DClinPsy Portfolio

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Be Here Now: Evaluating an Adapted Mindfulness-Based Intervention in a Mixed Population with Acquired Brain Injury (ABI) and Neurological Conditions

A thesis submitted to the University of Hertfordshire in partial fulfilment of the requirements of the degree of Doctor in Clinical Psychology

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THE GUEST HOUSE

This being human is a guest house.
Every morning a new arrival.

A joy, a depression, a meanness,
some momentary awareness comes
as an unexpected visitor.

Welcome and entertain them all!
Even if they are a crowd of sorrows
who violently sweep your house
empty of its furniture,
still, treat each guest honourably.
He may be clearing you out
for some new delight.

The dark thought, the shame, the malice
meet them at the door laughing and invite them in.

Be grateful for whatever comes
because each has been sent
as a guide from beyond.

Jelaluddin Rumi (translated by Coleman Barks)

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Glossary of Terms and Abbreviations

ABI	Acquired Brain Injury
ACT	Acceptance and Commitment Therapy
BPM	Buddhist Psychological Model
CBT	Cognitive-Behavioural Therapy
CFT	Compassion-Focused Therapy
DASS21	Depression Anxiety and Stress-Short Form
DBT	Dialectical Behaviour Therapy
FA	Focused Attention
FMI	Freiburg Mindfulness Inventory
HRQOL	Health-Related Quality of Life
IAA	Intention Attention Attitude Model of Mindfulness
LMM	Liverpool Mindfulness Model
MAAS	Mindful Attention Awareness Scale
MBI	Mindfulness-Based Intervention
MBCT	Mindfulness-Based Cognitive Therapy
MBSR	Mindfulness-Based Stress Reduction
MS	Multiple Sclerosis
MSES	Mindfulness Self-Efficacy Scale
MSES-R	Mindfulness Self-Efficacy Scale-Revised
mTBI	Mild Traumatic Brain Injury
MTBI	Moderate Traumatic Brain Injury
Neuro-QOL	Neurology Quality of Life
OM	Open Monitoring
PD	Parkinson's disease

PQoL	Perceived Quality of Life Scale
TAU	Treatment as Usual
TBI	Traumatic Brain Injury
UC	Usual Care
WLC	Wait-list control

Abstract

Acquired brain injury (ABI) and long-term neurological conditions (such as multiple sclerosis, Parkinson's disease), are major causes of disability in the UK, and can lead to significant physical, cognitive, neuro-behavioural, psychological and social difficulties for sufferers. Individuals affected by an ABI or neurological conditions commonly report difficulties around emotional adjustment, reduced attention, mental control, and self-efficacy and their health-related quality of life also often appears to be much reduced. Whilst conventional neuro-rehabilitation has tended to address physical and cognitive impairments and deficits rather than psychological sequelae, recently a growing trend for more holistic approaches appears to have emerged (e.g., Wilson *et al*., 2000, 2013). Amongst these approaches, mindfulness-based interventions (collectively known as MBIs) have sought to address this gap in terms of therapeutic intervention. There is a growing body of research evidence pointing to the utility of MBIs in the rehabilitation and support of these populations in improving perceived quality of life and increasing self-management of these conditions. However, the research still remains limited and debate persists in terms of the conceptual and theoretical framework of mindfulness.

The present study sought to evaluate the effectiveness of an adapted, short-form MBI group programme for a mixed population of patients (n = 22) currently offered in a local neuro-rehabilitation service. A specific pre-post control group design was adopted in order to investigate whether the intervention produced improvements in mindfulness skills, and whether these would in turn lead to improvements in measures associated with self-efficacy and perceived quality of life. Results indicated participants completing the MBI group programme showed significantly higher mean scores across measures of mindfulness. The results also indicated that these improvements were predictive of improvements across self-efficacy and quality of life measures, with large effect sizes observed. The findings would appear to support the research hypothesis that a suitably modified MBI is beneficial for a mixed ABI population. Findings, study limitations, clinical relevance and implications, as well as methodological and theoretical considerations and directions for future research are discussed in light of the main research questions.

1. Introduction

1.1 Acquired Brain Injury (ABI) and neurological conditions: brief overview

It is perhaps useful to provide an overview of the current understanding and definitions of Acquired Brain Injury (ABI hereafter) and neurological conditions and distinctions thereof in order to set the context of the present study more clearly, and to provide a rationale for the methodological paradigm selected to investigate the potential effectiveness of the MBI under evaluation.

1.1.1 Acquired Brain Injury

An ABI is defined as any brain injury sustained as a result of trauma (also known as Traumatic Brain Injury or TBI), stroke, cancer, infection or other insult, etc. which has occurred after birth rather than congenitally. For the purposes of the present study, the term TBI hereafter will be considered under the more general category of ABI. ABI is assumed to be an inclusive category that covers acute (i.e., rapid onset) brain injury of various causes, including:

- Trauma (due to head injury or post-surgical damage)
- Vascular accident (stroke or subarachnoid haemorrhage)
- Cerebral anoxic injury
- Toxic or metabolic insult (e.g., hypoglycaemia)
- Infection (e.g., encephalitis, meningitis) or other inflammation (e.g., vasculitis)
- Tumours

The Defense Centers of Excellence describes TBI as "*a blow or jolt to the head that disrupts the normal function of the brain. The severity of the TBI is determined at the time of the injury and may be classified as mild, moderate or severe*."(DVBIC, 2010). Mild TBIs are the most common, and 80 – 90% of all TBIs are classified as mild. Of note is that the course of recovery, symptoms, and evidence-based treatments are different for mild versus moderate-severe TBI.

Common symptoms associated with a TBI are:

Physical: headache, sleep disturbances, dizziness, balance problems, nausea/vomiting, fatigue, visual disturbances, sensitivity to light, ringing in ears
Cognitive: slowed thinking, poor concentration, memory problems, difficulty finding words
Emotional: anxiety, depression, irritability, mood swings

1.1.2 Neurological conditions

In contrast, whilst not technically classified as ABI, long-term neurological and neurodegenerative conditions such as Multiple Sclerosis (MS hereafter) and Parkinson's disease (PD hereafter) also tend to be diagnosed and treated within general neurology and neuro-rehabilitation services. Aside from the practical considerations, both MS and PD (among other rarer forms of neurological disorder) can be thought of as disorders where the brain and its functioning are in some way implicated and impaired.

MS is a relatively rare condition of the central nervous system (brain and spinal cord) with onset typically occurring in early adulthood. Diagnosis usually occurs between 20-50 years of age, with the course of the disease typically characterised by episodes during which white matter within the brain and spinal cord becomes inflamed and subsequently damaged by the immune system. White matter represents around 60% of brain volume and consists mainly of myelinated axons. Areas of inflammation cause scarring and hardening (a process known as *sclerosis*) across multiple areas in the brain and spinal cord which damage the protective myelin sheath in which nerve axons are encased and protected.

The condition is poorly understood due to the variability of clinical presentations and the relative frequency of episodes. These episodes may be asymptomatic in many individuals however symptoms can occur suddenly, followed by periods of good or complete recovery (*relapsing-remitting* MS). In others, symptoms may increase gradually and progressively over a longer period of time (*progressive* MS). It is estimated that around 80% of MS patients have the former type. The female-male ratio of the condition is 2:1. It is the most common disabling neurological condition among young adults.

PD is defined as a chronic progressive neurodegenerative condition resulting from the depletion and death of dopamine-containing cells of the *substantia nigra* in the brain. There is no consistently reliable test that can distinguish PD from other conditions with similar clinical presentations, which can prove problematic for diagnosis. Classic symptom

presentations include bradykinesia, rigidity and tremor, however due to the implication of dopaminergic pathways, depression is a common associated difficulty, as well as autonomic disturbances and pain (which may develop as the condition progresses).

1.1.3 Prevalence of ABI and neurological conditions

Within the general population, ABI and neurological conditions account for a significant proportion of short- and long-term disability (Department of Health, 2005, National Audit Office, 2011). Point prevalence rates remain relatively high (see Table 1). Prognoses and typical recovery trajectories are difficult to determine, due to the heterogeneity and variability of onset, course and symptomatology of the injury or condition, as well as other factors such as age, gender, physical health, social and environmental factors. In the case of stroke, mortality rates have halved over the last 20 years (Stroke Association, 2012). With increasing numbers of survivors of ABI and neurological conditions (due in part to advances in medical research), an increasing demand on services to develop effective rehabilitation pathways and interventions would seem crucial in the maintenance of individuals' quality of life, psychological well-being and functioning across all areas of their lives.

Table 1. UK prevalence/incidence rates for ABI and neurological conditions.

Condition	**Prevalence rate** *per 100,000 p.a.*	**Incidence (new cases)** *per 100,000 p.a.*	**Approximate numbers** *(total)*
ABI:			
Stroke	139 (F) ; 178 (M)[2]	240	300,000[2]
TBI	1,200	175	420,000
Infection	varies	varies	varies
Tumours	20[1]	7[3]	9,400[3]
Neurological:			
MS	100-140[1]	4[1]	85,000[1]
PD	100-180[1]	17[1]	120,000[1]

Source: [1]Neurological Alliance (2003), [2]Stroke Association (2013), [3]Office of National Statistics (2013).

1.2 Psychological difficulties associated with ABI and neurological conditions

It is apparent, then, that ABI, whether as a result of trauma (e.g., road traffic accidents) or organic/neurological in nature (e.g., encephalitis, cerebral tumour, MS, PD, stroke), is a major cause of disability in the UK. What also seems clear is that it can lead to significant physical, cognitive, neuro-behavioural and psychosocial difficulties. More specifically, individuals who have sustained an ABI or have developed a neurological condition commonly report complex and often chronic difficulties around emotional adjustment, reduced attention, mental control and self-efficacy (i.e., the ability to manage and cope with the impact of injury or condition on their general functioning, health and quality of life). The literature is clear and abundant in this regard (e.g., Ponsford, 1995; Rosenthal *et al*., 1998; Deb, 1999; Steadman-Pare *et al*., 2001; Alderman, 2003; Turner-Stokes and Hassan, 2002a, 2002b; Khan-Bourne and Brown, 2003; Williams *et al*., 2003; Fleminger and Worthington, 2009), and there continues to be increasing qualitative research evidence which supports this view.

Thus health-related quality of life (HRQOL hereafter) often appears to be much reduced among individuals with ABI and neurological conditions, and the incidence of psychological difficulties such as anxiety and depression is typically high within this population (e.g., Wellisch *et al*., 2002; Tyerman and King, 2004; Hackett *et al*., 2005). In the case of MS, mental health comorbidity appears to be under-reported (McGuigan and Hutchinson, 2006; Marrie *et al*., 2008). Various possible reasons for this are: a perceived sense of loss (loss of self-identity), the transition from a functioning to "non-functioning" status; the duration and severity of symptoms post-injury and uncertain prognosis (with lengthy or partial recovery trajectories in some cases, e.g., Dennison *et al*., 2009); the impact of physical, neuropsychological and cognitive impairments and perceived disability on functioning (in some cases, individuals remain unable to continue or return to work); and relationships. Recent literature (e.g., Uprichard, 2009; Rogan *et al*., 2013) has pointed to the contribution of avoidant coping styles strongly predicting and correlating with depressive symptoms and difficulties managing the emotional impact of ABI and subsequent levels of post-traumatic growth.

1.3 Approaches to the management and rehabilitation of ABI patients

Given the nature of their onset and course, it is understandable that conventional rehabilitation for ABI and associated neurological conditions has tended to address the physical and cognitive impairments and deficits rather than the psychological sequelae of brain injury or neurological disorder. This is certainly still borne out and emphasised within clinical guidelines to an extent. Nevertheless, there has been a growing recognition to address psychological issues within this population. As a leading exponent in the field, Turner-Stokes (2001) has recognised the differing needs of individuals who may require different services across the rehabilitation pathway and has proposed a "slinky" model (see fig. 1). The model highlights the importance of providing flexibility to allow access services at any time during their recovery, as well as facilitating seamless transition between services. It describes a progression of rehabilitation goals from reducing impairment to enhancing participation.

1.3.1 Current clinical guidelines: ABI

The BSRM/RCP National Clinical Guidelines for rehabilitation following ABI (RCP, 2003) briefly highlight recommendations for psychological interventions:

G128: "*patients should be provided with access to individual and/or group psychological interventions for their emotional difficulties adapted to take into account individual neuropsychological deficits*" (p. 45);

G131: "*patients should have access to specialist individual group neuropsycho-therapeutic interventions to facilitate long-term psychological, family and social adjustment, including sexual relationships. This need may not arise for many years post-injury*." (p. 45)

The NICE long-term rehabilitation for stroke guidelines (NICE, 2013) reiterate the need for psychological input for stroke victims and their families, however recommend further research in this area to provide more robust evidence. The authors of the National Clinical Guidelines for stroke (ICSWP, 2012) recommend brief, structured psychological therapy for stroke patients experiencing depression, and highlight the necessity for relevant adaptations in respect of those with neurological conditions. Similarly, the authors of the BPS Briefing Paper for stroke (Kneebone *et al.*, 2010), whilst recognising the utility of cognitive,

pharmacological and physical rehabilitation components, stress the need for a comprehensive, holistic model of care which incorporates the provision of psychological approaches.

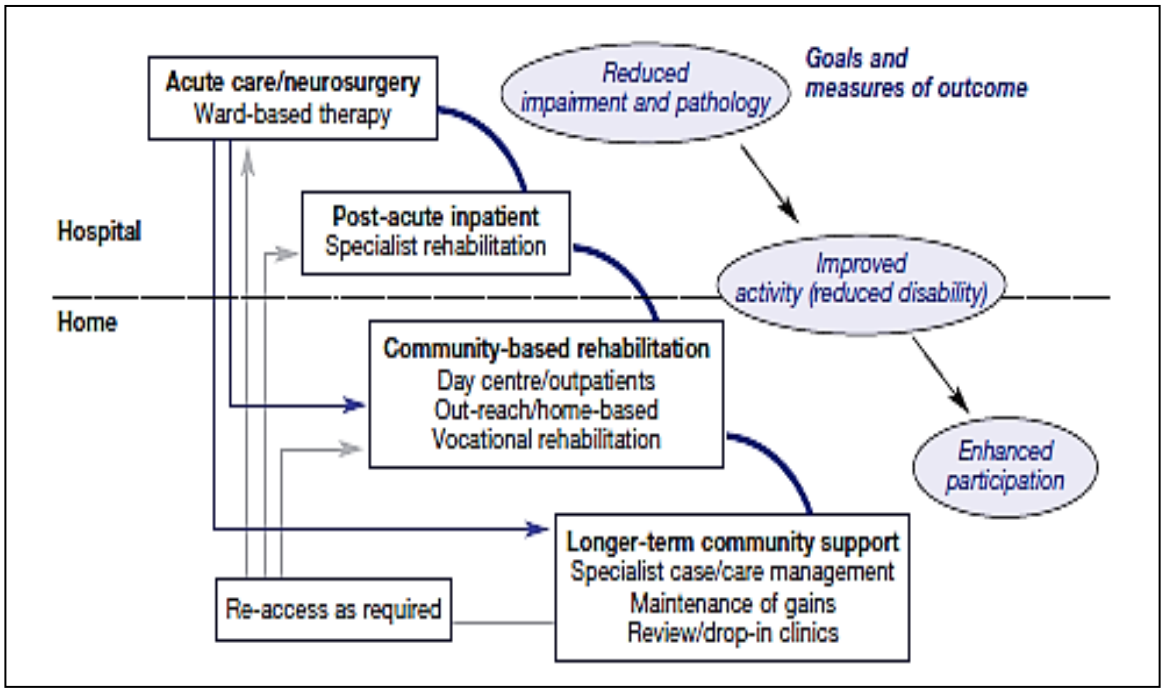

Fig. 1. The "slinky" model of the phases of rehabilitation (after Turner-Stokes, 2001).

1.3.2 Current clinical guidelines: neurological conditions

Other guidelines raise similar issues. The NICE guideline for PD (NCC-CC/NICE, 2006), for example, acknowledges depression as a particularly widespread difficulty amongst those with PD, and cites cross-sectional studies indicating depression affects around 40% of PD patients. However, the recommendations focus primarily on pharmacological treatment using antidepressant (and in some cases, antipsychotic) medication. A recent BPS Briefing Paper for PD (MacNiven and Gaskill, 2009) highlights the need for dedicated specialist clinical psychology and neuropsychology input and strongly recommends these as core services in PD management and rehabilitation. Furthermore, it states that quality of life issues are obvious in relation to reducing psychological distress and morbidity. It stresses that service provision needs to consider the chronic nature of PD and recognise the variability and diversity of individuals' difficulties over the course of the condition. Consequently, services should follow a model of holistic assessment and treatment, and take account of the patient's social context.

With regards to MS, current NICE guidelines (2003, although a recent scope consultation is expected to review and inform new guidance due in October 2014) provide a somewhat tentative and limited view of treatment options. Recommendation 152 (p.119) states that psychological intervention (CBT) should be considered but only as part of an overall programme of emotional management. It also highlights (Recommendation 155, p. 120) the need for psychologically-based treatment for MS sufferers presenting with '*marked*' anxiety. Recent patient information produced by the MS Society (2012) mentions multi-modal therapy (including visualisation techniques, meditation and guided imagery) as a potentially beneficial intervention in MS rehabilitation, however cautions that research is still scarce in this area and the evidence base is not sufficiently robust at present to inform relevant recommendations for its applicability.

Ostensibly, from a practical standpoint, there is a distinct emphasis in the clinical guidelines on physiotherapy, occupational therapy and cognitive assessments and interventions, as well as pharmacological treatments for psychological problems. However, whilst there is some recognition regarding the emotional aspects of injury and/or long-term conditions, these are often not highlighted as prominently, with the possibility of a potential impact on patients' well-being and long-term outcomes.

1.4 Recent developments in psychological approaches to neuro-rehabilitation

1.4.1 The emergence of holistic models of rehabilitation

However, over the last two decades or so, a growing trend for more holistic approaches to rehabilitation appears to have emerged (e.g., Wilson *et al*., 2000, 2002; Tyerman and King, 2003). Holistic approaches argue for the necessity to integrate, rather than separate, the cognitive, social, emotional and functional aspects of neurological injury and the promotion of awareness, acceptance and understanding in the process of rehabilitation. Amongst these approaches, mindfulness-based interventions (collectively known as MBIs) have sought to address this void in terms of therapeutic intervention. MBI approaches form part of the so-called "Third Wave" of behavioural therapies (including amongst others, Mindfulness-based Stress Reduction [MBSR], Mindfulness-based Cognitive Therapy [MBCT, Seagal, Teasdale and

Williams, 2002], Acceptance and Commitment Therapy [ACT, Hayes, 2004; Hayes *et al*., 2006] and Dialectical Behaviour Therapy [DBT, Linehan, 1993; Dimeff and Koener, 2007]).

These therapies are considered to sit within the broader cognitive-behavioural theoretical framework. Consequently, in the field of neurological rehabilitation, evidence of effectiveness comes from cognitive behaviour therapy (CBT) as a treatment modality that is useful not only in terms of symptom management, (e.g., fatigue), but also in reducing common psychological effects of chronic illness such as depression and anxiety, promoting coping strategies and adjustment, and globally improving quality of life and psychological well-being of these patients.

1.4.2 Self-efficacy and the "Third Wave" of behavioural therapies

Alongside this trend towards more holistic models, an increasing interest has also arisen for making sense of an individual's injury or condition and the perceived changes to one's identity as psychological dimensions, as considered in cognitive behaviour therapy (CBT hereafter) interventions. One of the psychological mechanisms through which CBT interventions have demonstrated their effectiveness is in relation to *self-efficacy*. Self-efficacy can be conceptualised as the individual's appraisal of the extent to which he/she has the capabilities required to organize and realize actions needed to obtain planned goals in a specific domain (Bandura, 1997). Its promotion has been demonstrated to be useful for the management of chronic diseases, such as MS, and appears positively linked to psychological adjustment and to improvements in quality of life (Thomas *et al*., 2006; Mohr *et al*., 2012; Graziano *et al*., 2013).

The key differentiating principle between the second and third generation or "wave" of behavioural interventions is that the earlier wave of traditional cognitive and/or cognitive-behavioural therapy (CBT) approaches focussed directly on the objective of *altering* psychological events (e.g., thoughts, beliefs, perceptions, schemas) through a variety of techniques (such as cognitive restructuring), whereas by contrast, the third wave aims to change the *function* of these events and the individual's relationship to psychological and contextual experiences rather than the events or experiences themselves or the content therein. A secondary objective is not necessarily to eradicate symptoms entirely, rather to embrace and accept negative or aversive experiences with a view to managing symptoms in a manner which facilitates and ultimately promotes self-efficacy and well-being.

It is within this context that the work of Barbara Wilson and colleagues at the Oliver Zangwill Centre has sought to adopt a model of rehabilitation incorporating holistic principles, developing a programme including both individual and group therapeutic intervention alongside others. One of the more recent additions to the programme has been the inclusion of Compassion-Focused Therapy (CFT hereafter: Gilbert, 2010) approaches which incorporate elements of mindfulness-based work in addressing commonly reported issues and challenges around self-criticism, rumination and post-injury adjustment within this population (Wilson *et al*., 2013).

In summary, if the premise of MBIs is on facilitating functional change, it could therefore be inferred that they may have a particular utility for supporting individuals with ABI and with long-term neurological conditions in adjusting to life post-injury and post-diagnosis, as well as re-engaging in living more meaningfully, in spite of their neurocognitive and physical impairment and the accompanying sense of uncertainty about their future. The management of psychological problems would therefore appear to be pivotal for individuals living with ABI and neurological conditions given how their chronic nature can not only hamper quality of life, but also bring about broader social, economic, interpersonal and psychological consequences due to reduced social, community and occupational functioning (Cicerone *et al*., 2008; Kangas and McDonald, 2011).

1.5 History and development of mindfulness meditation practice: adaptations and applications to healthcare settings

Whilst it is beyond the scope of the present study to describe in any great detail the history and development of mindfulness or meditation approaches and their clinical applications, it is nevertheless worth noting the influential impact of the work of Jon Kabat-Zinn in the secularization and adaptation of what essentially are considered Buddhist or Eastern philosophical traditions, as well as mindfulness' place within the therapeutic framework (i.e., as part of the aforementioned "Third Wave" of cognitive-behavioural paradigms). The emergence and development of MBIs in medical settings as an adjunct or alternative to conventional treatments for chronic health conditions was in large part conceived, developed and promoted by Kabat-Zinn at the University of Massachusetts Medical School.

1.5.1 Mindfulness-based Stress Reduction (MBSR)

Thus the Mindfulness-based Stress Reduction (MBSR) approach is based primarily on the work of Kabat-Zinn (1982, 1992). A student of *zen* and *vipassana* meditation as well as yoga, Kabat-Zinn recognised how due to its specific focus on attentional practices, meditation potentially lent itself well to adaptation within a medical setting and in particular with clinical populations struggling with long-term conditions. In a similar vein to traditional meditation practice, MBSR emphasises the cultivation and development of non-judgmental present-moment awareness and acceptance of perceptible sensory, emotional, psychological and cognitive events and processes. Simply put, MBSR encourages the principle of "being here now" and refraining from self-critical appraisals of one's experience, accepting this experience "as it is" rather than "as it should be". As such, it is a non-goal oriented intervention with a distinct focus on process rather than outcome. Typically an 8-session, 16-hour group-based intervention (numbers tend to be relatively small) initially designed for patients with chronic pain, MBSR has now been widely implemented in a variety of medical and psychiatric settings and across a range of populations.

1.6 Mindfulness-based interventions: conceptual and theoretical overview

1.6.1 The concept of "mindfulness" : definitions and operationalization

The practice of mindfulness is a method of attention regulation which originated in Eastern (predominantly Buddhist) contemplative and meditation traditions (Cullen, 2011). The term itself is an English translation of the Pali (the Buddhist language of psychology) word *sati*. *Sati* connotes three central concepts of awareness, attention and remembering (Germer, 2013). Mindfulness has been described as:

"*paying attention in a particular way: on purpose, in the present moment, and non-judgmentally*." (Kabat-Zinn, 1994, p. 4)

The majority of the psychological and neuroscience literature concerning mindfulness adopts the definition as proposed by Kabat-Zinn, albeit with some variation of emphasis. Kabat-Zinn was instrumental in translating more traditional, Buddhist approaches of

meditation practices into the secular context of Western general healthcare and psychological interventions (Kabat-Zinn *et al*., 1985, 1992; Kabat-Zinn, 2011). Thus, within this psychological context, mindfulness is conceptualised as non-judgmental awareness of the present moment, and is broadly thought to involve a particular attitude or stance in attentional focus.

Whilst differences of opinion do exist amongst clinicians and researchers between the more traditional, Buddhist perspectives of mindfulness and its "modern" psychological adaptations, there appears to be widespread agreement that a clearly formulated method of mental training – commonly referred to as *meditation* – is necessary for the development and enhancement of levels of mindfulness (Chiesa and Malinowski, 2011). It is therefore generally assumed that meditation practice facilitates increased levels of mindfulness. However, debate persists within the mindfulness community regarding its conceptualisation, and some subtle yet key differences remain between the principal models of mindfulness as regards a unitary definition of the construct and the purported mechanisms by which it operates. In recent years, four main models (amongst others) appear to have emerged, each of which merit further description in the light of the population under investigation and the specific psychological issues with which they present.

1.7 Models of mindfulness

1.7.1 Bishop et al. (2004): the 2-component model

Bishop *et al*. (2004) have proposed a 2-component stepwise model of mindfulness, comprising a component of initial self-regulation of attention elicited through an awareness to current and immediate experience (observing and attending to the changing field of thoughts, feelings and sensations from moment to moment). The second component, which Bishop and colleagues postulate occurs as a consequence of this attentional practice, is the adoption of a particular orientation towards one's experience in the present moment. This orientation consists of a stance characterised by curiosity, openness and acceptance. In short, this model of mindfulness can be defined as a process of regulating attention in order to engender a quality of non-elaborative and non-judgmental awareness to current

experience. What follows from this initial practice is a process of insight into the nature of one's mind and the adoption of a *de-centred* perspective.

1.7.2 Shapiro et al. (2006): the IAA model

Similarly, Shapiro *et al*. (2006) also addressed the question of how MBIs actually operate rather than the effectiveness of these interventions, and proposed three essential components (or *axioms*) of mindfulness within the framework of a model also known as the IAA Model. The three main components are: (i) Intention; (ii) Attention and (iii) Attitude. Shapiro and colleagues relate these three axioms to Kabat-Zinn's definition where (i) equates to "on purpose", (ii) equates to "paying attention" and (iii) to "in a particular way". They emphasise that these are not separate processes or stages *per se*, rather they are interwoven within a single cyclical or recursive process, and may occur simultaneously (fig. 2):

(i) Intention

The role of intention, as the IAA Model postulates, is linked to the origins of meditative practice as conceptualised within Buddhist traditions, for which intention equates to an extent with what is defined as *enlightenment* and *compassion*. An earlier study (Shapiro, 1992) found that as meditators continued to practice, their intentions shifted along a continuum from self-regulation to self-exploration, eventually leading to self-liberation (i.e., the experience of transcending the sense of being a separate self, a central tenet in the Buddhist meditative tradition). Intention can also be conceptualised as the *reason* or *motivation* for practising, and as such is considered a core component of mindfulness within the IAA Model, since this is crucial to an understanding of the process as a whole;

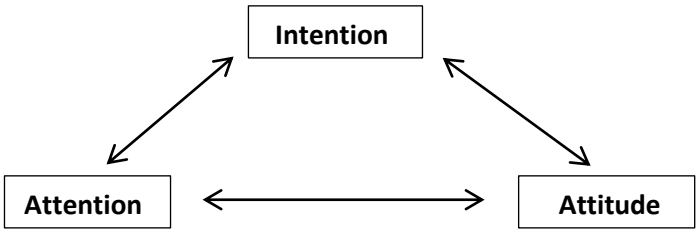

Fig. 2. The IAA Model of Mindfulness (Shapiro *et al*., 2006).

(ii) Attention

Within the psychology literature, attention has been posited as crucial to the healing process. This is not a recent theoretical consideration. Gestalt therapy emphasises present-moment awareness: Perls stated that "*attention in and of itself is curative*" (Perls, 1969, p.16). Attention is also an important element within CBT theory, which emphasises the capacity to observe, and therefore attend to, internal and external behaviours;

(iii) Attitude

The IAA Model, similarly to Kabat-Zinn (1990), defines attitude as the qualities an individual brings to attention, and has been conceptualised as the attitudinal foundations of mindfulness. The model posits that individuals can learn to attend to their own internal and external experiences, without evaluation or interpretation. This in turn will foster a practice of acceptance, kindness and openness even when what is occurring in one's field of experience is contrary to deeply held wishes or expectations. Mindfulness training thus allows one to be open to each experience as it arises, but to also allow it to pass away. Bringing an intentional attitude of patience, compassion and non-striving is thought to facilitate an ability to refrain from continually striving for pleasant experiences, or indeed to push aversive ones away. This component appears largely in line with Bishop and colleagues' concept of "orientation to experience".

1.7.3 The Buddhist Psychological Model (BPM; Grabovac et al., 2011)

In a bid to offer a model of mindfulness which sufficiently explains, describes and encapsulates the mechanisms and processes of change operating within the individual, Grabovac *et al*. (2011) have proposed a psychological model derived from more purist Buddhist traditions (the Buddhist Psychological Model, or BPM, fig. 3). In general terms, the BPM describes three main characteristics of mental activity which mindfulness practice targets and which appear crucial in the development of well-being and symptom alleviation or reduction:

(i) *Impermanence*: sensory and mental events are transient in nature and occur in a continuous stream of consciousness;

(ii) *Suffering:* this arises as a result of habitual reactions to the affective responses of these events;

(iii) *Not-self*: sensory and mental events do not constitute or contain any discrete, durable, static entity which one could define as a *self.*

As such, mindfulness as proposed by the BPM is defined as the moment-by-moment observation of, and subsequent insight (via attention regulation practices) into these three characteristics.

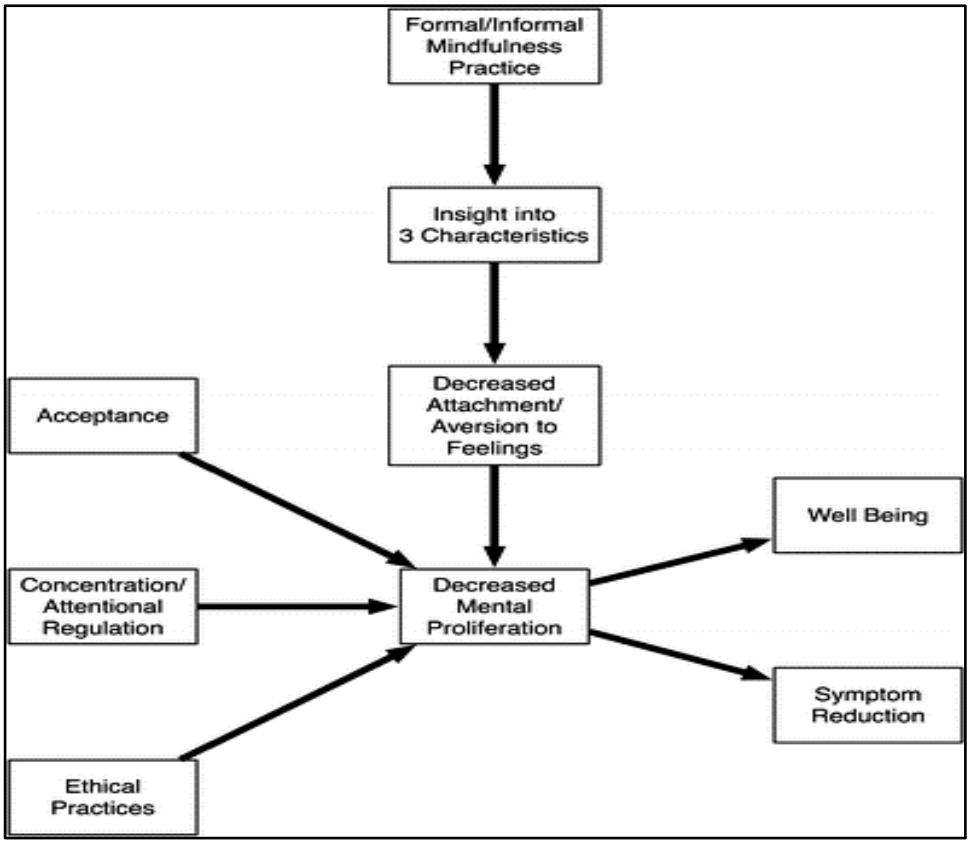

Fig. 3.The Buddhist Psychological Model of Mindfulness (Grabovac *et al*., 2011).

1.7.4 The Liverpool Mindfulness Model (Malinowski, 2012)

The Liverpool Mindfulness Model (LMM hereafter; Malinowski, 2012; fig. 4) is a more recent attempt to conceptualise and define the core components of mindfulness and to provide a framework for directing future research. As such, it is broadly consistent with the other interactional models of mindfulness in that it emphasises the central role of attentional skills, and structures the process of mindfulness into five main levels, namely:

Motivational factors (*level 1*) which determine whether or how an individual engages in the *mind training (level 2)*. It is postulated that this regular engagement in mindfulness practice

further facilitates and refines *mental core processes (level 3)* via the interaction of attentional skills and cognitive and emotional regulation. Improvements in these core processes result in an altered and more balanced *mental stance* or attitude (*level 4*), characterised by non-judgmental awareness, which in turn results in *positive outcomes* (*level 5*) across physical, mental and behavioural domains.

Similarly to other phenomenological accounts of mindfulness (Shapiro *et al*., 2006, Lutz *et al*., 2008), the LMM suggests that attentional control skills underpin the development of emotional regulation skills. The training of these attentional skills is also thought to underpin cognitive and emotional flexibility, facilitating the capacity to maintain a non-judging awareness of one's own thoughts, feelings and experiences generally. Consequently, this facilitates the quality of one's behaviour and leads to positive outcomes in terms of health and well-being (Chiesa and Malinowski, 2011; Malinowski, 2013).

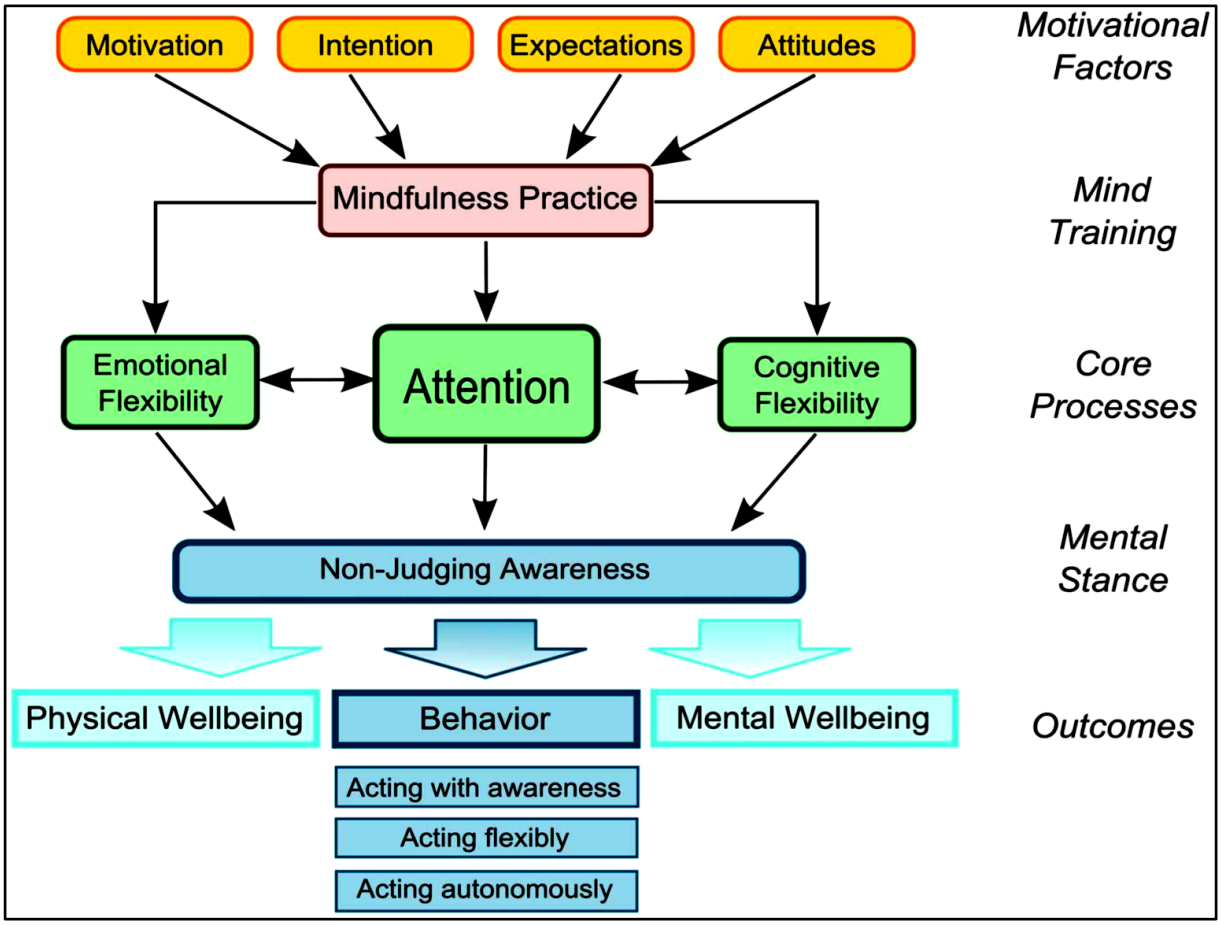

Fig. 4. The Liverpool Mindfulness Model (*after* Malinowksi, 2012).

Two specific attentional practices – Focused Attention (FA) and Open Monitoring (OM) – postulated by Lutz *et al*. (2008), whilst conceptually considered distinct from one another, are present in all forms of mindfulness training to varying degrees. The FA component is cultivated and developed initially to facilitate awareness of present-moment mental states, whereas the OM component consists of moment-to-moment attentional focus to anything occurring in the person's experience. With increasing experience , it is thought that OM practice relies progressively less on FA over time and can eventually be sustained without focussing on any explicit object (e.g., one's breathing).

In summary, these fundamental principles are captured by common psychological definitions of mindfulness which emphasise the fostering and development of attentional abilities combined with a specific, non-evaluative, non-critical attitude toward the different mental (or physical) experiences which may arise at any given moment.

1.8 Mechanisms of mindfulness: how mindfulness operates beneficially in psychological terms

Whilst the main accounts elucidated above appear largely consistent with one another with respect to identifying the core psychological facets of mindfulness, and the collective body of mindfulness literature has grown exponentially in recent years, there remains a relative paucity of theoretical reviews which integrate the existing mindfulness research into a comprehensive theoretical and conceptual framework with a view to identifying the mechanisms and processes of mindfulness. In a recent article, Hölzel *et al*. (2011) describe the processes through which mindfulness operates beneficially on the individual by referring to five essential stages:

1. *Attention regulation*: defined as sustaining attention on a chosen stimulus or object (usually external) and when noticing that the mind has become distracted, returning the attention to the object;
2. *Body awareness*: during this process, the focus is usually an object of internal experience (e.g., breathing, emotions, or other physiological sensations) and is linked to the process of focussing one's attention to the present moment;

3. *Emotional regulation – reappraisal*: approaching and re-construing ongoing emotional reactions differently and in a more positive, meaningful or benign light;
4. *Emotional regulation – exposure, extinction and reconsolidation*: this describes the process by which mindfulness practitioners expose themselves to whatever is present in their field of awareness (both internal and external events), allowing themselves to be affected by the experience, but refraining from engaging in internal reactivity towards it. The aim is to embrace and accept rather than avert distressing or unpleasant emotions with a view to gaining insight into the transient nature of such emotions or events which eventually pass away and are replaced by a sense of well-being or security;
5. *Change in perspective on the self*: in line with traditional Buddhist philosophical notions, the self is perceived as a product of an ongoing mental or psychological process rather than a permanent, static entity. The Buddhist view posits that identification with this static sense of self is the origin of psychological distress (Olendzki, 2010). Mindfulness practice is thought to foster the development of meta-awareness[1] which facilitates a detachment from one's identification with this static sense of self, thereby leading to a "deconstruction of the self" and eventual "self-liberation" (as reported by Shapiro, 1992). This also appears to be consistent with other theoretical notions of "de-centering" as proposed by Bishop *et al*. (2004).

1.8.1 Mindfulness and mental modes of processing

In a similar vein, Williams (2010) has drawn on evolutionary theory to postulate that emotions can be understood as automatic, transient processes and reactions which are sensitive to environmental contingencies. As such, emotions can be "*switched on*" or "*switched off*" in response to these contingencies. Williams has proposed that the failure to adequately "switch off" emotions is a result of the activation of mental representations of past, present and future created independently of these contingencies. According to Williams, these representations or "*simulations*" occur within the sphere of two distinct mental modes in which the mind operates and in which information is processed: a "doing" mode (verbal, conceptual) and a "being" mode (sensory, perceptual; Williams, 2008). It is posited that psychopathology arises from an excessive use of the "doing" mode in suppressing, avoiding or elaborating emotional expression.

[1] This can be defined as "awareness of awareness" itself.

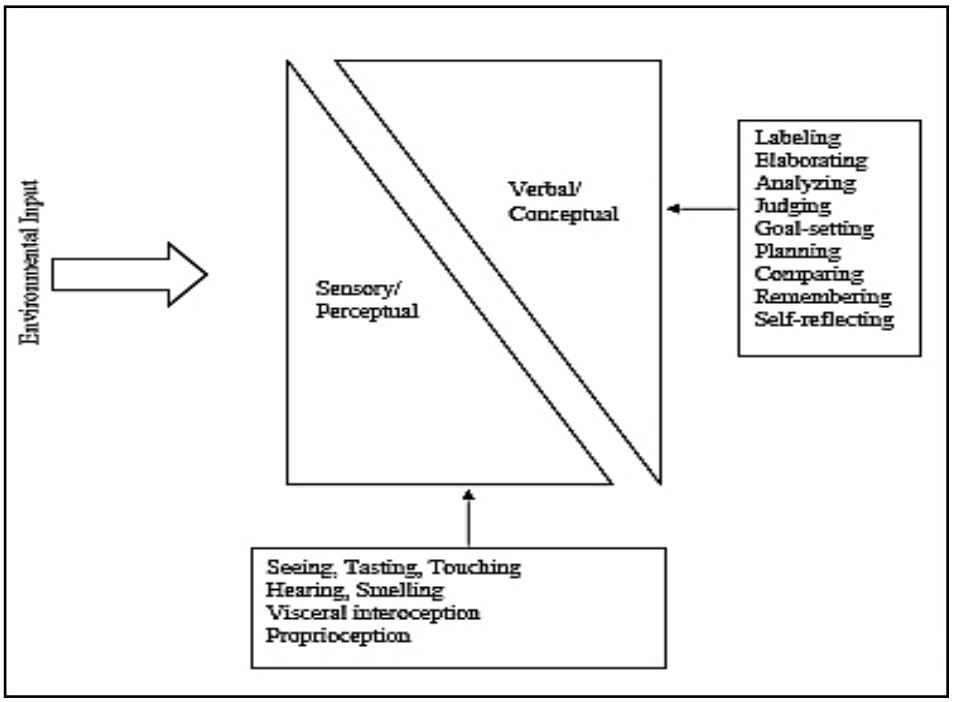

Fig. 5. The two modes of mind (*after* Williams, 2010).

Fig. 5 is intended as a schematic representation of the relative probability of the two *modes* in which the mind operates, as proposed by Williams: the conceptual (language-based) processing mode versus sensory-perceptual processing mode. In every waking moment one receives stimuli from internal and external sources such as sights, sounds, touch, smell and taste. However, these are generally filtered out or processed in favour of devoting one's attention in conceptual mode, i.e. thinking, planning, daydreaming, analysing, remembering, comparing, judging etc. Attentional training within mindfulness cultivates the ability to shift modes (from "doing" to "being") as an essential first step to being able to hold all experience (both conceptual and sensory) within a wider awareness which itself is neither merely sensory nor conceptual. This practice enables the individual to focus attention to both the objects themselves but also to their *reactions* to them and their associated implications.

1.8.2 The processes by which mindfulness works: examples

Within mindfulness training, one of the specific meditation practices, the Body Scan, is an example of how this attentional focus is thought to facilitate the mode of "being" and consequently enable the individual to relate differently to mental states (fig. 6). The attentional processes within the Body Scan consist of an attention engagement-disengagement cycle, which is repeated around 50 times. Each cycle entails 4 intentional

components: (1) shifting attention from one region of the body to another; (2) engaging attention at this site; (3) remaining in this place to discover and explore sensations experienced here; (4) disengaging attention before repeating (1) – shifting to the next part of the body. During this practice, two additional meta-intentions must be held in working memory: (1) to notice the mind wandering and return attention to the intended focus; and (2) to explore sensations – whilst acknowledging the mind wandering – adopting an attitude of friendly enquiry, curiosity and compassion rather than analysis, comparison or judgment.

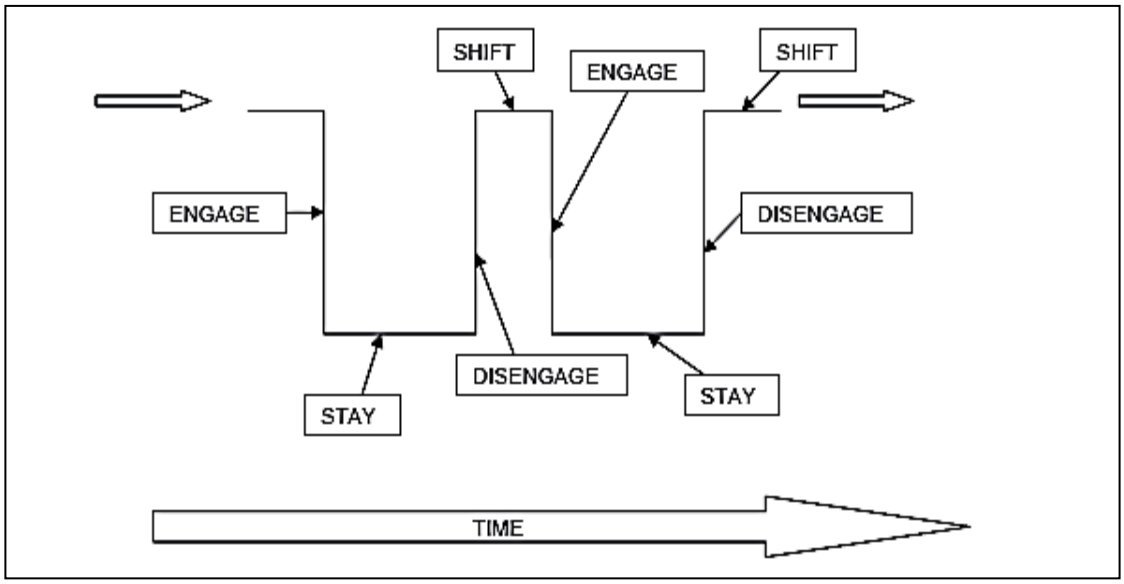

Fig. 6. Attentional processes during the *Body Scan* practice (*after* Williams, 2010).

In line with Williams' proposed account of the psychological processes involved in mindfulness, one of the central premises of the BPM (Grabovac *et al*., 2011) is that awareness occurs in relation to sensory impressions (i.e., physical sensations) or mental events (e.g., a memory, thought or emotion). This awareness is transient in nature: it lasts momentarily before passing away, with discrete sense impressions and mental events arising and ceasing in a rapid, continuous stream or flow (fig. 7). However, the BPM suggests that an individual's attentional resources are limited therefore one can only be aware of one object at a time.

According to the BPM, concomitant to the awareness of an object, an individual experiences any one of three categories of "feeling tone". This is not strictly equivalent to an emotion, rather a spontaneous affective response to the awareness of a sense impression or mental event. These responses are habitual and typically involve a desire to pursue pleasant

feelings whilst avoiding unpleasant ones (in Buddhist terminology, these are denoted as *attachment* and *aversion*, respectively). Contrary to widely-held assumptions regarding these processes as reactions to an *object* of awareness, the BPM proposes that attachment and aversion occur *in response to the feeling state itself* as opposed to the object.

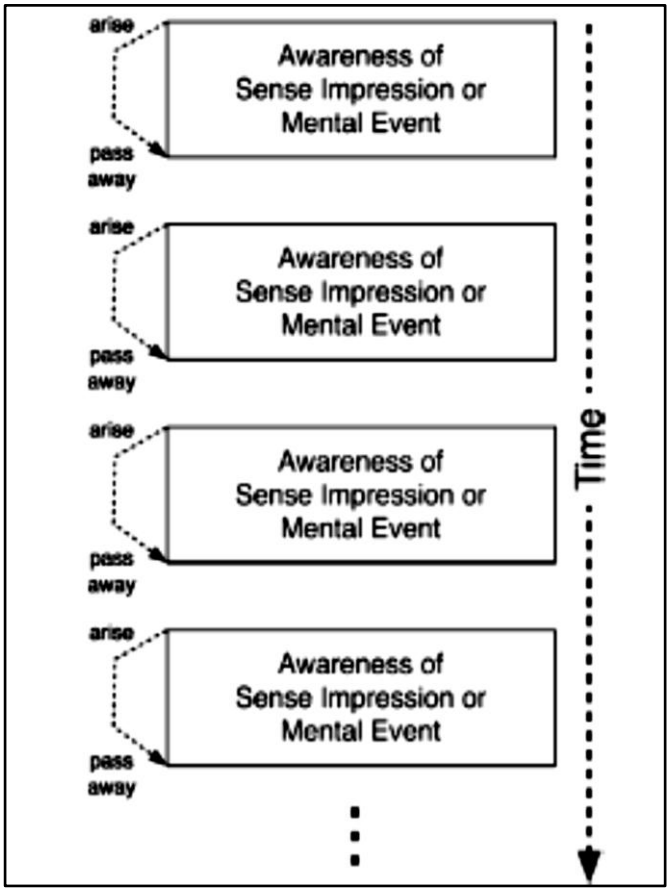

Fig. 7. The process of moment-by-moment awareness (*after* Grabovac *et al*., 2011).

These initial feeling tones or states are also succeeded by mental events with their own concomitant feelings. This in turn brings about a process of *mental proliferation* during which attachment or aversion occurs in reaction to the feelings associated with these mental events, and is experienced in the form of additional mental events. The implication of this process is that at times the proliferation may occur in a recursive fashion, with subsequent mental events apparently being quite far removed from the initial sense impression. As a result, one becomes unaware of the patterns of attachment and aversion and how they bring about mental proliferation, thereby ensuring the maintenance of the entire, habitual process. Thus for an MS sufferer, an initial sense of hopelessness about their prognosis might in turn lead to seemingly unconnected thoughts ranging from anger to denial.

1.8.3 The BPM perspective

As mentioned earlier, the BPM posits that all sensory impressions and mental events are considered to share three common characteristics: *impermanence*, *suffering* (which includes psychopathology or symptomatology) and *not-self*. These are essentially Buddhist terms of reference. It is the habitual reactions (in the form of attachment or aversion) to feeling states and associated mental proliferation that are the source of suffering (fig. 8). The BPM thus proposes that mindfulness practice (in the form of attention regulation resulting in sustained attention on an object) brings about an interruption and reduction in mental proliferation.

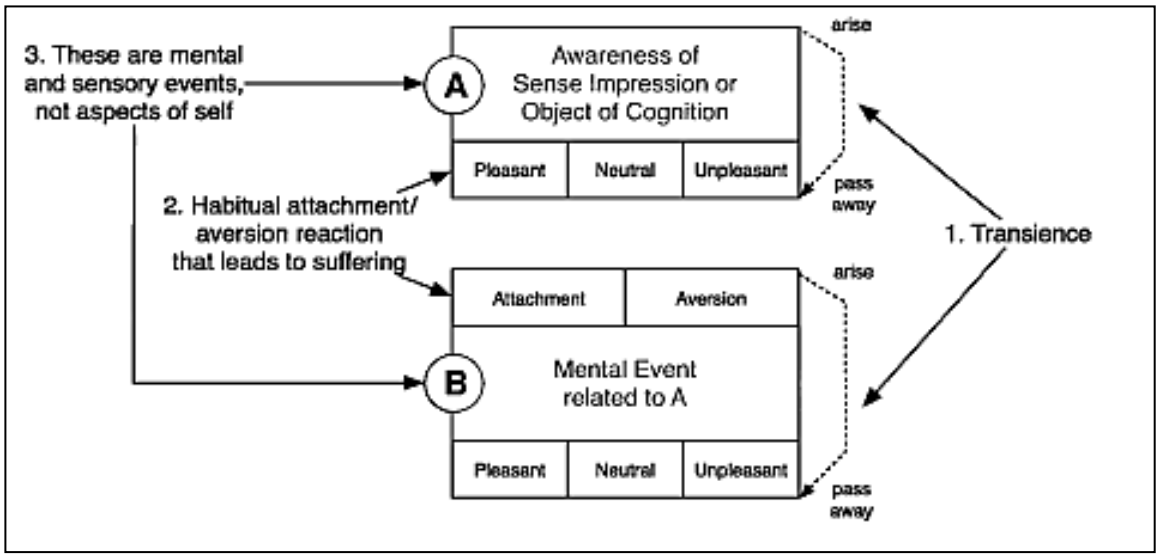

Fig.8. The 3 characteristics of sensory impressions/cognitions and associated mental events (*after* Grabovac *et al*., 2011).

Alongside this, when an individual permits the emergence and subsequent dissipation of sensory and mental events, without engaging in cognitive processing and elaboration (as a result of attachment or aversion), this engenders an increased sense of well-being. These events will continue to be experienced as pleasant, unpleasant or neutral. However, since mental proliferation will have been momentarily attenuated or interrupted, it is hypothesised that suffering does not occur.

This process is facilitated by encouraging an individual to develop an awareness of thoughts, feelings and bodily sensations as they arise, but gently allowing them to "step back" from these experiences without judging them or attempting to eradicate them (fig. 9). This can be done through a variety of practices, but most commonly involves focussing one's attention on one's breath. Over time, this practice fosters the capacity to be able to identify maladaptive patterns of processing sooner, thus reducing the propensity for emotional dysregulation or mental proliferation (this has often been described as "thoughts spiralling out of control", for example).

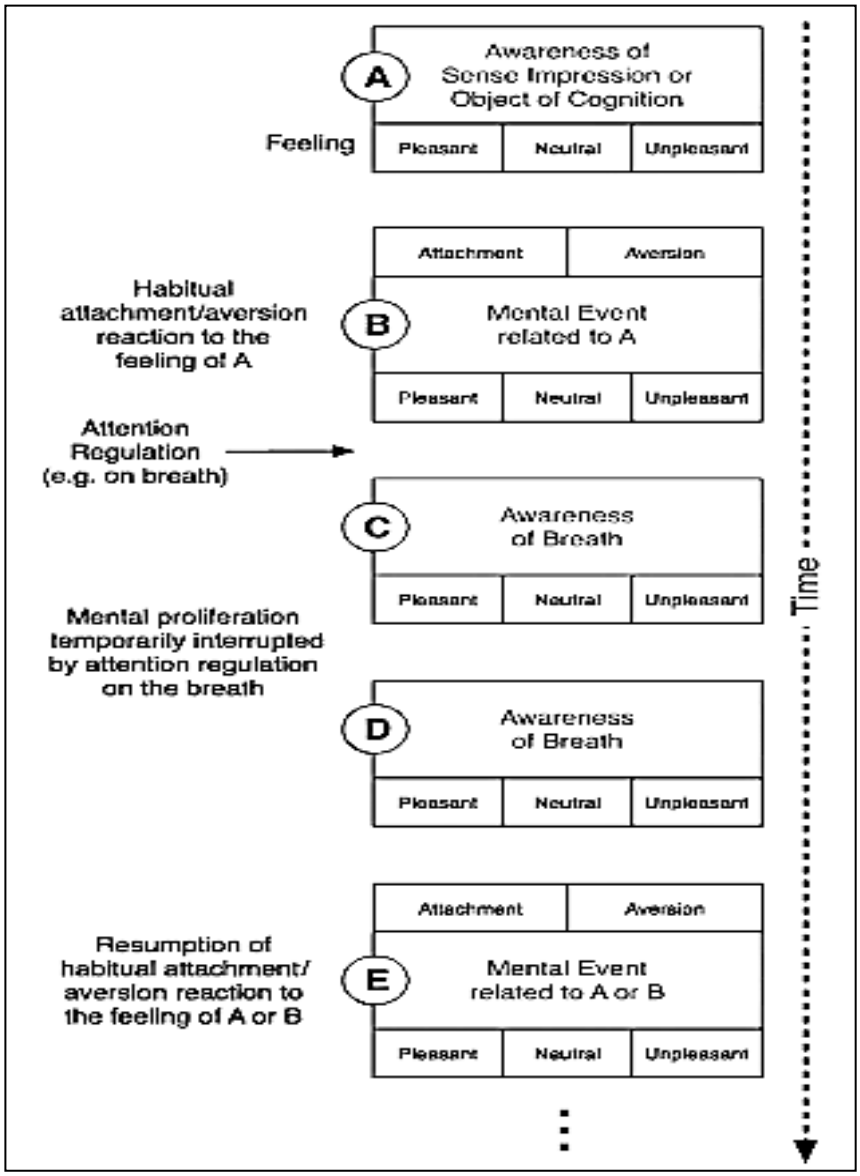

Fig. 9.The mechanisms by which regulation affects moment-by-moment awareness in mindfulness practice *(after* Grabovac *et al*., 2011*).*

1.8.4 Proposed alternative mechanisms for the operationalization of MBIs in psychological well-being

The aforementioned models of mindfulness are not the only explanations which have been proposed in terms of putative mechanisms or processes for its operationalization. Alternative proposed mechanisms for MBIs include: a perceptual re-distancing leading to increased tolerance and acceptance of somatic pain and/or maladaptive thinking or emotional processes; greater exposure to thoughts and feelings leading to reduced responses to fear or anxiety; greater self-awareness and self-motivation and efficacy leading to improvements in psychosocial coping strategies; reduced autonomic arousal leading to increased levels of relaxation; and on a biological level, modification of immune and neuroendocrine system pathways (Baer, 2003; Ludwig and Kabat-Zinn, 2008, Compare *et al*., 2012).

Similarly to Shapiro *et al*. (2006), Carmody *et al*. (2009) make reference to the concept of *reperceiving* which they define as involving a fundamental shift in perceptual perspective that enables a mindfulness practitioner to adopt a stance of observation in relation to moment-to-moment experience. This also facilitates recognition of the fleeting nature of thoughts, emotions and physical sensations. The authors describe this in similar terms to the Western psychological constructs of *decentering* and *defusion* (a term commonly used in ACT literature).

1.9 A review of the research literature concerning MBIs

1.9.1 The context of mindfulness research and its clinical applications with ABI

During 2012 and 2013, over 500 scientific articles on mindfulness were published, more than the total number of articles published between 1980 and 2000 (Shonin *et al*., 2013a, also see fig. 10 for a graphical representation of this increase in mindfulness research studies). There has been a veritable explosion in terms of mindfulness research undertaken which appears to have accompanied this surge of interest in the field and its perceived clinical applications and utility. Recent research findings have begun to suggest that Mindfulness-based Interventions (MBIs hereafter) may offer effective treatments for an increasingly broad range of psychological and somatic disorders and illnesses (Chiesa and Serretti, 2011;

Fjorback *et al*., 2011). Clinicians' views of MBIs also seem largely favourable to its purported benefits: a recent survey (Mental Health Foundation, 2010) found that 75% of GPs in the UK considered mindfulness to be beneficial for patients with mental health difficulties. Qualitative research would also appear to support the acceptability of MBIs amongst patients and service users (Williams *et al*., 2011, Shonin *et al*., 2013a).

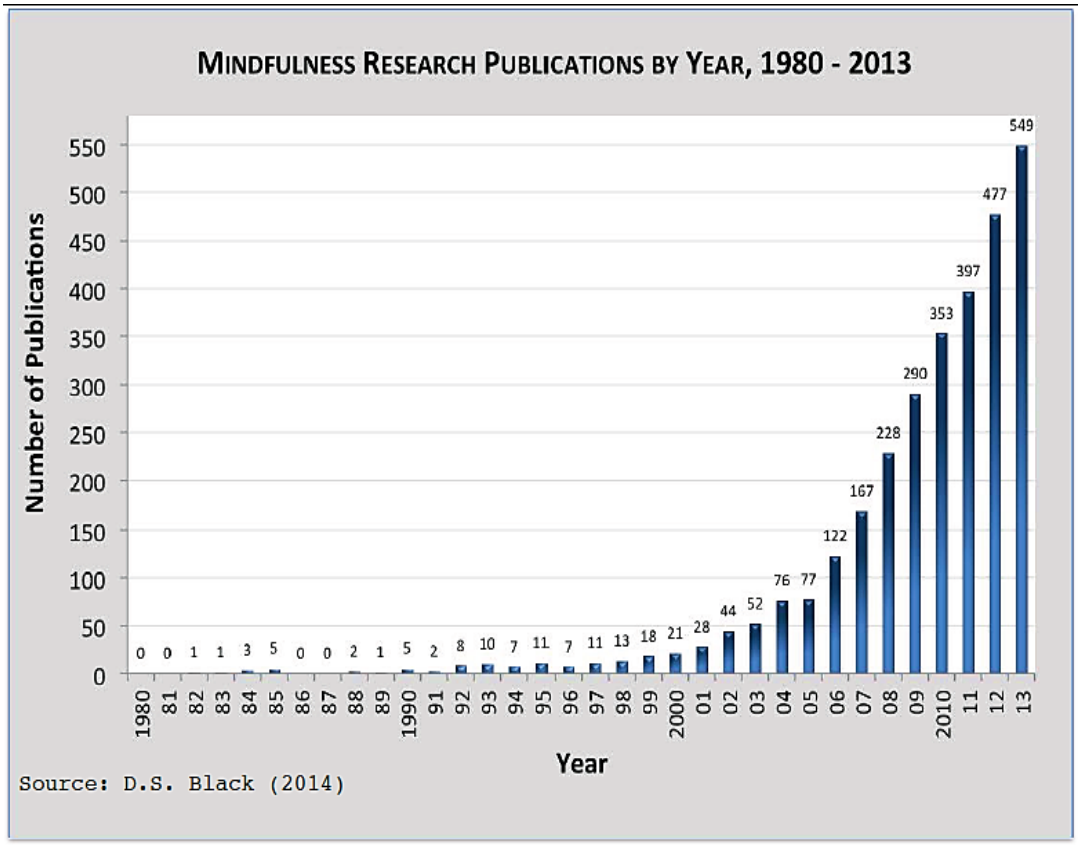

Fig. 10. Results obtained from a search of the term 'mindfulness' in the abstract and keywords of the ISI Web of Knowledge database. The search was limited to publications with English language abstracts. *Figure prepared by David S. Black, Institute for Prevention Research, Keck School of Medicine, University of Southern California* (2014).

However, whilst there appears to be a growing evidence base for the utility of MBIs across diverse clinical settings, a relative lack of research in certain areas, and in particular, the area of Acquired Brain Injury (ABI hereafter) and chronic neurological conditions, remains. The reasons for this dearth may be manifold, not least since historically ABI and neurological conditions present specific challenges to services as regards variable prognoses and recovery

trajectories, short-term and long-term rehabilitation needs, with traditional approaches involving physical or pharmacological treatments generally being preferred over potentially less cost-effective interventions. However, given the difficulties these populations commonly report with emotional and psychological adjustment, psychosocial issues and quality of life, the principles and practices underpinning MBIs would appear to lend themselves well as a viable therapeutic intervention supporting positive long-term outcomes.

1.10 Recent neuroscientific and neuropsychological evidence for mindfulness

From a neuroscience perspective, there is increasing evidence in support of the capacity for experientially dependent neuroplasticity in both the developing and injured brain (see Green and Turner, 2010, for a recent research digest). Whilst still limited in scope, more recent research considering the beneficial effects of MBIs on the *healthy* adult brain has yielded some interesting findings, with potentially important clinical implications within the field of neuro-rehabilitation. Neuroimaging studies employing functional magnetic resonance imaging (fMRI) and structural methods have begun to provide strong confirmatory evidence for MBIs engendering neuroplastic changes, as well as further elucidating the neural correlates of specific mental and behavioural gains as a result of meditation practice.

In what is considered a seminal study, Lazar *et al*. (2005) detected increases in cortical thickness within the anterior *insula* in experienced meditators. These findings were replicated subsequently by Hölzel *et al*. (2008), who further noted dose-dependent increases in grey matter density in the right anterior *insula*, left inferior temporal *gyrus* and right hippocampal regions. In a study by Farb *et al*. (2010) which evaluated an MBSR programme, participants demonstrated a significant difference in neural activity during experimentally induced sadness (exposure to a film) pre- and post-intervention, despite reporting the same degree of sadness prior to and following exposure to the stimulus.

The literature would therefore suggest that the activity of mindfulness may be (i) located in specific brain regions; and (ii) that regular practice results in the development of neural circuits in these regions. Thus, in line with the hypothesis proposed by Williams (2010), mindfulness facilitates shifts in regulation strategies from brain regions supporting cognitive-affective representations or “simulations” of the self towards those involved in viscero-

somatic information processing – in short, a shift from "doing" to "being" mode. Other studies evaluating the effects of MBIs have also reported specific patterns of neural activation in brain regions typically associated with sustained attention (Brefczynski-Lewis *et al*., 2007), interoceptive awareness (Critchley, 2004) and focus on endogenous body states (such as attention and monitoring of breathing; Vestergaard-Poulsen *et al*., 2009).

Encouraging recent evidence in terms of MBIs bringing about structural changes with neurological populations has also been provided by Pickut *et al*. (2013). In this longitudinal randomized controlled trial (RCT hereafter) using voxel based morphometry (VBM), significant changes in grey matter density involving the hippocampus and right amygdala were observed in a sample of 14 PD patients compared to a group receiving usual care (UC) alone. This suggests changes in neural networks and brain regions which have been posited to play an important role in PD and which appear to be implicated in the functional networks mediating the benefits of MBIs.

1.11 A literature review regarding the effectiveness of MBIs and ABI/neurological patient populations – evidence and future developments

It is generally accepted that there has also been an exponentially increasing evidence base for the success of MBIs across a range of medical, psychiatric and psychological disorders and conditions (Baer, 2003; 2006). MBIs appear to be particularly effective in reducing anxiety and depression symptomatology (Carmody and Baer, 2008; Hofmann *et al*., 2010). In addition, the literature supports the view that MBIs may be effective for panic disorders, binge eating disorders, and substance abuse; and they have even been deemed promising practices by the US Defense Centers of Excellence (Moore *et al*., 2011). More recent evidence supports their effectiveness with a number of chronic health conditions (e.g., chronic pain, anxiety, cancer – e.g., Speca *et al*., 2000). Grossman *et al*.'s (2004) meta-analysis examined the impact of MBSR on a range of health samples and found moderate to large (d = 0.40 – 0.90) effect sizes. However, very little research has been conducted with regard to its effectiveness with ABI or neurological patient populations. The few studies that have examined this question have tended to be pilot studies with small sample sizes, thereby rendering results difficult to generalize. Nevertheless, there are some notable findings from these studies which merit some consideration.

1.11.1 MBIs and Multiple Sclerosis

In a randomized controlled trial of MS patients, Grossman *et al*. (2010) provided evidence of MBIs improving quality of life and associated measures of psychological well-being for at least 8 months post-intervention. Interestingly, baseline neuropsychological status was not related to outcome. Simpson *et al*. (2014) have recently published a systematic review of MBIs with MS clinical populations, however only cite 3 studies included in the final analysis: Mills and Allen (2000); Grossman *et al*. (2010); and Tavee *et al*. (2011). The review reports encouraging results as regards improvements in measures related to HRQOL, anxiety, depression and fatigue (with effect sizes ranging from d = 0.39 to 0.86), however the authors note that the very small number of studies analysed, their variable methodological quality and the heterogeneity of the MBIs delivered in each study are not especially conducive in drawing firm conclusions regarding the clinical utility or benefit of MBIs for MS. Recently published research by Senders *et al*. (2014), which evaluated the relationship between trait mindfulness and perceived stress, coping (self-efficacy) and resilience in 119 MS patients found that greater trait mindfulness was significantly associated with decreased psychological stress, better coping skills, increased resilience, and higher quality of life. After controlling for confounders, results indicated that mindfulness accounted for 25% of the variation in perceived stress scores and 44%of the variation in resilience scores. These results would appear to further support mindfulness training to enhance psychological resilience and improve well-being for those living with MS.

1.11.2 MBIs and Parkinson's disease

As regards PD, in a qualitative study by Fitzpatrick *et al*. (2010) examining an 8-week MBCT course, results revealed PD patients perceived benefits associated with changes in coping styles and consolidation of coping skills as a result of group MBI. A recently published study protocol by Advocat et al. (2013) for a 6-week MBI lifestyle programme aimed at adults with PD aims to employ a mixed-methods, randomised 2-group control design together with qualitative in-depth interviews with participants. The authors highlight that research in this area is still in its infancy.

1.11.3 MBIs and ABI

Johansson *et al*. (2012) have provided further evidence that MBSR may be a promising non-pharmacological intervention for mental fatigue post-TBI or stroke. Azulay *et al*. (2013) found significant effects on measures relating to quality of life (d = 0.43) and perceived self-efficacy (d = 0.50). They concluded that the MBSR programme can be adapted for individuals with mild traumatic brain injury (mTBI). Furthermore, the improvements observed in these areas may be attributed to treatment directed at encouraging awareness and acceptance, thereby minimising the catastrophic appraisal of symptoms commonly associated with mTBI and chronic disability.

In a recent systematic review concerning stroke conducted by Lawrence *et al*. (2013), 4 studies involving 160 participants were reviewed. Three papers reported MBIs delivered to groups (including Johansson *et al*., 2012, as mentioned earlier); one paper reported an MBI which was delivered on a one-to-one basis. Results indicated a positive trend in favour of the benefits of MBIs across a range of psychological, physiological, and psychosocial outcomes including anxiety, depression, mental fatigue, blood pressure, perceived health, and quality of life. Similarly, in a systematic review examining yoga and mindfulness in stroke rehabilitation, Lazaridou *et al*. (2013) identified a study by Hofer *et al*. (2014) which noted significant clinical improvements following an integrative, "mindfulness-enhanced" neuro-psychotherapeutic rehabilitation programme for stroke victims.

Recent studies have found clinically meaningful improvements in ABI populations. More promising preliminary evidence for MBI as a potentially useful intervention in this regard has been indicated by Bédard *et al*. (2003). In this pilot study, participants with MTBI (or moderate TBI) were enrolled in a 12-week group intervention (manualized and based on Kabat-Zinn *et al*.'s MBSR programme and Kolb's [1984] experiential learning paradigm). The emphasis of this programme was on present-moment awareness, acceptance via insight meditation, breathing exercises, guided visualisation techniques and group discussion. Individuals were encouraged to view their TBI-related disabilities from a fresh perspective facilitated by approaching their circumstances via acceptance in order to move forward with their life. Treatment gains were shown to have been maintained after one year (Bédard *et al.*, 2005).

Three studies that altogether examined 32 individuals found positive effects of meditation/MBI on individuals with ABI, and merit particular consideration. One study (Azulay *et al*., 2013) examined the effects of an MBSR programme (adapted from Kabat-Zinn's MBSR programme) for a group of 22 individuals with persisting post-concussion symptoms with mild TBI who were concurrently participating in a TBI rehabilitation programme, had relatively intact memory, and were at least three months post-injury. They found improvements in perceived quality of life (d = 0.43), perceived self-efficacy (d = 0.50), working memory, and regulation of attention after 10 weeks of group-meditation-based stress reduction modified to specifically meet cognitive challenges using a standardized (i.e., manualized) curriculum. However, there were no effects of treatment on neurobehavioral symptoms. They noted that practising acceptance (which is considered a central tenet of mindfulness-based work) could be an important factor for individuals with TBI in particular with a view to help mitigate negative perceptions of self that may be associated with chronic symptoms (Azulay *et al*., 2013).

A pilot study with 10 participants (with a comparison group of three patients who did not complete the treatment) examined the impact of a 12-week MBSR group intervention, also standardized and with a manual, that focused on insight meditation, breathing exercises, guided visualization, and an emphasis on psychological well-being through awareness and acceptance (Bédard *et al*., 2003). This patient population had mild to moderate TBI, had completed rehabilitation, was considered to have good insight, and did not present with co-occurring psychological health conditions (70% were women). Participants reported improved quality of life and improved aspects of depression (specifically in the cognitive-affective area). In a follow-up study, seven of the participants were evaluated one year post-intervention (Bédard *et al*., 2005). These participants reported improved mental health as well as continued reduction in depressive symptoms.

In contrast, a larger, randomized controlled trial (McMillan *et al*., 2002), which consisted of 145 individuals with various severities of TBI who exhibited problems with attention on neuropsychological testing or who reported difficulties with attention in daily life three months to one year post-injury, examined the impact of brief mindfulness training for attention problems after TBI. This brief training consisted of a group intervention across five 45-minute sessions over four weeks, with regular practice encouraged between sessions

using audiotapes. Participants were followed up 12 months after the intervention. Data was collected in relation to the amount of mindfulness practice the participants engaged in during the 12 months following the training.

Although the published article did not report the amount of practice, it did report no significant differences within these variables through any of the groups. Importantly, and interestingly, the authors found no significant differences in cognitive functioning, mood, or symptoms, leading to the conclusion that brief exposure to mindfulness meditation "*could not be recommended as a treatment technique for traumatic brain injury cases*" (p.117). However, they noted that further research was needed and highlighted that the amount of therapist contact was low, possibly diluting the potential impact of the training on outcomes.

1.11.4 MBIs in non-clinical populations: relevance for ABI

While there appears to be a relative paucity of evidence regarding the effectiveness of MBIs in the treatment of ABI, there is other research suggesting that meditation/MBIs have a positive impact on some common symptoms of ABI. Although these studies excluded individuals with psychological or neurological disorders, their findings suggest that MBIs may have positive effects across cognitive and emotional domains:

- *Attention*: Studies have found that meditation positively impacts one's ability to sustain focused attention and cognitive efficiency (Kozasa *et al*., 2012). For example, one recent study (Lutz *et al*., 2009) examined intensive meditation training (for 10-12 hours daily over three months) and found that it improved participants' ability to sustain attention over time;
- *Memory and Executive Functions*: Even brief mindfulness practices have been found to have positive effects in terms of memory and executive functioning. Zeidan *et al*. (2010) found that novices in mindfulness practice who spent twenty minutes daily for four days in meditation training recorded significantly lower scores of fatigue, anxiety, and improved working memory, visuo-spatial processing, and executive functioning as compared to a control group whose members listened to a recorded book instead;

- *Depression*: In a sample of participants who had a history of at least one previous episode of major depression and had been in recovery for at least eight weeks, both guided meditation and loving kindness (also known as *metta*) meditation practices were associated with aspects of depression (Barnhofer *et al*., 2010). For example, those who tended to engage in ruminative thinking (cf. the BPM concept of *mental proliferation*) responded well to deep breathing, whereas those who did not often ruminate responded better to loving kindness meditation. Additionally, mindfulness has been linked to a greater ability to deal with negative emotions, which could decrease the development of depressive symptoms (Barnhofer *et al*., 2011);
- *Mood*: Long-term meditation practice has been associated with greater emotional stability and an improved ability to accept emotional states as well as awareness of moment-to-moment experiences (Taylor *et al*., 2011);
- *Pain*: Mindfulness-based practice has also been found to attenuate pain, irrespective of what form of mindfulness is practised (Gard *et al*., 2011). In this particular study, mindfulness practice appeared to reduce the unpleasant experiences of pain by 22% through decreasing cognitive control and increasing sensory processing in the brain (i.e., facilitating and developing the "being" mode over the "doing" mode).

1.12 Cautions and criticisms concerning the utility of MBIs in neurological populations

Debate persists as to the utility of MBIs in the field of neuro-rehabilitation. Certain clinicians appear to suggest that the ability of individuals with ABI to learn to meditate and/or benefit from meditation might depend on the severity of the ABI and the presence of specific neurocognitive and neurobehavioral deficits. Theoretically speaking, the location and extent of the injury, as well as time since injury and level of recovery, could also impact one's ability to meditate or sustain a level of dispositional mindfulness (including regular practice). This may also hold to an extent for those living with long-term neurological conditions where the onset, course and variability of pathology and symptomatology may be key factors in treatment gains and outcomes as well as individuals' beliefs or attitudes towards them.

A critical appraisal of this is also necessary in light of the heterogeneity of this clinical population. The question remains as to how far clinical improvements and/or quality of life can be attributed to mindfulness given the variability of recovery trajectories in individuals

and other potential moderating variables (such as age, gender, type of injury, time since injury, socio-economic circumstances, relationship status, occupational status, associated physical health issues, medication, patients' perceived level of support from others, etc.).

It is perhaps important to acknowledge that the studies mentioned above used modifications to typical MBSR programmes to help those with ABI perform meditation successfully (McMillan *et al*., 2002; Bédard *et al.*, 2003, 2005; Azulay *et al*., 2013). For example, one study adapted the MBSR programme by focusing on increasing attention skills, increasing awareness of internal and external experiences, and adopting a non-judgmental, accepting attitude throughout the practice.

Some within the meditation community believe that the central concepts of mindfulness practices would fit well with the symptoms and needs of individuals with ABI and their recovery and rehabilitation. Opponents of this view argue that the nature of an injury to the brain may prove too great an obstacle for traditional practices that require a level of sustained attention and focused cognitive activity due to the location of the injury. Additionally, a third contingent have proposed that it may be a little of both viewpoints, depending on the nature and severity of the ABI, the time since the injury, and where the individual currently resides in the rehabilitation process.

1.13 Summary of key points

- There is insufficient research on MBIs and ABI and neurological conditions; very few studies have examined the impact of meditation or MBIs in these populations, thus highlighting the need for more research in order to gain a better understanding of its potential role and impact, if any;
- At present, the few studies that have been published report some encouraging but mixed results, and caution should be exerted in interpreting these findings until further research has been published and methodological issues are considered;
- Some research suggests that meditation and MBIs may hold some benefits in the domains of attention, memory, executive functioning, depression, mood changes, and emotional reactivity in non-ABI populations. The neuroscience literature also appears to be providing evidence for the benefits of MBIs on a neurobiological level.

1.14 Rationale for this research

In conclusion, it is clear that ABI and neurological populations typically experience a range of cognitive, physical and psychological difficulties post-injury or diagnosis, and that this may continue for a considerable length of time. There is a growing body of research evidence suggesting the usefulness of MBIs in the rehabilitation and support of these patients in improving their perceived quality of life, as well as potentially reducing symptoms of psychological distress associated with adjustment to ABI or chronic conditions. However, the evidence still remains somewhat limited, both in terms of the number of studies conducted to date, and the lack of controlled trials. As such, this was considered an area worth exploring further. One of the aims of the present study was to add to this growing body of evidence by evaluating an intervention which is currently already being offered to patients in a neuro-rehabilitation service.

The study sought to employ a quantitative methodological design (using standardized, validated self-report questionnaires) in order to evaluate the efficacy of a specifically adapted MBI (based on an MBSR programme) in question for a mixed (i.e. with diverse clinical presentations) ABI sample, including MS, PD and other patients with neurological conditions. Specifically, it consisted of an experimental, randomly generated group pretest-post-test design. It was hypothesised that patients who received the mindfulness group intervention would show greater improvements on measures associated with increased psychological wellbeing, improved emotional regulation and a sense of managing with difficulties after injury as a result of the mindfulness techniques introduced as opposed to a waitlist control. It was also hypothesised that this in turn would lead to improvements on measures of health-related quality of life (HRQOL).

Furthermore, if findings were shown to be significant in terms of improving clinical outcomes, this may have important financial implications for the potential application of similar, adapted forms of MBI across services in light of the current constraints on resources in order to manage high volumes of referrals to services. It was hypothesised that the present study would consolidate and provide further supporting evidence for the efficacy of MBI in the management and rehabilitation of individuals with ABI and neurological conditions in terms of facilitating a reduction in psychological symptoms commonly associated with these.

1.15 Research questions and hypotheses

The two main aims of the study can be defined as follows:

(1) The first aim of the study was to evaluate how effective an adapted (i.e., specifically tailored, short-form) mindfulness-based group intervention was in facilitating mindfulness skills in a mixed patient population who have suffered an ABI or have a diagnosed neurological condition. Two different types of outcome measures for mindfulness will be used to capture a broad range of mindfulness skills relating to present-moment awareness, attention, and non-judgmental appraisals of physical, mental and sensory experiences.

(2) The second aim of the study concerned the question whether an improvement in participants' mindfulness skills would also lead to improvements in their self-efficacy as well as self-rated quality of life. More specifically, as a result of improved mindfulness skills, will individuals at the end of the intervention report improvements in their ability to regulate their emotions, tolerate unpleasant or distressing experiences, respond to these in a more equanimous manner and feel capable of managing the psychological impact of their injury or condition better? Will there also be improvements in their perceived quality of life across physical health, social, occupational and cognitive domains?

The study will employ a special pre- post control group design (see Methods for details) to evaluate the benefits of the MBI programme. The two aims above were translated into the following between- and within-groups comparisons representing the two intervention hypotheses of the study:

(1) The adapted MBI under investigation will lead to increases in mindfulness, self-efficacy and quality of life, and so the intervention group will report higher means on relevant outcomes measures at the end of the MBI training in comparison to a wait-list control group;

(2) The MBI training will lead to significant improvements in mindfulness skills which, in turn, will produce beneficial effects on self-efficacy and quality of life. It is therefore predicted that the means on relevant outcome measures will be higher at the end of the MBI training relative to the means at baseline assessment.

2. Methods

2.1 Study design

The present study employed a quantitative design in order to evaluate the efficacy of the adapted mindfulness-based intervention in question for an ABI sample (individuals with an ABI or diagnosis of a neurological condition). Specifically, it consisted of an experimental, randomly generated control group pretest-posttest design, consisting of three groups of participants. Participants were randomised either to an intervention group or a group who had been placed on a waiting list for the mindfulness programme at a later stage. This group of participants would therefore serve as controls and initially would not receive the intervention until the first two groups had completed the intervention. Therefore all groups would receive the intervention, but at different time points. The third group was assessed at a later stage, and received the intervention approximately 10 weeks after the initial group. At the time of analysis, post-intervention data was not available for this last group, and therefore has not been included in the results. Fig. 11 may assist in clarifying the study design.

The independent variable was the adapted MBI in question. The dependent variables of interest were: changes in mindfulness (Freiburg Mindfulness Inventory, FMI; Mindful Attention Awareness Scale, MAAS); self-efficacy (Mindfulness-based Self-Efficacy Scale-Revised, MSES-R) and health-related quality of life (Perceived Quality of Life Scale, PQoL). Further details concerning these variables and associated outcome measures are outlined later in this chapter.

2.2 Participants

A total of 22 individuals consented to participating in the study. Participants were all current adult patients within Hertfordshire Neurological Service and receiving treatment as part of their rehabilitation following ABI or a diagnosis of a neurological condition.

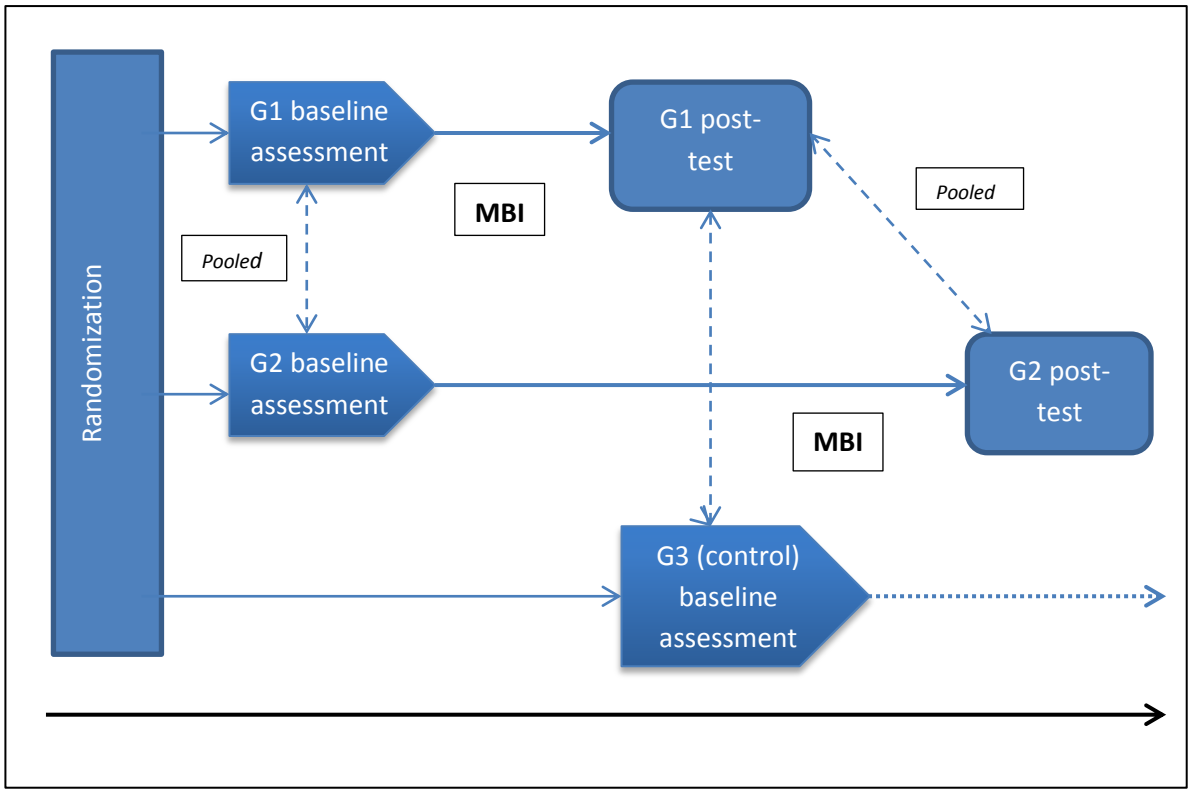

Fig.11.Schematic representation of the study design. Dotted arrows indicate planned comparisons or pooling of participants.

2.3 Selection criteria

2.3.1 Principal inclusion criteria

The principal inclusion criteria for eligibility and participation in the study are outlined below:

1. Individuals who had sustained an ABI (e.g. stroke, traumatic brain injury, viral infection, tumour, etc.) or had a diagnosis of a chronic neurological condition (e.g. MS, PD) ;
2. Individuals who had been identified by their healthcare team or treating clinician as potentially benefiting from a mindfulness-based psychological intervention as part of their ongoing care and rehabilitation package;
3. Individuals aged 18 years and above (the service in question does not have an upper age limit for patients);

4. Individuals who possessed an adequate level of physical and cognitive functioning as determined either by standardised measures or clinical assessment by qualified staff prior to referral to the group;
5. Individuals possessing a good level of fluency in, and comprehension of, the English language.

2.3.2 Principal exclusion criteria

Individuals who were considered to present with any or all of the following issues were deemed unsuitable and therefore excluded from the study:
1. Significant comorbidity including a current diagnosis of psychiatric disorder;
2. Significant cognitive impairment (as regards memory and processing ability);
3. Significant physical impairment, disability or mobility issues which would impact adversely on the ability to attend sessions or remain seated for lengthy periods of time ;
4. Severely limited or reduced fluency in, or comprehension of, written and spoken English.

2.4 Recruitment

2.4.1 Identification and selection of potential participants

All potential participants were identified via a referral database and associated waiting list for the group intervention managed within Hertfordshire Neurological Service (Hertfordshire Community NHS Trust). Participants were recruited from the Acquired Brain Injury Team referrals list within this database. Referral details provided in the referral forms made to Hertfordshire Neurological Service had previously been screened for suitability by the clinical psychologists or other members of the healthcare team working within the service. If deemed suitable, the individual in question was approached for consent for their personal information to be accessed as part of the research study. The length of time that individuals had been waiting between referral to the group and initial contact ranged from approximately 5 to 12 months.

Potential participants were initially approached concerning the study by telephone. A total of 46 patients from the mindfulness group referral and waiting list were contacted in

relation to the study. Two attempts at contacting individuals were made. Those individuals who did not respond to either of these two attempts were considered as not wishing to participate. However, a number of individuals who did not wish to participate in the study did express a desire to attend the mindfulness group. As mentioned earlier, potential participants had already been identified via their healthcare team as possibly benefiting from the mindfulness-based intervention, therefore were aware of being placed on the waiting list for the group intervention. This would have taken place after discussing this option with their healthcare team or relevant treating clinician.

In the case of some patients, brief screening psychometrics would have been administered to determine the individuals' baseline level of cognitive or neuropsychological functioning. These consisted of standard neuropsychological assessments which would have been conducted as a matter of protocol in terms of their package of rehabilitation care (e.g., for ABI patients) prior to individuals having been identified as suitable candidates for the MBI group, and referred accordingly via their clinicians. These may have included a selection of WAIS-IV (Wechsler, 2008) subtests focussing on attention as well as more specific neuropsychological measures relating to memory, information processing and cognitive impairment. These assessments would not have necessarily been undertaken as a definitive screening tool for the MBI, but may have informed clinical decisions concerning the suitability of the individual for referral to the mindfulness meditation group.

An important consideration in respect of this evaluation study was to the potential role of confounding variables as alternative explanations for outcomes. In the case of ABI and neurological conditions, this may relate to the extent to which improvements of a clinical or psychological nature as mentioned previously can be attributed to the intervention alone or indeed to natural rates of recovery (and hence improved adjustment/psychological well-being) among individuals living with these long-term conditions or injury. Where possible, additional factors to consider were the heterogeneity of the sample in terms of precise ABI sustained or neurological diagnosis (e.g., whether the classification of MS was primary progressive or relapsing-remitting), severity of the injury, time since injury or course of disease, as well as other potential moderators such as age, gender, occupational and marital status, and level of education across the sample.

2.5 Description of intervention

The intervention in question adopted a suitably modified (i.e., non-manualized) version of the traditional MBSR programme originally developed by Kabat-Zinn (1982, 1992). Standard MBSR programmes consist of 8 weekly sessions of 2 hours each including a day-long session of practice which usually takes place after the sixth session. Historically and currently, the programme under investigation in the present study has been delivered over 4 weeks and comprises 4 sessions of an hour each, with an emphasis on daily between-session practice and feedback/discussion of the same during sessions (for a similar study employing an adapted, short-form mindfulness programme, see McMillan *et al*., 2002). In a review of contact hours and psychological outcome measures, Carmody and Baer (2009) suggested that adaptations involving less "class" time may be beneficial for populations for whom reduction of psychological distress is an important goal and for whom longer time commitment may be a barrier to their access, ability or willingness to participate.

2.5.1 Content of sessions

Whilst not exhaustive, the following is intended as a descriptive guide to the content of each intervention session, in chronological order (see Appendix 1 for detailed session-by-session information and materials provided to participants):

Session 1: Introductions, aim of the group (focus on teaching mindfulness meditation skills), facilitator's personal experience of meditation/mindfulness practice; rules of the group, confidentiality, respecting others' opinions, invitation to record mindfulness meditation practice, general housekeeping rules; individual introductions, timetable of group; guidelines on how to meditate, meditation diary, articles on mindfulness and Jon Kabat-Zinn's work; definitions of mindfulness meditation and theoretical framework for MBI; meditation as fundamentally an experiential process; 2 x sets of guided mindfulness meditation practice and feedback to group;

Session 2: Introductions, feedback from and reflections on maintaining a mindfulness diary, 1 x guided mindfulness practice; feedback/reflections on this; applying mindfulness to everyday life – aims in applying mindfulness practice in relation to difficult experiences e.g. physical pain, anxious or critical thoughts, negative cognitions, awareness of

distracting/negative thoughts and “letting go”; goals re: applying mindful thinking in daily life and continuation of daily mindfulness meditation practice;

Session 3: Introductions, reflections on maintaining the mindfulness diary, 1 x guided mindfulness practice; feedback/reflections on this; application of mindfulness to everyday life re: experiential avoidance and unhelpful coping strategies; goals re: applying mindful thinking in daily life and continuation of daily mindfulness meditation practice;

Session 4: Introductions, reflections on mindfulness diary, 1 x guided mindfulness practice; feedback/reflections on this; learning to take care of oneself in relation to rumination and avoidance and learning to alter one’s response to negative events rather than attempting to alter the events in themselves.

Participants were also supplied with paper-based mindfulness diary sheets in which to record their practice (see Appendix 2 for an example of the diary).

2.6 Measures

2.6.1 Rationale for selected measures

The following empirically validated and standardized measures were suggested and discussed with a view to capturing both the process and impact of the intervention under evaluation in terms of the predicted reduction of individuals’ psychological symptoms and the enhancement of their psychological well-being in relation to measures of mindfulness, as defined by the presence of increased dispositional interoceptive awareness and attentional focus. In addition, it was suggested that a measure capturing key constructs associated with self-efficacy, e.g., acceptance, equanimity, distress tolerance, emotional regulation and adjustment (amongst others) would also be useful in order to examine possible effects of increased dispositional mindfulness on the sample in question, given the propensity for patients’ difficulties in these areas, as indicated and suggested by the literature.

Some thought was given to the respective length of questionnaires and their wording. Despite not including participants with gross cognitive impairment, particular attention was also paid to the cognitive demands the questionnaires might entail. Further discussion concerned their possible uses or adaptations for the purposes of this study. Outcome

measures were administered in paper form pre- and post-intervention for all groups in the presence of the researchers so as to facilitate any explanations of items. All measures were administered on site during a single sitting. Where this was not possible, arrangements were made to do this at the participant's home. In some cases, measures were forwarded by post and participants contacted to ensure their receipt and return.

The measures employed in the present study can be found in Appendix 3 in the order in which they are presented below. The final measures selected were as follows and were administered to participants in the order in which they are presented in the following section.

2.6.2 Primary outcome measures: measures of trait and dispositional mindfulness

Freiburg Mindfulness Inventory (FMI; Walach *et al*., 2006)

The FMI is a useful, valid and reliable questionnaire for measuring mindfulness, and is one of the most widely used measures in MBI research. It is suitable for all generalised clinical contexts, and does not assume any particular knowledge or endorsement of the Buddhist or Eastern religious or spiritual background of mindfulness. The 14 items on the FMI cover all aspects of mindfulness. All items are scored to obtain a single summary score; one item is reverse-scored. The FMI takes around 5 minutes to complete.

Mindful Attention Awareness Scale (MAAS; Brown and Ryan, 2003)

The MAAS is a 15-item scale designed to assess a core characteristic of dispositional mindfulness; that is, open or receptive awareness of, and attention to, present-moment experiences. The scale possesses strong psychometric properties and has been validated with a variety of clinical and non-clinical samples. The trait MAAS has shown excellent psychometric properties. Factor analyses with undergraduate, community and nationally sampled adult, and adult cancer populations have confirmed a single factor scale structure (Brown and Ryan, 2003; Carlson and Brown, 2005). Internal consistency levels (Cronbach's alpha) generally range from .80 to .90. The MAAS has demonstrated high test-retest reliability, discriminant and convergent validity, known-groups validity, and criterion validity.

Correlational, quasi-experimental, and laboratory studies indicate that the MAAS taps into a unique quality of consciousness that is related to, and predictive of, a variety of self-regulation and well-being constructs. A recent study combining both quantitative and qualitative data (Dobkin, 2008) found that the MAAS was a potentially useful process measure in assessing changes in mindfulness. All items are scored and added together to obtain a total (no items are reversed). The overall score is derived from computing the mean of the 15 item scores. The MAAS takes around 10 minutes to complete. Normative information on the trait MAAS is available for both community adults and university students: community adults (4 independent samples): *N* = 436; MAAS *M* = 4.20, *SD* = .69; university students (14 independent samples): *N* = 2277; MAAS *M* = 3.83, *SD* = .70.

2.6.3 Secondary outcome measures: measures of self-efficacy

Mindfulness–based Self-Efficacy Scale-Revised (MSES-R; Francis and Cayoun, 2011)

The MSES was originally developed as a 35-item self-report questionnaire constructed to measure the change in levels of self-efficacy before, during, and following MBI programmes (specifically Mindfulness-based Cognitive Therapy [MBCT]). The MSES-R is a shorter (22-item) version that emerged from psychometric data collected from a community sample (N = 521). It is a valid and reliable measure, with a six-factor structure (namely: equanimity, emotional regulation, social skills, distress tolerance, taking responsibility and interpersonal effectiveness). It is perhaps useful to further elaborate on the respective subscales:

- **Emotion Regulation** (subscale 1) relates to an involuntary or subconscious emotional response that is well modulated and falls within the expected normal range of responses;
- **Equanimity** (subscale 2) relates to the ability to normalise difficulties and prevent reactivity (e.g., not being overly critical or judgmental of oneself);
- **Social Skills** (subscale 3) relates to social abilities in the broader sphere of interaction with others;
- **Distress Tolerance** (subscale 4) also relates to emotional responses, but taps into voluntary responses, which inhibit avoidance of experiential intolerance or discomfort (e.g., the capacity to “sit with” distressing experiences);

- **Taking Responsibility** (subscale 5) relates to clarity of interpersonal boundaries and locus of control in terms of one's difficulties;
- **Interpersonal Effectiveness** (subscale 6) relates to the ability to connect with others within the intimate sphere of relationships.

The above factors have all been identified in the literature as important skills that may improve with mindfulness. The MSES-R is used for both clinical and research purposes, with the advantage of measuring the consequences, rather than just the processes, of mindfulness training. It is estimated that the MSES-R takes around 10-15 minutes to complete. An online version is available, however for the purposes of the study, was deemed potentially unsuitable for use by some participants.

Test-retest reliability for the MSES-R is very good (r = .88, N = 100, $p < .01$; shared variance for the 22-item scale was 78%). Internal consistency is indicated as reliably high (Cronbach's alpha = .86). The MSES-R possesses a good inverse relationship with the Depression Anxiety and Stress-Short Form measure (DASS21, Lovibond and Lovibond, 1995) and has shown good discriminant validity. The scale discriminates well between scorers who report having a mental illness from those who do not. Convergent validity is consistently in the good range with other mindfulness measures such as the Kentucky Inventory of Mindfulness Skills (KIMS, Baer, Smith & Allen, 2004), Five Facet Mindfulness Questionnaire (FFMQ, Baer *et al*., 2006), FMI and MAAS. Overall, the MSES-R can be considered to possess good construct validity and is considered a reliable measure.

2.6.4 Secondary outcome measures: measures of Health-related quality of life (HRQoL)

Perceived Quality of Life Scale (PQoL; Patrick *et al*., 1988, 2008)

The PQoL was initially developed as a cognitive appraisal of an individual's life satisfaction after intensive medical care. However, it has been applied to adults with chronic neurological disability including stroke and TBI (Cicerone and Azulay, 2007), and was therefore considered particularly appropriate for the population in the present study. This was due in part to its brevity and focus on social and physical health aspects. Consisting of 19 main items, it measures the extent to which an individual is satisfied with their functioning on an 11-point scale (i.e., 0-10) ranging from *extremely dissatisfied/unhappy* to

extremely satisfied/happy. An additional single item (item 20) addresses an individual's global level of happiness ("*How happy are you?*") and is used to examine convergent validity within the instrument.

The overall score for the PQoL is obtained by computing the mean or median of the 19 main item scores. Subscale scores of physical, social and cognitive health satisfaction may be used in further analysis. One item (item 7, relating to diet) does not appear to fall into any factor and it is advised that this be used on its own. For convergent validity purposes, the overall PQoL score can be correlated with item 20 (the happiness rating). The Pearson's or ICC correlation coefficient should exceed 0.70.

2.6.5 Feedback evaluation forms

In addition to the above measures, it was considered potentially useful to supply participants with a brief feedback evaluation form in order to encourage patients to provide qualitative data in terms of the perceived benefits, the practical and logistical aspects of the MBI group programme, as well as comments or suggestions for future improvements or changes to the structure or delivery of the MBI group (see Appendix 4 for a copy of the evaluation form). This is standard practice across all group-based interventions within the local service in which the present research was conducted. The evaluation form consisted of 10 items focussing on participants' views regarding the length of the intervention and individual sessions, the content and environment of the sessions and attendees' perceptions of how beneficial the group programme had been in terms of increased knowledge of mindfulness as well as the acquisition of mindfulness-based skills and across psychological symptoms (low mood, anxiety, anger). A space was provided at the end for further comments.

2.7 Procedure

2.7.1 Obtaining consent

Following initial contact as outlined above, all participants received a written participant information sheet outlining the nature, aims and expected timescale of the study, including all procedures, any potential risks and benefits involved (see Appendix 5). Potential

participants who had indicated an interest in the research were given a maximum of 10 working days following receipt of the relevant information sheet in which to decide whether they wished to take part in the study or not. They were also encouraged to contact the researchers if they wished to seek clarification on any of the information supplied to them concerning the study. A separate participant consent form (see Appendix 6) was drafted to explain that participation was entirely voluntary and that participants had the right to withdraw from the study at any time, without having to provide a reason for this. Participants were expected to sign this form and this took place in person with the researchers. A letter informing individuals' GP of their participation was also prepared (Appendix 7).

2.7.2 Randomisation procedure

The flowchart in Fig. 11 may assist in clarifying the study design and randomisation procedure. Participants were assigned to one of three groups according to a computer generated randomization list (computerized random numbers). As such, participants were randomly assigned with a 1:1 allocation ratio following permuted block design procedures, using block sizes of four. No stratification criteria were used. The allocation sequence was generated by an independent administrator not directly involved in this project after baseline measures had been collected, thus ensuring that recruiters were kept blind to the allocation of each participant. The allocation sequence was password protected and only accessible by the administrator.

2.7.3 Intervention setting and delivery

The intervention was delivered over four consecutive sessions, lasting approximately one hour each. Sessions took place once a week, therefore the total length of the intervention was approximately one month. The intervention took place in a clinical space within one of two main sites in Hertfordshire Neurological Service (one covering the North and East of the county, the other the South and West; the present study was conducted in the South and West). This is largely dependent on where patients live and takes into account distance they may be required to travel. The group was facilitated by an experienced clinical psychologist with extensive clinical expertise in mindfulness-based therapeutic techniques and training.

The facilitator was blinded to the participants' identities and randomization procedure. Three groups were run consecutively over a period of 14 weeks from January to April 2014.

2.7.4 Administration of measures

It was proposed that the questionnaires would be administered at 3 or 4 key points during the process:

- *Baseline assessment*

1. A set of self-report measures as detailed previously was administered initially to all participants in the first two groups who had agreed to take part in the study;
2. The same set of measures was administered to participants in a third waitlist control group. This took place after group 1 had completed the intervention;

- *Post-intervention*

3. These measures were administered again after participants had completed the group intervention (i.e., after session 4) within a timeframe ranging from 2-4 weeks of this date;
4. It was proposed that the same questionnaires would be administered approximately 3 months after the last session of each group intervention (follow-up). However, due to logistical issues and timing constraints, this was not possible.

It was expected that each set of measures would take approximately 30-45 minutes to administer, for a total of 180 minutes (3 hours). In some cases, participants were offered the opportunity of a short break within the allotted assessment appointment where they had indicated any difficulties with concentration levels or fatigue. No assessment lasted more than 50 minutes. All measures were administered face-to-face in consulting rooms located within the rehabilitation facility.

2.8 Determining the sample size

As highlighted previously, a recently published study (Johansson *et al*., 2012) suggested evidence for considerable improvement in symptomatology and some reduction in depression and anxiety of neurological patients following participating in an MBSR (Mindfulness-Based Stress Reduction) group. Based on this study, a power calculation was

conducted to establish the sample size. Assuming that the MBI training would lead to a substantial improvement corresponding to a strong effect size (i.e. Cohen's d = .80) a sample size of N = 42 would detect a mean difference between the intervention (n = 21) and the control group (n = 21) with a power of .80 and an alpha level of 5% (one-tailed). With an increase in the effect size the demand for the sample size would go down and so a sensitivity analysis was conducted in addition, as it was unlikely to recruit that many participants. The reason for this restriction to the recruitment of participants was down to the fact that the sample size was dependent on the waiting list which had accrued at the time the study commenced as well as the number of individuals agreeing to take part in the study. The figure below displays the result of a sensitivity analysis in relation the effect size d and the sample size required to detect it with a power of .80 and the alpha error (5%).

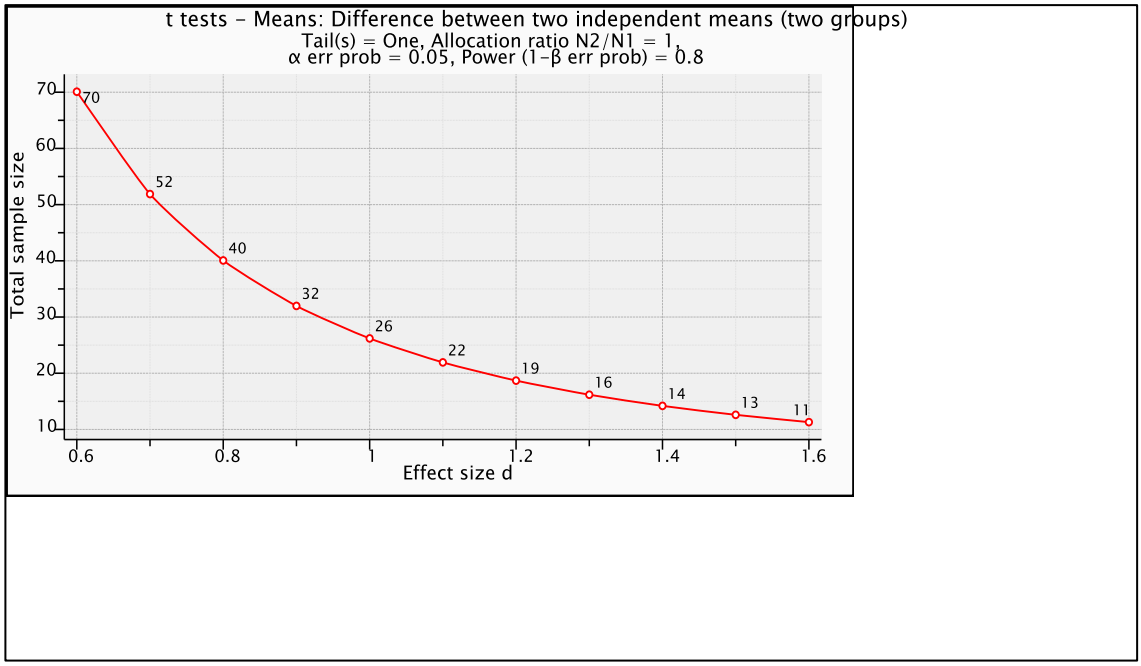

Fig. 12. G*Power 3 (Faul et al., 2007) result of a sensitivity analysis for the study.

According to the sensitivity analysis a sample size of around 26 would suffice to detect a large effect size of around 1.

2.9 Statistical Analyses

Descriptive statistics and suitable graphical data analysis were conducted to explore the distribution of the outcome measures for anomalies and normality. Mean differences

between groups were tested for statistical significance using the t-test for independent groups and with one-tailed p-values set at 5%, whereas mean differences from baseline to the end point were tested for statistical significance using the dependent samples t-test.

An intention to treat (ITT) analysis was also carried out to deal with any dropouts during the course of the intervention. Further analysis would involve an investigation of the individual change scores in the treatment group with a view to identifying important predictors of clinically significant change or, conversely, to identifying circumstances that may have prevented participants in benefiting from the intervention. This was achieved through a correlational analysis using Spearman's rank correlation as the sample size was rather small.

2.10 Ethical Considerations

2.10.1 Psychological and emotional distress

Because some of the practices in mindfulness-based interventions encourage an awareness of one's feelings or thoughts, some thought was given to potential upset or distress in participants. One consideration was that re-assessment measures may have highlighted the emotional and psychological impact of the brain injury or neurological condition on participants. However, all measures administered in the study were validated and standardised. Participants were informed that in such an event, they would be supported by qualified professionals within the service in managing any difficult emotions.

The intervention took place in a clinical setting which aimed to provide a safe and containing space for this to occur and for participants to discuss and process these feelings. This space is regularly used for group-based work. Participants were encouraged to be able to request individual consultation and/or debriefing with professionals outside of the intervention where they identified this as beneficial. Between sessions, there was regular liaison with participants' care team to ensure this support if offered in cases where this had been indicated or felt necessary. In addition, several procedures were put in place to reduce any further risk to participants:

1. Participants were provided with detailed information regarding the aim and nature of the study in order to provide informed consent. It was reiterated that participation was entirely voluntary and that they could withdraw from the study at any time, without explanation;

2. Participants were informed that their decision to participate or withdraw from the study would not affect any concurrent care management or treatment;
3. The group was facilitated by an experienced clinical psychologist with extensive clinical expertise in mindfulness-based therapeutic techniques and training. Part of the facilitator's role was to observe and attend to any participants who displayed signs of emotional distress (e.g. leaving the room, becoming tearful or visibly upset, etc.), with a view to offering support or guiding participants through grounding techniques, commonly used during MBIs for such purposes;
4. Participants were provided with contact details of researchers and facilitators, including possible routes to access support from other experienced clinicians within the service and who may have also been involved in participants' usual care.

2.10.2 Confidentiality

Personal details for all participants were stored as per standard protocol and in accordance with local clinical governance guidelines on the NHS computer network (electronic patient record management system). Any data transferred from this location were anonymised accordingly with no details which would allow the individual to be identified. Any transfers carried out used an encrypted storage device. No data from the study was stored on any personal, University or laptop computers. However, both University and NHS computers were used during the data analysis and writing up of the present study. Both computer systems are password protected and use secure accounts. Any information accessed and used on these systems was encoded in anonymised formats. Raw data were stored in a locked filing cabinet at the research site for the duration of the study.

2.10.3 Ethical review of the study

Relevant guidance notes were consulted and advice was sought in respect of ethical review. In view of relevant research authorities' considerations concerning minimal risk or harm to participants, the present study was deemed suitable for Proportionate Review. The study was reviewed by the Yorkshire and the Humber – South Yorkshire Local Research Ethics Committee (see Appendix 8 for the relevant letter of approval).

3. Results

The results of the data analysis for are presented in the following order:

(1) Descriptive statistics for the sample in question, including clinical profile and available socio-demographic information;
(2) Descriptive statistics in respect of the research hypotheses concerning main outcome measures (both psychological and in terms of health-related quality of life, or HRQoL) at baseline for the whole sample (Groups 1, 2 and 3);
(3) Distribution of mean scores for each of the primary and secondary outcome measures of interest at baseline assessment (i.e., pre-intervention, Groups 1, 2,3);
(4) Distribution of mean scores for each of the primary and secondary outcome measures of interest post-intervention (i.e., Groups 1 and 2);
(5) Statistical analysis in respect of the treatment completers and effects of the group on the outcome measures (i.e., Groups 1 and 2) relating to the main research hypotheses;
(6) Intention-To-Treat (ITT) analysis taking into account participants who dropped out of the study (i.e., did not or were unable to complete measures post-intervention, or who did not attend the MBI group following agreement to participate) and for whom outcome data was unavailable.
(7) Correlation analyses exploring the relationship between the outcome measures of interest pertaining to the intervention hypothesis;
(8) A summary of key findings following analysis.

3.1 Participants and Data Set

3.1.1. Socio-demographic and clinical profile of participants

A total of 22 individuals agreed to participate in the present study and were randomly assigned to one of three groups. Of these, 8 were allocated to the first group, 8 to the second, which ran immediately after the first group and completed, and 6 (of a possible 8) who had also agreed to take part in the study, attended a third group. This final group ran two weeks after the second group had completed treatment. The data and associated analyses are presented for the whole sample of 22 participants in the first instance. Tables 2 and 3 outline study participants' socio-demographic and clinical characteristics.

Table 2. Frequencies, percentages (and SDs) of socio-demographic variables for the total sample (N= 22) and by group.

			Group 1	Group 2	Group 3
Gender	Male	3 (13.6%)	0	2 (25%)	1 (16.67%)
	Female	19 (86.4%)	8 (100%)	6 (75%)	5 (83.33%)
	Total	22 (100%)	8 (100%)	8 (100%)	6 (100%)
Mean age		51.45 (8.52)	47.88 (9.31)	50.00 (7.56)	58.16 (5.08)
Ethnicity	White British	22 (100%)	8 (100%)	8 (100%)	6 (100%)
	Total	22 (100%)	8 (100%)	8 (100%)	6 (100%)
Marital status	Single	7 (31.8%)	2 (25%)	3 (37.5%)	2 (33.33%)
	Married	15 (68.2%)	6 (75%)	5 (62.5%)	4 (66.67%)
	Total	22 (100%)	8 (100%)	8 (100%)	6 (100%)
Employment status	Employed	10 (45.5%)	5 (62.5%)	3 (37.5%)	2 (33.33%)
	Unemployed	7 (31.8%)	2 (25%)	4 (50%)	1 (16.67%)
	Retired	2 (9.1%)	0	1 (12.5%)	1 (16.67%)
	Student	1 (4.5%)	1 (12.5%)	0	0
	Unavailable	2 (9.1%)	0	0	2 (33.33%)
	Total	22 (100%)	8 (100%)	8 (100%)	6 (100%)

As presented in Table 2, participants were predominantly female (86%), with the average age at baseline of 51.45 years (SD = 8.52).Group 1 consisted entirely of female participants, and had the lowest mean age (47.88 years, SD = 9.31). This is noteworthy in light of the tendency of certain neurological conditions (in particular, MS and PD) to be diagnosed between the ages of 20 and 50 years. In terms of ethnicity, the totality of participants described themselves as White British; this is representative of referrals received by the local

service. Also of note was participants' occupational status, with just under a third (32%) currently unemployed.

Table 3. Frequencies and percentages of neurological diagnosis by type (N = 22).

Diagnosis		Frequency	Percent (%)
Type	ABI	**4**	**18.2**
	MS	**12**	**54.5**
	PD	**4**	**18.2**
	Other Neuro	**2**	**9.1**
	Total	**22**	**100**

As presented in Table 3, it is perhaps worthwhile noting the proportions of participants in terms of their clinical diagnosis. Just over half of participants had a diagnosis of MS (54%), although the data did not distinguish between specific typology (e.g., whether benign, progressive or relapsing-remitting) or severity (e.g., time since diagnosis). This information is not routinely collected or held on the electronic patient record system as this is not a requirement of the service. Also, there were equal numbers of patients with a diagnosis of ABI and PD (n = 4 in each category, representing 36% of the total sample). As noted previously, the literature suggests that MS is a condition in which psychological issues are under-reported but particularly prominent (McGuigan and Hutchinson, 2006; Marrie *et al*., 2008).

3.2 Descriptive statistics: outcome measures at baseline assessment for the whole sample

3.2.1 Primary outcome measures: measures of mindfulness

Table 4 presents the results from the whole sample analysis for the two measures related to mindfulness. Boxplots of the distribution of scores relating to the FMI (general mindfulness) and MAAS (awareness and attention, dispositional mindfulness) are also shown (figs. 13 and 14 respectively). Results show a fairly symmetrical distribution of scores, with little variation across groups despite the apparent heterogeneity in clinical profile and the large proportion of female participants. Exploration of these two variables revealed that assumptions for the use of parametric tests were met.

Table 4. Primary outcome measures (mindfulness: FMI; MAAS) at baseline; descriptive statistics.

Group		FMI (pre-)	MAAS (pre-)
1	N	**8**	**8**
	Mean	**37.25**	**3.20**
	Median	**37.50**	**3.20**
	Minimum	**31.00**	**2.47**
	Maximum	**46.00**	**4.07**
	Std. Deviation	**4.95**	**.51**
	Skewness	**.37**	**.31**
	Kurtosis	**.31**	**.01**
2	N	**8**	**8**
	Mean	**34.88**	**3.28**
	Median	**36.00**	**3.23**
	Minimum	**18.00**	**2.13**
	Maximum	**48.00**	**4.07**
	Std. Deviation	**9.00**	**.58**
	Skewness	**-.67**	**-.88**
	Kurtosis	**1.10**	**1.70**
3	N	**6**	**6**
	Mean	**36.17**	**3.64**
	Median	**34.00**	**3.77**
	Minimum	**25.00**	**2.53**
	Maximum	**53.00**	**4.27**
	Std. Deviation	**9.58**	**.59**
	Skewness	**1.12**	**-1.61**
	Kurtosis	**1.80**	**3.48**
Total	N	**22**	**22**
	Mean	**36.09**	**3.35**
	Median	**36.50**	**3.33**
	Minimum	**18.00**	**2.13**
	Maximum	**53.00**	**4.27**
	Std. Deviation	**7.62**	**.56**
	Skewness	**-.05**	**-.43**
	Kurtosis	**1.06**	**-.36**

3.2.2 FMI

General levels of mindfulness were measured using the Freiburg Mindfulness Inventory (FMI). A total score for the FMI was computed by adding scores for all 14 individual items. One item (item 13) was reversed, in accordance with the protocol as defined by the authors. The total score for the FMI ranges from 14 to 56. Higher scores denote higher levels of general mindfulness. The authors do not recommend using separate factor-scale scores.

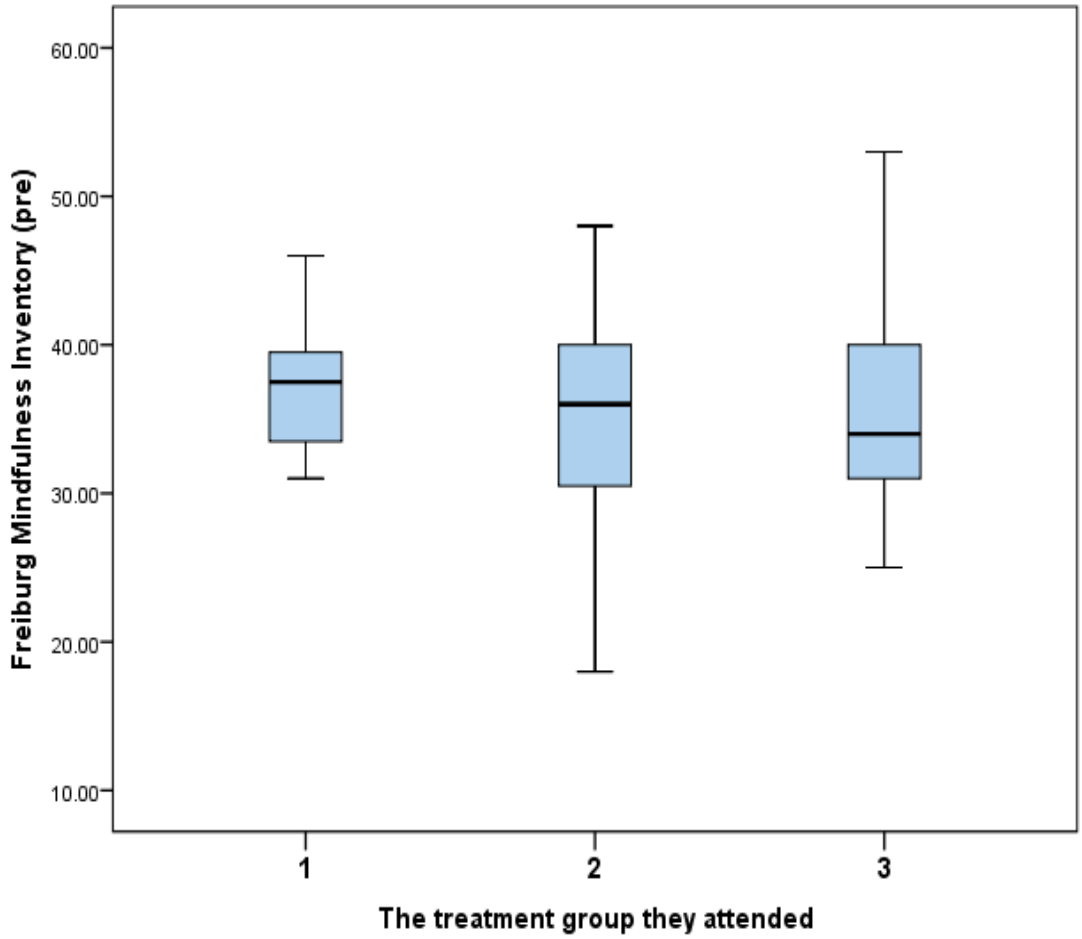

Fig. 13: Boxplots showing the distribution of FMI scores at baseline (N= 22).

3.2.3 MAAS

Dispositional levels of mindfulness as regards increased levels of attentional focus and awareness of present-moment experiences, both key concepts in the definition and operationalization of mindfulness, were measured using the 15–item Mindful Attention Awareness Scale (MAAS). A total score for the MAAS was computed by adding scores for all

individual items and dividing this by the number of items (i.e., 15) in order to derive an overall mean score. Higher scores reflect higher levels of dispositional mindfulness as defined by awareness and attention constructs. Mean scores range from 1 to 6 across the 15 items.

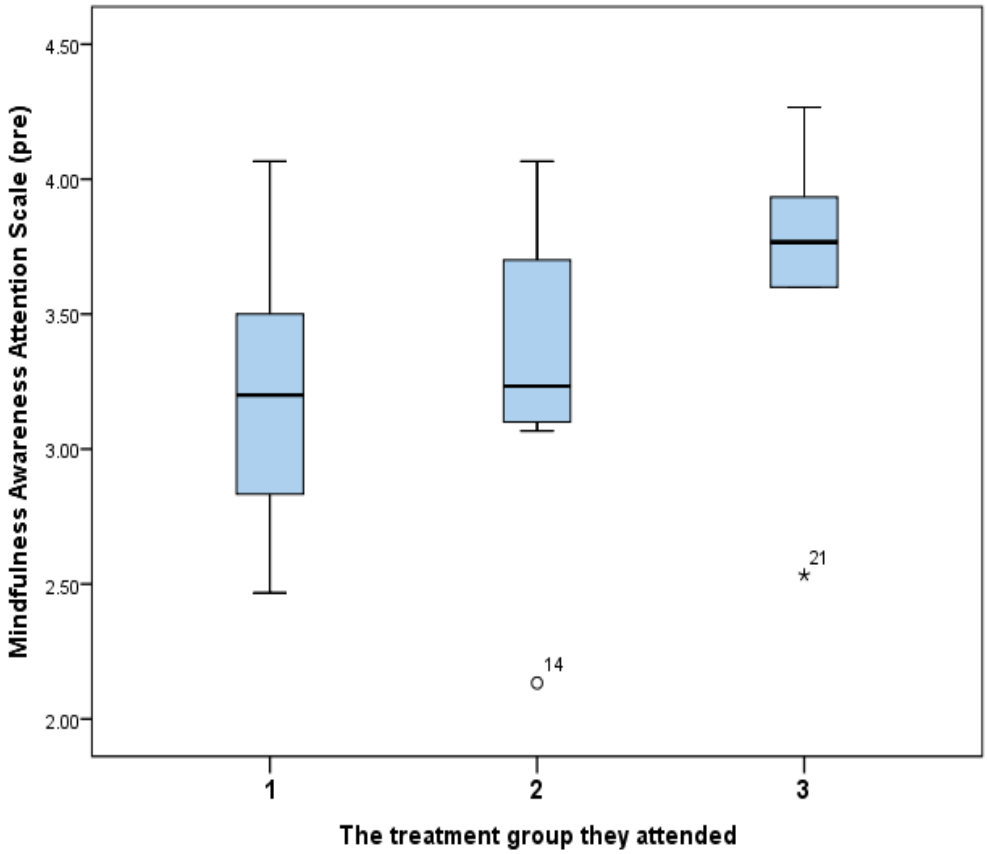

Fig. 14: Boxplots showing the distribution of MAAS scores (awareness and attention; dispositional mindfulness) at baseline (N = 22).Outliers are marked accordingly (o;⋆).[2]

It is perhaps worthwhile commenting on the extreme case as represented by participant 21 in Group 3 who reported a particularly low mean score on the MAAS at baseline assessment.

3.2.4 Secondary outcome measures: measures of self-efficacy (MSES-R)

Table 5 presents the results from the whole sample analysis for the outcome measure related to self-efficacy (MSES-R). Boxplots of the distribution of subscale scores relating to the MSES-R are also shown (fig. 15). Exploration of this variable revealed that assumptions for the use of parametric tests were met.

[2] Outliers are values at the lower or upper end that lie apart from the distribution. They are identified as cases that fall more than 1.5 box lengths (or 3 in extreme cases) from either hinge of the box.

Table 5. Secondary outcome measures (MSES-R) by subscale at baseline: descriptive statistics.

Group		Emotional Regulation	Equanimity	Social Skills	Distress Tolerance	Taking Responsibility	Interpersonal Effectiveness
1	N	**8**	**8**	**8**	**8**	**8**	**8**
	Mean	**11.88**	**11.13**	**8.00**	**6.75**	**7.00**	**8.38**
	Median	**11.00**	**11.00**	**8.00**	**7.50**	**7.00**	**8.50**
	Minimum	**1.00**	**7.00**	**4.00**	**2.00**	**6.00**	**2.00**
	Maximum	**19.00**	**16.00**	**12.00**	**11.00**	**8.00**	**12.00**
	Std. Deviation	**6.08**	**2.53**	**2.88**	**3.45**	**.76**	**3.25**
	Skewness	**-.48**	**.52**	**-.29**	**-.22**	**.00**	**-1.05**
	Kurtosis	**.03**	**2.26**	**-.66**	**-1.88**	**-.70**	**1.11**
2	N	**8**	**8**	**8**	**8**	**8**	**8**
	Mean	**8.38**	**9.50**	**8.13**	**6.50**	**5.00**	**6.25**
	Median	**8.50**	**9.50**	**8.00**	**7.00**	**4.00**	**6.00**
	Minimum	**2.00**	**6.00**	**4.00**	**2.00**	**3.00**	**3.00**
	Maximum	**15.00**	**13.00**	**12.00**	**11.00**	**11.00**	**9.00**
	Std. Deviation	**5.26**	**2.67**	**2.53**	**3.02**	**2.56**	**2.05**
	Skewness	**-.05**	**.00**	**-.12**	**-.19**	**2.31**	**.08**
	Kurtosis	**-1.94**	**-.86**	**-.21**	**-.72**	**5.56**	**-.44**
3	N	**6**	**6**	**6**	**6**	**6**	**6**
	Mean	**10.83**	**9.00**	**7.17**	**6.17**	**4.50**	**9.00**
	Median	**11.50**	**7.50**	**7.50**	**6.00**	**4.00**	**8.50**
	Minimum	**4.00**	**6.00**	**3.00**	**3.00**	**2.00**	**8.00**
	Maximum	**18.00**	**13.00**	**11.00**	**10.00**	**8.00**	**11.00**
	Std. Deviation	**4.96**	**3.16**	**2.99**	**2.99**	**2.17**	**1.26**
	Skewness	**.03**	**.80**	**-.17**	**.16**	**.79**	**.89**
	Kurtosis	**-.36**	**-1.87**	**-1.34**	**-2.04**	**.07**	**-.78**
Total	N	**22**	**22**	**22**	**22**	**22**	**22**
	Mean	**10.32**	**9.95**	**7.82**	**6.50**	**5.59**	**7.77**
	Median	**10.50**	**10.00**	**8.00**	**7.00**	**6.00**	**8.00**
	Minimum	**1.00**	**6.00**	**3.00**	**2.00**	**2.00**	**2.00**
	Maximum	**19.00**	**16.00**	**12.00**	**11.00**	**11.00**	**12.00**
	Std. Deviation	**5.46**	**2.79**	**2.68**	**3.04**	**2.17**	**2.60**
	Skewness	**-.11**	**.20**	**-.21**	**-.08**	**.52**	**-.50**
	Kurtosis	**-.87**	**-.64**	**-.88**	**-1.43**	**.13**	**-.07**

3.2.5 MSES-R

Self-efficacy was measured using the 22-item Mindfulness-based Self-Efficacy Scale-Revised (MSES-R), a relatively new measure developed for both clinical and research purposes and adapted from the 35-item MSES, 16 of the questionnaire items are reversed. The MSES-R possesses a 6–factor structure which taps into defined components of self-efficacy. The range of scores for each subscale is 0 to 4. Total scores for each subscale vary since certain subscales contain more items than others. It is perhaps worthwhile mentioning that a global score of self-efficacy may also be computed (total scores can range from 0 to 88).

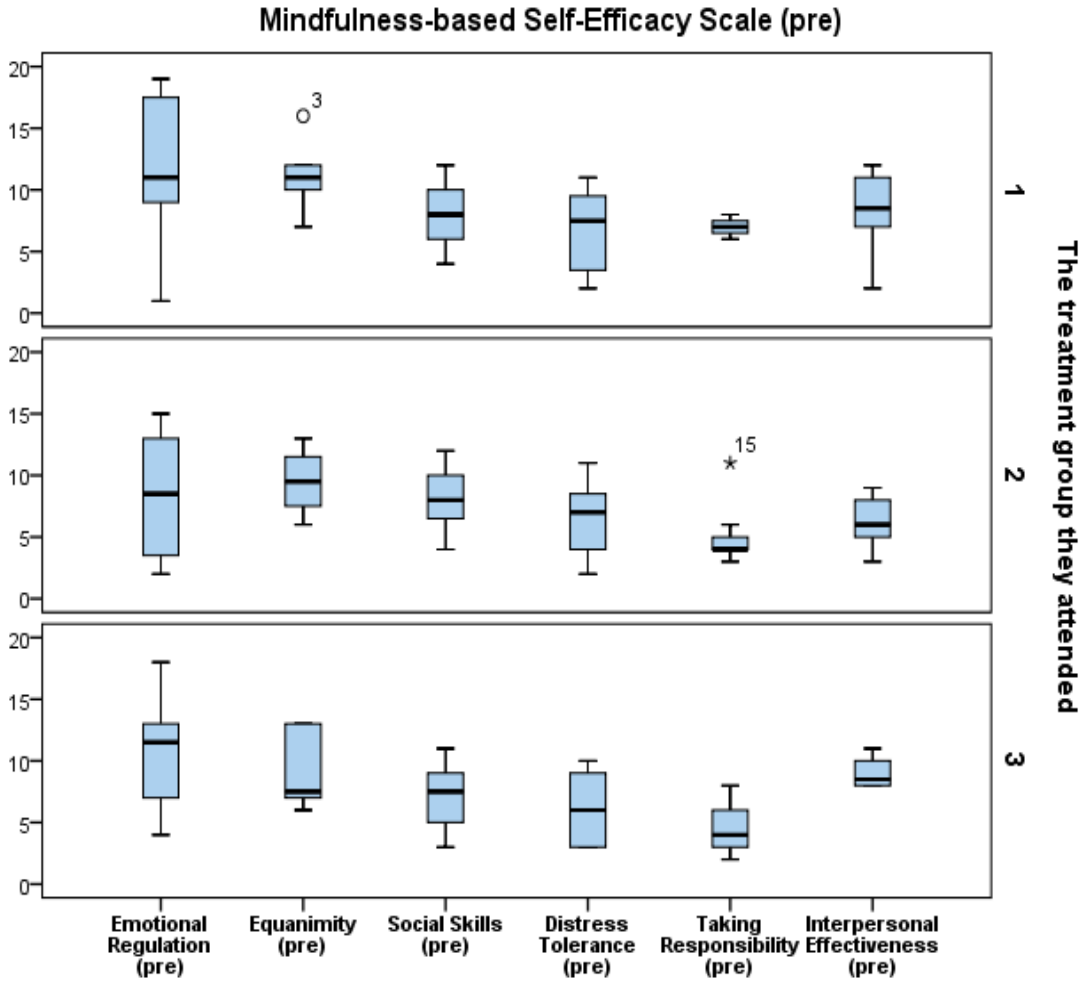

Fig. 15: Boxplots showing the distribution of MSES-R subscale scores (self-efficacy) at baseline (N= 22).

Of note is one outlier (participant 3) in group 1 for whom scores on the Equanimity subscale were relatively high in relation to other participants.

3.2.6 Secondary outcome measures: health-related quality of life (HRQOL)

Table 6 presents the results from the whole sample analysis for the outcome measure related to health-related quality of life (Perceived Quality of Life Scale, PQoL) at baseline assessment. A boxplot of the distribution of scores relating to the PQoL is also shown (fig. 16). Exploration of this variable revealed that assumptions for the use of parametric tests were met.

Table 6. Secondary outcome measures (quality of life: PQoL) at baseline: descriptive statistics.

Group	N	Mean	Median	Minimum	Maximum	Std. Deviation	Skewness	Kurtosis
1	**8**	**5.32**	**5.26**	**3.58**	**7.16**	**1.46**	**.05**	**-2.12**
2	**8**	**5.01**	**4.68**	**3.32**	**7.68**	**1.26**	**1.36**	**3.34**
3	**6**	**5.64**	**5.76**	**3.53**	**7.56**	**1.44**	**-.25**	**-.47**
Total	**22**	**5.29**	**5.00**	**3.32**	**7.68**	**1.34**	**.33**	**-1.01**

3.2.7 PQoL

Quality of life was measured using the Perceived Quality of Life Scale (PQoL) Scoring criteria involve computing the total of individual scores for 19 of the 20 items in the questionnaire and an overall score based on the mean or median of the 19 item scores. A population mean/median of 7.5 has been observed (N = 3359). Interpretation of the measure in cross-sectional use is [<7.5 score is Dissatisfied] and [>7.5 score is Satisfied with perceived health-related quality of life].

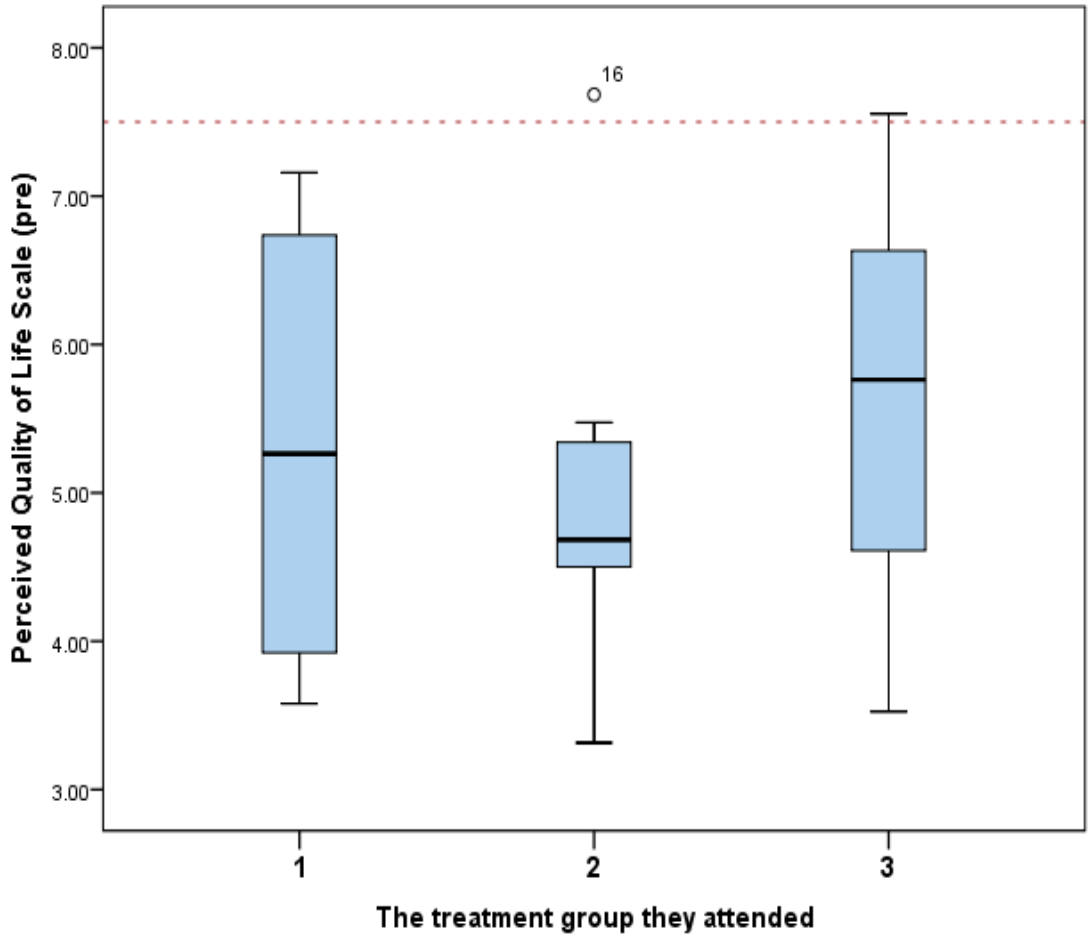

Fig. 16: Boxplots showing the distribution of PQoL scores (health-related quality of life) at baseline (N = 22).The dotted line indicates a mean/median score of ≥7.5, interpreted as a cut-off score ('Satisfied' with perceived quality of life).

3.3 Descriptive statistics: outcome measures at post-intervention

Since at the time of analysis data from only two of the three groups were available, the following section will present only data relating to Groups 1 and 2.Tables 7 and 8 outline the results of the data analysis in respect of the primary outcome measures pertaining to mindfulness at post-treatment assessment for these two groups for those participants who completed the intervention and/or were assessed. Boxplots showing the respective distributions of post-treatment scores are also included (figs. 17 and 18).

3.3.1 Primary outcome measures: measures of mindfulness (FMI)

Table 7: Primary outcome measures (mindfulness; FMI) post-intervention: descriptive statistics (n = 12).

Group	N	Mean	Median	Minimum	Maximum	Std. Deviation	Skewness	Kurtosis
1	**7**	**45.14**	**45.00**	**40.00**	**51.00**	**4.34**	**.12**	**-1.27**
2	**5**	**39.80**	**40.00**	**33.00**	**47.00**	**5.07**	**.17**	**1.16**
Total	**12**	**42.92**	**42.50**	**33.00**	**51.00**	**5.21**	**-.14**	**-.26**

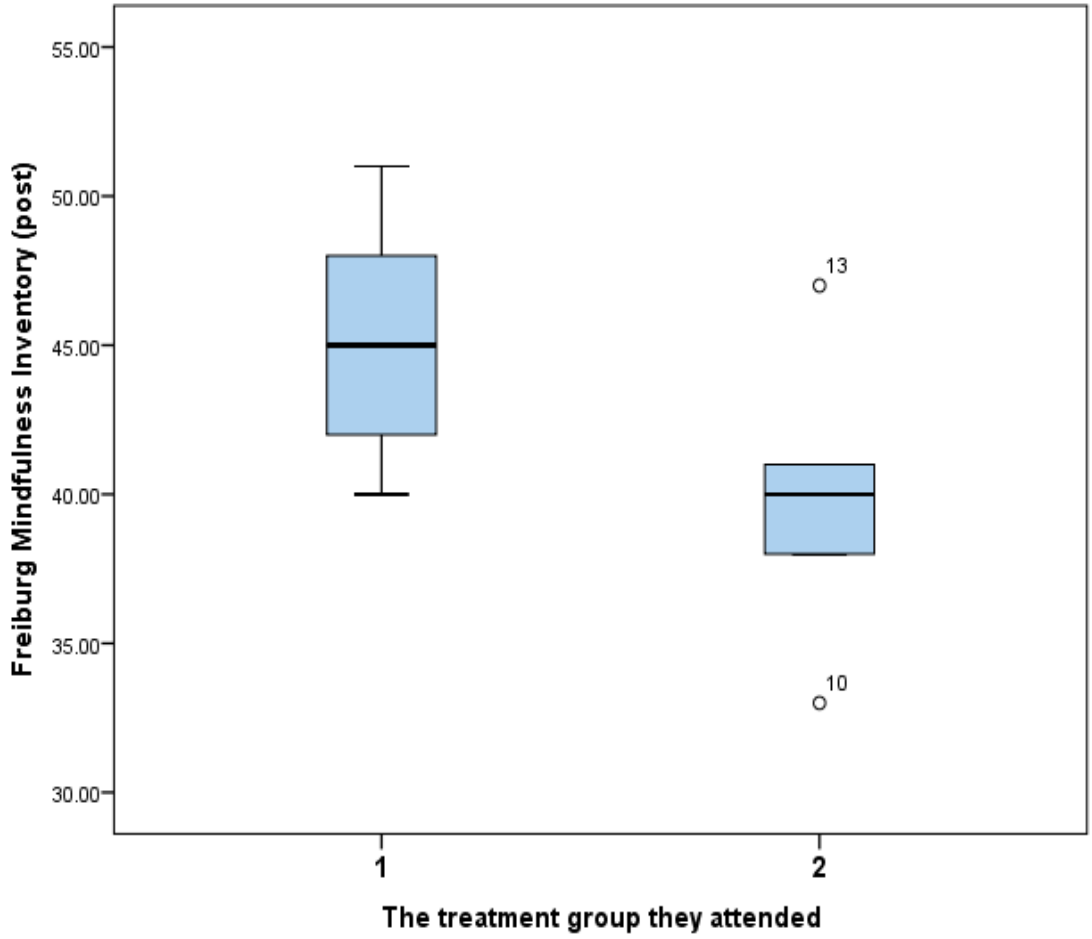

Fig. 17: Boxplots showing the distribution of FMI scores (general mindfulness) post-intervention (n= 12).

As can be seen from the above figure, two participants from the second group (10 and 13) appear to represent outliers.

3.3.2 MAAS

Table 8: Primary outcome measures (dispositional mindfulness; MAAS) post-intervention: descriptive statistics (n = 12).

Group	N	Mean	Median	Minimum	Maximum	Std. Deviation	Skewness	Kurtosis
1	**7**	**3.96**	**4.13**	**3.20**	**5.13**	**.73**	**.40**	**-.92**
2	**5**	**4.09**	**4.60**	**2.67**	**4.80**	**.89**	**-1.39**	**1.23**
Total	**12**	**4.01**	**4.20**	**2.67**	**5.13**	**.76**	**-.35**	**-.98**

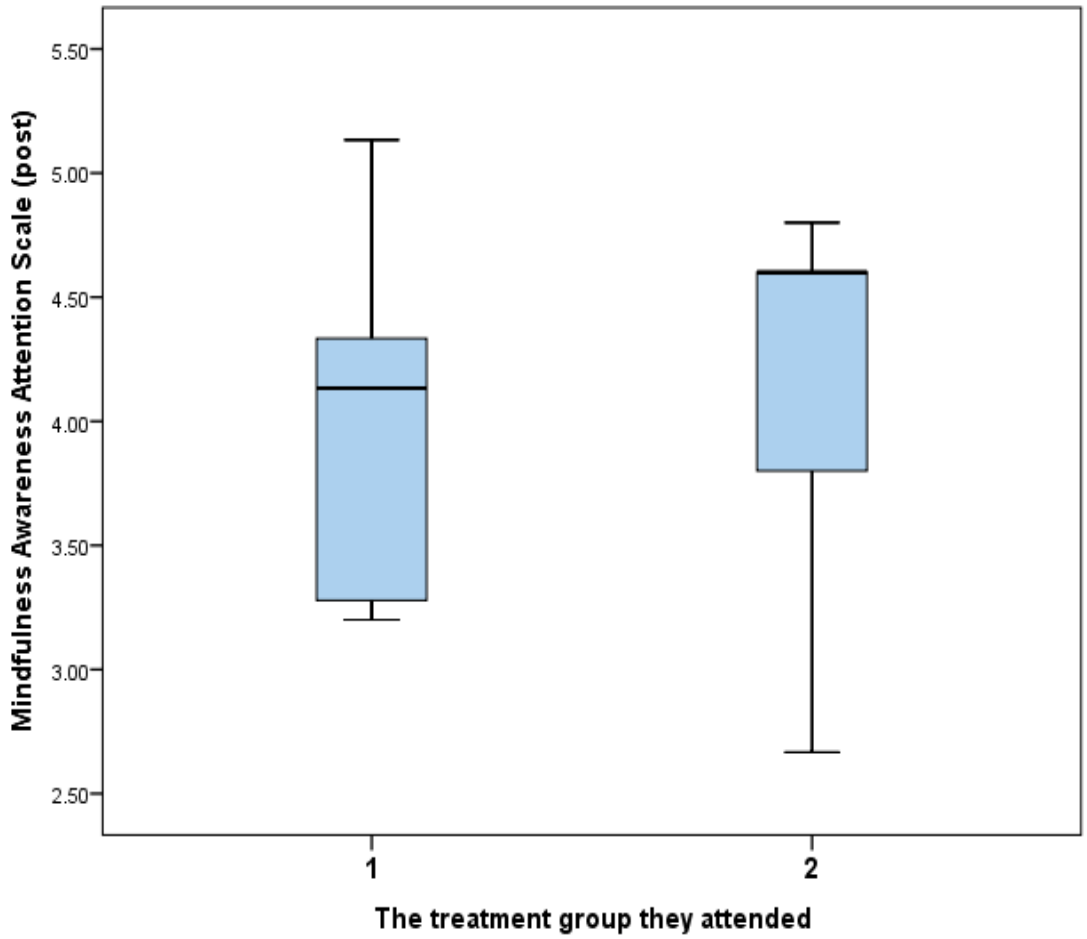

Fig. 18: Boxplots showing the distribution of MAAS scores (awareness and attention; dispositional mindfulness) post-intervention (n= 12).

3.3.3 Secondary outcome measures: measures of self-efficacy (MSES-R)

Table 9 presents the results from the analysis for Groups 1 and 2 in respect of the MSES-R outcome measure at post-intervention by subscale. A boxplot of the distribution of subscale scores relating to the MSES-R is also shown (fig. 19).

Table 9. Secondary outcome measures (self-efficacy; MSES-R) post-intervention: descriptive statistics.

Group		Emotional Regulation (post)	Equanimity (post)	Social Skills (post)	Distress Tolerance (post)	Taking Responsibility (post)	Interpersonal Effectiveness (post)
1	N	**7**	**7**	**7**	**7**	**7**	**7**
	Mean	**17.00**	**12.43**	**9.14**	**7.57**	**8.29**	**9.00**
	Median	**17.00**	**13.00**	**9.00**	**7.00**	**10.00**	**9.00**
	Minimum	**10.00**	**10.00**	**7.00**	**5.00**	**6.00**	**7.00**
	Maximum	**22.00**	**15.00**	**11.00**	**12.00**	**10.00**	**11.00**
	Std. Deviation	**3.65**	**1.62**	**1.57**	**2.37**	**2.14**	**1.29**
	Skewness	**-1.01**	**.01**	**.04**	**1.14**	**-.37**	**.00**
	Kurtosis	**2.59**	**.25**	**-1.68**	**1.18**	**-2.80**	**.31**
2	N	**5**	**5**	**5**	**5**	**5**	**5**
	Mean	**12.80**	**9.20**	**8.00**	**7.00**	**6.80**	**8.00**
	Median	**14.00**	**9.00**	**10.00**	**7.00**	**7.00**	**9.00**
	Minimum	**4.00**	**5.00**	**4.00**	**4.00**	**4.00**	**5.00**
	Maximum	**19.00**	**12.00**	**11.00**	**9.00**	**10.00**	**9.00**
	Std. Deviation	**5.54**	**2.68**	**3.24**	**2.12**	**2.77**	**1.73**
	Skewness	**-1.06**	**-1.00**	**-.59**	**-.52**	**-.01**	**-1.92**
	Kurtosis	**1.95**	**1.24**	**-2.90**	**-.96**	**-2.70**	**3.67**
Total	N	**12**	**12**	**12**	**12**	**12**	**12**
	Mean	**15.25**	**11.08**	**8.67**	**7.33**	**7.67**	**8.58**
	Median	**16.50**	**11.50**	**9.50**	**7.00**	**8.00**	**9.00**
	Minimum	**4.00**	**5.00**	**4.00**	**4.00**	**4.00**	**5.00**
	Maximum	**22.00**	**15.00**	**11.00**	**12.00**	**10.00**	**11.00**
	Std. Deviation	**4.81**	**2.61**	**2.35**	**2.19**	**2.42**	**1.51**
	Skewness	**-1.14**	**-.99**	**-.93**	**.61**	**-.36**	**-1.06**
	Kurtosis	**1.70**	**1.69**	**-.09**	**.50**	**-1.59**	**2.41**

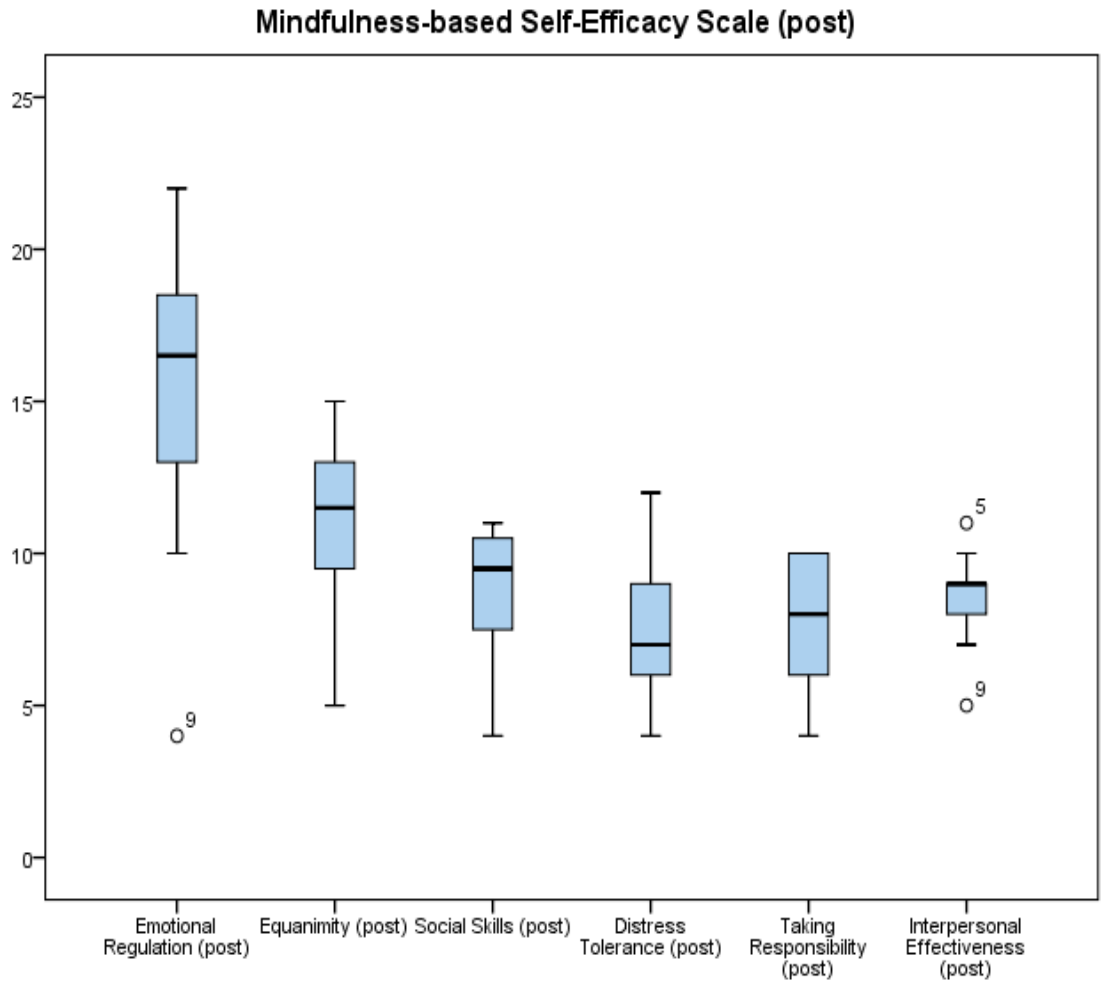

Fig. 19: Boxplots showing the distribution of MSES-R subscale scores (self-efficacy) post-intervention (n= 12).

It is perhaps worth commenting that in the case of one participant (9), scores on two of the MSES-R subscales represented outliers.

3.3.4 Secondary outcome measures: quality of life measure (PQoL)

Table 10 presents the results from the analysis for Groups 1 and 2 in respect of the PQoL (health-related quality of life) outcome measure at post-intervention. A boxplot of the distribution of scores relating to this measure is also shown (fig. 20).

Table 10. Secondary outcome measures (quality of life; PQOL) post-intervention: descriptive statistics (n = 12).

Group	N	Mean	Median	Minimum	Maximum	Std. Deviation	Skewness	Kurtosis
1	**7**	**6.53**	**6.89**	**5.26**	**8.11**	**1.00**	**.25**	**-.85**
2	**5**	**5.79**	**5.84**	**3.58**	**8.05**	**1.89**	**.01**	**-2.22**
Total	**12**	**6.22**	**6.37**	**3.58**	**8.11**	**1.41**	**-.46**	**-.47**

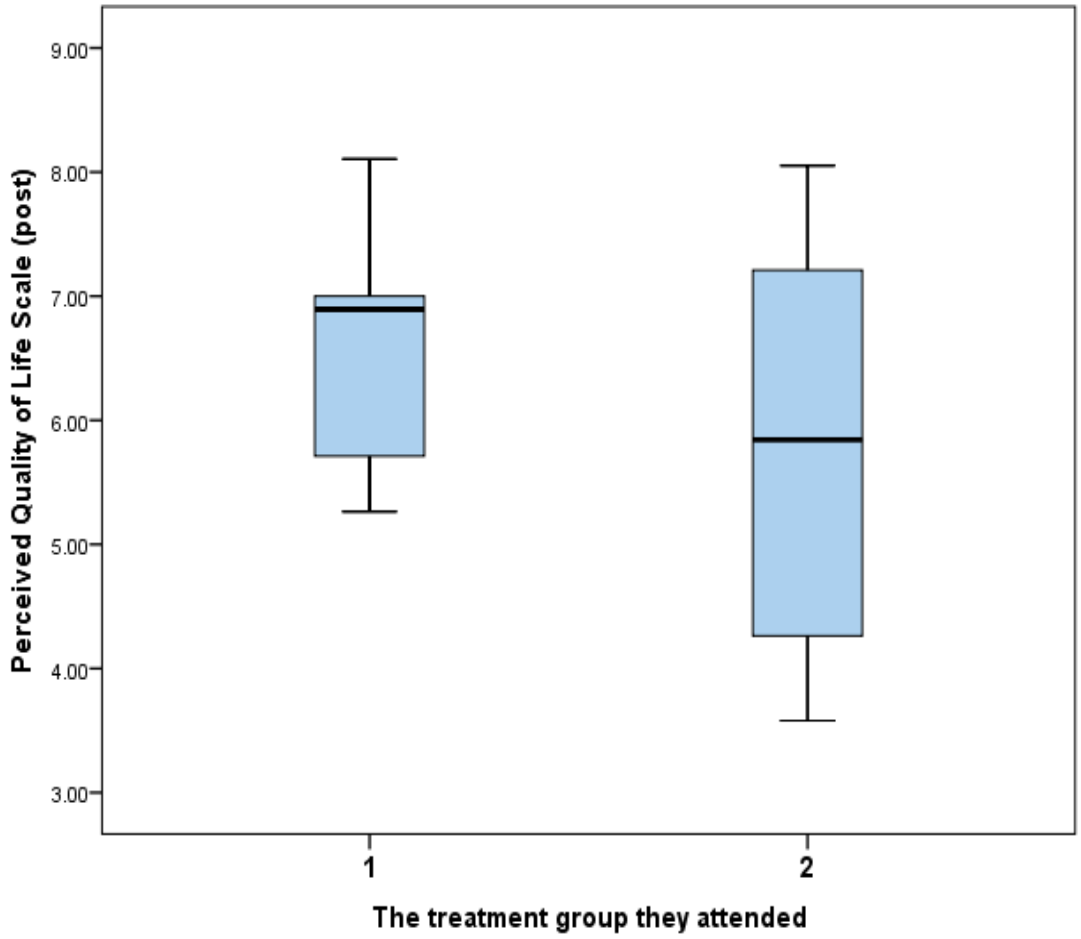

Fig. 20: Boxplots showing the distribution of PQoL scores (health-related quality of life) post-intervention (n= 12).

As the above figure shows, it is evident that the distribution of mean scores was wider amongst participants in Group 2.

3.4 Testing the intervention hypotheses: between-group comparisons

As previously outlined, the initial intervention hypothesis concerned the prediction that in comparison to a wait-list control group (i.e., group 3), as a result of receiving the mindfulness-based intervention, participants in the initial intervention group would show statistically significant improvements in measures associated with mindfulness as well as in relation to measures of self-efficacy and quality of life. Given the study design adopted as described earlier (Fig. 11), it was decided to conduct appropriate analyses to test this hypothesis accordingly. Results are presented in Table 11.

Table 11. Analysis of between-group comparisons (Group 1 post-intervention vs. Group 3 baseline, n = 13).

Primary outcome measures		**t**	**Significance (p, 1-tailed)**	**Mean differences (95% CI)**	**Cohen's d**
Mindfulness	FMI	2.238	.024	8.98 (.15 & 17.8)	1.21
	MAAS	.834	.21	0.31 (-.51 & 1.13)	0.47
Secondary outcome measures					
Quality of life	PQOL	1.303	.11	0.88 (-.61 & 2.38)	0.71
Self-Efficacy	MSES-R				
Subscales	Taking Responsibility	3.162	.005	3.79 (1.15 & 6.42)	1.76
	Emotional Regulation	2.581	.013	6.17 (.91 & 11.42)	1.42
	Equanimity	2.521	.014	3.43 (.44 & 6.42)	1.36
	Social Skills	1.525	.078	1.98 (-.88 & 4.83)	0.83
	Distress Tolerance	.945	.18	1.40 (-1.87 & 4.68)	0.52
	Interpersonal Effectiveness	.000	1.00	0.00(-1.57 & 1.57)	0

It can be seen from the table that across four of the measures of interest (or subscales thereof) statistically significant differences in mean scores were observed in the intervention group at post-intervention as compared to the control group at baseline assessment. Independent samples t-tests revealed significant differences in respect of the FMI, and three of the six MSES-R subscales (Taking Responsibility, Emotional Regulation and Equanimity respectively).

It was also decided to conduct the same analysis using the corresponding non-parametric t-tests (Mann-Whitney *U* test) in order to test the robustness of the t-tests due to the small sample sizes. The results from this analysis are displayed in Appendix 9 and would appear to lend further support the intervention hypothesis.

3.4.1 Effect sizes

Treatment effect sizes were calculated using Cohen's d statistic (Cohen, 1988). It can be seen that compared to the control group (i.e., Group 3), the mean differences in scores for the intervention group evaluated (i.e., Group 1) at post-treatment assessment in respect of the FMI amounted to a very large effect size (d = 1.21). Very large effect sizes were also noted in respect of three of the six subscales of the MSES-R measure (Taking Responsibility, d = 1.76; Emotional Regulation, d = 1.42, and Equanimity, d = 1.36), with a further subscale (Social Skills) indicating a large effect size (d = 0.83). With regards to the PQoL measure, a large effect size was also noted (d = 0.71).

3.5 Testing the intervention hypotheses: within-group improvements over time

As noted earlier, the intervention hypotheses concerned the prediction that as a result of attending the mindfulness-based intervention, participants would show improvements in outcome measures relating to mindfulness constructs (i.e., non-judgmental, present-moment awareness, attentional focus) as defined by current literature, as well as improvements in measures relating to components of self-efficacy and perceived quality of life. In order to ascertain changes in measures across time (i.e. pre-treatment and post-treatment), analyses consisted of paired samples t-tests, provided assumptions for the use of parametric tests were met (i.e. homogeneity of variance, few/no extreme scores, normal distribution of data). As highlighted earlier, given the small sample size involved and evidence that these groups did not differ considerably in terms of their distributions, these analyses were conducted by amalgamating the first two groups of participants into one single group (n = 12) and to test for statistically significant improvements over time.

3.5.1 Primary outcome measures: mindfulness (FMI, MAAS)

A paired-samples t-test was conducted to compare mean scores on outcome measures of mindfulness (FMI, MAAS) at baseline and post-intervention. Results indicated that there was a significant difference in scores for the FMI measure (t (11) = -3.376, p =.006) with participants achieving an average increase post-intervention of 6 points (mean = 42.92, SD = 5.21) in comparison to baseline assessment (mean = 36.50, SD = 7.60). The 95% confidence interval for the estimated population mean difference was between -10.6 and 2.23.

Paired-samples t-tests conducted in respect of the MAAS also revealed a significant difference in scores from pre- and post-intervention (t (11) = -3.05, p = 0.011). Mean scores pre- (mean = 3.26, SD = .45) and post-intervention (mean = 4.01, SD = .76) differed by an average of over 0.7 points. The 95% confidence interval for the estimated population mean difference was between -1.3 and 0.21.

3.5.2 Secondary outcome measures: quality of life (PQoL)

Similarly, a statistical analysis using the paired-samples t-test was conducted to compare mean scores on the PQoL. Results indicated a significant difference in scores (t (11) = -3.349, p = 0.006). Participants achieved a mean difference of over 0.8 points at baseline (mean =

5.36, SD = 1.43) and post-treatment assessment (mean = 6.22, SD = 1.41). The 95% confidence interval for the estimated population mean difference was between -1.42 and -.29.

3.5.3 Secondary outcome measures: self-efficacy (MSES-R)

As regards the MSES-R, the data were analysed for each of the six subscale scores using the paired-samples t-rest. Results indicated a significant difference in scores on the Emotional Regulation subscale (t (11) = -3.936, p = 0.002) and a significant difference on the Taking Responsibility subscale (t (11) = -2.821, p = 0.017). Within the Emotional Regulation subscale, participants achieved a mean difference in scores of 4.75 at baseline (mean = 10.5, SD = 6.11) and post-treatment assessment (mean = 15.25, SD = 4.81), whereas for the Taking Responsibility subscale, mean differences of 1.92 points were recorded between baseline (mean = 5.75, SD = 1.66) and post-treatment assessment (mean = 7.67, SD = 2.42).

However, an analysis of the data for the other four MSES-R subscales – Equanimity, Distress Tolerance, Social Skills and Interpersonal Effectiveness – yielded contrasting results. Paired-sample t-tests revealed no significant differences in mean scores for subscales relating to Equanimity (t (11) = .274, p = .789), Social Skills (t (11) = -.897, p = .389), Distress Tolerance (t (11) = .160, p = .876) and Interpersonal Effectiveness (t (11) = -.907, p = .384). It is perhaps worth noting that participants' mean scores showed a decrease as regards the Equanimity (pre-treatment mean = 11.33, SD = 2.02; post-treatment mean = 11.08, SD = 2.61; decrease of 0.25 points) and Distress Tolerance subscales (pre-treatment mean = 7.50, SD = 3.03; post-treatment mean = 7.33, SD = 2.19; decrease of 0.17 points).

3.5.4 Effect sizes and evaluation of the experimental hypotheses

Treatment effect sizes were calculated using Cohen's d statistic (Cohen, 1988). Effect sizes relating to primary and secondary outcome measures are presented in Table 12, along with an evaluation regarding the experimental hypotheses as defined previously. It can be seen that the mean differences in scores for completers at pre- and post-treatment assessment in respect of the mindfulness measures (FMI, MAAS) amounted to very large effect sizes (d = 0.98 and d = 1.20 respectively). A moderate effect size was noted for the PQoL (d = 0.61) and large effect sizes were also noted for two of the six subscales on the MSES-R (Emotional Regulation, d = 0.86; Taking Responsibility, d = 0.92).

Table 12. Effect sizes, confidence intervals and evaluation of experimental hypotheses (n = 12).

Primary outcome measures		**Cohen's d**	**95% CI**	**Decision**
Mindfulness	FMI	0.98	-10.6 and 2.23	Experimental hypothesis confirmed
	MAAS	1.20	-1.3 and 0.21	Experimental hypothesis confirmed
Secondary outcome measures				
Self-Efficacy	MSES-R			
Subscales	Taking Responsibility	0.92	-3.41 and -4.22	Experimental hypothesis confirmed
	Emotional Regulation	0.86	-7.41 and -2.09	Experimental hypothesis confirmed
	Interpersonal Effectiveness	0.33	-2.57 and 1.07	Experimental hypothesis rejected
	Social Skills	0.21	-1.73 and 0.73	Experimental hypothesis rejected
	Equanimity	0.11	-1.76 and 2.26	Experimental hypothesis confirmed
	Distress Tolerance	0.06	-2.13 and 2.46	Experimental hypothesis rejected
Quality of Life	PQoL	0.61	-1.3 and 0.21	Experimental hypothesis confirmed

3.6 Intention-to-treat (ITT) analysis

In order to test whether those participants who failed to complete or withdrew from the study (n=4) might have caused a bias towards an over-optimistic estimate of the effect sizes noted above, an Intention-to-treat (ITT) analysis was conducted. The four participants in question were therefore included in the analysis using their outcome measure scores at baseline assessment, for a total sample size n = 16. For ease of reference, mean differences are presented in Table 13 and are reported as negative values (i.e., baseline mean scores are subtracted from post-intervention mean scores as is standard practice) where there has been an increase in scores. Positive values denote mean scores which decreased for a specific outcome measure or subscale thereof.

3.6.1 ITT analysis of primary outcome measures (mindfulness: FMI, MAAS)

Paired-samples t-tests were conducted to compare mean scores on outcome measures of mindfulness (FMI, MAAS) at baseline and post-intervention. Results indicated that there was a significant difference in scores for the FMI measure (t (15) = -3.043, p =.008) with participants achieving a mean difference in scores of 4.81 in comparison to baseline assessment. The 95% confidence interval for the estimated population mean difference was between -8.18 and -1.44.

Paired-samples t-tests conducted in respect of the MAAS also revealed a significant difference in scores pre- and post-intervention (t (15) = -2.803, p = 0.013). Mean scores pre- (mean = 3.24, SD = .53) and post-intervention (mean = 3.81, SD = .83) differed by 0.57 points. The 95% confidence interval for the estimated population mean difference was between -1.00 and -0.14.

3.6.2 ITT analysis of secondary outcome measures: PQoL

Similarly, a statistical analysis using the paired-samples t-test was conducted to compare mean scores on the PQoL. Results indicated a significant difference in scores (t (15) = -3.022, p = 0.009). A mean difference of 0.65 points between baseline (mean = 5.16, SD = 1.33) and post-treatment assessment (mean = 5.81, SD = 1.46). The 95% confidence interval for the estimated population mean difference was between -1.09 and -.19.

Table 13. Intention-to-treat (ITT) analysis (n=16).

Primary outcome measures		**Mean scores**		**SD**	**Mean score difference**[1]	**Significance (p)**
Mindfulness	FMI	pre	36.06	7.12	-4.81	0.008
		post	40.88	6.41		
	MAAS	pre	3.24	.52	-0.57	0.013
		post	3.81	.83		
Secondary outcome measures						
Self-Efficacy	MSES-R					
Subscales	Emotional Regulation	pre	10.13	5.78	-3.56	0.004
		post	13.69	5.51		
	Equanimity	pre	10.31	2.65	0.18	.786
		post	10.13	2.94		
	Social Skills	pre	8.06	2.62	-0.38	.383
		post	8.44	2.53		
	Distress Tolerance	pre	6.63	3.14	0.13	.874
		post	6.50	2.53		
	Taking Responsibility	pre	6.00	2.10	-1.44	0.019
		post	7.44	2.58		
	Interpersonal Effectiveness	pre	7.31	2.85	-0.56	.378
		post	7.87	2.13		
Quality of Life	PQoL	pre	5.16	1.33	-0.64	0.009
		post	5.81	1.46		

[1] *Negative values denote improvements in mean scores.*

3.6.3 ITT analysis of secondary outcome measures: MSES-R

As regards the MSES-R, the data were analysed for each of the six subscale scores using the paired-samples t-rest. Results indicated a significant difference in scores on the Emotional Regulation subscale (t (15) = -3.423, p = 0.004) and a significant difference on the Taking Responsibility subscale (t (15) = -2.626, p = 0.019).Within the Emotional Regulation subscale, taking into account non-completers, participants achieved a mean difference in scores of 3.56 between baseline (mean = 10.13, SD = 5.79) and post-treatment assessment (mean = 13.69, SD = 5.51), whereas for the Taking Responsibility subscale, mean differences of 1.44 points were recorded between baseline (mean = 6.00, SD = 2.10) and post-treatment assessment (mean = 7.44, SD = 2.58).

3.6.4 Effect sizes and evaluation of the experimental hypotheses following ITT analysis

Treatment effect sizes were calculated using Cohen's d statistic (Cohen, 1988). Effect sizes relating to primary and secondary outcome measures are presented in Table 14, along with an evaluation regarding the experimental hypotheses as defined previously. It can be seen that the mean differences in scores for completers at pre- and post-treatment assessment in respect of the mindfulness measures (FMI, MAAS) amounted to large effect sizes (d = 0.71 and d = 0.82 respectively). A medium effect size was noted for the PQoL (d = 0.47) with medium effect sizes also noted for two of the six subscales on the MSES-R (Emotional Regulation, d = 0.63; Taking Responsibility, d = 0.61). Finally, a small effect size was noted for the subscale relating to Interpersonal Effectiveness (d = 0.22).

Table 14. Effect sizes, confidence intervals and evaluation of experimental hypotheses following Intention-to-treat (ITT) analysis (n= 16).

Primary outcome measures		**Cohen's d**	**95% CI**	**Decision**
Mindfulness	FMI	0.71	-8.18 and -1.44	Experimental hypothesis confirmed
	MAAS	0.82	-1.00 and -0.14	Experimental hypothesis confirmed
Secondary outcome measures				
Self-Efficacy	MSES-R			
Subscales	Emotional Regulation	0.63	-5.78 and -1.34	Experimental hypothesis confirmed
	Taking Responsibility	0.61	-2.60 and -0.27	Experimental hypothesis confirmed
	Interpersonal Effectiveness	0.22	-1.88 and 0.76	Experimental hypothesis rejected
	Social Skills	0.15	-1.26 and 0.51	Experimental hypothesis rejected
	Equanimity	0.07	-1.26 and -1.63	Experimental hypothesis rejected
	Distress Tolerance	0.04	-1.52 and 1.77	Experimental hypothesis rejected
Quality of Life	PQoL	0.47	-1.09 and 0.19	Experimental hypothesis confirmed

3.7 Correlational analyses

Given that the results of the analyses appeared to confirm the intervention hypothesis, it was considered useful to establish to what extent the outcome measures used in the current study potentially tapped into similar, or indeed different, aspects of the psychological variables of interest. To this end, it was decided to undertake correlational analyses to explore these relationships.

3.7.1 Primary outcome measures: mindfulness (FMI and MAAS)

Spearman's rho indicated that the FMI and MAAS measures of mindfulness were not correlated with each other in respect of the participants' mean scores. This held for baseline assessment (r_s = .09, n = 22, p = .34) as well as post-intervention for treatment completers (r_s = .07, n = 12, p = .41). Associated scatterplots for the correlational analyses were constructed and are also shown in figs. 21 and 22 respectively. This would appear to suggest that the FMI and MAAS tap into quite distinct components of mindfulness, with the former appearing to be a more 'general' measure of mindfulness, whilst the latter appears to capture aspects of mindfulness related to attentional focus and awareness of mental, physical and sensory experience.

3.7.2 Secondary outcome measures: self-efficacy (MSES-R)

Similarly to the primary outcome measures, it was considered useful to examine to what extent the two subscales of the MSES-R hung together in terms of their purported operational constructs of self-efficacy. Spearman's rho indicated that there was a moderate positive correlation between the Emotional Regulation and Taking Responsibility subscales of the MSES-R pre-intervention (r_s = .52, n = 22, p = .007) which was statistically significant. Post-intervention, however, Spearman's rho indicated a weaker correlation between the subscales (r_s = .33, n = 12, p = .15) which was not significant.

3.7.3 Secondary outcome measures: quality of life (MSES-R and PQOL)

An analysis of the relationship between the MSES-R self-efficacy subscales of interest and the quality of life measure (PQoL) was also conducted. Spearman's rho indicated a modest correlation between the Emotional Regulation subscale and the PQoL at baseline (r_s = .42, n = 22, p =.026) which was statistically significant. However, post-intervention, this correlation

was weaker (r_s = .28, n = 12, p =.19) and was not statistically significant. As regards the Taking Responsibility subscale, Spearman's rho indicated no correlation between the variables either pre-intervention (r_s = .02, n = 22, p = .47) or post-intervention (r_s = .12, n = 12, p = .36).

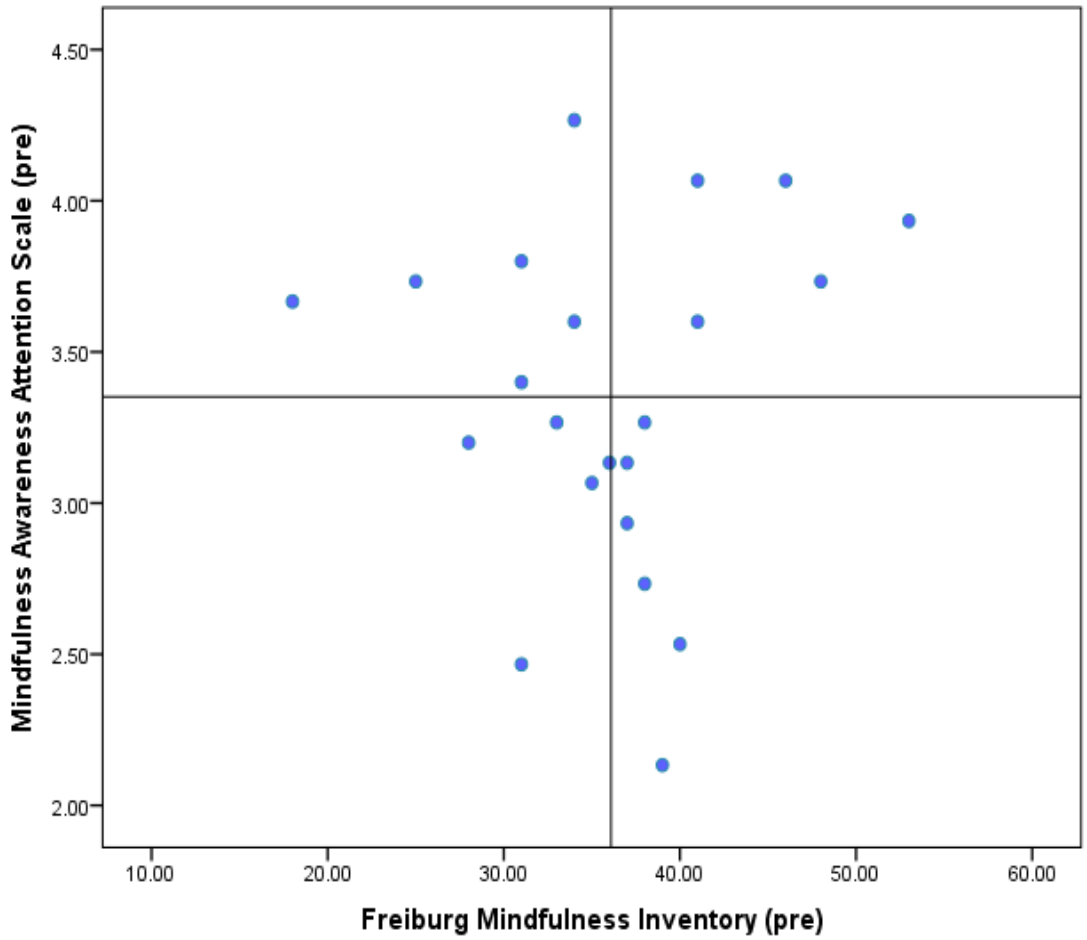

Fig. 21: Scatterplot showing correlational analysis of primary outcome measures (FMI vs. MAAS) at baseline assessment. Intersecting lines for the x- and y-axes indicate mean scores for each measure.

These results would appear to suggest that there is a relationship between the Emotional Regulation subscale of the MSES-R and the PQoL, and therefore it could be tentatively surmised that aspects of self-efficacy which relate to an ability to recognise, understand and manage difficult or uncomfortable emotional experiences appropriately may be correlated with participants' perceived quality of life.

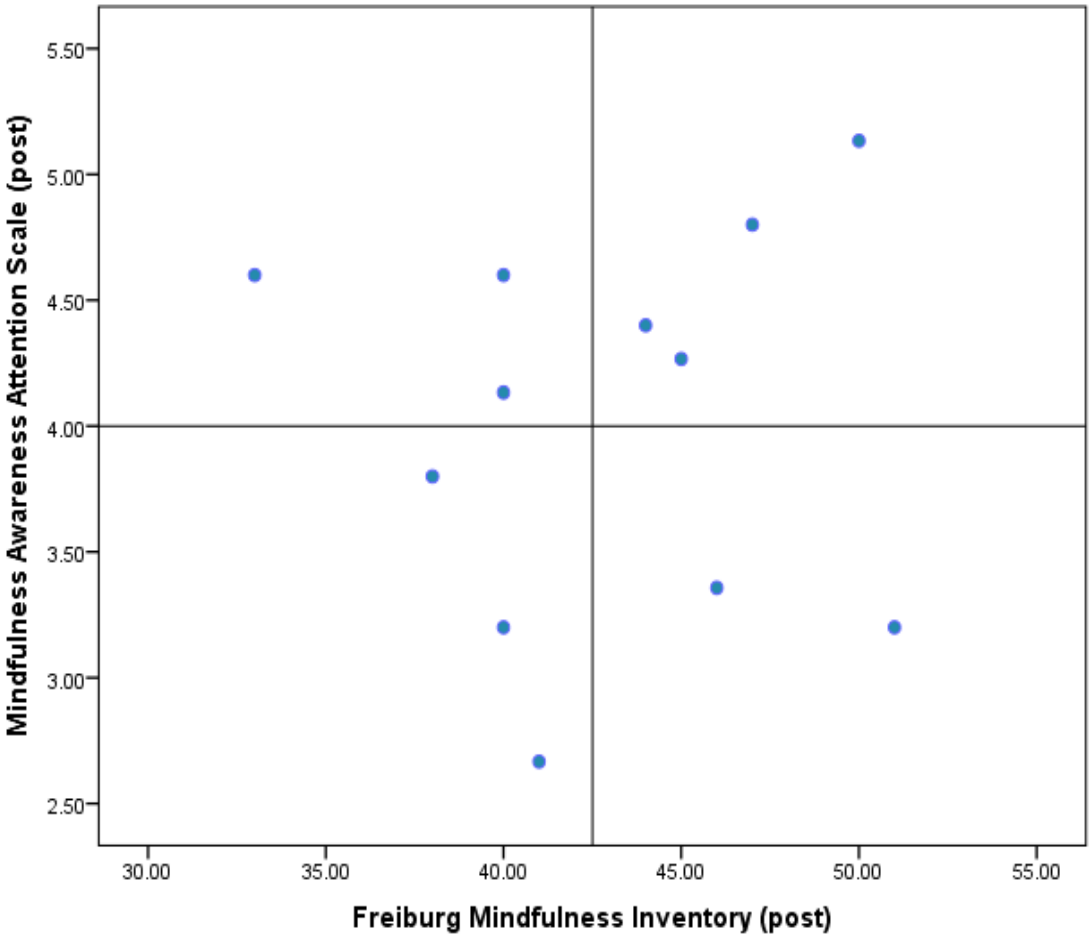

Fig. 22: Scatterplot showing correlational analysis of primary outcome measures (FMI vs. MAAS) post-intervention. Intersecting lines for the x- and y-axes indicate mean scores for each measure.

3.8 Analysis of gain scores

In light of the intervention hypotheses, which predicted that an increase in mindfulness skills (as defined and measured by the FMI and MAAS) would bring about improvements in participants' self-reported self-efficacy and perceived quality of life (as defined and measured by the MSES-R and PQoL respectively), it was important to explore the inter-individual differences in gain scores resulting from the MBI under evaluation in order to understand more fully the potential mechanisms of change involved in these improvements.

To this end, it was decided to further explore that to what extent the improvement in the latter scores could be reliably attributed to gains in the former. Additional correlational

analyses were conducted. In order to explore the relationship between mean differences and gain scores on the mindfulness measures and those variables associated with self-efficacy and quality of life, additional correlational analyses were conducted between these scores for treatment completers (n = 12). Table 15 presents the main descriptive statistics for the gain scores in respect of the variables of interest.

Table 15. Gain scores for selected variables of interest: descriptive statistics (n = 12).

Measure	Mean	Median	Minimum	Maximum	Std. Deviation	Skewness	Kurtosis
FMI	**6.42**	**6.50**	**-6.00**	**15.00**	**6.58**	**-.32**	**-.68**
MAAS	**.76**	**.83**	**-.60**	**2.20**	**.86**	**.04**	**-.89**
MSES-R: ER[1]	**4.75**	**6.00**	**-2.00**	**9.00**	**4.18**	**-.70**	**-1.03**
MSES-R: TR[2]	**1.92**	**2.00**	**-1.00**	**6.00**	**2.35**	**.32**	**-1.08**
PQoL	**.86**	**.79**	**-.32**	**2.63**	**.88**	**.56**	**-.09**

[1] *Emotional Regulation subscale.* [2] *Taking Responsibility subscale.*

It can be seen from the table that the FMI gain scores appeared to be more widely distributed than the other measures. Of particular note are the relatively small distribution patterns of the MAAS and PQoL gain scores.

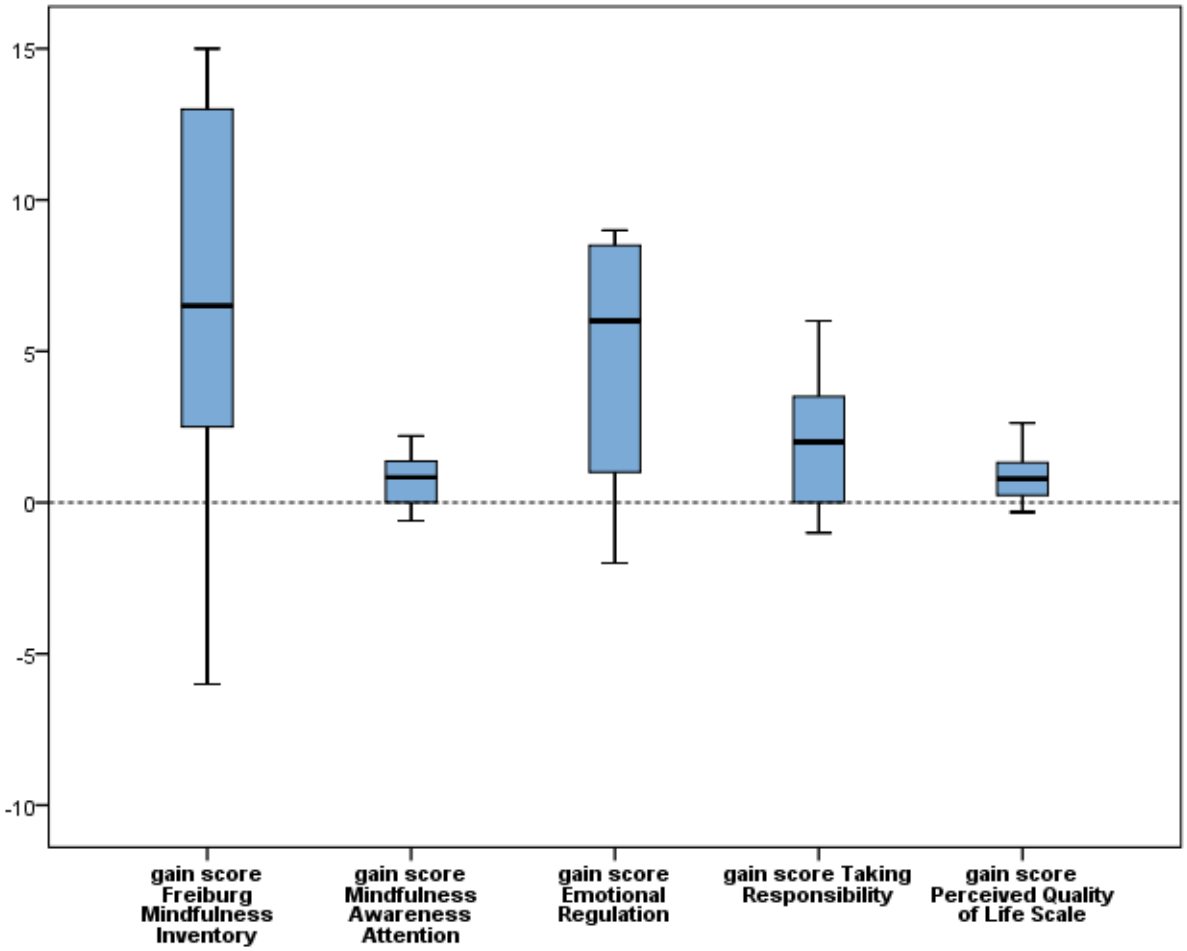

Fig. 23: Boxplots showing distribution of gain scores across primary and secondary outcome measures of interest (n = 12).

As can be seen from the above set of boxplots, the respective distributions of the gain scores for the variables of interest appear relatively normal. Median gain scores were higher for the FMI (6.5 points and the Emotional Regulation subscale of the MSES-R (6.00 points)

3.8.1 Gain score analysis for FMI and MAAS

In respect of the two primary outcome measures of mindfulness, Spearman's rho indicated that there was a weak-to-moderate positive relationship associated with gain scores on the FMI and the MAAS (r_s = -.33, n = 12, p = .14) which did not approach statistical significance.

3.8.2 Gain score analysis for FMI and MSES-R subscales of interest

Scatterplots relating to the gain scores in respect of the FMI mindfulness measure and the MSES-R subscales representing Emotional Regulation and Taking Responsibility are presented in figs. 24 and 25. It is perhaps worth noting that one participant did not appear to have shown improvements across either measure.

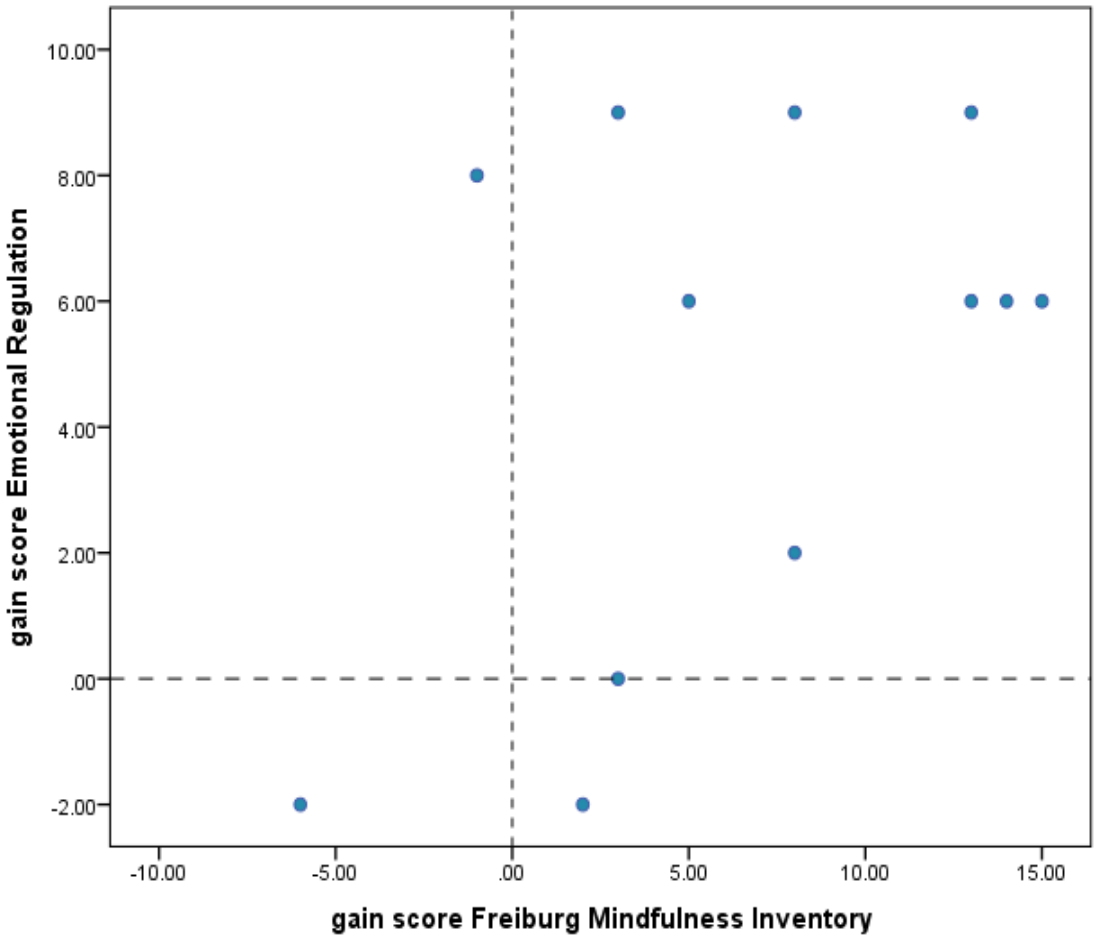

Fig. 24: Scatterplot showing correlational analysis of gain scores between the FMI and Emotional Regulation subscale of the MSES-R measure.

Spearman's rho indicated that there was a weak positive relationship associated with gain scores in respect of the FMI and the Emotional Regulation subscale of the MSES-R (r_s = .34, n = 12, p = .14) and a similarly weak positive relationship associated with gain scores on the Taking Responsibility subscale (r_s = .30, n = 12, p = .17).

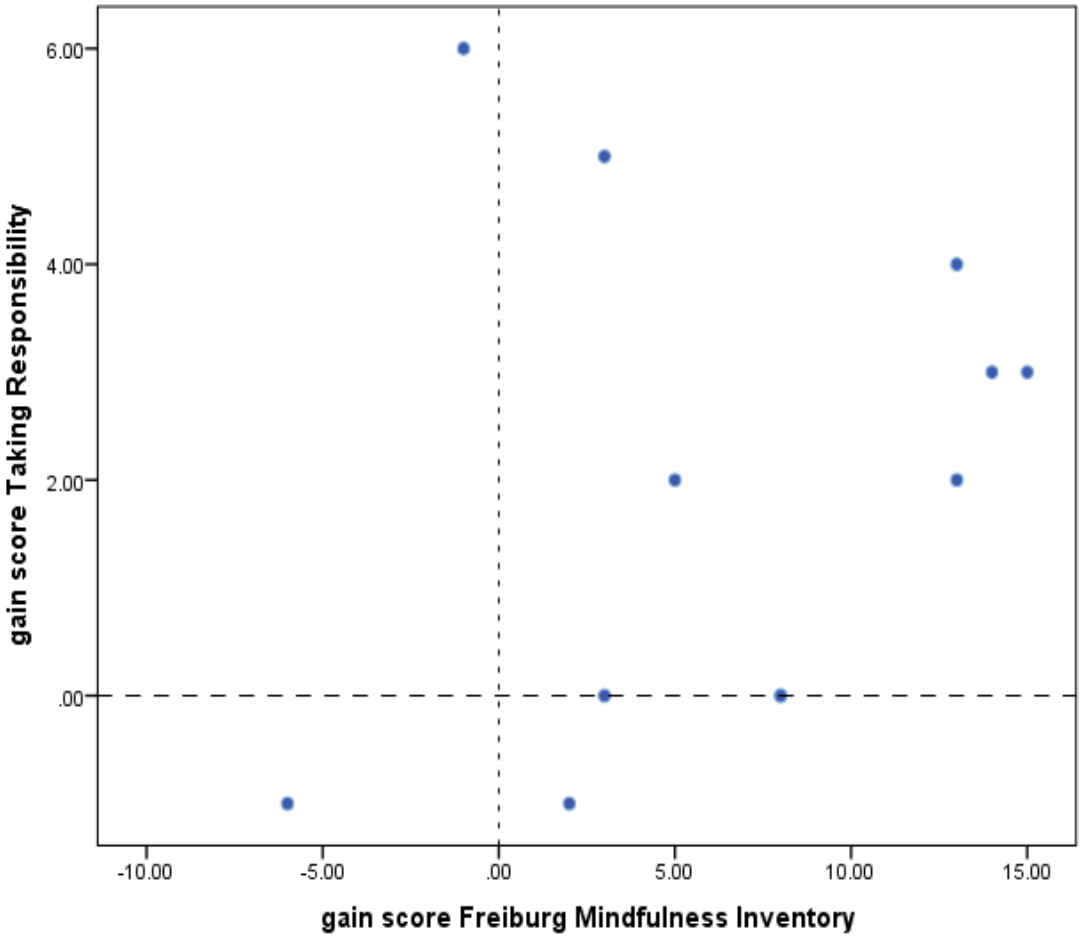

Fig. 25: *Scatterplot showing correlational analysis of gain scores between the FMI and Taking Responsibility subscale of the MSES-R measure.*

3.8.3 Gain score analysis for MAAS and MSES-R subscales of interest

Scatterplots relating to the gain scores in respect of the MAAS mindfulness measure and the MSES-R subscales representing Emotional Regulation and Taking Responsibility are presented in figs. 26 and 27 respectively. Again, it is worth noting that in the case of one participant, scores did not improve across either variable.

Spearman's rho indicated that there was a moderately positive relationship associated with gain scores in respect of the MAAS and the Emotional Regulation subscale of the MSES-R (r_s = .49, n = 12, p = .049) which was statistically significant. A moderately positive relationship associated with gain scores on the Taking Responsibility subscale was also noted (r_s = .48, n = 12, p = .058) which approached statistical significance.

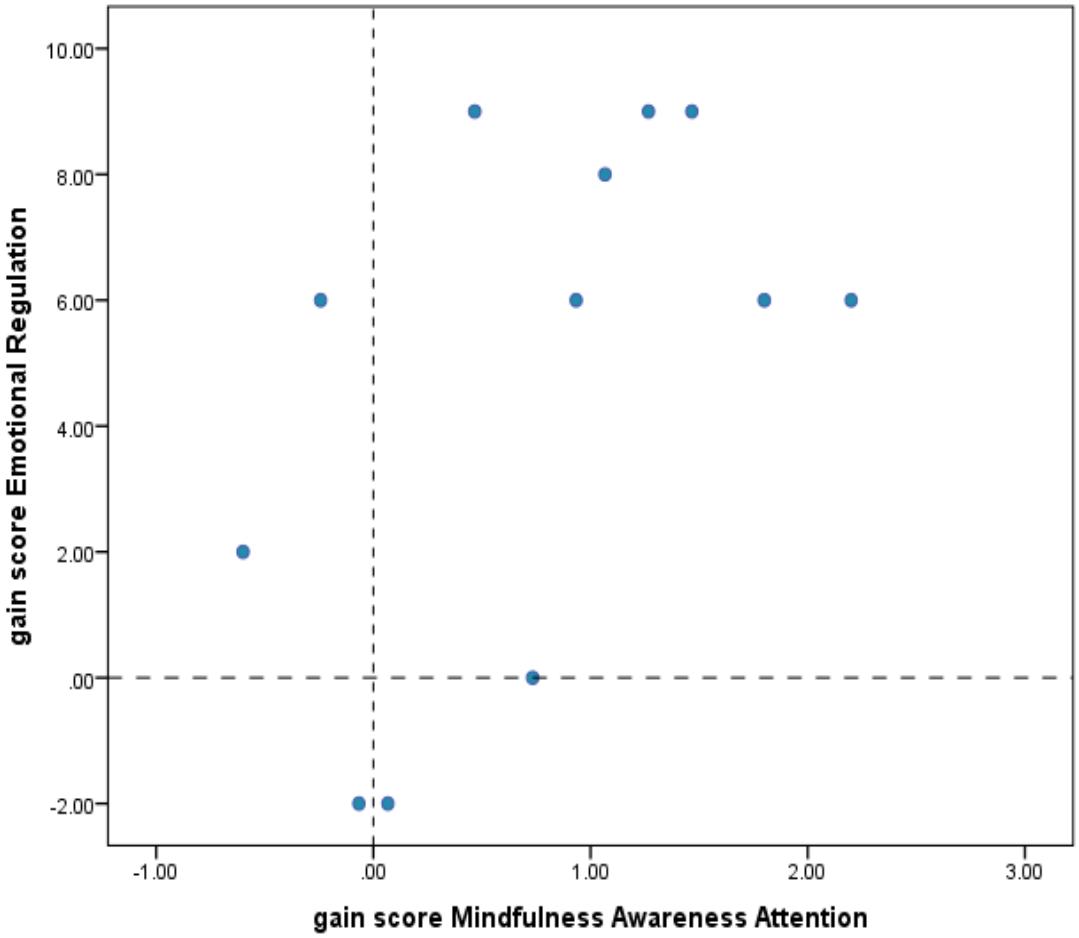

Fig. 26: *Scatterplot showing correlational analysis of gain scores between the MAAS and Emotional Regulation subscale of the MSES-R measure.*

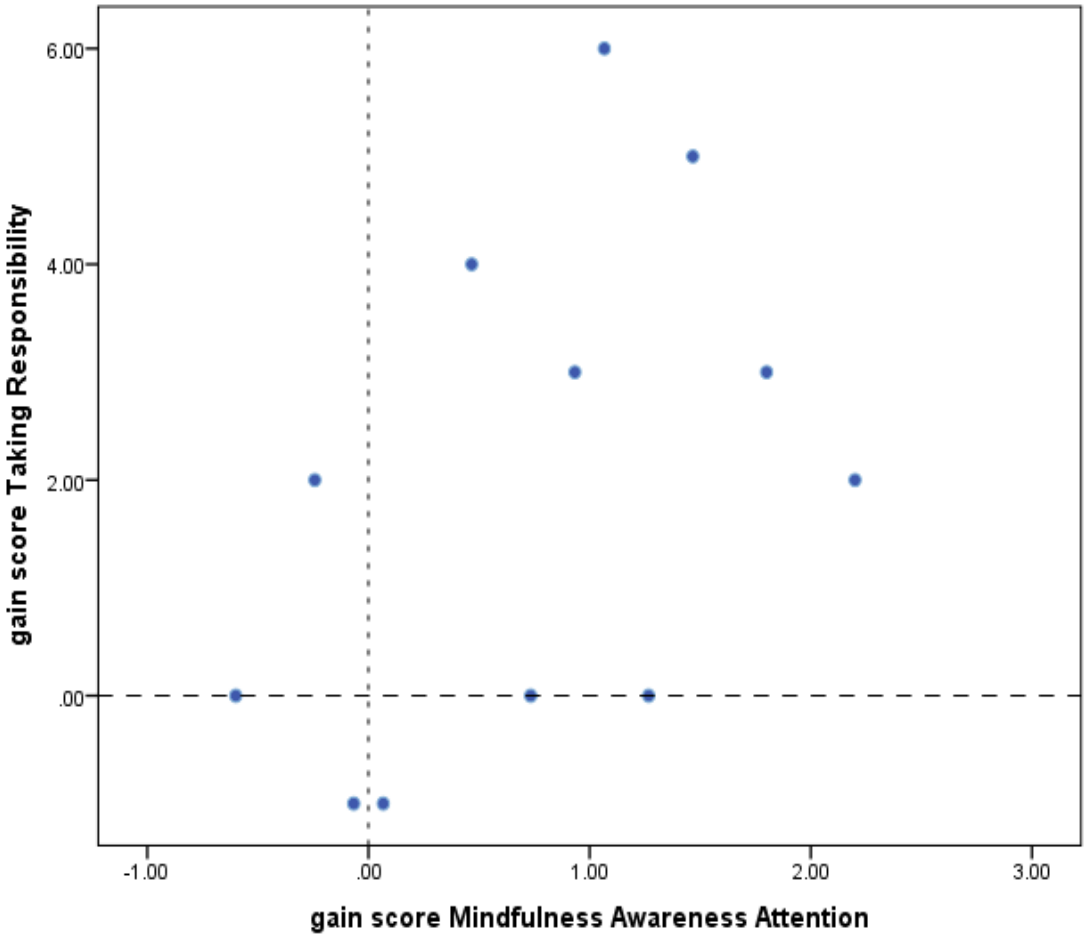

Fig. 27: *Scatterplot showing correlational analysis of gain scores between the MAAS and Taking Responsibility subscale of the MSES-R measure.*

3.8.4 Gain score analysis for primary outcome measures and PQoL

Scatterplots relating to the gain scores in respect of each of the primary outcome measures and the PQoL (quality of life) are presented in figs. 28 and 29 respectively. Again, it is worth noting that in the case of one participant, scores did not improve across either variable in respect of the MAAS.

Spearman's rho indicated that there was a weak positive relationship associated with gain scores in respect of the FMI and the PQoL measure (r_s = .24, n = 12, p = .22). As regards the MAAS, a moderately strong positive relationship associated with gain scores on the PQoL was noted (r_s = .59, n = 12, p = .021) which was statistically significant.

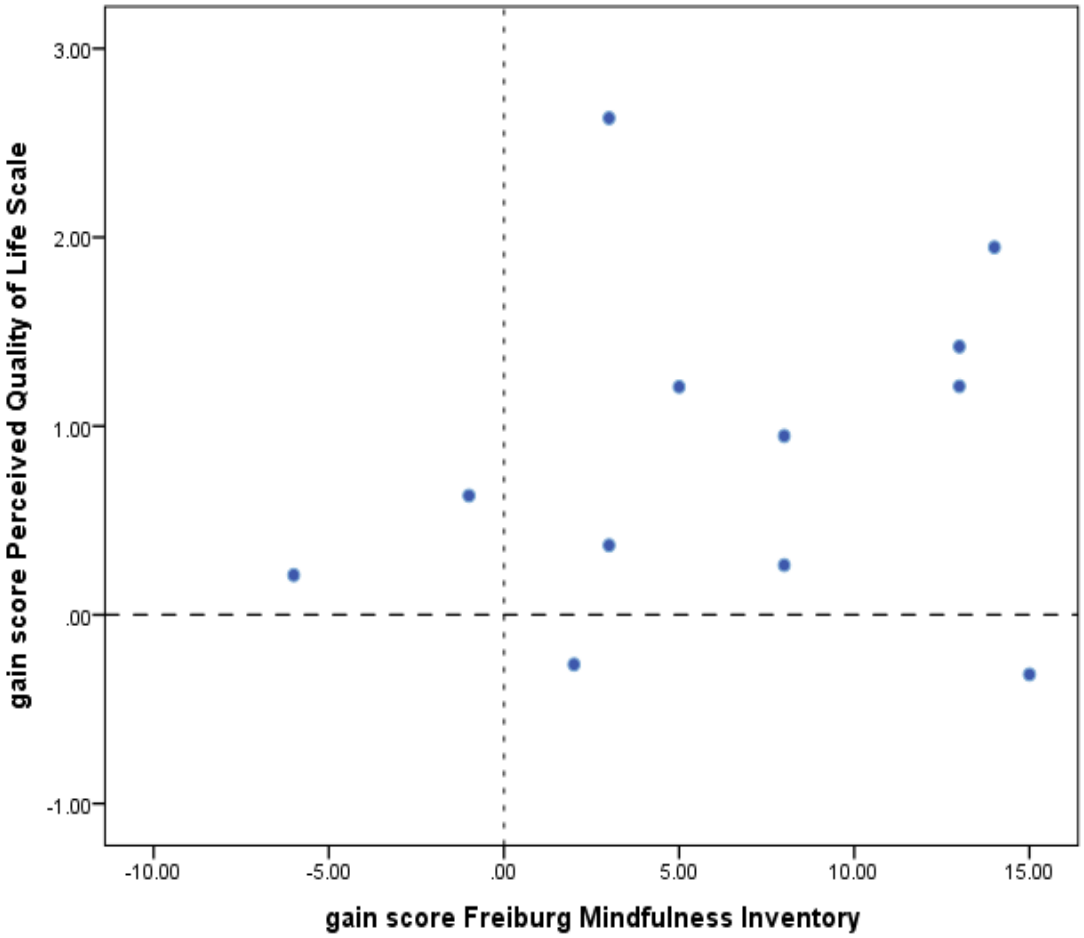

Fig. 28: *Scatterplot showing correlational analysis of gain scores between the FMI and Perceived Quality of Life (PQoL) measure.*

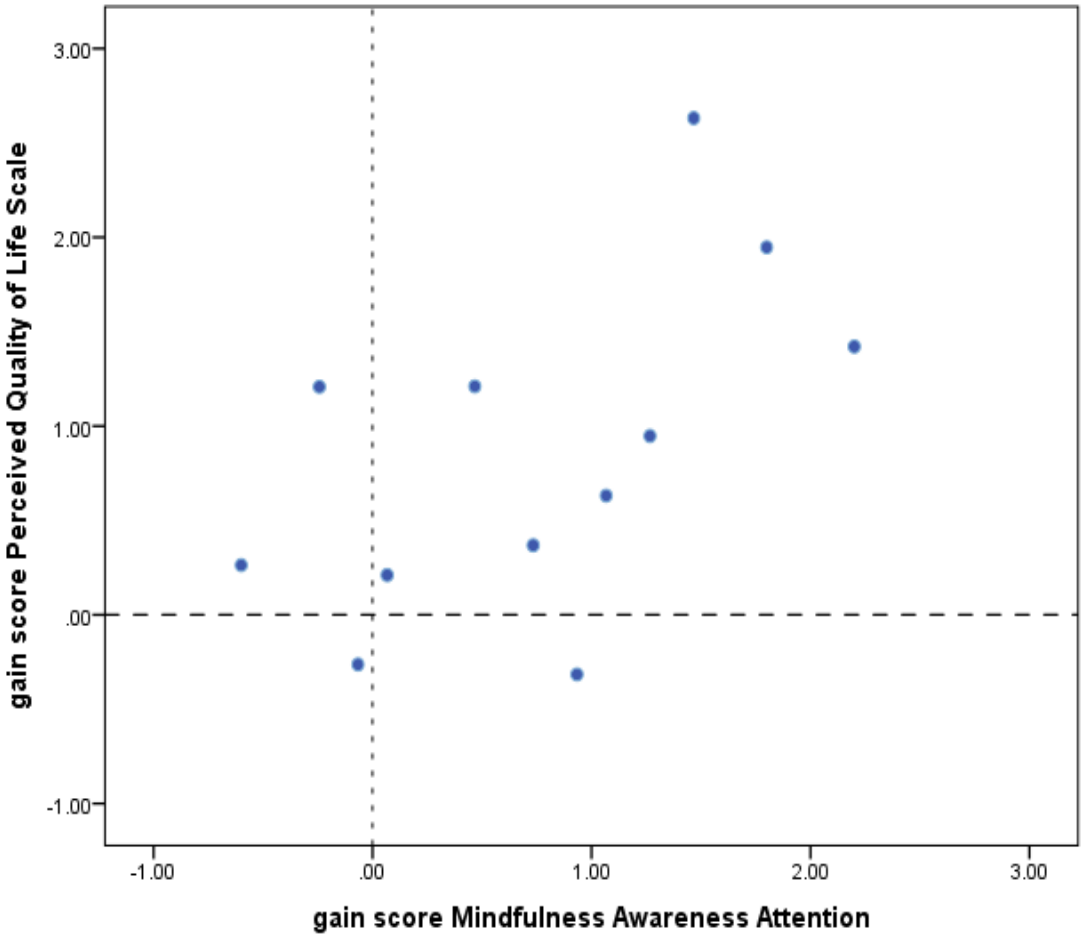

Fig. 29: *Scatterplot showing correlational analysis of gain scores between the MAAS and Perceived Quality of Life (PQoL) measure.*

3.9 Brief synopsis of results

- Compared to a wait-list control (WLC) group, significant differences in mean scores for the intervention group across the FMI and 3 of the 6 subscales for the MSES-R would appear to suggest the effectiveness of the MBI in question, with large effect sizes noted in respect of these
- Significant differences in mean scores pre- to post-intervention would appear to suggest that MBI in question is clinically effective in improving individuals' trait and dispositional mindfulness skills (for both primary outcome measures – FMI and MAAS)

- Significant differences in mean scores pre- to post-intervention as regards 2 of the 6 subscales within the self-efficacy secondary outcome measure (MSES-R; constructs relating to Emotional Regulation and Taking Responsibility) appear to suggest that the MBI in question was effective in bringing about clinical improvements in these areas
- Significant differences in mean scores pre- to post-intervention in respect of the secondary outcome measure related to health-related quality of life (PQoL) appear to suggest that the MBI in question was effective in bringing about clinical improvements in participants' perceived quality of life
- Large treatment effect sizes were noted in respect of the FMI and MAAS (d = 0.98 and d = 1.20 respectively)
- Similarly, large treatment effect sizes were noted in respect of the Emotional Regulation and Taking Responsibility subscales of the MSES-R (d = 0.86 and d = 0.92 respectively)
- A medium treatment effect size was noted in respect of the PQoL (d = 0.61)
- These findings held when treatment non-completers were taken into account and results were analysed via an Intention-to-treat (ITT) analysis (n = 16)
- Further correlational analyses revealed that the primary outcome measures of interest appeared to tap into very different aspects or constructs associated with mindfulness (i.e., there appeared to be very little overlap in terms of the components of mindfulness each measure purported to reflect)
- An analysis of gain scores on the FMI and MAAS in respect of the secondary outcome measures (for which a significant difference was noted) revealed a moderately strong relationship between the MAAS and the 2 subscales of the MSES-R as well as the PQoL which was statistically significant
- This would appear to suggest that improvements in mindfulness skills associated with awareness and attention (as measured by the MAAS) increased participants' ability to regulate their emotions and take responsibility (as measured by the MSES-R) and brought about an increase in their perceived quality of life (as measured by the PQoL).

4. Discussion

4.1 Outline of discussion section

The present study sought to evaluate the effectiveness of a recently instituted, modified, non-manualized, short-form Mindfulness-based intervention (MBI) with a mixed clinical population presenting with ABI or chronic neurological conditions (MS, PD). The intervention was delivered in a group format in a community neuro-rehabilitation setting. More specifically, the study was interested in ascertaining whether the MBI in question would bring about reliable clinical improvement in psychometric measures associated with increased mindfulness skills (FMI, MAAS) and whether as a result of these improvements, these were predictive of improvements in measures relating to self-efficacy (as measured by the MSES-R) and health-related quality of life (as measured by the PQoL).

This chapter is divided into three main areas. Firstly, the essential findings in relation to the experimental hypotheses, along with additional associated analyses, are summarized and interpreted. These are discussed in comparison to the published research literature. Findings are discussed in the context of possible implications of the present study as regards its clinical relevance. Secondly, study limitations and methodological issues are discussed, with an emphasis on continuing debates concerning the definitions, operationalization and psychometric properties of mindfulness. Lastly, in view of these considerations, potential future directions for research are discussed and preliminary conclusions from the study are drawn.

4.2 Overview of results: main findings

4.2.1 Participants: clinical and socio-demographic characteristics of the sample

It is evident from the participant dataset for the whole sample (n = 22) that the vast majority of participants in this study were women (86.4%), with over half of the sample having a diagnosis of MS (54.5%), and equal numbers of participants with a diagnosis of PD or an ABI (18.2% in each group) Overall, neurological conditions represented over 80% of the total sample. This is not particularly unusual in itself, given the higher prevalence amongst women

in the general population for certain neurological conditions (estimates concerning the female-male ratio for MS in the UK are approximately 2:1). This may also appear to reflect a commonly held belief regarding the purported tendency for women to report psychological difficulties or indeed present to services more readily than men.

In socio-demographic terms, the total sample could be considered relatively homogeneous, if ethnicity (all participants identified themselves as White British), age distribution, marital status and occupational functioning are taken into account (although there did appear to be a higher percentage of the sample who at the time of assessment were not in employment). However, it would have been perhaps useful to explore the relationships between these variables and outcome data in order to understand whether particular factors were in some way predictive of clinical improvements or otherwise.

4.2.2 Evaluation of research hypotheses: comparison to controls

Hypothesis (1): The adapted MBI under investigation will lead to increases in mindfulness, self-efficacy and quality of life, and so the intervention group will report higher means on relevant outcomes measures at the end of the MBI training in comparison to a wait-list control group.

Mean scores across all outcome measures for the initial intervention group at post-intervention were compared against corresponding baseline scores for the control group (group 3). Results revealed statistically significant improvements in the former in respect of the FMI mindfulness measure, as well as three of the six subscales of the MSES-R self-efficacy measure (Emotional Regulation, Equanimity and Taking Responsibility respectively). A calculation of effect sizes revealed large or very large effects for the above variables as well as for health-related quality of life (ranging from Cohen's d = 0.71 to 1.76). The research hypothesis was therefore confirmed.

4.2.3 Primary outcome measures: improvements in measures associated with mindfulness

Hypothesis (2): The MBI training will lead to significant improvements in mindfulness skills which, in turn, will produce beneficial effects on self-efficacy and quality of life. It is therefore predicted that the means on relevant outcome measures will be higher at the end of the MBI training relative to the means at baseline assessment.

An initial analysis of data available for participants from the first two groups (for which post-intervention scores were available; n = 12) found that participants exhibited statistically significant improvements in mean score differences relating to the primary outcome measures associated with mindfulness (FMI and MAAS) at post-intervention compared to baseline assessment. Treatment effect sizes were computed accordingly and results indicated large effect sizes for each measure. This clearly appears to provide evidence that the intervention was effective and produced considerable benefits in terms of mindfulness skills training and acquisition. The research hypothesis was therefore confirmed.

An Intention-to-treat (ITT) analysis was conducted to take into account participants who dropped out of the study, declined or did not complete assessments at post-intervention (n = 4). For these cases, the data were analysed using participants' baseline scores. Differences in mean scores were also found to be statistically significant for both the FMI and MAAS. Treatment effect sizes, whilst understandably smaller than the preliminary analysis, remained nonetheless large. This would further appear to support and confirm the research hypothesis. The effect sizes noted would seem consistent with, but suggest larger treatment effects, to similar studies in the current literature (see Azulay *et al*., 2013 for a similar recent study).

4.2.4 Secondary outcome measures: improvements in measures associated with self-efficacy and health-related quality of life

It was hypothesised that changes in respect of the secondary outcome measures employed in the study, which were associated with self-efficacy (MSES-R) and health-related quality of life (PQoL), would be contingent on changes in mindfulness (i.e. acquisition of mindfulness skills as measured by the FMI and MAAS). In line with this, analysis of the data revealed that mean scores pre- to post-intervention improved in two of the self-efficacy subscales

(concerned with Emotional Regulation [ER] and Taking Responsibility [TR] respectively) at a statistically significant level. Mean scores improved in a further two subscales (namely Social Skills and Interpersonal Effectiveness), however were not found to be statistically significant. In contrast, however, mean scores decreased in subscales associated with variables pertaining to distress tolerance and equanimity. A calculation of effect sizes indicated large effect sizes in respect of the ER and TR subscales of the MSES-R.

With respect to the quality of life measure (PQoL), an analysis of the data indicated statistically significant differences in mean scores post-intervention in the expected direction as proposed by the intervention hypothesis. A moderate effect size was observed.

As per the analysis undertaken with the primary outcome measures, an ITT analysis of the secondary outcome measures (n = 16) revealed statistically significant improvements in scores from baseline to post-intervention in regards to the ER and TR subscales of the MSES-R self-efficacy measure. Similarly, the ITT analysis indicated statistically significant improvements from pre- to post-intervention for the PQoL measure.

Moderate to large effect sizes were noted for the ER and TR self-efficacy variables, with a moderate effect size observed for the PQoL measure. Again, these were consistent with the recent literature (Bédard *et al*., 2003; 2005; Grossman *et al*., 2004; Azulay *et al*., 2013) and the findings provide further evidence for the effectiveness of the MBI in question in terms of improving patients' self-reported levels of self-efficacy in at least two distinct domains as well as their perceived quality of life.

4.3 Overview of additional analyses

4.3.1 Correlational analysis of primary outcome measures

In order to determine to what extent the outcome measures outlined above tapped into similar or distinct constructs, it was decided to conduct non-parametric correlational analyses (Spearman's *r*) in order to further examine the relationship between the two primary outcome measures as well as the secondary outcome measures. In terms of the FMI and MAAS, both at baseline and post-intervention, the analysis indicated no correlation between the measures. This appeared to suggest that the FMI and MAAS captured quite

different aspects of mindfulness as conceptualised by current research. Indeed, in psychometric terms, the FMI is considered a global measure of mindfulness, whilst the MAAS (as the name would suggest) emphasises components associated with attentional focus and awareness of moment-to-moment experience.

4.3.2 Correlational analyses of secondary outcome measures

Correlational analyses in respect of the ER and TR subscales of the MSES-R measure indicated a moderate positive association between these variables at baseline which was statistically significant. However, this association, whilst still positively correlated, was somewhat weaker at post-intervention and did not approach significance. An analysis of the potential relationship between the aforementioned MSES-R subscales and the PQoL measure revealed a modest association between the ER subscale and PQoL at baseline which was statistically significant, but which did not hold at post-intervention. The TR subscale did not appear to be correlated with the PQoL either pre- or post-intervention.

4.3.3 Gain score analysis

Given the initial findings providing preliminary evidence for the effectiveness of the MBI under evaluation, it was deemed useful to further analyse the individual gain scores in order to explore to what extent the size of improvements in self-efficacy and quality of life might be related to, and explained by, corresponding sizes of improvement in mindfulness skills as observed. According to this analysis, a median improvement of 6 points or over was observed on the FMI and ER measures, with smaller improvements noted for the MAAS, TR and PQoL.

An initial gain score analysis of the FMI and MAAS revealed a modest correlation between the two measures. This is an interesting finding when one considers that the preliminary correlational analysis conducted in respect of these two measures did not suggest an association between them. Further analyses in respect of gain scores on the FMI and MAAS as compared to the MSES-R and PQoL revealed a somewhat mixed picture, but three findings are noteworthy. It appears that the MAAS gain scores are positively correlated with

both the ER and TR subscales of the MSES-R, and that these relationships approach, or are statistically significant. A stronger relationship was noted in respect of MAAS and PQoL gain scores.

4.4 Interpretation of findings

In line with the recent literature, the results from this study would appear to broadly confirm the effectiveness of the MBI in question for the population evaluated in the current study. Despite some limitations, it could be surmised that the present research has contributed to the literature and evidence base which suggests that an adapted MBI provides demonstrable clinical benefits to this population with regards to measures of self-efficacy (i.e., participants' beliefs about being able to respond to and cope with the challenges of their diagnosis or condition and associated difficulties), specifically those concerned with regulating emotions and taking responsibility for the reactions and responses to one's difficulties.

The findings also appear to point to participants' registering a higher sense of satisfaction and consequent improved quality of life as a result of the intervention. These findings appear to support other studies which have examined this construct with similar populations (e.g., Bédard *et al*., 2003, 2005; Cicerone and Azulay, 2007), albeit employing different psychometrics to evaluate this. For example, Flugel Colle *et al*. (2010) reported a statistically significant improvement in overall quality of life and across specific domains of well-being (e.g., physical, mental, emotional and social activity) as a result of individuals with chronic conditions attending an MBSR programme.

There are a number of possible interpretations which may be drawn from the findings. The large treatment effect sizes which were observed in terms of the primary outcome measures (mindfulness) would appear to suggest that participants' training in mindfulness skills increased significantly as a result of the MBI. Perhaps more importantly, these increases appeared to directly influence and engender, to an extent, clinical benefits in terms of increased emotional regulation and taking responsibility within the context of self-efficacy. Additionally, clinical benefits were noted in terms of improved self-reported quality of life.

In speculating on what psychological processes or mechanisms might have brought about these benefits, it is perhaps useful to bear in mind the various theories and

conceptualisations concerning mindfulness' purported properties. Given that participants were all sufferers of chronic health conditions, with uncertain prognoses and a sense of lack of control over this, the opportunity to acquire new skills and mastery in a set of practical techniques to manage the psychological and emotional impact of their conditions may have brought about a perception of increased self-efficacy. This in turn may have had a further effect on their perceptions of how satisfied they may have felt in certain aspects of their lives. This appears to be reminiscent of the transactional theory and model of stress appraisal by Lazarus and Folkman (1984) which postulates that an individual's resources and perceived ability to cope are the drivers and mediators in the appraisal and subsequent response to stressors. A possible explanation for the present study's findings may be rooted in this ability having been developed or enhanced to an extent via the MBI.

From a psychological perspective, and perhaps connected to the idea of re-appraisal, within the intervention itself and the various exercises contained therein, the emphasis on developing an awareness of mental and sensory experiences in a manner which fostered a more detached perspective on these experiences so as to bring about what in the literature Carmody *et al*. (2009) and Shapiro *et al*. (2006), amongst others, have denoted as "re-perceiving" (i.e., a re-appraisal of distressing events) may have also contributed to an increased sense of self-efficacy in terms of an improved capacity for self-regulation and emotional control. This would also appear to be linked to the concept of *mental proliferation* as proposed by the BPM (Grabovac *et al*., 2011) and highlighted earlier, in which the practice of attention regulation appears to bring about an attenuation and interruption of this maladaptive process.

One cannot dismiss entirely the possible role of expectancy effects when considering the large treatment/training effect sizes observed in the first group in comparison to controls. There may have been a degree of enthusiasm among participants in terms of their receiving the intervention. Conversely, there is a possibility that those assigned to the control group may have experienced a sense of disappointment which may well have mitigated against otherwise spontaneous improvements over time.

It is also difficult to isolate the precise mechanisms of action or specific techniques that may account for the improvements seen. Other aspects of the group besides the mindfulness practices, such as the opportunity to take an active role in their own self-management,

social support, the normalisation of their difficulties with others, or cognitive techniques, may also have exerted beneficial effects. It is worth bearing in mind that the strong effect sizes noted in the study emerged despite variations in participants' attendance of individual sessions.

However, these interpretations remain speculative to an extent, and some caution must be exercised in terms of generalising findings in view of the study's limitations, methodological considerations and the specific format of the intervention under evaluation. These considerations merit further discussion and are set out later in this section.

4.5 Clinical relevance and implications

It is clear that psychological difficulties are common among populations adjusting to life post-ABI or indeed diagnosis of a long-term or progressive neurological condition, and that these may be overlooked. The quantitative literature continues to support and bear this out increasingly, and recent qualitative research in the area of ABI is also indicating this (e.g., Bamford, 2008). Thus the evidence base is growing exponentially in this area. Research with other populations is already influencing service and policy development, with some MBIs (e.g. MBCT) already included in clinical guidelines for the treatment of specific mental health or psychiatric disorders such as recurrent depression (NICE, 2009).

This would point to the increasing acceptability of MBIs across many settings and would appear to highlight their potential viability and benefit amongst populations with a variety of chronic health conditions. The promising results from the present study would appear to further support this view and it is hoped that in some way this might also contribute to the evidence base as regards future policy and guideline development in the neurological and neuropsychological arena. There is also an opportunity for the clinical psychology profession in developing a prominent role in terms of spearheading and developing MBI approaches with neurological populations and within neuropsychological services, influencing service organisation, development and delivery for ABI and neurological patients and informing future policy and clinical guidance. As mentioned earlier, the BPS has already published guidelines on this.

In practical and logistical terms, since MBIs are considered part of the "Third Wave" of cognitive-behavioural interventions, they may lend themselves more readily to manualization as well as to further adaptations or refinements, with interventions being specifically tailored to suit the needs of diverse populations, as was the case in the present study. This flexibility has potential benefits across a variety of service areas, not least in terms of service delivery (MBIs are equally applicable to group and individual therapeutic formats). The MBI evaluated in the present study did not appear to be harmful to participants (as further evidenced by anecdotal and written feedback via the evaluation forms) nor did the exercises and practices contained therein appear to be overly taxing or intensive for patients, with many providing informal feedback on the relative ease with which they were able to maintain the practices introduced between sessions. Integrating MBI approaches into long-term neuro-rehabilitation packages, self-management and care pathways as part of a more holistic approach to healthcare with this patient population (and in accordance with national clinical guidelines which increasingly emphasise and advocate for these approaches) would therefore also seem to be a relatively straightforward and safe practice.

In addition, there are potential financial implications to the adoption of MBIs with regards to neurological services. The need to find innovative and sustainable models of service for a population with long-term needs would appear vital in the current climate. With ever larger volumes of referrals, as well as improved prognoses and increased life expectancy within this population, group-based interventions such as MBIs, and in particular, briefer ones, as evaluated in the present study, may well be a cost-effective option in the long term (Segal, Williams and Teasdale, 2002). Furthermore, group-based interventions may provide psychosocial benefits in assisting patients to foster links and support amongst themselves (one participant discussed with others setting up a regular series of informal meetings with other members of the group in order to maintain mindfulness practice, share experiences and support each other). There may be a further role for clinical psychologists in facilitating this, and possibly in training professionals from other specialist disciplines to facilitate and deliver MBI programmes. Lastly, this study would suggest that MBIs may be offered as a potential adjunct to other types of therapeutic or rehabilitative interventions as well as concurrently with other conventional treatments.

4.6 Study limitations and suggested improvements or modifications

It is useful to consider both design limitations and potential methodological shortcomings in light of this study's findings, since in the first instance they may assist in the interpretation of findings in respect of validity and reliability. Secondly, they may prove useful indicators for future directions of research.

4.6.1 Statistical power of the study

Inadequate statistical power (mainly due to small sample sizes) is a major limitation of many MBI studies (Baer, 2003; Chiesa and Serretti, 2011). This could entail a threat to the external validity and therefore a lack of generalizability of findings. One limitation of this study was the small sample size, both in terms of the whole sample (i.e., the number of participants assessed at baseline, n = 22) and the sample for which the statistical analyses were conducted (within-groups comparison, n = 12; control group comparison n = 13; ITT analysis, n = 16). As mentioned previously, as per the original study design, an initial power calculation had indicated that a total sample size of N = 42 (21 in each group) was deemed necessary to detect a mean difference in mindfulness skills between the treatment and the control group. However, whilst the final sample size fell some way short of this, nevertheless large effect sizes were detected at both the between- and within-groups level of analysis.

4.6.2 Control group issues

This study used a small wait-list control (WLC) group. In order to perhaps draw firmer conclusions in respect of the hypothesis concerning changes in self-efficacy and quality of life being due to changes in mindfulness skills, a usual care (UC), larger wait-list control (WLC) or alternative treatment control arm may possibly have proven equally if not more robust. However it is perhaps worth noting that even in cases where an RCT design has been employed, only a small number of MBI trials could be deemed to be robust according to consolidated standards of reporting trials (CONSORT) guidelines (e.g., due to factors such as insufficient details for replication, an overall lack of transparency, absence of justification for sample sizes, etc.).

Whilst MBIs appear to have demonstrated much promise across an increasingly broad range of clinical settings and for a variety of psychological, physical and psychosomatic disorders and difficulties, questions do remain concerning the efficacy of such interventions. Indeed, in a preliminary analysis of 21 MBI studies, Baer (2003) found a mean effect size of 0.59 which, whilst superficially encouraging, nevertheless revealed a particular lack of methodological rigour in many cases.

4.6.3 Possible moderating variables within the sample regarding therapeutic benefits

Ethnicity: The sample identified itself in its entirety as White British. Whilst this is broadly representative of the local population from which the sample was drawn, this is certainly not the case for other areas in the UK, particularly large cities. This may have accounted for some of the group effects (i.e., participants may have experienced a sense of cohesion with some members identifying more readily with one another and gaining a sense of psychological support). An important consideration might be in terms of catering to more culturally or ethnically diverse groups, some of whom may have prior knowledge or exposure to similar practices – but this may also present a barrier to accessing such interventions.

Group effects: connected to the points made above, it was difficult to ascertain to what extent the improvements could be attributed to the MBI alone. Another limitation is the possible effect of participation in a group setting, which can have therapeutic effects (Yalom and Leszcz, 2005). However, it is noteworthy that other MBSR studies with control groups have shown that MBSR has positive effects beyond those attributable to participation in a group setting (Davidson *et al*., 2003, Tacon *et al*., 2003).

Female-to-male ratio: It is perhaps worth noting that the entirety of the first MBI group consisted of female participants, and it is possible that this may have impacted participants' ability to engage and to relate to each other. This may have indirectly caused a response bias to the intervention and subsequent reported benefits as recorded within the outcome measures. This aspect merits further consideration in terms of how future studies might control for this. It is likely that with large sample sizes available, and given that the gender

ratio in PD, for example, is considerably more equitable, this may enable the recruitment of more equal numbers of male and female participants.

Heterogeneity of sample: Given that the sample was mixed in terms of clinical presentations, it is perhaps important to consider individuals' rehabilitation trajectories and management of their respective chronic conditions. It was not possible to predict with any accuracy whether participants' physical or cognitive health might have deteriorated during the course of the study, and thus might account for non-attendance or attrition rates, or indeed impact responses to the outcome measures.

Clinical profile of participants: Very few MBI studies adequately control for potential confounding factors such as concurrent psychopharmacology, concomitant psychotherapy, and/or illness severity (Klainin-Yobas *et al*., 2012). As mentioned earlier, the course of MS and PD in particular are variable and unpredictable at best, as are recovery trajectories for ABI (e.g., stroke may present a much wider variation than other injuries), hence perhaps the difficulty in offering and monitoring psychological input to this client group. Also, it was unclear how many of the participants were on medication at the time of entering the study, and where this was not the case, whether their status changed during the course of the intervention. There may have also been a possible role due to effects and interactions of medication. This is an important issue to bear in mind. Given that first-line treatments for individuals with neurological conditions are frequently pharmacological in nature, perhaps the study could have included a brief questionnaire at assessment in order to ascertain the clinical characteristics of participants more comprehensively.

Dose-response effects: there was an indication that higher levels of attendance translated to larger self-reported improvements on outcome measures. Given that the first group ran according to plan, and the second and third groups encountered some unexpected scheduling issues (e.g. during Group 2, a session was cancelled due to adverse weather conditions), this may have also impacted on results. This needs to be borne in mind when interpreting findings and considering other possible factors contributing to observed treatment gains or lack thereof. It may have also been useful to conduct further analysis into dosage effects of the group intervention (i.e. to what extent might patterns of attendance have reliably predicted changes in outcome measures in the expected direction concerning the intervention hypotheses).

4.6.4 Lack of screening measures and follow-up

The lack of clinical information prior to recruitment also highlights further concerns in terms of the suitability of participants. The study did not adopt a specific protocol for screening participants in terms of their suitability for the MBI in question. Rather, it relied on the clinical judgements of referring professionals, which may or may not have included some form of clinical or neuropsychological assessment to determine this. The lack of screening measures pre-baseline assessment for all participants is an important consideration to be borne in mind, as screening may have highlighted any specific issues around cognitive or other impairments which may in turn may have impacted on participants' attendance, acceptability and/or reported improvements in relation to the intervention. It was also difficult to ascertain variations in participants' health status as they progressed through the study, and whether this may have also contributed to a response bias.

Similarly, due to time and resource constraints, it was not possible to follow participants up beyond the post-intervention phase in order to explore whether improvements were maintained over the longer term, especially since the intervention was of brief duration. The absence of a follow-up assessment, which appears to be increasingly used in mindfulness research, makes it difficult to provide a more robust interpretation of the encouraging findings as noted in this study.

4.6.5 Format of the intervention and treatment fidelity

The intervention evaluated in this study utilised an adapted, brief-session format which was loosely based on a typical MBSR programme. One possible consideration may be in respect of treatment fidelity (i.e., a non-manualized protocol) and duration and focus of intervention (4-session vs. 8-session model). Despite this study's strong findings, the question remains as to whether a 4-session model (consisting of one-hour sessions) is perhaps too brief and not sufficiently comprehensive for the cultivation and development of some of the more challenging practices which it is theorized lead to sustained clinical benefits over the longer term.

A further concern relates to the variations in credibility, expertise and competence of MBI facilitators (Shonin *et al*., 2013c). Whilst referring to the stream of mindfulness teachings

formulated by the likes of Kabat-Zinn (i.e., the teachings currently imparted by MBI instructors), Cullen (2011) states that MBIs are "*their own new lineage*" (p.186). Lineage is another important concept within Buddhism and essentially refers to the "authenticity" of Buddhist teachers. In addition to receiving direct instruction from an accomplished meditation teacher, authentic Buddhist masters generally undergo decades of daily focussed meditation training with the aim of relinquishing attachment to worldly concerns such as wealth, career or fame (Shonin *et al*., 2013a). This is in contrast to Western MBI instructors, who may have as little as a year's mindfulness experience following completion of a single 8-week course (Mental Health Foundation, 2010). Therefore, claims that MBIs constitute an authentic lineage in the traditional Buddhist sense may be considered somewhat unrealistic or spurious.

Additionally, data pertaining to participants' reported adherence to between-session practice was not elicited or collected for the purposes of this study, although within the context of each session, participants were encouraged to explore and discuss their practice with the facilitator. This was obviously difficult to monitor and control for given the nature of the intervention and participants not necessarily being required to complete "homework" or reporting perhaps higher levels of practice to what might in fact have been the case.

4.7 Further methodological considerations

4.7.1 Quantitative design

This study adopted a quantitative methodology, as this was considered a possibly more appropriate paradigm in which to provide more robust findings for the utility of MBIs with the sample population in question (Barker, Pistrang & Elliott, 2002). Moreover, the current quantitative research appears to have provided strong evidence for the effectiveness of MBIs. However, a qualitative element could perhaps have been more fully explored (e.g., semi-structured interviews with a selection of participants from each group, focus groups, or a specifically formulated evaluation questionnaire) and may have captured participants' views, experiences and perspectives on possible reasons for improvements or lack of perceived benefit of the MBI in question. This may have provided a richer and more subtle understanding of the mechanisms by which the intervention may have exerted its effects.

Alternatively, it may have also been useful to obtain qualitative feedback from carers or families in order to further elucidate and explain any findings and to shed light on perceived improvements from others' perspectives rather than relying on self-report from participants alone.

4.7.2 Selection of outcome measures

One potential point of discussion concerns the outcome measures selected in the present study, and how accurately they purported to measure what they aimed to measure. During the last decade, there has been a number of mindfulness measures developed, with a considerable degree of overlap in terms of their psychometric properties. One recent innovation in the field of neuro-rehabilitation has been the development and validation of the Neuro-QOL (Cella *et al*., 2012), which at the time of the present study being conducted, was not able to be employed. Preliminary validation studies suggest that this may be a more sensitive psychometric tool which includes separate scales for depressive and anxiety symptoms. These may have been particularly useful in capturing other psychological variables within the sample in this study.

4.7.3 Measuring mindfulness: the debate concerning psychometrics

The selection of outcome measures in relation to the present study merits further consideration and discussion, both in terms of the number of measures selected and in view of the characteristics of the sample. A current issue of debate concerns the apparent over-dependence in MBI studies on self-report measures, and this in itself raises further issues around how measurement of an ostensibly multi-dimensional construct such as mindfulness is possible.

Within the mindfulness research community, considerable debate persists with respect to how accurately and viably generic or specific, standardised measures of mindfulness tap into or indeed capture constructs both concerning psychological processes and consequences of mindfulness. This applies to the field of ABI as well as other long-term conditions. Recent theoretical debates concerning psychometrics have highlighted the difficulties and confusion

in defining and operationalizing mindfulness, with some disagreement as to whether it should be regarded as a construct reflecting a 'trait or state', and how this can be reflected in outcome measures. As Baer (2003) has noted,

"*the practice of mindfulness is concerned with the cultivation of awareness, insight, wisdom, and compassion, concepts that may be appreciated by many people, yet difficult to evaluate empirically*" (p.140)

It is also likely that the evaluation and measurement of constructs in a culture different to that from which these constructs have originated may represent a further limitation. In the relative absence of external referents to verify the validity of constructs of mindfulness used in self-report scales, much of the research findings based on these indirect assessments may pose problems in terms of validity. As has been mentioned earlier, within the traditional context, the term mindfulness is derived from the Pali word *sati* that conveys the meaning '*to remember'* (i.e*.,* remembering to maintain awareness), with four distinct phases described in the traditional literature. This is clearly distinct from the modern attempts at operationalizing a fixed trait-like definition of mindfulness that ignores the developmental and contextual aspects of this concept (Grossman and Van Dam, 2011). Individuals with no meditation experience respond to the word "mindfulness" questionnaire items differently from people with meditation experience, as seems likely from the results of a study (using the MAAS), where binge drinking university students scored significantly higher scores compared to experienced meditators (Leigh *et al*., 2005).

More such issues regarding reliability and validity of self-report questionnaires have been raised recently (Bergomi *et al*., 2012; Brown *et al*., 2011). In assessing all the available self-report scales of mindfulness, Bergomi *et al.* (2012) reported that these scales do not offer a comprehensive assessment of all aspects of mindfulness in samples from the general population. Similarly, Chiesa (2012) has asserted that modern attempts to operationalize mindfulness have consistently failed to provide a universally agreed, unequivocal definition of mindfulness that takes into account the complexity of the original traditional definitions of the term.

According to Grossman (2011), currently used self-report measures of mindfulness may in fact reduce, obscure and distort the meaning of "mindful awareness" in psychological sciences and research. Consequently, this could negatively impact the possibility of further

development of MBIs and their possible adaptations with specific clinical populations. A study by Höfling *et al*. (2011) which evaluated the construct validity of the MAAS by developing a short version of this instrument by including positively worded items, found that it is important to control for method effects due to item wording. This would appear to challenge Brown and Ryan's (2003) assertion that an assessment of "mindlessness" via only negatively worded items on the MAAS is empirically equivalent to mindfulness. One of the possible implications of this in terms of the present study might be that the wording of items may have induced a response bias in participants however the findings do not appear to have borne this out.

4.7.4 Defining mindfulness

Grossman (2011) has further queried whether self-report measures actually assess mindfulness, or whether the construct of mindfulness can be understood apart from mindfulness *training*, and whether there is empirical evidence to support the validity of mindfulness measures. In response to these criticisms, Brown *et al*. (2011) have discussed an established theory that attention (and secondarily meta-awareness) is core to the meaning of mindfulness. They further posit that it is the central feature of the MAAS and argue that mindfulness is an inherent capacity that varies between and within individuals. This view would appear to contradict Grossman's claims that mindfulness is a concept applicable to only a trained few. Furthermore, as assessed by the MAAS, mindfulness is associated with the same variety of outcomes as mindfulness training is theorized to produce. Brown and colleagues provide evidence that the MAAS is a valid instrument, concluding that although construct measurement is inevitably imperfect, such efforts are critical to building basic knowledge bases and tailoring or refining effective interventions across a range of clinical presentations and groups.

Whilst meditation and mindfulness interventions are often promoted as a means of reducing stress, enhancing psychological and mental well-being, and even managing physical ailments, it remains difficult to ascertain whether the techniques *per se* promoted within MBIs actually bring about the predicted outcomes researchers may propose. A meta-analysis by Eberth and Sedlmeier (2012) found large differences in effect sizes reported for MBSR

compared with mindfulness meditation, arguing that these effects might feasibly be attributed to other factors such as differences between groups, participants' expectations or psycho-education. Moreover, the emphasis between the interventions in terms of specific mindfulness practices may also have varied considerably.

Travis (2011) explored if psychological well-being and mindfulness are related to the type of meditation technique practiced and argued that it was difficult to interpret findings between different groups due to large demographic and process differences. In a recent meta-analysis, Sedlmeier *et al*. (2012) provided a comprehensive overview of the effects of meditation on psychological variables in non-clinical groups of adult meditators. The authors identified several methodological problems in a large number of studies and reported a lack of sufficient theoretical background in most studies. They examined 21 separate categories of dependent measures in a large number of meditation research reports and found that in general, meditation did not exert uniform effects on the categories of dependent measures examined. The authors compared meditation with relaxation response and cognitive training and concluded that in their opinion meditation is not merely a relaxation technique. Instead, they found that meditation has a substantial impact on psychological variables, and these effects would appear to be stronger for emotional than for cognitive variables.

Sedlmeier and colleagues also argue that the current state of theories on meditation and mindfulness does not enable researchers to derive very specific hypotheses, at least not for the majority of the dependent measures that have been studied in the research to date. They assert that in the absence of a clear theoretical basis for mindfulness, alternative explanations may appear to overshadow the veracity and reliability of the results. Since to an extent, the dependent measures examined in the vast majority of studies still lack precision, future researchers may find it useful to explore the respective effects whilst being aware of differences in the various techniques being studied. In the pursuit of measuring psycho-physical and neural correlates of meditation, the psychological, physiological, and behavioural measures currently employed by researchers may not be specific to the particular meditation or mindfulness sub-type.

Arguably an important concern in respect of this debate may be to the possible ethical implications for patients. If, unbeknownst to patients, MBIs are in fact attempting to teach Buddhism in what may be viewed as a 'reconstituted' form within healthcare settings, then

it would seem imperative to make this absolutely clear. Alternatively, given that MBIs claim a particular basis in Buddhist philosophy, if their primary intention is geared toward improving individuals' psychosomatic well-being, then perhaps there is still a need for clarity regarding what is actually implied by this basis. In other words, patients accessing MBI programmes should be made aware that mindfulness as currently operationalized in MBIs and the associated literature is by no means congruent with the traditional Buddhist perspective.

4.7.5 The question of specially tailored or adapted MBIs with neurological populations

The ongoing debate concerning whether all MBIs are necessarily the same also raises important issues regarding what particular considerations might feasibly need to be borne in mind when working with a population such as the one studied in the context of the present study. It is perhaps worth noting that an emphasis on less physically demanding practices may be more beneficial for ABI and neurological patients, but the question remains as to whether this might also paradoxically detract from the effectiveness of an MBI, if of course one of the major aims of these interventions is to alleviate symptoms of distress on a physical as well as a psychological level.

Again, this seems linked to the idea that the validity of the collective findings of MBI studies is perhaps somewhat restricted by a certain heterogeneity in how different MBIs conceptualize mindfulness as well as differences in MBI programme design (e.g., variations in programme length, duration of weekly sessions, quantity of psycho-education, amount of physical exercise/yoga, focus on different aspects of practice over others, etc.).For example, a recent meta-analysis by Vøllestad *et al*. (2012) incorporated seven different MBIs in which the total number of sessions ranged from 8 to 16, and the duration of individual sessions varied between 45 and 150 minutes (the standard duration being 120 minutes per session). There is a suggestion (and an ostensibly increasing empirical evidence base) that MBI-related clinical benefits are associated with the length, duration and amount of practice in which an individual engages with mindfulness. The underlying hypothesis is that regular, sustained practice is predictive of larger beneficial effects, although it is perhaps questionable that mere length or regularity of practice necessarily brings about these benefits as opposed to *depth* of mindfulness experience.

4.8 Possible future developments and directions for research

The collective body of literature examining MBIs in relation to this particular population remains limited and to an extent, in its infancy. As such, it only includes very few studies looking at MBI for this population. Moreover, the research tends to be mainly focussed on ABI and TBI, with more recent studies looking at discrete neurological conditions such as MS or PD. It would seem that more research is needed in the area, especially given the relatively high prevalence and incidence of neurological conditions and their potential burden on services.

From a methodological perspective, the adoption of more rigorous RCT designs, with some thought as to the exploration of a range of appropriate control arms would be welcomed (e.g., MBI vs. Treatment As Usual [TAU], MBI vs. CBT, MBI vs. other types of attentional training, MBI vs. CFT or ACT, both of which emphasise themes around acceptance and non-judgmental appraisal of one's circumstances). Alongside this, it would seem important to consider the development of longitudinal studies with an option for longer-term follow-up periods post-intervention. This further points to the need to employ longer timescales, recruit larger samples and adopt more powerful research designs before firmer conclusions may be drawn as to the efficacy of MBIs.

There is preliminary evidence to suggest the effectiveness and utility of manualized MBI programmes with neurological patients, although very little research has evaluated this with a mixed population. There is therefore scope for continued research in this area, both employing the traditional MBSR approach as well as perhaps considering other MBI formats such as MBCT, ACT or elements of CFT, as in the work of Wilson *et al*. (2013). These may emphasise aspects of mindfulness which may be deemed particularly suitable or pertinent to ABI and neurological populations. There is a further possibility that the encouraging findings of the present study could be replicated with other client groups who may exhibit similar difficulties. One possible application of this adapted model of MBI might be targeted for individuals with mild cognitive impairment or other chronic health conditions.

Given that the majority of MBIs tend to be delivered in group formats, Dimidjian and Linehan (2003) have posited that it may be important for future research to address whether the group setting and format for MBIs (in particular, MBSR and MBCT manualized

programmes) is an essential part of mindfulness skills training within clinical contexts, and this would certainly seem an important consideration within the field of neurorehabilitation. If so, it may also be useful to consider whether MBIs are able to be effectively incorporated or integrated into individual psychological interventions for this population (see Hofer *et al*., [2014] for a recent adaptation incorporating elements of mindfulness with stroke patients).

As Awasthi (2012) has recently asserted, attempts to include a more phenomenological account of mindfulness (and meditation in general) may help determine and formulate a clear and operational definition for developing future research. In agreement with Lutz and Thompson (2003), he proposes that one possible avenue might involve the adoption of a more neuro-phenomenological approach that can be used to guide the study of physiological processes. An integration of traditional ontology, first-person, qualitative phenomenological reports and neuroscientific evidence will perhaps enable the development of more comprehensive models of the mind to help find common ground for scientific research with the contemplative traditions.

4.9 Conclusions

There are a number of conclusions which may be drawn from this study. In the first instance, the present study appears to have demonstrated the feasibility of running a brief, suitably modified MBI programme for a mixed population of patients with an ABI or neurological condition. Secondly, the study has also provide encouraging results in terms of the potential effectiveness of an adapted MBI with this population, particularly with regards to mindfulness training effects, and would appear to point to increased mindfulness skills exerting positive effects in terms of individuals' reported self-efficacy (specifically, a capacity to regulate emotions and to take responsibility for their reactions to their difficulties) and health-related quality of life. Thirdly, the moderate to large effect sizes observed appeared to support these findings convincingly and provide further evidence for the effectiveness of an MBI for this population.

One of the strengths of this study was the use of a representative sample and the naturalistic setting in which it was conducted. In addition to this, the study is one of the first

to attempt to explore the mechanisms of mindfulness within a mixed clinical population, and one of the first to report data on outcome measures such as the MSES-R and PQoL within this group. However, the study had several limitations, which may have contributed to some of the less promising findings. These included a small sample size and multiple comparisons, a purely quantitative design, the lack of a follow-up assessment, and an over-reliance on self-report measures. Whilst it could be argued that the study did not allow firm conclusions to be drawn regarding observed changes in being directly attributable to mindfulness *per se*, and some thought should be given to the selection of psychometric instruments in terms of conceptualizing and operationalizing mindfulness as a definable construct, it will be important for future research to address these methodological issues.

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6. Appendices

Appendix 1: Outline of MBI sessions

Appendix 2: Mindfulness diary (sample)

Appendix 3: Outcome measures

Primary outcome measures: FMI

MAAS

Secondary outcome measures: MSES-R

PQoL

Appendix 4: Feedback evaluation form

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Appendix 9: Mann-Whitney *U* non-parametric test output

Appendix 1: Outline of MBI sessions

Mindfulness Meditation
Session 1

- Introductions
- Who we are
- This group will focus on teaching you mindfulness meditation
- My personal experience of meditation

- Rules of the group
  Confidentiality
  Respect what people say
  One at a time
  You are welcome to record the meditation
  Fire drills

Your introductions

- Dates of the group
- Times: approximately an hour

Handouts
- How to meditate guideline
- Meditation diary
- Articles on mindfulness meditation and Jon Kabat Zinn

What do you know about meditation?

Mindfulness meditation

- A meditation that encourages you to be in the moment
- Based in Buddhism, but not necessarily subscribe to Buddhism to meditate
- Now part of CBT, third wave

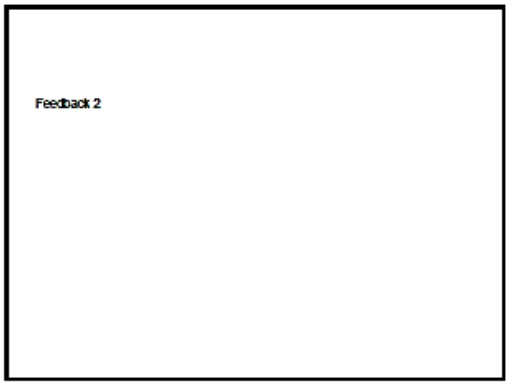
- Meditation is fundamentally an experiential process and so we will meditate rather than talk about it

I will guide you through the process
I will also meditate

Meditation 1

Feedback

Meditation 2


Feedback 2

Mindfulness Meditation
Session 2

- Quick introductions

Feedback from mindfulness diary

Mindfulness Practice

Feedback from mindfulness practice

Applying mindfulness to everyday living

- The aim is to apply mindfulness meditation in everyday life in relation to difficult experiences eg
  Pain
  Anxious thoughts
  Depressed thoughts
- In the same way that you let go of distracting thoughts/pain in meditation when you notice that you are caught up in negative thoughts in day- to- day life you try and let go of them
- They may well come back but once again you let go of them
- The idea is to let go of them and so you don't get caught up in them as much as you presently do

Goals over the next week

- Week 2-3 continue with your mindfulness meditation practice
- Also try and apply mindfulness thinking in your day-to-day life (see meditation diary)
- Any questions
- See you next week

Mindfulness Meditation
Session 3

- Quick introductions

Feedback from mindfulness diary

Mindfulness Practice

Feedback from mindfulness practice

Applying mindfulness to everyday living

- The aim is to apply mindfulness meditation in everyday life in relation to difficult experiences
- Principle of avoidance or being fearful of an experience
- We avoid situations which make us anxious or we get caught up in a negative spiral of thoughts
- Apply the mindfulness approach of noticing but letting go of unpleasant thoughts/feelings. You are not avoiding and it can also lessen fear response
- Negative thoughts/feelings may well come back but once again you let go of them
- The idea is to let go of them and so you don't get caught up in them as much as you presently do

Goals over the next two weeks

- Week 4-5 continue with your mindfulness meditation practice
- In week 4-5 also try and apply mindfulness thinking in your day-to-day life (see meditation diary)
- Any questions

Mindfulness Meditation
Session 4

- Quick introductions

Feedback from mindfulness diary

Mindfulness Practice

Feedback from mindfulness practice

Learning to take care of yourself

- Do you ruminate e.g. feeling anxious/sad/depressed or do you avoid feelings/thoughts/situations?
- Through the mindfulness practice you are able to notice but let go of ruminations
- Or you can learn to face thoughts/feelings/sensations which you would normally avoid
- The idea is to meditate but also apply this way of thinking in your day to day life
- By doing this you will be able to take more care of yourself
- You cannot always change events themselves but you can change your response to them

Goals over the next four weeks

- Continue with your mindfulness meditation practice
- Continue to apply mindfulness thinking in your day-to-day life
- Any questions

Appendix 2: Mindfulness diary (sample)

Week 2-3

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Y/N							
Distraction level out of 10 1=very few distractions 10= lots of distractions							
Reminder to apply mindfulness thinking in your everyday living	Y N	Y N	Y N	Y N	Y N	Y N	Y N

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Y/N							
Distraction level out of 10 1=very few distractions 10= lots of distractions							
Reminder to apply mindfulness thinking in your everyday living	Y N	Y N	Y N	Y N	Y N	Y N	Y N

Appendix 3: Outcome measures

Primary outcome measures:	FMI
	MAAS
Secondary outcome measures:	MSES-R
	PQoL*

*NB: the Perceived Quality of Life Scale (PQoL) measure has not been included due to copyright protection. Details regarding seeking permission to access and use the PQoL, are available at: http://depts.washington.edu/seaqol/PQOL

Freiburg Mindfulness Inventory

Description:

The FMI is a useful, valid and reliable questionnaire for measuring mindfulness. It is most suitable in generalized contexts, where knowledge of the Buddhist background of mindfulness cannot be expected. The 14 items cover all aspects of mindfulness.

The purpose of this inventory is to characterize your experience of mindfulness. Please use the last ___ days as the time-frame to consider each item. Provide an answer for every statement as best you can. Please answer as honestly and spontaneously as possible. There are neither 'right' nor 'wrong' answers, nor 'good' or 'bad' responses. What is important to us is your own personal experience.

1	2	3	4
Rarely	Occasionally	Fairly often	Almost always

I am open to the experience of the present moment.	1	2	3	4
I sense my body, whether eating, cooking, cleaning or talking.	1	2	3	4
When I notice an absence of mind, I gently return to the experience of the here and now.	1	2	3	4
I am able to appreciate myself.	1	2	3	4
I pay attention to what's behind my actions.	1	2	3	4
I see my mistakes and difficulties without judging them.	1	2	3	4
I feel connected to my experience in the here-and-now.	1	2	3	4
I accept unpleasant experiences.	1	2	3	4
I am friendly to myself when things go wrong.	1	2	3	4
I watch my feelings without getting lost in them.	1	2	3	4
In difficult situations, I can pause without immediately reacting.	1	2	3	4
I experience moments of inner peace and ease, even when things get hectic and stressful.	1	2	3	4

I am impatient with myself and with others.	1	2	3	4
I am able to smile when I notice how I sometimes make life difficult.	1	2	3	4

Scoring Information:

Add up all items to get one summary score. When scoring, please observe that there are a couple of reversed items. For these you need to reverse the scoring, preferably by a recode command that recodes 1 into 4, 2 into 3, 3 into 2 and 4 into 1.

The item to be recoded is "I am impatient with myself and with others."

At the moment, we do not recommend to use separate factor-scale scores. If you wish to do so, we recommend that you analyze your own data set and extract 4 to 6 factors according to the data structure you find and then proceed accordingly, adding up item scores per scale.

Reference:

Walach, H., Buchheld, N., Buttenmuller, V., Kleinknecht, N., Schmidt, S. (2006). Measuring Mindfulness--The Freiburg Mindfulness Inventory (FMI). *Personality and Individual Differences, 40*, 1543-1555.

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6
It seems I am "running on automatic," without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of What I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I drive places on 'automatic pilot' and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention.	1	2	3	4	5	6
I snack without being aware that I'm eating.	1	2	3	4	5	6

Mindfulness-Based Self Efficacy Scale - Revised© (MSES-R)

Bruno A. Cayoun,
MiCBT Institute & University of Tasmania

NAME…….....…… DATE…….... Session/Week No…..……

Circle one number in the shaded column according to how much you now agree with each statement below, using the following scale:

Not at all	A little	Moderately	A lot	Completely
0	1	2	3	4

Try not to spend too much time on any one item. There are no right or wrong answers.

1.	I get easily overwhelmed by my emotions	**0**	**1**	**2**	**3**	**4**
2.	I find it difficult to make new friends	**0**	**1**	**2**	**3**	**4**
3.	I try to avoid uncomfortable situations even when they are really important	**0**	**1**	**2**	**3**	**4**
4.	When I feel very emotional, it takes a long time for it to pass	**0**	**1**	**2**	**3**	**4**
5.	I feel comfortable saying sorry when I feel I am in the wrong	**0**	**1**	**2**	**3**	**4**
6.	It is often too late when I realise I overreacted in a stressful situation	**0**	**1**	**2**	**3**	**4**
7.	I get so caught up in my thoughts that I end up feeling very sad or anxious	**0**	**1**	**2**	**3**	**4**
8.	When I have unpleasant feelings in my body, I prefer to push them away	**0**	**1**	**2**	**3**	**4**
9.	I can resolve problems easily with my partner (or best friend if single)	**0**	**1**	**2**	**3**	**4**
10.	I can face my thoughts, even if they are unpleasant	**0**	**1**	**2**	**3**	**4**
11.	My actions are often controlled by other people or circumstances	**0**	**1**	**2**	**3**	**4**
12.	I get caught up in unpleasant memories or anxious thoughts about the future	**0**	**1**	**2**	**3**	**4**
13.	I can deal with physical discomfort	**0**	**1**	**2**	**3**	**4**
14.	I feel I cannot love anyone	**0**	**1**	**2**	**3**	**4**
15.	I am often in conflict with one (or more) family member	**0**	**1**	**2**	**3**	**4**
16.	I avoid feeling my body when there is pain or other discomfort	**0**	**1**	**2**	**3**	**4**
17.	I do things that make me feel good straightaway even if I will feel bad later	**0**	**1**	**2**	**3**	**4**
18.	When I have a problem, I tend to believe it will ruin my whole life	**0**	**1**	**2**	**3**	**4**
19.	When I feel physical discomfort, I relax because I know it will pass	**0**	**1**	**2**	**3**	**4**
20.	I can feel comfortable around people	**0**	**1**	**2**	**3**	**4**
21.	Seeing or hearing someone with strong emotions is unbearable to me	**0**	**1**	**2**	**3**	**4**
22.	If I get angry or anxious, it is generally because of others	**0**	**1**	**2**	**3**	**4**

If you use(d) the Internet automated scoring, what is the 4-character CODE given to you?:……..….

Appendix 4: Feedback evaluation form

MINDFULNESS MEDITATION GROUP FEEDBACK FORM

We are always looking for ways to improve our Service, and we would be grateful if you could find the time to answer the following questions on the services you have received.

1) I could easily understand the information presented in the group

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

2) I was happy with the number of group sessions

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

3) The sessions were long enough, i.e. an hour

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

4) I have learnt more about mindfulness meditation in this group

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

5) I have learnt more about ways to cope with my problems in my day-to-day life through mindfulness meditation

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

6) I found it helpful being with other people when learning this meditation technique

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

7) I feel more positive about coping with my day-to-day difficulties following the meditation group

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

8) I feel less anxious after having learnt mindfulness meditation

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

9) I feel less depressed after having learnt mindfulness meditation

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

10) I feel less angry after having learnt mindfulness meditation

Strongly agree □

Agree □

Neutral □

Disagree □

Strongly disagree □

Any other feedback:

Thank you!

Appendix 5: Participant information sheet/Letter of invitation

PARTICIPANT INFORMATION SHEET

***Be Here Now*: A study looking at a mindfulness-based group for people with an acquired brain injury (ABI) or neurological condition**

University of Hertfordshire/Hertfordshire Neurological Service (Hertfordshire Community NHS Trust)

What is this study about?

Research has shown that coping with the difficult emotions, lifestyle changes and symptoms associated with acquired brain injury (or ABI) and neurological conditions can be challenging for a lot of people. Many patients with ABI experience periods of feeling down, distressed and/or anxious and find it difficult to manage these feelings and adjust to life after an ABI. Mindfulness is a set of simple techniques which helps with distressing emotions. It's a way of paying attention to the present, using simple meditation and relaxation techniques such as focused breathing that help people become more aware of their feelings. Research shows that when people practice these they are able to manage their difficulties better. In this study we would like to find out whether a short, specially adapted mindfulness group programme currently being offered to ABI patients in Hertfordshire can be helpful for people who report difficulties with managing their feelings, and also help improve their quality of life after injury. We would like to invite you to take part in this study.

Who is conducting the research?

This study is part of a Clinical Psychology Doctorate led by Ross Canadé (Trainee Clinical Psychologist). It is being supervised by Mr Joerg Schulz (Senior Lecturer in Research Methods & Statistics) at the University of Hertfordshire, and Mr Daniel Friedland (Consultant Clinical Neuropsychologist) at Jacketts Field Neurological Centre (Hertfordshire Neurological Service).

How will this help people affected by ABI and neurological conditions?

We cannot promise the study will help you, but the evidence so far is showing more and more that mindfulness-based programmes are very helpful for people with chronic conditions (including those who have suffered a brain injury) in coping with some common difficulties and adjusting to their life. We hope that the information we get as a result of this study will help us make the programme more relevant to the needs of people with ABI. Because it is a shorter programme than usual, if our results show it does help people, we hope it will be able to be offered to more patients than is currently the case.

What will happen during the study?

We will ask you whether you would like to take part in the study. If you agree to take part, we will then allocate you to either the mindfulness group or a waiting list group. This means that some of you will start the course very soon after you've agreed to take part. Some of you may have to wait for a few weeks before you start. However, all of you will have the opportunity to be in the group at some point. The mindfulness course will consist of 4 one-

hour sessions (i.e. one mindfulness session per week). Each session lasts only one hour. The course will be delivered in a group format. We expect that there will be around 6-8 people to each group. The group is facilitated by a clinical psychologist who has a lot of experience in teaching and practising mindfulness techniques, and who has worked for a number of years with ABI patients.

As part of the programme, we will ask you to practice mindfulness meditation and the techniques regularly between sessions. In order to find out whether the programme is helping, we will also ask you to fill in 4 -5 short questionnaires at three points:

- before you start the group;
- when the group finishes;
- 3 months after the group has finished.

These questionnaires should take about 40-45 minutes to complete. Somebody will be with you to help complete these. At the end of the programme, we will ask you to feed back about your experiences and views about the mindfulness sessions.

Why are you being invited to take part in this study?

You have been invited to take part in this study because:

- you have an acquired brain injury (ABI) or neurological condition;
- you have been identified as someone who may benefit from a mindfulness-based group and are already on a waiting list for the group;
- you have NOT received any formal training in mindfulness methods before;
- you are NOT currently receiving any other psychological treatment;
- you do NOT have serious problems with concentration;
- you are NOT highly distressed.

When can I take part in this study?

We expect that you will be able to take part in the study from October 2013 - May 2014.

Time Commitment

The group typically takes an hour per session over 4 sessions. The group takes place once a week, so you will finish the group after 4 weeks. The questionnaires we will ask you to complete are relatively straightforward and take around 40-45 minutes of your time. We hope that we can arrange for you to complete these at a convenient time for you.

Participants' Rights

You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn or destroyed. You have the right to omit or refuse to answer or respond to any question that is asked of you without penalty.

You have the right to have your questions about the procedures answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

We think it is important to let your GP know that you are taking part in the study, so we will be writing to your GP to inform them of this.

Confidentiality

If you agree to take part, your name will not be recorded on any of the questionnaires and the information will not be disclosed to other parties. Your responses to the questionnaires will be used for the purpose of this study only. We will not have access to any of your medical records. You can be assured that if you take part in the study you will remain anonymous. When the data we have collected is analysed, it will remain anonymous.

Benefits and Risks

There are no known benefits or risks for you in this study. However, people who have been involved in previous mindfulness groups have said that they have found some of the techniques very helpful in managing with life after ABI or a neurological condition. They have also said that they enjoy being in a group.

Where is this research taking place?

This research is taking place at the University of Hertfordshire, Hatfield and the Hertfordshire Neurological Service.

Will you inform me of the results of the study?

Yes. When we have completed the study we will produce a summary of the findings which we will be more than happy to send to you if you are interested.

Interested?

If you are interested in taking part, or would like to find out more about this study or discuss anything in more detail, please contact Ross at r.f.canade@herts.ac.uk or call 01923 299124. Please note that enquiring about participation does not commit you in any way. If you decide you would rather not participate in this study, simply ignore this letter and no further contact will be made. If you would like to take part, please complete the enclosed consent form and return in the pre-addressed envelope provided within 10 days of receipt of this letter.

Appendix 6: Consent form

Centre Number:

Study Number:

Patient Identification Number for this trial:

INFORMED CONSENT FORM

Title of Project: ***Be Here Now*: A study looking at a mindfulness-based group for people with an acquired brain injury (ABI) or neurological condition**

Name of Researcher: Ross Canadé

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 17/10/2013, version 4 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Hertfordshire Neurological Service, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 7: Letter to GP

***Be Here Now*: A study looking at a mindfulness-based group for people with an acquired brain injury (ABI) or neurological condition**

University of Hertfordshire/Hertfordshire Neurological Service (Hertfordshire Community NHS Trust)

Dear Dr (Name),

(GP Surgery)

Re: *Patient name*

Date of birth: *D.O.B*

I am currently conducting a research study as part of my Doctorate in Clinical Psychology. This study will evaluate the effectiveness of a mindfulness-based group intervention for people with an ABI or neurological condition. This psychological intervention is currently being offered to some ABI patients as part of their standard rehabilitation within Hertfordshire Neurological Service. The study is a randomised trial, with some patients receiving the intervention at an earlier stage than others. For further information, please refer to the enclosed participant information sheet. Your patient, (*patient name)*, has agreed to take part in the study.

The study will involve administering a set of brief questionnaires at various time points. The questionnaires will consist of measures asking about mindfulness skills and patients' health-related quality of life. We will also ask participants for feedback about the group programme. These will be administered at Jacketts Field Neurological Centre wherever possible. We hope that the results of this study will demonstrate the usefulness of this intervention in patients' care.

It is expected that participants will be involved in the study for approximately 4 months. We do not anticipate that any aspects of the study will interfere with your patient's usual treatment. If you would like any further information about this project, please do not hesitate to contact me using the details above.

Yours sincerely,

Ross Canadé

Trainee Clinical Psychologist/Principal Investigator

Appendix 8: Ethics approval

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - South Yorkshire
North East REC Centre
Unit 002, TEDCO Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 428 3387

24 October 2013

Mr Rosario Canade
12 Apple Grove
Enfield
Middlesex
EN1 3DD

Dear Mr Canade

Study title:	**Be Here Now: Evaluation of an adapted Mindfulness-based Intervention in a mixed Acquired Brain Injury population**
REC reference:	**13/YH/0352**
Protocol number:	**LMS/PG/NHS/00111**
IRAS project ID:	**128519**

Thank you for your email of 17 October 2013, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Ms Joan Brown, nrescommittee.yorkandhumber-southyorks@nhs.net.

Confirmation of ethical opinion

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

Ethical review of research sites

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

Conditions of the favourable opinion

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

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

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

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

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

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

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

Registration of Clinical Trials

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

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

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

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

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of insurance or indemnity	Gallagher Heath	01 August 2013
GP/Consultant Information Sheets	1	14 September 2013
Investigator CV	Mr Canade, 1	01 October 2013
Letter from Sponsor	University of Hertfordshire	06 August 2013
Other: Supervisor CV - Mr Schulz	1	01 October 2013
Other: Study Protocol Flowchart	1	30 September 2013

Other: Mindfulness Meditation Session 1		
Other: Mindfulness Meditation Session 2		
Other: Mindfulness Meditation Session 3		
Other: Mindfulness Meditation Session 4		
Participant Consent Form	4	17 October 2013
Participant Information Sheet	3	30 September 2013
Protocol	2	30 September 2013
Questionnaire: Mindfulness Meditation Group Feedback Form	2	14 September 2013
Questionnaire: Freiburg Mindfulness Inventory		
Questionnaire: Day to Day Experiences		
Questionnaire: Mindfulness-Based Self Efficacy Scale		
Questionnaire: The Perceived Quality of Life Scale (PQOL)		
Questionnaire: QOLIBRI - Quality of Life After Brain Injury		
REC application	3.5	11 October 2013
Response to Request for Further Information	Email from Ross Canade	17 October 2013
Sample Diary/Patient Card	Mindfulness Diary Wks 1-2, 1	14 September 2013
Sample Diary/Patient Card	Mindfulness Diary Wks 2-3, 2	14 September 2013
Sample Diary/Patient Card	Mindfulness Diary Wks 3-4, 2	14 September 2013
Sample Diary/Patient Card	Mindfulness Diary Wks 4-5, 2	14 September 2013

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

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

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

13/YH/0352	**Please quote this number on all correspondence**

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

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

Yours sincerely

pp
Ms Susan Hampshaw
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

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

Copy to: *John Senior, University of Hertfordshire*
Dr Mark Whiting, Hertfordshire Community NHS Trust

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Hatfield
AL10 9AB
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tel +44 (0)1707 284000
fax +44 (0)1707 284115
herts.ac.uk

Rosario Canadé
Department of Psychology
School of Life and Medical Sciences

31 October 2013

Dear Rosario,

Re: **UNIVERSITY OF HERTFORDSHIRE SPONSORSHIP IN PRINCIPLE for the following:**
RESEARCH STUDY TITLE: Evaluation of an adapted Mindfulness-Based Intervention in a mixed Acquired Brain Injury (ABI) population
NAME OF CHIEF INVESTIGATOR: Rosario Canadé
IF STUDENT, NAME OF SUPERVISOR: Mr Joerg Schulz
UNIVERSITY OF HERTFORDSHIRE ETHICS PROTOCOL NUMBER: LMS/PG/NHS/00111

This letter is to confirm your research study detailed above has been reviewed and accepted and I agree to give full University of Hertfordshire sponsorship, so you may now commence your research.

As a condition of receiving full sponsorship, please note that it is the responsibility of the Chief Investigator to inform the Sponsor at any time of any changes to the duration of the project, changes of investigators, changes to the protocol and any future amendments, or deviations from the protocol, which may require re-evaluation of the sponsorship arrangements. Permission to seek changes as outlined above should be requested from myself before submission to an NRES (NHS) Research Ethics Committee (REC) and notification to the relevant University of Hertfordshire Ethics Committee with Delegated Authority (ECDA), and I must also be notified of the outcome. Please do this via email to research-sponsorship@herts.ac.uk

Please note that University Sponsorship of your study is invalidated if this process is not followed.

In the meantime, I wish you well in pursuing this interesting research study.

Yours sincerely

Professor J M Senior
Pro Vice-Chancellor (Research and International)

Appendix 9: Mann-Whitney *U* non-parametric test output

Mann-Whitney Test

Ranks

	Group	N	Mean Rank	Sum of Ranks
FMI	1	7	8.86	62.00
	3	6	4.83	29.00
	Total	13		
MAAS	1	7	7.64	53.50
	3	6	6.25	37.50
	Total	13		
PQOL	1	7	8.14	57.00
	3	6	5.67	34.00
	Total	13		
TS_MSES_ER	1	7	9.00	63.00
	3	6	4.67	28.00
	Total	13		
TS_MSES_EQ	1	7	8.71	61.00
	3	6	5.00	30.00
	Total	13		
TS_MSES_SS	1	7	8.14	57.00
	3	6	5.67	34.00
	Total	13		
TS_MSES_DT	1	7	7.79	54.50
	3	6	6.08	36.50
	Total	13		
TS_MSES_TR	1	7	9.36	65.50
	3	6	4.25	25.50
	Total	13		
TS_MSES_IE	1	7	7.14	50.00
	3	6	6.83	41.00
	Total	13		

Test Statistics[a]

	FMI	MAAS	PQOL	TS_MSES_ER	TS_MSES_EQ	TS_MSES_SS	TS_MSES_DT	TS_MSES_TR	TS_MSES_IE
Mann-Whitney U	8.000	16.500	13.000	7.000	9.000	13.000	15.500	4.500	20.000
Wilcoxon W	29.000	37.500	34.000	28.000	30.000	34.000	36.500	25.500	41.000
Z	-1.870	-.645	-1.144	-2.011	-1.766	-1.157	-.791	-2.428	-.147
Asymp. Sig. (2-tailed)	.061	.519	.252	.044	.077	.247	.429	.015	.883
Exact Sig. [2*(1-tailed Sig.)]	.073[b]	.534[b]	.295[b]	.051[b]	.101[b]	.295[b]	.445[b]	.014[b]	.945[b]

a. Grouping Variable: Group

b. Not corrected for ties.