*= clinically meaningful change; \*\* = statistically significant change

#### 2.4.2.1.2. Ambiguous Profiles

The participant profiles that showed ambiguous outcomes are shown in Figures 14-17.

##### 2.4.2.1.2.1. Mindful Awareness

Clinically meaningful increases in observational ability were reported by Participants 2, 3 and 9, and for acting with awareness by Participant 3. Clinically meaningful increases in non-reactivity were reported by Participant 11, and statistically significant increases were reported by Participant 2 (RCI = 2.63,  $p = 0.009$ ).

##### 2.4.2.1.2.2. Psychological Wellbeing

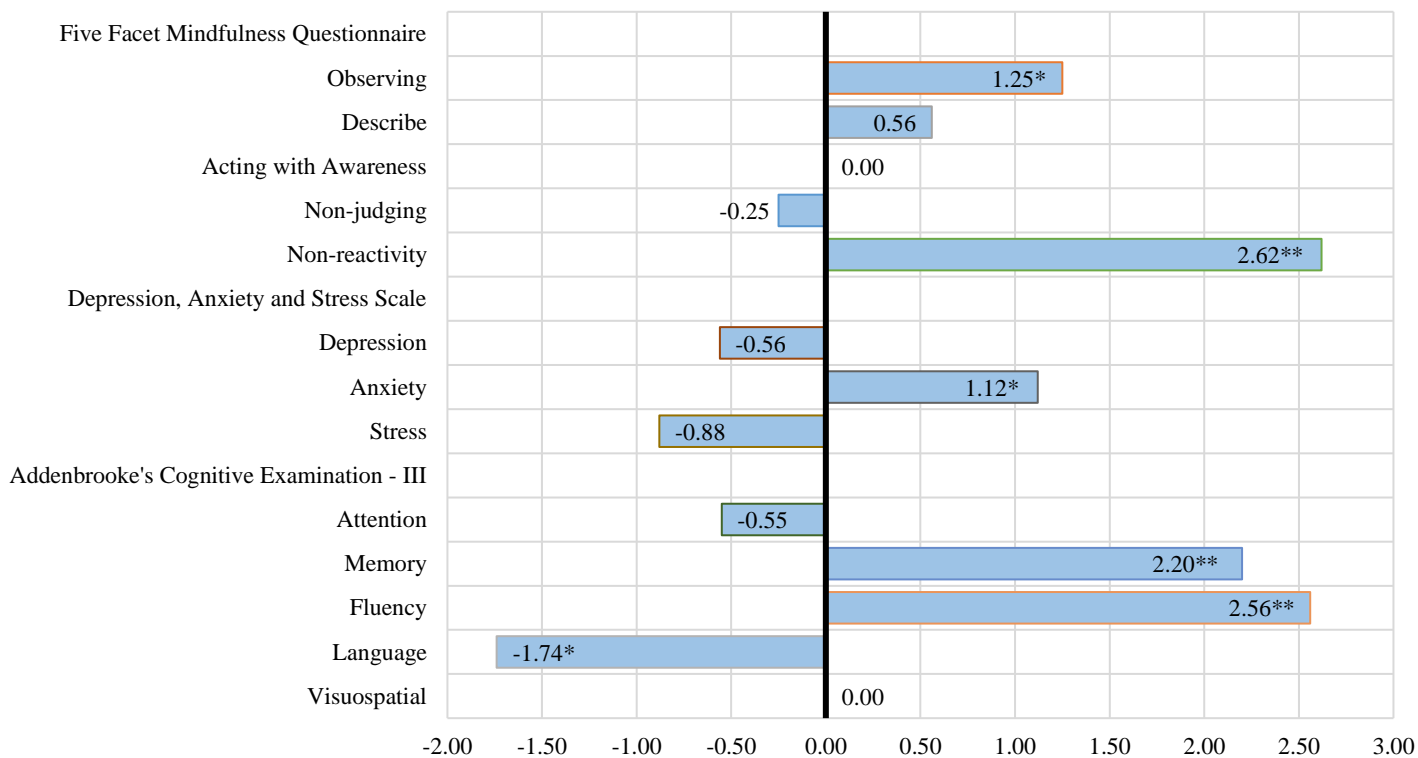
Statistically significant decreases in symptoms of depression were reported by Participant 3 (RCI = -2.70,  $p = 0.007$ ), and symptoms of stress by Participant 3 (RCI = -2.79,  $p = 0.005$ ) and Participant 11 (RCI = -2.35,  $p = 0.019$ ). However, clinically meaningful increases in symptoms of anxiety were reported by Participants 2 and 9.

### **2.4.2.1.2.3. Cognitive Performance**

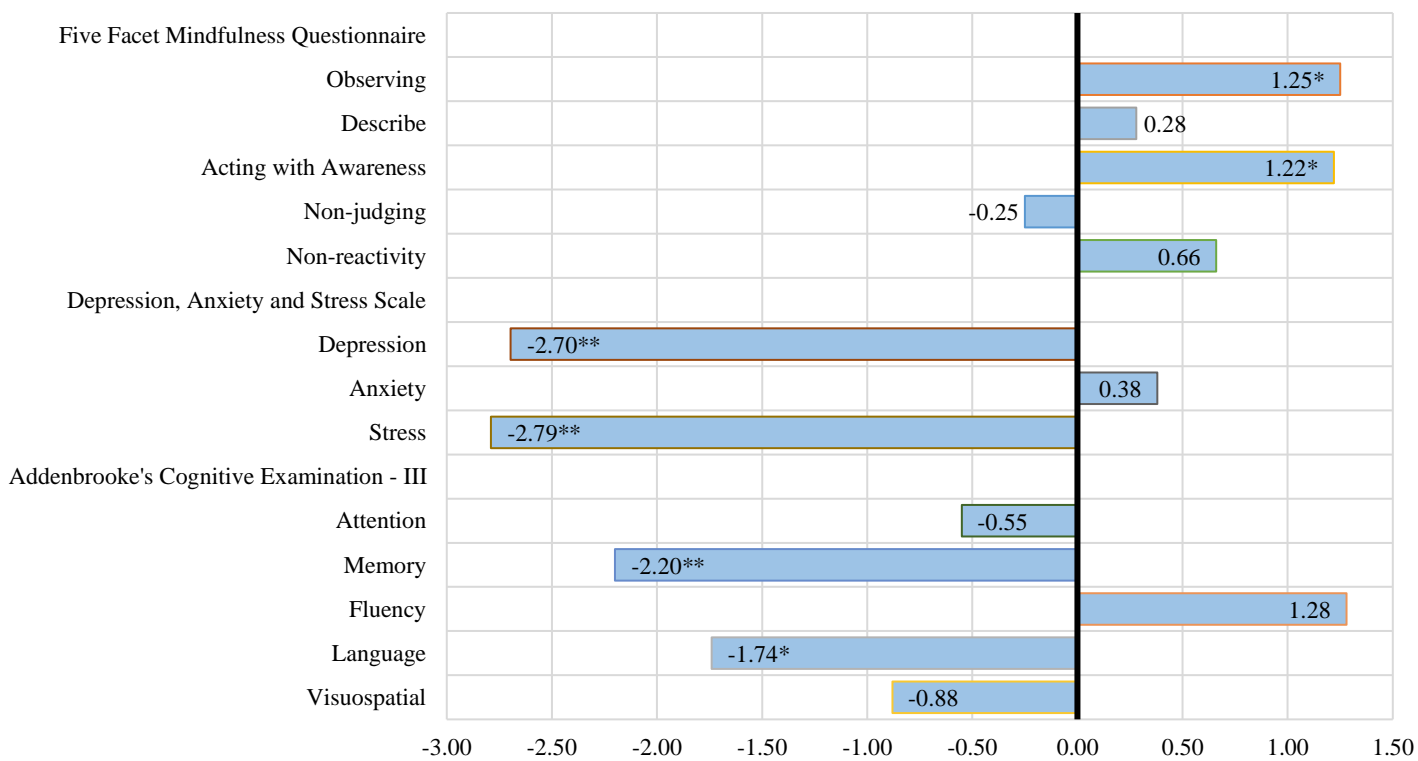
A clinically meaningful increase in memory performance was found for Participant 9, with statistically significant increases found for Participant 2 (RCI = 2.20,  $p = 0.028$ ) and Participant 11 (RCI = 4.41,  $p < 0.001$ ). A clinically meaningful increase in verbal fluency was found for Participant 9 and 11, with statistically significant increases found for Participant 2 (RCI = 2.56,  $p = 0.011$ ). Additionally, a statistically significant increases in visuospatial performance was found for Participant 9 (RCI = 2.63,  $p = 0.009$ ). However, there were clinically meaningful deteriorations in attentional performance found for Participants 9 and 11, and a clinically meaningful deterioration in language performance by Participant 2 and 3. There was also a statistically significant decrease in memory performance found for Participant 3 (RCI = -2.20,  $p = 0.028$ ).

### **2.4.2.1.2.4. Summary of Ambiguous Profiles**

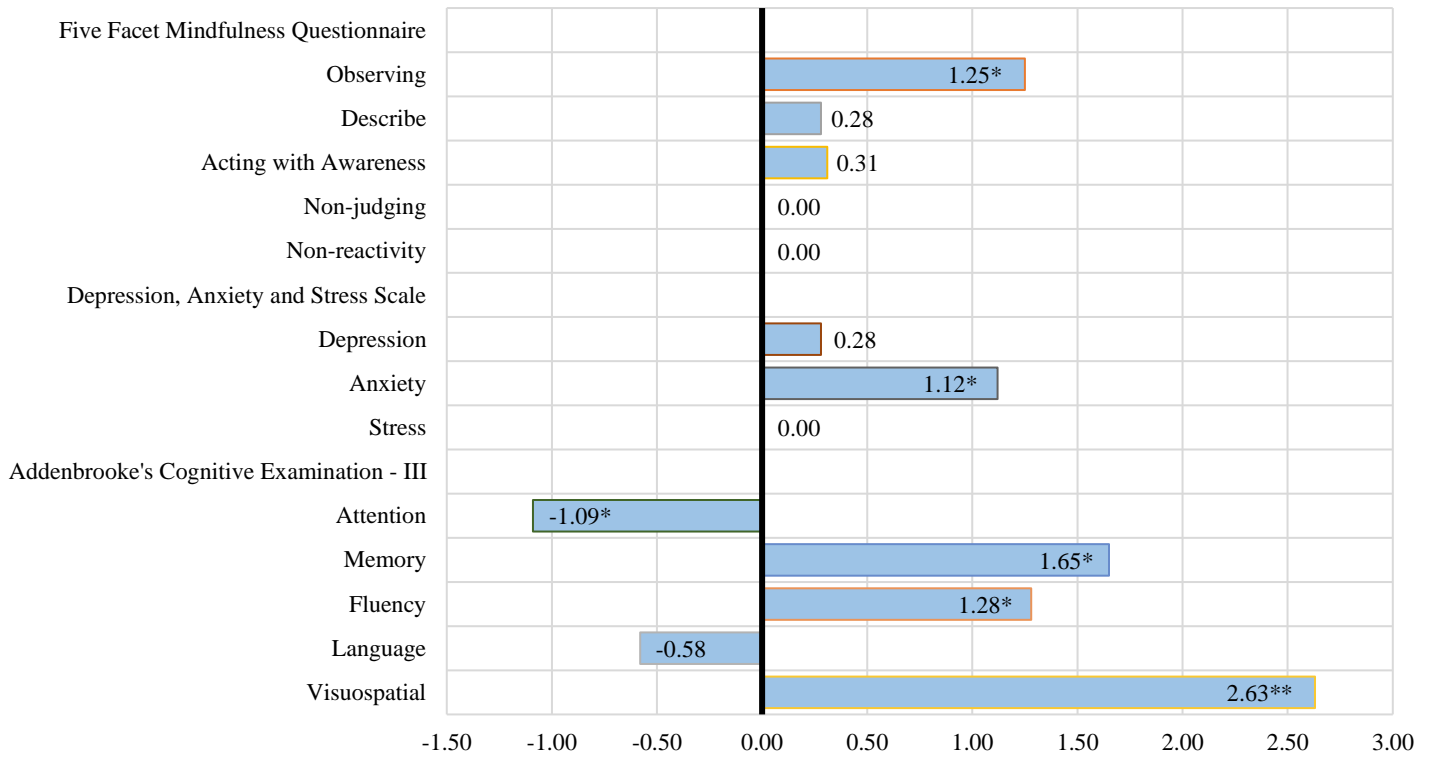
There were two profiles found to have benefits to mindful awareness and improved psychological wellbeing, but statistically and clinical meaningful deteriorations in performance in some cognitive domains, suggesting that the benefits in mindful awareness and reduced symptoms of psychological distress were not fully translated to better cognitive performance for participants 3 and 11. Two profiles showed improvements in mindful awareness, yet increased anxiety and both increased and decreased cognitive performance outcomes for participants 2 and 9. It is likely that improved mindful awareness can lead to higher reporting of anxiety once one becomes attuned to the somatisation of anxiety, which would account for this discrepancy.



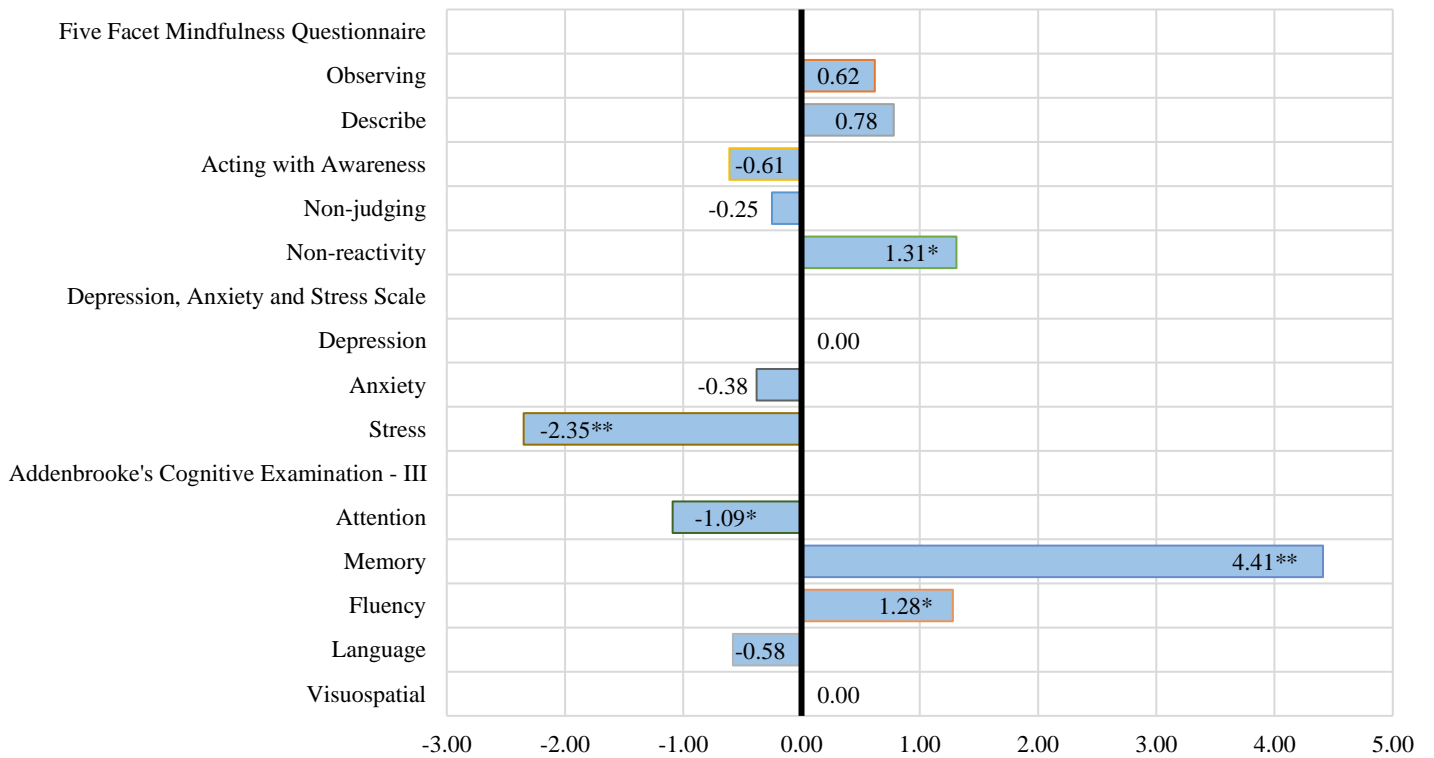
**Figure 14.** Reliable change indices profile for Participant 2.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 15.** Reliable change indices profile for Participant 3.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 16.** Reliable change indices profile for Participant 9.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 17.** Reliable change indices profile for Participant 11.  
 \*= clinically meaningful change; \*\* = statistically significant change

### **2.4.2.1.3. Absence of Measurable Benefits**

The participant profiles that showed no measurable benefit from the intervention are shown in Figures 18-21.

#### **2.4.2.1.3.1. Mindful Awareness**

A clinically meaningful increase in observational ability was reported by Participant 6. Clinically meaningful decreases in observational ability were reported by Participant 1 and 4. Likewise, a clinically meaningful decrease in non-reactivity was reported by Participant 6.

#### **2.4.2.1.3.2. Psychological Wellbeing**

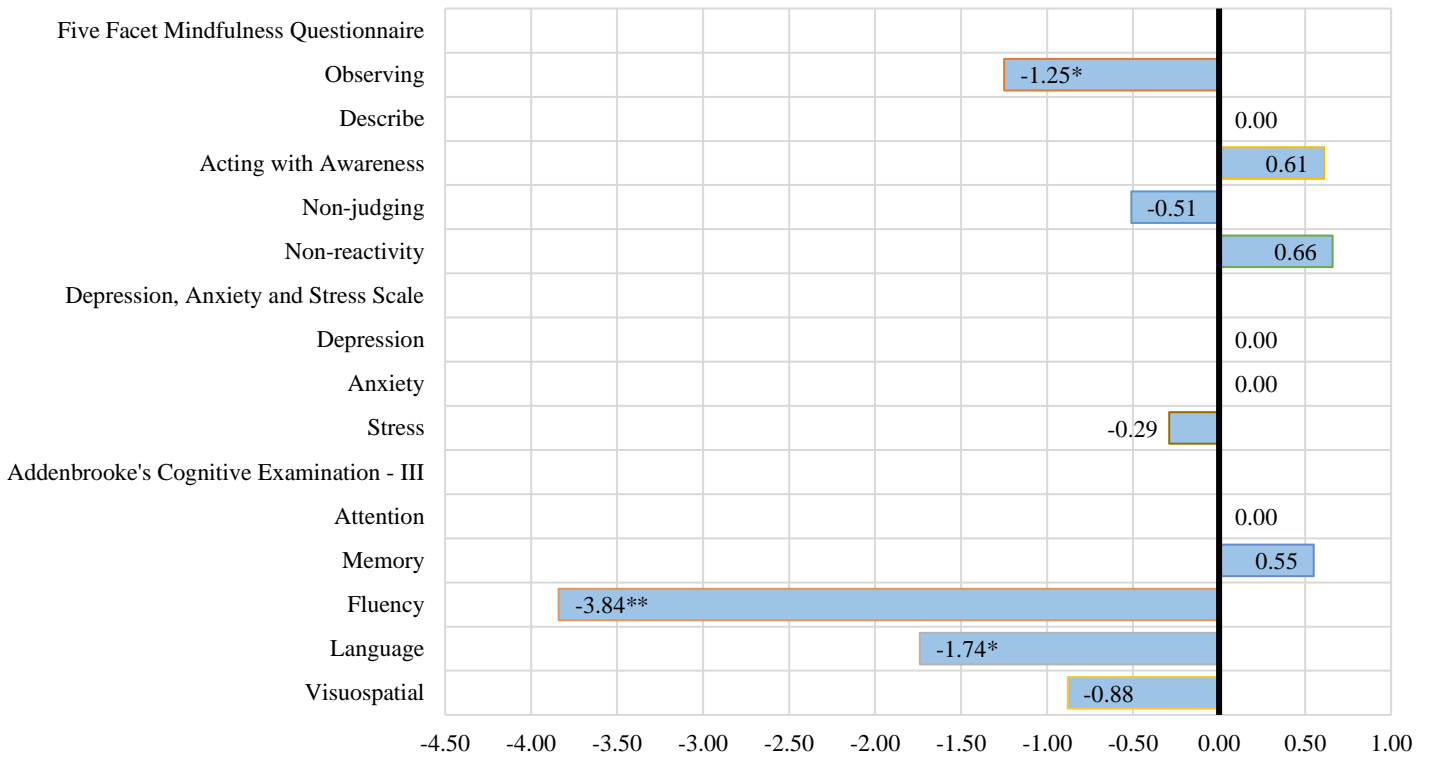
The only reportable finding for this category was a clinically meaningful increase in symptoms of anxiety as reported by Participant 4.

#### **2.4.2.1.3.3. Cognitive Performance**

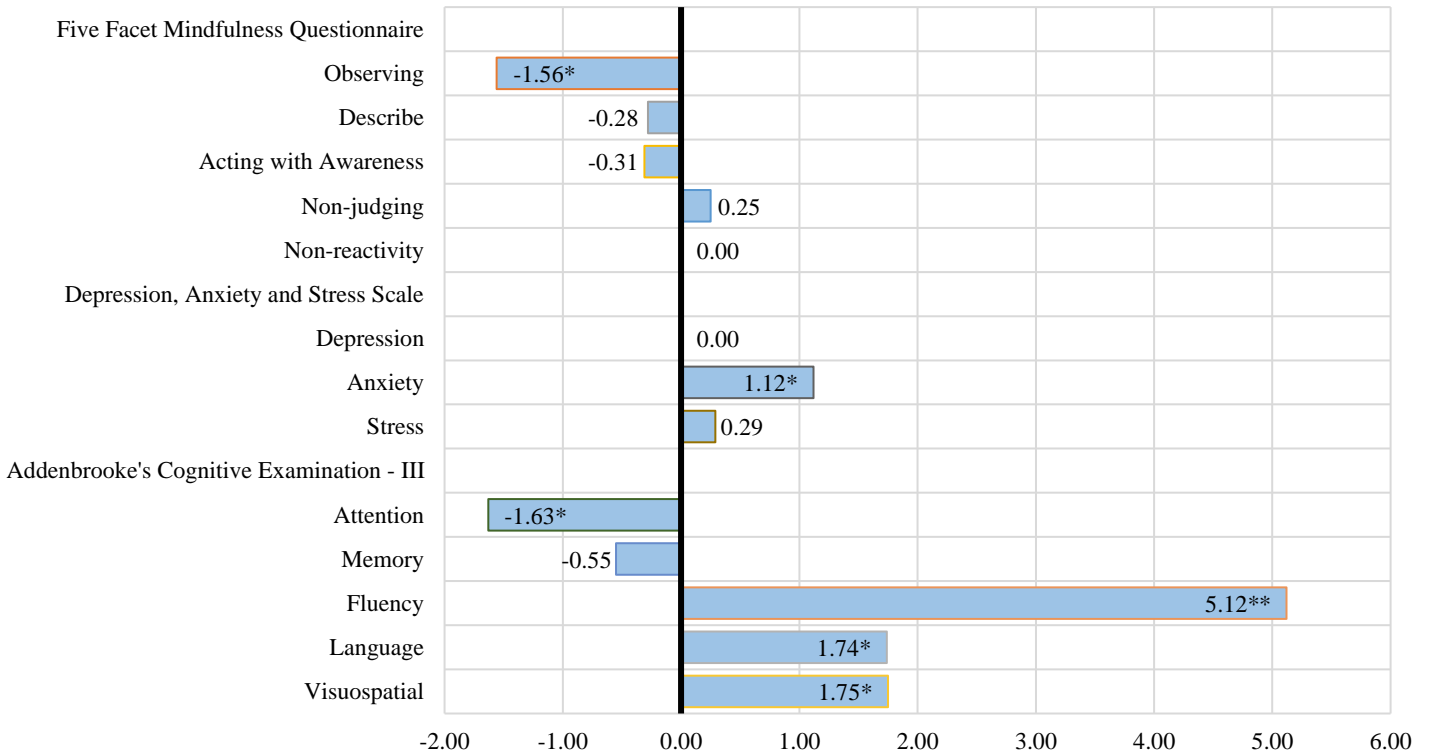
There were clinically meaningful increases found in language performance by Participant 13 and visuospatial performance by Participant 4. There was a statistically significant improvement in verbal fluency found for Participant 4 (RCI = 5.12,  $p < 0.001$ ). However, there were clinically meaningful deteriorations found in attentional performance for Participant 4, memory performance for Participants 6 and 13, and language performance by Participant 1. There was a statistically significant deterioration in verbal fluency found for Participant 1 (RCI = -3.84,  $p < 0.001$ ).

#### **2.4.2.1.3.4. Summary of Absence of Measurable Benefit**

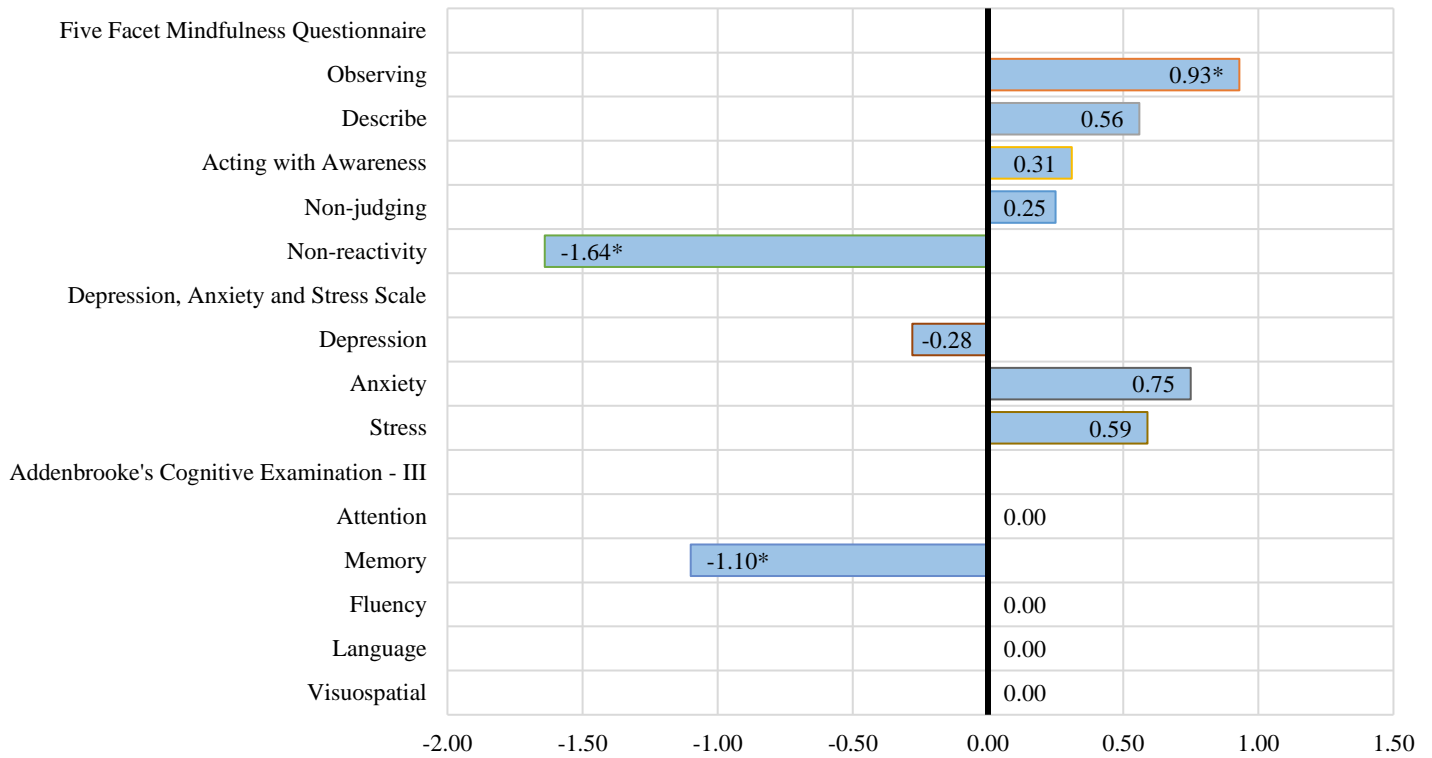
There were four profiles that showed no measurable benefit from the intervention. Participant 1 showed reduced outcomes in mindful ability alongside reduced outcomes for psychological wellbeing and cognitive performance. Participant 4 showed improved cognitive ability without benefits to mindful awareness or psychological wellbeing, suggesting more sporadic outcomes as a basis of internal inconsistency. Participant 6 showed improved observational ability but found no benefit to other subscales. Finally, participant 13 showed no benefit to mindful awareness but improved scores in one cognitive domain.



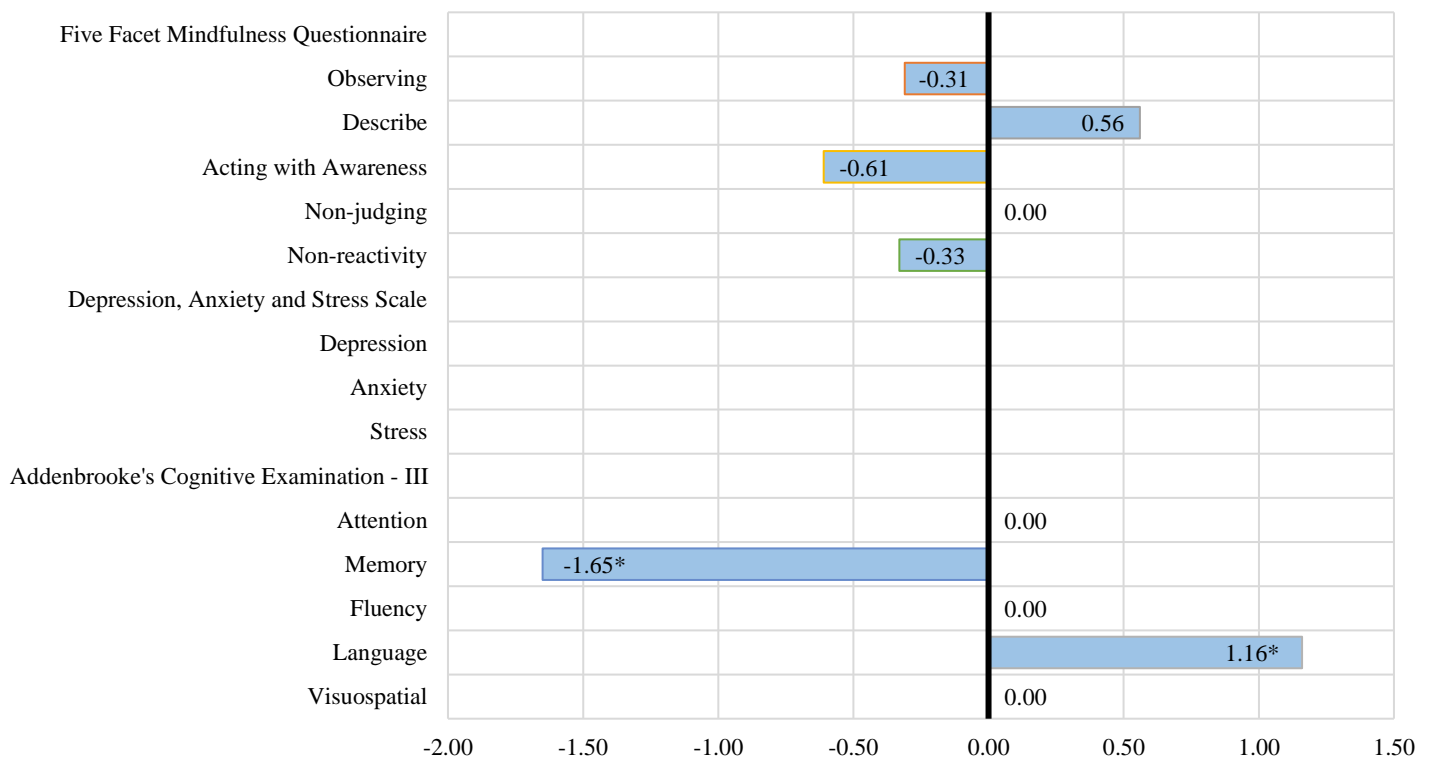
**Figure 18.** Reliable change indices profile for Participant 1.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 19.** Reliable change indices profile for Participant 4.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 20.** Reliable change indices profile for Participant 6.  
 \*= clinically meaningful change; \*\* = statistically significant change



**Figure 21.** Reliable change indices profile for Participant 13.  
 \*= clinically meaningful change; \*\* = statistically significant change

#### **2.4.2.1.4. Summary of Individual Profiles**

The individual performance profiles appear to show that more than half of the sample experienced improved psychological wellbeing following improved mindful awareness. Increases in symptoms of anxiety alongside increased observational awareness can be interpreted as a natural process of learning about the internal environment and still a beneficial outcome of the training. The results also provided evidence of internal inconsistency in cognitive performance, with deterioration on one cognitive task contrasting with improved scores on another. This was found irrespective of whether there were improvements in mindful ability, for example, with Participants 2, 3, 6, 9 and 11, or without changes in mindful ability, for example, with Participants 1, 4, and 13. This clarifies results of the correlational analyses, whereby there were ambiguous directions of correlations for mindful ability and cognitive performance outcomes due to both increased and decreased scores on cognitive tasks.

### **2.5. Discussion**

#### **2.5.1. Evaluation of Research Aims**

##### **2.5.1.1. Primary Aims**

###### **2.5.1.1.1. Trait Mindful Awareness**

The findings confirmed that mindfulness training improves mindful awareness in at least one mindfulness domain, evident in 77% of the sample. There were improved mindful abilities found in at least two mindfulness domains for 54% of the sample, with more than half of the sample learning multiple mindfulness skills following the intervention. This appears to be greater for observational awareness and non-reactivity, suggesting that sensory processing improvements may also be linked with the ability to inhibit automatic reactions in emotionally charged situations, so that uncomfortable events can be recognised and accepted with a flexible attitude. Therefore, the intervention met its primary aim with practice-based evidence that mindfulness training will improve trait-mindful awareness.



## **2.5.1.2. Secondary Aims**

### **2.5.1.2.1. Trait Mindful Awareness and Psychological Wellbeing**

There was also evidence of a consistent relationship between improved mindfulness ability and improved psychological wellbeing, as predicted based on the findings of Baer et al. (2008). There were reductions in reported symptoms of depression, anxiety or stress for 58% of the sample, and of those, 86% responded in more than one psychological wellbeing subscale. This suggests that for more than half of the sample, improving psychological wellbeing impacted on multiple levels. It could be inferred that for an additional 15% of the sample, increased reports of anxiety may indicate the start of somatisation awareness towards better wellbeing management, with a similar finding described by Metternich et al. (2008). There was a particular association found for improved trait-mindful awareness and fewer stress symptoms.

### **2.5.1.2.2. Trait Mindful Awareness and Cognitive Performance**

The association between mindful ability and cognitive performance was less conclusive. Overall, 77% of the sample showed improved performance in at least one cognitive domain and 60% of those improved performance in more than one subscale. There was evidence of improved cognitive performance alongside improved mindful awareness in 54% of the sample. There were moderate associations between the ability to reduce judgments about experiences with improved performance on attentional tasks. Nevertheless, 77% of the sample improved performance on verbal fluency, yet this was found to have low association with changes in mindfulness domains. This would suggest that other variables were influencing the changes in cognitive performance. These findings provide evidence of internal inconsistency in cognitive profiles, and so are likely to be impacted by the nature of the condition. Despite this, the research aims were met fully by 38% of the sample, suggesting that there may be future benefits with adopting this intervention into clinical practice. As cognitive restructuring happens over time, it would be predicted that continued mindfulness practice by those participating in the intervention may show further cognitive improvements at follow up.

### **2.5.1.2.3. Trait Mindful Awareness and Self-Perception**

Due to the lack of standardisation, it was not possible to evaluate the measure for self-perception in a comparative way as with other outcome measures.

### **2.5.1.3. Summary of Research Aims**

Overall, there were positive changes with increasing trait mindful awareness in the management of FCD symptoms. It is likely that with larger samples, the beneficial impact will prove to be generalisable in overcoming the debilitating experiences of FCD.

## **2.5.2. Evaluation of Outcome Measures**

### **2.5.2.1. Self-Report Measures**

The use of self-report measures may come under scrutiny for lacking objective validity or inducing social desirability. However, with the impact of internal inconsistency on objective measures, conclusions such as those given by Nicholson et al. (2020) indicate that that it would be more efficacious to measure the subjective experiences of FCD with subjective measures, supporting their use in this area of research.

The FFMQ appeared sensitive to changes in mindful ability in this sample and proved to be an adequate measure for further research assessing the abilities most influenced by mindfulness training. Similarly, the DASS showed discernible results in the reporting of symptoms of mental health distress, allowing the impact of changes in mindfulness ability on psychological wellbeing to be categorised comparatively.

The QABB was not originally aimed to be used as a quantifiable measure and this posed difficulties in both administration and interpretation as part of the research. A better measure of self-perception for future research may be one that identifies self-efficacy in cognitive ability more distinctly, such as in Metternich, Schmidtke and Hull (2009).

### **2.5.3. Performance Assessment Measures**

Conclusions about cognitive ability cannot be made from results of the ACE-III as there are likely to be ceiling effects to the scores for those who were able to perform well. It is difficult

to evaluate screening tools for cognitive ability in FCD that are ecologically valid, due to the phenomenon of internal inconsistency, as evidenced by these findings and previous studies (Stone et al., 2015; Jones et al., 2016; Ball et al., 2020; Lerner, 2020; McWhirter et al., 2020). This poses a need for further research into appropriate neuropsychological measurement devices that can accurately assess the varying cognitive performance in FCD. In the meantime, it is suggested that referral for treatment is more beneficial than extensive neuropsychological testing in FCD, especially when resources are limited (McWhirter & Carson, 2023).

## **2.5.4. Clinical Implications**

### **2.5.4.1. Theory to Treatment**

This study has supported predictions that mindfulness-based interventions assist with emotion regulation, supporting the findings of previous studies within the context of FCD (Baslet et al., 2015; Iani et al., 2019). The training provided means of behavioural activation towards wellbeing management that can be adopted into everyday routines, and was related to fewer psychiatric symptoms, as suggested in prior studies (Baer et al., 2008; Carmody & Baer, 2008). There was some anecdotal evidence of improvements in metacognitive appraisals which could indicate some interoceptive recovery as posited by Garland et al. (2015), with more rigorous measurement needed for future research. As attentional performance was associated with fewer self-judgemental evaluations, these findings support the mindfulness-to-meaning theory in that a certain amount of cognitive reserve was made accessible when less attention was paid to distressing internal interpretations, improving cognitive agility. The changes in observational ability and attentional processing suggests that those benefitting from the intervention have likely experienced a shift from effortful cognitive control to externally directed attention, through strengthening both sensory processing and attentional pathways and suppressing rumination. Therefore, mindfulness techniques can act as a cognitive remediation strategy in FCD, supporting the findings of Sumantry and Stewart (2021). In summary, it can be assumed from these preliminary findings that mindfulness-based interventions meet the neuropsychosocial needs of those with FCD and support effective symptom management.

It could be argued that sharing information about symptoms of the condition, attentional and memory processes, and stress management assisted with a platform understanding on which to base mindfulness practices as part of a stepped care approach. For example, using the helpful

analogy from Stone, Burton and Carson (2020) that it is possible to retrain the software of the brain. Coincidentally, the review by McWhirter and Carson (2023), published after development of this intervention, suggested ways in which to conceptualise symptoms of functional cognitive disorder to assist with understanding, which were already included into the training programme, such as the relevance of attentional processing, normalising cognitive lapses and the influence of autonomic nervous system processes on cognition. This provided assurance that the original protocol provided by Baslet and colleagues (Baslet et al., 2015; Baslet & Oser, 2016; Baslet et al., 2020) was adapted appropriately towards the underpinning mechanisms of FCD. Further adaptations to the training programme have been suggested to conceptualise self-compassion to promote accurate health appraisals, as these discussions were less accessible to those experiencing negative self-perceptions.

#### **2.5.4.2. Engagement**

Due to the limited available participant pool, this study compared the outcomes of participants with varied symptomatology, differing abilities, and a range of durations since assessment and diagnosis. During administration, some participants were less able to apply the training techniques, for reasons such as limited comprehension, difficulties incorporating mindfulness practice into daily routines, and interferences from health comorbidities and social circumstances. These barriers had the potential to limit engagement and beneficial gains from the intervention. Similarly, some participants were not satisfied with the clinical judgements of their experiences being functional in nature, asserting that the therapy may not have been enough for their needs and continued to seek alternative explanations. Others appeared to be influenced by external motivators and continued to attend due to reinforcement through access to healthcare, rather than intrinsic motivation to make changes to their experiences. These factors could explain the variation in measurable benefits across the sample and reiterated the findings of Howlett et al. (2007). Barriers to engagement are likely to have skewed group level correlational analyses, whereby benefits may be underestimated. Screening processes have now included formalised assessments of readiness for change to reduce the impact of low comprehension or motivation on the achievable benefits of future training courses. This will help with both tailoring the intervention in a person-centred way for those in need of individual support, as well as boosting morale and harnessing greater connection in group dynamics. It

is hoped that this will result in more meaningful changes from future interventions which were potentially limited in the study.

### **2.5.4.3. Guidelines for Treatment**

This study provided insight of how best to support those with FCD, informing the knowledge base about the effectiveness of addressing emotion regulation, behavioural activation towards wellbeing management, cognitive remediation, and more accurate evaluation of cognitive processes in future interventions. The scope to adopt mindfulness techniques is far reaching, being adaptable to use in combination with other healthcare disciplines, for instance, combining with physiotherapy programmes to help support sensory and attentional processing, as well as mediating health anxiety (Dallocchio et al, 2016; Lehn et al, 2016). The use of mindfulness techniques could be used as a foundation for further physical health and mental health support as part of stepped care for managing FCD, reducing the requirement of extensive healthcare provision.

Anecdotally, the intervention had high acceptability from all who completed it. Foremost, it was important to deliver the intervention as a group format to: a) normalise the experiences of those making minor cognitive errors (Metternich et al., 2008; Pennington, Newson et al., 2015) and b) assist those who were otherwise isolated by the condition (Libbon et al., 2019). Verbal feedback from participants suggested that the opportunity to connect with others going through similar experiences developed naturally through discourse and there was a resounding request for peer support to continue following the training. Collaborative focus groups are in development for coproduction of the functional pathway within the memory service.

### **2.5.5. Future Research**

It is intended for this study to become part of a wider research project fostering a larger pool of data to be analysed, with dissemination aimed at increasing awareness of the plight of those with FCD who are reviewed within a healthcare system that lacks an appropriate treatment pathway. This research is due to be presented at NHS Trust research and innovation events as well as being adopted by other NHS Trusts nationally. Future research would hope to include formal measures of acceptability as a means of capturing the importance of this intervention to

those who have so often been disregarded by health systems, to include collaboration of patient experience in discussions of treatment pathway commissioning.

Furthermore, there is a need for multisite researchers and universities to collaborate with clinical investigations into effective treatments for FCD. Currently, the need for intervention is disproportionately high when compared to the limited attention being paid to clinical research in the FCD literature. Most importantly, future research is needed to understand the relative efficacy and conceptual coherence of the treatment components identified in the systematic literature review in Chapter 1 of this volume and investigated in this research report, namely the influence of emotion regulation, behavioural activation, metacognitive adjustments, and cognitive remediation for management of FCD, to strengthen future formulations of intervention need.

### 3. References

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## **4. Press Release for Systematic Literature Review**

The Swiss cheese model. An analogy used to describe the layers of systems working together to reduce the impact of risk, error, or failure. With that in mind, how can the fields of neurology, healthcare and empirical research allow those with the most common, distressing and disabling neurological condition slip through so many holes?

Functional neurological disorder, often shortened to FND, is a diagnosis given to a range of experiences resulting from the signals in the brain not arriving at their intended destination. This is despite there being no injury or damage to the brain cells, the nerve pathways, or the part of the body they were intended to control. This happens because of disruptions to the function of the brain, meaning the way that the brain works, and is how the condition got its new name. Previously, FND has been termed hysteria or conversion disorder, but a lot more is now understood about how people experience this condition.

There are several different presentations of FND, with this review focussing on one of them, functional cognitive difficulties. This may look like memory slips, difficulties concentrating or finding words, and everyday tasks feeling like they take a lot of cognitive effort. These experiences may change in different situations, meaning that their cognitive performance can fluctuate and is not easy to assess. It is common for those experiencing these medically unexplained difficulties to over monitor their health, with associated symptoms of anxiety, depression and stress making it more likely for cognitive errors to occur. This vicious cycle can result in loss of independence, loss of employment and fear for the future.

Cognitive difficulties associated with FND are the most common experience of those seeking healthcare support at neurology clinics, more so than those caused by neurodegeneration, brain injury or disease. Consequently, this involves a significant investment of healthcare resources. Yet there are currently no treatment guidelines available for healthcare teams to rely on whilst supporting those in their care. Anecdotally, those with functional cognitive difficulties feel disregarded, often signposted to several different services to no avail. The distinct lack of focus in research literature validates this.



This systematic literature review explored the theoretical explanations and underpinning mechanisms of cognitive difficulties in FND. Investigating the nature of the experiences helped to formulate the intervention needs then propose potential treatment components that would be expected from effective interventions. These were summarised as:

1. emotion regulation: the ability to manage and respond to emotional experiences in a balanced way
2. behavioural activation: deliberately performing behaviours and prioritising activities that improve wellbeing management
3. metacognitive adjustments: reflecting, monitoring, and evaluating cognitive abilities more accurately
4. executive control remediation: directing attention to sensory processing and away from health monitoring

Similarly, to assess whether an intervention was effective in the rehabilitation of functional cognitive difficulties, interventions would also be expected to:

5. measure the impact on cognitive performance: neuropsychological assessment of cognitive performance before and after an intervention

The expected treatment components were compared to available interventions found in empirical literature. A systematic search of literature databases, using the OVID electronic gateway to search Medline, APA PsychInfo and Embase databases, yielded five research studies. These involved a range of treatment approaches, including transcranial brain stimulation, memory training exercises, stress management groups, or dance and exercise activities. Therefore, there is scope for a wide variety of treatments to encompass the varying experiences of those with functional cognitive difficulties. When comparing the limited number of studies to the expected treatment outcomes, it became evident that they did not meet the holistic needs of those with functional cognitive difficulties. Therefore, no treatment guidelines could be concluded from this systematic review.

Is this area of research the dark matter of neuroscience, where people's needs are so elusive that very little is understood about them? Is the size of the gap between prevalence of the condition and underwhelming volume of research simply due to a lack of devices available to measure these difficulties? Or do we owe it to those experiencing functional cognitive difficulties to pay more attention to how they experience healthcare?

Further research is needed to evaluate whether combining the expected treatment components would provide helpful interventions to alleviate the neurological, psychological, and social impact of cognitive difficulties in FND. Resources could be channelled more effectively towards research investigations and practice-based evidence from clinics, making a step forward in providing treatment guidelines of effective management strategies for this condition.

## **5. Press Release for Empirical Research Paper**

Imagine feeling thirsty and I hand you a bottle of cold water with ice cubes in. As you lift the bottle to take a drink, the ice cubes fall to the neck of the bottle and prevent the water flowing through to allow you to quench your thirst. So, you try harder, tipping the bottle up and down trying to manoeuvre the ice cubes, and you may eventually get a few drops of water to drink. But as you work harder, getting more fatigued and frustrated, you start to believe that there must be something wrong with you, why is it that you cannot access this water? As unpleasant emotions start to rise, the neck of the bottle narrows, letting even fewer drops of water through. How much effort does it now take to drink the water and is the effort going to help you achieve your goal?

This is what it is like to live with functional cognitive disorder, shortened to FCD in neurology spaces. This condition occurs when the signals of the brain do not manage to reach their intended target despite there being no damage to the brain itself. In this analogy, every drop of water would represent something to access, for instance, pleasant experiences that we want to enjoy, a heartfelt conversation with a loved one, mental notes to help us remember something from the shop on the way home, or locating where we last left the screwdriver. Each ice cube represents a challenge in everyday life, like pain or a time deadline, a preoccupation with perfectionism or over monitoring of our health. These pose blocks to information processing, limiting cognitive agility. As one tries harder to control and access these experiences, this reduces the capacity for information to be filtered through the cognitive systems. Reduced capacity to pay attention to surroundings or memory cues increases anxiety, which in turn perpetuates the cognitive failures.

Those with FCD often experience memory lapses, lose their train of thought, struggle to find the words they need, and have a reduced capacity to process information coming in. Yet there is so little understood about how to help someone manage these experiences.

Theoretically, there appear to be parallels between the difficulties experienced in FCD and the benefits offered through mindfulness practices. Mindfulness-based interventions have been shown to improve recognition and tolerance of unpleasant emotions, offer strategies to help balance mental wellbeing, make more balanced evaluations about abilities, and improve focus and sensory processing. This study evaluates the effectiveness of a novel intervention of

mindfulness training aimed at improving mindful awareness, psychological wellbeing, and cognitive performance in FCD. An intervention protocol by Baslet and Oser (2016) was adapted to include remediation of the cognitive, psychological, and social aspects of the condition.

Thirteen people with FCD took part in the mindfulness training and completed questionnaires and cognitive screens before and after the intervention. Statistical analysis of the outcomes found clinically meaningful improvements in observational awareness and statistically significant changes in the ability to moderate emotional reactions. This suggests that the mindfulness training improved trait-mindfulness abilities in the sample. Correlational findings showed consistent negative associations between improved mindfulness abilities and fewer symptoms of depression, anxiety and stress, meaning that as mindfulness awareness improved, psychological wellbeing also improved. Additionally, positive correlations were found for improved mindful awareness and improved performance on attentional tasks, meaning that as mindfulness strategies strengthened awareness, performance in some cognitive areas improved. Measurable benefits were found for more than half of the sample.

This study confirmed predictions that support for emotion regulation, wellbeing management, accurate evaluations of abilities and broadening attentional processes are viable treatment components that help manage the experiences of those with FCD. These treatment expectations were evidently provided through mindfulness training. Anecdotally, the intervention was so well received that those involved requested access to ongoing peer support from the clinic to continue mindfulness practices, as well as evidencing commissioning needs in support of an FCD healthcare pathway. This doctoral thesis has translated into improvement in service delivery, with practice-based evidence strengthening clinical practice and the empirical literature, contributing towards future development of treatment guidelines in the management of FCD.

## 6. Appendices

### 6.1. Appendix A: Letter from ethics committee granting full ethical approval for research



Miss Hayley Wolstencroft  
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Email: [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)  
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13 July 2023

Dear Miss Wolstencroft

**HRA and Health and Care  
Research Wales (HCRW)  
Approval Letter**

**Study title:** Investigating the efficacy of mindfulness-based intervention for improving mindful awareness and psychological wellbeing with functional cognitive disorder.

**IRAS project ID:** 318564

**Protocol number:** RG\_22-127

**REC reference:** 23/HRA/2450

**Sponsor** Research Governance and Integrity

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

#### **How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

**What are my notification responsibilities during the study?**

The “[After HRA Approval – guidance for sponsors and investigators](#)” document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **318564**. Please quote this on all correspondence.

Yours sincerely,  
Anna Bannister

Approvals Specialist

Email: [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)

*Copy to: Dr Birgit Whitman*

## List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Insurance]	1.0	01 August 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Insurance]	1.0	07 June 2023
IRAS Application Form [IRAS_Form_23062023]		23 June 2023
IRAS Application Form XML file [IRAS_Form_23062023]		23 June 2023
IRAS Checklist XML [Checklist_23062023]		23 June 2023
Letter from sponsor [Confirmation of Sponsorship]	1.0	07 June 2023
Organisation Information Document [Organisation Information Document]	1.0	10 July 2023
Research protocol or project proposal [Protocol]	1.0	10 July 2023
Schedule of Events or SoECAT [Schedule of Events]	1.0	05 June 2023
Summary CV for Chief Investigator (CI) [CV Hayley Wolstencroft]	0.1	29 September 2022
Summary CV for student [CV Hayley Wolstencroft]	0.1	29 September 2022
Summary CV for supervisor (student research) [CV Chris Jones]	0.1	29 September 2022

## Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
<p>Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.</p>	<p>NHS Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. HRA and HCRW Approval has been issued The NHS organisation has not provided a reason as to why they cannot participate The sponsor may start the research prior to the above</p>	<p>An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other agreement to be used with participating NHS organisations of this type.</p>	<p>Study funding arrangements are detailed in the Organisation Information Document.</p>	<p>The Chief Investigator may be responsible for all research activities performed at participating NHS organisations.</p>	<p>Where an external individual is conducting only research activities that are limited to access to staff, or staff data (in either identifiable or anonymised form), or anonymised patient data then a Letter of Access is required only if these activities will take place in NHS facilities. This should be issued on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm standard DBS checks. Where these activities will not take place in NHS facilities then no arrangements under the HR Good Practise Pack are required.</p>



	<p>deadline if the participating NHS organisation positively confirms that the research may proceed.</p> <p>The sponsor should now provide the local information pack to participating NHS organisations in England and/or Wales. A current list of R&amp;D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose</p>				
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**Other information to aid study set-up and delivery**

<p><i>This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.</i></p>
<p>The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.</p>