The role of mindfulness based cognitive therapy in the management of psoriasis

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Contents

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Abbreviations

ACT	Acceptance Commitment Therapy
ACTH	Adrenocorticotrophic Hormone
ALS	Amyotrophic Lateral Sclerosis
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
AUCg	Area Under the Curve with reference to ground (zero)
AUCi	Area Under the Curve with reference to increase (s1)
AVP	Arginine Vasopressin
BDI	Beck Depression Inventory
BMI	Body Mass Index
BSQ	Brief Stress Questionnaire from PSS
CAR	Cortisol Awakening Response
CASP	Critical Appraisal Skills Programme
CBG	Corticosteroid Binding Globulin
CBT	Cognitive Behavioural Therapy
CEQ	Credibility and Expectation Questionnaire
CHD	Coronary Heart Disease
CI	Confidence intervals
CRH	Corticotropin Releasing Hormone
DLQI	Dermatology Quality of Life Index
DynCh	Dynamic Change
ED	Emotional Disclosure Therapy
EHR	Estimated Hazards Ratio,
EMS	Early Maladaptive Schemas
EPQ-R	Eysenck Personality Questionnaire
FA	Framework Analysis
FFMQ	Five Facet Mindfulness Questionnaire
FINER	Feasible Interesting Novel Ethical Relevant
GHQ-12	General Health Questionnaire
GP	General Practice
HADS	Hospital Anxiety and Depression Scale
HPA	Hypothalamic-Pituitary-Adrenal
HR	Heart Rate
HRQOL	Health Related Quality of Life
IBS	Irritable Bowel Syndrome
IFN-γ	Interferon-γ

IL	Interleukin
IPQ-R	Illness Perceptions Questionnaire-Revised
IRAS	Integrated Research Application System
KIMS	Kentucky Inventory of Mindfulness Skills
K-S	Kolmogorov-Smirnov
MAAS	Mindful Awareness Acceptance Scale
MBCT	Mindfulness Based Cognitive Therapy
MB-EAT	Mindfulness Based Eating Awareness Training
MBSR	Mindfulness Based Stress Reduction
MID	Minimal Important Difference
mm	Millimetres
NICE	National Institute of Health and Clinical Excellence
nmol/L	Nanomoles per litre
PAIS	Psychosocial Adjustment to Illness Scale
PASI	Psoriasis Area Severity Index
PI	Primary Investigator
PICOT	Population Intervention Comparison group Outcome of interest Time
PIS	Patient Information Sheet
PMR	Progressive Muscle Relaxation
PNI	Psychoneuroimmunology
PNS	Parasympathetic Nervous System
POMS	Profile of Mood States
PSS	Perceived Stress Scale
PT	Peripheral Temperature
PUVA	Psoralin with Ultra Violet A
QoL	Quality of Life
RCT	Randomised Controlled Trial
s1	Saliva sample 1 (0 minutes post awakening)
SAM	Sympathetic-Adrenal-Medullary
SAPASI	Self-Assessed Psoriasis Area Severity Index
SCL	Skin Conductance
SCL-90	Symptoms Checklist
SD	Standard Deviation
SE	Standard Error
SNS	Sympathetic Nervous System
SR-CSM	Self-Regulatory Common Sense Model of illness
SSE	Sample Size Estimate
SSHS: C	Stanford Scale of Hypnotisability, Form C
SSPS	Statistics Package for Social Sciences
STAI	State Trait Anxiety Inventory

STATA	Data Analysis and Statistical Software
Study ID	Study Identification
TAU	Treatment As Usual
T-cell	T-lymphocyte
TH	T-Helper cells
TIA	Transient Ischemic Attack
TNF-α	Tumor Necrosing Factor-α
TSST	Trier Social Stress Test
UKGPRD	UK General Practice Research Database
UVB	Ultra Violet B
VAS	Visual Analogue Scales
VIF	Variance Inflation Factor
WHO	World Health Organisation
WLC	Waitlist Control
WTCRF	Wellcome Trust Clinical Research Facility
XLC	Extraction Liquid Chromatography

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Psoriasis is a chronic skin condition that can impair physical, psychological and social functioning. A sub-population of people living with psoriasis believe that psychological stress exacerbates their physical symptoms. Stress may exacerbate psoriasis via a psychoneuroimmunological pathway. The cortisol awakening response can be used to indicate whether this pathway is functional or dysfunctional. People with psoriasis have an elevated risk of emotional distress (anxiety and depression) and an impaired quality of life. Mindfulness based cognitive therapy has been effective in reducing stress, emotional distress, quality of life impairment as well as improving physical health. The aim of this thesis is to examine the efficacy and acceptability of mindfulness-based intervention for people living with psoriasis and whether the cortisol awakening response mediates the relationship between perceived stress and physical severity of psoriasis.

This thesis adopted a mixed-methods design. A pilot, randomised control trial examined the effects of mindfulness based cognitive therapy upon the physical severity, perceived stress, emotional distress, quality of life and cortisol awakening response of people living with psoriasis. These variables were entered into a correlation analysis to examine whether the cortisol awakening response was associated with any of the reported study outcomes (physical severity, perceived stress, emotional distress and quality of life). Completers of the mindfulness intervention were invited to a semi-structured interview to explore the characteristics of the participants who adhered to the intervention and their experiences of participating.

The mindfulness intervention significantly improved physical ($z=1.96$, $p=0.05$) and quality of life ($z=2.30$, $p=0.02$) measurements without changing perceived stress ($z=0.07$, $p=0.94$), emotional distress ($z=1.60$, $p=0.12$) or cortisol awakening responses ($z=-0.33$, $p=0.74$). The overall cortisol awakening response was not associated with physical severity ($r=-0.30$, $p=0.07$) or perceived stress ($r=-0.20$, $p=0.25$) but was significantly correlated with emotional distress ($r=-0.35$, $p=0.04$). The intervention was perceived as an acceptable adjunct treatment option. Participants reported some process barriers that inhibited their learning of mindfulness skills. A profile emerged that described a sub-population of people with psoriasis. This sub-population may be more likely to accept and adhere to mindfulness based cognitive therapy.

This thesis provides preliminary support to the concept that increasing mindfulness skill can reduce the physical severity and quality of life impairment in people with psoriasis. It recommends that a fully powered trial be conducted to examine the effectiveness of mindfulness in improving physical and overall functioning for people with psoriasis. This thesis suggests clinicians screen their patients and offer a psychological intervention best suited to their needs and characteristics.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another.

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Within the University of Manchester there is a wonderful research community that encourages broader learning through journal clubs, seminar series and small research groups. These opportunities have helped me generate a wider understanding of my topic and health psychology in general and I am very thankful for being part of such a dynamic and progressive group.

I met and worked with a superb group of participants during this PhD and I am I would like to take this opportunity to thank every participant who kindly volunteered their time for this study. It was a pleasure to work with you all for those months in 2011.

In the first week of my PhD I encountered a group of fellow students all looking equally terrified. We very quickly became an essential support group to each other. Providing practical support such as, "section break>page set-up>landscape," through to the greatest psychological support, "there is a meal deal at Pizza Express." Kim, Kathy, Jo and Neesha thank you for everything over the past three years. A PhD can be an isolating experience and I am really grateful for finding a fantastic group of friends.

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Finally, Daniel, my incredible husband, I dedicate this thesis to you, thank you for "hanging onto the tail of the tiger."

The Author

I was brought up to appreciate a holistic understanding of health, illness and medicine. My father was a GP and my mother a physiotherapist. Both worked in different countries and set up clinics in Africa, India and Papua New Guinea. Their experiences and the stories, which they told, lead to my interest in health and medicine. I began to see that across different cultures there are many different ways to achieve physical health but that there is a commonality too. The way people think, feel and cope with their illnesses is crucial in determining full health.

I studied psychology at A-Level and decided to progress to a degree in Experimental Psychology (Magdalen College, Oxford). This course was mostly cognitive based and helped me to develop my systematic and scientific framework for understanding human psychology. During the health psychology module, in my third year, I decided to pursue this area further but from an alternative perspective. I moved to City University, London to complete my Master of Science degree in Health Psychology. The teaching style in City was completely different to that in Oxford and I appreciated the contrast.

During my Masters degree I began working part-time as a personal tutor for Kensington & Chelsea Tutors. I continued this work for First Tutors until 2012, when I had to stop to focus on my thesis. This work sharpened my ability to communicate psychological concepts to people without an established understanding of psychology. This was an important skill, as I believe research needs to be readily accessible to all not just academics. My teaching experience reinforced my understanding of original psychological theories on which health psychology is based.

Prior to starting my PhD I worked in secondary research as a project manager and guideline implementation advisor at the National Collaborating Centre for Mental Health (NCCMH). This collaborating centre produced mental health guidelines for the National Institute of Health and Clinical Excellence (NICE). Working at NCCMH threw me into a variety of different working situations, from presentations at the House of Lords, to working with service users in South London drug rehabilitation units. I learnt how research could be implemented across a variety of NHS settings in the UK: from providers' policy change to introducing new interventions within a local clinic. During my time at NCCMH I organised an Antenatal and Postnatal Mental Health (APMH) conference, I published three articles for clinical audiences (mainly nurses and GPs) to support the implementation of the APMH and Dementia NICE guidelines and I developed a range of educational aids for different service users.

Working at the NCCMH demonstrated how research could lead to improvements in health provision. The production of the Depression with a chronic physical health problems (DCHP) guideline reinforced my interest in the link between physical and mental health. I decided I would like to be involved in primary research that explored the links between physical and mental health.

I have had mild psoriasis for ten years and the studentship to examine the psychosocial effects of living with psoriasis seemed to be the perfect opportunity to follow an area of research in which I was interested both academically and personally.

After conducting a systematic review in the first year of my PhD research, I decided to use Mindfulness Based Cognitive Therapy (MBCT) as the intervention for the study. I completed the MBCT course and the facilitator training and became personally interested in mindfulness. My Father has practised Buddhist meditation for many years so I have been aware of the concepts and had opportunity to discuss the principles of MBCT practice with him.

Nearing the end of my PhD, I hope I have learnt to conduct research with scientific integrity whilst maintaining a creative and personal interest in the topic. I have moved back to Oxford and there is a team here within the Oxford Cognitive Therapy Centre who would like me to continue with my research into the use of MBCT for people with psoriasis.

1. Introduction

The skin is the largest human organ and acts as an interface between an individual's internal and external environment. It is an organ visible to other people and therefore any physical changes to the skin present within a social context. Human emotions can generate visible physiological changes to the skin, from the skin colour flushing red when experiencing embarrassment or draining to a pale colour when experiencing fear. These responses to psychological states may have established the lay perception that stress can influence skin disease progression.

Psoriasis is a skin disease characterised by an excess of skin cells production resulting in thick, red, scaly plaques, which can present anywhere on the skin, including areas visible to other people. There is an established lay perception that stress exacerbates physical psoriasis symptoms and this is presented in the mainstream media. Influential United Kingdom (UK) based Internet sites such as www.nhs.co.uk and www.bbc.co.uk present stress as a common trigger for a psoriasis flare. The stress-psoriasis link has been researched and integrated into clinical understanding for several decades (Winchell & Watts, 1988), however, it is not unanimously accepted by researchers and clinicians (Hunter et al., 1989).

Psychodermatology examines the interaction between the mind and the skin and asserts that skin disorders which are associated with psychological states can be classified into three categories; psychophysiological disorders, primary psychiatric disorders and secondary psychiatric disorders (Koo & Lebwohl, 2001). Psoriasis is defined as a psychophysiological disorder that can be exacerbated by stress. However, it has been suggested that psoriasis could also be categorised as a secondary psychiatric disorder as clinical studies have reported an increased prevalence for clinical depression (10-62%) and clinical anxiety (43%) in people living with psoriasis (Hayes and Koo, 2010).

If stress does cause exacerbations of psoriasis then psychoneuroimmunology (PNI) offers a possible pathway to explain this association. Stress has been reported to modulate the hypothalamic-pituitary-adrenal (HPA) axis function and can alter the output of the hormone cortisol (Biondi & Picardi, 1999, Ader, 1991). Cortisol has been found to modulate the production of pro-inflammatory cytokines involved in the pathogenesis of psoriasis (Wiegers & Reul, 1998, Chapman & Moynihan, 2009). Changes to stress levels may alter cortisol levels, which may influence epidermal cell turnover production.

Psoriasis remains incurable, therefore treatments aim to manage the symptoms as effectively as possible whilst causing minimal side effects. The first recorded treatment of psoriasis described in the Papyrus Ebers (1500BC) recommended applying a mixture of onions, sea salt and urine to the skin (Bechet, 1936). Thankfully, treatment options have evolved and are now highly effective in targeting causal factors such as the immunomodulating biologics treatments, which suppress tumour-necrosing factor-alpha (TNF-α), a cytokine that has been found to exacerbate psoriasis. Despite this advancement in the management of psoriasis, no treatment is 100% effective for all patients and many treatments can introduce side effects. As stress has been suggested as a cause of psoriasis, stress-reduction techniques have been used, which may improve physical symptoms and possibly the distress that some people with psoriasis experience. An example of a successful stress reduction treatment is MBCT, which has been found to improve both physical and mental health outcomes (Grossman et al., 2004, Fjorback et al., 2011). The efficacy and acceptability of MBCT for people living with psoriasis has not been examined in this context.

Health psychologists examine and explore physical health conditions within the biopsychosocial model of health and illness (Engel, 1977). Through a series of interlinked study phases, this health psychology thesis aims to elucidate whether stress causes psoriasis via a mediating PNI pathway. This thesis also examines whether MBCT is an effective and acceptable treatment option for this patient group.

2. Literature review

This chapter reviews the research literature relevant to psoriasis; the stress-psoriasis link, including the PNI pathway, and, stress reduction interventions aimed at improving physical and psychological outcomes in people with psoriasis.

2.1 Psoriasis

2.1.1   Clinical characteristics

Psoriasis is a chronic inflammatory autoimmune disease. There is some debate as to whether the subtypes of psoriasis (chronic plaque, acute guttate, erythrodermic, inverse and pustular (generalised and palmar-plantar)) are independent conditions, or variants of the same disease (Griffiths et al., 2007). People with psoriasis most commonly present with one sub-type alone and of these approximately 90% of cases are chronic plaque psoriasis (Griffiths & Barker, 2007). Around 50% of people with psoriasis will also have psoriasis related nail changes such as pitting and 'oil droplet' patterns.

Psoriasis plaques can appear anywhere on the body and are most commonly found on extensor aspects (knees and elbows) and the scalp. The plaques are red, thick and scaly and have a clear demarcation from the healthy skin (Figure 1). The top layer of the skin (epidermis) is predominantly made up of keratinocytes (skin cells), which in healthy skin take 28 days to move from the bottom to the top of the epidermis where they are scuffed off. In psoriatic skin this process takes approximately six to eight days (Halprin, 1972), resulting in an overproduction of skin cells which have not had enough time to fully develop, and remain 'sticky' forming the plaque. These plaques contain many inflammatory cells making them thicker and elevated levels of blood vessels which are larger and more tortuous leaving the skin appearing pink or red.

Figure 1: A photograph of a psoriasis plaque (Permission of Prof. C. Griffiths)

Figure 1: A photograph of a typical psoriasis plaque. Clear demarcation of the red, thick, raised and scaly plaques from the healthy skin.

The disease can present any time from birth until death but there is a bimodal distribution across the age of onset with 75% of cases beginning before the age of 40 (type 1) and 25% above the age of 40 (type 2) (Henseler & Christophers, 1985). More recent studies suggest some genetic and cellular distinctions between these two types of psoriasis (Shaw et al., 2010, Allen et al., 2005).

2.1.2 Symptoms

Psoriasis alternates between periods of activity and inactivity. Itch is the most commonly reported symptom of psoriasis (Fleischer et al., 1996, Fortune et al., 1998) and it has been implicated in causing the greatest disruption to quality of life (QoL) (Globe et al., 2009). Other symptoms include bleeding, cracking, and, dry skin (Globe et al., 2009). The signs and symptoms of psoriasis range from mild through to severe which can lead to hospitalisation, 0.13% of all UK hospital admissions have a primary diagnosis of psoriasis (Conway & Currie, 2008).

2.1.3 Prevalence and incidence

The prevalence of psoriasis within the UK population is estimated at 1.5% (Gelfand et al., 2005b) however this may be an underestimate as many people with the condition may not seek medical help (Hunter, 1989). A prospective cohort study using the UK general practice research database (UKGPRD) found an incidence rate of 14 cases of psoriasis per 10,000 people (Huerta et al., 2007).

Psoriasis is equally distributed between the sexes, but global epidemiological studies demonstrate an inter-racial and geographical variation in prevalence (Campalani & Barker, 2005). The condition is most common in Caucasians, with the highest prevalence at 4.8% in Norway (Kavli et al., 1985). It is 50% less prevalent in African-American compared to

Caucasian-American skin (Gelfand et al., 2005a) and almost absent in some races such as Japanese and Native Americans (Langley et al., 2005).

2.1.4 Pathogenesis

A serendipitous discovery in 1979 found the immunosuppressive drug ciclosporin, which was being used to treat arthritis also helped to improve psoriasis in people with psoriatic arthritis (Mueller & Hermann, 1979). Studies have found bone marrow transplantation can transmit (Gardembas-Pain et al., 1990) and clear psoriasis (Eedy et al., 1990) and this has been linked to the location of immune cell maturation. A particular type of immune cell, the T-lymphocyte (T-cell), is consistently found to be over-represented within psoriatic plaques and their presence will reduce as the plaques diminish (Valdimarsson et al., 1986). T-cells are known to regulate skin cells (keratinocytes), which produce pro-inflammatory cytokines (Lydyard et al., 2004). These pro-inflammatory cytokines are signalling molecules that encourage inflammation and the production of more keratinocytes (Lowes et al., 2004). The cytokines currently implicated in triggering psoriasis include interferon-γ (IFN-γ), tumor necrosing factor-α (TNF-α), interleukin (IL)-1, IL-6, IL-17, and IL-23 (Hall et al., 2012).

2.1.5 Genotype to phenotype

Heredity can be indicated as a possible cause of psoriasis as 34% of people with psoriasis have a first-degree family member and 18% have a second/third-degree family member living with the disease (Mallbris et al., 2005). There is also 70% concordance between monozygotic (Brandrup et al., 1982); and 20% between dizygotic twins (Farber et al., 1974).

Chronic plaque psoriasis is strongly associated with HLA-Cw06 on chromosome 6. Approximately 60% of patients with early onset psoriasis have this allele (Strange et al., 2010). As genetic inheritance cannot account for all the variance (only 34%) in psoriasis risk, the genotypes must interact with environmental stimuli to produce the psoriasis phenotype and rare disease variants probably make up a high proportion of risk. Environmental triggers identified include drugs (anti-malarial, beta-blockers and the withdrawal of corticosteroids; (Rongioletti et al., 2009)), alcohol (Poikolainen et al., 1994), smoking (Naldi et al., 1992) and stress (Fortune et al., 1998).

2.1.6 Co-morbidities

Ten percent of people with psoriasis develop psoriatic arthritis, an inflammatory joint condition distinct from rheumatoid arthritis (Wilson et al., 2009). This population of people with psoriasis also has a high prevalence of other immune mediated inflammatory conditions such as Crohn's and ulcerative colitis (Yates et al., 1982, Cohen et al., 2009). A sub-population of people with psoriasis drink more alcohol (Kirby et al., 2008), smoke more cigarettes (Neimann et al., 2006) and have a higher body mass index (BMI) (Neimann et al., 2006) than the general population average. These lifestyle factors may contribute to elevated risk for cardiovascular disease (Mehta et al., 2009) and diabetes (Solomon et al., 2010) found in people with severe psoriasis.

It has been proposed that the genetic predisposition of patients combined with environmental triggers leads to an inflammation profile, which may be mediating all of these co-morbidities.

Several studies have found a higher risk of cancer in this patient population as compared to the general population (Brauchli et al., 2009). A current treatment method for psoriasis is ultraviolet light therapy, which is known to increase the risk for skin cancer (Margolis et al., 2001), it is unsurprising therefore that skin cancer accounts for a large proportion of this increased risk for cancer in general. The remaining cancers incidences were associated with increased smoking and alcohol consumption and, as previously mentioned, people with psoriasis tend to smoke and drink more than the general population (Kirby et al., 2008).

A population based cohort study reports clinically assessed data extracted from patient's electronic medical records between 1987 and 2002. The data estimates that 2.6% of severe psoriasis cases or 1.2% of mild psoriasis cases will develop clinically recognised depression; 0.8% will have anxiety, and, 0.04%will exhibit suicidality (Kurd et al., 2010).

2.1.7 Assessment, treatment and adherence

It is assumed that there is a group of people living with psoriasis who have not sought any medical help (Hunter, 1989). Those who do present with psoriatic symptoms in primary care will have the physical severity of their condition measured and often in secondary/tertiary care their QoL will be also be measured. These tools provide a snapshot of a condition that is identified as cyclical in nature and they may therefore under or overestimate the severity of the overall psoriasis. With these tools there is room for disparity on the subjective clinician ratings such as 'how red is a typical plaque.' The most commonly used in tool in clinical practice is the psoriasis area severity index (PASI; (Fredriksson & Pettersson, 1978)). This tool may be improved by increasing the severity weighting attributed to areas that may be more distressing to display psoriasis e.g. the face, hands and genitals compared to those areas which may be considered less distressing (Kirby et al., 2000). There are some criticisms of this instrument. It has been described as slow and cumbersome (Louden et al., 2004) to use in clinical settings and has displayed poor sensitivity to smaller changes in psoriasis severity (Feldman & Krueger, 2005). Despite these criticisms of the PASI, it remains the gold standard tool in the UK for classification of the clinical severity of the disease. On the basis of the PASI scores, psoriasis severity can been classified into three categories: mild (PASI < 7), moderate (PASI 7-12) and severe (PASI >12) (Schmitt & Wozel, 2005).

At present, psoriasis is not curable but its symptoms can be managed (Laws & Young, 2010, Menter & Griffiths, 2007). Mild psoriasis cases can often be adequately managed within a primary care setting with the prescription of topical treatments such as emollients, vitamin D analogues, keratolytics, corticosteroids, coal tar and retinoids. Topical preparations, however, can thin the skin and are not considered suitable if more than 30% of the body surface is covered as it is very hard to administer effectively and high levels of steroids may destabilise the

skin. If the symptoms have not improved after two to three months, despite the use of a spectrum of topical preparations, or, there are further complications, the primary care staff may refer the patient onto secondary care where second line treatments are managed. These include phototherapy (ultra violet B (UVB), psoralin with ultra violet A (PUVA)) and systemic therapies (Methotrexate, Ciclosporin, and Acitretin). Systemic therapies (oral or injected) are immunosuppressive and many focuses on T-cells. The final option are biologics (injected), which are immunomodulators suppressing TNF-α (Adalimumab, Etanercept, Infliximab).

People with psoriasis are confronted with treatment decisions when balancing the efficacy of a treatment with its side effects. For example, topical preparations can be messy and time consuming to apply to the skin (Stern, 2007) and phototherapy is associated with an increased risk of skin cancer (Margolis et al., 2001) but can result in 85-90% skin clearance for up to six months. Systemic treatments can be highly effective and used for a long time but some people experience stomach upsets, fatigue and all service users must be closely monitored for the biomarkers of liver damage, kidney damage, anaemia, infections and cancer. Biological agents are currently being monitored on safety registers, in part because they compromise the immune system and can leave patients susceptible to infectious diseases. Clinicians usually adopt a stepped-care approach moving from the topical through to the biological options unless the specific signs or side effects of the condition warrant a leap to a particular treatment.

The development of highly effective and safe treatments is somewhat undermined by the findings from the World Health Organisation (WHO; (De Geest & Sabate, 2003)), which report that 50% of people living with long-term conditions are not adhering to their medication regime. A recent meta-analysis found estimates of compliance to psoriasis-specific medications vary from 27 to 97% (Augustin et al., 2011). People with psoriasis do not adhere to their physical treatment regimen either through unintentional non-adherence (forgetting), intentional non-adherence (e.g. making an informed decision not to adhere) or, because the treatments get in the way of daily functioning so they cannot be adhered to (Richards et al., 2006).

2.2 Stress and psoriasis

This section aims to clarify what stress is, as the term has been used interchangeably to refer to different concepts across the literature, and will begin to outline how stress and psoriasis have been proposed to interact.

2.2.1 Stress

The term, stress, can refer to a stimulus or a response. A stress stimulus or "stressor" is an event or situation which can be internal (e.g. an individual's memory of being asked to leave a hairdresser because of their psoriasis), or, external (e.g. going on a romantic date with a new partner). An early stress theory suggested that exposure to a stressor will automatically generate a physical stress response (physiological arousal) via the sympathetic nervous system (SNS) e.g. the heart rate may increase (Selye, 1976) in order to facilitate the fight or flight response.

Selye's (1976) automatic stress response theory does not account for why two people may respond differently to the same stressor, or, how an individual may have had no reaction to an event of going to the hairdressers before noticing their psoriasis symptoms but may develop a stronger reaction to the same event post diagnosis. The transactional model of stress (Lazarus & Folkman, 1984) places the individual as an active interpreter of stimuli rather than as a passive recipient who automatically responds as Selye hypothesised. Lazarus and Folkman's (1984) model suggests two levels of appraisal. First, the primary appraisal assesses whether an event is classified as a threat, as positive, or as an irrelevant stimulus. If the event is classified as a non-threat then the physical arousal state will return to homeostasis via the parasympathetic nervous system (PNS). If the stimulus is classified as a threat, the second level of appraisal evaluates whether the individual has the necessary resources to cope with this threat and then decides upon a coping strategy. If the individual concludes that they have the resources and relevant coping mechanisms to deal with the threat, they may experience eustress (positive stress) and the physical arousal will be returned to homeostasis via the PNS. If they conclude that they cannot cope then they can experience stress (negative stress) and the physical arousal will remain elevated. In this thesis psychological stress is defined as the experience of this negative stress.

2.2.2 Stress causing psoriasis

A relationship between stress and psoriasis has been long established in the literature (Winchell & Watts, 1988). Between 37 and 78% of people with psoriasis report stress either causes or exacerbates a psoriasis flare (Gupta & Gupta, 1996, Picardi & Abeni, 2001). There has also been a long established, although not unanimous, recognition from clinicians that stress may be an important trigger in psoriasis flare (Seville, 1977). Across the literature, the terms 'cause' and 'exacerbate' have been used interchangeably when referring to the impact stress has upon the

physical psoriasis symptoms, therefore it is not clear whether participants believe stress started their psoriasis, makes it worse, or both.

The evidence for this association across the literature is not conclusive. Earlier research relied on retrospective accounts of experiencing stress states prior to a psoriasis flare (Fortune et al., 1998, Polenghi et al., 1989, Fava et al., 1980, Seville, 1977). An individual's current emotional representation can influence the memory recall of emotional responses (Levine, 1997). Being questioned about whether stress exacerbates psoriasis flare may develop a representation that stress causes psoriasis. This representation may bias the individual's memory recall as to whether they were feeling stressed before their psoriasis flare. The onset of psoriasis may cause stressful events, such as sexual, social or work difficulties. A critique reports that the temporality of whether stress preceded or was caused by psoriasis has not adequately been accounted for even in recent studies (Dellavalle & Johnson, 2005).

Additionally, several retrospective studies examining this causal relationship contained methodological flaws, for example failing to control for seasonal variation or to differentiate between daily and chronic stress (Gupta & Gupta, 1996, Picardi & Abeni, 2001). Seasonal variation is important to control for because UV light is known to be effective in clearing psoriatic skin (Faber & Peterson, 1961) therefore some people with psoriasis experience symptom reduction during summer and exacerbation during winter. Acute stress events such as rushing to meet a deadline at work produces different demands upon an individual than chronic stress such as long term caring for an ill relative. Acute and chronic stress have been found to produce different effects in physical stress reactions (McEwen, 2004) and psychological adjustment (Westbrook et al., 2011). These may, therefore, produce different psychophysiological effects in people with psoriasis.

More recent prospective studies found stressful life events (stressors) to predict the exacerbation of physical psoriasis severity (Malhotra & Mehta, 2008, Verhoeven *et al.*, 2009, Manolache *et al.*, 2010). The studies all used a stressful live events scale (Singh *et al.*, 1981, Holmes & Rahe, 1967, Vingerhoets *et al.*, 1989) to represent stress. The scales used ignore the transactional model of stress, and therefore individual differences (Lazarus & Folkman, 1984). They measure the amount of stressors present in an individual's daily life, rather than the amount of appraisals that result in perceived stress. These studies conclude that stress triggers psoriasis but the life events scales, which ignore the active interpretation of events by individuals, may consequently under or over estimate the amount of stress the members of the study experienced.

Alternatively, future studies could employ an instrument which takes account of an individuals' context and provides an objective rating of how stressful an event may be for the patient. The Life Event and Difficulty Schedule (LEDS; (Brown & Harris, 1978) is scored by an investigator

who is cognisant of the individual's biography and current situation. This allows them to make an informed, yet not biased by personal attribution, judgement as to how stressful an event will be for the individual. This measurement method may increase the validity of how stressed a participant is judged to be.

One small scale study examined prospectively whether nine women's perceived stress, as recorded on a visual analogue scale, predicted physical psoriasis symptoms (Berg et al., 2008). This study did not find self-reported stress exacerbated physical psoriasis symptoms. Well-designed prospective studies, which include a perceived stress, rather than a stressful event scale, are needed in order to clarify whether perceived stress exacerbates psoriasis symptoms.

Those who believe that stress causes their psoriasis have been labelled stress responders and those who do not believe stress to cause their psoriasis as non-stress responders (Koo, 1995). Stress responders have been found to have more psoriasis flares, more stress and relied more on the approval of others than non stress responders (Gupta et al., 1989). Stress responders were also found to demonstrate a different psychophysiological reaction to experimentally induced acute stressors than non-stress responders (Richards et al., 2005). These distinctions are useful to categorise the different groups within a psoriasis population.

Despite the inconclusive evidence base as to whether stress causes or exacerbates physical psoriasis symptoms, the stress-psoriasis link has become part of the research and clinical rhetoric. Psoriasis support groups report to their users that stress is one trigger of physical symptoms (Psoriasis and Psoriatic Arthropathy Alliance, 2012). Studies exploring the pathogenesis of psoriasis have attributed the variance in risk, which is not explained by genetics, to environmental influences including stress (Peters et al., 2000). Stress exacerbating physical psoriasis is, despite an inconclusive research base, an established link and consequently there was a call for interventions to reduce stress in order to reduce physical psoriasis flare. These interventions and their proposed mechanisms will be systematically explored later in this chapter (Section 2.4).

2.2.3 Psoriasis causing psychological and social disability

Psoriasis can also act as a stimulus, which some people may appraise as a threat. An individual may interpret that they cannot cope with the stress generated by living with psoriasis, as hypothesised by the transactional model of stress (Lazarus & Folkman, 1984).

A significant proportion of people living with psoriasis also suffer from distress (Fortune et al., 2005) such as depression (Schmitt & Ford, 2007, Hayes & Koo, 2010); anxiety (Hayes & Koo, 2010, Kurd et al., 2010), pathological worrying (Fortune et al., 2000) and suicidality (Kurd et al., 2010, Gupta et al., 1993). The level of distress (anxiety/depression) has not been found to correlate with the physical severity of psoriasis (Fortune et al., 1997, Main et al., 2000, Richards et al., 2001). Even after an effective treatment has improved physical symptoms, the levels of

anxiety and depression remain constant, suggesting that the distress is either caused or maintained by beliefs, attributions or schemas rather than just the presence of the physical psoriasis symptoms (Fortune et al., 2004, Mizara et al., 2012). Those who have lived with psoriasis for longer tend to have lowered levels of distress (Wahl et al., 1999) than people who have been living with psoriasis for less time, perhaps due to a psychological acceptance or adaptation to living with the condition.

Psoriasis is a disease of the skin and as such may be visible to other people. It is unsurprising, therefore, that this patient population report high levels of social anxiety and its constituent components such as perceived stigma, embarrassment, interpersonal difficulties, low self-esteem and poor self-image (Magin et al., 2009). Sufferers report a variety of social functions that are impaired as a result of their condition, including the avoidance of activities where they would have to expose their skin such as sports or sexual contact and they report difficulty in being able to maintain relationships or some occupations (de Korte et al., 2004).

Quality of life measurements aim to capture the impact which psoriasis has upon an individual's physical, psychological and social functioning. The level of functional impairment experienced by people with psoriasis, as measured by the SF-36, is similar to that experienced by people living with cardiovascular disease and some types of cancer (Rapp et al., 1999). One study reported the distress experienced by people with psoriasis accounted for more variance in QoL scores than the physical status of psoriasis (Fortune et al., 1997). However, other studies have reported that physical severity (Wahl et al., 1999) and disease-specific characteristics such as pain and discomfort (Ljosaa et al., 2011) significantly contribute to explaining the variance in QoL scores. Intervention studies have found that QoL improves if physical severity improves (Krenzer et al., 2011). In addition to distress and physical severity of psoriasis, other variables predict QoL scores. For example, the longer an individual has lived with psoriasis the smaller their QoL impairment (Lee et al., 2010); Wahl et al., 1999). As QoL scales are designed to capture physical, psychological and social aspects of living with a condition, it is unsurprising that both physical and psychosocial elements contribute to variance in QoL outcomes. However, Fortune et al.'s (1997) study could suggest that for some people with psoriasis the distress is a greater burden than the physical symptoms of psoriasis.

One of the most common symptoms reported by people with psoriasis is itch (Fleischer et al., 1996, Fortune et al., 1998). Stress has been found to intensify the itch sensation and stress responders have reported more itch than non-stress responders (Niemeier et al., 2002). The neuroendocrine explanations of this phenomenon point to opioid peptides, which are released in response to stress and may exacerbate itch (Paus et al., 2006). Itch has been reported to impair sleep, social and sexual life quality and was strongly positively correlated with QoL (Amatya et al., 2008). Distress (anxiety, depression, worry, hopelessness) was found to be both a

consequence of itch and an aggravating factor for maladaptive scratching coping behaviours (Verhoeven et al., 2008, Schneider et al., 2006).

A recent paper reported that skin pain and discomfort explain 40% of the variance in QoL, whilst controlling for demographic and physical severity variables, and this association was mediated by sleep disturbance (Ljosaa et al., 2012). An individual, who is experiencing more pain from their psoriasis, will have more sleep disturbance and this decreases their QoL. This study also found a significant association between emotional representations of psoriasis and QoL, but these representations did not mediate the relationship between skin symptoms and QoL. This suggests that negative emotional representation of psoriasis does reduce the QoL, but experiencing pain may not necessarily lead to negative emotional representations. The authors intimate that this is not a stable conclusion as they measured the participants' emotional representations, which might not be as sensitive to current levels of distress as tools specifically designed to measure distress, such as the hospital anxiety and depression scale (Zigmond & Snaith, 1983).

Research evidence suggests that physical severity; somatic characteristics (pain and discomfort) and distress contribute to the QoL impairment in people with psoriasis. These associations may be mediated by variables such as sleep or decreased social functioning. This composite score is an important tool to understand the biopsychosocial burden of living with psoriasis. QoL measurements are currently considered as more appropriate clinical measurements to assess the overall severity of psoriasis upon a person rather than reliance on only objective physical measurements (Krueger et al., 2000). Recently the categorisation of psoriasis severity has been amended to include QoL (Mrowietz et al., 2011). An individual can now be classified as having severe psoriasis if they have slightly lower PASI scores (PASI>10) than the original classification (PASI>12; (Schmitt & Wozel, 2005) combined with a QoL score from the Dermatology Quality of Life Index (DLQI; (Finlay & Khan, 1994)) >10.

2.2.3.1 Mechanisms causing or maintaining distress in people with psoriasis

2.2.3.1.1 Dispositional characteristics

Studies have explored the mechanisms which might exacerbate or maintain the high prevalence of distress disorders within this particular patient population. Dispositional characteristics were found not to be associated with psychological or social disability in people with psoriasis (Baughman & Sobel, 1971, Gilbert *et al.*, 1973) and they were not examined any further until recently, with the focus on alexithymia. Alexithymia is the relative inability to describe and express personal emotions and people with psoriasis have an elevated prevalence in comparison to disease free populations (Allegranti et al., 1994). Alexithymia has been associated with anxiety sensitivity and accounted for a significant amount of variance (10%, F=42.86, p<0.001) in anxiety levels within a psoriasis population (Fortune et al., 2002a). Another construct similar to alexithymia is high emotional control, which is an excessive

suppression of emotions and this is hypothesised to lead to negative effects upon health (Hamilton-West, 2011). People with psoriasis, particularly older patients, have been found to have higher levels of emotional control over anger and anxiety than people with another skin condition vitiligo (Kossakowska et al., 2009). The evidence suggests that there is a sub-population of people with psoriasis who have difficulty in expressing their emotions and this may lead to elevated distress levels.

2.2.3.1.2 Cognitive models

Cognitive models of distress depict three levels of cognition that contribute to an overall understanding of why distress begins and how it is maintained. Figure 2 depicts these three cognitive levels.

Figure 2: A flow chart to represent the levels of cognitions, adapted from Westbrook et al. (2011)
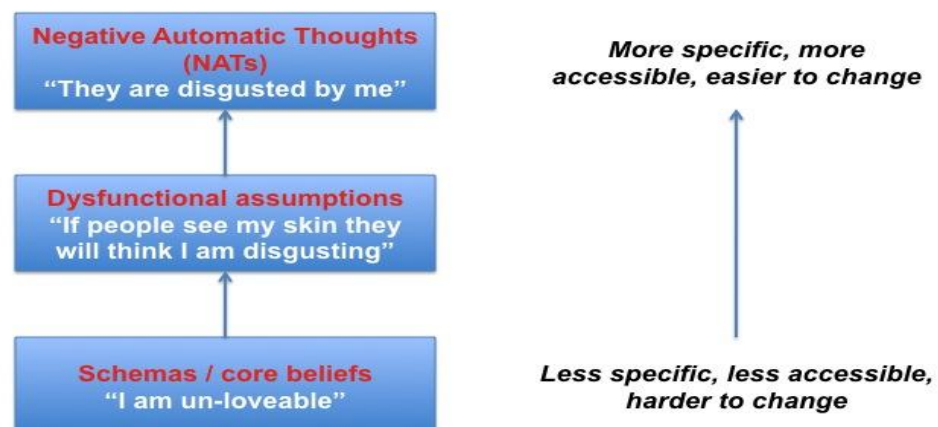
Figure 2: A schematic of cognitive levels progressing from the more rigid core beliefs through the dysfunctional assumptions to the more flexible automatic thoughts.

If an individual with psoriasis holds a core belief that they are "un-loveable" then they are likely to form an assumption that other people will see their psoriatic plaques as disgusting. When confronted by a situation where another person has seen their psoriasis, they may automatically think, "they are disgusted by me" rather than waiting for a reaction.

These beliefs (cognitions) can also influence information processing (e.g. attention deployment) which has been found to contribute to the maintenance of distress disorders (Wells & Matthews,

1996). People with psoriasis have been found to display an attention bias towards disease-related, self-referent and others'-behaviour related when compared to a control group (Fortune et al., 2003a). Attention biases can maintain distress disorders because a belief that "you are disgusting" is maintained if the individual pays more attention to, and has preference to recall supportive negative evaluations (threats) (Dozois & Dobson, 2001, Wells & Matthews, 1996) rather than neutral or positive experiences.

Other research has examined neuro-cognitive information processes in people with psoriasis. People with psoriasis had significantly smaller bilateral insular cortex responses (an area associated with the processing of facial expression) than controls when presented with facial expressions of disgust (Kleyn et al., 2009). This reduced neurocognitive information processing response was interpreted to represent a coping response. People with psoriasis may be blocking the processing of other people's disgust in order to protect themselves from the associated distress. This study demonstrated a possible subconscious alteration in information processing which may be caused by maladaptive beliefs. If an individual with psoriasis believes that "If people see my skin they will think I am disgusting" but cannot avoid people seeing their skin, then they may block other people's disgust emotion, in order to protect themselves from the hurtful experience of perceiving that someone else thinks they are disgusting.

Recently, there has been an investigation into the early maladaptive schemas (EMS) present in people with psoriasis (Mizara et al., 2012). EMSs are core belief structures (e.g. "I am un-loveable") that influence beliefs and assumptions, as demonstrated in Figure 2. People with psoriasis were found to have higher levels of emotional deprivation, social isolation, defectiveness, failure, vulnerability to harm, subjugation and emotional inhibition than disease free controls. This concept of emotional inhibition is very similar to the dispositional characteristic of alexithymia, and serves to strengthen the findings that a group of people with psoriasis have difficulty in understanding and expressing their emotions. These EMSs were also found to be associated with levels of distress within this population. This study's results could suggest that either some people with psoriasis are susceptible to developing distress disorders because they have pre-existing maladaptive EMSs or that living with psoriasis over a long period of time can lead to the development of maladaptive EMSs.

2.2.3.1.3 Social cognition models

There is a lack of correlation between the physical severity of symptoms and distress in people living with psoriasis (Fortune et al., 1997, Main et al., 2000, Richards et al., 2001). Therefore, some people with severe psoriasis may not experience any distress, whereas others with mild symptoms of psoriasis may experience severe distress. This suggests that there are individual internal differences that will mediate why some people with psoriasis report distress and others do not. Social cognition models attempt to explore the internal factors involved in this active interpretation of living with a threat such as psoriasis by exploring both social (family member's

beliefs) and cognitive (threat appraisals) factors. The self-regulatory common sense model of illness (SR-CSM; (Leventhal et al., 1984)) is a social cognition model which examines the content of cognitions, which will be developed through social learning, relating to an illness in order to explain the variation in an individual's distress levels, health behaviours and QoL impairments. The processes all take place within a social context but this is not explicitly demonstrated in Figure 3, which is a visual representation of the SR-CSM.

Figure 3: A representations of the Self-Regulatory Common Sense Model of illness adapted from Leventhal et al. (1984)

		Cognitive				
		representation				
		of the psoriasis threat	⇒	**Coping**	⇒	**Appraisal**
		(Illness representations)				
	⇒	⇑		⇑		⇑
Psoriasis Information						
Socio-demographics		⇐*Feedback*⇐	⇐	⇐	⇐	⇐
Clinical characteristics						
Social (family, society)						
	⇒	⇓		⇓		⇓
		Representation of				
		emotion	⇒	**Coping**	⇒	**Appraisal**
		(Emotional distress)				
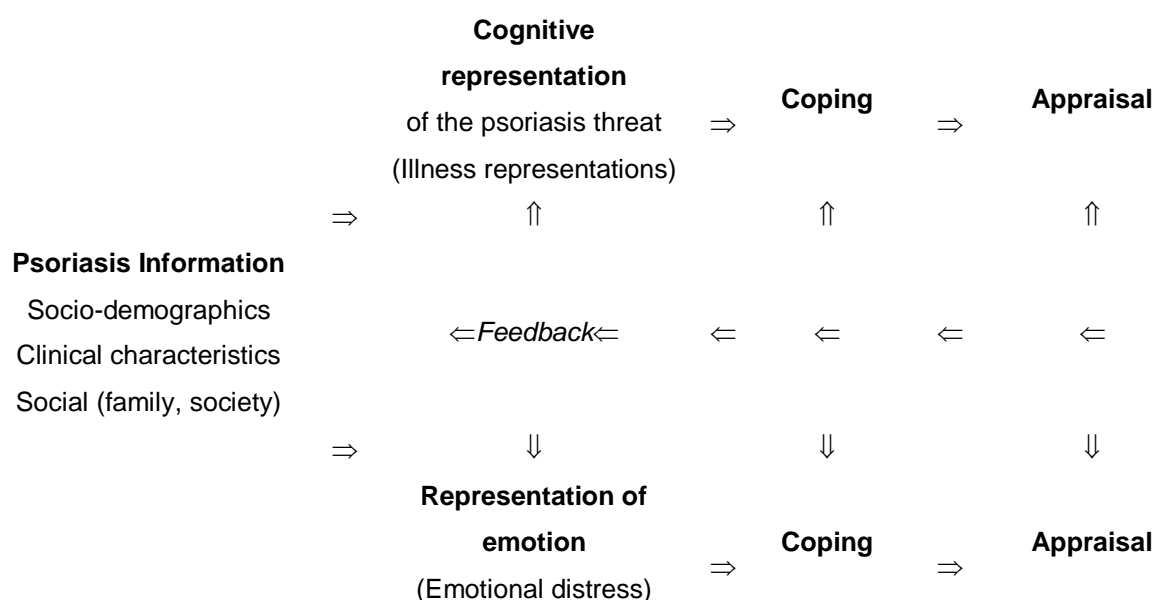
Figure 3: This representation of Leventhal's self regulatory common sense model of illness of health and illness is adapted to represent responses to psoriasis risk information. The processes involved in this model all take place within a social context but this is not depicted in the diagram.

Cognitive representation and coping arm

The SR-CSM suggests there is parallel cognitive and emotional processing of a health threat such as psoriasis. The cognitive representation asks, 'what is psoriasis?' and the answers to these questions are informed by social influences such as doctors, families, media representations and other lay sources. These social influences will interact with other pre-existing beliefs in order to guide an individual's *cognitive representation* of their illness. The model identifies five key illness-related cognitive representations: causation, timescale, control, consequence and identity. Once these cognitive representations have been formulated, the individual will then ask 'what can I do to make this better?' which is a problem-focused *coping* strategy. A coping strategy such as adhering to a medical treatment program will then be *appraised* as to how effective it has been in ameliorating the psoriasis (illness threat) and the

appraisal will feedback into the current cognitive representation of 'illness controllability.' The SR-CSM model has been revised and now includes two more illness representations: illness coherence, which is an individual's overall coherent understanding of their illness; and the control subscale has been divide into treatment control and personal control dimensions (Moss-Morris et al., 2002). Although the original model was developed through analysis of qualitative interviews with patients (Leventhal et al., 1984), a quantitative measurement tool has been developed and revised in order to capture the degree of agreement individual patients have with each illness representation (Illness Perceptions Questionnaire-Revised (IPQ-R; Moss-Morris et al., 2002).

Studies examining the illness representations in a psoriasis population have combined physical severity ratings with the IPQ-R data (O'Leary et al., 2004; Fortune et al., 1998). Stress was the highest rated causal belief, followed by genetics. Participants were more likely to believe that genetics caused their psoriasis if they had family members with psoriasis. The three most commonly associated consequences of living with psoriasis were that psoriasis has major consequence upon patients' lives, it is a serious condition and it has changed the way in which the individuals' see themselves. The participants' representations of the condition's chronicity were that it would be a permanent and recurrent problem, and 46.6% of the study population agreed/strongly agreed that 'what I do can determine whether my psoriasis gets better or worse,' demonstrating personal control over their condition. None of the cognitive illness representations were associated with the physical severity of the condition. The illness representations collectively accounted for more variance in psychological and social disability and distress than the physical severity ratings (O'Leary et al., 2004, Fortune et al., 1998). These findings further support the assumption that the distress experienced by people living with psoriasis is due to their interpretation of their illness rather than its physical severity. A cognitive behavioural therapy (CBT) study (Fortune et al., 2004a) reported their intervention led to physical psoriasis severity, distress and QoL improvements. Participants were found to change their illness identity, cause and consequences representations as a result of participation. This study highlighted how illness identity, the belief that stress causes psoriasis and that psoriasis has serious consequences upon an individual's life may be key illness representations which maintain distress, QoL and may even exacerbate physical symptoms of psoriasis.

Emotional representation arm
The individual will develop an *emotional representation* of their illness, 'how do I feel about psoriasis?' This may include shame or embarrassment and an individual will consequently develop emotion-focussed *coping* strategies to answer the implicit question 'what can I do to make myself feel better?' Many people with psoriasis adopt avoidant coping responses to deal with their negative emotional representations of living with psoriasis (Fortune et al., 1997). Avoidant coping can comprise of behavioural disengagement such as *avoiding* the perceived threats, for example avoiding swimming, which can impact on social functioning, or *escaping,*

for example through drug or alcohol misuse. Avoidant coping can also involve mental disengagement or denial. The use of avoidant coping strategies has been found to contribute to the overall QoL impairment experienced by people with psoriasis more than physical variables (Fortune et al., 1997). This further supports the assertion that how an individual responds to a health threat with their personal psychological representations and consequent coping behaviours can have more of an effect upon their overall functioning than the severity of the disease itself.

There is a bi-directional link between the cognitive and emotional arms of the SR-CSM model: the emotional response informing the cognitive representations just as the cognitive representations can account for distress (Leventhal et al., 1984). The degree and causality of the link between these arms is not currently clear.

A number of cognitive therapy programmes have targeted the content of maladaptive illness-related cognitions in people with psoriasis in order to reduce associated distress. These interventions will be reviewed later in this chapter (Section 2.4).

2.2.4 Psychological and social disability exacerbating psoriasis

Living with distress can exacerbate the physical severity of psoriasis because it has been found to interrupt the efficacy of physical treatment options. People with psoriasis who worried excessively reached skin clearance in phototherapy significantly slower than those without a co-morbid distress (Fortune et al., 2003b). Worrying appears to produce a physical response, which has a detrimental effect on treatment outcomes.

Distress has also been found to reduce psoriasis patients' treatment adherence (Richards et al., 2006). If the physical therapies for psoriasis keep improving in their level of efficacy but patients do not use them appropriately, then their therapies lose their utility.

The cognitive and emotional representations of the SR-CSM, can lead to avoidant 'escape' coping health behaviours. Alcohol misuse is a maladaptive behaviour commonly found in people living with psoriasis (McAleer et al., 2011). Alcohol misuse is more likely if the individual is also suffering from distress (Rodgers et al., 2000), which suggests it may be an avoidant emotion focussed coping behaviour to deal with the negative emotional representation of living with psoriasis. Increased alcohol consumption can exacerbate the physical symptoms of psoriasis (Poikolainen et al., 1990) and increase the overall risk of mortality (Poikolainen et al., 1999). High alcohol consumption can modulate metabolic and immunological changes, which may contribute to psoriasis flare-ups (Tobin et al., 2009).

People with psoriasis are more likely to smoke cigarettes and just as with alcohol, this is increased if distress is present (Rodgers et al., 2000). Smoking, like alcohol consumption, also exacerbates the physical symptoms of psoriasis (Fortes et al., 2005, Li et al., 2012). Cigarette

smoke has been reported to produce pro-inflammatory effects, which could exacerbate psoriasis (Francus et al., 1992).

Alcohol and cigarette use may be used as an emotion focussed coping mechanisms to deal with the distress of living with psoriasis, but these behaviours may exacerbate the physical psoriasis symptoms and other co-morbid health conditions.

Obesity has been associated with distress disorders (Simon et al., 2006) and psoriasis (Henseler & Christophers, 1995). Metabolic syndrome is a group of medical risk factors including high lipid levels, central obesity and insulin resistance (obesity, alcohol and cigarette consumptions) that increase an individual's likelihood of developing coronary heart disease (CHD), stroke and type-2 diabetes. As some people with psoriasis demonstrate a metabolic syndrome this may help explain why people with psoriasis have an increased risk of cardiovascular disease and diabetes (Boehncke & Boehncke, 2009).

2.2.5 Summary of stress and psoriasis

There is rhetoric across clinical and research settings that stress exacerbates the physical symptoms of psoriasis, despite inconclusive supporting evidence. The next section will propose a PNI pathway that could mediate the relationship between stress and physical psoriasis symptoms.

The key progression within this field of research began when Fortune et al., (1997), Main et al., (2000) and Richards et al., (2001) repeatedly reported that there was not a direct connections between psoriasis severity and association emotional distress and quality of life impairment. This lack of correlation led to the examination of the active interpretation of psoriatic symptoms. These appraisals may have been driven by beliefs (Fortune et al., 2004; O'Leary et al, 2004), deeper schema (Mizara et al., 2012) or more permanent traits such as alexithymia (Fortune et al., 2002a).

QoL measurements in psoriasis are composite scores, which represent the biopsychosocial consequences (physical symptoms, emotional distress and social difficulties) of living with the condition. Distress can also increase the likelihood of engaging in maladaptive health behaviours such as increased alcohol and cigarette consumption, which can exacerbate the physical psoriasis symptoms further and also contribute to other co-morbid physical health problems such as cardiovascular disease.

2.3 Psychoneuroimmunology

Stress responders believe their physical psoriasis symptoms are exacerbated when they experience stress. One area of research, which provides an explanatory framework for how stress influences the presentation of physical psoriasis symptoms, is the field of PNI.

2.3.1 Sympathetic-Adrenal-Medullary and Hypothalamic-Pituitary-Adrenal Axes

2.3.1.1 Sympathetic-Adrenal-Medullary axis

When an individual encounters a stimulus which they appraise as a stressor (threat), there is an automatic physical arousal response produced by the SNS, which occurs within seconds of experiencing the stressor. The SNS begins this fight or flight response (Cannon, 1932) via the Sympathetic-Adrenal-Medullary (SAM) axis. In the SAM axis the sympathetic pre-ganlionic neurons in the spinal cord are activated which release noradrenaline and adrenaline (catecholamines). These catecholamines signal to the pre/para-verterbral neurons, which innervate organs (e.g. the heart) to increase heart rate leading to release of glucose, which enables the individual to produce appropriate coping behaviours such as fight or flight (Sapolsky, 2002). Although these physiological changes (increased heart rate) enable enough blood and oxygen to reach the muscles to fight or flight frequent activation (chronic stress) can cause physiological wear and tear (allostatic load) (Hamilton-West, 2011).

2.3.1.2 Hypothalamic-pituitary-adrenal axis

The HPA axis in contrast to the SAM has a slow reaction to the stressor, in the tens of minutes, and produces a sustained stress response (Baer et al., 2001). The hippocampus, amygdala and prefrontal cortex pass memory, attention, sensory and arousal information about a potential stressor to the hippocampal paraventricular nucleus. The nucleus excretes corticotrophin releasing hormone (CRH) and arginine vasopressin (AVP). Corticotrophin releasing hormone and AVP act upon the anterior pituitary, which releases adrenocorticotrophic hormone (ACTH). This stimulates the inner adrenal cortex to release glucocorticoids (e.g. cortisol in humans), which, amongst other things, can modulate the immune response. Cortisol regulates CRH through a negative feedback cycle (Miyakaki et al., 2000). Cortisol therefore has an inhibitory feedback response upon the HPA axis function.

As with the SAM axis, this HPA activation is adaptive but chronic stimulation (chronic stress) might lead to allostatic load including scarring of the HPA axis, which could impair its functioning (McEwen & Stellar, 1993). The skin has been found to have a peripheral equivalent of the HPA axis, which appears to co-ordinate the peripheral skin stress response in alignment with the central HPA axis response (Hall et al., 2012). The HPA axis is represented in Figure 4.

Figure 4: Diagram depicting the HPA axis
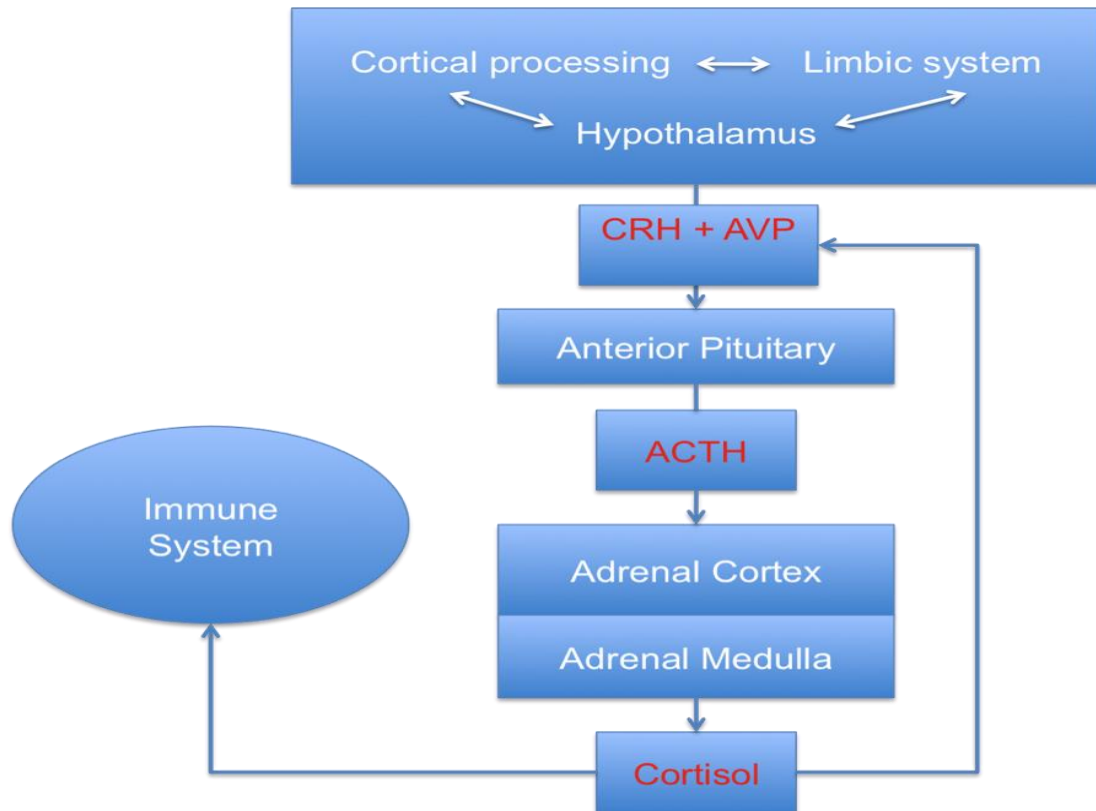
Figure 4: A simplified schematic of the HPA axis pathway, including the organs, neurotransmitters and hormones, which can influence the immune system.

2.3.2 The immune system

The human immune system is influenced by cortisol output from the HPA axis. The immune system includes a cellular component, which matures within bone marrow, thymus, spleen and lymph nodes (Lydyard, 2004). The immune cells are interdependent and work together to protect the body from infection and danger. There are six types of cells; dendritic cells (identifying and then presenting antigens to other cells to the immune system); macrophages (act similarly to dendritic cells); granulocyte leukocytes (remove bacteria); B-cells (antibodies); natural killer cells (specifically to kill parasites) and T-cells. T-cells can generate T-helper cells (TH), which activate other immune cells to isolate/remove threats. T-cells also generate T-killer cells. T-cells differentiate into TH cells by cytokines. One transformation, which is possibly important in psoriasis pathogenesis, is that of Th1 to TH-17 cells and this change happens when the cytokine IL-6 is present. TH-17 cells produce IL-17, IFN-γ and TNF -α.

The influence of perceived stress upon the immune system cytokines has been examined within a wound-healing framework. Trials comparing the healing time of punch-biopsy wounds between people who are chronically stressed and a control group; and between a group of participants during a non-stressed and a stressed time period reported wounds in the stressed groups to heal slower than those in the non-stressed group (Kiecolt-Glaser et al., 1995; Marucha et al., 1998). Blood samples were taken from participants in these studies and the mRNA was analysed. Those in the stressed group had a reduced amount of T-cell immune pro-inflammatory cytokines such as IL-1β in response to lipopolysaccharide (a molecule which elicits immune responses in animals) stimulation in comparison to the non-stressed group (Kiecolt-Glaser et al., 1995; Marucha et al., 1998). People with psoriasis who were exposed to an acute stress test were found to express a larger number of T-cells and NK cells. The T-cells and NK cells were employed in innate immune responses, in comparison to healthy controls (Buske-Kirschbaum et al., 2007, Schmid-Ott et al., 2009).

Stress appears to modulate T-cell function and pro-inflammatory cytokine in skin, indeed these immune system components play a key role in psoriasis pathogenesis (Hall et al., 2012; Chapman and Moynihan, 2009). Stress has also been found to activate mast cells, which release IL-6, histamine and other factors which may play a role in the pathogenesis of psoriasis plaques.

Psychoimmunological pathways have been examined within a skin barrier function model. The functionality of the skin barrier has been implicated in the pathogenesis of psoriasis, and stress has been found to interrupt its function. Stress and sleep interruption have also been found to interrupt the recovery of the skin barrier after trauma (Hall et al., 2012, Altemus et al., 2001). The combination of research from stress-skin models strengthens the feasibility of the link between stress and the characteristic symptoms of psoriasis.

2.3.3 Cortisol

An established finding within psychophysiology is that stress increases salivary and serum cortisol levels in humans (Ader, 1991, Biondi & Picardi, 1999). Cortisol can modulate production and receptor expression of cytokines (Wiegers & Reul, 1998) and cytokines such as IL-1, IL-17 and TNF- α are implicated in the pathogenesis of psoriasis (Chapman & Moynihan, 2009). These cytokines will also feedback into the HPA axis (Turnbull & Rivier, 1999) creating a cycle between HPA system activation, cortisol excretion and pro-inflammatory cytokines as described in Figure 5.

Figure 5: A diagram depicting the HPA feedback system
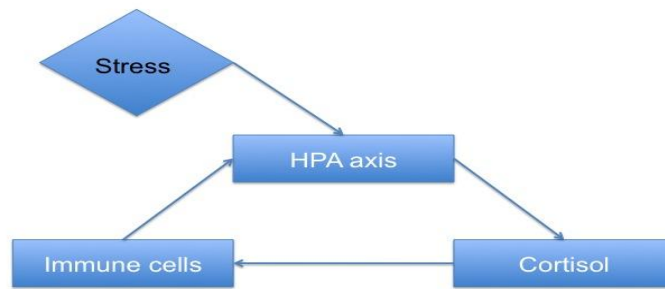
Figure 5: A representations of the negative feedback system, indicating the pathway some immune cells follow to feedback into the HPA axis.

A study divided healthy participants into those who showed a high cortisol increase to experimentally induced acute stressors (responders) and those who did not (non-responders) Kunz-Ebrecht et al., 2003). The study found that the responders had lower levels of IL-6 and IL-1ra together with higher perceived stress scores and were more likely to experience distress. So in healthy participants high cortisol reactivity to a stressor resulted in lower cytokine expression and higher perceived stress and distress. The authors propose two explanations for the findings: (1) the HPA axis output of cortisol impairs the activation of IL-6 and (2) the cytokines may be feeding back and regulating HPA axis functioning (the cycle). These studies support the proposal that stress, via HPA axis cortisol output, can influence immune system functioning and this has been shown to impair wound healing in the skin (Kunz-Ebrecht et al., 2003) and could therefore theoretically play a part in exacerbating physical psoriasis symptoms.

Neuroendocrine function has been measured in people with psoriasis and this group have generally been reported to display a hyporeactive cortisol response to acute stress (Karanikas et al., 2009; Schmid-Ott et al., 1998), however one study did not find any difference between a healthy control group and a psoriasis group (Buske-Kirschbaum et al., 2006). People with psoriasis who are stress responders had lower serum cortisol levels after an acute stress test (Trier Social Stress Test (TSST); (Kirschbaum et al., 1993)) than non-stress responders (Richards et al., 2005). Morning levels of serum cortisol in people with psoriasis have been negatively correlated with the amount of daily life stressors but not correlated with physical severity (Evers et al., 2010). Participants were split into those who experienced high and low daily stressors and there was a significant difference between the two groups on serum cortisol levels but not on physical severity. These studies suggest that people with psoriasis who are currently stressed may have a lower diurnal pattern of serum cortisol and a smaller reactivity to

an acute stressor. This lower cortisol level and hyporeactivity may modulate T-cell and cytokine expression in the skin, which could be exacerbating psoriasis symptoms.

2.3.3.1 Circadian cortisol pattern

Free circulating cortisol is a dynamic construct, which varies across the day (diurnal patterns) and in response to stressors such as stress and awaking (reactivity). The average diurnal cortisol patterns in healthy controls are depicted in Figure 6 (Reference: http://www.wardelab.com/img/reports/20-3-F2.jpg Downloaded: 29th June 2010).

Figure 6: Graph depicting the diurnal cortisol patterns in healthy participants
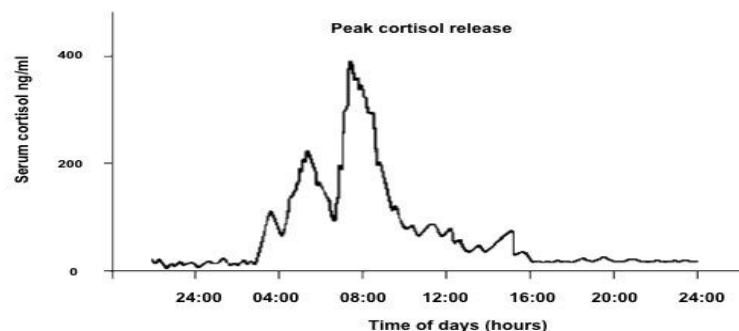
Figure 6: The graph depicts the diurnal variation of the amount of cortisol (nanograms per millilitre) found within the blood serum of healthy people over 24 hours.

Figure 6 shows the peak of blood serum cortisol just prior to 08.00. It was assumed that time period would reliably be associated with a rise in serum cortisol. This assumption was used in laboratory research protocols and blood serum or salivary cortisol, which have high concordance, was collected between 08.00 and 09.00 in the morning. The single samples taken at this time proved to have very large variation (range 165 – 690 nanograms per millilitre (ng/ml)) to the extent that healthy participants' cortisol levels overlapped with the levels recorded in people living with Cushings disease (characterised by chronic elevated levels of cortisol) (Laudat et al., 1988). Pruessner et al.,1997) recognised this unreliable measure and developed an alternative hypothesis and methodology. He proposed that cortisol peaks in response to the stress of an individual waking up and, as people wake at different times, taking a measure at 08.00 would be meaningless without knowing the true awakening time of that person. The study examined three different age groups by taking cortisol measurements during the first hour of awakening across two to three different days with gaps in between the testing

days. Pruessner et al. (1997) found an increase of 50 – 75% in cortisol levels immediately upon awakening and 30 minutes later, and suggested that by measuring this rise the awakening response would be a more reliable marker of cortisol levels. He also found low intra-individual differences in the waking cortisol response this has led to the Cortisol Awakening Response (CAR) becoming one of the most popular and effective ways to measure cortisol reactivity (Chida & Steptoe, 2009).

2.3.3.2 The cortisol awakening response

Elevated or attenuated CAR can signal a dysfunctional HPA axis, which in turn can modulate the amount of cortisol produced. The CAR has become a key research construct within PNI. The sharp rise in cortisol, recently estimated at between 50% and 160% (Clow et al., 2004), is still conceptualised as a physiological reaction to the naturally occurring stressor of awakening from sleep (Wilhelm et al., 2007). It has been suggested that the CAR is a more important dimension of the cortisol profile than the overall magnitude of diurnal cortisol output within an individual (Mikolajczak et al., 2010, Clow et al., 2004, Fries et al., 2009). Free circulating cortisol is commonly measured from saliva samples because these techniques are easy to administer and less likely to evoke a stress response than blood collection techniques.

It has been observed that if cortisol levels remain elevated during sleep, there is an attenuated CAR and this may be due to a higher measurement at immediately upon awakening (s1). This measurement, s1, is now entered into studies exploring awakening response reactivity in order to take account of the pre-awakening levels of cortisol (Clow et al., 2009). If a group displays a higher s1 and a small CAR then there may be higher overall diurnal patterns of cortisol excretion. If a group demonstrated a lower s1 and a small CAR then they may have a lower overall diurnal pattern of cortisol.

There are many variables, which are reported to affect the diurnal cortisol secretion pattern. These include lifestyle influences such as caffeine (Lovallo et al., 2005), alcohol (Badrick et al., 2008), cigarette consumption (Badrick et al., 2007); demographics such as gender (Kirschbaum & Hellhammer, 1999), socioeconomic status (Cohen et al., 2006), ethnicity (DeSantis et al., 2007), age (Ice, 2005); physical health status including BMI (Ursache et al., 2012, Therrien et al., 2007). Variables which confound results include the use of steroid based medications (Masharani et al., 2005) and pregnancy (Obel et al., 2005). There are inconsistent findings as to which variables must be controlled for when examining the CAR (Clow et al., 2004). Recent studies exploring the influence of psychological and physical health conditions consistently control for age, gender and BMI (Sjors et al., 2012, Merswolken et al., 2012) but there does not seem to be an accepted set of variables to control for.

2.3.3.3 CAR and psychological outcomes

Whilst the relationship between psychological variables and diurnal cortisol patterns has been explored quite extensively, there has been a large variation in the methodology used. The

variation in methodology has meant that no strong conclusions can be drawn from the evidence base. Therefore this section will focus only on studies which have included a measurement of CAR rather than diurnal cortisol patterns. Within the CAR literature there have also been methodological variations. The CAR can be measured in several different ways. First each time point (0, 15, 30, 45 minutes post awakening) can be compared between groups to examine any significant differences. Secondly, composite scores can be calculated from the four collection points. These composite scores include the area under the curve (AUC) with reference to ground/zero (AUCg), AUC with reference to the increase from s1 (0 minute collection point) (AUCi) or it can be measured by subtracting the s1 from the peak (usually at 30 minutes post awakening), called the dynamic change score (Pruessner et al., 2003). AUCg represents the *overall CAR*, whereas AUCi and dynamic change responses represent only the *CAR reactivity* levels. This next section shall report either *overall CAR* or *CAR reactivity*. Figure 7 presents a hypothetical data set and the three collection methods for CAR.

Figure 7: A diagram representing the CAR composite scores (AUCg, AUCi and Dynamic Change)
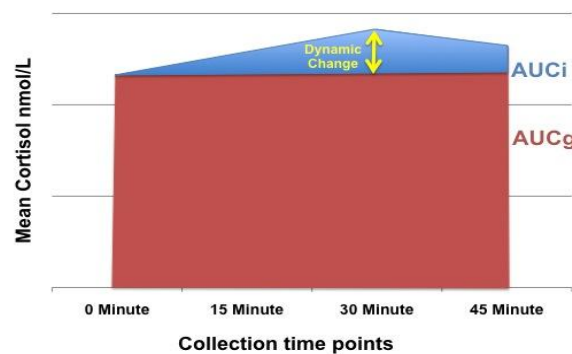
Figure 7: This diagram presents the areas that are calculated for the two composite CAR scores (AUCg and AUCi) and the dynamic change score. AUCg is the red and blue section summed together. The AUCi is the blue section. Dynamic change is depicted with the yellow arrow.

Acute stress is associated with a greater overall CAR (AUCg) whereas chronic stress is associated with an attenuated overall CAR (Pruessner et al., 1999). A meta-analysis included 62 papers that examined the associations between overall CAR, CAR reactivity and psychological variables (Chida & Steptoe, 2009). Two robust findings emerged after controlling for confounding variables such as smoking. Firstly, general life stress and job stress were associated with an increased CAR reactivity. Secondly, fatigue, burnout and exhaustion were

associated with an attenuated CAR reactivity. Overall CAR was significantly positively correlated to general life stress but negatively correlated to distress disorders (Post Traumatic Stress Disorder). Acute stressors seem to produce elevated CAR (overall and reactivity) but if this high CAR reactivity becomes a chronic state then this appears to lead to an attenuated CAR (overall and reactivity) (Wong et al., 2012). Chronic stimulation of the HPA axis can lead to a strain on the physiological systems, called allostatic load (McEwen & Stellar, 1993). Allostatic load has been measured with an index of biological markers, such as C-reactive protein, insulin and creatinine. High allostatic load was found to be associated with an attenuated CAR reactivity response and smaller cortisol reactivity to an experimentally social stressor (Juster et al., 2011). Acute stress appears associated with elevated CAR reactivity but if an individual encounters many acute stressors, which develop into a chronic stress state this can increase the allostatic load on the HPA function.

In the meta-analysis there was no overall association between depression and CAR (overall or reactivity) (Chida & Steptoe, 2009). A recent prospective study found that an elevated CAR reactivity was a risk factor, independent of life events, for major depression (Vrshek-Schallhorn et al., 2012). However, people living with recurrent depression have been found to present an attenuated overall CAR (Gex-Fabry et al., 2012). To explain how an elevated CAR is a risk for depression but an attenuated CAR is a consequence of depression, the scar hypothesis (Gex-Fabry et al., 2012) proposes that a consistently large physiological response to the awakening stressor could lead to the HPA system becoming worn out or scarred from overstimulation and result in attenuated CAR in people living with depression. An elevated CAR could be a risk factor for depression; overstimulation of the HPA axis may scar its function leading to an attenuated CAR and attenuated CAR was associated with depression.

Anxiety, like depression, was not associated with CAR (overall or reactivity) in the meta-analysis (Chida & Steptoe, 2009). However, people with clinical anxiety disorders such as panic and agoraphobia have demonstrated higher s1 and a larger CAR reactivity in comparison to healthy controls (Vreeburg et al., 2010b). A greater CAR reactivity has been reported to increase risk for acute stress disorder in response to traumatic stressor events (Inslicht et al., 2011). There is some evidence to suggest that this elevated cortisol reactivity reduces when people are in remission from an anxiety disorder. However, this is still in contention and research is exploring whether anxiety exhibits the same scar effects as seen in depression (Vreeburg et al., 2010b).

A cohort study examining CAR reactivity in people with or without distress and those with or without a family history of distress found the people with a family history of distress had higher CAR reactivity than those without, and that these levels were equal to people who had distress disorders (Vreeburg et al., 2010a). It has been suggested that elevated CAR reactivity is a trait marker indicating a biological vulnerability to developing distress, which supports the scar and allostatic load hypotheses (McEwen & Stellar, 1993).

Recent studies have examined specific psychological mechanisms associated with CAR measurements. Significant positive correlations emerged between CAR and optimism (Endrighi et al., 2011), worry, rumination (Zoccola et al., 2011) and preservative thinking (worry and stress-related thinking) (O'Connor et al., 2012). This is a relatively new area of research, and there is no conclusive evidence yet to explain which psychological mechanisms influence the emerging association between CAR and distress.

CAR has begun to be entered as an outcome variable within psychological intervention studies. For example a recent study examined the effect of MBCT upon the outcomes of depression and CAR. Depression scores were correlated with an attenuated overall CAR. The MBCT intervention was found to improve symptoms of depression but did not lead to any change in CAR (Gex-Fabry et al., 2012).

2.3.3.4 Cortisol reactivity and physical health outcomes

The CAR has been explored as a possible mediating response to explain why distress can be a risk factor for several physical health conditions. People with diabetes were found to have an attenuated CAR reactivity but a normal diurnal cortisol profile in comparison to a healthy control group (Bruehl et al., 2009). People living with amyotrophic lateral sclerosis (ALS), a disease of the brain and spinal cord, were found to have an attenuated CAR reactivity, but no difference in their overall CAR in comparison to healthy controls (Roozendaal et al., 2012). The physical severity of ALS and severity of depression were negatively correlated with the CAR reactivity but not with overall CAR, so the more attenuated the CAR reactivity the more severe the level of depression and ALS. Women with irritable bowel syndrome (IBS) have been found to have a higher $s1$, together with an attenuated CAR reactivity in comparison to healthy controls (Suarez-Hitz et al., 2012). This group also had an attenuated cortisol reactivity response to a social stress test. These associations suggest physical health conditions are sometimes accompanied by an attenuated CAR reactivity. These studies do not explain whether the change in CAR function is a risk or consequence of physical health conditions or whether it is caused by the distress, which often accompanies living with a chronic physical health condition.

The role of distress in the CAR-physical health link has begun to be explored. People with CHD demonstrated elevated CAR (overall and reactivity) and their level of anxiety was found to significantly predict the CAR (overall and reactivity) independent of physical disease status (Merswolken et al., 2012). People living with breast cancer were found to demonstrate significant differences on distress scores as compared to healthy controls but there were no differences between these groups on CAR (overall or reactivity) (Vedhara et al., 2006). No firm conclusions can be drawn as to the role of CAR in physical health conditions yet as there are many methodological and occasionally theoretical inconsistencies present within this evidence base.

Although cortisol reactivity to acute stressors has been measured in people with psoriasis the CAR has not previously been examined.

2.3.4 Summary of PNI

Stress has been shown to modulate HPA axis function, cortisol secretion and immune system cytokines production. Pro-inflammatory cytokines are involved in the pathogenesis of psoriasis and therefore this pathway (Stress – HPA axis function – cortisol – immune system – pro-inflammatory cytokines) could possibly explain the clinical and research hypothesis that stress causes physical psoriasis symptoms.

Cortisol output is dynamic and one robust characteristic is the hormone's distinctive rise in response to awakening in humans, also known as the CAR. The CAR is a marker for HPA axis function. It is a relatively new area of research and while there are no conclusive associations it appears that CAR (both overall and reactivity) is greater in people currently experiencing acute stress and it may be a risk factor for developing distress disorders such anxiety and depression. CAR (overall and reactivity) is attenuated in people suffering from chronic stress, fatigue and distress disorders such as depression. The scar and allostatic load hypotheses suggest that a hyperactive CAR may increase allostatic load upon the HPA axis which could impair its functioning, as signalled by an attenuated CAR.

An attenuated CAR reactivity has been found in chronic physical health conditions such as diabetes and IBS but has not been measured in a population of people with psoriasis. People with psoriasis have been found to produce lower blood serum cortisol levels than controls in response to experimental stress and these levels have been negatively correlated with stressful events. As CAR is a distinct element of the cortisol profile, it will be useful to examine how this correlates with the physical severity and psychological variables within a population of people with psoriasis.

2.4 Psychological interventions to reduce the physical severity of psoriasis: A systematic review.

The previous sections outlined the burden which living with psoriasis places upon psychological, emotional, social and possibly HPA axis function. In response to clinical and research observations, that stress causes or exacerbates psoriasis flare, a variety of stress management methods have been trialed within this population. If stress causes psoriasis flare then a technique that successfully reduces stress would be assumed to reduce physical psoriasis symptoms, particularly in stress responders. The stress management techniques may also target mechanisms that maintain associated distress and QoL impairment.

Psychological interventions in chronic physical health conditions often target the secondary psychiatric (Koo & Lebwohl, 2001) distress in co-morbid physical and mental health conditions. They emphasise targeting distress (anxiety or depression), QoL impairment or health behaviours (treatment adherence) and the physical symptoms are either not measured or included as a secondary objective (Lamers *et al.*, 2011, Petrak & Herpertz, 2009). When the aim of an intervention is to improve distress then the theoretical basis would draw upon clinical psychology models and adapt them to the specific needs of a chronic physical health condition population. Currently techniques which aim to identify and manipulate maladaptive cognition content such as CBT are reported to achieve the greatest success in improving distress in people with chronic physical health conditions (Pilling et al., 2009). A core element of cognitive therapies is to challenge the content of maladaptive cognitions and this has been accepted as a necessary element in order to effect emotional improvements. Other stress reduction techniques employ alternative techniques that do not specifically identify and challenge the content of cognitions. Cognitive techniques are accepted as the most effective interventions for people with chronic physical health conditions but it is not understood whether cognitive challenge is essential over and above any other form of stress management technique, especially in improving physical symptoms in co-morbid conditions.

Psychodermatology classifies conditions as either (1) psychophysiological (2) primary psychiatric or (3) secondary psychiatric (Koo & Lebwohl, 2001). Interventions that target distress in psoriasis treat it as a secondary psychiatric condition. Focussing on the psychiatric model of explanation can miss the mechanisms of how stress and psoriasis interact and may miss the full continuum of people who need additional support. There is some evidence to suggest psoriasis is a psychophysiological condition, where psychological state influences the physiological state. This literature review suggests stress might exacerbate the physical symptoms of psoriasis through a PNI pathway. This presents a different theoretical framework (psychophysiological), which must examine how psychological mechanisms of change could improve the physical symptoms of psoriasis.

In order to inform this research project as to which is the most appropriate intervention to employ with this study population, a systematic examination of the literature was conducted and a synthesis of the results presented. The following section presents the methods and results of this review. This review has been accepted for publication and the reference for the manuscript (in press) is available in Appendix 9.1.

2.4.1 Review aims

This review primarily aimed to examine if stress management techniques can improve physical psoriasis symptoms. There were four research questions:

1. Can stress management techniques improve the physical symptoms of psoriasis?
2. Can stress management techniques improve stress, distress and QoL for people with psoriasis?
3. Is cognitive challenge essential to facilitate changes to physical, psychological, emotional and QoL outcomes?
4. How reliable are the conclusions from these studies given the study quality?

2.4.2 Methods

This review was conducted systematically in order to reduce bias in the inclusion and synthesis of results. The procedures for this review will now be outlined.

2.4.2.1 Data collection

Electronic databases (Cochrane Library, MEDLINE, EMBASE, SIGLE and PsychInfo) were searched (May, 2010) with strategies (MeSH terms and keywords) tailored to each database (re-run in November 2010). The searches were run from inception until current day across all the databases and further details of the search terms are available in Appendix 9.2. Journal alert services were enlisted until January 2011. The reference lists of relevant reviews were searched and members of the cross-discipline research team recommended the key journals for hand searching. The journals were hand searched by the author in December 2010.

Studies were included if they met the PICOS (Population, Intervention, Comparator, Outcome, Study design) criteria: a population aged >/=18 years with a primary diagnosis of psoriasis; a defined stress reduction intervention (no additional oral, topical or pharmacological); a comparison group; a primary outcome of physical severity with or without secondary outcome of psychological and QoL; a randomised control trial (RCT) or quasi-RCT design. Searches were confined to English language peer-reviewed journals.

Initial sifts were combined and duplicates deleted. Of the original search results 40% were scrutinised by members of the wider research team to test the inclusion criteria. The full papers were then collected and examined to check for eligibility.

2.4.2.2 Data extraction

A data extraction form was developed and piloted with two reviewers. Discrepancies were resolved and minor adaptations made during discussion. Three members of the research team performed the data extraction. Before discussion there was an 81% agreement across researchers on the study quality. Discrepancies were resolved with discussion resulting in 100% concordance.

2.4.2.3 Quality assessment

A debate continues as to how quality of included studies within a systematic review should be assessed (Juni et al., 2001). The reporting of a study may exaggerate or underestimate the quality of the study's methodological rigour. A study's rigour will drastically affect the validity of a study's findings. Within meta-analyses quality rating can be used to weight statistical pooling. This review, however, was not a meta-analysis and quality checks were included simply to inform an overview of the evidence base rather than to define a hierarchy of study quality.

Studies were graded for quality on a scale based on the Cochrane instructions (Khan et al., 2001) including how randomisation was conducted; how free of bias the outcome assessor was; and an evaluation of the statistical rigour of the study. Based on clinical and research experience, the research team added five quality markers (1) whether there was a clinician-reported diagnosis of psoriasis; (2) the design (quasi or full RCT); (3) how much training/experience the researcher had in delivering the intervention; (4) validation of the outcome measures used and; (5) whether the statistics used and reported results were relevant to answer the original research questions of the study. The highest quality score (total) across these eight checks is 32 indicating optimum quality.

2.4.2.4 Data synthesis

The studies were individually examined for content, efficacy and quality and then tabulated to offer a summary of how effective stress reduction methods have been in changing physical severity and associated distress. The process of synthesising the data produced emergent themes regarding the content of the intervention techniques.

The types of interventions used in each study were examined in more depth and discussed with the wider research team to develop consensus as to whether the intervention included a cognitive challenge element or not. Some studies combined cognitive challenge interventions together with other non-cognitive challenge elements (combined focussed).

2.4.3 Results

The initial search yielded 730 trials, 720 were rejected either as duplicates (24 trials) or based on their title and abstract (696 trials). A hand search was conducted of the British Journal of Health Psychology; Health Psychology; Psychology & Health; Journal of Psychosomatic Medicine; Journal of Behavioural Medicine; Social Science & Medicine; British Journal of

Clinical Psychology; Psychology Health and Medicine; Journal of the American Academy of Dermatology; British Journal of Dermatology; Clinical Dermatology. Two additional papers were found (Vedhara et al., 2007). Full reports were collected for these 12 trials and two papers were removed: one included no statistical analysis (Boncz et al., 1990) and the other did not include a measurement of psoriasis (Schulte et al., 1985). Figure 8 contains details of the study selection process.

Figure 8: A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart
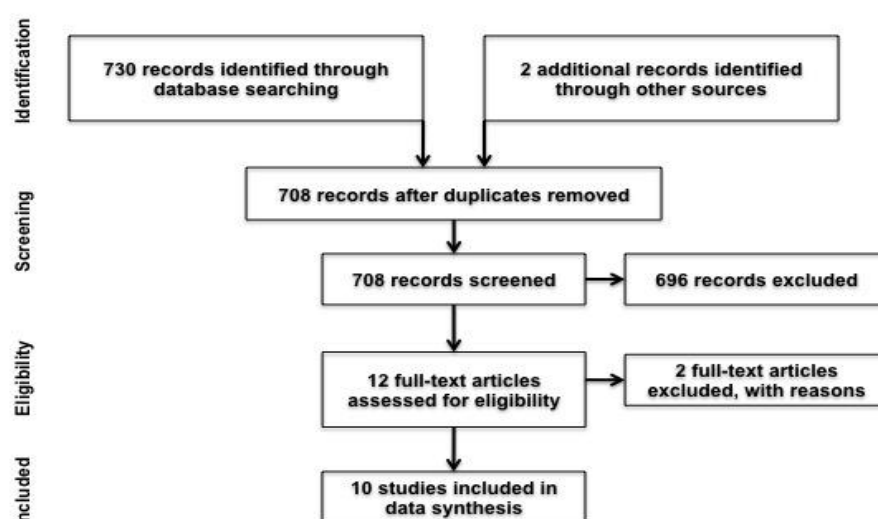
Figure 8: The flow diagram charts the progression of a systematic search process from the database searches through to the final ten included studies.

A meta-analysis could not be conducted due to the heterogeneity of primary outcomes used across the included studies (only 4/10 used the same primary physical outcome and only 3/10 used the same psychological outcome). The primary outcome was the effect of the intervention upon the physical severity of psoriasis and the secondary outcomes were the effects upon psychological stress/distress, QoL or mediating biomarkers.

The primary outcome statistics are reported in Table 1 but the statistics for any sub-analyses are presented in the results section. The studies are presented in quality rank order for descriptive rather than absolute ranking.

Table 1: Results table for stress reduction interventions for people with psoriasis

Studies	Quality	Study characteristics	Intervention	Results
Fortune et al., 2002.	**Ranking:** 1st **Score:** 25.67	*N* = 93. Mean Age: (Treatment) = 42.9 years (SD=11.6); (Control) = 43.1 (SD=12). Years with psoriasis: (Treatment) = 20.6 (SD=11.0); (Control) =18.8 (SD=11.1). 70% female in treatment; 65% female in control.	Weekly 2.5-hour group sessions for 6 weeks **Treatment:** CBT **Control:** TAU	✔ **Physical, (**PASI): Sig (t=-2.20, p<0.05). ✔ **Psychological**, (HADS)**:** Sig (HADS: Depression: t=4.7, p<0.001. Anxiety: t=-2.8, p<0.001). ✔ **QoL**, (PDI)**:** Sig (t = -3.33, p<0.001). **Attrition:** 25% in treatment group and 21% in control group at 6 weeks. 30% in treatment and 43% in control by 6 months.
Kabat-Zinn et al., 1998.	**Ranking:** 2nd **Score:** 25.33	*N* = 37. Mean Age = 42.9 (SD=15.1). Years with psoriasis =11.2 (SD=8.9). 54% female.	**Treatment:** MBSR; solitary (few minutes whilst in light booth) for approximately 13 weeks (3 sessions per week) **Control:** TAU.	X **Physical, (**Clinician ratings (photographs). Pre-defined end points: Sig 'halfway point': EHR = 3.88, p<0.05 and 'clearing point'. EHR = 3.75, p<0.05 ✔ **Psychological, (**SCL-90 and STAI): Ns. **Attrition:** 38%

Tausk et al., 1999.	**Ranking:** 3rd **Score:** 25.00	N = 11. Mean age=? Years living with psoriasis=? % female ?.	Group based. **Treatment:** Single blinded active hypnosis for 3 months+3 months un-blinded. **Control:** Neutral hypnosis (3 months)+active hypnosis (3 months).	✔ **Physical** (PASI): Ns. X **Physical** (Self report VAS 1-100 score): Ns. Sig in PASI and VAS clinical outcomes between highly and moderately hypnotisable participants (statistic not reported, p <0.05)**. Attrition:** 19%
Vedhara et al., 2007	**Ranking:** 4th **Score:** 24.5	N = 59. Mean Age = 50 (SD=13). Years with psoriasis = 22 (SD=15). 54% female.	ED via phone for 4 days + 12-week follow-up. **Treatment:** ED. **Control:** neutral writing task.	✔ **Physical** (PASI)**:** Ns ✔ **Psychological** (POMS and HADS)**:** Ns ✔ **QoL** (DLQI)**:** Ns **Attrition:** 14%
Zacharaie et al., 1996	**Ranking:** joint 5th **Score:** 23.00	N = 51.Mean age = 39.6 (SD=11.5). Years living with psoriasis = ? 62.76% female.	90 minute group weekly for month + fortnightly for 6 weeks. **Treatment**: psychotherapy + home practice **Control:** Stopped all TAU.	✔ **Psychological** (BDI and Brief Stress Scale)**:** Sig (statistic not reported, p <0.05) ✔ **Physical** (PASI)**:** Ns. **Attrition:** 12%

Gaston et al., 1998.	**Ranking:** joint 5th **Score:** 23.00	N = 24; Mean Age = 34.3 (SD=11.3). Years with psoriasis = 13.7 years (SD=9.5). 72% female.	12 weeks, 60 minutes one to one. **Treatment:** meditation. **Comparison:** meditation plus imagery. **Control:** WLC group and assessment control group.	X **Physical, (**clinician ratings)**:** Sig (partial r =0.30, p <0.05) ✔ **Psychological**, (PAIS)**:** not reported. **Attrition:** 25%
Paradisi et al., 2010	**Ranking:** 7th **Score:** 21.5	N = 78. < 45 years old = 40% Pennebaker, 66.7% King, 38.5% control. Years with psoriasis=?. Pennebaker= 53.3% female King = 58.3% female. Control group = 38.5% female.	ED for 3 days + phototherapy 3x week <8 weeks. **Treatment 1** Pennebaker ED. **Treatment 2** King ED. **Control:** phototherapy.	✔ **Physical** (PASI, SAPASI)**:** Ns but phototherapy effects maintained in Pennebaker group compared to both of the other groups (statistic not reported). ✔ **Psychological** (GHQ-12)**:** Ns. ✔ **QoL** (Skindex-12)**:** Ns. **Attrition:** 49%
Price et al., 1991.	**Ranking:** 8th **Score:** 20.6	N = 31.Mean age: treatment = 42.82 years (SD=?), control = 46 years (SD=?). Years with psoriasis: Treatment= 17 years (SD=?). Control = 25 years (SD=?). 47.83% female.	90 minutes group for 8 weeks **Treatment:** Psychotherapy. **Control:** TAU	✔ **Psychological** (HADS and EPQ-R)**:** Sig on HADS anxiety (F (1,21) = 2.81, p<0.05) and EPQ-R neuroticism (F (1,21) = 7.83, p <0.001) X **Physical** (clinician ratings and self ratings on VAS)**:** Ns. **Attrition:** 26%

Kienan et al., 1995.	**Ranking:** 9th **Score:** 20.17	N = 32.Mean Age = 40 (range 18 - 60). Years with psoriasis=14.3 (range=1-39). 37.5% female.	One to one for 6 weeks. **Treatment**: Biofeedback and relaxation. **Comparison**: relaxation. **Control:** TAU	**X Physical (self-report):** subjective symptom scale**):** Sig (F (2,29) = 3.29, p < 0.05) **X Physical (clinician-rated):** severity scale and symptom improvement scale**):** Ns for both scales. **Attrition:** 0 %
Lazaroff et al., 2000.	**Ranking:** 10th **Score:** 13.5	N = 30 (psoriasis patients) Median age range = 21 – 30 years. Years with psoriasis=?. 57% female.	3 x 30 minute groups per day (14 days). **Treatment:** Musical Resonance Therapy. **Control:** instructed to "somehow relax"	**X Physical** (Self reported stimulus to scratch and clinician rated degree of sickness)**:** Found a reduction in clinical outcomes but not statistically tested. **Attrition:** 0 %

Key: N = study population, **Sig** = Significant difference between groups post intervention. **Ns =** Non-significant difference between groups at post-intervention, ✔ **=** validated outcome measure, **X =** non-validated outcome measure**, SD** = standard deviation.**?** = unknown, **BDI** = Beck Depression Inventory, **CBT** = cognitive behavioural therapy, **DLQI** = dermatology quality of life questionnaire, **ED** = emotional disclosure therapy, **EHR** = estimated hazards ratio, **EPQ-R** = Eysenck personality questionnaire, **GHQ-12** = general health questionnaire, **HADS** = hospital anxiety depression scale, **MBSR** = mindfulness based stress reduction, **PAIS** = Psychosocial Adjustment to Illness Scale; **PASI** = psoriasis area severity index, **POMS** = profile of mood states, **PSS** = perceived stress scale, **SAPASI** = self-assessed psoriasis area severity index, **SCL-90** = symptoms checklist, **STAI** = State trait anxiety inventory, **TAU** = treatment as usual, **VAS** = visual analogue scale, **WLC** = waitlist control.

2.4.3.1 Study Quality

The RCT is considered the gold standard atop the hierarchy of evidence (Woolfe et al., 1990, Sackett et al., 1996). The RCT design is assumed to yield results with the least bias as randomisation will remove most individual variation (Khan et al., 2001). Seven studies, in this review, used RCT design whilst others used a quasi-RCT (patient preference technique, a controlled trial design without randomisation and a multiple time-series design (with randomisation)). Four studies were either preliminary reports or pilot as opposed to full-scale studies.

The minimum accepted power of a test is usually 80% certainty that the test will reject a false null hypothesis (type two error) (Pallant, 2010b). Only one study included a power analysis but it did not meet the sample size needed to achieve 80% power (Tausk and Whitmore, 1999). Thus, no study in this review was a full scale RCT that met the 80% power estimation.

The quality scores developed in this study are used as additional indicators of quality to assess the current status of the evidence base. The quality check scale is presented in Appendix 9.3. Table 2 presents the scores on each of the quality ratings and totals. The average study score was 22.2/32. The areas where quality was lowest were 'intervention facilitator quality' (1.4/3) and 'statistical rigour' (5.5/9). 'Intervention facilitator quality refers to if the intervention facilitator had was reported to have relevant training and experience in delivering the intervention. Statistical rigour referred to the use of appropriate statistical tests and full reporting of results, including the non-significant results.

Table 2: Summary of study quality ratings

Studies	Diagnosis (3)	Design (2)	Randomisation (4)	Scale rating (5)	Facilitator (3)	Outcome assessor (4)	Relevance (2)	Statistics (9)	Total
Fortune et al., 2002b	2	1	3	4.67	2	4.5	2	6	*25.17*
Kabat-Zinn et al., 1998	2	2	2	3.33	2	4	2	7	*24.33*
Kienan et al., 1995	2	2	3	1.67	1	2.5	2	6	*20.17*
Lazaroff et al., 2000	2	1	1	1	1	1.5	2	4	*13.5*
Price et al., 1991	2	2	3	3.6	1	2	2	5	*20.6*
Tausk et al., 1999	2	2	4	5	2	3	2	5	*25*
Zachariae et al., 1996	2	2	3	4	1	4	2	5	*23*
Gaston et al., 1988	2	2	3	3	2	4	2	6	*24*
Vedhara et al., 2007	2	2	4	4.5	1	4	0	7	*24.5*
Paradisi et al., 2010	2	2	4	5	1	1.5	2	4	*21.5*
Total	20	18	30	35.77	14	31	18	55	221.77
Average	2	1.8	3	3.6	1.4	3.1	1.8	5.5	22.18

2.4.4 Synthesis of the studies

Two of the ten studies employed a combined focus intervention combining cognitive techniques alongside non-cognitive focussed techniques. Eight studies adopted single focussed interventions (e.g. just cognitive therapy focus or just arousal reduction focus). It was not possible to conclude whether one type of intervention was superior to others largely due to poor design and reporting, as reflected in the quality assessment.

Cognitive therapy interventions are usually designed to manipulate automatic assumptions and/or unhelpful cognitions in order to manage the subsequent distress (see section 2.2.3.1). Interventions, which aim to reduce stress without targeting the content of cognitions and assumptions, are labelled as non-cognitive focussed interventions in this review for the purpose of comparison to cognitive challenge based interventions. Stress may impact psoriasis severity via other physiological stress parameters such as skin blood flow. Most of the studies that were examined lacked clarity regarding as to which mechanisms (e.g. physical relaxation or cognitive challenge) were targeted for which outcome (e.g. reduction in skin blood flow or reduction in distress). Each study is examined in more detail within each theme.

2.4.4.1 Single focus interventions

Fortune et al (2002b) used CBT and found significant differences in physical, psychological and QoL variables between the treatment (Treatment as usual (TAU) plus CBT) and control group (TAU). This study emerged as the gold standard in terms of design and methodology.
The study adopted a patient preference design, which although considered inferior to RCT (Green et al., 2008), is widely used in mental health studies as it is correlated with motivation to adhere to the intervention (Brewin and Bradley, 1989).

Vedhara et al (2007) used an Emotional Disclosure (ED) arousal reduction intervention. Participants spent 20 minutes writing or talking about their thoughts/the most upsetting times of their lives over the phone (one-to-one) over four consecutive days. Control participants were also called and asked to write about what had happened either that day or the day before. Results showed mood predicted severity of psoriasis in the intervention group but not in the control group.

This study had a rigourous design but by excluding group comparisons in preference for regression analyses the authors missed the opportunity to examine the effectiveness of the intervention in comparison to its well-designed control comparison.

Paradisi et al (2010) employed an ED arousal reduction intervention as an adjunct to phototherapy. They found no difference on physical severity, psychological or QoL outcomes between the intervention and control groups post-intervention. They did find, that the beneficial physical and QoL effects from phototherapy were maintained in the intervention group but not in the control groups.

Paradisi et al (2010) did not present the full between-groups analyses but merely reported they had not reached significance. The study reported a high attrition rate (49%), which was neither explained nor examined further. The author contacted Andrea Paradisi in December 2010 regarding some of the missing information regarding attrition rates, why there was no further between group analyses and other design queries. Whilst some questions were answered there was no explanation of the high attrition rate or why the between groups analyses had not been conducted.

Kabat-Zinn et al (1998) found participants who received a mindfulness arousal reduction intervention in addition to phototherapy reached skin clearance faster than those who did not. There was no difference between groups on the psychological outcomes.

Physical severity, assessed against four pre-defined photographic end points, was not a validated physical outcome measure which weakened the study design.

Tausk et al (1999) conducted a hypnosis arousal reduction intervention as an adjunct to TAU but did not find a difference between the intervention and control groups on physical outcomes. They did find differences in the physical outcomes between participants who were deemed highly or moderately hypnotisable, Form C (SSHS: C; (Weitzenhoffer, 1959)). Despite its good quality design there were no patient demographics or statistical analysis reported.

Gaston et al (1988) explored whether meditation alone or meditation plus imagery arousal reduction interventions as adjuncts to TAU changed physical outcomes in people with scalp psoriasis. The results showed significant differences in physical outcomes between participants who received the intervention compared to those who did not post-intervention but there was no additional effect of imagery over and above the effect of meditation. The psychological measurements were entered as predictor variables only and not compared between groups.

Gaston et al (1988) included a measure of meditative strength (clinician and self-report). Clinician's ratings were negatively related to the severity of psoriasis (partial $r = 0.55$, $p < 0.05$) but statistics of self-reported meditative strength were not reported. This rigorous arousal reduction study indicated skill acquisition (meditative strength) as an important variable for future research. The study did not use validated outcome measures.

Lazaroff et al (2000) in a musical resonance arousal reduction intervention found a larger reduction in the physical symptoms for in-patients who received the therapy compared to those who were instructed to 'somehow relax' for the equivalent 30 minutes.
This paper did not report baseline measurements, so it cannot be assumed that the groups were equivalent. The intervention group showed an 86% reduction in the intention to scratch, compared

with a 29% reduction in the control group. The clinician ratings of physical severity showed a 65% reduction in the intervention group versus a 20% reduction in the control group. It is not known if these results demonstrate a significant difference between the two groups, as the statistical methods were not described.

Additional design problems include the lack of validated outcome measurements and a lack of statistics/significance tests to support the paper's statements.

Kienan et al.'s (1995) study of progressive muscle relaxation (PMR) compared PMR, PMR plus biofeedback (auditory feedback on physical measures (heart rate)) and TAU. This is the only arousal intervention to include a physical technique rather than solely relying upon mental instructions. The authors reported significant differences between PMR conditions and the control group on self-reported but not on clinician reported physical outcomes. There was no additional benefit of biofeedback. The level of potential bias in the outcome assessment was high: psoriasis severity was rated on an un-validated scale and it was unclear how independent of the research the un-blinded outcome assessor was.

In summary, six out of the seven studies using an arousal reduction intervention reported some improvement in the physical outcomes but none reported improvements in psychological outcomes. Many of these studies had lower standards of methodological rigour. The gold standard study (Fortune et al, 2002b) employed a cognitive technique and found improvements in physical, psychological and QoL outcomes, which suggests that targeting cognitions may be key for psychological improvement. All studies reported a relatively high attrition rate, which suggests that no single stress reduction intervention is ideal for all people with psoriasis.

2.4.4.2 Combined focus interventions

Zachariae et al (2004) reported no differences in physical or psychological outcomes between participants who received TAU and those who received TAU plus combination psychotherapy (including CBT, relaxation and imagery) group. There were differences between the groups on biological parameters such as Laser Doppler Skin Blood Flow (statistic not reported, p=0.05) and psychological outcomes.

A questionnaire completed twelve months after the study categorised participants as stress responders or non-stress responders but no significant differences were found between participants (p value not reported).

Zachariae et al (1996) used the clinical imagery scale (Zachariae, 1993) measuring visual, kinaesthetic, tactile and somatic ability. Significant correlations were found between blood flow and visual: r= -0.44, p<0.05; kinaesthetic: r= -0.46, p<0.05; tactile: r= -0.52, p<0.05; somatic: r= -0.46, p < 0.05 variables.

This study lacked statistical reporting and gave little detail of the qualifications and experience of the intervention facilitator.

Price et al (1991) reported no difference in physical outcomes between participants who received TAU or TAU plus combined group psychotherapy (relaxation including self-hypnosis and cognitive counseling). There was a difference, however, between distress (HADS; F=2.81, p<0.05) and neuroticism and extraversion outcomes (Eysenck Personality Questionnaire-Revised; F=7.83, p<0.001 (Eysenck et al., 1985)) favouring the psychotherapy group.

Participants rated the course on an non-validated usefulness scale as 5.86/6 but with no further explanation or analysis from the authors. Furthermore, self-hypnosis cannot easily be assessed and the cognitive intervention was specifically targeted to patient identified problematic areas, therefore this design had no effective control and therefore had an inherent bias.

The combined focus interventions included cognitive elements to reduce distress and arousal reduction elements to reduce physical and psychological stress. Two studies found improvements in psychological but not physical outcomes. This may be due to the highly specific cognitive techniques employed compared with the less well defined arousal reduction techniques e.g. self-hypnosis. The relatively high attrition rate suggests that one or both of the included elements did not suit all participants.

2.4.4.3   Results synthesis summary

Five studies in this review used the validated PASI to measure the physical severity of psoriasis. The remaining studies used non-validated clinician ratings of psoriasis severity. Three studies including one that used PASI (Fortune et al., 2002b) found a significant post-intervention difference between the intervention and control groups. These were rated as some of the better studies in terms of quality (Kabat-Zinn et al., 1998, Fortune et al., 2002b, Gaston et al., 1988).

Seven of the studies include a validated psychological outcome measurement: Hospital Anxiety Depression Scale (HADS; (Zigmond & Snaith, 1983)); Psychological Adjustment to Illness Scale Self-Report (PAIS: (Derogatis & Lopez, 1983)); Symptom Checklist (SCL-90; (Derogatis et al., 1973); State-Trait Anxiety Inventory for Adults (STAI; (Speilberger et al., 1970); General Health Questionnaire (GHQ-12; (Goldberg, 1972); Eysenck Personality Questionnaire (EPQ-R; (Eysenck et al., 1985); Profile of Mood States (POMS; (McNair et al., 1971); Beck Depression Inventory (BDI; (Beck et al., 1961) and the Brief Stress Questionnaire (BSQ; derived from Perceived Stress Scale; (Cohen et al., 1983). However, only three of these studies reported a significant difference in the psychological outcome, post-intervention, between the intervention and control groups. Again these were rated as the higher quality studies (Gaston et al., 1988, Fortune et al., 2002b, Price et al., 1991) within this review.

Only three studies included a QoL measurement and only one of these Fortune et al (2002b) found a significant difference between groups at post-intervention.

2.4.5 Review discussion

The degree of heterogeneity in design and physical/psychological outcome measures across the 10 studies prevented a meta-analysis. The team tried to minimise over-interpretation of data by checking the PI's decisions at different points across the review process. Any differences between assessments of study quality were resolved with discussions within the team. These checks conformed to Cochrane guidelines (Khan et al., 2001) increasing the transparency and reliability of the methodology. Although some RCTs demonstrated negative findings there may still be a publication bias.

There were more non-significant differences on psoriasis outcomes (7/10) than significant differences (3/10). This was also true for psychological distress (4/7 non-significant results) and there were too few studies measuring QoL to make a decision either way. The three studies that reported a significant improvement in the physical severity of psoriasis (the primary research question of the review) employed CBT, mindfulness-based and meditation stress reduction techniques. CBT has been recognised as the most effective treatment option to reduce distress in physical health conditions (Pilling et al., 2009), and now it has also proved successful in reducing the physical symptoms of psoriasis (Fortune et al., 2002b). Mindfulness and meditation both lead to improvements in the physical severity of psoriasis without a cognitive therapy element. The study that employed mindfulness did not use the full eight-week course, it found mindfulness to improve skin clearance during phototherapy but did not examine whether mindfulness can independently improve physical symptoms and it did not include measurements of QoL (Kabat-Zinn et al., 1998).

This review highlights two messages: first, the need for improvement scientific quality both in design and in reporting within this cross-disciplinary area of research. Second, the mechanisms of change need to be examined. While the synthesis suggested that stress reduction without cognitive challenge components interventions were more effective at changing physical than psychological outcomes and interventions which include cognitive challenge were more effective in improving the psychological outcomes we were unable to definitely conclude this suggestion because of the poor quality of the design and reporting found across these studies. Management of psychological research in the field of psoriasis requires close liaison between psychologists and dermatologists. Psychologists need to be advised by dermatologists on how to control for variables such as seasonal variation in disease and dermatologists can be guided by psychologists to appreciate and measure appropriately core psychological concepts, for example, the differences between state and trait outcome measurements (two examples found in this review).

The review process and results synthesis lead to a set of recommendations intended to help increase the study rigour of future studies.

2.4.5.1 Recommendations

1. Future research should compare arousal reduction with cognitive techniques in order to identify the active element for change.

2. Psychological interventions are more dependent on the skills of the practitioner delivering the therapy than some forms of medical treatments and if not delivered effectively this could mask whether its therapeutic mechanisms are effective. Future research should routinely measure treatment fidelity and skill acquisition.

3. Beliefs about treatment efficacy are associated with physical outcomes (Horne, 1999) and adherence and consequent skills acquisition may be related to these beliefs. If participants have little confidence in an intervention then they are unlikely to engage fully and learn the necessary skills. A validated credibility/expectation questionnaire (Borkovec and Nau, 1972) accounts for post-treatment outcome variance (Newman and Fisher, 2010), should be used to explore why some participants do not adhere to interventions and whether these groups are differentiated by their belief systems.

4. Stress reduction interventions could be particularly useful for psoriasis stress responders. We recommend well-controlled patient preference trials (Brewin and Bradley, 1989) or explicitly measuring individual differences (stress responders or non-stress responders) in *a priori* beliefs.

5. Psoriasis can show improvement during the summer due to the beneficial effects of UV exposure and this should be controlled for. Vedhara et al (2007) found that seasonal variation was the only significant predictor of PASI in their study.

6. The PASI is a validated and accepted tool and we recommend its use in this field of research. We advise against using a non-validated psoriasis severity measure.

7. Due to its widespread acceptability by clinicians in this field we recommend that a psoriasis specific measure is routinely included to reflect changes in QoL.

8. Future studies must report all results with full details including effects sizes to allow for full scientific understanding and meta-analyses in this field.

9. Too much variation exists in descriptions of intervention content. We recommend researchers should follow Vedhara et al's (2007) example and develop a comprehensive, detailed and specific protocol.

2.5 Mindfulness

The systematic review of psychological interventions (see section 2.4) reported the highest quality, gold standard, study employed CBT and improved physical, psychological and QoL outcomes in people with psoriasis (Fortune et al., 2002b). A quarter of the treatment group in Fortune et al.'s (2002b) study dropped out therefore CBT may not be suitable for all people with psoriasis. The two other interventions, which reported an improvement to the physical severity of psoriasis, were meditation (Gaston et al., 1988) and Mindfulness Based Stress Reduction (MBSR; (Kabat-Zinn et al., 1998). MBSR incorporates meditation within it therefore mindfulness-based interventions appear to be a suitable alternative to the traditional CBT based interventions. Mindfulness showed promise, in the review, by significantly reducing time to skin clearance during phototherapy (Kabat-Zinn et al., 1998). There has not been a study that examined the effect of a full eight-week mindfulness-based intervention's upon the physical, psychological and QoL outcomes in people with psoriasis.

Mindfulness is derived from traditional Eastern (predominantly Buddhist) psychology and philosophy (Rapgay & Bystrisky, 2009). A secular, pragmatic eight-week stress reduction course was developed to facilitate teaching these ancient practices to a modern audience (Kabat-Zinn, 1982). In the accompanying manual mindfulness was described as 'paying attention in a particular way; on purpose, in the present moment and non-judgementally' (Kabat-Zinn, 1990).

There are different methods of delivering mindfulness training. The original course, MBSR (Kabat-Zinn, 1982), was combined with some compatible techniques from cognitive therapy to form MBCT initially to treat people with recurrent depression (Teasdale et al., 1995). Mindfulness based stress reduction and MBCT share the same aim but MBCT is taught within a cognitive framework of understanding, which includes exercises and techniques that help identify signatures associated with a specific condition for example how emotions, thoughts and behaviours interact in maintaining anxiety or depression. Mindfulness has been recognised as a constituent part to other types of therapies such as Acceptance Commitment Therapy (ACT; (Hayes, 2004) but for the purpose of this literature review only MBSR and MBCT based interventions shall be included.

The systematic review reported that psychological interventions were being used to reduce physical severity of psoriasis without a clear theoretical understanding of how this would happen. A sub-group (stress responders) of people with psoriasis believe that the physical severity of their condition is exacerbated or caused by stress and PNI

research has suggested a possible HPA-cortisol-immune system pathway, which could mediate this relationship. Mindfulness was originally described as a stress reduction technique (Kabat-Zinn, 1982) and studies have reported that healthy participants who are trained in mindfulness report reductions in perceived stress scores in comparison to a control group (Warnecke et al., 2011). Theoretically, if mindfulness can reduce the stress experienced by people with psoriasis then this may reduce the HPA-cortisol reactivity-immune system dysfunction and consequently ameliorate the physical symptoms of psoriasis.

2.5.1 Cognitive mechanisms of mindfulness

Cognitive behavioural therapy is based on the cognitive principle that reality is experienced through cognitive processes while mindfulness-based interventions suggest reality can also be experienced through present moment physical/bodily perception. Cognitive behavioural therapy aims to generate a meta-cognitive perspective which allows individuals to identify and challenge maladaptive cognitive patterns (Westbrook et al., 2011). Mindfulness-based interventions suggest that reaching a meta-cognitive state allows individuals to identify how their thoughts, emotions and behaviours are all interlinked and then by increasing attention control, thought mindfulness practice, the individual can choose to remain in the present moment, and its physical sensations rather than slipping into automatic maladaptive thought patterns. Cognitive behavioural therapy encourages cognitive challenge whereas mindfulness-based interventions rely on the attention workspace being filled with present moment experiences, which can reduce conditioned responses such as emotional reactivity to a stimulus. Sustained attention to difficult stimuli, through non-judgemental observation can lead to a reduction in avoidant coping behaviours (Baer, 2003).

Several cognitive mechanisms have been proposed to explain how mindfulness can reduce perceived stress levels. Through meditation, breathing exercises and mindful-movement practices, mindfulness-based interventions aim to teach participants to become aware of and increase flexibility to switch between different cognitive modes of mind (Williams, 2010, Westbrook et al., 2011). One mode is the conceptual or 'doing' and this consists of thinking, analysing, remembering, comparing and judging and is essential for higher order information processing. The other mode is perceptual or 'being' and consists of the concrete sensory perceptions such as hearing and visceral interoception (Williams, 2010, Kabat-Zinn, 1990). The conceptual mode is essential for performing human processes such as understanding language and it very adaptive. The perceptual and conceptual modes can be visualised on a continuum (Figure 9). If an individual overuses the conceptual mode, which involves anticipating the future, using recollection from the past to inform the present decision and associating new stimuli with previous representations this could filter new information to concord with pre-existing

beliefs, which maintain negative emotional reactions (Williams, 2010; Westbrook et al., 2011)

Figure 9: A diagram to represent the conceptual and perceptual modes of mind adapted from Williams, 2010
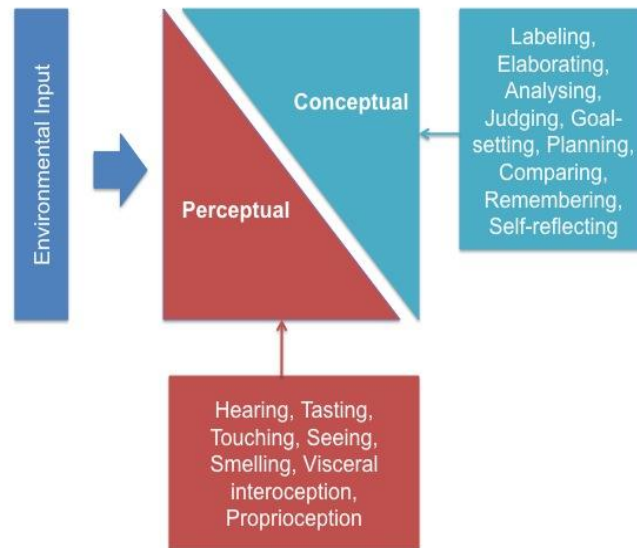
Figure 9: The diagram depicts how environmental inputs can be interpreted differently on an information-processing continuum. While people will use both conceptual and perceptual processing, mindfulness aims to encourage an individual's information processing style to integrate more perceptual and less conceptual processing.

The transactional model of stress suggests that individuals appraise a stimuli to assess whether it is a threat and whether they have the resources to be able to manage or whether the stimuli is perceived as stressful (Lazarus & Folkman, 1984). When a person uses the conceptual mode of mind, the new stimuli is automatically appraised through a filter which is shaped by pre-existing beliefs (illness-related cognitions) which can manipulate how a stimuli is appraised (Weinstein et al., 2009). People with psoriasis who perceive more stress as a result of living with psoriasis have been found to experience poorer mental health and overall QoL (Fortune et al., 1997). Their increased perceived stress may also exacerbate the physical symptoms of psoriasis through the proposed PNI pathway.

Mindfulness fosters switching into the perceptual mode, which allows a more objective neutral appraisal of incoming stimuli rather than an automatic emotionally reactive

appraisal. This reduction in reactivity during stimuli appraisal has been supported by a study which induced an acceptance-based processing state in participants, through a brief mindfulness instruction and this lead to a reduction in their level of emotional reactivity to distressing film clips (Erisman & Roemer, 2010).

Anticipated and perceived social threat have been highlighted as key areas of stress for people with psoriasis (Magin et al., 2009). Participants with social anxiety disorder found MBSR training to reduce their emotional responses to possible social threats and to reduce activity in the amygdala which is associated with emotional processing (Goldin & Gross, 2010). This suggests that developing mindfulness skills can reduce emotional reactivity to some of the key stimuli, which produce negative emotional response in some people with psoriasis.

Some people with psoriasis engage in avoidant coping styles (Fortune et al., 1997) either directly avoiding situations or escaping perhaps through increased alcohol consumption and these can contribute to poor emotional health and possible exacerbation of the physical symptoms (Poikolainen et al., 1990). The antithesis to avoidant coping is an approach coping style which can involve actively moving towards a problem, acceptance and cognitive reinterpretation (seeing the positive in a situation) (Fortune et al., 2002c). Mindfulness approaches encourage participants to increase their levels of present moment attention which can reduce the level of cognitive distortion and maladaptive responding which might allow for more adaptive coping strategies. Mindfulness approaches also specifically teach acceptance of whatever is present, which is an active coping strategy.

Mindfulness-based interventions aim to develop less negative emotional appraisals and more adaptive coping strategies for people with psoriasis. A multi-study research project specifically explored the relationships between stress appraisal, coping styles and well being in a healthy population across a laboratory based and a longitudinal design (Weinstein et al., 2009). This study found people with a higher mindfulness skill level (Mindful Awareness Acceptance Scale (MAAS; (Brown & Ryan, 2003) to employ more benign stress appraisals (perceived less threat) and more adaptive (more approach and less avoidant) coping styles than less mindful people. This effect remained even after controlling for personality constructs such as optimism and neuroticism. These cognitive mechanisms mediated the associated between mindfulness and well being one month later. This suggests that changing maladaptive stress appraisal and coping style patterns in a healthy population can improve psychological health. Improving stress appraisals and coping styles may be helpful for people with psoriasis who experience poor psychological health (distress and QoL impairment).

Mindfulness training teaches participants to closely attend to physical sensations. In people with psoriasis attending to the physical sensation of an itch may help participants to get to know what these sensations are really like and notice the difference between the physical sensation and its associated psychological/emotional reactions attached to them, such as worry and anxiety (Schneider et al., 2006, Verhoeven et al., 2008). Bringing attention to the physical and automatic emotional reaction to a stimuli (itch) can increase an individual's ability to control their emotional reactions and improve an individual's flexibility in how to respond (Wells, 2009). People with psoriasis may then be more able to separate the automatic emotional representation from the physical observations and this may help reduce associated stress. If mindfulness can reduce stress then this could theoretically reduce the physical severity of psoriasis as proposed by the HPA axis – cortisol – immune system hypothesis.

Some people with psoriasis experience high levels of distress therefore it is also important to examine how mindfulness can improve mechanisms that maintain distress in people with psoriasis. Emotional suppression and alexithymia have been highlighted as factors that may maintain distress within this population (Kossakowska et al., 2009, Fortune et al., 2002a). This population have been found to display a neuro-cognitive adaptation of respond less to facial expression of disgust, perhaps as a protective coping strategy (Kleyn et al., 2009). One element in mindfulness practice is to practice bringing attention to all thoughts, emotions and physical sensations, whether they are positive, neutral or negative. Bringing attention to and accepting these elements of the lived experience may help reduce the emotional suppression and avoidance reported in people with psoriasis. The state of increased awareness of the present moment, has been hypothesised to reduce cognitive processes such as rumination and over-generalisation of autobiographical memories (Chambers et al., 2009), which both characterise depressed and anxious patients (Raes et al., 2005).

2.5.2 Mindfulness based intervention and physical health

Some of the mindfulness practices encourage a state of physical arousal reduction (relaxation), similar to that in the hypnosis trance state (Tausk et al., 1999). These states of relaxation can reduce psychological and physiological arousal. If mindfulness skills reduce the frequency with which an individual enters a state of physiological arousal. This may be a mechanism for improving physical health status (Hamilton-West, 2011).

Emotional reactivity to a stimulus activates the SNS, producing a physiological arousal response. SNS activation is characterised by increases in heart rate and perspiration and can be monitored by measures of skin conductance (SCL), heart rate (HR) and peripheral temperature (PT). Mindfulness has been reported to reduce emotional reactivity (Erisman & Roemer, 2010) and SCL (physical arousal response) (Lush et al., 2009) in response to acute stress.

The original MBSR course aimed to improve the QoL for people living with chronic pain (Kabat-Zinn, 1982). Since then mindfulness-based interventions have been trialled with many other physical health populations, particularly those that are theorised to contain a psychological element as psoriasis does. A meta-analysis, which included 20 studies, examined the effect of MBSR upon physical health conditions such as pain, cancer and heart disease (Grossman et al., 2004). The meta-analysis found MBSR to improve both the physical and mental functioning across in these populations with a medium effect size.

A review of 13 research papers concluded that mindfulness-based interventions improved immune function and distress outcomes, with a small to moderate effect size, for people with cancer (Shennan et al., 2011). The included studies often displayed poor methodological rigour and the review recommended future research to include qualitative investigations into the patient's perspective in order to expand upon the predominately quantitative evidence base.

A study from this review (Shennan et al., 2011) included immune system outcomes (Witek-Janusek et al., 2008). Women with early stage breast cancer had elevated levels of IL-4, IL-6 and IL-10 and decreased levels of IFN-γ and NK cell activity. These abnormal immune cell levels returned to a healthy level in the women who participated in an MBSR group but not in the control group. The treatment group also displayed lower diurnal levels of blood serum cortisol and improved QoL outcomes in comparison to the control group. Mindfulness based stress reduction appeared to modulate IL-6 and IFN-γ cell function. These cells are implicated in the pathogenesis of psoriasis (Chapman & Moynihan, 2009). Mindfulness based stress reduction may be able to improve the function of immune cells implicated in causing psoriasis.

Witek-Janusek et al.'s (2008) study reports that the diurnal serum cortisol was reduced in the mindfulness treatment group as compared to the control group suggesting the mindfulness intervention might have affected cortisol secretion. The cortisol response has, subsequently, been entered as an outcome in an exploratory RCT to examine the effects of a mindfulness-based intervention (combination of MBSR, MBCT and Mindfulness Based Eating Awareness Training (MB-EAT; (Kristeller & Wolever, 2011)) upon eating behaviours, weight/fat measurements, distress and cortisol levels (Daubenmier et al., 2011). The CAR reactivity (dynamic change) and diurnal pattern were measured. Obese members of the mindfulness treatment group demonstrated a reduction in the CAR reactivity and improvements in distress scores in comparison to the control group. This study suggested that mindfulness training could improve HPA function as measured by the CAR. It also reiterates that BMI may influence the CAR.

Another study examining the effectiveness of MBCT upon overall CAR in people with depression (Gex-Fabry et al., 2011) found the longer someone had lived with depression the more attenuated the overall CAR was but overall CAR did not improve as a result of participating in a MBCT intervention. These studies suggest CAR may mediate the stress-psoriasis link and if mindfulness-based interventions can modulate the CAR, then this may help improve the physical symptoms of psoriasis.

2.5.3   Mindfulness-based intervention and psychological/emotional health

Mindfulness based cognitive therapy has been recommended as a treatment option for people with recurrent depression in the National Institute of Health and Clinical Excellence (NICE) guideline's for depression and depression in people with physical health conditions (National Institute for Health and Clinical Excellence, 2009b). Mindfulness based cognitive therapy has accounted for a 44% reduction in the depressive relapse risk and equals anti-depressant effectiveness for long term maintenance (Williams & Kuyken, 2012).

Mindfulness-based interventions have improved psychological health status in a range of disorders including health anxiety (McManus et al., 2012), bipolar disorder (Williams et al., 2008) and suicidality (Hargus et al., 2010). A recent meta-analysis, which conducted its systematic search from October 2010 and only included RCTs with a sample size of over 30 participants, examined the effects of MBSR and MBCT upon mental health (Fjorback et al., 2011). The review found mindfulness-based interventions to improve stress, anxiety and depression with a moderate effects size across non-clinical, clinical and physical health populations. The review called for future research to include long-term follow-up and encouraged head to head trials of mindfulness-based interventions against other active interventions.

Whilst mindfulness-based interventions are proving effective in ameliorating existing psychological and distress they are also beginning to be used in a preventative framework, giving people the skills the need to protect themselves from developing poor psychological and emotional health (Warriner et al., 2012).

2.5.4   Measurement of mindfulness skill scores

One recommendation from this study's systematic review was for studies to include a measurement of skill acquisition in order to ascertain whether the group facilitator successfully taught the mindfulness skills to the participants (treatment fidelity). There are a few self-report measurement scales which have been developed to measure mindfulness skills including the Kentucky Inventory of Mindfulness Skills (KIMS: (Baer et al., 2004)), Five Facet Mindfulness Questionnaire (FFMQ; (Baer et al., 2006)) and the Mindful Attention Awareness Scale (MAAS: (Brown & Ryan, 2003). These three scales

have all reached acceptable levels of psychometric validation but a search across the Web of Knowledge search engine found 24 studies to have employed the MAAS compared to nine studies for the KIMS and 11 for the FFMQ. As more studies have employed the MAAS it is a more comparable tool.

2.5.5 Acceptability of mindfulness-based interventions

No previous research has examined the effectiveness of an eight-week mindfulness-based intervention with a population of people with psoriasis. Recently there has been a call for more exploratory stage research into how psychological intervention work. Exploratory stage research examines an intervention's mechanism of change and explores participants' perspectives of the intervention. This is especially important for interventions administered to a population suffering from complex sequelae of physical, psychological and emotional symptoms (Lewin et al., 2009, Macran et al., 1999). This type of research will help explain the process and appropriateness of an intervention for specific population.

Mindfulness has emerged from a Buddhist tradition. Interventions which emerge from religious and/or non-orthodox medicine routes may be less readily accepted than traditional biomedical treatment options (Foote-Ardah, 2004). Mindfulness has however, recently gained a media acceptance from high profile celebrity endorsers such as Ruby Wax and Goldie Hawn. Combined with the fast emerging evidence base and incorporation into the NICE clinical guidelines this may override the possible initial hesitation to engage in an alternative medicine choice.

There have been qualitative investigations into the acceptability of mindfulness-based interventions across different populations including depression and anxiety (Finucane & Mercer, 2006), depression and epilepsy (Walker et al., 2010), health anxiety (Williams et al., 2011) and improving health and well being in an urban youth population (Kerrigan et al., 2011). These qualitative explorations present an overall acceptance and favourable opinion of the mindfulness-based interventions by the participants. Across these four studies there were three main thematic areas. The first explored the pre-course individual differences such as levels of expectation and motivation (Finucane & Mercer, 2006). Secondly there were evaluations of the process of learning mindfulness including assessing whether the time dedicated to practice the exercises was worthwhile (Williams et al., 2011) and the benefits and problems of learning within a group format (Walker et al., 2010, Finucane & Mercer, 2006). Finally, the studies examined the participant's perspectives on the outcomes which included a sense of normalisation (Williams et al., 2011), a change in reactions to stressors (Kerrigan et al., 2011) and a shift in the overall life perspective (Kerrigan et al., 2011, Williams et al., 2011).

A study quantitatively examined why participants dropped out of an MBCT course for people with depression (Crane et al., 2010). Participants who dropped out tended to be younger and to have higher levels of depressive rumination and impaired problem solving. This supports the recommendation that mindfulness-based interventions should only be delivered to people who are not currently experiencing an episode of active anxiety or depression. Mindfulness practices may overload the already restricted capacity of someone experiencing an active episode (Barnhofer et al., 2009).

These pre-existing studies provide a rich framework exploring the acceptability and adherence to mindfulness-based interventions. This framework can aid an investigation to explore the perspective of people with psoriasis and their unique psychological, emotional and physiological characteristics.

2.5.6 Summary of mindfulness-based interventions

Mindfulness-based interventions aim to reduce automatic negative threat appraisals, encourage approach coping styles and increase flexibility in patient's reactions to living with psoriasis symptoms such as itch and pain. These interventions do not aim to challenge the content of cognitions as cognitive techniques have previously relied upon. Theoretically mindfulness may reduce the levels of stress, which via the HPA axis – cortisol – immune system pathway could reduce the physical severity of psoriasis. Mindfulness might reduce associated distress and QoL impairment by helping people with psoriasis to disassociate emotional reactions from physical triggers, which may be maintaining elevated levels of distress and encourage acceptance based coping strategies. Mindfulness-based interventions have demonstrated moderate effect sizes in improving both physical and psychological/emotional health status. Participants in these studies have favourably evaluated the interventions and found mindfulness based interventions to be an acceptable treatment option.

2.6 Literature review summary

There is some supporting evidence for stress exacerbating psoriasis but it is not conclusive due to poor methodology, such as predominantly retrospective reporting. More conclusive is the evidence that suggests that there is a higher incidence of distress and impaired QoL in people with psoriasis compared to the general population. Increased distress also exacerbates maladaptive health behaviours such as increased alcohol consumption and poor treatment adherence, which exacerbate the physical severity of psoriasis.

Social cognition models such as the SR-CSM attempt to explain the variation in distress, QoL and health behaviours across this population by examining the emotional and cognitive representations which people with psoriasis hold of their condition. Variation in these representations has been found to explain the variation in physical/psychological health status and QoL in people with psoriasis.

A PNI pathway offers an explanation of how stress could exacerbate the physical symptoms of psoriasis. Stress influences HPA axis function. One of the HPA axis outputs is cortisol, which can modulate the production of immune system pro-inflammatory cytokines, including those that are involved in the pathogenesis of psoriasis.

A robust characteristic in the diurnal pattern of free circulating cortisol is its 50-160% increase at awakening from sleep (CAR). The evidence base suggests that when an individual is experiencing acute stress such as job stress, the CAR reactivity increases. This CAR hyper-reactivity causes allostatic load and if the hyper-reactivity is repeated and becomes chronic this is hypothesised to scar the HPA axis and interrupt it's functioning. People with distress have been found to have an attenuated CAR, possibly due to poor HPA function, which theoretically may impact upon immune system cell functioning. People with chronic physical health conditions such as diabetes have also been found to have an attenuated CAR. The directionality between attenuated CAR, physical health conditions and distress is still being researched but the CAR could theoretically mediate the stress-psoriasis link. People with psoriasis have demonstrated an attenuated cortisol response to acute stress stimuli. When people with psoriasis are experiencing more stressful life events then their CAR is more attenuated. The CAR has not been measured in people living with psoriasis.

Psychological interventions have been administered to people with psoriasis to improve their physical, associated emotional and QoL outcomes. A systematic search of studies

employing such interventions rated a CBT intervention study as the gold standard in terms of methodology. This CBT study (Fortune et al., 2002b) improved physical, emotional and QoL outcome variables. The study, however, experienced high attrition rates, which suggests CBT is not suitable for all people with psoriasis. Cognitive techniques such as CBT employ a cognitive challenge technique, whereas the other interventions did not use cognitive challenge. In order to understand whether cognitive challenge was essential to improving physical, emotional and QoL outcomes, it was recommended to examine the effects of a non-cognitive challenge based intervention within this population. The only other two interventions from the review, which found a significant improvement in physical symptoms, were a mindfulness-based intervention and a meditation intervention. Meditation is integrated into mindfulness and therefore mindfulness was chosen as a non-cognitive challenge alternative to CBT.

Mindfulness-based interventions have been shown to be effective across mental and physical health conditions. Mindfulness has also been found to improve HPA and immune system functioning, which might impact the pathogenesis of psoriasis. Mindfulness might reduce physiological arousal, emotional reactivity and encourage adaptive coping styles all of which may improve physical, emotional and QoL outcomes in people with psoriasis.

Participants have reported mindfulness-based interventions to be acceptable treatment options but that there were some process and conceptual barriers, which might reduce adherence to the mindfulness protocol.

This literature review suggests that stress could exacerbate physical psoriasis symptoms via a PNI pathway. Living with psoriasis can lead to increased distress and impaired QoL. Some people may avoid their distress by engaging in coping behavioural such as drinking excessive alcohol, which can further exacerbate psoriasis symptoms. This thesis aimed to test the efficacy of stress reduction intervention. Mindfulness appears to be an appropriate and acceptable intervention to offer to people with psoriasis in order to reduce their perceived stress and consequently reduce their physical psoriasis symptoms. Mindfulness may also improve distress and QoL outcomes, thus interrupting the stress-psoriasis-distress cycle. If the CAR mediates the stress-psoriasis link and the mindfulness intervention improves stress and physiological symptoms then it should also change the CAR.

Study aims

Primary aim: To examine the effectiveness and mechanisms of change of MBCT upon the physical, psychological and QoL outcomes in people living with psoriasis

Secondary aim: To examine whether the CAR mediates the association between stress and physical psoriasis symptoms.

Tertiary aim: To explore whether MBCT would be an acceptable and useful intervention for people with psoriasis.

<u>Research Questions and constituent hypotheses</u>

Intervention effectiveness

1. **Does Mindfulness Based Cognitive Therapy (MBCT) improve physical, psychological and QoL outcomes in people living with psoriasis?**
   a. *The intervention group, which received MBCT, will have lower perceived stress levels than a control group who continued with treatment as usual (TAU).*
   b. *The intervention group, which received MBCT, will have lower physical severity ratings than a control group who continued with treatment as usual (TAU).*
   c. *The intervention group, which received MBCT, will have lower distress ratings than a control group who continued with treatment as usual (TAU).*
   d. *The intervention group, which received MBCT, will have QoL impairment than a control group who continued with treatment as usual (TAU).*

2. **Do illness representations affect how MBCT influences the primary outcomes within this population?**
   a. *Stress responders (those who believe stress caused their psoriasis) in the treatment group will experience greater change scores in their physical severity ratings than non-stress responders.*
   b. *There will be no change in the illness representations between the treatment and control group at follow-up 1.*

3. **Did the participants of the MBCT course successfully learn the mindfulness skills?**
   a. *Participants who receive the MBCT intervention will report higher follow-up MAAS scores in comparison to their pre-intervention MAAS scores.*

4. **Do beliefs in credibility/expectancy affect the primary outcomes?**
   a. *Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their physical symptoms than those who had weaker beliefs.*
   b. *Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their perceived stress levels than those who had weaker beliefs.*

Cortisol association

5. **Is the CAR cortisol correlated with stress and physical severity of psoriasis?**

   a. *The CAR cortisol will be significantly negatively correlated with physical severity scores.*

   b. *The CAR cortisol will be significantly negatively correlated with perceived stress scores.*

6. **Does the CAR change in participants who have completed the MBCT training course?**

   a. The CAR will be significantly different between the treatment and control group at post-intervention.

Acceptability of and adherence to the MBCT intervention

7. **What are participants' experiences of the MBCT course?**

8. **What are the perceived benefits and the perceived barriers to participating in the MBCT course?**

9. **What individual differences are found in those participants who adhered to the MBCT intervention?** *

This research question was developed after high attrition was experienced during the quantitative data collection.

3. Methods

This chapter outlines the methods employed to meet the overall study aims, specific research questions and hypotheses, which emerged from the literature review in Chapter 2.

3.1 Study aims

Primary aim: To examine the effectiveness and mechanisms of change of MBCT upon the physical, psychological and QoL outcomes in people living with psoriasis

Secondary aim: To examine whether the CAR mediates the association between stress and physical psoriasis symptoms.

Tertiary aim: To explore whether MBCT would be an acceptable and useful intervention for the target population.

The research questions and their constituent hypotheses were developed with the FINER (Feasible, Interesting, Novel, Ethical, Relevant; (Hulley et al., 2007) and PICOT (Population, Intervention, Comparison group, Outcome of interest, Time) criteria (Guyatt & Rennie, 2002).

Research Questions and constituent hypotheses

Intervention effectiveness

1. **Does MBCT improve physical, psychological and QoL outcomes in people living with psoriasis?**

    a. *The intervention group, which received MBCT, will have lower perceived stress levels than a control group who continued with treatment as usual (TAU).*

    b. *The intervention group, which received MBCT, will have lower physical severity ratings than a control group who continued with treatment as usual (TAU).*

    c. *The intervention group, which received MBCT, will have lower distress ratings than a control group who continued with treatment as usual (TAU).*

    d. *The intervention group, which received MBCT, will have QoL impairment than a control group who continued with treatment as usual (TAU).*

2. **Do illness representations affect how MBCT influences the primary outcomes within this population?**

a. *Stress responders (those who believe stress caused their psoriasis) in the treatment group will experience greater change scores in their physical severity ratings than non-stress responders.*

b. *There will be no change in the illness representations between the treatment and control group at follow-up 1.*

3. **Did the participants of the MBCT course successfully learn the mindfulness skills?**

a. *Participants who receive the MBCT intervention will report higher follow-up MAAS scores in comparison to their pre-intervention MAAS scores.*

4. **Do beliefs in credibility/expectancy affect the primary outcomes?**

a. *Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their physical symptoms than those who had weaker beliefs.*

b. *Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their perceived stress levels than those who had weaker beliefs.*

Cortisol association

5. **Is the CAR cortisol correlated with stress and physical severity of psoriasis?**

a. *The CAR cortisol will be significantly negatively correlated with physical severity scores.*

b. *The CAR cortisol will be significantly negatively correlated with perceived stress scores.*

6. **Does the CAR change in participants who have completed the MBCT training course?**

a. The CAR will be significantly different between the treatment and control group at post-intervention.

Acceptability of and adherence to the MBCT intervention

7. **What are participants' experiences of the MBCT course?**

8. **What are the perceived benefits and the perceived barriers to participating in the MBCT course?**

9. **What individual differences are found in those participants who adhered to the MBCT intervention?** *

This research question was developed after high attrition was experienced during the quantitative data collection.

Health service research recommends that a complex non-pharmacological intervention such as MBCT should be explored with a combination of qualitative and quantitative

techniques in order to assess the individual, social and biological influences upon the phenomenon under examination (O'Cathain et al., 2007). The intervention efficacy and cortisol association research questions are most appropriately examined with quantitative methodology. However, the acceptability and adherence research questions are most appropriately explored with qualitative methods. This study requires a mixed methods design in order to answer its research questions. These methodological paradigms shall be discussed after the MBCT protocol is outlined.

3.2 Mindfulness Based Cognitive Therapy intervention

The primary investigator (PI) completed the eight-week mindfulness course as a participant at Manchester Breathworks® (2010). This included attending four four-hour group sessions, a daylong retreat and daily personal practice over two months. The course taught the techniques of mindfulness for people with chronic physical health conditions. Upon completion the PI kept up with her daily personal practice and applied to join the University of Bangor's teacher development retreat. The PI was offered a place and attended the week-long retreat in Wales (July 2010) to develop her skills as a mindfulness group facilitator. The retreat developed the trainees' personal mindfulness practice and the skills necessary to facilitate a mindfulness group. During the retreat the students would lead mindfulness practices and receive feedback from their group and from the highly experienced trainers. At the end of the week, the PI became a qualified MBCT practitioner.

The PI continued with her personal mindfulness practice every day and wrote and reviewed, with her supervision team, a protocol for an 8-week mindfulness course tailored for people with psoriasis. She also used this time to record two mindfulness CDs for future group participants to use in their home practice. The PI ran a pilot course at the University of Manchester, with supervision from a consultant health psychologist and a teacher from Breathworks®. The course was reviewed and tailored within the supervision team before the PI facilitated the two study groups under supervision from a consultant health psychologist.

The MBCT course was delivered to participants in a group format (between six to eight people), in sessions that lasted two hours and were held on Wednesday evenings for eight consecutive weeks at the Manchester Wellcome Trust Clinical Research Facility (WTCRF).

A typical mindfulness group session began with a guided formal practice (the body scan or sitting meditations), which can take up to 40 minutes. During the body scan the PI lead participants in selectively paying attention to the current physical sensations across the body in a systematic format. The sitting meditation included different aspects each week as the participants developed deeper mindfulness skills. These practices aimed to develop participants' non-judgemental awareness of their breath, sounds, sights and eventually their thoughts and emotional states. These formal practices were followed by reflective discussion and questions. These feedback sessions were very important for participants to learn from one another and to hear alternative perspectives upon their experiential learning. Participants also reviewed their experiences of home practice from

the previous week and the difficulties they had encountered, such as not having enough time, getting bored or falling asleep. These feedback sessions were forums for the PI and other group members to offer suggestions of how to overcome the problems encountered. The sessions also included cognitive thought exercises, to aid the comprehension of the concepts touched upon during meditation such as differentiating between thoughts, emotions and behaviours and appreciating how these interact especially in relation to living with psoriasis. Shorter meditations were taught including movement sessions such as mindful-Yoga and mindful-walking. Poems were read out as another method of communicating some of the more subtle aspects of the course. Other tools to aid the transference of mindful skills into everyday life included brief grounding exercises such as the 'Three stage breathing exercise,' which aimed to anchor participants into the present moment and the facilitator suggested to use this tool during stressful situations in order to help control emotional reactivity.

At the end of the first and fourth sessions participants were given a home practice CD, which contains a variety of guided meditations. These meditations were recorded by the PI and breached no copyright. At the end of each weekly session participants were given a booklet which expanded upon topics covered in the groups, outlined home practices and served as a diary for people to keep confidential records on their progress which they were given the chance to discuss in the following week (an example booklet is presented in appendix 9.4).

Participants were invited to practice the formal meditations at home for 30-40 minutes every day. The group facilitator suggested combining these longer formal practice times with shorter practices, such as the 'three stage breathing space,' and informal efforts throughout the day to re-connect with the methods of mindful living such as reconnecting with the present moment. Other techniques were offered to assist the development of a mindful-perspective such as keeping a diary of un/pleasant events and monitoring how they affected cognitions, emotions and physical sensations.

Participants, who were not participating in the MBCT course, continued with their psoriasis medical treatment as usual, no physical treatments were removed or altered at any time during the study.

3.3 Quantitative and qualitative methodologies

Purists from quantitative and qualitative methodological positions have created an incompatibility thesis (Howe, 1988) whereby the two paradigms cannot be combined because they are based on opposing assumptions regarding the nature or reality (ontology) and the way we can understand this reality (epistemology).

As a basic explanation quantitative inquiry is aligned with a positivist ontological position where reality is independent of individual and social interpretation. For example an individual's belief would be treated the same as a physical entity such as atomic mass. Research aims to be objective and free from individual or societal values. The focus is on the reliable and valid interpretation of numerical data (Dures *et al.*, 2010, Johnson & Onwuegbuzie, 2004, Tashakkori & Teddlie, 2003).

Qualitative purists reject positivism and assume a constructivist ontological position that suggests there is no one reality but rather multiple versions of reality, which humans individually and collectively construct. They favour a subjective, value-laden approach to exploring individual and social phenomena. This approach principally focuses on the meanings emerging from textual data (Dures et al., 2010, Johnson & Onwuegbuzie, 2004, Tashakkori & Teddlie, 2003).

Both paradigms demonstrate great strengths but also weaknesses. Quantitative research creates generalisable research findings, which some feel may have higher credibility. This form of research, however, may miss phenomena that are not directly within the focus of research question. Qualitative research can obtain rich detailed information, which is especially useful when exploring novel and complex interventions such as MBCT. The findings, however, while they can be transferred, they cannot be generalised, as quantitative results are, far beyond the specific population under investigation (Johnson & Onwuegbuzie, 2004).

The physical and psychological symptoms of chronic physical health conditions such as psoriasis unfold over time and the effects of a complex intervention such as MBCT will not only affect the participant within the clinical setting but also across their own social environment. These complexities cannot be addressed with the gold standard RCT and there has been a call for evidence based recommendations to be informed by both quantitative and qualitative research (Turner-Stokes et al., 2006).

3.4 Mixed Methods

Rather than adopting a purist's perspective of the ontological and epistemological positions mixed methods researchers adopt a pluralistic "third wave" philosophical position of pragmatism (Johnson & Onwuegbuzie, 2004, Tashakkori & Teddlie, 2003). This is not committed to one ontological position and its associated methodologies but see value in adopting the most appropriate methodological techniques to comprehensively answer the research questions under consideration (Creswell, 2003). This pluralistic approach is particularly promoted within research areas where the topics are often "interdisciplinary, complex and dynamic" (Johnson & Onwuegbuzie, 2004) and is well suited to applied research settings and complex interventions.

In combining quantitative and qualitative techniques this enables the researcher to combine the advantages from each perspective and the disadvantages can be answered by the other techniques strengths, allowing for complementary and a more complete data analysis (Creswell, 2003).

3.5 This study's mixed methods design

Recommendations for good mixed methods design practice have emerged from systematic reviews of mixed methods designs across different research settings (Creswell, 2003, Turner-Stokes et al., 2006, Dures et al., 2010, Tashakkori & Teddlie, 2003). This study's design is informed by these recommendations.

Rationale

Due to the novel research area with a complex intervention and population, complementary mixed methods design was employed in order to gain a more comprehensive understanding of this pilot research. The qualitative exploration helped explain the quantitative research findings and in combination they provided a well-informed platform for further research into this area.

Priority

The quantitative examination of the effectiveness of MBCT upon the primary and secondary outcome variables was the primary aim of the study and therefore its principal element. The qualitative exploration of the acceptability and usefulness of MBCT for people with psoriasis was a secondary aim and a subsidiary element.

Implementation

Two quantitative data sets were collected in parallel: (1) the physical, psychological and QoL data with (2) the cortisol data. The qualitative data were collected after the quantitative data.

Integration

The quantitative and qualitative data were integrated at the interpretation stage of analysis.

The research process was iterative. During the quantitative data collection stage a very high attrition rate was experienced, in response to these rates a second research question was included in the qualitative design. A theme emerged from the qualitative analysis, which offered a possible explanation of the quantitative findings and this lead to the extraction of extra descriptive data from the quantitative set, which would otherwise have not been reported.

3.6 Principal quantitative study methods: Study phase I

The principal quantitative study preliminarily examined whether MBCT changed the primary outcomes of self-assessed physical severity of psoriasis and perceived stress or the secondary outcomes of distress, QoL impairment and illness representation. It included measurements of possible mediating and confounding variables including Illness representations, mindfulness skill acquisition and *a priori* beliefs of credibility and expectancy.

Research Questions

(1) **Does MBCT improve physical, psychological and QoL outcomes in people living with psoriasis?**

(2) **Do illness representations affect how MBCT influences the primary outcomes within this population?**

(3) **Did the participants of the MBCT course successfully learn the mindfulness skills?**

(4) **Do beliefs in credibility/expectancy affect the primary outcomes?**

3.6.1 Design

A pilot RCT design was employed to answer the primary research question. Participants were randomly allocated to a treatment or control group. Measurements were collected from both groups before and after the treatment group received the MBCT intervention. The control group participants were also offered the MBCT intervention after their waiting period in order to reduce any bias in the control group from being disappointed at not receiving the intervention.

Originally the pre to post intervention data from the control group were going to be used to supplement the RCT primary analysis. However, due to the high attrition rates experienced, a non-randomised comparison group was recruited, from an eligible population, to act as a second control group, which could be compared to a group including all of the participants from the treatment and control group who completed the MBCT intervention. The design is visually presented in Table 3.

3.6.2 Groups

Members of the treatment group entered the MBCT on the 18th May 2011 whereas the control group waited eight weeks and continued with TAU. Once the treatment group had finished their MBCT course they continued with TAU and a final measurement was taken eight weeks later. After the control group had waited for eight weeks they entered the MBCT course and then completed a final set of measurements eight weeks after their final MBCT group session.

The original design included just the treatment and control groups, however, in response to the extremely high attrition rates from the treatment group a non-randomised comparison group was recruited from the eligible population who had expressed an interest in joining the study but could not commit to the time commitment. This comparison group was intended to act as a second control group who were not trained in mindfulness and not a randomised control group.

Table 3: Pilot RCT plus supplementary comparison group design

Group	Activity	May 2011	8 wks	July 2011	8wks	Sept 2011	8 wks	Nov 2011
		Baseline **Comparison**		**Primary** **Analysis**				
Treatment **group**	Intervention		MBCT		TAU		End of participation	
	Measurements	**Baseline** *		**Follow-up 1**^	Interviews	Follow-up 2		
Control **group**	Intervention		TAU		MBCT		TAU	
	Measurements	**Baseline**		**Follow-up 1***		Follow-up 2^	Interviews	Follow-up 3
Comparison **group**	Intervention	Not entered into study			TAU		TAU	
	Measurements			Follow-up 1*		Follow-up 2^		Follow-up 3

*MBCT = Mindfulness Based Cognitive Therapy Intervention, TAU = Treatment as usual. *=Pre-intervention, ^=Post-intervention*

3.6.3 Sampling

As this phase of the study employed quantitative methodology a probability sampling technique was used to increase external validity.

3.6.3.1 Sample size

Good clinical practice suggests that novel interventions should be examined with a pilot study in order to assess whether they are a viable option for the target population and to inform the methodology of a fully powered RCT (Campbell et al., 2000). Mindfulness based cognitive therapy has not previously been administered to people with psoriasis therefore it was decided to conduct a pilot study to inform a future fully powered RCT. Research suggests a sample size of n=30 for a pilot study (Lancaster et al., 2002) and a previous pilot study assessing the effectiveness of MBCT in a population with chronic depression employed a sample size of n=28 (Barnhofer et al., 2009). The review of psychological interventions studies with psoriasis populations reported high attrition rates of up to 49% (Paradisi et al., 2010). This study aimed to recruit a sample of 60 participants.

3.6.3.2 Recruitment strategy

The primary mode of recruitment was by approaching patients attending either the general dermatology or psoriasis specific (tertiary referral) outpatient clinics at the Salford Royal NHS Foundation Trust (UK). In addition to this recruitment method promotional material was distributed to: local general practice surgeries; psoriasis support groups; on-line via the Salford Dermatology Centre website/social media feeds; University of Manchester research volunteer e-mails and on local radio infomercials.

Due to high levels of attrition in the treatment group the research team decided to recruit a non-randomised comparison group. The comparison group was recruited from people who were eligible to enter and had expressed an interest in being part of the study but could not commit due to practical reasons such as not living near enough or having other commitments on the evenings when the courses were run.

3.6.3.3 Inclusion and exclusion criteria

People were included in this study if they met the criteria as outlined in Table 4. This criterion was informed by the literature review (See Chapter 2). If participants' circumstances changed during the study they were still invited to complete the course but their data was excluded from the analysis.

Table 4: Inclusion and exclusion criteria

Inclusion	Exclusion
Aged 16 years and over.	A diagnosis of psoriatic arthritis.
A GP or dermatologist's diagnosis of plaque psoriasis.	A severe cognitive impairment (This may preclude the ability to focus attention, which is a key skill in MBCT).
Willing/able to complete all the measurement.	Starting a new psoriasis or mental health medication, which may alter mood within the previous three months before the study starts or during the study.
Willing to participate in a stress reduction intervention.	Currently undergoing psychological/psychiatric treatment.
Provides informed consent.	Not likely to be available for the study period (six months).

3.6.3.4 Randomisation

Participants were sequentially recruited, once six people had agreed to participate in the study, their study identification (study ID) numbers were sent to an independent member of the research team who was not involved in any other part of the recruitment process. These ID numbers were then randomly allocated at a ratio of 1:1 within this block of 6 either to the treatment or control group. Block randomisation was used because after participants had completed their baseline measurements, they needed to be informed of the date they would be starting the MBCT course so their group allocation needed to be known whilst recruitment of more participants will still continuing. The comparison group were not randomised.

3.6.4 Data collection

Data to answer the primary analysis were collected from the treatment and control group at week 0 (baseline) and week 8 (follow-up 1). The data collection points are presented in Table 3.

The baseline dataset:

This comprised of the treatment and control group at week 0.

Follow-up 1 dataset*:*

Treatment and control group at week 8.

Due to the high attrition experienced in this study a supplementary analysis was included. This was a non-randomised design, which examined whether there was a

difference between the new *active group* (all participants from the treatment and control group who had completed the MBCT intervention) and the non-randomised *comparison group* at post-intervention.

Pre-intervention dataset:
The active group's pre-intervention dataset was a combination of the treatment group's measurements from week 0 (pre-intervention) combined with the control group's week 8 data (pre-intervention). The comparison group's pre-intervention dataset was collected at week 8.

Post-intervention dataset:
The active group's post-intervention dataset was a combination of the treatment group's week 8 (post-intervention) and the control group's week 16 (post-intervention). The comparison group's post-intervention dataset was collected at week 16.

In order to examine whether effects were maintained after the completion of the MBCT course. Data were collected from participants eight weeks after they completed the final MBCT session.

8-week post-intervention follow-up dataset:
The treatment group's 8-week post-intervention data was collected at week 16. The control group's was collected at week 24. The active group's was a combination of these two datasets.

After recruiting the comparison group it was possible to form a larger sample size of data collected at the first measurement time point, which could strengthen statistical tests conducted to examine relationships between study outcome variables.

First measurement dataset:
The first measurements of the treatment and control group were collected at week 0 and combined with the first measurements of the comparison group collected at week 8 to form a first measurement dataset with a larger sample.

3.6.4.1 Self report outcomes

Participants were sent a booklet of questionnaires to complete at each measurement point (baseline and follow-ups 1, 2 and 3). Each scale is described in the order that they were presented in the booklet (available in Appendix 9.5). Permission was granted from all authors of the scales for them to be included in this research.

3.6.4.1.1 Demographics

Data were collected on age, years living with psoriasis, gender, whether the individual had a first/second degree relative with psoriasis, the biomedical treatments currently being used and relationship status (Appendix 9.5).

3.6.4.1.2 Perceived Stress Scale: Primary outcome variable

The PSS (Cohen et al., 1983) aimed to measure an individual's perceived stress over the previous month. The scale is one of the most widely used measurements of stress across healthy and patient populations.

Participants marked their choice on a five point Likert scale, from 0=never to 4=very often. There were four positive questions which were reverse scored then all 10 scores were summed for a PSS total. The original paper describing the PSS psychometric development (Cohen et al., 1983) report the reliability coefficient alpha for this 10—item scale as 0.78 and test re-test reliability coefficient of r=0.85.

3.6.4.1.3 Self Assessed Psoriasis Area Severity Index: Primary outcome variable

The SAPASI (Feldman et al., 1996) is a tool for people with psoriasis to self-assess the severity of their condition. The measure covers the same components that are assessed by clinical staff using the psoriasis area severity index (PASI; (Fredriksson & Pettersson, 1978)) It aimed to be quick and simple to be completed by people with no clinical training.

The SAPASI is comprised of two A4 pages, the first instructed participants to colour in the areas on a mannequin (anterior and posterior aspects) where their psoriasis is active. The second page comprised of three visual analogue scales (VAS), which have six intersecting lines to demonstrate increasing severity. The three scales score redness (erythema), thickness (induration) and scaliness (desquamation).

The rater first scored the four body areas (head, upper extremities, trunk and lower extremities) with the scores presented in Table 5.

Table 5: SAPASI body surface area coverage scores

Score	% Coloured in on the mannequin
0	None
1	<10%
2	11-30%
3	31-50%
4	51-70%
5	71-90%
6	91-100%

The score allocated to each body area was weighted (head x 0.1; upper extremities x 0.2; trunk x 0.3; lower extremities x 0.4). These weighted scores were summed to produce the total area of active psoriasis score. For each of the VAS the distance in millimetres (mm) from zero to the participant's intersecting mark was measured. These measurements were added together, divided by the length of the VAS then multiplied by four. This result was multiplied by the total area score to give the final SAPASI score. The scoring sheet can be found in Appendix 9.5. The overall SAPASI score has been categorised into levels of severity: (1) mild (PASI < 7) (2) moderate (PASI 7-12) and (3) severe (PASI >12) (Schmitt & Wozel, 2005).

The SAPASI's psychometric properties were assessed by comparison with the PASI, which has been used extensively in both clinical and research dermatology settings. The SAPASI demonstrated high criterion validity by correlating significantly with all components of the PASI with an overall correlation of r = 0.59, p=0.0001. Test re-test reliability found a correlation between the two time points of r=0.82, p<0.0001 and inter-rater reliability between five raters was r=0.95, P<0.001 (Feldman et al., 1996). This work has been re-run and good correlation between the SAPASI and PASI was found (r^2=0.26, p=0.0001; (Feldman et al., 2005).

3.6.4.1.4 Dermatology Life Quality Index: secondary outcome variable

The DLQI (Finlay & Khan, 1994) is an easy to use measurement which aims to quantify the health related quality of life (HRQOL) of people living with a skin condition. This was the first dermatology-specific HRQOL measure and is now used extensively in research and clinical settings. At the participating dermatology centre these scores are collected routinely and are combined with the PASI score to determine overall psoriasis severity and this can determine treatment choice. In the clinic a patient is not classed as having severe psoriasis unless they have both a PASI score above ten and a DLQI score above ten.

The DLQI included ten questions, nine of which followed a four point Likert scale 0 = Not at all / Not relevant; 1 = a little; 2 = a lot and 3 = very much. Question 7 was slightly different; if the first question was answered 'yes' this equated to 3 points but if answered 'no' participants were asked a following question which they could answer: a lot = 2, a little = 1 or not at all = 0. The total score is the sum of the ten questions; there was no reverse scoring. The measures test-retest reliability was assessed over one week and was found to be very high (0.99). This measure is widely and commonly used across research and clinical dermatology settings including psoriasis.

3.6.4.1.5   Hospital Anxiety and Depression Scale: secondary outcome variable

The HADS (Zigmond & Snaith, 1983) was designed to assess levels of anxiety and depression in people with physical illness. The HADS is a screening tool and not a diagnostic tool but scores between 8-10 suggest possible caseness and a score over 11 is thought to correlate well with a clinical diagnosis of anxiety or depression.

Participants were presented with 14 statements and asked, over the past week, how much they agree with each statement. They responded by checking a box on a four point Likert scale from 0-3.

The seven odd numbered questions related to anxiety and the seven even questions to depression. Questions 2,4,7,9,12 and 14 were all reverse scored. The 14 scores were summed for a total HADS score; the seven even for a HADS-depression score and the seven odd for a HADS-anxiety score.

The anxiety subscale items had Spearman's R correlations in the range of +0.46 to +0.76, which is significant at $p < 0.01$. The depression scale had correlations between +0.30 to +0.60, which were significant $p < 0.02$. The Anxiety subscale had a correlation with psychiatrist ratings of $r = 0.70$ and the depression had $r = 0.74$, both of which were significant at $p < 0.001$. The HADS is commonly used across chronic health populations including those with psoriasis.

3.6.4.2   Illness Perception Questionnaire-Revised: Secondary outcome variable

The SR-CSM (Leventhal et al., 1984) attempted to identify the beliefs which people hold about their physical health conditions and how these can impact upon psychological adjustment, behavioural actions and physical functioning. These beliefs were originally measured by the Illness Perception Questionnaire (IPQ; (Weinman et al., 1996)). This scale was latterly revised to improve some of the psychometric properties from the original scale (IPQ-R; (Moss-Morris et al., 2002)).

The IPQ-R questionnaire is divided into eight sub-sections. The first assesses the identity sub-scale. Participants were asked whether they believed a list of 17 symptoms were related to their psoriasis, to which they either circled yes or no. The next section grouped 38 items into seven subscales (timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence and emotional representation). Each item is scored on a five point Likert scale with from strongly disagree to strongly agree. The next section presented 18 possible causes for their condition and participants were asked to mark how much they agreed (1=strongly disagree to 5=strongly agree) with each. The final question asked participants to rank in order of importance the top three variables, which they believed causes their condition.

The identity score was the sum of the yes-rated symptoms in the 'this symptom is related to my psoriasis' column. For each subscale scores were summed then divided by the number of items included within each subscale. Thirteen of the 28 items were reversed scored. Each of the 17 causes was scored individually on the 1-5 Likert scale. The rank scores were kept in their raw data form.

The internal reliability for each of the subscales ranged from α = 0.79 to 0.89. Test-retest reliability across a three week time period ranged from 0.46 to 0.88 and across six months ranges from 0.35 – 0.82. Moss-Morris et al. (2002) conducted the IPQ-R sensitivity tests on eight different illness type groups the groups produced statistically different scores on all of the scales supporting known group validity. The psychometric status remained at an acceptable level in patients with psoriasis (Fortune et al., 2002a). This scale has been used extensively across various physical health conditions including psoriasis.

3.6.4.3   Mindfulness Awareness Attention Scale: process outcome variable

This scale was recommended by Breathworks®, a UK company that specialise in delivering mindfulness interventions to people living with stress and chronic pain/illness. This scale is the most frequently used measurement of mindfulness skill in research studies (see Chapter 2). The MAAS (Brown & Ryan, 2003) is designed to tap into dispositional characteristics of present moment awareness and attention skills, which are key skills in the MBCT course. The scale has been used extensively in international research.

This scale included 15 items relating to present moment awareness and attention which participants scored on a six point Likert scale (1=almost always to 6=almost never). There was no reverse scoring. The mean score is derived from the 15-item questionnaire.

Brown and Ryan (Brown & Ryan, 2003) found good internal consistency (α>0.82) and test re-test reliability across four weeks (interclass r = 0.81). Correlating MAAS scores with years of mindfulness practice assessed criterion specific validity and a positive correlation was found (r=0.36, p<0.05). This scale has been used in many mindfulness studies across healthy and patient populations.

3.6.4.4   Credibility and Expectation Questionnaire: process outcome variable

The belief in an intervention's credibility and the expectancy that it is going to be effective has been highlighted as a possible confounding variables among non-specific therapeutic effects (Kazdin, 1979) but it has not regularly been assessed within this area of research (see review recommendations Chapter 2). This tool has been used before in mindfulness based intervention studies (Kingston et al., 2007, Shawyer et al., 2012).

Participants answered three items relating to expectancy and three to credibility on a nine point Likert scale ranging from for example 1=not at all useful to 9=very useful. A mean score was taken for each of the sub-scales. This tool had high internal consistency for the expectancy factor with α's ranging from 0.79-0.90 and for credibility with α's from 0.81-0.86, good test re-test reliability (r=0.85). The CEQ has been used in trials assessing the efficacy of treatments in patient populations.

3.6.4.5 Group attendance and home practice estimates: process outcome variable

After completing the intervention participants were asked to report how much they had practiced on each week during the eight-week course. A similar questionnaire was sent to these participants at the end of their eight weeks post-intervention follow-up asking to report how much they have continued with their practice after finishing the taught course.

3.6.5 Analysis

The analysis plan for each research question is presented sequentially.

<u>Primary analyses</u>

Does MBCT improve physical, psychological and QoL outcomes in people living with psoriasis?

The intervention group, which received MBCT, will have lower perceived stress levels than a control group who continued with treatment as usual (TAU).

The intervention group, which received MBCT, will have lower physical severity ratings than a control group who continued with treatment as usual (TAU).

The intervention group, which received MBCT, will have lower distress ratings than a control group who continued with treatment as usual (TAU).

The intervention group, which received MBCT, will have QoL impairment than a control group who continued with treatment as usual (TAU).

The primary analysis was to examine whether any differences on primary (PSS and SAPASI) or secondary (HADS and DLQI) outcome variables emerged between the randomised treatment and control groups a follow-up 1, which were not evident at baseline (these data collection points are **highlighted in red** in Table 3).

A supplementary analysis was conducted to examine differences between the comparison group participants, who continued with TAU, to all participants who had completed the MBCT training, who were re-named the active group. The pre-intervention scores (demarked with * in Table 3) for the active group were the combination of the treatment group's baseline scores with the control group's follow up 1 scores. The post-intervention scores (demarked with **^ *** in Table 3) for the active group

were the follow-up 1 scores for the treatment group and the follow-up 2 scores for the control group. The pre-intervention scores for the comparison group were collected at follow up 1 and the post-intervention scores from the comparison group were collected at follow up 2.This test of difference between the active and comparison group was intended to support the primary analysis and not as an independent stand-alone analysis.

<u>Secondary analyses</u>

Do illness representations affect how MBCT influences the primary outcomes within this population?

Stress responders (those who believe stress caused their psoriasis) in the treatment group will experience greater change scores in their physical severity ratings than non-stress responders.

There will be no change in the illness representations between the treatment and control group at follow-up 1.

The participants were split in to stress responders (self-reported by agreeing with the IPQ-R cause subscale that stress causes psoriasis) and non-stress responders (did not agree) and primary and secondary outcome were compared between the two groups.

Illness representation scores were compared between the treatment and control group at follow-up 1, just as the primary and secondary scores had been examined in the primary analysis.

Did the participants of the MBCT course successfully learn the mindfulness skills?

Participants who receive the MBCT intervention will report higher follow- up MAAS scores in comparison to their pre-intervention MAAS scores.

Participant's pre-intervention MAAS scores were compared to their post-intervention and two-month follow-up scores.

Do beliefs in credibility/expectancy affect the primary outcomes?

Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their physical symptoms than those who had weaker beliefs.

Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will experience a greater change to their perceived stress levels than those who had weaker beliefs.

Pre-intervention CEQ scores were entered into a correlation with primary outcome change scores.

3.6.5.1 Statistical methods

The following statistical tests were all performed in Statistics Package for Social Sciences (SPSS) version 19 and Data Analysis and Statistical Software (STATA version 9).

3.6.5.1.1 Missing data

The data were screened for missing values. There were no missing values on any of the primary (PSS, SAPASI) or secondary (HADS, DLQI) outcomes. There were a maximum of two cases missing on some subscales of the IPQ-R, the CEQ and MAAS datasets. As these were such a small proportion of the overall dataset (n=39) and not from the primary variables of interest it was deemed appropriate by the research team to substitute the mean of the particular scale in to replace the two missing items.

The data were then screened and any errors cases, such as extreme outliers, were re-entered after referencing the raw data.

3.6.5.1.2 Descriptive data and tests for normality

The categorical and continuous data were separately examined with frequencies and descriptive data then the continuous data were explored to assess whether the distributions were normally distributed using the Kolmogorov-Smirnov (K-S) test. As the primary variables were not normally distributed and the sample size was small non-parametric tests were employed to explore the data further, each non-parametric test will be described next. Parametric alternatives were employed for variables, which were normally distributed to check for sensitivity.

3.6.5.1.3 Comparison with previous data

The literature review (see Chapter 2) presented the findings from previous studies within this research area. To aid the interpretation and generalisation of this study's findings data were compared to previous studies with a one-sample t-test. An estimation of the previous study's data distribution was extracted from the reported mean and standard deviation and this was compared with the current study's data distribution to check for similarity.

3.6.5.1.4 Correlations

The demographic and outcome variables were entered into a non-parametric correlation (Spearman's rank order) in order to examine the direction and strength of association between the variables at the first measurement point.

The CEQ and the change scores of primary and secondary variables (SAPASI, PSS, HADS, DLQI) were entered into a parametric correlation analysis to examine whether the pre-course beliefs were associated with the amount of change experienced from pre to post-MBCT.

3.6.5.1.5 Primary analysis with primary and secondary variables

Previously treatment and control groups have been compared at baseline to check the efficacy of the randomisation process. However, there is now agreement across statisticians that these baseline comparisons should not be conducted because with a small sample there may be large differences but these will not be significant and conversely with a large sample, very small differences can become significant (Peduzzi et al., 2002). Therefore descriptive data statistics are presented for the two groups at baseline and judged by eye as to whether there are differences between the groups after randomisation.

As the supplementary analysis compared the active group participants to a non-randomised comparison group, comparison tests were used on the pre-intervention scores to examine whether there were any systematic differences between the groups (active and comparison).

Analysis of Covariance

A one-way, between groups Analysis of Covariance (ANCOVA) tested for differences in outcomes between the two groups at post-intervention whilst controlling for participants pre-intervention scores. This is accepted as the gold standard method for analysing an RCT (Blance et al., 2007). Controlling for baseline scores reduces the standard error around the estimate of the treatment effect and thus increases the statistical power for detecting an effect. This study had a small sample size, which reduced the power of statistics to be able to detect a difference if one exists. ANCOVA increases the power (sensitivity) of the test for a main effect. ANCOVA was the most appropriate statistical test for this study's small underpowered sample size.

Bootstrap estimate

An ANCOVA is a parametric statistical test and as the primary and secondary outcome variables were not normally distributed and therefore a bootstrap estimate was applied to the data. Bootstrapping is a re-sampling technique, which drew replacement samples from the original dataset's mean and variance scores in order to form a number of replications (set to 1000 repetitions in this analysis) and produced an estimate to compare between the groups (Tabachnick, 2001, Howell, 2002, Efron & Tibshirani, 1993). Bias corrected bootstrap estimates adjusted for the difference between the 1000 bootstrap estimates of the distribution and the actual original distribution. Bias corrected

bootstrapping was used instead of percentile confidence interval bootstrap estimates, as these require a minimum sample size of 50 participants (Efron & Tibshirani, 1993).

The bootstrap option was not available in SPSS v.19 and this analysis was performed using Data Analysis and Statistical Software (STATA version 9). In this study the number of replications was consistently set to 1000 replications and a different Mersenne twister seed was set for each separate analysis in order to preserve the pseudorandom numbers generation (Tabachnick, 2001).

Secondary analyses with process outcome

Credibility, expectancy and MAAS scores were all normally distributed. A paired-samples t-test examined participants' scores on a measurement scale across two time points. Credibility and expectancy were measured at pre and post intervention time points. The paired-sample t-test was an appropriate technique to measure any differences in participants CEQ scores from pre-to post-intervention time points.

A one-way, repeated measure Analysis of Variance (ANOVA) compared participants' responses across three occasions. Mindfulness skill acquisition (MAAS) scores were normally distributed and MAAS was measured at pre-intervention, post-intervention and at 8 weeks post-intervention. The ANOVA was an appropriate technique to test for differences in MAAS scores across the study time scale.

3.7 Concurrent quantitative study methods: Study phase II

The cortisol and cortisone data were collected at the same time as the physical, psychological and QoL measurements. The design, groups and sampling were all exactly the same as was reported in phase I therefore this section only presents the data collection and analysis stages.

<u>Research Questions</u>

(5) Is the CAR cortisol correlated with stress and physical severity of psoriasis?

(6) Does the CAR change in participants who have completed the MBCT training course?

3.7.1 Data collection

Saliva collection followed a standard protocol from Sarstedt (Sarstedt, Ltd., Leicester, UK). Participants were sent four Salivette® Cortisol devices (Sarstedt, Ltd., Leicester, UK), together with the self-report questionnaires, at each measurement point (baseline, follow-ups' 1,2,3) along with written instruction on how to collect and label their samples (Appendix 9.6). As soon as the participant awoke they were instructed to put the first swab from the tube into their mouth and hold it for two minutes then to spit the swab back into the tube. This procedure was repeated, with separate swabs at 15 minutes, 30 minutes and 45 minutes after awaking, during this time participants were instructed to eat and drink nothing but water. Participants only had to label the tube with which time point it refers to e.g. "30min," then keep in a fridge before posting in pre-paid envelopes to the research team.

The laboratory analysis measured both cortisol and its antecedent cortisone. Salivary cortisone is considered to be a more accurate marker than salivary cortisol for free circulating serum cortisol because confounding variables such as corticosteroid binding globulin (CBG) interrupt cortisone less than they do cortisol (Perogamvros et al., 2010). Cortisone is produced when cortisol is oxidised by an enzyme (11β-hydroxysteroid dehydrogenase) resulting in high cortisone concentrations compared to cortisol concentration (Perogamvros et al., 2009). Cortisol measurements were taken in order to be able to compare to previous research and cortisone measurements were included in order to check the sensitivity of the cortisol scores.

3.7.1.1 Adherence

The CAR measures the reactivity i.e. the rise in cortisol in response to awakening as well as the overall CAR. If a participant does not place the 0 minute swab in their mouths

as soon as they awake then they may miss the true rise in cortisol to awakening. The importance of adhering to the patient protocol regarding saliva collection was communicated to participants as clearly as possible by the research team at every collection time point throughout the study.

3.7.1.2 Laboratory analysis

The laboratory analysis of the saliva samples followed a standard protocol used in the University Hospital of South Manchester. Upon receipt participants' Salivette® Cortisol devices (Sarstedt, Ltd., Leicester, UK), were frozen at -20 ^oC until all samples across the study period (6 months) had been collected. The samples were then thawed and centrifuged in a microcentrifuge at 1000 x g for 4 minutes. The liquid saliva from the swabs was mixed with methanol and water and loaded into cartridges (Using the Spark Holland Symbiosis^{TM} (Emmen, The Netherlands) in extraction Liquid Chromatography (XLC) mode. The solution was then separated into its constituent components using a chromatography column (Phenomenex®, Macclesfield, UK). Cortisol and cortisone levels were measured using Mass Spectrometry. The liquid fractions were then transformed into ionised gas particles (given an electrical charge), and the ions, which have individual mass to charge ratios, are sorted by their masses. Finally, the peak amount of each ion is calculated (with TargetLynx^{TM}) indicating a response rate for cortisol and cortisone within that sample.

3.7.1.3 Inter and intra assay variance

Inter- and intra-assay variance was not tested in this batch of samples. The XLC-MS/MS technique for analysis of cortisol and cortisone simultaneously has been documented in the same laboratory where this batch were analysed. Batches can be entered together at one time. Within one time point the variance between batches for cortisol ranged from 3.2% to 10.4% and for cortisone ranged between 0.6% – 8.7%. The variance between different time points of analysis for cortisol ranged between 1.6% to 4.4% and for cortisone was 2.3% to 5.4% (Jones et al., 2012). These values all fall within the acceptable range (<15%) of percentage deviation from the mean as outlined by the Food and Drug Administration (Food and Drug Administration, 2001).

3.7.1.4 Composite awakening response measures

The analysis produced a cortisol and cortisone measurement for 0 minutes, 15 minutes, 30 minutes and 45 minutes post-awakening for all participants at each assessment point. The mean across all participants was recorded for each time point and the 0 minute time point was used as a stand-alone s1 measurement (Clow et al., 2009) but further composite scores were also calculated from these four time point scores.

The AUC with reference to ground/zero (overall CAR) (AUCg) and with reference to s1/0 Minute post awakening (cortisol/cortisone reactivity) (AUCi) and the dynamic change

response (the difference from the highest to the lowest reported measurement) are represented in Figure 10.

Figure 10: A diagram to demonstrate the methods to calculate the CAR composite measures scores
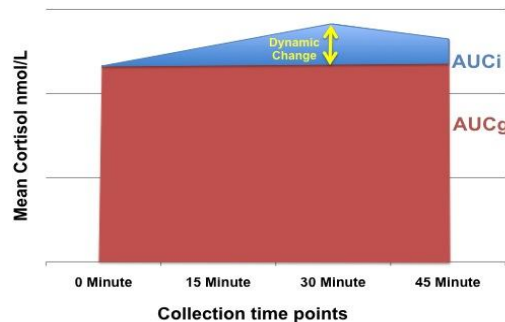
Figure 10: This diagram demonstrates the areas that are calculated for each CAR composite score. The AUCi is coloured in blue, the AUCg is the AUCi and the red area and the dynamic change is represented with the yellow arrow.

These composite scores were calculated in SPSS. The AUCg was calculated with the following formula:

*AUCg = (time between samples (15minutes) / 2) * (0 minute + (2 * 15 minute) + (2 * 30 minute) + 45 minute)*

The AUCi with:

*AUCi = AUCg - (0 minute * (3 * time between samples 15minutes))*

And dynamic change with:

Dynamic change = Maximum value of (15 minutes, 30minutes, 45 minutes) – 0 minute

3.7.2 Analysis

5) **Is the CAR cortisol correlated with stress and physical severity of psoriasis?**

    a. *The CAR cortisol will be significantly negatively correlated with physical severity scores.*

    b. *The CAR cortisol will be significantly negatively correlated with perceived stress scores.*

The first measurement scores (n=39) were entered into a correlation analysis to examine the strength and direction of correlations between the CAR AUCg, AUCi and

dynamic change responses with the demographic, physical, psychological and QoL variables.

6) **Does the CAR change in participants who have completed the MBCT training course?**
   a. The CAR will be significantly different between the treatment and control group at post-intervention.

The CAR scores were entered into a comparison between the treatment and control group at time 1 and between the active and comparison group at post-intervention.

3.7.2.1 Statistical methods

The data were screened and values where cortisol or cortisone measurements were missing for any of the time points were excluded as without all four time measurements (0, 15, 30, 45 minutes post awakening) the composite scores could not be calculated. The data were screened for any outliers.

3.7.2.1.1 Descriptive data

In addition to the demographics and variables used in phase I BMI was entered into the demographic measurements and subsequent analyses. BMI is well established as having a significant association with CAR in disease-free populations (Steptoe et al., 2004) and various patient populations (Ursache et al., 2012).

The rise in cortisol/cortisone from the moment of awakening across the subsequent 45 minutes has been measured in previous literature by presenting individual time points and the percentage change from the 0 minute to 30 minutes post awakening (Clow et al., 2004). In order to assess this percentage in this study population the mean scores of each time point were plotted and the percentage change calculated. The four time points display the shape of the CAR, whether it is a shallow or steep increase.

3.7.2.1.2 Tests for normality

The cortisol and cortisone measurements at 0 minutes post-awakening (s1) and the composite scores were tested to see whether their distributions were similar to a normal distribution using the K-S test of difference.

3.7.2.1.3 Adherence checks

Previous research (Kupper et al., 2005, O'Connor et al., 2009) suggested that if a healthy participant's awakening response did not demonstrate a rise in cortisol levels from 0 minutes to 45 minutes post awakening then this might suggest that the participant had not adhered to the saliva collection protocol. This study is the first to measure the CAR in people with psoriasis therefore we cannot assume that no awakening rise

equates to non-adherence, as it may reflect a true observation within this patient group. Consequently, all participants without CAR rise were included in the analysis.

Those who reported no rise post-awakening were compared to those who did report a rise on the demographic, physical and psychological outcomes to examine whether there were any systemic differences between these participants.

3.7.2.1.4 Comparison to previous literature

These data cannot be compared to data from previous studies because of the variation in laboratory analysis methods used across the previous studies and the current study.

3.7.2.1.5 Primary analysis

Correlation

The cortisol and cortisone scores were entered with the demographic, physical, psychological and QoL scores into a non-parametric correlation (Spearman). The data did not meet the assumptions necessary to be entered into a regression model.

The normally distributed variables (AUCg cortisol, all cortisone, HADS and PSS outcomes) were entered into a parametric correlation (Pearson) to check the sensitivity of the non-parametric analysis.

3.7.2.1.6 Secondary analysis

Only one of the composite variables was used in the group comparisons because if all the composite scores were included this would have increased the number of statistical tests being used which may have driven up the likelihood of performing a type 1 error. The AUCg was the only composite score significantly correlated with other outcomes in the correlation analysis and was consequently chosen as the composite score to be entered into the ANCOVA.

ANCOVA

As with phase I, the data were entered into an ANCOVA to test for differences in AUCg cortisol and cortisone between the participants who had and had not received the MBCT intervention whilst controlling for pre-intervention scores. Two analyses were run, one between the treatment and control group and one between the active and comparison group.

Although the AUCg cortisol and cortisone data were both normally distributed, they were drawn from a small sample and to maintain consistency, bootstrapping was performed on the ANCOVA statistical tests.

3.8   Sequential qualitative study methods: Study phase III

The aims of phase III were iteratively expanded due to the high attrition rates experienced during data collection in phase I/II. A supplementary aim was introduced to explore the beliefs and attitudes of the course completers and to identify any individual differences, which might have contributed to their continued adherence.

Research questions
  (7) What are participants' experiences of the MBCT course?
  (8) What are the perceived benefits and the perceived barriers to participating in the MBCT course?
  (9) What individual differences are found in those participants who adhered to the MBCT intervention? *

*This research question was developed after high attrition was experienced during the effectiveness study.

3.8.1   Sampling

The quantitative study generated the subgroup of interest for this sequential qualitative study i.e. participants who adhered to the mindfulness training for eight weeks (n=14). Due to the high attrition rates in study phase I/II it was possible to homogenously sample the whole of this specific population of people with psoriasis who had completed the MBCT course. This sampling technique meant that sampling could only continue until all available participants were sampled. The focussed research questions were answered adequately and saturation was achieved with this sample (Morse, 2007).

3.8.2   Recruitment

The participant information sheet (Appendix 9.7) informed participants that they would be invited to an interview after the completion of their mindfulness training. This invitation was offered to them during the last two weeks of their mindfulness course (both in the treatment and control group). Willing participants returned an informed consent form to the group facilitator and their contact details were, with permission, passed to the independent research assistants who then arranged a time and place for the interview to take place.

3.8.3   Data collection

This study's research questions were interested in individual participant's perspectives rather than the collective consensus on the MBCT course, therefore a topic group would not be appropriate. Additionally, one of the topics of interest was an evaluation of the group dynamic during the course, which could not be discussed as a group as valid self-disclosure may be inhibited by the group demand characteristics. The most appropriate

method of data collection to meet these study aim requirements was a one-to-one interview.

This study's research questions emerged from pre-specified focussed aims; there are *a priori* questions that looked for specific answers such as was the MBCT intervention perceived as effective or not, whilst remaining open to new emergent explanations. This research took place within an applied research setting i.e. using a complex intervention within a patient population and a semi-structured interview was the most appropriate technique to answer the study research questions (Pope et al., 2000).

3.8.3.1   Topic guide

Topic areas were selected from themes that emerged from previous qualitative studies exploring the acceptability of mindfulness-based interventions in the literature review (see Chapter 2). Two independent researchers conducted the interviews, not the PI. The interviewers were given a list of the topic areas and example questions or prompts below each heading, this allowed the interviewers freedom to use naturally forming questions related to the topic heading or to use an example question if one did not naturally emerge.

There were four original topic headings, generated to answer the first two research questions, "What are participants' experiences of the MBCT course?" and "What are the perceived benefits and the perceived barriers to participating in the MBCT course?" These with their example prompt questions can be found in Appendix 9.8:

(1) The course: problems and benefits
(2) Home practice
(3) Skills
(4) Perceptions of efficacy

In response to the third research question, "What individual differences are found in those participants who adhered to the MBCT intervention? Three more topic areas, which were informed by a health psychology model SR-CSM were added to the topic guide:

(1) Stereotypes
(2) Living with psoriasis
(3) Stress

The topic areas were discussed within the supervisory team and the interviewers in order to clarify and quality check that the topic areas were driven by the research aims and that there were no missing areas. A dialogue remained open between the two

interviewers and the PI to suggest any helpful questions, which helped probe difficult areas or possible new avenues to explore in the next interview. This iterative process kept the topic guide questions emerging but the overall topic areas remained constant throughout the interviews.

3.8.3.2 Interview conduct

The interviewers, with prior experience with qualitative methods and specifically with conducting semi-structured interviews, agreed to facilitate half of the interviews each. The PI could not conduct the interviews, as she had been the MBCT-group facilitator and this may result in social desirability of answers.

The interviews took place in private rooms within the University of Manchester and occurred within one month of a participant's final mindfulness group session. The interviewers contacted the PI immediately before and after the interview in accordance with University Policy. Interviews were recorded on digital devices (Olympus dictation recorder (DS-2400). The time, data and participant number were recorded then the interviews began.

3.8.4 Data management

This study was designed to expand upon the partial insights of phase I/II, which explored the effectiveness of a complex intervention upon the physical and psychological symptoms of psoriasis. In response to a criticism that qualitative methods were unwieldy and opaque (Murphy et al., 1998) a systematic approach was developed to answer specific *a priori* questions within a specified population in a timely and visible analytic process (Swallow *et al.*, 2003, Srivastava & Thompson, 2009). This approach is called Framework Analysis (FA) and aims to describe and interpret a phenomenon under investigation (Ritchie & Spencer, 1994) with a mixed inductive and deductive approach rather than a purely inductive approach which is often a feature of much qualitative research (Pope et al., 2000). One of the original aims of FA was to appraise the effectiveness of interventions within applied policy research (Ritchie & Spencer, 1994). The approach is consequently well suited to the aims of this study.

FA data management consists of a five step process (Ritchie & Spencer, 1994):
- (1) Familiarisation
- (2) Identifying a thematic framework
- (3) Indexing
- (4) Charting
- (5) Mapping and interpretation

The topic guide areas were informed by the SR-CSM health psychology model and previous acceptability of mindfulness-based intervention study themes. These topic areas were combined to develop an *a priori* framework template for analysis.

3.8.4.1 Familiarisation

The PI transcribed all of the digital recordings (Olympus dictation recorder (DS-2400), which allowed her to be immersed in the raw data. The transcripts were read and initial ideas and recurrent themes were handwritten onto the transcript margins.

Identifying a thematic framework

These initial themes were then either added as subtheme to the themes (topic areas) in the framework template or left as independent emergent themes, which did not map onto the template. This process was tailored by the overall aim to answer the research questions of the study.

Indexing

A numbered list was prepared of the total themes and subthemes in Microsoft® Word. The initial familiarisation had included all of the transcripts and not just a sample of them, which mean that rather than returning to each individual transcript to index the text with the numerical themes and subtheme, the data could be directly imported into the charting stage (Ritchie & Lewis, 2003).

Charting

This stage of sorting the data by theme and subtheme was performed in Microsoft® Excel, which has previously been reported as an appropriate software for charting in FA (Swallow et al., 2003). Participants' study ID numbers were placed in the columns along with attendance levels, age, gender and group allocation, in order to aid contextualisation. Ritchie and Spencer originally propose that the participants should be reported in rows and not in columns as this study has (Ritchie & Spencer, 1994). This slight variation in chart design was purely as the PI found this alternative format easier to use.

Mapping and interpretation

Extracts were lifted from the transcripts (with identifying line number) and inserted into the corresponding *'theme'*'study ID'* cells. This process was time consuming and involved members of the wider research team to disconfirm/confirm the primary researcher's analytic choice. This process involved returning to the raw data and refinement of the original themes until there was unanimous agreement.

Previous FA studies have developed a visual representation of the FA process to elucidate the methods (Swallow et al., 2003), a visual representation of the process employed in this study are presented in Figure 11.

Figure 11: Study data management process

Familiarisation	•The primary investigator transcribed the interviews from the Olympus digital recorder into written transcripts in Microsoft® Word. •Initial ideas were handwritten onto the transcripts as shown below: 48 Yeah sometimes I would sort of hear a question and think 'oh I don't know if that applies to me' but _group_ 49 then you would be talking to the next person to us and they would come up with something that I _learning_ 50 would not have thought about. It is hard to describe really but yeah I think there is more input and 51 more ideas in a group whereas if its one on one I'm not very good with sort of expressing myself _benefits_ 52 whereas the group you can listen to other people and think 'oh yeah I've done that.' You can agree 53 with them and stuff like that. So I think a group session is really good. Definitely.
Identifying a thematic framework	•Data which corresponded with themes from a priori research into the acceptability of mindfulness-based intervention and from the Common Sense Model of Self Regulation (CSM-SR) were combined with new emergent themes. •Across the cases these themes were drawn together to make analytical themes. •Broke the large dataset into smaller themes.

Indexing	**Coding Frame:** 3.1 Group Format 3.1.1 Aiding learning 3.1.2 Disrupted learning 3.1.3 Downward self comparison 3.1.4 Non-therapeutic benefits	**Transcript** 3.1.1 I would hear a question and think 'oh I don't know if that applies to me' but then you would be talking to the next person to us and they would come up with something that I would not have thought about. 3.1.2 They were just quite bad mannered really you know arriving late and but I know that you get that with lots of people but that type of thing was disruptive when you were trying to relax or meditate and then someone would come strolling in. 3.1.3 I remember the first week when we sat in the room and I just thought "crikey" you know sometimes you think you've got it bad and then you look at other people and you think "they've got it much worse" 3.1.4 It's a massive help because you feel so alienated and you just feel completely on your own so just being with other people with psoriasis can help you know

Charting

	A	B	C	D Female, 30 years old. SAPASI 12.38, PSS 13. Attendance 7/8 sessions	E Female, 47 years old. SAPASI 9.58, PSS 27. Attendance 8/8 sessions
			Positive	"Yes and no, in a way I thought yes its not just me and people have it worse but at the same time you can notice how much worse it can be and that I could quite easily have it just as bad as that." line 135;"...she said all her friends call her a 'stress head' and when she was talking I thought 'yeah'" line 96; "I remember the first week when we sat in that room and I just thoguht 'crikey you know sometimes you think you've got it bad and then you look at other people and you think they've got it much worse'" line 92	"with it being a group you didn't feel , if you didn't understand something ...then somebody else would say exactly what you were thinking or feeling...whereas if I had of been sat there on me own I might have been more conscious of not feeling something and i might have been a bit more uncomfortable and uneasy about it." line 144; "I think that by seeing other people with psoriasis with short sleeves on and things like that and just hearing people with psoriasis talk I have always thought that is a huge help... it's a massive help because you feel so alienated and you just feel completely on your own so just being with other people with psoriasis can help you know" line 309 , "I couldn't really split that into what has been the help then being with other people with psoriasis, what has been the help psychologically" line 319
1. Process		**1.2 Group**	**Negative**	"I felt like I had loads and loads to contribute but then at one point I thought I need to keep quiet really because I don't want people thinking its just me speaking all the time" line 51; "he was covered in it and I just thought I felt sorry for him and i thought well and then i thought i dont particularly want anyone to feel sorry for them because i have got it as well" line 145, "...I could see that in years to come it could possibly get worse and that's from the first week thats what hit me when i went in there because i dont think i have ever seen so many people with psoriasis at one time." line 140	"They were quite bad mannered really you know arriving late and but I know you get that with lots of people but that sort of thing was disruptive when you were trying to relax or meditate and then someone would come strolling in" line 129 "...some of the people that were in the group thre was one man in particular who seemed to like to be, well there was a couple of men actually that seemed to like to take all the attneiton and just you know going out and we'd all wait to be starting a session and things and that type of thing I found irritating" line 122

Mapping and Interpretation

• Exploring categories emerging across one theme's row over all of the participant's accounts.

Figure 11: A diagram mapping the Framework Analysis process used with the qualitative data including; the familiarisation, identifying a thematic framework, indexing, charting, mapping, and, interpretation phases with examples from the data set in this thesis.

3.8.5 Data analysis

The aim of this stage of FA was to develop an explanatory account of the qualitative data in answer to the study's research questions. These accounts lifted the analysis from the theme lists, which emerged from the data management stage and allowed the interpretation to explore co-existent, but not causal, links across multiple phenomena from the data (Ritchie & Lewis, 2003).

Ritchie and Spencer (1994) outline three analytic stages:
   (1) Detection
   (2) Categorisation
   (3) Classification

Detection

The text extracts, which were presented, in the cells across from each theme row were explored again with an intention to explore any overarching dimensions which emerged from exploring the data for each theme across all the participants data cells.

Categorisation

The multiple categories were then refined into fewer overarching categories, which were labelled with appropriate descriptive titles.

Classification

These broader categories were then examined together in order to develop an overarching explanatory account. This process was performed by the PI individually and then discussed with the wider research team at regular meetings. At these meetings the PI would present the raw textual data in the Microsoft® Excel worksheet to demonstrate the abstract dimensions anchor within the raw data.

This process continued until the PI and wider research team agreed upon the final set of themes.

3.8.6 Rigour

This section draws upon established guidance (Morse et al., 2002, Sandelowski, 1993, Critical Appraisal Skills Programme, 2006), which provides a framework to explore the quality of qualitative methods such as semi-structured interviews and FA techniques.

The guidelines helped inform the design and procedures employed within this study and the areas of rigour are described for the data collection stage and the data management/analysis stage. Reliability and validity are replaced with the terminology

transferability and credibility within this section, as these terms have been deemed more appropriate for qualitative rigour analysis (Golafshani, 2003).

Data Collection

The PI facilitated the MBCT groups and the interview central topic of interest was the evaluation of the MBCT groups. If the PI conducted the exit interviews this would have introduced a high level of potential bias. Participants may have been more likely to produced socially desirable answers if interviewed by the PI. To reduce the likelihood of introducing this bias two independent researchers conducted the interviews. Both interviewers had completed training in qualitative data collection and analysis and have prior experience with semi-structured interviews. The interviewers experience and skills increased the credibility of the data collected by these researchers.

All interviews took place in the same setting (private room in University of Manchester). The interviews were digitally recorded on Olympus (DS-2400) devices to allow for high quality recording and stored as digital files. The interviewers talked to the PI after each interview in order to explain any contextual details, which were also written down in field reports. The contextual details increased the precision of the phenomenon under consideration that can improve credibility and transferability. The ability to re-listen to the original audio files increases the transparency of the analysis process.

Data management and analysis

The data to support each theme and category were visible in the cells of the Microsoft® Excel worksheet, which could be cross-referenced to the original transcripts (via line references) to check for context. The worksheet presented supportive and disconfirmatory cases in two rows for every theme to allow for analysis of deviant cases in the analysis stage. The worksheet presentation style also facilitated the cross participant comparison process and this remains visible for readers to assess (Green & Thorogood, 2009).

During the data analysis stage the PI was aware of her position as the MBCT facilitator and as a researcher exploring the effectiveness of the MBCT intervention. Reflexive accounts (Appendix 9.9) reported these personal contextual issues and demonstrate an awareness of how these issues could produce effects such as an attentional bias towards positive findings (Green & Thorogood, 2009). These issues were discussed with the wider research team and three transcripts were sent to an independent researcher, for concurrent analysis. There were no major differences between the rater's initial coding, which increased confidence in credibility. The audit trail and higher explanatory accounts were discussed with the same independent rater who performed the additional coding and with the wider research team, which included experts in health psychology

and dermatology in order to increase the credibility of the interpretations (Silverman, 2006, Green & Thorogood, 2009).

3.9 Ethical considerations

Ethical approval was obtained (reference 10/H1013/77). Subsequent approval was granted from The University of Manchester Senate Ethics committee, Site Specific approval from Salford Royal NHS Foundation trust (reference 2010/279derm) and the Wellcome Trust Clinical Research Facility (reference CRF-SSA-382). The patient information sheet (PIS) is presented in Appendix 9.7.

3.10 Methods summary

This study's research questions required a mixed methods study design to answer them appropriately. The two parallel quantitative study phases were conducted, followed by the qualitative study phase. The two quantitative studies employed psychometrically valid tools to collect physical (SAPASI, CAR), psychological (PSS, HADS) and QoL (DLQI) outcome data. These data were analysed with a sensitive statistical test (ANCOVA), which is the gold standard to examine the effectiveness of an intervention in a RCT design. Phase II measured the statistical relationship between the CAR with the other outcome variables and examined whether it could mediate the stress-psoriasis link. Phase III employed a systematic, transparent qualitative data analysis technique to explore the *a priori* research questions and gain an understanding of participating in the MBCT intervention. The results from these three phases are presented in Chapters four to six.

4. Study phase I results:

Physical, psychological and quality of life outcomes

This chapter presents the results of the analyses planned in Chapter 3. It details the recruitment and group allocation procedures then presents whether the outcome variables were normally distributed by comparing their distributions to a normal distribution with the Kolomogorov-Smirnov (K-S) test of normality. Next the sample is described with descriptive statistics (measurements of central tendency and range) of the outcomes and these data were compared to relevant previous studies' samples. The chapter then examines the relationships between variables at first measurement with correlation analyses. The QoL variable was entered as the dependent variable into a regression in order to examine whether physical or psychological variables accounted for more variance in QoL scores within this study population. The primary analysis was an ANCOVA with bias corrected bootstrap estimates to test for an effect of the MBCT intervention within a RCT design. This was supplemented with another ANCOVA to test between the active (all participants who completed the MBCT course) and non-randomised comparison group. The chapter presents tests for differences (Mann-Whitney) in baseline scores between those who completed and those who did not complete the MBCT course. Finally, primary, secondary and process outcomes were tested to see if they changed across time from pre-intervention, post-intervention to follow-up (repeated measured ANOVA).

4.1 Sampling

4.1.1 Recruitment

From February to May 2011 recruitment posters, online promotions and radio adverts were distributed across patient support groups, general practice (GP) surgeries in Salford and Manchester. The primary mode of recruitment was the PI attending the specialist psoriasis clinic and the dermatology clinic at Salford Hospital. Both clinics lasted one morning once a week and the PI would be invited to meet patients either before or after their consultation in order to inform them of the study opportunity. The PI was often invited to sit in on the consultation by the patient and health care provider

which also enabled the PI to gain valuable understanding of the real life difficulties encountered by people living with psoriasis.

4.1.2 Randomisation

From the 80 people approached 31 met the inclusion criteria and reported that they could commit to an eight-week course during May to August 2011. These 31 completed the baseline measures and were block randomised in multiples of six, at a ratio of 1:1 (treatment and control group). Fifteen participants were allocated to the treatment group and 16 to the waitlist control group. After group allocation two participants from the treatment group had to be excluded and their baseline data removed because they no longer met the inclusion criteria (both started a new medical treatment regime). This left 13 participants in the treatment group and 16 in the control group.

4.1.3 Attrition

Four of the 13 treatment group participants dropped out before starting the course; two had a new commitment, which prevented their involvement and two (both related) had a difficult family situation and felt they could no longer commit. Then another two members became ineligible (one newly diagnosed with psoriatic arthritis and one became hospitalised with a co-morbid illness). Of the seven participants who began the groups, one left during the group and this was due to work commitment changes. The six who completed the eight-week course were retained through to the final follow up measurement time point.

Of the 16 participants who entered the control group, 13 completed the follow-up 1 measurement (two reported their commitments had changed and one person could not be contacted after the baseline measurements). A further three participants dropped out between completing their follow-up 1 measurements and attending the first MBCT session (reporting that their commitments had changed). From the ten participants who started the group, one had to be excluded because they started on biological medication (injections which block specific immune responses), which is an exclusion criterion, and one person chose to stop attending the group as they felt it was not right for them. After follow-up time 2 another person had to be excluded as they became hospitalised with a non-psoriasis related illness.

There was a high rate of attrition before the intervention started (13/29 dropped out across the two groups). The majority of participants reported that they could no longer commit to such a time consuming intervention due to other commitments only one participant reported that the intervention was "not right" for them. In order to maximise the data collection for this pilot study a non-randomised comparison group was recruited for data collection only, from the eligible people who had expressed an interest during recruitment but could not commit to attend the intervention. Ten comparison group

participants completed the measures at follow-up 1 and eight completed them at follow-ups 2 and 3. The two participants who did not return measurements after follow-up 1 could no longer be contacted. This process is represented in Figure 12.

Figure 12: A CONSORT diagram of recruitment
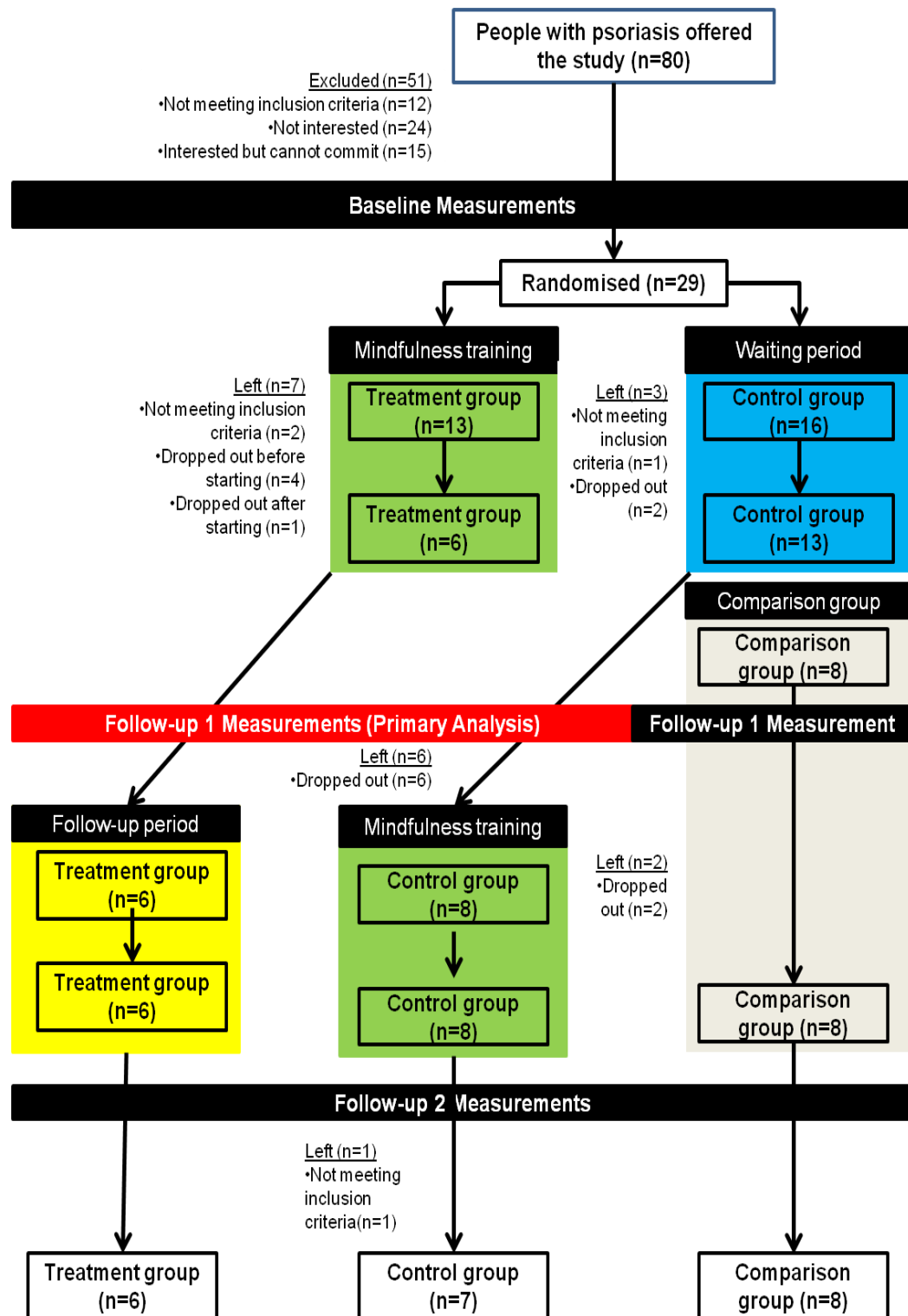
Figure 12: This flow diagram details participant recruitment and attrition from baseline to follow-up 3.

4.2 Data description

This section presents the frequencies, measures of central tendency and tests of normality (K-S) on the sample (n=29). These baseline scores were compared to previous studies conducted with people living with psoriasis in order to gauge the comparability of this study's population. There were no missing data for the primary or secondary outcomes (SAPASI, PSS, HADS, DLQI) but one participant did not complete all the demographics and two participants did not complete all of the IPQ-R subscales. The means were substituted for these missing data points because there were few missing values.

Descriptive statistics are first presented for the demographics and primary study outcomes of physical status (SAPASI), stress (PSS) and secondary outcomes of distress (HADS) and QoL (DLQI) scores. Next, the process variables (CEQ and MAAS) are described and finally the illness representations (IPQ-R).

4.2.1 Demographic, primary and secondary outcome descriptive data

Of the 29 included participants who completed baseline measurements 55.2% (n=16) were female; 41.4% (n=12) were single or separated; 72.4% (n=21) had a relative with psoriasis; and 55.2% (n=16) were using topical rather than systemic or biological psoriasis treatments.

The distress measurement has an overall score (HADS) and two sub-scales (HADS depression and HADS anxiety). The two subscales are included in order to present a better description of general distress. For continuous variables the baseline descriptive data, results of the K-S test, along with measurements of skewness (distribution symmetry) and kurtosis (distribution peakedness) for the continuous variables are presented in Table 6.

Table 6: Baseline descriptive data and normality: Demographic, physical, psychological and QoL outcomes

	N	Range	Mean (SD)	Kolmogorov-Smirnov			Skewness	Kurtosis
				Statistic	d.f.	p-value		
Age (years)	29	22.00 - 70.00	41.17 (2.43)	0.14	29	0.18	0.55	-0.40
Years with Psoriasis	29	3.00 - 43.00	21.21 (1.98)	0.17	29	0.04 *	0.38	-0.75
SAPASI (0-72)	29	0.62 - 21.52	7.42 (1.01)	0.19	29	0.01 **	1.32	1.18
PSS (0-40)	29	11.00 - 33.00	22 (1.21)	0.10	29	0.20	0.20	-0.99
HADS (0-42)	29	0.00 - 31.00	14.31 (1.58)	0.09	29	0.20	0.19	-0.72
HADS Depression (0-21)	29	0.00 – 13.00	5.48 (4.26)	0.20	29	0.004 **	0.41	-1.19
HADS Anxiety (0-21)	29	0.00 – 20.00	8.83 (0.94)	0.07	29	0.20	0.21	-0.31
DLQI (0-30)	29	1.00 - 30.00	8.24 (1.56)	0.22	29	0.001 ***	1.52	1.48

Statistically significant difference at the *P<0.05 level **p<0.01 level and ***p<0.001 level.

Number of years living with psoriasis, SAPASI, HADS depression and DLQI score distributions were all significantly different from a normal distribution. The skewness scores were positive indicating scores were clustered at the lower end of the scales. Dermatology life quality index and SAPASI scores were the only variables which demonstrated a positive kurtosis indicating a peaked distribution (smaller variation in scores) while all other variables at baseline found negative kurtosis values suggesting flatter distributions (larger variation in scores).

The sample size was small and one of the primary outcomes (SAPASI) was not normally distributed therefore non-parametric statistics were chosen for the further analyses. The median is used as the measurement of central tendency in non-parametric statistics, however the majority of previous studies have reported the mean as the measure of

central tendency. This results chapter shall used the median, as is used within the non-parametric tests and the mean, in order to allow for comparison to previous research.

4.2.1.1 Distress caseness descriptive data

A score on the anxiety or depression subscale between 8-10 is considered possible caseness and a score over 11 is considered probable caseness. Caseness indicates a clinical psychology classification of depression or anxiety. Figure 13 represented the percentages from the sample, which reached possible and probable caseness for anxiety and depression.

Figure 13: A diagram presenting the percentage of participants who possibly and probably have a clinical distress disorder
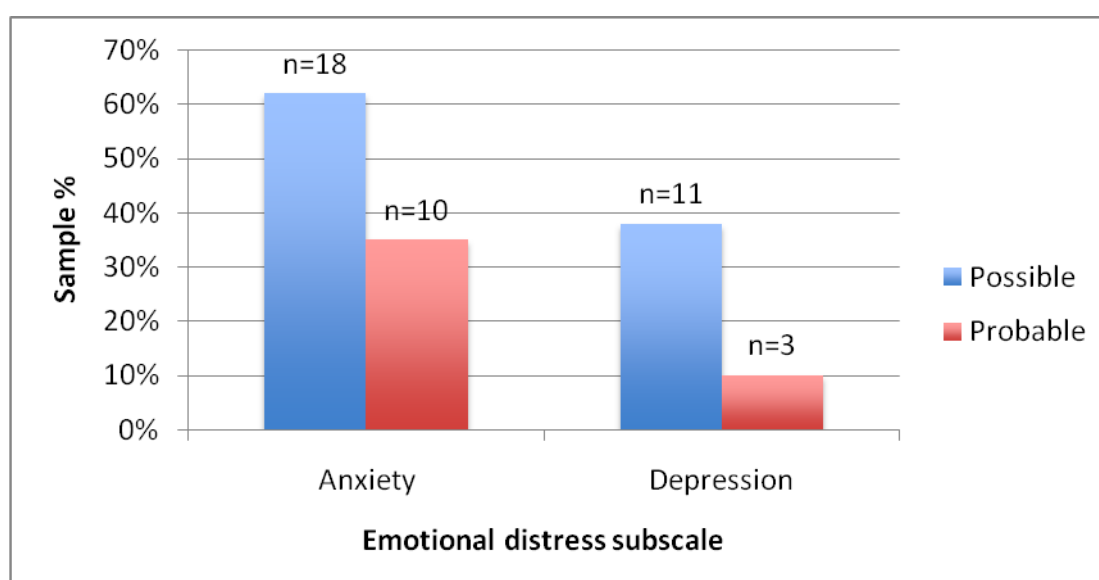
Figure 13: This graph represents 62% of the sample achieved HADS scores derived from the questionnaire, that would be classified as possible clinical anxiety; 35% probably clinical anxiety; 38% possible depression; and 10% probable depression.

The sample seems to be more likely to receive a diagnosis of clinical anxiety than clinical depression.

4.2.2 A comparison of the primary and secondary outcome data with previously published studies

Data from a larger UK study (n=141) with a diagnosis of psoriasis was compared with this study's data on SAPASI, PSS and the HADS sub-scales (HADS anxiety and HADS depression) (O'Leary et al., 2004). The DLQI scores were compared to a cross sectional, multi-centre study, which was run across Finland and Sweden (Hjortsberg et al., 2011). These comparisons are presented in Table 7.

Table 7: Primary and secondary outcome data comparison to previously published data

	This study (2012) n= 29 Mean (SD)	O'Leary et al (2004) n=141 Mean (SD)	Hjortsberg et al (2011) n=266 Mean (SD)	Comparison (independent t-test)
SAPASI	7.42 (5.45) [Median: 6.2]	12.36 (8.40)		t= -4.88, p<0.001***
PSS	20.59 (6.51) [Median: 21]	28.03 (8.04)		t=-6.16, p<0.001***
HADS	14.31 (8.50) [Median: 14]			
HADS depression	5.48 (4.26) [Median: 5]	5.26 (4.03)		t=0.28, p=0.78
HADS anxiety	8.83 (5.07) [Median: 9]	8.13 (4.10)		t=0.74, p=0.47
DLQI	8.24 (8.40) [Median: 4]		6.8 (6.1)	t=-0.90, p=0.19

Statistically significant difference at the *P<0.05 level **p<0.01 level and ***p<0.001 level.

This study's participants scored significantly lower than O'Leary et al.'s (2004) on SAPASI and PSS but scores were not significantly different on HADS and DLQI variables. This sample has less severe psoriasis and perceived less stress than the comparison studies but this study's participants were still experiencing equivalent distress and QoL impairment.

4.2.3 Illness perception questionnaire-revised descriptive data

The IPQ-R contains seven subscales which measure participant's illness representations.

Identity subscale

The percentage of the sample (n=29), which agreed or strongly agreed with each symptom either being experienced since contracting psoriasis and/or as a consequence of psoriasis, is presented in Figure 14.

Figure 14: A chart of participants' beliefs of disease identity

Symptoms that participants have experienced since being diagnosed with psorisis but may not be related to their condition.

Symptoms, which participants believe are related to their diagnosis of psoriasis.
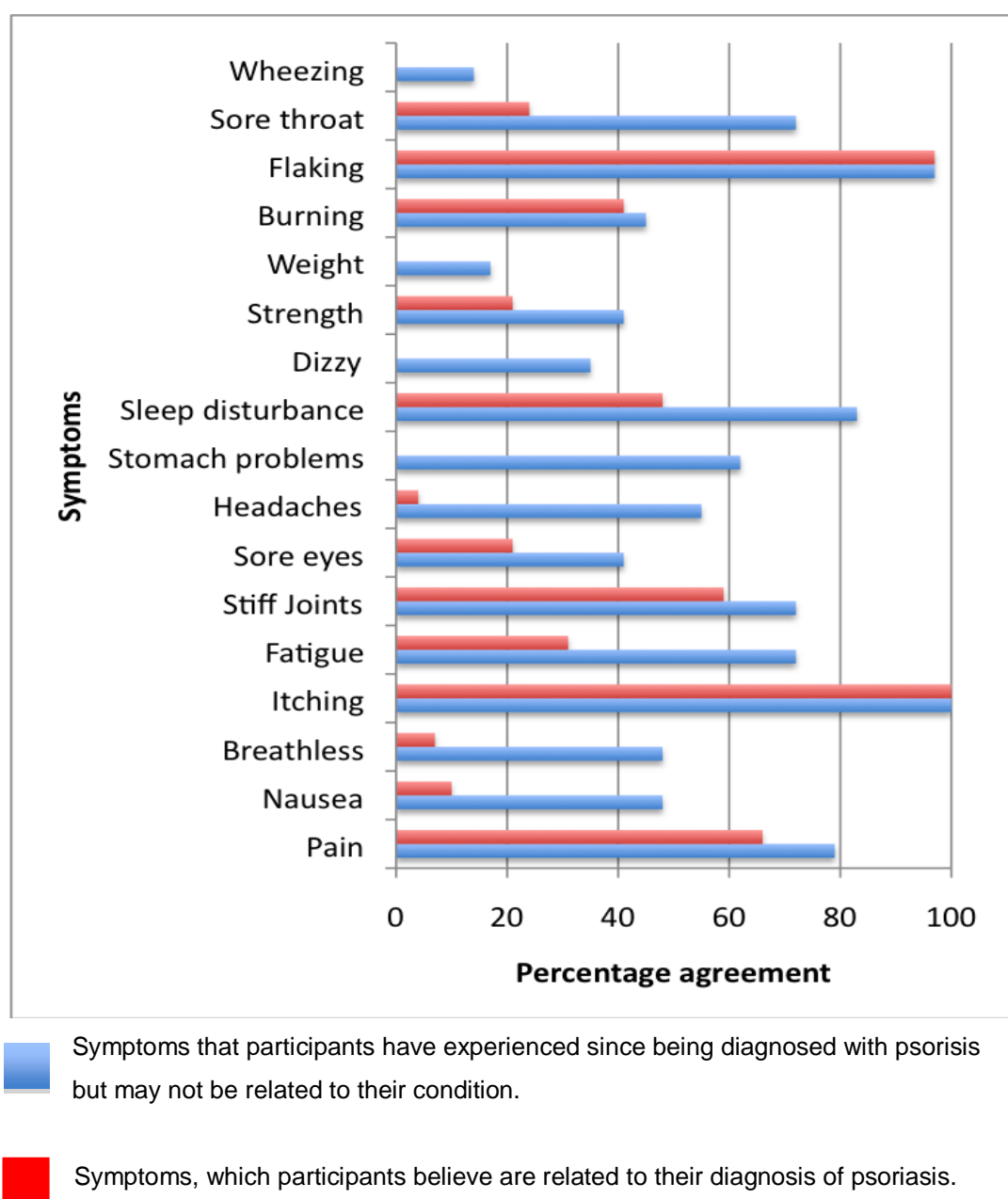
Figure 14: The bar chart represents the percentage of participants who agreed or strongly agreed that they had experienced each symptom since being diagnosed with psoriasis or as a result of that diagnosis.

The symptoms, which over 25% of the study's participants believed were related to their psoriasis, were itching (100%), flaking (97%), pain (66%), stiff joints (59%), sleep disturbance (48%) and fatigue (31%).

In the qualitative study, participants reported how their sleep quality and levels of energy had improved as a result of the MBCT programme. Sleep and energy were not in the

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original focus of this study but they were retrospectively examined in response to the qualitative study findings. 83% of the participants had experienced sleep disturbances since being diagnosed with psoriasis and 48% believed these disturbances were caused by their condition. Additionally, 72% believed they had experienced fatigue since their diagnosis and 31% believed this symptom was a consequence of their psoriasis.

Cause subscale

The percentage of participants who agreed or strongly agreed with each of the 18 possible cause items is presented in Figure 15.

Figure 15: Participants' beliefs in the causes of psoriasis
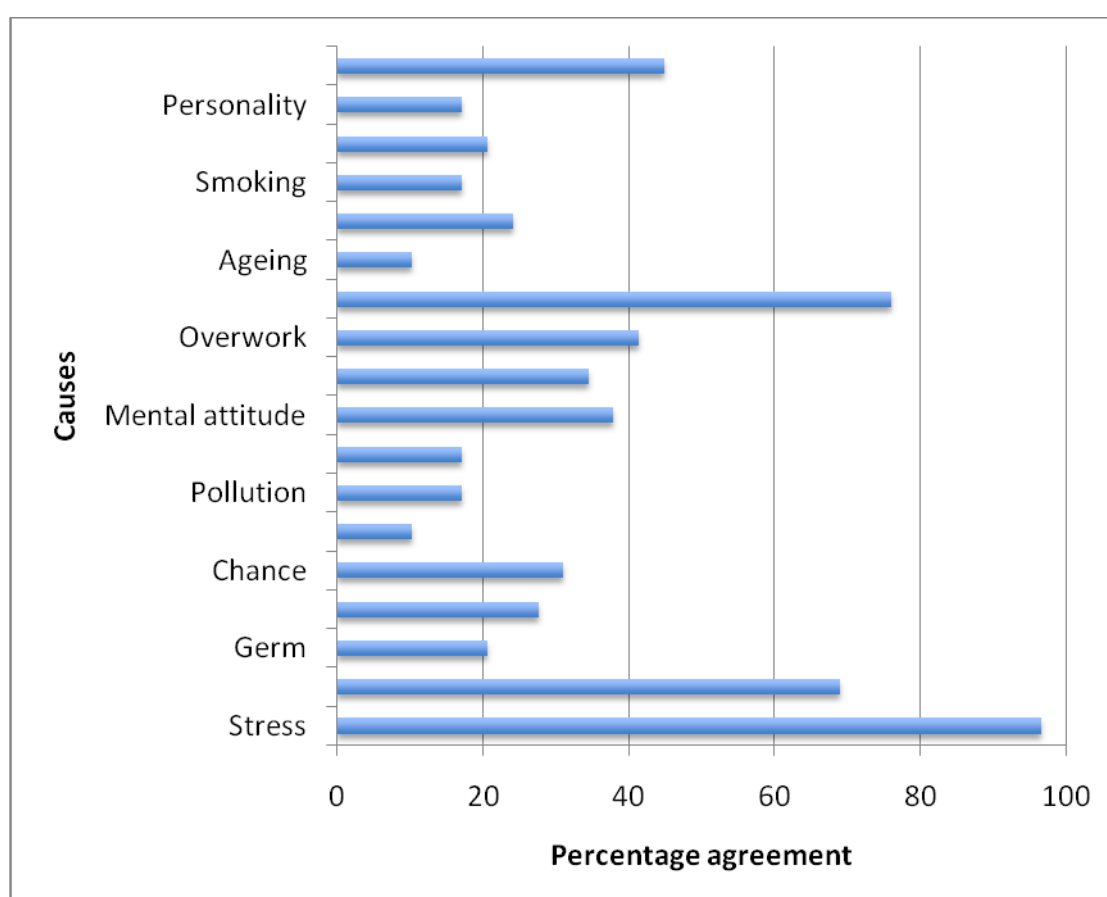
Figure 15: This chart presents the percentage of the participants who agreed or strongly agreed that each of these factors (on the *y* axis) caused their psoriasis.

Previous research split people with psoriasis into two groups, those who did (stress responders) and did not (non-stress responders) believe their condition was caused by stress (Koo, 1995). In this current study, 96.6% (n=28) of the sample believed stress caused their psoriasis (stress responders). 75.9% (n=22) believed emotional state caused it and 69% (n=20) believed hereditary factors caused their condition.

The descriptive data and normality tests (K-S) of the remaining subscales, including identity, are presented in Table 8.

Table 8: Baseline descriptive data and normality: IPQ-R subscales

	N	Range	Mean (SD)	Kolmogorov-Smirnov				
				Statistic	d.f.	p-value	Skewness	Kurtosis
Identity (0-14)	29	1-11	5.21 (2.61)	0.16	29	0.05	0.39	-0.53
Timeline (acute/ chronic) (0-30)	29	21-30	27.25 (2.69)	0.16	29	0.07	-0.86	-0.41
Timeline (cyclical) (0-20)	29	4-18	12.79 (3.72)	0.15	29	0.13	-0.86	0.26
Personal Control (0-30)	29	12-30	18.57 (4.92)	0.10	29	0.20	0.56	-0.10
Treatment control (0-25)	29	10-24	17.61 (3.14)	0.13	29	0.20	-0.37	0.66
Cons-equences (0-30)	29	8-30	18.90 (6.02)	0.11	29	0.20	-0.02	-0.73
Illness coherence (0-25)	29	9-25	18.29 (4.19)	0.11	29	0.20	-0.25	-0.53
Emotional represent-ation (0-30)	29	6-30	18.68 (5.62)	0.09	29	0.20	-0.25	-0.12

The higher the scores on the sub-scales equates to the stronger the beliefs which participants hold, for example participants hold a strong belief (28 out of a possible maximum 30) that psoriasis is a chronic condition (timeline acute/chronic).

None of the sub-scales were significantly different from a normal distribution; therefore further parametric statistics were used.

4.2.4 A comparison of the IPQ-R subscale data to previously published studies

The mean IPQ-R scores from this study were compared to the mean IPQ-R scores from the comparison study (O'Leary et al, 2004). The comparison study's population reported stress (70% agreement) and hereditary (58%) causes to be the most commonly endorsed. This current study's population reported stress (97% agreement), emotional state (75% agreement) and hereditary (69% agreement) on cause subscale. The continuous data variables are presented in Table 9.

Table 9: IPQ-R outcome data comparison with previously published data

	This study (2012) n= 29 Mean (SD)	O'Leary et al (2004) n=141 Mean (SD)	Comparison (independent t-test)
Identity	5.21 (2.69)	4.68 (2.78)	t= 1.09 p=0.29
Timeline acute/chronic	27.25 (2.74)	24.94 (4.26)	t=4.46 p<0.001***
Timeline cyclical	12.79 (3.72)	13.20 (3.40)	t=-0.59 p=0.56
Personal Control	18.57 (4.92)	16.94 (4.55)	t=1.72 p=0.10
Treatment Control	17.61 (3.14)	14.07 (3.23)	t=5.85 p<0.001***
Consequences	18.29 (4.27)	19.33 (4.65)	t=-0.39 p=0.70
Illness coherence	18.29 (4.19)	13.28 (5.06)	t= 6.21 p<0.001***
Emotional Representation	18.68 (5.62)	19.24 (5.53)	t=-0.52 p=0.61

Statistically significant difference at the *P<0.05 level, **p<0.01 level and ***p<0.001 level.

This population scored significantly higher than O'Leary et al's (2004) on the illness beliefs of time chronic, treatment control and illness coherence. This sample have stronger beliefs that psoriasis is chronic, that their treatments can control the symptoms

and they believe that they understand their illness more than the sample from O'Leary et al.'s (2004) sample.

4.2.5 Process outcome descriptive data

In addition to the primary and secondary outcomes two scales were used to assess (a) the pre-course beliefs about the credibility and expectancy of the MBCT course (Credibility Expectancy Questionnaire (CEQ) (Borkovec & Nau, 1972) and (b) the pre-existing level of mindfulness skills (MAAS). The hours of practice and the level of attendance were included in order to assess participants' adherence to the intervention.

The MAAS measurement was included in the baseline booklet along with the primary and secondary variables (n=29). The pre-CEQ was administered immediately before the first group session (n=22) and the post-CEQ after the final group session (n=14). The attendance and practice variables were only collected from participants who completed the MBCT courses, including participants who were later excluded from the primary analyses because they no longer met the inclusion criteria (n=15). Table 10 presents the descriptive data and tests of normality (K-S) for the process measures measured at baseline.

Table 10: First measurement spread of descriptive data: Process outcomes

	N	Range	Mean (SD)	Kolmogorov-Smirnov				
				Statistic	d.f.	p-value	Skewness	Kurtosis
MAAS (1-6)	29	1.28 – 5.90	3.56 (1.17)	0.16	29	0.05	0.37	-0.03
Pre-Cred (1-9)	22	3.50 – 8.75	5.78 (1.35)	0.16	22	0.14	0.55	0.12
Pre-Exp (1-9)	22	1.23 – 8.50	5.50 (1.50)	0.14	22	0.20	-0.57	2.42
Attendance (0-8)	15	5 - 8	6.53 (1.25)	0.25	15	0.02*	-0.22	-1.65
Practice during (hours)	15	1 - 6	2.88 (1.47)	0.26	15	0.01**	0.84	0.69
Practice after (hours)	15	1 - 4	2.04 (1.09)	0.23	15	0.03*	0.80	-0.37
Post-Cred (1-9)	14	2.67 – 9.00	6.76 (1.53)	0.20	14	0.12	-1.48	3.27
Post-Exp (1-9)	14	1.00 – 7.67	5.26 (1.59)	0.15	14	0.20	-1.32	3.45

Statistically significant difference at the *P<0.05 level, **p<0.01 level and ***p<0.001 level.

Table 10 key:

Pre-Cred	pre-MBCT credibility	**Post-Cred**	post-MBCT credibility
Pre-Exp	pre-MBCT expectancy	**Post-Exp**	post=MBCT expectancy

The process variables, apart from attendance and practice, were normally distributed and therefore parametric statistics were used with these data.

4.2.6 A comparison of the mindfulness skill variable to a previous study

Data were compared, with a one sample t-test, to MAAS data from a previous study which employed this measurement (Shapiro et al., 2011). Shaprio et al.'s (2011) sample consisted of 30 healthy volunteers, with a baseline mean MAAS of 3.56 (SD 0.87). There was no significant difference in MAAS scores between the current study population and Shapiro et al.'s (2011) study population (t=0.36, p=0.72). This suggests that this study sample were did not enter this study with very high or very low pre-existing mindfulness skill levels.

4.2.7 Summary

The primary and secondary outcome variables were not-normally distributed so further analyses employed non-parametric statistical tests. The process variables (MAAS and CEQ) and the IPQ-R variables were normally distributed and therefore parametric statistical tests were employed with these data. The level of attendance and practice variables were not normally distributed and were entered into non-parametric statistical tests for the remainder of the analyses.

This study's population scored significantly lower on physical severity and perceived stress scales but similarly on distress, QoL and pre-course levels of mindfulness as compared to previous studies (O'Leary et al., 2004; Hjortsberg et al., 2011; Shapiro et al., 2011).

Only one member of the study population did not believe their condition was caused by stress (stress responder) and the three causes which were most agreed upon for causing their psoriasis were stress, emotional state and hereditary causes. In addition to the symptoms frequently associated with psoriasis such as itching and flaking, participants also reported other symptoms related to psoriasis including sleep disturbance (48%) and fatigue (31%). These quantitative data regarding sleep and fatigue help develop a theme of sleep disruption that emerged from the sequential qualitative study.

4.3 Correlations and regression

4.3.1 Correlations

First measurements were collected from the treatment and control group (n=29) at week 0 and from the comparison group (n=10) eight weeks later. Measurements from these two collection points were amalgamated to form a first measurement group in order to increase the sample size (n=39). Correlations with a larger sample size (n=39) drawn from the eligible population provide a more representative description of the strength of relationships between variables that would exist in the full population compared to the smaller sample (n=29) from just the treatment and control group.

The demographics, illness representations and primary and secondary variables were entered into a non-parametric correlation because the primary variables were not normally distributed.

A theme emerged from the qualitative study suggesting that age changed participant's levels of distress and/or perceived consequences of living with psoriasis. In response to this theme, age and years living with psoriasis were also entered into the correlation.

Ability to use mindfulness skills was also entered into a correlation with the demographic and primary and secondary variables to explore whether pre-existing mindfulness skills were associated with any variables. Mindfulness measurements were only taken from active group members therefore there were only 29 rather than 39 participants in these correlations.

The process measurements CEQ and MAAS were also entered into a parametric correlation with the primary and secondary outcome change score to examine whether *a priori* skills and beliefs influenced the amount of change to outcomes each participant experienced.

The red highlighting is to indicate a significant correlation.

Table 11: Non-parametric (Spearman) correlation matrix for first measurement demographic, primary and secondary outcomes

		Gender	Age	PSO Age	Single	Topical	No related	SA PASI	PSS	HADS	HADS DEP	HADS ANX	DLQI
Gender	Coefficient	1.000	-.240	-.108	.223	.003	-.163	.209	-.161	-.032	.042	.035	.111
	Sig.	.	.141	.514	.172	.987	.321	.201	.328	.846	.802	.835	.501
	N	39	39	39	39	39	39	39	39	39	39	39	39
Age	Coefficient	-	1.000	.105	-.110	-.058	.607***	.103	.141	-.026	.027	-.183	-.075
	Sig.	-	.	.526	.504	.725	.000	.533	.393	.874	.869	.264	.648
	N	-	39	39	39	39	39	39	39	39	39	39	39
PSO Age	Coefficient	-	-	1.000	.040	-.046	.107	-.012	.042	.158	.188	.032	-.019
	Sig.	-	-	.	.808	.780	.518	.944	.801	.338	.250	.844	.910
	N	-	-	39	39	39	39	39	39	39	39	39	39
Single	Coefficient	-	-	-	1.000	.273	-.117	.139	.066	.215	.326*	.117	-.044
	Sig.	-	-	-	.	.092	.479	.397	.688	.189	.043	.479	.792
	N	-	-	-	39	39	39	39	39	39	39	39	39
Topical	Coefficient	-	-	-	-	1.000	.160	-.074	-.369*	-.320*	-.107	-.125	-.250
	Sig.	-	-	-	-	.	.331	.654	.021	.047	.517	.447	.126
	N	-	-	-	-	39	39	39	39	39	39	39	39
No-related	Coefficient	-	-	-	-	-	1.000	-.062	.039	-.099	.074	-.215	-.179
	Sig.	-	-	-	-	-	.	.709	.813	.549	.655	.189	.276
	N	-	-	-	-	-	39	39	39	39	39	39	39

*Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.*

Within this sample the older participants were less likely to have any relatives with psoriasis. If participants were single they were more likely to experience depressive symptoms. Participants using topical treatments experienced less perceived stress and distress than participants using systemic or biologic treatments.

Table 12: Non-parametric (Spearman) correlation matrix for first measurement primary and secondary outcomes

		SA PASI	PSS	HADS	HADS DEP	HADS ANX	DLQI
SA PASI	Coefficient	-	.212	.371*	.339*	.373*	.572***
	Sig.	-	.195	.020	.035	.019	.000
	N	-	39	39	39	39	39
PSS	Coefficient	-	-	.782***	.632***	.619***	.571***
	Sig.	-	-	.000	.000	.000	.000
	N	-	-	39	39	39	39
HADS	Coefficient	-	-	-	.853***	.827***	.623***
	Sig.	-	-	-	.000	.000	.000
	N	-	-	-	39	39	39
HADS DEP	Coefficient	-	-	-	-	.739***	.510***
	Sig.	-	-	-	-	.000	.001
	N	-	-	-	-	39	39
HADS ANX	Coefficient	-	-	-		-	.678***
	Sig.	-	-	-		-	.000
	N	-	-	-		-	39

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

More severe participants' psoriasis symptoms were related to more distress (both anxiety and depression) and greater QoL impairment. Higher stress levels were related to more distress (both anxiety and depression) and more QoL impairment. QoL was strongly (p<0.001) positively correlated with physical severity, perceived stress and distress. Perceived stress and psoriasis symptom severity levels were not significantly correlated.

Table 13: Non-parametric (Spearman) correlation matrix for first measurement illness representation and primary and secondary outcomes

		Age	PSO AGE	SA-PASI	PSS	HADS	HADS DEP	HADS ANX	DLQI	TAC	CYC	CON	PC	TC	IC	ER
ID	Coefficient	.007	-.084	.415**	.289	.308	.250	.376*	.362*	.130	.130	.417**	-.094	.107	-.121	.462**
	Sig.	.965	.611	.009	.075	.056	.124	.018	.024	.430	.429	.008	.570	.517	.465	.003
	N	39	39	39	39	39	39	39	39	39	39	39	39	39	39	39
TAC	Coefficient	-.299	-.324*	.285	.142	.118	.000	.048	.174	-	-.205	.375*	-.274	-.123	-.139	.211
	Sig.	.065	.044	.079	.390	.474	.999	.773	.291	-	.212	.019	.092	.456	.400	.196
	N	39	39	39	39	39	39	39	39	-	39	39	39	39	39	39
CYC	Coefficient	-.004	-.055	.027	.271	.004	-.053	.058	.213	-	-	.105	-.040	.054	.059	.211
	Sig.	.979	.739	.873	.095	.983	.749	.725	.193	-	-	.524	.809	.742	.721	.197
	N	39	39	39	39	39	39	39	39	-	-	39	39	39	39	39
CON	Coefficient	-.383*	-.425**	.321*	.286	.352*	.224	.300	.521**	-	-	-	-.209	-.281	.042	.615***
	Sig.	.016	.007	.046	.078	.028	.170	.064	.001	-	-	-	.202	.083	.801	.000
	N	39	39	39	39	39	39	39	39	-	-	-	39	39	39	39
PC	Coefficient	.059	.156	-.004	.178	.215	.155	.237	-.104	-	-	-	-	.439**	.123	.134
	Sig.	.720	.341	.980	.279	.189	.347	.146	.530	-	-	-	-	.005	.454	.416
	N	39	39	39	39	39	39	39	39	-	-	-	-	39	39	39

		Age	PSO AGE	SA-PASI	PSS	HADS	HADS DEP	HADS ANX	DLQI	TAC	CYC	CON	PC	TC	IC	ER
TC	Coefficient	.028	.144	.005	.073	.026	-.079	.116	-.148	-	-	-	-	-	-.003	-.044
	Sig.	.867	.381	.977	.657	.876	.634	.484	.369	-	-	-	-	-	.986	.790
	N	39	39	39	39	39	39	39	39	-	-	-	-	-	39	39
IC	Coefficient	-.106	.187	-.012	-.080	-.224	-.283	-.335**	-.112	-	-	-	-	-	-	-.018
	Sig.	.520	.253	.942	.626	.170	.081	.037	.496	-	-	-	-	-	-	.914
	N	39	39	39	39	39	39	39	39	-	-	-	-	-	-	39
ER	Coefficient	-.284	-.151	.320*	.592*	.551***	.314	.517***	.597***	.211	.211	.615***	.134	-.044	-.018	-
	Sig.	.079	.359	.047	.000	.000	.051	.001	.000	.196	.197	.000	.416	.790	.914	-
	N	39	39	39	39	39	39	39	39	39	39	39	39	39	39	-

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

Table 13: Key

ID	Identity	**PC**	Personal control
TAC	Timeline acute or chronic	**TC**	Treatment control
CYC	Timeline cyclical	**IC**	Illness coherence
CON	Consequences	**ER**	Emotional response

If participants believed they had more symptoms associated with their psoriasis then their physical psoriasis score, anxiety levels and QoL impairment were higher and they were more likely to hold a negative emotional representation of their condition. Viewing psoriasis as a chronic condition was associated with actually having had psoriasis for a shorter period of time. These, younger participants also believed it caused them more serious consequences in their lives. They tended to have more serious psoriasis, were more likely to experience distress, impaired QoL and hold a negative emotional representation of psoriasis. The more personal control a participant believed they had over their psoriasis they also believed the treatment they were using was controlling their psoriasis. The more their condition made sense to participants the less anxiety they experienced. If participants held a negative emotional representation of their psoriasis then their psoriasis symptoms were more severe, they had higher perceived stress, distress (especially anxiety) levels, more QoL impairment and believed their condition caused serious consequences in their lives.

Table 14: Non-parametric (Spearman) correlation matrix for baseline mindfulness, primary and secondary outcomes

		Gender	Age	PSO Age	Single	Topical	No related	SA-PASI	PSS	HADS	HADS DEP	HADS ANX	DLQI
MAAS	Coefficient	-.145	.338	.324	-.226	-.087	-.051	-.202	-.481 **	-.541 **	-.398 *	-.601 ***	-.468 **
	Sig.	.452	.073	.086	.238	.653	.794	.293	.008	.002	.033	.001	.010
	N	29	29	29	29	29	29	29	29	29	29	29	29

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

If participants had higher mindfulness skill they reported less stress, distress (both anxiety and depression) and a less QoL impairment.

4.3.2 Process measurement correlations

Process measurements, including group attendance and practice time, were entered into a parametric correlation (Pearson) with the change scores from the primary and secondary outcomes. This correlation matrix is presented in Table 15.

Table 15: Parametric correlation (Pearson) matrix for process outcomes, primary and secondary outcome change scores

		SAPASI change	PSS change	HADS change	DLQI change
Pre-credibility	Coefficient	.052	.586*	.083	.143
	Sig.	.860	.028	.777	.625
	N	14	14	14	14
Pre-Expectancy	Coefficient	-.296	.670**	.255	-.296
	Sig.	.305	.009	.380	.305
	N	14	14	14	14
Pre-MAAS	Coefficient	-.137	-.040	-.440	-.103
	Sig.	.642	.893	.116	.725
	N	14	14	14	14
Attendance	Coefficient	.169	.039	.146	.527
	Sig.	.563	.894	.619	.053
	N	14	14	14	14
Practice during	Coefficient	.346	.016	.026	.261
	Sig.	.226	.958	.930	.368
	N	14	14	14	14

Statistically significant correlation at the $*P<0.05$ level $**p<0.01$ level and $***p<0.001$ level.

The significant positive correlations between pre-credibility and expectancy beliefs and perceived stress scores suggest that if participants believed MBCT was going to be useful and was credible then they experienced a greater change in the stress scores. There were no other significant correlations between process variables and percentage change scores in the primary and secondary variables.

4.3.3 Regression

The DLQI is a composite score that aims to capture the physical, psychological and social impact of a condition upon the individual. Previous studies have examined whether physical (PASI/SAPASI) or psychological (PSS or HADS) accounts for more variance in the overall QoL score than the others. Within this sample QoL (DLQI) was significantly positively correlated with physical severity (SAPASI) (r=0.57), perceived stress (PSS) (r=0.57) and distress (HADS) (r=0.62). Neither variable was found to have a Variance Inflation Factor (VIF) > 10 (SAPASI VIF = 1.20; HADS VIF = 1.20), which would disregard the multicollinearity assumption necessary for variables to be entered into a regression model (Pallant, 2010).

Pallant (2010) recommends that the sample size for a regression is n=15 participants per variable. This study's sample size is n=39, therefore one variable could not be entered. As previous literature is predominately interested in whether the psychological or physical components account for the variance in QoL only HADS and SAPASI were entered into the regression model.

SAPASI and HADS were entered as dependent variables into a linear regression analysis to examine how much variance they explained of the dependent variable DLQI. The regression model is presented in Table 16.

Table 16: Results of the regression model

Independent variable	Adjusted R-square	Unstandardised Beta	Standardised Beta	t	Sig.	95% Confidence Interval (Beta)	
						Lower	Upper
SAPASI	0.30	0.39	0.32	2.78	0.01 **	0.12	0.67
HADS	0.27	0.56	0.58	4.96	0.001 ***	0.33	0.79
	Total adjusted R-square			F		Sig.	
SAPASI and HADS	0.57			26.23		<0.001 ***	

*Statistically significant statistic at the *P<0.05 level **p<0.01 level and ***p<0.001 level.*

SAPASI and HADS accounted for 57% (Adjusted R square) of the variance in DLQI and this model is statistically significant (F=26.23, p<0.001). The HADS was found to make the largest unique contribution to explaining DLQI (standardised beta = 0.58). SAPASI made a smaller contribution to the overall DLQI (standardised beta = 0.32). Both SAPASI (t=2.78, p=0.01) and HADS (t=4.96, p<0.001) made significant unique prediction of DLQI.

4.3.4 Summary

In this sample distress and physical severity scores were significantly correlated, which has not always previously been reported (Fortune et al., 1997, Main et al., 2000, Richards et al., 2001). Over 60% of people with psoriasis in previous studies believe that their perceived stress levels cause their psoriasis (Fortune et al, 1997) but not in this study's cross sectional correlation. Perceived stress and physical severity were the only primary/secondary variables that did not significantly correlate with each other.

The identity, consequences and emotional representations of illness were the beliefs, which were significantly correlated with most primary/secondary outcome variables. Identity and consequence beliefs may be important in maintaining poor physical or emotional functioning as they were the beliefs which significantly changed in participants who completed a CBT programme for people with psoriasis which improved physical, psychological and QoL outcomes (Fortune et al., 2004a). These three illness representations were considered important and entered into further analyses.

The level of mindfulness skill was significantly correlated with perceived stress, distress and QoL. Elevated mindfulness skills were associated with lower perceived stress, distress and QoL impairment. If people believed MBCT was credible and expected it to be helpful they demonstrated a larger change in their perceived stress scores.

A linear regression reported distress to be a better predictor of QoL than physical severity but they both contributed a statistically significant unique contribution.

4.4 Pre to post MBCT changes

4.4.1 Primary and secondary outcomes

The control group also completed the MBCT group after their eight-week waiting period (TAU). The pre to post MBCT primary and secondary outcome scores from the treatment and control group participants who completed the course (n=14) were examined to see if there were any changes in participants' scores across the study time period. This analysis does not include a comparison to a control group therefore any changes may be related to other factors and not the MBCT intervention. These results were intended to supplement the primary ANCOVA analysis rather than stand alone analyses.

The primary and secondary outcomes were not normally distributed therefore the pre to post changes were compared with a related samples Wilcoxon Signed Rank test (non-parametric t-test). After the MBCT intervention six participants remained in the treatment group and eight in the control group. These analyses were conducted on the 14 participants' scores. The group descriptive data and tests of difference results are presented in Table 17.

Table 17: Pre to post test of difference scores primary and secondary outcomes

Variable	Pre-MBCT mean (SD)	Post-MBCT mean (SD)	Difference over time test statistic	P-value
SAPASI	6.35 (3.85)	4.16 (2.79)	Z=-2.20	0.03*
PSS	17.93 (5.73)	16.07 (6.12)	Z=-1.45	0.15
HADS	13.79 (8.01)	9.43 (6.57)	Z=-2.91	0.004**
DLQI	7.35 (6.62)	4.79 (5.51)	Z=-2.82	0.01**

*Statistically significant statistic at the *P<0.05 level **p<0.01 level and ***p<0.001 level.*

4.4.2 Process outcomes

The process measures were used to assess whether the MBCT course had changed participant's beliefs in the credibility and expectancy (CEQ) of the MBCT course and whether the mindfulness skills (MAAS) had been learnt as a result of the course. All participants (the active group) who had completed the MBCT course (n=14) were examined. The process outcomes were normally distributed therefore parametric paired samples t-tests were used. The descriptive data for the pre, post and follow-up process scores are presented in Table 18 and the results for each of the process outcomes.

Table 18: Pre to post intervention process outcome scores

	Pre-intervention Mean (SD)	Post-intervention Mean (SD)	8-week follow-up Mean (SD)
Credibility	5.68 (1.19)	6.76 (1.53)	
Expectancy	5.44 (1.52)	5.25 (1.59)	
MAAS	3.32 (0.93)	3.64 (0.67)	3.91 (0.81)

4.4.2.1 CEQ

A significant difference was found between pre and post credibility scores (t= -2.65, p=0.02) but no significant difference was found between pre and post expectancy scores (t=0.33, p=0.76). These results are presented in Figure 16.

Figure 16: Pre-intervention to post-intervention CEQ outcomes
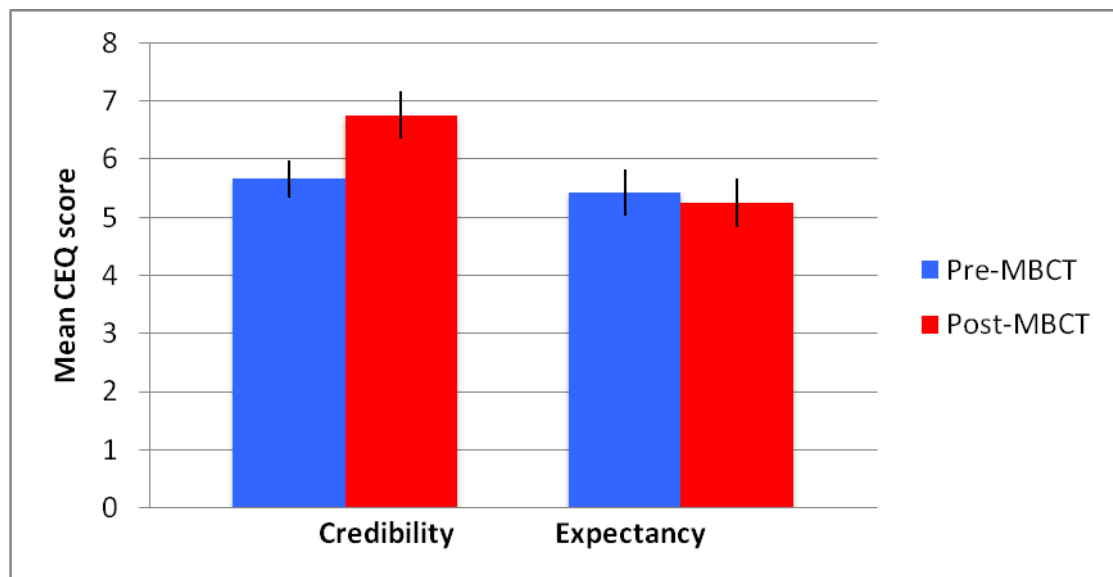
Figure 16: The bar chart represents the mean scores on the credibility and expectancy subscales of the CEQ before and after completing the MBCT training with the standard error (SE) bars.

4.4.2.2 MAAS

MAAS scores were compared across the three time where data was collected (pre-intervention, post-intervention and an 8 week follow-up) and there was a significant effect for time, Wilks' Lambda = 0.51, F=5.77, p=0.02. These scores are presented in Figure 17.

Figure 17: Pre-intervention, post-intervention and two month follow-up for the MAAS outcome
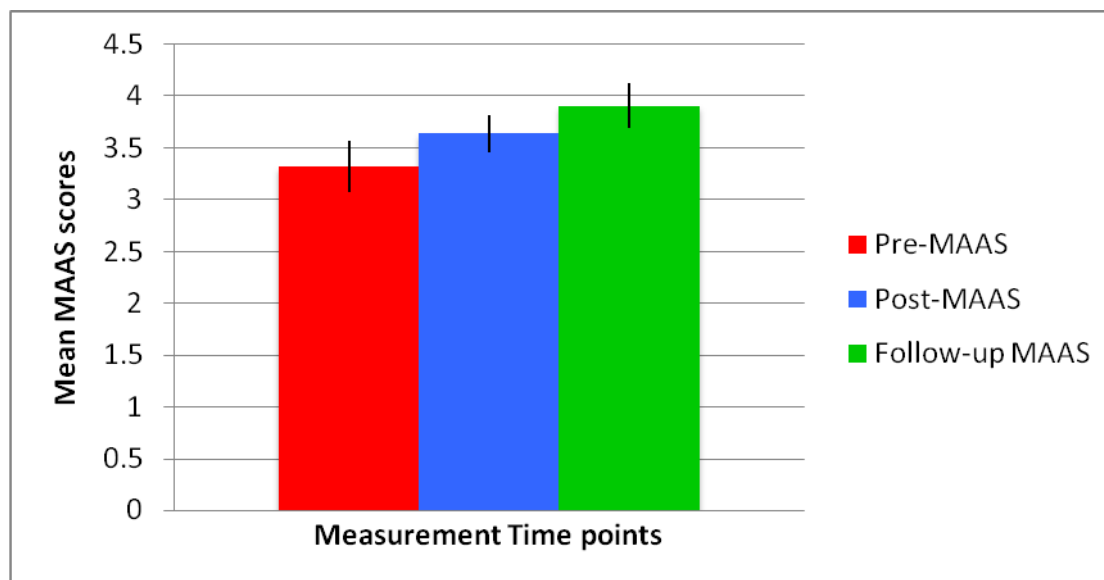
Figure 17: The chart presents the mean scores from all participants taken pre, post and eight weeks after the MBCT intervention. The error bars represent the SE.

Participants' mindfulness skill level and belief in the credibility of the MBCT intervention increased after participating in the groups but their level of expectancy that it would be beneficial for them did not change.

4.4.3 Summary

The SAPASI, HADS and DLQI scores were all significantly different at post-intervention when compared to pre-intervention scores. The mean scores show these variables to decrease in participants after completing the MBCT course. There was no significant difference in PSS scores. These data suggested that SAPASI, HADS and DLQI but not PSS scores improved as a result of participating in the MBCT intervention. This will next be tested with the more sensitive ANCOVA analysis.

The beliefs in MBCT credibility and mindfulness skill scores of those who completed the eight-week mindfulness course increased from the pre-intervention levels, while the beliefs in the expectancy for change did not alter across the study time. The more people believed MBCT was going to be effective the more improvement they experienced in their stress levels.

4.5 Primary analysis ANCOVA (treatment and control groups)

The primary analysis (ANCOVA) examined differences between the treatment and control groups at follow-up 1 in order to examine whether there were any changes in the primary or secondary study outcomes in participants who received the MBCT intervention. The descriptive data for these two groups are first presented at baseline then at follow-up 1.

4.5.1 Treatment and control group baseline measurements

4.5.1.1 Demographic, primary and secondary study outcomes

Table 19 presents the baseline descriptive data for the treatment and control group on demographic, primary and secondary study outcome variables. Both the median and means were presented as measurements of central tendency because of some variables were not normally distributed and therefore further analyses used the median rather than then mean.

Table 19: Treatment and control group baseline demographic, primary and secondary outcome scores

	Treatment n=13			Control n=16		
	Range	Median	Mean (SD)	Range	Median	Mean (SD)
% Females	61.5% (n=8)			50.0% (n=8)		
% Single	38.5% (n=5)			43.8% (n=7)		
% with relative	69.2% (n=9)			75.0% (n=12)		
% Using topical	46.2% (n=6)			62.5% (n=10)		
Age	32-70	47.00	47.92 (9.95)	22-68	31.00	35.69 (13.01)
Years with Psoriasis	15-40	25.00	26.69 (7.91)	3-43	13.50	16.75 (10.71)
SAPASI	1.70-19.70	6.00	6.61 (4.87)	0.62-21.52	6.79	8.08 (5.95)
PSS	11-33	18.00	19.69 (7.06)	11-31	21.50	21.31 (6.15)
HADS	0-26	11.00	11.92 (8.27)	1-31	16.00	16.25 (8.44)
DLQI	1-30	3.00	6.62 (7.99)	1-29	6.50	9.56 (8.74)

Despite randomisation the control group's measurements of central tendency showed the control group to be younger and consequently had lived with psoriasis for a shorter time period.

4.5.1.2 Illness representations

The identity, consequence and emotional representation subscale scores were significantly correlated with the primary and secondary outcome variables and were therefore also entered into an ANCOVA. The treatment and control group's baseline IPQ-R scores for these variables are presented in Table 20. These variables were not found to be significantly different from a normal distribution therefore only the mean, and not the median, was presented for these variables.

Table 20: Treatment and control baseline illness representation scores

	Treatment			Control		
	N	Range	Mean (SD)	N	Range	Mean (SD)
Identity	13	2.00 -10.00	5.62 (2.47)	16	1.00 – 11.00	4.88 (2.73)
Consequences	13	8.00 – 30.00	17.23 (6.48)	16	11.00 – 28.00	20.25 (5.45)
Emotional representation	13	6.00 – 25.00	16.67 (5.71)	16	13.00 – 30.00	20.31 (5.15)

The illness representations appear similar between the treatment and control group.

4.5.2 ANCOVA between treatment and control group with primary and secondary variables at follow-up 1

At follow-up 1 primary and secondary outcome data from the 6 treatment group participants and 13 control group participants were entered into an ANCOVA with each outcome's respective baseline scores entered as covariates. As the sample size was small and the data were not normally distributed bias corrected bootstrapping was performed on each of the variables during an analysis of co-variance (ANCOVA). The number of repetitions, for the bootstrap estimate, was set at 1000 and the seed was set at a different value for each of the four primary outcomes: SAPASI seed=3042012, PSS seed=13054, HADS seed=90962370 and DLQI seed=687427. The baseline/follow-up-1 mean and standard deviations and the difference between the groups' co-efficient are presented in Table 21. The results of the ANCOVA are then presented for each primary/secondary outcome below the table.

Table 21: ANCOVA comparison of primary and secondary outcome scores between the treatment and control group at follow-up 1

Variable	Groups	Baseline Mean (SD)	Follow-up 1 Mean (SD)	The difference at follow-up 1 Co-efficient (95% Confidence intervals (CI))
SAPASI	Treatment	5.94 (3.97)	3.65 (1.37)	3.30
	Control	7.65 (5.68)	7.02 (5.53)	(-0.00 – 6.60)
PSS	Treatment	18.00 (5.66)	16.67 (6.77)	0.20
	Control	20.84 (6.63)	18.85 (6.38)	(-5.15 – 5.55)
HADS	Treatment	12.50 (7.50)	10.33 (6.83)	2.76
	Control	15.46 (8.37)	15.54 (7.90)	(-0.61 – 6.13)
DLQI	Treatment	5.67 (5.09)	3.67 (3.56)	4.15
	Control	9.15 (7.45)	10.85 (9.03)	(0.62 – 7.67)

4.5.2.1 SAPASI

After adjusting for baseline scores the bootstrap estimate of the difference in SAPASI scores between the treatment and control groups was significant ($z=1.96$, $p=0.05$).

The minimal important difference (MID) accepted for research for pharmaceutical effectiveness is a 50% decrease in SAPASI score (Carlin et al., 2004). This group reported a 39% decrease, which is less than the MID for pharmaceutical trials but indicates that this could be a useful adjunct to pharmaceutical therapy. The results are presented in Figure 18.

Figure 18: SAPASI scores baseline to follow-up 1 between the treatment and control group
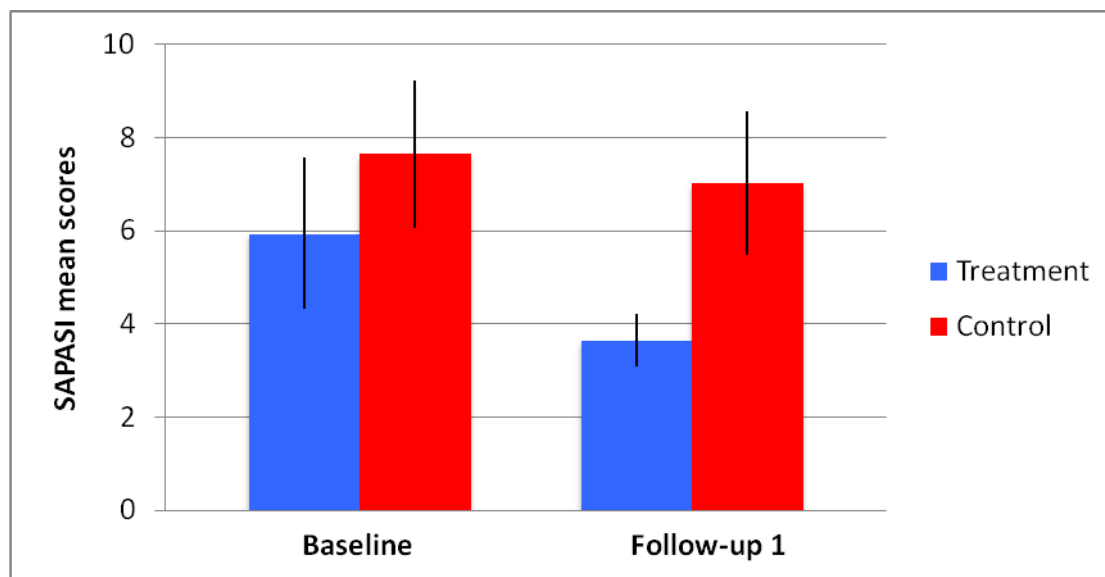
Figure 18: The mean SAPASI scores, with SE bars, of the treatment and control groups at baseline and follow-up 1 are presented in the bar chart.

4.5.2.2 PSS

After adjusting for baseline scores the bootstrap estimate of the difference in PSS scores between the treatment and control groups was not significant ($z=0.07$, $p=0.94$). The results are presented in Figure 19.

Figure 19: PSS scores baseline to follow-up 1 between the treatment and control group
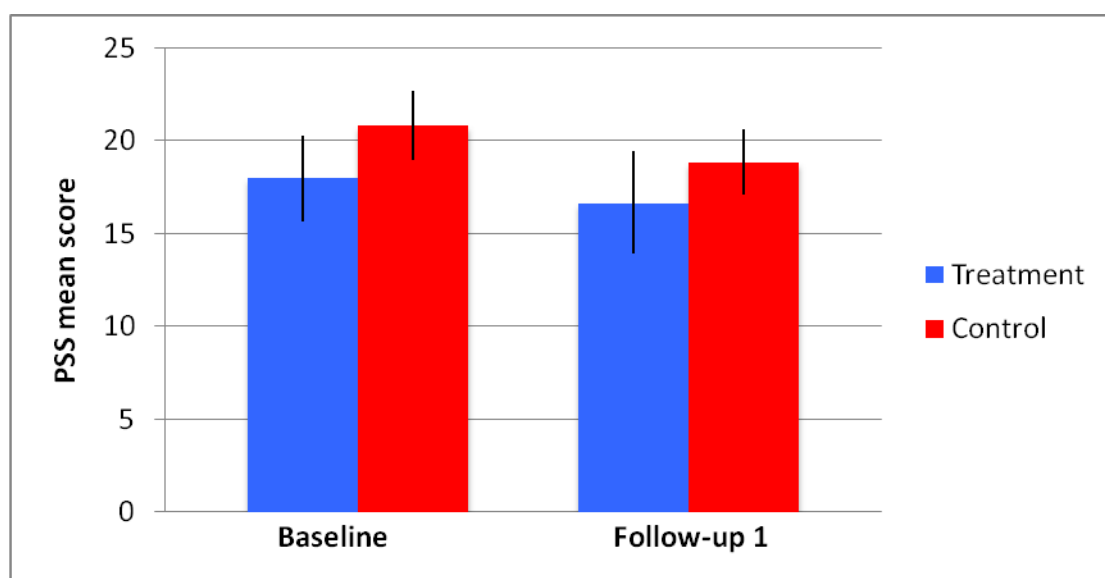
Figure 19: The mean PSS scores, with SE bars, of the treatment and control groups at baseline and follow-up 1 are presented in the graph.

4.5.2.3 HADS

After adjusting for baseline scores the bootstrap estimate of the difference in HADS scores was not significantly different between the treatment and control group (z=1.60, p=0.12). The results are presented in Figure 20.

Figure 20: HADS scores baseline to follow-up 1 between the treatment and control group
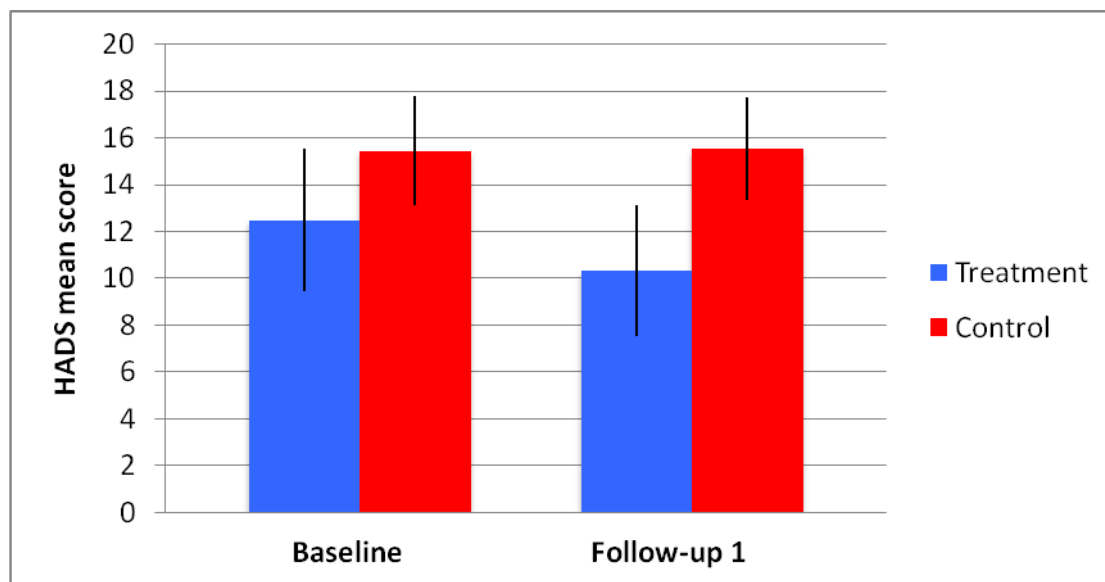
Figure 20: The mean HADS scores, with SE bars, of the treatment and control groups at baseline and follow-up 1 are presented in the chart.

4.5.2.4 DLQI

After adjusting for baseline scores the bootstrap estimate of the difference in DLQI scores between groups was also significant (z=2.30, p=0.02). The results are presented in Figure 21.

Pharmaceutical research accepts a five point reduction in DLQI scores to be the MID (Khilji et al., 2002). This sample reported a two point decrease in DLQI scores, which again, although this is smaller than the MID is demonstrates MBCT could be a useful adjunct therapy.

Figure 21: DLQI baseline scores to follow-up 1 between the treatment and control group
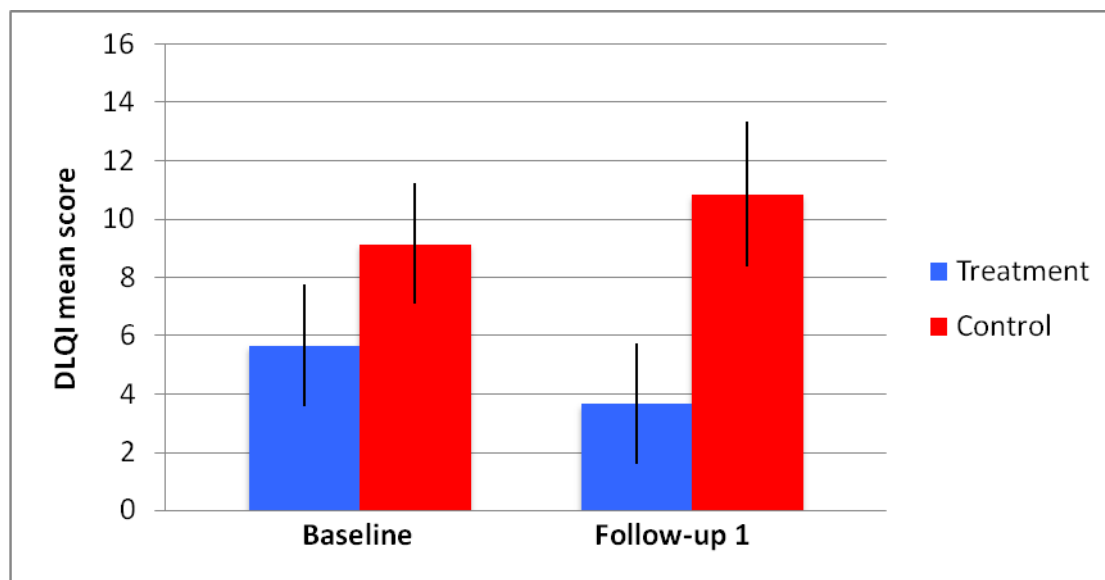
Figure 21: The mean DLQI scores, with SE bars, of the treatment and control groups at baseline and follow-up 1 are presented in the chart.

These results suggest that the SAPASI and DLQI scores reduced and the PSS and HADS scores did not change as a result of participating in the MBCT course.

4.5.2.5 Treatment group participant's change scores

There were six participants from the treatment group who had data collected at both baseline and follow-up time 1. The change scores for each participant (Baseline minus Follow-up time 1) are presented in Table 22 and Figure 22.

Table 22: Treatment group participants' change scores (SAPASI, PSS, HADS and DLQI)

	105	114	136	149	168	174
SAPASI change score	5.58	6.03	1.78	0.6	-0.23	0
PSS change score	8	-12	1	6	5	1
HADS change score	5	2	7	-1	0	0
DLQI change score	5	3	1	2	0	1
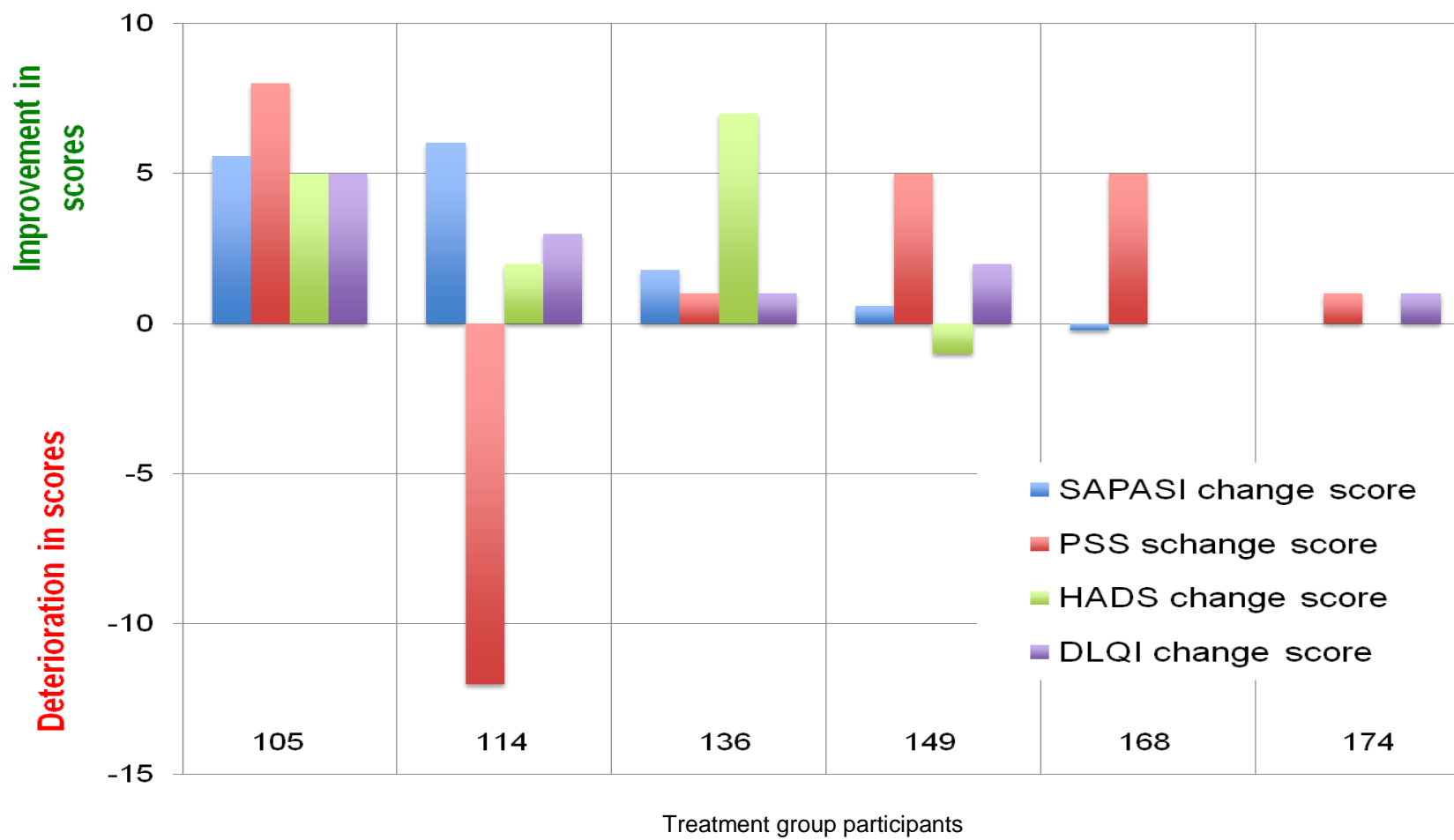
Figure 22: Treatment group participants change scores

The average change in SAPASI across the six treatment group participants was 2.29 points, for PSS 1.5 points, for HADS 2.17 points and for DLQI 2.00 points. Participant 105 reported consistent improvement in all four measurements. Participant 114 reported improvements in three measurements but recorded a large deterioration in their perceived stress scores between baseline and follow-up 1. Participant 136 was found to improve their SAPASI, PSS and DLQI scores minimally but their HADS scores demonstrated the largest improvements from all six participants. Participant 149 had a small deterioration in their HADS scores but an improvement in the other measures over the same time. Participant 168's SAPASI scores became slightly higher, PSS scores improved and there were no changes to HADS o DLQI scores. Participant 174 reported no change to the SAPASI or HADS scores and a small improvement to their PSS and DLQI scores.

4.5.3 Tests for sustained effects in primary and secondary outcomes

The treatment group's scores on the primary and secondary variables were examined again eight weeks after the MBCT intervention finished. The difference between the end of intervention scores (Follow-up 1) and 8 weeks later (Follow-up 2) were compared in order to examine whether effects were sustained or changed in the eight weeks after the intervention finished. The means and standard deviations for the primary variables at follow-up 1 and follow-up 2 are presented in Table 22.

Table 23: Treatment group's primary and secondary outcome scores at follow-ups 1 and 2

Variable	Follow-up 1 Mean (SD)	Follow-up 2 Mean (SD)
SAPASI	3.65 (1.37)	2.81 (1.12)
PSS	16.67 (6.77)	14.17 (5.53)
HADS	10.33 (6.83)	9.83 (6.01)
DLQI	3.67 (3.56)	2.00 (1.41)

There were no significant differences in the treatment group's primary or secondary outcomes between follow-up 1 and follow-up 2: SAPASI (z=-1.78, p=0.08), PSS (t=1.11, p=0.32), HADS (z=0.00, p=1.00) or DLQI (z= -0.96, p=0.34). The changes, which the ANCOVA reported in the treatment group's SAPASI and DLQI scores were maintained and the PSS and HADS also did not change over two months after the end of the MBCT intervention.

4.5.4 ANCOVA between the treatment and control group with illness-related cognitions at follow-up 1

The identity, consequence and emotional representations as measured by the IPQ-R were entered into an ANCOVA with bias corrected bootstrap estimates. ANCOVA tested for differences between the treatment and control group at follow-up 1 with each representation's respective baseline scores entered as covariates. The number of repetitions, for the bootstrap estimate, was set at 1000 and the seed was set at: Identity = 282330, consequences = 66942691 and emotional representation = 15070873. The baseline/follow-up-1 mean and standard deviations and the difference between the groups' co-efficient are presented in Table 23. The results of the ANCOVA are then presented for each representation outcome below the table.

Table 24: ANCOVA comparison of illness representation scores between the treatment and control group at follow-up 1

IPQ-R subscale	Group	Baseline Mean (SD)	Follow-up 1 Mean (SD)	The difference at follow-up 1 Co-efficient (Confidence intervals (CI))
Identity	Treatment	5.67 (2.34)	4.83 (1.60)	-0.67 (-2.39 – 0.82)
Identity	Control	4.85 (2.70)	4.84 (3.08)	-0.67 (-2.39 – 0.82)
Consequences	Treatment	18.17 (5.15)	19.33 (5.35)	-0.51 (-1.81 – 2.80)
Consequences	Control	20.62 (4.89)	21.15 (5.49)	-0.51 (-1.81 – 2.80)
Emotional Representation	Treatment	16.17 (5.98)	14.33 (5.05)	-0.94 (-4.29 – 2.48)
Emotional Representation	Control	20.92 (5.06)	19.15 (5.21)	-0.94 (-4.29 – 2.48)

After adjusting for baseline scores the bootstrap estimate of the difference between the treatment and control groups was not significant for the identity representation (z=0.74, p=0.47), the consequences representation (z=0.36, p=0.73) or the emotional representation (z=-0.94, p=0.59). These results suggest these representations did not change as a result of participating in the MBCT course.

4.5.5 Tests for sustained effects in illness representations

The treatment group's scores on the three illness representations were examined again eight weeks after the MBCT intervention finished. The difference between post-intervention scores (Follow-up 1) and 8 weeks later (Follow-up 2) were compared in order to examine whether effects changed in the eight weeks after the intervention finished. The means and standard deviations at follow-up 1 and follow-up 2 are presented in Table 24.

Table 25: Treatment group's identity, consequences and emotional representation scores at follow-ups 1 and 2

Variable	Follow-up 1 Mean (SD)	Follow-up 2 Mean (SD)
Identity	4.83 (1.60)	4.83 (1.94)
Consequences	19.33 (5.35)	19.00 (5.44)
Emotional Representation	14.33 (5.05)	15.83 (2.30)

There were no significant differences in the treatment group's illness representations between follow-up 1 and follow-up 2: identity (t=0.00, p=1.00), consequences (t=0.38, p=0.75) or emotional representation (t=-1.22, p=0.28). The participants' illness representations did not change over two months after the end of the MBCT intervention.

4.5.6 Summary

The primary analysis found significant differences between the treatment and control group at follow-up 1 on the primary outcome SAPASI and the secondary outcome DLQI but did not find any significant differences between these groups on any illness representations, the primary outcome PSS or the secondary outcome HADS, despite the pre-to post-MBCT differences on the HADS scores. These effects appear to have been maintained over a two-month follow-up period. When examining the treatment group participant's individual change scores from baseline to follow-up time 1, there were three participants who appeared to have improved in several of the measures and three which reported minimal changes.

4.6 Supplementary analysis ANCOVA (active and comparison groups)

Due to the high attrition, the primary ANCOVA between the treatment and control group at follow-up 1 was based on a very small sample size (n=19). To supplement the primary analysis an ANCOVA examined the difference in primary and secondary outcomes between all participants who had completed the MBCT course (active group) to a non-randomised comparison group of participants who had not entered the MBCT intervention.

The comparison group (n=10) was a non-randomised group of eligible participants that were recruited from eligible people with psoriasis who had expressed an interest in joining the study but could not commit to the MBCT evening training groups for personal reasons. The comparison group's pre-intervention measurements were collected at follow-up 1 and their post-intervention measurements at follow-up 2. The active group's (n=19) pre-intervention scores was an amalgamation of the treatment group's baseline measurements (pre-MBCT course) and the control group's follow-up 1 measurements (pre-MBCT course). Their post-intervention scores were the combined treatment group's scores at follow-up 1 (post-MBCT course) and the control group's scores at follow-up 2 (post-MBCT course).

4.6.1 Pre-intervention comparison between the active and comparison groups

The comparison group had not been randomised therefore it was necessary to investigate whether the comparison and active group at baseline were different on demographic variables or the primary and secondary outcomes. As the primary outcomes were non-parametric the difference between the groups was tested with Cramer's V for non-continuous variables and Mann-Whitney U-test for continuous variables. The descriptive data between the two groups are presented in Table 25.

Table 26: Active and comparison pre-intervention demographic, primary and secondary outcome scores

	Active n=14			Comparison n=10		
	Range	Median	Mean (SD)	Range	Median	Mean (SD)
% Females		57.1%			60.0%	
% Single		21.4%			66.7%	
% Relative w psoriasis		78.6%			22.2%	

	Active n=14			Comparison n=10		
% Using topical	71.4%			66.7%		
Age	28 – 68	45.50	43.57 (11.20)	27 – 60	34	38.67 (11.03)
Years living with Psoriasis	8 – 43	20	23.36 (10.82)	2 - 35	12	14.67 (11.09)
SAPASI	1.97-14.50	5.25	6.35 (3.85)	0.80 – 31.70	3.37	6.53 (9.13)
PSS	8.00-28.00	16.50	17.93 (5.73)	5.00 – 26.00	12.00	12.60 (6.06)
HADS	0.00-32.00	13.00	13.79 (8.01)	1.00 – 24.00	7.00	9.90 (7.80)
DLQI	1.00-24.00	5.00	7.36 (6.62)	0 – 9.00	5.50	4.80 (3.49)

There was a significant difference between the active and comparison group, at the pre-intervention time point on treatment type (Cramer's V = 0.44, p=0.04), the number of participants with a relative with psoriasis (Cramer's V = 0.54, p=0.01) and PSS (z=19.50, p=0.01). The comparison group had more members who were single, fewer members with a relative with psoriasis and were less stressed than the active group.

There were no differences between the active and comparison group on scores of: gender (Cramer's V =0.02, p=0.94), treatment type (Cramer's V = 0.03, p=0.90), SAPASI (z= -0.85, p=0.39), HADS (z= -1.50, p=0.13) or DLQI (z= -0.62, p=0.54).

There was a significant difference between the groups on one primary outcome (PSS) and this pre-intervention difference was controlled for in the ANCOVA.

4.6.2 ANCOVA between the active and comparison group with primary and secondary outcomes at post-intervention

At post-intervention, data from the 14 active and the 8 comparison group participants were entered into an ANCOVA with each outcome's respective pre-intervention scores entered as covariates. As the data were not normally distributed bias corrected bootstrapping was performed on each of the variables during each ANCOVA test. The number of repetitions was set at 1000 and the seed was set at a different level for each of the four primary outcomes: SAPASI seed=4483, PSS seed=70339707, HADS seed=870590 and DLQI seed=05446. The pre/post intervention mean and standard

deviations and the difference between the groups' co-efficient are presented in Table 26. The results of the ANCOVA are then presented for each primary/secondary outcome below the table.

Table 27: ANCOVA comparison of primary and secondary outcome scores between the active and comparison group at post-intervention

		Pre-intervention Mean (SD)	Post-intervention Mean (SD)	The difference at post-intervention Co-efficient (CI)
SAPASI	Active	6.35 (3.85)	4.16 (2.79)	2.58
	Comparison	7.49 (10.09)	8.26 (10.09)	(-0.17 – 5.34)
PSS	Active	17.93 (5.73)	16.07 (6.11)	0.52
	Comparison	11.38 (4.24)	14.86 (5.15)	(-6.96 – 8.00)
HADS	Active	13.79 (8.01)	9.43 (6.57)	2.49
	Comparison	8.75 (6.69)	8.00 (6.03)	(-1.18 – 6.16)
DLQI	Active	7.36 (6.62)	4.79 (5.51)	3.86
	Comparison	5.00 (3.30)	7.57 (5.94)	(0.14 – 7.58)

4.6.2.1 SAPASI

After adjusting for pre-intervention SAPASI scores, the bootstrap estimate of difference between the active and comparison group was not significant for SAPASI scores (z=1.84, p=0.07). The results are presented in Figure 22.

Figure 23: SAPASI scores pre-intervention to post-intervention between the active and comparison group
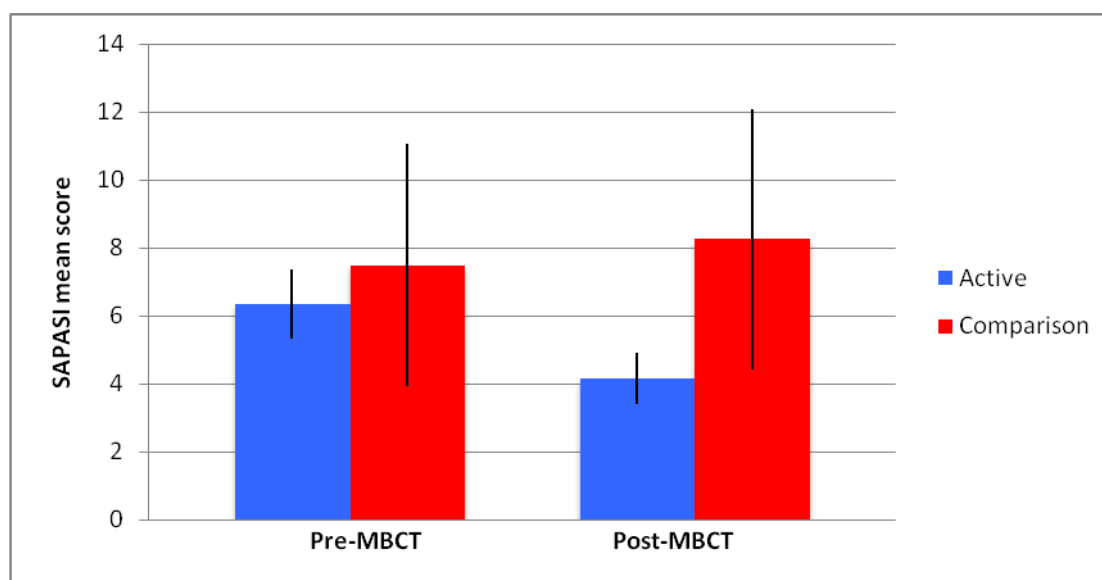
Figure 22: The mean SAPASI scores, with SE bars, of the two groups at pre-MBCT and post-MBCT are presented in this chart.

4.6.2.2 PSS

After adjusting for pre-intervention PSS scores, the bootstrap estimate of difference between the active and comparison group was not significant for PSS scores (z=0.14, p=0.89). The results are presented in Figure 23.

Figure 24: PSS scores pre-intervention to post-intervention between the active and comparison group
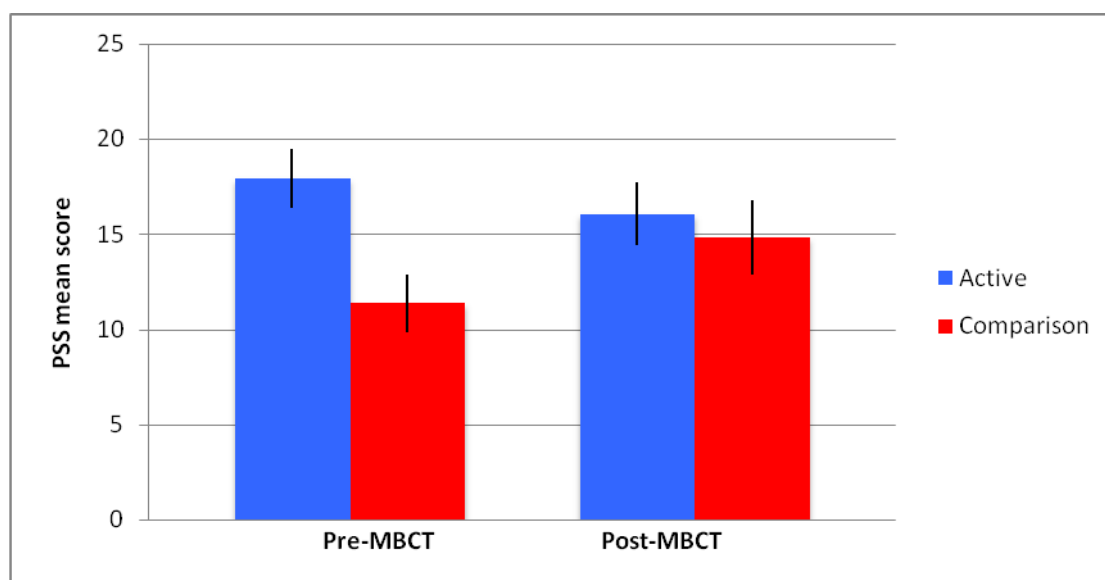
Figure 23: The mean PSS scores, with SE bars, of the two groups at pre-MBCT and post-MBCT are presented in the bar chart.

4.6.2.3 HADS

After adjusting for pre-intervention HADS scores, the bootstrap estimate of difference between the active and comparison group was not significant for HADS scores (z=1.33, p=0.18). The results are presented in Figure 24.

Figure 25: HADS scores pre-intervention to post-intervention between the active and comparison group
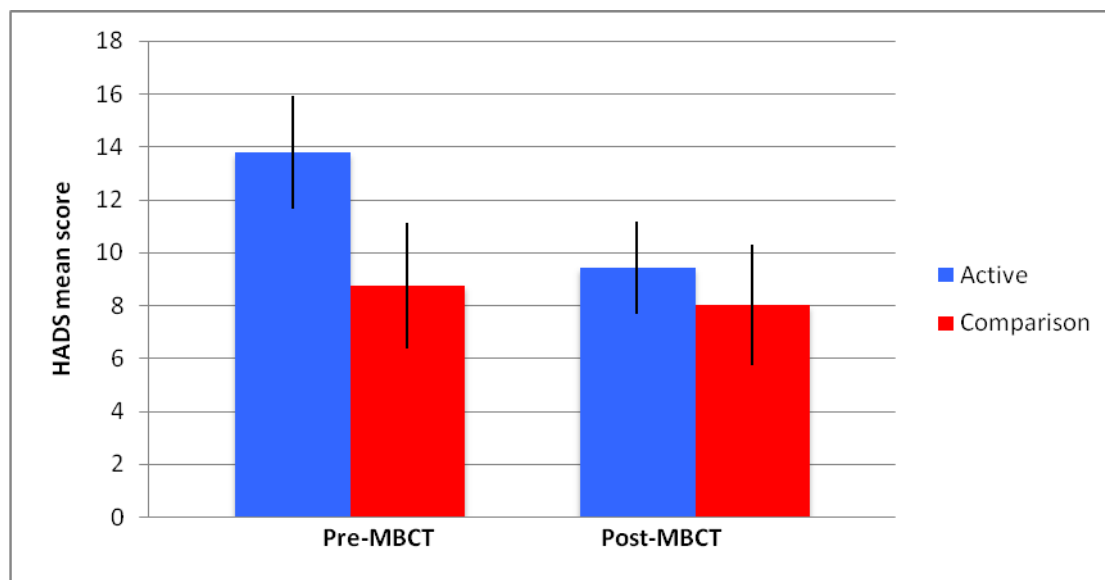
Figure 24: The mean HADS scores, with SE bars, of the two groups at pre-MBCT and post-MBCT are presented in the chart.

4.6.2.4   DLQI

After adjusting for pre-intervention DLQI scores, the bootstrap estimate of difference between the active and comparison group was significant for DLQI scores ($z=2.03$, $p=0.04$) suggesting the reductions were due to the intervention. The results are presented in Figure 25.

Figure 26: DLQI scores pre-intervention to post-intervention between the active and comparison group
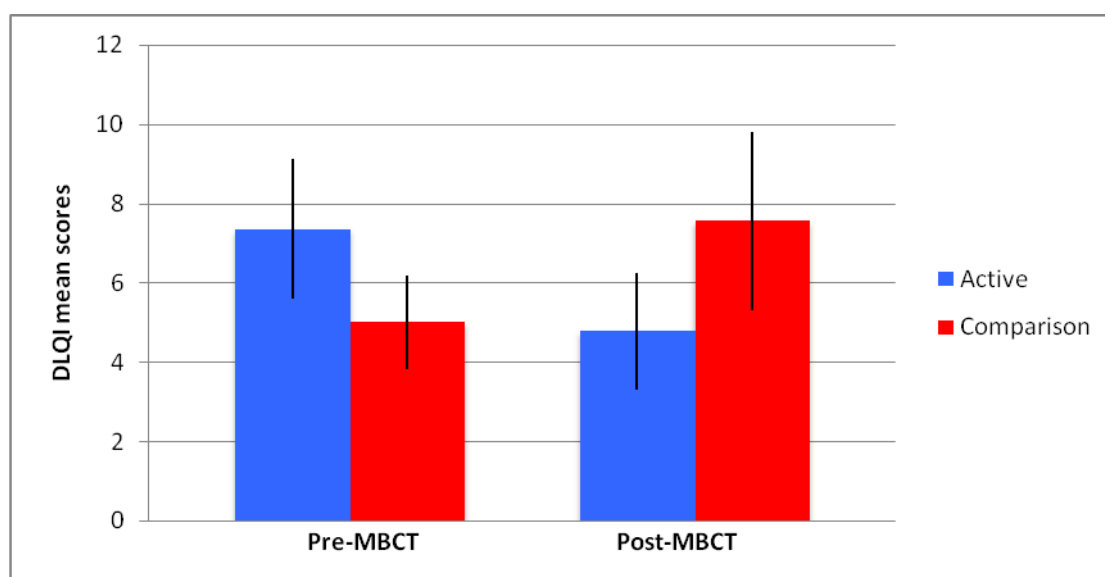
Figure 25: The mean DLQI scores, with SE bars, of the two groups at pre-MBCT and post-MBCT are presented in the bar chart.

The supplementary analysis results supported the primary analysis' findings that the DLQI scores reduced and the PSS and HADS scores did not change as a result of participating in the MBCT course. However, the improvement in SAPASI scores was no longer present in the supplementary analysis.

4.6.2.5 Active group participant's change scores

Fourteen participants completed the MBCT course over two months. The change scores (first measurement minus post-MBCT) are presented for each participant in Table 27 and graphically in Figure 26.

Table 28: Active group participants' change scores (SAPASI, PSS. HADS and DLQI)

	105	114	136	149	168	174	118	102	123	124	133	134	138	140
SAPASI change score	5.58	6.03	1.78	0.60	-0.23	0.00	5.00	-1.20	2.60	8.85	-1.20	1.12	1.00	0.80
PSS change score	8.00	-12.00	1.00	5.00	5.00	1.00	5.00	-16.00	1.00	8.00	4.00	7.00	10.00	-1.00
HADS change score	5.00	2.00	7.00	-1.00	0.00	0.00	8.00	1.00	4.00	17.00	5.00	1.00	10.00	2.00
DLQI change score	5.00	3.00	1.00	2.00	0.00	1.00	2.00	-2.00	3.00	12.00	3.00	3.00	1.00	2.00
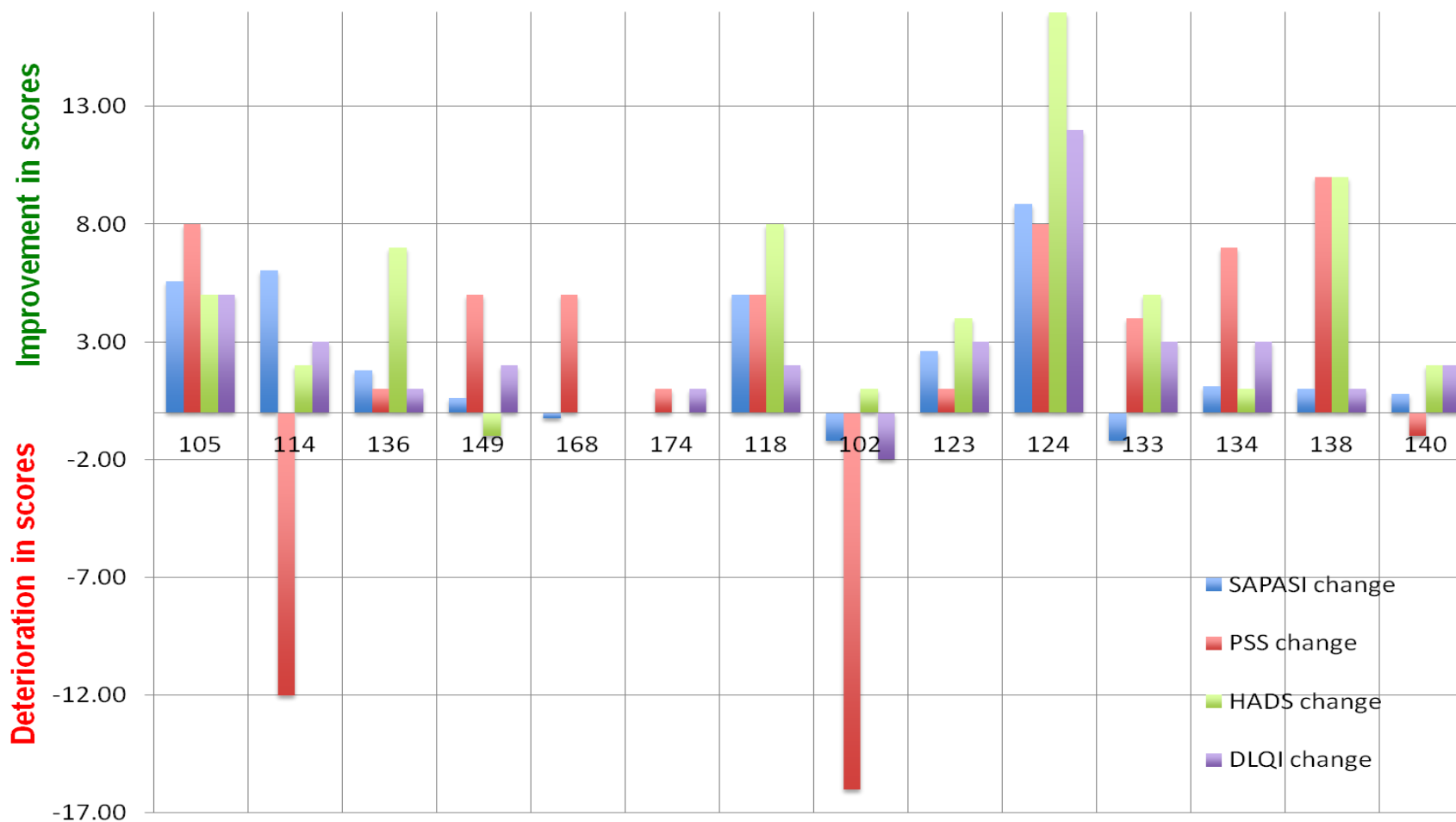
Figure 27: Active participant's individual change scores

The average change SAPASI change score from these 14 participants was 2.20, PSS change score was 1.86, HADS change score was 4.36 and DLQI change score was 2.57.Seven of the 14 (50%) participants who completed the MBCT course demonstrated an improvement in all of the primary and secondary variables (SAPASI, PSS, HADS and DLQI). Two participants had large deteriorations in their PSS scores (12 and 16 points) and one participant had a smaller deterioration of one point. One participant reported a two-point deterioration in DLQI scores, this same participant had a large deterioration in PSS scores and a small drop in their SAPASI score.

4.6.3 Tests for sustained effects

The active group's scores on the primary and secondary variables were tested again eight weeks post intervention for any maintained effects. One participant from the active group did not submit this two month follow-up time point measurement therefore this analysis was conducted on 13 participants. The means and standard deviations for the primary variables at post-intervention and eight weeks later are presented in Table 27.

Table 29: Active group's primary and secondary outcome scores at post-intervention and 8-week later

	Post-intervention Mean (SD)	8 week follow-up Mean (SD)
SAPASI	3.75 (2.42)	3.48 (2.03)
PSS	15.54 (6.01)	14.23 (4.78)
HADS	8.31 (5.27)	9.23 (4.68)
DLQI	3.46 (2.50)	3.54 (2.57)

There were no significant differences in the active group's primary outcomes between post-intervention and the 8 week follow-up: SAPASI (z= -1.22, p=0.22), PSS (z= -0.51, p=0.61), HADS (z= 1.08, p=0.28) or DLQI (z=0.44, p=0.66). The changes, which the ANCOVA reported in the active group's DLQI scores were maintained and the SAPASI, PSS and HADS also did not change over two months after the end of the MBCT intervention.

4.6.4 Summary

The comparison group were not randomised and the active group had higher perceived stress levels than them suggesting people were more likely to enter the MBCT intervention if they were currently experiencing stress. This suggestion was explored further in the sequential qualitative study.

The additional analysis comparing all mindfulness trained participants and the non-randomised non-trained comparison group was included in order to supplement the primary analysis with a larger sample size (n=22). A significant difference was found between these groups on the QoL scores, where the active group's scores improved. There were no differences between the groups on clinical, perceived stress or distress scores. These effects were maintained for two months after the final MBCT group session. The individual change scores show that 50% of participants who completed the mindfulness training reported some improvements to all of the primary and secondary outcome measurements.

4.7   Completers and non-completers

A high proportion of this study's participants did not complete the study. The non-completer's baseline scores were compared to those participants who remained adherent to the MBCT course (completers) to examine if there were any systematic differences between these two groups.

4.7.1   All study completers and non-completers

From the 29 participants assessed at baseline, 13 completed the MBCT intervention and 16 dropped out or were excluded. Cramer's V was used to test for difference between the groups on categorical demographic variables: gender (Cramer's V = 0.12, p=0.53), relationship status (Cramer's V = 0.36, p=0.07), type of treatment (Cramer's V = 0.26, p=0.17) or relatives with psoriasis (Cramer's V = 0.91, p=0.62).

Mann Whitney U-tests (for not normally distributed variables) and Independent T-tests (for normally distributed variables) were used to test the difference between the groups on the continuous demographic outcomes: age (t=1.11, p=0.28) or years with psoriasis (t=1.10, p=0.28). The primary outcomes: SAPASI (z=1.10, p=0.73) or PSS (t=0.70, p=0.48). The secondary outcomes: HADS (t=0.31, p=0.76) or DLQI (z=0.29, p=0.77). The process variables: MAAS (t=-0.58, p=0.57), pre-credibility (t=0.26, p=0.80) or pre-expectancy (t=0.99, p=0.33).

There were no significant differences between study completers and non-completers on any of the outcomes.

4.7.2   Treatment group completers and non-completers

Thirteen participants were allocated to the treatment group after baseline measurements and six participants completed the intervention. No significant differences were detected between completers and non-completers on: gender (Cramer's V = 0.22, p=0.43), relationship status (Cramer's V = 0.10, p=0.73), treatment (Cramer's V = 0.07, p=0.80), relatives with psoriasis (Cramer's V = 0.28, p=0.31), age (t=-0.80, p=0.44), years with psoriasis (t=0.47, p=0.65), MAAS (t=-0.58, p=0.57), SAPASI (z=0.14, p=0.87), PSS (t=0.65, p=0.52), HADS (t=-0.29, p=0.78), DLQI (z=0.00, p=1.00), pre-credibility (t=0.01, p=1.00) or pre-expectancy (t=0.02, p=0.99).

4.7.3   Summary

There were no significant differences on pre-intervention demographic, primary, secondary or process variables between any of the study completers and study non-completers.

4.8   Sample size estimate for a future full RCT study

This pilot study has found MBCT to produce a significant improvement to SAPASI and DLQI outcomes in people with psoriasis. From this pilot study a sample size estimate (SSE) was calculated to determine how many participants were needed for a RCT study to achieve 80% power (probability) that the study will correctly reject a false null hypothesis.

To calculate this SSE the first measurement mean of the primary outcome SAPASI score was used, as this was generated from a larger sample of the target population (n=39). The first measurement mean SAPASI score was 7.19 (SD=6.46). Research and clinicians accept a 50% reduction in SAPASI scores to be a relevant clinical response (Koek et al., 2009). SAPASI scores start from 0, therefore a 50% reduction of 7.19 would be 3.59 (Minimal Important Difference (MID)). The MID divided by the standard deviation (SD=6.46) leaves an effect size (Cohen's d) value of 0.56. Based on an effect size 0.56, with statistical power level at 80% and a two-tailed hypothesis with a probability level of 0.05, the SSE for a future 80% powered RCT to compare a treatment and control group on the primary outcome of SAPASI would need a total sample of 104 participants (52 per group).

4.9 Chapter summary

The study encountered a high, 45%, attrition rate. Participants dropped out of the study stating practical reasons such as not having enough time to commit to the course. The majority of drop out participants left the study before starting the intervention groups; only one participant reported that the group "was not for him."

Compared to an estimate of the UK psoriasis population (O'Leary et al., 2004), this study's sample reported less severe physical symptoms and stress levels but still encountered high levels of distress (35% with probable anxiety disorder and 10% with probable depression disorder) and QoL impairment.

The primary and secondary outcomes were all significantly correlated with each other apart from physical severity and perceived stress scores. Distress made a larger unique contribution to explaining the QoL outcome but physical severity also made a significant contribution.

This pilot study found the MBCT course improved the mean self-reported physical severity and QoL in participants with psoriasis but not perceived stress or distress levels. A supplementary analysis supported the improvement to QoL but not to physical severity. Pre to post analysis reported improvements to physical severity, distress and QoL scores. These effects did not change in the post-intervention follow-up assessment.

The individual change scores demonstrate that 50% of the participants experienced an improvement in all four primary and secondary outcome measurements. A graph of the change scores from all participants in the mindfulness training (active group) demonstrates that individuals report more improvement than deterioration. Two participants, however, report large deterioration in their PSS scores from pre to post treatment.

All bar one participants believed that stress caused their psoriasis, labelled stress responders. Participants' beliefs about the symptoms associated with their psoriasis, the conditions' consequences upon their lives and the participants' emotional representation of psoriasis were significantly correlated with physical severity, distress and QoL outcomes. Although physical severity and QoL outcomes changed, none of these illness representations changed as a result of participating in the MBCT course.

Participants learned mindfulness skills after participating in the MBCT groups. If participants' levels of expectation that MBCT would be useful and that it was a credible

treatment option were high they experienced a greater change in their perceived stress scores but not in their physical severity scores.

This pilot study's findings are not conclusive regarding the efficacy of MBCT for people with psoriasis mainly due to the small sample size. This study, however, presents a strong case for further examination of this intervention within a fully powered RCT study. A sample size estimate was developed from the first measurement physical severity scores. A future RCT (80% power) would require 104 participants (52 per group). As this study and previous psychological intervention studies with this population have encountered nearly 50% attrition rate, any future study should aim to recruit a minimum of 200 participants.

5. Study phase II results: cortisol and cortisone outcomes

This is the first study to examine the cortisol awakening response (CAR) in people with psoriasis. Salivary cortisone is produced when salivary cortisol is oxidised by an enzyme. Cortisone concentrations are much higher than cortisol concentrations and have been reported as more sensitive markers of free circulating cortisol than salivary cortisol.

The data for phase II was collected concurrently with the data from phase I so there is no description of sampling in this chapter, as it is the same process as explained in Chapter 4, section 4.1. In addition to the outcomes, which were collected in phase I, data was also collected in order to calculate a BMI score for each participant, as BMI has previously been associated with CAR (Ursache et al., 2012; Steptoe et al., 2004). Three composite CAR scores were generated from the four daily collection points (0, 15, 30, 45 minutes post awakening) for the cortisol and cortisone analytes. These data were tested for normality with the Kolomogorov-Smirnov (K-S) test of normality, then described (measured of central tendency) and entered into a correlation analysis with demographics, physical severity, perceived stress, distress and QoL outcomes. Finally these one composite score was entered into an ANCOVA to test for difference between participants who had completed the mindfulness based cognitive therapy (MBCT) course and participants who had not entered the MBCT course.

5.1 Data description

First measurements were collected from the treatment and control group (n=29) at week 0 and from the comparison group (n=10) eight weeks later. Measurements from these two collection points were amalgamated to form a first measurement group (n=39) in order to increase the sample size and therefore strengthen the associations measured in the correlation analysis.

Following mass spectrometry extraction one participant's sample (pt 177) produced no results across all time points (0, 15, 30 and 45 minutes), one participant's (pt 113) samples did not produce a result at the 30-minute or 45-minute time points and one (pt 103) did not produce a result at the 45min time point.

Only 30 participants returned data for the BMI calculation, there were too many missing data cells to substitute the mean, therefore analyses which included the BMI were only conducted on the 30 participants who provided the data. A sensitivity analysis was not conducted to check the difference of high and low BMI because BMI has been accepted as a well-established predictor of CAR (Ursache et al., 2012; Steptoe et al., 2004)

5.1.1 Demographic data for first measurement group

Of the 39 participants at first measure 56.4% (n=22) were female; 46.2% (n=18) were single or separated; 59.0% (n=23) had a relative with psoriasis; and 56.4% (n=22) were using topical steroidal treatments, the remaining participants were using either systemic or biologic treatment options. The continuous demographic variables are presented in Table 28.

Table 30: First time measures: descriptive data

	N	Range	Mean (SD)
Age (years)	39	22.00 -70.00	40.58 (12.37)
Years with Ps	39	2.00 - 43.00	19.66 (10.83)
BMI	30	19.00 – 38.00	26.03 (5.49)

BMI was entered into this analysis because a robust association between CAR and BMI has previously been reported (Ursache et al., 2012; Steptoe et al., 2004). The mean BMI score is 26, which has been classified as overweight (World Health Organistion, 2000).

5.1.2 Awakening response curve

Previous research in disease free populations found free-cortisol in saliva samples to rise by approximately 50 - 160% from s1 to s1+30 minutes and then to gradually return to baseline levels throughout the day (Clow et al., 2004). The mean cortisol and cortisone values across 0 minutes to 45 minutes post awakening, from the first measurements were plotted in Figures 26 and 27 to display the awakening response curve.

Figure 28: Cortisol mean values at awakening

	0 Minute	15 Minute	30 Minute	45 Minute
Cortisol Mean	9.26	10.20	11.27	10.53
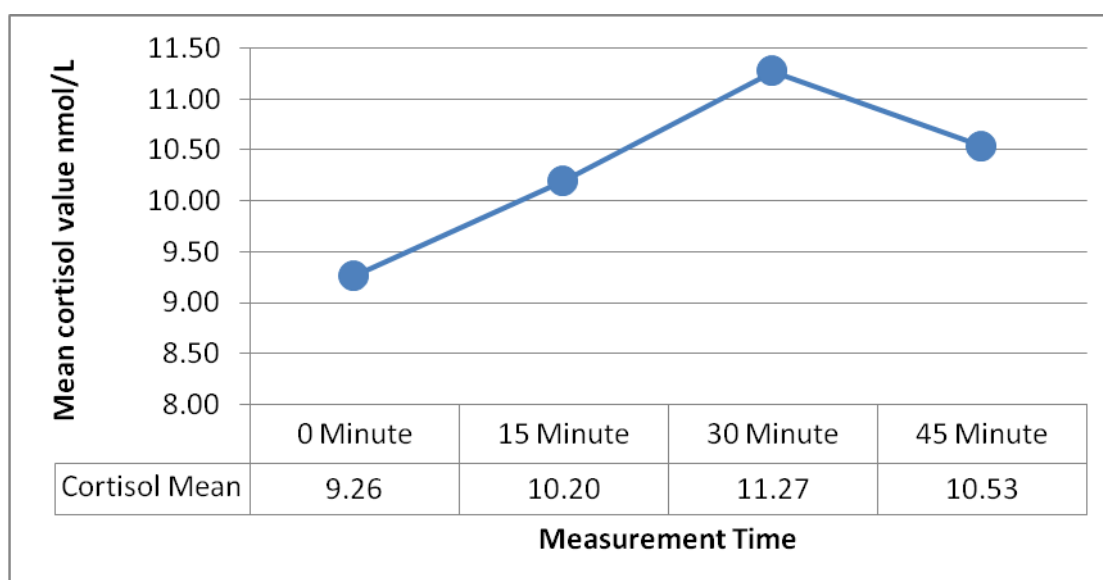
Figure 26: The mean saliva cortisol concentration (nanomoles per litre) measured by XLC-MS/MS, at 0, 15, 30 and 45 minutes post awakening are plotted to demonstrate the average cortisol rise to awakening.

The mean saliva cortisol concentrations increased by 22% from 9.26 nmol/L at 0-minute to 11.27 nmol/L at 30-minute post awakening.

Figure 29: Cortisone mean values at awakening

	0 Minute	15 Minute	30 Minute	45 Minute
Cortisone Mean	19.44	23.53	24.91	24.98
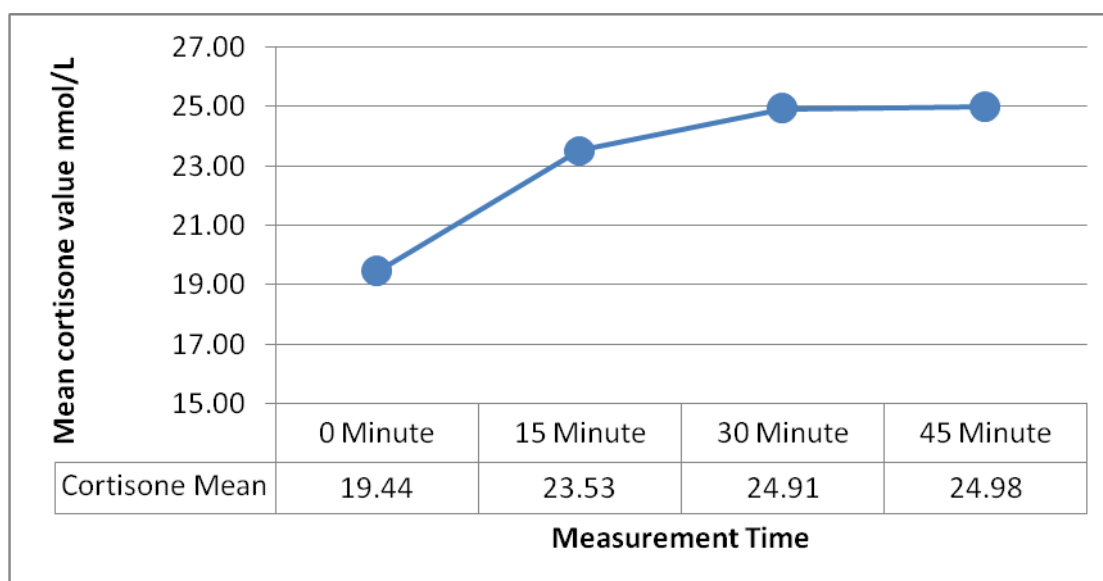
Figure 27: The mean saliva cortisone concentration (nanomoles per litre) measured by XLC-MS/MS, at 0, 15, 30 and 45 minutes post awakening are plotted to demonstrate the average cortisone rise to awakening.

The mean saliva cortisone concentrations increased by 28% from 19.44 nmol/L at 0-minute to 24.91 nmol/L at 30-minute post awakening.

5.1.3   Composite scores of the awakening response

The s1 measurement was the 0 minute collection point and was available from all apart from Pt 177. The AUCg, AUCi and dynamic change measurements cannot be calculated unless all 4-time points have a value; therefore the cases without a value for all the measurement times (n=3) were excluded in any analyses where the AUCg, AUCi and dynamic change was used.

If the s1 had a higher score than the following time points the AUCi resulted in a negative value (Negative AUCi). A negative AUCi was reported in 10 cortisol cases and 7 cortisone cases.

Negative Dynamic Change, where the 0 minute score was higher than the sequential scores, were transformed to positive as they measured the reactivity range of change rather than the direction of change.

A summary of the participant data available to be entered into the composite CAR scores is presented in Table 29.

Table 31: Number of cases available for cortisol and cortisone composite score calculations

	Cortisol	Cortisone
S1	N=38	N=38
AUCg	N=36	N=36
AUCi	N=36	N=36
Dynamic Change	N=36	N=36

5.1.4   Composite score descriptive data

The composite scores (AUCg, AUCi and Dynamic Change) were calculated (see chapter 3 section 3.7.1.4) screened and tested with the K-S test to examine whether the sample distributions were significantly different from a normal distribution. The S1, the composite scores and the K-S tests (including skewness and kurtosis) for both cortisol and cortisone are presented in Table 30.

Table 32: First time measurement descriptive data spread: Cortisol and cortisone composite scores

	N	Range	Mean (SD)	Kolmogorov-Smirnov test			Skew-ness	Kurtosis
				Statistic	d.f.	p-value		
Cortisol								
S1	38	0.58 – 39.17	9.26 (8.54)	0.24	38	<0.001 ***	2.01	4.33
AUCg	36	22.20 – 1482.90	478.92 (275.28)	0.14	36	0.10	1.50	4.13
AUCi	36	-722.47 – 431.93	49.49 (229.64)	0.19	36	0.003 **	-1.93	5.36
Dyn Ch	36	0.08 – 17.65	5.72 (4.73)	0.15	36	0.04 *	1.05	0.39
Cortisone								
S1	38	2.61 – 38.27	19.44 (8.38)	0.99	38	0.20	0.27	-0.11
AUCg	36	158.78 – 1742.77	1076.47 (334.95)	0.07	36	0.20	0.39	0.77
AUCi	36	-383.47 – 884.12	177.37 (240.02)	0.13	36	0.13	0.47	1.24
Dyn Ch	36	0.03 – 28.70	9.10 (7.18)	0.12	36	0.20	0.39	0.77

*Significant difference from a normal distribution at the *P<0.05 level, **p<0.01 level and p<0.001 level.*

The cortisol scores were not normally distributed apart from overall cortisol (AUCg), therefore non-parametric statistics were used with these variables but parametric tests were used for the AUCg variable to check for sensitivity. The cortisone scores were all normally distributed so these will all be tested with parametric statistics. These data cannot be compared to previous samples as the cortisol extraction techniques are different and therefore any comparison would not be meaningful.

5.1.5 Group comparison between the AUCi positive group and the AUCi negative group

Results from previous studies within healthy populations have suggested that when the S1 cortisol value was higher than the following time points (indicated by a negative AUCi score) this indicated non-adherence to the saliva collection protocol (Thorn et al., 2006). If a participant did not collect their 0 minute swab at their true awakening point then they may miss the cortisol rise over the next minutes. Non-adherence could not be assumed in this population of people with psoriasis, as their CAR has not been measured before therefore a negative AUCi (no cortisol rise) maybe a true response within this patient population rather than non-adherence. To examine if there was any systematic differences on physical severity, psychological or QoL outcomes between participants who produced a negative CAR reactivity response (AUCi < 0) to those who did (AUCi > 0) a between group comparison was conducted with Mann-Whitney U-test (not normally distributed variables) and Independent T-test (normally distributed variables).

When the first measurement group was split into those with AUCi positive and those with AUCi negative cortisol scores. There was no significant difference between the groups on SAPASI (z=1.20, p=0.23), PSS (t=0.53, p=0.96), HADS (t=0.50, p=0.62) or DLQI (z=1.59, p=0.11).

5.1.6 Summary

This sample had a mean BMI, categorising them as overweight (World Health Organistion, 2000). While the 0 minute to 45 minutes post awakening scores formed a similar CAR shape to that previously reported (sharp increase from 0 min to 30 min followed but a decrease at 45minutes) the percentage increase was lower (22% for cortisol and 28% for cortisone) than has been reported in healthy populations (50-160% cortisol) (Clow et al., 2004). The cortisol composite values were not normally distributed and therefore non-parametric statistics were used for analyses, which include these scores. The cortisone composite scores were normally distributed and therefore parametric statistics were used for further analyses with these scores. A sub-group from this sample reported a 0 minute score (s1) which was higher than the following scores (15, 30, 45 minutes post awakening), which resulted in a negative increase (AUCi) score. This negative response has previously been assumed to be non-adherence to the protocol because if people do not put the 0 minute swab in their mouths exactly as they wake up they may miss the morning cortisol increase. However, as no one has measured CAR in people with psoriasis it could not be assumed that this lack of cortisol rise was due to non-adherence but may have been a genuine response profile in this population. Both negative and positive AUCi scores were included in the further analyses.

5.2 Primary analysis: correlations and regression

Associations were explored between the cortisol and cortisone composite outcomes with the demographic, physical and psychological outcomes with the first measurement dataset (treatment, control and comparison group data combined, n=39). Study phase I reported several significant correlations (see chapter 4 section 4.3.1) between MAAS and the other primary and secondary outcomes. MAAS was included in these correlations as it appeared to be an important outcome variable.

All cortisol and cortisone variables were entered into non-parametric (Spearman) correlations with the primary and secondary outcomes. All the normally distributed outcomes were subsequently entered into a parametric correlation to check for sensitivity of the non-parametric correlation. Statistically significant correlation coefficients are highlighted in red.

Table 31 presents the **cortisol** composite scores non-parametric correlation analysis with the demographic outcomes. This was run with the n=39 cases where there were data available for the cortisol composite scores. Only 30 participants returned the BMI data therefore these analyses were run with 30 cases.

Table 33: Non-parametric (Spearman) correlation matrix for the first measurement demographic and cortisol outcome scores

		BMI	Gender	Age	PSO Age	Single	Topical	No related
S1 Cortisol	Coefficient	.151	-.128	-.129	-.138	-.096	-.007	.039
	Sig.	.425	.444	.442	.410	.566	.965	.817
	N	30	38	38	38	38	38	38
AUCg Cortisol	Coefficient	.284	-.140	-.053	-.189	-.088	.110	-.135
	Sig.	.135	.416	.757	.270	.608	.524	.434
	N	29	36	36	36	36	36	36
AUCi Cortisol	Coefficient	.324	-.151	.055	-.062	-.051	.214	-.081
	Sig.	.087	.380	.748	.719	.768	.210	.640
	N	29	36	36	36	36	36	36
Dynamic Change Cortisol	Coefficient	.331	-.022	-.020	-.183	.038	.081	-.044
	Sig.	.074	.897	.904	.272	.819	.629	.794
	N	30	38	38	38	38	38	38

None of the cortisol composite outcomes were correlated with any demographic variables.

Table 32 presents the **cortisone** composite scores non-parametric correlation analysis with the demographic outcomes.

Table 34: Non-parametric (Spearmans) correlation matrix for the first measurement demographic and cortisone outcome scores

		BMI	Gender	Age	PSO Age	Single	Topical	No related
S1 Cortisone	Coefficient	.107	.123	-.037	-.114	.059	-.009	.104
	Sig.	.573	.461	.826	.497	.723	.956	.533
	N	30	38	38	38	38	38	38
AUCg Cortisone	Coefficient	.266	.076	.171	-.102	-.044	.111	-.102
	Sig.	.163	.659	.318	.554	.799	.519	.554
	N	29	36	36	36	36	36	36
AUCi Cortisone	Coefficient	.182	-.185	.309	.061	-.240	.271	-.222
	Sig.	.343	.280	.067	.724	.158	.110	.193
	N	29	36	36	36	36	36	36
Dynamic Change Cortisone	Coefficient	.390	-.189	.115	-.153	-.105	.094	-.173
	Sig.	.033	.256	.490	.361	.530	.575	.299
	N	30	38	38	38	38	38	38

*Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.*

The dynamic change (reactivity) cortisone variable was significantly positively correlated to BMI. This suggests that as BMI scores increase so does dynamic cortisone scores.

Table 33 presents the non-parametric correlation analysis between the **cortisol and the cortisone** composite scores. Cortisone has a higher concentration in saliva samples than cortisol and is meant to be a more sensitive measurement of free circulating cortisol than salivary cortisol. This correlation analysis aimed to check related these two analyte scores were within this population.

Table 35: Non-parametric (Spearman) correlation matrix between the cortisol and cortisone composite scores

		S1 Cortisol	AUCg Cortisol	AUCi Cortisol	Dynamic Change Cortisol	S1 Cortisone	AUCg Cortisone	AUCi Cortisone	Dynamic Change Cortisone
S1 Cortisol	Coefficient	1.000	.830**	-.451**	-.405*	.687**	.578**	-.274	-.212
	Sig.	.	.000	.006	.012	.000	.000	.106	.200
	N	38	36	36	38	38	36	36	38
AUCg Cortisol	Coefficient	-	1.000	.003	.077	.411*	.667**	.147	.249
	Sig.	-	.	.988	.655	.013	.000	.393	.144
	N	-	36	36	36	36	36	36	36
AUCi Cortisol	Coefficient	-	-	1.000	.946**	-.370*	.051	.626**	.617**
	Sig.	-	-	.	.000	.026	.767	.000	.000
	N	-	-	36	36	36	36	36	36
Dynamic Change Cortisol	Coefficient	-	-	-	1.000	-.345*	.117	.674**	.718**
	Sig.	-	-	-	.	.034	.497	.000	.000
	N	-	-	-	38	38	36	36	38
S1 Cortisone	Coefficient	-	-	-	-	1.000	.710**	-.513**	-.345*
	Sig.	-	-	-	-	.	.000	.001	.034
	N	-	-	-	-	38	36	36	38

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

		S1 Cortisol	AUCg Cortisol	AUCi Cortisol	Dynamic Change Cortisol	S1 Cortisone	AUCg Cortisone	AUCi Cortisone	Dynamic Change Cortisone
AUCg Cortisone	Coefficient	-	-	-	-	-	1.000	.146	.266
	Sig.	-	-	-	-	-	.	.397	.117
	N	-	-	-	-	-	36	36	36
AUCi Cortisone	Coefficient	-	-	-	-	-	-	1.000	.901**
	Sig.	-	-	-	-	-	-	.	.000
	N	-	-	-	-	-	-	36	36
Dynamic Change Cortisone	Coefficient	-	-	-	-	-	-	-	1.000
	Sig.	-	-	-	-	-	-	-	.
	N	-	-	-	-	-	-	-	38

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

As expected the cortisol and cortisone scores were significantly correlated with each other. The composite scores that did not significantly correlate with each other were the overall CAR (AUCg) and CAR reactivity (AUCi and dynamic change) measurement.

Table 34 presents the non-parametric correlation analysis between the **cortisol** composite scores and the MAAS, SAPASI, PSS, HADS (with depression and anxiety subscales) and DLQI outcomes.

Table 36: Non-parametric (Spearman) correlation matrix for cortisol, physical, psychological, mindfulness and QoL outcome data

		MAAS	SAPASI	PSS	HADS	HADS depression	HADS anxiety	DLQI
S1 Cortisol	Coefficient	.416	-.234	-.262	-.341	-.257	-.137	-.152
	Sig.	.028	.158	.113	.036	.119	.413	.361
	N	28	38	38	38	38	38	38
AUCg Cortisol	Coefficient	.522**	-.303	-.195	-.300	-.197	-.151	-.046
	Sig.	.006	.072	.254	.076	.249	.380	.791
	N	26	36	36	36	36	36	36
AUCi Cortisol	Coefficient	.148	-.254	.126	.017	.059	-.108	-.081
	Sig.	.471	.134	.464	.920	.733	.529	.638
	N	26	36	36	36	36	36	36
Dynamic Change Cortisol	Coefficient	.058	-.158	.153	.006	.046	-.056	-.003
	Sig.	.771	.343	.360	.973	.785	.738	.987
	N	28	38	38	38	38	38	38

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

MAAS was significantly positively correlated with s1 and overall CAR (AUCg), as mindfulness skill (MAAS) increases so to does the first cortisol measurement at awakening (s1) and the overall CAR (AUCg). HADS was significantly negatively correlated with s1 cortisol, as distress (HADS) increases the s1 decreases.

The **cortisone** composite scores were entered into a non-parametric correlation analysis with the physical, psychological, QoL and mindfulness skill outcomes. The results are presented in Table 35.

Table 37: Non-parametric (Spearman) correlation matrix for cortisone, physical, psychological, QoL and mindfulness skill outcome data

		MAAS	SAPASI	PSS	HADS	HADS depression	HADS anxiety	DLQI
S1 Cortisone	Coefficient	.219	-.100	-.202	-.233	-.138	-.118	-.209
	Sig.	.263	.550	.223	.159	.410	.480	.208
	N	28	38	38	38	38	38	38
AUCg Cortisone	Coefficient	.430*	-.156	-.059	-.218	-.144	-.163	-.050
	Sig.	.028	.363	.732	.202	.401	.343	.772
	N	26	38	38	38	38	38	38
AUCi Cortisone	Coefficient	.332	-.175	.079	-.073	-.113	-.150	.023
	Sig.	.097	.306	.646	.672	.513	.384	.892
	N	26	36	36	36	36	36	36
Dynamic Change Cortisone	Coefficient	.204	-.108	.172	-.016	-.061	-.079	.122
	Sig.	.297	.518	.302	.925	.716	.638	.467
	N	28	38	38	38	38	38	38

Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.

MAAS was significantly positively correlated with the overcall CAR (AUCg) cortisone. If AUCg cortisone was higher then MAAS was higher.

All the **cortisone** outcomes, the **AUCg cortisol**, **PSS** and **HADS** were normally distributed and were entered into a parametric correlation to check for the sensitivity of the non-parametric correlation. Table 36 presents the parametric correlation matrix.

Table 38: Parametric (Pearson) correlation matrix for normally distributed cortisol, cortisone, physical, psychological, QoL and mindfulness skill outcome data

		MAAS	SAPASI	PSS	HADS	HADS depression	HADS anxiety	DLQI
AUCg Cortisol	Coefficient	.461*	-.325	-.165	-.346*	-.220	-.137	-.244
	Sig.	.027	.053	.335	.039	.197	.425	.151
	N	26	36	36	36	36	36	36
S1 Cortisone	Coefficient	.319	-.167	-.260	-.291	-.236	-.123	-.256
	Sig.	.120	.315	.115	.076	.154	.463	.118
	N	28	38	38	38	38	38	38
AUCg Cortisone	Coefficient	.499*	-.220	-.164	-.353*	-.227	-.258	-.275
	Sig.	.015	.196	.338	.034	.184	.129	.104
	N	26	36	36	36	36	36	36
AUCi Cortisone	Coefficient	.223	-.225	.087	-.151	-.084	-.215	-.170
	Sig.	.273	.186	.612	.380	.627	.209	.321
	N	26	36	36	36	36	36	36
Dynamic Change Cortisone	Coefficient	.114	-.149	.243	-.028	-.018	-.060	.036
	Sig.	.603	.384	.154	.869	.914	.722	.836
	N	28	38	38	38	38	38	38

*Significant correlation at the *p<0.05 level, **p<0.01 level and p<0.001*** level.*

The MAAS scores were significantly positively correlated with AUCg cortisol and AUCg cortisone. If mindfulness skills were higher then the AUCg cortisol and cortisone were higher. The HADS scores were significantly negatively correlated with AUCg cortisol and cortisone. If HADS scores were higher then the AUCg cortisol and cortisone scores were lower.

This parametric correlation was run with normally distributed outcomes and had found two outcomes (MAAS and HADS) to be significantly correlated with the overall CAR (AUCg) of both cortisol and cortisone.

5.2.1 Regression

A significant correlation was reported between the overall CAR (AUCg) cortisol and cortisone with MAAS and HADS. MAAS and HADS could not both be entered into a regression because they correlated with each other above 0.7 ($r = -0.76$), which disregards multicollinearity assumptions (Pallant, 2010). This suggests that MAAS and HADS are both measuring different elements of a similar construct.

5.2.2 Summary

Cortisol and cortisone overall CAR values (s1 and AUCg) did not significantly correlate with the reactivity scores (AUCi and Dynamic Change). Increases in BMI were associated with increases in the cortisone reactivity values (dynamic change).

Cortisone has been used as a more sensitive marker of free circulating cortisol. As distress (HADS) increased the overall CAR (s1 and AUCg) cortisol and cortisone reduced. Higher mindfulness skills (MAAS) were associated with increased overall CAR (s1 and AUCg) cortisol and cortisone scores. The literature has previously reported distress to be associated with attenuated overall CAR cortisol but this is the first time it has been correlated with cortisone. Mindfulness skill has not previously been associated with overall CAR cortisol or cortisone responses.

The AUCg score was the composite score which was correlated with the most other outcomes, therefore this outcome was chosen to be included in the further analyses.

5.3 Pre to post MBCT changes

Only one CAR composite score (AUCg) from the cortisol and cortisone outcomes was entered into these analyses in order to reduce the likelihood of increasing a type 1 error. The pre to post MBCT AUCg cortisol and cortisone scores from the treatment and control group participants who completed the course (n=14) were examined to see if there were any changes in participants' scores across the study time period. From these participants only n=12 had a valid AUCg score. This analysis does not include a comparison to a control group therefore any changes may have been caused by other factors and not the MBCT intervention. These results were intended to supplement the ANCOVA analysis rather than stand alone analyses.

AUCg cortisol and cortisone outcomes were normally distributed therefore the pre to post changes were compared with a related samples paired samples t-test. The group descriptive data and tests of difference results are presented in Table 37.

Table 39: Pre to post MBCT change in AUCg cortisol and cortisone data

Variable	Pre-MBCT mean (SD)	Post-MBCT mean (SD)	Difference over time test statistic	p-value
AUCg cortisol	549.07 (194.52)	519.49 (513.82)	t=0.19	0.85
AUCg cortisone	1262.81 (404.18)	1099.40 (328.83)	t=1.27	0.23

There were no pre to post changes in either AUCg cortisol or cortisone scores.

5.4 Secondary analysis: ANCOVA (treatment and control groups)

The secondary research question for study phase II aimed to examine differences in overall CAR cortisol and cortisone (AUCg) between the treatment and control groups at follow-up 1, whilst controlling for the baseline scores. A supplementary analysis was conducted comparing the active group to the non-randomised comparison group.

5.4.1 Treatment and control group baseline measurements

To reduce the number of tests used and consequently reduce the likelihood of increasing the chance of a type I error, only the AUCg for cortisol and cortisone were used in the between group analyses. The ANCOVA tested for differences between the treatment and control group at follow-up 1 (n=19). One participant in the control group did not produce a cortisol/cortisone measurement across the four measurement points (0 minutes, 15 minutes, 30 minutes, 45 minutes) and therefore their AUCg composite score could not be calculated. Table 38 presents the treatment and control group AUCg for cortisol and cortisone.

Table 40: Treatment and control group baseline AUCg cortisol and cortisone outcome data

	Treatment			Control		
	N	Range	Mean (SD)	N	Range	Mean (SD)
AUCg Cortisol	6	259.80 – 664.65	441.78 (117.00)	12	22.20 – 750.68	401.41 (227.44)
AUCg Cortisone	6	664.65 – 1531.13	1114.56 (349.62)	12	158.78 – 1556.40	1032.78 (394.85)

The randomisation appears to have been effective as there the AUCg cortisol and cortisone distribution is similar between the groups.

5.4.2 ANCOVA between treatment and control group with AUCg cortisol and cortisone outcomes at follow-up 1

A one-way between groups ANCOVA was used to compare the AUCg cortisol cortisone scores between the treatment group, who had received the MBCT intervention and the control group, who had not received the intervention at follow-up 1. Participants' baseline AUCg cortisol and cortisone scores were used as the covariates in this analysis. Although the AUCg cortisol and cortisone outcomes were normally distributed

the sample size was still small and therefore a bootstrap estimate was performed on each outcome. The number of repetitions was set to 1000, the seed for AUCg Cortisol was set to 53731909 and the seed for AUCg Cortisone was set to 19115849. The baseline/follow-up-1 mean and standard deviations and the difference between the groups' co-efficient are presented in Table 39. The results of the ANCOVA are then presented for AUCg cortisol and cortisone below the table.

Table 41: ANCOVA comparison of AUCg cortisol and cortisone data between the treatment and control group at follow-up 1

		Baseline Mean (SD)	Follow-up 1 Mean (SD)	The difference at follow-up 1 Co-efficient (confidence intervals (CI))
AUCg Cortisol	Treatment	441.78 (117.00)	697.28 (787.71)	-111.97 (-768.55 – 544.63)
	Control	401.41 (227.44)	584.95 (205.86)	
AUCg Cortisone	Treatment	1114.56 (349.62)	1045.26 (347.50)	339.85 (-39.52 – 719.21)
	Control	1032.78 (394.85)	1353.67 (331.73)	

5.4.2.1   AUCg cortisol

After adjusting for baseline scores the bootstrap estimate of the difference in AUCg cortisol between the treatment and control group at follow-up 1 was not significant (z= -0.33, p=0.74). The results are presented in Figure 28.

Figure 30: AUCg cortisol baseline to follow-up scores between the treatment and control group
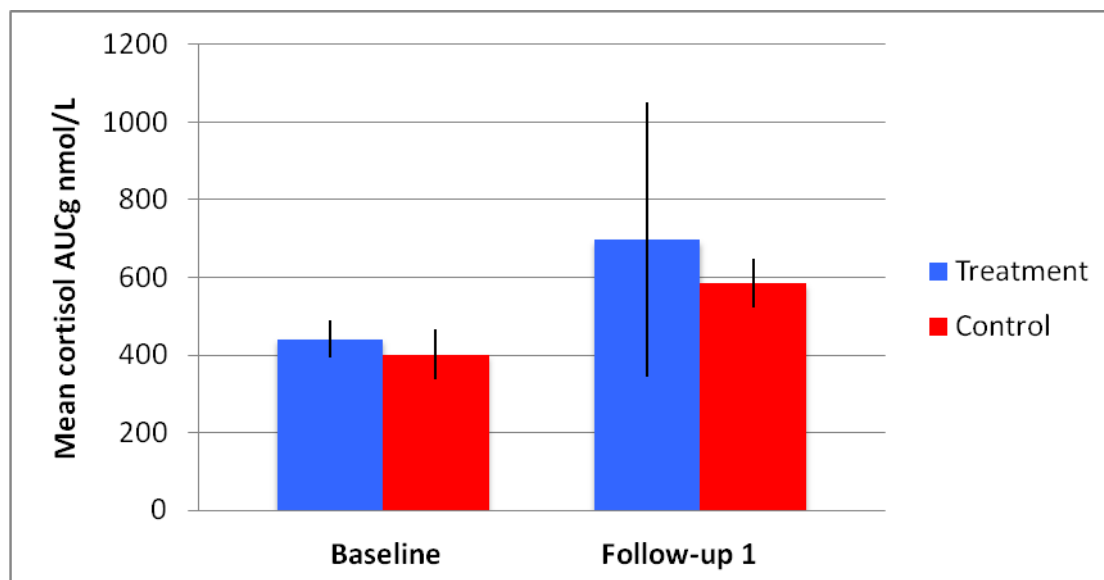
Figure 28: The mean AUCg cortisol values, determined by XLC-MS/MS, with standard error (SE) bars, of the treatment and control groups at baseline and follow-up 1 are presented in the bar chart.

5.4.2.2 AUCg cortisone

After adjusting for baseline scores the bootstrap estimate of the difference in AUCg cortisone between the treatment and control group at follow-up 1 was not significant (z=1.76, p=0.08). The results are presented in Figure 29.

Figure 31: AUCg cortisone baseline to follow-up 1 scores between the treatment and control group
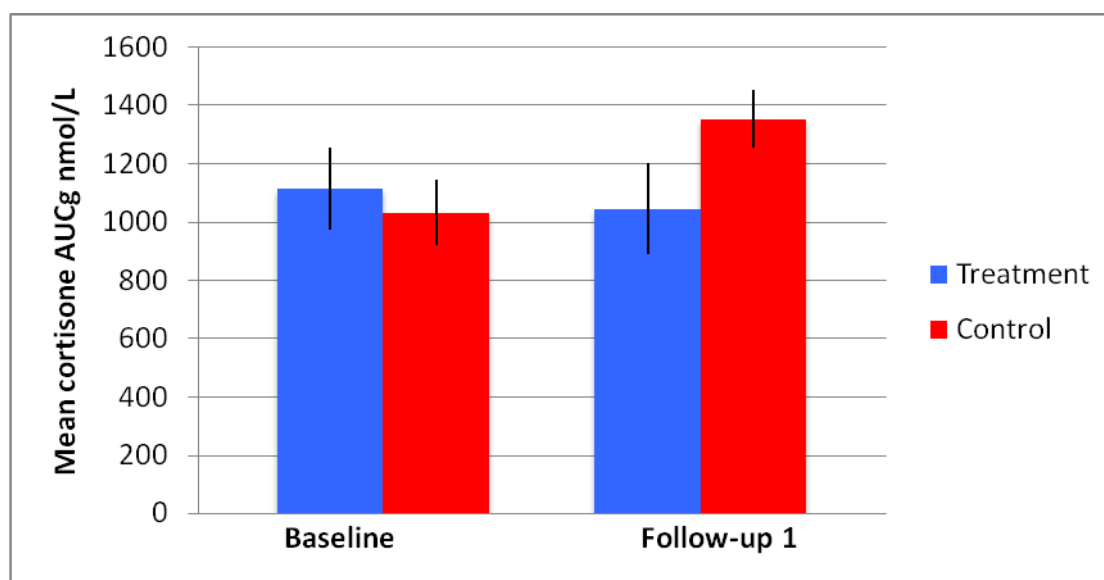
Figure 29: The mean AUCg cortisone values, determined by XLC-MS/MS, with SE bars, of the two groups at baseline and follow-up 1 are presented in the bar chart.

5.4.2.3 Treatment group participant's individual cortisol and cortisone change scores

Change scores for the six participants who completed the mindfulness training were calculated for AUCg cortisol (Baseline AUCg cortisol minus Follow-up time 1 AUCg cortisol) and AUCg cortisone (baseline AUCg cortisone minus Follow-up time 1 AUCg cortisone). These change scores are presented alongside the SAPASI, PSS, HADS and DLQI change scores in Table 42. Figure 32 includes the AUCg cortisol and cortisone change scores from the six treatment group participants. Figure 33 includes the SAPASI, PSS, HADS and DLQI change scores for the treatment participants and are presented here in order to compare the measures for all participants.

Table 42: Treatment group individual change scores (AUCg cortisol and AUCg cortisone, SAPASI, PSS, HADS and DLQI)

	105	114	136	149	168	174
AUCg Cortisol change score	-78.45	310.12	-1501.8	105.38	Cannot calculate	69.23
AUCg Cortisone change score	-154.27	582.15	27.83	-239.78	Cannot calculate	96.52
SAPASI change score	5.58	6.03	1.78	0.6	-0.23	0
PSS change score	8	-12	1	6	5	1
HADS change score	5	2	7	-1	0	0
DLQI change score	5	3	1	2	0	1
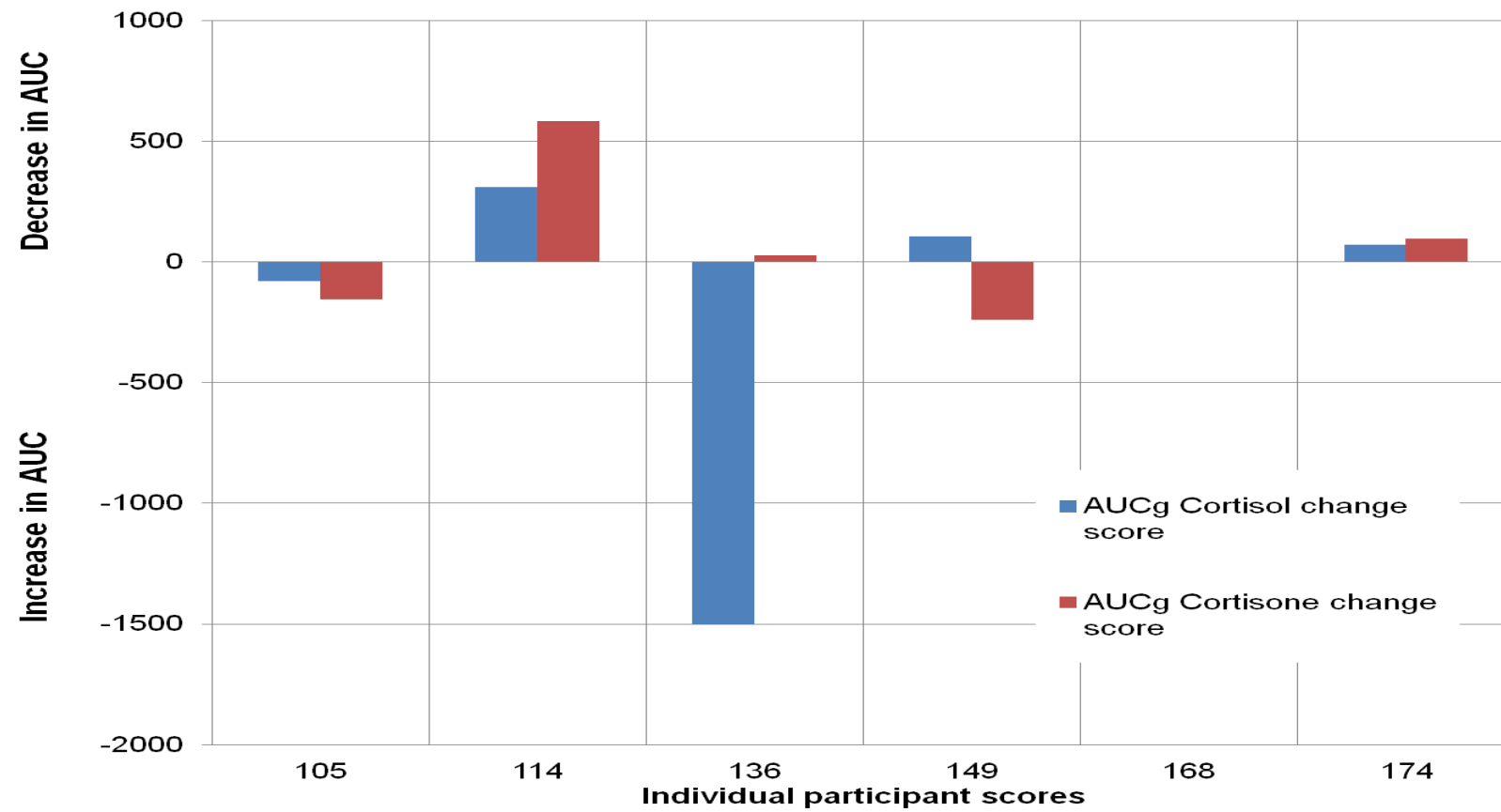
Figure 32: Individual participants AUCg cortisol and cortisone change scores
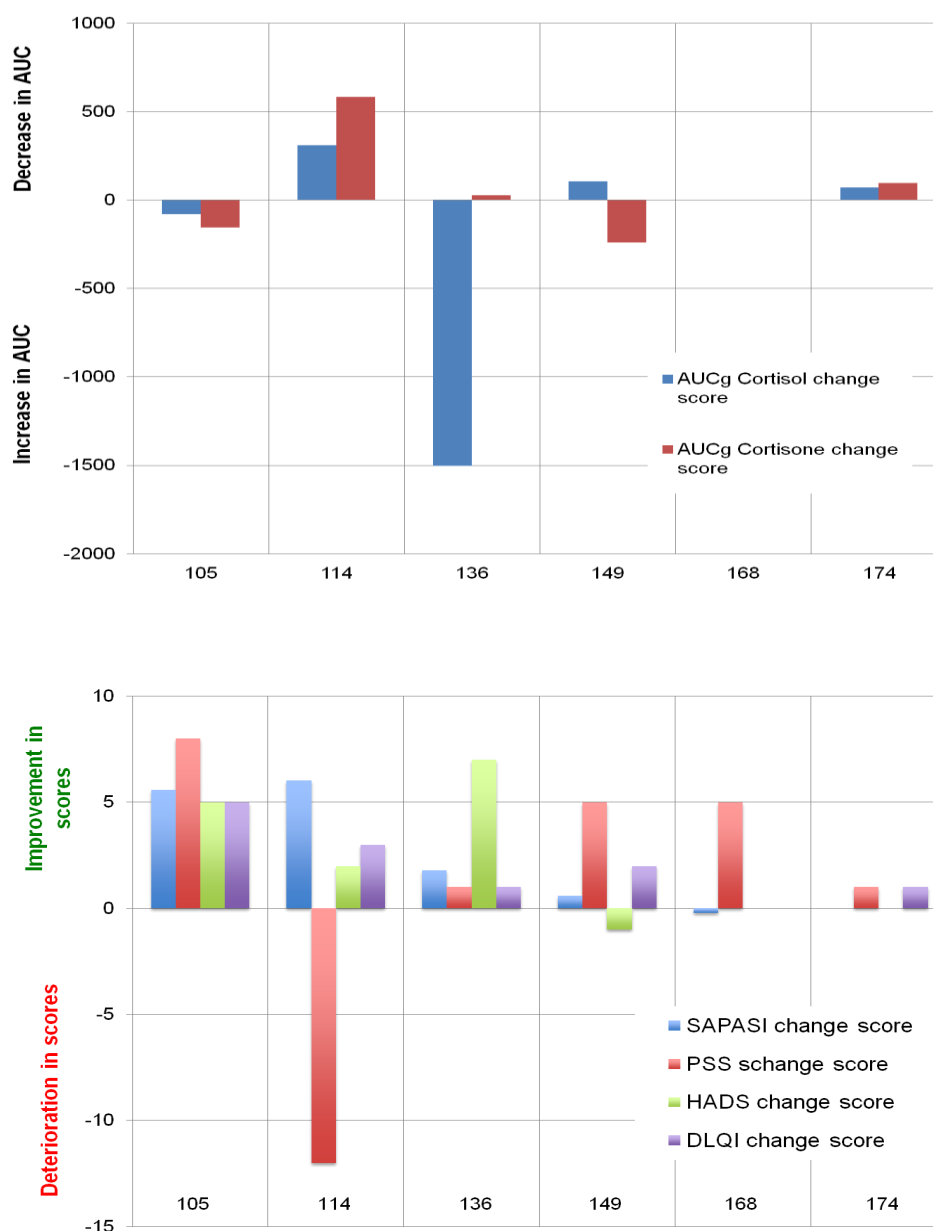
Figure 33: Treatment group participants change scores (Cortisol/Cortisone, SAPASI, PSS, HADS and DLQI)

The average change in AUCg cortisol from baseline to follow-up time 1 was -219.10 (and increase in AUCg size) while the average AUCg cortisone was 62.49 (slight decrease). Participant 105 demonstrates an improvement in all measures accompanied with a relatively small increase to both AUCg cortisol and cortisone. Participant 114 is marked by their relatively large decrease in PSS which is accompanied by a decrease in both AUCg cortisol and cortisone. Participant 136 reported improvements in all measures and a markedly large increase to AUCg cortisol but a small increase to AUCg cortisone. Participant 149 improved in all measures apart from HADS and was found to

have a decrease in AUCg cortisol but an increase in cortisone. Unfortunately the saliva swabs from participant 169 did not all produce a measureable amount so there is no AUCg cortisol/cortisone data for this participant. Finally, participant 174 experienced an improvement in PSS and DLQI but no change to SAPASI or HADS scores. These results were accompanied by a slight decrease in both AUCg cortisol and cortisone scores.

5.4.2.4   Summary

The secondary analysis, which examined whether the MBCT course led to any changes in overall CAR (AUCg) cortisol or cortisone, suggests that the intervention did not lead to any changes in these outcomes. Individual change scores demonstrated variation some participants experiencing increases, some decreases and some different changes between the AUCg cortisol and cortisone scores.

5.5 Supplementary analysis: ANCOVA (active and comparison groups)

To supplement the ANCOVA between the treatment and control group another ANCOVA was run to examine the difference in AUCg cortisol and cortisone between all participants who had completed the MBCT course (active group) to a non-randomised comparison group of participants who had not entered the MBCT intervention.

5.5.1 Pre-intervention comparison between active and comparison groups

As the active group was not randomised the active and comparison group's AUCg cortisol and cortisone scores were compared at the pre-intervention point to examine whether there were any differences between the groups before the active group entered the MBCT course. One member of the active group did not have a complete value set for their cortisol/cortisone scores and therefore could not be included in the analysis). These descriptive data are presented in Table 40.

Table 43: Active and comparison scores pre-intervention AUCg cortisol and cortisone outcomes

	Active n=13			Comparison n=10		
	N	Range	Mean (SD)	N	Range	Mean (SD)
AUCg Cortisol	13	22.20 – 750.68	549.07 (194.52)	10	136.28 – 817.58	485.52 (207.66)
AUCg Cortisone	13	158.78 – 1531.13	1262.81 (404.18)	10	638.33 – 1277.25	988.33 (221.29)

An independent t-test found no significant difference between the active and comparison groups on AUCg Cortisol (t=-0.90, p=0.38) or on AUCg Cortisone (t=0.50, p=0.62).

5.5.2 ANCOVA between the active and comparison group with AUCg cortisol and cortisone at post-intervention

An ANCOVA was run to test for difference between the active and comparison group on AUCg cortisol and cortisone post-intervention whilst controlling for the pre-intervention scores.

The ANCOVA was run in STATA with bootstrapping. The number of repetitions was set to 1000, the seed for AUCg Cortisol was set to 684 and the seed for AUCg Cortisone was set to 7200066. The pre/post intervention mean and standard deviations and the

difference between the groups' co-efficient are presented in Table 41. The results of the ANCOVA are then presented AUCg cortisol and cortisone below the table.

Table 44: ANCOVA comparison of AUCg cortisol and cortisone scores between the active and comparison group at post-intervention

		Pre-intervention N Mean (SD)	Post-intervention (N) Mean (SD)	The difference at Post-intervention controlling for Pre-intervention
AUCg Cortisol	Active	N=13 526.82 (202.79)	N=13 532.21 (494.08)	-66.64 (CI -394.78 – 261.50)
	Comparison	N=8 450.24 (216.80)	N=7 475.79 (169.52)	
AUCg Cortisone	Active	N=13 1254.03 (388.26)	N=13 1131.69 (335.68)	19.68 (CI -323.75 – 363.11)
	Comparison	N=8 963.46 (242.19)	N=7 1815.00 (293.19)	

5.5.2.1 AUCg cortisol

After adjusting for pre-intervention AUCg cortisol scores, the bootstrap estimate of difference between the active and comparison group was not significant (z=-0.40, p=0.69) indicating no reliable effects of the intervention. The results are presented in Figure 30.

Figure 34: AUCg cortisol scores pre-intervention to post-intervention between the active and comparison group
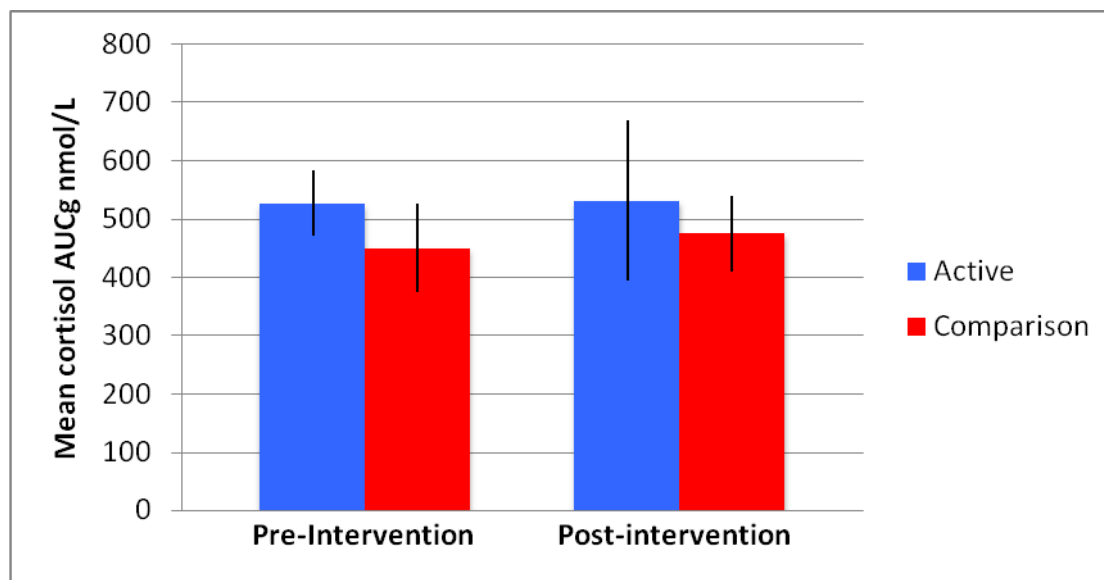
Figure 30: The mean AUCg cortisol values, determined by XLC-MS/MS, with SE bars, of the two groups at pre-intervention and post-intervention are presented in the bar chart.

5.5.2.2 AUCg cortisone

After adjusting for pre-intervention AUCg cortisone scores, the bootstrap estimate of difference between the active and comparison group was not significant (z=0.11, p=0.91). The results are presented in Figure 31.

Figure 35: AUCg cortisone scores pre-intervention to post-intervention between the active and comparison group
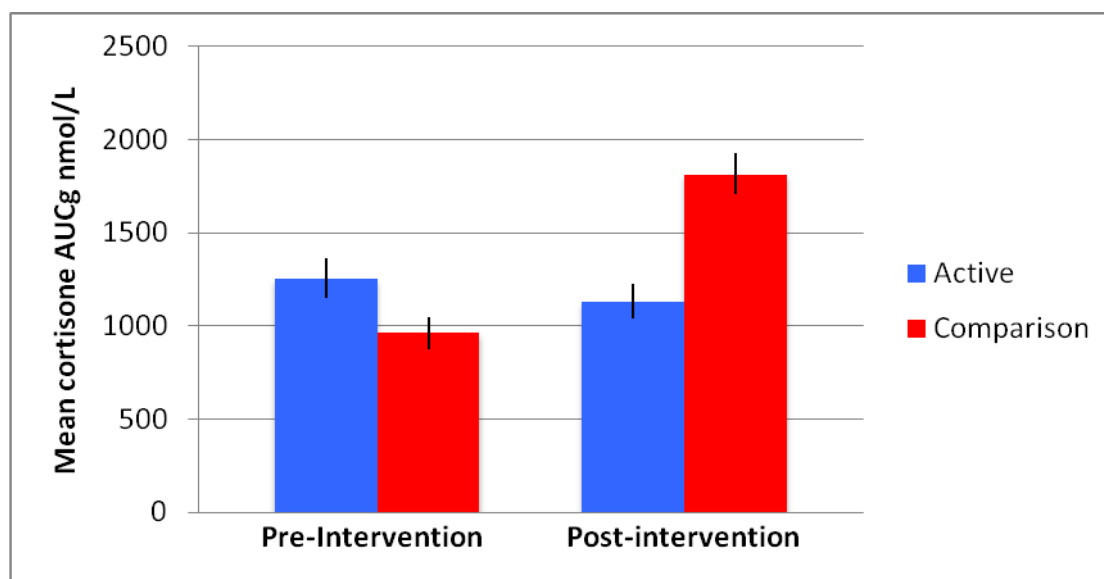
Figure 31: The mean AUCg cortisone values, determined by XLC-MS/MS, with SE bars, of the two groups at pre-intervention and post-intervention are presented in the bar chart.

5.5.2.3 Active group participant's individual cortisol and cortisone change scores

The AUCg cortisol and cortisone change scores for the 14 participants who completed the mindfulness training course are presented in table 45 and figure 36. The AUCg cortisol and cortisone change scores are also presented in figure 37 together with the SAPASI, PSS, HADS and DLQI change scores in order to examine the individual changes across all measures.

Table 45: Active group participants AUCg cortisol and cortisone individual change scores

	105	114	136	149	168	174	118	102	123	124	133	134	138	140
AUCg Cortisol	-78.46	310.12	-1501.8	105.38	259.8	69.225	766.32	-207.98	255.82	222.98	142.73	-63.52	-684.83	334.2
AUCg cortisone	-154.28	582.15	27.83	-239.78	1148.63	96.52	890.17	-282.9	-375.52	105.3	338.47	6.3	-1519.27	966.75
SAPASI change score	5.58	6.03	1.78	0.60	-0.23	0.00	5.00	-1.20	2.60	8.85	-1.20	1.12	1.00	0.80
PSS change score	8.00	-12.00	1.00	5.00	5.00	1.00	5.00	-16.00	1.00	8.00	4.00	7.00	10.00	-1.00
HADS change score	5.00	2.00	7.00	-1.00	0.00	0.00	8.00	1.00	4.00	17.00	5.00	1.00	10.00	2.00
DLQI change score	5.00	3.00	1.00	2.00	0.00	1.00	2.00	-2.00	3.00	12.00	3.00	3.00	1.00	2.00
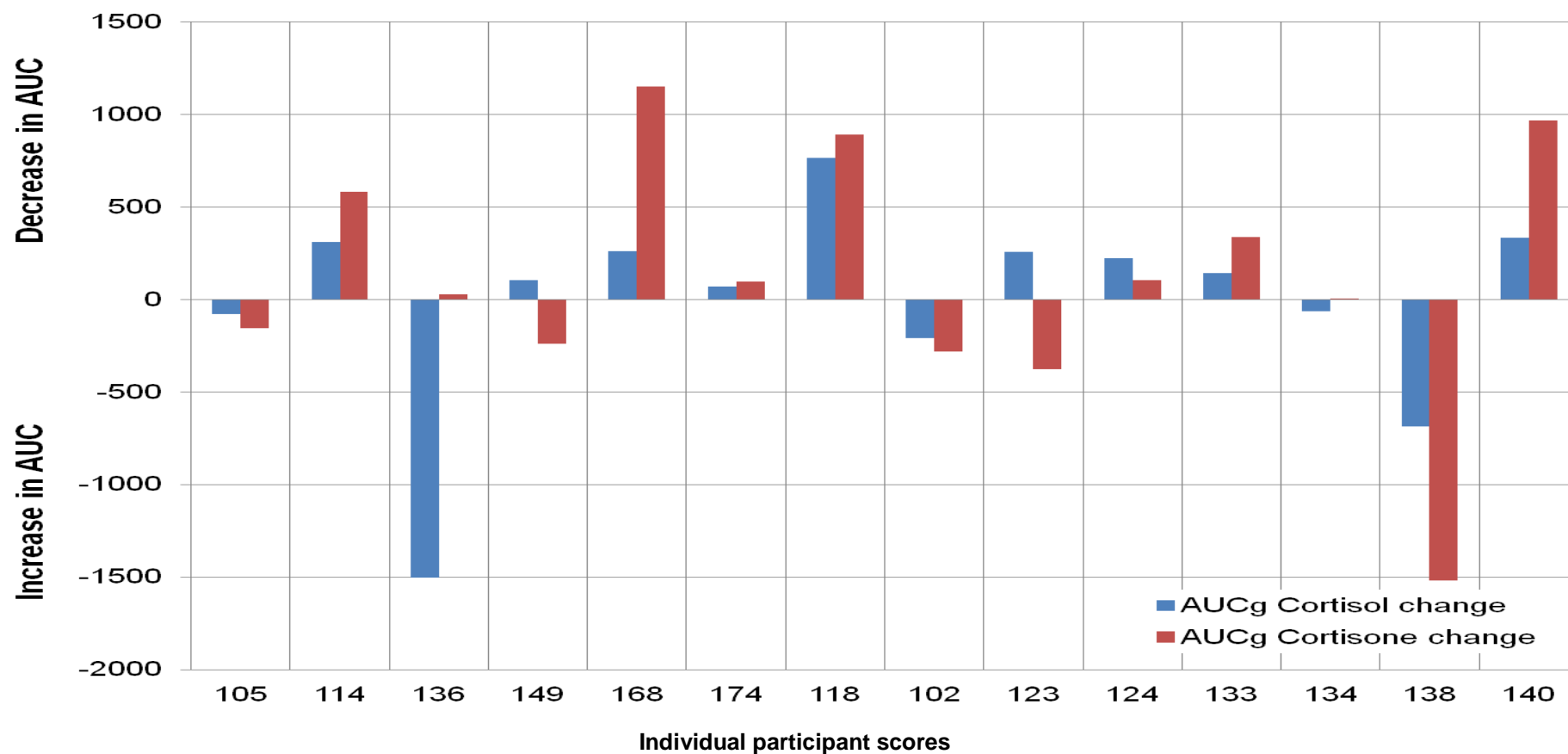
Figure 36: Active group participant individual cortisol and cortisone change scores
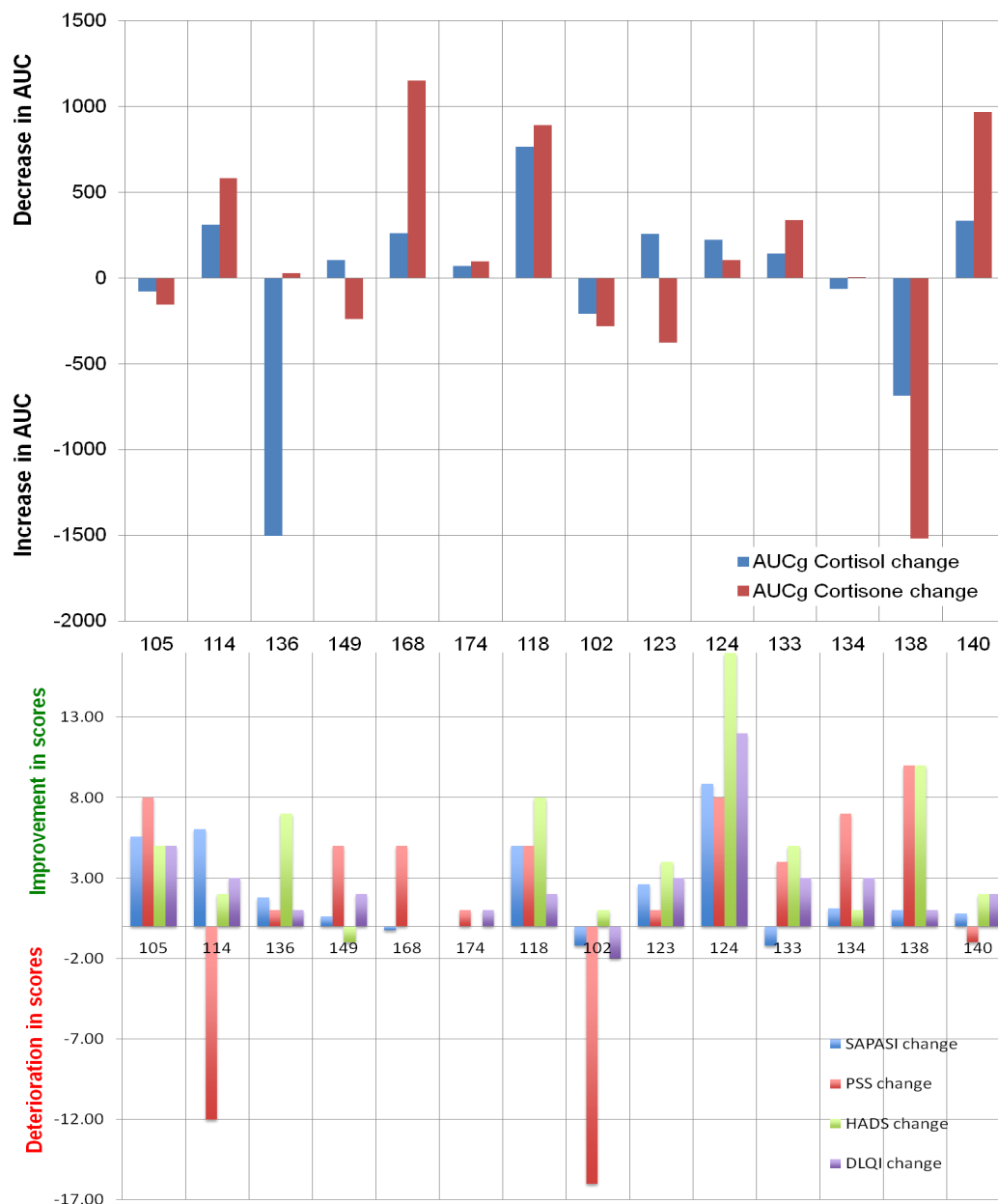
Figure 37: Active group participants' individual change scores (Cortisol, Cortisone, SAPASI. PSS, HADS and DLQI)

The average change in AUCg cortisol from pre to post MBCT training was -5.00 (very small increase) whilst the average change to AUCg cortisone was 113.60 (decrease). Seven out of the 14 participant who completed the mindfulness training demonstrate a decrease in both AUCg cortisol and cortisone and three participants experienced an increase. One participant was found to demonstrate a relatively large increase in AUCg cortisol combined with a small increase in AUCg cortisone. Another reported a small increase in cortisol but decrease in cortisone AUCg. Two members of this group were found to produce a decrease in cortisol but an increase in cortisone AUCg.

Of the seven participants (105,136,118,123,124,134,138) who appeared to improve on all four measurements (SAPASI, PSS, HADS and DLQI) three demonstrated an increase in both AUCg cortisol and cortisone, two a decrease, one a large increase in AUCg cortisol with a relatively small increase in cortisone, one a relatively equal decrease in cortisol and increase in cortisone and the final participant demonstrated a relatively minor decrease in AUCg cortisol and increase in cortisone.

5.5.3 Summary

This non-randomised group supplementary ANCOVA analyses supports the secondary ANCOVA findings that AUCg cortisol and cortisone did not change in participants as a result of participating in the MBCT course. The individual change scores demonstrate a lot of variation in ndividual change scores. Of those participants who appeared to improve on the SAPASI, PSS, HADS and DLQI some experienced increases and others decreases to their AUCg cortisol and cortisone scores.

5.6   Completers and non-completers

Due to high attrition from this study baseline scores from completers were compared to non-completers to examine if there were any systematic differences on cortisol and cortisone composite scores between these groups.

5.6.1   All study completers and non-completers

Differences between all those who completed the intervention (n=13) and those who did not (n=16), after removing the cases where AUCg cannot be calculated, at baseline, were examined with an Independent T-test and no significant differences were found between the groups on AUCg Cortisol (t=-.99, p=0.33) or AUCg Cortisone (t=-0.19, p=0.85).

5.6.2   Treatment group completers and non-completers

Differences between those who were allocated to the treatment group and either completed (n=6) or did not complete the intervention (n=7) after removing the cases where AUCg cannot be calculated, at baseline, were compared with an independent t-test and no significant differences were found on AUCg Cortisol (t=-1.14, p=0.28) or on AUCg Cortisone (t=-1.18, p=0.28).

5.6.3   Summary

No differences in cortisol or cortisone composite scores were found between any study completers or non-completers before the intervention began.

5.7 Chapter summary

As anticipated, measures of cortisol were closely correlated to measures of cortisone within this sample population but there was a lack of correlation between overall CAR (s1 and AUCg) and reactivity scores (AUCi and Dynamic Change). This may have been due to the combination of the positive and negative cortisol reactivity scores (AUCi). Perhaps the negative cortisol reactivity scores were caused by non-adherence to the study protocol. These non-adherent cases may have obfuscated the genuine CAR reactivity scores.

The study predicted that cortisol and cortisone CAR would be correlated with the physical severity of psoriasis and with participant's perceived stress scores, however these significant correlations were not found. There was however, a significant negative correlation with distress scores and a significant positive correlation with the measurement of current mindfulness ability (MAAS).

This chapter reported that overall cortisol or cortisone CAR (AUCg) scores did not change as a result of participating in the MBCT intervention. Chapter 4 reported how distress scores also did not change as a result of the intervention. These two negative findings are linked because distress scores and cortisol/cortisone response scores are significantly correlated.

There was a large amount of variation in the individual participant's change scores, four demonstrated quite large increases in AUCg and two report large decreases. Some were found to have an increase in AUCg cortisol and a decrease in AUCg cortisone.

6. Study phase III: Acceptability and adherence

Phase III was a sequential qualitative study aimed to help qualify the interpretation of the quantitative findings from phase I/II, with the participant's perspective. The initial research questions for this qualitative study were, "What are participants' experiences of the MBCT course?" and "What are the perceived benefits and the perceived barriers to participating in the MBCT course? The topic guide formulated to address this question and the subsequent analytical process was based on a template, informed by previous studies. These studies had examined the acceptability of mindfulness-based interventions within other populations such as clinical depression and anxiety (Finucane & Mercer, 2006), depression and epilepsy (Walker et al., 2010), health anxiety (Williams et al., 2011) and improving health and wellbeing in an urban youth population (Kerrigan et al., 2011).

In light of the high attrition experienced within phase I/II (see Chapter 4, section 4.1.3) the topic guide and analysis was expanded to answer an additional research question, "What individual differences are found in those participants who adhered to the MBCT intervention?" The aim being to identify individual factors common to those who maintained adherence and perceived the intervention as acceptable in order to inform future screening, which could tailor psychological adjunct interventions to those who are most likely to accept, adhere to and hopefully benefit most. The additional topics to answer this second question were based on the SR-CSM (Leventhal et al., 1984) a well established model within health psychology. The *a priori* categories and theory of the model were used as a template in the data collection and analysis stages. The data were compared to the template to see how much it could explain and what additional, novel categories emerged.

6.1 Description of the participants

Participants who had completed the eight-week mindfulness course (n=14) were invited to attend an interview to discuss the acceptability of the intervention. Eleven members agreed to attend the interviews, one person become hospitalised with a co-morbid illness and two felt they could not attend as they were either too busy or had moved further away. Two of these eleven failed to turn up to the interviews and due to time constraints no more interviews could be arranged. The baseline descriptive data for these 9 participants are presented in Table 42.

Table 46: Baseline descriptive scores for study phase III participants

Demographic data	Mean (SD) or % (n)
Age	45.00 (13.30)
Years living with Psoriasis	23.00 (13.14)
Female	67% (n=6)
Without a long term partner	11% (n=1)
With 1st or 2nd degree relative with psoriasis	56% (n=5)
Using topical treatments	76% (n=6)
Physical, Psychological and Quality of Life	
SAPASI	7.18 (5.77)
PSS	21.44 (7.37)
HADS	14.89 (9.21)
DLQI	9.44 (8.86)
Process components	
Attendance	6.23 (1.19)
Practice hours per week during course	2.42 (1.11)
Practice hours per week after course	2.00 (1.07)

6.2   Overarching themes

From the process of familiarisation, indexing, charting, mapping and synthesising (see Chapter 3, section 3.8.4) four overarching themes emerged from the data; these were process issues, outcomes, post-course issues and individual differences. These themes and their respective subthemes are presented in Table 43 and each theme will be described sequentially.

Table 47: Qualitative themes and subthemes

Theme	Sub-theme
PROCESS ISSUES	Timing structure
	Group format
	Content
	Formal practice
	Informal practice
OUTCOMES	Physical
	Emotional
	Cognitive
	Behavioural
POST-COURSE ISSUES	Future implementation and support
INDIVIDUAL DIFFERENCES	Illness beliefs
	Attitudes

6.3   Theme 1: Process Issues

Theme 1 is concerned with the participants' experience of the process of learning mindfulness training. The MBCT protocol is outlined in Chapter 3, section 3.2.

6.3.1   Timing structure of the course

There was a variation in participant's speed of learning the course material, some wanted the course to be taught in smaller sessions more frequently whereas others wanted the course to be taught in longer sessions but less frequently. The individual differences in the speed of processing information are a common challenge in all group training environments (Gettinger, 1984).

The information processing theory (Miller, 1956) suggests that people tend to 'chunk' information into semantically related categories, which forms a schema and aids recall. The volume of information contained within one 'chunk' and the semantic meaning attached to it varies between individuals, dependent upon personal and social influences. If some participants held more established schemas understanding mindfulness related topics this may have allowed them faster processing of congruent course material (Miller, 1956).

Some participants felt the two-hour long session delivery format was an acceptable length of time:

> *"I think 2 hours is good anything less I don't think would have been as useful"* Pt 140.

While others felt that too much information was presented in the two-hour session and would have preferred more frequent 'bite-size' sessions:

> *"I would have probably liked two sessions a week rather than one session…If it was bite size portions like you say it might have been better for me to adapt more"* Pt 149.

These differences were echoed when participants discussed the acceptability of the eight consecutive week format. Some found the time scale suitable:

> *"You couldn't actually have done it in less than eight weeks. Yeah I think that it's the right length of course for what we did."* Pt 134.

One participant found the course pace too intensive:

"It's quite intensive, I think it may have benefitted from maybe been broken up…I think if you did it in smaller chunks then allow people to go practise with that and then have another small like chunk…Why not make it err five weeks and then do one session every couple of months...have a drop in workshop." Pt 168

However, another would have preferred the delivery format to be more intensive:

"I would have preferred a more intensive course…yeah personally I would have preferred a shorter blast." Pt 123.

6.3.2 Group format

The MBCT training was delivered in groups of six to eight people. Overall, the social learning resulting from the group format was perceived to be a positive training delivery method. However, participants also provided constructive feedback for course facilitator training, regarding individual differences in learning and information processing styles. The influence of the social context upon different individuals can help or hinder learning (Bandura, 1989). These challenges of group format delivery need to be met by the competence of the group's facilitator in order to effectively deliver mindfulness training. Some participants found the social element of the learning environment helpful as it fostered vicarious learning:

"I would hear a question and think 'oh I don't know if that applies to me' but then you would be talking to the next person to us and they would come up with something that I would not have thought about." Pt 149

And the group format diluted one participants' perceived performance-related stress:

"If I had of been sat there on me own I might have been more conscious of not feeling something and I might have been a bit more uncomfortable and uneasy about it." Pt 105

This reduction of individual-focussed attention may have been helpful for some participants' learning styles; however, some participants reported how the group format allowed them to 'hide' within the group. This may have reduced the participants' chance to *feedback*, which is a learning method emphasised in the mindfulness programme:

"So in a larger group you can hide more." Pt 149

Other participants suggested they did not feedback or question some elements because they felt inhibited by the group format:

> *"There were probably some questions that I would have asked at the time but I didn't feel comfortable…"* Pt 124

A few participants appraised the behaviour of some of the group members as 'disruptive' and were irritated and distracted:

> *"They* (other members of the group) *were quite bad mannered really you know arriving late…but that sort of thing was disruptive when you were trying to relax or meditate and then someone would come strolling in."* Pt 105

The group format, however, was reported to provide other beneficial non-therapeutic effects for people living with psoriasis. The non-therapeutic benefits of participating in a group intervention have long been recognised (Omer & London, 1989):

> *"Just hearing people with psoriasis talk I have always thought that is a huge help… it's a massive help because you feel so alienated and you just feel completely on your own so just being with other people with psoriasis can help you know."* Pt 105

6.3.3 Course content

The mindfulness training was predominantly delivered through experiential learning where the facilitator led the participants in trying out the formal practices and new methods of appraising daily experiences. Individual differences emerged across the participants in their learning styles, which a facilitator may have to accommodate within the training programme. For example, Kolb (1984) classifies a person demonstrating a need for concrete theory over experiential learning as an 'assimilator,' as someone who prefers to 'think' rather than 'act.' Kolb's meshing hypothesis suggests that teaching styles should match these learning styles, however, there is a paucity of supporting evidence for this hypothesis (Mayer, 2011, Pashler et al., 2008). For example group facilitators may need to offer some concrete learning (theory/evidence) to help support 'assimilator'-type learning style participants to learn the mindfulness skills. Some participants found the experiential learning style insufficient and expected more concrete content:

> *"A lot of it was saying' just do it and just feel it' but to me I am just thinking 'well what is the theory behind' and I was doing that all the time."* Pt 168

Whereas other participants reported how experiential teaching resulted in effective learning:

> "The body scan I really liked that erm and I think that I have become more mindful of my body." Pt 124

When describing the course information there was variation in participants perceived ability to understand and use the information effectively. This may be related to information processing styles, which may have reduced self-efficacy beliefs. For example, if a participant had not been able to process the information effectively because the facilitators teaching style did not support their learning style, then they may have felt that they were incapable of learning mindfulness. These reflections again highlight a need to make sure course facilitators are trained to deliver teaching in an explicit framework to aid information processing, called scaffolding in Vygotskian learning terms (Vygotsky, 1976) and to effectively support the range in ability of group members as well as their information processing speed and capacity. Some participants reported the intellectual pitch as ideal:

> "The structure was spot on, it flowed, it built on what had gone before explained there was good interplay between theory and practice." Pt 124

> "When you sort of look back at it particularly you sort of realise that the things were introduced gradually, we would sort of have something new pretty well every week. Well we did have something new every week but I was thinking of the practical things not just the other side and I think it was handled very well it's a very good course" Pt 134

While some participants explained how the intellectual level of the course content was sometimes 'challenging':

> "The information I thought was very good on the sheets and it was quite I think for me, it was quite intellectually challenging at times. " Pt 140

> "At first it kind of a bit mind-blowing sort of thing. It's like 'woah' (laughs) all this information going in. It's great information, that is definite but it seemed like a lot all at once." Pt 149

6.3.4 Formal practice

Participants practised the formal practices (e.g. body scan and sitting meditation) during each group session, then participants were offered the opportunity to feedback any difficulties or benefits they experienced. The group facilitator offered practical advice

during the group sessions to help overcome some of the barriers such as alternative sitting postures to relieve discomfort and simple techniques such as holding an arm in the air to help with falling asleep during the practices. The facilitator could also offer feedback to improve self-regulation capabilities by drawing attention to an individual's small accomplishments thus improving self-efficacy beliefs, which may help to manage future obstacles (Bandura, 1989). The barriers which participants in this study reported were all documented as 'common barriers' in one MBCT training book (Segal et al., 2002). These barriers included concern about 'feeling nothing' or mind wandering:

"I still have a bit of trouble like when she'd say concentrate on the toes of your left feet and I couldn't feel anything at all (laughs)." Pt 134

"The three stage breathing my mind can wonder before I even get up to the breathing stage." Pt 102

Some participants identified difficulties in staying awake or experiencing physical discomfort, whilst remaining still for the longer meditations:

"By the time you got to your elbow you might just nod off because you are not thinking about anything else that is going on but apparently you are not supposed to do that." Pt 168

"The sitting meditation and breathing I find it really, really uncomfortable I haven't yet found a comfortable position." Pt 102

Participants were instructed to practise at home between the group sessions as this practice during the acquisition stage assimilates the new skills into pre-existing schema and neural networks allowing the skill, via reinforcement and neuronal plasticity, to become semi-automatic and less effortful.

The reported barriers to performing these home practices highlight how learning takes place within a social environment external to that of the course. Participants found it hard to remove themselves from their social environment to practise:

"Taking yourself away from other people in your house and you know it's a little bit antisocial you know 'oh I've got to go and do my mindfulness now.'" Pt 140

Time spent adhering to biological treatment regimes was perceived as necessary but one female participant described making time for her mindfulness practice as self-indulgent and appeared incongruous with her beliefs about her social role and

entitlements. It has been identified that women can often feel distress when partaking in activities which dedicate time to themselves due to cognitive dissonance between her perceived role as caregiver and actions such as individualised self-improvement (Toner, 1994). Mindfulness may raise a conflict for women who feel that dedicating time to practicing and attending mindfulness groups is selfish. This raises the issue of whether mindfulness practice was perceived as a viable treatment option or rather as an indulgent pastime:

> *"It does seem to be a bit self centred at times I did feel that as well that everything was about me."* Pt 140

The majority of participants encountered difficulties with self-regulation and found it challenging to schedule their time to fit the practice in. Social cognition theory suggests that increasing an individual's control belief can improve performance, which will, through self-regulation, lead to reciprocal improvements to control beliefs. Trainers could tailor specific small goals (e.g. using the short the three stage breathing space everyday one week) to individuals who are struggling, which may increase their self-efficacy and control beliefs:

> *"I was doing it really well for the first couple of days and then I was like 'oh I'll just miss today' and then 'oh I'll do it tomorrow' and then the end of the weeks comes and 'erm I did two!'"* Pt 165

The practice goal needed to be manageable by the individual. Rather than practising with the aim to reach a distal, unspecific goal of improved wellbeing, the facilitator might need to reinforce the goal target with 'nudges' or tailor smaller goals to match the self-efficacy beliefs of an individual (Bandura, 1989). In the intervening days between the group sessions motivation declines and practise appeared to dwindle:

> *"I was sort of motivated more when I knew I was coming on the Wednesday. To be honest with you. I would sort of think by Sunday night 'oh I haven't really done very much' so you know that would motivate me."* Pt 140

Persevering with skill practice can reinforce the neural network connection and consequently transferred the skills from labour intensive thinking to a more automatic expertise (Marteau et al., 2011). One participant described how scheduling and performing the practices became easier during the course:

> *"It certainly felt like a drag at the beginning and I hold up my hand and say I didn't do as much as I should have done and then it got more still probably as*

much as I should have done but it built up gradually and um now I am really quite happy about it." Pt 134

6.3.5 Informal practice

The informal practice relates to the integration of mindfulness skills into daily life rather than the dedicated time for following the formal practices on the CD. The author of the original MBSR eight-week course argued that while the informal practice is helpful it must be combined with formal practice otherwise it "loses much of its ability to stabilize the mind" (Kabat-Zinn, 1990).

Several participants became aware during the interview that they had been integrating informal mindfulness practice into their lives and that they enjoyed this piecemeal integration of the skills as opposed to the structured formal practice. By explaining how they used the informal skills participants appeared to reduce dissonance between their goal to 'be mindful' and their lack of personal control to overcome the formal practice barriers. The use of informal practice may therefore make participants feel like they are practising the skills but as Kabat-Zinn (1990) this cannot replace the hard work of formal practice:

> *"I was thinking more of the sort of the practices on the CD …I do walk the dog everyday and I do then tend to think of the mindfulness so perhaps I am being a bit harsh on myself"* Pt 140.

> *"I can do washing up you know I can think about so I can do it like when I am in the shower. I can do it while I am doing something but I'd rather do it that way, right its 3 o'clock I am going to do some mindfulness because its not going to work like that for me"* Pt 102.

The reports of using informal mindfulness skills effectively were more common in the members of the group who were also using the formal practices, which echoed Kabat-Zinn's (1990) assertion that informal practice only becomes effective when combined with the formal practice elements. These participants demonstrated being more aware and remaining in the present moment when using the informal practices:

> *"I noticed lips tingling with the toothpaste and things that I had never noticed and obviously things are happening all the time you are just not as tuned into your body as perhaps you should be."* Pt 105

6.3.6 Process theme summary

The majority of the sub-themes to the 'Process Theme' were documented in previous studies exploring the acceptability of a mindfulness intervention (Finucane & Mercer, 2006, Walker et al., 2010, Kerrigan et al., 2011). A novel finding from this study was the variation in participants learning styles and how these styles combined with *a priori* knowledge of mindfulness might impact upon an individuals' rate of information processing. The results also suggest recommendations for MBCT group facilitators in order to increase self-efficacy and control beliefs in group participants. Improving these beliefs may help participants overcome practice barriers and better adhere to the MBCT protocol. The improved adherence may consequently improve the outcomes experienced by participants in MBCT courses.

6.4 Theme 2: Outcomes

Previous research, into mindfulness acceptability, explored participants' perceptions on the value and usefulness of the intervention and included comparisons between emotional regulatory abilities before and after the course. This study found the outcomes to fall into four categories perceived physical, cognitive, emotional and behavioural outcomes. These outcomes were perceived to improve, stay the same or deteriorate as a result of the training programme.

6.4.1 Perceived physical effects

There was no uniform agreement across the group relating mindfulness to symptoms of psoriasis. Some participants noticed objective improvements in the physical symptoms of their psoriasis:

> *"Well yeah I do actually think my psoriasis is better objectively I think my psoriasis is better since doing the mindfulness."* Pt 124

Whilst others reported no change in the appearance of their psoriasis but did notice a change in their reactions to their condition:

> *"The actual psoriasis I would say is much the same but I have noticed that I am not getting as much discomfort from it."* Pt 134

The ability to better control reactions to psoriasis might contribute to the improved sleep and greater energy, which some participants reported. This improvement in sleep, fatigue and energy, was not quantitatively measured in this study but these symptoms have been previously associated with mindfulness training in non-psoriasis populations (Carlson & Garland, 2005, Shapiro & Carlson, 2009, Howell *et al.*, 2008):

> *"I'm more energised within myself so, but I am also more healthily tired"* Pt 124.

> *"I am sleeping better because it* (the psoriasis) *disturbed me a lot at night"* Pt 134

Another physical change noticed by one participant was a reduction in sighing. Although this habit change was not explored any further in the interviews, sighing has previously been hypothesised as a method to relieve tension (Wilhelm et al., 2001) and return the body to homeostasis. Less sighing could indicate a reduction in the number of times the body has entered a state of arousal which needed to be 're-set' by the physical reflex of sighing:

"I used to sigh a lot…but I don't seem to do it anymore, why I don't know but it's only since I have been doing the course." Pt 149.

6.4.2 Perceived emotional effects

Participants often reported how the MBCT has made them feel 'calm', which might be the participants' emotional interpretation of the physical reduction in arousal. Calm is the linguistic antonym to anxiety and a reduction in anxious and stressed emotional states was one of the aims of the mindfulness intervention:

"I think it just calms you down its just sort of brings you back to reality" Pt 140

"The biggest thing is that I do feel calmer" Pt 134.

Participants reported an increase in confidence and sociability, which might suggest an improvement in perceived self-efficacy in dealing with social interactions. This may be an important mechanism as previous research has found that people living with psoriasis experience poor self-esteem and social isolation (Fortune et al, 2005):

"I have become more confident" Pt 124

"I have noticed that definitely since I been doing this I have just felt a lot more at ease just being not it's not my friends just with people that I don't know…and I think I don't know it's not one of the practices but I felt a lot more sociable" Pt 102.

One of the objectives of the mindfulness course was to become aware of automatic reactions and gain more cognitive control over responses. Participants mentioned a change in their emotional reactivity from uncontrolled to controlled responses:

"I spilled the tea… and usually I would have let out an expletive and you know I would have immediately accelerated into heightened annoyance by the time I kind of was ok before I even got to that point …I think mindfulness has given me a time delay in the sense that I don't react the reaction is put on pause a bit of, is delayed sufficiently to not react… and I want that because I think I react more I think that I am a reactor I have reacted" Pt 124.

Feelings of control are negatively correlated with perceived stress (Cohen, 1978, Lazarus, 1966), which could suggest that increased feelings of control may reduce feelings of stress. One participant echoed an overall increase in feelings of control:

"I was more in control I felt a lot more in control" Pt 105

The practice of approaching negative thoughts in order to foster awareness and an attitude of acceptance is a key component of the training. One participant reported experiencing distress when trying to move towards the negative. A fear of negative thoughts is indicative of anxiety therefore people with current high levels of anxiety may not find the course suitable. Practitioners encourage delivering mindfulness during periods of remission from clinical anxiety and depression rather than during an active period because of concerns that mindfulness practices may overload the restricted capacity of someone experiencing clinical symptoms (Hayes et al., 2004, Barnhofer et al., 2009):

> *"…Focussing on what stresses us so focus on the negative emotion. That I couldn't do I tried but it got me completely freaked out, panicked myself stupid and felt awful for the next couple of days"* Pt 165.

6.4.3 Perceived cognitive outcomes

Participants described a change in the way they thought as a result of the course rather than a change in the content of their thoughts. They reported a change in their cognitive awareness of the present moment experience both of the external world and of their internal processes. Increased present moment awareness facilitates self-regulation and improves an individual's ability to cope as a result of having a fuller understanding of what is currently present (Baer, 2003). Present moment awareness of internal and external states also facilitates greater mastery over on-line processing of information without engaging in counterproductive ruminative thinking patterns (Wells, 2002):

> *"Now if I take the dog for a walk ...I try not to think of sort of everything else I have got to do I try and think of 'oh those leaves have turned colour, different colour and you know those berries there' you know which really I wasn't very good at before"* Pt 140

> *"It made me really, really aware of how stressed I was and how disconnected I am from my body"* Pt 124.

Participants reported using meta-cognitive skills such as the awareness of an attention shift and to differentiate between thoughts and facts:

> *"I think the thing that its taught me to do more than anything is you never really realise that you very rarely think in the present at least I didn't until this course you don't concentrate on what you are doing you either are mulling over in my*

case things I have done wrong or perceived to have done wrong in the past" Pt 134.

"I think it's the little things you need to focus on what is actually real or what your mind has blown into a 'what if' situation." Pt 165

These changes in the way participants were thinking were reported to help develop an acceptance of their psoriasis and reduce the associated levels of worry:

"I can deal with it (psoriasis) *in a way in like putting topical steroids on in that I can deal with it that way but I can also change the way I think now"*

"I can't stop it from being active but I think I can change the way I feel" Pt 102.

"I sort of think, well I can't change that and put that to one side and not sort of worrying about the things that I cannot change" Pt 105.

6.4.4 Perceived behavioural outcomes

Participants reported that the physical symptom of 'itch' and its consequent 'scratching' behaviour has a serious negative consequence upon their lives:

"When I first really started looking for treatment for psoriasis it was because in my work I was scratching… so the itching …it's the one place where psoriasis really threatens me professionally." Pt.124

An improvement in managing this symptom could potentially contribute to a rise in an individual's overall QoL. One participant noticed that their increase in cognitive control had allowed them more behavioural control to respond to the symptom of 'itch' rather than just reacting:

"(The teacher) *said something along the lines of "sometimes we react and sometimes it is better not to act now" … it really made sense to me that when I am scratching I am reacting in a way by scratching and itching I am reacting by itching and I have worked really, really hard at allowing you know going to meet the itch."* Pt 124.

One of the perceived physical effects of the course was an improvement in energy levels. This perceived energy fostered a belief that participants could achieve more and they consequently reported improved perceived self-efficacy in completing behavioural tasks such as the housework:

"I felt more energised, more positive and I was achieving a lot more. Sort of housework wise and things like me general run of the mill things that I tend to put off." Pt 105

6.4.5 Outcome theme summary

Participants reported experiencing many of the main mindfulness course aims (awareness and acceptance). Some participants reported changes in the way they interpret stimuli and in how they react emotionally and respond behaviourally to them. The only negative outcome was increased stress when approaching avoidant stimuli but this was only recorded by one participant who may have been clinically anxious.

The changes in sleep, fatigue and energy appeared novel and to warrant further examination and this theme was iteratively fed back into the quantitative study, which re-examined whether participants perceived their psoriasis to cause them sleep/fatigue difficulties.

6.5 Theme 3: Beliefs regarding the post-course future

Participants were interviewed during the first month after finishing the mindfulness course. They expressed a belief that the effects of the training may become more apparent with more practise in the future and presented intentions of continuing with their mindfulness practice:

> *"I am just not quite fully there yet and that's why I think it's something you have to work on and practising"* Pt 102

The skill set was perceived to be a "life-long tool" rather than a temporary fix:

> "*I think almost like a lifetime really of something that you have just got to keep at if you want it to be of any use to you,*" Pt 140

The challenge of translating behavioural intention into behavioural action is a constant challenge in health psychology and there was awareness among participants that their intentions may not necessarily translate to a "life-long" behavioural change:

> *"I think leaving people on their own to leave it I think they got lots of good intentions but it wouldn't surprise me if a lot just fell away."* Pt 168

There appeared to be a willingness to maintain the practice and a request for reminders and 'top-up groups.' These suggestions were similar to public health 'nudge' techniques, which are brief interventions distributed across a variety of domains such as in financial, social and occupational sectors to improve the translation of an individual's intentions into behaviours, once the individual has a pre-existing motivation (Thaler & Sunstein, 2008):

> *"I mean whether or not you could sort of do group session at a GP or at a health centre… somewhere locally or you know just somewhere in communities… that you could go to as and when you had time and when you need it…"* Pt 105.

> *"I suppose the only other tip I might give is say if* (the facilitator) *contacted people periodically or give people a nudge by email just like 'hope you are getting along ok' that might actually help people to think, 'oh I have lapsed a bit' and keep up with it"* Pt 168.

6.5.1 Post-course theme summary

A central component of health psychology research focuses on health behaviour change and these models and strategies may be important in realising participants' intentions to continue with mindfulness practice.

6.6 Theme 4: Individual Differences

Biomedical interventions for psoriasis vary in their acceptability both in terms of physical efficacy (skin clearance) and usability (side-effects). This variation in acceptability also exists across psychological interventions. Study phase I/II demonstrated a 48% attrition rate in the people recruited to join the mindfulness groups (Chapter 4, section 4.1.3). The non-completers may have perceived the MBCT intervention as an unacceptable adjunct therapy. By interviewing participants who adhered to the eight-week mindfulness training this study aimed to generate a profile of people who found the groups acceptable. With a future aim of tailoring psychological interventions to specific populations identified through a screening process, rather than trying "one fits all" delivery approach. This tailoring may improve adherence and outcomes achieved through psychological interventions.

6.6.1 Illness beliefs

The SR-CSM (Leventhal et al., 1984) was used as a template to explore the emergent themes. The SR-CSM includes eight representations, which people hold of their illness. These representations can affect future information processes (e.g. attentional biases) and mediate the response to illness in terms of psychological adjustment, behavioural actions and physical functioning. The data mapped well onto this model and five of the seven illness representations emerged in accordance with the SR-CSM.

During the iterative analysis a typology of 'efficacy evaluation' emerged from the data. Participants aligned into three discrete dimensions based on their beliefs as to how effective the intervention had been for them. Two participants were identified as holding an evaluation of 'weak' efficacy:

> *"So I can't say that there has been any improvement while I have been on the course or anything like that. Not for me anyway."* Pt 149

Four participants reported 'moderate' efficacy:

> *"Some parts I think have been useful um and others less so but I think that's sort of same with anything you go for."* Pt 165

Three participants reported 'strong' efficacy:

> *"I think it was one of the best courses I have ever done. I think in terms of what I got from the course for myself erm around managing stress and my general sense of well being."* Pt 124

Three illness beliefs (SR-CSM) were consistent across all three typologies whereas two beliefs diverged across the dimensions.

6.6.1.1 Convergent illness beliefs

All the participants displayed similar illness beliefs towards the stress-psoriasis causal/trigger link, personal control and treatment control.

6.6.1.1.1 Causal beliefs

Previous research found 60% of people with psoriasis believe stress is one cause for their condition (Fortune et al, 1998). The terms 'cause' and 'trigger' appeared to be used interchangeably within this population, suggesting some confusion regarding whether stress causes or exacerbated psoriasis:

> *"I know in my case that it* (the cause) *was actually stress and after a reorganisation at college and then some family difficulties."* Pt 134.

> *"I definitely think stress induces psoriasis and I practically see it, the more stressed I get you can just see it coming out."* Pt 165

This possible 'cause/trigger' confusion became still further convoluted when one participant differentiated between different types of stress causing different forms of psoriasis. This unique distinction emerged as a result of the interview process, "I have never thought about it before…" suggesting that this cognitive assumption may not have been immediately accessible to the participant:

> *"I wouldn't say any* (types of stress) *affect any of them differently. Actually no that's not right I think if I had a really bad throat infection I think I would probably develop the Guttate where it would go absolutely everywhere like the rain drops effect whereas if it was just something stressful it would appear in certain patches like on my legs on my ribs at the front at the front of my torso and just a bit on the arms and the arm pits so actually yeah it does go in different places, I have never thought about it before but yeah it does, it does."* Pt 102.

Participants also made reference to both genetic and inflammatory causal agents, which suggested that participants in this study have some, albeit incomplete knowledge of psoriasis aetiology:

> *"I mean I know it was hereditary … I also know that either a stress or an infection bring it out and I know in my case that it was actually stress."* Pt 134

6.6.1.1.2 Perceived personal control

The data suggested that participants believed they had a lack of personal control over their psoriasis. Perceived control is one of the core constructs found across self-regulation theories of emotion and health to specifically influence whether an individual perceives an illness to cause them stress (Cohen, 1978, Lazarus, 1966). Theoretically, participants perceive their condition as stressful unless they also have adequate resources to cope with the uncontrollability of their psoriasis. There was a strong sense that participants perceived psoriasis as uncontrollable, unpredictable and difficult to manage:

> *"It's worrying that it's going to get worse and you are not going to be able to control it"* Pt 102

> Interviewer: 'What is difficult about living with the condition?'
> *"I think the unpredictability of it really"* Pt 140

> *"I find that it is a very frustrating thing because you'll have say an ointment which will work quite well and then it will stop working and then something else will be tried and that might work quite well and then you'll go back to the original one which may or may not work."* Pt 134

6.6.1.1.3 Perceived treatment control

Participants appeared somewhat confused and dissatisfied with the biomedical management of their psoriasis. Treatment dissatisfaction can lead to lowered adherence to biomedical treatments and increased levels of consequent distress (Richards et al., 2006). This reinforces the need for more research on beliefs about medicines necessity and concerns within this population. Participants explained how the treatments could be highly efficacious but the benefits either disappeared or involved a trade-off between experiencing side effects and efficacy:

> *"You know the drug will only work for so long."* Pt 165

> *"It* (medical psoriasis treatment) *is helping it a lot but there are side-effects this is the problem with a lot of the treatments of psoriasis. Erm so it is good and part of my problem at the moment is I have had to sort of reduce the dosage and so it's come back."* Pt 140

One participant identified that their psoriasis had not been determined to be clinically severe enough to qualify for phototherapy, which they believed would be more efficacious:

> *"I mean I have heard UV treatment is really good but they only offer that to people who you know it's all over their body its really affecting their life erm and as I say mine is quite localised it's only occasionally on my hands and so I don't really qualify for that."* Pt 123

Many participants seemed aware that there was no current complete cure for their psoriasis and some have taken personal control to 'shop around' for alternatives to the biomedical treatments:

> *"I try to find my own kind of holistic remedies."* Pt 123

> *"I have been though like a lot of the drugs and things like that for it. So that's why I thought I'd give the course a go. It's er anything to sort of alleviate the symptoms."* Pt 149

6.6.1.2 Divergent illness beliefs across the efficacy belief typological dimensions

6.6.1.2.1 Participants with a weak efficacy belief

The participants with weak efficacy beliefs about the course perceived their psoriasis to cause them serious physical consequences such as pain but fewer serious psychological, emotional or social consequences:

> *"I think the course would be a lot better for people who have an issue with their psoriasis whereas I don't you see. The psoriasis is me and if you don't like me, tough!* (laughs) *you know what I mean I don't hide it or anything else like that. The only time that I have problems with my psoriasis is when I am in pain."* Pt 149

> *"My psoriasis, it's not so bad but for a lot of people it really messes their lives up because of the embarrassment or discomfort."* Pt 168

These participants compared themselves with similar others and judged themselves as better off. This 'downward social comparison' has frequently been observed in people living with chronic physical health conditions as a coping mechanism to reduce the experience of negative emotions (Taylor, 1983). Consistent with this assertion, one participant reported previously experiencing very serious distress earlier in their life but explained that this distress has gone. The downward social comparison may have helped alleviate this distress:

"I've been to some very dark places where I've not wanted to live or anything like that. So if somebody is like that then maybe the mindfulness can help them…There have been times when I have been extremely depressed with it but I don't feel like that anymore at all. As I say, I think it's an age thing that, you know, you sort of realise there are far worse things in the world and other people have to deal with far worse than psoriasis really." Pt 149

The mechanism for this change in distress over time was not explored in detail within these interviews. This implied modification of emotional representation over time could suggest that younger people may experience more negative social anxiety representation of their illness. Alternatively, when someone is first diagnosed with psoriasis they may experience more distress than someone who has lived with the condition for a longer period of time. The change in illness beliefs across time has not been well explored in previous research. This study criterion excluded participants who were under 16 years of age with the youngest person in the sample being 22. It is possible that this sampling criterion missed the age range where psoriasis generates the strongest negative emotional representations. One participant alluded to a stronger focus in younger years to find a partner, which results in a higher value on physical appearance and social evaluations and if these were not realised this can lead to increased distress:

"Although it gets on my nerves sometimes, and as a teenager and you are chasing girls and stuff, when I get older I just let my charm and looks take over but as a young'un I was really wound up about it." Pt 168

A participant reported that "acceptance" of their condition could explain this change in perceived consequences and emotional representations over time. The mindfulness course aimed to develop the skills of awareness and acceptance in this population. If participants already had a high level of these skills then perhaps the course could not offer any more to these participants:

"My psoriasis is here to stay and that's it. So I have accepted that fact. I think people that can't accept it…can struggle with it. I think the group, the sessions would be fantastic for them to kind of step back from problems and things like that you know." Pt 149

Members of the 'weak efficacy belief' dimension appear to hold beliefs, which have changed over time from serious consequences and strong negative emotional representations of their illness to more positive beliefs. These beliefs may have changed as a result of 'downward social comparison' or through 'acceptance.' This lack of strong

negative representations may have reduced their motivation to overcome the practice barriers, which were outlined in theme 1.

> *"I personally struggle to engage with it because I was having a lot going on in my personal life"* Pt 168

> *"I didn't get a chance to practise as much as it would have been best to. I think erm as long as you can do the practice at home then you will gain more from it."* Pt 149

6.6.1.2.2 Participants with a moderate efficacy belief

The four participants with moderate efficacy beliefs also perceived their illness as currently causing serious physical effects:

> *"I couldn't take a shower without screaming."* Pt 165

They also perceived serious psychological, emotional, social and occupational consequences, which the "weak efficacy group" did not refer to:

> *"It's painful and it's embarrassing and the creams and the treatments they give you are so messy and disgusting that you can't really functioning properly"* Pt 165

> *"In a sexual way as well my boyfriend even though it doesn't bother him it doesn't necessarily make me feel comfortable either because when its bad and it's all over then no I don't feel attractive at all."* Pt 102

> *"I get it on my hands and it stops me from working."* Pt 123

These participants reported experiencing more current distress from living with psoriasis than those with the 'weak efficacy belief'. Distress such as anxiety and depression is separate from the psychological/emotional *consequences* of psoriasis. The consequences refer to experiencing individual negative psychological/emotional states such as shame and poor self-image whereas the representation of distress refers to a more consistent developed sense of anxiety or depression. The experience of negative psychological/emotional consequences of an illness can lead to distress. A high proportion of people living with psoriasis report experiencing anxiety, which can develop from anticipating and experiencing the negative social evaluations and stigmatising attitudes of others (Richards et al., 2001):

> *"I don't feel good I can't relax. I'm anxious and then because I can't relax I don't particularly feel like being intimate."* Pt 102

Participants also reported experiencing depression and anger. The association between depression and anger was not probed any further in this data collection and although a recent study reported that people with psoriasis experience more anger if they have depression than if they do not (Sampogna et al, 2012), the directionality has not yet been explored:

> *"When I get flare ups I do get a bit more depressed and just erm irritated by that."* Pt 123

> *"So you get annoyed and upset and depressed with it because it's so hurts as well as looking unattractive (*laughs*)"* Pt 165.

Despite these strong negative illness perceptions three of the four participants in this category reported a lack of current perceived stress:

> *"Generally I am quite a relaxed person I don't have much in my life that is that stressful."* Pt 123

> *"I have changed my job so that's helped, which had caused my stress."* Pt 165

One participant referred to a change in how they coped with stress. This improvement in perceived stress was explained as a result of having more time and by getting older. This possibly referred again to the unknown mechanism of change in beliefs and perceived stress over time.

> *"Well again I don't get as stressed as I used to and I think that's as you get older you do tend to cope with things… I am now semi-retired … I think stress comes when you do not have time…and you don't seem to do anything properly that's when I get quite stressed really"* Pt 140

The three members who reported negative illness representations (consequences and emotional representation) from their psoriasis but currently reported low levels of perceived stress did not appear to be able to overcome the practice barriers:

> *"A certain time each day that is what you are going to put aside for but there always seem to be other things going on which you know is a very poor excuse, a very lame excuse really"* Pt 140

They reported lowered motivation to overcome barriers to practising:

> "Sometimes I would rather just sit and watch the telly or read a book than meditate and sometimes I would just be too tired and I knew I would just fall asleep." Pt 123

The remaining participant from the 'moderate efficacy belief' group did report high current perceived stress levels:

> "I can't relax but I have always been like that." Pt 102

This participant, unfortunately, was hospitalised with a transient ischemic attack (TIA) during the course and although they returned to the sessions found it very difficult to enter a routine where they could incorporate the practice again:

> "Basically I am on sick leave at the moment and I got a bit poorly (TIA) a few weeks ago so because of that things have changed and I think if I had been in my usual routine I think things would have been different." Pt 102

All members of the moderate efficacy belief group perceived negative consequences and emotional representations of living with psoriasis however, three of them did not perceive their current life as 'stressful.' This lack of proximal stress may have removed the motivation to overcome practice barriers and achieve more positive outcomes. The fourth person in this category may have developed a stronger efficacy belief if she had not encountered a serious adverse event during the eight-week course.

6.6.1.2.3   Participants with a strong efficacy belief

The three participants with the strongest efficacy beliefs perceived their psoriasis to have serious consequences for them physically. The physical consequences of experiencing pain and itch have generally been well represented in quantitative measurements of functioning and illness representations (IPQ-R and DLQI):

> "My works needs me to be really, really present and given some level of interest … I was scratching so the itching is really that's it for me that's well I think it's because it's the one place where psoriasis really threatens me professionally." Pt 124.

The concept of sleep disruption, however, is only measured within the identity scale of the IPQ-R. The clinical QoL tool (DLQI) does not include an assessment of sleep quality/quantity:

> *"This is why I don't sleep well because I end up sticking my feet out of the end of the bed because I can't stand them underneath the covers then I wake up cold so I have to stick them back under again and the whole thing repeats."* Pt 134

Psoriasis also caused these participants psychological/emotional negative consequences such as shame and poor self-image:

> *"I won't wear short sleeves and yesterday was on* (the) *beach and I had long sleeves on trousers and even though the sun would have done it good I still can't I haven't got the confidence because of reactions that I have got in the past"* Pt 105

> *"I think I look a mess with it when it's bad hence I cover up."* Pt 134

They explained how the symptoms interfered with performing activities:

> *"I can't now go to the gym because I can't go in chlorine and water and I can't wear trainers and socks and you are not allowed on the gym without trainers and if I walk far it gets really bad."* Pt 134

Members of this dimension held negative emotional representations of their illness similar to those reported in the moderate efficacy belief group. Participants reported loneliness:

> "*You feel so alienated and you just feel completely on your own."* Pt 105

They also expressed some embarrassment:

> *"I feel a fool wondering round in almost flip flopping open sandals and people looking at me and thinking 'she's crazy' or not very smart … I still feel self conscious about where it shows."* Pt 134

Depression also featured in their accounts:

> *"It was really, really depressing me."* Pt 124

In contrast to the 'moderate efficacy belief' group, however, this group of participants also reported currently perceiving themselves to be stressed:

> *"I had come expecting it to help I mean I wouldn't have come otherwise I am a very stressed person."* Pt 134

> *"I work in a very stressful job…I am continually giving up myself in terms of my listening and working out how to help people resolve their problems."* Pt 124

> *"Work has been so stressful …one of me colleagues had a heart attack and everybody is very stressed. People are in tears every day."* Pt 105

The adherence behaviours of this group of participants were different to the 'weak' and 'moderate' efficacy belief groups. They appeared to have high motivation to overcome practice barriers:

> *"I feel like it's quite addictive and if I have done one earlier in the day then I fell 'oh I love this, it's great I want to do more'."* Pt 105

The group demonstrated flexible attitudes and reported adapting their lifestyle patterns in order to incorporate the mindfulness work:

> *"I changed my routine and I get up at quarter past five and I have yet to fall asleep in the morning"* and *"I think I had to learn that (*that morning practices work for him*) for myself."* Pt 124

The high efficacy belief group held strong perceptions that psoriasis has a serious negative effect upon their lives and also perceived their daily life as stressful. They were motivated, which appeared to influence their willingness and success in overcoming the MBCT practice barriers (theme 1).

6.6.2 Individual attitudes

Whilst exploring the individual illness representations some values emerged which expanded upon the SR-CSM (Leventhal et al., 1984) template. These accounts were explored further and a set of attitudes emerged, which might explain why this group of people self-selected to join the mindfulness-training course and maintained adherence. Many of the participants appeared not adhere to the dominant biomedical-dualistic representations of health and illness but rather reflected several values (critical thinking, consumerism, holism and openness), which have previously been found to increase the likelihood of accessing alternative treatment options (Shiapush, 1999). Participants perceived themselves to be "psychologically minded":

> *"I think you know if you are someone who is a bit you know if they are not psychologically minded or if they are not if they don't get it I think it might be difficult to sell* (the concept of mindfulness)." Pt 124

Participant appeared to be emotionally literate, as they demonstrated an ability to analyse their thoughts and feelings:

> *"I was considered very confident and good at my job because actually I wasn't confident, I wasn't at all confident about things."* Pt 134

> *"It's the little things you need to focus on what is actually real or what your mind has blown into a 'what if' situation."* Pt 165

The participants described themselves as open to new things, which helped them to engage with and gain benefits from mindfulness:

> *"I think if they are open to new things. You know some people aren't. Some people will try different things… but er some people are very closed and they won't accept anything new and stuff so. It's finding the right person I think."* Pt 149

> *"Someone could do the course and walk away having got nothing from it simply because they weren't open enough to it."* Pt 124

Participants described needing this openness as a pre-requisite to participating in the MBCT course because it could be perceived as a stereotypically alternative medicine (e.g. homeopathy). They identified that this might be a barrier to people who place higher value upon biomedical models and lower value on alternative models of treatment:

> *"It's like homeopathic, some people accept it and some people don't and I think that would be the same with meditation. Some will be like 'oh no it's just an old load of sitting there and humming ain't it, sitting there, going 'hmmmmmm' and how is that going to help me?' You know it's kind of teaching it to people and trying to get them to accept it as a new kind of thing as…as well as the drugs and the treatments."* Pt 149

One participant did not appear to align with an alternative therapy stereotype and sought out scientific affirmation that mindfulness was efficacious and not "hippy rubbish". Social cognition theory suggests that people tend to model behaviours more if they perceive

themselves to 'identify' with the type of people who use the behaviour and if the behaviours seem effective (Bandura, 1989). One member sought external scientific validation in order to strengthen their belief in the therapy's efficacy and to remove the alternative therapy label, to which they may not have felt aligned:

> *"I guess the scientific studies were, did give me that kind of 'oh it does work after all' because a lot of holistic therapies kind of tend to be quite faith based erm which does not work for all people its dismissed as 'hippy rubbish' so yeah the actual scientific research that gave you a bit more confidence"* Pt 123

6.6.3 Individual differences summary

Many of the themes, which emerged from the data, conformed to the SR-CSM (Leventhal et al., 1984) template. The participants believed that stress can influence their physical psoriasis symptoms but there was some confusion as to whether it exacerbated or caused their symptoms. They perceived that they had little personal control over their condition and that biomedical treatments can temporarily help manage but not permanently cure their psoriasis. The absence of a permanent cure led some participants to search for additional therapies to try in an additive method of trial and error. There was a variation across the participants in their representations of the consequences of psoriasis and the emotional representation of the condition. These beliefs diverged across the three dimensions of the efficacy evaluation typology. Participants who believed the MBCT course was very effective reported that their psoriasis caused them a greater range of more serious consequences and a more negative emotional representation than the participants who believed the course had weak efficacy.

Participants reported that their illness beliefs and ability to cope with stress had changed over time and as they have become older they felt better equipped to cope with the challenges of living with psoriasis.

The majority of the participants presented themselves as emotionally literate and open to trying alternative therapies but one participant did not appear to align with this perspective and was searching for scientific validation of mindfulness in order to transform the intervention into an evidence based mainstream intervention, to which he felt more aligned with.

6.7 Summary of the themes

When exploring the participants' reported experience of the mindfulness course it appeared that the majority of participants accepted the principles and format of the intervention but found the large time commitment of practising the formal skills to be the major barrier to adherence.

The emergent process theme highlighted possible areas where group facilitators could receive additional training to reduce some barriers, which participants reported. Members of a MBCT course who struggle with experiential learning could be offered some concrete learning tools in order to facilitate the learning process. A few participants found dedicating time for home practice as self-indulgent and incongruous with their social role and entitlement whereas the majority of participants struggled with self-regulation, such as poor time management, in achieving their goal of improved wellbeing.

When discussing the effects of the course participants reported changes across physical, cognitive, emotional and behavioural outcomes. A typology of 'efficacy evaluation' emerged with three dimensions weak, moderate and strong. All the participants reported similar representations regarding the cause, timeline and control of their psoriasis. The representations regarding the consequences and emotional regulation of their psoriasis, however, varied across the three typologies.

Illness beliefs and coping resources were reported to change across time and younger people or people who had been living with the condition for less time might have more need for a psychological intervention than older people who had been living with their condition for a longer period.

The majority of participants in this study presented themselves as emotionally literate and open to the use of alternative therapies. These themes shall be interpreted and discussed in Chapter 7.

7. Discussion

Despite advances in pharmaceutical treatments for psoriasis there is no cure and research continues for the optimum management for the condition. This thesis aimed to examine whether a reduction in stress through mindfulness training, could improve the physical symptoms of psoriasis via a PNI pathway. Some people with psoriasis experience high levels of distress and impaired QoL (Fortune et al., 2005) as a consequence of the beliefs or illness representations they hold of their condition (Fortune et al., 2004a). This thesis also examined whether learning mindfulness skills, without challenging the content of these illness representations, could ameliorate the associated distress and disability.

Mindfulness-based interventions have been shown to improve perceived levels of stress (Warnecke et al., 2011), distress (Fjorback et al., 2011), immune system biomarkers (Witek-Janusek et al., 2008), physical conditions (Grossman et al., 2004) and clearance of psoriasis during phototherapy (Kabat-Zinn et al., 1998) without challenging the content of cognitive representations as CBT does. Mindfulness-based interventions could be a suitable alternative to CBT techniques which are currently accepted as the most effective management of stress in people with chronic physical health conditions (Pilling et al., 2009).

7.1 Summary of literature review

7.1.1 Stress-psoriasis links

Chapter 2 contains a summary of the literature review but this section will attempt to visually represent the possibly pathways which the literature suggests connects stress and psoriasis. The stress-psoriasis link is represented in Figure 32.

Figure 38: Diagram depicting a summary of the possible pathways between stress and psoriasis
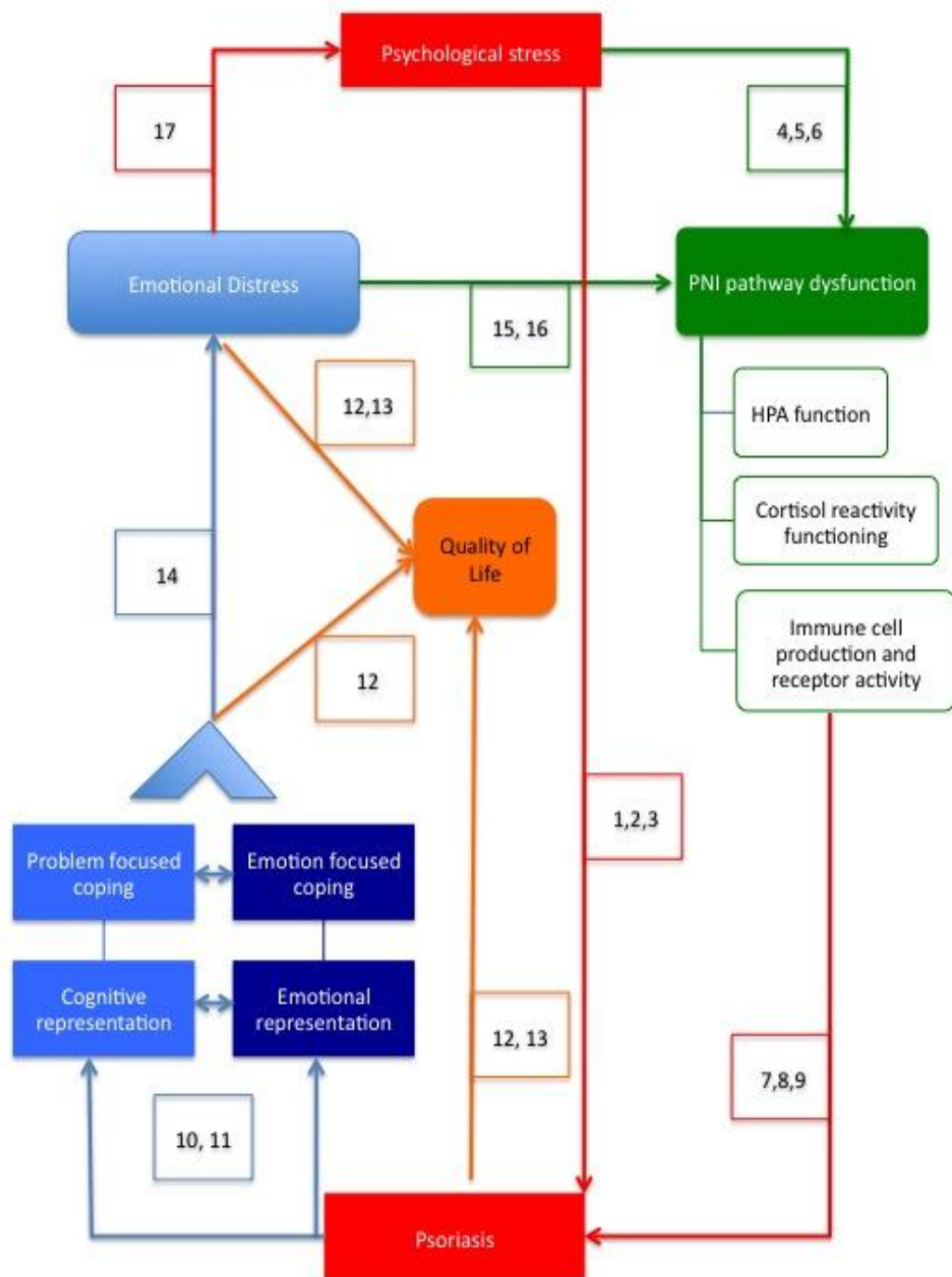
References:
1. Fortune et al., 1998
2. Manolache et al., 2010
3. Peters et al., 2000
4. Marucha et al., 1998
5. Biondi and Picardi, 1999
6. Pruessner et al., 1999
7. Karanikas et al., 2009
8. Evers et al., 2010
9. Richards et al., 2005
10. Fortune et al., 1998
11. O'Leary et al., 2004
12. Fortune et al., 1997
13. De Korte et al., 2004
14. Fortune et al., 2004a
15. Gex-Fabry et al., 2012
16. Vreeburg et al., 2010b
17. Leventhal et al,. 1984

Figure 32: A diagram to present an overview of the evidence. Retrospective reports of perceived stress and prospective studies of stressful life events have suggested stress triggers psoriasis. Stress has been reported to influence the concentration of pro-inflammatory cytokines in the skin; the production of free circulating cortisol; and the reactivity of the cortisol awakening response. Psoriasis has been associated with hypoactive cortisol responses. Psoriasis leads to different illness representations, which consequently influence distress and QoL impairment in people. Living with distress is related to the CAR and perceived stress levels.

The illustration above demonstrates the two strands of research, one examining whether stress exacerbates psoriasis signs and symptoms and the other how psoriasis is linked to stress and distress. The two arms connect to form a cyclical rather than a linear relationship.

7.1.2 Psychological interventions to break the stress-psoriasis cycle

Psychological interventions offered to people with psoriasis either targeted:

- Maladaptive *cognitive representations* of psoriasis (cognitive based therapies);
- Elevated *physiological arousal* levels by developing an alternative state of relaxation such as progressive muscle relaxation, hypnosis, musical resonance therapy or meditation;
- Or they offered people with psoriasis an alternative method to *process information* without cognitive challenge such as emotional disclosure and mindfulness-based therapy.

The gold standard study (Fortune et al., 2002b), found CBT decreased psoriasis severity, related stress, distress and QoL impairment. It is unlikely however, that CBT will be a panacea for everyone with psoriasis who could benefit from an intervention, as no single medical treatment will suit all patients in a psoriasis clinic. The high rates of attrition (<49%, (Paradisi et al., 2010) found in this study's systematic review of intervention studies, indicates that one intervention will not suit all.

The review found three studies, which reported an improvement in the physical symptoms of psoriasis (Kabat-Zinn et al., 1998, Gaston et al., 1988, Fortune et al., 2002b). These three studies employed , MBSR, meditation and CBT respectively. The meditation technique is incorporated within mindfulness-based interventions and therefore mindfulness may be used as an alternative to CBT for people with psoriasis.

Mindfulness based cognitive therapy rather than MBSR was chosen because its cognitive framework helps to target condition-specific aspects (physical sensations, cognitive-emotional cycles) rather than MBSR, which teaches a broader set of stress reduction techniques to a more generic population. Cognitive-based interventions aim to identify and challenge the content of beliefs and therefore would target the cognitive and emotional representations highlighted in Figure 34. Mindfulness-based interventions aim to offer an alternative way of experiencing and coping with daily life. The comparison of cognitive and mindfulness based intervention and how they will aim to help people with psoriasis is visually represented in Figure 33.

Figure 39: Illustration of core concepts within cognitive and mindfulness based interventions
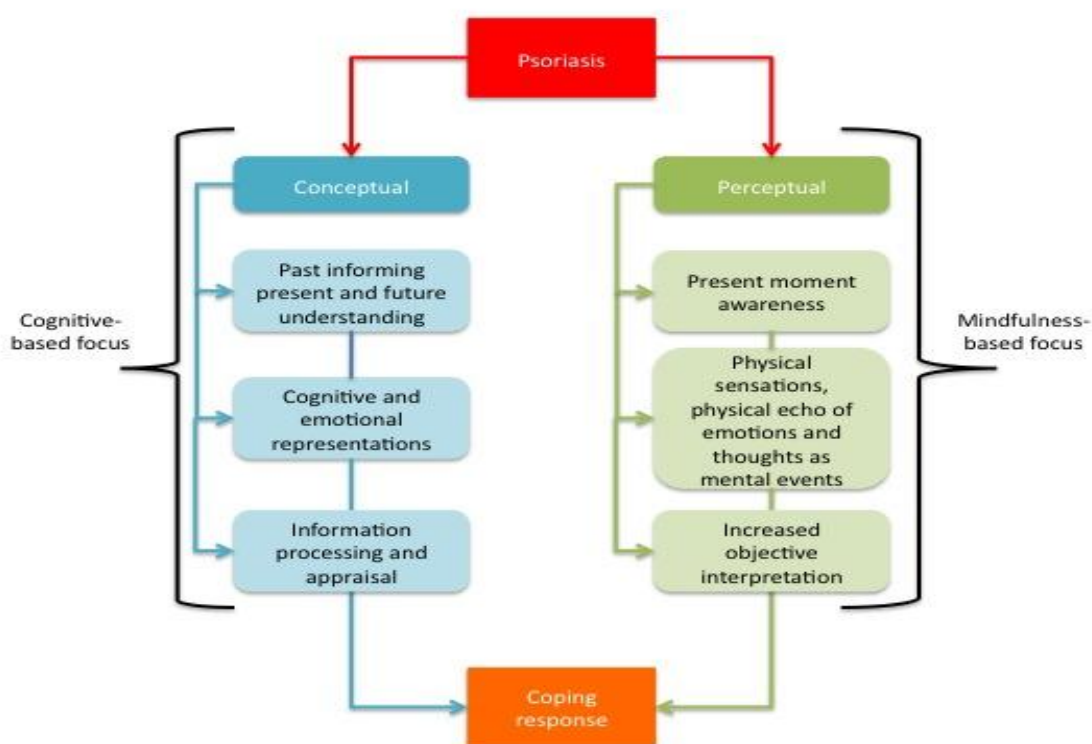
Figure 33: A schematic demonstrating that cognitive based therapies target identifying and challenging the conceptual mode of mind, which contains representations, which can influence information processing and situation appraisals. Mindfulness based therapies develop the use of the perceptual mode of mind which pays attention to the present moment sensations such as internal physical sensations, the physical echo of emotions and seeing thoughts objectively as mental events rather than the absolute truth. The mode of processing information will impact upon the coping responses.

The conceptual mode of mind (thinking, planning, comparing) is essential to daily life but mindfulness-based interventions promote gaining awareness of the perceptual (present moment awareness of physical and psychological concepts) in order to shift an individual from solely perceiving life through a cognitive perspective. The flexibility to move from a predominantly conceptual mode of mind to include a perceptual mode allows an individual more freedom to perceive stimuli as they are, rather than as cognitive representations. The perceptual mode increases one's capacity to appraise a situation more objectively without a pre-existing cognitive filter or schema. Established cognitions can lead to a person automatically feeling stressed and consequently using maladaptive coping behaviours to reduce the stress. By decreasing the influence of these cognitions the individual is less likely to engage in automatic emotional and behavioural responses. Mindfulness also aims to cultivate a non-judgemental acceptance of the positive, negative and neutral content in the conceptual or perceptual modes. This coping can promote positive acceptance based coping strategies. Theoretically mindfulness could help people with psoriasis and an emerging evidence base supports the use of mindfulness-based interventions for physical and emotional health problems, including psoriasis specifically (Grossman et al., 2004, Fjorback et al., 2011).

7.1.3 Psychoneuroimmunological pathway

A PNI pathway can explain in theoretical terms how stress exacerbates psoriasis. Stress can trigger a hypothalamic-pituitary-adrenal (HPA) axis cascade and one output is the hormone cortisol. Acute stress can increase cortisol levels and chronic stress can reduce it (Ader, 1991, Biondi & Picardi, 1999). Both acutely elevated and chronically depressed cortisol levels are harmful to immune functioning. Cortisol modulates the production of immune cytokines, including those implicated in the pathogenesis of psoriasis (Weigers and Reul, 1998; Chapman and Moynihan, 2009). Both acute and chronic stress can reduce the number of immune cytokines in human skin (Kiecolt-Glaser et al., 1995; Marucha et al, 1998). The proposed pathway, which was tested in this study, is visually represented in Figure 34.

Figure 40: Diagram illustrating the proposed PNI pathway from stress to psoriasis

References:

1. Ader, 1991

2. Biondi and Picardi, 1999

3. Kiecolt-Glaser et al., 1995

4. Marucha et al., 1998

5. Fortune et al., 1998

6. Weigers and Reul., 1998

7. Chapman and Moynihan., 2009

Figure 34: Schematic diagram demonstrating the associations with stress, altered cortisol levels, pro-inflammatory cytokine concentration and psoriasis symptoms.

The cortisol awakening response (CAR) is a distinct and robust element of the human cortisol response, which indicates how well the HPA axis is functioning. Acute stress is associated with an increased overall CAR and CAR reactivity levels. Prolonged maintenance of an elevated CAR might down-regulate the HPA axis. This could lead to poor function and an attenuation of CAR (overall and reactivity levels). A reduced CAR is a consistent feature in people suffering from chronic stress (Chida & Steptoe, 2009, Juster et al., 2011, Gex-Fabry et al., 2012). Some chronic physical health conditions (diabetes, amyotrophic lateral sclerosis) have been associated with attenuated CAR reactivity (Bruehl et al., 2009; Roozendaal et al., 2012). A recent study reported distress to account for more variance in CAR (reactivity and overall) scores than the physical health condition (coronary heart disease) (Merswolken et al., 2012). Merswolken et al.'s (2012) study suggests that the CAR may be more closely related to distress than the physical disease.

7.2 Main research findings

Table 44 presents the study research questions, hypotheses and a statement of whether these hypotheses were supported.

Table 48: Summary of main research findings

Research question	Hypothesis	Results
Does MBCT improve physical, psychological and QoL outcomes in people living with psoriasis?	*The intervention group, which received MBCT, will have lower perceived stress than a control group who continued with treatment as usual (TAU).*	Rejected hypothesis.
	The intervention group, which received MBCT, will have lower physical severity ratings of their psoriasis than a control group who continued with treatment as usual (TAU).	Accepted experimental hypothesis.
	The intervention group, which received MBCT, will have lower distress ratings than a control group who continued with treatment as usual (TAU).	Rejected hypothesis.
	The intervention group, which received MBCT, will have lower QoL impairment ratings than a control group who continued with treatment as usual (TAU).	Accepted experimental hypothesis.
Do illness representations affect how MBCT influences the primary outcomes within this population?	*Stress responders (those who believe stress caused their psoriasis) in the treatment group will experience greater change scores in their physical severity ratings than non-stress responders.*	Unable to perform analysis. (96.6% of sample were stress responders)
	The intervention group will have the same illness representation scores as the treatment group after the MBCT intervention has been administered.	Accepted null hypothesis.

Research question	Hypothesis	Results
Did the participants of the MBCT course successfully learn the mindfulness skills?	*Participants who receive the MBCT intervention will report higher follow-up MAAS scores in comparison to their pre-intervention MAAS scores.*	Accepted experimental hypothesis.
Do beliefs in credibility/expectancy affect the primary outcomes?	*Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will achieve greater improvement in their perceived stress levels than those who had weaker beliefs.*	Rejected hypothesis
	Participants who have stronger beliefs in the credibility/expectancy of the MBCT course will achieve greater improvement in their physical symptoms than those who had weaker beliefs.	Rejected hypothesis
Is the CAR cortisol correlated with stress and physical severity of psoriasis?	*The CAR cortisol will be significantly negatively correlated with perceived stress scores.*	Rejected hypothesis
	The CAR cortisol will be significantly negatively correlated with physical severity scores.	Rejected hypothesis
Does the CAR change in participants who have completed the MBCT training course?	*The CAR will be significantly different between the treatment and control group at post-intervention.*	Rejected hypothesis

Research question	Results
What are participants' experiences of the MBCT course?	Participants in the MBCT course appeared to find the course an acceptable adjunct therapy in addition to their traditional psoriasis treatments. The overall evaluations suggest it is an interesting course, for some people it was beneficial and for the majority it was a big commitment in terms of time and energy. The MBCT course might not be suitable for people who were currently experiencing an active episode of anxiety or depression.
What are the perceived benefits and the perceived barriers to participating in the MBCT course?	Participants reported physical benefits (improvements to psoriatic symptoms and increased energy levels), cognitive benefits (increased present moment awareness), emotional benefits (more calm and confident) and behavioural benefits (reduced automatic scratching in response to an itch). All participants reported some barriers to participation. Many of the barriers (e.g. difficulty finding the time to practice and problematic group dynamics) echoed those that had been reported in previous studies exploring the acceptability of mindfulness-based interventions (Finucane & Mercer, 2006, Walker et al., 2010, Kerrigan et al., 2011). The MBCT course is taught in a particular teaching style for example relying on experiential learning. Some participants found experiential learning to be a barrier to their assimilation of the mindfulness skill set. It emerged that different elements of the teaching format can help some but hinder others.
What individual differences are found in those participants who adhered to the MBCT intervention?	Some participants believed the MBCT intervention had been very helpful, some moderately helpful and some thought it had not helped them. Those who did not believe the course had been beneficial for them, reported that their psoriasis caused them few serious psychological, emotional or social consequences either because they had accepted their psoriasis or because they did not see their psoriasis as severe as others peoples. Consequently this group reported lower motivation and low success in overcoming the common barriers such as scheduling enough time to practise. The moderate efficacy group did perceive that psoriasis caused them serious psychological, emotional and social consequences but reported that currently they were not experiencing high levels of stress and that they had low motivation to overcome the barriers.

	The high efficacy group reported serious psychological, emotional and social consequences and also displayed high levels of current perceived stress. This group reported high motivation to overcome the practice barriers and specifically reported the link between increased practice and increased benefits from the mindfulness techniques.
	The participants in this study were interpreted as being emotionally literate, psychologically minded and open to trying alternative interventions in adjunct to their biological management techniques. One participant who was more sceptical of alternative treatment options sought scientific evidential support to increase the validation of the mindfulness based techniques.

7.3 Main methodological features: strengths and weaknesses

The principal drive for this pilot study was to examine the effectiveness of a MBCT intervention for people with psoriasis. People living with this condition experience a variety of physical, psychological and social symptoms. Mindfulness based cognitive therapy is an intervention that has not previously been used with this population. Consequently, a sequential qualitative study was incorporated into the overall research project in order to gain an insight into any changes. The use of a mixed-methods approach allowed the strengths of one paradigm to supplement the weaknesses of the other and help strengthen the conclusions drawn from this project.

7.3.1 Quantitative methods

Strengths

The principal research question, "Does MBCT improve physical, psychological and QoL outcomes in people living with psoriasis?" was answered with a pilot RCT design. The RCT is reported to remove the greatest amount of bias thus leaving the most reliable findings (Woolfe et al., 1990). The primary analysis to answer the research question used an ANCOVA which is the gold standard statistical test to examine the effects of an RCT (Blance et al., 2007). Using the most appropriate statistical test for the RCT ensures the results are as reliable and without bias as possible.

The methodology for the concurrent quantitative studies followed the CONSORT checklist (Moher et al., 2001) in order to increase the reliability of the findings and transparency of the study process. A member of the research team, who did not recruit or enrol participants, performed the block randomisation of study ID numbers without any other participant details. This minimised the potential for bias in allocating participants to either the control or treatment group because the researcher did not know the physical severity or distress scores of the participants, nor had they met them before so could not make a judgement about which participants might respond better to the MBCT intervention.

The MBCT group facilitator had been trained to deliver the course and had experience in running a trial group before starting the study groups. Ongoing supervision was conducted with a consultant health psychologist and occasionally with highly qualified practitioners from the Breathworks® centre in Manchester, who specialise in using mindfulness-based interventions for people living with long-term health conditions. This training and supervision provides a degree of reassurance about treatment fidelity. There was, however, no independent assessment of the facilitator's skills and adherence to the MBCT protocol. The facilitator kept all planning and field notes of what

happened before and during each session and these can be audited to check for MBCT protocol adherence (a field note example provided in Appendix 9.10).

The systematic review (Chapter 2) of previous studies that had employed psychological intervention for people with psoriasis produced a list of recommendations for future studies to improve the quality and therefore reliability and validity of future study's findings. The review recommended including a measurement of skill acquisition, which this study included in order to check whether the participants had genuinely learnt the mindfulness skills, which the facilitator intended to convey. This increases confidence that any effects of participating in this group could have been due to learning mindfulness skills rather than unintended and unmeasured, other effects.

This study also included a measurement of pre and post course expectancy and credibility beliefs in order to measure whether *a priori* beliefs impacted upon the efficacy of a psychological intervention. This measurement checked the validity of the observed effects as they may have been caused by participants wanting a change to happen rather than as a result of learning mindfulness skills as recognised by the Hawthorne Effect; (Roethlisberger & Dickson, 1939).

The review highlighted how seasonal variation can account for differences in symptom severity of psoriasis. This study was conducted across the summer months from May until August in order to capture data across one season rather than crossing into another season. This was planned in order to reduce the possible confounding seasonality effects and increase the validity of the observed effects.

The review recommended only using validated measurements, in order to increase the validity and comparability of findings. It also highlighted the importance of including a QoL measurement as this composite score captures the biopsychosocial consequences of with living with psoriasis. The outcome measurements used in this study, including a QoL measurement, were all well- validated for use with a psoriasis population. The use of these measurements increases this study's result comparability and reliability.

Saliva collection and analysis followed established protocols for saliva collection, storage and analysis in order to produce comparable and reliable results. These protocols therefore enhance the reliability and generalisability of the cortisol and cortisone results.

This study measured both cortisone and cortisol from the saliva samples. Salivary cortisone has been recommended as a more reliable marker of free-circulating cortisol

than salivary cortisol. This more sensitive measurement increases the reliability of the assumptions generated from these analyses.

The composite scored generated from the salivary cortisol and cortisone levels measured both the overall CAR and the CAR reactivity. Previous studies have used these two measurements interchangeably to represent CAR. By including these both, this increased the comparability of these results to previous studies, increasing the studies generalisability.

Weaknesses

This study was a pilot study and previous pilot studies have used a sample size of n=30 to inform a future RCT (Lancaster et al., 2002). The review (Chapter 2) of psychological interventions used with psoriasis populations reported high attrition rates (<49%, Paradisi et al., 2010). This study intended to recruit n=60 participants, which could allow for an attrition rate of 50%, and leave n=30 remaining for analysis. The recruitment phase was planned to be twice as long but due to an unavoidable delay in the ethics procedure recruitment was cut short. Despite attempts to expand the methods of recruitment by using radio infomercials and patient support groups, only 29 participants were recruited over the three months recruitment. This study, like previous intervention studies, experienced high attrition and the primary analysis was run between a treatment group n=6 compared to a control group n=13.

These small group sizes mean the statistical tests had less power to detect a difference if (a real) one existed (type 2 error). Analysis of covariance, however, increased the sensitivity to detect a main effect. Although the power of the tests was reduced because of small sample size, using ANCOVA subsequently increased the power to detect a main effect. ANCOVA is a powerful statistical test and may have masked the individual differences observed within this small sample. This was addressed by presenting numerical and graphical representations of the individual change scores for participants who completed the MBCT training.

The 48% attrition rate in this study is higher than the attrition rate experienced in previous intervention studies. For example 25% of people left the CBT intervention (Fortune et al., 2002b). Perhaps more needs to be done to examine why, when people have identified themselves as experiencing stress and distress and have selected to join an intervention group then leave. The majority of the participants who left this study did so before attending the first session, which indicates that they might have been put off by the time commitment rather than the content of the intervention. Cognitive behavioural therapy is more established than MBCT and people may agree to dedicate their time for an intervention with a well-known evidence base as opposed to a new

intervention that is less well known. Alternatively, fewer participants may drop out of CBT courses because CBT is a more acceptable treatment option than MBCT for people with psoriasis.

After seeking statistical advice a supplementary analysis was added to the study in order to support the primary analysis with a larger sample size. A non-randomised comparison group was recruited from eligible people who had expressed an interest in joining the MBCT group but could not commit to the eight-week course at the time it was running. This non-randomised group allowed for further comparisons between the active and comparison groups in addition to the small treatment and control group comparisons. The lack of randomisation leaves these comparisons open to more bias, as it is unknown whether confounding variables have been cancelled out through randomisation. This strategy was a positive response to the high attrition encountered however results from a non-randomised group analysis were limited and it would not be recommended for future studies. It is recommended that future studies conduct a cluster RCT, running multiple MBCT groups with one consistent control group.

A research question was added to the qualitative study to explore the reasons why the study completers had adhered to the MBCT intervention. It is important to understand why some people adhere whilst others do not, whether there any modifiable features of adherence that can be identified. Tailoring an intervention to the most appropriate audience will increase adherence.

The outcome assessment was not blinded and was conducted by the PI, which potentially carries an inherent bias. In order to reduce the likelihood of this bias interfering with the outcome assessment the supervision team checked a sample selection of questionnaire booklets to ensure a valid and reliable data extraction technique was being employed.

The saliva samples were collected on one morning at each measurement time. Some larger scale studies have collected saliva on three consecutive days then generated a mean score for the 0,15, 30, 45-minute time points to increase the reliability of the measurement (O'Connor et al., 2009). This study did not have the resources to collected saliva samples on three days and this may have reduced the reliability of the saliva samples collected.

A problem common to all saliva home collection studies is the issue of non-adherence. Ten participants' CAR reactivity score was negative which indicates that their 0-minute time point was higher than their 15, 30 and 45-minute collection points. They did not produce a rise in cortisol/cortisone in response to awakening. This is likely to be caused

by non-adherence to the collection protocol. If these participants collected their first swab minutes later than when the genuinely woke up then this may remove the rise response, which was expected. It may be that people with psoriasis are missing this rise in their cortisol response to awakening. CAR reactivity and overall CAR were not associated within this sample, which may be because these reactivity scores were not genuine but artefacts of participants' non-adherence. Studies with more resources have used monitoring devices to check participant's adherence levels (Kupper et al., 2005). Other studies have excluded participants, who did not produce a rise in response to awakening, from further analyses (O'Connor et al., 2009).

With hindsight, the resources and scope of this study may have been too small to try and include a pre to post cortisol study. It may have been better to collect samples across three days at baseline. This would have enabled the author to produce a more reliable picture of the cortisol and cortisone AUCg response in people with psoriasis, which has not previously been done.

7.3.2 Qualitative methods

All completers of the MBCT course (n=13) were invited to interview and nine participants took up this offer within the time frame available to conduct the interviews. Data were collected with semi-structured interviews with a topic guide which had been developed to test previous themes from MBCT acceptability studies and the SR-CSM of illness representations. This topic guide allowed for specific concepts to be explored within this population but also for the development of new themes. The data management and analysis was performed with FA techniques (Ritchie & Spencer, 1994).

Strengths

The sequential qualitative study offered an explanation for some of the quantitative findings and helped to understand adherence and acceptability of this complex intervention. The qualitative methodology was informed by the CASP guidance (Critical Appraisal Skills Programme, 2006) and appropriate methods of data collection and analysis was used to answer the research questions and has maintained transparency to allow for external audit of this work. The Framework Analysis techniques encourage a transparent and systematic approach to qualitative methodology, which increased the rigour in this study.

The sample size was small enough to allow for all members to be invited to interview. This homogenous sampling technique removed any bias in the recruitment phase.

The PI had facilitated both MBCT groups therefore in order to remove potential bias (upon interviewing ability and the participants' responses) from the interview process the PI did not conduct the interviews. Two independent members of the research team who

had not been part of any other stage of this research project, collected data. The two researchers who conducted the semi-structured interviews were trained in using semi-structure interview techniques, have previous experience and the process was under conducted with supervision guidance. This allowed for reassurance that the data was collected in accordance with qualitative data collection principles. The analysis stage was supervised and an external expert in qualitative methodology was used to check analysis credibility and technical rigour.

Weaknesses

The independent interviewers reduced the possible bias in the interview process. However, their inexperience with the MBCT procedure may have prevented them from pursuing areas in more depth. This sequential study was never intended to use in-depth interviewing techniques. It had a discrete set of *a priori* considerations used to formulate the topic guide, which the interviewers delivered skilfully. With hindsight, if the PI had conducted the interviews this may have allowed her to further probe the subtleties of mindfulness training because of her own personal understanding. Although the participants may have been inhibited with their criticism of the course or the facilitator this could have been accounted for in the personal reflection of the PI. The balance between reducing bias versus gaining a deeper insight into why and how mindfulness was or was not helpful for individuals, perhaps should have tipped in favour of generating a deeper understanding.

Some participants missed their original interview and another interview time could not be found within the timeframe available. If the study period had been longer, then more participants may have been able to be included in the final sample. However, this study had a highly specific population of interest (completers of the MBCT course with psoriasis) and discrete research questions and therefore the sample size was quite suitable for the research aims and the research team felt that the analysis has reached saturation.

7.4 Interpretation of results from study phase I, II and III

7.4.1 Efficacy of MBCT

The literature review (Chapter 2) suggested that perceived stress (phase I primary outcome) could exacerbate or even cause physical psoriasis symptoms (phase I primary outcome) (Fortune et al., 1998, Polenghi et al., 1989, Fava et al., 1980, Seville, 1977). Living with chronic stress can result in an attenuated CAR (Pruessner et al., 1999). This attenuated CAR might signal poor HPA axis functioning, which can influence the cortisol levels and the pro-inflammatory cytokines involved in the pathogenesis of psoriasis (Hall et al., 2012; Chapman and Moynihan, 2009). Mindfulness based cognitive therapy has been reported to significantly improve perceived stress levels (Warnecke et al., 2011). If MBCT could reduce the perceived stress levels in people with psoriasis then this could improve the HPA axis functioning (measured by CAR) and consequently improve the physical severity of psoriasis.

Results from the first phase primary analysis, suggested an improvement in physical severity without an improvement in perceived stress scores. The ANCOVA in phase II found the CAR did not change as a result of the MBCT intervention either. These preliminary findings indicate that MBCT can improve the physical severity of psoriasis but not by reducing stress or improving the HPA axis functioning (CAR).

The degree of physical improvement in this study's participants was 39% indicating MBCT is a useful adjunctive treatment. The improvement was maintained for a further two months after the end of the study, which may mean that the participants experience long-term benefits from developing these skills. The percentage improvement is less than the MID of 50% used in pharmaceutical trials for psoriasis (Carlin et al., 2004) but MBCT was not intended as a stand-alone treatment.

Although the powerful ANCOVA test suggests a statistically significant difference between the treatment and control group on SAPASI and DLQI improvement and between the active and comparison group on DLQI scores, the individual change score show that these changes are minimal. Across all of the participants who completed the MBCT course the average individual change score to SAPASI was 2.20 (out of a maximum of 72 points), for PSS was 1.86 (maximum of 40), HADS was 4.36 (maximum of 42) and DLQI was 2.00 (maximum of 30). Fifty percent of those who completed the mindfulness training self-reported improvements in all four of the primary and secondary variables and the other 50% were found to have mixed results, some improvements and some deterioration. While these individual change results are quite positive they are

limited and perhaps CBT remains as a more reliably effective psychological intervention for people with psoriasis.

One participant (Pt102) reported a large increase in their PSS score and also smaller increases in her SAPASI and DLQI scores. Participant 102 had a transient ischemic attack (TIA) during week three of the MBCT course. The deterioration of her scores could be attributed to the TIA and the subsequent time off work rather than a detrimental effect of the MBCT course. This participant explained that if she had not had the TIA she could have benefitted from the training more than she did.

> *"Basically I am on sick leave at the moment and I got a bit poorly (TIA) a few weeks ago so because of that things have changed and I think if I had been in my usual routine I think things would have been different."* Pt 102

Chapter 2 aimed to systematically review the existing literature regarding whether psychological intervention could improve the severity of psoriasis. The highest quality study from this review used cognitive challenge techniques and reported an improvement in physical severity (Fortune et al., 2002b). The review recommended using a comparable intervention, which did not include a cognitive challenge component to examine whether physical severity could be reduced without cognitive challenge. This pilot study supports the concept that cognitive challenge is not necessary to reduce physical severity in people with psoriasis. As discussed beforehand, these results are tentative due to the small population and the variability in change scores but the concept of whether cognitive challenge is necessary has at least been challenged and future studies could clarify this further.

The quantitative results of phases I and II provided no clear explanation how MBCT changed the psoriasis symptoms. Phase III's qualitative data suggested that people were sleeping better and feeling less tired since participating in the study. A review reported that poor sleep quality has a robust association with function of immune system cytokines production (Bryant et al., 2004). Some of these cytokines are involved in the pathogenesis of psoriasis (Chapman and Moynihan, 2009). If MBCT improves sleep quality, this could reduce the physical symptoms of psoriasis via an immune system pathway. This assertion is supported by a study where a mindfulness-based intervention increased well-being by improving sleep quality (Howell et al., 2008).

Many of this study's participants identified that psoriasis caused them pain (66%) and in the interviews they explained that since their participation in the MBCT course their psoriasis was causing them less discomfort and disturbance at night. A study has reported that skin pain and discomfort were significantly associated with sleep disturbances in people living with psoriasis (Ljosaa et al., 2011). Mindfulness based

cognitive therapy may be reducing the amount of pain and discomfort for patients which could also beimproving their sleeping patterns.

Participants also reported that their psoriasis was itchy (100%) and the itch-scratch cycle has previously shown to impair sleep quality (Amatya et al., 2008) and overall QoL (Globe et al., 2009). During interview participants stated that MBCT had improved their behavioural control reducing automatic scratching. Mindfulness may enable people to control this automatic emotional and behavioural reactivity to itch. This increased emotional and behavioural control may have developed from the participants' increased awareness of the perceptual mode of mind (Williams et al., 2010). They learned to experience the present moment itch or pain sensation, and adopted an attitude of acceptance.

Participants clearly described using these mindfulness skills. They explained that they were more aware of the present moment bodily sensation, accepting their psoriasis, and noticing what was "real" (perceptual) and what they had constructed (conceptual). This suggests that mindfulness skills had been learnt and assimilated into their daily lives. Phase I found their mindfulness skill level, as measured by the MAAS, to have improved significantly. Pre-course levels of credibility and expectancy were not associated with the physical severity change score. This demonstrates that the effects may have been caused by developing mindfulness skills rather than pre course beliefs that the intervention was going to help them. The combination of these results suggest that these learnt skills may have reduced their automatic reactions to psoriasis symptoms. This change could enable them to sleep better (perhaps itch less) and therefore improve their immune system functioning ameliorating the physical symptoms.

Pre-course expectancy and credibility beliefs were significantly positively correlated with changes in perceived stress levels. Possibly, the desire for the course to reduce stress may have influenced the positive reporting rate as described in the Hawthorne effect (Roethlisberger & Dickson, 1939). Pre-course expectancy and credibility levels have not routinely been measured in psychological interventions studies (see recommendation from Systematic Review Chapter 2). In this study these beliefs had an effect upon perceived stress levels therefore future studies should control for them.

Another possible route for improvement in physical symptoms is via arousal reduction. Participants reported feeling calmer which might be their interpretation of the reduced physiological arousal they experienced as a result of mindfulness training. One participant reported less sighing, which has been hypothesised as a method to relieve tension (Wilhelm et al., 2001) and return the body to homeostasis. Reduced sighing could imply a reduction in the frequency of the body entering a state of arousal which

needed to be re-set by the reflex of sighing. Participants also mentioned they were reacting less to potential stressors. Together these reports suggest that mindfulness training helped participants reduce the amount of times they enter a state of arousal. Hamilton-West (2011) proposed arousal reduction is the mechanism of change in MBCT and reducing physical arousal could reduce the allostatic load upon HPA axis function (as measured by CAR) (Hamilton-West, 2011; McEwen and Stellar, 1993). However, the CAR responses were not altered by the MBCT training in this study. Dysfunction of the HPA axis may take longer than eight weeks to recover. A longitudinal study would be able to elucidate this mechanism.

Some people with psoriasis experience high levels of distress and impaired QoL (Schmitt and Ford, 2007; Hayes and Koo, 2010; Kurd et al., 2010; Rapp et al., 1999). This study's participants experienced elevated distress (35% probable anxiety caseness and 10% probable depression caseness) compared to the general UK population (National Institute for Health and Clinical Excellence, 2009a). Their mean QoL impairment was 8.24/30 (DLQI), which might not seem high but the new guidelines for classifiying psoriasis report a DLQI over 10 as severe (Mrowietz et al., 2011).

The QoL measurements such as DLQI are composite measurements aiming to capture the physical, psychological and social functioning impairments from living with a condition such as psoriasis. In phase I distress (HADS) was the strongest predictor of DLQI but physical severity (SAPASI) remained a significant predictor. However, the primary ANCOVA in phase I reported a significant improvementin DLQI scores but not in HADS scores. These findings either suggest that the improvement in physical severity (SAPASI) was so large, that it changed the DLQI scores without the HADS scores significantly imporoving. Alternatively, there may have been a simulataneous improvement in HADS scores alongside the SAPASI scores but only the SAPASI reached significance. The pre to post-intervention changes did find a significant improvement in HADS scores so it is possible the study sample size was too small for the ANCOVA to detect an effect on the HADS outcome. These preliminary results could indicate that MBCT improved HADS minimally and SAPASI more, which accounts for the improvement in DLQI scores.

This study found a two point decrease in DLQI scores, which is less that the accepted MID of five points (Khilji et al., 2002) suggesting MBCT could be a useful adjunct rather than stand alone treatment. These effects did not change for two months post MBCT, signifying these beneficial effects could be sustained rather than temporary. These effects must be considered together with the individual change score data as whilst they are tempting, they could be exaggerated due to powerful statistical tests.

The systematic review identified the gold standard study, (Fortune et al., 2002b). also altered participants' illness representations (identity, consequences and emotional cause subscales) (Fortune et al., 2004a). The current study reduced physical severity and QoL impairment but not HADS or stress levels and there were no changes to participant's illness representations. From the combination of these studies it is suggested that cognitive challenge techniques are necessary in order to improve stress and distress levels. It is acceptable to compare these two interventions (CBT and MBCT) as they are delivered in a similar format. Any differences should result from the course content rather than unmeasured effects. To examine the mechanisms of change more closely (e.g. is cognitive challenge necessary to improve distress in people with psoriasis) a head to head trial between the two interventions would need to be conducted

In this study, distress (HADS) was the only outcome to significantly correlate with the CAR (both cortisol and cortisone). The CAR may be a physical expression of distress and therefore it is not suprising that while distress did not change as a result of the MBCT intervention neither did the CAR.

In the interviews participants reported improvements to specific elements which can contribute to stress and distress. For example they felt more in control and less automatic reactivity. Feeling out of control is one of the key components of stress (Cohen, 1978, Lazarus, 1966). The MBCT course may improve some factors that contribute to stress and distress but it may take longer to reduce established distress.

Mindfulness based cognitive therapy has been recommended for the treatment of distress in people with long-term conditions (National Institute for Health and Clinical Excellence, 2009b). The seminal MBCT papers focussed on its use to prevent depression relapses and necessitated long follow-up periods (Teasdale et al., 1995). Participants in the current study reported that the intervention was a "life long" tool rather than a "quick fix." They thought it might be more beneficial to them in the long-term future. This suggests that the reduction in physical and QoL impairment occurred without the participants feeling as though they were getting emotionally/psychologically better. Psychological and emotional variables may have some influence on psoriasis disease progression but mindfulness may act through other mechanisms i.e. arousal reduction or improved sleep quality.

7.4.2 Stress – CAR – Psoriasis link

The secondary aim of this study was to examine whether the CAR mediates the association between stress and physical psoriasis symptoms. Stress affects the HPA axis and modulates the release of cortisol (Ader, 1991; Biondi and Picardi, 1999). CAR is a discrete function of the HPA axis and can signal whether the axis as is functioning normally. Chronic stress is associated with an attenuated CAR (Pruessner et al., 1999)

and this is related to physical conditions such as diabetes (Bruehl et al., 2009). An attenuated CAR signals dysfunction in the HPA axis altering cortisol output thereby affecting the production of the pro-inflammatory cytokines involved in the pathogenesis of psoriasis (Hall et al., 2012; Chapman and Moynihan, 2009). The CAR has not previously been measured in people with psoriasis.

From this basis it was assumed that CAR would correlate with the physical severity of psoriasis and the perceived stress levels, however it was not associated with either. The CAR did correlate with negatively with distress and positively with mindfulness skill, which were negatively correlated with each other. The CAR appears to be associated with distress rather than the physical severity of symptoms.

Previously, clinical depression was correlated with an attenuated CAR (Gex-Fabry et al., 2012) possibly due to increased allostatic load, scarring of the HPA axis and attenuated CAR (Gex-Fabry et al., 2012). Although causality cannot be inferred from correlations it could be hypothesised for future studies to test whether living with psoriasis leads to some people developing distress and an attenuated CAR. Mindfulness skills were positively correlated with CAR and negatively with distress therefore they could possibly protect people with psoriasis from becoming emotionally distressed and consequently developing an attenuated CAR.

7.4.3 Which patients with psoriasis will benefit most from MBCT?

The final aim of the study was to explore whether MBCT would be an acceptable and useful intervention. People with psoriasis often do not adhere to their medical treatment regimens (Richards et al., 2006) and the systematic review found many do not complete psychological interventions. One treatment, whether it is physical or psychological, will rarely suit all patients. Interventions should be tailored to those who will gain the most benefit rather than using a trial and error model.

The systematic review suggested that stress responders would be more likely to adhere and accept psychological interventions. Previous researchers found between 37-78% of people with psoriasis believed that stress exacerbates their condition i.e. stress responders (Picardi & Abeni, 2001). In this study 97% of participants were stress responders. They explained how they could *"practically see it coming out"* with stress. Stress responders have previously been reported to experience more physical flares, greater psoriasis related stress and a dampened serum cortisol response to an acute stressor, than non-stress responders (Gupta et al., 1989; Richards et al., 2005). A linear relationship between physical severity and distress has not been reported in previous studies (Fortune et al., 1997, Main et al., 2000, Richards et al., 2001) but was found in this study. This is probably because previous studies included a mixture of non-stress and stress responders but participants in this study were almost all classified as stress

responders. We can conclude that stress responders may be more likely to volunteer and adhere to a MBCT intervention.

The procedure of agreeing to a statement that stress causes psoriasis may also highlight another characteristic of compliant participants. They are happy to accept that emotions and psychological state might have an influence upon physical symptoms. During the interviews participants presented themselves as open to try new treatment options and did not rigidly adhere to the biomedical model of health and illness. Participants demonstrated beliefs such as consumerism (shopping around to try new treatments), openness, critical thinking and holism, all of which have previously been associated with an increased likelihood of accessing complementary and alternative treatment options (Shiapush, 1999). People without these beliefs and attitudes may be less likely to respond well to MBCT.

Mindfulness was perceived, in this study, as an alternative therapy and while participants were open to such therapies some other people with psoriasis may not find this an acceptable treatment option. One participant explained how the negative connotations of alternative therapies can be diminished by presenting a strong scientific evidence base in favour of mindfulness. He explained how the scientific evidence base validated his decision to adhere to the MBCT course. Mindfulness practice was perceived, by some, as self-indulgent. People may not have practised because some viewed mindfulness as an enjoyable lifestyle choice and not a genuine treatment option. MBCT may need to be presented as a practical tool to improve physical healing as opposed to simply improving personal well-being.

Previous studies found people with psoriasis to have high levels of alexithymia, which is a relative inability to describe and express personal emotions (Allegranti et al., 1994). This construct was not specifically measured within this population but adherent participants in this study seemed to be quite aware of their internal psychological states and how these can influence emotions, physical reactions and social behaviours. This lends weight to the suggestion that people who are more psychologically aware will be more likely to join and adhere to a MBCT group and conversely that people who experience alexithymic symptoms would be less likely to join an MBCT group.

Participants in the low efficacy typology group did not believe they needed help, despite joining and adhering to the MBCT course. They claimed that their psoriasis previously caused them serious consequences but they have now accepted it. They did not frequently practise the mindfulness techniques and they felt they did not get much benefit from the course. Incongruently, they also explained how they were currently experiencing some distress. Perhaps they were not ready to face these difficulties or

maybe they had genuinely accepted their condition. It would seem important to screen participants before they enter a mindfulness intervention. They need to be open to new experiences, ready to discuss their personal and emotional worlds and to be encountering some negative consequences from their condition in order to overcome the barriers to practicing the mindfulness.

There was no gender predominance in this study, which suggests that MBCT will appeals to both men and women. The mean age of this study population was consistent with other psychological intervention studies. People tend to agree to participate in psychological interventions to help manage their psoriasis when they are in their 40's, usually after living with their condition for many years.

Some interviewees said they would have benefitted more from MBCT when they were younger because with time they had adapted to and accepted living with psoriasis. Others said they needed it more when they were in their teens and twenties because of their heightened anticipatory anxiety of negative social evaluation, particularly in relationships at this age. Previous research has reported that distress and QoL impairment decrease the longer people have lived with psoriais (Young et al., 2010; Wahl et al., 1999). Younger people with psoriasis have been reported to display less emotional control over anger and anxiety (Kossakowska et al., 2009). Participants in this study reported how the mindfulness skills had developed their control over their emotions. It may be better for people to develop these skills earlier in life.

Younger people may not be as motivated to join and adhere to psychological interventions such as MBCT. Participants who have dropped out of previous mindfulness-based interventions were more likely to be the younger participants (Crane et al., 2010). Younger people may benefit more from a psychosocial intervention such as mindfulness but they are less likely to volunteer (the mean age of participants in this study was 41 years) and more likely to drop out if they do.

One participant explained that moving towards negative thought and feelings caused her a lot of distress. Fear of negative thoughts is a symptom of an active anxiety episode. This participant had a baseline HADS score of 30 (Anxiety=20 and Depression=10). A score over 12 on the anxiety subscale is used as a classification of probable clinical anxiety, which suggests this participant was suffering from a clinical anxiety disorder. Some MBCT clinicians advise against delivering MBCT to people in an active episode of depression or anxiety (Hayes et al., 2004, Barnhofer et al., 2009) because MBCT skill learning may overload their already restricted cognitive capacity. The MBCT course may not be acceptable or helpful to these participants but may become more suitable for them when they are in remission. A screening process could pick up people who are

clinically anxious or depressed and this course could be offered to them at a time when they are in remission.

7.4.4 Recommendations for MBCT group facilitators

Participants described barriers that might have prevented them from gaining the maximum benefit from the MBCT course. In response to these barriers several recommendations have emerged for MBCT group facilitators. If group facilitators can respond to these recommendations, this may increase adherence to the MBCT protocol and consequent beneficial effects for participants.

Participants varied in how much and how quickly they could assimilate new information. Once someone has learned as much as they can, remaining information will be lost. If a previous sessions' skill set has not be assimilated before entering the next class, the new information might be lost. Without this knowledge base the scaffolding for progressing is absent. At Breathworks® participants can either attend one, four-hour session every two weeks, or one, two-hour session every week. Offering participants a variety of session lengths might help to tailor the intervention to the participant's individual learning speed. This strategy may increase adherence and effective learning.

The PI attended a teacher-development training course to learn how to facilitate MBCT groups. The course did not specifically teach facilitators how to manage difficulties such as people hiding within the group setting or members dominating and annoying other participants. A recommendation for the MBCT training courses would be to include specific training in how to manage the group dynamics. This may ensure that all members get an equal chance to learn the mindfulness skill set.

The training could also help facilitators to identify and respond to different learning styles. This study found some members to demonstrate an assimilator learning style and explained that they could not focus on experiential learning because they were so fixated on understanding the concrete theoretical premise of MBCT. Although the main drive of MBCT is to teach the skills experientially rather than remaining in the conceptual mode of theoretical understanding. Some materials could be included or time allocated for people to discuss the theoretical underpinnings of mindfulness with members of the group. This may allow people with these learning styles to learn more without removing anything from the other group members' experiences.

It seems important for group facilitators to tailor specific, attainable goals to individual members. Reaching these goals can increase their self-efficacy and control beliefs. If these beliefs are enhanced through positive reinforcement then the participants may be more capable in overcoming the barriers to practicing mindfulness.

Participants lost their motivation to practise during the weeks between sessions because the goal of achieving well-being became too distant. Facilitators could develop proximal goals for the individual members such as not shouting at their partner for a week. They could offer prompts to remind participants during the intervening week of their goals and how they planned to achieve them. Perhaps future studies could employ behaviour change techniques targeted to improve self-efficacy and control beliefs (Michie et al., 2011) in this population.

7.5 Future research

The results from this mixed-methods study have generated new research questions from a theoretically grounded evidence base.

7.5.1 Fully powered RCT

This pilot study (underpowered) suggests that MBCT can reduce the physical symptoms of psoriasis. These findings are consistent with a similar, also underpowered study, which found MBSR to speed up skin clearance during phototherapy (Kabat-Zinn et al., 1998). These findings justify running a fully powered, large scale RCT study to examine the effects of MBCT upon the physical symptoms of psoriasis. Results from the current study were used to estimate a sample size (SSE) for a future RCT. The SSE for an 80% powered RCT to compare a treatment and control group on the primary outcome of SAPASI would need a total sample of 104 participants (52 per group).

The present study found a significant correlation between psoriasis and distress, which is inconsistent with previous literature. This correlation may have emerged because all the study participants were stress responders. In a larger RCT it may be possible to compare outcomes between stress responders and non-stress responders to see if this classification accounts for differences in their responsiveness to psychological interventions. However, patient preference may dictate that more stress responders will enter a psychological intervention than non-stress responders.

The current study's results imply that cognitive challenge is necessary to improve distress in people with psoriasis because CBT, which contains cognitive challenge, improved distress whilst MBCT, which does not contain cognitive challenge, did not. As recommended in the systematic review (Chapter 2) a direct head to head trial between CBT and MBCT is warranted. A fully powered RCT comparing physical symptoms, distress and QoL outcomes across CBT, MBCT and control groups would help elucidate whether cognitive challenge is necessary for improvements in distress.

A hypothesis that sleep-quality may mediate how mindfulness improves physical psoriasis symptoms emerged from this study. Sleep has been found to moderate the function of immune system cytokines including those involved in the pathogenesis of psoriasis (Bryant et al., 2004). It is recommended, therefore, that a future study include a more detailed examination of the role of sleep.

Mindfulness-based interventions have previously been effective in improving distress scores (National Institute for Health and Clinical Excellence, 2009b, Fjorback et al., 2011) but the current study did not find any similar improvements. The measurements of distress should be included in future studies but the follow-up period should be

elongated in order to observe whether distress changes over a longer period in people living with a co-morbid physical health condition.

7.5.2 Longitudinal prospective trial

The scar hypothesis (Gex-Fabry et al., 2012) predicts that that long-term distress could disrupt the HPA axis and result in an attenuated overall CAR. The current study implies that stress responders with psoriasis who have higher distress levels will have an attenuated overall CAR.

Some participants in this study explained that their psoriasis previously generated distress but that with time they had either accepted their condition or developed coping strategies to reduce this distress. This highlights a need for early and preventative interventions. The CAR was positively correlated with the levels of mindfulness skill. Causality cannot be inferred but if more mindful people have a healthier CAR then mindfulness may prevent distress and attenuated CAR.

A longitudinal prospective study with people newly diagnosed with psoriasis could elucidate this possible pathway. Early diagnosis patients could be offered MBCT or TAU then their distress, physical severity and CAR could be monitored over time. This study would examine whether altered CAR is a risk factor and/or a consequence to distress and of more clinical relevance, whether MBCT could reduce the likelihood of developing distress and altered CAR.

A study that prospectively examined the association between depression and inflammation used a six-year time scale (Stewart et al., 2009). The CAR stimulates HPA axis function, which modulates inflammatory process; therefore this six-year period could be applied to this longitudinal study.

7.6 Implications for clinical practice

Without further research the implications of MBCT for clinical dermatology are limited. Currently, there are two underpowered RCT's that have found mindfulness-based interventions to reduce the physical severity of psoriasis. While this is promising it is not an evidence base. A fully powered RCT would be required before mindfulness-based intervention would be considered as a possible adjunct treatment option.

The majority of participants did not report any adverse effects from participating in MBCT and therefore clinicians could inform their patients that these courses are safe and available. One participant, who may have been clinically anxious, reported that the moving towards negative feelings exercise caused her distress. MBCT should not be offered to people experiencing current clinical anxiety or depression. Perhaps CBT would be a more appropriate treatment choice for people who are currently anxious or depressed (Pilling et al., 2009).

This study has begun to develop a profile of people with psoriasis who may be more likely to accept, adhere and benefit from MBCT. Clinicians (psychologists or dermatologists) could screen their patients and offer MBCT to:

- Stress responders (believe their condition is exacerbated by stress).
- People who display openness to new experiences.
- People who display an awareness and ability to discuss their psychological and emotional states.
- People who currently perceive themselves as stressed and experiencing negative consequences on their daily functioning (psychological, social, physical) as a result of living with psoriasis.
- People who are not currently clinically anxious or depressed.

The intervention may be most useful to people who are newly diagnosed with psoriasis, however, they may not be ready to enter a psychological intervention and if they are younger they may be more likely to drop out of the MBCT classes.

7.7 Conclusions

People with psoriasis, who believe stress worsens their condition, are happy to join MBCT groups. This intervention could be a useful and acceptable adjunct treatment to reduce physical symptoms and QoL impairment in people with psoriasis. A fully powered RCT is needed to clarify MBCT efficacy and whether cognitive challenge is necessary to improve distress within this population.

The HPA axis (as measured by CAR) was proposed to mediate the stress-psoriasis link. This study does not support this hypothesis but suggests the function of the HPA axis to be related to emotional distress levels more than the physical severity of disease. Living with psoriasis is linked to some people experiencing distress and chronic distress could interrupt the HPA axis and its resultant CAR.

Participants encountered some barriers in learning the mindfulness skills and there are areas where group facilitators can overcome these difficulties.

This research programme provides a theoretical stance and a preliminary evidence base, which supports further investigation in to this promising field.

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Appendices

9.1 Review paper

The systematic review presented in Chapter 2 has been accepted for publication and is currently in press with the Journal of Psychology, Health and Medicine.

Can stress reduction interventions improve psoriasis? A review.

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Abstract

Psoriasis remains incurable and many sufferers experience related psychological distress and a lower quality of life comparable with other chronic diseases. A subpopulation, of people with psoriasis, believes their condition is exacerbated by psychological stress. This review analyses whether stress-reduction interventions can reduce: the physical severity of psoriasis and; related psychological distress.

A systematic search across EMBASE, MEDLINE, The Cochrane Library SIGLE and PsychInfo, identified 730 trials and 10 were included.

Three trials found a significant difference in psoriasis outcomes between groups post-intervention, ($p<0.05$). Seven studies included a psychological outcome and three found a significant difference ($p<0.05$). Three trials included a quality of life measurement and one of these reported a significant improvement ($p<0.001$).

Due to low quality evidence is currently insufficient to judge stress reduction interventions as either effective or ineffective. We make nine recommendations for future research in this multidisciplinary field.

Keywords: Psoriasis, psychological interventions, arousal reduction, review

Introduction

Psoriasis is a long term, inflammatory skin condition that affects 1.5 - 3% of northern Europeans (Griffiths and Barker, 2007). The most common form is plaque psoriasis characterised by red, scaly plaques prevalent on elbows, knees and scalp.

Between 39% - 61% of people living with psoriasis report that their condition is exacerbated by stress and worry (Fortune et al., 1998; Fortune et al., 2000; Farber and Nall, 1974; Seville, 1977; O'Leary et al., 2004), although this is not a universal finding (Berg et al., 2008). People with psoriasis who report more stress and believe their condition is worsened by stress are labelled stress responders (Gupta et al., 1989). This group show differences in biomarkers of stress in that they have a relatively low cortisol response to acute stress compared with low stress reactors (Richards et al., 2005). Stress may trigger flares of psoriasis in stress responders but not in non-stress responders.

Living with psoriasis can lead to psychological and social difficulties. Other people may display disgust and recoil from contact with someone with psoriasis erroneously believing the condition is contagious. Consequently people with psoriasis often avoid situations where they anticipate negative reactions e.g. using a public swimming pool (Ramsay and O'Reagan, 1988). Experiencing negative reactions may lead to avoidant behaviours, increased vulnerability to distress and psoriasis related disability (Fortune et al., 2002a). People living with psoriasis have higher levels of anxiety and depression, suicidal ideation and reduced quality of life (QoL) than disease free populations (Kurd et al., 2010).

We performed a review of the evidence for efficacy of specific stress reduction interventions for reducing psoriasis severity and improving psychological and QoL outcomes in psoriasis.

Design

Data collection

Electronic databases (Cochrane Library, MEDLINE, EMBASE, SIGLE and PsychInfo) were searched (May, 2010) with strategies (MeSH terms and keywords) tailored to each database (re-run in November 2010). Journal alert services were enlisted until January 2011. The reference lists of relevant reviews were searched and members of the cross-discipline research team recommended the key journals for hand searching.

Studies were included if they met the PICOS (Population, Intervention, Comparator, Outcome, Study) design criteria (Figure 1): a population aged >/=18 years with a primary diagnosis of psoriasis; a defined stress reduction intervention (no additional oral, topical or pharmacological); a comparison group; a primary outcome of physical severity with or without secondary outcome of psychological and QoL; a randomised controlled trial

(RCT) or quasi-RCT design. Searches were confined to English language peer-reviewed journals.

Initial sifts were combined and duplicates deleted. Of the original search results 40% were scrutinised by members of the wider research team to test the inclusion criteria. The full papers were then collected and examined to check for eligibility.

Data extraction

A data extraction form was developed and piloted with two reviewers. Discrepancies were resolved and minor adaptations made during discussion. Three members of the research team performed the data extraction. Before discussion there was an 81% agreement across researchers on the study quality. Discrepancies were resolved with discussion resulting in 100% concordance.

Quality assessment

Studies were graded for quality, based on the Cochrane scale (Khan et al., 2001), including how randomisation was conducted; how free of bias the outcome assessor was; and an evaluation of the statistical rigour of the study. Based on clinical experience, the research team added five quality markers: (1) whether there was a clinician-reported diagnosis of psoriasis; (2) the design (quasi/full RCT); (3) how much training/experience the facilitator had in delivering the intervention; (4) validation of the outcome measures used and; (5) whether the statistics and results adequately answered the study's research questions. The highest quality score (total) across these eight checks was 32 indicating optimum quality.

Data synthesis

Studies were examined for content, efficacy, quality and summarised for how effective stress reduction methods were in changing physical severity and associated distress and QoL. Themes emerged regarding the content of the intervention techniques.

Results

The initial search yielded 730 trials, 720 were rejected either as duplicates (24 trials) or based on their title and abstract (696 trials). A hand search was conducted of the British Journal of Health Psychology; Health Psychology; Psychology & Health; Journal of Psychosomatic Medicine; Journal of Behavioural Medicine; Social Science & Medicine; British Journal of Clinical Psychology; Psychology Health and Medicine; Journal of the American Academy of Dermatology; British Journal of Dermatology; Clinical Dermatology. Two additional papers were found (Vedhara et al., 2007). Full reports were collected for these 12 trials and two papers were removed: one included no statistical analysis (Boncz et al., 1990) and the other did not include a measurement of psoriasis (Schulte et al., 1985). Table 1 contains details of the included studies.

A meta-analysis could not be conducted due to the heterogeneity of primary outcomes used across the included studies (4/10 used the same physical outcome and 3/10 used the same psychological outcome).

Study Quality

The RCT is considered the gold standard design assumed to yield results with the least bias (Khan et al., 2001). Seven studies used a RCT design: one used a patient preference design; one a controlled trial design without randomisation and one a multiple time-series design (with randomisation). Four studies were either preliminary or pilot studies.

The minimum accepted power of a test is usually 80% certainty that the test will reject a false null hypothesis (type two error). Only one study included a power analysis but it did not meet the sample size needed to achieve 80% power (Tausk and Whitmore, 1999). Thus, no study in this review was a full scale RCT that met the 80% power estimation. The quality scores used as additional indicators of quality are presented in Table 2. The average study score was 22.2/32. The lowest quality scores were facilitator quality (1.4/3) and statistical rigour (5.5/9).

Synthesis of the studies

Two studies combined arousal reduction (e.g. relaxation) and cognitive therapy (e.g. CBT) components and eight studies adopted a single focus. Due to poor design and reporting we were unable to conclude any one intervention was superior.

Cognitive interventions are designed to manipulate negative automatic assumptions in order to manage the subsequent distress. Interventions aiming to reduce stress without targeting cognitions are labelled arousal reduction interventions. Most studies we examined lacked clarity regarding which mechanisms were targeted for which outcome.

Single focus interventions

Fortune et al (2002b) used CBT and found significant differences in physical, psychological and QoL variables between the treatment (Treatment as usual (TAU) plus CBT) and control group (TAU). This study emerged as the gold standard in terms of design and methodology.

The study adopted a patient preference design, which although considered inferior to RCT (Green et al., 2008), is widely used in mental health studies as it is correlated with motivation to adhere to the intervention (Brewin and Bradley, 1989).

Vedhara et al (2007) used an Emotional Disclosure (ED) arousal reduction intervention. Participants spent 20 minutes writing or talking about their thoughts/the most upsetting times of their lives over the phone (one-to-one) over four consecutive days. Control participants were also called and asked to write about what had happened either that day or the day before. Results showed mood predicted severity of psoriasis in the intervention group but not in the control group.

This study had a rigourous design but by excluding group comparisons in preference for regression analyses the authors missed the opportunity to examine the effectiveness of the intervention in comparison to its well-designed control comparison.

Paradisi et al (2010) employed an ED arousal reduction intervention as an adjunct to phototherapy. They found no difference on physical severity, psychological or QoL outcomes between the intervention and control groups post-intervention. They did find,

that the beneficial physical and QoL effects from phototherapy were maintained in the intervention group but not in the control groups.

Paradisi et al (2010) did not present the full between-groups analyses but merely reported they had not reached significance. The study reported a high attrition rate (49%), which was neither explained nor examined further.

Kabat-Zinn et al (1998) found participants who received a mindfulness arousal reduction intervention in addition to phototherapy reached skin clearance faster than those who did not. There was no difference between groups on the psychological outcomes.

Physical severity, assessed against four pre-defined photographic end points, was not a validated physical outcome measure which weakened the study design.

Tausk et al (1999) conducted a hypnosis arousal reduction intervention as an adjunct to TAU but did not find a difference between the intervention and control groups on physical outcomes. They did find differences in the physical outcomes between participants who were deemed highly or moderately hypnotisable, Form C (SSHS: C; (Weitzenhoffer, 1959))

Despite its good quality design there were no patient demographics or statistical analysis reported.

Gaston et al (1988) explored whether meditation alone or meditation plus imagery arousal reduction interventions as adjuncts to TAU changed physical outcomes in people with scalp psoriasis. The results showed significant differences in physical outcomes between participants who received the intervention compared to those who did not post-intervention but there was no additional effect of imagery over and above the effect of meditation. The psychological measurements were entered as predictor variables only and not compared between groups.

Gaston et al (1988) included a measure of meditative strength (clinician and self-report). Clinician's ratings were negatively related to the severity of psoriasis (partial r = 0.55, p < 0.05) but statistics of self-reported meditative strength were not reported. This rigorous arousal reduction study indicated skill acquisition (meditative strength) as an important variable for future research. The study did not use validated outcome measures.

Lazaroff et al (2000) in a musical resonance arousal reduction intervention found a larger reduction in the physical symptoms for in-patients who received the therapy compared to those who were instructed to 'somehow relax' for the equivalent 30 minutes.

This paper did not report baseline measurements, so it cannot be assumed that the groups were equivalent. The intervention group showed an 86% reduction in the intention to scratch, compared with a 29% reduction in the control group. The clinician ratings of physical severity showed a 65% reduction in the intervention group versus a 20% reduction in the control group. It is not known if these results demonstrate a

significant difference between the two groups, as the statistical methods were not described.

Additional design problems include the lack of validated outcome measurements and a lack of statistics/significance tests to support the paper's statements.

Kienan et al's (1995) study of progressive muscle relaxation (PMR), compared PMR, PMR plus biofeedback (auditory feedback on physical measures (heart rate)) and TAU. This is the only arousal intervention to include a physical technique rather than solely relying upon mental instructions. The authors reported significant differences between PMR conditions and the control group on self-reported but not on clinician reported physical outcomes. There was no additional benefit of biofeedback. The level of potential bias in the outcome assessment was high: psoriasis severity was rated on an un-validated scale and it was unclear how independent of the research the un-blinded outcome assessor was.

In summary, six out of the seven studies using an arousal reduction intervention reported some improvement in the physical outcomes but none reported improvements in psychological outcomes. Many of these studies had lower standards of methodological rigour. The gold standard study (Fortune et al, 2002b) employed a cognitive technique and found improvements in physical, psychological and QoL outcomes, which suggests that targeting cognitions may be key for psychological improvement. All studies reported a relatively high attrition rate, which suggests that no single stress reduction intervention is ideal for all people with psoriasis.

Combined focus interventions

Zachariae et al (2004) reported no differences in physical or psychological outcomes between participants who received TAU and those who received TAU plus combination psychotherapy (including CBT, relaxation and imagery) group. There were differences between the groups on biological parameters such as Laser Doppler Skin Blood Flow (statistic not reported, p=0.05) and psychological outcomes.

A questionnaire completed twelve months after the study categorised participants as stress responders or non-stress responders but no significant differences were found between participants (p value not reported).

Zachariae et al (1996) used the clinical imagery scale (Zachariae, 1993) measuring visual, kinaesthetic, tactile and somatic ability. Significant correlations were found between blood flow and visual: r = -0.44, p<0.05; kinaesthetic: r = -0.46, p<0.05; tactile: r = -0.52, p<0.05; somatic: r = -0.46, p < 0.05 variables.

This study lacked statistical reporting and gave little detail of the qualifications and experience of the intervention facilitator.

Price et al (1991) reported no difference in physical outcomes between participants who received TAU or TAU plus combined group psychotherapy (relaxation including self-hypnosis and cognitive counseling). There was a difference, however, between distress (HADS; F=2.81, p<0.05) and neuroticism and extraversion outcomes (Eysenck

Personality Questionnaire-Revised; F=7.83, p<0.001 (Eysenck et al., 1985)) favouring the psychotherapy group.

Participants rated the course on an non-validated usefulness scale as 5.86/6 but with no further explanation or analysis from the authors. Furthermore, self-hypnosis cannot easily be assessed and the cognitive intervention was specifically targeted to patient identified problematic areas, therefore this design had no effective control and therefore had an inherent bias.

Summary of combined focus interventions

The combined focus interventions included cognitive elements to reduce distress and arousal reduction elements to reduce physical and psychological stress. Two studies found improvements in psychological but not physical outcomes. This may be due to the highly specific cognitive techniques employed compared with the less well defined arousal reduction techniques e.g. self-hypnosis. The relatively high attrition rate suggests that one or both of the included elements did not suit all participants.

Summary of the studies outcomes and quality ratings

Five studies used the validated Psoriasis Area Severity Index (PASI; Fredriksson and Pettersson, 1978). The remaining studies used non-validated clinician ratings. Three studies including one using PASI (Fortune et al., 2002b) found a significant post-intervention difference between the intervention and control groups. These three studies were judged as the best quality of those reviewed (Fortune et al., 2002b).

Seven studies include a validated psychological outcome measurement: Hospital Anxiety Depression Scale (HADS; (Zigmond and Snaith, 1983)); Psychological Adjustment to Illness Scale Self-Report (PAIS: (Derogatis and Lopez, 1983)); Symptom Checklist (SCL-90; (Derogatis et al., 1973); State-Trait Anxiety Inventory for Adults (STAI; (Speilberger et al., 1970); General Health Questionnaire (GHQ-12; (Goldberg, 1972); Eysenck Personality Questionnaire (EPQ-R; (Eysenck et al., 1985); Profile of Mood States (POMS; (McNair et al., 1971); Beck Depression Inventory (BDI; (Beck et al., 1961) and the Brief Stress Questionnaire (BSQ; (Cohen et al., 1983). However, only three studies reported a significant difference in psychological outcomes, post-intervention between the intervention and control groups. Again these were rated as the higher quality studies (Fortune et al., 2002b).

Only three studies included a QoL measurement one of which (Fortune et al; 2002b) found a significant difference between groups post-intervention.

Conclusions

The degree of heterogeneity in design and physical/psychological outcome measures across the 10 studies prevented a meta-analysis. We tried to minimise over-interpretation of data by checking reviewers' decisions at different points across our review process. Any differences between assessments of study quality were resolved with discussions within the team. These checks conformed to Cochrane guidelines (Khan et al., 2001) increasing the transparency and reliability of our methodology.

Although some RCTs demonstrated negative findings there may still be a publication bias.

There were more non-significant differences on psoriasis outcomes (7/10) than significant differences (3/10). This was also true for psychological distress (4/7 non-significant results) and there were too few studies measuring QoL to make a decision either way.

Our review highlights two key messages: (1) the need to improve scientific quality, design and reporting, within this cross-disciplinary area of research and; (2) the mechanisms of change need to be identified. Our synthesis suggested that arousal reduction interventions were more effective at changing physical than psychological outcomes whereas interventions including cognitive therapy were more effective in improving the psychological outcomes. However, we were unable to demonstrate this conclusively due to poor quality of design and reporting. Psoriasis research requires close liaison between psychologists and dermatologists. Psychologists need to be advised by dermatologists on key physical variables and dermatologists guided by psychologists to appreciate and measure appropriate core psychological concepts. Despite advances in pharmacotherapy psoriasis remains a difficult to manage long-term condition. If, as research suggests, some stress responders could be helped with stress reduction techniques (Gupta et al., 1989; Zachariae et al., 2004; Richards et al., 2005) then it is a priority to determine which interventions work and why. Whilst psychological techniques can never be as standardised as pharmacological treatment they should still be tested within a scientific framework and variability reduced as much as possible to increase treatment confidence.

Recommendations

1. Future research should compare arousal reduction with cognitive techniques in order to identify the active element for change.

2. Psychological interventions are more dependent on the skills of the practitioner delivering the therapy than some forms of medical treatments and if not delivered effectively this could mask whether its therapeutic mechanisms are effective. Future research should routinely measure treatment fidelity and skill acquisition.

3. Beliefs about treatment efficacy are associated with physical outcomes (Horne, 1999) and adherence and consequent skills acquisition may be related to these beliefs. If participants have little confidence in an intervention then they are unlikely to engage fully and learn the necessary skills.

4. Stress reduction interventions could be particularly useful for psoriasis stress responders. We recommend well-controlled patient preference trials (Brewin and Bradley, 1989) or explicitly measuring individual differences in a prior beliefs towards the approach. A validated credibility/expectation questionnaire (Borkovec and Nau, 1972) accounts for post-treatment outcome variance (Newman and Fisher, 2010), should be

used to explore why some participants do not adhere to interventions and whether these groups are differentiated by their belief systems.

5. Psoriasis can show improvement during the summer due to the beneficial effects of UV exposure and this should be controlled for. Vedhara et al (2007) found that seasonal variation was the only significant predictor of PASI in their study.

6. The PASI is a validated and accepted tool and we recommend its use in this field of research. We advise against using a non-validated psoriasis severity measure.

7. Due to its widespread acceptability by clinicians in this field we recommend that a psoriasis specific measure is routinely included to reflect changes in QoL.

8. Future studies must report all results with full details including effects sizes to allow for full scientific understanding and meta-analyses in this field.

9. Too much variation exists in descriptions of intervention content. We recommend researchers should follow Vedhara et al's (2007) example and develop a comprehensive, detailed and specific protocol.

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Table 1

Studies	Quality	Study characteristics	Intervention	Results
Fortune et al, 2002a.	**Ranking:** 1st **Score:** 25.67	*N* = 93.Mean Age: (Treatment) = 42.9 years (s.d.=11.6); (Control) = 43.1 (s.d.=12). Years with psoriasis: (Treatment) = 20.6 (s.d.=11.0); (Control) =18.8 (s.d.=11.1). 70% female in treatment; 65% female in control.	Weekly 2.5-hour group sessions for 6 weeks **Treatment:** CBT **Control :** TAU	✔ **Physical, (**PASI): Sig (t=-2.20, $p<0.05$). ✔ **Psychological**, (HADS)**:** Sig (HADS: Depression: t=4.7, $p<0.001$. Anxiety: t=-2.8, $p<0.001$). ✔ **Quality of Life**, (PDI)**:** Sig (t = -3.33, $p<0.001$). **Attrition:** 25% in treatment group and 21% in control group at 6 weeks. 30% in treatment and 43% in control by 6 months.
Kabat-Zinn et al, 1998.	**Ranking:** 2nd **Score:** 25.33	*N* = 37. Mean Age = 42.9 (s.d=15.1). Years with psoriasis =11.2 (s.d=8.9). 54% female.	**Treatment**: MBSR; solitary (few minutes whilst in light booth) for approximately 13 weeks (3 sessions per week) **Control:** TAU.	X **Physical, (**Clinician ratings (photographs). Pre-defined end points: Sig 'halfway point': EHR = 3.88, $p<0.05$ and 'clearing point'. EHR = 3.75, $p<0.05$ ✔ **Psychological, (**SCL-90 and STAI): Ns. **Attrition:** 38%
Tausk et al, 1999.	**Ranking:** 3rd **Score:** 25.00	*N* = 11. Mean age=? Years living with psoriasis=? % female ?.	Group based. **Treatment:** Single blinded active hypnosis for 3 months+3 months un-blinded. **Control:** Neutral hypnosis (3	✔ **Physical** (PASI)**:** Ns. X **Physical** (Self report VAS 1-100 score): Ns. Sig in PASI and VAS physical outcomes between highly and moderately hypnotisable participants (statistic not

			months)+active hypnosis (months).	reported, p <0.05). **Attrition:** 19%
Vedhara et al, 2007	**Ranking:** 4th **Score:** 24.5	*N* = 59. Mean Age = 50 (s.d.=13). Years with psoriasis = 22 (s.d.=15). 54% female.	ED via phone for 4 days + 12-week follow-up. **Treatment:** ED. **Control:** neutral writing task.	✔ **Physical** (PASI)**:** Ns ✔ **Psychological** (POMS and HADS)**:** Ns ✔ **Quality of Life** (DLQI)**:** Ns **Attrition:** 14%
Zacharaie et al, 1996	**Ranking:** joint 5th **Score:** 23.00	*N* = 51.Mean age = 39.6 (s.d.=11.5). Years living with psoriasis = ? 62.76% female.	90 minute group weekly for month + fortnightly for 6 weeks. **Treatment**: psychotherapy + home practice **Control:** Stopped all TAU.	✔ **Psychological** (BDI and Brief Stress Scale)**:** Sig (statistic not reported, p <0.05) ✔ **Physical** (PASI)**:** Ns. **Attrition:** 12%
Gaston et al, 1998.	**Ranking:** joint 5th **Score:** 23.00	*N* = 24; Mean Age = 34.3 (s.d=11.3). Years with psoriasis = 13.7 years (s.d=9.5). 72% female.	12 weeks, 60 minutes one to one. **Treatment:** meditation. **Comparison**: meditation plus imagery. **Control:** WLC group and assessment control group.	X **Physical, (**clinician ratings)**:** Sig (partial r =0.30, p <0.05) ✔ **Psychological**, (PAIS)**:** not reported. **Attrition:** 25%
Paradisi et al, 2010	**Ranking:** 7th **Score:** 21.5	N = 78. < 45 years old = 40% Pennebaker, 66.7% King, 38.5% control. Years with psoriasis=?. Pennebaker= 53.3%	ED for 3 days + phototherapy 3x week <8 weeks. **Treatment 1** Pennebaker ED. **Treatment 2** King ED. **Control:** phototherapy.	✔ **Physical** (PASI, SAPASI)**:** Ns but phototherapy effects maintained in Pennebaker group compared to both of the other groups (statistic not reported). ✔ **Psychological** (GHQ-12)**:** Ns.

				✓ **Quality of Life** (Skindex-12)**:** Ns.
		female		**Attrition:** 49%
		King = 58.3% female.		
		Control group = 38.5% female.		
Price et al, 1991.	**Ranking:** 8th **Score:** 20.6	N = 31.Mean age: treatment = 42.82 years (s.d.=?), control = 46 years (s.d=?). Years with psoriasis: Treatment= 17 years (s.d.=?). Control = 25 years (s.d=?). 47.83% female.	90 minutes group for 8 weeks **Treatment:** Psychotherapy. **Control:** TAU	✓ **Psychological** (HADS and EPQ-R)**:** Sig on HADS anxiety ($F_{(1,21)}$ = 2.81, $p<0.05$) and EPQ-R neuroticism ($F_{(1,21)}$ = 7.83, $p <0.001$) **X Physical** (clinician ratings and self ratings on VAS)**:** Ns. **Attrition:** 26%
Kienan et al, 1995.	**Ranking:** 9th **Score:** 20.17	N = 32.Mean Age = 40 (range 18 - 60). Years with psoriasis=14.3 (range=1-39). 37.5% female.	One to one for 6 weeks. **Treatment**: Biofeedback and relaxation. **Comparison**: relaxation. **Control:** TAU	**X Physical (self-report):** subjective symptom scale)**:** Sig ($F_{(2,29)}$ = 3.29, $p < 0.05$) **X Physical (clinician-rated):** severity scale and symptom improvement scale)**:** Ns for both scales. **Attrition:** 0 %
Lazaroff et al, 2000.	**Ranking:** 10th **Score:** 13.5	N = 30 (psoriasis patients) Median age range = 21 – 30 years. Years with psoriasis=?. 57% female.	3 x 30 minute groups per day (14 days). **Treatment:** Musical Resonance Therapy.	**X Physical** (Self reported stimulus to scratch and clinician rated degree of sickness)**:** Found a reduction in physical outcomes but not statistically tested.

				Control: instructed to "somehow relax"	**Attrition:** 0 %

Studies	Diagnosis (3)	Design (2)	Randomisation (4)	Scale rating (5)	Facilitator (3)	Outcome assessor (4)	Relevance (2)	Statistics (9)	*Total*

Key	N = study population, **Sig** = Significant difference between groups post intervention. **Ns =** Non-significant difference between groups at post-intervention, ✔ = validated outcome measure, **X =** non-validated outcome measure, **s.d.** = standard deviation. **?** = unknown. **BDI** = Beck Depression Inventory, **CBT** = cognitive behavioural therapy, **DLQI** = dermatology quality of life questionnaire, **ED** = emotional disclosure therapy, **EHR** = estimated hazards ratio, **EPQ-R** = Eysenck personality questionnaire, **GHQ-12** = general health questionnaire, **HADS** = hospital anxiety depression scale, **MBSR** = mindfulness based stress reduction, **PAIS** = Psychosocial Adjustment to Illness Scale; **PASI** = psoriasis area severity index, **POMS** = profile of mood states, **PSS** = perceived stress scale, **SAPASI** = self-assessed psoriasis area severity index, **SCL-90** = symptoms checklist, **STAI** = State trait anxiety inventory, **TAU** = treatment as usual, **VAS** = visual analogue scale, **WLC** = waitlist control.

Fortune et al., 2002b	2	1	3	4.67	2	4.5	2	6	*25.17*
Kabat-Zinn et al., 1998	2	2	2	3.33	2	4	2	7	*24.33*
Kienan et al., 1995	2	2	3	1.67	1	2.5	2	6	*20.17*
Lazaroff et al., 2000	2	1	1	1	1	1.5	2	4	*13.5*
Price et al., 1991	2	2	3	3.6	1	2	2	5	*20.6*
Tausk et al., 1999	2	2	4	5	2	3	2	5	*25*
Zachariae et al., 1996	2	2	3	4	1	4	2	5	*23*
Gaston et al., 1988	2	2	3	3	2	4	2	6	*24*
Vedhara et al., 2007	2	2	4	4.5	1	4	0	7	*24.5*
Paradisi	2	2	4	5	1	1.5	2	4	*21.5*

et al., 2010								
Total	20	18	30	35.77	14	31	18	55	221.77
Average	2	1.8	3	3.6	1.4	3.1	1.8	5.5	22.18

Table 2

Figure 1

```
┌─────────────────────────────┐      ┌─────────────────────────────┐
│ 730 records identified through │    │ 2 additional records identified │
│   database searching           │    │   through other sources        │
└─────────────────────────────┘      └─────────────────────────────┘
              │                                      │
              ▼                                      ▼
        ┌───────────────────────────────────────────────┐
        │      708 records after duplicates removed       │
        └───────────────────────────────────────────────┘
                            │
                            ▼
        ┌─────────────────────────┐      ┌─────────────────────────┐
        │   708 records screened   │─────▶│  696 records excluded    │
        └─────────────────────────┘      └─────────────────────────┘
                     │
                     ▼
        ┌─────────────────────────┐      ┌─────────────────────────┐
        │   12 full-text articles  │─────▶│   2 full-text articles   │
        │  assessed for eligibility │     │    excluded, with        │
        └─────────────────────────┘      └─────────────────────────┘
                     │
                     ▼
        ┌─────────────────────────┐
        │   10 studies included in │
        │         synthesis        │
        └─────────────────────────┘
```

Figure 2

Key	■	Significant difference between groups on physical outcome	▨	Non-significant difference between groups on physical outcome	□	Unknown as data not reported

9.2   Systematic review search terms and strategy

Population terms	Intervention	Outcome	Comparison
Skin disease exp MeSH	Psychotherapy exp MeSH	Quality of life exp MeSH	clinical trials as topic MeSH
Skin diease.mp	Psychotherapy.mp	Quality of life.mp	randomized controlled trials as topic MeSH
Skin disorders exp MeSH	Cognitive techniques exp MeSH	Health status indicators MeSH	randomi?ed control trial
Dermatology MeSH	Counselling psychology. MeSH	Health status indicators.mp	intervention stud*.mp
Derma* .mp	Counsel?ing.mp	Anxiety MeSH	intervention studies MeSH
	Complementary therapy exp MeSH	Anxiety.mp	Double-Blind Method MeSH/
	Alternative medicine.mp	Depression MeSH	control group.mp.
	Alternative medicine exp MeSH	Depression.mp	controlled trial.mp.
	Holistic health exp MeSH	Mood disorders MeSH	case control study MeSH
	Holistic health.mp	HADS.mp	control* design.mp.
	Biofeedback exp MeSH	Hospital Anxiety and Depression Scale MeSH	quasi*experimental.mp.
	Biofeedback.mp	Named inventories, questionnaires and rating scales MeSH	program* evaluation MeSH
	Physical therapy modalities MeSH		
	Support group exp MeSH		
	Support group.mp		
	Hypnosis exp MeSH		

	Hypnosis.mp		
	Hypnotherapy exp MeSH		
	Hypnotherapy.mp		
	Massage exp MeSH		
	Massage.mp		
	Creative arts therapy exp MeSH		
	Therapeutic touch.mp		
	Relaxation exp MeSH		
	Relaxation.mp		
	Relaxation therapy exp MeSH		
	Muscle relaxation exp MeSH		
	Progressive relaxation therapy exp MeSH		
	Stress management exp MesH		
	Stress management.mp		
	Mindfulness exp MeSH		
	Stress reduction.mp		
	Meditation exp MeSH		
	Meditation.mp		

25. skin disease.mp. or exp skin disease/

EMBASE - 808

<u>Population</u>   <u>Intervention</u>

26. exp psychiatric treatment/

27. exp feedback system/

28. biofeedback.mp.

29. exp alternative medicine/

30. counseling/ or counsel?ing.mp.

31. behavio?r therapy.mp.

32. support group.mp.

33. stress management.mp. or stress management/

34. stress reduction.mp.

35. arousal reduction.mp.

36. relaxation.mp.

37. meditation/ or meditation.mp.

38. mindfulness.mp.

39. 26 or 27 or 28 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38

40. 25 and 39

Outcome

41. quality of life.mp. or exp "quality of life"/

42. exp mood disorder/

43. exp "named inventories, questionnaires and rating scales"/

44. HADS.mp. or "Hospital Anxiety and Depression Scale"/

45. 41 or 42 or 43 or 44

46. 40 and 45

Comparison

47. randomi*ed control trial.mp.

48. clinical trial/

49. intervention study/

50. controlled study/

51. control group/

52. case control study/

53. program* evaluation.mp.

54. 47 or 48 or 49 or 50 or 51 or 52 or 53

55. 46 and 54

Medline 238

Outcome

1. HADS

2. exp Depression/ or depression.mp.

3. anxiety.mp. or exp Anxiety/

4. quality of life.mp. or exp "Quality of Life"/

5. health status indicators.mp. or exp Health Status Indicators/

6. 2 or 3 or 4 or 5

Population

7. Dermatology/co, ed, mt, nu, pc, px, th [Complications, Education, Methods, Nursing, Prevention & Control, Psychology, Therapy]

8. exp Skin Diseases/co, nu, pc, px, rh, th [Complications, Nursing, Prevention & Control, Psychology, Rehabilitation, Therapy]

9. 7 or 8

Intervention

10. exp Complementary Therapies/

11. exp Psychotherapy/

12. exp Physical Therapy Modalities/

13. 10 or 11 or 12

14. 6 and 9 and 13

15. from 14 keep 1-641

Comparison

16. clinical trials as topic/ or randomized controlled trials as topic/ or intervention studies/

17. Double-Blind Method/ or controlled trial.mp.

18. control* design.mp.

19. control group.mp.

20. Program Evaluation/

21. quasi*experimental.mp.

22. control groups/

23. 16 or 17 or 18 or 19 or 20 or 21 or 22

24. 14 and 23

4 duplicates between Medline and EMBASE

PsychInfo no C or O

Population

1. exp Skin Disorders/

Intervention

2. exp Biofeedback/ or biofeedback.mp.

3. psychotherapy.mp. or exp Psychotherapy/

4. alternative medicine.mp. or exp Alternative Medicine/

5. holistic health.mp. or exp Holistic Health/

6. exp Cognitive Techniques/

7. counseling psychology/

8. counsel?ing.mp.

9. support group.mp. or exp Support Groups/

10. hypnosis.mp. or exp Hypnosis/

11. hypnotherapy.mp. or exp Hypnotherapy/

12. exp Massage/ or massage.mp.

13. exp Creative Arts Therapy/

14. therapeutic touch.mp.

15. relaxation.mp. or exp Progressive Relaxation Therapy/ or exp Muscle Relaxation/ or exp Relaxation Therapy/ or exp Relaxation/

16. exp Stress Management/ or exp Mindfulness/ or stress reduction.mp.

17. meditation.mp. or exp Meditation/

18. stress management.mp.

19. 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18

20. 1 and 19

Duplicate 1

Cochrane 161 clinical trials

<u>Population</u>

#1MeSH descriptor Skin Diseases explode all trees 19908 edit delete

#2 derma* 15369 edit delete

<u>Intervention</u>

#3 MeSH descriptor Psychotherapy explode all trees 11010 edit delete

#4 MeSH descriptor Complementary Therapies explode all trees 9826 edit delete

#5 (mindful*) 215 edit delete

#6 MeSH descriptor Counseling explode tree 1 2210 edit delete

#7 (counsel?ing) 2350 edit delete

#8 (counsel?ing):kw 9 edit delete

#9 'stress reduction' 3 edit delete

#10 MeSH descriptor Self-Help Groups explode all trees 497 edit delete

#11 (support group) 163738 edit delete

#12 MeSH descriptor Relaxation, this term only 192 edit delete

#13 MeSH descriptor Physical Therapy Modalities explode all trees 10033 edit delete

#14 (arousal reduction) 473 edit delete

#15 (#1 OR #2) 28780 edit delete

#16 (#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13) 177133 edit delete

#17 (#16 OR #14) 177334 edit delete

#18 (#15 AND #17) 9151 edit delete

<u>Outcome</u>

#19 MeSH descriptor Quality of Life, this term only 10895 edit delete

#20 MeSH descriptor Depression explode all trees 3872 edit delete

#21 MeSH descriptor Anxiety explode all trees 3904 edit delete

#22 (hospital anxiety and depression scale) 1331 edit delete

#23 MeSH descriptor Stress, Psychological explode all trees 2514 edit delete

#24 (#19 OR (#20 AND #21) OR #22 OR #23) 14912 edit delete

#25 (#18 AND #24)

No duplicates

CINAHL

Comparison

S32   S22 and S31   Search modes - Boolean/Phrase   View Results (9)

  S31   (S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30) Search modes -

  S30   control* design   Search modes - Boolean/Phrase View Results (788)

  S29   program* evaluation   Search modes - Boolean/Phrase View Results (16334)

  S28   case control study   Search modes - Boolean/Phrase View Results (5354)

  S27   intervention study   Search modes - Boolean/Phrase View Results (1308)

  S26   quasi experimental   Search modes - Boolean/Phrase View Results (4830)

  S25   control group   Search modes - Boolean/Phrase   View Results (22338)

  S24   randomi?ed control trial   Search modes - Boolean/Phrase   View Results (391)

  S23   controlled trials   Search modes - Boolean/Phrase View Results (10349)

  S22   S20 and S21   Search modes - Boolean/Phrase   View Results (116)

  S21   S15 or S16   Search modes - Boolean/Phrase   View Results (45541)

  S20   (S1 or S2) and (S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S13)

  S19   S1 or S2   Search modes - Boolean/Phrase   View Results (48076)

Outcome

  S18   ((quality of life) and (S13 or S14)) and (S1 or S2) Search modes - Boolean/Phrase

  S17   (quality of life) and (S12 or S13)   Search modes - Boolean/Phrase   Rerun

S16   quality of life   Search modes - Boolean/Phrase
Rerun

S15   Perceived Health   Search modes - Boolean/Phrase
Rerun

Intervention

S14   ("progressive muscle relaxation") or (MH "Progressive
Muscle Relaxation (Iowa

S13   (MH "Psychology, Applied+")   Search modes -
Boolean/Phrase   Rerun

S12   (S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11)
Search modes -

S11   ("progressive muscle relaxation") or (MH "Progressive
Muscle Relaxation (Iowa

S10   ""counselling""   Search modes - Boolean/Phrase
Rerun

S9   "counseling"   Search modes - Boolean/Phrase   Rerun

S8   (MH "Psychology, Applied+")   Search modes -
Boolean/Phrase   Rerun

S7   "support group"   Search modes - Boolean/Phrase
Rerun

S6   (MH "Therapeutic Exercise+")   Search modes -
Boolean/Phrase   Rerun

S5   ("psychotherapy") or (MH "Psychotherapy+")   Search
modes - Boolean/Phrase

S4   "mindfulness"   Search modes - Boolean/Phrase
Rerun

S3   (MH "Alternative Therapies+")   Search modes -
Boolean/Phrase   Rerun

Population

S2   "derma*"   Search modes - Boolean/Phrase   Rerun

S1   ("skin diseases") or (MH "Skin Diseases+")

SIGLE 150

Population

((skin disease)) AND

Intervention

(psychotherapy OR relaxation OR complementary therapy OR
alternative therapy OR counseling OR counselling OR stress
management OR arousal reduction OR stress reduction OR
support group OR exercise therapy OR meditation OR hypnosis
OR biofeedback OR hypnotherapy OR cognitive therapy OR CBT

OR music therapy OR therapeutic touch OR progressive
relaxation therapy OR meditation OR mind-body) AND

Outcome
(HADS OR depression OR anxiety OR quality of life OR hospital
anxiety and depression scale) AND

Comparison
(control group OR controlled design OR randomised control trial
OR intervention study OR quasi experimental OR program
evaluation OR case control study OR controlled trial)

9.3 Systematic review quality scale

Diagnosis confirmation:

confirmed date of clinician diagnosis	1
confirmed clinician diagnosis	2
self diagnosis	3

Design:

RCT	1
Quasi with matched control group	2

Randomisation:

Adequate / patient preference	1
Partial	2
Unknown	3
Inadequate	4

Intervention led by:

Experienced, qualified practitioner	
with external quality assessment	1
Experienced, qualified practitioner	2
Qualified practitioner	3
Unknown experience/qualification	3

Outcome assessor

Fully blinded assessor/s	1
Assessor/s not blinded but separate from research team	2
Self assessment	3
Assessment by non blinded members of research team	4
Unknown	4

Outcome measures:

Fully validated	1
Some support for validation	2
Clinician opinion without tools	3
Without validation	4

Statistics provided:

Descriptive data

Basic descriptive statistics with OR without full detail (1/2)

total : 2

Comparisons:

% change with OR without full detail (3/4)

Correlations with OR without full detail (3/4) or Regression with OR without full detail (3/4)

Predictive analyses with OR without full detail (3/4)

Group comparison with OR without full detail (3/4)

total: 4

Rigour:

Power calculation provided (1)

Intention to treat used (1)

total: 2

TOTAL: 8

Statistics strong: (6-8)

Statistics moderate: (3-5)

Statistics weak: (1-2)

Scale validation: (the lower the better)

Not validated and not used before and no inter-rater reliability	1
Not validated but used before / not validated and inter-rater reliability	2
Not validated but used before and inter-rater reliability	3
Validated	4

9.4 MBCT example session handout (unformatted)

Week four: Thoughts are not facts

Mental models:

John was on his way to school
He was worried about the Maths lesson
He was not sure he could control the class again today
It was not part of the janitor's duty

The mind makes a running commentary of the inputs from our surroundings and these commentaries influence our feelings. A marriage counsellor's example:

Person A: "Would you like fish or chicken tonight?"
Person B: "I do not mind"

Without focussing on who we think person A or person B is, Person A felt that person B does not care about what they make for dinner and that Person B never cares about Person A. Person B felt like they wanted to be helpful and not difficult about what they wanted. Different interpretations and different emotional reactions.

We shall try separating events from their interpretations.

Our aims:
We need to try and reduce our personal identification with our thoughts.
Try to stop relating from our thoughts (so we are our thoughts) and start relating to our thoughts (as mental events).
Recognising that thoughts are just thoughts, they are not facts/reality even the ones which say they ARE fact. We have a choice in how we shall respond to them.
Using gentle curiosity in order to relate to our thoughts.

"Awareness is not the same as thought. It lies beyond thinking, although it makes use of thinking, honouring its value and its power. Awareness is more like a vessel which can hold and contain our thinking, helping us to see and know our thoughts as thoughts rather than getting caught up in them as reality"

Jon Kabat-Zinn, Mindfulness Meditation for Everyday Life.

Practical methods to see your thoughts differently

The cinema

Try seeing your awareness as a cinema screen and your thoughts as pictures/words moving across the screen. You are not them but you can see them and they can move you just as a film does.

Try seeing certain repetitive thinking patterns as films. Oh here is 'I am not good enough for this job, they all wish they hadn't hired me.' Just as with films such as 'Gone with the Wind' the first 6, 7, 8 times you see it you will be swept away with the emotions but in the end you know it is just a film and it does not stir up such strong emotions anymore.

You could try this in the silent meditation.

The waterfall

Sometime the thoughts are too painful to put our attention on to them, this is ok. Maybe try focussing your attention on to the physical echo, the physical sensations in the body when this thought enters your awareness. You can also try exploring the feelings as well, "I am nervous, tense, suspicious. I cannot trust people when this thought gets into my head." Detail the emotional reactions as well as the physical reactions, "there is a ball, which is hard in my left shoulder when I think about her."

By viewing the thoughts, bodily sensation and feelings in this gentle descriptive manner, you are placing yourself behind the waterfall and the powerful force of thoughts and emotions are still very much in your awareness, rushing past you. You are aware of their power but also that they are NOT you.

We are often so close to our thoughts it is very hard to see them as different entities to ourselves, but little by little if we change our stance then our emotional reactions will change in subtle but important ways.

Within you there is stillness and sanctuary to which you can retreat at anytime and find yourself.

Siddhartha
By Herman Hesse

Step but step process…

Watch the thoughts come in and leave without feeling you need to follow them (cinema, waterfall perspective)

View your thoughts as mental events rather than a fact. Even the ones (thoughts) which tell you that they ARE TRUE!

Try writing the thoughts down on paper, this allows you to see them without being overwhelmed by them. The pause between thinking and writing down is a moment of reflection.

Ask yourself the following questions:

Did this thought pop into my head automatically?

Does it fit with the facts of the situation?

Is there something about it which I can question?

How would I have thought about it at another time/in another mood?

Are there alternative interpretations?

For very difficult thoughts it may be useful to dedicate some time in your sitting practice to specifically take a look at the problem with your "wise mind" not the problem solving mind.

Thoughts in meditation…

Ask yourself some of these questions and return to the breath after each one…

Perhaps I am confusing a thought with a fact?

Perhaps I am jumping to conclusions?

Perhaps I am thinking in black and white terms?

Perhaps I am condemning myself totally because of one thing?

Perhaps I am concentrating on my weaknesses and forgetting my strengths?

Perhaps I am blaming myself for something which isn't my fault?

Perhaps I am judging myself?

Perhaps I am setting unrealistically high standards for myself so that I will fail?

Perhaps I am mind reading/crystal ball staring?

The mountain meditation

Picture the most beautiful mountain you know – or can imagine. Notice its overall shape, the lofty peak, the base rooted in the rock of the earths crust, the sloping slides. Note how massive it is, how unmoving, how beautiful.

See if you can bring the mountain into your own body – your head becomes the lofty peak; your shoulders and arms the sloping sides of the mountain; your buttocks and legs the sold base rooted to your cushion on the floor or to your chair.

Become the breathing mountain, unwavering in your stillness, completely what you are – beyond words and thought, a centred, rooted, unmoving presence.

As the light changes, as night follows day and day night, the mountain just sits, simply being itself. It remains still as the seasons flow into one another and as the weather changes moment by moment. Storms may come, but still the mountain sits.
Calmness abiding all change.

Jon Kabat-Zinn, "Wherever you go there you are."

The most important thing is to be gentle with you when asking these questions. Gentle curiosity and interest into these thoughts.

Home practice:

Start to prepare for when the course ends and you integrate mindfulness into you life.

40 minutes practice for 6 of the next 7 days.
This 40 minutes can be broken into whichever practices you wish
The Body Scan
Mindful movement
Sitting meditation
You could do 2 x 20 minute practices or 30 minutes + 10 minutes practice later.
Maybe include some silent meditation too.
Three stage breathing space: regular
Three-stage breathing space: coping
Notice and jot down how you are relating to your thoughts day-to-day as well as during practice. Home practice record forms attached as before.

Home practice record form:

Day	Practice	Comments
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		
Monday		

Two kinds of intelligence

There are two kinds of intelligence; one acquired
as a child in school memorizes facts and concepts
from books and from what the teacher says,
collecting information from the traditional sciences
as well as from the new sciences.

With such intelligence you rise in the world.
You get ranked ahead or behind others
in regard to your competence in retaining
information. You stroll with this intelligence
in and out of fields of knowledge, getting always more
marks on your preserving tablet.

There is another kind of tablet, one
already completed and preserved inside you.
A spring overflowing its spring box. A freshness
in the centre of your chest. This other intelligence
does not turn yellow or stagnate, it's fluid,
and it doesn't move from the outside to inside
through the conduits of plumbing learning.

This second knowing is a fountainhead
From within you, moving out.

The Esential Rumi, translation by Coleman Barks with John Moyne, Harper, San
Francisco, 1995.

General comments on day-to-day relationship to thoughts…

9.5 Questionnaire booklet

Some background information about you and your psoriasis

Please fill in the boxes or tick the boxes as appropriate

Question 1	**Current age**	___ years

Question 2	**Gender**	
	Male	☐
	Female	☐

Question 3	**What is your marital status?**	
	Single	☐
	Stable relationship	☐
	Civil partnership/married	☐
	Separated/divorced	☐
	Widowed	☐

Question 4	**How many years have you been living with psoriasis?**	___ years

Question 5	**Tick all treatments you currently use for your psoriasis**	
	Topical treatments (e.g. Dovonex)	☐
	Systemic treatments (e.g. Methotrexate, Ciclosporin, Acitretin)	☐
	Biologic treatments (e.g. Adalimumad(Humira), Etanercept (Enbrel), Infliximab (Remicade))	☐
	Phototherapy	☐

Other over the counter treatments

(e.g E45, other moisturisers)

Other complementary/alternative treatments

(Please name)

Question 6

Have any other members of your family been diagnosed with psoriasis?

Mother, Father, Sister, Brother

Grandparent, Grandchild, Cousins, Blood related
Aunt/Uncle, Nephew/Niece, Half-brother/sister

Step-family members

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts **during the last month.** In each case, you will be asked to indicate by circulating *how often* you felt or thought a certain way.

**0 = Never   1 = Almost Never   2 = Sometimes   3 = Fairly Often   4 = Very Often**

1.	In the last month, how often have you been upset because of something that has happened unexpectedly	0	1	2	3	4
2.	In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3.	In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4.	In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5.	In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6.	In the last month, how often have you found that you could not cope with all the things you had to do?	0	1	2	3	4
7.	In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8.	In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9.	In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10.	In the last month, how In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

Cohen (1983) Mind Garden, Inc

Self-Assessed Psoriasis Area Severity Index:

How bad is your psoriasis TODAY?

We need to know where you have psoriasis and how red, thick, scaly it is to tell how bad your psoriasis is.

1. As best you can, please shade in (with pen or pencil) on the drawing exactly where you have psoriasis.
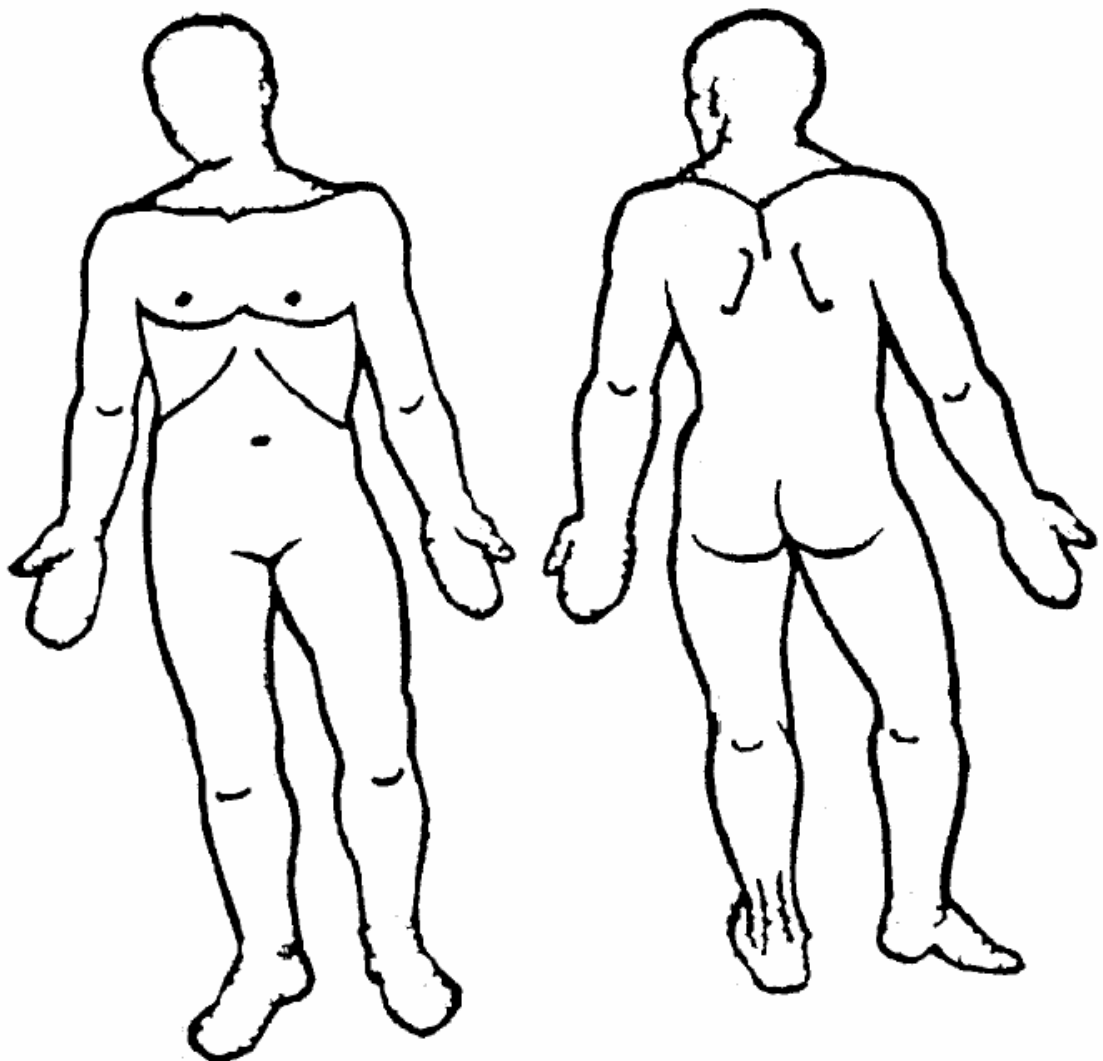
Feldman et al (1996)

2. Answer each question by placing a mark anywhere on the line to show how red, thick and scaly an average spot of your psoriasis is (see example)

Example:

Very Good   **Very bad**
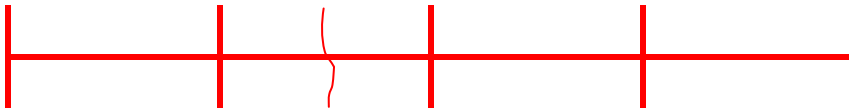
What colour is an average spot of your psoriasis?

No redness	Slightly pink	Red	Bright red	Dark red
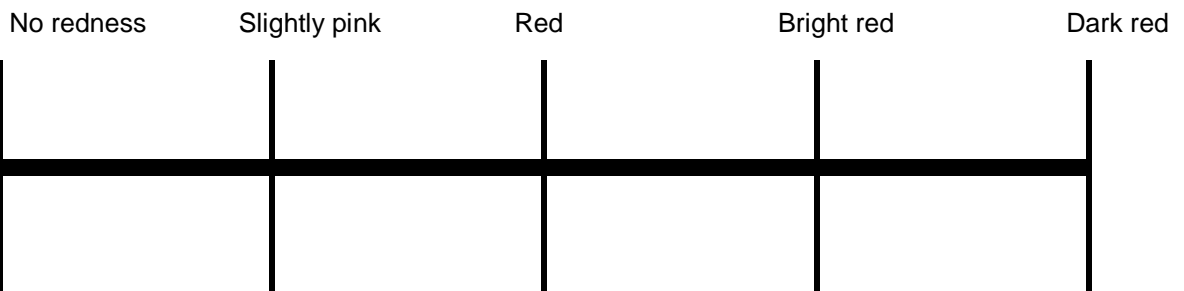
How thick is an average spot of your psoriasis?

No thickness	Slightly raised	Raised	Very raised	Markedly raised
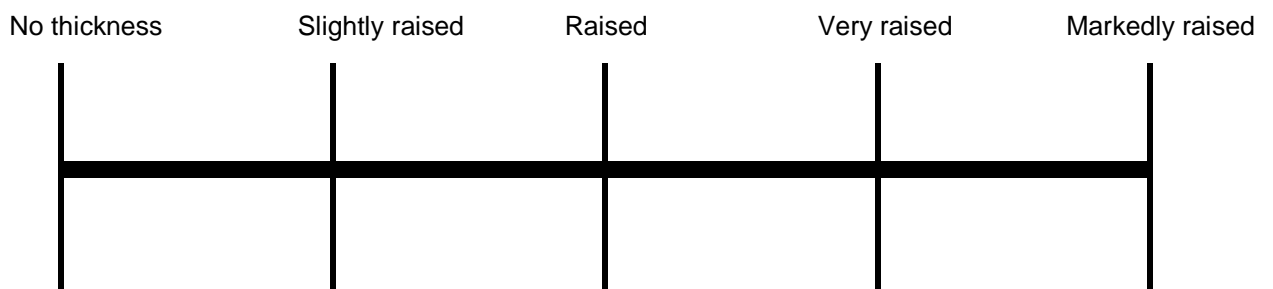
How scaly is an average spot of your psoriasis?

No scale	Slight scale	Scaly	Flaky	Very flaky
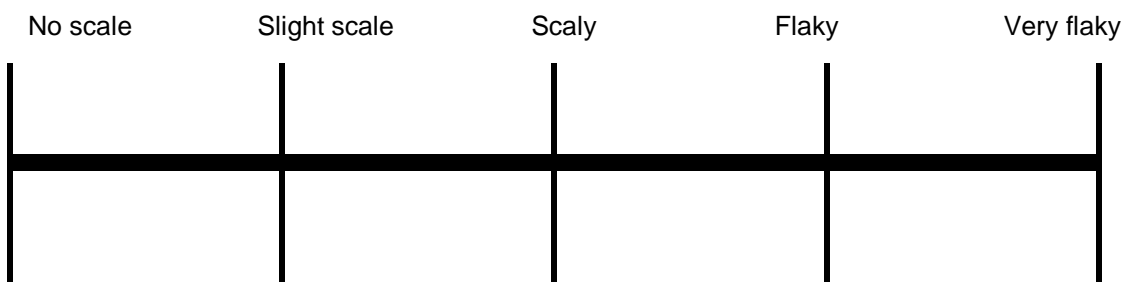
Feldman et al (1996)

Dermatology Quality of Life Index

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

1. Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?

    Very much   r
    A lot   r
    A little   r
    Not at all   r

2. Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?

    Very much   r
    A lot   r
    A little   r
    Not at all   r

3. Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?

    Very much   r
    A lot   r
    A little   r
    Not at all   r Not relevant r

4. Over the last week, how much has your skin influenced the **clothes** you wear?

    Very much   r
    A lot   r
    A little   r
    Not at all   r Not relevant r

5. Over the last week, how much has your skin affected any **social** or **leisure** activities?

    Very much   r
    A lot   r
    A little   r
    Not at all   r Not relevant r

6. Over the last week, how much has your skin made it difficult for you to do any **sport**?

    Very much   r
    A lot   r
    A little   r
    Not at all   r Not relevant r

7. Over the last week, has your skin prevented you from **working** or **studying**?

    Yes   r
    No   r Not relevant r

    If "No", over the last week how much has your skin been a problem at **work** or **studying**?

    A lot   r
    A little   r
    Not at all   r

8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much	r
		A lot	r
		A little	r
		Not at all	r Not relevant r

9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much	r
		A lot	r
		A little	r
		Not at all	r Not relevant r

10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much	r
		A lot	r
		A little	r
		Not at all	r Not relevant r

[a]AY Finlay, GK Khan, April 1992 www.dermatology.org.uk, this must not be copied without the permission of the authors

The Hospital Anxiety and Depression Scale

Read every sentence. Place an **"X"** on the answer that best describes how you have been feeling during the **LAST WEEK.** You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.

I feel tense or 'wound up':	
Most of the time	
A lot of the time	
From time to time (occasionally)	
Not at all	
I still enjoy the things I used to enjoy:	
Definitely as much	
Not quite as much	
Only a little	
Hardly at all	
I get a sort of frightened feeling as if something awful is about to happen:	
Very definitely and quite badly	
Yes, but not too badly	
A little, but it doesn't worry me	
Not at all	
I can laugh and see the funny side of things:	
As much as I always could	
Not quite so much now	
Definitely not so much now	
Not at all	
Worrying thoughts go through my mind:	
A great deal of the time	
A lot of the time	
From time to time, but not often	
Only occasionally	
I feel cheerful:	
Not at all	
Not often	
Sometimes	
Most of the time	
I can sit at ease and feel relaxed:	
Definitely	
Usually	
Not often	
Not at all	

I feel as if I am slowed down:	
Nearly all the time	
Very often	
Sometimes	
Not at all	
I get a sort of frightened feeling like "butterflies" in the stomach:	
Not at all	
Occasionally	
Quite often	
Very often	
I have lost interest in my appearance:	
Definitely	
I don't take as much care as I should	
I may not take quite as much care	
I take just as much care	
I feel restless as I have to be on the move:	
Very much indeed	
Quite a lot	
Not very much	
Not at all	
I look forward with enjoyment to things:	
As much as I ever did	
Rather less than I used to	
Definitely less than I used to	
Hardly at all	
I get sudden feelings of panic:	
Very often indeed	
Quite often	
Not very often	
Not at all	
I can enjoy a good book or radio/TV program:	
Often	
Sometimes	
Not often	
Very seldom	

Zigmond and Snaith (1983)

Illness perceptions questionnaire – revised (IPQ-R)

YOUR VIEWS ABOUT YOUR PSORIASIS

Listed below are a number of symptoms that you may or may not have experienced since developing psoriasis. Please indicate by circling *YES* or *NO*, whether you have experienced any of these symptoms since your illness, and whether you believe that these symptoms are related to your illness.

		I have experienced this symptom *SINCE MY PSORIASIS*		This symptom is RELATED TO MY PSORIASIS	
I1	Pain	YES	NO	YES	NO
I2	Nausea	YES	NO	YES	NO
I3	Breathlessness	YES	NO	YES	NO
I4	Itching	YES	NO	YES	NO
I5	Fatigue	YES	NO	YES	NO
I6	Stiff joints	YES	NO	YES	NO
I7	Sore eyes	YES	NO	YES	NO
I8	Headaches	YES	NO	YES	NO
I9	Upset stomach	YES	NO	YES	NO
I10	Sleep difficulties	YES	NO	YES	NO
I11	Dizziness	YES	NO	YES	NO
I12	Loss of strength	YES	NO	YES	NO
I13	Weight loss	YES	NO	YES	NO
I14	Burning	YES	NO	YES	NO
I15	Skin flaking	YES	NO	YES	NO
I16	Sore throat	YES	NO	YES	NO
I17	Wheezing	YES	NO	YES	NO

Moss-Morris et al (2002)

We are interested in your own personal views of how you see your psoriasis. Please indicate how much you agree or disagree with the following statements about your psoriasis.

	VIEWS ABOUT YOUR PSORIASIS	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
V1	My psoriasis will last a short time					
V2	My psoriasis is likely to be permanent rather than temporary					
V3	My psoriasis will last for a long time					
V4	My psoriasis will pass quickly					
V5	I expect to have psoriasis for the rest of my life					
V6	My psoriasis will improve in time					
V7	The symptoms of my psoriasis change a great deal from day to day					
V8	My symptoms come and go in cycles					
V9	My psoriasis is very unpredictable					
V10	I go through cycles in which my psoriasis gets better and worse					
V11	My psoriasis is a serious condition					
V12	My psoriasis has major consequences on my life					
V13	My psoriasis does not have much effect on my life					
V14	My psoriasis strongly affects the way others see me					
V15	My psoriasis has serious financial consequences					
V16	My psoriasis causes difficulties for those who are close to me					
V17	There is a lot which I can do to control my symptoms					
V18	What I do can determine whether my psoriasis gets better or worse					
V19	The course of my psoriasis depends on me					
V20	Nothing I do will affect my psoriasis					
V21	I have the power to influence my psoriasis					
V22	My actions will have no affect on the outcome of my psoriasis					

	VIEWS ABOUT YOUR PSORIASIS	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
V23	There is very little that can be done to improve my psoriasis					
V24	My treatment will be effective in curing my psoriasis					
V25	The negative effects of my psoriasis can be prevented (avoided) by my treatment					
V26	My treatment can control my psoriasis					
V27	There is nothing which can help my psoriasis					
V28	The symptoms of my psoriasis are puzzling to me					
V29	My psoriasis is a mystery to me					
V30	I don't understand my psoriasis					
V31	My psoriasis doesn't make any sense to me					
V32	I have a clear picture or understanding of my psoriasis					
V33	I get depressed when I think about my psoriasis					
V34	When I think about my psoriasis I get upset					
V35	My psoriasis makes me feel angry					
V36	My psoriasis does not worry me					
V37	Having psoriasis makes me feel anxious					
V38	My psoriasis makes me feel afraid					

Moss-Morris et al (2002)

POSSIBLE CAUSES OF YOUR PSORIASIS

We are interested in what **you** consider may have been the cause of your illness. As many people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your psoriasis rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your psoriasis. Please indicate how much you agree, disagree that they were causes for you by ticking the appropriate box.

	POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
C1	Stress or worry					
C2	Hereditary – it runs in the family					
C3	A germ or virus					
C4	Diet or eating habits					
C5	Chance or bad luck					
C6	Poor medical care in my past					
C7	Pollution in the environment					
C8	My own behaviour					
C9	My mental attitude e.g. thinking about life negatively					
C10	Family problems or worries caused by my illness					
C11	Overwork					
C12	My emotional state e.g. feeling down, lonely, anxious, empty					
C13	Ageing					
C14	Alcohol					
C15	Smoking					
C16	Accident or injury					
C17	My personality					
C18	Altered immunity					

Please list in rank-order the three most important factors that you now believe caused **<u>YOUR psoriasis.</u>** You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me are:

1. …………………………………………………………………………
2. ……………………………………………………………………..
3. …………………………………………………………………………

Moss-Morris et al (2002)

Mindful Attention Awareness Scale (MAAS)

Please indicate the degree to which you agree with each of the following items using the scale below. Simply circle your response to each item.

1	2	3	4	5	6
almost always	very frequently	somewhat frequently	somewhat infrequently	very infrequently	almost never

1	I could be experiencing some emotion and not be conscious of it until sometime later.	1	2	3	4	5	6
2	I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
3	I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
4	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
5	I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
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
7	It seems I am "running on automatic" without much awareness of what I'm doing.	1	2	3	4	5	6
8	I rush through activities without being really attentive to them.	1	2	3	4	5	6
9	I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	1	2	3	4	5	6
10	I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
11	I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6
12	I drive places on "automatic pilot" and then wonder why I went there.	1	2	3	4	5	6
13	I find myself preoccupied with the future or the past.	1	2	3	4	5	6
14	I find myself doing things without paying attention.	1	2	3	4	5	6
15	I snack without being aware that I'm eating.	1	2	3	4	5	6

Credibility Expectancy Questionnaire – Version II

We would like you to indicate below how much you believe, **right now**, that the treatment you are receiving will help you to reduce your stress and trauma symptoms. Belief usually has two aspects to it: (1) what one thinks will happen and (2) what one **feels** will happen. Sometimes these are similar, sometimes they are different. Please answer the questions below. In the first set, answer in terms of what you **think.** In the second set answer in terms of what really and truly **feel.**

SET I

1. At this point, how logical does the treatment offered you seem?

1	2	3	4	5	6	7	8	9
Not at all				Somewhat logical				Very logical

2. At this point, how useful do you **think** the treatment will be in reducing your trauma symptoms?

1	2	3	4	5	6	7	8	9
Not at all useful				Somewhat useful				Very useful

3. How confident would you be in recommending this treatment to a friend who experiences similar problems?

1	2	3	4	5	6	7	8	9
Not at all				Somewhat				Very much

4. By the end of the therapy period, how much improvement in your trauma symptoms do you think will occur?

1	2	3	4	5	6	7	8	9
None at all								Total Improvement

SET II

For this set, close your eyes for a few moments and try to identify what you really feel about the treatment and its likely success. Then answer the following questions.

5. At this point, how much do you really *feel* that therapy will help you to reduce your trauma symptoms?

1	2	3	4	5	6	7	8	9
Not at all useful				Somewhat useful				Very useful

6. By the end of the therapy period, how much improvement in your trauma symptoms do you really *feel* will occur?

1	2	3	4	5	6	7	8	9
Not at all				Somewhat				Very much

Devilly & Borkovec (2000)

9.6 Saliva collection protocol

Instructions for saliva (spit) sample collection

It is very important that you follow these instructions carefully. This is the first collection time (one morning where you collect 4 saliva samples).

1. **Choose a morning to collect your saliva**

➢ Please **choose a morning** when you will collect your saliva before the
……………

➢ It is best to choose a weekday morning (or a morning when you get up at your usual time rather than a morning when you might have a lie in).

2. **The night before the morning of collection**

➢ You need to collect the first sample **AS SOON AS YOU WAKE UP** on the morning of collection so it may be a good idea to place the 4 Salivette® tubes, which you will need, next to your bed before you go to sleep.

➢ Maybe set an extra **alarm to remind** you to collect your saliva when you wake up.
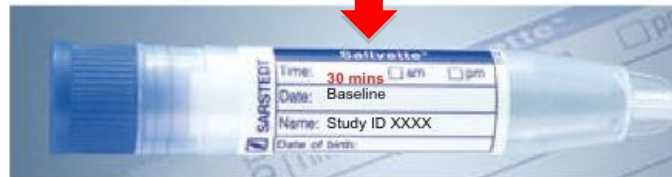
3. **The morning of collection**

➢ Please **do not drink or eat or smoke anything other than water** for the first hour you are awake on the day of collection.

➢ Please collect your saliva samples (remember to only drink water until you have collected all 4 samples):

   o **0 minutes** - As soon as you wake up (whilst you are still lying in bed)

   o **15 minutes** after waking up

   o **30 minutes** after waking up

   o **45 minutes** after waking up

> ➢ While you are holding the sample swab in your mouth please write on the collection tube which sample it is in the box marked 'time' e.g. "30min" (see below)

<div style="border:1px solid red; color:red; text-align:center; font-weight:bold;">
Please can you write in the time (as appropriate):

"0 min" or "15 min" or "30 min" or "45 min"
</div>

4. How to collect your saliva

Follow these steps to collect your saliva; you will repeat these steps 4 times in the morning of collection:

a. Remove the top cap of the tube to expose the round sponge.

Do **not** remove the holder that the sponge is sitting in.

b. Place the sponge directly into your mouth by tipping the tube so the sponge falls into your mouth. Do **not** touch the sponge with your fingers.

c. Keep the sponge in your mouth. Very gently chew and roll the sponge around in your mouth for 2 minutes. Spit the sponge back into the tube. Do **not** touch the sponge with your fingers.

    d.   Replace the cap. Make sure cap is on tightly.

    e.   **Refrigerate** the Salivette® tube and post it with your questionnaires in the pre-paid **return envelope to Beth Shackleton within 3 days**.

        Room 1.222 Stopford Building,
        University of Manchester,
        Oxford Road, Manchester M13 9PL

If you forget to take the sample as soon as you wake up then please do not do the sampling that day but do it the following day. It is much better that your samples arrive a little late but are accurate than them arriving earlier but collected at different times than those which I have set out here.

Collection times reminder:
0 minutes (as soon as you wake up whilst still in bed)
15 minutes
30 minutes
45 minutes

Write the times on the tubes, place them into a fridge then post them back within 3 days of collection.

Thank you very much for taking the time and effort to collect these saliva samples in accordance with the guidance I outlined in this document.

If you have any questions about this process please call me on
0161 2755382 or 07576955036 or email me on
Bethany.shackleton@postgrad.manchester.ac.uk

9.7 Patient Information Sheets

Mindfulness Based Cognitive Therapy for Stress Reduction for people with psoriasis

Participant Information Sheet

Preliminary examination into how useful mindfulness based cognitive therapy stress reduction programme can be for people with psoriasis.

Introduction

You are being invited to take part in a university research study, which is aiming to see if mindfulness based cognitive therapy for stress reduction can help people living with psoriasis. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet carefully and feel free to discuss this with colleagues, friends or family if you wish.

What is the purpose of the study?

The link between stress and psoriasis has been recognised for a long time. Living with psoriasis can make some people feel stressed and stress may make the symptoms of psoriasis worse. The aim of this study is to see how useful and acceptable the mindfulness programme is for people living with psoriasis. If the programme is helpful and acceptable to you then it will be used in a full-scale trial to statistically assess its effectiveness, in the future.

Why have I been chosen?

You have been chosen because you are an adult with plaque psoriasis.

Do I have to take part?

No. It is up to you to decide if you want to be involved in this preliminary study. If you do wish to participate, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

What is Mindfulness?

Mindfulness aims to help people feel less stressed and better able to cope with whatever turns up in the daily lives. It is a set of teachings, which has been adapted from a Buddhist meditation technique into a fully secular (non-religious) stress reduction course. Mindfulness has been used internationally to help people living with many different conditions including chronic pain, depression and stress.

What happens in a Mindfulness session?

Typically each session will be a mixture of formal practices, short examples and an opportunity for the instructor and the group to talk through the principles of how mindfulness can be used. An example of a formal practice is the 30-minute Body Scan. During the Body Scan the group is invited to lie down or stay sitting on a chair and the instructor will lead the group to focus on different parts of the body. The Body Scan is a tool, which helps us learn to focus our attention in the present rather than always flitting between worrying about the future and churning over the past.

At the end of each session the instructor will offer certain practices which participants are encouraged to use at home between the group sessions. The mindfulness research suggests that more home practice leads to more benefits from the course but it is not compulsory. Every member of the group will be given a CD which has all of the home practices on it. You will only be able to perform the home practices if you have access to a CD player or you can copy the CD onto your computer and play it from there.

Questionnaires

You will be asked to fill out a booklet of questionnaires at either 3 or 4 time points during this study. To answer all the questions in the booklet should take you about 20 minutes. All questionnaires will have a study participant ID number on them and no personal information. Only the primary investigator, Beth Shackleton will have access to the list, which matches the study ID number to participant's personal details and this will be kept in a locked cabinet on University premises.

What will happen to me if I take part?

If you agree to take part you will be given a start date (either May or July 2011). On this day you will be sent a selection of questionnaires, which will take a few minutes to complete and four bottles to collect you saliva (spit) in. These tubes will be marked with a number (this is your study participant ID number) and a space for you to write in the time of day when you collected your sample. To collect the samples you will be asked to hold a piece of cotton swab in your mouth for a short while, at 4 times points within the first hour you wake up. Once collected you would be asked to seal the tube and place

them into your home freezer until you are ready to send them back in a pre-paid envelope to Beth Shackleton (Full details will be sent to you).

Once the research team receives your samples, they will be sent for analysis at The University Hospital of South Manchester. The samples will only have your Study Participant ID number and time of collection on them to identify them, there will be no personal details attached to them. All samples will be destroyed by September 2012.

The samples will be tested to see how much cortisol is present. Cortisol is sometimes produced more when someone is feeling stressed and we would like to see if the cortisol levels change from before and after taking part in the Mindfulness groups.

Depending upon which group you are entered into you will either begin your classes straight away after we receive you questionnaires and cortisol samples back or you will be asked to wait 8-weeks before starting the course.

The mindfulness sessions will take place at the Wellcome Trust Clinical Research Facility on the University of Manchester, Oxford Road campus and will happen every week on Wednesday evenings (6pm – 8pm) for 8-weeks. You will be invited to attend one session at a weekend between the 6th and 7th group session. This will be open from 10am until 4pm as a chance to consolidate your practices. Your travel expenses to the classes will be paid for by the study upon receiving travel receipts.

You will be given some exercises and a CD with verbal instructions to practice at home to help with learning the techniques of mindfulness.

Following the final session you will be asked to repeat the questionnaires and saliva collection straight away and again for one final time another 8 weeks later.

We will be inviting 2 people from each group to come to an audio-recorded informal interview to ask about how you useful you felt the mindfulness based cognitive therapy for stress reduction programme was and any problems you may have experienced.

What are the possible disadvantages and risks of taking part?
There are no known risks from taking part in this programme. Many people use mindfulness as a general stress reduction technique or as an aide to living with many physical conditions such as chronic pain. We will not ask you to stop taking any medication or to stop using any other type of treatment, which you usually use for your condition. You will need to commit to coming to the classes for 2 hours a week, every week, for 8 weeks.

What are the possible benefits of taking part?

There are no immediate benefits to you from taking part in this study.

What happens when the research study stops?

After the final group has finished their final set of questionnaires I will contact you to inform you and ask whether you would like to have a copy of the written report sent to you. Once the final report is written all saliva samples and questionnaires will be destroyed. You are welcomed to contact Beth Shackleton with any questions after the study completion until October 2012 when she will be leaving her post.

What if there is a problem?

Complaints

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by e-mail to research-governance@manchester.ac.uk (University of Manchester).

Harm

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

All information collected about you during the course of the study will be kept strictly confidential and stored in secured premises at the University. This includes any completed questionnaires and audio recordings. Any information about you will have your name and address removed so that you cannot be recognised from it. All information related to this study will be kept for 10 years and then confidentially destroyed.

Who is organising and funding the research?

The Medical Research Council and Pfizer Pharmaceuticals are jointly funding this study, which is being organised and managed by the University of Manchester.

Who has reviewed the study?

The study was given a favourable ethical opinion by the North West -8 Research Ethics Committee (Greater Manchester, East).

Contact details

The supervisors for this study are Dr Christine Bundy and Professor Christopher Griffiths who are based at the University of Manchester.

Christine.bundy@manchester.ac.uk or 0161 275 231
Christopher.griffiths@manchester.ac.uk

Thank you for taking the time to read this information sheet. If you are interested in joining this study then please
contact Beth Shackleton on:

Bethany.shackleton@postgrad.manchester.ac.uk

0161 275 5382 or 0757 695 5036

Mindfulness Based Cognitive Therapy for Stress Reduction for people with psoriasis

Participant Information Sheet: Interviews

One-to-one interviews to assess the effectiveness and acceptability of the mindfulness based cognitive therapy for stress reduction groups.

You have said you are interested in explaining in an hour long face to face interview what you feel about the 8-week mindfulness course, which you have just completed. We think it is very important to assess what participants in the study really felt about it and as you are the experts (having completed it) we would like you to educate us on how to improve it.

What is the purpose of the study?

Learning how to practice mindfulness is a necessarily personal journey and people may experience very different things. Some parts of the course may have been very helpful, some may have been very annoying and some may have been better if slightly altered. We are very interested in receiving your feedback and trying to piece together a fuller picture of what works and what does not work and if there are any aspects of the course which we could change in the future.

Why have I been chosen?

You have been chosen because you have completed the mindfulness course with us.

Do I have to take part?

No. It is up to you to decide if you want to be involved in these interviews. If you do wish to participate, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

What will happen to me if I take part?

You will be invited to come for a 1-hour face-to-face interview with a member of the research team (not Beth Shackleton who delivered the groups). The session will be audio-recorded but the recording will be labelled with a participant number rather than

any of your personal information. You will be asked some questions but they will be open and not structured so you will have an opportunity to share you feelings and experiences.

What are the possible disadvantages and risks of taking part?
All data will be completely anonymous and locked in a password locked office in order to minimise the chance of data being stolen and the possibility of someone recognising your voice on the audio recording.

What are the possible benefits of taking part?
There are no immediate benefits to you for taking part in this study.

What happens when the research study stops?
After the completion of the study, those who express an interest in receiving copies of the transcription write up will be sent a copy. You will be able to contact Beth Shackleton with any questions regarding the study until October 2012 when she will be leaving her post at Manchester.

What if there is a problem?
Complaints
If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by e-mail to research-governance@manchester.ac.uk

Harm
In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?
All information collected about you during the course of the study will be kept strictly confidential and stored in secured premises at the University. This includes any completed questionnaires and audio recordings. Any information about you will have your name and address removed so that you cannot be recognised from it. All information related to this study will be kept for 10 years and then confidentially destroyed.

Who is organising and funding the research?

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Contact details

The supervisors for this study are Dr Christine Bundy and Professor Christopher Griffiths who are based at the University of Manchester.

Christine.bundy@manchester.ac.uk or 0161 275 231

Christopher.griffiths@manchester.ac.uk

Thank you for taking the time to read this information sheet. If you are interested in joining this study then please contact Beth Shackleton on:

Bethany.shackleton@postgrad.manchester.ac.uk

0161 275 5382

0757 695 5036

9.8 Semi-structure interviews topic guide

<u>Objectives</u>:

The aim of these semi-structured interviews is to gather responses to the research questions, "What are participants' experiences of the MBCT course?" "What are the perceived benefits and the perceived barriers to participating in the MBCT course?" and "What individual differences are found in those participants who adhered to the MBCT intervention?"

The questions in the topic guide are based on findings from previous studies, which examined the acceptability of a mindfulness intervention (Finucane and Mercer, 2006). Some questions aim to expand upon sub-scales of the quantitative Illness Perceptions Questionnaire-Revised (IPQ-R, Moss-Morris et al, 2002) based on the Self-Regulatory Common Sense Model of illness (SR-CSM) in order to examine if there is a specific set of illness representations associated with people who find the course more or less acceptable.

Interviews aim to run for 1 hour so you may not be able to cover all the topics in detail and it is best to follow what the interviewee focuses on. The topic guide below aims to guide the discussion rather than as a strict set of questions.

<u>Introduction</u> **5 minutes**

Welcome to the interview. Thank you for coming along.

This is a chance for you to describe your experience on the mindfulness course and to let us know if there were parts you particularly liked or disliked, areas where you think the course could be improved and whether you think it is useful and should be offered to other people with psoriasis?

Confidential, free to leave at any time, you can withdraw your data at any time.

There are no right or wrong answers. The interviews will be used as part of the PhD study.

<u>The course: problems and benefits</u> **15 minutes**

Can you say a bit about what you thought about the Mindfulness course?

Are there any areas, which were problematic for you and how would you change them?

Can you identify any particular elements of the course, which you think you will use in your everyday life/were very useful to you personally?

Was the information pitched at the correct level? Was there too much or to little information? What would you like?

Was the timing of the course ok? Too long too short? What would you like?

Was the structure of the course ok? 8 weekly meetings? Would you like anything else?

Do you think other people who are living with psoriasis would find this an acceptable course to take part in?

Would you recommend it to a friend? And if so why particularly?

Home practice **10 minutes**

The mindfulness course asks you to do a lot of practice alone, what do you think about this?

Did you feel motivated to practice at home and if so why?

Did you develop a routine/habit with mindfulness?

Skills **5 minutes**

Do you feel like you have learnt anything from the course? If so what?

Could you describe what mindfulness is to someone else?

Which is your favourite practice (formal or informal) and why?

Perception of efficacy **10 minutes**

Do you think mindfulness can help people and if so how?

Would anything raise your confidence about how helpful mindfulness can be?

Stereotypes **5 minutes**

Do you think mindfulness can help some people but not others? If so why? What are the differences between people?

Living with psoriasis **10 minutes**

Are there some parts of living with psoriasis, which are worse then others?

Have you always felt the same about your condition or have there been times when you have felt differently?

Do your feelings towards the condition change when you are experiencing a flare up of symptoms?

Has the mindfulness course changed the way you feel about your psoriasis?

Stress **10 minutes**

Do you think stress does or does not have any impact upon your psoriasis?

Could you try and describe what stress is?

Perhaps to describe someone whom does/does not cope well with stress?

How do you generally cope with stress? Well or poorly?

What influences how stressed you get?

End **5 minutes**

Have you any questions, or any other comments? ***Thank you very much for your time***

9.9 Reflexivity

In this section I reflect upon the context within which this research was conducted and upon my personal position as a researcher. In generating awareness of the context and my role as researcher, I hope to increase the transparency and clarity of the research process undertaken within this thesis.

Research setting

Within the UK, there is an appreciation that stress and psoriasis interact: stress may contribute to physical psoriasis symptoms and visa versa. Prominent UK websites such as www.bbc.co.uk and www.nhs.co.uk present stress as a trigger for psoriasis. This acceptance of the psychological factors involved in physical health conditions has not always been present in the UK and is absent in some countries. Within the UK there will be some people who disregard the psychological aspects of diseases for example, a dismissive physician or an unsympathetic employer. These social groups will influence whether people believe stress is involved in their psoriasis and this may influence whether they would join a stress-reduction course.

The majority of participants who volunteered to join this study were recruited from a dermatology clinic that is nationally recognised as a leading centre for advocating the psychological aspects of living with psoriasis. Patients attending this clinic will have experience of clinicians who are sensitive to the psychological consequences of living with psoriasis. The results of the studies from this thesis are most transferrable to people who believe that there is a psychological involvement in living with psoriasis.

Supervision

I am a health psychologist, my academic goals are to further our understanding of how psychological processes influence physical health and I therefore have a bias to remove any cognitive dissonance that this belief is incorrect. The members of my supervision team who are all involved in cross-disciplinary research between psychology and dermatology will share this bias to examine *how* psychology influences psoriasis rather than *if* it does.

One supervisor is a health psychologist with a special interest in psoriasis and the other is a dermatologist with a special interest in psychological influences upon skin conditions. The two approaches helped the research to remain clinically relevant whilst exploring psychological mechanisms of change.

Personal experience

As the author of this thesis, the PI in the research projects and the facilitator of the MBCT groups, I must reflect on how I may have exerted bias on all aspects of the thesis: from choosing which literature to include within the literature review to the interpretation of

quantitative and qualitative data. I will have exerted a bias, whether intentional or not upon these processes but I have attempted to remove it as much as possible. For example by conducting a systematic literature review search with a team of researchers who checked my methods. Through adopting an RCT design where an independent researcher allocated participants into the treatment and control groups. One area where my influence may have been greatest was upon the interpretation of the semi-structured interview data.

Framework analysis includes a mixture of inductive and deductive reasoning but the analysis of the transcripts relies on a construction of reality, based on the reports from the participants, and the interpretation of the researcher. To help contextualise the data-interpretation I will now present my position as the primary interpreter.

I have lived with psoriasis for ten years and I have my own cache of experiences with physicians, treatments, and the psychological aspects of the disease. I discussed this with my supervision team in order to keep these possible biases open for scrutiny. In the past I believed emotional stress did cause some of my psoriatic flares. I considered this bias when examining quantitative and qualitative data in order to check whether I am hoping for an effect or whether the evidence is really there.

I participated in a MBCT course, completed the trainer development retreat and delivered the MBCT course to the participants becoming personally involved in mindfulness practice. This was helpful for understanding the barriers and experiences which participants described in the interviews. This involvement also meant I developed a bias that I wanted the MBCT course to be effective for the participants.

As I had only facilitated one pilot MBCT group, I was not very confident of my skills. I wanted the MBCT course to be effective to prove my capability in delivering it. This was particularly important when I was exploring participants' explanation of what the benefits and negatives of the course were. I reflected on this bias before I began my analysis of the transcripts. I discussed this with my supervisor and sent my transcripts to an independent researcher to check my initial and abstract analysis.

Training
I believe the training courses that I attended, both at the University of Manchester and external courses, helped to develop my research skills. The focus on generic, non-subject specific skills, was valuable. These skills contributed to the development of this thesis and also to my personal development as a researcher.

I was able to attend a variety of different research seminar series from psychological sciences, primary care and dermatology. I also started a health psychology journal club with a group of

students. The seminars and journal clubs helped develop my presentation skills and gave me a much broader understanding of the fields in which my research was based.

9.10 Example field notes (week 4)

All members attended but one participant (p.168) was very late at arriving. This seemed to make some other participants cross because he arrived during the mindful body scan practice.

Participants mentioned that they were all falling asleep during the body scan practices at home. I gave some information about trying to hold the hand in the air whilst practicing to help them stay awake. A couple also mentioned becoming very uncomfortable so I will send the whole group the selection of alternative sitting and lying positions to help them.

All members were more involved with the thoughts are not facts exercise than they have been with previous cognitive structure experiments in weeks 1-3. They had many readily available examples.

No one seemed to like the cinema metaphor of how to watch thoughts but many liked the river metaphor.

Some members keep repeatedly asking for more scientific and theoretical understanding of what we are learning. I have tried to explain that we as a group are going to try learning experientially first then they can come and ask me at the end of the group. They make it clear they are frustrated then do not come and speak to me at the end of the group. I will bring in some information regarding Jon Kabat-Zinn next week for the video session.

One member said she really liked the poems but most of the group do not seem to engage with the poem reading. I will keep them in the hand outs as they might be useful for personal reflection later on.

All members report that they will not have enough time to practice so I emphasise trying to do a small amount but frequently and trying to integrate mindfulness into their daily lives perhaps with the three stage breathing space.

I felt that this group went well this week although I am getting frustrated with the two men who arrive late, interrupt me to ask quite challenging questions but then do not take the time to come and talk to me when I wait after the end of the groups. They seem to not take me seriously and want to show that they do not believe in mindfulness to the rest of the group. The rest of the groups however did respond this week by answering them rather than me having to answer their questions, which was reassuring. I must be aware that I am finding them challenging and bear this is mind so that I do not disadvantage them in future groups. They do keep turning up so that is a positive.

It became rushed again, so I think I need to spend a little less time on the feedback session in next week to make sure I get to explain the core concepts in the learning section of the group.