Morita Therapy for Depression and Anxiety:

Intervention Optimisation and Feasibility Study

Volume 1 of 2

Submitted by Holly Victoria Rose Sugg to the University of Exeter

as a thesis for the degree of

Doctor of Philosophy in Medical Studies

In November 2017

Signature: ………………………………………………………………………

Dedication

For my Mum

Acknowledgements

Abstract

Background. Depression and anxiety are common and debilitating disorders, and at least one third of patients do not respond to available interventions. Morita Therapy, a Japanese psychological therapy which contrasts with established Western approaches, is currently untested in the UK and may represent a potentially effective alternative approach.

Aim. To optimise and investigate the feasibility and acceptability of Morita Therapy as a treatment for depression and anxiety in the UK.

Design. Three studies were undertaken in line with the MRC framework (2008) for complex interventions. *Study One*: scoping and systematic review to describe the extent, range and nature of Morita Therapy research activity reported in English. *Study Two*: intervention optimisation study, integrating literature synthesis with qualitative research, to develop the UK Morita Therapy outpatient protocol. *Study Three*: mixed methods feasibility study encompassing a pilot randomised controlled trial (RCT) and embedded qualitative interviews to prepare for a fully-powered RCT of Morita Therapy versus treatment as usual (TAU).

Results. *Study One*: 66 papers meeting the inclusion criteria highlighted heterogeneity in the implementation of Morita Therapy, and an absence of both UK-based research and relevant unbiased RCTs. *Study Two*: a potentially deliverable and acceptable therapy protocol and tailored therapist training programme were developed for a UK population. *Study Three*: 68 participants were recruited and 94% retained at four month follow-up; 70.6% of Morita Therapy participants adhered to the minimum treatment dose, and 66.7% achieved remission in depressive symptoms (compared to 30.0% in TAU). Qualitative and mixed methods findings indicated that Morita Therapy was broadly acceptable to therapists and participants, and highlighted potential moderators of acceptability, treatment adherence and outcomes.

Conclusions. Patients in the UK can accept the premise of Morita Therapy and find the approach beneficial. It is feasible to conduct a large-scale UK-based trial of Morita Therapy with minor modifications to the pilot trial protocols.

Notes on Thesis Structure

Volume One of this thesis contains Chapters One to Eight inclusive; Volume Two contains Appendices and References.

The intervention optimisation study and protocol for the feasibility study, reported in Chapters Five and Six respectively, are based on published articles: the intervention optimisation study has been published in *Pilot and Feasibility Studies* (Sugg, Richards and Frost, 2017); the protocol for the feasibility study has been published in *Trials* (Sugg, Richards and Frost, 2016). Both articles are open access and subject to a Creative Commons Attribution 4.0 International Public License (CC BY 4.0). Additional information has been provided and formatting adjustments have been made to the articles in order to integrate them into the thesis as a whole. The original articles are provided in Appendix III (intervention optimisation study) and Appendix VII (feasibility study protocol).

Word count: 99,925

Table of Contents

List of Tables

List of Figures

List of Appendices

Appendix I: Summary tables of papers included in the scoping and
systematic review

Appendix II: Intervention optimisation study management and data
collection

Appendix III: Published paper from the intervention optimisation study

Appendix IV: The UK Morita Therapy Outpatient Protocol

Appendix V: Intervention optimisation study data analysis

Appendix VI: Morita Therapist Training Programme

Appendix VII: Published protocol paper for the feasibility study

Appendix VIII: Feasibility study recruitment

Appendix IX: Feasibility study management and data collection

Appendix X: Feasibility study qualitative data analysis

Appendix XI: Example page of therapeutic diary

List of Abbreviations

A&E	Accident and Emergency
AccEPT	Accessing Evidence-Based Psychological Therapies Clinic
ACT	Acceptance and Commitment Therapy
ADM	Anti-Depressant Medication
BA	Behavioural Activation
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRD	Centre for Reviews and Dissemination
DNA	Did Not Attend
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-III-R	Diagnostic and Statistical Manual of Mental Disorders (third edition, revised)
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders (fourth edition, text revision)
DSM-V	Diagnostic and Statistical Manual of Mental Disorders (fifth edition)
EBM	Evidence-Based Medicine
EBP	Evidence-Based Practice
GAD	Generalised Anxiety Disorder
GAD-7	Seven item Generalised Anxiety Disorder questionnaire
GP	General Practitioner
IAPT	Improving Access to Psychological Therapies
ICD-10	International Statistical Classification of Diseases and Related Health Problems (10th revision)
IPT	Interpersonal Therapy
MASA	Morita Attitudinal Scale for Arugamama
MBCT	Mindfulness-Based Cognitive Therapy
MCID	Minimum Clinically Important Difference
MCS	Mental Component Scale
MDC	Mood Disorders Centre
MRC	Medical Research Council
N/A	Not Applicable

NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
OCD	Obsessive Compulsive Disorder
PCS	Physical Component Scale
PenCLAHRC	NIHR Collaboration for Leadership in Applied Health Research and Care, South West Peninsula
PenPIG	NIHR Collaboration for Leadership in Applied Health Research and Care, South West Peninsula PPI Group
PHQ-9	Nine item version of the Patient Health Questionnaire
PICOS	Population(s), Intervention(s), Comparator(s), Outcome(s), Study design(s)
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PT	Participant
PTSD	Post-Traumatic Stress Disorder
RCT	Randomised Controlled Trial
SCID	Structured Clinical Interview for DSM-IV-TR Axis I Disorders
SD	Standard Deviation
SF-36	Short Form 36 Health Survey Questionnaire
SOM	Standard Outcome Measure
TAU	Treatment As Usual
TH	Therapist
TRD	Treatment-Resistant Depression
UK	United Kingdom
USA	United States of America
WSAS	Work and Social Adjustment Scale

CHAPTER ONE. INTRODUCTION

This thesis reports the optimisation and investigation of the feasibility and acceptability of Morita Therapy as a treatment for depression and anxiety in adults in the UK, to prepare for a fully-powered randomised controlled trial (RCT) of Morita Therapy plus treatment as usual (TAU) versus TAU alone. As a Japanese psychotherapy for common mental health disorders, Morita Therapy aims to re-orientate patients in the natural world through facilitating their acceptance and allowance of unpleasant thoughts and emotions as natural phenomenon. As such, Morita Therapy contrasts with the focus of established Western approaches on symptom reduction and control (Krech, 2014). At present, the acceptability and effectiveness of Morita Therapy for a UK population is unknown. Thus, such investigations begin within this thesis.

The purpose of this chapter is to outline the requirement for this programme of research in terms of the burden of depression and anxiety, the effectiveness of current treatment options and the importance of providing patients with alternative choices. In this context, Morita Therapy is introduced as an approach with the potential to provide patients with a meaningfully distinct alternative to current treatments; Chapter Two presents a fuller discussion of and rationale for investigating this particular approach. This chapter concludes with an overview of this thesis and a summary of each chapter.

1.1 Background

1.1.1 The burden of depression and anxiety

Depression and generalised anxiety disorder (GAD) are the two most common mental health disorders, with one in six people in the UK experiencing such a disorder each year (McManus, Bebbington, Jenkins et al., 2016). Overall, the cost of depression and anxiety in the UK is significant at an annual rate of £17bn in lost output and direct health care costs, and a £9bn impact on the Exchequer through benefit payments and lost tax receipts (Layard, 2006). Between 2011 and 2030, the effect of depression alone on aggregate economic output is predicted to be US$5·36 trillion globally (Bloom, Cafiero, Jané-Llopis et al., 2011).

Both disorders can be diagnosed using the DSM-V (American Psychiatric Association, 2013), with the diagnosis of depression also made using the ICD-10 (World Health Organization, 1992) (currently under revision (World Health Organization, 2017)). In both systems, a diagnosis of depression is primarily based on low mood and/or a loss of interest or pleasure; other symptoms include changes in appetite, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue, difficulties concentrating and thoughts of worthlessness and/or suicide (American Psychiatric Association, 2013). A diagnosis of GAD is primarily based on excessive anxiety and worry about everyday events and problems; other symptoms include restlessness, becoming easily fatigued, difficulty concentrating, irritability, muscle tension and sleep disturbance (American Psychiatric Association, 2013).

In terms of days lost to disability, depression is the leading cause of disability worldwide, affecting 350 million people across the globe (Marcus, Yasamy, Van Ommeren et al., 2012). Epidemiological studies illustrate the high prevalence rates for depression. In the USA, lifetime prevalence has been estimated at 16.2%; twelve month prevalence rates are 6.6% (Kessler, Berglund, Demler et al., 2003). In the UK, the Adult Psychiatric Morbidity Survey estimated a point prevalence of 3.3% (Stansfeld, Clark, Bebbington et al., 2014).

For individuals, depression is often chronic and recurrent (Keller, 2001; Kessler et al., 2003). At least half of people who recover from an episode will experience at least one more; each episode increases the risk of future relapse (Eaton, Shao, Nestadt et al., 2008; Kupfer, 1991; Moffitt, Caspi, Taylor et al., 2010). Rates of both psychiatric and physical comorbidity, and risk for suicide, are also high (Andrews, Henderson and Hall, 2001; Harwood, Hawton, Hope et al., 2001; Kasper, Schindler and Neumeister, 1996; Kessler, Berglund, Demler et al., 2005a; O'Brien, Singleton, Bumpstead et al., 2001; Rosenthal, 2003).

GAD is the second most frequently identified common mental health disorder in the UK, and accounts for up to 30% of the mental health problems presented to General Practitioners (McManus et al., 2016; Stansfeld et al., 2014). The lifetime prevalence of GAD has been estimated at 5.7%; the point prevalence at 5.9%, which is shown to be rising from previous years (Kessler et al., 2005a; Stansfeld et al., 2014). GAD is typically chronic and disabling, and rates of

comorbidity are high (Holaway, Rodebaugh and Heimberg, 2006; Wittchen, 2002).

Furthermore, the comorbidity between anxiety and depression makes a strong contribution to the total disability attributed to mental disorders, with mixed anxiety and depression estimated to cause one fifth of lost working days in Britain (Andrews, Sanderson, Slade et al., 2000; Das-Munshi, Goldberg, Bebbington et al., 2008; Wittchen, 2002). The National Psychiatric Comorbidity Survey estimates a point prevalence of mixed anxiety and depression at 7.8% in the UK: the most frequently identified diagnosis (Stansfeld et al., 2014). Such comorbidity is associated with increased severity, chronicity, disability and use of health services (Alonso, Angermeyer, Bernert et al., 2004; Andrews, Slade and Issakidis, 2002; Kessler, Chiu, Demler et al., 2005b).

1.1.2 Current treatment options

Several interventions are considered efficacious in treating depression and GAD. Medication and Cognitive Behavioural Therapy (CBT) have the strongest evidence-base, with evidence also for Interpersonal Therapy (IPT), Behavioural Activation (BA), and applied relaxation for GAD: thus, medication, CBT, IPT and BA are currently recommended by the National Institute for Health and Clinical Excellence (NICE) for the treatment of depression; medication, CBT and applied relaxation for GAD (National Collaborating Centre for Mental Health, 2011; NICE, 2009).

The forthcoming update to the NICE guidelines for depression (In Consultation) will expand these recommendations. Thus, for the first-line treatment of less severe depression, group-based CBT, individual self-help, short-term psychodynamic therapy and physical activity are recommended alongside individual CBT, BA, IPT and medication. For more severe depression, the recommended options are group or individual CBT, BA, short-term psychodynamic therapy and medication. Collaborative care, incorporating a multi-professional approach to patient care, is also recommended for such patients. In addition, stepped care, in which low-intensity treatment is provided followed by high-intensity treatment if necessary, is recommended as a means of organising the delivery of psychotherapy.

For patients who do not respond to first-line treatments ('treatment-resistant depression'), few alternative treatments exist: NICE recommends combining psychotherapy with medication, augmenting medication or trying another psychotherapy of the aforementioned options. Similarly, for those with chronic depression, CBT in combination with medication is recommended. Whilst acceptance-based models of psychotherapy, such as Acceptance and Commitment Therapy (ACT) and Mindfulness-based Cognitive Therapy (MBCT), are also available, these are not recommended by NICE except in the case of MBCT as a possible relapse-prevention intervention for patients who are not currently depressed.

1.1.3 The effectiveness of current treatments

Research providing evidence for the effectiveness of the aforementioned NICE recommended treatments also suggests that they are approximately equally effective (e.g. Amick, Gartlehner, Gaynes et al., 2015; Cuijpers, Andersson, Donker et al., 2011; Cuijpers, Sijbrandij, Koole et al., 2013; Dugas, Brillon, Savard et al., 2010; Hunot, Churchill, Silva de Lima et al., 2007; Luborsky, Rosenthal, Diguer et al., 2002; Luty, Carter, McKenzie et al., 2007; Mitte, 2005; Richards, Ekers, McMillan et al., 2016; Spielmans, Berman and Usitalo, 2011; Wampold, Minami, Baskin et al., 2002). However, research also demonstrates that they are not effective for all patients: many people are refractory to such interventions (Rush, Fava, Wisniewski et al., 2004). Indeed, current treatments appear to have had little impact on the prevalence of common mental disorders in the UK, and both depression and anxiety remain chronic disorders despite the available interventions (Andrews et al., 2000; Stansfeld et al., 2014).

The results of multiple RCTs were examined by NICE to inform the updated guidelines for depression (In Consultation). For trials of recommended psychotherapies which report the number of patients reaching remission of depressive symptoms (n=32), the average remission rate was 44.3% (range 3.4 - 92.7%). Similarly, for trials of anti-depressant medication (ADM) which reported this data (n=32), the average remission rate was 41.8% (range 16.6 – 62.9%). Thus, on average, over 50% of patients remain depressed following treatment by ADM or recommended psychotherapies.

Similarly, data suggests that between one third and half of depressed patients treated with psychotherapy or ADM do not respond to treatment (typically defined as a 50% reduction in symptom severity from baseline) (Amick et al., 2015; Depression Guideline Panel, 1993; DeRubeis, Hollon, Amsterdam et al., 2005; Jarrett and Rush, 1994; Luty et al., 2007; Richards et al., 2016; Westen and Morrison, 2001). Indeed, a large portion of the disease burden of depression is attributable to treatment-resistant depression (Greden, 2001; Malhi, Parker, Crawford et al., 2005). For such patients, whilst CBT is one key recommendation made by NICE, the effectiveness of CBT is comparable to that found in other trials: one recent large-scale trial showed only 55% of non-responders to ADM alone responded to CBT as an adjunct to ADM, with only 40% achieving remission (Wiles, Thomas, Abel et al., 2013).

Research suggests a similar pattern in the treatment of GAD: meta-analyses indicate only 46% of patients who receive psychotherapy based on CBT principles respond to treatment (Hunot et al., 2007) and only 44% of patients who complete any form of empirically supported psychotherapy can be deemed to be 'improved' (Westen and Morrison, 2001). More recent trials of psychotherapy for GAD demonstrate an average response rate of 66% (range 40 – 92%) (Dugas et al., 2010; Newman, Castonguay, Borkovec et al., 2011; Stanley, Wilson, Novy et al., 2009; Westra, Arkowitz and Dozois, 2009). Thus, similarly to depression, between one third and half of patients remain anxious following recommended treatments for GAD.

The 'Improving Access to Psychological Therapies' (IAPT) programme, a large-scale UK initiative to provide NICE recommended psychotherapies for depression and anxiety within the stepped-care model (Clark, Layard, Smithies et al., 2009; NHS England, undated), provides further comparable data. According to the report of the first million patients receiving treatment, remission or 'recovery' is reached by fewer than 50% of patients who complete treatment, and only 64.6% show a reliable improvement in symptoms (Community & Mental Health team, 2016; IAPT, 2012).

Thus, even when only those patients who complete treatment are taken into account, between one third and half of patients remain depressed and/or anxious following NICE recommended interventions. Such failure to respond to

treatment increases patients' risk of future relapse and the maintenance of recurring and chronic problems (Hollon, Muñoz, Barlow et al., 2002). Thus, there is scope to develop and test new potentially effective treatments for depression and anxiety. The rationale for such research is twofold: firstly, on a population level, alternative treatments may prove more effective than current options; secondly, on an individual level, it is important to provide patients with choice in treatment options.

1.1.4 Supporting patient choice

The importance of providing patient choice and considering patient preferences for treatment is enshrined in the forthcoming NICE guidelines for depression (In Consultation). In order to provide such choice, treatments which are qualitatively distinct from the current options and thus have potential to offer patients a meaningful alternative warrant particular investigation.

By establishing an opportunity for patients to choose between truly distinct treatments, work on matching patients to treatments may be facilitated. This individualisation of depression treatment stems from the evidence that current treatments are approximately equally effective (commonly referred to as the 'dodo bird verdict' (Rosenzweig, 1936)) and the reasons posited for this. Whilst some argue that common therapeutic factors, such as empathy and other therapist effects, account for the effects exerted by all psychotherapies (Luborsky et al., 2002; Messer and Wampold, 2002; Rosenzweig, 1936), such assertions have not been proven in trials comparing 'effective' with 'less effective' therapists. Others suggest that psychotherapies have different but equally effective mechanisms of change and/or that treatment effectiveness does vary at the level of the individual: that matching patient characteristics to treatment type can produce significant differences in the effectiveness of different treatments for different patients (Beutler, Engle, Mohr et al., 1991; Blatt and Felsen, 1993; Cuijpers and Christensen, 2017; Luborsky et al., 2002; Reynolds, Taylor and Shapiro, 1993).

Whilst this argument is not new (Kiesler, 1966; Paul, 1967; Stiles, Shapiro and Elliott, 1986), little progress has been made in our understanding of which patients might benefit from which treatments, and little evidence currently exists

to guide treatment choice (Cuijpers, 2014; Cuijpers and Christensen, 2017; NICE, 2009). However, work continues in an attempt to identify moderators of treatment effect and key factors in predicting the most optimal treatment option for individuals (e.g. DeRubeis, Cohen, Forand et al., 2014; Fournier, DeRubeis, Shelton et al., 2009; Kessler, Van Loo, Wardenaar et al., 2017; Kraemer, 2013). In the context of different treatments potentially proving effective for and acceptable to different patients, the provision of radically different approaches should aid this matching of patients to treatments.

1.1.5 Morita Therapy: an alternative approach

Morita Therapy is a Japanese psychotherapy developed by Dr Masatake (Shōma) Morita (1874-1938) in 1919 (Morita, Kondo and LeVine, 1998). Originally developed as an inpatient treatment for psychological problems similar to GAD, Morita Therapy is now applied to a wider range of conditions, including depression (Ogawa, 2013). The approach is practiced in Japan and applied to a limited degree in countries including Australia, China, North America, Russia and Rwanda (Ogawa, 2013).

Morita Therapy is a holistic approach aiming to improve everyday functioning rather than targeting specific symptoms (Ogawa, 2013). Through conceptualising unpleasant emotions as part of the natural ecology of human experience, Morita Therapy seeks to re-orientate patients in the natural world and potentiate their natural healing capacity. Morita therapists thus help patients to move away from symptom preoccupation and combat, which are considered to exacerbate symptoms and interfere with this natural recovery process (Nakamura, Kitanishi, Maruyama et al., 2010).

By helping patients to accept unpleasant thoughts and emotions as natural phenomena which ebb and flow as a matter of course, Morita Therapy is in sharp contrast to the focus of established Western approaches on symptom reduction and control (Krech, 2014). In Morita Therapy, patients are taught to live with, rather than be without, their symptoms. Thus, Morita Therapy has potential to provide patients in the UK with a distinct alternative to current treatment options. In Chapter Two, the distinctive philosophical and cultural basis of Morita Therapy, grounded in an Eastern rather than Western

worldview, and the related differences between Morita Therapy and current treatment options are fully explored. In this context, Chapter Two culminates in a discussion of the potential value of Morita Therapy as a UK treatment alternative which offers a fundamentally different approach to mental health (section 2.5.2).

1.1.6 The need for this thesis

As with the development of many other treatments to date (Hollon et al., 2002), initial evidence for the effectiveness of Morita Therapy is largely based on case studies, predominantly conducted in Japan. An existing literature review of forty-nine such case studies and four quasi-experimental studies indicates that Morita Therapy has been reported as effective for a diverse range of issues, but that further work is required to both standardise its delivery and investigate its efficacy in controlled trials (Minami, 2011a). In relation to this, in the context of evidence-based medicine and the need for experimental research, the full rationale for each study within this thesis is presented in Chapter Three; a summary is presented below.

From contacts within the Japanese Society for Morita Therapy coupled with data within the existing review, upon commencing this thesis it was considered highly unlikely that research into Morita Therapy had been undertaken in the UK. In the context of cultural differences (see Chapter Two), the effectiveness and appropriateness of Morita Therapy within Japan cannot be assumed to translate to a UK context. Thus, it was anticipated that existing research cannot provide definitive evidence of how appropriate or effective Morita Therapy is for a UK population, nor demonstrate the views of UK patients and therapists about Morita Therapy. However, in the absence of a systematic and up to date review of the literature, it cannot be established with confidence whether an RCT, or indeed any research, on Morita Therapy has been undertaken in the UK. Thus, a scoping and systematic review enables confirmation of this gap in research whilst also providing opportunities to examine and summarise the extent, range and nature of Morita Therapy research activity available in English, and to appraise any RCTs of Morita Therapy identified.

Assuming the results of such a review reveal that the effectiveness of Morita Therapy has not been established for UK-based depressed patients, a fully-powered UK-based RCT of Morita Therapy is required. However, to maximise the chances of success in such a trial, it is necessary to first address several uncertainties (Thabane, Ma, Chu et al., 2010). Firstly, given the lack of UK-based research in the context of potential cultural differences, alongside the availability of a variety of Morita Therapy methods and lack of thorough treatment manuals (see Chapter Two), developmental work is required to develop a UK Morita Therapy outpatient protocol. Secondly, a feasibility study is required to prepare for the design and conduct of a large-scale trial by addressing the clinical, procedural and methodological uncertainties associated with such a trial (discussed fully in Chapter Three).

1.2 Thesis overview

In response to the need for UK-based Morita Therapy research, the overall aim of this programme of work is to optimise and investigate the feasibility and acceptability of Morita Therapy as a treatment for depression and anxiety in the UK. Thus, three studies were conducted in line with the Medical Research Council Framework (2008) for the development and evaluation of complex interventions: (1) a scoping and systematic review, primarily designed to describe the extent, range and nature of research activity reported in English in the field of Morita Therapy; (2) an intervention optimisation study designed to develop a deliverable and acceptable Morita Therapy outpatient protocol for a UK clinical population; (3) a mixed methods feasibility study designed to prepare for a fully-powered RCT of Morita Therapy plus treatment as usual (TAU) versus TAU alone.

1.2.1 Thesis structure and content

Chapter One has provided an outline of the prevalence and importance of the problem and illustrated the requirement for this thesis in terms of the effectiveness of current treatments and the importance of providing patients with alternative choices. Morita Therapy has been introduced as an approach with potential to provide patients with a meaningfully distinct alternative to current treatments.

Chapter Two outlines the origin, definition and international development of Morita Therapy in the context of the philosophical and cultural underpinnings of the approach, and in contrast to established Western models of mental health and treatment. The implications of this discussion for this thesis are presented, highlighting the potential for Morita Therapy to provide patients in the UK with a fundamentally different approach to mental health.

Chapter Three outlines the methodology underpinning this thesis and methods adopted throughout. Part one (methodological framework) situates this thesis in the context of evidence-based medicine, the development and evaluation of complex interventions and the value of mixed methods in health services research. Part two (methodological approach) provides the overarching design of this thesis, including the rationale for each of the studies undertaken and a justification of the methods employed.

Chapter Four presents the scoping and systematic review describing the extent, range and nature of research activity reported in English in the field of Morita Therapy, and assessing existing evidence on the effectiveness of Morita Therapy. The implications of the review for this thesis, in terms of the current status of Morita Therapy research in the UK and beyond, are discussed.

Chapter Five presents the intervention optimisation study undertaken to develop a deliverable and acceptable Morita Therapy outpatient protocol for a UK clinical population. Thus, this process was used to develop a therapy protocol and tailored therapist training programme which were fit for purpose in proceeding to a UK-based Morita Therapy feasibility study.

Chapters Six and Seven present the methods and results of the mixed methods feasibility study, incorporating a pilot RCT and embedded qualitative interviews, undertaken to prepare for a fully-powered RCT of Morita Therapy plus TAU versus TAU alone. Key clinical, methodological and procedural uncertainties associated with a large-scale trial are addressed.

Chapter Eight concludes this thesis with: (1) a summary of key findings; (2) a discussion of the substantive, methodological and theoretical contributions made within this thesis; (3) a discussion of the strengths and limitations of each

study and this thesis overall, and of alternative methodological approaches which could have been adopted; (4) recommendations for future research; (5) a discussion of the clinical implications of this thesis; (6) a discussion of the personal learning obtained through the completion of this thesis; (7) a summary of key conclusions.

CHAPTER TWO. SUBJECT OVERVIEW

This chapter describes Morita Therapy in depth. Firstly, the core features are presented, including the emphasis on nature, conceptualisation of psychopathology, process and objectives. Secondly, the philosophical and cultural background of Morita Therapy is discussed. Thirdly, a comparison between Morita Therapy and Western psychotherapies is presented. Fourthly, the development and diversity of Morita Therapy over different formats, patient conditions and countries is described. Finally, the implications of these considerations are discussed, highlighting the potential for Morita Therapy to provide UK patients with a fundamentally different approach to mental health.

2.1 What is Morita Therapy?

In Japan during the 1910s-1920s, Dr Shōma Morita developed a theory of psychopathology and related mode of treatment, Morita Therapy, based on his clinical observations and own experiences of neurotic symptoms (Kitanishi, 2005; Morita et al., 1998). Rather than targeting specific symptoms, Morita Therapy is a holistic approach which aims to re-orientate patients in nature, ultimately enabling them to live more fulfilling lives (Ogawa, 2013). The focus is on learning to accept and live with suffering as it is, with unpleasant thoughts and emotions considered natural phenomena rather than something to control or eliminate (Nishizono, 2005). Morita's concepts, outlined below, are embedded in his philosophy of human nature concerning how the mind interacts with the body, and one's health interacts with their relationship to the natural world (Fujita, 1986; Kondo, 1998).

2.1.1 Nature

According to Fujita (1986), internal and external human conflicts arise from circumstances in which modern humans are estranged from nature: people often seek to challenge, conquer and control the environment, essentially living in opposition to it (Reynolds, 1995a; Sato, 2011). Nature here does not refer only to an isolated notion of the natural world as distinct from humans, but more broadly to the reality or truth of all phenomena, encompassing both human nature and the environment (Fujita, 1986; Morita et al., 1998). Morita

Therapy seeks to redress this ultimately self-defeating imbalance by moving patients from an unnatural, inauthentic state to a natural, authentic state in which they observe, accept and live in harmony with the natural world, including their human nature (Fujita, 1986; Kitanishi, 2005; Morita et al., 1998; Sato, 2011). This is considered to be achieved by accepting the body and mind's natural reactions to life, as opposed to resisting the inevitable cycles and fluctuations of (human) nature (Morita et al., 1998).

Human nature

According to Morita, all phenomena, including those of the mind and body, are in a constant state of flux: as humans are part of nature, always interacting with their environments, their thoughts and emotions shift accordingly (Fujita, 1986; Morita et al., 1998; Ogawa, 2007). Thus, all emotions are natural, integral, legitimate and unavoidable features of human experience, induced by the circumstances of life (Morita et al., 1998). As such, Morita Therapy conceptualises them only as pleasant or unpleasant (desired or undesired) but not as positive or negative (Minami, 2013; Reynolds, 1976). Indeed, these responses are considered functional: the mind and emotions are capable of such shifts for the purpose of adapting to situations; ultimately, anxiety and pain are necessary for survival, driving the perseverance and improvement of life (Fujita, 1986; Kora, 1995; Morita et al., 1998). As such, they allow life to flow in a balanced way, as long as they are not intellectually judged as either 'positive' or 'negative' (Kondo, 1975).

As per the nature of the world, these responses cannot be controlled or manipulated by will: "our emotions evade our rule as the weather evades our command" (Ogawa, 2007) (p.92). Accordingly, the aim of Morita Therapy is not to change thoughts or emotions. Instead, Morita noted that all emotions will naturally dissipate, if left to do so ('the law of emotion') (Kora, 1995; Morita et al., 1998). As emotions cannot be controlled, people are not considered responsible for them; in contrast, behaviour is considered controllable: the action one takes need not be dictated by one's emotions or preferences, and people are considered responsible for taking the action which needs to be taken, regardless of accompanying emotions (Morita et al., 1998; Ogawa, 2007).

Desire for life

Morita's concept of 'desire for life', or desire to live, may be defined as the natural motivational appetite for self-improvement, self-actualisation and self-fulfilment; an instinctive force fundamental to human nature (Fujita, 1986; Kondo, 1975; Kora, 1995; Morita et al., 1998). This concept may be considered akin to the humanistic notion of a life-propelling inner force: an innate and purposive drive to strive and preserve life (Carleton, 2002). This inherent energy and intelligence strives for the optimal health which results when the body, mind and emotions are allowed to flow naturally, unimpeded by self-imposed obstacles (section 2.1.2) (Ogawa, 2007). Thus, Morita therapists do not teach patients how to live meaningful lives, but rather help them to remove the obstacles to their intuitive desire to do so.

According to Morita, with desire for life comes an inevitable fear of death: desire and fear are two sides of the same coin (Minami, 2013; Morita et al., 1998). Therefore, the stronger one's desire towards self-fulfilment, the more likely one is to experience self-concern and disappointment (Fujita, 1986; Ogawa, 2013). Thus, desire both propels one to live, and causes suffering, due to the discrepancy between the ideal (desired state) and the realities of life (Kitanishi, 2005; Morita et al., 1998; Ogawa, 2007). Accordingly, "those who suffer the most can be the most accomplished and successful because of their drive for advancement" (Ogawa, 2007) (p.43). Thus, suffering does not indicate a deficit, but an excess: a key concept in counteracting feelings of inadequacy and worthlessness (Kitanishi, 2005; Morita et al., 1998; Reynolds, 1976).

Arugamama

Arugamama (literally, 'as it is') means to accept things as they are: to concede to phenomenological reality and obey nature (Fujita, 1986; Morita et al., 1998; Ogawa, 2007; Reynolds, 1976). This is conceptualised as a state of insight into human nature in which the authentic experience of the self, including the fluidity of thoughts and emotions, is accepted as such without judgement or resistance (Ishiyama, 2011; Kora, 1995). This does not refer to an intellectual, wilful acceptance but rather an embodied, empirical, intuitive acceptance in which one is immersed in action, has no awareness of the self as set apart from

nature, and thus no self-consciousness and resulting difficulties (Nakai, 1947: cited in Fujita, 1986; Kitanishi, 2005; LeVine, 1998), living "in a state of nature, [in the] here and now" (Fujita, 1986) (p.8).

According to Morita, with arugamama people leave symptoms as they are and lead life as it is (Fujita, 1986; Kora, 1995). This acceptance of and response to reality, with its impermanence and transition, is considered to free people to change: people can adapt to life circumstances with spontaneity and flexibility (Kora, 1995; Ogawa, 2013). Thus, arugamama denotes not resignation but empowerment through the knowledge of what is and is not controllable: one can identify what is happening in the moment and act accordingly, taking action to change situations in line with their desire for life, whilst allowing the mind and body's natural transformations (Kora, 1995; Ogawa, 2007).

2.1.2 Psychopathology in Morita Therapy

With suffering considered a natural phenomenon originating secondarily to the desire for life, according to Morita problems do not stem from suffering itself but from the meaning attached to suffering: from a resistance to suffering and a fixation on the discrepancy between the ideal and real (Fujita, 1986; Morita et al., 1998; Ogawa, 2013). Thus, it is the lack of naturalness, the distortion of the arugamama attitude, which is believed to cause difficulties (Fujita, 1986). This is conceptualised as a misdirection of desire for life, with this intuitive energy squandered through futile efforts to eliminate unpleasant thoughts and emotions (Fujita, 1986; Kora, 1995; Ogawa, 2007).

The vicious cycle of symptom aggravation

Two self-defeating components, Toraware (mental preoccupation with symptoms) and Hakarai (attempts to control, fight or avoid symptoms), are conceptualised as producing a vicious cycle which maintains and exacerbates suffering (henceforth referred to as 'the vicious cycle') (Morita et al., 1998; Reynolds, 1982). Toraware is characterised by:

- Attentional fixation on symptoms (Morita et al., 1998). This results in rumination and sensitivity to symptoms, perpetuating a cycle of increased

distress and fixation (Morita et al., 1998; Ogawa, 2013). In this way, people are 'self-centred': fixated on internal states (Kora, 1995; Morita et al., 1998).

- Contradiction between ideal and real (Morita et al., 1998). People with this trait exhibit a perfectionist, unrealistic, judgemental and dogmatic worldview and/or self-image; a discrepancy between how things *should* be and how they *are*, leading to a conditional acceptance of experiences, the self and the world (Kora, 1995; Minami, 2013). This represents an attachment to ideas (the ideal), considered an illusionary product of the ever-changing mind, rather than an acceptance of reality, and leads to labelling of thoughts and emotions as positive/ acceptable or negative/ unacceptable, rather than experiencing them only as they are (Morita et al., 1998).

Hakarai encapsulates futile attempts to control or remove these otherwise natural experiences, which maintain attention on them and aggravate them through the secondary distress of being unable to eliminate them (Minami, 2013; Morita et al., 1998). These efforts may be made cognitively, such as wilful attempts to suppress emotion, or behaviourally, such as activities undertaken to escape emotion (Nakamura et al., 2010). Hakarai is understood to interfere in the law of emotion, impeding the mind and body's capacity to dissipate emotions in line with their natural course (Minami, 2013).

2.1.3 Key features in the process of Morita Therapy

Overall, the role of the Morita therapist is to help patients to re-establish contact with nature, ultimately cultivating an allowance of authentic human nature with its natural ebb and flow of emotion. More specifically, Morita therapists facilitate patients' understanding of the vicious cycle, their capacity to be with symptoms, and their engagement in purposeful action (Minami, 2013).

Fumon

In an effort to shift patients' attention away from their symptoms and towards purposeful behaviour, the traditional Morita therapist's stance towards a patient's expression of complaints is Fumon (selective non-response, or strategic inattention) (Nakamura et al., 2010). As such, Morita therapists do not

dwell on patients' symptoms or past, and do not attempt to elucidate reasons for suffering beyond the vicious cycle (Nakamura et al., 2010; Ogawa, 2013).

Rest

Traditionally, Morita Therapy begins with absolute bed rest, taking a restorative approach to potentiate a patient's natural healing capacity (Kitanishi, 2005; Minami, 2013; Morita et al., 1998). Through this elimination of external stimuli and the need to confront suffering, the vicious cycle is thought to be broken: thoughts and emotions run their natural course, allowing patients to experience how they naturally ebb and flow (Fujita, 1986; Kora, 1995; LeVine, In press; Morita et al., 1998; Reynolds, 1982).

Paradoxically, rest is understood to begin the process of diminishing self-centredness with increased self-focus (Reynolds, 1976). Patients, "having saturated themselves with self-focus" (Ogawa, 2013) (p.165), reach a state of ennui and begin to redirect their attention from introversion (self-preoccupation and fixation on symptoms) to extroversion (ecological awareness and purposeful behaviour), returning to all of their senses with increased peripheral consciousness (Fujita, 1986; LeVine, 1993b; LeVine, In press; Morita et al., 1998; Ogawa, 2013). Accordingly, the patient's spontaneous desire *to do* is heightened, motivated by a revitalised desire for life rather than pursued as a means to feel better (Fujita, 1986; Kora, 1995; Morita et al., 1998; Ogawa, 2013). This desire is then cultivated through action-taking.

Action-taking

A key feature of Morita Therapy is taking, and being absorbed in, purposeful action: activity undertaken for the sake of activity itself, not for overcoming suffering (Fujita, 1986). Such action is not pursued with an overinvestment in outcomes; rather, patients are instructed "to 'jump into doing' what is immediate and necessary" (Ogawa, 2013) (p.64). This action-taking is intended to be both a cause and consequence of the patient's spontaneity and natural appetite for activity, constructively channelling the resurfacing desire for life, and inducing the confidence to undertake activity in an unconscious manner (Fujita, 1986; Minami, 2013; Morita et al., 1998).

Through an immersion in acting upon what is significant in their environments and continuing action in the presence of emotions, patients cultivate persistence and continue to experience how thoughts and emotions naturally ebb and flow if left alone (Fujita, 1986; LeVine, 1993a; Morita et al., 1998). Indeed, it is understood that patients' attentional fixation on their symptoms is dissipated (Morita et al., 1998) and they move beyond conscious and evaluative processing of the self: they "forget anxious thoughts and feelings and become one with action" (Ishiyama, 1986c) (p.379), a fluid mental state in which attention moves freely from one event to another with full contact between the self and the environment (Ishiyama, 1986c; Morita et al., 1998; Ogawa, 2007).

Experiential learning

The overarching method of Morita Therapy is experiential learning. Given views on the dichotomous nature of the intellect (section 2.2) and tendency for this to perpetuate the vicious cycle through misinterpretation and over-analysis, experiential learning is considered to bring a deeper level of insight (Kondo, 1975; Morita et al., 1998; Ogawa, 2013). Through direct emotional experiences, contact with nature and personal discovery, patients are thought to develop intuitive, empirically-based and embodied understandings of natural rhythms and, consequently, a more realistic and spontaneous attitude with restored authenticity and desire for life (Fujita, 1986; Morita et al., 1998; Ogawa, 2013). Thus, arugamama is not an intellectually induced state willed or born out of cognitive re-appraisal, but a continually evolving state both cultivated and expressed through living purposefully in the here and now (Ogawa, 2013).

2.1.4 Key objectives of Morita Therapy

The overarching objective of Morita Therapy is to cultivate arugamama: an acceptance of reality, including suffering, as it is (Reynolds, 1976). Thus, the aim is to remove the distortion of this attitude and disruption of natural cycles caused by the vicious cycle (Fujita, 1986; Morita et al., 1998; Nakamura et al., 2010). Through what is akin to a process of (experiential) re-education, patients are understood to learn the futility of resisting nature, "the quality of non-resistance" (Krech, 2014) (p.39). The purpose, therefore, is *not* to overcome suffering or eliminate symptoms: given Morita's mechanisms of

psychopathology, such attempts are considered counter-productive (Minami, 2013).

The process of therapy is intended to restore and foreground attention on desire for life: through building tolerance for and acceptance of suffering, patients shift from being dominated and directed by this to being dominated and directed by the desires underlying it, re-channelling their energy into purposeful action which fulfils the expectations of such desires (Fujita, 1986; Reynolds, 1976). Thus, conduct becomes dictated by external reality rather than internal states; patients move from being self-oriented to being reality-oriented (Kora, 1995; Krech, 2014). When patients reduce engagement in the vicious cycle and shift their attention to everyday living in this way, their symptoms naturally reduce as a by-product of living more meaningful, constructive and adaptable lives (Kora, 1995; Nakamura et al., 2010; Ogawa, 2013).

2.2 Philosophical and cultural background

As philosophical concepts and cultural values are considered to have a significant impact upon definitions of mental illness and related psychotherapeutic approaches, a full understanding of Morita Therapy necessitates an understanding of the distinctive philosophical and sociocultural milieu in which it was developed (Busfield, 2001b; Fujita, 1986; Tanaka-Matsumi, 2011; Tseng, Chang and Nishizono, 2005).

2.2.1 Traditional Eastern and Western worldviews

With East Asian cultures generally forming in isolation from Europe, it is understood that differences in thought patterns and philosophy emerged between them (Watts, 2012). The core distinction between these worldviews may be described in terms of the extent to which the world is categorised and dichotomised, the associated way in which the relationship between humans and nature (as well as self/others, mind/body and reason/emotion) is conceptualised, and the related way in which people within these cultures understand and respond to phenomenological reality.

Eastern and Western modes of thought

The dominant epistemology of the West, considered both a cause and consequence of the rise of science in Europe, can be traced in particular to the philosophies of Plato, Aristotle, Descartes and Kant (Fujita, 1986; Murase and Johnson, 1974; Williams, 2001). These systems emphasise the rational application of the intellect in line with the divisions arising from self-conscious reflection between reason/ emotion, mind/ body, subject/ object, and internal experience/ external world (Fujita, 1986; Murase and Johnson, 1974; Williams, 2001). This dichotomisation is characteristic of Western thought which is analytical, discriminatory and conceptual: ideas are kept consistent by delineating categories as a means to intellectually understand the complexities of the world (DeVos, 1980; Reynolds, 1982; Suzuki, Fromm and De Martino, 1960; Watts, 2012).

This dualistic thinking led to a conceptual distinction between humans and nature: nature is objectified, reduced to systems of abstraction, and studied through scientific techniques which approach it as external to and separate from humans; humans have been understood in terms of the detached ego, as autonomous individuals who observe and control the environment (Davidson, 2001; Fujita, 1986; Kjolhede, 2000; Pederson, 1977; Watts, 1961; Watts, 2012). Accordingly, dominant Western philosophy emphasises the importance of the individual and advocates bringing objective reality, including the external world, in line with one's will through the manipulation of thought (DeVos, 1980; Reynolds, 1976; Tseng et al., 2005). Arguably, this has resulted in a conflict between humans and nature: the Western mind is predisposed to seek to challenge, conquer and control nature (Fujita, 1986; Reynolds, 1995a; Sato, 2011; Tseng, 2005).

In contrast, Eastern thought is considered totalising, integrative and non-discriminatory (Suzuki et al., 1960). In these terms, the world is not divided and the notion of an independent ego is a socially conditioned fiction; instead, all phenomena are mutually interdependent and understandable only in relation to each other and the context: man cannot be set apart from nature (Brazier, 2012; Watts, 1961; Watts, 2012). Accordingly, Eastern philosophy is naturalistic; humans are part of and subordinate to nature; harmony, rather than

individualism and conflict, is therefore stressed: humans adapt themselves to nature rather than attempting to adapt nature to themselves (Morton and Olenik, 2004; Reynolds, 1976; Reynolds, 1995a; Tseng et al., 2005; Watts, 2012).

In sum, Eastern thought emphasises holism, harmony, acceptance and intuition; Western thought emphasises dualism, individualism, control and rationality (Blocker and Starling, 2010; Chang and Rhee, 2005; Knoblauch, 1985; Suzuki, 2010; Tseng, 2005). In Western culture, man is *in* the world and 'nature' is the verbal reconstruction of the environment; in Eastern culture, man is *of* the world and 'nature' is experienced and felt without the application of thoughts and words (Davidson, 2001; Watts, 2012). These tendencies may be viewed as reflected and reinforced in dominant religious traditions: Western traditions suggest nature conforms to a pattern assigned by an omnipotent God ("the ego of the Universe" (Watts, 2012) (p.88)), and that man has a dominion over nature afforded to him by God; Eastern traditions suggest nature *is* a pattern, a spontaneous and self-governing embodiment of the absolute (Kitanishi, 2005; Morton and Olenik, 2004; Norbury, 2011; Watts, 2012).

Taoism, Buddhism and Confucianism

Eastern worldviews are entrenched in philosophical systems including Taoism, (Zen) Buddhism and (neo) Confucianism (Chang and Rhee, 2005) which, without clear differentiations between self, others and nature, all emphasise harmonious living (Tseng, 2005).

Taoism, a Chinese philosophy, has shaped much thought across East Asia (Hu and Allen, 2005). 'Tao' means the way, course or flow of nature; it is understood as the organic operating principle of the universe which regulates itself spontaneously, always in flux yet balanced by opposing forces (Creel, 1956; Hu and Allen, 2005; Watts, 2012; Young, Tseng and Zhou, 2005). Taoism emphasises monism and eternal cycles: all phenomena exist as inseparable parts of the universal whole; all actions and experiences are movements within the Tao, from which it is impossible to deviate (Creel, 1956; Watts, 2012; Young et al., 2005). Taoism thus stresses the virtue of 'not-contending', of yielding to rather than interfering in the way of nature (Watts, 1961; Young et al., 2005).

Buddhism, particularly the Mahayana school, has been disseminated to much of East Asia from India (Morton and Olenik, 2004). The underlying premise is that pain and conflict are unavoidable, arising from 'egocentric' attachments to phenomena which are in fact transient and illusionary, such as emotions and indeed the 'self' (Chang and Rhee, 2005; Kapleau, 2000; Kitanishi, 2005). Thus, suffering is caused by not being able to control things according to one's will: in believing our minds, bodies and other phenomena belong to and thus can be controlled by us, a vicious cycle of trying to wrest pleasure from pain and self from not-self ensues (Brazier, 2012; Kitanishi, 2005; Tseng et al., 2005; Watts, 1961). Buddhism rejects these dualisms, holistically identifying all things with intrinsic Buddha-nature and understanding them as empty of anything *but* Buddha-nature (Kapleau, 2000; Watts, 1961).

It is argued that an illusion of permanent and independent phenomena is a product of the discriminative and limiting nature of thought and language: people talk about two or more things as separate entities when in fact there is only one 'reality' (Blocker and Starling, 2010; Kapleau, 2000; Watts, 1961). Thus, Buddhism emphasises that reality exists beyond words, in experience (Chang and Rhee, 2005). Buddhism is considered to teach people to reach a selfless state (enlightenment) in which the ego and intellect are transcended, all phenomena (including human life) are understood as relational and impermanent, and one's Buddha-nature can be realised (Blocker and Starling, 2010; Chang and Rhee, 2005; Kapleau, 2000; Morton and Olenik, 2004).

Taoism and Buddhism epitomise the Eastern worldview in emphasising humans as part of the universe: the need for humans to accommodate and harmonise with nature (Brazier, 2012; Tseng, 2005). For both, the governing principles of nature encompass a self-determining spontaneity that cannot be comprehended intellectually, but only in a state of 'egolessness' (Kitanishi, 2005; Watts, 2012; Young et al., 2005). They both consider self-centred desire to be the root of suffering and have at their basis a philosophy of acceptance and nullification: non-interference in the way of nature; consciousness undisturbed by the grasping ego (Blocker and Starling, 2010; Kitanishi, 2005; Watts, 2012).

Confucianism, an ideological system considered at the core of much Asian thought, emphasises the cultivation of the ideal moral character through

practical learning, pursued for no reward other than they joy of doing good and following the 'Way' (akin to the 'Tao') (Fujita, 1986; Lau, 1979; Yan, 2005). Key teachings, in line with other Eastern philosophies, include minimising self-centredness and living in harmony with others (Chen, 2001). Neo-Confucianism combines this system with elements of Taoism and Buddhism, emphasising the consistent principle that the inner nature of all things is the same: Buddha-nature in Buddhist terms; human nature as embedded in the Tao in Taoist terms; human heartedness in Confucian terms (Blocker and Starling, 2010; Chen, 2001; Fujita, 1986; Kapleau, 2000; Watts, 1961). What follows is a belief that human nature is basically benevolent and self-sufficient: every person has the potential to live with satisfaction, and can be trusted to act with authenticity and spontaneity (Tseng, 2005; Yan, 2005).

Zen Buddhism, which emphasises the everyday world in the present moment, developed through an interaction between Mahayana Buddhism, Taoism and Confucianism (Kjolhede, 2000; Smith, 2000). Zen challenges the notion that there exists an 'ego' or fixed 'self', as per all Buddhist thought, and epitomises the Buddhist distrust of logic and language with a distinctively practical focus on holistic and direct experience through meditation and koans (paradoxical questions) (Kapleau, 2000; Smith, 2000; Suzuki, 1961; Watts, 1961). With koans designed so that the intellect or 'ego' cannot answer them, it is believed that people realise there is no ego which is acting, there is only action (Watts, 1961); with meditation intended to wholly focus the mind, people are considered to enter "a full rapport with life" (Kapleau, 2000) (p.12). This way, sudden and direct enlightenment is considered possible: a state of awareness in which the boundaries between mind/ body and self/ nature are transcended (Blocker and Starling, 2010; Kapleau, 2000; Suzuki, 1961).

Relationship to suffering and healing

The epistemological and philosophical traditions discussed influence how suffering and healing are understood (Busfield, 2001b; Tseng et al., 2005). Firstly, from a Western rational viewpoint, a dualism exists between reason and emotion: emotions are considered unreasonable, chaotic and often pathologised; to be rational (ideal) is to be in control of oneself, including one's emotions (Williams, 2001). Eastern thought, alternatively, understands reason

and emotion as embodied and mutually constituted, and unpleasant emotions as authentic and natural rather than pathological and to be controlled (Craib, 2002; Williams, 2001).

Secondly, considered key to Western culture and embedded in dichotomous thought are prevailing ideologies of happiness: in 'the pursuit of happiness', people seek to experience the pleasant and eliminate suffering, focusing on the future, to when this may be attained (Craib, 2002; Flora, 2009; Tseng, 2005; Williams, 2001). As such, Western patients are likely to operate in the realm of the ego, focus on the ways things *ought* to be, and seek manipulation of their phenomenological world through symptom control or elimination, as if symptoms were detachable entities for which a 'cure' can be sought (Craib, 2002; Reynolds, 1976; Smith, 2000; Watts, 2012).

In contrast, Eastern thought understands apparently opposite emotions as mutually interdependent: one cannot experience happiness without sadness (Watts, 2012). As such, the focus is shifted from future goals and what ought to be, to the present, to what *is*: emotions, the self, and reality are accepted without resistance, allowing them to run their natural course in line with the Tao, in which moments of happiness spontaneously come and go, and to pursue them is to miss the experience itself (Kitanishi, 2005; Reynolds, 1976; Smith, 2000; Watts, 2012). The spontaneity of Eastern naturalness specifically denotes a path of *non-pursuit* and non-interference: it is an inner resistance to symptoms, rather than symptoms themselves, which must be cured (Blocker and Starling, 2010; Reynolds, 1976; Watts, 1961; Watts, 2012).

2.2.2 Japanese philosophy

In line with Eastern thought, Japanese culture understands humans as an integral part of nature (Ogawa, 2013). Traditionally, the Japanese people have appreciated the beauty of their environment and lived according to seasonal rhythms, cultivating and celebrating a symbiotic relationship with nature (Blocker and Starling, 2010; Fujita, 1986; Morton and Olenik, 2004). The centrality of love of and reverence for nature is perhaps not surprising given the environment and climate of Japan (Suzuki, 2010). Whilst the richness of the environment may have impressed upon those first arriving "a pervading

sentiment of gratitude" which has been "stored up in the[ir] racial consciousness" (Sansom, 1978) (p.46), that humans are at the mercy of the natural world also cannot be far from the Japanese consciousness: Japan is located upon one of the world's most dangerous tectonic plates and in one of its most hazardous climatic zones, making it liable to earthquakes, tsunamis and severe weather changes (Blocker and Starling, 2010; Morton and Olenik, 2004; Norbury, 2011; Ogawa, 2007).

Although much Japanese thought derives from China, Japan has retained its own distinctive perspective by adapting incoming systems to compliment indigenous values, which are considered to be even more sensual, aesthetic, holistic and naturalistic (and suspicious of that which is intellectual, rational and abstract) than those of the Chinese (Blocker and Starling, 2010; Morton and Olenik, 2004). These values are epitomised by Shintoism, the indigenous Japanese religion (Inoue, Jun, Mizue et al., 2003). Characterised by the worship of natural phenomena which are considered to possess an inherent life force, Shintoism focuses on celebrating life in the here and now and expressing gratitude and appeasement towards nature (Blocker and Starling, 2010; Ellwood and Pilgrim, 2016; Morton and Olenik, 2004). As per Eastern worldviews, practice and action are prioritised over abstract thought and words (Japanese Literature, undated). Shintoism has permeated Japanese society and, as such, the involvement of humans with nature and an emphasis on the here and now is at the centre of Japanese culture (Blocker and Starling, 2010; LeVine, 1998; Norbury, 2011).

Shintoism contains no absolutes, allowing it to be syncretised with Taoism, Buddhism and Confucianism when introduced into Japan in the 6th century (Nishizono, 2005; Norbury, 2011). Indeed, Zen Buddhism resulted from combining and interpreting these philosophies through the lens of the indigenous Shinto perspective (Morton and Olenik, 2004). As such, the Japanese reduced "any transcendental, metaphysical aspects of Buddhism to ordinary phenomenal reality"; for example, taking the notion of sudden enlightenment literally and the notion that all things are Buddha-nature further in inferring that Buddha is nothing *but* such things: there is nothing beyond this concrete world (Blocker and Starling, 2010) (p.32). Hence, Zen becomes the

celebration of everyday phenomena in the here and now, by looking at them from a completely different perspective (Blocker and Starling, 2010).

Shintoism and Buddhism remain the dominant religions in Japan today, and the ways in which both Zen and a sensitivity to nature infuse Japanese culture can continue to be seen in Japanese art, poetry, drama, literature, swordsmanship and practices such as the tea ceremony (*chadō*) (Blocker and Starling, 2010; Chiba, 2010; Kapleau, 2000; Morton and Olenik, 2004; Suzuki, 2010). In particular, in the composition of Japanese landscape art humans are subordinate to nature, and Japanese aesthetics show an acceptance and indeed appreciation of the impermanence and imperfection of all things, including the human condition (Blocker and Starling, 2010; Morton and Olenik, 2004).

2.2.3 The sociohistorical context of Morita Therapy

Following the national isolation of the Tokugawa regime, the Meiji Restoration of 1868 effected significant sociological change in Japan as communication with and the impact of the West increased (Hiraki, 2011; Morton and Olenik, 2004; Nishizono, 2005). The corresponding modernisation or "Westernisation" of Japan created a deep sense of cultural dissonance, as attempts were made to combine Japanese traditions and Eastern worldviews with Western systems and science (Blocker and Starling, 2010; Fujita, 1986; Nishizono, 2005).

Accordingly, the traditional holistic spirit of harmonious integration with nature was brought into conflict with dichotomous and rationalistic Western ideologies which approach nature as an isolated object to be studied and controlled (Fujita, 1986; Kitanishi, 2005). Furthermore, the competitive nature of industry and ideological emphasis on individualism contrasted with the traditional Japanese family consciousness and attitude of self-inhibiting sensitivity to others (Blocker and Starling, 2010; Fujita, 1986; Kondo, 1975; Nishizono, 2005). It was in the context of these conflicts between traditional and modern values, and the neuroses they were understood to produce, that Morita developed his therapy (Fujita, 1986; Nishizono, 2005; Ogawa, 2013).

2.2.4 Eastern philosophy reflected in Morita Therapy

Although Morita clarified that his therapy was not derived from Buddhism, the convergence between Morita Therapy and Zen principles, as well as those of other Eastern philosophies, has been noted by many authors (Brazier, 2003; Hashi, 2013; Kitanishi, 2005; LeVine, 1998; Matesz, 1990; Mercer, 2015; Ogawa, 2007; Reynolds, 1982; Rhyner, 1987; Rush, 2000). Certainly, Morita borrowed many terms from Buddhism, Taoism and Japanese literature, and Morita Therapy is considered grounded in both the naturalistic worldview and Japan's distinctive culture (Fujita, 1986; Kitanishi, 2005; Kondo, 1998; Nakamoto, 2010; Ogawa, 2013; Reynolds, 1976).

Morita Therapy clearly incorporates Eastern naturalism in aiming to correct self-centredness by de-centralising the self (or de-emphasising the ego) through a unity of mind, body and nature, expressed and experienced through action, whereby one harmonises with nature by adapting to phenomenological reality (Fujita, 1986; Kitanishi, 2005; Morita et al., 1998; Young et al., 2005). Accordingly, Morita's approach is monistic and holistic, focusing on the whole person rather than their symptoms (Morita et al., 1998; Nakamoto, 2010). Furthermore, both Zen and Morita affirm and accept desires and conflicts (Kitanishi, 1992). As in Eastern thought, Morita Therapy stresses the necessity of opposites and that suffering is an integral part of life: a consequence of desire which cannot be transcended, and which is unproblematic unless resisted (Kitanishi, 2005; Reynolds, 1982; Tseng, 2005; Young et al., 2005).

As epitomised in Zen meditation, Morita Therapy emphasises non-interference in the natural flow of thoughts and emotions through self-consciousness and ego mechanisms such as obsession, rationalisation, resistance and attachment (in essence, Morita's vicious cycle) (Kapleau, 2000; Reynolds, 1976; Watts, 1961). Both Zen and Morita Therapy stress that thoughts and emotions need not cause difficulties unless they are intellectually evaluated as good or bad, inciting attempts to cling to or banish them (Kapleau, 2000; Kondo, 1975). Thus, conflicts are considered to be caused by the ego: the way in which the ego grasps for things which are transient and illusionary (the ideal) and, in its false conception of a fixed and autonomous 'self', resists anything which

threatens its position, opposing the natural (the real) and trying to gain control over it through thought (the vicious cycle) (Kitanishi, 2005) (p.175).

As Zen Buddhism emphasises, that there even exists a distinct 'self' is considered a misconception (Kapleau, 2000; Reynolds, 1976). This ideology of egolessness is key to the Morita Therapy process: shifting focus from the self to the environment; moving beyond conscious self-evaluation towards a state in which attention moves freely from one external event to another (Ishiyama, 1986c; Kitanishi, 2005; LeVine, 1998). In accordance with Zen meditation and the paradoxical nature of intense self-enquiry within koan practice, the Morita Therapy rest phase diminishes egocentric thinking through facilitating a widening of awareness (Kapleau, 2000; Kondo, 1992; LeVine, 1998).

It is understood that once disruptive ego mechanisms are broken down, natural energies are liberated, and adaptability and spontaneity of behaviour becomes possible: key to both arugamama and Zen enlightenment (DeVos, 1980; Kitanishi, 1992; Reynolds, 1976; Suzuki, 1961). Such spontaneity is, in Morita Therapy, characterised by free-flowing desire for life, unimpeded by self-consciousness: a concept akin to Buddha-nature, human nature within the Tao, and Confucian human-heartedness, all suggesting an authenticity which provides the means and drive to live a meaningful life (Blocker and Starling, 2010; Brazier, 2012; Chen, 2001; Fujita, 1986; Ogawa, 2007; Watts, 1961).

Both Zen and Morita Therapy stress putting principles into everyday practice, mindfully focusing on tasks, and losing the self in productive effort (Kapleau, 2000; Kitanishi, 1992; Kumasaka, 1965; Reynolds, 1976). Morita's action-based method may also be traced to neo-Confucianism, which holds that "knowledge becomes genuine knowledge by means of action" (Fujita, 1986) (p.39). Morita's holistic focus on experience and embodiment, and associated distrust of the divisive rather than relational nature of language and cognition, also conforms to Eastern viewpoints, epitomising Zen (Kapleau, 2000; Kitanishi, 1992; Murase and Johnson, 1974; Watts, 1961; Watts, 2012). Through directly experiencing the activities of the body in relation to the environment, the (illusionary) dualism between self (observer) and the world (observed) is considered to fall away (Davidson, 2001; LeVine, 1998; Morita et al., 1998; Nakamoto, 2010; Reynolds, 1976; Watts, 1961). Thus, both Zen and Morita

target not the intellect but the phenomenology of existence: what it *feels* like to be alive, epitomising the Japanese focus on the phenomenological reality of the everyday world in the here and now (Davidson, 2001; Watts, 1961).

2.3 Distinguishing Morita Therapy and Western psychotherapies

All psychotherapies may be considered to have cultural bases: just as Morita Therapy is infused with an Eastern worldview, the generally empirical and rational ways in which the West approaches mental health are grounded in Western worldviews (Fujita, 1986; Murase and Johnson, 1974; Reynolds, 1976; Tanaka-Matsumi, 2011). As such, given the conceptualisation of the detached 'ego', it is argued that "Western psychology has directed itself to the study of the psyche or mind as a clinical entity" (Watts, 1961) (p.16).

For example, psychoanalysis, born out of positivism, is based on a view of the mind as an isolated object, emphasising the autonomy of the individual and the resolution of suffering (Carleton, 2002; DeVos, 1980; Fujita, 1986; Tseng, 2005). Accordingly, Morita, a contemporary of Freud, strongly criticised psychoanalytic theory, challenging its dualistic and static nature which restricted consciousness to the mind and posited an 'unconscious' existing as if it were a concrete, permanent structure (Davis and Ikeno, 2002; Gibson, 1974; Kitanishi, 2005; Kondo, 1998). Indeed, Morita's method is the antithesis of Freud's focus on historical events and intellectual analysis, with such explorations considered to increase counter-productive thoughts of the 'self' (Kjolhede, 2000; Murase and Johnson, 1974).

Morita Therapy is therefore in stark contrast to Western models of mental health and associated treatments (Krech, 2014). Although certain parallels may be drawn between Morita Therapy and other contemporary approaches (Hofmann, 2008; Nakamoto, 2010; Reynolds, 1976; Spates, Tateno, Nakamura et al., 2011), philosophically and epistemologically, Morita Therapy has a phenomenological focus which rejects the entire premise of Western treatments, grounded in the dualisms of mind/body, self/others and spirit/nature (Hall, 2011a; Kitanishi, 2005; LeVine, 2016a; Morita et al., 1998). Morita Therapy is monistic, holistic, experiential and intuitive: it emphasises the reality of the present and proposes that the 'truths' of (human) nature can be directly

experienced through bodily engagement with everyday living; Western therapies tend to be mechanistic, verbal and logical: they emphasise specific techniques, internal processes and rational understanding in an effort to relieve suffering (Burston, 2003; Carleton, 2002; LeVine, 1998; Murase and Johnson, 1974; Reynolds, 1976; Reynolds, 1982; Tseng, 2005). Whereas such approaches may be seen to intellectualise emotions, Morita Therapy may be seen to de-intellectualise emotions (and, indeed, living in general).

With its aim of accepting and living in harmony with nature, Morita Therapy is thus qualitatively different to Western approaches in both method and objective (Tseng, 2005). In contrast to Cognitive Behavioural Therapy (CBT) (Beck, 2011) and Behavioural Activation (BA) (Lewinsohn, Biglan and Zeiss, 1976), Morita Therapy does not seek to reduce symptoms through the modification of thought and/or behavioural patterns, which would be considered counter-productive (Reynolds, 1976). Although approaches such as Mindfulness-Based Cognitive Therapy (MBCT) (Segal, Williams and Teasdale, 2002) and Acceptance and Commitment Therapy (ACT) (Hayes, Strosahl and Wilson, 1999) also cultivate acceptance, in Morita Therapy acceptance has a uniquely active, spontaneous and paradoxical quality: it cannot be brought about through deliberate cognitive reappraisal, only through everyday behavioural experience (Ogawa, 2013; Tateno, 2014; Watts, 1961). Indeed, in Morita Therapy it is understood that there is no 'I', or ego, which may choose to accept symptoms before proceeding with life; one must proceed with life in the here and now, with or without symptoms (Ogawa, 2013; Watts, 1961).

Further differences are also noteworthy. Whilst BA and ACT are directive in activity scheduling and/or prior goal discrimination, Morita Therapy allows action-taking to come about naturally and spontaneously through the inherent purposefulness of the resurfacing desire for life (Ogawa, 2007; Ogawa, 2013). In addition, whilst approaches such as MBCT may be seen to magnify the subjective self, increasing self-awareness in order to shift subjective experiences, Morita Therapy minimises it, shifting attention outwardly to induce a 'mindless' state in which one is fully absorbed in the present moment and thus unaware of internal states (Morita et al., 1998; Ogawa, 2013).

In sum, the key distinctions between Morita Therapy and Western therapies are: (1) underlying philosophy and epistemology; (2) goals: acceptance and allowance versus symptom reduction; (3) methods: experiential embodiment versus cognitive reappraisal, external versus internal attentional focus; (4) impetus for action: spontaneity of desire for life versus planned action-taking. Overall, whilst Morita Therapy emphasises readjustment in social terms through accommodating environmental forces, with resulting individual improvement, Western therapies typically emphasise personal recovery through individualised mechanisms for resolving internal conflicts, with resulting improvements in social terms (Murase and Johnson, 1974). In Morita Therapy, symptoms are not isolated and treated as if they were independent entities or illnesses to be cured, rather they're approached as part of oneself: indeed, they *are* oneself, in so much as one is one's phenomenological experience (Reynolds, 1976). Thus, Morita Therapy moves beyond symptom relief, emphasising personal growth and addressing a patient's overall outlook and way of life (Kitanishi, 2005; Tateno, 2014).

2.4 The development and diversity of Morita Therapy

In an effort to modernise and universalise Morita Therapy, the scope of the approach (where, with whom, and how it is practiced) has been broadening for some time (Kitanishi and Mori, 1995; Reynolds, 1976).

2.4.1 Morita Therapy formats

Inpatient treatment

Morita Therapy was developed as a structured inpatient treatment in Morita's own home: a safe and ecologically-based environment which was understood to facilitate patients' natural healing capacities (LeVine, 1998; Morita et al., 1998; Ogawa, 2013). This involved four successive stages of: (1) isolated rest; (2) light monotonous work; (3) intensive outdoor work; (4) preparation for daily living (Morita et al., 1998). Both the environment and stages were designed to expand patients' peripheral attention from internal states to the external environment; to enable them to experience how the mind may be either fixated

on symptoms or tasks at hand, and how emotions naturally ebb and flow when left unattended (LeVine, 1998; Morita et al., 1998; Ogawa, 2013).

The rest phase is, arguably, crucial to Morita's experiential therapy: the starting point for patients becoming engaged in their external environment as, paradoxically, their initially consuming self-focus begins to dissipate (LeVine, 1998). Stages two and three are of an occupational therapeutic nature in which purposeful tasks typically involving hands (stage two) and whole body movements (stage three) are used to absorb patients' attention and channel their resurfacing desire for life; gradually, patients' spontaneity and engagement with others, objects and nature are increased (LeVine, 1998; Minami, 2013; Morita et al., 1998). Stage four involves reintegrating patients back into their real lives in society (Morita et al., 1998). Stages two onwards include daily diary writings by patients which receive comments by the therapist consistent with Morita's principles (Kora, 1995; LeVine, 1998).

A number of inpatient clinics still operate in Japan as well as China (Jiangbo, 2000; Ogawa, 2013; Reynolds, 1976), whilst the only inpatient clinic in the English-speaking world operates in Australia (LeVine, 2016b). There is a great deal of variation in the practices of contemporary clinics, particularly in terms of how broadly Morita's theory is interpreted and applied to different patient conditions; the degree to which they implement Fumon or allow discussion of patient symptoms; the extent to which they emphasise nature, insight, rest, work and/or recreational activity, and the relationship between Morita Therapy and Zen Buddhism (Ohara and Reynolds, 1968; Reynolds, 1976).

Outpatient treatment

Outpatient (or neo-) Morita Therapy is applied throughout Japan and in other countries to a limited degree, and practiced in a diverse range of settings including via correspondence (Kitanishi, 2005; Minami, 2013; Reynolds, 1976). Accordingly, the Japanese Society for Morita Therapy developed outpatient guidelines which include the use of diary guidance and summarise the therapeutic components as "increasing client awareness and acceptance of emotions"; "recognising and mobilising the client's desire for life"; "clarifying the vicious cycle"; "giving instructions for constructive action"; "facilitating client's re-

evaluation of their behavioural patterns and lifestyle" (Nakamura et al., 2010) (p.8-19). Rather than adhering to a strict Fumon stance, the outpatient therapist does enquire into unpleasant emotion as necessary to portray empathy and elucidate the vicious cycle (Hashimoto, 2016; Ishiyama, 1988b).

There is variation in the application of the outpatient guidelines, perhaps due to the absence of a systematic Morita Therapy education system or widely accepted Morita Therapy manual (Ogawa, 2013). Indeed, many practitioners refer to implementing 'outpatient Morita Therapy' with little further delineation of what their process entails (Richards, 2016): thorough protocols detailing the precise nature of these approaches are rarely developed and/or published (Kitanishi, 2016). The breadth and scope of outpatient application was highlighted in the 9th International Congress of Morita Therapy (Richards, 2016). Current methods range from progressively staged approaches adapted for outpatient settings (Crowder, 2016; LeVine, 1993b) to individual counselling methods with no such structure (Ishida, 2016) such as the active counselling method (Ishiyama, 2011) and modal model (Minami, 2013). Approaches further extend (Ogawa, 2013) to include group-based (Ashizawa, Anazawa and Honma, 2000; Murray and Ishiyama, 2016), psychosocial (Minami, 2016) and psychoeducational (Kobayashi, 2016; Semenova, 2016) interventions. Approaches often entail an arguably loose application of Morita Therapy principles and/or methods: they may be based on Morita's perspective, make use of Morita's strategies, and/or use Morita Therapy as a framework (Huckvale, 2016; Kobayashi, 2016; Minami, 2016; Semenova, 2016), and at times do so in combination with other approaches such as mindfulness (Yamada, 2016) and art therapy (Huckvale, 2016).

2.4.2 Conditions treated with Morita Therapy

Morita Therapy was originally developed to treat 'Shinkeishitsu': a psychiatric diagnostic term developed by Morita to describe an arguably 'culture-bound' syndrome (Kitanishi, Nakamura, Miyake et al., 2002; Russell, 1989). This term denotes a form of 'neurasthenia', or neurosis: a category still applied in Japan, where DSM (Diagnostic and Statistical Manual) and ICD (International Classification of Diseases) classifications have not been widely used until recently (Someya and Takahashi, 2001). Nonetheless, Shinkeishitsu is

considered to correspond to DSM-V anxiety disorders, alongside elements of mood and personality disorders (Fujita, 1986; Kitanishi et al., 2002; Morita et al., 1998; Ogawa, 2013; Reynolds, 1995a). Shinkeishitsu is characterised by strong desires for success and social approval and related manifestations of fear: such people tend to be introspective, perfectionist, self-conscious and self-critical (Fujita, 1986; Ogawa, 2013). Thus, Shinkeishitsu refers to a condition in which neurotic symptoms are formed through the mechanisms of Morita's vicious cycle (Kitanishi et al., 2002).

Whilst Shinkeishitsu is a condition to which the Japanese are considered particularly inclined, Shinkeishitsu processes are also considered present to some degree in everyone (Morita et al., 1998). After all, Morita Therapy is based on Morita's perception of *universal* human nature: all possess desire for life to which Morita's mechanisms of psychopathology are related (Koschmann, 1976: cited in Reynolds, 1989; Fujita, 1986). Thus, Morita Therapy is considered relevant wherever patients resist suffering and, with it, their authentic and natural selves: a principle widely applicable to human difficulties (Fujita, 1986; Kitanishi, 2005). Accordingly, Morita Therapy is now applied to a diverse range of conditions and, in contemporary Japan, often to Shinkeishitsu tendencies mixed with depression or other symptom combinations (Kitanishi, 2005; Kitanishi and Mori, 1995; Nishizono, 2005; Reynolds, 1995a).

The array of conditions now treated with Morita Therapy internationally was, again, well demonstrated during the 9th International Congress (Richards, 2016). Patient groups include 'at risk' children (Crowder, 2016), victims of sexual assault (Ogawa, 1988) and civil war victims and perpetrators (Minami, 2016); conditions include depression (Kobayashi, 2016; Niimura, Kitanishi and Masafumi, 2016), bipolar II disorder (Kitanishi and Nakamura, 1989: cited in Kitanishi, 2005), schizophrenia (Chen, 2000; Semenova, 2016; Toki, 2016), panic disorder (Tatematsu, 2000), obsessive compulsive disorder (Hinoguchi, 2016; Qiyi and Xiongwei, 2000; Tateno, 2014), social phobia (Shioji, Nakamura and Ushijima, 2000), trauma (LeVine, 2016b), eating disorders (LeVine, 1993a), insomnia (Itoh, Yamadera, Sasaki et al., 2000), chronic pain (Ashizawa et al., 2000; Murray and Ishiyama, 2016), occlusal discomfort syndrome (Ishida, 2016) and atopic dermatitis (Hosoya, 2016).

2.4.3 International developments

Morita Therapy is now practiced in Australia, China, North America, Russia and Rwanda, predominantly by a limited number of Japanese practitioners who have transported the treatment to different cultures (Ishiyama, 1987; Kitanishi and Mori, 1995; Minami, 2016; Ogawa, 2013). With regards to English-speaking countries, both inpatient and outpatient treatment are provided in Australia by an Australian practitioner who trained in Japan (LeVine, 1998), and outpatient counselling-based methods are used in North America by Japanese practitioners (Ishiyama, 1986c; Ogawa, 1988).

Morita Therapy principles have also influenced other Western approaches: in North America, ideas from Morita Therapy and another Japanese approach consisting of intensive reflection on past experiences (Naikan Therapy) have been modified and combined to form 'Constructive Living' (Reynolds, 1995b); in England, the My Time mental-health provider for refugees and asylum seekers (http://www.richmondfellowship.org.uk/my-time) incorporates elements of Morita Therapy such as Fumon; progressive activity; unity of mind, body and environment; and horticultural therapy (Ogawa, 2013).

2.5 Implications for this thesis: Translating Morita Therapy to the UK

In the context of cross-cultural differences (section 2.2), there were several issues to consider in translating Morita Therapy to a UK context.

2.5.1 Applying and adapting Morita Therapy across cultures

That Morita Therapy has both been applied internationally and survived the rapidly changing environment of Japan, with its growing emphasis on Western values and changes in patient profiles, is considered testament to its adaptability and transcultural potential (Nishizono, 2005; Kitanishi, 2010: cited in Ogawa, 2013; Reynolds, 1989). It is suggested that this transcultural application is made possible by Morita's holistic approach to well-being, theory of universal human nature, widely applicable mechanisms of psychopathology and focus on everyday living (Fujita, 1986; Ishiyama, 1987; Kondo, 1992; Morita et al., 1998; Nishizono, 2005; Ogawa, 2013).

However, it follows from the differences in worldviews discussed that receptivity to and expectations for psychotherapy would differ across Eastern and Western cultures (Tanaka-Matsumi, 2011). Given the grounding of Morita Therapy in both Eastern naturalism and Japan's distinctive culture, it is therefore argued that considerable modifications are necessary to achieve cultural accommodation in the West (Ishiyama, 1994; Ogawa, 2013; Ohara, 1990; Reynolds, 1989; Reynolds, 1995a; Tanaka-Matsumi, 2011; Tseng, 1999). Particular concerns relate to rest, Fumon, the translation of Zen terms into English, and Westerners' receptivity to the notion of accepting rather than controlling symptoms (Kitanishi and Mori, 1995; Kondo, 1998; LeVine, 1998; Ogawa, 2013; Koschmann, 1976: cited in Reynolds, 1989; Reynolds, 1995a). Indeed, Reynolds, considering Morita Therapy to be confined to the needs of early 20th century Japanese patients, modified the approach for a North American context by extracting and assimilating elements of Morita Therapy into what was considered a more Western-appropriate mode of treatment ('Constructive Living') (Reynolds, 1989).

However, the difficulty is the extent to which Morita Therapy can be modified and still called 'Morita Therapy': there are concerns that the treatment's essential, defining elements are being displaced (LeVine, 1998; Ogawa, 2013; Ohara, 1990). Accordingly, authors challenge the degree to which Reynolds truly adopts Morita's principles within Constructive Living, and note concerns around the potential misuse of Morita Therapy across cultures, particularly through an over-reliance on the verbal approaches and abstract knowledge which Morita precisely warned against (Kondo, 1998; LeVine, 1998; Ogawa, 2013). Such authors urge those adapting Morita Therapy to pay due attention to the centrality of Morita's four stages, including rest, to the defining progressive and experiential nature of the approach (Kondo, 1998; LeVine, 1998), and to ensure modification is undertaken without "corrupting its theory, offsetting its goals, or tempering its principles" (Ogawa, 2013) (p.48).

This thesis sought to circumvent such concerns by maintaining a purist stance towards Morita Therapy, as far as possible in an outpatient context. Thus, in optimising Morita Therapy for a UK population (see Chapter Five) it was considered critical to retain its distinctive philosophical and experiential basis

rather than diluting this through assimilation into established Western treatment modes, as typically seen in the application of Eastern approaches to the treatment of depression in the West (e.g. the integration of Eastern mindfulness practices and Western Cognitive Therapy within MBCT (Segal et al., 2002)). Indeed, that the distinctive philosophical, cultural and experiential basis of Morita Therapy needs to be diluted to make it suitable for the West is thus far largely an assumption (LeVine, 1998).

2.5.2 A fundamentally different approach to mental health

That Morita Therapy challenges some fundamental assumptions and paradigms of Western culture by offering an alternative philosophical basis for understanding and approaching mental health, and with it the potential for re-defining culturally constituted notions of (ab)normality and (un)naturalness (Busfield, 2001a), may be exactly what gives Morita Therapy value for Western patients. Indeed, it is argued that healing approaches associated with the universal principles of Buddhism, such as Morita Therapy, are applicable across cultures and, for the West, may reawaken its "dormant healing potentials, which have been eclipsed by its characteristic patterns of thinking" (Chang and Rhee, 2005) (p.165).

In the context of suggestions that some patients and practitioners in the West are experiencing increasing discontent with Western approach towards psychiatry and medicine (Robertson and Walter, 2013), Morita Therapy may provide a welcome shift away from this model. Perhaps indicative of this discontent is the growing interest in Eastern-aligned approaches seen in the West: the increasing number of Westerners using Eastern, complementary and alternative therapies; the current proliferation of mindfulness practices; the shift towards acceptance-based models in mental health treatment; the interest in 'holistic health' and healing (as opposed to 'curing') as a subjective and holistic experience (Berliner and Salmon, 1980; Cassell, 2004; Coulter and Willis, 2004; Egnew, 2005; Fisher and Ward, 1994; Hall, 2011b; Hiraki, 2011; Miles, 2009b; Roemer and Orsillo, 2002; Scott, Warber, Dieppe et al., 2017; Walsh, 1989).

Particular difficulties with Western approaches are highlighted in relation to the 'disease-based', biomedical, reductionist approach to health care, in which

arguably natural human responses are unhelpfully pathologised, and diagnostic labels prioritised over individuals' unique and holistic experiences of illness (Bakx, 1991; Green, Carrillo and Betancourt, 2002; Miles, 2009b). With regards to CBT, which may be considered heavily aligned with Western values of autonomy, control and rationality (Hays and Iwamasa, 2006), critics similarly argue that the approach is overly mechanistic, and insufficiently holistic and experiential (Gaudiano, 2008; Roemer and Orsillo, 2002). Thus, the holistic focus of Morita Therapy on acceptance, experience and the naturalness of emotions may provide UK patients and practitioners with a welcome alternative.

In essence, one cannot know whether a therapy must be supported by prevailing cultural trends in order to be effective, or whether a therapy which runs counter to cultural trends may be effective for that very reason, until that therapy is implemented within the culture in question (LeVine, 1998; Reynolds, 1989; Young et al., 2005). Whilst, it is argued, "the effectiveness of Morita Therapy depends on whether or not patients can share the human understanding of East Asian philosophy" (Kitanishi, 2005) (p.171), whether or not UK patients are able to do so is yet to be established. Thus, this thesis begins empirical investigations into the acceptability and feasibility of this fundamentally different way of perceiving and approaching mental health and illness in the UK.

2.6 Chapter summary

This chapter has described and discussed Morita Therapy in terms of the key principles, processes and objectives of the approach; its philosophical and cultural basis in light of the distinctions between traditional Eastern and Western epistemologies; a comparison to Western psychotherapies; and its development and diversity over different formats, countries and patient conditions. The discussion of the impact of these considerations on this thesis has highlighted the potential for the distinctive worldview underpinning Morita Therapy to provide UK-based patients with a fundamentally different approach towards mental health. Chapter Three outlines the methodological framework underpinning this thesis and the methodological approaches adopted throughout.

CHAPTER THREE. METHODOLOGICAL OVERVIEW

This chapter outlines the methodology underpinning this thesis and methods adopted throughout. Part one (methodological framework) discusses evidence-based medicine, the need for experimental research, and how bias may be minimised within randomised controlled trials (RCTs). Subsequently, the Medical Research Council framework for complex interventions is outlined and mixed methods research for complex interventions is discussed. Part two (methodological approach) provides the overarching design of this thesis, including a description and justification of the methods employed within each study, followed by a discussion of reflexivity (for which the first-person voice is adopted).

CHAPTER THREE. PART ONE.

Methodological Framework

3.1 Evidence-based medicine

Evidence-based medicine (EBM) and practice (EBP) are long-standing fields which continue to evolve (Sackett, Rosenberg, Gray et al., 1996; Skelly and Chapman, 2011). In the UK and North America, the EBM movement has been taking hold since medical successes began to generate the potential to distinguish between beneficial and less beneficial treatments in the early 20th century (Spring, 2007). The McMaster group, credited with a pivotal role in developing EBP, was established in the 1980s, and EBP has since gained increasing traction in clinical psychology, social work, and allied disciplines (Lilienfeld, Ritschel, Lynn et al., 2013; Spring, 2007).

3.1.1 What is evidence-based medicine?

With a view to improving quality in health care services, EBM seeks to move from clinical decision-making based on clinical experience and intuition to one informed by the scientific evaluation of evidence and systematic application of knowledge (Guyatt, Rennie, Meade et al., 2002; Lilienfeld et al., 2013; Montori and Guyatt, 2008; Spring, 2007). Sackett et al. (1996) define EBM as "the conscientious, explicit, and judicious use of current best evidence in making

decisions about the care of individual patients" (p.71). In practice, this is a bottom-up process in which clinical expertise and clinical evidence are integrated (Sackett et al., 1996). Here, clinical expertise refers to "the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice" (Sackett et al., 1996) (p.71); clinical evidence refers to clinically relevant research evidence bearing on whether and why a treatment works (Lilienfeld et al., 2013; Sackett et al., 1996).

Although the role of patients was not explicitly demarcated in Sackett et al.'s (1996) definition, its importance was acknowledged: clinical expertise is indicated in part by "the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions" (p.73), and "patient centred clinical research" is prioritised within the definition of clinical evidence (p.72). Subsequent definitions explicitly integrate patient preferences and characteristics with research evidence and clinical expertise, creating a three-legged definition of EBM (Spring, 2007).

The role of patients and the public in evidence-based medicine

The consideration of patient preferences within EBM represents the movement away from the paternalistic care model, in which healthcare professionals remain ultimately responsible for clinical decision-making, towards a more shared care model in which patients are more fully involved in decision-making (Spring, 2007). Such involvement is advocated on ethical grounds, considered to improve both patient satisfaction and outcomes, and, ultimately, directed towards engaging patients more fully in health self-management (Edwards, Elwyn, Wood et al., 2005; Gravel, Légaré and Graham, 2006; Spring, 2007).

Alongside this move towards shared clinical decision-making, patients and the public are increasingly involved in research itself. A call for greater patient and public involvement (PPI) (Tallon, Chard and Dieppe, 2000) and acknowledgement of its importance have been met with the development of infrastructure and guidance to support it. The James Lind Alliance (http://www.lindalliance.org) brings patients, carers and clinicians together on equal footing to work on health conditions (Partridge and Scadding, 2004); INVOLVE provide guidance on good practice in PPI (http://www.invo.org.uk);

PPI has been introduced as policy in the UK: the National Institute for Health Research will not grant funds in the absence of PPI within the research programme (http://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/how-to-apply/support-for-study-teams/involving-the-public/). Through these mechanisms, patients and the public can be involved at all levels of research from design through to write up, as active and equal partners in the research endeavour (Richards, 2015b).

Despite acknowledgement of the vital role of PPI in producing appropriate and high quality research, and the moral imperative to involve people in research which is intended to benefit them, improvements in this area are still required (Madden and Speed, 2017; Staley, 2009; Staniszewska, Brett, Mockford et al., 2011). In particular, a more critical and contextualised approach towards PPI is considered necessary to ensure meaningful and significant involvement; higher quality reporting of PPI is required to facilitate a deeper understanding of the role, mechanisms and impact of involvement, thus enabling its future optimisation (Madden and Speed, 2017; Staley, 2009; Staniszewska et al., 2011).

3.1.2 Generating evidence

As noted, EBM emphasises utilising the best research evidence in clinical decision-making. It is argued that such evidence is required in order to protect patients from risks such as medical incompetence and overestimation of treatment effects (Kelly, Morgan, Ellis et al., 2010). Evidence is now key to policy determinations; for example, the National Institute for Health and Clinical Excellence (NICE) commissions systematic reviews of the evidence-base for an intervention before determining if it should be provided by the National Health Service (NICE, 2012). Thus, for an intervention to become the standard of care in the UK, evidence is essential.

Approaches to generating evidence include experimental approaches (in which factors are deliberately controlled and manipulated) and non-experimental approaches. Non-experimental approaches include case studies and series (descriptive clinical evaluations of single patients or patient groups who have received an intervention) and cohort studies (observations of any changes in

data routinely collected from a group of people). Single-subject designs, such as pre-post studies, provide a quasi-experimental approach to investigating relationships between variables through the administration of repeated measures of targeted symptoms (Backman and Harris, 1999). What constitutes the most suitable design for generating 'the best evidence' depends upon the uncertainty or question being addressed (Sackett and Wennberg, 1997). For questions regarding intervention effectiveness, the best evidence may be defined as that which is "the least likely to be biased", and thus most trustworthy (Kelly et al., 2010) (p.1057).

3.1.3 The importance of experimental research

Bias, or compromised internal validity, refers to the production of results which differ systematically from the 'truth' (Eccles, Grimshaw, Campbell and Ramsay, 2003). Where studies are subject to such bias, secure inferences of cause and effect between the intervention and outcomes cannot be established: a key limitation of non-experimental approaches (Field and Hole, 2003). As noted by Burns, Rohrich and Chung (2011), case studies and expert opinion are "often biased by the author's experience or opinions and there is no control of confounding factors" (factors, other than the intervention, which influence outcomes) (p.2). Accordingly, the major concern with such approaches is their potential to distort, and likely overestimate, treatment effects (Barton, 2000; Cook, Guyatt, Laupacis et al., 1992; Mulrow and Oxman, 1997; Sackett et al., 1996). For such reasons, evidence generated through non-experimental approaches and clinical experience runs the risk of promoting treatments which are useless or harmful (Cook et al., 1992; Evans, Thornton, Chalmers et al., 2011). This potential for harm is well demonstrated by the case of thalidomide, which resulted in birth defects in thousands of babies (Vandenbroucke, 2013).

In comparison, experimental research is considered to minimise bias through controlling confounding variables, thus enabling causality to be established with greater certainty (Eccles, Grimshaw, Campbell et al., 2003). These factors have supported a hierarchy of evidence for establishing treatment effects (Figure 1, overleaf), in which study designs are ranked according to the probability of bias: randomised controlled trials (RCTs) and systematic reviews of these are placed highest, and case studies and expert opinions lowest

(Barton, 2000; Burns et al., 2011; Kelly et al., 2010). RCTs allow the comparison of the effects of alternative approaches through the random allocation of participants to one of two (or more) groups (randomisation). For assessing intervention effectiveness, the RCT is considered the method which is least prone to bias and thus the 'gold standard' for establishing causality (Barton, 2000; Collins and MacMahon, 2001; Eccles et al., 2003; Kelly et al., 2010; Sackett et al., 1996; Spring, 2007).

Figure 1. The hierarchy of evidence (Reprinted from Clarity Informatics (2014))

3.1.4 Addressing bias in randomised controlled trials

Sources of potential bias are commonly classified in terms of selection, performance, attrition and detection (Higgins, Altman, Gøtzsche et al., 2011), alongside issues of spontaneous remission and regression to the mean (Field and Hole, 2003). The internal validity of an investigation into intervention effectiveness depends on the extent to which such sources of potential bias have been avoided, through randomisation and other procedural measures, as outlined below (Higgins and Altman, 2008).

Selection bias

Selection bias occurs whenever those who receive an intervention differ systematically from those who do not, in ways likely to affect outcomes (Cullum and Dumville, 2015). These confounding variables may be known or unknown. Variables which are believed to impact upon the relevant outcomes may be managed through stratification in randomisation: the equal division of participants into groups based on these variables (Silcocks and Gheorghe, 2014). However, given that which patient characteristics might predict treatment response remains largely unknown, other unknown confounding variables may remain (Cuijpers, Reynolds, Donker et al., 2012). Through randomisation with appropriate sequence generation (pre-specified rules for allocating participants) and allocation concealment (prevention of researchers' knowledge of forthcoming allocations) (Higgins and Altman, 2008), all known and unknown confounding variables are made as unsystematic as possible: (hopefully) distributed randomly across groups, thus preventing selection bias (Field and Hole, 2003). Randomisation is also the best method available for addressing spontaneous remission and regression to the mean (Torgerson and Torgerson, 2008).

Spontaneous remission

Many patients will recover from illnesses such as depression without any intervention: natural healing processes, social support, and positive experiences may generate such improvement; indeed, illnesses may be 'self-limiting' and improve by themselves (Evans et al., 2011; Lilienfeld et al., 2013). A meta-regression of 19 studies indicated that 23% of untreated cases of depression remit with 3 months, 32% within 6 months and 53% within 12 months (Whiteford, Harris, McKeon et al., 2013). Thus, researchers must include techniques to disentangle the impact of these temporal changes from the impact of the intervention itself (Field and Hole, 2003).

Regression to the mean

Regression to the mean is a statistical phenomenon due to measurement error. Due to high levels of error in the measurement of extreme scores, where

patients score either very high or very low scores on a first assessment, they are by chance likely to produce scores closer to the mean (or their 'true state') at subsequent assessments, regardless of any intervention (Field and Hole, 2003). Thus, researchers must take care when attributing any decreases from very high scores or increases from very low scores to the intervention itself. A large enough RCT utilising concealed random allocation reduces the risk of serious imbalances across groups in characteristics likely to affect outcomes and factors including the impact of spontaneous remission and regression to the mean, allowing the comparison of groups which should differ only with respect to the intervention received (Lamb and Altman, 2015; Nichol, Bailey and Cooper, 2010; Schulz, Chalmers, Hayes et al., 1995).

Performance bias

Performance bias refers to systematic differences between groups in the way in which care is delivered, aside from the intervention in question (Higgins and Altman, 2008). Thus, all factors other than the intervention must be applied equally to all groups. Blinding of participants may reduce such bias; otherwise, part of any benefit apparently effected by the intervention may in fact be due to the participant's knowledge that they have received an intervention (Evans et al., 2011). However, such blinding may not be possible (for example, where participants take an active role such as engaging with a psychological therapy) (Higgins and Altman, 2008; Lamb and Altman, 2015).

Attrition bias

Differential attrition (whereby the rate of participant withdrawal and thus missing data is higher in one group) threatens internal validity as some characteristics of the groups may be influencing retention, or differences may be present between those who do and do not withdraw, with the bias originally avoided through randomisation then re-emerging (Moran and Whitman, 2014; Robinson, Dennison, Wayman et al., 2007). Thus, strategies (such as maintaining frequent contact) must be employed to optimise retention, especially if a study includes a control group, in which enthusiasm for participation may be lower (Higgins and Altman, 2008; Hunt and White, 1998; Moran and Whitman, 2014).

Detection bias

Detection bias refers to systematic differences between groups in how outcomes are measured (Higgins and Altman, 2008). Alongside ensuring the same outcome measures and procedures for collecting outcome data are in place for all participants, and undertaken by independent researchers, one way to minimise such bias is to blind the researchers who collect data, so that their knowledge of which intervention has been received cannot have an impact on outcomes (Evans et al., 2011; Higgins and Altman, 2008).

3.1.5 Randomised controlled trials: other considerations

The above considerations relate to internal validity and stress the need for RCTs which incorporate procedural measures to reduce bias. Other issues to be considered in designing and interpreting an RCT include external validity (the extent to which the results may be generalised to the wider population) and precision (the extent to which the results are free from random error) (Higgins et al., 2011). For example, while differential attrition may threaten internal validity, the overall ability to recruit and retain participants (and resulting sample) determines how well the target population is represented, and thus external validity (Coday, Boutin-Foster, Sher et al., 2005; Moran and Whitman, 2014). The trial's exclusion and inclusion criteria may also affect the extent to which the results may be extrapolated to the wider population (Rawlins, 2008).

Furthermore, a sufficient sample size is essential to generating the statistical power required to assess intervention effectiveness: as sample sizes increase, confidence intervals become narrower and thus results become more precise, although with diminishing returns past a certain point (Taub, Douiri and Walker, 2014). Thus, "a small trial with a low risk of bias may provide very imprecise results", because of wide confidence intervals (Higgins et al., 2011) (p.3). Poor recruitment and/or retention, resulting in an under-powered study, can in particular result in a failure to identify clinically relevant effects, increasing the chance that an effective intervention may be unduly abandoned (Burns et al., 2011; Moran and Whitman, 2014). Even RCTs with the power to detect treatment effects may lack the power to detect differences in adverse effects, or the length of follow-up required to ascertain long-term benefits and harms; thus,

RCTs are not free from limitations, and there are circumstances in which cohort or case studies may be considered for augmenting understanding (Bothwell, Greene, Podolsky et al., 2016; Rawlins, 2008; Skelly and Chapman, 2011).

3.1.6 Contextualising evidence-based medicine

EBM is not value-free paradigm: it is informed by a Western scientific epistemology and aligned with the biomedical theory of disease (Barry, 2006; Jagtenberg, Evans, Grant et al., 2006; Kelly et al., 2010; McKenzie, 2012; Miles, 2009b; Tonelli and Callahan, 2001). As such, EBM prioritises a particular form of knowledge (that derived from RCTs: scientific, technical and rational) over another (that derived from clinical judgement: contingent, tacit, practical and experiential) (Buetow, Upshur, Miles et al., 2006; Gabbay and le May, 2004; Pope, 2003; Tonelli and Callahan, 2001; Williams and Garner, 2002). Thus, EBM is viewed as a social movement as well as a scientific enterprise, representing a shift from the arguably 'eminence-based' 'art' of medicine towards the 'evidence-based' application of science (Britten, 2010; Isaacs and Fitzgerald, 1999; Leggett, 1997; Miles, 2009b; Pope, 2003). As such, EBM has been met with some resistance, with evidence indicating that many clinicians perceive EBM as a threat to their clinical expertise and continue not to use evidence in everyday decision-making (Adams, 2000; Gabbay and le May, 2004; Hay, Weisner, Subramanian et al., 2008; Miles, 2009b; Pope, 2003).

Critics of EBM contend that it oversimplifies the nature of clinical work and advocate for the role of clinical judgement (Miles, 2009b; Pope, 2003; Williams and Garner, 2002). Critics argue that EBM does not pay due attention to individuality and patient variation, noting difficulties inherent in translating the aggregate results of an RCT to clinical practice: population efficacy does not necessarily translate to effectiveness for individuals (Pope, 2003; Williams and Garner, 2002). Furthermore, through a reliance on measuring phenomena which are accepted within a biomedical theory of disease, critics argue that psychological and social factors important in the causation and treatment of disease in individuals are being neglected (Leggett, 1997; McKenzie, 2012; Tonelli and Callahan, 2001; Williams and Garner, 2002).

Similarly, this reductionism is seen to advance health care which is insufficiently humanistic, personal, holistic and responsive to individual patients' experiential perspectives: the 'disease' has been prioritised over the person who suffers from it (Leggett, 1997; Miles, 2009a; Miles, 2009b; Williams and Garner, 2002). Thus, many criticisms directed at EBM mirror those directed at Western approaches towards mental health treatment (see Chapter Two), concerning a lack of holism and individualisation in the biomedical approach.

3.1.7 Evidence-based medicine in Japan

Whilst EBM marks a shift away from the traditional approach to health care which prioritises clinical judgement (Bhandari, Zlowodzki and Cole, 2004), this approach remains in some places the dominant healthcare model. The 'apprenticeship system' found in Japan, whereby methods and expertise are passed from older to younger generations (Bartholomew, 1989), is akin to this form of 'eminence-based' practice, with which EBM may be considered to conflict (Isaacs and Fitzgerald, 1999; Yokota, Kojima, Yamauchi et al., 2005).

Reasons posited for the lack of acceptance of EBM within Japan reflect the criticisms noted above: concerns that EBM disregards the value of clinicians' experience and skill, and takes insufficient account of individual differences (Yokota et al., 2005). Accordingly, experimental approaches and meta-analyses are rarely utilised within Japanese clinical psychology, and Japan is considered to lag behind other 'developed countries' in conducting high quality clinical research (Fukui and Rahman, 2002; Shimoyama, 2011). Thus, evidence of intervention effectiveness in Japan continues to rely largely on case studies and clinical impressions.

3.2 Developing and evaluating complex interventions

As the principles, and therefore methods, of EBM were established with a biomedical focus (Kelly et al., 2010), attention now turns to how such carefully controlled methods can be applied to circumstances which draw on multiple disciplines and in which patients, interventions and contexts are complex and variable.

3.2.1 What is a complex intervention?

Complex interventions are typically non-pharmacological interventions which aim to change behaviour at an individual or organisational level (Clark, 2013), and are "widely used in the health service, in public health practice and in areas of social policy" (Craig, Dieppe, Macintyre et al., 2008) (p.6). Traditionally defined as "interventions with several interacting components", the focus is on the characteristics of the intervention itself: the number and difficulty of behaviours required by those delivering or receiving the intervention; number of groups or organisational levels targeted; number and variability of outcomes; and degree of flexibility or tailoring permitted (Craig et al., 2008) (p.6). Subsequent definitions pay increased attention to context and implementation, with complex interventions now considered much more than the sum of their component parts (Anderson, Petticrew, Chandler et al., 2013; Datta and Petticrew, 2013; Richards, 2015a).

3.2.2 The Medical Research Council Framework

In 2000, the UK Medical Research Council (MRC) developed a methodological framework for developing and evaluating complex interventions, updated in 2008 (Craig et al., 2008; Medical Research Council, 2000). The aim was to provide a phased and structured approach to complex intervention design, development, evaluation and implementation, in order to improve the quality and generalisability of complex interventions in health care (Campbell, Fitzpatrick, Haines et al., 2000).

3.2.3 Why was the MRC Framework developed?

As noted by Craig et al. (2008), the MRC framework sought to guide researchers and funders in recognising and adopting appropriate methods for tackling the additional challenges presented by complex interventions, alongside the practical and methodological difficulties of any evaluation, such as intervention standardisation (Hawe, Shiell, Riley et al., 2004; Rifkin, 2007); contextual, organisational and logistical issues (Ogilvie, Mitchell, Mutrie et al., 2006; Petticrew, Cummins, Ferrell et al., 2005; Rychetnik, Frommer, Hawe et

al., 2002; Wolff, 2001); and the length and complexity of the relationships between interventions and outcomes (Victora, Habicht and Bryce, 2004).

The updated framework sought to rectify a number of initial limitations, specifically an over-emphasis on clinical trials and evaluation, and the linearity implied by the model (Craig et al., 2008). As such, the 2000 framework may be said to have too closely represented the biomedical approach (for example, adopting a model based on that typically used in pharmacological evaluations) on which EBM was founded (Kelly et al., 2010). Thus, the broader and more flexible 2008 framework provides a range of methods, recognising the value of qualitative and descriptive research; and a more iterative, programmatic approach in which feedback loops may be incorporated and due consideration is given to intervention development, piloting and implementation (Craig et al., 2008; Craig and Petticrew, 2013; Richards, 2015a).

3.2.4 An overview of the MRC Framework

The MRC framework encompasses four stages of develop-test-evaluate-implement (Figure 2). At all stages, researchers aim to address key uncertainties before proceeding (Richards, 2015a). In practice, researchers often move iteratively between stages rather than following a linear or cyclical sequence (Craig et al., 2008; Hallberg, 2015).

Figure 2. Revised MRC framework (Reprinted from Craig et al., 2008, p.8)
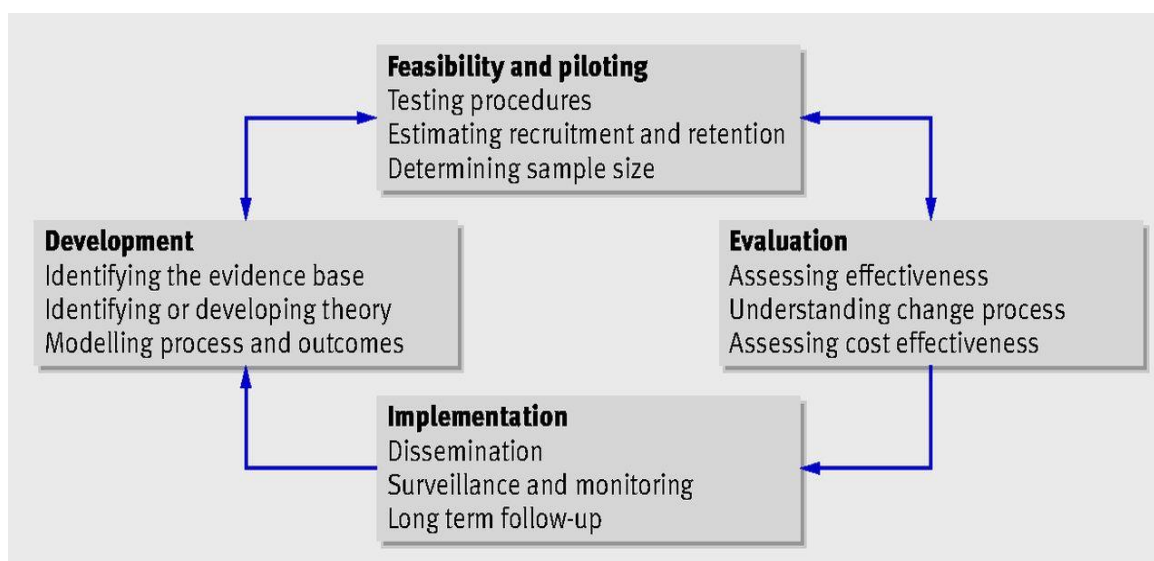
Develop

The aim of this stage is to develop an intervention to the point where it can reasonably be expected to have a worthwhile effect (Craig et al., 2008). This involves identifying the intervention's existing evidence base, ideally by systematic review; gaining a theoretical understanding of the changes to be effected by the intervention and how they should be achieved; and modelling the intervention to address who will deliver it, how long delivery will take and what each partner will do as part of it (Abraham, Denford, Smith et al., 2015; Buhse and Muhlhauser, 2015; Craig et al., 2008; Cullum and Dumville, 2015; Denford, Abraham, Smith et al., 2015; Faes, Reelick, Esselink et al., 2010; Lovell, Bower, Richards et al., 2008; Sermeus, 2015). Also crucial to consider here is implementation: whether it would be possible to use this intervention, by whom and in what setting (Craig et al., 2008; Denford et al., 2015).

Test

Following development, uncertainties may remain with the potential to threaten the success of an evaluation of intervention effectiveness (Hallberg, 2015; Thabane et al., 2010). This feasibility and piloting stage seeks to address these issues by testing the feasibility and acceptability of the research design, procedures and intervention; estimating likely rates of recruitment and retention; and providing data needed to calculate the required sample size for an evaluation to be powered to detect between-group differences (Feeley, Cossette, Côté et al., 2009; Jeray and Tanner, 2012; Lancaster, Dodd and Williamson, 2004; Robb, 2013; Taub et al., 2014). To gauge when to proceed, each uncertainty should be judged against criteria to be met in order to deem the proposed evaluation 'feasible' (Thabane et al., 2010).

Evaluate

The main aim of this stage is to establish whether a causal relationship exists between the intervention and any effect, and the magnitude of any effect (Richards, 2015a). Whilst randomisation should always be considered as the most robust method of preventing selection bias, circumstances in which this may not be appropriate deem an awareness of the range of possible

approaches key to making the most suitable methodological choices at this stage (Craig et al., 2008; Lamb and Altman, 2015; Seers, 2007). Two other forms of investigation should also take place here: process evaluations to understand the mechanisms by which the intervention exerts its effect, and economic evaluations to estimate the cost of an intervention's benefit compared to alternatives (Craig et al., 2008; Moore, Audrey, Barker et al., 2015b; Oakley, Strange, Bonell et al., 2006; Payne and Thompson, 2015).

Implement

This stage, which should be considered throughout the develop-test-evaluate cycle, involves translating evidence into practice or policy (Craig et al., 2008; Grol, Wensing, Eccles et al., 2013). With the development of 'implementation research', how to successfully embed an intervention within practice has received increasing attention over the past decade (Damschroder, Aron, Keith et al., 2009; Eccles and Mittman, 2006; van Achterberg, 2015). This involves systematic approaches to examining factors which may facilitate or hinder routine adoption of the intervention (Dogherty and Estabrooks, 2015; Grol and Grimshaw, 2003; Skolarus and Sales, 2015). Key factors here include PPI, active dissemination of results, formative assessment of the effectiveness of implementation efforts, and monitoring long-term outcomes to identify actual effects and any unanticipated consequences (Craig et al., 2008; Richards, 2015a; Stetler, Legro, Wallace et al., 2006; van Achterberg, 2015).

3.3 Mixed methods research for complex interventions

The MRC framework stresses the importance of qualitative research in answering fundamental questions about complex interventions. Whereas quantitative research, dealing with numbers, seeks to enumerate; qualitative research, dealing with words, seeks to explain and interpret phenomenon in terms of the meanings people bring to them (Pope and Mays, 2006a).

3.3.1 Qualitative methods in health services research

Traditionally employed in the social sciences, qualitative research was originally perceived as an unscientific and anecdotal approach with no place within EBM (Britten, 2010). However, as EBM is arguably a social movement as well as a

scientific enterprise, it requires the investigation of subjective and social processes best suited to qualitative research, and qualitative methods have been promoted in response to some of the criticisms directed towards EBM (Britten, 2010; Williams and Garner, 2002). Researchers have increasingly acknowledged the value of qualitative methods to health services research and, in order to understand service user perspectives, qualitative research is increasingly common in the field and alongside RCTs (Bradley, Curry and Devers, 2007; Glogowska, 2015; Lewin, Glenton and Oxman, 2009; Pope and Mays, 2006a).

Using qualitative research in conjunction with trials allows one to address the diversity of enquiries relating to acceptability, feasibility, evaluation and implementation, facilitating the simultaneous investigation of both exploratory and explanatory questions (Boeije, Drabble and O'Cathain, 2015). Quantitative and qualitative approaches are now seen as complementary, expanding the scope of enquiry by allowing access to a wider range of data (O'Cathain and Thomas, 2006; Pope and Mays, 2006a). Accordingly, a 'third methodological movement' in which mixed methods research integrates quantitative and qualitative methods is now emerging as a dominant paradigm in health research (Bradley et al., 2007; Creswell and Plano Clark, 2007; Doyle, Brady and Byrne, 2009; O'Cathain, Murphy and Nicholl, 2007b; Teddlie and Tashakkori, 2009).

3.3.2 Qualitative and quantitative paradigms

One's methodological choices are related to theoretical perspectives, and beliefs about how the social world can be studied (ontology) and how to assess the validity of social knowledge obtained (epistemology) (Pope and Mays, 2006a). Typically, quantitative approaches are associated with positivism and a belief in an external, objective social reality; qualitative approaches with interpretivism, and a belief that social reality is constructed through subjective meanings (O'Cathain and Thomas, 2006).

Arguably, methods associated with different theoretical perspectives, ontologies and epistemologies in this manner cannot and should not be mixed (Johnson and Onwuegbuzie, 2004; O'Cathain and Thomas, 2006). In the 'paradigm wars' debating the worth and position of quantitative and qualitative research, the

incompatibility of these worldviews has been consistently stressed (Glogowska, 2015). However, as a third paradigm arguably capable of bridging the gap between positivist and non-positivist positions, mixed methods may provide an opportunity to overcome this 'false dichotomy', with the philosophy of pragmatism offering an epistemological justification and logic for mixing quantitative and qualitative methods (Borglin, 2015; Doyle et al., 2009; Onwuegbuzie, Johnson and Collins, 2009).

The pragmatic perspective

Both pragmatism and mixed methods designs are characterised by the importance given to the research question(s), which inform the methods chosen (Borglin, 2015; Johnson and Onwuegbuzie, 2004). Research objectives are approached from a pluralistic perspective, rejecting the need to choose between positivist and constructivist paradigms (Borglin, 2015). Thus, pragmatism is signified by being pragmatic: regardless of philosophy, the method leading to the best evidence with regards to the research objectives should be used (Johnson and Onwuegbuzie, 2004).

The pragmatic approach also emphasises abduction, intersubjectivity and transferability (Morgan, 2007). Abduction allows for moving between induction and deduction, enabling both theory generation and verification (Borglin, 2015; Johnson and Onwuegbuzie, 2004; Morgan, 2007). Intersubjectivity acknowledges that researchers move between various frames of reference and allows for both a single 'reality' and individual interpretations of that reality, transcending the subjective-objective dichotomy (Morgan, 2007). Transferability focuses on investigating factors which affect whether knowledge obtained in one setting can be transferred to others, rejecting the need to define knowledge as either context-dependent or universal (Morgan, 2007).

3.3.3 Defining mixed methods

As a relatively new and evolving area, confusion persists as to what mixed methods research entails (Doyle et al., 2009). Certainly, mixed methods studies include qualitative and quantitative dimensions, but difficulties arise in terms of how these dimensions relate (Doyle et al., 2009; Tashakkori and

Creswell, 2007). Over time, definitions have shifted from studies including at least one quantitative and one qualitative method, to a methodological orientation mixing the approaches in all phases of the research process including philosophical position, inferences and interpretation of results (Creswell and Plano Clark, 2007).

Accordingly, Creswell and Plano Clark (2007) define mixed methods as "a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of qualitative and quantitative approaches in many phases of the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies." (p.5). Thus, mixed methods research incorporates both an overarching framework to guide the integration of quantitative and qualitative data throughout a project, and the specific techniques and procedures required to do so.

3.3.4 Mixed methods research designs

Mixed methods are employed in a range of forms and varied design classifications have been developed (Borglin, 2015). Creswell and Plano Clark's (2007) approach offers six prototypes which differ according to key issues in the combination of quantitative and qualitative strands: the priority, in addressing the research questions, given to either or both equally; the order in which they are conducted; the extent to and process by which they interact, with integration at the design level or during data collection, interpretation or analysis. Two of these prototypes are 'embedded' and 'multiphase' designs (Creswell and Plano Clark, 2007).

An embedded design involves a single study in which one strand is prioritised and the other added in a supportive role. The strands are mixed purposefully at the design level so that the supplemental strand enhances the overall design; it may be undertaken before, during or after the dominant strand, informing what the dominant strand involves or aiding the explanation of results obtained from it (Creswell and Plano Clark, 2007). The premise is that one method is

insufficient: different research questions require different types of data (Creswell and Plano Clark, 2007).

The multiphase design includes an iteration of quantitative and qualitative studies within a programme of research (Creswell and Plano Clark, 2007). The strands, undertaken either sequentially or concurrently but with equal priority, are mixed at the design level to address an overall objective (Creswell and Plano Clark, 2007). As each new approach builds on previous learning, this design is particularly suitable for addressing incremental research questions within the MRC framework, and typically employed in large studies with numerous research questions designed to advance one overarching objective (Borglin, 2015; Creswell and Plano Clark, 2007).

One further consideration in the relationship between quantitative and qualitative strands is sampling. Mixed methods sampling strategies may be identical: the same participants included in both strands; nested: a subgroup from one strand is included in another; parallel: participants, selected from a homogenous group, are in either one or the other strand; or multilevel: participants, drawn from a heterogeneous sample, are different in different parts of the study (Onwuegbuzie and Collins, 2007).

3.3.5 The value of mixed methods for complex interventions

Embedded and multiphase designs highlight the suitability of mixed methods for researching complex interventions.

Complexity

The problems encountered in health services are multifaceted and, to be of value in the reality of health care, research must embrace this complexity with practical and methodological tools equipped to manage it (Borglin, 2015; Griffiths and Norman, 2012; Ong, 1993). There is growing recognition of the appropriateness of mixed methods for this purpose: with single methods insufficient to tackle complex research questions, the integration of a wide spectrum of methodologies is necessary for a comprehensive and in-depth understanding and evaluation of health services phenomenon (Borglin, 2015; O'Cathain et al., 2007b; Wisdom, Cavaleri, Onwuegbuzie et al., 2012).

Advantages of gathering quantitative and qualitative information

Both quantitative and qualitative methods have limitations: quantitatively examining many individuals may diminish the understanding of any one, whereas one cannot generalise from a qualitative study of a few individuals (Creswell and Plano Clark, 2007). Using both methods together may address the limitations of each whilst retaining their strengths (Borglin, 2015; Creswell and Plano Clark, 2007; Johnson and Onwuegbuzie, 2004).

Mixed methods also offer the potential to answer specific research questions involving integration. Alongside separate research questions for each strand, Creswell and Plano Clark (2007) advocate for a mixed methods research question framing the integration of both to be included in the research design. Thus, one may address questions whereby qualitative methods help explain quantitative results, or quantitative methods help generalise qualitative explorations (Creswell and Plano Clark, 2007). As such, mixed methods potentially offer a deeper understanding of phenomena than possible from one method alone.

Furthermore, mixed methods may enhance the accuracy, relevance, credibility and transferability of results (Borglin, 2015; Glogowska, 2015; O'Cathain, Murphy and Nicholl, 2007a). Through triangulation, more than one type of data may be used in illuminating a concept, with one form used to check the validity of another (Barbour, 1999; Pope and Mays, 2006a). Where quantitative and qualitative results concur, data may be considered more reliable; where they conflict, important questions, which would otherwise have been missed, may be raised for further investigation.

Iterative knowledge development

In describing a phased, iterative approach to researching complex interventions which highlights the value of both quantitative and qualitative methods, the MRC framework supports mixed methods research. The multiphase design is particularly suited to the MRC framework's programmatic approach: with methodological strands informing each other, feedback loops and the

simultaneous investigation of exploratory and explanatory questions may be readily incorporated (Borglin, 2015).

By providing such opportunities, mixed methods may also help reduce levels of avoidable research waste in studies which fail to provide useful, credible or appropriate information (Chalmers and Glasziou, 2009). For example, in a multiphase design, systematic review results may suggest qualitative research necessary to develop an intervention before proceeding to testing; in an embedded design, qualitative interviews within a pilot trial may provide important insights regarding intervention acceptability and, potentially, the need for further intervention development before proceeding to evaluation. Indeed, such approaches are utilised within this thesis.

Part Two overleaf

CHAPTER THREE. PART TWO.

Methodological Approach

3.4 Methodological design and philosophical stance

To optimise and investigate the feasibility and acceptability of Morita Therapy for a UK population, a scoping and systematic review, optimisation study and mixed methods feasibility study were undertaken. These studies can be considered to comprise two stages (development and testing) of a multiphase mixed methods design organised in line with the MRC framework. Figure 3 (overleaf) provides an overview of this programme of research. The feasibility study, incorporating a pilot RCT and qualitative interviews, employed an embedded mixed methods design. A combination of multilevel and nested sampling strategies was used: participants in the optimisation and feasibility studies were recruited at different times from different populations using different criteria; participants in the qualitative strand of the feasibility study comprised a sub-group of those in the pilot RCT.

3.4.1 Pragmatism

The pragmatic perspective, commonly associated with mixed methods research (section 3.3.2), underpins this thesis. Thus, within this multiphase design, the research objectives and methods which were considered to facilitate the best evidence with regards to them were prioritised. For example, the feasibility study included quantitative and qualitative strands to best address the variety of uncertainties associated with running a large-scale trial of Morita Therapy. Consistent with pragmatism, deductive and inductive modes of reasoning were combined, the research objectives were approached from a pluralistic perspective, and a singular view and multiple views of reality were allowed for in how the findings were understood and interpreted.

Thus, this research encompasses multiple philosophical paradigms. In conducting a pilot RCT, a positivist worldview and associated 'cause and effect' reasoning has been upheld: for example, the effect of Morita Therapy on depressive symptoms was measured. In exploring participants' views through qualitative interviews, an interpretivist worldview and belief that reality is socially

constructed has been upheld: data were interpreted so as to allow for multiple participant meanings which are shaped by social interaction with others, including myself as the researcher.

Figure 3. Programme of research to develop and test Morita Therapy
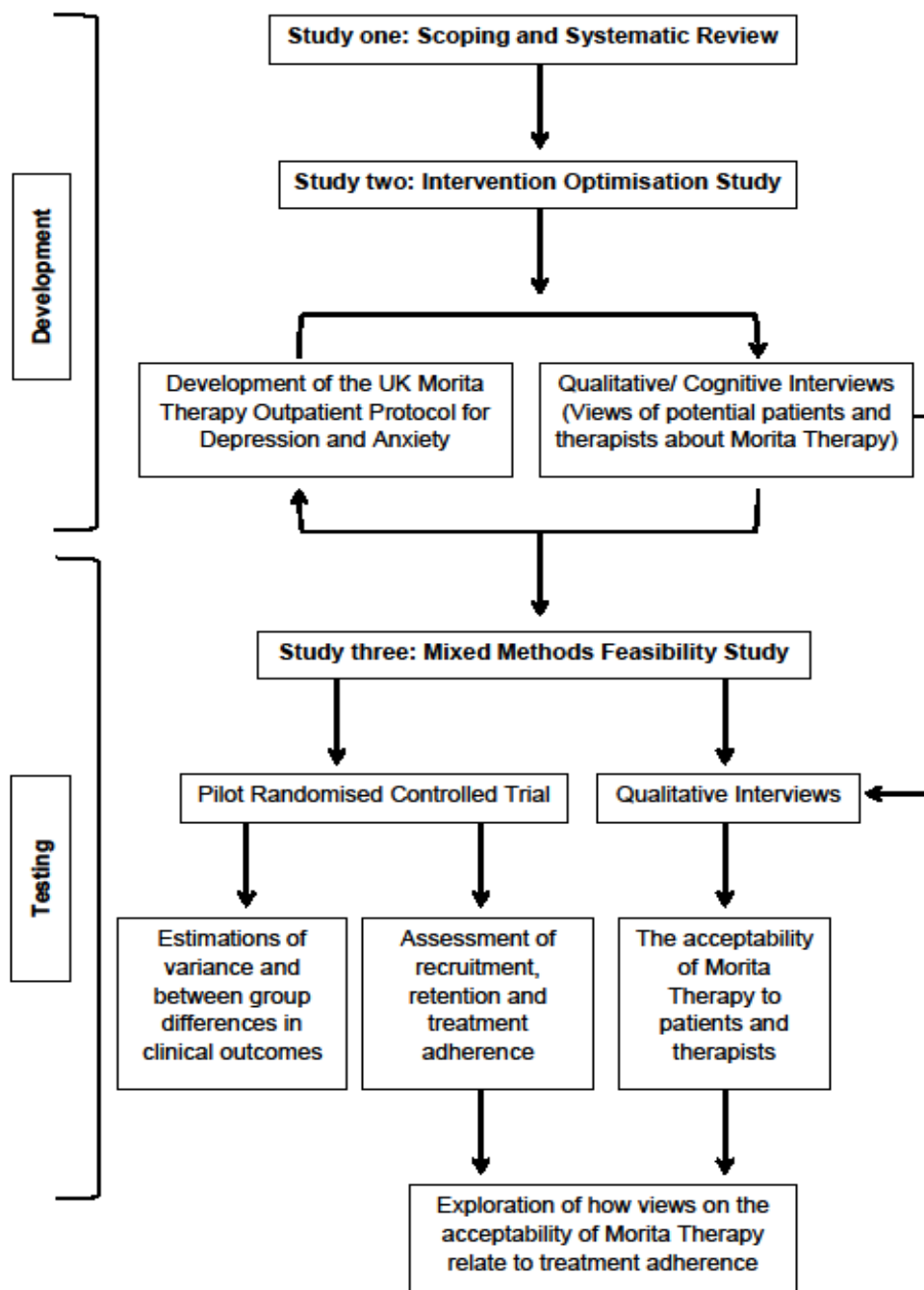
3.5 Scoping and Systematic Review

The scoping and systematic review sits within the MRC framework's development phase. The primary aim was to describe the extent, range and nature of research activity reported in English in the field of Morita Therapy.

3.5.1 What are scoping and systematic reviews?

Through identifying, evaluating and summarising all relevant empirical evidence on an intervention using systematic and transparent methods, systematic reviews are undertaken with the aim of providing a reliable estimate of an intervention's effectiveness (Centre for Reviews and Dissemination (CRD), 2009). On the other hand, a scoping review is a technique to comprehensively map all relevant literature in a field (Arksey and O'Malley, 2005). Although scoping reviews may be considered one form of systematic review (Meyer and Kopke, 2015), there are key differences. Systematic reviews tend to address well-defined questions with appropriate study designs identified a priori whereas scoping reviews address broader topics where various study designs may be applicable; systematic reviews aim to provide answers from a relatively narrow range of quality assessed studies whereas scoping reviews are less likely to address specific research questions or assess study quality (Arksey and O'Malley, 2005).

Common objectives of a scoping review include examining the extent, range and nature of research activity in a field; summarising and disseminating research findings; and identifying gaps in the existing literature (Arksey and O'Malley, 2005). Accordingly, a scoping review was chosen to address the primary aim of this review, with systematic review methods incorporated to address research questions specified in relation to any identified RCTs (CRD, 2009; Higgins and Green, 2011).

3.5.2 The use of a scoping and systematic review in this thesis

A systematic review of all Morita Therapy literature would have been required to establish the effectiveness of Morita Therapy (Cullum and Dumville, 2015). However, this approach was not chosen for the following reasons:

- The resources required to translate the Japanese literature into English were beyond the scope of this PhD.
- This thesis investigates Morita Therapy specifically for a UK population. Considering cultural differences (see Chapter Two), the effectiveness of Morita Therapy within Japan and elsewhere outside the UK cannot be assumed to translate to a UK context.

From contacts within the Japanese Society for Morita Therapy and data within an existing literature review (Minami, 2011a), it was considered highly unlikely that research into Morita Therapy had been undertaken in the UK. A scoping and systematic review of the Morita Therapy research activity reported in English was chosen to enable confirmation of this gap in research. Such a review also provided opportunities to examine and summarise the extent, range and nature of Morita Therapy research activity available in English; and to appraise any RCTs identified in English, in terms of both risk of bias and evidence relating to effectiveness.

Thus, a two-stage scoping and systematic review was conducted. Firstly, Arksey and O'Malley (2005)'s framework, as informed by systematic review methods (CRD, 2001), was followed in order to conduct a scoping review in a rigorous and transparent manner. Accordingly, guided by the objective to identify all relevant literature regardless of study design, this process included:

1. Identifying the research question, using the PICOS method (CRD, 2009) to define the patient population(s) (P), intervention(s) (I), comparator(s) (C), outcome(s) (O) and study design(s) (S) of interest.
2. Comprehensively searching a variety of sources to identify relevant studies.
3. Selecting studies based on PICOS criteria, with the addition of language (Cullum and Dumville, 2015).
4. Charting, or extracting, key items of information from included studies in an approach akin to a narrative review (Pawson, 2002).
5. Collating, summarising and reporting the results to provide a descriptive account.

Secondly, for any RCTs identified, further steps were undertaken in line with guidance for undertaking systematic reviews (CRD, 2009; Higgins and Green,

2011) in order to address the following research questions: (1) what is the quality of any RCTs identified?; (2) what can they tell us about the effectiveness of Morita Therapy for mental health difficulties? These steps were:

1. Assessing risk of bias using criteria as suggested by the Cochrane Handbook for systematic reviews (Higgins and Green, 2011). Such assessments are required, given the potential for bias within RCTs (section 3.1.4), to determine the internal validity of studies and thus the likely robustness of their results (CRD, 2009).
2. Reporting the results (means and standard deviations) of all standard outcome measures at baseline and follow-up, and using these statistics to calculate follow-up between-group differences and the 95% confidence intervals around these figures.
3. Considering the use of further statistical synthesis techniques, such as meta-analysis, which, if appropriate, would provide a more precise and reliable estimate of the effectiveness of Morita Therapy than possible from individual studies alone (Oxman and Guyatt, 1993). Both the quality and clinical diversity of the RCTs were taken into account in assessing the appropriateness and usefulness of such methods (Higgins and Green, 2011).

The details of the scoping and systematic review are presented in Chapter Four.

3.6 Intervention Optimisation Study

The intervention optimisation study sits within the MRC framework's development phase. The lack of UK-based Morita Therapy research in the context of potential cultural differences, availability of a variety of Morita Therapy methods and lack of thorough treatment manuals (see Chapter Two) highlighted the requirement for this preparatory work. The aim was to develop a deliverable and acceptable Morita Therapy outpatient protocol for a UK clinical population.

3.6.1 A person-based approach to intervention development

The person-based approach is a method for optimising intervention acceptability and feasibility prior to a feasibility study, to increase the likelihood of a successful outcome in that study (Yardley, Ainsworth, Arden-Close et al., 2015a). The approach promotes iterative qualitative studies to ground interventions in an in-depth understanding of how potential users may view and engage with them (Yardley et al., 2015a). The method includes intervention planning, whereby user perspectives of the proposed or similar interventions are qualitatively explored; design, whereby themes from the planning stage inform the development of 'guiding principles' comprising the intervention's key objectives and features; and development, whereby user reactions to every intervention element are obtained and the intervention modified accordingly (Yardley et al., 2015a).

3.6.2 The use of the person-based approach in this thesis

As the core features of Morita Therapy (see Chapter Two) may be considered akin to the 'guiding principles' developed during the earlier phases of the person-based approach, the final development phase was utilised to optimise the acceptability and feasibility of Morita Therapy over four iterative stages:

1. Interviews explored potential patients' and therapists' views and understandings of Morita Therapy.
2. Resulting qualitative themes were developed into recommendations for optimising Morita Therapy and a draft therapy protocol was developed by synthesising the Morita Therapy literature in line with these.
3. Repeat interviews investigated how therapists related to the intervention content and protocol format.
4. Resulting qualitative themes were addressed through protocol modification and tailoring the proposed therapist training programme.

By integrating literature synthesis and qualitative research in the cross-cultural adaptation of Morita Therapy for the UK, this approach prioritised the perspectives of those who will deliver and receive the intervention, whilst ensuring adherence to its core features. This was essential to proceeding to

the feasibility study with a treatment which is both true to the essence of Morita Therapy and potentially appropriate, accessible and deliverable for the target population, particularly in the context of the aforementioned contrast between Morita Therapy and established Western approaches (see Chapter Two).

3.6.3 Qualitative research methods

To explore participants' views and understandings of Morita Therapy, multiple data collection and analytical techniques were available. Justifications for the methods chosen are outlined below.

Data collection techniques

Semi-structured individual interviews, using a combination of qualitative and cognitive (Willis, 1999) interviewing techniques, were chosen. Individual interviews were preferred over focus groups, whereby a group discussion is held (Kitzinger, 1994), given mental health is a sensitive topic less suited to this approach (Fitzpatrick and Boulton, 1996). Furthermore, probing responses may be more difficult in this setting (Fitzpatrick and Boulton, 1996) and, in the context of this study, capturing interviewees' immediate responses to the intervention would have been difficult to achieve.

Semi-structured qualitative interviewing techniques enabled individual perspectives of Morita Therapy to be fully appreciated through open-ended questions and exploration of interviewees' responses (Britten, 1995). The inclusion of a list of topics to cover (a topic, or interview, guide) (Turner III, 2010) also ensured discussion of each intervention element and consistency of questions across interviews. Cognitive interviewing techniques, widely used when seeking an understanding of the cognitive processes involved in task completion, were then integrated to capture interviewees' immediate responses to Morita Therapy (Ericsson and Simon, 1998; Pressley and Afflerbach, 1995; Willis, 1999; Zhelev, Garside and Hyde, 2013).

Cognitive interviews include 'think aloud interviewing' and 'verbal probing' (Willis, 1999). The person-based approach promotes think aloud interviewing for capturing participants' immediate reactions to an intervention such as a web-based one, whereby participants may reveal how they interpret the information

by explaining their thought processes as they engage with it (Yardley et al., 2015a; Yardley, Morrison, Bradbury et al., 2015b). In the absence of directly observing interviewees deliver or receive Morita Therapy, vignettes of therapy delivery (stage one) and the draft therapy protocol (stage three) were used to elicit views and understandings of the approach. Accordingly, a variation of think aloud interviewing was utilised to allow participants to voice their thoughts about Morita Therapy as they occurred to them.

Analytical techniques

The framework approach (Ritchie, Lewis, Nicholls et al., 2013), chosen for this study, is a development of the matrix-based analysis methods described by Miles, Huberman and Saldana (2014) (Pope and Mays, 2006b). The approach is increasingly used in health care research and particularly suited to applied research where objectives are typically set in advance (Pope and Mays, 2006b). Whereas grounded theory involves the inductive process of generating theory from data, an advantage of framework lies in enabling both inductive and deductive approaches: beginning from the study aims yet based in participants' original accounts (Pope and Mays, 2006b; Ritchie et al., 2013). Additionally, the approach is systematic and transparent, using a more explicit process than the thematic analysis approach (Pope and Mays, 2006b). Overall, framework is considered suitable for both health services research (Green and Thorogood, 2014) and data collected via cognitive interviewing (Collins, 2014).

The details of the intervention optimisation study are presented in Chapter Five.

3.7 Mixed Methods Feasibility Study

A fully-powered RCT would be required to establish the effectiveness of Morita Therapy versus treatment as usual (TAU) for treating depression and anxiety in the UK. In line with the MRC framework's testing phase, the aim of this study was to prepare the ground for the design and conduct of such a trial, or to conclude that such a trial would not be appropriate and/or feasible.

3.7.1 What are feasibility and pilot studies?

Whilst some make clear distinctions between feasibility and pilot studies, others regard the terms as interchangeable (Richards, 2015a). Suggested definitions describe pilot studies as smaller replicas of proposed trials, undertaken to test how well the study protocol elements work together; feasibility studies as 'pre-study' research, undertaken to gather information related to discrete aspects of the proposed trial (Arain, Campbell, Cooper et al., 2010; Giangregorio and Thabane, 2015). Their shared aim therefore is "to inform the development and conduct of a planned research project" (Giangregorio and Thabane, 2015) (p.129).

Areas in which these studies may inform trials can be clinical, procedural and/or methodological (Giangregorio and Thabane, 2015). Each element being assessed should include 'criteria for success', clearly defined a priori, to be met in order to deem the proposed trial feasible (Thabane et al., 2010). The potential outcomes of these criteria for the proposed trial are that it is feasible as proposed, feasible with protocol modification or careful monitoring, or not feasible (Giangregorio and Thabane, 2015).

3.7.2 Why conduct a feasibility or pilot study?

A major driving force behind the MRC framework was the recognition that, in the absence of preparatory work, many trials fail to achieve their goals or deliver clear results (Richards, 2015c; Vickers, 2014). Poor design choices and issues of intervention delivery, acceptability, adherence, recruitment, retention and smaller than anticipated effect sizes may undermine trials, ultimately contributing to research waste (Craig et al., 2008; Dodd, White and Williamson, 2012; McDonald, Knight, Campbell et al., 2006; Nichol et al., 2010; Richards, 2015c; Treweek, Mitchell, Pitkethly et al., 2010; Wood, White and Thompson, 2004). Many such issues may be eliminated or minimised through feasibility and pilot studies (Richards, 2015c; Thabane et al., 2010). Thus, they encourage methodological rigour and enhance the likelihood of making valid inferences from large-scale, resource-intensive trials (Feeley et al., 2009; Giangregorio and Thabane, 2015; Lancaster et al., 2004).

3.7.3 The use of a feasibility study in this thesis

A number of uncertainties were present which prevented moving directly to a fully-powered evaluation of Morita Therapy, and were appropriate to address within a feasibility study (Thabane et al., 2010):

- Clinical uncertainties. The operationalisability and acceptability of the UK Morita Therapy outpatient protocol was unknown. Gathering data on this was essential to ensure that the treatment administered in any large-scale trial is deliverable and acceptable to those involved.

- Procedural uncertainties. Information was required on likely rates of recruitment to and retention in a trial of Morita Therapy, and of treatment adherence, to assess the feasibility of a trial and inform the required sample size.

- Methodological uncertainties. Estimates of the variance in participant outcomes and information on how these correlate with baseline scores were also required to inform future sample size calculations.

To collect such data, a mixed methods embedded design incorporating exploratory and explanatory components was employed (Creswell and Plano Clark, 2007). Thus, qualitative interviews were embedded within a pilot RCT of Morita Therapy plus TAU versus TAU alone for depression and anxiety. The quantitative and qualitative strands were prioritised equally and mixed interactively at the design level to address the study purpose (Creswell and Plano Clark, 2007). The data for these strands were collected concurrently, analysed sequentially (with quantitative data guiding the qualitative interview sampling), and integrated to help explain variability in participants' treatment adherence and ultimately develop a richer understanding of the feasibility and acceptability of Morita Therapy.

3.7.4 Embedded qualitative interviews

The qualitative interviews included a nested sample from the pilot RCT: all those randomised to Morita Therapy were invited, with a sub-group selected for analysis on the basis of treatment adherence and quantitative outcomes.

Individual semi-structured interviews and framework analysis were utilised, given the advantages of these techniques (section 3.6.3).

3.7.5 Mixed methods analysis

Multiple analytic strategies are available for integrative mixed methods analysis, classified by Creswell and Plano Clark (2007) as side-by-side comparisons, joint displays and data transformation. Within this study, three forms of the joint display strategy were utilised:

1. A typologies/ statistics display, with participants classified according to qualitatively derived characteristics, to explore how treatment adherence varies for participants whose views on the acceptability of Morita Therapy were organised into different typologies.
2. A categories/ themes display, with participants classified according to quantitatively derived characteristics, to explore views of Morita Therapy across participants with various degrees of treatment adherence.
3. A case-oriented merged analysis display, with each participant's data organised along a quantitative scale of treatment adherence, to integrate views of Morita Therapy and the number of treatment sessions attended for each participant at an individual level.

The choice and development of these techniques was guided by the nature of and inferences obtained from the quantitative and qualitative data separately, and by examples from prior mixed methods research (e.g. Li, Marquart and Zercher, 2000; McEntarffer, 2003; Mendlinger and Cwikel, 2008; Wittink, Barg and Gallo, 2006, cited by Creswell and Plano Clark, 2007); (e.g. Hill, Kuyken and Richards, 2014). These techniques enabled the integration of quantitative and qualitative data, and thus the comparison of results generated, in different ways: participant data was both categorised and examined at an individual level; analysis was both quantitatively and qualitatively driven.

The details of the feasibility study are presented in Chapters Six and Seven.

3.8 Reflexivity

I acknowledge that, just as approaches towards mental health and research are culturally situated and not value-free (as discussed), nor am I a "disembodied researcher" (Giltrow, Gooding, Burgoyne et al., 2005) (p.209): I have an active role in the research process in which my own identity, experiences and preconceptions, and the related methodological choices that I make, shape the research. Thus, within this section I seek to make this subjectivity explicit.

I have had both personal and professional encounters with depression, and worked within a clinical and research setting involving both theoretical and hands-on experience with depression treatments for six years. These experiences directed my interest towards this topic and potentially influenced data collection and analysis: I likely identified with participants as an 'insider' with some empathy towards them (Hellawell, 2006). As a white, British, tertiary-educated female in my late-twenties during data collection, I am also an 'insider' and 'outsider' to the extent that I interviewed participants with similar and differing characteristics respectively: I identified with some participants, and they with me, more than others (Hellawell, 2006). I acknowledge the tensions arising from these different social positions (Finlay, 2002): if, for example, an older male had been interviewed by another older male, different meanings may have been (co-)constructed.

I also acknowledge that my cultural situation and research experience (consisting of qualitative and quantitative research, including trials) aligned me with the research paradigm of this PhD: I have assumptions consistent with a traditional Western epistemological position which directed my methodological approach (Crotty, 2003; Cruz, 2015). This positioning was also relevant to my communications with Japanese Morita therapists (e.g. during the 9th International Congress), whereby I experienced at times a profound sense of "outsiderness" (Hellawell, 2006), reticence and concern about developing and testing (within a Western research paradigm) a treatment established within the Japanese culture: whether or not it is my place to do so, and whether the trial results would be seen to reflect the potential of Morita Therapy in the UK and/or the competency of UK researchers to work with Morita Therapy.

My cultural situation and personal and professional experiences are also relevant to my preconceptions about mental health treatment, presenting a lens through which I came to understand Morita Therapy. Upon commencing this PhD, I simultaneously, and perhaps somewhat contradictorily, held positive views of Cognitive Behavioural Therapy and the notion of controlling one's thoughts and emotions, and a belief in the potential value of challenging cultural assumptions about mental health and exploring alternative approaches. As such, I approached the study of Morita Therapy with degrees of both scepticism and intrigue. As my understanding of the approach grew, so too did my sense of excitement and optimism. As someone who found the principles personally beneficial, I embarked on this project with the hope that Morita Therapy would help others too. Indeed, as an applied Health Services Researcher, it makes sense that I would hope to make a difference in this way, and without some degree of hopefulness about the approach it is unlikely that my primary supervisor would have conceived of this project at the outset.

This degree of investment in Morita Therapy was potentially compounded by my perception of my primary supervisors' own interest in and optimism about the approach, as well as my role in the development of the UK Morita Therapy outpatient protocol. As someone with this involvement in both clinical protocol development and therapist training, I also had a significant degree of (clinical) understanding of the treatment (including therapists' views, reservations and enthusiasm about the approach) which may have influenced the ways in which I interacted with participants and undertook qualitative analysis. However, this understanding may have also given me helpful insights into the potential risks and benefits of Morita Therapy, and the ways in which a UK population might relate to the approach.

My degree of investment in and knowledge about Morita Therapy, which participants may have perceived in me, may have limited their willingness to talk openly about their views and experiences of the approach. Additionally, as I undertook the majority of interviews in the same setting as participants received Morita Therapy, the line between their Morita therapist and myself as a researcher may have been blurred; indeed, several participants asked if I could offer them Morita Therapy as a therapist. The extent to which participants

perceived me as a (health) professional may have contributed to the degree of power imbalance between us (Etherington, 2007), influencing how they spoke about Morita Therapy. I attempted to limit the impact of such concerns by stressing the importance of sharing with me both negative and positive views of Morita Therapy, and by being aware of how my views might influence my own responses. However, my knowledge of Morita Therapy and understanding of depression may have also allowed me to understand and probe into participants' responses in greater depth, to build rapport and facilitate participants' disclosure.

My degree of investment in the pilot trial itself, with a 'successful' trial potentially presenting more future opportunities for me as a researcher, was particularly reflected in the difficulties I encountered managing a professional training year student: my reluctance to hand over responsibility for aspects of the trial to someone who was less invested in it. However, these factors also contributed to meticulous trial management on my part. Thus, my own identity, experiences and values have played multiple roles in the research process, and may present both strengths and weaknesses for this research.

3.9 Chapter summary

This chapter has provided a methodological framework for this thesis by describing evidence-based medicine, the MRC framework and mixed methods research for complex interventions; and an overview of the methodological design and approaches used within each study. In Chapter Four, the scoping and systematic review describing the extent, range and nature of research activity reported in English in the field of Morita Therapy is presented.

CHAPTER FOUR. SCOPING AND SYSTEMATIC REVIEW

Following guidance on reporting scoping reviews and the PRISMA statement for systematic reviews (Arksey and O'Malley, 2005; Liberati, Altman, Tetzlaff et al., 2009), this chapter presents the objectives, methods and results of a scoping and systematic review undertaken to, primarily, describe the extent, range and nature of research activity reported in English in the field of Morita Therapy. The review was conducted by HVRS (PhD candidate) with assistance from DAR (primary supervisor) and a professional training year student on a placement with the team (VT); the contributions of DAR and VT are detailed within the methods section (4.2). This chapter concludes with a discussion of the key findings and their implications for this thesis. Further reflections on this review, including a discussion of its strengths and limitations, are presented in Chapter Eight.

4.1 Aim and objectives

The primary aim of this review was to describe the extent, range and nature of research activity reported in English in the field of Morita Therapy. The overall objective was to identify all literature relevant to this aim, regardless of study design. The specific objectives were to map the fields of study, summarise the range of research and findings, and identify gaps in the existing literature. Two research questions were also specified in the event that any randomised controlled trials (RCTs) of Morita Therapy were identified:

1. What is the quality of any RCTs identified?
2. What can they tell us about the effectiveness of Morita Therapy for mental health difficulties?

4.2 Method

A two-stage process was undertaken. Firstly, Arksey and O'Malley (2005)'s framework for scoping reviews, as informed by systematic review methods (Centre for Reviews and Dissemination (CRD), 2001), was followed. Secondly, for any RCTs identified, further steps were undertaken in line with guidance for undertaking systematic reviews (CRD, 2009; Higgins and Green, 2011).

4.2.1 Identification of the research question

To formulate a search strategy for this review, the PICOS (CRD, 2009) method was employed:

- P (Population): any patient population or presentation.
- I (Intervention): any intervention which the author(s) defined as Morita Therapy, or Morita-based Therapy, including all in/outpatient formats.
- C (Comparator): any or no comparators.
- O (Outcomes): any papers describing the application of Morita Therapy using patient-focused data, with no restrictions placed on how effectiveness, outcomes, patient experiences or views were measured. Thus, data were referred to in the broadest sense, including all patient-focused empirical and/or clinical data (e.g. clinical opinions and observations; questionnaires; surveys; narrative descriptions; qualitative data).
- S (Study design): all designs with no methodological restrictions.

Additional inclusion criteria

- Any publication status.
- Written in English. Given the resource limitations of a PhD, translation of papers was not possible.

Exclusion criteria

- Purely theoretical, conceptual, socio-historical or discussion papers.
- Conference proceedings.
- Abstracts for which full texts were unavailable.

4.2.2 Identifying relevant papers: search strategy

To ensure a comprehensive search of the literature, the following databases were searched: Cochrane Library, Embase, PsycINFO, PubMed, Scopus, Web of Science. Upon advice from the University of Exeter Medical School Institute for Health Research Evidence Synthesis and Modelling for Health Improvement (ESMI) team (http://medicine.exeter.ac.uk/esmi/), these databases were considered to provide a spread of purpose and content, thus allowing a broad

approach to identifying potential literature. The databases were searched from date of inception until present day (March 2016) to ensure the historical context of the literature, as well as all up to date papers, was obtained. The search term "morita OR moritian" was used in title, abstract and key word fields.

Where possible in the databases, results were restricted to those written in English only. Within the databases which allowed differentiation by specific author (PsycINFO, Scopus and Web of Science), searches were also conducted for key authors in the field, as identified from prior knowledge and the results of the first search (Ishiyama, Fumihiko; Kitanishi, Kenji; Kondo, Akihisa; Kora, Takehisa; LeVine, Peg; Nakamura, Kei; Ogawa, Brian).

Grey literature

Following the initial database searches and upon guidance from the ESMI team, grey literature searching took place using British Library EThOS, Dogpile, Google Advanced Search and OpenGrey to help ensure literature was not omitted. These databases were searched by looking for "morita" or "moritian" in the title and specific authors as detailed above.

Hand-searching and existing networks

Lists of publications from known authors were checked for any publications not already identified, and known author publications not already identified were hand-searched for any empirical or clinical data. The volumes of the 'Journal of Morita Therapy' (from 2012 to present), unavailable electronically, were hand-searched for eligible papers. An unsuccessful request to provide any additional English-language papers contained in the volumes from inception to 2012 was also made to the Journal Editor.

Forwards and backwards citation checking

Backwards citation checking was undertaken by searching the reference lists of all included papers; forwards citation checking using the Scopus database.

4.2.3 Study selection

Citations were imported into EndNote X7.7 (DISC bv, 2016), where duplicate citations were removed. The first stage of screening, of titles and abstracts (Pham, Rajic, Greig et al., 2014), was completed independently by two reviewers (HVRS and VT). In cases of disagreement, the study was discussed with a third reviewer (DAR) until consensus was achieved. Where available, full text copies were retrieved for all potentially eligible citations and reviewed by HVRS in discussion with DAR, allowing consensus to be reached about the papers to be included in the review. Following retrieval of these papers, hand searching and citation checking was undertaken, as described above, to ensure comprehensiveness. Where full papers were not available electronically, the first authors were contacted to request these where possible (i.e. an email address or online profile could be identified for the author).

4.2.4 Data charting

Data were collected from all papers as suggested by Arksey and O'Malley (2005). In Excel v.14 (Office, undated), a data-charting form was iteratively developed as batches of data were extracted by HVRS in discussion with DAR (Levac, Colquhoun and O'Brien, 2010). The following information, where present, was extracted in an approach akin to a narrative review (Pawson, 2002): publication year; publication status/ document type; type of report (primary or secondary); country; patients' diagnosis/ symptom profile and age range; total number of patients; intervention format (in- or outpatient); summary and duration of intervention; outcome measures, if any; study design, if any; comparators, if any; a summary of the study's aims, methods, results and conclusions.

4.2.5 Randomised controlled trials: risk of bias assessment

For RCTs, risk of bias was assessed (CRD, 2009). Thus, in addition to the above data charting, an assessment of internal validity was conducted using criteria as suggested by the Cochrane Handbook for systematic reviews (Higgins and Green, 2011): adequate sequence generation; concealment of allocation; blinding of participants and outcome assessors; handling of

incomplete outcome data; selective outcome reporting; other potential threats to internal validity. Summary assessments were made for each study by counting the number of domains in which the study was considered at low risk of bias.

4.2.6 Collating, summarising and reporting results

The overall aim of this step was to focus on the landscape of the literature as a whole, to aid identification of any gaps in the current evidence-base. Therefore, a descriptive account of the data was developed (Arksey and O'Malley, 2005). Firstly, basic numerical analysis of the extent, nature and distribution of included papers was conducted. Thus, papers were mapped according to geographical distribution; patient population; study design; type of Morita Therapy intervention; outcome measures used and/or type of data presented.

'Papers' included primary studies and reviews/ secondary reports (defined as brief and ad hoc reports of data collected within other studies, with no attempt to systematically identify nor synthesise studies as per the identified reviews) which were included in order to access data not originally reported in English. Although some studies reported within these papers may have been originally reported in English and thus included as primary papers, no double counting took place as the data describes the nature of each included *paper* (whether primary study or review/ secondary report), not each included *study* (of which each review/ secondary report contained multiple). Thus, each review/ secondary report is counted and reported as a single paper; the studies contained therein have not been counted or reported individually. For example, for geographical distribution, two reviews including data from studies conducted in a mixture of locations are counted and reported as two papers of mixed locations.

Secondly, the literature was organised according to study design (or type of paper, for secondary reports) to produce a narrative account. To ensure clarity and consistency in reporting, a template was developed and applied to each study design category (Arksey and O'Malley, 2005). This template included commentary on all papers included in that category under the following headings: interventions; sample sizes; participants; outcomes; research methods; evidence relating to effectiveness.

Randomised controlled trials: statistical analysis

For RCTs, the results (means and standard deviations) of all standard outcome measures at baseline and follow-up, as reported in the published papers, were also presented. These statistics were used to calculate between-group differences at follow-up, with 95% confidence intervals, in STATA v.14 (StataCorp, 2015). The appropriateness of further statistical synthesis techniques, such as meta-analysis, was considered in light of the quality and clinical diversity of the RCTs (Higgins and Green, 2011).

4.3 Results

4.3.1 Inclusion of papers

A total of 3846 unique records were identified (Figure 4). After screening, 197 full text papers were reviewed; 131 did not fulfil study inclusion criteria and were excluded; 66 papers were included.

Figure 4. Scoping and systematic review PRISMA diagram
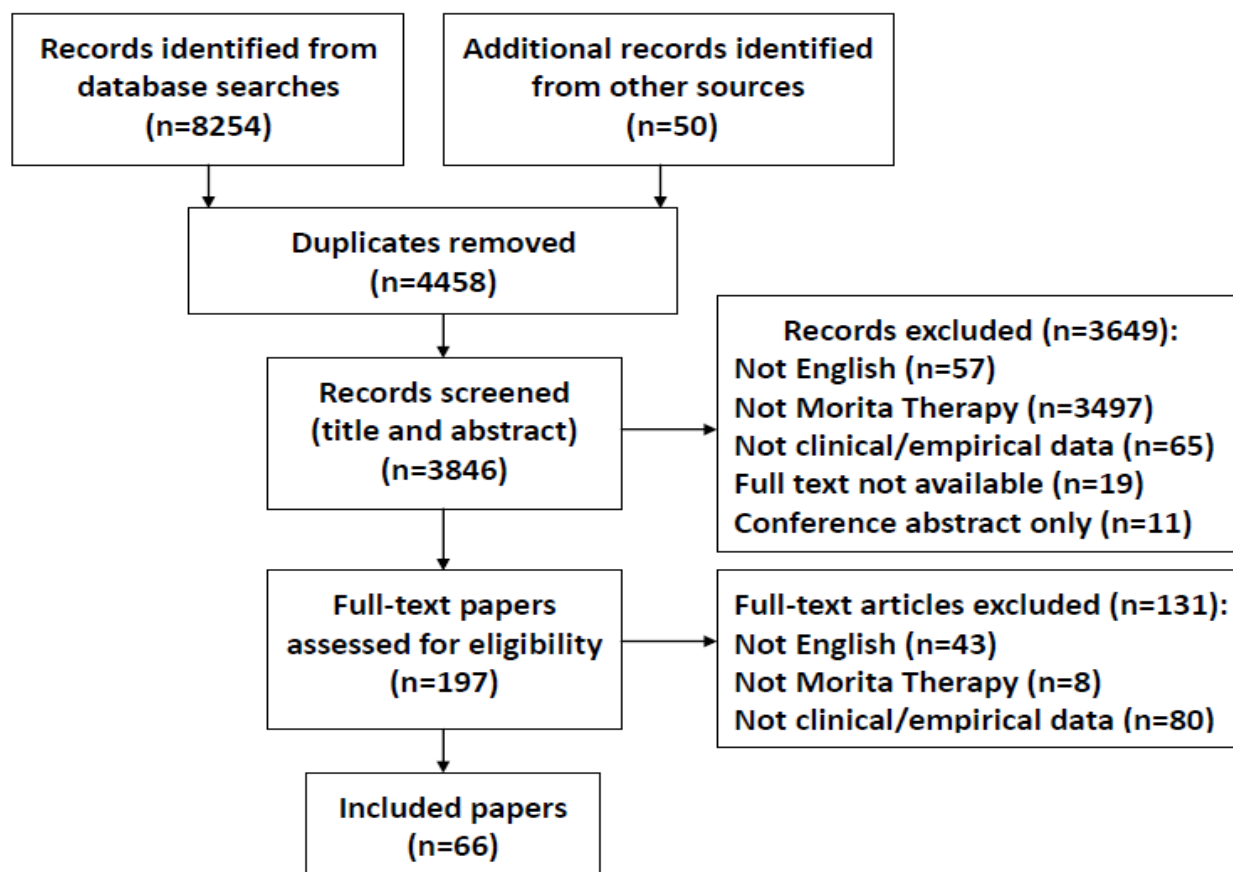
4.3.2 Characteristics of included papers: numerical analysis

This section describes the extent, nature and distribution of included papers.

Geographical distribution

Figure 5 describes papers according to the country in which Morita Therapy was implemented. The largest proportion described interventions implemented in Japan (n=29; 43.9%); smaller proportions in China (n=12; 18.2%, including two reviews), Canada (n=12; 18.2%), the USA (n=7; 10.6%) and Australia (n=2; 3.0%). Two reviews (3.0%) included studies from a mixture of locations (Australia, China, Japan and the USA).

Figure 5. Distribution of Morita Therapy papers by country (n=66)
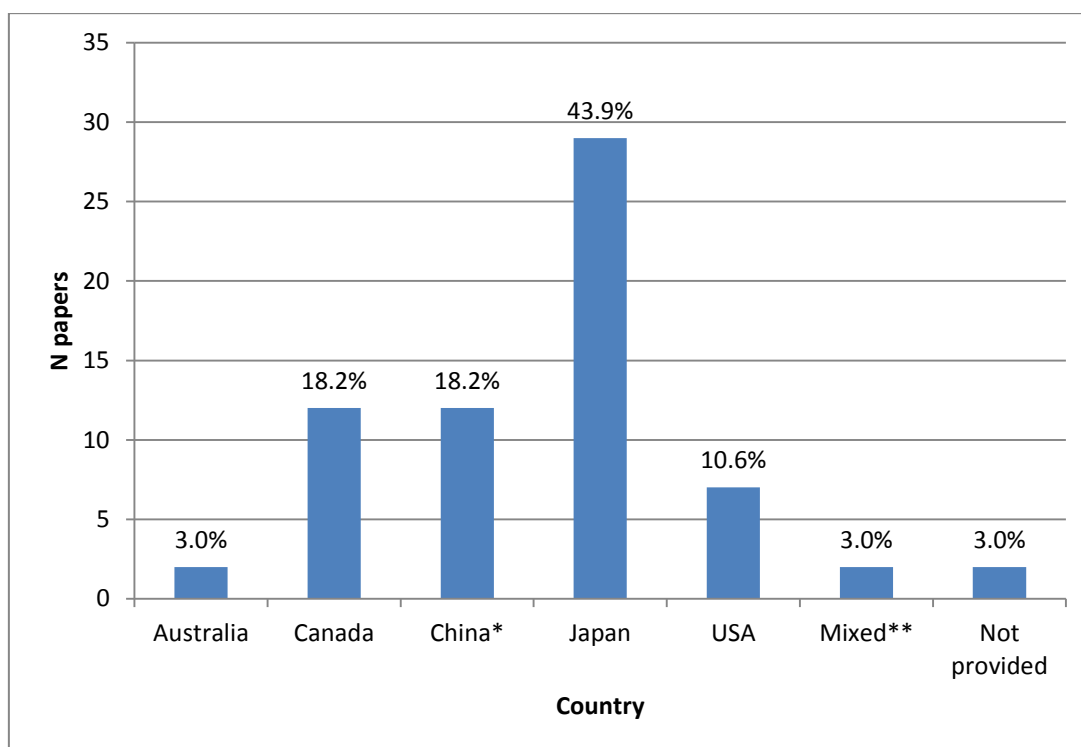
*Includes two reviews
**Includes two reviews. Australia; China; Japan; USA
Notes: percentages may not always total 100 due to rounding.

Patient population

Figure 6 (overleaf) describes papers according to patient diagnosis or condition. Half of the papers, including one review, reported studies of anxiety disorders (n=33; 50.0%), the most frequent form being Japanese Shinkeishitsu (n=11; 16.7%). The second largest category was subclinical issues (n=10; 15.2%)

such as shyness, communication apprehension or feelings of inferiority. Other patient profiles included personality disorder (n=3; 4.5%); schizophrenia (n=3; 4.5%, including one review); depression (n=2; 3.0%), including post-schizophrenic depression (n=1; 1.5%); physical conditions (n=2; 3.0%); victims of sexual abuse or assault (n=2; 3.0%); eating disorder (n=1; 1.5%); insomnia (n=1; 1.5%); somatoform disorder (n=1; 1.5%). Five papers (7.6%), including two reviews, presented data on a mixture of conditions.

Figure 6. Number and proportion of papers according to patient population (n=66)
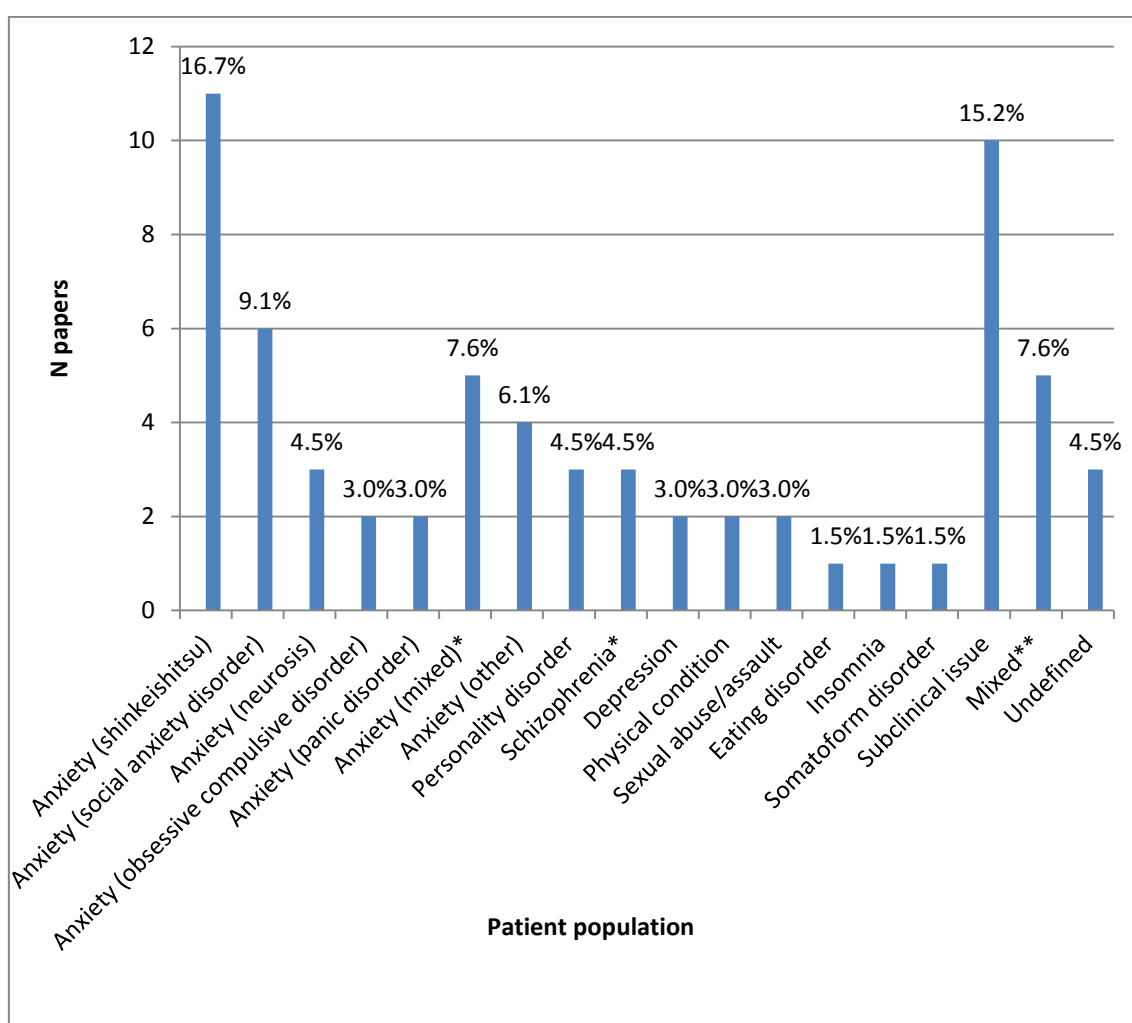
*Includes one review.
**Includes two reviews. Gastric atony, dementia, low-grade fevers, proteinuria, empyema, hypertrophic rhinitis, insomnia, paroxysmal neurosis, depression, obsessive compulsive disorder, shinkeishitsu, neurotic disorder, social phobia, anxiety, social withdrawal, panic disorder, somatoform disorder, schizophrenia, dysthymia, phobia, post-traumatic stress disorder, mood disorder, eating disorder, adjustment disorder, pain disorder, sleep disorder, substance abuse disorder, personality disorder, bipolar II, psychosomatic illness, other subclinical issues
Notes: percentages may not always total 100 due to rounding.

Mapping geographical distribution by patient population

The largest proportion of papers focusing on anxiety disorders derived from Japan (n=19; 28.6% of all papers) (Table 1), with papers focusing on such disorders accounting for the majority of papers based in Japan. Papers from China, Canada, the USA and Australia cover a range of conditions. Papers focusing on depression derived from China (n=1; 1.5%) (post-schizophrenic depression) and the USA (n=1; 1.5%) (dysthymia or depression). Additional papers (one review and one secondary report) presenting data on multiple conditions, including depression, included data collected in Japan (n=1; 1.5%) and Japan, China, Canada and the USA (n=1; 1.5%).

Table 1. Geographical distribution of papers according to patient population (n=66)

	Japan		China		Canada		USA		Australia		Mixed		Not provided	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Anxiety (shinkeishitsu)	9	13.6	-	-	1	1.5	-	-	-	-	-	-	1	1.5
Anxiety (social anxiety)	2	3.0	-	-	3	4.5	1	1.5	-	-	-	-	-	-
Anxiety (neurosis)	-	-	3	4.5	-	-	-	-	-	-	-	-	-	-
Anxiety (OCD)	1	1.5	1	1.5	-	-	-	-	-	-	-	-	-	-
Anxiety (panic disorder)	2	3.0	-	-	-	-	-	-	-	-	-	-	-	-
Anxiety (mixed)	3	4.5	1*	1.5	-	-	-	-	-	-	-	-	1	1.5
Anxiety (other)	2	3.0	1	1.5	1	1.5	-	-	-	-	-	-	-	-
Personality disorder	1	1.5	-	-	2	3.0	-	-	-	-	-	-	-	-
Schizophrenia	-	-	3*	4.5	-	-	-	-	-	-	-	-	-	-
Depression	-	-	1	1.5	-	-	1	1.5	-	-	-	-	-	-
Physical condition	1	1.5	-	-	-	-	1	1.5	-	-	-	-	-	-
Sexual abuse/assault	-	-	-	-	1	1.5	1	1.5	-	-	-	-	-	-
Eating disorder	-	-	-	-	-	-	-	-	1	1.5	-	-	-	-
Insomnia	1	1.5	-	-	-	-	-	-	-	-	-	-	-	-
Somatoform disorder	-	-	1	1.5	-	-	-	-	-	-	-	-	-	-
Subclinical issue	3	4.5	-	-	4	6.1	2	3.0	1	1.5	-	-	-	-
Mixed	3**	4.5	-	-	-	-	-	-	-	-	2***	3.0	-	-
Undefined	1	1.5	1	1.5	-	-	1	1.5	-	-	-	-	-	-
Total	29	43.9	12	18.2	12	18.2	7	10.6	2	3.0	2	3.0	2	3.0

*Includes one review
**Gastric atony, dementia, low-grade fevers, proteinuria, empyema, hypertrophic rhinitis, insomnia, paroxysmal neurosis, obsessive disorders (n=1); social phobia and/or avoidant personality disorder (n=1); shinkeishitsu, delusional-type neurosis, obsessive-compulsive neurosis, chronic unipolar depression (including bipolar II), dysthymia, schizophrenia, borderline personality, psychosomatic illness (n=1)
***Includes two reviews. Japan & China: anxiety disorder, schizophrenia, mood disorder, somatoform disorder, eating disorder, adjustment disorder, pain disorder, sleep disorder, substance abuse disorder, personality disorder, other subclinical issues (n=1); Japan, China, Australia & USA: depression, obsessive compulsive disorder, shinkeishitsu, neurotic disorder, social phobia, anxiety, social withdrawal, bulimia nervosa, panic disorder, somatoform disorder, schizophrenia, dysthymia, borderline personality disorder, phobia, post-traumatic stress disorder (n=1)
Notes: percentages may not always total 100 due to rounding; OCD=obsessive compulsive disorder

Study designs adopted

The largest proportion of papers were narrative case studies (n=26; 39.4%) (Figure 7). The second largest category (n=11; 16.7%) was defined as clinical impressions: reports of clinical/ empirical data in the form of clinicians' general reflections on or brief examples of patient(s) they have treated, in order to illustrate their approach to or the principles of Morita Therapy, without utilising any study design nor providing in-depth information on individual patients in the form of a case study.

Only 10.6% (n=7) of papers presented comparative studies comparing Morita Therapy against alternative approaches: five (7.6%) were RCTs and two (3.0%) were non-randomised comparative studies. Other designs included measures repeated before and after therapy (n=6; 9.1%) and cross-sectional observational studies in which follow-up surveys were sent to former patients (n= 5; 7.6%). Reviews accounted for 6.1% of papers (n=4); seven papers (10.6%) were counted separately as 'secondary reports' summarising data from studies originally published in Japanese or Chinese.

Figure 7. Number and proportion of papers according to study design (n=66)
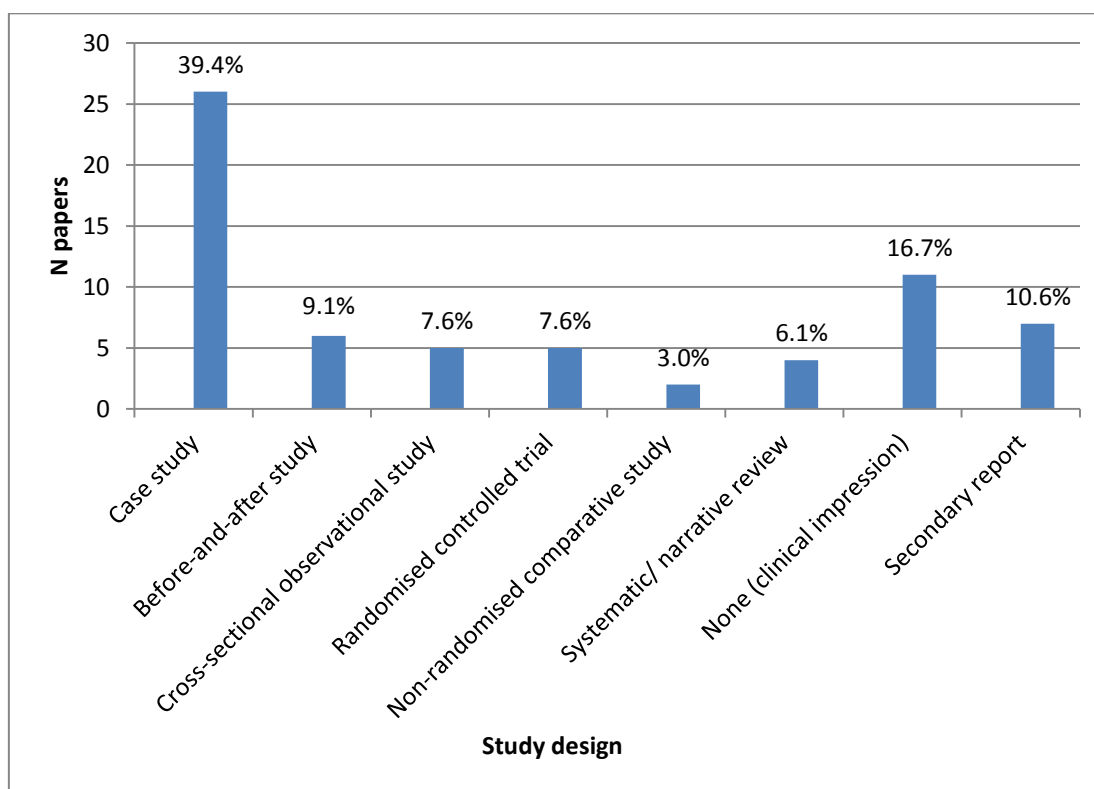
Notes: percentages may not always total 100 due to rounding

Mapping geographical distribution by study design

The largest proportions of papers utilising case studies derived from Japan (n=13; 19.7% of all papers) and Canada (n=9; 13.6%) (Table 2). The case study design accounted for almost half of papers based in Japan and the majority of those conducted in Canada, as well as both studies (3.0%) conducted in Australia and both studies (3.0%) in which the location was not provided. RCTs and non-randomised comparative studies were based in China (n=3; 4.5% and n=1; 1.5% respectively) and the USA (n=2; 3.0% and n=1; 1.5% respectively).

Before-and-after studies were conducted in Japan (n=1; 1.5%), China (n=3; 4.5%) and Canada (n=2; 3.0%); cross-sectional observational studies (follow-up surveys) in Japan (n=4; 6.1%) and China (n=1; 1.5%). Both systematic reviews (3.0%) included studies based in China and both narrative reviews (3.0%) included studies based in various locations. Secondary reports included data collected in Japan (n=6; 9.1%) and China (n=1; 1.5%).

Table 2. Geographical distribution of papers according to study design (n=66)

	Japan		China		Canada		USA		Australia		Mixed		Not provided	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Case study	13	19.7	-	-	9	13.6	-	-	2	3.0	-	-	2	3.0
Before-and-after study	1	1.5	3	4.5	2	3.0	-	-	-	-	-	-	-	-
Cross-sectional observational study	4	6.1	1	1.5	-	-	-	-	-	-	-	-	-	-
Randomised controlled trial	-	-	3	4.5	-	-	2	3.0	-	-	-	-	-	-
Non-randomised comparative study	-	-	1	1.5	-	-	1	1.5	-	-	-	-	-	-
Systematic/ narrative review	-	-	2	3.0	-	-	-	-	-	-	2*	3.0	-	-
None (clinical impression)	5	7.6	1	1.5	1	1.5	4	6.1	-	-	-	-	-	-
Secondary report	6	9.1	1	1.5	-	-	-	-	-	-	-	-	-	-
Total	29	43.9	12	18.2	12	18.2	7	10.6	2	3.0	2	3.0	2	3.0

*Japan & China (n=1); Japan, China, Australia & USA (n=1)
Notes: percentages may not always total 100 due to rounding.

Mapping study design by patient population

Table 3 (overleaf) describes papers by study design for each patient diagnosis/ condition treated. The largest proportion of case studies treated anxiety disorders (n=15; 22.7% of all papers) alongside subclinical issues (n=6; 9.1%). Other study designs covered a range of patient populations. RCTs were utilised for various anxiety disorders (n=3; 4.5%), schizophrenia (n=1; 1.5%) and subclinical issues (communication apprehension) (n=1; 1.5%); non-randomised comparative studies for schizophrenia (n=1; 1.5%), depression and dysthymia (n=1; 1.5%). The systematic reviews were undertaken for unspecified anxiety disorders (n=1; 1.5%) and schizophrenia/ schizophrenia-like symptoms (n=1; 1.5%). Both narrative reviews (n=2; 3.0%) included a mixture of conditions. Secondary reports included data on anxiety disorders (n=5; 7.6%), post-schizophrenic depression (n=1, 1.5%) and a mixture of conditions (n=1; 1.5%).

Table 3 overleaf

Table 3. Distribution of study design according to patient population (n=66)

	Case Study		Before-and-after study		Cross-sectional observational study		Randomised controlled trial		Non-randomised comparative study		Systematic/narrative review		Clinical impression		Secondary report	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Anxiety (shinkeishitsu)	4	6.1	-	-	3	4.5	-	-	-	-	-	-	1	1.5	3	4.5
Anxiety (social anxiety disorder)	4	6.1	1	1.5	-	-	1	1.5	-	-	-	-	-	-	-	-
Anxiety (neurosis)	-	-	2	3.0	-	-	1	1.5	-	-	-	-	-	-	-	-
Anxiety (OCD)	1	1.5	-	-	-	-	1	1.5	-	-	-	-	-	-	-	-
Anxiety (panic disorder)	1	1.5	-	-	-	-	-	-	-	-	-	-	1	1.5	-	-
Anxiety (mixed)	2	3.0	-	-	1	1.5	-	-	-	-	-	-	-	-	2	3.0
Anxiety (other)	3	4.5	-	-	-	-	-	-	-	-	1	1.5	-	-	-	-
Personality disorder	2	3.0	-	-	-	-	-	-	-	-	-	-	1	1.5	-	-
Schizophrenia	-	-	-	-	-	-	1	1.5	1	1.5	1	1.5	-	-	-	-
Depression	-	-	-	-	-	-	-	-	1	1.5	-	-	-	-	1	1.5
Physical condition	-	-	-	-	1	1.5	-	-	-	-	-	-	1	1.5	-	-
Sexual abuse/assault	1	1.5	-	-	-	-	-	-	-	-	-	-	1	1.5	-	-
Eating disorder	1	1.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Insomnia	1	1.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Somatoform disorder	-	-	1	1.5	-	-	-	-	-	-	-	-	-	-	-	-
Subclinical issue	6	9.1	1	1.5	-	-	1	1.5	-	-	-	-	2	3.0	-	-
Mixed	-	-	1*	1.5	-	-	-	-	-	-	2**	3.0	1***	1.5	1****	1.5
Undefined	-	-	-	-	-	-	-	-	-	-	-	-	3	4.5	-	-
Total	26	39.4	6	9.1	5	7.6	5	7.6	2	3.0	4	6.0	11	16.7	7	10.6

*Social phobia and/or avoidant personality disorder
See overleaf for further notes

**Anxiety disorder, schizophrenia, mood disorder, somatoform disorder, eating disorder, adjustment disorder, pain disorder, sleep disorder, substance abuse disorder, personality disorder, other subclinical issues (n=1); depression, obsessive compulsive disorder, shinkeishitsu, neurotic disorder, social phobia, anxiety, social withdrawal, bulimia nervosa, panic disorder, somatoform disorder, schizophrenia, dysthymia, borderline personality disorder, phobia, post-traumatic stress disorder (n=1)
***Gastric atony, dementia, low-grade fevers, proteinuria, empyema, hypertrophic rhinitis, insomnia, paroxysmal neurosis, obsessive disorders
****Shinkeishitsu, delusional-type neurosis, obsessive-compulsive neurosis, chronic unipolar depression (including bipolar II), dysthymia, schizophrenia, borderline personality, psychosomatic illness
Notes: percentages may not always total 100 due to rounding; OCD=obsessive compulsive disorder

Type of Morita Therapy intervention

There is little standardisation and transparency in the implementation of Morita Therapy (see Chapter Two) and the papers identified reflect this. No authors refer to the use of published treatment manuals. Particularly in the context of outpatient Morita Therapy, less constrained by the four-staged inpatient structure of Morita's original method (Morita et al., 1998), authors/ clinicians typically appear to have developed their own approach to Morita Therapy based on its traditional principles and/or techniques, and it is difficult to assess the extent to which these interventions are comparable across authors/ clinicians. Some authors refer to the use of a particular model (such as the Ishiyama (2011) counselling model), for which sufficient details to enable replication appear to be held by and passed down to individuals rather than accessible through publication. Overall, descriptions of the intervention tended to be subsumed within descriptions of the *principles* of Morita Therapy, with either little information provided as to how these principles were operationalised, or highly individualised accounts of operationalisation provided in the form of narrative case studies (such as excerpts of clinician/ patient conversation, included to demonstrate the application of a principle).

The information provided on interventions was used to categorise them according to whether they took place in an inpatient or outpatient setting, and whether outpatient Morita Therapy involved face-to-face individual therapy ('outpatient counselling') or another format (Figure 8, overleaf). The largest proportion of papers (n=23; 34.8%) involved outpatient counselling; a similar figure (n=21; 31.8%, including one review) involved inpatient Morita Therapy; 7.6% (n=5) involved a Morita-based group intervention; 3.0% (n=2) involved the Morita-based Seikatsu-no Hakkenka self-help group; 3.0% (n=2) involved tutors or school counsellors applying Morita Therapy techniques with students. Other

papers included idiosyncratic and highly modified versions of the therapy (n=3; 4.5%), a mixture of therapy types (n=8; 12.1%, including three reviews) or the intervention was undefined (n=2; 3.0%).

Figure 8. Number and proportion of papers according to type of Morita Therapy intervention (n=66)
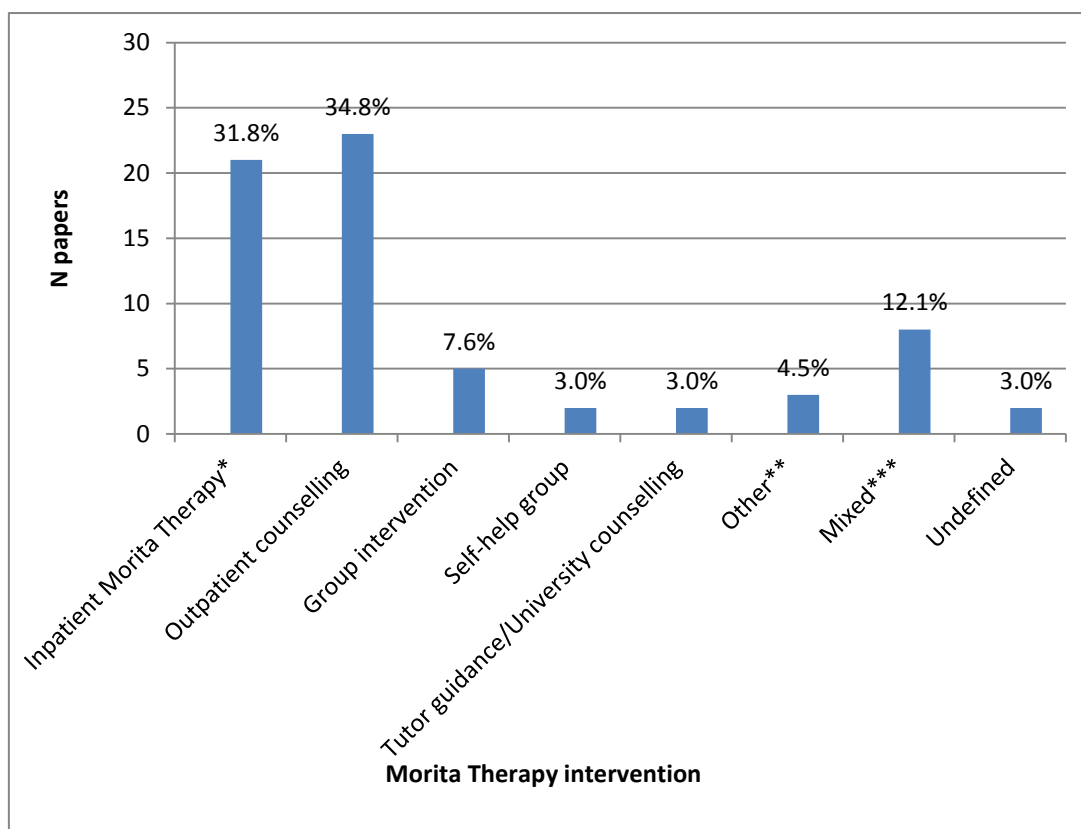
*Includes one review
**Letter therapy; Walking Training therapy; home care with Morita trained family members
***Includes three reviews. Inpatient; outpatient; group intervention; self-help group; patients treated at school or welfare counselling centres; patients treated by non-mental health professionals such as dentists employing Morita Therapy techniques
Notes: percentages may not always total 100 due to rounding.

Outcome measures used/ type of data presented

The majority of papers (n=41; 62.2%) presented narrative descriptions of outcomes (Figure 9, overleaf), including clinical opinions or observations (n=31; 47.0%) and patient self-report in the form of quotes or diary excerpts (n=10; 15.2%). With regards to quantitative outcome measures, 30.3% (n=20) of papers, including all four reviews, reported standard (published) outcome measures; 12.1% (n=8) reported author-developed measures to capture the specific changes Morita Therapy was expected to effect; 4.5% (n=3) reported a test of physical symptoms.

Figure 9. Number and proportion of outcome measures employed/ types of data presented in papers (n=66)
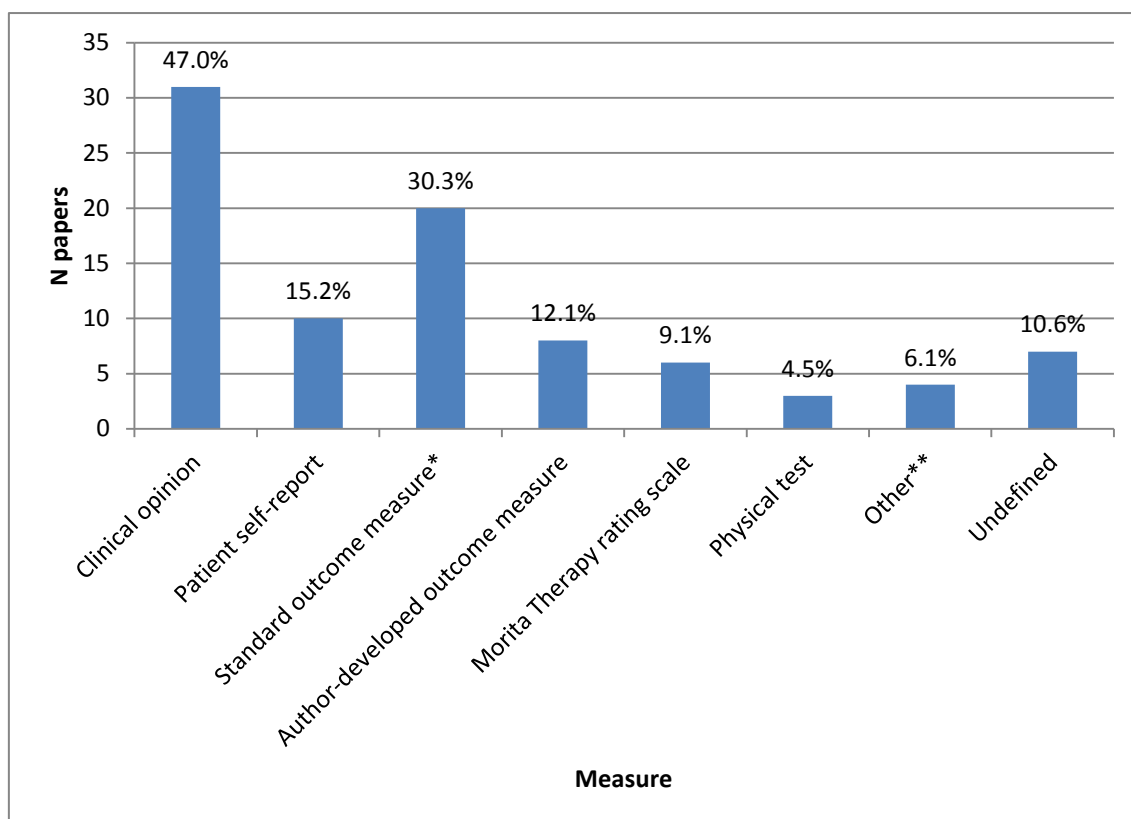
*Includes four reviews
**Job/school status; life table analysis; extemporaneous speech task; extent of behaviour change
Notes: N papers = number of papers including measure (as some papers included multiple measures, total is higher than total number of papers; % given is % of total number of papers (n=66) including the measure, thus percentages do not total 100).

Six papers (9.1%) included the three or four point Morita Therapy rating scale. This scale is used for clinicians to assess, on the basis of their observations or patient-completed questionnaires, whether patients have experienced cure (complete disappearance of observable symptoms and subjective complaints), improvement (disappearance of observable symptoms with occasional subjective complaints), limited improvement (some reductions in both symptoms and subjective complaints), or no improvement. On the three-point scale, both cure and improvement are considered to comprise cure.

Quantitative outcome measures were heterogeneous: aside from the Morita Therapy rating scale, only seven measures were reported by more than one paper: an author-developed measure by Ishiyama (unpublished), reported five times; the Social Avoidance and Distress Scale (Watson and Friend, 1969), reported three times; and the Social Disability Screening Schedule (Wu, 1998),

Yale-Brown Obsessive Compulsive Scale (Goodman, Price, Rasmussen et al., 1989), Symptom Checklist-90 (Derogatis, 1996), Hamilton Rating Scale for Anxiety (Hamilton, 1959) and Beck Depression Inventory (Beck, Steer and Brown, 1996), each reported two times. The author-developed measures were not validated and papers rarely reported whether the standard outcome measures used were validated.

4.3.3 Narrative account of each study design

To summarise the range of research and findings, this section provides a narrative account of the papers included within each type of study design in terms of interventions, sample sizes, participants, outcomes, research methods and evidence relating to effectiveness. Only data from research studies are included; clinical impressions (n=11) are not included.

Summary tables documenting information about each paper included within each study design can be found in Tables 1-6 in Appendix I. For RCTs, this information alongside quality assessment and statistical analyses is presented below. With the exception of these reviewer-conducted analyses, it should be noted that the opinions of the study author(s), not those of the reviewers, are presented with regards to evidence relating effectiveness.

Randomised controlled trials (RCTs) (n=5)

Three RCTs were conducted in China; two in the USA which form parts of unpublished theses (Table 4, overleaf).

Table 4. Details of included randomised controlled trials (n=5)

Author/ Year	Country	Sample (SD = Standard Deviation)	Patient diagnosis/ condition	Intervention summary	Control group	Research methods	Outcome measures (SOM = Standard Outcome Measures)
Chen (2000)	China	Patients (n=73); mean age of intervention group 31.2 years (SD 6.5), mean age of control group 29.3 years (SD 7.6)	Schizophrenia with acute symptoms under control	Modified inpatient Morita Therapy (excluding bed rest); duration 12 weeks (n=35)	Undefined (n=38)	Quantitative. Baseline/ follow-up measures.	SOM: negative symptoms; psychiatric symptoms
Hou, Song, Cui et al. (2000)	China	Patients (n=257); aged over 18 years	Neurosis	Outpatient counselling; 2-5 sessions per week over 20 weeks (n=129)	Acupuncture; 20 sessions (n=128)	Quantitative. Baseline/ follow-up measures. Longer-term follow-up (12 months).	SOM: depression; anxiety
Qiyi and Xiongwei (2000)	China	Patients (n=64); mean age of intervention group 34.5 years (SD 14.0), mean age of control group 31.7 years (SD 12.4)	Obsessive-Compulsive Disorder	Original inpatient Morita Therapy, plus pharmacology; duration undefined (n=31)	Pharmacology alone (n=33)	Quantitative. Baseline/ follow-up measures. Longer-term follow-ups (6 and 12 months).	SOM: obsessive compulsive symptoms; anxiety; social disability
Aposhyan (1995) Thesis – not published	USA	Patients (n=22); mean age 26.88 (SD 6.46)	Social phobia	Group Morita Therapy; 4 sessions over 4 weeks (n=11)	Wait list (n=11)	Quantitative. Baseline/ follow-up measures. Longer-term follow-up (1 month).	SOM: social avoidance/ distress; fear of negative evaluation Author-developed measure: anxiety acceptance; problem severity; coping effectiveness
Ogrisseg (1999) Thesis – not published	USA	Patients (n=31); mean age 32.3 years (SD 10.46)	Communication apprehension	Psycho-educational Morita Therapy group workshop; 3 sessions (n=14)	Stress management workshop; 3 sessions (n=17)	Quantitative. Baseline/ follow-up measures. Longer-term follow-up (5 weeks).	SOM: communication anxiety; social avoidance/ distress Author-developed measure: anxiety acceptance; problem severity; coping effectiveness Speech task; Heart rate

Interventions. Two RCTs utilised inpatient Morita Therapy: one of twelve week's duration with bed rest excluded (Chen, 2000); one of undefined duration including the original four phases (Qiyi and Xiongwei, 2000). One utilised outpatient counselling, between two and five sessions over 20 weeks (Hou et al., 2000). Few details were provided of this intervention aside from the inclusion of diary completion. The two USA studies utilised group-based approaches informed by the Ishiyama (2011) counselling model, either three (Ogrisseg, 1999) or four sessions (Aposhyan, 1995).

Sample sizes. Sample sizes ranged from 22 to 257 (mean 89, SD 96). Aside from Hou et al. (2000) (n=257), all studies included sample sizes of 73 or below. No studies included details of a power calculation or justified the sample size.

Participants. Inpatient interventions targeted schizophrenia with acute symptoms under control (mean age 31.2 years (SD 6.5) and 29.3 years (SD 7.6) for Morita Therapy and control groups respectively) (Chen, 2000) and obsessive-compulsive disorder (mean age 34.5 (SD 14.0) and 31.7 (SD 12.4) for Morita Therapy and control groups respectively) (Qiyi and Xiongwei, 2000). Outpatient Morita Therapy targeted neurosis in adults (Hou et al., 2000). Group interventions in the USA targeted communication apprehension (mean age 32.3 years, SD 10.5) (Ogrisseg, 1999) and social phobia (mean age 26.9 years, SD 6.5) (Aposhyan, 1995).

Outcomes. All studies utilised standard (published) quantitative outcome measures to evaluate symptom severity; social avoidance, distress or disability. In addition, the two USA studies included author-developed measures to assess anxiety acceptance, problem severity and coping effectiveness (Aposhyan, 1995; Ogrisseg, 1999), and one included an extemporaneous speech task and heart rate monitoring to assess anxiety (Ogrisseg, 1999).

Research methods. All participants were randomised. Control groups ranged from defined alternative treatments (three session stress management workshop (Ogrisseg, 1999); 20 sessions of acupuncture (Hou et al., 2000)) to wait-list (Aposhyan, 1995) and treatment as usual (defined as medication alone) (Qiyi and Xiongwei, 2000). Chen (2000) did not define the control group. All studies included baseline and follow-up (i.e. completed at the end of treatment,

or at a comparable time point for control groups with no treatment) measures. Four included longer-term follow-ups ranging from one to twelve months post-treatment.

Risk of bias. Two studies were assessed as low risk of bias on two out of six domains (Chen, 2000; Hou et al., 2000); the remainder on one domain (Table 5, overleaf). None were considered at high (or unclear) risk of bias from selective reporting: the results of all measures referred to in the studies' methods were reported. For two studies (Chen, 2000; Hou et al., 2000), whilst attrition was not explicitly reported, the n provided indicated all randomised participants provided data at subsequent time points and thus risk of attrition bias was rated as low. Other studies either failed to report rates of or reasons for attrition and therefore risk of attrition bias was rated as unclear or high. For all studies, all remaining criteria were rated as either unclear or high risk. No studies reported blinding of participants, personnel or outcome assessors. No studies reported how the randomisation sequence was generated nor indicated the inclusion of any measures of allocation concealment. In one study (Aposhyan, 1995), participants initially randomly assigned were allowed to change groups to accommodate their schedules, producing high risk of selection bias and serious quality issues.

Table 5 overleaf

Table 5. Risk of bias in included randomised controlled trials

| Study | Risk of Bias | | | | | | Summary assessment* |
| | Selection | | Performance | Detection | Attrition | Reporting | |
	Generation of random sequence	Allocation concealment	Blinding of participants/ personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	
Chen (2000)	Unclear risk. Quote: "patients were randomly divided". No details of sequence generation.	High risk. No indication	High risk. No indication	High risk. No indication	Low risk. Data suggests 0% attrition.	Low risk. All outcomes reported	2/6
Hou et al. (2000)	Unclear risk. Quote: "patients were randomly divided". No details of sequence generation.	High risk. No indication	High risk. No indication	High risk. No indication	Low risk. Data suggests 0% attrition.	Low risk. All outcomes reported	2/6
Qiyi and Xiongwei (2000)	Unclear risk. Quote: "patients were randomly assigned". No details of sequence generation.	High risk. No indication	High risk. No indication	High risk. No indication	Unclear risk. Attrition unreported.	Low risk. All outcomes reported	1/6
Ogrisseg (1999)	Unclear risk. Quote: "patients were randomly assigned". No details of sequence generation.	High risk. No indication	High risk. No indication	High risk. No indication	High risk. 3/34 dropped out before treatment; reasons unreported.	Low risk. All outcomes reported	1/6
Aposhyan (1995)	High risk. Quote: "patients were randomly assigned", but allowed to change groups to accommodate their schedules.	High risk. No indication	High risk. No indication	High risk. No indication	High risk. Attrition: 9%; reasons unreported.	Low risk. All outcomes reported	1/6

*Number of domains in which the study was considered at low risk of bias

Evidence relating to effectiveness. The results of standard outcome measures are presented alongside reviewer-conducted calculations of follow-up between-group differences in Table 6 (overleaf).

Results are mixed. Two studies show follow-up between-group differences which favour Morita Therapy compared to wait-list control (Aposhyan, 1995) and undefined control (Chen, 2000) on all outcomes. Whilst small sample sizes suggest these results should be interpreted with caution, the lower margin of error does consistently favour the Morita Therapy group. Hou et al. (2000) show consistently negligible follow-up between-group differences, with confidence intervals which show that the true population effect may or may not favour Morita Therapy compared to acupuncture.

Two studies report mixed results: Qiyi and Xiongwei (2000) show follow-up between-group differences which consistently favour Morita Therapy compared to medication alone. However, whilst the lower margin of error on the Yale-Brown Obsessive Compulsive Scale favours the Morita Therapy group, the confidence intervals for other measures indicate the true population effect may or may not favour Morita Therapy. Similarly, the follow-up between-group differences in Ogrisseg (1999) favour the stress management workshop on one measure and Morita Therapy on two measures. Of those two, only the Stimulus-Response Inventory of Anxiousness-Speech has a lower margin of error which continues to favour Morita Therapy. Furthermore, given the small sample size, it is difficult to draw any conclusions from these figures.

Table 6. Results of standard outcome measures in randomised controlled trials with follow-up between-group differences

Study	Outcome measure	Participants	Baseline			Follow-up			Between-group difference at follow-up	
			n	Mean	SD	n	Mean	SD	Difference	95% CI
Chen (2000)	Scale for the Assessment of Negative Symptoms	Morita Therapy Undefined control	35 38	68.3 66.7	7.5 8.3	35 38	42.6 60.3	7.5 5.9	17.7	14.6 to 20.8
	Brief Psychiatric Rating Scale	Morita Therapy Undefined control	35 38	36.5 38.1	4.2 5.3	35 38	26.2 35.7	4.3 2.9	9.5	7.8 to 11.2
Hou et al. (2000)	Hamilton Rating scale for depression	Morita Therapy Active Control	129 128	21.46 22.39	6.27 6.56	129 128	12.78 13.16	5.61 5.72	0.38	-1.0 to 1.8
	Hamilton Rating Scale for anxiety	Morita Therapy Active Control	129 128	21.48 20.86	5.42 6.32	129 128	14.13 13.96	3.53 4.10	-0.17	-1.1 to 0.77
Qiyi and Xiongwei (2000)	Yale-Brown Obsessive Compulsive Scale: thoughts	Morita Therapy Medication alone	31 33	12.30 12.70	2.78 3.70	31 33	4.36 9.24	2.85 2.75	4.88	3.4 to 6.3
	Yale-Brown Obsessive Compulsive Scale: actions	Morita Therapy Medication alone	31 33	11.00 10.88	3.57 2.89	31 33	4.39 5.33	2.07 2.29	0.94	-0.2 to 2.0
	Hamilton Rating Scale for anxiety	Morita Therapy Medication alone	31 33	29.36 26.81	7.68 4.33	31 30	12.45 13.90	9.16 6.41	1.45	-2.6 to 5.5
Ogrisseg (1999)	Personal Report of Communication Apprehension	Morita Therapy Active Control	14 17	71.5 73.8	17.4 17.2	14 17	68.7 69.6	12.9 17.9	0.9	-10.8 to 12.6
	Stimulus-Response Inventory of Anxiousness-Speech	Morita Therapy Active Control	14 17	35.7 35.8	6.6 4.8	14 17	30.9 37.0	9.9 6.0	6.1	0.2 to 12.0
	Social Avoidance and Distress Scale	Morita Therapy Active Control	14 17	9.1 8.0	7.0 7.0	14 17	9.2 8.0	7.1 7.5	-1.2	-6.6 to 4.2
Aposhyan (1995)	Social Avoidance and Distress Scale	Morita Therapy Wait list Control	11 11	20.6 21.2	5.5 3.6	11 11	12.8 19.8	5.3 6.0	7.0	2.0 to 12.0
	Fear of Negative Evaluation Scale	Morita Therapy Wait list Control	11 11	25.0 25.6	4.5 3.5	11 11	19.1 26.9	5.5 3.1	7.8	3.8 to 11.8

Notes: 95% CI = 95% confidence intervals around the follow-up between-group difference; SD=standard deviation

Potential for statistical synthesis. Further synthesis of results was deemed unwarranted and unfeasible given the diversity and heterogeneity of studies (Higgins and Green, 2011): they examined different intervention types with different patient diagnoses and control conditions, evaluated with a range of measures. Furthermore, these studies are considered to be at high risk of bias, limiting the usefulness of any statistical synthesis (Higgins and Green, 2011). Given none of these studies were conducted within the UK nor with a depressed patient population, further synthesis would be unable to provide evidence of the effectiveness of Morita Therapy for depression in the UK.

Non-randomised comparative studies (n=2)

Details of non-randomised comparative studies are included in Table 1 (Appendix I). One forms part of an unpublished dissertation (Hanson, 2002).

Interventions. One study utilised the original inpatient approach, plus medication, for twelve months (Wang, Ma, Sun et al., 2000); one utilised outpatient counselling (weekly sessions over eight weeks) based on Reynolds' Constructive Living approach (1995b) (Hanson, 2002).

Sample sizes. Wang et al. (2000) included 60 Morita Therapy participants, 60 individuals with no history of psychosis and an undefined number in the other comparison group; Hanson included 80 participants (20 within each of four groups).

Participants. Wang et al. (2000) targeted patients with chronic schizophrenia, mean age 40.3 years (SD 7.8); Hanson (2002) targeted patients with depression or dysthymia, mean age 32.5 years (SD not provided, range 18-47 years).

Outcomes. Both studies utilised quantitative measures: Wang et al. (2000) measured bone mineral content; Hanson (2002) measured symptoms and level of functioning using standard outcome measures and an original drawings method.

Research methods. Wang et al. (2000) collected follow-up data after treatment and two years later; Hanson (2002) administered measures at pre-

and post-treatment. Wang et al. (2000) included two control groups who did not receive Morita Therapy: one group with chronic schizophrenia and one 'normal comparison' group with no history of psychosis. Hanson (2002) included three control groups: one received dietary brain-chemistry treatment, one received combined Morita Therapy and dietary brain-chemistry treatment, and one received no treatment.

Evidence relating to effectiveness.   According to Wang et al. (2000), there were no significant post-treatment differences between the Morita Therapy and normal comparison groups, whilst there were significant differences between the non-treatment and normal comparison groups and between the Morita Therapy and non-treatment groups (favouring Morita Therapy), although these did not persist at two year follow-up. Hanson (2002) reported that mean post-treatment scores, adjusted for pre-treatment scores, were statistically significantly better for the Morita Therapy group compared to the brain-chemistry and non-treatment groups, and for the combined group compared to all other groups.

Before-and-after studies (n=6)

Details of before-and-after studies are included in Table 2 (Appendix I). One forms part of an unpublished dissertation (Donahue, 1988).

Interventions. One study utilised the original inpatient approach alongside medication (duration undefined) (Kuroki, Tatebayashi and Tashiro, 2000). In one study, patients' significant others were trained in Morita Therapy ideas in order to treat patients at home using the original inpatient method (mean duration 72.2 days, SD 24.6) (Jiangbo, 2000). Two studies utilised outpatient counselling: one eight week intervention including the withdrawal of medication within two weeks (Tiancheng, 2000); one three session re-framing intervention based on Morita Therapy (Ishiyama, 1991). Two studies utilised group counselling interventions consisting of weekly sessions over four (Donahue, 1988) and five weeks (Mingyi, Chengjun, Zhongtang et al., 2000).

Sample sizes. Sample sizes ranged from five to 32 patients (mean 16, SD 10.3).

Participants. Three studies targeted anxiety disorders (Ishiyama, 1991; Jiangbo, 2000; Tiancheng, 2000); one cardiac neurosis (Mingyi et al., 2000); one shy adolescent females (Donahue, 1988); one social phobia and/or avoidant personality disorder (Kuroki et al., 2000).

Outcomes. All studies used quantitative measures; one added the clinician's assessment of cure or improvement (Tiancheng, 2000) and one added one hour structured qualitative follow-up interviews, although further details of data collection and/or analysis were not provided (Ishiyama, 1991). Four studies included standard outcome measures and/or author-developed outcome measures to assess symptoms; insight; social avoidance; difficulty in taking-action; confidence; anxiety acceptance; problem severity; coping effectiveness; effect of symptoms on family life, social activities and work or study. One study measured outcomes in terms of whether the patient returned to school or work (Kuroki et al., 2000) and one assessed the extent of behaviour change during treatment (Donahue, 1988). One study (Jiangbo, 2000) utilised the three point Morita Therapy rating scale. The basis on which the clinician made this assessment (whether this was purely observational or based on patients' questionnaire responses) was unclear.

Research methods. All measures were completed pre- and post-treatment, with some repeated at various intervals during treatment. Two studies included longer-term follow-ups whereby measures were completed at two and five years post-treatment (Kuroki et al., 2000) or qualitative interviews completed at 1.5 months post-treatment (Ishiyama, 1991). Various quantitative analysis methods were used, including inferential and descriptive statistical analyses and descriptive analysis of graphical data.

Evidence relating to effectiveness. The authors reported improvements from pre- to post-treatment for the majority of measures, with three studies using inferential statistical analysis reporting the majority of differences as statistically significant (Donahue, 1988; Mingyi et al., 2000; Tiancheng, 2000). In Tiancheng (2000) and Jiangbo (2000), cure was considered by the authors to have been achieved by 37.5% (n=12) and 16.7% (n=1) respectively, and improvement by 40.6% (n=13) and 83.3% (n=5) respectively. According to Kuroki et al. (2000), 75% of patients were in school or work at discharge, and

25% continued adequate social activity at five year follow-up. According to Ishiyama (1991), in follow-up interviews no patients reported emotional deterioration and all reported general improvements in their social behaviour.

Cross-sectional observational studies (n=5)

Details of cross-sectional observational studies are included in Table 3 (Appendix I).

Interventions. The majority of these studies reported outcomes from ongoing treatment centres or groups. Two reported different data from the same hospital-based study utilising the original inpatient method lasting between 25 days and six months (Suzuki, Kataoka and Karasawa, 1982; Suzuki and Suzuki, 1981). One reported outcomes from the ongoing Japanese self-help group Seikatsu-no Hakkenkai, in which members provide each other with mutual support and insights based on Morita Therapy principles (Hasegawa, 1990). One utilised group Morita Therapy for two years (Ashizawa et al., 2000). One utilised outpatient counselling consisting of weekly sessions for one month followed by biweekly sessions for an average of 11.2 weeks, and focused on understanding symptoms, modifying action, externalising attention, and guidance for practical living (Zhen-tao, Tao-tson, Ji-uin et al., 1990).

Sample sizes. Sample sizes ranged from 13, to 1287 in Suzuki's studies (1981; 1982). In Hasegawa (1990), the survey was administered to 1085 group members.

Participants. Suzuki's studies (1981; 1982) report data from Shinkeishitsu patients (mean age 26 years, SD not provided). Other patients treated included those with chronic pain (age undefined) (Ashizawa et al., 2000); those with neurosis who were still functioning at work, school or home (age undefined) (Hasegawa, 1990); those with various DSM-III-R diagnoses who were randomly sampled from patients seeking treatment (mean age 26.5 years, SD not provided) (Zhen-tao et al., 1990).

Outcomes. One study used an undefined questionnaire (Hasegawa, 1990) and one used an author-developed questionnaire to measure degree of improvement in chronic pain, satisfaction with life and effect of treatment

(Ashizawa et al., 2000). Two administered a questionnaire to assess cure and improvement according to the four-point Morita Therapy rating scale (Suzuki and Suzuki, 1981; Zhen-tao et al., 1990). The subsequent Suzuki study (1982) used life table analysis to assess the mean time taken for symptoms to improve.

Research methods. These studies used follow-up questionnaires/surveys. Two studies did not define the time point at which the survey was administered (Hasegawa, 1990; Zhen-tao et al., 1990); within the Suzuki studies (1981; 1982), the survey was sent to former inpatients at least two years (on average, 6.3 years) after discharge; in Ashizawa et al. (2000), the survey was administered to people attending the 100th group meeting celebration.

Evidence relating to effectiveness. Ashizawa et al. (2000) reported only correlations between questionnaire items. According to Hasegawa (1990), questionnaire responses suggested patients developed insight into themselves, modified self-defeating ideas, changed the focus of attention towards realistic living, and showed signs of personal growth and symptom relief. Zhen-tao et al. (1990) reported that 78.4% (n=80) reached cure or improvement; 21.6% (n=22) limited or no improvement. In Suzuki and Suzuki (1981), 71% (n=914) returned questionnaires. According to the authors, these indicated through patients' retrospective self-evaluation that, at time of discharge, 12.1% (n=110) were cured or highly improved, 66.5% (n=608) were fairly improved and 19.8% (n=181) were unimproved; and at time of follow-up, 59.4% (n=543) were cured or highly improved, 36.7% (n=335) were fairly improved and 3.9% (n=36) were unimproved. Suzuki et al. (1982) subsequently reported that at least 90% of patients improved greatly within 8 years of treatment.

Case studies (n=26)

Details of case studies are included in Table 4 (Appendix I).

Interventions. Over half of studies (n=14) utilised outpatient counselling. One combined outpatient counselling with medication and sleep hygiene education (Itoh et al., 2000). Duration was defined in terms of number of sessions attended (ranging from one to seven) or number of weeks' or months' treatment (ranging from 19 weeks to 18 months to date (treatment ongoing)). Four

studies did not define duration. Studies generally provided a narrative account of the implementation of Morita Therapy principles and techniques for the specific individual(s) treated, typically referring to Fumon, acceptance/ positive reinterpretation of symptoms and advice for constructive action-taking, sometimes within an explicitly modified form of outpatient therapy such as the conflict-focused model (Tamai and Tashiro, 1989). Two studies did not provide details of treatment aside from what was considered to be the author's unique addition to Morita Therapy: use of a narrative (Alfonso and Guthrie, 1990) or a model of mental operation (Tashiro, Tamai and Nakao, 1993).

Nine studies utilised inpatient Morita Therapy. The majority of these (n=8) involved the original inpatient approach; one did not provide details (Reynolds, 1982). Four studies provided treatment duration (ranging from 70 days to five months). The remaining three studies utilised idiosyncratic forms of Morita Therapy: therapy by correspondence over a five month period (France, Cadieax and Allen, 1995); Walking Training Therapy incorporating behavioural elements of Morita Therapy (Kurokawa, 2006); use of Morita Therapy techniques in University counselling (Jamieson, 1990).

Sample sizes. The sample sizes ranged from one to five. The majority of studies (n=20) treated a single patient.

Participants. The majority of interventions (n=15) targeted anxiety disorders, most frequently Shinkeishitsu (n=4) and social anxiety (n=4). Six studies targeted subclinical issues such as test anxiety (Ishiyama, 1983); on occasion these were aimed at specific patient populations such as school teachers with nervous disorders (Terada, Ochiai, Ohta et al., 2000), University students who were presumed to exhibit some Shinkeishitsu traits (Jamieson, 1990) and bisexual patients during the 'coming out' process (LeVine, 1991). Other presentations included childhood sexual abuse (Kelly, 1993), bulimia nervosa (LeVine, 1993a), insomnia (Itoh et al., 2000) and borderline personality disorder (Morley, 1990; Tamai, Takeichi and Tashiro, 1991). Patient ages ranged from 17 to 53 years.

Outcomes. The majority of studies reported the author/clinician's narrative observations and opinions of patient outcomes. Five studies included patient

self-report, three in the form of extracts from patients' diaries completed during treatment which were considered to demonstrate changes in patients' attitudes (Chang, 1974; Kondo, 1953; Reynolds, 1982), one in the form of the author's reiteration of changes the patient reported to them (Jamieson, 1990), and one in the form of qualitative information, although details of how this was collected and analysed were not provided (Ishiyama, 1986a). Only three studies used standard outcome measures, to assess obsessive compulsive symptoms (Tateno, Yano, Kawakami et al., 2015), the presence of eating disorders (LeVine, 1993a), and personality and self-concept (Kelly, 1993). One study used an author-developed measure of anxiety acceptance, problem severity, and coping effectiveness (Ishiyama, 1986a), and one used an undefined measure to assess the nature of inner conflicts (Tashiro et al., 1993).

Research methods. The majority of studies (n=17) detailed no research methods. All studies using outcome measures (n=5) included at least pre- and post-treatment completion of measures. Six studies included follow-ups, ranging from three weeks to 40 months post-treatment.

Evidence relating to effectiveness. All authors (who were also the treating clinicians) reported positive outcomes. Authors suggested that the narrative data indicated reductions in symptoms and increases in: acceptance and allowance of unpleasant emotions, action in the presence of unpleasant emotions, focusing attention on goals and daily activities, and recognition and acceptance of desires. Authors reported post-treatment improvements on all outcome measures, with changes said to be either maintained or improved upon at any subsequent follow-up.

Systematic/ narrative reviews (n=4)

Details of reviews are included in Table 5 (Appendix I). Two systematic reviews reported studies conducted in China, originally written in Chinese. Two narrative reviews form part of unpublished dissertations. Whilst some data from the narrative reviews may have been originally reported in English and thus overlap with data contained elsewhere in this review, Japanese and Chinese studies which were inaccessible to the reviewer formed the majority of data contained therein.

Interventions. In both systematic reviews, Morita Therapy was defined as any care practice defined as Morita Therapy by the carers and involving at least two of the four phases, with no further details provided on the interventions implemented in included studies aside from duration: from six weeks to ten months (He and Li, 2007) and six weeks to twelve months (Wu, Yu, He et al., 2015). The narrative reviews collated data from a range of interventions with variable and/or undefined durations including original inpatient treatment, modified inpatient treatment omitting bed rest, outpatient counselling, self-help groups, patients treated at school or counselling centres or by non-mental health professionals (Minami, 2011a; Nakamoto, 2010).

Sample sizes. The systematic reviews included 449 patients from six RCTs (Wu et al., 2015) and 1123 patients from twelve RCTs (He and Li, 2007).

Minami (2011a) included 49 case studies and four before-and-after designs. Nakamoto (2010) included 191 case studies, two secondary reports summarising data from other studies, and eleven quantitative studies, two of which were RCTs which are already included as primary studies in this review. The studies included within these narrative reviews were of various sample sizes.

Participants. The systematic reviews were of studies based in China with patients with unspecified anxiety disorder (aged 16-60 years) (Wu et al., 2015) and schizophrenia/ schizophrenia-like symptoms (aged 15-65 years) (He and Li, 2007). The narrative reviews included studies targeting a large variety of patient conditions and ages.

Outcomes. All reviews included a wide variety of standard outcome measures, typically evaluating symptom severity. The majority of papers in the narrative reviews also reported clinician observed or patient self-reported narrative data.

Research methods. Both systematic reviewers included all RCTs comparing Morita Therapy to another intervention and targeting the relevant disorder, and searched a variety of databases. Both narrative reviewers included any articles which contained efficacy data and searched the Japanese Journal of Morita

Therapy; in addition, one reviewer searched PsychINFO (Nakamoto, 2010). Minami (2011b) conducted a thematic analysis on narrative case study data.

Evidence relating to effectiveness. Wu et al. (2015) graded the quality of evidence as very low, noting that unclear randomisation methods, lack of blinding and low quality outcome reporting were common and, as such, that they were unable to draw conclusions as to the effectiveness of Morita Therapy for anxiety disorders. Whilst considering included schizophrenia studies to be of medium-poor quality, He and Li (2007) reported that mental state and activities of daily living did tend to improve with Morita Therapy, although data on symptoms were inconsistent.

Minami (2011a) reported six themes from narrative case study data: acceptance, symptom reduction, engagement in action in spite of symptoms, improved relationships, personality aspects, and experience of no significant effect from treatment. Each included quantitative study reported significant treatment effects. Nakamoto (2010) reported that the vast majority of included studies reported positive outcomes.

Secondary reports (n=7)

Details of papers which included brief and ad hoc reports of data collected within other studies (with no attempt to systematically identify nor synthesise studies, as per the reviews above), or those which included Morita Therapy studies alongside studies of other therapies, are included in Table 6 (Appendix I). The information below is a summary of the primary Morita Therapy studies (n=38) reported within these papers (as far as possible from the details contained within the secondary reports), which were originally published in Japanese or Chinese and thus inaccessible to the reviewer first-hand.

Interventions. The majority of studies (n=26) reported outcomes from inpatient treatment, often reporting the outcomes from ongoing treatment centres. Three employed the original inpatient approach; the remainder were undefined. Two studies reported outcomes from Morita-based group therapy and one from a Morita-based self-help group. Two reported the outcomes of a mixture of

inpatient and outpatient treatment, with no further details provided. For the remainder of studies (n=7), the intervention was unspecified.

Sample sizes. For twelve studies, the sample size was not provided. Sample sizes for the remainder ranged from three to 1317.

Participants. The patient condition was unspecified for many studies (n=19). The remainder related to Shinkeishitsu (n=14), other anxiety disorders (n=4) or post-schizophrenic depression (n=1). The age range was only specified for one study (17-46 years).

Outcomes. The majority of studies (n=17) employed the three or four-point Morita Therapy rating scale to assess cure and improvement. There was variation between studies in terms of whether these assessments were made on the basis of patient-completed questionnaires, clinical observations alone, or in an unspecified manner. Other measures included the Rorschach test (n=7), physical tests (n=2), Social Disability Screening Schedule (n=1), projective drawing technique (n=1), sentence completion technique (n=1), temperament schedule (n=1) and extraversion-introversion index (n=1). One study included mixed narrative data from clinical observations and patient self-report. Measures were undefined for six studies.

Research methods. The majority of studies (n=23) used a follow-up survey within a cross-sectional observational design. One RCT, in which a twelve week inpatient Morita Therapy intervention plus medication was compared to undefined inpatient treatment plus medication for post-schizophrenic depression, was reported as part of a meta-analysis which otherwise included studies on other therapies (De Silva, Cooper, Li et al., 2013). Eleven studies used a before-and-after design; one used post-treatment measures only; one used a non-randomised comparative design in which the comparison group received non-directive therapy; one reported mixed data from case studies. Beyond this, details of research methods were largely absent.

Evidence relating to effectiveness. According to authors' accounts using the Morita Therapy rating scale, rates of cure were between 41-87%, rates of improvement between 8-45%, and rates of either cure or improvement between

75-100%. The authors reported that narrative data suggested Morita Therapy leads to improvements in acceptance of symptoms, appreciation of desires, objective awareness, adaptive action-taking, productivity, lifestyles and social relationships; alongside reductions in maladaptive behaviours, self-preoccupations and symptoms (Ishiyama, 1988a). Other measures were reported to generally indicate positive changes, although mixed findings were found using the Rorschach test. The RCT included within the meta-analysis of De Silva et al. (2013) was reported to show reductions in social disability from baseline to follow-up favouring inpatient Morita Therapy compared to undefined inpatient treatment: De Silva et al. (2013) calculated and reported the effect size as 0.66; 95% confidence intervals 0.26-1.05.

4.4 Key findings and implications

The aim of this review was to describe the extent, range and nature of research activity reported in English in the field of Morita Therapy. Specific objectives were to map the fields of study, summarise the range of research and findings, and identify gaps in the existing literature. Two research questions were specified for RCTs: (1) what is the quality of any RCTs identified?; (2) what can they tell us about the effectiveness of Morita Therapy for mental health difficulties?

In accordance with the nature of scoping reviews, the inclusion criteria were deliberately broad (Arksey and O'Malley, 2005). A total of 66 papers met the inclusion criteria: 44 primary studies, conducted with 3268 patients in total; four reviews and seven papers reporting data from other studies, including 313 studies between them; eleven clinical impressions without any study design or in-depth patient information. The mapping and narrative organisation of studies, alongside the assessment of quality and clinical outcomes in the RCTs, highlights both the heterogeneity of Morita Therapy studies and the significant gaps and weaknesses in the research, as summarised below.

4.4.1 Mapping of included studies and gaps in research

Geographical distribution. The largest proportion of studies have been conducted in Japan, with a smaller number conducted in English-speaking

countries including the USA, Canada and Australia. However, there is a complete absence of UK-based research.

Patient population. In line with the original use of Morita Therapy (Morita et al., 1998), half of studies target anxiety disorders. Whilst two narrative reviews combine data on depression with other disorders, only two studies which uniquely target depression were identified. These include one RCT in China, originally published in Chinese and thus accessed through a secondary report of the data, targeting post-schizophrenic depression and comparing inpatient Morita Therapy to undefined inpatient treatment; and one non-randomised comparative study in the USA targeting depression or dysthymia and comparing outpatient Morita Therapy counselling to dietary brain-chemistry treatment. Thus, no RCTs: a) target depression in Western patients; b) investigate outpatient Morita Therapy for depression; or c) target depression with no history of schizophrenia.

Study design. The majority of data consist of case studies and clinical impressions, and the vast majority of studies lack control of confounding variables. Few studies ensure unbiased selection of participants, data collection or analysis; the majority of researchers reporting results are themselves Morita therapists. Thus, these studies are highly prone to bias (Burns et al., 2011). As much of this research is undertaken either within Japan or by Japanese clinicians who have transported Morita Therapy elsewhere, these findings corroborate the discussion in Chapter Three: with the 'eminence-based' rather than 'evidence-based' model of healthcare continuing to dominate in Japan, high-quality clinical research is rare (Fukui and Rahman, 2002; Isaacs and Fitzgerald, 1999; Shimoyama, 2011; Yokota et al., 2005).

Type of Morita Therapy intervention. In relation to this thesis, it is noteworthy that only group-based Morita Therapy has been tested within an RCT in the West. More generally, the ways in which Morita Therapy is implemented are highly variable and often not transparent, with few studies describing Morita Therapy in a reproducible manner. No authors refer to the use of published treatment manuals, again reflecting the nature of research in Japan in which knowledge is largely passed through generations in an 'apprenticeship system' (Bartholomew, 1989). Whilst case studies frequently describe their approach to

treatment in detail, these are highly individualised accounts with little guidance as to generalising the approach. Thus, the studies highlight difficulties inherent in defining how Morita Therapy is implemented, attempting to replicate any approach, and comparing outcomes across studies.

Measuring outcomes. Almost half of studies rely on clinical opinion or observation, which is highly prone to bias (Burns et al., 2011). A number of studies, including the majority of Japanese studies for which secondary reports were identified, use the Morita Therapy rating scale to assess whether patients achieve cure, improvement or no cure. The definitions of these categories are broad and subjective: there is no uniform definition and the meaning of 'cure' differs across therapists; the reliability and validity of these scales has not been established (Ishiyama, 1988a; Reynolds, 1976). In addition, whether these assessments are made on the basis of patient self-report or clinical judgement alone is variable and often unclear. As such, the reliability and validity of such findings is highly questionable.

There is much heterogeneity in the quantitative outcome measures administered and few of those used are reported to be validated. Less than a third of studies include standard (published) measures and, of those, few studies use the same measures; thus, studies are difficult to compare.

This review also highlights the lack of rigorous qualitative research into Morita Therapy. Authors reporting qualitative information rely on clinical observations, anecdotal patient reports or data collection and analysis methods which are not reported in sufficient detail to enable either replication or assessment of rigour. No RCTs included qualitative studies to access patients' accounts of therapy or how these relate to treatment adherence or outcomes. Thus, whilst anecdotal reports provide some insights, Morita Therapy from the direct perspective of its recipients remains largely unexplored.

Evidence relating to effectiveness. The vast majority of studies claim to demonstrate the efficacy of Morita Therapy and appear to provide some evidence of potential effectiveness. However, considering the above limitations, such results should be interpreted with extreme caution. Studies which lack control of confounding variables are liable to overestimate treatment effects,

and those subject to bias are unable to establish cause and effect between the intervention and outcomes (Barton, 2000; Cook et al., 1992; Field and Hole, 2003; Mulrow and Oxman, 1997; Sackett et al., 1996).

4.4.2 Research questions regarding randomised controlled trials

(1) What is the quality of any RCTs identified?

A limited number of RCTs in China and the USA were identified; however, an assessment of internal validity indicates that there remains an absence of unbiased evidence for Morita Therapy. The majority of quality criteria were rated as unclear or at high risk of bias and no studies were found to be of consistently low risk: two were at low risk in two out of six domains; three were at low risk on one domain. No studies reported how the randomisation sequence was generated nor the use of allocation concealment, leading to potential selection bias (Field and Hole, 2003; Higgins and Altman, 2008). One study had serious quality issues as the original participant allocation was changed. Furthermore, whilst two studies appeared to experience no attrition, other studies failed to report either rates of or reasons for attrition, with potential for attrition bias (Moran and Whitman, 2014; Robinson et al., 2007). Similarly, no studies included blinding of participants or personnel (admittedly rarely possible in the reality of testing complex interventions (Higgins and Altman, 2008)) nor of outcome assessors, leading to potential performance and detection bias (Evans et al., 2011; Higgins and Altman, 2008).

(2) What can the RCTs tell us about the effectiveness of Morita Therapy for mental health difficulties?

Whilst most of the RCTs suggest the potential effectiveness of Morita Therapy on at least some outcome measures, albeit rarely in comparison to active controls, as well as being subject to bias these studies potentially lack external validity and precision (Higgins et al., 2011). In the absence from all studies of a justification of sample size, and with sample sizes as small as eleven participants per group, the use of inferential statistics and statements is often potentially inappropriate (Coday et al., 2005; Moran and Whitman, 2014). The confidence intervals calculated around the between-group follow-up differences

suggest the majority of results are imprecise. Considering all limitations, authors' conclusions as to the effectiveness of the approach should be interpreted with caution, and this absence of high-quality research creates a significant gap in the evidence-base for Morita Therapy.

4.4.3 Implications for this thesis

Quality and methodological rigour. Whilst there is some, largely anecdotal, evidence to suggest Morita Therapy may have benefits for patients, the quality and methodological rigour of studies should be improved in order to assess the effectiveness of the approach. Alongside ensuring internal validity to enable cause and effect to be established, studies making inferential statements should be sufficiently powered to do so, and those which are insufficiently powered should take care in interpreting results with caution and reporting confidence intervals to enable the precision of results to be considered.

Standardising and manualising Morita Therapy. In the context of much heterogeneity and little transparency in the implementation of Morita Therapy, this review indicates that further work is required to standardise and manualise the approach to enable wider implementation and comparisons of effectiveness to be made across studies. Within the UK, further developmental work is required to produce a thorough treatment manual.

Testing Morita Therapy in the UK. The lack of UK-based research in the context of potential cultural differences (see Chapter Two) highlights the requirement to test Morita Therapy with a specifically UK-based population. Whilst Morita Therapy studies have been undertaken in the West, this thesis represents not only the first UK-based Morita Therapy study but the first RCT of Morita Therapy for depression in Western patients (assuming such a study would have been published in English). Indeed, given the volume of Japanese and Chinese studies accessed through reviews and secondary reports, this review suggests this thesis may represent the first RCT of outpatient Morita Therapy for depression in the world.

Other implications. The lack of understanding of Morita Therapy patients' views and experiences of the approach should be rectified through high-quality

and rigorous qualitative research, as deemed crucial in the development and evaluation of complex interventions (Craig et al., 2008). Furthermore, as few studies have examined Morita Therapy for depression, further research is warranted which assesses the feasibility, acceptability and effectiveness of Morita Therapy for patients with this specific condition.

4.5 Conclusion and chapter summary

This review has highlighted the absence of UK-based research and unbiased RCTs of Morita Therapy, as well as a lack of qualitative research and research on Morita Therapy for depression. Furthermore, this review indicates that no RCTs of Morita Therapy for depression have been undertaken in the West (assuming such studies would have been published in English). At this time, it is not possible to determine whether Morita Therapy is a feasible, acceptable or effective treatment for UK patients with depression and anxiety. To determine effectiveness, a rigorous large-scale RCT is still required. Commensurate with the MRC framework (Craig et al., 2008), prior to such a trial, preparatory work is needed to develop a thorough UK Morita Therapy outpatient protocol, determine the acceptability and feasibility of Morita Therapy for a UK population, and inform the design of a large-scale trial. To address the first point, Chapter Five presents an intervention optimisation study undertaken to develop a deliverable and acceptable Morita Therapy outpatient protocol for a UK clinical population.

CHAPTER FIVE. INTERVENTION OPTIMISATION STUDY

This chapter presents the objectives, methods and results of the intervention optimisation study undertaken to optimise the acceptability and feasibility of Morita Therapy for a UK population before proceeding to the feasibility study (see Chapters Six and Seven). Further discussion of this study, including its strengths and limitations, is presented in Chapter Eight. This study received ethical approval from the University of Exeter Medical School (reference 15/02/066) (Appendix II) and has been reported in Sugg et al. (2017) (Appendix III). This chapter is based on the published article; additional information is provided.

5.1 Study objective and research questions

The objective of this study was to develop a deliverable and acceptable Morita Therapy outpatient protocol (Appendix IV) for a UK clinical population.

This study addressed four research questions:

1. Stage One: What are the views and understandings of potential patients and therapists about Morita Therapy?
2. Stage Two: What can the English-language literature on Morita Therapy contribute to the development of an optimal draft protocol?
3. Stage Three: What are therapists' views of Morita Therapy, focusing on operationalisability and the accessibility of the draft protocol?
4. Stage Four: How should the protocol be optimised and on what should a therapist training programme focus?

5.2 Methods/ Design

5.2.1 Study design

Corresponding to the person-based approach's intervention development phase (Yardley et al., 2015a), the protocol was developed over four stages combining exploratory and explanatory components. Stage One involved in-depth exploratory interviews combining qualitative and cognitive interviewing (Willis, 1999) to investigate participants' views and understandings of Morita Therapy.

In Stage Two, the resulting qualitative themes were developed into recommendations for optimising Morita Therapy and the Morita Therapy literature was synthesised in line with these to develop a draft protocol. Stage Three involved repeat in-depth explanatory interviews with therapists, to investigate how they related to the intervention content and protocol format. In Stage Four, these qualitative themes were addressed through protocol modification and tailoring the focus of the therapist training programme.

5.2.2 Qualitative interviews: Participants and recruitment

Participants were purposively sampled to reflect the feasibility study's proposed population and account for factors deemed potentially relevant in forming views of Morita Therapy (Yardley et al., 2015a). Thus, participants aged >=18 with self-reported experience of depression, whether current or historic, and a range of previous therapy experience (potential patient sub-group) and therapists trained in complex psychological interventions such as Cognitive Behavioural Therapy (CBT) (therapist sub-group) were sampled.

Potential patients were recruited by email circulation to former participants at the University of Exeter's Mood Disorder's Centre (MDC) (http://www.exeter.ac.uk/mooddisorders/) who had consented to such contact; therapists by email circulation to current or former MDC therapists.

Sample size

In order to achieve sampling adequacy, the purpose of the study was prioritised: an estimation was made of the number of participants required to sufficiently answer the research questions by achieving both breadth and depth of information (Bowen, 2008; Gaskell, 2000; Marshall, 1996). This estimation was informed by the concept of data saturation (the point at which the analysis of more data provides no new insights about the phenomenon under inquiry) (Glaser and Strauss, 1967; Mason, 2010; Morse, 1995) and the related findings of Guest, Bunce and Johnson (2006), in which the authors systematically documented the degree of saturation over the course of the analysis of 60 interviews and concluded that saturation occurred within the first twelve interviews, after which point new themes emerged infrequently.

Whilst these findings suggest that twelve interviews could provide a thorough picture of participants' perspectives of Morita Therapy, it is difficult to determine their generalisability, and an estimation of sampling adequacy was also informed by the heterogeneity of the population and the number of sub-groups to be included in the sample (Ritchie et al., 2013). As noted, the sample contained therapist and potential patient sub-groups. Given the potential for patients' perspectives of Morita Therapy to be influenced by their previous experiences of psychological therapy, the potential patient sub-group was further divided based on this criterion. In an effort to both achieve symbolic representation across sub-groups and capture the diversity of views within sub-groups (Ritchie et al., 2013), the objective was to include a quota of five participants within each of the resulting three sub-groups (therapists; potential patients with therapy experience; potential patients without therapy experience). The final sub-group sample sizes were constrained by the number of participants meeting these criteria who were able to be recruited within the time and resource constraints of a PhD.

5.2.3 Procedure

Interviews were held at University of Exeter premises or the participant's home, depending on participant preference, and lasted between 45 and 130 minutes. Interviews combined qualitative techniques with those of cognitive interviewing (Willis, 1999).

Stage One

Interviews explored perceptions of Morita Therapy in principle and practice. Prior to interview, participants were emailed a summary of core Morita Therapy principles (Appendix II) on which they were asked to provide feedback at the beginning of their interview. In line with prior research investigating novel interventions (Johnson, Newton, Jiwa et al., 2005; Richards, Lankshear, Fletcher et al., 2006), the vignette method was then employed to elicit participants' views and understandings of the approach in practice.

Vignettes (audio-recordings) of Morita Therapy were available to the study team from a case study completed by a Morita therapist on a placement with the

University of Exeter, during which they implemented the counselling-based modal model developed during this placement (Minami, 2013). Five audio-recording clips, ranging from three to five minutes, were selected on the basis that they each captured a core element of the approach: (1) explanation of diaries; (2) positive reinterpretation/ desires and the vicious cycle; (3) normalisation/naturalisation, acceptance, metaphor use and Fumon; (4) encouraging action-taking with symptoms; (5) facilitating rest (see Table 7, p.136 for definitions of these terms).

During interviews, these vignettes were played to participants. Topic guides for potential patients and therapists (Appendix II), structured according to the order in which the vignettes were played, were based on Morita Therapy literature, the vignettes' content and prior research addressing similar questions (Richards et al., 2006). A variation of the think aloud technique (Willis, 1999) was employed, whereby participants were invited to voice their thoughts during or after each vignette, according to their preference. In practice, the majority of participants provided feedback after each. At the end of each vignette, the open question "what are your thoughts on that?" was asked to allow flexibility and enable participants' spontaneous and/or unanticipated responses to be captured (Yardley et al., 2015b).

Focused questions were also included to ensure discussion of each intervention element (Yardley et al., 2015b). Individual responses were probed to investigate participants' meanings, enabling both the exploration of participants' views on pre-defined topics of interest and the elicitation of participants' own themes (Taylor, 2011). Furthermore, explanations of Morita Therapy concepts, such as fears and desires forming two sides of the same coin (Table 7), were provided by the interviewer as additional triggers for participants' views and responses where the content of the vignettes did not convey the concept in a sufficiently clear or thorough way to enable participants to provide informed views of it. At the end of the interview, participants were asked to share any views not already discussed.

Qualitative data analysis

Interviews were recorded, transcribed verbatim, managed within NVivo10 (QSR International, undated) and analysed by HVRS (PhD candidate) using Framework analysis to enable an abductive approach (Ritchie et al., 2013). Familiarisation with the data was achieved through producing and reading transcripts. A thematic framework was developed during preliminary analysis and subsequently as batches of transcripts were analysed, iteratively combining the topic guide with the overall narratives in context. Using this framework, transcripts were coded at the individual level and analysed thematically across the whole dataset as well as in the context of each interview using a constant comparison approach (Thorne, 2000), whereby each piece of data (e.g. one statement or theme) was compared with others for similarities and differences (Miles and Huberman, 1994).

To identify any sub-group differences, the Stage One analysis was undertaken firstly for potential patients without experience of therapy, secondly for potential patients with therapy experience, and finally for therapists. Given the resulting convergence of views within similar thematic frameworks, data for all participants together were charted in analytic/framework matrices which summarised participants' views on each theme/constituent theme to allow within and across case analyses, the exploration of relationships between themes and further refinement of themes; data were abstracted and interpreted to structure and make sense of participants' perspectives (Miles and Huberman, 1994; Ritchie et al., 2013; Spencer, Ritchie, O'Connor et al., 2014). This refinement and interpretation was informed by HVRS's initial impressions of the most striking and important elements of the data for answering the research questions: these insights shaped the formation of final themes. Appendix V provides examples of this analytic process. As explanations were formulated in this way, negative cases were explored and explanations of variance provided (Dingwall, Murphy, Watson et al., 1998), ensuring perspectives which diverged from dominant themes were not overlooked (Yardley, 2008).

Stage Two

In developing the draft protocol, the English-language clinical materials describing the delivery and operationalisation of Morita Therapy, including the one available therapy protocol (the modal model) (Minami, 2013), guidelines for outpatient Morita Therapy (Nakamura et al., 2010), Morita's own account of the original inpatient method (Morita et al. (1998)) and other accounts by clinicians (Ishiyama, 2011; LeVine, 1993a; LeVine, In press; Ogawa, 2007; Ogawa, 2013) were examined as a guide to implementing the approach. Aside from Morita's original work, these sources were identified through an examination of the clinical materials produced in English by the members of the International Committee of Morita Therapy (http://moritatherapy.org/icmt-member-list/), who by virtue of this membership were known to be the key authors in the field. The volume of clinical materials to refer to was restricted by the fact that thorough protocols detailing the precise nature of how Morita Therapy is practiced are rarely developed and/or published, in either English or Japanese (Kitanishi, 2016); and no authors refer to the use of published treatment manuals within reports of their research activities, with few describing the intervention in a manner which would be reproducible (see Chapter Four).

Grounding the development of the protocol in the available clinical materials ensured adherence to the fundamental, defining features of Morita Therapy (Table 7, overleaf), considered akin to 'guiding principles' (Yardley et al., 2015b) which were essential to include in the therapy protocol and formed the basis of the intervention. With regards to elements of Morita Therapy for which multiple options were available within the literature, recommendations were developed for optimising the approach in response to the Stage One qualitative findings, and the delivery options contained in the literature which were considered most likely to address the issues raised were selected for inclusion in the therapy protocol. In addition, specific Stage One interview findings were integrated into the protocol to address participants' concerns and confusions, stress potentially valuable features of the approach and guide therapists in applying the techniques for this population.

Table 7. Key principles and practices of Morita Therapy ('guiding principles')

	Term	Definition
Key principles	Natural world	Morita Therapy conceptualises unpleasant thoughts and emotions as part of the natural ecology of the human experience. It draws upon the natural world, and the place of humans within it, to emphasise that symptoms are not subject to the patient's control, and will naturally pass with time.
	Acceptance and allowance/ vicious cycle	All emotions and thoughts are accepted as they are. Attempts to control or resist symptoms are considered to exacerbate them within a vicious cycle; therapists thus help patients to move away from symptom preoccupation and combat and towards acceptance and a focus on action. Thus, the objectives of therapy are to shift attention and perspective, rather than controlling or 'fixing' symptoms.
	Rest	Morita Therapy seeks to potentiate patients' natural healing capacities, in contrast to resisting and exacerbating symptoms. Patients sit with their thoughts and emotions as they are, to learn how they naturally ebb and flow with time if left unattended, and to build a natural desire to take action.
	Action-taking *with* symptoms	Patients learn to undertake purposeful and necessary action, with or without their symptoms. Morita Therapy thus aims to improve everyday functioning in spite of symptoms, with symptoms reducing as a by-product of moving from a mood-oriented to purpose-oriented and action-based lifestyle.
Key practices	Positive reinterpretation	Therapists 'positively reinterpret' symptoms as desires by seeing these as two sides of the same coin, aiding acceptance of symptoms as natural and inevitable. For example, social anxiety represents a desire to be accepted by others.
	Normalisation	Therapists label thoughts and emotions as 'unpleasant' and 'pleasant' but not 'good' or 'bad'. They emphasise that all emotions are natural, or normal, and will ebb and flow on their own so long as attempts are not made to resist them.
	Fumon (inattention to symptoms)	Therapists, in an effort to shift patients' attention away from symptom preoccupation and combat, will not focus on discussion or analysis of patients' symptoms or their causes, but will 'steer' the conversation towards action-taking and the external environment.
	Diaries	Patients complete daily diaries on which therapists provide comments which facilitate an acceptance of internal states and refocus attention on action and the external environment.
	Four-phased model	In traditional inpatient Morita Therapy (Morita et al., 1998), rest and action-taking are structured within four phases: 1) complete bed rest; 2) light repetitive activities; 3) more challenging activities; 4) social reintegration. The process is understood to aid experiential acceptance of the natural ebb and flow of thoughts and emotions, to re-orientate patients in nature and to refocus attention from internal to external states.

Stage Three

Interviews were repeated with the therapists from Stage One, to enable them to reflect on the development of the approach and how well the protocol addressed their previous issues, plus an additional therapist recruited in the manner described, to also capture the views of a therapist naïve to Morita Therapy. The draft protocol was emailed to therapists to read prior to their interview and the interview focused on discussing their thoughts on the protocol. The topic guide (Appendix II), based on the protocol as well as the Stage One findings, was structured as follows: therapists' first impressions of the protocol, the extent of understanding about Morita Therapy and its delivery that they had obtained from the protocol, how user-friendly they perceived the protocol to be, how the protocol compared to other therapy protocols, their views on operationalising Morita Therapy in practice, areas on which they thought therapist training should focus, and their suggestions for improving the protocol.

To elicit views on all components of the protocol, each protocol section was reviewed in turn during the interview. A variation of the think aloud technique (Willis, 1999) was employed, whereby participants were invited to voice their thoughts as they reviewed the protocol. Individual responses were probed to investigate participants' meanings, enabling both the exploration of participants' views on pre-defined topics of interest and the elicitation of participants' own themes (Taylor, 2011). At the end of the interview, participants were asked to share any views not already discussed. Interviews were analysed as described above.

Stage Four

In amending the protocol in response to the Stage Three qualitative findings, the aforementioned Morita Therapy literature was re-examined for further guidance and to ensure changes were grounded in the treatment's fundamental features. The Stage Three findings also enabled the therapist training programme to be tailored, by highlighting key issues and content to focus on.

5.3 Results

Ten potential patients were interviewed. All reported experience of depression; six had experience of psychotherapy and four did not (Table 8). The majority were female (n=8, 80%); ages ranged from 22 to 63 years. Four therapists were interviewed in Stage One and five in Stage Three. All were trained in CBT and a mixture of other treatments such as Behavioural Activation; ages ranged from 43 to 63 years.

Table 8. Participant characteristics (intervention optimisation study)

	Potential patients (n=10)	Therapists (stage 1) (n=4)	Therapists (stage 3) (n=5)
Gender			
Male	2 (20.0)	2 (50.0)	2 (40.0)
Female	8 (80.0)	2 (50.0)	3 (60.0)
Age			
18-30	2 (20.0)	0 (0.0)	0 (0.0)
30-50	4 (40.0)	2 (50.0)	3 (60.0)
50-70	4 (40.0)	2 (50.0)	2 (40.0)
Ethnic origin			
White British	10 (100.0)	4 (100.0)	5 (100.0)
Education			
<A-levels	1 (10.0)	0 (0.0)	0 (0.0)
A-levels	2 (20.0)	0 (0.0)	0 (0.0)
Undergraduate degree	5 (50.0)	1 (25.0)	1 (20.0)
Post-graduate diploma	0 (0.0)	1 (25.0)	2 (40.0)
Post-graduate degree	1 (10.0)	1 (25.0)	1 (20.0)
Doctoral degree	1 (10.0)	1 (25.0)	1 (20.0)
Mental health difficulty			
Depression	10 (10.0)	N/A	N/A
Anxiety	8 (80.0)	N/A	N/A
Continued overleaf			

Previous therapy experience			
None	4 (40.0)	N/A	N/A
Cognitive Behavioural Therapy	4 (40.0)	N/A	N/A
Mindfulness-based Cognitive Therapy	3 (30.0)	N/A	N/A
Behavioural Activation	1 (10.0)	N/A	N/A
Interpersonal Therapy	1 (10.0)	N/A	N/A
Area(s) of clinical training			
Cognitive Behavioural Therapy	N/A	4 (100.0)	5 (100.0)
Behavioural Activation	N/A	4 (100.0)	4 (80.0)
Eye Movement Desensitisation and Reprocessing	N/A	1 (25.0)	2 (40.0)
Interpersonal Therapy	N/A	1 (25.0)	1 (20.0)
Dialectical Behaviour Therapy	N/A	1 (25.0)	1 (20.0)

Notes: data are number (%)

5.3.1 Stage One Results

To reflect the convergence of views and understandings expressed by all potential patients and therapists, the results of all participants are reported together. Participants' perspectives could be understood within three key themes: translating principles into practice, respecting the individual and shifting the understanding framework. Together, these themes capture the elements of the data which were most striking during data analysis and deemed most important in considering how to optimise Morita Therapy for this population. Each key theme encompassed a number of constituent themes (Figure 10, overleaf).

Thus, the themes capture (1) the tension participants expressed between the Morita Therapy principles and how these were put into practice in the vignettes: the constituent themes of theme one essentially demonstrate the journey participants' experienced through typically identifying with the principles on paper to questioning the way these were communicated and raising challenges as to putting them into practice; (2) each key feature of the vignettes, in terms of the tone and style of the therapist, which participants typically indicated could be modified to improve acceptability; (3) the overarching sense from

participants that, in light of the comparisons made between Morita Therapy and other treatments, for the approach to be acceptable a shift in participants' paradigms and expectations must be facilitated, particularly in terms of the notion of accepting emotions and the goals of therapy.

Figure 10. Stage One Themes and Constituent Themes
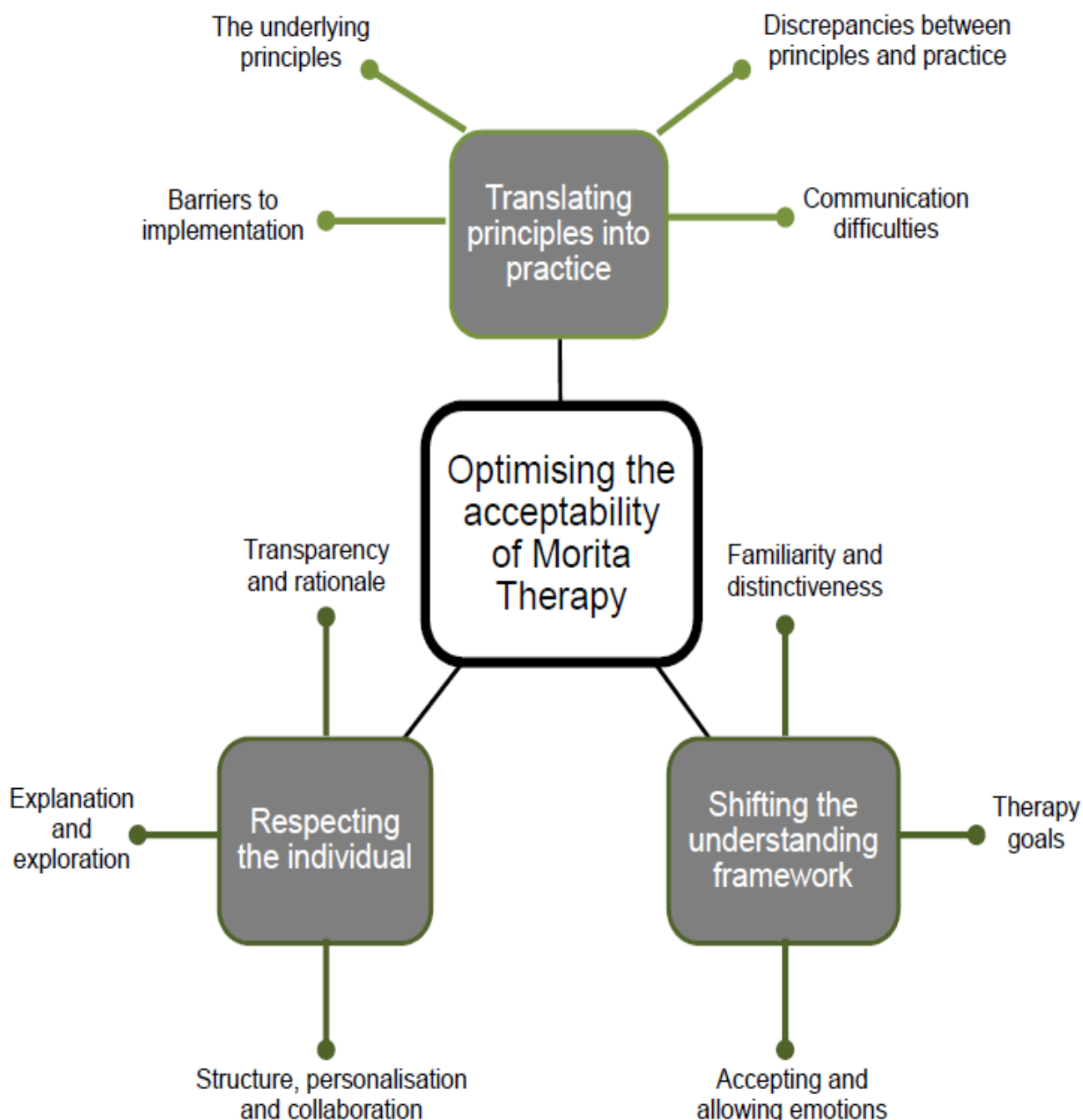
Theme one: Translating principles into practice

This theme illustrates participants' responses to the Morita Therapy principles as summarised on paper (constituent theme (a)), the extent to which these principles were considered present in the vignettes and to which the expectations they established were met in practice (constituent theme (b)). In addition, the difficulties participants identified when considering the implementation of principles in practice (constituent theme (c)) and extent to which particular features of therapy were considered to be expressed with clarity within the vignettes (constituent theme (d)) are presented.

(a) The underlying principles

Generally, having read the summary of Morita Therapy, participants responded positively to the underlying principles (i.e. desire for life; naturalness of emotion; vicious cycle; the mind's natural healing capacity through rest; focus on action-taking; acceptance of and obedience to nature), noting that these resonated with them in several ways. Firstly, participants appreciated the focus on learning to live with symptoms, acknowledging from their experiences the futility of fighting unpleasant emotions. In this way, participants considered Morita Therapy a realistic and constructive approach. For those who expressed that CBT was an unappealing approach, largely due to its perceived rigid structure and focus on changing thoughts and feelings, this was a particularly positive and preferable feature of Morita Therapy.

> I like that it's about acceptance and accepting um the bad feelings you have rather than fighting them…because it doesn't work... It's realistic. (PT02)

Participants also appreciated Morita Therapy's connection to the natural world, in both the literal and more abstract sense. Thus, participants often acknowledged that "people feel better when they're in nature" (PT03), that the use of naturalistic metaphors to describe emotions made sense (with some participants spontaneously describing emotions in such terms), and that it is helpful to see oneself as embedded within a larger whole:

> That greater sense of being one with it all… I think that's a very positive
> thing because it diffuses one's own emotion…it puts what you are going
> through in context. (PT06)

Participants also valued the way in which all emotions were considered natural
rather than some being considered unacceptable, noting that this was a
"compassionate" (PT03), humane and inclusive approach which helped reduce
negative judgement:

> I subscribe to the principles around emotions being a natural
> phenomenon…It bodes well if the emphasis steers away from seeing
> emotional experience as a negative, wrong thing. (TH04)

The idea of desire for life, the concept of emotions existing as two sides of the
same coin (with fears or unpleasant emotions being a reflection of underlying
desires), and the explanation of the vicious cycle were all features participants
noted made sense and resonated with their personal experiences:

> It does get into a cycle…it almost feels easier to feel sad…you do
> generally go over and over the unpleasant things. (PT08)

Participants also valued the use of rest and the concept of the mind's natural
healing capacity, appreciating the need for recuperation and noting that this was
a feature missing from other therapies:

> Giving yourself a bit of space…I don't always think there's that in other
> kinds of therapies, there's not that kind of re-charging space um yeah,
> that's nice. (PT02)

Thus, in theory, the principles of Morita Therapy, particularly the connection to
the natural world and concept of 'living with' symptoms, resonated for
participants and largely received positive feedback.

(b) Discrepancies between principles and practice

A sense of a lack of explicit and apparent translation of the principles into
practice (i.e. the therapy as delivered in the vignettes) was expressed upon
participants listening to the vignettes. For some, it was unclear in general which

principles were being communicated: "I have no idea what he was trying to get across there." (PT01). Other participants commented on how the practice did not meet their expectations of therapy established by the principles, expressing disappointment that certain appealing features were absent from the vignettes. This related particularly to the theoretical focus on the natural world, with participants also surprised not to hear the use of naturalistic metaphors in practice: "I liked the nature thing, but I didn't hear that brought in." (PT09).

These discrepancies between principles and practice led to a sense of participants being unsure what Morita Therapy was based on or communicating overall:

> I don't think that [the vignettes] matched this [summary of principles] at all, really, so I'm going away from this…still wondering what Morita Therapy is. (PT07)

With regards to rest, the use of rest as explained within the vignettes (including a marathon metaphor) did not meet participants' expectations of rest as informed by the principles, and served to confuse or lead participants astray in their interpretation of the meaning of rest.

> What I construed from what I read is it's more like actually if you don't feel able then rest should be the mainstay of what you're doing, rather than an hour in your day or a few minutes in your marathon…I feel slightly less clear about the use of that natural healing. (TH04)

A lack of information and clarity around rest provided within the vignettes led some participants to explicitly note that the purpose and conditions for rest were unclear. Some therapists noted the danger of misrepresenting rest as a form of "relaxation" (TH01), whilst potential patients often began to misconstrue the purpose of rest in these terms: as a relaxing break from unpleasant thoughts and feelings, as opposed to an opportunity to experience their natural ebb and flow. For such participants, their further considerations around how to implement rest revolved around this misinterpretation, with participants suggesting tools such as mindfulness techniques (PT06) for inducing relaxation.

> That's what people sort of artificially do by the aid of medication, shut you
> down and so I think it's good to find natural ways in encouraging that
> rest, relaxation. (PT03)

The sense that there was a discrepancy between the principles and practice in general was related to the view that Morita Therapy in practice is a subtle approach, with the principles being implicitly incorporated into the therapist-patient dialogue within the vignettes rather than explicitly discussed. For potential patients, this subtlety may have contributed to the view that it was unclear what the treatment was really about. Following several vignettes, however, some participants began to recognise some of the techniques being implemented:

> [I]t's implicitly doing that thing of boosting their…you know, 'you are
> being very productive, you are getting a lot done, you do love and care
> for your children'… doing that underneath, which I quite like. (PT09)

Therapists were more able to recognise the subtlety of the approach and thus more able to read into what was happening in the vignettes. Thus, at times, therapists contradicted the view that the practice failed to match the principles, with TH03 noting that the therapy "was translated well into practice". Nonetheless, in practice, a more explicit connection to nature and explanation of rest in particular were desired by participants in general.

(c) Barriers to implementation

For several features of therapy, participants acknowledged their value in principle whilst proceeding to note multiple difficulties around committing to them in practice. For example, some participants described keeping diaries as "overwhelming" (PT02), "threatening" (PT06) and "daunting" (PT04), with a particular concern around not being able to communicate thoughts and feelings coherently. In line with this sense of insecurity, participants also noted the need for reassurance that the diary was being completed "correctly", and potentially a more structured diary to guide them. Sometimes these concerns were specific to the fact that participants would not receive the therapist's comments on their diaries until the following week:

> At your first meeting you would probably hope that prospectively he would, you know, take a minute to review some of it and give you a bit more feedback so as you knew what you were doing. (PT01)

Participants also noted a number of practical difficulties, such as memory problems, tiredness and dyslexia. Such difficulties were unique to one or two participants, suggesting the need for a personalised and flexible approach to identifying and working with the individual's concerns and capabilities. Therapists also noted some concerns around commenting on diaries, highlighting the need for further guidance around the nature of these comments:

> It's like when you went school and you had your homework handed in… certainly some of the early comments can be what we might call really, um, defining comments… that's a key for our training. (TH01)

Whilst participants recognised the value of focusing attention on and encouraging action-taking in spite of symptoms, they also expressed tension between whether or not it is possible, realistic and/or helpful to take action despite emotions, noting that their emotions were "debilitating" (PT05).

> My emotions do sometimes completely wipe me out and it says…you don't have to live by your emotions… actually I have not been able to do that… But I now realise that, well that's how you never get better…you can feel rubbish and still get something done and it does help. (PT03)

When considering the implementation of rest, participants again envisaged several struggles. These typically centred on practicalities such as time, although fears of worsening rumination and difficulties 'sitting with' unpleasant thoughts and feelings were also noted.

> What would a therapist do if somebody's doing this and they find it intolerable to be at the mercy of their thoughts… it might be too much. (PT06)

Participants also noted that taking rest would induce feelings of guilt, and thus highlighted the importance of stressing the purpose and permissibility of rest,

exploring the reasons why people might feel guilt, and drawing a parallel to physical illness for which it may be considered more acceptable to rest.

> You can see yourself as a slacker or a quitter and all those things are very negative…it's all about 'how many hours do you work'…everybody is totally wired that way, so it's going the opposite. (PT03)

Furthermore, in terms of engaging in both rest and action-taking, participants sought more structure and clear timeframes. Therapists expressed confusion and concern around how these opposing states should be balanced, and how to know when "enough is enough" in terms of rest (TH04).

> Um, dealing a little bit with this like paradox with action and also inaction, which is new… What are the parameters of rest, how is it structured…I'd like a little bit more structure around once you got to action. (TH01)

Thus, participants noted practical constraints and sought specific frameworks, alongside expressing a sense of insecurity, fear and, at times, scepticism, for elements of therapy such as the diary, rest and action-taking.

(d) Communication difficulties

In listening to the vignettes, participants sometimes misinterpreted or were unclear as to the messages being conveyed, creating a sense of confusion and some disagreement. This was significantly experienced in relation to the concept of fears and desires (or unpleasant emotions and 'positive' attributes) forming two sides of the same coin: although valued in theory, the translation of this concept into practice using the positive reinterpretation technique was subject to mixed views. Participants did value the way in which this "flagged up the qualities of the patient" (TH03) and put a "positive slant" on difficulties (PT08). Some participants were even able to reinterpret their own experiences in accordance with this:

> I really like this coin thing…it made me think of when my brother came to stay…I was just really anxious because I just cared too much... it's almost like the more anxious you feel the more important it is, and that's certainly making me think. (PT02)

However, a lack of clarity and specificity in positive reinterpretation led participants to an over-generalised conception of the two sides of the coin, whereby all positive emotions and experiences were viewed as present on one side alongside all negative emotions and experiences on the opposing side, appearing to induce an (inaccurate) interpretation of the message as 'life generally involves both good and bad' and one should 'look on the bright side'. This led to some confusion and disagreement, with the message largely lost that specific unpleasant emotions (or fears) are direct inevitable reflections of, and contingent upon, specific qualities (or desires).

> There's always a positive and a negative with everything, and that's like two sides of the coin…I'm unemployed at the moment, which is a negative thing, but I've tried to say to people well on the positive side I've had this experience which has taught me to learn how to deal with the whole situation. (PT10)

Participants also experienced a lack of clarity that emotions but not situations themselves were being reframed as positive, and a lack of specificity in reinterpreting emotions associated with depression as opposed to anxiety.

> I remember somebody saying to me once 'nothing is either good or bad, it's the way we react to it'…What I was going through with my parents…I'd be very interested to see how anybody could reframe [that] for me in an acceptable way. (PT06)

When the concept of the two sides of the coin was explained by the interviewer with an increased level of clarity and specificity, participants expressed a clearer understanding of and more positive response to this concept. Thus, whilst participants expressed some confusion and disagreement in response to positive reinterpretation, there was potential to recommunicate this message in a more helpful manner.

Theme two: Respecting the individual

This theme captures the extent to which Morita Therapy as delivered within the vignettes was considered be a well explained, transparent and individualised approach. Some absence of this led to a sense of unease and a struggle to

relate to an approach participants considered somewhat superficial and oversimplified. This is discussed in relation to the provision of transparency and rationale (constituent theme (a)); exploration and explanation of patients' individual difficulties (constituent theme (b)); therapy structure, collaboration and personalisation of techniques (constituent theme (c)).

(a) Transparency and rationale

Participants expressed a view that, within the vignettes, there was a lack of disclosure as to the pathway or process of therapy being followed. There was a suggestion from therapists that this lack of involvement of the patient in the therapy plan and expected treatment outcomes may be related to the culture in which Morita Therapy was developed, and that in translating the therapy to the UK this may not be an acceptable approach:

> [I]t sounded like a very culturally defined way of working…that goes to underlying philosophies or logic of the culture where there's a stronger belief in Taoist or Zen type ways of life…that's all very much going with the flow, here we're not and what people are often, you know, they always wanna know what they're signing, what the small print is. (TH01)

In actuality, potential patients expressed mixed views as to whether this lack of transparency was acceptable or not. Those who did not have prior experience of therapy were more open to this approach and the notion of 'trusting your therapist', finding the amount of rationale sufficient and acknowledging that further explanation might entail "second guessing" by the patient (PT02; PT04).

> This therapist here obviously knows something I don't but I'm open, I mean I'm open to trying anything but it's like they know something that isn't just going by textbook. (PT10)

However, participants who had previous treatment experience or positive views of CBT, as well as the therapists, expressed the need for full disclosure as to the overall therapy plan and discomfort with the absence of this, perhaps reflecting their expectations of treatment as shaped by other approaches in which such transparency is provided.

> It's a bit sort of open-ended, too open-ended, I felt he should [say] 'look, we're going to do this'… explain a bit more of the plan. (PT07)

For such participants, there were also specific therapy features for which it was felt that further rationale provision was necessary to explain why patients were being asked to undertake potentially challenging activities, such as rest and diaries:

> As human beings, we need to know, we need to understand, and by explaining something that's showing respect…they're asking you to do something which you might find difficult…a bit threatening. (PT06)

Similarly, a view was expressed that the therapist should explain Fumon (therapists' inattention to symptoms) early in therapy to prepare patients for its use and underscore its purpose in moving patients away from the vicious cycle:

> Maybe that is about giving some education upfront before you start the therapy which is…'often people might come into therapy wanting answers, wanting a deeper understanding, but sometimes that in itself can perpetuate problems…and therefore to anticipate that you might feel that's not addressed in the therapy, but come into it anyway'. (TH04)

In line with these views, it was suggested that if it is a necessary to manoeuvre therapy without the patient's full awareness, it would be respectful to alert the patient to this and request that they have faith in the process:

> Even saying 'now look, what we've been saying, this might not make sense to you but there's a reason why we're not going into a full explanation…if we could just go with it and trust the process'. (PT06)

Thus, whilst participants expressed mixed views on the need for increased transparency during therapy, they also suggested that the provision of additional explanations and justifications might address any discomfort experienced by the patient in relation to this.

(b) Explanation and exploration

Overall, participants expressed a view that the patient as an individual was not sufficiently explored within the vignettes, nor were adequate responses to their questions provided, leading to feelings that the approach was somewhat repetitive, "crude" (PT07), and lacking depth and space for the patient.

> The therapist was quite overwhelming really, he mentioned lots of examples…if he'd just mentioned one example and explored it with her, that would have been more fruitful. (TH03)

With regards to Fumon (inattention to symptoms), the implementation of this led some participants to view the therapy as potentially "dismissive" (PT02) and lacking due acknowledgement of patients' difficulties. Similar views were expressed in relation to the normalisation technique:

> That example slightly trivialises what it feels like to be anxious…[It's] a little bit flippant…[and] patronising. (PT03)

Potential patients appeared to receive this technique within a particular understanding framework in which some emotions are considered 'healthy' and others 'unhealthy'. The blanket approach within the vignettes towards stating that all emotions are 'normal', rather than encouraging participants to re-evaluate the latter, led them to assume the therapist was referring only to the former: emotions they already considered healthy or 'normal', and therefore required no intervention. Thus, potential patients expressed a sense that normalisation was not applicable to the severity of their difficulties:

> It's as if he's talking about just uncomfortable feelings, about being nervous or worried about something, it was somehow at that…superficial, like natural level…he wouldn't be touching my experience at all. (PT06)

These views were exacerbated by the examples of anxiety utilised within the vignettes. In the absence of clarification that these were intended as either metaphors for the function of anxiety or explanations for the origin of anxiety, examples such as the anxiety a person feels if they almost drop a baby were

interpreted literally by participants, who thus noted that if they only experienced anxiety in such 'normal' circumstances, they would not seek therapy.

> There's a healthy level and an unhealthy level… using analogies like dropping a baby, I mean that's normal for everybody whereas if she's worried about just opening the front door 'cos she thinks a burglar's gonna come in, that's not really so normal. (PT08)

Thus, participants expressed the need to distinguish between 'healthy' and 'unhealthy' levels of distress, and perhaps express these along a spectrum in order to enhance the relevance of the normalisation technique as a means of validating the origin and function of such emotions. Additionally, participants felt more in-depth explanations of why differences exist between people, and how 'normal' levels of distress become exacerbated into 'severe' levels, would be helpful. Participants suggested that such explanations could be usefully provided whilst staying true to the Morita Therapy principles, through reference to the functionality of emotions, vicious cycle and two sides of the coin.

> Do the normalising of emotions…how fear allows you to be protective of yourself…that being the flip side of the coin…but I might do a bit more illustrating of 'but the reason why you're here is because some of that, you're bringing in lots of judgments on yourself about the anxiety you're having' and then bringing in that vicious cycle. (TH04)

When, as suggested, unpleasant emotions were explained by the interviewer in terms of positive reinterpretation and the vicious cycle, participants expressed a clearer understanding of the Moritian perspective which appeared to appease their sense of being dismissed. Thus, whilst difficulties were noted around a lack of exploration and explanation of the individual patient's difficulties, particularly during normalisation, suggestions were made for circumventing these issues through reference to other Morita Therapy principles.

(c) Structure, personalisation and collaboration

Participants generally expressed positive views of the lack of clear structure and script in the vignettes, noting that the approach had a more open and fluid style than they would expect from treatment: "It's quite liberating… I like the idea of

having a bit more of a fluid therapy" (TH04). For potential patients who had no prior experience of treatment or expressed negative views of other treatments, this was related to a sense that the approach was more gentle and personalised in comparison to other therapies, with the style described as conversational or "like good advice" (PT04).

> This one seems more personable, rather than scripted, which is quite nice, it feels like it's more reactionary towards the person rather than 'today we're going to cover these ten things on my plan'... It seems like a really friendly way of talking about it. (PT01)

However, therapists and potential patients who expressed positive views of other therapies noted that the approach was lacking in personalisation and collaboration, with suggestions that this may be an issue of cultural translation and an area in which therapists require more guidance.

> I see this as the wise sage, guru in the room with somebody who's, you know, stroking their beard and giving out wisdom and we've, our orientation over the years has been much more collaborative. (TH01)

With regards to the use of metaphors, therapists were keen to personalise these more in practice. Potential patients indicated the value of this in making metaphors relatable to their experiences, noting metaphors can otherwise be "frustrating" (PT07). There were several other specific ways in which participants considered that more personalisation and collaborative working should be incorporated, relating to the lack of exploration of the individual's particular experiences, the need to receive feedback from the patient and confirm their understanding, and the need to allow patients the space to answer questions and provide examples for themselves.

> The therapist says quite a lot and doesn't check in to whether the client understands… Allow her to identify it more. (TH03)

When participants, especially therapists, recognised the therapist and patient engaging in a more collaborative and individualised process, they valued this approach:

> I loved the way he drew stuff out of her to illustrate the two sides of the
> coin yeah, I felt that was really well done…the way he stayed with what
> she was saying, and reflected it back. (TH03)

Thus, whilst suggestions were made for improving the extent of personalisation
and collaboration in the approach, participants also valued the individualised
manner in which some discussions were undertaken, as well as appreciating a
lack of script and directive structure within the vignettes.

Theme three: Shifting the understanding framework

This theme reflects the extent to which Morita Therapy was considered a
distinctive approach in comparison to other therapies (constituent theme (a)),
and to which participants considered Morita Therapy to converge with their prior
expectations about what constitutes effective therapy. This is discussed with
particular reference to the Moritian perspective on emotions (constituent theme
(b)) and the goals of Morita Therapy (constituent theme (c)). The related need
to deconstruct patients' frames of reference and shift their expectations of
treatment in order to helpfully present Morita Therapy to them is considered.

(a) Familiarity and distinctiveness

Participants noted several ways in which both Morita Therapy overall and
certain features of the approach appeared familiar or distinct from other
therapies, which often appeared to form the basis of their interpretation and
understanding of Morita Therapy. Overall, therapists acknowledged Morita
Therapy as a novel and potentially "frame-shaking" (TH01) approach with a
distinctive cultural framework, noting the uniqueness of the underlying
philosophy in terms of de-focusing attention on the self, engaging in rest rather
than immediate action-taking, and allowing emotions to run their natural course
rather than fighting them. Thus, therapists recognised a necessary shift in
culturally-based preconceptions, noting challenges they felt they may face in
delivering these messages to patients.

> The whole idea of decentralising the focus on the self, which is a very
> Western kind of philosophical preoccupation…I thought was very
> good…Seeing oneself embedded within nature and going with the

rhythm, the natural flow of the world and sort of the environment around you, is different. (TH02)

Related to this underlying philosophy, participants also noted the appeal of a therapy which takes a more "spiritual", "holistic" (TH03) and anti-diagnostic approach:

> I like the idea that this is very open, whereas sometimes other therapies you go and talk to people, and as soon as you say something that sounds similar to this category, you must be in this category…it's all very <u>defining</u>, whereas this isn't defining you or saying 'you're this, that or the other', it's just 'this is life'…I prefer it for that. (PT08)

However, potential patients were less likely to note the distinctive philosophical framework underlying Morita Therapy, often interpreting Morita Therapy through the lens of other treatment modes and attempting to 'fit' the approach into those principles. Thus, participants, particularly those with positive views of mindfulness, often considered Morita Therapy as similar to mindfulness and suggested that mindfulness techniques may be incorporated into the approach, suggesting they were seeking ways in which Morita Therapy converged with an approach which already appealed to them:

> It obviously links in very much with mindfulness which is about not judging… I like the way it's like an extension of mindfulness. (PT06)

Alternatively, participants with positive views of CBT attempted to extract aspects of Morita Therapy which appeared consistent with the CBT model, and were thus more inclined to perceive Morita Therapy as an approach somewhat similar to CBT. In such cases, the distinctive philosophy of Morita Therapy which could not be interpreted in line with the theory of other therapeutic approaches caused some confusion:

> It seems like a weird sort of hybrid of CBT and mindfulness, but with a bit of nature stuff and spirituality thrown in…like it wants to be a little bit CBT, but it wants to stick to its tradition, and it's confused itself so therefore I'm confused. (PT09)

Some specific features of Morita Therapy were also perceived as familiar from other approaches. Participants' (mis)interpretations of the nature and purpose of such features demonstrated how these understanding frameworks can lead to some inaccurate assumptions. In terms of action-taking, some participants assumed Morita Therapy would involve "working towards specific goals" in a similar manner to Behavioural Activation (TH02). Similarly, participants had several misconceptions about the diary, such as assuming that the patient should record only negative thoughts and feelings, and/or that the objective was to uncover patterns between actions and feelings.

> I assumed the negative actually, so if I then sat down at the end of the
> day and I thought 'right, how do I feel about myself'…I would think 'well, I
> did that wrong'. (PT08)

These ways in which Morita Therapy presented to participants as similar to, or distinct from, other approaches appeared to provide a specific framework of expectations and understandings in which they came to view Morita Therapy, thus providing context for this whole theme.

(b) Accepting and allowing emotions

Potential patients expressed tension between a willingness to accept and allow emotions, as encouraged by Morita Therapy, and seeking tools or techniques to change emotions. As noted above (theme one: translating principles into practice), in principle participants responded positively to the notion of accepting unpleasant emotions as a natural and universal phenomenon, appreciating the permissibility of unpleasant emotions and futility of fighting them. However, potential patients appeared to agree with these messages to only a certain degree, with objections being raised and confusion caused as they experienced the full extent of these principles as implemented in the vignettes. Many such views were contradictory to the positive responses towards Morita Therapy's principles, although potential patients did not appear to recognise this.

> If I was coming in and was on, you know, my eighth week of therapy and
> I was still experiencing all my things and you're just saying it's okay and
> it's normal and it's a sort of Buddhist thing you know, you have to

experience the pain and all of that goes with it, okay I get it but I'm still experiencing all of it… That's great as a theoretical spiritual discussion, how are you gonna make me any better. (PT09)

Thus, from the presentation of normalisation, potential patients appeared to value the message that unpleasant emotions were *permissible*, but did not appear to go so far as to recognise that such emotions were *inevitable*. Similarly, potential patients seemed to accept that such emotions would arise, but continued to expect guidance on how to subsequently 'deal with' them:

> Worry is going to be there, it's how you deal with that, that's quite nice…do you put your effort into worrying about the fact you're worrying or do you put your energy into what can I do anyway, either to appease the worry, get rid of the worry, [or] work out how to fix it. (PT01)

Thus, there appeared to be a distinction for potential patients between *accepting* that unpleasant feelings would occur, and *allowing* them to run their natural course without interference. Such interpretations indicated possible constraint by prior understanding frameworks, with potential patients viewing the therapist's meaning through a particular lens of definitions and distinctions. Thus, the Morita therapist and the potential patients did not appear to ascribe the same meanings to concepts such as 'acceptance' and 'normality'. This may be due to the use of 'acceptance' within other approaches such as mindfulness, which convey the message that unpleasant emotions will occur whilst concurrently providing guidance on how to intervene in them. Thus, potential patients distinguished between 'fighting' emotions (which they agreed was unhelpful) and 'managing' emotions (which they did not consider to be mutually exclusive with accepting emotions), further indicating that 'acceptance' for these participants did not extend to include 'allowance' as intended from a Moritian perspective.

> The way it says to work with your moods, I found that the most helpful because if you're really distressed about something actually fighting it doesn't get you anywhere…[later in interview]: So it's finding ways of managing that anxiety, which I presume he's gonna talk about. (PT03)

Unaware of the distinctive meanings held by the therapist, potential patients were inclined to note that they were already aware of the messages being conveyed, leading them to somewhat disregard these as unable to provide any new understanding, and to continue to seek solutions to the 'problem' of unpleasant emotions. Thus, potential patients expressed a somewhat inconsistent sense of accepting their unpleasant emotions as normal whilst noting that this did not make them feel better, and thus seeking concrete tools or techniques to do so.

> Trying to pretend like it doesn't exist and trying not to feel like that is, that doesn't work, it's just kind of accepting it…[later in interview]: It does help but it doesn't stop you having those feelings…I know it's normal, I know it's natural but…it's like, how do I sort that out, how do I limit it. (PT02)

Therefore, potential patients had difficulty shifting their approach towards unpleasant emotions in line with the Moritian perspective that they must be lived with: their desires to not feel this way were raised in contradiction to their own recognition that such feelings were a natural part of human life. This may have been a demonstration of a culturally bound sense that one can or should be able to override the natural way of things, if only they are taught the right tools to exert their control:

> I'm always a person who prefers to be told that I have entire control… I like having a technique and practising it and seeing change and feeling control over the way that I think and feel and all of that, so for people like me it might sit a bit uncomfortably. (PT09)

This seeking a means of control was expressed particularly strongly by potential patients who expressed positive views of mindfulness or CBT. Such participants were particularly prone to suggesting that mindfulness techniques could and should be incorporated into Morita Therapy as a means of managing emotions. Thus, overall, within their current frameworks of understanding and expectations, potential patients struggled to identify, appreciate and value the extent of the messages conveyed within Morita Therapy.

(c) Therapy goals

Related to the views around accepting and allowing emotions are the pre-conceptions participants held around what the goals or outcomes of effective therapy should be. For Morita Therapy, the purpose is to improve everyday functioning and live constructively in spite of symptoms. Despite potential patients' positive views of the holistic and anti-diagnostic nature of the therapy, they struggled to adopt this approach when considering the value of the therapy overall. Thus, potential patients tended to focus more narrowly on mood-orientated goals: the purpose of therapy is to feel better.

> I would see them really struggling when they don't even have anything to sort of grasp onto…they're still not feeling any better…it will be interesting to see if it works because initially I would say it wouldn't. (PT09)

Accordingly, the only way in which some participants appeared to be able to conceptualise therapy was as something providing an explanation for difficulties and/or a set of techniques to directly manipulate emotional experience; a therapy which does not offer this proved confusing, disquieting and insufficient, a view again reinforced by favourable views of other therapies.

> I can understand he's saying 'look, you're fine because you're getting on with your life and you're doing all these things and, you know, isn't that marvellous' and she's, but you're still worried, um so I don't really know, I don't really understand what it's about. (PT07)

The specific features of Morita Therapy were thus interpreted within this understanding framework that the goal of therapy is to improve mood: the components of therapy were considered as a means to this end. Thus, despite guidance on the alternative functions of such features, participants were rarely able to recognise the value of them, either in themselves or as a means of changing one's perspective or goals. For example, participants often interpreted the therapy's connection to the natural world as a literal engagement in nature for the purpose of improving mood. Similarly, PT02 considered rest

and action-taking as potential skills to manage anxiety, and struggled with the concept of shifting the goal towards constructive living:

> [A]ctually doing is an irrelevance...you have got to find some way of dealing with this question of 'why the hell are we here', which needs to be answered before you can be productive. (PT02)

However, potential patients who did not have experience of other therapies more often noted the value of such aspects of therapy in themselves. Generally, these participants valued the ways in which the therapy provided insight and changed one's perspective, enabled understanding of emotions without necessarily changing them, helped shift the focus of one's attention, and potentially changed one's relationship to emotions.

> I think it gives you more scope to understand where they land…And possibly why you are thinking like that…As opposed to saying that, you know, this can all change. (PT01)

In line with this, PT09 in fact shifted their own perspective somewhat over the course of the interview, coming to a more Morita-congruent understanding of the approach:

> I like the um, it's like 'things aren't perfect, you have this anxiety, but you get stuff done', and it's like just focus on that, cos you can't do anything about that…it's good, it makes sense…there's all these 'if you change your thoughts you'll change your feelings' but that doesn't always apply, and I think that's sticking in the trying to change a thing that you can't change…it's all about kind of acceptance and learning to live with and doing things despite and I guess the hope that the more you do that, the less impact it has. (PT09)

Similarly, therapists recognised the techniques being implemented in the vignettes, and the value of therapy in providing insight:

> It's quite clever I guess, I mean he's getting her to recognise the value of certain emotional and cognitive aspects of people's experience which people generally evaluate as being negative… This is an intervention to

try and get her to change her, how she actually um, her relationship with her emotions I think, which is good…to reframe her experience and…re-focus her attention on different aspects of her ongoing experience and get [her] to start to appreciate and value that. (TH02)

These struggles with and interpretations of the purpose and objectives of Morita Therapy highlighted the need to be explicit about the goals of the approach; in particular, the ways in which these may differ from patients' prior experiences and expectations.

Summary of Stage One Results

The Stage One qualitative findings indicated that the core Morita Therapy principles were largely acceptable to participants, albeit with potential for improvement in how these are conveyed and structured in order to enhance the relevance, comprehensibility and appeal of the approach. Theme one demonstrated the tension participants expressed between the Morita Therapy principles and how these were put into practice in the vignettes, with participants highlighting some disappointment with perceived discrepancies between principles and practice, and indicating both barriers to implementing elements of Morita Therapy such as rest and some failure of the vignettes to accurately communicate positive reinterpretation. Theme two demonstrated key features of the vignettes, in terms of the tone and style of the therapist, which participants typically indicated could be modified to improve acceptability. Highlighted was the need to enhance the transparency, individualisation and depth of the approach to ensure participants feel acknowledged and respected. Finally, theme three demonstrated the overarching sense from participants that, in light of the both the distinctions and similarities noted between Morita Therapy and other treatments, there is a need to shift participants' understanding frameworks and carefully manage their expectations of treatment in order to optimise the acceptability of the approach.

5.3.2 Stage Two Results

The Morita Therapy literature demonstrated a range of potential options and methods for implementing, communicating and structuring the key features of

Morita Therapy, which were thus open to tailoring to the target population. Overall, the delivery options could be considered to fall along a spectrum (Minami, 2013) from prescriptive inpatient settings adhering to a four-phased experiential structure (Morita et al., 1998) to exploratory outpatient counselling methods with no such structure, such as the active counselling method (Ishiyama, 2011) and modal model (Minami, 2013) (as presented in the vignettes), which apply and extend the guidelines for outpatient Morita Therapy (Nakamura et al., 2010).

In developing the therapy protocol, the variety of options available in the literature were selected from in accordance with recommendations refined from the Stage One qualitative themes, which shaped the design of the therapy protocol in multiple ways (Tables 9 to 11, overleaf).

Table 9 overleaf

Table 9. The use of Stage One findings to inform Stage Two therapy protocol development:

Theme one (Translating principles into practice)

Constituent theme(s)	Recommendations for therapy protocol development	Incorporation into therapy protocol design
The underlying principles; Discrepancies between principles and practice Definition: In theory, the Morita Therapy principles, particularly the connection to nature, resonated positively for participants. However, a lack of explicit translation of these into practice (i.e. the vignettes) was expressed, with confusion caused as to the nature of Morita Therapy.	Enhance the core components and overarching structure of therapy to clarify the essence and process of Morita Therapy and facilitate the incorporation of key principles in practice. Strengthen the use of nature in practice, as a positive feature for participants and a key principle of the approach.	Core components were clearly delineated in an introductory section, to help ground therapists in these. Therapy was structured according to the four-phased experiential approach; clear guidance on managing expectations was included in which this structure is made explicit to patients at the start of therapy. The central role of nature was incorporated throughout/ stressed in the "role of the therapist" section. For therapist techniques and treatment phases, guidance was provided for bringing nature into practice: example nature metaphors; examples for engaging with nature; guidelines for discussing humans' place within nature.
Barriers to implementation Definition: Participants noted difficulties around implementing several features of therapy in practice; desired specific frameworks for elements such as the diary, rest and action-taking; and indicated some misunderstanding of rest.	Therapists should be alert to the difficulties patients may face regarding diaries/ rest, and approach these with reassurance and flexibility. The function and importance of these features should be stressed, to encourage patients to overcome challenges. Structure is required to provide clarity on the timeframes for rest and action-taking, and to address the issue of patients feeling incapacitated by depression.	Potential fears/ barriers to engagement were highlighted, alongside guidance on managing these. Guidance was included on stressing the rationale for, function and importance of these features. For rest, this was done with particular reference to drawing on physical health analogies and natural metaphors. The use of a phased approach provided structure and, as opposed to strict timeframes, included guidelines on the indicators for progressing to the next phase.

	The diary exchange should allow time to thank the patient, check their understanding of the therapists' comments and provide further guidance on completing the diary where needed. Therapists require clear guidance for commenting on diaries.	Clear guidelines for commenting on diaries and the process of diary exchange were provided.
	To avoid misinterpretation of the meaning of rest, the rationale should be made clear to patients, and the conditions specified in detail.	Thorough guidance for rest was incorporated, including instructions and conditions; warning points for potential misinterpretations; guidelines for managing expectations, preparing patients for the experience and managing any patient guilt.
Communication difficulties Definition: The positive reinterpretation technique created some confusion and disagreement in practice.	The purpose of positive reinterpretation should be made clear to therapists to facilitate its correct implementation. More clarity/ specificity are required to convey the intended message and provide explanations for patients' specific issues.	Guidelines on the purpose/ use of positive reinterpretation were provided, including warning points/ specific examples of how positive reinterpretation may be misunderstood and for how the experience of depression should be deconstructed.

Table 10. The use of Stage One findings to inform Stage Two therapy protocol development:
Theme two (Respecting the individual)

Constituent theme	Recommendations for therapy protocol development	Incorporation into therapy protocol design
Transparency and rationale Definition: Participants expressed mixed views as to the perceived lack of transparency and rationale provided in the vignettes, particularly in relation to Fumon (inattention to symptoms).	A middle ground should be found between insufficient and excessive explanation, in both the overall approach and specific features. An explanation of Fumon should be provided to patients to prepare them and explain its purpose.	Guidelines for appropriately explaining the purpose and importance of the overall approach were included in the "beginning therapy" section, and provided for each therapy feature. Guidelines on explaining Fumon to patients were included in the "beginning therapy" section.
Exploration and explanation Definition: Participants expressed a view that the patient as an individual was not sufficiently explored within the vignettes, nor were adequate responses to their questions around the differences between people and causes of difficulties provided. This related in particular to Fumon, normalisation and related metaphors.	A balance should be found between normalising and trivialising emotions. Appropriate empathy and acknowledgement should be shown, and the therapist should be clear that they are normalising emotions as opposed to situations. The technique should be personalised to the individual's specific feelings, and discussions on the functionality of emotion would be valued. Care should be taken with metaphors which may be misunderstood as examples of when emotions are acceptable. These should either be personalised to address the patient's specific feeling, or clarified as an explanation of the origin and function of unpleasant emotions.	Within "progressive enabling", clear guidelines/ warning points were provided for the use of normalisation and the incorporation of discussions on the functionality of emotions. Guidance was provided on the use of metaphors in the context of positive reinterpretation as well as therapy as a whole, which included examples/ warning points for how metaphors should and should not be implemented.

	The explanations for unpleasant emotions and differences between people sought by patients may be addressed through positive reinterpretation and explanations of the vicious cycle.	The importance of explaining the vicious cycle and exploring emotions through positive reinterpretation was stressed. The principles of nature, desire to live well and the vicious cycle were clearly delineated as the means to provide patients with the explanations they seek.
	Therapists require clear guidance on balancing Fumon with validation and empathy.	A "role of the therapist" section was included which stressed the importance of establishing a safe space and therapeutic relationship through empathy and validation, and addressed how to balance this with Fumon.
Structure, personalisation and collaboration Definition: Several participants noted that the approach was lacking in personalisation and collaboration, particularly in relation to metaphor use and receiving feedback from the patient/ allowing the patient to self-explore.	It should be clarified that personalisation and collaboration are essential features of the approach, as per other therapeutic modes. Therapists should endeavour to build an understanding framework with patients, from which the patient can self-discover and answer questions themselves. The therapist should engage in feedback and confirmation of patients' understandings as the therapeutic techniques are applied. It would be valuable to personalise metaphors where possible.	Within the "role of the therapist" section, the importance of a personalised and collaborative approach was stressed, with guidance provided on the specific means of implementing this. For each treatment phase, clarity was provided on the ways in which therapists should be directive (such as the requirements and conditions of the phase) and should not be directive (such as the specific action to be undertaken). Recommendations for personalising metaphors were included.

Table 11. The use of Stage One findings to inform Stage Two therapy protocol development:
Theme three (Shifting the understanding framework)

Constituent theme(s)	Recommendations for therapy protocol development	Incorporation into therapy protocol design
Accepting and allowing emotions; Therapy goals Definition: Participants expressed tension between allowing emotions, and seeking tools or techniques to change them, indicating possible constraint by prior understanding frameworks. Thus, potential patients struggled to identify and appreciate the extent of the messages conveyed. Related are the pre-conceptions participants held around therapy goals: some focused on mood-orientated goals and interpreted the features of therapy as only a potential means to this end; others appreciated the value of changing perspective, attention and relationships to emotions.	Therapy needs to be received within the correct understanding framework to be effective/ relatable. Thorough explanation at the start of therapy should help patients to appreciate how it may differ from their prior expectations and experiences, and begin to conceptualise effective therapy as something other than that which provides a set of tools for manipulating symptoms. Therapists should take care to explain the Moritian view of *allowing* emotions, noting any tools to control or manage emotions constitute part of the vicious cycle, and that Moritian 'techniques' instead involve reducing engagement in the vicious cycle. Therapists should take care to communicate what is and is not being claimed as acceptable for the patient to tolerate and be aware of the dangers and potential misinterpretations inherent in the normalisation/ acceptance messages. Therapists should clarify the process patients will move through and changes which may be effected for them, to ensure they understand the therapy goals and progress they can expect.	Within the "beginning therapy" section, a "managing patients' expectations" section was included with guidance on providing an upfront explanation of the Moritian view of emotions, goals of treatment, and ways in which treatment may differ from patients' prior experiences and expectations. Throughout the protocol, the Moritian view of accepting emotions as inevitable features of human life, and the value of allowing them to run their natural course, was highlighted. Warning points/ guidance around how the messages of accepting natural rhythms and learning to 'be with' symptoms should be conveyed, within this understanding framework, were provided throughout. The use of a structured phased approach enables the conveyance of a process patients will progress through and the experiential learning they can expect to gain.

| **Familiarity and distinctiveness**

Definition: Participants noted several ways in which therapy overall and particular features (such as diaries) appeared familiar or distinct from other therapies, which appeared to provide a specific framework of expectations and understandings within which they came to view Morita Therapy. | Therapists require a clear grounding in the ways in which this treatment differs from others, to avoid slipping into an inappropriate way of working.

The distinctions to other treatments, particularly regarding diaries, should be highlighted to therapists and noted to patients within detailed instructions.

Therapists should be alert to the potential for patients to utilise mindfulness techniques, and curb this with thorough explanation of the purpose of rest. | A "differences between Morita Therapy and other therapies" section was included, to ensure therapists' awareness of these.

Specific differences to diaries used within other treatments were noted, and detailed diary instructions to provide to patients included.

The conditions for and purpose of rest were clearly detailed. |

Overall, the significant ways in which the Stage One findings informed the development of the therapy protocol may be summarised as follows. The treatment approach was shifted along the spectrum of available treatment modes from the counselling-based method alone (as presented in the vignettes played to participants during their interviews) towards the traditional four-phased experiential approach. This addressed the Stage One findings by strengthening the core components and overarching structure of the approach, reinforcing the process and purpose of therapy, and balancing otherwise somewhat paradoxical features such as rest and action-taking within a clearly defined structure.

To address the challenges highlighted by participants in relation to completing diaries and rest and increase the likelihood of engagement with these components, the need for an individualised, flexible and reassuring approach to identifying patients' concerns and capabilities was stressed. The importance of delivering therapy in a personalised, collaborative and well-explained manner was also emphasised, with the inclusion of explicit rationales for both therapy overall and each therapy component provided to patients. Clear guidance and warning points, suggested by the qualitative findings, on implementing techniques such as positive reinterpretation and normalisation were incorporated, to address the misunderstandings indicated and concerns raised by participants.

One key qualitative message was that care would be required in explaining the purpose of therapy and managing the ways in which it may differ from patients' preconceptions and prior experiences. Thus, one protocol inclusion was a "managing expectations" section, intended to facilitate a shift in patients' understanding frameworks from the beginning of treatment, and ensure provision of the desired level of transparency and rationale.

5.3.3 Stage Three Results

Therapists' perspectives in the context of the draft protocol could be understood within two key themes: addressing insecurities, and enhancing operationalisability and accessibility. Each key theme encompassed a number of constituent themes (Figure 11, overleaf). Theme one illustrates the

overarching sense of a lack of confidence expressed by therapists in terms of orientating and adhering to Morita Therapy, with each constituent theme capturing a way in which these insecurities manifested. Theme two captures the more practical issues highlighted by therapists, with each constituent theme capturing an area in which the operationalisability of Morita Therapy might be enhanced through modification of the therapy protocol. The challenges expressed within theme one often shaped the suggestions made within theme two.

Figure 11. Stage Three Themes and Constituent Themes
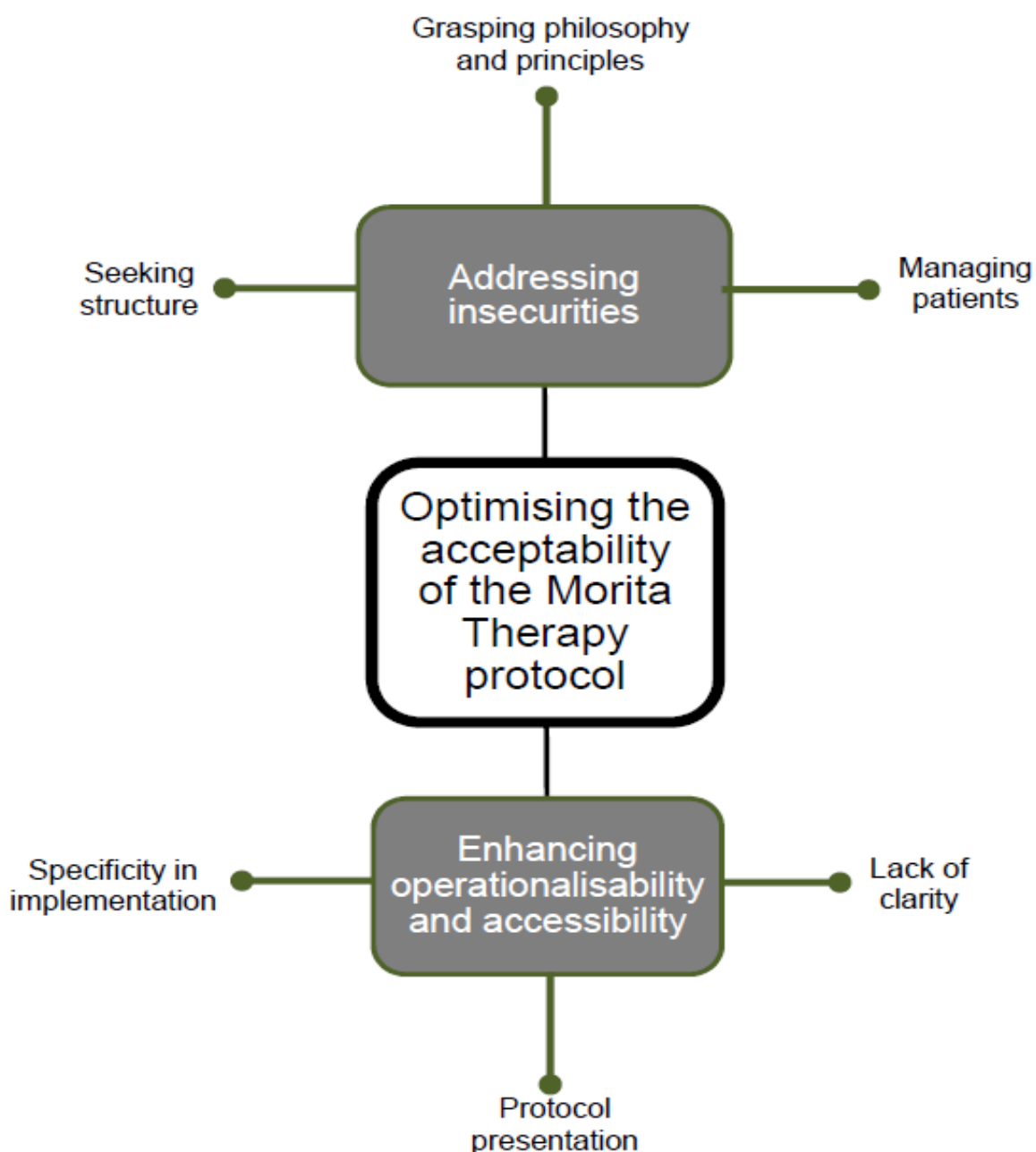
Theme one: Addressing insecurities

This theme illustrates the lack of confidence therapists' generally expressed around orientating to and delivering Morita Therapy. This captures therapists' perceived level of grounding in the philosophy and principles of the approach (constituent theme (a)), concerns around managing patients' expectations of and responses to the approach (constituent theme (b)), and suggestions for enhancing the structure of the approach to assuage their associated anxieties (constituent theme (c)).

(a) Grasping philosophy and principles

Therapists noted that, in general, the protocol was thorough, provided much understanding of Morita Therapy, and responded effectively to the issues raised during the Stage One interviews.

> It was very comprehensive, clear, um and it answered quite a lot of the issues we talked about… [The] phases worked really well and it helped me understand like the essence of it around the vicious cycle. (TH01)

Considering the approach "novel" (TH02), philosophically distinct from other treatments, and only deliverable from a thorough grounding in the principles ("the therapist has to kind of embrace the philosophy before they can understand the structure" (TH03)), therapists often focused on the extent to which they felt they were able to grasp the philosophy underlying approach:

> What I'm reading I think is generally bedding in, but because it is quite different at the outset, and actually philosophically there's a difference, it's all about the connection to being part of nature, that's quite different to well all the other therapy models that I've come into contact with, so it's almost like I go back to 'right, ground yourself back there again'. (TH04)

Thus, therapists demonstrated some lack of confidence in their abilities and some concerns around orienting to, and demonstrating "fidelity to" (TH01), the underlying theory and ideas:

> This is very novel and new ideas, I haven't got much scaffolding to kind
> of actually integrate some of the philosophical ideas and some of the
> terminology… It's something I think that would er take me a little bit of
> time to kind of integrate and orientate myself to. (TH02)

Accordingly, therapists noted the need for the protocol to emphasise "key
beliefs that a Morita Therapist would have" (TH01), and key Morita Therapy
principles to adhere to, "so that you can stay rooted to those" (TH01).

> Outlining and highlighting the principles to kind of keep the therapist's
> mind on those, and kind of bring those principles to the fore, 'cos they're
> very important. (TH02)

Related to the anxiety of familiarising themselves with a new approach,
therapists' often sought to simplify the approach and make sense of it through
the lens of more familiar therapies:

> The overlaps were because activity is very much a part of it, so you know
> with CBT and BA, and kind of being with the moment and the thinking
> that any emotion, negative or positive will pass, um and certainly within
> CBT the thinking is often about that. (TH05)

Thus, whilst noting the usefulness of the current protocol, therapists expressed
some lack of confidence around orientating and adhering to the underlying
philosophy and principles of Morita Therapy, and suggested ways in which this
might be assuaged, such as understanding the therapy in more familiar terms.

(b) Managing patients

Therapists acknowledged the usefulness of the protocol section on managing
patients' expectations ("these were quite nice and instructional" (TH04)) and the
guidance on providing rationale for engagement with the treatment elements:

> Some of the explanations to guide the therapist and also to try and I think
> guide the patient into engaging in some of these techniques and
> approaches is very good… the metaphors and analogies that are being

used are, are to I guess socialise the patient to these different kinds of methods, I thought that was very, very well thought through. (TH02)

However, therapists also expressed trepidation around how to manage patients' expectations and responses in light of the potential challenges and difficulties they envisaged patients presenting with, anticipating some possible incompatible expectations of treatment alongside a degree of reluctance and scepticism from patients:

> How do you apply these [principles] in different responses that patients might have?... Even if it's always with a caveat 'well, suspend disbelief at the moment, suspend your concerns and let's just try it, let's be curious about it' and then that's fine, I mean if that's the get-out clause after everything, that's fine. (TH01)

Thus, therapists sought examples of managing typical patient responses, stressed the importance of role playing these during therapist training, and desired a summary sheet for patients prior to starting therapy in order to prepare them for the approach:

> Role play would be good, definitely...just to familiarise the therapists with the sort of territory and how to respond potentially perhaps, to any potential challenges or difficulties. (TH02)

In particular, therapists often noted concerns around implementing rest and doubts around the rationale for this, which appeared to accentuate their anxieties around encouraging patients to engage with it.

> The fact that we're encouraging rest in the early stages is, we are actually in some way accepting that they will avoid, and they will try, but is that counter to them then if they're-, isn't that just then part of Hakarai, the lying in bed, and fighting symptoms… that puzzled me a bit. (TH01)

Accordingly, to facilitate their management of patients' (potentially negative) responses to the notion of rest, therapists sought more clearly defined instructions for instigating rest and desired flexibility around engaging patients in rest dependent on patient presentation and preference.

> Are we, irrespective if you like of the level of um disability, call it, that a client comes in with, is every client to go through all phases, so even if a client for example isn't sufficiently incapacitated by fatigue…[if] they're still functioning, are we still sort of imposing the rest phase? (TH04)

Therapists also noted that a handout which could be provided to patients' significant others could help build a support system for them during rest (TH01). Thus, although therapists expressed anxieties around managing patients' expectations and responses, particularly in relation to the rest phase, they also made several suggestions for facilitating these aspects of treatment.

(c) Seeking structure

In order to assuage some of their anxieties around adhering to the approach and ensuring it was delivered within the specified eight to twelve sessions, therapists sought to enhance the structure of the approach through clearly defined timeframes for each treatment phase:

> [With] eight to twelve sessions, you've got the two first sessions where you're setting it up… [and] six or so sessions to then pack in so it's like, you know, two sessions of rest, two sessions of this, two sessions of that… it would need to be, yeah, very clear for the therapist. (TH02)

Similarly, therapists desired content outlines for each therapy session.

> Whether there's scope to have a session guide that kind of keeps the objectives for the early stages, so sessions one and two, or the phases and then um just pointers or reminders…kind of the beginner's guide might be helpful in summary sheets. (TH04)

However, therapists also acknowledged the potential incompatibility of such structure with the approach of Morita Therapy as a fluid treatment which responds to the pace of the individual patient.

> There might be a little bit of tension there between the philosophy underpinning this and that kind of natural, ecological movement through the healing process I guess and um the need to deliver this within, and

respond within, a certain time frame… That real kind of fragile-ness and subtlety about it, so that's kind of what I liked about it…I think it would be a shame if that got lost. (TH02)

Thus, therapists expressed some tension between staying true to the naturally progressive nature of Morita Therapy and their desire, in the context of their anxieties around adhering to the approach, to rely on clearly defined timeframes and session structures.

Theme two: Enhancing operationalisability and accessibility

This theme illustrates areas in which therapists felt more guidance was required in the protocol to enable the delivery of therapy, particularly in terms of providing more clarity around specific therapy features (constituent theme (a)) and more specificity in terms of illustrating how the approach is implemented for individual patients (constituent theme (b)). Also captured are therapists' suggestions for improving the format and presentation of the protocol itself (constituent theme (c)).

(a) Lack of clarity

Therapists indicated that further clarity was required in relation to certain aspects of Morita Therapy which currently caused them some confusion or lack of confidence. Firstly, this related to balancing potentially incompatible features of the therapy such as direction with collaboration:

> Occasionally there feels like there's um, slight conflict… on the one hand it feels as if it should be fairly non-directive, client-led approach, but then at other times it feels like actually there's, I can see how one might, as a therapist, Morita therapist, actually need to be quite directive... maybe [the protocol needs] a section on when might a more directive approach be needed or necessary, and when it's not. (TH04)

Similarly, therapists noted tension between Fumon (inattention to symptoms) versus empathy, and acceptance versus acknowledgement of difficulties:

> The possible tight rope on this is like normalising, um trivialising versus like empathising… how you do it in such a way as it doesn't immediately set-up them just not turning up… They really are the kernel of our, of some of the training issues. (TH01)

Secondly, noting the subtlety of the indicators of therapeutic progress as a means of evaluating when treatment should be terminated, and their reliance on the therapists' clinical judgement, therapists suggested the need for more guidance in assessing these:

> It's quite subtle, you know, 'has the client's lifestyle reached a satisfactory level of adaptation', so how… this is very reliant on the therapist and also the patient's feedback… I wonder if some thought needs to be around that. (TH02)

The need for more clearly defined indicators was also expressed in relation to progressing through treatment phases, with therapists suggesting value in delineating these clearly in line with examples and treatment objectives:

> [The] means to evaluate progress feel less obvious... making sure that I feel clear on the purposes of each phase might then enable me to feel more clarity… [we need] some bullet points around that, so in summary, you know 'phase one objectives are…, these are the ways in which we might do that, and this is what we might see'. (TH04)

The need for more guidance regarding indicators of progress was expressed particularly in relation to the rest phase, which appeared to be related to therapists' concerns around whether rest in practice would function as intended (theme one, constituent theme (b): managing patients):

> After two weeks, if there's rest and there's still no real progress, what do you do and how do you shift forward, so those kind of turning points along the way, how do you negotiate those if there's no shift or there's nothing happening or um and, or what indications do you use? (TH02)

Therapists, in seeking a glossary of Japanese terms, also queried whether they should use these with patients, alongside noting the lack of explicit specification

of the number and spacing of therapy sessions in the protocol. Thus, therapists indicated that further clarity was required in the protocol, particularly in terms of balancing therapy features and assessing indicators of progress.

(b) Specificity in implementation

Whilst appreciating the overall picture provided by the protocol, therapists also indicated a need for more specific detail and examples to facilitate the implementation of therapy (corresponding with the above views on assessing indicators of progress): "The devil is in the detail now, how you operationalise it, but I think it covered everything really well" (TH01).

> One of the questions I was left with was um how would it look [laughs] as a therapist delivering it… having a kind of dialogue of patient-therapist can be quite helpful, just to give, you know, the therapist an idea of how that, how it would look. (TH05)

Thus, therapists appreciated the current inclusion of Stage One interview findings to alert them to the views and responses of individual potential patients ("I also liked the way that you'd reflected on what patients had said, I thought that was really very important" (TH01)) and desired more specific clinical illustrations and verbatim examples to guide them in operationalising therapy:

> Actual illustrations of some of the key interventions um and how they sit within the structure I think would be useful…'cos some of the ideas are quite subtle and quite nuanced. (TH02)

In particular, therapists indicated the need for specific examples to aid them in identifying patients' individual manifestations of engagement in the vicious cycle (TH03), and selecting appropriate activities for patients to engage in:

> Where is the context for this new desire for little activities in the context of someone's busy life, do you want them to go do a bit of Origami or crocheting in their lunch break, do you want them to go outside into the warm sunlight and just sit…How much joyousness does there have to be in the early action phase? (TH01)

Furthermore, therapists sought more specific guidance on how they implement Fumon (inattention to symptoms) in practice, noting the potential value of diary examples to guide them in operationalising this technique, amongst others, within their diary comments:

> I was really interested in the selective inattention…how [do] you express it in a therapy session, but also it would be useful if, maybe for the training, if you could do some possible diary sheets filled in…then we can have a chat about the types of things you would pay attention to. (TH01)

Accordingly, therapists anticipated value in focusing on the specific implementation of techniques during training: "I will really value being trained to actually do it… when I have tried to digest the protocol, I really want that kind of experiential next step." (TH04). Thus, therapists indicated the need to address the detail of operationalising therapy, facilitated by clinical illustrations to guide them.

(c) Protocol presentation

Overall, therapists considered the protocol understandable, "user-friendly" (TH05), "well laid-out" (TH02) and "easy to follow" (TH03). However, they did consider the protocol somewhat difficult to digest and indicated the potential value of additional summaries and crib sheets of key therapy components:

> Even if it's just like one side of A4 of the phases and what would be in there, and then you can refer back to [the protocol] to get more detail but yeah, just having something more summarised. (TH05)

This connected to therapists' perceived level of grounding in the philosophy of Morita Therapy and concerns around ensuring adherence to the key principles (theme one, constituent theme (a): grasping philosophy and principles):

> I was going for these little crib sheets: I've got core beliefs for therapists, tools… the desire for life table, and then I might have another sheet which might be Morita metaphors, er narrative or examples that can commonly be used…, indicators of progress… [and] key platforms which are, you know, 'do not veer from these'. (TH01)

To enhance the usefulness of the protocol during treatment, therapists noted the need to further compartmentalise information into summaries and bullet points, and highlight key points such as the Stage One interview findings and related 'warning points':

> I'm wondering if there might be a way of putting a summary of each stage before you go into all the, er, detail... I'd find it quite difficult to navigate around it whilst delivering therapy… It might be good to have bullet points and, and [highlight] warning areas. (TH03)

Thus, in the context of the protocol presenting as detailed and somewhat overwhelming, therapists indicated various ways in which key information could be highlighted within summary sheets and through amendments to the protocol design, thus potentially improving its functionality.

Summary of Stage Three Results

The Stage Three qualitative findings highlighted therapists' anxieties around orientating and adhering to the Morita Therapy principles, and managing patients' expectations and responses, with therapists at times seeking more clearly defined timeframes and session content outlines in order to assuage their anxieties. The findings further indicated that the protocol required improvements in format and presentation to enhance ease of use, and additional guidance, specificity or clarity to address the issues raised around balancing features of therapy, assessing indicators of progress, and operationalising the approach for individual patients.

5.3.4 Stage Four Results

Tables 12 and 13 (overleaf) provide details of how the protocol was optimised, and the therapist training programme tailored, in response to the Stage Three findings.

Table 12. The use of Stage Three findings to inform Stage Four therapy protocol modification/ therapist training programme: Theme one (Addressing insecurities)

Constituent theme	Modification to therapy protocol	Tailoring of therapist training programme
Grasping philosophy and principles Definition: Therapists expressed some lack of confidence around orientating and adhering to the underlying philosophy and principles.	A crib sheet highlighting key principles to adhere to was developed.	A focus was maintained on grounding in the key principles in order to enhance therapists' confidence in orientating and adhering to the approach.
Managing patients Definition: Therapists expressed trepidation around managing patients' expectations and responses, particularly in relation to rest, for which therapists sought more clearly defined instructions and flexibility around engaging in rest dependent on patient presentation and preference.	Instructions for rest were clarified. To adhere to the literature which deems rest fundamental to Morita Therapy, it was clarified that all patients, regardless of presentation, should engage in as much rest as possible. Thus, in the event of patients' reluctance to engage in rest, it was stressed that reiterating its importance and rationale should be prioritised over missing it. A pre-treatment patient 'Morita Therapy Information Sheet', to begin expectation management at the earliest opportunity, and available to provide to patients' significant others in preparation for rest, was developed.	Role plays focused on managing patient expectations and responses, delivering rationale and guiding patients through the treatment phases.
Seeking structure Definition: Therapists sought to enhance the structure of the approach through clear timeframes and session content outlines.	To adhere to Morita Therapy practice, session content outlines were not provided. Crib sheets were developed which clarified the session structure and highlighted discussions to be held at key points of therapy (such as transitioning between treatment phases).	

Table 13. The use of Stage Three findings to inform Stage Four therapy protocol modification/ therapist training programme:
Theme two (Enhancing operationalisability and accessibility)

Constituent theme	Modification to therapy protocol	Tailoring of therapist training programme
Lack of clarity Definition: Therapists indicated the need for further clarity, particularly in relation to balancing features of therapy and assessing indicators of progress.	Within the "the role of the therapist" section, guidance was added on balancing direction with collaboration; within the "therapy structure" section the number and spacing of therapy sessions was specified; to the appendix a glossary of Japanese terms was added with confirmation that therapists do not need to use these. The protocol was re-structured to summarise key objectives of each treatment phase and link these explicitly to each indicator of progress, assessing indicators and example illustrations in tables for each phase and ending treatment.	Role plays focused on implementing and balancing therapeutic techniques, and assessing indicators of progress.
Specificity in implementation Definition: Therapists indicated a need for more specific detail, clinical illustrations and verbatim examples.	Verbatim illustrations available from the literature were incorporated, specifically in identifying engagement in the vicious cycle and the indicators of progress. Within the details for each action-based treatment phase, the types of/conditions for activities to be engaged in were clarified.	Role plays focused on implementing Fumon and identifying personalised/ suitable patient activities. Commenting on mock diaries/ discussions on principles to adhere to in doing so were included.
Protocol presentation Definition: Therapists considered the protocol difficult to digest and indicated the value of crib sheets, summaries, and compartmentalising/ highlighting key information.	Summary sheets were developed for the vicious cycle, therapist beliefs, metaphors, therapeutic tools, therapist responses, session structure, introducing therapy, negotiating rest, and each treatment phase in terms of purpose, conditions and indicators of progress. Summaries/concise guidance were added; guidance was deconstructed into bullet points and tables; key features, tips, techniques and warning points were delineated in boxes; colour and bold text were incorporated to highlight key information.	

To summarise the significant adaptations to the protocol:

- Verbatim illustrations were incorporated.

- Assessing indicators of therapeutic progress was clarified.

- Guidance on balancing direction with collaboration was added.

- The types of/conditions for activities to be engaged in were clarified.

- Summary sheets, and a pre-treatment patient 'Morita Therapy Information Sheet', were developed.

- The presentation was amended to include summaries and concise guidance; bullet points, tables and boxes; colour and bold text.

- The number and spacing of therapy sessions (eight to twelve weekly one hour sessions, as per the modal model (Minami, 2013)) was specified.

In addition, the proposed therapist training programme was tailored to maintain a focus on grounding in the key principles, include role plays in areas therapists indicated necessary, and incorporate the provision of diary comments (Appendix VI).

The final UK Morita Therapy Outpatient Protocol (Appendix IV) comprises twelve sections: (1) Morita Therapy overview; (2) Morita Therapy principles: nature, mechanisms of psychological suffering, mechanisms of change and psychological wellbeing; (3) differences between Morita Therapy and other therapies; (4) the role of the therapist: establishing a safe space and therapeutic relationship, accepting and respecting nature, the Fumon stance, direction and progression in the therapist's role, and experiential learning; (5) therapeutic techniques: guidance on the diary and the techniques of discovering and reactivating constructive desires, validation and normalisation, increasing awareness of the vicious cycle, re-evaluating behavioural patterns and lifestyles, accepting natural rhythms and learning to 'be with' symptoms, and metaphor making; (6) therapy structure; (7) beginning therapy and managing expectations; (8 – 11) guidelines for completing each treatment phase in turn; (12) termination and evaluation of treatment, including indicators of therapeutic progress; appendices which include a glossary of Japanese terms and information on the development of Morita Therapy and the protocol.

5.4 Chapter summary

This chapter has presented the aims, methods and results of an iterative four-stage process informed by the person-based approach to develop a Morita Therapy outpatient protocol with optimal acceptability and feasibility for a UK clinical population. Within this process, qualitative findings were integrated with Morita Therapy literature in order to sensitively adapt the intervention across cultures whilst carefully ensuring adherence to its fundamental features. As such, a therapy protocol and tailored therapist training programme were developed which were fit for purpose in proceeding to a UK-based Morita Therapy feasibility study. Chapter Six presents the design, methods and procedures employed in this feasibility study.

CHAPTER SIX. MIXED METHODS FEASIBILITY STUDY: METHODS

This chapter describes the methods of the feasibility study undertaken to prepare for a fully-powered randomised controlled trial (RCT) of Morita Therapy plus treatment as usual (TAU) compared with TAU alone for the treatment of depression and anxiety in adults in the UK. These methods have been reported in Sugg et al. (2016) (Appendix VII). This chapter is based on the published article; additional information is provided.

The chapter is organised into ten main sections: study purpose and research questions (6.1); study design (6.2); pilot RCT (6.3); semi-structured interviews (6.4); data management (6.5); analysis (6.6); ethical issues (6.7); patient and public involvement (6.8); dissemination protocol (6.9); study set-up and management (6.10).

6.1 Study purpose and research questions

The purpose of this study was to prepare the ground for the design and conduct of a fully-powered RCT of Morita Therapy plus TAU versus TAU alone, or to determine that such a trial is not appropriate and/or feasible.

Seven research questions were addressed to meet this purpose:

1. What proportion of participants approached to take part in the trial will agree to do so?
2. What proportion of participants who agree to take part in the trial will remain in the trial at four month follow-up?
3. What proportion of participants who agree to take part in Morita Therapy will adhere to a pre-defined per-protocol dose of Morita Therapy?
4. What is the variance in participant outcomes following Morita Therapy plus TAU and TAU alone, and how do they correlate with participants' baseline scores?
5. What are the estimated between-group differences (and 95% confidence intervals) in participant outcomes following Morita Therapy plus TAU and TAU alone?
6. How acceptable is Morita Therapy to participants and therapists?

7. How do participants' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?

6.1.1 Criteria for success

Relating to the above research questions, the criteria to be met in order to deem a fully-powered RCT feasible to run as is (Thabane et al., 2010) were:

1. A sufficient number of participants to populate a fully-powered trial are likely to be recruited and retained, i.e. we recruit at the rate anticipated in the pilot trial (12% of those invited) and experience an attrition rate no higher than 20% of those randomised, in line with other National Institute of Health Research (NIHR) mental health trials (Rhodes, Richards, Ekers et al., 2014; Richards, Hill, Gask et al., 2013; Wiles et al., 2013). Whether protocol modification or close monitoring during a fully-powered RCT will address any failure to meet these criteria will be considered (Thabane et al., 2010).

2. The levels of engagement with and adherence to Morita Therapy are likely to be on par with other NIHR mental health trials (Rhodes et al., 2014), i.e. at least 65% of participants allocated to Morita Therapy attend at least 40% of treatment sessions. Any failure to meet this criterion will be considered in the light of participants' views on the acceptability of Morita Therapy in order to determine whether protocol modification or close monitoring are sufficient to deem a fully-powered RCT feasible (Thabane et al., 2010).

3. It is likely that a Morita Therapy outpatient protocol can be produced which is acceptable to patients and therapists, and deliverable by therapists, as defined by responses to qualitative interviewing.

6.2 Study design

A mixed methods embedded design (Creswell and Plano Clark, 2007) incorporating exploratory and explanatory components was employed. Thus, semi-structured interviews were embedded within a pilot RCT of Morita Therapy plus TAU versus TAU alone for adults with depression, with or without anxiety disorders. Quantitative and qualitative components were given equal priority and mixed interactively at the design level to address the study purpose (Creswell and Plano Clark, 2007). For these two components, data were

collected concurrently and analysed sequentially (with quantitative data informing the sampling of qualitative interviews for analysis: section 6.5.2). Quantitative data were used to assess the feasibility of trial recruitment, retention and treatment adherence, and to inform the sample size calculation required for a fully-powered trial. Qualitative data were collected on participants' and therapists' views of Morita Therapy. Qualitative data on acceptability and quantitative data on treatment adherence were integrated to help explain variability in the number of treatment sessions participants attended, and to provide a more in-depth understanding of the feasibility and acceptability of Morita Therapy.

6.3 Pilot randomised controlled trial

6.3.1 Sample size

A conventional power calculation is inappropriate for the purpose of a pilot trial (Thabane et al., 2010). Instead, the sample size was calculated in order to provide useful information about the aspects of the study being assessed for feasibility (Thabane et al., 2010), following advice from the University of Exeter Medical School Institute for Health Research Health Statistics Group (https://medicine.exeter.ac.uk/research/healthresearch/healthstatistics/). Thus, confidence intervals were constructed based on certain criteria for success (Thabane et al., 2010), specifically: recruiting at a rate of 12% of those invited and experiencing an attrition rate no higher than 20% of those randomised. It was anticipated that a total of 570 potential participants would be invited to participate in the trial. Thus, it was expected that 72 participants would be recruited into the trial, and 60 participants followed-up (30 in each arm).

Inviting 570 potential participants was sufficient to estimate participation rates (as percentage of subjects invited) of 10% with a margin of error of +/- 2.46%, or 12% with a margin of error of +/- 2.67%, or 15% with a margin of error of +/- 2.93%, based on 95% confidence intervals. Recruiting 72 participants was sufficient to estimate follow-up rates (as percentage of participants randomised) of 80% with a margin of error of +/- 9.24% or 85% with a margin of error of +/- 8.25%, based on 95% confidence intervals.

In addition, the standard deviation of participant outcomes and the correlation between baseline and four month follow-up scores was calculated, to be used in refining future sample size calculations to incorporate the additional precision obtained from adjusting for baseline scores when comparing outcome scores between groups. In this vein, 30 participants in each group was sufficient to estimate: (i) the standard deviation of continuous outcomes to within 22% of their true value based on the upper limit of the 95% confidence interval; (ii) a Pearson's correlation coefficient between baseline and follow-up scores with a margin of error of +/- 0.1 if the true correlation is 0.8, or +/- 0.14 if the true correlation is 0.7, or +/- 0.17 if the true correlation is 0.6.

30 participants per group is also in line with the general rule of thumb for using pilot studies to reliably estimate variance for participant outcomes (Browne, 1995). Considering these factors, 60 participants at follow-up was considered to be both sufficient to provide useful information and reasonable to recruit for within the constraints of a pilot trial. Therefore, 72 was selected as the target sample size, inflating the sample by 20% to take account of predicted attrition.

6.3.2 Participant inclusion and exclusion criteria

Eligible participants were aged ≥18 with Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association, 2000) Major Depressive Disorder, with or without accompanying DSM anxiety disorder(s).

Given the exploratory nature of this trial (and any fully-powered evaluation), and thus the requirement for reasonable internal validity with a homogenous and tightly defined population, people who were cognitively impaired, had bipolar disorder or psychosis/psychotic symptoms, or were substance dependent were identified and excluded. Cognitive impairment was determined using the Mini-Cog (Borson, Scanlan, Brush et al., 2000), whereby a score of 0, or 1-2 with an abnormal clock-face, indicated sufficient cognitive impairment to be excluded (Borson et al., 2000). Bipolar disorder, psychosis and substance dependence were established according to the DSM.

Participants whose risk of suicide was sufficiently acute to demand immediate management by a specialist mental health crisis team, and those who were

currently in receipt of psychological therapy, were also excluded. Psychological therapy included any formal standard course of psychological (talking) therapy, such as Cognitive Behavioural Therapy. Ad hoc contact with a therapist or counsellor was not considered to meet this exclusion criterion. Participants were eligible regardless of whether they were in receipt of antidepressant medication or had received psychological therapy in the past.

6.3.3 Participant identification and recruitment

The main recruitment method was through searches of General Practice records, conducted by Practice staff. All Practices who were able to access the University of Exeter's Mood Disorders Centre (MDC) Accessing Evidence-Based Psychological Therapies (AccEPT) Clinic (those within the National Health Service Northern, Eastern and Western Devon Clinical Commissioning Group) were eligible to participate.

It was anticipated that at least six Practices would undertake four searches over a ten month period, yielding a total of at least 24 searches. This was based on other trials of depression (Kuyken, Hayes, Barrett et al., 2015; Richards et al., 2013; Wiles et al., 2013) which indicated that each search of an average size Practice should yield approximately 37 potentially eligible participants.

Record searches were limited to patients aged ≥18 and seen within the past three months for depression. The resulting names were screened by the GP with whom the patient was registered for any patients known to meet exclusion criteria or for whom the GP considered the trial unsuitable. The remaining patients were sent invitations to participate by Practice staff.

Adverts were also placed on the websites of the University of Exeter Medical School and AccEPT Clinic; leaflets and flyers were placed in the waiting rooms of consenting Devon General Practices; an email invitation was circulated to former MDC participants who had consented to such contact. All invitations and adverts included a 'study summary sheet' and 'permission to contact form' (Appendix VIII).

6.3.4 Screening and baseline

All people who returned their 'permission to contact form' were telephoned to assess possible eligibility using a standard two-question case-finding instrument for depression (Whooley, Avins, Miranda et al., 1997). Baseline interviews were arranged with potentially eligible and willing participants, who were sent a confirmation letter and full participant information leaflet (Appendix VIII). Baseline interviews were held at University of Exeter premises or the participant's home, depending on participant preference. At interview, the study was explained in full and eligibility assessed according to the Mini-Cog (Borson et al., 2000) and standard clinical interview (Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Clinical Trials Version (First, Williams, Spitzer et al., 2007)) (SCID). If eligible and once fully informed, participants were asked to complete a consent form (Appendix VIII) and entered into the trial. Ineligible participants were returned to the care of their GP.

6.3.5 Randomisation, allocation concealment and blinding

Participants were allocated in a 1:1 ratio to Morita Therapy plus TAU or TAU alone, stratified according to their symptom severity on the nine item version of the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer and Williams, 2001), specifically whether they scored <19 or ≥19, given that a score of 19 is the median score of depressed participants in previous research (Rhodes et al., 2014; Richards et al., 2013). To maximise the likelihood of balance in the stratification variable across the two arms, allocation was minimised. To ensure allocation concealment, randomisation was undertaken through the use of an externally administered, password-protected randomisation website independently developed and maintained by the Exeter Clinical Trials Unit (https://www.exeter.ac.uk/ctu/).

The study researchers were not blinded to group allocation due to the resource limitations of a PhD: HVRS (PhD candidate), who was responsible for randomising participants, informing them of the outcome and passing the details of participants randomised to Morita Therapy to the AccEPT Clinic, was also, by necessity, responsible for collecting follow-up data and conducting qualitative

interviews with Morita Therapy participants. Baseline and follow-up data were self-reported; all research measures were applied equally to both groups.

6.3.6 Action upon randomisation

Upon randomisation, the study researchers wrote to the participant and their GP to inform them of their allocation. For participants randomised to Morita Therapy plus TAU, a 'Morita Therapy Information Sheet' summarising the approach, developed during the intervention optimisation study (see Chapter Five) was included; and the study researchers securely and separately emailed a password-protected 'Clinical Information Form' (anonymised description of participants' depressive symptoms and other relevant clinical information) and 'Patient Details Form' (participant demographics) to the AccEPT Clinic (Appendix VIII).

6.3.7 Trial interventions

Morita Therapy plus treatment as usual

Participants allocated to Morita Therapy plus TAU were asked not to engage in other formal courses of psychological therapy during the course of their treatment. Otherwise, these participants were free to access any other usual care and medication in liaison with their GP.

Morita Therapy consisted of eight to twelve one hour face-to-face weekly sessions delivered at the University of Exeter's MDC AccEPT clinic (http://www.exeter.ac.uk/mooddisorders/acceptclinic/) by two professionally accredited research therapists experienced in both the delivery of complex psychological interventions and adopting different modes of treatment, including experimental treatments. Therapists were trained in Morita Therapy over 6 months; training included background reading, attending presentations, involvement in the development of the therapy protocol (see Chapter Five), and practical training led by DAR (primary supervisor), a clinically qualified academic and ten-year member of the Japanese Society for Morita Therapy. Practical training was experiential: role plays, diary examples, additional reading and peer support as per the tailored therapist training programme (see Chapter

Five; Appendix VI). Therapists were not accredited in Morita Therapy as there is no Morita Therapy accreditation process either within the UK or Japan.

Therapists followed the UK Morita Therapy outpatient protocol developed during the intervention optimisation study (see Chapter Five; Appendix IV). DAR provided fortnightly supervision of cases together with advice and support. A qualitative checklist highlighting the key components of Morita Therapy, and key discussions to be held in facilitating patients' engagement with the treatment phases, was used as an aide memoir to structure supervision discussions and the assessment of adherence and fidelity (Appendix IX). With the patient's consent, all therapy sessions were audio recorded. The first two recordings for each therapist were used to confirm their adherence to the therapy protocol and a further 10%, stratified by length of time in treatment, were used to evaluate fidelity to the protocol, which informed therapist supervision.

During therapy, patients progressed through four phases of rest and increasing action-taking in order to address fatigue, expand peripheral attention and move from a mood-oriented to purpose- and action-oriented lifestyle. Therapists aided patients in re-appraising their symptoms as part of the natural ecology of human experience; recognising the vicious cycle of symptom aggravation created by fixation on symptoms, contradictions between the 'real' and 'ideal', and attempts to fight or control otherwise inevitable emotions; and moving from a position of preoccupation with symptoms to acceptance of spontaneous affective experiences. Therapists continually reinforced the patient's shift from self-reflection towards a focus on constructive action and the external environment. Patients completed daily diaries in which therapists commented to increase communication and the opportunity for therapeutic reinforcement.

Treatment as usual alone

TAU alone was selected as the trial comparator as a reflection of the comparator which would be selected for a fully-powered RCT, in which the key interest would be whether Morita Therapy plus TAU has superior or equivalent effectiveness to current clinical practice in the UK, in which people have access to GP care and a range of other treatments. Thus, a large scale RCT would be a pragmatic trial embedded within the healthcare environment in which Morita

Therapy would be delivered, seeking to establish whether Morita Therapy could be useful in addition to the options currently available to depressed patients in the UK.

Thus, in this study, 'treatment as usual' was operationalised by making no specific patient-level recommendation or requirement to alter the usual treatment received by depressed patients in the UK, and no restrictions were placed on the treatment options available to these participants. GPs were free to treat and refer participants as would be their normal practice and participants were free to access any other care and services, including formal courses of psychological therapy such as Cognitive Behavioural Therapy.

All participants, irrespective of their allocation, were free to choose whether they took antidepressant medication. The treatments received in the course of participants' treatment as usual were recorded at follow-up.

6.3.8 Outcomes

Given this was a feasibility study with a range of aims, there was no single primary outcome measure. Rather, a variety of data were collected at baseline and four months post-randomisation: severity of depressive symptoms (PHQ-9 (Kroenke et al., 2001)); severity of generalised anxiety symptoms (seven item Generalised Anxiety Disorder questionnaire: GAD-7 (Spitzer, Kroenke, Williams et al., 2006)); quality of life (Short Form 36 Health Survey Questionnaire: SF-36 (Ware, Kosinski, Dewey et al., 2000); Work and Social Adjustment Scale: WSAS (Mundt, Marks, Shear et al., 2002)).

Given Morita Therapy does not directly target symptom reduction but rather is intended to help patients reduce engagement in the vicious cycle and move towards a positon of acceptance and increased functioning in spite of symptoms, participants' attitudes (including fixation on symptoms, avoidance of and attempts to control symptoms, and judgement towards symptoms and self) were measured using a questionnaire developed for measuring Morita Therapy-specific outcomes (Morita Attitudinal Scale for Arugamama: MASA (Richards, Mullan, Ishiyama et al., 2011)).

Data were collected on the flow of participants through the trial. For Morita Therapy participants, therapists also informed the study researchers of the number of therapy sessions attended and reason for ending treatment. An economic evaluation was not conducted as part of this study, although at follow-up methods for collecting data on participants' use of health and social care services as used in recent mental health trials (Rhodes et al., 2014) were incorporated (establishing the rates and nature of hospital visits; use of community, social and complementary services; use of psychotropic medication since baseline) in order to characterise treatment as usual and thus inform future calculations of the costs of each arm for a large-scale RCT.

At four months post-randomisation, it was anticipated that treatment for Morita Therapy participants would be complete. Follow-ups were held at University of Exeter premises or the participant's home, depending on participant preference. The option of completing follow-up questionnaires via post or email was provided to participants who were unable or unwilling to complete a face-to-face interview.

6.4 Semi-structured Interviews

Semi-structured interviews were embedded in the pilot trial to explore participants' and therapists' views on the acceptability of Morita Therapy.

6.4.1 Sample and setting

All participants who were allocated to Morita Therapy plus TAU, and the two therapists providing Morita Therapy during the study, were invited to a post-treatment semi-structured interview. Participant interviews were held at University of Exeter premises or the participant's home, depending on participant preference; therapist interviews at the AccEPT Clinic.

6.4.2 Recruitment

The purpose and content of the interview was explained to participants in the participant information leaflet, and their consent to participate was determined at baseline. Therapists were sent an interviewee information leaflet explaining the interview prior to a pre-trial meeting at which their consent to participate was

established. Upon completion of Morita Therapy (delivery, for therapists), consenting participants were contacted to establish whether they were still willing to be interviewed, remind them of what would be involved and answer any questions. For willing participants, an interview was arranged no sooner than 48 hours later and a confirmation letter was sent explaining the opportunity to rearrange or cancel the interview at any time.

6.4.3 Interview process and questions

Semi-structured interviews were undertaken to allow participants to describe their views of Morita Therapy, following topic guides developed for participants and therapists (Appendix IX). Individual responses were also probed to investigate participants' meanings, enabling both the exploration of participants' views on pre-defined topics of interest and the elicitation of participants' own themes (Taylor, 2011). Interviews were audio-recorded with participants' consent.

Topic guides

Topic guides were established on the basis of recent mental health trials addressing similar research questions (Hill et al., 2014; Rhodes et al., 2014; Richards et al., 2013) (which ask about views and experiences of treatment, barriers to and impact of treatment), Morita Therapy literature and the intervention optimisation study findings (Chapter Five). Questions were designed to explore participants' views and experiences of the underlying principles and concepts of Morita Therapy; its implementation, process, mechanisms and impact. Following the first three participant interviews, the participant topic guide was amended to include additional questions based on the views already elicited.

In exploring responses, views and experiences of the defining features of Morita Therapy in practice, such as the four phases and daily diaries, were explored in particular. In addition, probe areas included elements of therapy which had presented as confusing or challenging during the optimisation study, such as rest, positive reinterpretation, normalisation, Fumon (inattention to symptoms), acceptance, provision of rationale, expectations of treatment and the extent to

which Morita Therapy met these (for participants); how user-friendly and helpful the therapy protocol was, ways in which the protocol could be improved, and views on using the protocol as part of training new therapists (for therapists).

Questions on the feasibility and appropriateness of the trial procedures were included to explore procedures that facilitated the efficient running of the trial and any considered problematic, with the particular aim of identifying any issues requiring resolution before proceeding to a large-scale trial. Finally, participants were invited to share any views not already discussed.

Field notes

The interviewer (HVRS) made field notes during each interview and summarised these at interview completion (see Appendix X for an example). Field notes were used to help inform changes to the patient topic guide (see above), to facilitate the selection of interviews for analysis (section 6.6.2) and alongside transcripts during qualitative analysis.

6.5 Data management

6.5.1 Quantitative data management

All data were double-data entered into Excel v.14 (Office, undated) and merged into one Excel database. Inaccuracies were resolved through reference to original data sources (i.e. participant files). Treatment adherence data were analysed within Excel. Recruitment, retention, baseline and outcome data were imported into and analysed in STATA v.14 (StataCorp, 2015). Following published guidance (Ware, Kosinski, Bjorner et al., 2008), Physical and Mental Health Component Scores were calculated from raw scores on the SF-36. Variables were cleaned by generating descriptive statistics and frequency data.

6.5.2 Qualitative data management

With participants' permission, interviews were recorded and transcribed verbatim by the study researchers and a specialist in qualitative research. Transcribers were briefed by the study researchers and used a common template for transcription (Appendix X). Transcripts were checked for

consistency of style and accuracy. NVivo10 (QSR International, undated) was used to organise the data and help ensure a systematic analysis.

6.6 Analysis

There were three strands of analysis: quantitative, qualitative and mixed methods. First, quantitative trial data and qualitative interview data were analysed separately. Next, quantitative and qualitative data were integrated in a mixed methods analysis (Creswell and Plano Clark, 2007).

6.6.1 Quantitative analysis

Recruitment, retention, treatment adherence and estimates of the participant-related data were analysed to inform the feasibility of and sample size calculation for a fully-powered trial.

Underpinning principles

All analyses were undertaken on an intention to treat basis i.e. all participants were analysed, in their allocated arms. Emphasis was on quantification and estimation rather than hypothesis testing. Missing data were not imputed, although outcome data that were missing in each arm and the reasons for missing data were reported. CONSORT guidelines, including the pilot and feasibility extension (Eldridge, Chan, Campbell et al., 2016), were followed in reporting all data.

Recruitment and retention

Count data, expressed as a percentage of both the total number of potential participants invited and in relation to the preceding step in recruitment, were used to quantify the flow of the participants through the trial. Margins of error were estimated for each parameter. For each arm, the number of participants who withdrew, could not be contacted or did not provide follow-up data for another reason were quantified; data were expressed as a percentage of the total number of participants in each arm.

Baseline characteristics

Descriptive statistics were calculated to describe participants' baseline demographic and clinical characteristics. Frequency and percentage information were calculated from categorical data on participants' gender, ethnic origin, level of education, marital status, history of depression, thresholds met on the PHQ-9 and GAD-7, secondary SCID diagnoses, current antidepressant use and previous psychotherapy or counselling. Means and standard deviations were calculated to describe continuous data on participants' age, number of children, PHQ-9 and GAD-7 total scores.

Receipt of the intervention

Descriptive statistics were used to describe the number of Morita Therapy sessions attended by participants allocated to Morita Therapy plus TAU. The percentage of participants who adhered to a per-protocol dose of Morita Therapy (≥5 sessions), completed treatment, withdrew from treatment and ended treatment for other reasons were calculated. For participants who withdrew from treatment, the reasons for withdrawal reported to the study team by the therapist were categorised and reported as the percentage of participants who withdrew due to patient preference, time or personal circumstances, moving away, the patient feeling ready to end treatment, and enactment of the 'did not attend' (DNA) protocol.

Outcomes

To measure the variance in participant outcomes, estimates were made of the standard deviation around the mean PHQ-9, GAD-7, SF-36, WSAS and MASA scores at baseline and four months for both groups. The correlation between participants' scores on these measures at baseline and four months was estimated, to refine the sample size calculation for a fully-powered trial. Although insufficiently powered to make inferential statements on between (or within) group differences and as such no p values were calculated, the observed differences between Morita Therapy plus TAU and TAU alone on the mean changes in these measures from baseline to four month follow-up, and the 95% confidence intervals around these figures, were also calculated.

Descriptive statistics related to treatment response were also generated to describe the number and percentage of participants in each arm who demonstrated a ≥50% reduction in score from baseline to follow-up and/or a follow-up score <10 on the PHQ-9 and GAD-7 (a score of 10 representing moderate depression and moderate anxiety on the PHQ-9 and GAD-7 respectively (Kroenke et al., 2001; Spitzer et al., 2006)).

Economic data

Descriptive statistics were used to describe the use of health services since baseline assessment for participants in each arm.

6.6.2 Qualitative analysis

The qualitative data from the semi-structured interviews were analysed to explore the acceptability of Morita Therapy to participants and therapists.

Analytic sample

The number of therapist interviews to be analysed was limited by the number of therapists delivering Morita Therapy within the trial. It was anticipated that a subset of 18 participant interviews would be sampled for analysis. The size of this sample was guided by the purpose of the study and the concepts of sampling adequacy and data saturation (as discussed in Chapter Five) (Bowen, 2008; Glaser and Strauss, 1967; Mason, 2010), including the findings of Guest et al. (2006) which suggested that an analysis of twelve interviews could provide a thorough picture of participants' views of Morita Therapy. In addition, an estimation was informed by the heterogeneity of the population, and the number of selection criteria to be applied to/sub-groups to be included in the sample, alongside resource constraints (Ritchie et al., 2013).

The sample was selected in order to achieve maximum variation according to criteria deemed important in addressing the research questions (Bryman, 2016). Thus, through utilising a combination of probability and purposive sampling orientations within a strategy suited to mixed methods research, the aim was to both capture symbolic representation and a breadth of information by including all key manifestations of these criteria, and explore the depth and diversity of

views within each manifestation of the criteria (Ritchie et al., 2013; Teddlie and Yu, 2007). These criteria were participants' adherence to treatment, in order to facilitate the mixed methods analysis (section 6.5.3), and whether or not participants' demonstrated a response to treatment (defined as a follow-up PHQ-9 score <10), given the potential for participants' views of Morita Therapy to be confounded by the degree to which their symptoms improved. The objective was to include a quota of three participants within each category/cell contained in this sampling matrix (Table 14).

Table 14. Proposed sampling matrix

		Adherence to treatment		
		Withdrew < 5 sessions	Withdrew ≥ 5 sessions	Completed treatment
Treatment response? (follow-up PHQ-9 score <10)	**Yes**	n=3	n=3	n=3
	No	n=3	n=3	n=3

Framework

Interviews and field notes were analysed by HVRS using Framework analysis (Ritchie et al., 2013) to allow for the combination of inductive and deductive approaches in the development of analytic categories. HVRS achieved familiarisation with the data through reading transcripts and developed an initial thematic framework as preliminary analysis was undertaken and subsequently as batches of transcriptions were analysed, iteratively combining the topic guide and the overall impression of the narratives in context. Using this framework, transcripts were coded at the level of individual participants (by HVRS, with a subset double-coded by JF (second supervisor)) and then analysed thematically across the whole dataset as well as in the context of each participant's interview using a constant comparison approach (Thorne, 2000), whereby each piece of data (e.g. one statement or one theme) was compared with others for similarities and differences (Miles et al., 2014).

Data were then charted in analytic/framework matrices which summarised participants' views on each theme/constituent theme to allow within and across

case analyses and the exploration of relationships between themes, completed by HVRS in discussion with JF; throughout the analytic process data were abstracted and interpreted by HVRS in discussion with JF and with the aid of thematic maps to make sense of participants' perspectives, understand and structure the relationships between themes, and conceptualise the overall picture of participants' views and experiences of Morita Therapy (Braun and Clarke, 2006; Miles and Huberman, 1994; Ritchie et al., 2013; Spencer et al., 2014). Appendix X provides examples of the analytic process. As explanations were formulated in this way, negative cases were explored and explanations of variance provided (Dingwall et al., 1998), thus ensuring all observations relevant to the research question were incorporated. Data collection and analysis were iterative: HVRS's interviewing style was amended to respond to emerging themes and explore deviant cases further in subsequent interviews as appropriate.

In preparation for the mixed methods analysis, the final qualitative analysis was used to develop typologies of different views on the acceptability of Morita Therapy; original transcripts and the framework matrices informed the development of mini-summaries of each participant's views of Morita Therapy.

6.6.3 Mixed methods analysis

Mixed methods analysis integrating qualitative and quantitative data was undertaken to explore how data on the acceptability of Morita Therapy relates to and explains treatment adherence. Three forms of joint display were used, as developed from methods summarised by Creswell and Plano Clark (2007):

(1) Joint typologies/ statistics display

This technique was driven by the qualitative data to explore how treatment adherence varies for participants whose views on the acceptability of Morita Therapy were organised into different typologies. Thus, typologies of participants' different views and experiences of Morita Therapy were developed from the qualitative data, along two continuums representing the acceptability of the principles and process of therapy. For each typology, data were presented on the number of treatment sessions attended for each participant to whom the

typology applied and as a mean number of sessions for all participants within that typology. Alongside this, data on therapist fidelity to the therapy protocol (assessed as detailed in section 6.3.7) were also presented where the qualitative data suggested challenges or confusions related to particular sections of the protocol or phases of therapy, such as participants' understanding of the rest phase. This allowed the exploration of whether issues with the acceptability of Morita Therapy related to the treatment itself or the therapists' delivery of treatment, and thus aided the identification of any 'fatal flaws' (O'Cathain, Hoddinott, Lewin et al., 2015) of Morita Therapy requiring refinement in the future.

(2) Joint categories/ themes display

This technique was driven by the quantitative data to explore views of Morita Therapy across participants with various degrees of treatment adherence. Thus, categories of participants were identified by their degree of treatment adherence (whether they attended <5 or ≥5 treatment sessions) and reason for ending treatment (withdrawal or treatment completed). For each category, summaries of participants' views were presented according to the themes identified in the qualitative analysis, allowing the exploration of similar and different views on acceptability within and between these categories.

(3) Case-oriented merged analysis display

Data on participants' views on acceptability and the number of treatment sessions they attended were integrated in a case-oriented display organised according to the quantitative data. Thus, cases (individual participants) were positioned on a scale of treatment adherence from one to twelve sessions attended and presented alongside participant quotations and mini-summaries developed from the qualitative data to illustrate each participant's main views on the acceptability of Morita Therapy. These qualitative data were reviewed for similarities and differences across the number of sessions attended.

To provide further context and enable the exploration of how the data also related to quantitative treatment outcomes, participants' reasons for withdrawing from treatment and whether or not they demonstrated a response to treatment

(defined as a PHQ-9 <10 at follow-up) were also presented within these displays and discussed within the analysis.

6.7 Ethical issues

This study was conducted in such a way as to protect the human rights and dignity of the participants, as reflected in the Helsinki Declaration (World Medical Association, 2001). The study received ethical approval from the National Research Ethics Service South West – Frenchay (reference 15/SW/0103) and governance assurance from the National Health Service Research and Development Directorate (reference CG/JL) (Appendix IX), and was approved by the University of Exeter Medical School following independent peer review.

Participants did not receive any financial inducement to participate. Good Clinical Practice Guidelines, data protection and freedom of information acts were conformed to. All data were stored securely and anonymised wherever possible. All identifiable participant information was stored separately to questionnaire data which were coded by trial ID number only. No published material will contain identifiable participant information.

6.7.1 Informed consent and withdrawal

The study researchers were fully trained and supervised by senior academic and clinically qualified staff. All information leaflets and consent forms were produced using the current Health Research Authority's online guidance for writing such documents (http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/), and were based on similar materials used in other mental health trials as informed by Patient and Public Involvement.

Informed consent was determined by a two phase process. Potential participants received a 'study summary sheet' and a form on which to complete their contact details and confirm their permission for a researcher to contact them. Those who returned this form were telephoned to assess their potential eligibility and answer any questions. For those who were eligible and willing, a participant information leaflet was sent and a baseline interview arranged at

least 48 hours later, to allow the participant time to reflect on their decision to participate and change their mind if they so wished. Full informed consent was only obtained at this interview where the information leaflet was fully explained and the opportunity to ask questions given.

Consent to participate in the qualitative interview was optional; participants could participate in the pilot RCT only. The purpose and content of the interview was explained in the participant information leaflet (or interviewee information sheet, for therapists), and it was noted that a decision not to be interviewed would not affect participation in the trial. At baseline interview (for participants) and the pre-trial meeting (for therapists), any questions were answered, the opportunity to stop and/or withdraw from the interview at any time explained, and steps to maintain confidentiality clarified. Willing participants were asked to indicate their decision on the consent from. Consent for audio recording of the interview and/or therapy sessions was also optional.

Informed consent was treated as an ongoing process whereby participants were free to withdraw their consent to participate at any time; communication and recording systems to enable such wishes to be monitored and acted upon were set up. When obtaining consent, participants were advised of this fact and that they may be asked to give a reason for their withdrawal but would not have to provide one. Participants allocated to Morita Therapy plus TAU could withdraw from therapy and continue their involvement in the trial through participation in the follow-up and qualitative interview if they so wished.

Should it have come to our attention that a participant lost capacity to consent during the study according to the Mental Capacity Act 2005 (Department of Health, 2005), the participant would have been withdrawn from the study as per information provided to participants in the participant information leaflet. Within this leaflet, participants were also informed that if they should withdraw or be withdrawn from the study, any data already provided would be retained to be used confidentially in relation to the purpose for which consent was sought.

6.7.2 Risks and benefits

No treatment was withheld from participants taking part in this study. All participants remained under the care of their GP and had access to primary care services in the usual way. Participants allocated to TAU alone were returned to the care of their GP with no restrictions placed on treatment options. Participants allocated to Morita Therapy plus TAU were asked not to engage in other formal courses of psychological therapy during their treatment, as it is not considered good practice to engage in different psychological therapies concurrently. Should these participants have wished to engage in psychological therapy elsewhere, a discussion would have been held with their therapist to establish which therapy option was in the participant's best interests.

Participants allocated to Morita Therapy plus TAU took part in an alternative therapeutic approach to psychopathology which is practiced in Japan and somewhat elsewhere. Morita Therapy has been practiced since the 1920s and is not known to be associated with any risks to patients. It is possible that participation in therapy focused on psychopathology may cause distress to some participants, however participants in the Morita Therapy arm received an intensive level of monitoring so that any worsening or at suicidal risk could be identified and directed to appropriate care. Similarly, any impact of potentially distressing questions within the assessment and outcome measures could be addressed by following protocols for responding to risk and directing participants to appropriate care. Additionally, any serious adverse events reported to a therapist or researcher which were thought to be treatment related (see Appendix IX for reporting form) would have been reported to the trial sponsor, Research Ethics Committee and independent oversight clinician (section 6.10).

The patient information leaflet explained that participants allocated to Morita Therapy plus TAU would no longer be offered such therapy once they had received a full 'dose' (up to twelve sessions), but would be referred back to their GP with whom they could consider access to other treatments. Participants were reminded of these factors throughout the study.

The University of Exeter has insurance to cover the potential legal liability for any harm to participants arising from the management of this study. Potential participants were also provided with information about the possible benefits and risks of taking part in the trial in the participant information leaflet, and given the opportunity to discuss this issue with the study researchers before consenting. Should any new information have come to light which may have affected participants' willingness to participate in the study, they would have been informed of this in writing.

6.7.3 Managing risk of suicide

Inherent in the nature of the population under scrutiny is the risk of suicide. Good clinical practice was followed in monitoring for suicide risk during all appointments, and it was explained to participants that their GP or specialist would be contacted if deemed necessary in line with our risk protocol (Appendix IX). If an acute risk was present, advice was sought from the participant's GP (or the duty GP) immediately and/or locally established suicide management plans were followed. All clinicians and researchers were familiar with established risk protocols used in previous research trials and/or within the AccEPT Clinic, specifically trained in risk assessment and supervised by experienced clinicians. Systems were set up to ensure that senior academic and clinically qualified staff were notified in the event of a risk to a participant's safety.

6.8 Patient and public involvement

The patient materials were developed on the basis of both consultation with a Public and Patient Involvement (PPI) Expert and similar materials used in other mental health trials which had received feedback from PPI groups such as the NIHR Collaboration for Leadership in Applied Health Research and Care, South West Peninsula (PenCLAHRC) (http://clahrc-peninsula.nihr.ac.uk/) PPI Group (PenPIG). This feedback helped to ensure that this study respected the rights, safety and dignity of participants. Ensuring that the research materials were sensitive and consistent with the views of people with depression also potentially aided participant recruitment and participants' engagement in and openness during interviews.

Following completion of the study, a former trial participant expressed interest in supporting the dissemination of study results and future research into Morita Therapy in a PPI capacity. Thus, to ensure that the study results reached former participants and people with mental health issues in a way that is meaningful and accessible, this PPI representative has been consulted on the development of a summary sheet explaining the results of the study and their implications in lay terms. This summary sheet has been sent to consenting former participants, and to the AccEPT Clinic Lived Experience Group to be further disseminated to patients and the public as they see fit, using their own conference and group meetings. This PPI representative has also consented to be involved in the further dissemination of study results to patients and the public at relevant conferences. National good practice guidance for researchers on public involvement in research and the paying of representatives (http://clahrc-peninsula.nihr.ac.uk/) has been, and will continue to be, followed where relevant.

6.9 Dissemination protocol

In addition to the dissemination of results to participants and the public detailed above, and dissemination within this thesis, the intention is to publish results in peer reviewed scientific journals. Authors will be those considered to have made a substantive intellectual contribution to the study. The main output from this study is the information required to design and seek funding to conduct a definitive trial of Morita Therapy. Thus, the long term aim is to contribute to national guidelines for the treatment of depression and anxiety.

The investigators and relevant authorities have access to the trial dataset. Furthermore, anonymised research data and outputs will be stored in the University of Exeter's Open Research Exeter repository (https://ore.exeter.ac.uk/repository/) in order to facilitate open access to, and the impact of, this research.

6.10 Study set up and management

HVRS (PhD candidate) was the Chief Investigator, responsible for the study design, set-up and management. In tasks relating to participant recruitment,

collection of follow-up data, interview transcription and data entry, HVRS was assisted by a professional training year student on a twelve month placement with the study team (together with HVRS referred to as 'the study researchers'). Trial conduct was discussed between HVRS and supervisors at monthly supervision meetings. An AccEPT Clinic Protocol detailing the administrative and research procedures to be followed was developed by HVRS, disseminated to AccEPT Clinic staff and discussed during a pre-trial meeting. HVRS handled all research-related queries and was in regular communication with AccEPT Clinic staff.

Although the convention of a formal Data Monitoring and Ethics Committee was not considered appropriate for the scale of this study, an independent clinician acted in this capacity to review any serious adverse events thought to be treatment related, and any substantive protocol amendments. Any such amendments would have been communicated to the relevant authorities as deemed necessary.

6.10.1 Execution dates

The preparatory period started in October 2014. Recruitment ran from October 2015 for approximately eleven months. Follow-up and qualitative data were collected from January 2016 to January 2017. Data analysis was conducted from February 2017 for five months. The study protocol paper (Sugg et al., 2016) was published following submission in December 2015.

6.11 Chapter summary

This chapter has presented the design, methods and procedures of the mixed methods feasibility study undertaken to prepare for a fully-powered RCT of Morita Therapy plus TAU compared with TAU alone for the treatment of depression and anxiety in adults in the UK. Study results are described in Chapter Seven.

CHAPTER SEVEN. MIXED METHODS FEASIBILITY STUDY: RESULTS

This chapter presents the results of the mixed methods feasibility study, incorporating a pilot randomised controlled trial (RCT) and embedded qualitative interviews, undertaken to prepare for the design and conduct of a fully-powered RCT of Morita Therapy plus treatment as usual (TAU) versus TAU alone, or to determine that such a trial is not appropriate and/or feasible. This chapter describes the results obtained in response to each of the seven research questions:

1. What proportion of participants approached to take part in the trial will agree to do so?
2. What proportion of participants who agree to take part in the trial will remain in the trial at four month follow-up?
3. What proportion of participants who agree to take part in Morita Therapy will adhere to a pre-defined per-protocol dose of Morita Therapy?
4. What is the variance in participant outcomes following Morita Therapy plus TAU and TAU alone, and how do they correlate with participants' baseline scores?
5. What are the estimated between-group differences (and 95% confidence intervals) in participant outcomes following Morita Therapy plus TAU and TAU alone?
6. How acceptable is Morita Therapy to participants and therapists?
7. How do participants' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?

Chapter structure

This chapter is divided into four parts. Part one, the quantitative analysis of the pilot RCT data, describes the findings regarding questions one to five. Part two, the qualitative analysis of the embedded qualitative interviews, describes the findings regarding question six. Part three, the mixed methods analysis integrating data from the pilot RCT and embedded qualitative interviews, describes the findings regarding question seven. Part four summarises the key findings in relation to each research question.

CHAPTER SEVEN. PART ONE.

Results of the quantitative analysis of pilot RCT data

This part of Chapter Seven is organised into five main sections: participant flow and retention (7.1.1); baseline characteristics (7.1.2); receipt of Morita Therapy (7.1.3); treatment outcomes (7.1.4); economic data (7.1.5).

7.1.1 Participant flow and retention

The CONSORT (Eldridge et al., 2016) flow chart for the feasibility study is presented in Figure 13, overleaf.

Recruitment

Within an eleven month period between October 2015 and September 2016, 68 participants were randomised into the trial (Figure 12): 34 (50%) to Morita Therapy; 34 (50%) to treatment as usual (TAU).

Figure 12. Graph of participant recruitment
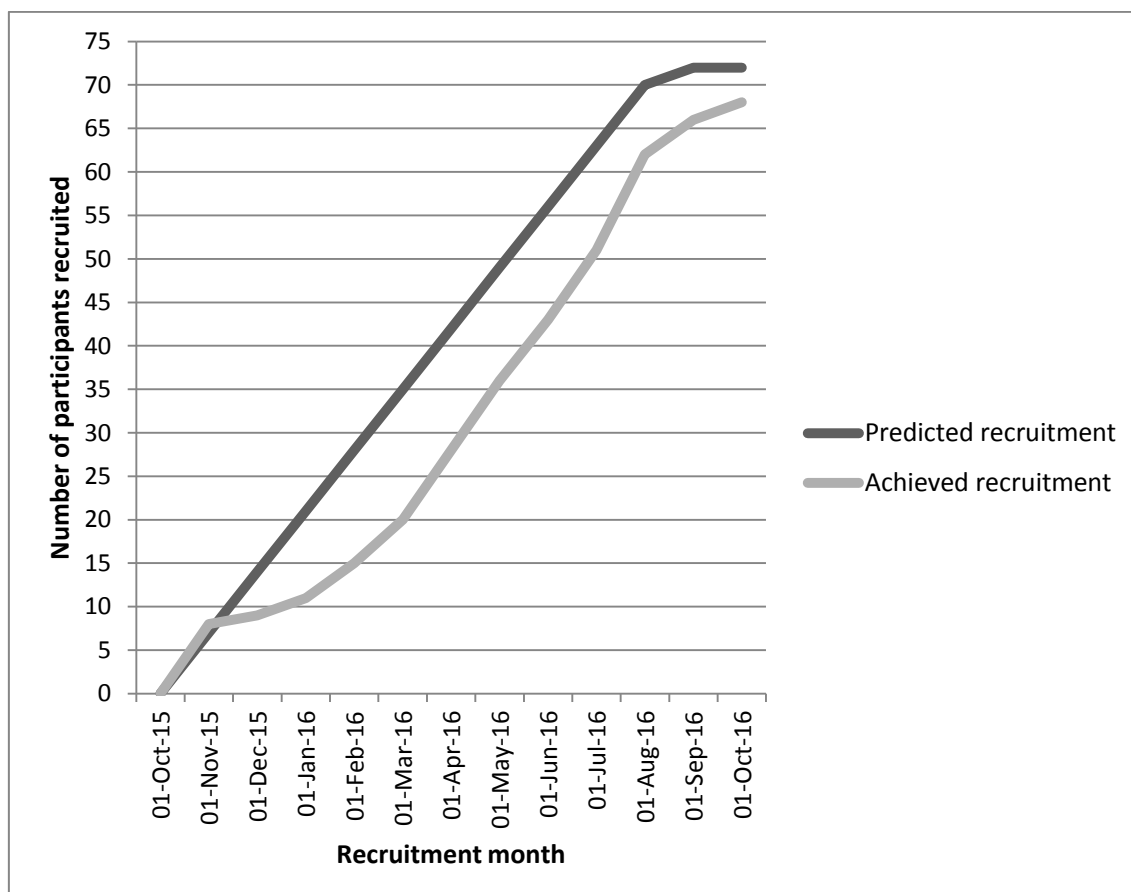
Figure 13. Feasibility study CONSORT diagram
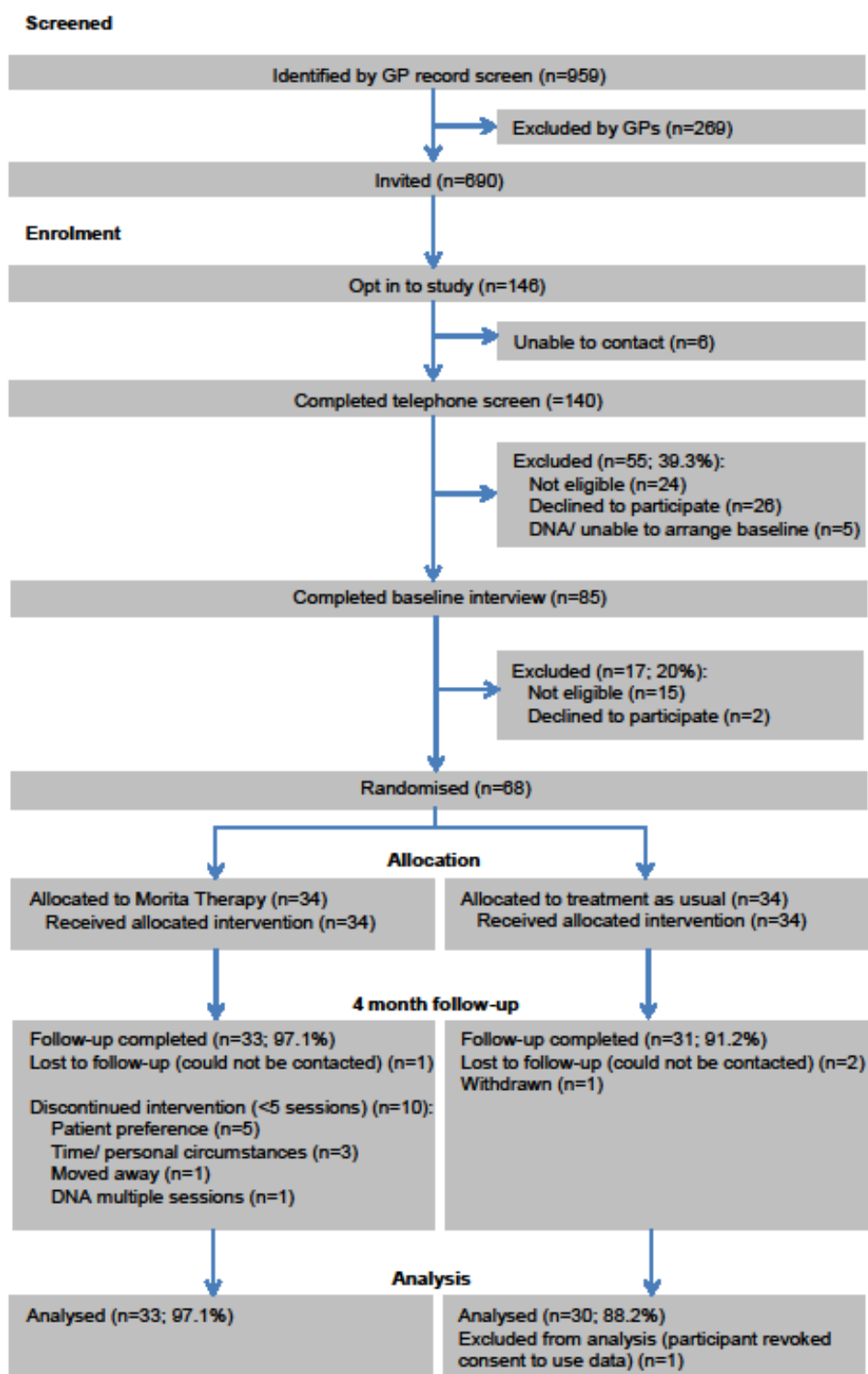
As a variety of recruitment sources were utilised (see Chapter Six) and all are presented together in the CONSORT flow chart, Table 15 is provided to show the flow of participants through the trial for each recruitment source separately.

Table 15. Participant flow according to recruitment source

Recruitment source	Number of patients (% of total n)				Randomisation rate (as % of those opting in via this source)
	Opted in (n=146)	Telephone screened (n=140)	Assessed (n=85)	Randomised (n=68)	
GP invite	90 (61.6)	90 (64.3)	46 (54.1)	35 (51.5)	38.9
Leaflet/ flyer in General Practice	25 (17.1)	25 (17.9)	18 (21.2)	15 (22.1)	60.0
Email circulation to former participants	13 (8.9)	13 (9.3)	10 (11.8)	9 (13.2)	69.2
Website advert	3 (2.1)	3 (2.1)	2 (2.4)	1 (1.5)	33.3
Word of mouth	9 (6.2)	9 (6.4)	9 (10.6)	8 (11.8)	88.9
Unknown	6 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0.0

Notes: percentages may not always total 100 due to rounding.

The most successful method of recruitment in terms of randomisation rate was word of mouth, with 88.9% (8/9) of participants opting in via this method being randomised. The majority of potential participants opting into the study were recruited via GP record search (n=90, 61.6%; Table 15). Prior to the participant recruitment period, six General Practices were recruited to undertake four record searches over the course of the recruitment period. One Practice subsequently declined participation due to lack of time; one Practice declined to undertake the third and fourth searches due to the low numbers of potentially eligible patients previously identified. Thus, four Practices undertook four

searches during the recruitment period (in October 2015, January 2016, April 2016 and June 2016), and one Practice undertook two. Due to below-target recruitment rates to date (Figure 12), an additional two Practices were recruited in January 2016, and undertook three searches each; one further Practice was recruited in April 2016 and undertook two searches. Thus, a total of 27 record searches were conducted by Practices across the whole recruitment period. These yielded a total number of 959 potentially eligible participants and, following exclusions by GPs based on the study criteria and their clinical discretion (n=269, 28%; Table 16), study invitations were sent to 690 patients.

Table 16. Participants excluded from invitation by GPs

Reason for exclusion	Number of patients excluded (%) (n=269)
Current psychological therapy	111 (41.3)
Substance dependence	19 (7.1)
Not depressed	17 (6.3)
Acutely suicidal	13 (4.8)
Bipolar disorder or psychotic symptoms	9 (3.3)
Cognitively impaired	7 (2.6)
Other	78 (29.0)
Unknown	15 (5.6)

Notes: percentages may not always total 100 due to rounding.

Over the recruitment period, 146 patients opted into the trial, i.e. completed and returned a 'permission to contact form' to the study team. Of those, 4.1% (6/146) could not be contacted for telephone screen. Of those contacted for telephone screen (140/146; 95.9%), 39.3% (55/140) were excluded at this stage (Table 17, overleaf). Baseline interviews were conducted with 85 participants (58.2% of those who opted in (85/146); 60.7% of those assessed at telephone screen (85/140)). Of those who attended baseline interview, 20% (17/85) were excluded at this stage (Table 17, overleaf). In total, 46.6% of those who opted into the study (68/146) were randomised into the trial.

Table 17. Reasons for potential participants excluded at telephone screen and baseline interview

	Telephone screen	Baseline interview
	N patients excluded (%)	
	(n=55)	(n=17)
Met study exclusion criteria	24 (43.6)	15 (88.2)
Current/ planned psychological therapy	*13 (23.6)*	*0 (0.0)*
Not depressed	*10 (18.2)*	*9 (52.9)*
Bipolar disorder/ mania	*1 (1.8)*	*3 (17.6)*
Substance dependence	*0 (0.0)*	*1 (5.9)*
Acutely suicidal	*0 (0.0)*	*1 (5.9)*
Psychotic symptoms	*0 (0.0)*	*1 (5.9)*
Declined to proceed	26 (47.3)	2 (11.8)
Time commitment	*9 (16.4)*	*0 (0.0)*
Unable/ unwilling to travel for therapy appointments	*5 (9.1)*	*0 (0.0)*
Too anxious to participate	*4 (7.3)*	*0 (0.0)*
Personal circumstances	*3 (5.5)*	*0 (0.0)*
Unwilling to be randomised	*2 (3.6)*	*0 (0.0)*
Did not consider self eligible	*1 (1.8)*	*0 (0.0)*
Moving away	*1 (1.8)*	*0 (0.0)*
Undisclosed	*1 (1.8)*	
Unwilling to consent to all clauses	*0 (0.0)*	*1 (5.9)*
Unwilling to complete paperwork	*0 (0.0)*	*1 (5.9)*
Did not attend/ unable to arrange baseline interview	5 (9.1)	N/A

Notes: percentages may not always total 100 due to rounding.

The 690 study invitations sent to potentially eligible participants identified via GP record search translated to 35 participants randomised into the trial, at a rate of 5.1% of those invited, with 33 of those randomised recruited from alternative sources (see Table 15). The proportion of patients invited via GP record search who opted into the study by returning their permission to contact form was 13.0% (90/690).

Based on the 95% confidence interval for the recruitment rate of participants recruited via <u>GP record search only</u>, it is estimated that in a future trial the proportion of patients invited via GP record search who are randomised into the trial would be between 3.4% and 6.6%; the proportion invited who return a permission form would be between 10.5% and 15.5%.

Retention

Four month follow-up data were collected from January 2016 to January 2017 inclusive. The retention rate was 94% (64/68).

The retention rate was 97% (33/34) in the Morita Therapy arm and 91% (31/34) in TAU. Several participants randomised to TAU expressed some disappointment at the time of their allocation. In the Morita Therapy arm, one participant was lost to follow-up as they could not be contacted; in TAU, two participants were lost to follow-up as they could not be contacted and one participant withdrew from the study on the basis that they had not received active treatment. An additional TAU participant, after attending follow-up, revoked consent for their data to be included in the trial. Thus, whilst they are included within the CONSORT figures, their data have not been included the analysis of baseline characteristics or treatment outcomes.

The option of completing follow-up questionnaires via post or email rather than during face-to-face interview was used by 21.2% (7/33) of those retained in the Morita Therapy arm and 38.7% (12/31) in TAU. As such, not all follow-up data were collected at precisely four months post-baseline assessment. The average length of time between baseline assessment and completion of follow-up data for all participants was 4.3 months (range 3.8-6.1), or 18.5 weeks. The range in the intervention and control groups was 3.8-6.1 months and 4.0-5.6 months respectively. All but one of the participants in the Morita Therapy arm (33/34, 97%) ended treatment prior to providing follow-up data; this participant provided follow-up data between therapy sessions ten and eleven.

From the 95% confidence interval around the retention rate, it can be inferred that in a future trial the proportion of randomised participants who would complete a four month follow-up would be between 88.3% and 99.7%.

7.1.2 Baseline characteristics

At baseline, the mean age was 49.2 years (SD 15.2) (Table 18). The majority of participants were female (n=41, 61%), White British (n=61, 91%) and married or cohabiting (n=39, 58%). A small minority had no qualifications (n=5, 7.5%), 19% (n=13) were qualified at GCSE or O Level, 22% (n=15) post GCSE or O Level, 28% (n=19) at undergraduate level and 22% (n=15) at postgraduate level. At baseline, 60% of participants (n=40) were taking antidepressant medication. The majority had previously experienced psychotherapy (n=49, 73%) and/or counselling (n=29, 43%), the most common form being Cognitive Behavioural Therapy (n=41, 61%).

The mean PHQ-9 score at baseline was 16.8 (SD 4.6): 31% (n=21) met the cut-off for moderate depression, 37% (n=25) for moderately severe depression and 27% (n=18) for severe depression. The majority had experienced at least one previous episode of depression (n=54, 81%), with the mean age of depressive onset 27.1 years (SD 17.6) and mean length of current depressive episode 21.3 months (SD 32.4). The majority (n=49, 73%) had a secondary SCID diagnosis of a current anxiety disorder, the most common being generalised anxiety disorder (n=30, 45%). The mean GAD-7 score at baseline was 12.7 (SD 4.4): 15% (n=10) met the cut-off for mild anxiety, 42% (n=28) for moderate anxiety and 39% (n=26) for severe anxiety.

Table 18. Participant baseline characteristics

	Morita Therapy (n=34)	Treatment as usual (n=33*)	Total (n=67)
Gender			
Female	22 (64.7)	19 (57.6)	41 (61.2)
Male	12 (35.3)	14 (42.4)	26 (38.8)
Age (years)			
Mean (SD)	49.8 (14.8)	48.6 (15.9)	49.2 (15.2)
Ethic origin			
White British	31 (91.2)	30 (90.9)	61 (91.0)

Continued overleaf

White other	2 (5.9)	0 (0.0)	2 (3.0)
Mixed other	0 (0.0)	2 (6.1)	2 (3.0)
Asian Indian	0 (0.0)	1 (3.0)	1 (1.5)
Asian other	1 (2.9)	0 (0.0)	1 (1.5)
Education			
No qualifications	3 (8.8)	2 (6.1)	5 (7.5)
GCSE or O Level	7 (20.6)	6 (18.2)	13 (19.4)
Post GCSE or O Level	7 (20.6)	8 (24.2)	15 (22.4)
Undergraduate degree	9 (26.5)	10 (30.3)	19 (28.4)
Postgraduate qualification or higher	8 (23.5)	7 (21.2)	15 (22.4)
Marital status			
Married or cohabiting	23 (67.6)	16 (48.5)	39 (58.2)
Number of children			
Mean (SD)	1 (1)	1 (1)	1 (1)
History of depression			
One or more previous episodes	29 (85.3)	25 (75.8)	54 (80.6)
Age of onset (mean (SD))	28.9 (17.8)	25.2 (17.4)	27.1 (17.6)
Duration of current episode in months (mean (SD))	13.1 (12.8)	30.3 (43.8)	21.3 (32.4)
PHQ-9 (depression) score			
Mean (SD)	17.4 (4.7)	16.1 (4.5)	16.8 (4.6)
PHQ-9 depression threshold met			
Mild (scored 5-9)	0 (0.0)	3 (9.1)	3 (4.5)
Moderate (scored 10-14)	9 (26.5)	12 (36.4)	21 (31.3)
Moderately severe (scored 15-19)	14 (41.2)	11 (33.3)	25 (37.3)
Severe (scored 20-27)	11 (32.4)	7 (21.2)	18 (26.9)
GAD-7 (anxiety) score			
Mean (SD)	13.3 (4.8)	12.2 (4.0)	12.7 (4.4)
GAD-7 anxiety threshold met			
Non-clinical (scored <5)	2 (5.9)	1 (3.0)	3 (4.5)
Mild (scored 5-9)	4 (11.8)	6 (18.2)	10 (14.9)
Moderate (scored 10-14)	13 (38.2)	15 (45.5)	28 (41.8)
Severe (scored 15-21)	15 (44.1)	11 (33.3)	26 (38.8)

Continued overleaf

Secondary SCID diagnoses (current)			
Any anxiety disorder	21 (61.8)	28 (84.8)	49 (73.1)
Generalised anxiety disorder	13 (38.2)	17 (51.5)	30 (44.8)
Social phobia	5 (14.7)	11 (33.3)	16 (23.9)
Panic disorder with agoraphobia	6 (17.6)	8 (24.2)	14 (20.9)
Panic disorder without agoraphobia	7 (20.6)	3 (12.6)	10 (14.9)
Post-traumatic stress disorder	3 (8.8)	7 (21.2)	10 (14.9)
Obsessive Compulsive Disorder	2 (5.9)	5 (15.2)	7 (10.4)
Specific phobia	1 (2.9)	4 (12.1)	5 (7.5)
Agoraphobia without panic disorder	1 (2.9)	1 (3.0)	2 (3.0)
Antidepressant treatment			
Currently prescribed antidepressants	20 (58.8)	20 (60.6)	40 (59.7)
Previous psychotherapy/ counselling **(at least one course of)**			
Any psychotherapy (not including counselling)	23 (67.6)	26 (78.8)	49 (73.1)
Cognitive Behavioural Therapy	20 (58.8)	21 (63.6)	41 (61.2)
Mindfulness-based Cognitive Therapy	8 (23.5)	6 (18.2)	14 (20.9)
Behavioural Activation	1 (2.9)	3 (9.1)	4 (6.0)
Eye Movement Desensitization and Reprocessing	2 (5.9)	2 (6.1)	4 (6.0)
Counselling	15 (44.1)	14 (42.4)	29 (43.3)
Other psychotherapy	9 (26.5)	10 (30.3)	19 (28.4)

Notes: data are number (%) unless stated otherwise; SD=standard deviation; SCID=Structured Clinical Interview for DSM-IV-TR Axis I Disorders; PHQ-9=Patient Health Questionnaire 9; GAD-7=Generalised Anxiety Disorder Questionnaire 7; percentages may not always total 100 due to rounding; *34 participants were randomised into treatment as usual, with 33 participants' characteristics included due to one participant revoking consent to include data.

7.1.3 Receipt of Morita Therapy

No participants in the intervention group declined to start Morita Therapy and 70.6% (n=24) adhered to a per-protocol minimum dose (≥five sessions, corresponding to 40% of the maximum available twelve sessions). The mean number of sessions attended for all participants was 7.7 (range 1-14; SD 4.0); the mean number attended for those who did and did not adhere to the

minimum dose was 9.8 (range 5-14; SD 2.5) and 2.6 (range 1-4; SD 1.0) respectively. All but one participant ended treatment before providing follow-up data.

Overall, 18 participants (52.9%) completed treatment at the social reintegration (final) phase, having completed between eight and fourteen sessions (mean 10.9 sessions; SD 1.6); 15 (44.1%) ended treatment prior to the point at which their therapist believed they were ready to do so (categorised as 'withdrew'), the majority of whom did so during the rest (first) phase (n=10; 66.7%). The therapist ended treatment early, following six sessions, for the remaining participant (n=1; 2.9%) due to pain interfering with their ability to engage in treatment.

Of those who withdrew (Table 19, overleaf), one participant (2.9%) was discharged following two sessions due to missing multiple sessions, as per the DNA protocol, and could not be contacted to determine a reason. Nine participants (26.5%) withdrew having completed less than five sessions; the reasons provided may be categorised as patient preference (55.6%; coded red); time or personal circumstances (33.3%; coded yellow); moving away (11.1%; coded blue). Five participants withdrew after attending five or more sessions, due to patient preference (40%); time or personal circumstances (20%); and the patient feeling ready to end treatment prior to the point at which their therapist considered treatment complete (40%; coded green).

Table 19. Point of and reason for withdrawal from Morita Therapy

No. sessions	Reason for withdrawal (as reported to research team by therapist)	Latest phase of treatment
1	Patient felt unable to complete the rest phase in a meaningful way given family and career demands	Rest (1)
2	None provided, 'Did Not Attend' protocol enacted	
	Patient did not consider the therapy suited to them or to their liking	
	Patient felt unable to provide the necessary time and investment	
	Patient described needing more intensive support with increased anxiety triggered by threatening neighbour	
3	Patient felt unable to provide the necessary level of personal commitment at this time	
	Patient did not consider the therapy suited to them	
	Patient described difficulties with rest and diary completion	
4	Patient felt they were making little progress and found some of the process difficult to understand	
	Patient moved away	
5	Patient felt they were not in the right place to continue therapy given their separation from their partner	Light activities (2)
	Patient found rest difficult, had little support from their partner and felt they were avoiding something terrible	
7	Patient described mood deterioration and difficulty with diary completion	Heavy activities (3)
	Patient felt ready to end treatment	
8	Patient felt ready to end treatment	Light activities (2)

7.1.4 Treatment outcomes

Variability in outcomes

The standard deviations around mean scores on the PHQ-9, GAD-7, Work and Social Adjustment Scale (WSAS), Morita Attitudinal Scale for Arugamama (MASA), and physical and mental component scales (PCS, MCS) of the SF-36, and their 95% confidence intervals, at baseline and four month follow-up, are provided in Table 20, overleaf. The pooled standard deviation (SD) around the mean PHQ-9 score at baseline was 4.6; equivalent figures for the intervention and control groups were 4.7 and 4.5 respectively. At follow-up, the pooled SD around the mean PHQ-9 score was 6.4; equivalent figures for the intervention and control groups were 6.5 and 5.7 respectively.

The 95% confidence intervals indicate that, in a future trial, the pooled SD around the mean PHQ-9 score at baseline would be between 3.9 and 5.6 (from 3.8 to 6.2 and from 3.6 to 6.0 for the intervention and control groups respectively); at follow-up, between 5.5 and 7.8 (from 5.2 to 8.6 and from 4.6 to 7.7 for the intervention and control groups respectively).

Table 20 overleaf

Table 20. Variability in outcomes at baseline and four month follow-up

Outcome	Morita Therapy				Treatment as usual				All participants			
	n	Mean	SD	95% CI	n	Mean	SD	95% CI	n	Mean	SD	95% CI
PHQ-9 baseline	34	17.4	4.7	3.8 to 6.2	33	16.1	4.5	3.6 to 6.0	67	16.8	4.6	3.9 to 5.6
PHQ-9 4 months	33	8.4	6.5	5.2 to 8.6	30	12.4	5.7	4.6 to 7.7	63	10.3	6.4	5.5 to 7.8
GAD-7 baseline	34	13.3	4.8	3.9 to 6.4	33	12.2	4.0	3.2 to 5.3	67	12.7	4.4	3.8 to 5.3
GAD-7 4 months	32	6.8	5.2	4.2 to 7.0	30	8.7	4.7	3.7 to 6.3	62	7.7	5.0	4.3 to 6.1
WSAS baseline	34	22.7	7.9	6.3 to 10.3	33	22.1	7.4	6.0 to 9.8	67	22.4	7.6	6.5 to 9.2
WSAS 4 months	32	13.5	11.0	8.9 to 14.7	30	18.0	9.4	7.5 to 12.7	62	15.7	10.5	8.9 to 12.7
MASA baseline	34	80.7	29.3	23.6 to 38.5	33	72.7	23.0	18.5 to 30.5	67	76.8	26.5	22.6 to 31.9
MASA 4 months	32	114.4	40.3	32.3 to 53.6	30	91.8	27.7	22.1 to 37.3	62	103.5	36.3	30.9 to 44.2
SF-36 PCS baseline	34	49.6	12.3	10.0 to 16.2	33	52.2	10.6	8.5 to 14.0	67	50.9	11.5	9.8 to 13.9
SF-36 PCS 4 months	33	47.9	13.0	10.5 to 17.2	30	51.1	10.8	8.6 to 14.5	63	49.4	12.0	10.2 to 14.6
SF-36 MCS baseline	34	25.0	8.8	7.1 to 11.6	33	23.8	6.6	5.3 to 8.7	67	24.4	7.8	6.6 to 9.3
SF-36 MCS 4 months	33	39.8	11.9	9.6 to 15.7	30	30.1	11.0	8.8 to 14.8	63	35.2	12.4	10.5 to 15.0

Notes: SD=standard deviation of the mean; 95% CI = 95% confidence intervals around the standard deviation; PHQ-9=Patient Health Questionnaire 9; GAD-7=Generalised Anxiety Disorder Questionnaire 7; WSAS=Work and Social Adjustment Scale; MASA=Morita Attitudinal Scale for Arugamama; SF-36= Short Form 36 Health Survey Questionnaire; PCS=Physical Component Scale; MCS=Mental Component Scale

Correlation between baseline and four month scores

The size of the correlations between Morita Therapy participants' PHQ-9, GAD-7, WSAS, MASA and MCS scores at baseline and follow-up were all in the medium range (Spearman's Rho ranging from 0.37 to 0.45), with the PCS correlation in the large range (Spearman's Rho 0.78), according to commonly used guidelines (Cohen, 1988). For TAU, the equivalent correlations were in the large range (Spearman's Rho ranging from 0.51 to 0.76), with the exception of the MCS, which was in the medium range (Spearman's Rho 0.39). The 95% confidence intervals associated with each correlation are provided (Table 21).

Table 21. Correlation between participant scores at baseline and four months

Association	Participants	n	Rho	95% CIs	p
PHQ-9 at baseline and 4 months	All	63	0.42	0.19 to 0.61	<0.001
	Morita Therapy	33	0.37	0.04 to 0.64	0.032
	Treatment as usual	30	0.71	0.47 to 0.85	<0.001
GAD-7 at baseline and 4 months	All	62	0.40	0.17 to 0.59	0.001
	Morita Therapy	32	0.40	0.07 to 0.66	0.022
	Treatment as usual	30	0.51	0.18 to 0.73	0.004
WSAS at baseline and 4 months	All	62	0.52	0.31 to 0.68	<0.001
	Morita Therapy	32	0.45	0.12 to 0.69	0.009
	Treatment as usual	30	0.76	0.55 to 0.88	<0.001
MASA at baseline and 4 months	All	62	0.58	0.39 to 0.73	<0.001
	Morita Therapy	32	0.45	0.12 to 0.69	0.009
	Treatment as usual	30	0.73	0.50 to 0.86	<0.001
SF-36 PCS at baseline and 4 months	All	63	0.68	0.52 to 0.80	<0.001
	Morita Therapy	33	0.78	0.59 to 0.88	<0.001
	Treatment as usual	30	0.58	0.27 to 0.78	<0.001
SF-36 MCS at baseline and 4 months	All	63	0.42	0.20 to 0.61	<0.001
	Morita Therapy	33	0.43	0.10 to 0.67	0.012
	Treatment as usual	30	0.39	0.04 to 0.66	0.033

Notes: Rho=Spearman's Rho; 95% CI = 95% confidence intervals around Spearman's Rho; PHQ-9=Patient Health Questionnaire 9; GAD-7=Generalised Anxiety Disorder Questionnaire 7; WSAS=Work and Social Adjustment Scale; MASA=Morita Attitudinal Scale for Arugamama; SF-

36= Short Form 36 Health Survey Questionnaire; PCS=Physical Component Scale;
MCS=Mental Component Scale

Between-group differences in treatment outcomes

This study was not powered to detect clinically meaningful differences in the
effectiveness of Morita Therapy versus TAU, thus inferential statements on
between (or within) group differences cannot be made and no p-values have
been calculated.

From baseline to follow-up, participants' symptoms of depression (PHQ-9)
reduced in both groups: averaging 9.0 points (SD 5.9) in the Morita Therapy
arm; 3.5 points (SD 4.2) in TAU. Participants' symptoms of anxiety (GAD-7)
also reduced in both groups: averaging 6.6 points (SD 5.6) in the Morita
Therapy arm; 3.3 points (SD 4.3) in TAU. Participants' acceptance and
allowance of symptoms (MASA) increased in both groups: averaging 32.8
points (SD 37.2) in the Morita Therapy arm; 17.2 points (SD 19.0) in TAU.

Participants' impairment in functioning (WSAS) reduced in both groups:
averaging 9.7 points (SD 9.7) in the Morita Therapy arm; 3.7 points (SD 6.5) in
TAU (Mundt et al., 2002). Participants' mental health function (MCS) increased
in both groups: averaging 14.7 points (SD 11.3) in the Morita Therapy arm; 6.6
points (SD 10.3) in TAU (Ware et al., 2008). From baseline to follow-up,
participants' physical health function (PCS) did not improve: the mean reduction
was 1.7 points (SD 6.6) in the Morita Therapy arm; 2.2 points (SD 8.5) in TAU.

Depressive symptoms (PHQ-9) reduced from baseline to follow-up by an
average of 5.5 points more in the Morita Therapy group compared to TAU.
Based on this sample and the confidence intervals provided (Table 22,
overleaf), it can be said with 95% certainty that the true mean reduction in
participants' PHQ-9 scores from baseline to four month follow-up will be greater
following Morita Therapy, compared to TAU, by somewhere between 2.9 and
8.1 points. To put these findings in context, the published minimum clinically
important difference on the PHQ-9 is 2.59 to 5.00 (Löwe, Unützer, Callahan et
al., 2004).

Table 22. Treatment outcomes at baseline and four month follow-up with between-group differences

Outcome measure	Participants	Baseline			4 months			Change from baseline to 4 months			Between-group difference	
		n	Mean	SD	n	Mean	SD	n	Mean	SD	Mean	95% CI
PHQ-9	All	67	16.8	4.6	63	10.3	6.4	63	-6.3	5.8		
	Morita Therapy	34	17.4	4.7	33	8.4	6.5	33	-9.0	5.9	-5.5	-8.1 to -2.9
	Treatment as usual	33	16.1	4.5	30	12.4	5.7	30	-3.5	4.2		
GAD-7	All	67	12.7	4.4	62	7.7	5.0	62	-5.0	5.2		
	Morita Therapy	34	13.3	4.8	32	6.8	5.2	32	-6.6	5.6	-3.3	-5.8 to -0.7
	Treatment as usual	33	12.2	4.0	30	8.7	4.7	30	-3.3	4.3		
WSAS	All	67	22.4	7.6	62	15.7	10.5	62	-6.8	8.8		
	Morita Therapy	34	22.7	7.9	32	13.5	11.0	32	-9.7	9.7	-5.9	-10.1 to -1.7
	Treatment as usual	33	22.1	7.4	30	18.0	9.4	30	-3.7	6.5		
MASA	All	67	76.8	26.5	62	103.5	36.3	62	25.3	30.6		
	Morita Therapy	34	80.7	29.3	32	114.4	40.3	32	32.8	37.2	15.5	0.4 to 30.7
	Treatment as usual	33	72.7	23.0	30	91.8	27.7	30	17.2	19.0		
SF-36 PCS	All	67	50.9	11.5	63	49.4	12.0	63	-1.9	7.5		
	Morita Therapy	34	49.6	12.3	33	47.9	13.0	33	-1.7	6.6	0.6	-3.2 to 4.4
	Treatment as usual	33	52.2	10.6	30	51.1	10.8	30	-2.2	8.5		
SF-36 MCS	All	67	24.4	7.8	63	35.2	12.4	63	10.8	11.5		
	Morita Therapy	34	25.0	8.8	33	39.8	11.9	33	14.7	11.3	8.1	2.7 to 13.6
	Treatment as usual	33	23.8	6.6	30	30.1	11.0	30	6.6	10.3		

Notes: SD=standard deviation of the mean; 95% CI = 95% confidence intervals around the mean between-group difference; PHQ-9=Patient Health Questionnaire 9; GAD-7=Generalised Anxiety Disorder Questionnaire 7; WSAS=Work and Social Adjustment Scale; MASA=Morita Attitudinal Scale for Arugamama; SF-36= Short Form 36 Health Survey Questionnaire; PCS=Physical Component Scale; MCS=Mental Component Scale

Improvement in depression and anxiety

Depressive symptoms reduced by 50% or more from baseline to follow-up for 66.7% (22/33) of Morita Therapy participants and 13.3% (4/30) of TAU participants (Table 23). At follow-up, 66.7% (22/33) of Morita Therapy participants scored below the threshold for moderate depression (PHQ-9 <10) compared to 30.0% (9/30) in TAU. Anxiety symptoms reduced by 50% or more from baseline to follow-up for 53.1% (17/32) of Morita Therapy participants and 33.3% (10/30) of TAU participants. At follow-up, 75.0% (24/33) of Morita Therapy participants scored below the threshold for moderate anxiety (GAD-7 <10) compared to 53.3% (16/30) in TAU.

Table 23. Treatment response (≥50% reduction in score from baseline to four months and/or scoring below threshold for moderate symptoms (<10) at four months)

Outcome measure	Participants	n	n (%) showing 50% reduction	n (%) scoring <10 at follow-up	n (%) either showing 50% reduction or scoring <10 at follow-up
PHQ-9	All	63	26 (41.3)	31 (49.2)	32 (50.8)
	Morita Therapy	33	22 (66.7)	22 (66.7)	23 (69.7)
	TAU	30	4 (13.3)	9 (30.0)	9 (30.0)
GAD-7	All	62	27 (43.5)	40 (64.5)	40 (64.5)
	Morita Therapy	32	17 (53.1)	24 (75.0)	24 (75.0)
	TAU	30	10 (33.3)	16 (53.3)	16 (53.3)

Notes: TAU=treatment as usual; PHQ-9=Patient Health Questionnaire 9; GAD-7=Generalised Anxiety Disorder Questionnaire 7

7.1.5 Economic data

Participants' use of health services (in addition to Morita Therapy) since baseline assessment is presented in Table 24 (overleaf). These data were collected for exploratory purposes and in order to define TAU, therefore the costs associated with these services are not presented.

Table 24. Service use at four month follow-up

Service	Participants	n	%	No. contacts		Duration of contacts (minutes)	
				Mean	SD	Mean	SD
Antidepressant medication (continuing at follow-up)	Morita Therapy (n=32)	14	43.8				
	TAU (n=31)	14	45.2				
Psychological therapy	Morita Therapy (n=32)	0	0.0	-	-	-	-
	TAU (n=31)	5	16.1	5.4	4.4	68.0	47.6
Counselling	Morita Therapy (n=32)	0	0.0	-	-	-	-
	TAU (n=31)	3	9.7	6.3	2.1	60.0	0.0
Hospital admission	Morita Therapy (n=33)	2	6.1	1.5	0.7		
	TAU (n=31)	1	3.2	1.0	0.0		
Hospital outpatient appointment	Morita Therapy (n=32)	9	28.1	2.1	1.5		
	TAU (n=31)	9	29.0	2.1	3.0		
A&E attendance	Morita Therapy (n=32)	3	9.4	1.0	0.0		
	TAU (n=31)	3	9.7	1.3	0.6		
GP appointment	Morita Therapy (n=32)	20	62.5	4.8	4.0	12.0	2.4
	TAU (n=31)	17	54.8	2.5	2.0	12.8	6.2
GP home visit	Morita Therapy (n=32)	2	6.3	1.0	0.0	12.5	3.5
	TAU (n=31)	0	0.0	-	-	-	-
GP telephone contact	Morita Therapy (n=32)	10	31.3	3.5	5.0	6.9	4.5
	TAU (n=31)	5	16.1	2.4	1.7	5.0	3.1
Practice nurse	Morita Therapy (n=32)	7	21.9	3.6	5.3	9.3	6.7
	TAU (n=31)	10	32.3	1.6	1.1	12.0	5.8
Psychiatrist	Morita Therapy (n=32)	0	0.0	-	-	-	-
	TAU (n=31)	1	3.2	12	0.0	50.0	0.0
Occupational therapist	Morita Therapy (n=32)	2	6.3	2.5	0.7	35.0	35.4
	TAU (n=31)	1	3.2	5.0	0.0	45.0	0.0
Social worker	Morita Therapy (n=32)	1	3.1	5.0	0.0	60.0	0.0
	TAU (n=31)	0	0.0	-	-	-	-
Advice service	Morita Therapy (n=32)	2	6.3	1.0	0.0	75.0	21.2
	TAU (n=31)	1	3.2	1.0	0.0	60.0	0.0
Helpline	Morita Therapy (n=32)	1	3.1	1.0	0.0	60.0	0.0
	TAU (n=31)	2	6.5	25.0	0.0	30.0	0.0
Chiropractor	Morita Therapy (n=32)	5	15.6	3.8	3.0	29.0	17.5
	TAU (n=31)	3	9.7	2.0	1.7	41.7	10.4
Acupuncture	Morita Therapy (n=32)	1	3.1	1.0	0.0	30.0	0.0
	TAU (n=31)	1	3.2	9.0	0.0	60.0	0.0
Physiotherapist	Morita Therapy (n=32)	1	3.1	3.0	0.0	60.0	0.0
	TAU (n=31)	1	3.2	4.0	0.0	60.0	0.0
Mental Health support worker	Morita Therapy (n=32)	1	3.1	1.0	0.0	60.0	0.0
	TAU (n=31)	1	3.2	6.0	0.0	60.0	0.0

Notes: SD=standard deviation of the mean; TAU=treatment as usual; A&E=Accident and

Emergency; GP=General Practitioner

Service use was comparable across the two arms with the exception of psychological therapy, which was proscribed in the Morita Therapy arm (0% in the Morita Therapy arm; 16.1% (n=5) in TAU) and counselling (0% in the Morita Therapy arm; 9.7% (n=3) in TAU). Compared to baseline assessment, antidepressant medication use reduced in both groups (58.8% (20/34) to 43.8% (14/32) and 60.6% (20/33) to 45.2% (14/31) in the intervention and control groups respectively).

Thus, whilst antidepressant medication use and use of other services is comparable across the Morita Therapy and TAU groups, all participants in the Morita Therapy group received psychological therapy (i.e. Morita Therapy) whereas 8 participants (26%) in the TAU group received either psychological therapy or counselling. This data may be used to inform calculations of the Excess Treatment Costs (i.e. the additional costs of providing Morita Therapy in addition to TAU) for any future trial.

CHAPTER SEVEN. PART TWO.

Results of the qualitative analysis of embedded qualitative interviews

This part of Chapter Seven provides the results of the qualitative analysis undertaken to answer the question: how acceptable is Morita Therapy to participants and therapists? This part is organised into five main sections: participants (7.2.1); the acceptability of Morita Therapy to participants (7.2.2); the acceptability of Morita Therapy to therapists (7.2.3); a summary of participants' views on the acceptability of the trial procedures (7.2.4); connecting threads across participants' and therapists' views of Morita Therapy (7.2.5).

7.2.1 Participants

Post-treatment qualitative interviews were conducted with consenting Morita Therapy participants (n=28/34; 82.4%) and the two therapists who delivered Morita Therapy during the pilot trial. Six Morita Therapy participants did not participate in an interview because they either could not be contacted to arrange an interview (n=3; 8.8%); declined an interview (n=2; 5.9%) or had moved away (n=1; 2.9%). Interviews lasted between 24 and 93 minutes.

Data from 16 participant interviews were purposively sampled for analysis. This sample size was constrained by the number of participants meeting criteria for each category within the proposed sampling matrix (Table 25 includes the available number of participants and number included in the analysis within each category).

Table 25. Final sampling matrix

		Adherence to treatment		
		Withdrew < 5 sessions	**Withdrew ≥ 5 sessions**	**Completed treatment**
Treatment response? (follow-up PHQ-9 score <10)	**Yes**	Available: 3 Included: 3	Available: 1 Included: 1	Available: 14 Included: 6
	No	Available: 2 Included: 2	Available: 3 Included: 3	Available: 1 Included: 1

Thus, all participants who withdrew from treatment or completed treatment but did not demonstrate a response (i.e. follow-up PHQ-9 score <10) were included in the analysis, yielding ten interviews (Table 26, overleaf). An additional six interviews were selected from the 14 available from participants who completed treatment and demonstrated a response. These were selected on the basis of additional criteria deemed potentially relevant in forming views of Morita Therapy: the presence or not of co-morbid generalised anxiety disorder (three participants per quota); participants' experience or not of Cognitive Behavioural Therapy (three per quota); participants' gender (three per quota) and therapist, of the two available (three per quota). The selection of a specific six participants from this category enabled the fulfilment of these criteria. Thus, the final sample size for analysis was 16 interviews.

Table 26 overleaf

Table 26. Characteristics of participants included in analysis

ID	Adherence to treatment	Follow-up PHQ-9 score	Treatment response	Gender	Therapist ID	Previous therapy/ counselling	Current co-morbid anxiety conditions
MT16	Completed	1	Yes	M	TH01	CBT; Counselling	None
MT33	Completed	1	Yes	M	TH02	None	None
MT43	Completed	5	Yes	F	TH02	None	GAD; Panic disorder
MT45	Completed	6	Yes	M	TH01	CBT	GAD; Panic disorder
MT55	Completed	4	Yes	F	TH02	CBT	None
MT63	Completed	2	Yes	F	TH01	Mindfulness	GAD; Panic disorder with agoraphobia
MT58	Completed	18	No	F	TH01	CBT; Mindfulness	GAD
MT37	Withdrew ≥ 5	1	Yes	F	TH01	Counselling	GAD; Panic disorder
MT19	Withdrew ≥ 5	17	No	M	TH01	CBT; Counselling	None
MT28	Withdrew ≥ 5	24	No	M	TH01	Counselling	Panic disorder with agoraphobia; PTSD
MT51	Withdrew ≥ 5	17	No	M	TH02	CBT; Counselling	GAD; Panic disorder; Social phobia
MT15	Withdrew < 5	6	Yes	F	TH02	CBT; Counselling	None
MT50	Withdrew < 5	9	Yes	F	TH01	Mindfulness	None
MT54	Withdrew < 5	5	Yes	F	TH02	CBT; Counselling	GAD
MT17	Withdrew < 5	11	No	F	TH02	CBT; Mindfulness	Panic disorder with agoraphobia
MT61	Withdrew < 5	12	No	M	TH02	CBT; Counselling	Panic disorder with agoraphobia; Social phobia; OCD

Notes: PHQ-9=Patient Health Questionnaire 9; treatment response defined as post-treatment PHQ-9 score <10; CBT=Cognitive Behavioural Therapy;

GAD=Generalised anxiety disorder; PTSD=post-traumatic stress disorder; OCD=obsessive-compulsive disorder

7.2.2 The acceptability of Morita Therapy to participants

Participants' views relating to the acceptability of Morita Therapy were understood within five key themes: (1) the impact of incompatible expectations and understandings; (2) identifying with the principles of Morita Therapy: receptivity and relevance; (3) approaching and understanding Morita Therapy as a process; (4) facilitating the process: (overcoming) challenges and barriers; (5) the value and impact of Morita Therapy. Each theme encompassed a number of constituent themes (Figure 14, p.232). These themes were developed in order to explore and explain the relationships between the constituent themes and the acceptability of Morita Therapy, within a model of how Morita Therapy was experienced by different participants. Figure 14 illustrates the relationships (and conflicts) between themes and how these shape an overall picture of engagement with, and acceptability and impact of, Morita Therapy.

During analysis it was clear that participants' views comprised different categories which manifested as important in assessing acceptability. Particularly salient was the sense that participants' expectations and understandings either facilitated or hindered their engagement with Morita Therapy. To capture this, the first three themes essentially convey different typologies of participants' approaches towards and experiences of treatment. Whilst these themes are not mutually exclusive, participants' accounts typically fell within either theme one or themes two and three. Thus, participants who brought expectations of treatment which were inconsistent with Morita Therapy generally misunderstood the approach and considered it to be unacceptable (theme one), with a failure to both identify with the Morita Therapy principles and understand treatment as a process to progress through. In contrast, those whose prior expectations and experiences facilitated their identification with the principles (theme two) typically engaged with the approach from the offset, with their overwhelmingly positive experiences of treatment tied to their understanding of Morita Therapy as a process (theme three) and leading to positive accounts of the value and impact of Morita Therapy (theme five).

Theme four (facilitating the process: (overcoming) challenges and barriers) describes the difficulties participants experienced in engaging with Morita

Therapy on a practical rather than conceptual level. Whilst whether such difficulties amounted to barriers to continuing treatment was often moderated by themes one, two and three (participants with incompatible expectations and understandings of treatment were less likely to tolerate such difficulties), this theme also captures how for some participants the principles of Morita Therapy may be acceptable (i.e. they identify with the principles as per theme two) whilst the process of treatment is not. Thus, the relationship between this theme and the preceding themes highlights a key thread throughout participants' accounts and this model of Morita Therapy: the distinction between Morita Therapy in principle and practice. Overall, whilst an ability to identify with the principles manifested as highly important in seemingly essentially priming participants for the approach, the challenges of translating these principles into a process which is feasible to engage with (as per theme four) further shapes the acceptability of treatment.

Thus, these are not five discreet, nor equally weighted, themes. The themes were developed so as to explore and explain the views of participants with varying experiences of Morita Therapy in depth. This model of Morita Therapy is therefore not intended to provide a representative account of acceptability across the themes: theme one, in which the most negative views are described, is dedicated to the accounts of a minority of participants who discontinued treatment and were therefore purposively sampled for analysis in order to gain insights into any issues with the acceptability of Morita Therapy, thus facilitating the further optimisation and application of the approach in the future.

Figure 14 overleaf

Figure 14. Final thematic map (embedded qualitative interviews: participants)
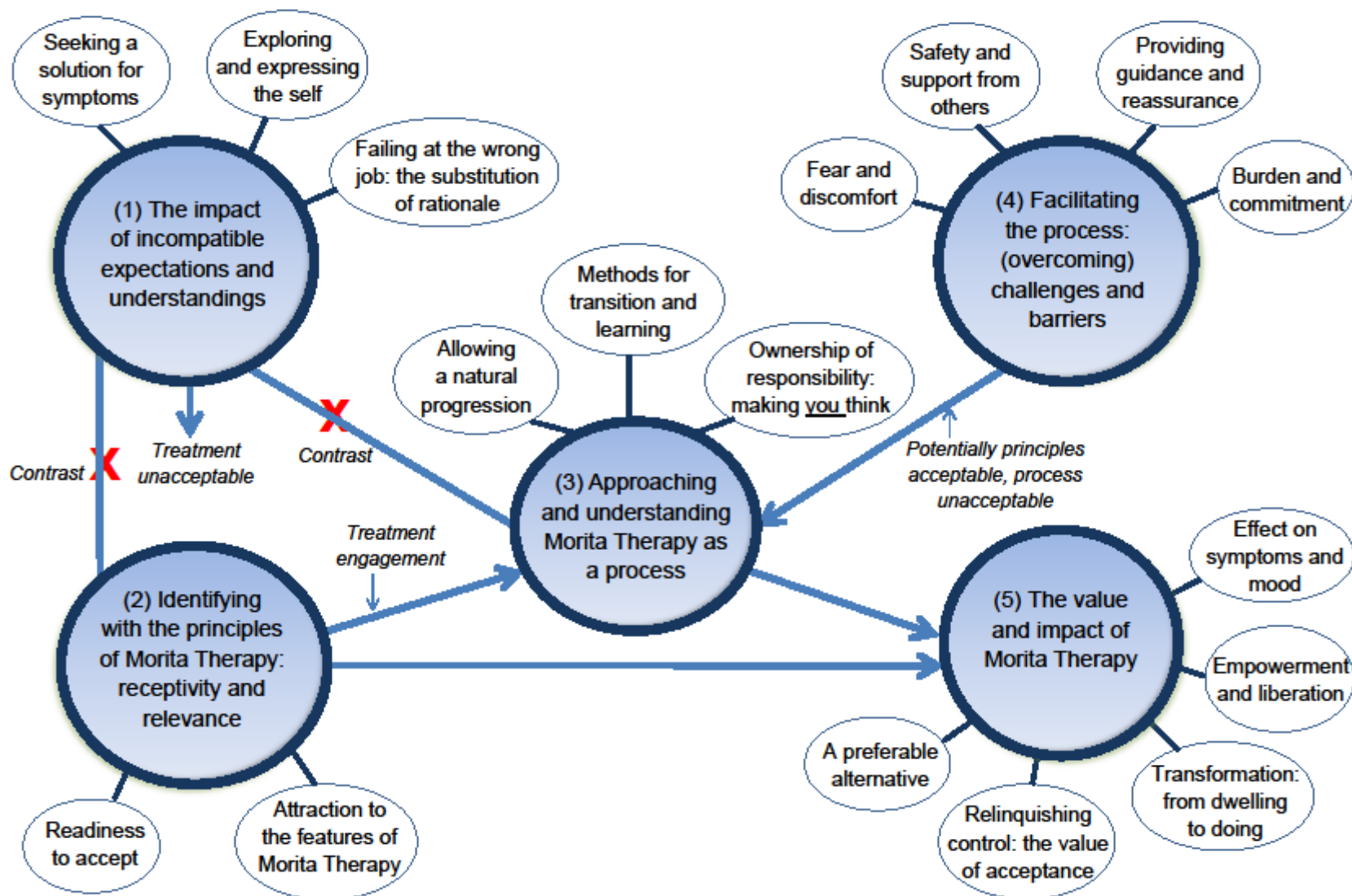
Theme one: The impact of incompatible expectations and understandings

This theme captures a mismatch between Morita Therapy and the expectations of and hopes for treatment held by some participants, who were typically either seeking a solution for symptoms (constituent theme (a)) or hoping to explore and express themselves (constituent theme (b)). Included are the ways in which these preconceptions of treatment can feed participants' construction of rationales for treatment which are inconsistent with Morita Therapy (constituent theme (c)). As such, Morita Therapy fails to achieve its assigned purpose, and/or fails to provide participants with the approach they seek. For these participants, Morita Therapy is thus generally not perceived as an acceptable or helpful approach. This theme contrasts with other themes: participants' accounts typically fall either within this theme or themes two, three and five.

(a) Seeking a solution for symptoms

Several participants expressed a desire for therapy to "resolve the[ir] problems" (MT19) through providing a cure, answers or techniques to remove symptoms.

> People are looking for answers, really… [to] help them to stop these sort of thoughts or feelings. (MT61)

One participant acknowledged the influence of previous treatment experience on such expectations, essentially expressing his socialisation into a model of using techniques to manage emotions as a barrier to Morita Therapy:

> It might be better off to use Morita for young – for people who are just starting out in depression… they haven't had that NHS kind of – I don't know – bombard them with all these different techniques. (MT51)

Accordingly, these participants expressed resistance to the underlying premise of Morita Therapy to allow unpleasant thoughts and emotions as natural and inevitable: their goal was to eliminate the unpleasant:

> It's like a computer; you would replace the chip, why can't you do it in your head? It would just make you feel better… Why can't I be happy all the time instead of having one day good, one bad! (MT28)

These participants typically appeared to view the therapist as a holder of expert knowledge and abilities: someone who should 'fix' them or impart powerful techniques. Accordingly, there was an expression of high expectations of treatment and a sense of handing responsibility for improvement over to the therapist:

> I was just looking for – to be like trained in different techniques that would be vastly different to anything I'd ever seen before or experienced. And it would be, sort of, almost ground breaking… [However,] I was almost encouraged to come up with [techniques] myself, and I found that I was almost thinking, well, you're the therapist, you're experienced and you're professional, you should be telling me, not me telling you. (MT51)

Accordingly, there was often little understanding of how Morita Therapy might work, and a sense of little belief that it was the responsibility of the patient to know this:

> I don't know what the idea was, I don't know whether it was a case of trying to find out more about the person on an unconscious level or what. I've no idea, I'm not a psychiatrist so I don't know. (MT61)

Indeed, there was a sense that, particularly as a treatment deriving from a different culture, this was a somewhat esoteric approach presumably offering something which cannot be understood by the layman:

> From what I understood it was, um, originated out of oriental thinking and the way that they approach life is from a left handed point of view… Left handed people in the Far East have a completely different way of looking at things… I don't know, it's a method that's supposed to help me get better but I don't understand how these things work. (MT19)

In the context of their expectations of Morita Therapy and hopes for treatment, one participant stated:

> There has to be some kind of trance-like therapy that you could put somebody in and encourage that sort of regression… [Within remote tribes] you'd eat this root and then you'd almost have like an out of body

> LSD experience and you'd have to really face all of your demons… he
> went through that, yeah, it looked horrible but it sorted him out. (MT51)

This account demonstrates a desire for a somewhat mystical treatment
approach which induces an inner revelation with little effort on the part of the
patient. As a Japanese approach, the appeal of Morita Therapy appeared
somewhat shaped by these 'other culture' preconceptions which are not
consistent with the reality of Morita Therapy. Thus, these participants
expressed the desire for treatment to provide a (possibly esoteric) solution or
techniques for eliminating symptoms, and as such they did not identify with the
premise of Morita Therapy.

(b) Exploring and expressing the self

Several participants expressed hopes and expectations that treatment would
provide exploration, analysis and discussion of their difficulties, which again
shaped their views of Morita Therapy, particularly the Fumon technique
(therapists' purposive inattention to symptoms).

> I was hoping it was like a situation where I could open myself up…
> analysing why, you know, how I'm feeling…or why you feel bad. (MT61)

Accordingly, these participants found Fumon uncomfortable, with a sense that
this stifled their self-expression and the desire for someone to talk to and
understand them:

> It's like, talk about it and understand… that's why I use the Samaritans,
> it's like they just talk and all my feelings are coming out… I need
> someone to understand what's in my head. (MT28)

At times the challenges of Fumon were explicitly shaped by participants'
previous treatment experiences, in which the therapist did discuss and analyse
difficulties:

> I definitely struggled with it because that is the way that it has always
> been done with anyone I've ever seen. And […], I don't know, I guess
> you're looking for something to fill that void. (MT51)

Indeed, one participant who would have liked to continue counselling but was unable to afford it found that this treatment style was unable to provide them with the approach they sought, and somewhat hindered their relationship with their therapist:

> The relationship between me and [the counsellor] was so important to everything, and I don't know if it was the – if it was [name of therapist] or if it was the programme itself, but I just felt like I didn't click with them... I felt like, a bit like they were just saying 'oh, shut up'… it didn't give me a good feeling about the whole thing. (MT54)

Fumon was typically referred to in relation to therapists' diary comments, with this creating a sense of dismissal of participants' diary accounts ("It made it feel that it wasn't important." (MT19)) and thus feelings of being unable to share in the way that they desired:

> I didn't put down how I was feeling that day, or how the week had been going, and that's 'cos it wasn't asked. Sometimes I feel that issue's got to be talked about, it's got to be brought out and dealt with. (MT28)

Thus, participants seeking this exploratory and analytical approach felt somewhat "shut down" (MT54) by and disappointed in Morita Therapy.

(c) Failing at the wrong job: the substitution of rationale

For participants whose accounts fall within the constituent themes above, there was a tendency for the aforementioned expectations of treatment to shape misunderstandings of the purpose of Morita Therapy. In particular, participants typically substituted the rationale for rest (which is, primarily, to experience the natural ebb and flow of thoughts and emotions) with one more consistent with their preconceptions. For example, a participant who sought techniques and a cure expressed the following views of rest:

> I was given very little information and very little in the way of kind of techniques and training and then sent out there to be alone with my feelings… If it was that easy we'd all just go and lie in a room with the lights off and we'd just conquer it that way. (MT51)

Indeed, such participants generally viewed all elements of the Morita Therapy process (such as phase two light activities) as means to overcome symptoms, whether successful or unsuccessful: "It's brilliant for distraction from flying... the colouring really works" (MT58). Alternatively, one participant, whose expectations of treatment focused on in-depth self-analysis, potentially on "an unconscious level", had the following recollections of rest:

> They said that we were gonna sort of analyse your sleeping thing and arrange for you to sleep for a certain time… Actually planning something like that was really like, well, 'this isn't gonna work'. (MT61)

Thus, participants were assigning a Morita Therapy incongruent purpose to rest; the achievement of which rest was not intended or able to fulfil. In turn, participants expressed a sense of "lost faith" (MT51) in treatment. Running through such misunderstandings was also a construction of the concepts and process of Morita Therapy as relevant to emotions but not thoughts. For example, in considering the 'natural ebb and flow' (which, in Morita Therapy, incorporates all internal states) several participants believed this referred only to emotions. Thus, some participants who struggled more with unpleasant thoughts considered Morita Therapy somewhat irrelevant to their needs:

> I understood the principle of the emotions flowing and life getting in the way and putting the blocks in the way, um, but I just could not feel the flow… I'm a logician rather than an emotional person… emotion doesn't take, it doesn't even get included in the analysis. (MT19)

Accordingly, some participants experienced ongoing thoughts as a barrier to engaging with Morita Therapy: within their misconstrued rationale for rest, these participants believed they should be deliberately "switching off" thoughts (MT19) in order to experience emotions in the way that they were 'supposed to' ("sensing emotion on an on-demand basis." (MT19)):

> I understood that it was for, if emotions came, then if you're there on your own they would come and then you would notice them go. I found it really difficult to allow myself to do it, um, without being distracted by

what I should be doing, where I should be doing it, the house is a mess –
I found it really difficult just to shut off, like, your mundane stuff. (MT58)

This understanding also was shaped by participants' hopes for treatment: it was typically those who sought to permanently 'turn off' unpleasant thoughts and "relax" (MT28) who understood rest as a time to do so. Whilst the idea of this appealed to participants, as rest progressed and this assigned objective remained unmet, participants experienced an increasing sense of "pressure" to achieve the unachievable alongside a sense of both themselves and the therapy having "failed" (MT19):

Trying to wipe them [thoughts] out, it just doesn't, you can't, there's just certain things you couldn't, and the more I tried the more I used to get frustrated. (MT28)

Somewhat ironically, this view tallies with the intended message of the rest phase: that emotions and thoughts naturally ebb and flow and cannot be controlled by will. However, for such participants these experiences led to frustration as opposed to a lesson learned: their views and understandings of Morita Therapy were shaped by their inaccurate and unmet expectations of treatment, which ran counter to the principles of the approach.

Theme two: Identifying with the principles of Morita Therapy: receptivity and relevance

This theme explores how the acceptability of Morita Therapy is linked to participants bringing insights, experiences and expectations to treatment which facilitate their identification with the Morita Therapy principles, such as the underlying premise of accepting unpleasant thoughts and emotions (constituent theme (a)) and/or particular elements of treatment (constituent theme (b)). This theme contrasts with theme one ('the impact of incompatible expectations and understandings'), with each theme capturing different ways in which different participants embarked upon their journey with Morita Therapy.

(a) Readiness to accept

In recalling what appealed to them about Morita Therapy before treatment, many participants expressed a sense of readiness to accept symptoms as part of oneself and life; a fundamental principle of Morita Therapy:

> What attracted me was…it was a way of getting back to nature and realising that it's a part of you and part of the human experience, and stop catastrophising everything. (MT63)

Some participants expressed prior understandings that their difficulties could not be controlled or removed ("I knew I couldn't change things" (MT37)), and/or came to treatment with experiences and insights which allowed the concept of the ebb and flow of thoughts and emotions to resonate with them:

> Learning to accept that those are my difficulties and yes they'll come and go, like they explained it a bit like the weather and kind of storms will pass and it sounds quite cliché but that is exactly how I've experienced it. (MT15)

In contrast to participants seeking a solution for symptoms (theme one, constituent theme (a)), some explicitly noted approaching treatment without an expectation of a cure, and described the importance of this in terms of shaping their experiences of therapy:

> With the NHS, I felt that I was going to be cured, that was the impression: that they were going to cure me. Well, with this, it teaches you how to live with it, which is much more sensible because I came away from the NHS feeling a lot worse because I'd failed. (MT55)

Thus, understandings were often shaped by previous treatment experience, typically cognitive behavioural therapy (CBT) and counselling, which participants felt through "being focused on your past and trying to stop you having these thoughts and feelings" (MT50) had failed to resonate with them:

> CBT focuses on trying to change your way of thinking whilst Morita Therapy actually focuses on accepting your feelings and um putting it

into perspective and I found that a lot easier to understand and connect with. (MT16)

Similarly, many participants came to treatment with insights into themselves and their symptoms which enabled them to easily identify with the concept of the 'vicious cycle' (the exacerbation of symptoms through a fixation on and attempts to control or remove them): "[The vicious cycle is] the really big one for me, yeah, because I know I do that." (MT58). Again, these understandings were at times expressed in relation to other treatment approaches, which some participants believed had 'fed into' this vicious cycle:

> [Morita Therapy] just reinforced what I'd already sort of hooked onto as a major problem for me… [CBT] was sort of feeding my need to fix myself… I came away from CBT going 'I've got to stop thinking these things, I've got to think differently' and you don't have that kind of control over your thoughts, I don't think. (MT45)

Thus, often through an understanding of the role that certain perceptions and behaviours play in maintaining their symptoms, these participants were equipped to move away from the notion of 'fixing' or curing symptoms and towards a position of accepting and allowing them, thus engaging with the underlying premise of Morita Therapy.

(b) Attraction to the features of Morita Therapy

There was a sense from many participants that, aside from the underlying premise of acceptance, specific elements of Morita Therapy 'grabbed' them from the offset and encouraged them to engage with the approach. Different features manifested as salient for different participants. Often, participants were attracted to "the use of the natural world" (MT43). For some, this appealed in the sense of "getting back to nature" (MT63); for others, the appeal was more literal, typically shaped by already finding enjoyment in nature:

> I'm very much into the natural world, anyway, 'cos I'm a gardener, I belong to Greenpeace and, so that was not hard to get into. (MT55)

For these participants, both understanding human nature in relation to the wider natural world and the more literal engagement with nature inherent in Morita Therapy were highly valued features. In contrast, several participants whose accounts fell within theme one ('the impact of incompatible expectations and understandings') found this way of understanding human nature a difficult concept to connect with:

> The idea would be to look at the emotion as like a season, but it's a bit easier to kind of sit and go through summer, winter, autumn and spring than it is to just sit there and just – and, you know, depression can be quite severe… it's quite difficult to just sit there and believe that you could just cope with it like you could do a snowstorm. (MT51)

This excerpt is illustrative of a major distinction between participants whose accounts fall within themes one and two: those whose expectations and understandings were incompatible with Morita Therapy struggled to connect with the elements of treatment, such as understanding human nature through reference to the natural world, in general; whereas others demonstrated a level of readiness for Morita Therapy and described the ways in which such elements of treatment resonated for them. Other ways in which the approach appealed to participants within this theme included its focus on action-taking, with a sense that this sounded helpful and/or complimented participants' habits:

> Where I'm reasonably sensible with anxiety is I do <u>do</u> things… I <u>won't</u> avoid things… So that's why I actually – if I was designing a therapy, I would probably come up with something similar to Morita. (MT45)

For some participants, understanding their difficulties as reflections of underlying desires (or "goals" (MT16)) was also appealing and pertinent:

> We were just talking about the flip side, which I can really – which I really saw… I can remember sitting down when they were talking to me and thinking yes, this – I understand what you're talking about. (MT58)

Similarly, the concept of working with 'the authentic self' was appealing and beneficial for several participants:

> The thought of somebody nurturing you and slowly trying to find what
> things you're looking for and what your values are and what little things
> you can go and do that are true to your authentic self... That's what I've
> been looking for, for the last twenty years! (MT50)

Thus, some participants welcomed the holistic focus on activity, values and overall objectives, as opposed a narrower symptom-focus. Overall, different elements of Morita Therapy resonated for different participants, attracting them to the approach and seemingly facilitating their engagement with treatment.

Theme three: Approaching and understanding Morita Therapy as a process

This theme captures how participants who found Morita Therapy acceptable and beneficial tended to understand the components of treatment as a part of a progressive journey. Broadly speaking, this theme contrasts with theme one ('the impact of incompatible expectations and understandings') in terms of 'tools for learning versus learning tools': the acceptability of Morita Therapy was linked to participants' understandings of the treatment components as part of a naturally unfolding and experiential process (constituent theme (a)) which provided accumulative opportunities for learning and re-focusing attention (constituent theme (b)) and for owning responsibility for change (constituent theme (c)), as opposed to expecting a somewhat passive receipt of treatment and attempting to isolate each treatment component as a potential technique for overcoming symptoms (as per theme one).

(a) Allowing a natural progression

Many participants spoke of Morita Therapy in terms of providing an experiential progression which unfolded naturally and gently. Within this, participants conveyed a sense of helpful balance in the process: the four-phased structure and therapist guidance was coupled with an individualised progression and lack of directive instructions. This process enabled participants to gradually and safely 'build up' themselves and their activity levels:

> It gave you structure and really made it secure, it helped you to build
> your self-confidence up again so for someone like me where my

confidence was low, just being able to re-build the confidence levels and just being able to um build up on things gradually. (MT16)

Similarly, several participants referred to the value of Morita Therapy, often in comparison to other treatments they had tried, as a natural and gentle process:

It's a completely different way from the NHS way, I can tell you that. It's a gentle way… It was just this brilliant, gradual process, it sort of – the first stage broke me down, and then it was re-building me. (MT55)

Within this, participants appreciated the way in which they were able to take small "bite-sized" (MT43) steps during treatment, which felt "doable" (MT43). This process was aided by proceeding through the phases at a pace which felt natural to them:

There was no timeframes for me either, it's just a case of when I thought I was ready or when [name of therapist] thought I was ready, then we'd go to the next phase, it wasn't a case of, um, two weeks of this, two weeks of that, two weeks of that, it was an open-ended book, so it could take as long as it needed. (MT33)

Thus, participants expressed a sense of the treatment progressing according to their individual state, with a nondirective level of therapist guidance which enabled "self-realisation" (MT63). In line with this, some participants highlighted the importance of Morita Therapy in providing an experiential, rather than purely intellectual, process. As one participant noted: "the treatment was working without me realising" (MT33).

I've been allowed to discover it, guided gently and then I had to discover it for myself. And I think if you find it for yourself, and aren't following lots of instructions, it's almost like nature teaches you... It's kind of hit me at a bit of a visceral level… Everybody's told me it's normal, the counsellor told me it was normal, but nobody guided me how to feel it… [Morita Therapy] let me feel it and showed me that feeling it was normal. (MT63)

Coupled with this was a sense that, whilst the precise purpose and process of therapy was initially unclear at times, this became more apparent through actual

engagement with treatment. Indeed, some participants acknowledged this as a necessary element of treatment in order to allow the learning process to naturally unfold in the absence of the imposition of expectations:

> It's much better that you don't tell them and then it's like – well, 'is this supposed to be happening', and you realise it's a natural process… It was better that I didn't know what to expect...otherwise you don't know if it's involuntarily gone into your mind or whether you're really experiencing it. And I know I was <u>really</u> experiencing it! (MT55)

Linked to these perceptions was a sense of needing to approach Morita Therapy with a degree of open-mindedness:

> I tried to keep an open mind, I mean, obviously, I couldn't quite see how it might work [laughs] um, so I thought I'll just go with it. (MT43)

Thus, for many participants, the ability to allow themselves to trust in the process and learn from the experiences provided enabled them to receive Morita Therapy as a gentle, individualised and, at times, powerful treatment approach.

(b) Methods for transition and learning

Many participants spoke of Morita Therapy in terms of providing accumulative opportunities for learning about human nature and for transitioning from a position of fixation on and interference with symptoms (i.e. the vicious cycle) to an acceptance of symptoms and external focus of attention. Key to this was the incorporation of methods, such as rest, the diary, and natural world metaphors, for learning that "all emotions pass, happy, joy, sad, all those wonderful emotions, everything passes" (MT63):

> Being with your thoughts and then learning that thoughts come and go and feelings come and go, so they're not gonna be there forever… You relate it to different seasons of the year, and storms come, but they pass, and the sea goes calm and all of those sorts of things, you realise that happens with you naturally as a human being. (MT50)

Similarly, participants found these aspects of treatment helpful as a means of highlighting how the vicious cycle manifests for them:

> I remember [rest] and all those thoughts and feelings that kept coming and going, and that was a really big moment I think for me, in kind of realising how much I do battle with my own feelings. (MT15)

Participants also described some elements of treatment, such as phase two (light activities), as a means of refocusing attention from internal to external states:

> The second stage is looking at lighter, repetitive activities, um, and trying to focus very much on those activities and you then find yourself looking outside rather than looking in… The connection with nature, I think I started noticing a lot more, and actually looking out and looking around more, and using that as a way to draw myself out of myself. (MT43)

This facilitation of movement away from the vicious cycle was also expressed in relation to Fumon (therapist's inattention to symptoms):

> What was good about what [therapist] was doing was they would go 'Stop' as soon as I started that conversation, 'You're now scratching the itch', you know, 'Your mind wants to fix it and we're gonna sit here and fix it for half an hour, and fixing it's the problem, right?' So they would stop me immediately from that, and I did go away from – after a couple of sessions, thinking 'What they're actually saying is I'm just wasting my time'. (MT45)

Participants also understood the phases of treatment, as well as the diaries, as methods for highlighting and enabling action-taking:

> As you went through the phases and actually started to introduce different things and get a bit more active in different ways, that all helped... I was able to use Morita as a framework to help structure things to get me back up, so I could get back into doing job applications. (MT16)

When viewed in this way, the components of Morita Therapy as well as the overall process were considered largely acceptable, albeit at times somewhat challenging:

> Phase One was a long time [laughs]! But it had to be, it had to be. But yeah, as I say, it worked. It wasn't pleasant but when I got to the end of it I could see we'd done it…'cos I learned that you can get through it and come out the other side. (MT55)

Thus, for these participants there was a sense that the elements of Morita Therapy were not judged in terms of how enjoyable they were in themselves, nor in terms of how successful they were as tools for managing symptoms, but in terms of how successful they were in 'doing their job' as methods for learning and transition; in contrast to theme one ('the impact of incompatible expectations and understandings'), this accurate understanding of the purpose of Morita Therapy appeared crucial in relation to participants' willingness to tolerate challenging components of treatment, and how successful participants considered Morita Therapy to be.

(c) Ownership of responsibility: making <u>you</u> think

In contrast to theme one ('the impact of incompatible expectations and understandings'), which indicated some participants' desire for a somewhat passive role, many participants described the value of Morita Therapy partially in terms of the process 'making them think'. This was often expressed in contrast to participants' preconceptions and previous treatment experiences, in which there was a tendency for abdication of responsibility:

> [My private therapist] was more like getting professional advice as to how to deal with the problems, rather than a therapy, as such. It had become, for me, a way of going 'What do you think I should do?'. (MT63)

The therapists' facilitation of participants' own thinking processes was expressed particularly in relation to their provision of diary comments:

> I quite liked it towards the end of the treatment, instead of [therapist's name] making comments they would help me comment on my own

thoughts so I can understand, er, how to apply the Morita Therapy… and just the way they sometimes wrote questions which was quite useful, so like triggers for discussion or triggers for thoughts. (MT16)

There was thus a welcome sense that, rather than the therapist providing answers and imparting knowledge, they instead provided subtle cues and suggestions which encouraged participants to take responsibility for their own learning and application of the Morita Therapy principles:

With the use of the diary, it's just picking out the salient points that are making you think… Instead of saying 'you need to do this', it's a case of 'there's your diary from last week, go through – read it back and have a look at my comments', and you start picking up on certain things… [My therapist] was allowing me to pick up on very subtle signals, you know, so - in trying to do that for myself. (MT33)

Participants also spoke of the therapist "challenging" them (MT43) in order to facilitate a shift in perspective, re-evaluation of themselves and their lives, and a sense of self-efficacy.

I want to walk on my own with Morita in mind, was actually what I said, it just came out, which is what I think is really important. (MT63)

Thus, this ownership of responsibility encouraged by Morita Therapy through challenging and making participants think appeared to equip some participants to proceed post-treatment with a sense of self-sufficiency.

Theme four: Facilitating the process: (overcoming) challenges and barriers

This theme presents the difficulties associated with engaging in the phases and process of Morita Therapy, including the more practical rather than conceptual elements of treatment such as: fear and discomfort (constituent theme (a)), needing safety and support from others (constituent theme (b)), needing sufficient therapist guidance and reassurance (constituent theme (c)), and the burden and commitment of treatment (constituent theme (d)). Whilst the fear and discomfort described by participants related to some unique features of

Morita Therapy, the challenges described in other constituent themes, such as the time needed to attend appointments, may well apply to many forms of psychological therapy.

Included are the ways in which these difficulties were minimised and managed for participants, and the factors which shape whether and how the challenges of therapy become barriers to therapy. This latter issue links closely with the expectations and understandings captured in previous themes: participants who held incompatible expectations and understandings of treatment (theme one) were less likely to tolerate the challenges of treatment than those who identified with the principles (theme two) and accurately understood the purpose of the treatment components (theme three). Nonetheless, for a subset of participants who did identify strongly with the Morita Therapy principles (as per theme two), the challenges of engaging with treatment were such as to warrant their discontinuation with treatment. Thus, the relationship between this theme and the preceding themes highlights the distinction throughout participants' accounts between identification with the principles of Morita Therapy and the feasibility of engaging with the process of therapy itself.

(a) Fear and discomfort

Participants often spoke of the fears they had held around what elements of Morita Therapy would involve, and the discomfort they had experienced when engaging with such elements. This was most significantly expressed in relation to rest, and typically connected to participants having avoided their thoughts and feelings for some time (often by "keeping busy" (MT17) or "battling negative emotion" (MT51)) and/or fearing a reduction in activity levels and thus potentially "going backwards" (MT15). Participants also described the experience itself, in terms of being alone with their thoughts and feelings, as uncomfortable:

> That first stage of it, I hated… Your thoughts start racing around, the sleep doesn't come and [name of therapist] said, you know, 'Just go with it, let it all come out', 'cos before I tried my hardest to block it off. After nine days I thought 'Oh heck!'. It was horrible. (MT55)

248

For one participant, the completion of the diary also induced a sense of discomfort, in terms of their reluctance to focus attention on themselves:

> The main reason [for discontinuing treatment] was having to write about myself, my daily life and my daily routine and stuff. I don't even like myself, so I'm not really that keen on writing about myself. (MT61)

Most participants spoke of the challenges of the rest phase. Whether or not these challenges were *acceptable* to participants, or developed into barriers to continuing therapy, was linked to the participant's expectations, understandings and approach to treatment: those who assigned alternative and incorrect purposes to rest which it failed to meet (as per theme one) were disinclined to tolerate this phase; those who were more open-minded and understood rest as a means of learning (as per theme three) tended to persevere with this phase. As noted in theme three ('approaching and understanding Morita Therapy as a process'), for participants in the latter category, there was accordingly an acknowledgement that rest was a necessary component of treatment, despite its challenges: "I think the first phase was the hardest, definitely the hardest, but I think that's the one you've got to break through." (MT31).

In terms of facilitating the process in light of these challenges, several participants spoke of the importance of timetabling in rest periods. There was also a sense from some participants of commitment to the trial and treatment, "will power" (MT63) and an unwillingness to "give up at the first hurdle" (MT31), which encouraged them to endure these challenges. Thus, whilst participants often spoke of the fear and discomfort they experienced in relation to rest in particular, they also suggested some important factors in overcoming these challenges.

(b) Safety and support from others

Several participants spoke of the importance of feeling safe, supported and encouraged by their significant others during Morita Therapy. This manifested particularly in relation to the rest phase, with several participants noting the value of including their partner in the therapy session in which rest was explained:

> My husband was really up for it, he was very supportive… If I'd have done it on my own I might have given in, perhaps, a few times, but it was helpful, I think, including your partner. (MT55)

Indeed, some participants described a lack of support from significant others or "difficulties with their partner" (MT15) as factors in their decision to discontinue therapy, indicating that an increased sense of external support might have enabled their engagement: "[If] my wife had been around then I would've had the encouragement to pursue it" (MT19).

For one participant, the lack of safety and support they felt within several relationships led them to discontinue therapy, despite having identified with the principles and being keen to engage, highlighting the particular importance of creating a safe space for participants to undertake rest and indicating the need for a certain degree of stability in participants' lives to enable their engagement with treatment:

> Because of my neighbour who was being threatening and harassing, I didn't feel safe to sit in that environment twenty-four seven… and my Mum started drinking terribly badly, so that all got so bad I just thought 'I need to do something quickly with my life'. (MT50)

One participant also expressed some challenges in terms of explaining Morita Therapy to family and colleagues:

> Trying to explain to the Western culture that's so work focused and so structured, that actually it's – you need to rest, is really – and I think it's contrary to quite a lot of other therapies… I could see [it] would be off-putting actually just to explain to people what it is that you're doing…generally everyone was really interested, even my mum, who's still a bit 'Oh I don't know about these Eastern philosophies!' (MT43)

Thus, some concerns around support from others related to the treatment having originated from a different culture and a sense of potential judgement, particularly around engaging with rest as a notion which runs counter to typical Western practices. Overall, participants indicated the importance of a safe and supportive environment for facilitating their engagement in Morita Therapy.

(c) Providing guidance and reassurance

Participants at times recalled discomfort with a lack of clear instruction and sufficient reassurance being given around elements of treatment. This manifested particularly in relation to the diary:

> One thing I struggled with was having just a blank canvas in the diary… I found it quite hard to understand exactly what was needed. (MT16)

This discomfort often related to participants' concerns that they were 'doing it correctly', indicating a need for the therapist to assuage such fears:

> Because it's an anxiety and depression thing as well, [say] 'don't worry if you - don't think you're doing it wrong, try not to overthink that and just to actually go with it and see what happens, because there's no wrong or right way'. (MT43)

In the context of therapy sessions feeling somewhat intensive and providing a lot of information to digest, participants also spoke of means of and resources for facilitating their understanding of the therapy and its requirements:

> What might have helped was if I had taken a note, because it's a very emotional time when you're having the therapy... I think they gave me a handout actually, for the rest phase, and that was really useful. (MT63)

> I quite like the idea that you could, on a more practical basis, that you could have copies of the audio. Because often what you find is you have – you go in, and because you're concentrating so much on what the therapist is saying, sometimes you forget little things. (MT50)

> I didn't want to tell them that I'd zoned out… maybe breaking it down a bit and then, I don't know, asking me for examples or something after each [principle]. (MT15)

Thus, whilst many participants were comfortable with trusting the process and allowing the rationale to unfold with time (theme three, constituent theme (a): allowing a natural progression), participants also indicated that providing audio-recordings and handouts, ensuring regular input from the participant within the

therapy room, providing a more detailed "framework" (MT17) for diary completion and assuring participants that there is no 'correct' way of doing this were potential ways of minimising any challenges associated with a lack of clear guidance and reassurance.

(d) Burden and commitment

There was a sense from many participants that Morita Therapy felt onerous and required a large commitment. Some participants spoke of the difficulty of attending treatment sessions themselves, and appreciated the therapist's flexibility in accommodating their commitments:

> We were able to adjust times and actually have a fairly regular time, which worked most of the time but occasionally it, it had gotten to the challenge of trying to work out the best way of meeting up. (MT16)

At times these types of challenges were expressed in relation to elements of treatment, typically rest and the diary, which participants often struggled to "find the time" for (MT58/ MT43).

> I'm very lucky that I was retired, um, all the time I was thinking – I was trying to think how I would have dealt with it if I was still at work… it would be a very hard therapy to roll out from that point of view. (MT63)

For several participants, this time commitment amongst work and caring responsibilities was a key factor in their decision to discontinue therapy, regardless of whether they identified with the principles and/or accurately understood the purpose of these treatment elements. Participants who were keen to proceed with therapy expressed feelings of "I can't divide myself in four different ways" (MT37) and being unable to "give it the time that it required" (MT17), generally suggesting a lack of their own time coupled with an understanding that dedicating a significant time to Morita Therapy was the only way to engage in it "in a meaningful way" (MT54).

For participants with incompatible expectations and understandings of treatment (theme one) who struggled to understand the purpose of the treatment

elements, the requirements of therapy at times created a sense of burden and pressure to achieve:

> It's all the things you have to do that got to me, you know – it was pressurising me into doing it, every day you had to remember certain things… Then more and more, every week there's a bit more added and that's when it became too much. (MT28)

Thus, in the absence of understanding Morita Therapy as a process alongside the failure of treatment components to achieve their assigned (incorrect) purpose (such as reducing symptoms), participants appeared to consider these components as somewhat devoid of meaning and simply extra things which they 'had to do', creating a sense of pressure to "perform" (MT19) for a therapy which was not working for them. Whilst this sense of pressure was only expressed by participants who held incompatible expectations and understandings of treatment, the overall commitment required by Morita Therapy was a barrier for participants who did and did not identify with the principles alike.

Theme five: The value and impact of Morita Therapy

This theme captures the ways in which participants identified the value of Morita Therapy for them, and the impact treatment had on them and their lives, in terms of providing a preferable alternative to other therapies (constituent theme (a)), the value of acceptance (constituent theme (b)), transformation from dwelling to doing (constituent theme (c)), empowerment and liberation (constituent theme (d)) and effect on symptoms and mood (constituent theme (e)). Participants whose accounts fall within theme one ('the impact of incompatible expectations and understandings') rarely described any benefits of treatment, suggesting the impact of Morita Therapy is somewhat contingent upon holding compatible expectations and understandings. It is therefore the views of those who identified with the Morita Therapy principles (theme two) and/or approached Morita Therapy as a process (theme three), and thus proceeded to find Morita Therapy beneficial, which are represented within this theme.

(a) A preferable alternative

Participants often made comparisons between Morita Therapy and other treatments they had tried, typically describing Morita Therapy as preferable to (mindfulness-based) CBT and counselling. With a sense that Morita Therapy is realistic and accepting, participants welcomed a move from "thinking positively" towards "accepting that not everything is positive" (MT43) and considered the naturalisation of unpleasant experiences "less judgemental and conflicting" than CBT (MT17). Typically, participants contrasted the accepting and allowing stance of Morita Therapy with the controlling and combative stance of CBT:

> You just go with the emotions, you know, instead of fighting with it, I think with CBT you tend to try and control what you're doing whereas this was totally the opposite way round. (MT33)

Through taking an experiential approach towards accepting emotions, participants expressed a sense of Morita Therapy having made fundamental and instinctive changes to their perspective through an internalisation of the principles, and (mindfulness-based) CBT, in comparison, being a "tool-kit" approach (MT43):

> I'm hoping that I can – not so much manage it better but live with it better… CBT managed it and it was very easy to forget… I have done other work in the past but this seems to have struck a chord of change within, not just a 'Right, this is a strategy'… That never, ever worked for me. It's something fundamentally, I hope, I feel very optimistic, has changed with my acceptance of these feelings. (MT63)

There was thus a sense that Morita Therapy was a more "holistic" (MT43), in-depth, pervasive and potentially sustainable and life-changing approach: that patients are not "seen as a bunch of symptoms" (MT15) and are offered more than "short-term fixes" (MT63):

> This has such a different focus and way of looking at things. It's not a sticking plaster like CBT, it's getting more to the root of yourself and reconnecting to things… It's more interesting and engaging. (MT43)

> It's more of a philosophy to take you through life, a long term thing. Um,
> and I think that's where people will benefit from it, whereas some forms
> of therapy are just very intense and just about the there and now, and
> then you have to keep going to get the benefit, whereas this just kind of
> goes with you and grows with you, I guess, over time. (MT50)

Related to this, participants noted the value of Fumon (therapists' inattention to
symptoms) in shifting their attention away from difficulties, in comparison to
other treatment approaches which explicitly focus discussion on these
elements:

> It's a really good thing, [name of therapist] didn't let me go backwards…
> when I went on [to the past] they changed the subject. Whereas in the
> NHS one, that's what they concentrate on. (MT55)

Accordingly, through the learning they acquired from Morita Therapy, some
participants reflected on other treatment approaches as potentially unhelpful in
terms of focusing on symptoms and offering only techniques: "I've talked things
to death and I've realised that counselling can become scab picking" (MT63).
Amongst participants who completed treatment, one exception to this view was
expressed by the single participant who did not respond to treatment: whilst
valuing Morita Therapy, this participant also indicated some incompatible
expectations and understandings in terms of seeking a cure and isolating
components of therapy as techniques ("[I use] nature more as a tool now"
(MT58)), and in turn intended to seek further counselling in order to focus on
overcoming their difficulties and "getting rid of that baggage" (MT58). This
exception aside, participants who completed treatment generally valued Morita
Therapy in comparison to other approaches they had tried.

(b) Relinquishing control: the value of acceptance

The impact of Morita Therapy for participants often centred on their re-
evaluation of emotions and thoughts, leading to an acceptance and allowance
of both pleasant and unpleasant experiences and a sense of relinquishing
attempts to control the uncontrollable. Critical to this attitude was the

knowledge, obtained through Morita Therapy, that symptoms ebb and flow and pass:

> It's a therapy that says [your thoughts] can't be changed and once you get to grips with that and learn that they're just all part and parcel of the natural world and they will come and go…you become much more comfortable with those difficult times, and actually they go away a lot quicker. (MT50)

Connected to this attitude of acceptance, participants also felt that Morita Therapy had normalised emotions as natural phenomena experienced by everyone:

> I realised that other people are feeling this as well, even though I can't see it… I'm stopping feeling as if this is just me. It's normalised. (MT63)

Similarly, participants felt that Morita Therapy had made all emotions and symptoms permissible, demonstrating that it is "okay to be with" them (MT33) as opposed to needing to resolve them:

> It's about giving yourself permission <u>not</u> to treat all the signals that's going on in here as serious and prompt and, you know, needing to be dealt with... I don't need to take the emotion so seriously; the urge to do something about it so seriously. So Morita has reinforced that it's okay to do that. (MT45)

Participants also often referred to acceptance within the context of nature: through either their own (frequently spontaneous) use of natural world metaphors for understanding symptoms, or more explicit references to having come to view themselves as "part of the circle of life" (MT33). Often, participants expressed an attitude of acceptance in terms of "what will be will be" (MT33) and "it's just how it is" (MT43), demonstrating not only an acceptance of thoughts and emotions but a sense of "letting go" (MT45) of concern around all aspects of life which they felt they were unable to predict or control:

> I don't worry about things, not anymore... [Name of therapist] has taught me to let things go, there's nothing you can do to change anything, if it's going to happen it will happen, you've just got to go with it and take the rough with the smooth... realising that has helped me. (MT37)

As a result of this changed perspective on thoughts, emotions and life more generally, participants expressed less judgemental and more accepting attitudes towards both themselves and others; for example: "I'm less critical of others" (MT63), "I'm definitely more understanding of a lot more people now" (MT33). In terms of their depression, participants noted: "I'm less likely to give myself a hard time for having a bad day" (MT17) and "[Morita Therapy] taught me how to not be ashamed of it" (MT55). Thus, more widely, participants noted the positive impact of the acceptance, normalisation and permissibility of difficulties on their self-image and relationships.

(c) Transformation: from dwelling to doing

Participants expressed changes in their attention and behaviour which incorporated a shift from fixating on symptoms and engaging in the vicious cycle towards focusing outwardly on action and the external environment, essentially describing having moved from 'living in their head' to 'engaging with life':

> For me it has been, yeah, to concentrate on what actually needs to be done… to get away from the 'Should I be doing this?'…and actually break things down into – 'is there anything that I need to do now?' That's been helpful, and I think just getting out of the cycle of depression, it's because you're doing things rather than just dwelling on them. (MT43)

Participants often expressed a sense of having learned to pay less attention to (fixing) symptoms, being "more present" (MT43) in the moment and "getting more involved" (MT33) with others, activity and life:

> It's about moving your focus away from what's going on inside to carrying on what's going on in the real world… my mind is completely outside of myself, I'm looking forward and I'm interested in what I'm doing and I'm taking full part in it, and to be honest with you I don't even think about anxiety. (MT45)

257

Similarly, participants were more engaged with nature and the external environment, which typically brought them joy:

> I've really enjoyed actually getting out, observing, thinking about nature, animals, and the observation side of things…I tend to spot a lot of things, which I may have done anyway but I think just noticing it more, but maybe questioning it less. (MT43)

Participants also referred to changes in the impetus for action-taking, in terms of now being motivated by the action itself rather than a desire to control or avoid symptoms:

> [I think] 'I'm gonna do this thing even if I'm feeling bad' and [I'm] not trying to use the activity to distract myself or push those feelings away, which is what I was doing, more kind of doing it and accepting how I feel. (MT15)

Thus, there was an overall sense of transition from participants' lives being dictated by their symptoms to being dictated by activity and external factors.

(d) Empowerment and liberation

Running through participants' accounts of acceptance and transition was a sense of empowerment through freedom from former restrictions, fears, judgements and struggles.

> It shows you that there's a cycle of things, they come and go, and so you're not scared of them anymore, or doing unhealthy behaviour to try and stop them. (MT50)

Indeed, one participant discontinued therapy largely because it facilitated an understanding that she did not require help with her difficulties, stating: "I think I'd go as far as to say that I'm not as scared, if [the depression] does come back" (MT15). Similarly, by relinquishing attempts to 'fix' unpleasant emotions through understanding them as inevitable, participants expressed a sense of relief and liberation of energy:

> I accept that it's almost, um, honestly being able to stop trying to cure yourself and just, yeah, give up that struggle. I remember…thinking 'Oh yeah, I can actually just pack all this cr*p in', 'cos it's just self-perpetuating worry… It's a feeling of – a little bit of relief. (MT45)

Participants also felt empowered to take action through learning that they can do so regardless of how they are feeling. As such, some participants felt able to tackle activities (such as driving (MT63)) which they had not done for years. Often, the ability to take action in the presence of unpleasant emotions had helped enable participants to make drastic changes in their lives:

> Changing jobs in the middle of the therapy…I think it was partly Morita helping, it gave me the confidence to try and make those changes which I, without it I don't think I would have. (MT16)

This empowerment through acceptance often manifested itself in terms of increased self-confidence and a sense of "feel[ing] better equipped" (MT43) to dictate and manage situations:

> I would have thought 'Oh gosh, I've got to drive to [place]… What's gonna happen when I get to [the bridge]?', 'cos that's one of my dreads… Now I just think, I'll get there, if I can go then I'll go, if I can't I'll just sit there and reverse or whatever I've got to do, but handle the situation. (MT37)

Similarly, participants noted feeling "a lot more in control" (MT16) in terms of having an increased sense of power and autonomy over their lives. This appeared to have manifested through a redirection of efforts and altered ownership of responsibility: through accepting what cannot be controlled (internal states) and focusing attention on what can be controlled (behaviour):

> Through the process you appreciate that it's part of the natural world to actually feel the way you do and stop fighting your feelings, 'cos you can't change your feelings, but you can change the way you actually act… I've definitely got more control over what's happening day-to-day, um, more inclination to actually do things." (MT43).

Overall, there was a sense of joy, power and liberation inherent in the acceptance of difficulties, taking of action and related improvement in symptoms: "The visceral thing for me has been the joy, sheer joy of actually being able to take action without – and overcoming the fear" (MT63).

(e) Effect on symptoms and mood

When prompted with questions on whether Morita Therapy had helped them with their difficulties, participants often stated "a lot", with some describing specific ways in which their symptoms had improved: "I've been able to come off my medication and actually feel a lot more positive and actually feel a lot better." (MT16). However, participants' spontaneous accounts of the impact of treatment typically focused on their changed outlooks and behaviours, with reductions in symptoms generally considered secondary to this or described through the lens of acceptance. Thus, a sense of priority was given to adopting Morita Therapy principles over reducing symptoms (as is the intention of Morita Therapy): "My view now is totally different...I've seen a different side of it now" (MT37).

> [Depression has] definitely lifted and even though things might still be a bit gloomy, that's just the way they are, but there's good things happening as well, and yeah, I feel a lot better about life. (MT43)

> [My friends] said 'You just seem different, I don't know what it is, you're normally faffing and worrying and –', of course, I worry, but it's normalised life for me. (MT63)

Thus, whilst many participants often referred to (an acceptance of) some continued unpleasant thoughts and emotions, they typically noted these were of reduced duration due to their reduced engagement in the vicious cycle and increased action-taking:

> My anxiety's gone, my depression's gone and I'm in a much better place. I had a bad little patch…but then a day later I was absolutely fine, so instead of being stuck in that cycle for weeks, it was only like a couple of days. (MT50)

Similarly, participants also described more frequent pleasant experiences, and more thorough engagement with and enjoyment of these, particularly as this time was no longer being spent trying to analyse, anticipate and pre-empt unpleasant experiences:

> I get many more of those [good days] than I used to get. Probably more good days than bad days… Those periods of anxiety are shorter, they're no less intense, but they're shorter, um, and when they stop I can enjoy the rest of the day, because there's no point in going back over what happened this morning. (MT45)

In considering the value and impact of Morita Therapy, a common and revealing sentiment was "I wish people had access to it" (MT43). Thus, whilst indicating increased acceptance of difficulties, participants also conveyed the positive impact this had on their symptoms and mood as a by-product, and considered Morita Therapy a valuable approach in the treatment of depression and anxiety.

A summary of the acceptability of Morita Therapy to participants

Participants' views relating to the acceptability of Morita Therapy were understood within five key themes. Firstly, the ways in which expectations and understandings of treatment which are incompatible with Morita Therapy shape participants' views of acceptability were explored. This theme highlighted key inconsistencies between Morita Therapy and the hopes of some participants that treatment would provide a solution for their symptoms, and/or an opportunity to explore and express themselves. Included were the ways in which these preconceptions can feed participants' construction of Morita Therapy-incongruent rationales for treatment, such as misunderstanding rest as an opportunity for overcoming symptoms. As such, for these participants, Morita Therapy failed to achieve its assigned purpose, and/or failed to provide them with the approach they seek, and was generally not perceived as acceptable or helpful.

Secondly, in contrast to theme one, the ways in which participants' prior insights, experiences and expectations could facilitate engagement with Morita Therapy by allowing them to identify with its principles was discussed,

highlighting the importance of such identification in shaping views on acceptability. This theme stressed the role of participants' readiness to accept unpleasant thoughts and emotions, as per the underlying premise of Morita Therapy, and highlighted how various elements of treatment, such as the connection to the natural world or focus on the authentic self, might 'grab' participants from the offset and encourage them to engage with the approach.

Thirdly, the ways in which some participants approached and understood the treatment elements as a part of a progressive journey were explored. Thus, the acceptability of Morita Therapy was linked to participants' understandings of the treatment components as part of a gentle, naturally unfolding and experiential process which provided accumulative opportunities for learning about human nature, re-focusing attention from internal to external states, and owning responsibility or 'making them think'. For these participants, treatment components were judged in terms of how well they achieved these purposes, rather than in terms of how enjoyable or successful in overcoming symptoms they were, and thus challenging components such as rest were typically considered worthwhile. This theme also contrasted theme one, in which participants tended to seek a somewhat passive role in treatment and attempted to isolate each treatment component as a potential technique for overcoming symptoms.

Fourthly, the difficulties associated with engaging in the process of Morita Therapy, including the more practical rather than conceptual elements of treatment, were presented. Key challenges were the fear and discomfort participants experienced around rest in particular, and factors which may be relevant in many forms of psychological therapy such as needing safety and support from others, needing sufficient therapist guidance and reassurance, and the burden and commitment of treatment. Also discussed were factors which shaped whether these challenges amounted to barriers to continuing treatment, highlighting that whilst participants' expectations and understandings of treatment often moderated the extent to which they were willing to tolerate such challenges, the practice of Morita Therapy still presented as unacceptable for some participants despite their strong identification with the principles.

Finally, the value and impact of Morita Therapy, as expressed by participants who identified with the principles of therapy and/or approached therapy as a process, were discussed. These included participants' accounts of Morita Therapy providing a preferable alternative to other therapies such as CBT; the value of the acceptance, normalisation and permissibility of difficulties; a sense of transformation from participants' lives being dictated by symptoms to being dictated by activity and external factors; expressions of empowerment and liberation from former restrictions, fears, judgements and struggles; and the effect of therapy on symptoms and mood as a by-product of such changes.

Together, these themes provide a model of how different participants experienced Morita Therapy. Highlighted throughout participants' accounts, and key to how the themes relate to each other in forming an overall picture, is:

1. The importance of participants' expectations, understandings and receptivity to the Morita Therapy principles in terms of facilitating their engagement with treatment. Thus, the first three themes captured typologies of experiences, and how these shaped acceptability, with a particular contrast established between those who hold expectations and understandings of treatment which are incompatible with Morita Therapy (theme one) versus those who identify with the principles (theme two) and accurately understand the purpose of the treatment components as part of a process (theme three).

2. The distinction between Morita Therapy in principle and practice. Thus, whilst the importance of identification with Morita Therapy on a conceptual level was stressed, theme four captured the challenges of engaging with Morita Therapy on a more practical level. Whilst participants who did not identify with the principles were less likely to tolerate these challenges, it was also true that for some the practicalities of treatment were unacceptable despite their identification with the principles; therefore, it appears that it is one thing to connect to the Morita Therapy principles, and another to be able to engage in the process.

The implications of these key considerations around moderators of acceptability and the challenges of translating principles into practice will be discussed in Chapter Eight.

7.2.3 The acceptability of Morita Therapy to therapists

Therapists' views relating to the acceptability of Morita Therapy were understood within four key themes: (1) Morita Therapy as beneficial; (2) Morita Therapy in practice: room for improvement?; (3) applying Morita Therapy to different patients; (4) facilitating therapy delivery. Each theme encompassed a number of constituent themes (Figure 15, overleaf).

Figure 15 illustrates the overall picture of and relationships between these themes. Therapists generally spoke highly of Morita Therapy, especially the principles and particular components of the approach, and noted the positive benefits of Morita Therapy for many patients (theme one). However, some challenges and uncertainties were experienced in relation to operationalising treatment and applying the principles in practice (theme two). Thus, a key thread throughout therapists' accounts is the distinction between Morita Therapy in principle and practice: whilst the value of the principles is stressed within theme one, the challenges therapists encountered, for both themselves and patients, in translating these principles into practice is highlighted within theme two.

These challenges were often noted in the context of applying Morita Therapy to different patient presentations and responses: therapists highlighted patient variability, considered the suitability of Morita Therapy for different patients and stressed the importance of patients grasping the Morita Therapy principles as a moderator of their views of and responses to treatment (theme three). Within the analysis of the interviews it was clear that this patient variability was a key factor connecting themes one and two: therapists often referred to the same components of treatment as both potentially beneficial and potentially challenging, depending on the patient in question. Finally, in particular light of these challenges, therapists noted several ways in which the delivery of Morita Therapy had been, and could be, supported and facilitated (theme four).

Figure 15. Final thematic map (embedded qualitative interviews: therapists)
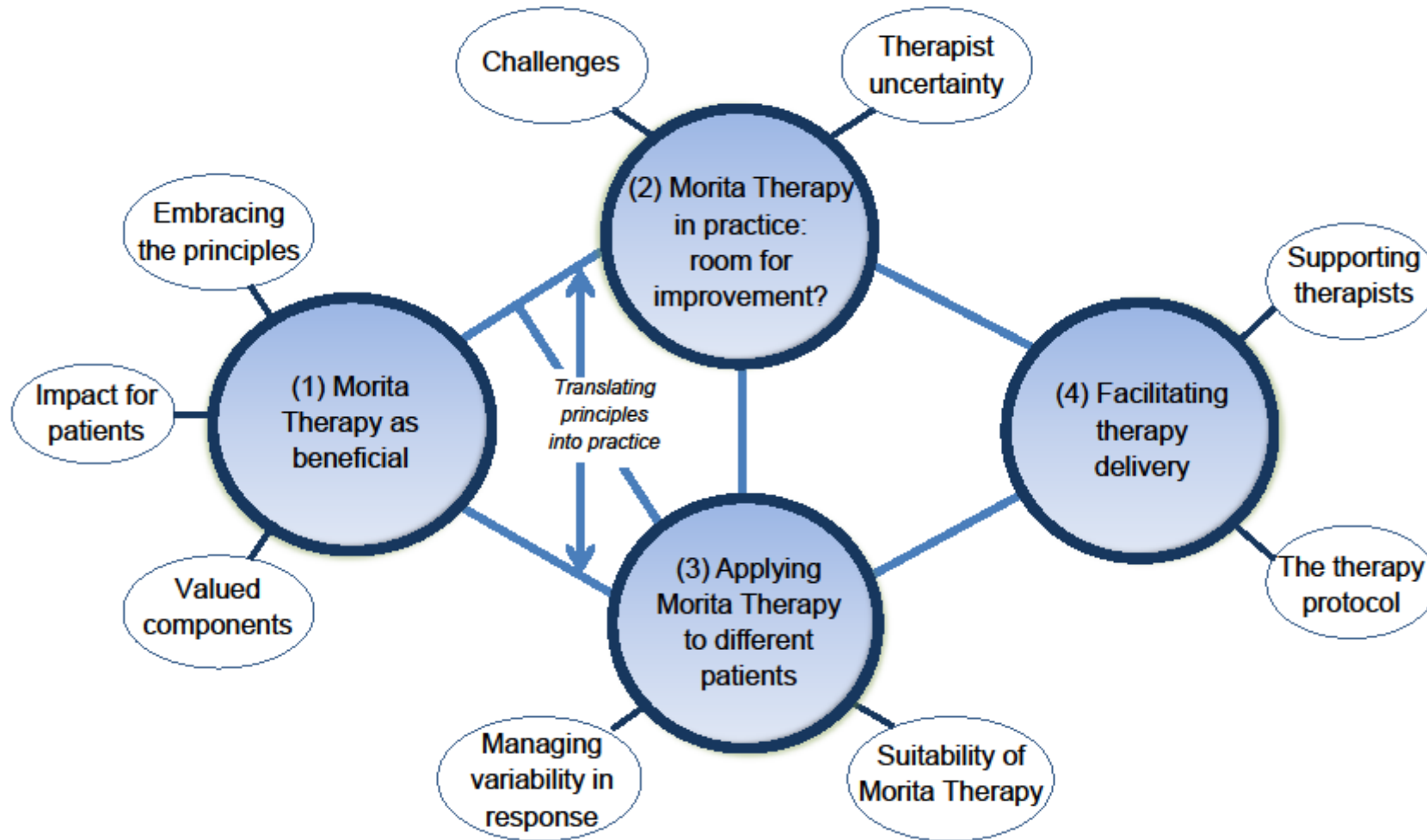
Theme one: Morita Therapy as beneficial

This theme illustrates how therapists generally spoke positively about Morita Therapy as both a treatment approach and a particular perspective on human nature and mental health. Therapists highly valued the worldview offered by Morita Therapy and the principles of the approach (constituent theme (a)), noted specific components of treatment which they considered particularly helpful in translating these principles into practice (constituent theme (b)) and described the impact and benefits of Morita Therapy for many patients (constituent theme (c)).

(a) Embracing the principles

In general, therapists spoke highly of the underlying worldview and principles of Morita Therapy, expressing their enjoyment of learning about and delivering the approach: "I thought it was a great overall journey, I really enjoyed it" (TH02). Particularly valued by therapists were principles around working with authentic human nature, accepting and allowing unpleasant emotions as natural phenomena and focusing on action-taking.

> I like the authenticity of it, the fact that it's about bringing us back to being features, organisms of this planet and therefore, you know, the things that we experience are so natural. I like the steer away from – we've got to fix all the things that are uncomfortable. (TH01)

Therapists thus appreciated the move away from the approach of fixing symptoms and towards an approach of acceptance and connection to nature, and considered this valuable in helping patients with their difficulties.

> Morita Therapy is a sustainable therapy…which embraces a unique engagement with nature as an underpinning that we are part and parcel of nature and that we can't change it... there is a value in accepting the natural rhythms of life. (TH02)

Therapists also noted how the Morita Therapy principles chimed with their personal beliefs and lifestyles, suggesting this identification with the principles

and "a strong belief in some of the logic" (TH02) was an important part of delivering Morita Therapy.

> It fits, probably, with my outlooks on life, some of my ways of living, some of my desires, um, as a therapy, and that helps… the fact that I am a lover of the natural world…[and] have a real acceptance of the fact that we do have a whole repertoire of emotions as human beings. (TH01)

Indeed, therapists suggested the Moritian perspective had impacted upon their own life and views, and potentially on their future therapeutic practice:

> I sit more comfortably now with my own emotions, I fight it less… and I'm more, I think, akin with the people that I love, as a consequence of that… I will probably pay more attention to emotion in therapy and probably project through my questions and enquiry and therapy approach, um, a sense of how natural emotions are. (TH01)

Thus, therapists valued the underlying principles of Morita Therapy, particularly those centred on authenticity and naturalness, and noted their own identification with and embracing of such principles.

(b) Valued components

Therapists highlighted several components of Morita Therapy in practice which they found particularly valuable in delivering the approach and facilitating patients' engagement with the principles, such as diaries, Fumon (inattention to symptoms) and working with desires. Therapists noted that the diaries were features which "people found hugely helpful" (TH02) in terms of reflecting on their own changes during treatment and receiving therapist comments.

> It was a really beautiful way of reinforcement: repeat, repeat, repeat, I found myself kind of really – and thought this would be incredibly repetitive for people – but actually a number of times they would feedback that that was useful. (TH01)

Therapists also noted that the diaries were a "really useful tool" (TH01) for them which they found highly informative:

> You can see a lot of the way that people actually do process and
> ruminate through the diary… [they] do give you a window into them
> thinking out loud. (TH02)

Whilst therapists experienced some concern around Fumon (inattention to symptoms) potentially lacking empathy, they also reflected that this technique had worked well and been well received by patients in practice: "I think it's valuable, um, I used it probably quite compassionately, or I hope I did" (TH02). Therapists indicated they became more adept at and "comfortable with using it as [their] experience went on" (TH01), and noted the importance of explaining the technique to patients at the start of therapy as a means of preparing and anchoring patients.

Corresponding with their appreciation of the Moritian focus on authenticity, therapists also valued working with patients' desires, noting how this allowed patients to reframe their fears and reflect on their authentic goals and values.

> The other fundamental thing that's been helpful is this desire and fear
> mechanism… you can actually help move people along a journey by
> getting them to reflect on their desires. (TH02)

Overall, therapists also stressed the importance of Morita Therapy providing an experiential approach through the treatment phases:

> My sense is that the experiential part is necessary in order a) for people
> to feel physically the physical wave of emotion, the ebb and flow, but also
> to have that experience of what happens when I don't do the behaviour
> that I normally do that perpetuates this cycle. (TH01)

Thus, therapists emphasised diaries, Fumon, working with desires and the overall experiential phased approach as central to and valuable in delivering Morita Therapy.

(c) Impact for patients

Therapists indicated the benefits of Morita Therapy for many of their patients, noting that "a lot of people just had this sense of – I can only call it acceptance

really" (TH02). More specifically, therapists highlighted the value of Morita Therapy in facilitating patients' acceptance and allowance of unpleasant emotions and ability to live more natural and meaningful lives with increased action-taking and "psychological flexibility" (TH02).

> People would have, in the main, been able to embrace the principle around emotions being natural… people have been able to embrace a more natural way of living, and that may be about just being a bit more authentic, that might be actually allowing the feelings that they have rather than pursuing expectations about how they think they should be... People have been able to therefore move on from that point and lead more meaningful lives in line with their desires. (TH01)

Therapists also stressed the particular benefits for patients of connecting to nature, which they noted manifested differently for different patients, with some engaging in nature in an explicit, physical way and others connecting more to natural world metaphors: "people grasped nature in different ways" (TH01).

> [Patients] did actually get the sense of wellbeing about the natural world... [they realised] they could actually be, and gain a great deal from being, outside and being in the natural world, being part of it. (TH02)

With regards to the benefits of the treatment in practice, therapists noted in particular the important lessons and concepts patients learned through their engagement with phases one (rest) and two (light activities).

> One and Two are gateway[s]… they give them the Eastern frame, rather than the Western frame, so, like: we don't fix it, you endure it and you be with it... Everyone learned that you can be with it. (TH02)

As a by-product of their identification with the principles, therapists also suggested that patients' symptoms typically reduced:

> For patients who really grasped the principles I would say they would, as a kind of side-line almost, they will have experienced improvement in their symptoms that were giving them distress…they would be less distressed and more fulfilled, less preoccupied, less ruminative. (TH01)

Thus, therapists indicated that, through their engagement with principles and practice of Morita Therapy, many patients were able to live more authentic and meaningful lives in which they accepted their difficulties and also experienced reduced symptoms.

Theme two: Morita Therapy in practice: room for improvement?

This theme illustrates the challenges in implementing and engaging with Morita Therapy in practice, which therapists highlighted for both themselves and patients (constituent theme (a)), and areas in which therapists indicated their uncertainty or a lack of clarity in terms of how to operationalise Morita Therapy (constituent theme (b)). Included within these constituent themes are suggestions therapists made for how these difficulties might be circumvented.

(a) Challenges

Therapists described multiple challenges in operationalising components of Morita Therapy in practice, such as the diaries, treatment timeframes, and treatment phases. These challenges related to both therapists' experiences of delivering treatment, and patients' experiences in engaging with treatment. With regards to diaries, therapists highlighted their cumbersome size, patients' occasional practical difficulties such as dyslexia, and some lack of patient understanding of the instructions. Furthermore, therapists noted the challenges of engaging patients with their diary comments in a meaningful way:

> For some people it didn't work particularly well… quite often they would read through my comments and go, like, 'Yeah, yeah, I can see that, yeah, I can ', but not many would actually say 'I don't understand what you've written there'… there weren't so many people that would pick up on it and question it or reflect critically. (TH01)

In terms of the timeframes for treatment (session length and number), therapists indicated that this felt constrained: "It always felt like we were on a relatively limited timeframe" (TH01). As such, therapists considered whether a more flexible timeframe might be helpful in ensuring patients have "an adequate dose of experiencing the principles of Morita Therapy" (TH01), particularly during each treatment phase, and whether the option for longer treatment sessions

might enable their facilitation of patients' experiential engagement with therapy through in-session rest periods and/or engagement with nature.

In relation to the rest phase specifically, therapists highlighted various challenges that patients encountered, often related to the time commitment, ensuring an appropriate environment and the need for supportive significant others. These challenges were considered compounded by the fear and discomfort that sitting with unpleasant experiences induced for patients. Also highlighted were the challenges some patients faced in understanding the purpose of rest, particularly in the context of rest presenting as "frame-shaking" (TH02) compared to the approach of other treatments in which increasing activity is prioritised.

> It was hard to be too prescriptive for people around rest in terms of hours… lifestyles got in the way a lot, um, people's discomfort with embarking on it, particularly people, perhaps, who lived alone… It's a bit overwhelming and because it comes so early in therapy it's often hard for people to grasp 'why, why am I doing this?' (TH01)

In terms of phase two (light activities), therapists similarly noted challenges in relation to identifying appropriate activities and ensuring sufficient time was devoted to these to enable patients to learn the intended lessons. A particular challenge was highlighted around the purposes of phase two, with therapists discussing patients' difficulties in understanding the relevant distinctions: absorbing attention within the external environment versus distracting themselves from unpleasant experiences; progressing through activities as a learning process versus discovering enjoyable hobbies.

> Sometimes we get a little bit lost in people – 'oh yeah, I really enjoy knitting so I shall do that'…half of me never really understood whether they were getting back into the sort of hobby or whether they were really actually utilising it [as intended]. (TH02)

Finally, therapists indicated difficulties in relation to the concept of fears and desires forming two sides of the same coin, both in terms of what they felt able to convey and what they felt patients could understand.

> I found it quite a hard thing to convey, um, or never quite knew when to
> come in with it… It's quite a difficult construct. (TH01)

Overall, therapists indicated several challenges both they and patients
experienced whilst engaging with Morita Therapy in practice, highlighting
difficulties associated with operationalising the diaries, treatment phases and
timeframes, and the concept of underlying desires in particular.

(b) Therapist uncertainty

Therapists indicated several ways in which they experienced uncertainty in
operationalising Moritian concepts in practice, typically related to the treatment
phases and indicators of therapeutic progress. With regards to the latter,
therapists struggled to identify whether those specified within the therapy
protocol were being experienced by patients.

> More clarification around those would have been helpful. There were
> times, I think, where treatment concluded because we'd got to Session
> Twelve, rather than there being clear indicators that sufficient progress
> had been made in experiencing and embodying the principles… That,
> sometimes, was quite hard to feel like there was clear evidence. (TH01)

Similarly, therapists struggled to identify when patients had undertaken an
"adequate dose" (TH02) of rest, and when they had learned the intended
lessons of this phase. Thus, therapists suggested that tools to quantify the
amount of rest undertaken, potentially as a diary section, and to assess
"embodiment of the ebb and flow of emotion" (TH01) would be valuable.
Therapists also noted uncertainty around changes they identified within
patients' diary accounts, in terms of whether these reflected genuine changes in
patients' outlooks or whether "they're just trying to please the therapist" (TH02).

Furthermore, in the absence of both a patient "problem framework" (TH02)
presented to therapists at the start of treatment and enquiring directly with
patients about their symptom levels, therapists struggled to identify the extent to
which patients' symptoms had been addressed during therapy. Therapists
indicated some discomfort with relying on patients' understanding and

internalisation of the principles, which in itself was difficult to assess, as an indicator that patients had been adequately helped with their difficulties.

> You've got to be very, very sure that an understanding of the concepts or an understanding of principles equals, um, a good outcome… I'm still to this day really not that clear on the sort of outcome indicators. (TH02).

In relation to the phases overall, therapists indicated some uncertainty around distinguishing between phases two, three and four. Often this uncertainty related to a lack of clarity as to the purpose of each phase, alongside whether patients must progress through these phases sequentially or not. Related to this was some uncertainty around the purpose and nature of activities to be engaged in during each phase, such as whether phase two activities should be enjoyable and/or maintained beyond engagement in phase two.

> The distinction between [phases] two and three is most difficult… whether [in phase three] they then drop their activities in two or they keep them going, or whether the activities serve their purpose… I mean, do they do them forever? (TH02)

Therapists also suggested some uncertainty around whether, through the experiential nature of therapy, the more cognitive elements of the vicious cycle (such as patients' discrepancies between how things 'are' and how things 'should be') would be sufficiently addressed for patients. Therapists suggested that more guidance on managing this gap between the ideal and real, such as examples of relevant metaphors, would be helpful.

> We could do some distortion work, or challenge that through thinking… are they continuously going to do the crochet when they're actually preoccupied with rumination…around gaps in the way 'I should be''? (TH02)

Therapists similarly noted that they struggled, when working with "unrealistic desires" (TH02), to know whether these should be mediated or simply brought to the patients' awareness. Thus, therapists indicated that they experienced some lack of clarity in delivering features of Morita Therapy, particularly in terms

of assessing indicators of progress, operationalising the treatment phases, and addressing the cognitive components of patients' distress.

Theme three: Applying Morita Therapy to different patients

This theme illustrates the ways in which, throughout their accounts of Morita Therapy and particularly in relation to the challenges they experienced in delivering the approach, therapists indicated much variability in patients' responses to and understandings of the treatment components (constituent theme (a)). This patient variability connects themes one ('Morita Therapy as beneficial') and two ('Morita Therapy in practice: room for improvement?'): therapists often referred to the same components of treatment as both potentially beneficial and potentially challenging, depending on the patient in question. Constituent theme (b) presents therapists' views on the suitability of Morita Therapy for different patients and the factors deemed important in whether patients benefitted from the approach.

(a) Managing variability in response

In considering the suitability and usefulness of the components of Morita Therapy for patients, therapists often referred to variability in patient's responses to and understandings of treatment, indicating that broad generalisations were difficult to make. Often these views were expressed in relation to patients' understanding of and learning acquired from the treatment phases. For example, in relation to the purpose of phase two (light activities):

> Some people grasped that… others used it as a kind of fix, so it was about 'when I feel really unsettled, I pick up the colouring'. (TH01)

Furthermore, therapists indicated that this variability amongst patients required them to adopt an individualised and flexible approach, which was at times challenging, and that for different patients they struggled in different ways to know how best to apply and optimise the components of therapy. For example, in terms of engaging patients in rest:

> I tried different things, right the way down to, you know, sitting in a chair resting… Some people got [the learning from rest] without the titration

> and a lot of it, and some got it with a lot of it, and some I was trying to get them to do it right up to Week Four and it was basically not – evidently they weren't getting anything from it. (TH02)

Thus, this patient variability was also linked with the challenges and uncertainties therapists experienced in relation to aspects of treatment such as establishing the necessary dose of rest and assessing indicators of therapeutic progress (theme two: Morita Therapy in practice: room for improvement?). Other components of Morita Therapy with regards to which patient variability was stressed were diaries and the understanding of fears and desires forming two sides of the same coin.

> Diaries were incredibly variable, and some of that depended on people's ability to, simply, write, and how literate they were… you can get one full side of really neat, intense writing versus four or five words. (TH01)

> The two sides of the coin was quite a hard concept for some people to grasp… There were some really [sighs] helpful moments for some people, where actually it was something I could readily see how it would apply and then for other people I found it harder as a concept to say, yeah, this is where this is so relevant. (TH01)

Thus, therapists indicated much variability across patients around the ability to apply, understand and benefit from the components of Morita Therapy, creating a requirement for an individualised approach which was challenging to adopt.

(b) Suitability of Morita Therapy

In considering patient variability and the suitability of Morita Therapy, whilst struggling to discriminate between particular patient characteristics as potential predictors or moderators of response, one factor which therapists consistently deemed important was patients' ability to grasp the principles.

> I don't know that you could pinpoint 'this characteristic is a make or break for Morita Therapy'… there's something about an ability – my sense is – an ability to relate… if it didn't conceptually gel with people, that they might just walk away from it. (TH01)

Therapists connected this ability to relate to the principles with patients' readiness to accept difficulties rather than seeking to cure them, a degree of "openness" to treatment (TH01) and a level of prior insight which allowed them to identify with the vicious cycle in particular. Therapists also highlighted patients' orientation towards nature as an important factor in embracing the principles.

> The characteristics of some of the people who actually got a lot from it, there was a lot of bias coming into the room with them tending towards a sort of naturalistic view of the world…and actually really very much seeing a positive place for themselves outside of – in nature. (TH02)

Therapists also indicated the importance of a degree of "emotional intelligence" (TH01) and perseverance in the context of Morita Therapy presenting some challenging experiences for patients.

> Where they were prepared to come back and say, you know, how hard this is… Those people, actually, were the ones who are showing you they want to try and learn, they're prepared to share their distress with the therapist and be, perhaps, more authentic. (TH01)

Related to the importance of understanding the principles, therapists considered whether the experiential aspects of Morita Therapy are necessary in order to embed the principles or whether patients' conceptual identification with the principles might be sufficient. These considerations linked to patient variability (constituent theme (a): managing variability in response): therapists typically concluded that different patients appeared to embed or benefit from the principles in different ways (if at all).

> How necessary is it to go through that [rest], I don't know… For some people, I think it was definitely – it helped assimilate the whole principles, the basis of it. For others, they might have conceptually grasped it sufficiently and then applied the principle during other activities... To hear that message about the naturalness of emotions…I think [that alone] can be quite a helpful intervention, but not for everybody. (TH01)

276

Therapists also suggested patient characteristics for which Morita Therapy might be less suitable, typically related to patients' understandings and expectations of treatment. Thus, therapists indicated that those who sought a "more talking framework" (TH02) or "wanted to be treated for their symptoms" (TH01) were less likely to find Morita Therapy beneficial. Therapists also indicated patients' current coping mechanisms and cognitive patterns as important factors in their response to treatment, suggesting that where patients struggled with a "gap between the way things are and the way things should be" (TH02) or "entrenched ways of managing emotion" (TH01) such as "avoidance" (TH01) and "rumination" (TH02), Morita Therapy was more challenging to deliver. Overall, the importance of grasping the principles (whether cognitively or experientially), identifying oneself in terms of the vicious cycle, connecting with nature and seeking a treatment approach in line with that of Morita Therapy were considered important to the effectiveness of the approach.

Theme four: Facilitating therapy delivery

This theme illustrates therapists' views on how their delivery of Morita Therapy had been facilitated and supported by their supervisor and the study researcher, namely through trial management, therapist training and supervision (constituent theme (a)) and the therapy protocol itself (constituent theme (b)). Included are the suggestions therapists made for improving the protocol and further supporting therapists delivering therapy in the future.

(a) Supporting therapists

Therapists indicated that they had felt well equipped for and supported throughout therapy, in terms of the trial management, therapist training and supervision. Regarding the trial, therapists commented that it was "organised" (TH01) and "worked really well" (TH02), noting that the risk, adverse events and 'did not attend' protocols were appropriate. Whilst indicating the usefulness of the assessment information passed from the study researcher to the AccEPT Clinic, therapists suggested that the provision of more detailed information on patients' "current difficulties" capturing "how the clients saw their problems" (TH01) would have further facilitated their delivery of treatment in order to provide them with a form of 'problem statement' at the start of treatment.

In terms of training, therapists indicated that all necessary aspects had been addressed and stressed the importance of the training session in focusing on the key principles and how these are operationalised in practice:

> It was really helpful having the sessions with yourself and [supervisor] at the outset to try and thrash out the 'how', you know, 'how' and 'what', really. So, what the principles were, what the therapy was about, what its aims and objectives were, but then the 'how' of well, how are we going to do this in sessions. (TH01)

Therapists also noted the importance of supervision, particularly in allowing "room for thoughtful discussion" (TH02), providing an opportunity to discuss the specific application of Morita Therapy to individual patients in the context of patient variability (theme three: applying Morita Therapy to different patients), and aiding adherence to the key principles:

> One of the values of what [supervisor] could do was just bring it back to the principles, really, and I think that was really helpful. (TH02)

Similarly, therapists valued both themselves and their supervisor listening to tapes of therapy delivery to check fidelity to the protocol with the aid of the fidelity checklist developed by the study team.

> Having those sessions recorded [and] listened back through to kind of see, you know, were we keeping sort of fidelity to the principles and how those sessions were intended to go was helpful. (TH01)

Therapists also noted the usefulness of the fidelity checklist as an aide memoir during therapy sessions, to facilitate their adherence to the key elements of the approach. Overall, therapists indicated that they felt well equipped and supported by the study researcher, supervisor, and materials provided.

(b) The therapy protocol

Therapists indicated the usefulness and appropriateness of the therapy protocol both in terms of embedding the principles of Morita Therapy before starting treatment and as a more practical guide to implementing the approach during treatment. In terms of the protocol as a learning and training aid:

> The detail was really helpful at the start when we were trying to get our heads around 'how's this gonna work, how does it translate into practice' and the embellishment around – so the principles and trying to get a kind of theoretical, conceptual understanding. (TH01)

In terms of the protocol as a practical guide and aide memoir during treatment to facilitate the structuring of sessions and fidelity to the approach:

> I don't think it deviated too much from the way we were asked to deliver it, really, we actually did stay with the general content, which is all credit to you, really, the manual was put together really well... it was a constant aide memoir really for me, throughout therapy. (TH02)

Therapists also noted the value of the protocol in allowing the approach to be flexible and individualised for different patients, particularly in the context of patient variability (theme three: applying Morita Therapy to different patients):

> [One thing] I like about it is that it tries to really impart the necessary components of Morita Therapy without being too prescriptive about every single thing that you need to do within a session, for example, and allows a bit of clinical judgement and creativity to get the intervention to fit the client, in a way that perhaps other protocols don't. (TH01)

Therapists also commented that the changes made to the therapy protocol during the intervention optimisation study (see Chapter Five) responded well to their feedback, such as providing summary sheets and more eye-catching guidance:

> Your response to our request of 'can we get some summary sheets', now they lived in my blue to-hand folder and these were really, really helpful… Warning points [and] traps that therapists might fall into, it's helpful to have highlighted those. (TH01)

Therapists did make some suggestions for additions to the protocol such as a summary sheet describing Morita Therapy overall and further clinical examples illustrating individualised manifestations of the vicious cycle and different options for conveying fears and desires to cover a wider range of patient

presentations. In considering the usefulness of the protocol for future therapist training, therapists similarly considered it fit for purpose whilst suggesting the potential addition of diary examples. Thus, whilst suggesting minor additions to the protocol, therapists considered the protocol comprehensive and appropriate for both learning the background and principles of Morita Therapy and operationalising the approach in practice.

A summary of the acceptability of Morita Therapy to therapists

Therapists' views relating to the acceptability of Morita Therapy were understood within four key themes. Firstly, therapists' views of Morita Therapy as a positive and beneficial approach were presented. Therapists' generally spoke positively about Morita Therapy as both a treatment approach and a particular perspective on human nature and mental health. Therapists highly valued the worldview and principles underpinning Morita Therapy, alongside noting specific treatment components such as diaries, Fumon (inattention to symptoms) and working with desires which they considered particularly helpful in translating these principles into practice. Therapists also described the impact and benefits of Morita Therapy for many patients, particularly in terms of acceptance, connection to nature, and related improvements in symptoms.

Secondly, therapists described several challenges, for both themselves and patients, encountered in operationalising Morita Therapy in practice. Key difficulties involved the use of diaries; strict number and length of treatment sessions; discussions of fears and desires forming two sides of the same coin; and the implementation of treatment phases in terms of ensuring an adequate dose, choosing appropriate activities and facilitating patients' accurate understanding of the purpose of those activities. Therapists also indicated several areas in which they had experienced uncertainty in operationalising therapy, typically related to distinguishing between treatment phases and identifying indicators of therapeutic progress.

Thirdly, throughout their accounts and particularly in relation to the challenges they experienced, therapists indicated much variability in patients' responses to and understandings of the components of the approach. This patient variability connected themes one and two: therapists often referred to the same

components of treatment as both potentially beneficial and potentially challenging, depending on the patient in question. Whilst therapists struggled to generalise in terms of potential predictors or moderators of response to Morita Therapy, they consistently highlighted the importance of patients grasping the principles of the approach and indicated certain patient presentations for which they had found Morita Therapy more difficult to deliver.

Finally, therapists noted ways in which their delivery of Morita Therapy had been facilitated by their supervisor, the study researcher and materials they had been provided with. Whilst making suggestions for minor additions to the therapy protocol, therapists indicated that they had been well equipped and supported through the training, supervision and trial procedures in place. In particular, therapists indicated the usefulness and appropriateness of the therapy protocol both in terms of embedding the principles of Morita Therapy and as a practical guide to implementing the approach during treatment.

7.2.4 A summary of participants' views on the acceptability of the trial procedures

A descriptive account of participants' views on the trial procedures is summarised below. An in-depth qualitative analysis including participant quotes is not included as this was not considered necessary to meet the objective of collecting this information (to identify any issues with the trial procedures which would require addressing before proceeding to a large-scale trial).

Trial management

Participants commented that trial participation was straightforward and not very onerous, although one participant noted that there were a lot of questionnaires. Participants noted that the trial was well run, organised and efficient. One participant suggested that paying participants' travel expenses would be helpful. Participants valued the communication received and flexibility offered for appointments. Trial information was considered informative and succinct.

Randomisation

Whilst some discomfort was expressed due to a desire to receive Morita
Therapy, generally participants were comfortable with randomisation, often due
to understanding the need to randomise from a scientific perspective and/or a
willingness to participate in the trial in order to potentially help others. However,
there was a mixture of participants who did and did not understand the nature
and purpose of randomisation. Several participants had not understood the
difference between being eligible for the trial and being randomised, and some
had not realised that they would be asked to complete follow-up questionnaires
if randomised to treatment as usual.

AccEPT Clinc

Participants noted that it was easy to arrange therapy appointments and that,
whilst not offering sufficient parking, the clinic building was pleasant. Some
unique difficulties were expressed: one participant was unable to enter the
building for arranged out-of-hours appointments and their clinic discharge letter
was sent to the wrong GP; one participant commented that the clinic
receptionist could have been more enabling for patients, such as being
forthcoming with directions.

Morita Attitudinal Scale for Arugamama (MASA)

Although generally considering the MASA questionnaire relevant to the changes
they experienced during treatment, participants indicated that the clarity of the
questionnaire could be improved. Firstly, the questionnaire specified no
timeframes within which to consider the relevance of each statement.
Secondly, the wording of some statements was considered confusing and/or
ambiguous, such as which 'situation' to consider for the statement "I thought
about the situation all the time". Some participants would have also preferred
labels which they understood, rather than, for example, "SKS Subscale".
Finally, some participants disagreed that some statements with which
agreement was intended to score 'negatively' were indeed negative from a
Moritian perspective. For example, agreement with the statement "I have

thoughts that I cannot stop" was considered to show a helpful awareness of their lack of control, as opposed to an unhelpful desire to stop thoughts.

Summary

Care should be taken in ensuring participants' understanding of the randomisation process, and minor amendments to the MASA questionnaire would be helpful. However, overall, participants indicated that the trial was well run and raised no issues which suggest that the procedures of a large-scale trial should not mirror this pilot trial.

7.2.5 Connecting threads across participants' and therapists' views of Morita Therapy

There are several key threads running through both the participant and therapist data on acceptability which are brought together in this section in order to demonstrate the convergence of views between participants and therapists, and the key findings in relation to the overall question: how acceptable is Morita Therapy to participants and therapists?. Figure 16 (overleaf) presents these links, including relevant constituent themes, colour-coded as referred to in each section below. Although both participants and therapists spoke about some aspects of treatment which the other group did not, no clear disagreements between the participant and therapist data were identified.

Figure 16 overleaf

Figure 16. Connecting threads across participant and therapist data on acceptability
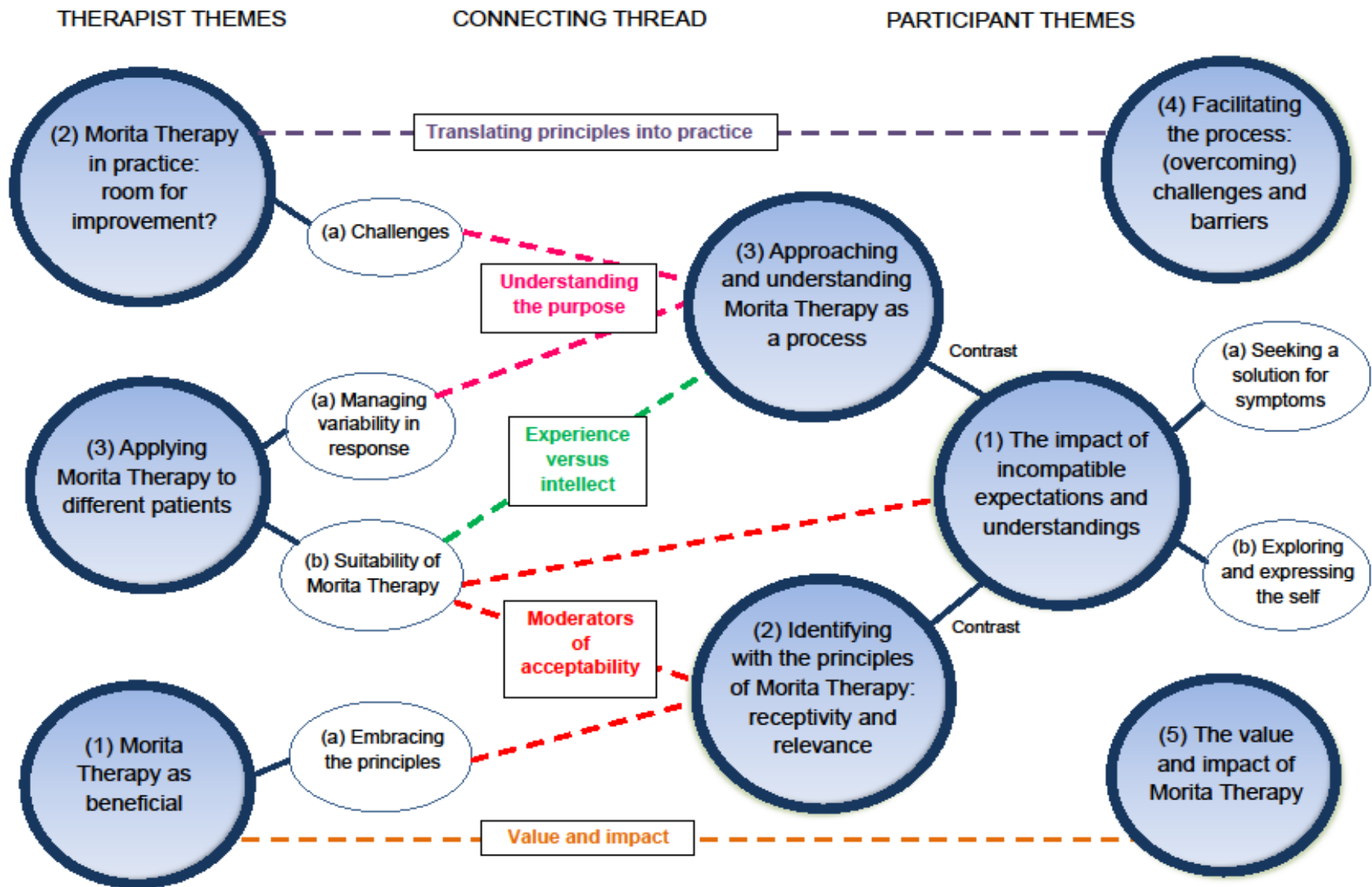
Value and impact

Participants and therapists spoke of the value and impact of Morita Therapy in similar terms (Figure 16, coded **orange**). Thus, therapists and many participants valued the underlying principles of Morita Therapy such as accepting and allowing symptoms as natural phenomena, working with the authentic self and focusing on action-taking. Similarly, they both described the impact of Morita Therapy in terms of the value of acceptance, a freedom from former restrictions and/or progression towards more active and meaningful living, and an improvement in symptoms as a by-product of such changes.

Moderators of acceptability

A key issue running through the accounts of both therapists and participants is the importance of patients relating to the Morita Therapy principles (Figure 16, coded **red**), with therapists also indicating the importance of the principles chiming with their own beliefs and lifestyles in facilitating their delivery of therapy. Participants highlighted the ways in which their prior experiences, insights and expectations essentially primed them for such identification, and this ability to identify with the principles manifested as a key moderator of acceptability: the accounts of participants who found Morita Therapy acceptable fell within this typology, whereas the accounts of participants who did not find Morita Therapy acceptable fell within the typology captured by theme one, whereby participants held expectations and understandings of treatment which were incompatible with Morita Therapy and ran counter to the principles.

Therapists similarly highlighted patients' ability to grasp and internalise the Morita Therapy principles as the defining factor when considering potential moderators of acceptability and engagement. As per the participant data, therapists connected this ability to relate to the principles with patients' prior insights into their symptoms, orientation towards nature, extent of openness towards treatment, and readiness to accept difficulties. Data from both participants and therapists further indicates that this identification with and grasping of the Morita Therapy principles is central to whether or not patients benefitted from treatment: "For patients who really grasped the principles I

would say they would, as a kind of side-line almost, they will have experienced improvement in their symptoms" (TH01).

In indicating certain patient presentations for which they had found Morita Therapy more difficult to deliver, therapist data also supports the participant typology capturing how incompatible expectations and understandings of treatment are associated with viewing Morita Therapy as unacceptable. Thus, therapists highlighted that patients who "wanted to be treated for their symptoms" (TH01) or sought a "more talking framework" (TH02) were less likely to find Morita Therapy beneficial.

Principles versus practice

The distinction between Morita Therapy in principle and practice, and the challenges of translating the principles into practice, ran through both participants' and therapists' accounts (Figure 16, coded **purple**). Whilst therapists described several components of delivering Morita Therapy which had at times facilitated their translation of the principles into practice, they also indicated that these same components could pose challenges for both themselves and patients in practice, largely depending on the patient in question. Similarly, participants highlighted the challenges of engaging with the process and practicalities of therapy. Key difficulties raised by both participants and therapists related to engaging with the treatment phases, especially rest, and completing diaries.

Understanding the purpose

Some of the challenges therapists described in relation to patients' understanding of treatment components such as the phases also chime with the participant data (Figure 16, coded **pink**). Thus, therapists indicated that some patients grasped the purpose of each treatment component as a means of progressing through a learning process, whereas others "used it as a kind of fix" (TH01). This concurs with the analysis of participant data: participants who found Morita Therapy acceptable and were more likely to tolerate the challenges of engaging with the approach tended to accurately understand the treatment components as part of a progressive process providing opportunities

to learn and refocus attention; those who did not find Morita Therapy acceptable tended to mistakenly attempt to isolate each treatment component as a potential technique for overcoming symptoms.

Experience versus intellect

In considering *how* to sufficiently embed the principles for patients alongside potentially overcoming some of the practical challenges highlighted, whilst noting that "the experiential part is necessary" (TH01) for patients to learn important lessons therapists also suggested that some patients might be able to embed the principles (thus benefitting from treatment) without engaging in the whole process. This is potentially supported by the accounts of multiple participants who spoke of the value and impact of having learned about the Morita Therapy principles without having engaged in treatment beyond the rest phase (e.g. MT15; MT50); however, similarly to the therapists (Figure 16, coded **green**), many participants did stress the importance of a degree of experiential progression. Thus, the means by and degree to which the principles of Morita Therapy are most helpfully translated into practice remains an issue for further discussion.

Trial procedures

Both therapists and participants, whilst making suggestions for minor improvements, signified that the trial procedures were largely acceptable. Therapists indicated that they had been well equipped and supported through the trial, training, supervision and therapy protocol; patients indicated that the trial was well run and raised no issues which suggest that the procedures of a large-scale trial should not mirror this pilot trial.

CHAPTER SEVEN. PART THREE.

Results of the mixed methods analysis of the relationship between treatment adherence and acceptability

This part of Chapter Seven reports the results of the mixed methods analysis undertaken to answer the question: how do participants' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?. The results are presented using three forms of joint display: a typologies and statistics display to explore how treatment adherence varies for participants whose views on acceptability are organised into different typologies (7.3.1); a categories and themes display to explore views across participants with various degrees of treatment adherence (7.3.2); a case-oriented merged analysis display to integrate views and the number of treatment sessions attended for each participant (7.3.3). A summary of key findings is provided in section 7.3.4.

7.3.1 Typologies and statistics display

This technique was driven by the qualitative data. Thus, firstly, typologies of participants' views on the acceptability of Morita Therapy were developed from the qualitative data (Figure 17, overleaf). Five typologies were derived from the 16 interviews analysed. Whilst the size of each typology within Figure 17 represents the number of participants whose views fall within that typology, it should be noted that a sub-sample of interviews were selected for analysis on the basis of treatment adherence amongst other factors, and that these 'weightings' are therefore only applicable within this sample and are not considered generalisable beyond this. Each typology is described in detail alongside example participant vignettes to illustrate the key features which define each typology.

Figure 17. Typologies of acceptability
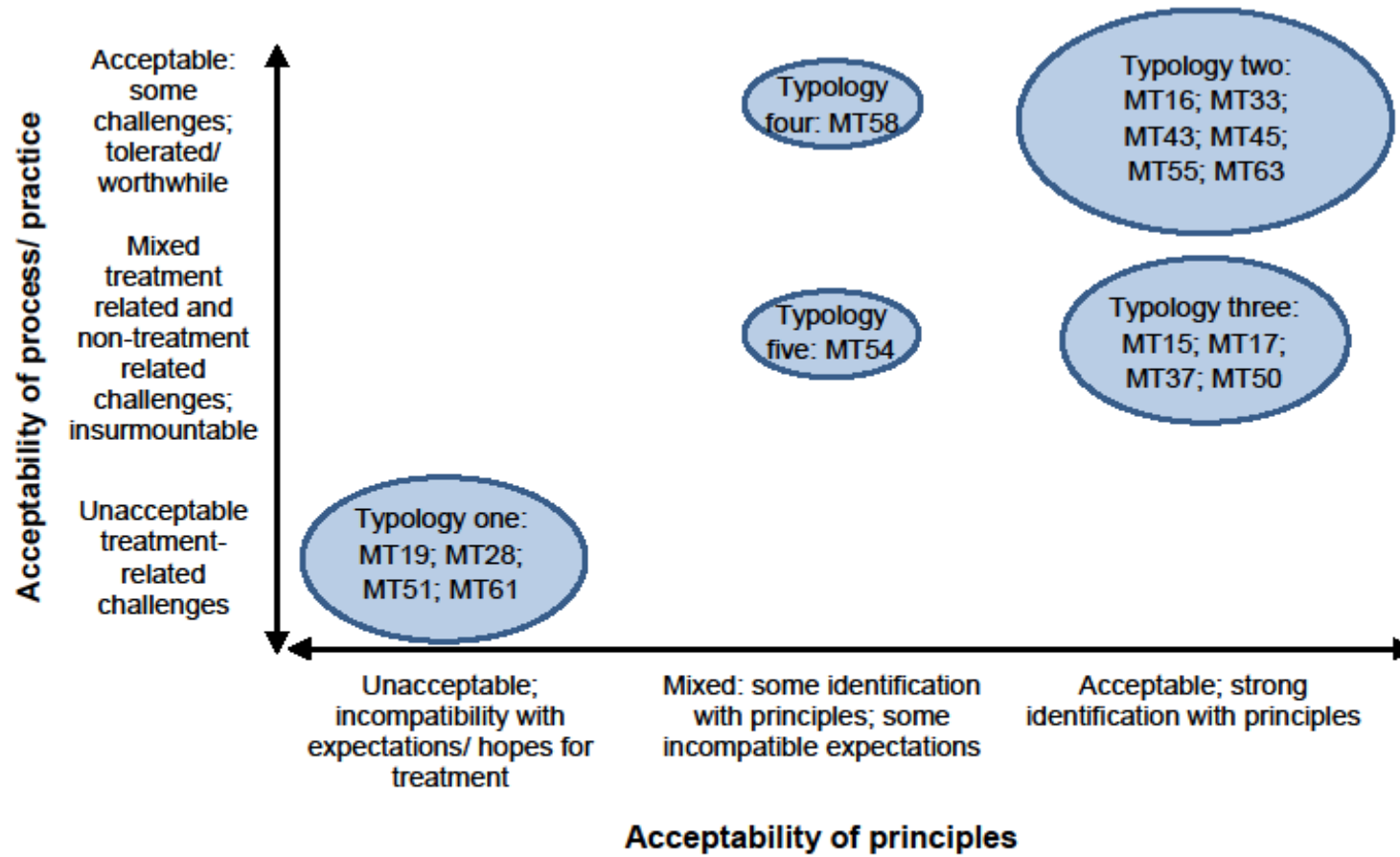
The typologies are displayed along two continuums of acceptability relating to (a) the principles and (b) the practice of Morita Therapy, reflecting how this distinction between Morita Therapy in principle and practice ran through participants' qualitative accounts: the qualitative analysis indicated both the importance of participants holding compatible expectations and understandings of treatment which enabled their identification with the Morita Therapy principles, and the challenges of translating these principles into a process which is feasible for participants to engage with. Thus, the x axis (from unacceptable principles to acceptable principles) represents the extent to which the Morita Therapy principles, such as the connection to nature, focus on action-taking and desires, and concept of the vicious cycle, as well as the underlying premise of accepting and allowing unpleasant thoughts and emotions, were considered acceptable by participants; the y axis (from unacceptable practice/ process to acceptable practice/ process) represents the extent to which the process and practice of Morita Therapy, such as engagement in the four phases and completion of daily diaries, were considered acceptable by participants.

Secondly, for each typology, data are presented on treatment adherence for participants to whom the typology applies (Table 27, overleaf). Data are organised by typology: the number of treatment sessions attended by participants for whom both the principles and practice were unacceptable are presented at the top of the table; the number of treatment sessions attended by participants for whom both the principles and practice were acceptable are presented at the bottom of the table. To provide further context for this information and enable the exploration of how the data also relate to quantitative treatment outcomes, participants' reasons for withdrawing from treatment and whether or not they demonstrated a response to treatment (defined as a PHQ-9 <10 at follow-up) are also presented.

Table 27. Joint typologies (acceptability) and statistics (adherence) display

Typology of acceptability	Patient ID	No. therapy sessions		Reason for withdrawing from treatment (N/A = completed treatment)	Treatment response?[1]	Therapist fidelity to protocol?[2]
		Each	Mean			
Principles: unacceptable (incompatibility with expectations/hopes for treatment); Process/practice: unacceptable (treatment-related challenges)	MT61	3	5	Discomfort with writing about self in diary; failure of rest to meet expected purpose	No	Yes
	MT19	5		Pressure of completing phases in absence of therapy fulfilling expected purpose	No	Yes
	MT51	5		Lack of techniques provided; challenges of rest in context of not fulfilling expected purpose	No	Yes
	MT28	7		Pressure of completing phases in absence of therapy fulfilling expected purpose	No	Yes
Principles: mixed (some incompatible expectations); Process/practice: mixed treatment related and non-treatment related challenges (insurmountable)	MT54	1	N/A	Time difficulties with rest/diary; difficulties with Fumon (therapists' inattention to symptoms)	Yes (attributed to life changes)	N/A
Principles: mixed (some incompatible expectations); Process/ practice: acceptable (some challenges; tolerated/ worthwhile)	MT58	9	N/A	N/A	No	N/A
Principles: acceptable (strong identification with principles); Process/practice: mixed treatment related and non-treatment related challenges (insurmountable)	MT17	2	3.5	Time difficulties with rest	No (though improved)	N/A
	MT50	2		Safety issues (personal relationships) during rest	Yes	N/A
	MT15	3		Time difficulties with rest; no longer felt need for therapy	Yes	N/A
	MT37	7		Time difficulties with attending sessions; no longer felt need for therapy	Yes	N/A
Principles: acceptable (strong identification with principles); Process/ practice: acceptable (some challenges; tolerated/ worthwhile)	MT33	9	10.8	N/A	Yes	N/A
	MT63	10		N/A	Yes	N/A
	MT45	11		N/A	Yes	N/A
	MT55	11		N/A	Yes	N/A
	MT16	12		N/A	Yes	N/A
	MT43	12		N/A	Yes	N/A

[1]Treatment response defined as follow-up PHQ-9 score <10; [2]Therapist fidelity to the protocol assessed where issues with the acceptability of the principles/ understanding of treatment were indicated i.e. where an incorrect purpose was assigned to rest. N/A=not applicable.

Typology one. The typology that appears at the bottom left of Figure 17 represents the views of participants (MT19; MT28; MT51; MT61) who considered both the principles and practice of Morita Therapy unacceptable. These participants all expressed understandings of, expectations or hopes for treatment which were incompatible with Morita Therapy, such as seeking a solution for symptoms (with their accounts comprising participant qualitative theme one: the impact of incompatible expectations and understandings). They also expressed challenges of engaging with treatment which they considered insurmountable, such as the pressure of completing the activities associated with the treatment phases (see participant qualitative theme four: facilitating the process: (overcoming) challenges and barriers). Rarely were such challenges expressed as insurmountable *because* they were in the context of participants' demanding personal circumstances, such as a lack of time to complete the phases; rather, participants within this typology focused on the challenges of treatment regardless of their personal circumstances.

> Example vignette. MT61 approached treatment hoping for an opportunity to open-up and express themselves, and seeking answers to enable them to stop unpleasant thoughts and feelings. They struggled to identify with the principles of Morita Therapy, with neither the ebb and flow of emotions nor understanding emotions through reference to nature resonating for them. They also misunderstood the purpose of rest as an opportunity for the therapist to analyse their sleep, potentially to find out more about them on an unconscious level, and felt that it was unrealistic to schedule and report on their own sleep in this way. They withdrew from treatment after three sessions due to the discomfort of writing about themselves in the diary, in the context of disliking themselves.

Table 27 indicates that these participants who found both the principles and practice unacceptable attended, on average, five treatment sessions (range 3-7) of a maximum of twelve before withdrawing from treatment for treatment-related reasons. None of these participants demonstrated a response to treatment. For this typology, participants' incompatible expectations of treatment were associated with inaccurate understandings of treatment (in all cases, relating to the purpose of the rest phase) (see participant qualitative

theme one). Therefore, to explore whether these misunderstandings were a product of the therapists' particular explanation of therapy, as opposed to the UK Morita Therapy protocol itself, therapist fidelity to the therapy protocol was assessed for each relevant therapy session. It was found that in all cases therapists showed fidelity to the therapy protocol in explaining the rest phase (Table 27), and thus a lack of therapist fidelity does not account for these misunderstandings.

Typology two. In contrast to typology one, the typology that appears at the top right of Figure 17 represents the views of participants (MT16; MT33; MT43; MT45; MT55; MT63) who considered both the principles and practice of Morita Therapy acceptable. These participants all identified with and were receptive to the Morita Therapy principles, such as the underlying premise of accepting and allowing unpleasant thoughts and emotions and/or components of the approach such as the connection to nature (as per participant qualitative theme two: identifying with the principles of Morita Therapy: receptivity and relevance). In addition, whilst typically expressing some challenges of engaging in treatment such as the discomfort of rest (see participant qualitative theme four: facilitating the process: (overcoming) challenges and barriers), these participants considered them tolerable and worthwhile. These views appeared to be facilitated by these participants' accurate understandings of the elements of treatment as part of a progressive process for learning and re-focusing attention, as opposed to features which should be enjoyable or effective in reducing symptoms (as per participant qualitative theme three: understanding and approaching Morita Therapy as a process).

> Example vignette. MT63 was attracted to and identified strongly with the underlying premise of therapy in terms of re-orientating in nature and understanding unpleasant thoughts and emotions as part of the natural human experience. Whilst noting that sitting alone with their thoughts was a terrifying experience, they understood the purpose of rest and learned the futility of engaging in the vicious cycle, as per their normal coping strategies. Thus, they considered these challenges worthwhile in terms of the lessons they learned. They also described the diary and spending time in nature in terms of teaching them how all things naturally

pass. They highly appreciated therapy as a natural process of self-
discovery which the therapist gently guided them through, and noted the
value of an experiential approach which affected them on visceral,
emotional and intellectual levels. They experienced a strong impact of
therapy in terms of normalising difficulties, increasing action-taking,
decreasing self-criticism and symptoms. Compared with other
treatments, such as MBCT, they felt that Morita Therapy had
fundamentally changed their attitude towards and acceptance of
difficulties, as opposed to providing strategies for tackling symptoms
which potentially contribute to the vicious cycle.

Table 27 indicates that these participants who found both the principles and
practice acceptable attended, on average, 10.8 treatment sessions (range 9-
12). All of these participants completed treatment and demonstrated a
response to treatment.

Typology three. The typology that appears on the right of the x axis and middle
of the y axis of Figure 17 represents the views of participants (MT15; MT17;
MT37; MT50) who, whilst similarly identifying with the Morita Therapy principles
as per participant qualitative theme two ('identifying with the principles of Morita
Therapy: receptivity and relevance'), experienced more significant challenges
with the process and practice of therapy (see participant qualitative theme four:
facilitating the process: (overcoming) challenges and barriers). Typically, these
challenges related to the time commitment of therapy, as well as difficulties with
the discomfort and fear associated with rest, which these participants
considered insurmountable in the context of their personal circumstances such
as work and family commitments. Thus, unlike the views of participants within
typology one, these participants were keen to continue treatment (which
connected to their identification with the principles) and generally accurately
understood the components of treatment as part of a process for learning and
re-focusing attention (as per participant qualitative theme three: understanding
and approaching Morita Therapy as a process) but found it unfeasible to
engage with the treatment at this point in their lives.

Example vignette. MT50 found that all of the principles strongly
resonated with them: understanding human emotion as cyclic and

through reference to nature, both learning to be with unpleasant thoughts and emotions and learning to take small steps of action, and nurturing one's authentic self. Accordingly, they had hoped treatment would help them to be more at ease with their feelings and to take more action which was true to their values. They expressed an accurate understanding of the purpose of therapy as a process for learning. They engaged in one day of rest and, whilst noting the discomfort of the experience, also noted the valuable lesson they had learned in terms of realising unpleasant thoughts and emotions come and go. They would have liked to continue therapy but withdrew after two sessions as they felt unsafe resting at home in the context of a threatening neighbour. They expressed a significant impact of treatment in terms of knowing difficulties will pass, like the weather, and thus having more acceptance and less fear of their symptoms, consequently finding they pass more quickly. They noted that Morita Therapy is a philosophy for life whereas other treatments offer short-term fixes and risk highlighting and exacerbating symptoms.

These participants who found the principles acceptable and practice unacceptable withdrew because of the practical challenges of engaging with treatment in the context of their personal circumstances, alongside at times feeling that they no longer required therapy (Table 27). They attended, on average, 3.5 treatment sessions (range 2-7) and all but one (MT17) demonstrated a response to treatment, although MT17 did show an improvement in symptoms.

Typologies four and five. Within the sample of interviews analysed, the typologies in the middle of the x axis of Figure 17 were more anomalous, representing two participants (MT58; MT54) with mixed views on the acceptability of the principles: some identification with and/or positive views of the principles were expressed, whilst some incompatible expectations and hopes for treatment were also held, and thus the accounts of these participants fell within both participant qualitative themes one ('the impact of incompatible expectations and understandings') and two ('identifying with the principles of Morita Therapy: receptivity and relevance').

Firstly, MT58 (typology four) expressed identification with certain principles such as the vicious cycle and conceptualising fears and desires as two sides of the same coin. However, they also sought to overcome their difficulties through treatment, and tended to isolate each treatment component such as light activities and nature as potential tools for tackling or distracting from symptoms. They expressed challenges of engaging with treatment related to these inaccurate understandings of the purpose, such as struggling to engage in rest without being distracted. However, they considered the challenges tolerable and did not refer to difficulties in the context of demanding personal circumstances. They indicated some benefits of treatment, such as reduced self-criticism and engagement in the vicious cycle, but intended to seek counselling in order to work through some challenges of their past and continued to hope that they would overcome their difficulties in the future. MT58 completed treatment at nine sessions but did not demonstrate a response to treatment (Table 27).

Secondly, MT54 (typology five) expressed interest in the theory and ideas of Morita Therapy, and stated they were interested in therapy involving a process. However, they had been receiving private counselling which they could no longer afford; thus, ideally they would have continued this type of treatment. As such, they struggled with Fumon (therapists' inattention to symptoms), feeling that this shut them down and inhibited their ability to build rapport with the therapist. They also expressed significant challenges associated with the time commitment of rest and diary completion in the context of their childcare commitments. Whilst disappointed not to continue with treatment, they withdrew for these reasons after attending one session (Table 27). Although demonstrating a response to treatment, they attributed this to changed life circumstances rather than therapy.

Summary. Overall, the two continuums (acceptability of principles; acceptability of practice) utilised in the development of typologies of participants' views both appear to play a role in explaining treatment adherence as well as being associated with whether participants respond to treatment. With regards to treatment adherence, generally participants who experienced significant challenges in engaging with the process of therapy in the context of their

personal circumstances attended the fewest number of sessions, withdrawing for these reasons regardless of the extent to which they identified with the principles. Participants who did not identify with the principles and, largely in light of this, found the process of treatment unacceptable (regardless of their personal circumstances) generally attended more sessions, but did not complete treatment. Participants who identified with the principles and experienced challenges of the treatment in practice which they considered worthwhile attended the most sessions, and all completed treatment.

In terms of treatment response, participants' views on the principles and extent to which they identify with these appear to be a key factor, over and above the number of treatment sessions attended or challenges experienced with the process of therapy. Thus, those participants who strongly identified with the principles generally demonstrated a response to treatment, largely regardless of treatment adherence; those who did not find the principles acceptable or had mixed views on the acceptability of the principles did not respond to treatment, again largely regardless of treatment adherence.

7.3.2 Categories and themes display

This technique was driven by the quantitative data. Thus, categories of participants defined by their treatment adherence were identified, and similar and different views on the acceptability of Morita Therapy within and between these categories are presented (Table 28, overleaf). Categories of treatment adherence include those who completed treatment at the top of the table, those who withdrew from treatment having attended five or more sessions (the minimum treatment dose), and those who withdrew from treatment having attended fewer than five sessions at the bottom of the table. Participants' views are presented in terms of the five themes identified in the participant qualitative analysis; constituent themes from the qualitative analysis are referred to as relevant within each cell. To ease identification of the extent to which participants within each category of treatment adherence expressed views associated with each qualitative theme, references to the (number of) participants with views captured within that theme are included in bold text.

Table 28. Joint categories (attendance) and themes (acceptability) display

Category of treatment adherence	Qualitative themes				
	The impact of incompatible expectations and understandings	Identifying with the principles of Morita Therapy: receptivity and relevance	Approaching and understanding Morita Therapy as a process	Facilitating the process: (overcoming) challenges and barriers	The value and impact of Morita Therapy[2]
Completed (n=7) **MT16; MT33; MT43; MT45; MT55; MT58; MT63 (treatment response[1] from all but MT58)**	**Single entry (MT58)**: hoped to become "a whole new person" and sought tools to overcome difficulties; misunderstood rest as a time when they should turn off thoughts.	**All participants** indicated a readiness to accept difficulties; this was less apparent with MT58 although they identified strongly with the vicious cycle. The features of connecting to nature, action-focus and/or working with desires resonated for all.	**All participants except MT58** understood the elements of treatment as a means of learning, enabling action and/or refocusing attention. Most valued the gradual, gentle, individualised process; indicated open-mindedness and/or willingness to trust the process; and valued the therapy making them think. **MT33/ MT55/ MT63** valued the experiential focus.	**All participants except MT45** indicated challenges, particularly in terms of the time commitment and fear and discomfort around rest. All considered challenges worthwhile in the context of the learning they facilitated.	**All participants** described the value of accepting unpleasant thoughts and emotions, related sense of empowerment/ liberation, and positive impact on mood/ symptoms. Most indicated a transition from dwelling on symptoms to activity and external focus. **All except MT58** described the therapy as preferable to other approaches e.g. CBT/ counselling.
Withdrew ≥5 (n=4) **MT19; MT28; MT37; MT51 (treatment response[1] from MT37 only)**	**Theme dominated by entries from MT19/ MT28/ MT51**: all sought a cure or "resolution" of difficulties, and self-expression or analysis. All misconstrued the purpose of rest in these terms and generally believed they should be "switching off" rather than experiencing thoughts during rest.	**Single entry (MT37)**: readiness to accept. Others indicated some attraction to the use of the natural world, but rarely as a way of understanding emotions.	**Single entry (MT37)**: sense of open-mindedness/ allowing purpose to unfold through engagement with therapy; appreciation of the therapy "making you think".	**All participants** indicated significant challenges, particularly in terms of the time commitment and pressure of activities. MT51 also described the challenges of rest in the absence of techniques to manage thoughts/ emotions. Challenges were not considered worthwhile.	**Single entry (MT37)**: preferred approach to other therapies; indicated an acceptance of difficulties, decreased avoidance and worry, and positive impact on mood.

Withdrew <5 (n=5) **MT15; MT17; MT50; MT54; MT61 (treatment response[1] from MT15; MT50; MT54)**	**Significant entry (MT61)**: sought a solution to difficulties and in-depth analysis; understood rest as an analysis of sleep. **MT54** sought a more counselling-type approach.	**Significant entries (MT15/ MT17/ MT50)**: readiness to accept difficulties alongside identification with elements of therapy such as the connection to nature, action-focus and/or working with desires/values. **MT54** had some interest in ideas/ process.	**Significant entries** (**MT15/ MT50); minor entry (MT17)**: understood rest and natural world metaphors as means of learning about the nature of emotions. MT50 also valued the gradual, nurturing, experiential process.	**All participants** indicated significant challenges, typically in the context of their personal lives i.e. an inability to dedicate the required time to therapy or unavailability of a safe space for rest. MT61 was unwilling to write about self in diary. Challenges were barriers to treatment (i.e. participants' reasons for discontinuing therapy).	**Significant entries (MT15/ MT17/ MT50)**: described the value of accepting emotions, a related sense of empowerment/ liberation, alongside decreased rumination and/or increased focus on action-taking. MT15/ MT50 also described a positive impact on mood/ symptoms.

[1]Treatment response defined as follow-up PHQ-9 score <10. [2]CBT=Cognitive Behavioural Therapy.

The results indicate that participants who completed treatment very rarely expressed incompatible expectations or hopes for treatment (the single participant who did so was the single participant in this category who did not respond to treatment (MT58)), instead all indicating identification with the principles, particularly in terms of a readiness to accept difficulties as well as a connection to other significant features of therapy such as the natural world. All participants (except MT58) indicated an understanding of therapy as a process and means of learning, enabling action and/or refocusing attention, and typically appreciated the gradual and individualised nature of this process as well as indicating an open-mindedness towards treatment and an enjoyment of therapy 'making them think'. Several participants appreciated the experiential nature of treatment. Most participants experienced challenges with the process and practical elements of treatment, but considered these tolerable and/or worthwhile in terms of the changes they induced. All of these participants described the value and impact of Morita Therapy in terms of acceptance, empowerment and effect on symptoms; most indicated a transition 'from dwelling to doing' and described Morita Therapy as preferable to other approaches such as CBT.

The views of participants who withdrew having attended five or more sessions may be seen in contrast to the views of those who completed treatment. These participants' views dominated the theme 'the impact of incompatible expectations and understandings': most of these participants sought or expected a different approach, which shaped their (largely negative) views of Morita Therapy. Accordingly, whilst occasionally expressing a positive view of a feature of Morita Therapy such as the connection to the natural world, these participants rarely expressed a strong identification with or receptivity to the principles of therapy. The one exception to this (MT37) is shown by the single participant in this category who responded to treatment despite withdrawing; similarly, MT37 is the only participant within this category who indicated an open-mindedness towards treatment and an appreciation of the treatment 'making them think', and the only participant who described the value and impact of Morita Therapy. All of these participants expressed significant treatment-related challenges which were not considered worthwhile, typically

relating to the time commitment and feeling a sense of pressure and failure around the completion of activities associated with the treatment phases.

For participants who withdrew having attended fewer than five sessions, views were more mixed. One participant in this category (MT61) expressed significant incompatible expectations and understandings of treatment, whilst one other (MT54) expressed minor incompatible expectations and understandings. The other three participants (MT15; MT17; MT50) expressed a strong identification with the principles of therapy, particularly in terms of a readiness to accept difficulties alongside a connection to other elements of treatment; these participants also indicated an understanding of therapy as a process and means of learning, with MT50 in addition appreciating the gradual and experiential nature of this process. These same participants also described the value and impact of Morita Therapy, particularly in terms of acceptance and empowerment. All of these participants indicated significant challenges with the practicalities of engaging with treatment, such as time difficulties, typically in the context of their personal circumstances and commitments, which in all cases accounted for their withdrawal from treatment.

7.3.3 Case-oriented merged analysis display

Data on participants' views on acceptability and the number of treatment sessions they attended are integrated in a case-oriented display, organised according to the quantitative data (Table 29, p.304). This table positions participants on a scale of treatment adherence (from one to twelve sessions attended) alongside summaries of their qualitative data and whether they demonstrated a response to treatment (defined as a PHQ-9 <10 at follow-up). The qualitative data presented reflect that contained within the typologies (section 7.3.1) and categories (section 7.3.2) tables discussed above, and has been further classified into views which are 'positive', 'mostly positive', 'mostly negative' and 'negative'.

For participants who attended five or fewer sessions (n=7) views were mixed, as reflected in the discussions above. Three of these participants (MT17; MT50; MT15), who attended either two or three sessions, expressed mostly positive views of therapy, indicating a strong identification with the principles

and a good understanding of the purpose of therapy as a process for learning. They all expressed a reluctant withdrawal from treatment due to significant difficulties engaging with therapy in the context of personal circumstances and commitments, such as time constraints and unsafe home environments in which to undertake rest. Two of these participants demonstrated a response to treatment, whereas MT17 described some impact of treatment and did show improved quantitative scores.

The remaining four participants (MT54; MT61; MT19; MT51) who attended between one and five sessions all expressed negative or mostly negative views of therapy which are comparable in nature and dominated by incompatible expectations of treatment and a lack of identification with the principles, although MT54 showed more interest in the process and theory of the approach. Thus, all of these participants sought to overcome their symptoms and/or a more counselling-based mode of discussing their difficulties. Similarly, they showed misunderstandings of the purpose of treatment, misinterpreting rest in particular as a means of relaxing, switching off unpleasant thoughts or receiving a form of sleep-analysis. These participants all expressed treatment-related challenges such as the pressure of completing the phases, difficulties with Fumon (therapists' inattention to symptoms) or discomfort completing the diary, which led to their withdrawal from therapy. MT54 also struggled with the time commitment of therapy in the context of their personal circumstances. Only one (MT54) of these participants responded to treatment; however, they did not attribute this improvement to therapy.

One of two participants who attended seven sessions (MT37) expressed mostly positive views of therapy, comparable to the views expressed by those who attended more sessions (see below). This participant identified with the principles and expressed some understanding of the purpose of therapy as a process. They reluctantly withdrew from treatment due to the time commitment, demonstrated a response to treatment and considered the approach preferable to CBT. The other participant (MT28) who attended seven sessions expressed mostly negative views of therapy. They held incompatible expectations and understandings of treatment, seeking a means to remove unpleasant thoughts and understanding rest as a time to switch off such thoughts. They withdrew

due to a sense of pressure to engage with the practical elements of treatment, and did not demonstrate a response to treatment.

Participants who attended nine or more sessions all expressed either positive or mostly positive views of Morita Therapy which are similar in nature, indicating strong identification with the principles and the acceptability of both the principles and practice of therapy. Despite some challenges of engaging with treatment, particularly in terms of the time commitment and discomfort of rest, all but one (MT58) of these participants understood the purpose of the treatment elements as a means of learning and/or refocusing attention, and appreciated and understood Morita Therapy as a progressive process. Thus, all of these participants considered the practical challenges worthwhile. All but one (MT58) of these participants demonstrated a response to treatment; MT58 was the only participant who held some incompatible expectations of treatment in terms of seeking tools, and thus tended to isolate the treatment elements as a means of overcoming or distracting from symptoms. These participants generally expressed a preference for Morita Therapy in comparison to other treatments, such as CBT.

Table 29 overleaf

Table 29. Case-oriented merged analysis display

ID	Views of Morita Therapy[1]	No. sessions attended												Treatment response[2]
		1	2	3	4	5	6	7	8	9	10	11	12	
MT54	Mostly negative. Interest in ideas/ process ("it was interesting that there was a process… I was interested in the ideas behind it"). However, incompatible hopes for treatment ("I'd also been seeing a [counsellor]… he was really great, but I couldn't afford that anymore") and some inaccurate understandings of rest ("they're telling me that I'm really anxious and I need a holiday"). Withdrew due to difficulties with Fumon ("I felt that I was being shut down") and the time commitment of rest ("getting a deep rest with childcare responsibilities was just impossible"). No impact.	●												Yes (attributed to life changes, not therapy)
MT17	Mostly positive. Attracted to principles of acceptance, understanding through nature and action-focus ("it sounded like a nice way of looking at things… living with it and getting on with things"). Identified with emotions as cyclic ("I know from my experience that my depression comes and goes"). Understood therapy as a process for "building yourself up". Withdrew due to difficulties attending sessions around work ("even though I wanted to do it…I just don't have the time"). Some impact in terms of changed perspective and increased acceptance ("[It] made me look at things slightly differently… I'm less likely to give myself a hard time for having a bad day"). Preferred to CBT as "less judgemental and conflicting".		●											No (though improved)
MT50	Mostly positive: "It is a very valuable form of therapy". Principles of acceptance, nature and authentic self resonated ("it really resounded…your thoughts and feelings as part of a circle that comes and goes"). Attracted to experiential process with "small steps" of action-taking. Good understanding of purpose of rest ("you realise your anxiety gets to a certain point…but it doesn't get any further and it's not the end of the world, it just goes!"). Withdrew "because of my neighbour who was being threatening and harassing, I didn't feel safe to sit in that environment" during rest. Impact in terms of increased acceptance/ decreased symptoms ("you might feel bad, just be with it and it will pass. So that's been really helpful… I've improved quite markedly"). Preferred to therapy which focuses on symptoms as "that's just gonna highlight them and make them worse"; whereas Morita Therapy is "a philosophy to take you through life".		●											Yes

MT15	Mostly positive. Identified with acceptance/vicious cycle ("learning to accept that those are my difficulties and yes they'll come and go… that is exactly how I've experienced it"). Difficulties with lack of support from partner and discomfort of rest, though understood the purpose ("all those thoughts and feelings that kept coming and going, that was a really big moment…in realising how much I do battle with my own feelings"). Withdrew because "trying to get the rest period into my life was quite difficult" and "I realised how far I've actually come" so no longer felt need for therapy. Some impact through reduced fear/ engagement in the vicious cycle, and increased activity ("it definitely helped me already in terms of just that mind-set of 'don't try and push everything away all the time' and you can still do things even if things are feeling difficult for you").	●														Yes
MT61	Negative. Significant incompatible expectations ("I was hoping that it would give me a chance to express myself"; "people are looking for answers…to stop these thoughts or feelings"). Significant inaccurate understandings of rest ("they said that we were gonna analyse your sleeping thing and arrange for you to sleep… [perhaps] trying to find out more about the person on an unconscious level"). Principles did not resonate ("I can see the similarities, but does nature have a brain?"). Withdrew due to diary ("I don't even like myself, so I'm not really that keen on writing about myself"). No impact.	●														No
MT19	Mostly negative. Some identification with connection to nature as a "nature boy", but significant incompatible expectations ("I was hoping to find a way to resolve the problems that I had… I can't think of any other goals other than to make one feel better"). Significant inaccurate understandings: rest misunderstood as a time to "switch off" thoughts and force emotion ("I couldn't do the quiet time… I couldn't do the sensing emotion on an on-demand basis"). Difficulties with Fumon in the diary as it "made it feel like [diary entry] wasn't important". Withdrew because "I couldn't jump through the hoops that were being set… I felt pressurised". No impact.			●												No
MT51	Mostly negative. Attracted to concept of "grounding yourself within nature" but "as a way of trying to calm and relax yourself"; nature metaphors did not resonate. Significant incompatible expectations (was looking to be "trained in different techniques that would be vastly different... almost ground breaking"). Related significant inaccurate understandings (e.g. with regards to rest: "if it was that easy we'd all just go and lie in a room with the lights off and we'd just conquer it that way"). Difficulties with Fumon as "you need someone to fill that void". Withdrew because of a lack of techniques imparted			●												No

	by the therapist and "I needed answers, I wanted to understand how I could correct it". No impact.															
MT28	Mostly negative. Significant incompatible hopes to stop unpleasant thoughts ("it's like a computer, like it would only replace the chip, why can't you do it in your head? It would just make you feel better") and have someone to talk to ("I need someone to understand what's in my head"), thus difficulties with Fumon. Significant inaccurate understandings: rest misunderstood as a time to "relax" by "letting go" of unpleasant thoughts, but "the thoughts just didn't go". Withdrew because "it was pressurising me into doing it… every day you had to remember certain things". Very minor impact on attitude towards others: "If someone upsets me I just let it go…it does help you – it makes you, like, it learns you to let it go".					●								No
MT37	Mostly positive: "I enjoyed it". Identification with nature metaphors and underlying premise ("I knew I couldn't change things, I mean, nobody can change what's going on with the weather"). Some appreciation of therapy as a process for making you think and refocusing attention ("it's things to take your mind off of what's going on in your head"). Withdrew due to time difficulties in attending sessions ("it was becoming just impossible…I can't divide myself in four different ways"). Significant impact in terms of changed outlook, increased activity/ acceptance, and decreased symptoms ("I don't tend to worry about things… If it happens it happens"). No longer felt need for therapy. Preferred to CBT as "less superficial".					●								Yes
MT58	Mostly positive: "It has definitely helped". Some incompatible expectations ("I was just hoping that it would either, ideally, stop the depression altogether… [or] give me the tools to carry on"). Vicious cycle strongly resonated ("[that's] the really big one for me - yeah, because I know I do that"). Difficulties with rest in terms of time commitment and discomfort ("I found the resting really, really difficult"). Misunderstood rest as a time to "switch off" thoughts and limited understanding of therapy as process, instead seeking "tools" ("[I use] nature more as a tool now"; "it's brilliant for distraction from flying… the colouring really works"). Some impact in terms of increased acceptance/ activity, and decreased symptoms ("the vicious cycle, most of the time, doesn't last as long as it would have"). However, still seeking counselling to "deal with baggage".								●					No
MT33	Mostly positive: "It definitely worked". Few expectations; natural world metaphors resonated ("'cos of my hobby, so - enjoying the outdoors… using the weather as a way of describing Morita Therapy for me really worked"). Appreciated therapy as a process (with "no								●					Yes

	timeframes") for refocusing attention, learning to "be with" and "making you think". Good understanding of therapy purpose ("it's learning to – you can't fight the weather, you can't fight nature, so why fight the emotions"). Minor time difficulties with rest, but thought worthwhile ("the first phase was the hardest…but I think that's the one you've got to break through"). Significant impact in terms of increased acceptance/ activity, and improved mood ("I'm not depressed anymore"). Noted distinction to CBT ("you just go with the emotions, instead of fighting with it…with CBT you tend to try and control what you're doing whereas this was totally the opposite").															
MT63	Mostly positive: "It's phenomenal". Attraction to acceptance/ natural world element ("it was a way of getting back to nature and realising that it's a part of you and part of the human experience"). Appreciated as an experiential "natural progression" which "hit me on a bit of a visceral level". Good understanding of purpose ("I've been allowed to discover it, guided gently and then…it's almost like nature teaches you"). Difficulties with rest but considered worthwhile for learning ("it was terrifying… [but] I can see why it was useful… Having to sit with uncomfortable emotions has made me realise that they pass"). Significant impact in terms of increased acceptance/ activity (e.g. "it's normalised life for me"), and preferred to MBCT/counselling which were "short-term fixes" and "can become scab picking" ("I have done other work in the past but this seems to have struck a chord of change within, not just a 'Right, this is a strategy'").												●		Yes
MT45	Positive: "If I was designing a therapy, I would probably come up with something similar". Significant prior insight into vicious cycle ("It just reinforced what I already hooked onto as a major problem for me"); acceptance, action-taking and Fumon strongly resonated ("It makes sense to me, the way my mind works, that I'm struggling against something I don't need to struggle against"). Appreciated therapy as a process and good understanding of purpose ("we did one of those walk around the trees and just look, you know, in other words it's pointless, this urge to fix this"; "it's about moving your focus away from what's going on inside to carrying on what's going on in the real world"). Significant impact in terms of increased acceptance/ external focus, and decreased symptoms ("I'm interested in what I'm doing and I'm taking full part in it…I don't even think about anxiety"). Preferred to CBT which "was feeding my need to fix myself".												●		Yes
MT55	Mostly positive: "I don't know how it works, but it does". Few expectations; preferred not to know much. Vicious cycle/ connection to nature resonated ("I'm very much into the natural world, anyway").												●		Yes

			●	Yes
	Difficulties with rest but considered worthwhile as understood the purpose ("that first stage of it, I hated… [But] I learned that you can get through it and come out the other side"). Appreciated therapy as a "brilliant, gradual process, it sort of – the first stage broke me down, and then it was, rebuild me". Significant impact in terms of changed perspective, increased activity and improved mood ("it's just made me look at things in a completely different way… It taught me how to not be ashamed of it"). Preferred to CBT which entails unrealistic expectations ("with the NHS, I felt that I was going to be cured…with this, it teaches you how to live with it, which is much more sensible").			
MT16	Mostly positive. Acceptance, the ebb and flow, and connection to nature resonated ("what I found really useful is to be able to relate how you're feeling to patterns or what happens in nature"). Appreciated therapy as a process which "gave you structure" to "gradually build up your activity levels" and make you think. Good understanding of the purpose to "let your feelings actually become part of you rather than battling your feelings". Minor difficulties with time commitment of sessions and diary as "cumbersome" and "a blank canvas". Significant impact in terms of improved "confidence"/ mood, and job change ("[I've] come off my medication and actually feel a lot more positive and actually feel a lot better"). Preferred to CBT which "focuses on trying to change your way of thinking whilst Morita Therapy actually focuses on accepting your feelings and putting it into perspective and I found that a lot easier to understand".		●	Yes
MT43	Mostly positive: "I wish people had access to it". Was "interested in the theory and attracted to the…natural world element". Appreciated therapy as a helpfully "bite-sized" process for learning, accepting difficulties and enabling action ("through the process you appreciate that it's part of the natural world to actually feel the way you do, and stop fighting"). Good understanding of purpose ("it's trying not to control your feelings and having that rest and just seeing what happens, and that they come and go"). Minor difficulties in terms of "explaining therapy to others", diary as "onerous" and rest ("there were periods when it was quite upsetting"). Significant impact in terms of increased acceptance/ action-taking ("getting out of the cycle of depression, it's because you're doing things rather than just dwelling on them"). Preferred to CBT as "a much more holistic way, and I felt that CBT was a bit of a toolkit".		●	Yes

[1]CBT=Cognitive Behavioural Therapy; MBCT=Mindfulness-based Cognitive Behavioural Therapy; [2]Treatment response defined as post-treatment

PHQ-9 score <10.

7.3.4 Summary of the key mixed methods findings

Three forms of joint display were utilised to explore the relationship between participants' treatment adherence and views of Morita Therapy: a typologies and statistics display; a categories and themes display; a case-oriented merged analysis display. Data on treatment response (whether participants scored PHQ-9 <10 at follow-up) was also presented to aid further interpretation. All mixed methods techniques supported similar findings.

Firstly, participants with mixed views on acceptability, typically expressing a strong identification with the Morita Therapy principles alongside significant challenges of engaging with treatment in the context of personal circumstances, attended the least sessions, generally withdrawing at session two or three due to the challenges noted. However, possibly in light of the principles resonating for such participants, they typically demonstrated a response to treatment. Secondly, participants with predominately negative views, which generally related to them holding incompatible expectations or hopes for treatment, considered both the principles and practice of therapy unacceptable, attending between one and seven sessions before withdrawing for treatment-related reasons. None of these participants demonstrated a response to treatment.

Thirdly, participants with predominantly positive views of therapy, indicating the acceptability of both the principles and practice (typically a strong identification with the principles alongside some tolerable/worthwhile challenges of engaging with treatment) attended the most sessions. All completed, and demonstrated a response to, treatment. Only one participant who completed treatment did not strongly identify with the principles, and they did not demonstrate a response. Thus, whilst the acceptability and challenges of engaging with the process of therapy (and whether or not such challenges are in the context of demanding personal circumstances) appears strongly related to treatment adherence, the extent to which participants identify with and are receptive to the Morita Therapy principles (or, in contrast, hold incompatible expectations and/or understandings of treatment) appears to be a factor in treatment adherence which is also strongly associated with whether participants demonstrate a response to treatment, largely regardless of the number of treatment sessions attended.

CHAPTER SEVEN. PART FOUR.

Summary of feasibility study results

The feasibility study was designed to address seven research questions. Study results with respect to each question are summarised below.

(1) What proportion of participants approached to take part in the trial will agree to do so?

Recruitment methods performed reasonably well. The number of participants recruited (n=68) was very close to target and 5.1% of patients invited via GP record search were randomised. Based on the 95% confidence intervals, it is estimated that in a future trial the randomisation rate from GP searches alone would be between 3.4% and 6.6%.

(2) What proportion of participants who agree to take part in the trial will remain in the trial at four month follow-up?

The performance of retention procedures was strong with a 94% (64/68) retention rate overall; 97% (33/34) in the Morita Therapy arm and 91% (31/34) in TAU. Based on the 95% confidence intervals, it is estimated that in a future trial the retention rate would be between 88.3% and 99.7%.

(3) What proportion of participants who agree to take part in Morita Therapy will adhere to a pre-defined per-protocol dose of Morita Therapy?

Adherence to the minimum dose of Morita Therapy (≥5 sessions) was 70.6% (n=24). The mean number of sessions attended for all participants was 7.7 (range 1-14; SD 4.0); the mean number attended for those who did and did not adhere to the minimum dose was 9.8 (range 5-14; SD 2.5) and 2.6 (range 1-4; SD 1.0) respectively.

(4) What is the variance in participant outcomes following Morita Therapy and TAU, and how do they correlate with participants' baseline scores?

At four month follow-up, the pooled SD was 6.4; 6.5 and 5.7 for the intervention and control groups respectively. Based on the 95% confidence intervals, it is

estimated that in a future trial the pooled SD on the PHQ-9 score at follow-up would be between 5.5 and 7.8. The magnitude of correlation (using Spearman's Rho) between participants' baseline and follow-up PHQ-9 scores was 0.42 for all participants (95% confidence intervals 0.19-0.61); 0.37 and 0.71 in the intervention and control groups respectively. These figures can be used to inform sample size calculations for a future trial.

(5) What are the estimated between-group differences (and 95% confidence intervals) in participant outcomes following Morita Therapy and TAU?

This study was not powered to enable inferential statements on between-group differences to be made. In this study, PHQ-9 scores reduced from baseline to follow-up by an average of 5.5 points more in the Morita Therapy group compared to TAU. Based on the 95% confidence intervals, it can be said with 95% certainty that the true mean reduction in participants' PHQ-9 scores from baseline to four month follow-up will be greater following Morita Therapy, compared to TAU, by somewhere between 2.9 and 8.1 points.

(6) How acceptable is Morita Therapy to participants and therapists?

The qualitative results indicated that Morita Therapy was generally acceptable to therapists and many participants, with both emphasising the value and impact of the approach. The analysis of participant interviews highlighted: (1) typologies of participants' views, suggesting potential moderators of acceptability, in which the importance and impact of participants' identification with the Morita Therapy principles alongside the central role of their expectations and understandings of treatment was stressed; (2) a distinction between the principles and practice of Morita Therapy, indicating the challenges and implications of translating the principles into a process which is feasible for patients to engage with.

The analysis of therapist interviews supported these findings: therapists (1) highlighted patients' ability to grasp the Morita Therapy principles as the defining factor when considering potential moderators of acceptability and outcome; (2) illustrated the tension between their strongly positive views of the

principles and the difficulties they experienced with operationalising these in practice, particularly in the context of much variability across patients in their ability to apply, understand and benefit from the components of Morita Therapy. Both participants and therapists made some suggestions for tackling the practical challenges moving forwards, with therapists raising the possibility of some patients embedding the principles, and thus benefitting from treatment, *without* engaging in the process. Finally, therapists suggested ways in which the delivery of Morita Therapy could be supported and facilitated, indicating the appropriateness and usefulness of the UK Morita Therapy outpatient protocol.

(7) How do participants' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?

The mixed methods results indicated that: (1) the acceptability and challenges of engaging with the practice and process of Morita Therapy, and whether or not such challenges were experienced by participants in the context of demanding personal circumstances, appears strongly related to treatment adherence: participants who experience more practical challenges generally attend fewer treatment sessions; (2) the extent to which participants identify with and are receptive to the Morita Therapy principles (or, in contrast, hold incompatible expectations and/or understandings of treatment) appears to be a factor in treatment adherence which is also strongly associated with whether participants demonstrate a response to treatment, largely regardless of the number of treatment sessions they attend: participants who describe strongly identifying with the principles typically respond to treatment in anywhere between two and twelve sessions.

Thus, both the qualitative and mixed methods data suggest key factors in acceptability, treatment adherence and outcomes appear to be patients' identification with the Morita Therapy principles, and the challenges of translating these principles into practice. The implications of these findings are discussed further in Chapter Eight, overleaf.

CHAPTER EIGHT. DISCUSSION AND CONCLUSIONS.

This chapter summarises the key findings of this thesis, in which the optimisation and investigation of the feasibility and acceptability of Morita Therapy as a treatment for depression and anxiety in the UK has been reported. The substantive, methodological and theoretical contributions of this thesis are presented; strengths, limitations and alternative methodological approaches are discussed. Recommendations for future research and a discussion of clinical implications are provided. This chapter concludes with a discussion of the personal learning obtained through the completion of this thesis (for which the first-person voice is adopted) before summarising key conclusions.

8.1 Summary of results

This thesis has presented a programme of work informed by the development and feasibility phases of the MRC framework (Craig et al., 2008). Firstly, a scoping and systematic review was undertaken (Chapter Four) to describe the extent, range and nature of Morita Therapy research activity reported in English. 66 papers met the inclusion criteria: 44 primary studies, conducted with 3268 patients in total; four reviews and seven papers reporting data from other studies, including 313 studies between them; and eleven clinical impressions. The identified gaps in research and methodological weaknesses of studies have been discussed in depth in Chapter Four. To summarise, previous studies are highly prone to bias, none have been conducted in the UK, and no RCTs: a) targeted depression in Western patients; b) investigated outpatient Morita Therapy for depression; or c) targeted depression with no history of schizophrenia.

The review also highlighted heterogeneity and lack of reference to published treatment manuals in the implementation of Morita Therapy. As such, further work was required to develop a UK Morita Therapy outpatient protocol. This was achieved within an intervention optimisation study (Chapter Five) in which, through an iterative process combining literature synthesis with qualitative research, a therapy protocol and tailored therapist training programme were developed which were fit for purpose in proceeding to a UK trial of Morita Therapy. In line with key qualitative findings, this protocol was structured

according to the four-phased model of Morita Therapy, included detailed guidance and warning points, and supported therapists in managing patients' expectations of treatment.

Subsequently, a mixed methods feasibility study was conducted to prepare for a fully-powered randomised controlled trial (RCT) of Morita Therapy plus treatment as usual (TAU) versus TAU alone (Chapters Six and Seven). This study demonstrated that it is possible to recruit participants in a trial of Morita Therapy (n=68) and to retain them at four month follow-up (94% retention rate). Furthermore, adherence to the minimum dose of Morita Therapy (70.6%) and remission in depressive symptoms following Morita Therapy (66.7%) were on a par with other psychological therapies. Whilst qualitative and mixed methods analyses indicated potential moderators of acceptability and treatment adherence, Morita Therapy was broadly acceptable to therapists and participants. Thus, overall, the data indicates that patients in the UK can accept the premise of Morita Therapy and find the approach beneficial, and that it is feasible to conduct a large-scale UK-based trial of Morita Therapy.

8.2 Contribution to knowledge

8.2.1 Substantive contribution

This thesis has made several original contributions in the field of Morita Therapy. Firstly, the review is the first to describe all Morita Therapy literature containing clinical or empirical data written in English, regardless of study design or publication status. Secondly, the first UK Morita Therapy protocol, optimised for this population, has been developed. Finally, the feasibility study has contributed important information towards the development and evaluation of Morita Therapy in the UK, supporting inferences about the suitability of the UK Morita Therapy outpatient protocol and providing robust and relevant evidence on the feasibility of a fully-powered RCT. This study represents not only the first study of Morita Therapy in the UK but the first RCT of Morita Therapy for depression within English-speaking countries (assuming any previous such studies would have been published in English). Indeed, given the volume of Japanese and Chinese studies accessed through reviews and

secondary reports, the review findings suggest that this study may represent the first RCT of outpatient Morita Therapy for depression in the world.

8.2.2 Methodological contribution

As mixed methods studies typically involve the integration of data only at the point of discussion, despite such methods running the risk of producing invalid conclusions which cannot be easily interrogated (Borglin, 2015), the feasibility study is unusual for including mixed methods *analysis.* As such, it provides an example of how a research question can be designed to specifically address the integration of data, how such integration can be undertaken with rigour, and how such integration generates additional learning, thus adding value through producing "a whole…that is greater than the sum of the individual qualitative and quantitative parts" (Fetters and Freshwater, 2015) (p.116). Thus, a strong methodological contribution has been made to the field of health services research, in light of the current dearth of explicit examples of both the use and usefulness of integrative mixed methods analysis (Fetters and Freshwater, 2015; Guetterman, Fetters and Creswell, 2015).

Furthermore, the potential value of integrative mixed methods analysis in the field of individualising depression treatment has been demonstrated, with the current mixed methods findings suggesting potential moderators of adherence and outcomes in Morita Therapy (section 8.4.2). This mixed methods approach allows the researcher to move beyond quantitative only techniques of regression currently applied in this field, by relating information on both outcomes and treatment adherence directly to participants' views and experiences themselves. Without this process, it would not have been possible to understand the relationship between participants' personal circumstances, expectations, understandings, identification with treatment and treatment adherence/ outcomes in the current study. Thus, such methods have been shown to have promise in understanding moderators and predictors of treatment response highly relevant to this wider research field.

8.2.3 Theoretical contribution

In the context of the contrast between traditional Eastern and Western worldviews and their relationship with approaches towards suffering (see Chapter Two), the findings of this thesis are relevant to a broader discussion concerning the way in which mental health, and perhaps health care more widely, is approached in the West. Through the application of an Eastern philosophical framework with Western patients, Morita Therapy can be considered to challenge culturally constituted expectations and understandings of (ab)normality, (un)naturalness, mental health and healing (Busfield, 2001a; Ishiyama, 1994). Thus, the holistic and phenomenological emphasis of Morita Therapy on rest, experience, acceptance and the naturalness of unpleasant thoughts and emotions challenges the dualistic and 'disease-based' emphasis of Western approaches on activation, intellect, control, and the medicalisation of unpleasant thoughts and emotions (Bakx, 1991; Blocker and Starling, 2010; Chang and Rhee, 2005; Craib, 2002; Fujita, 1986; Green et al., 2002; Knoblauch, 1985; Murase and Johnson, 1974; Suzuki, 2010; Tseng, 2005; Williams, 2001).

Whilst authors have suggested that such features of Morita Therapy require dilution for a Western population (Ishiyama, 1994; Ogawa, 2013; Ohara, 1990; Reynolds, 1995a; Tanaka-Matsumi, 2011; Tseng, 1999), according to the current qualitative findings not only did many participants find this approach acceptable, but it was precisely this distinctly Eastern perspective and method which were of value to them. Many participants described a highly valued shift from perceiving unpleasant experiences as phenomena in need of cure and control, as per Western worldviews, towards perceiving them as natural phenomena which do not require resolution, as per Eastern worldviews (Murase and Johnson, 1974; Reynolds, 1982; Tseng, 2005). For many participants this shift was described as fundamental, sustainable and pervasive: they experienced a change in their outlook towards not only their symptoms, but themselves, others and the world more broadly, suggesting that adopting such a perspective may have potential to induce enduring and far-reaching benefits beyond the 'management' of symptoms.

If participants find value in reappraising their understandings of mental health based on Western worldviews, it might follow that it is this worldview which should be reappraised more broadly: in the context of the continued and/or worsening prevalence, chronicity and recurrence of depression and anxiety (see Chapter One), perhaps there is scope for a more fundamental shift in how mental health is approached in the West. If better health is correlated with the experience of positive mood/affect only for those within cultures in which positive affect is considered highly desirable (i.e. Western cultures) (Yoo, Miyamoto, Rigotti et al., 2017), perhaps it is unwise to place such a value on positive affect; perhaps a wider cultural acceptance of negative affect as something *not* undesirable or in need of resolution, and a societal de-prioritisation of 'the pursuit of happiness' (Flora, 2009) in favour of 'going with the flow' of all emotional experiences, might contribute to the prevention of poor mental health in individuals in the West. The findings of this thesis thus potentially support the arguments of those who express discontent with the Western approach towards medicine and psychiatry more generally (Robertson and Walter, 2013), not only challenging the pathologisation of arguably natural experiences, but indicating the potential value of holistic and phenomenological approaches towards healing in general.

8.3 Strengths, limitations and alternative methodological approaches

8.3.1 Scoping and Systematic Review

A strength of the review is that a broad and inclusive approach to identifying all literature relevant to the objective, and a rigorous and transparent method for identifying and mapping the literature, were adopted. A wide variety of electronic databases were searched, supplemented with extensive additional efforts to identify papers from grey literature and other sources. As such, it was possible to identify gaps in the evidence base alongside summarising a large body of research.

However, it is possible that some relevant data was not included in the review as not all full texts could be accessed (n=19) (although a screening of abstracts confirmed none of these studies were RCTs nor targeted depression) or they were contained in volumes of the Japanese Journal of Morita Therapy which

were not available despite requests made to the Journal Editor. In addition, only English papers were included in the review. Whilst alternative options were considered in order to enable access to a wider range of literature, such as translating foreign-language papers or collaborating with contacts in Japan and elsewhere, the resources and/or time required for such alternatives were beyond the scope of this PhD. Although this led to the exclusion of many Morita Therapy papers, it is assumed that this does not impact upon the conclusion that no Morita Therapy studies have been undertaken within the UK. Furthermore, whilst not ensuring all relevant papers were included, a reasonable overall picture of the Japanese and Chinese literature was presented through the inclusion of secondary reports.

Given the extensive variation in how Morita Therapy is implemented and, at times, integrated into other approaches (see Chapter Two), there was some difficulty and compromise inherent in determining the definition of eligible interventions. Whilst a broad and inclusive approach was taken by including all papers in which authors defined the intervention as Morita Therapy or Morita-based Therapy, those studies in which Morita Therapy was combined with other approaches (e.g. Constructive Living (Reynolds, 1995b)) were excluded given both the need for a clear definition and the resource limitations of a PhD. However, it is possible that this reliance on the author's definition of their intervention drew a rather arbitrary line in the sand. Indeed, one included study implemented Morita Therapy as per the Reynolds (1995b) Constructive Living approach, as the author had defined the approach as Morita Therapy. It is possible some excluded studies may have incorporated more elements of traditional Morita Therapy than those included studies which were explicitly labelled as such and yet implemented interventions very loosely based on Morita Therapy techniques or principles.

In organising the literature thematically according to study design, this aspect of the included studies was prioritised at the expense of, for example, intervention type or patient condition. Although this information was reported, presentation of the findings along such lines may have highlighted different aspects of the literature. However, study design was considered the most meaningful unit of analysis in order to present an overview of all research and findings, and a

further strength of the review is the consistent approach to reporting taken by applying a template to each study design, allowing both the overall heterogeneity of studies and the key methodological weaknesses to be presented.

Finally, the ability to further synthesise the RCT results and thus form more reliable conclusions as to the effectiveness of Morita Therapy was constrained by the heterogeneity of RCTs in terms of intervention type, control condition, patient population and outcome measures, alongside the finding that these studies were at high risk of bias. Such factors deemed further synthesis unwarranted and unfeasible (Higgins and Green, 2011). Indeed, given none of these studies were conducted within the UK nor with a depressed population, further synthesis would have been unable to provide evidence as to the effectiveness of Morita Therapy for depression and/or in the UK.

8.3.2 Intervention Optimisation Study

A strength of the optimisation study was that it showcased best practice in intervention development by transparently illustrating a systematic and iterative approach which prioritised the perspectives of those who will deliver and receive the intervention. Through integrating the views of potential patients and therapists with Morita Therapy literature, it was possible to sensitively optimise Morita Therapy across cultures whilst carefully ensuring adherence to the fundamental features of the approach.

As discussed in Chapter Two, the extent to which Morita Therapy can be optimised and still termed 'Morita Therapy' is open to debate. Whilst some argue that the approach requires considerable modification for a Western population (Ishiyama, 1994; Ogawa, 2013; Ohara, 1990; Reynolds, 1989; Reynolds, 1995a; Tanaka-Matsumi, 2011; Tseng, 1999), others contend that such adaptation entails the displacement of essential, defining elements (LeVine, 1998; Ogawa, 2013; Ohara, 1990). Such authors urge those adapting Morita Therapy to ensure the principles, goals and progressive experiential process, centred on the four phases, remain intact (Kondo, 1998; LeVine, 1998; Ogawa, 2013). A strength of the optimisation study was that it addressed such concerns by grounding the UK protocol in the Morita Therapy literature and

maintaining a purist stance towards Morita Therapy, as far as possible in an outpatient context. Thus, the distinctive principles, goals, philosophical basis and experiential approach, including the four phases, were retained and indeed enhanced through the optimisation of the intervention.

Furthermore, the extent to which the philosophical, cultural and experiential basis of the approach needs to be diluted for a Western population has been thus far largely an assumption (LeVine, 1998). Through this process, such assumptions have begun to be set aside: this represents the first study to directly seek and accommodate the views of UK-based patients and therapists themselves in an empirically driven and patient-centred approach towards developing Morita Therapy.

In line with the person-based approach, this development process was thus grounded in "a sensitive awareness of the perspective and lives of the people who will use [it]" (Yardley et al., 2015a) (p.1), utilising cognitive interviewing techniques, written materials and vignettes of therapy in order to elicit views on every intervention element, and repeating interviews to check acceptability and accessibility. Without undertaking this study, it would not have been possible to understand the expectations, understandings and needs of stakeholders, and the ways in which these may shape their delivery of and engagement with the intervention. This process may be considered analogous to that deemed good practice by the James Lind Alliance, in which patients and clinicians are brought together within the research process to ensure consideration of their priorities (Partridge and Scadding, 2004), and is aligned with branches of health services research which deem working with patients essential in order to bridge the translational gap between clinical practice and patients' acceptance and uptake of interventions (e.g. 'The Third Gap', University of Exeter Medical School).

This process thus enabled progression to the feasibility study with a therapy protocol which, whilst adhering to the essence of Morita Therapy, has enhanced acceptability and feasibility for a UK population, thus maximising the likelihood of a successful outcome in the feasibility study (Yardley et al., 2015a). Whilst this was key in the specific cross-cultural adaptation of Morita Therapy as a novel intervention within the UK, a generalisable approach to optimising

interventions which is likely to be relevant and interesting to others in both the development and evaluation of complex interventions has been presented.

In terms of limitations, HVRS (PhD candidate) conducted all interviews and was involved in the protocol development process. Thus, particularly in the repeat interviews, although questions were posed to deliberately elicit negative views, participants may have been reluctant to express criticism of the draft protocol. However, participants did freely indicate ways in which the protocol was currently confusing, insufficient or inaccessible. In addition, in the absence of vignettes demonstrating a variety of treatment models, it was not possible to elicit participants' views on all available implementation options so as to select a favoured approach, and instead their feedback on the modal model (Minami, 2013) was used to guide the positioning of the UK version along the available spectrum of approaches. Furthermore, although the interview sample was diverse in age, gender and therapy experience and may well represent those most likely to be interested in receiving Morita Therapy, certain sectors of the UK population such as ethnic minority groups were clearly underrepresented.

8.3.3 Feasibility Study

Study design

A strength of the feasibility study is the suitability of the methods for such a study. The study purpose and research questions accorded with The National Institute for Health Research Evaluation Trials and Studies (2015) definition of a feasibility study, endorsed by Arain et al. (2010). The pilot trial and qualitative interviews were designed to allow key clinical, methodological and procedural uncertainties associated with a large-scale trial to be tested using appropriate quantitative, qualitative and mixed methods, and criteria for success were specified a priori (Thabane et al., 2010). Findings have been described in line with guidance for reporting the results of feasibility studies (Eldridge et al., 2016; Thabane et al., 2010).

To embrace the complexity of developing and evaluating interventions and provide a comprehensive understanding of the intervention in question, it is contended that no one method will suffice (Borglin, 2015). Thus, a further

strength of this study is the explicit commitment to a mixed methods approach (Hill et al., 2014; O'Cathain, Murphy and Nicholl, 2008). The embedded mixed methods design reflected key decisions which were reached on the levels of interaction, priority, timing and procedures in the mixing of the quantitative and qualitative components (Creswell and Plano Clark, 2007). Guidance on maximising the impact of qualitative research in feasibility studies (O'Cathain et al., 2015) was carefully considered, and the study has been described in line with guidelines for Good Reporting of a Mixed Methods Study (O'Cathain et al., 2008).

Quantitative components

Precision and accuracy of data

Margins of error associated with the recruitment rate, retention rate and variability in the primary outcome for a future trial (PHQ-9) in the pilot trial were less than the margins of error for the same parameters considered acceptable for the purpose of this study (Sugg et al., 2016). Thus, key parameters have been calculated with an acceptable level of precision to help determine the feasibility of and sample size required for a fully-powered trial.

Outcome data were collected at four months post-baseline. Given only one participant (following a high number of therapy session cancellations) provided follow-up data prior to ending treatment, conducting follow-ups at four months appears appropriate moving forwards. Thus, pilot data on retention, variability in outcomes and correlations between scores is likely to represent an accurate estimation of such figures in a fully-powered trial.

Potential bias

Due to the resource limitations of a PhD, the study researchers were not blinded to group allocation. Whilst baseline and follow-up data were self-reported, and all research measures were applied equally to both groups, it is possible that this introduced detection bias into the study, and it will impact on the judgement of this study against quality criteria relevant, for example, in conducting a systematic review (Evans et al., 2011; Higgins and Altman, 2008). To avoid such implications in the future, it is of course crucial that good practice

is followed in any large-scale trial by ensuring that researchers collecting follow-up data are blinded to group allocation.

Furthermore, the option of completing follow-up questionnaires via post or email rather than during face-to-face interviews was used by more participants in TAU (12/31) than the Morita Therapy group (7/33), and led to some variability around the data collection time point: follow-up data was completed between 3.8-6.1 and 4.0-5.6 months after baseline for Morita Therapy and TAU participants respectively. Thus, some differences between the groups in terms of how and when outcomes were measured were present, which may also have introduced detection bias (Higgins and Altman, 2008). Whilst provision of the option to complete follow-up questionnaires via post or email may have facilitated a higher retention rate, in any future trial efforts should be made to engage all participants in the same methods of data collection at the same time points.

Finally, whilst retention rates were comparable across the two arms, the rate of withdrawal was higher in TAU (3/34) than Morita Therapy (1/34). To avoid the potential bias which arises from differential attrition, with withdrawal potentially more likely within a control group in which enthusiasm for participation may be lower, additional strategies such as maintaining more frequent contact with TAU participants should be employed in any large-scale trial (Higgins and Altman, 2008; Hunt and White, 1998; Moran and Whitman, 2014; Robinson et al., 2007). Furthermore, Patient and Public Involvement (PPI) could be utilised in this area to better understand how to maintain TAU participants' engagement in the trial.

Qualitative components

Sample

Qualitative data was analysed from 16 participants. The overall sample size, and the sample size of each sub-group (e.g. those who completed treatment but did not respond), was constrained by the number of participants in the pilot trial who fulfilled the sampling criteria. Nonetheless, it was possible to explore the views of participants who, together, fulfilled all the manifestations of treatment adherence and response that were intended to be sampled. Only additional participants who completed and responded to treatment were not sampled, and,

as analysis continued to the point at which no new themes were emerging and both the breadth and depth of data were explored, data saturation and sampling adequacy were considered achieved (Bowen, 2008; Guest et al., 2006). On this basis, it is suggested that the analysis of 16 purposively sampled participant interviews had potential to generate a good understanding of the acceptability of Morita Therapy, and key insights were gained in relation to issues with acceptability in particular.

Two therapists were interviewed, as dictated by the number of therapists delivering treatment in the trial. Thus, whilst their views were explored in-depth and provided several insights into how the delivery of Morita Therapy might be facilitated, involving a larger number of therapists may have generated new or different results and it is difficult to determine the extent to which the views of these therapists are transferable to the broader context of therapists who might deliver Morita Therapy in the future.

Data collection and analysis

Qualitative data were analysed using Framework analysis, thus ensuring a systematic, transparent and rigorous process (Barbour, 2001; Gale, Heath, Cameron et al., 2013; Parkinson, Eatough, Holmes et al., 2016; Ritchie et al., 2013). This approach was flexible enough to abductively explore views on predefined topics, such as components of Morita Therapy considered challenging within the optimisation study, whilst remaining open to discovering unexpected views (Gale et al., 2013; Pope and Mays, 2006b; Ritchie et al., 2013). The use of matrices also allowed the depth of each participant's views to be explored in the context of their whole account, as well in the context of the data set as a whole (Ritchie et al., 2013). This within and across case analysis, alongside the interpretation of data, enabled the development of a detailed account of acceptability within a model of how Morita Therapy was experienced by different participants, incorporating both exploratory and explanatory insights.

However, there were potential limitations in the use of this approach, alongside the use of post-treatment interviews. The analysis may not have readily reflected how participants' views changed over time; for some factors deemed

important in the acceptability of Morita Therapy, such as understanding the purpose of the treatment components, temporal challenges were encountered: it was difficult to ascertain the extent to which such understandings had been held early in treatment and thus shaped views on acceptability, versus the extent to which such understandings had resulted from participants' engagement in treatment. Whilst some participants claimed, for example, very early identification with the Morita Therapy principles, this is difficult to confirm with only retrospective accounts. However, there does remain a distinction between the qualitative accounts of those who found Morita Therapy more and less acceptable which cannot be accounted for by receipt of the intervention alone: those who found Morita Therapy less acceptable did typically attend five treatment sessions, thus receiving the approach, suggesting the views of those who found Morita Therapy acceptable were not shaped purely by receipt of the intervention. Nonetheless, in the future it may be informative to capture the views and values of participants before as well as after treatment, to assess the nature of this relationship in more depth.

Furthermore, as this study was embedded within a PhD, only one researcher conducted data analysis. In any future trial, one would of course wish to follow good practice in involving at least two independent researchers in data analysis, enabling the consideration of differing perspectives and enhancing the credibility and reliability of data interpretation (Barbour, 2001; Ritchie et al., 2013). However, the rigour of the approach was enhanced through an engagement in reflexivity and PhD supervision, with JF (second supervisor) second coding a proportion of raw data and reviewing coding frameworks until consensus on emerging themes and the further interpretation of data could be achieved, thus providing opportunities for others' perspectives to be appreciated (Barbour, 2001; Houghton, Casey, Shaw et al., 2013; Ritchie et al., 2013).

Mixed methods components

A strength of the mixed methods analysis is that it combined different data types in ways that were systematic, transparent and rigorous, thus producing conclusions which can be readily traced and understood. Furthermore, by manipulating and integrating data through multiple techniques (representing participants' experiences using typologies; grouping individuals into categories;

ordering data within a case-oriented display), it became possible to identify new relationships between acceptability, attendance and outcomes; insights which were strengthened through the use of different techniques (both quantitatively and qualitatively driven; operating at the levels of both categorised data and individual participant data) which all supported similar findings. Thus, the mixed methods analysis generated insights which would not have been possible from a separate examination of quantitative and qualitative results alone, and are unlikely to have been possible from a comparison of quantitative and qualitative results within only this discussion (as per typical mixed methods studies (Borglin, 2015)), thus facilitating a more complex picture of the acceptability of Morita Therapy (Creswell and Plano Clark, 2007).

A potential limitation of the mixed methods analysis relates to the number and range of included cases. Whilst little guidance is currently available on the appropriate sample size for mixed methods analysis, and an equivalent concept to qualitative data saturation (Morse, 1995) is yet to be developed, it is likely that considerations of the study purpose and heterogeneity of data are relevant. In the current study, the sample reflected those included in the qualitative analysis, and thus was subject to the same constraints regarding the number of participants in the pilot trial who fulfilled the qualitative sampling criteria. However, the qualitative interviews were sampled for analysis with the subsequent mixed methods analysis in mind: as much variation in treatment adherence was sampled for as possible, with only additional participants who completed and responded to treatment not sampled. Nonetheless, the results were based on a limited amount of data and may not reflect the relationship between acceptability and adherence in full, or be transferable to other contexts such as different therapies for depression or Morita Therapy with a different patient population.

Therapist characteristics

The trial therapists were highly experienced in both the delivery of complex psychological interventions and adopting different modes of treatment. To help ensure the transferability to a large-scale trial of a) the views of these therapists about Morita Therapy and b) the views of patients generated in response to Morita Therapy delivered by these therapists, it will be important to ensure that

therapists with comparable levels of skill and experience are employed. Both the therapy protocol and therapist training programme were developed in response to the views of a larger number of therapists, suggesting their appropriateness for therapists more broadly. Following the same training procedures, using the same (or a similar) protocolised form of Morita Therapy, and continuing the provision of expert supervision should also help to constrain opportunities for the delivery of Morita Therapy in a large-scale trial to vary greatly from the feasibility study.

The therapists in the current study also had an interest in Morita Therapy and identified strongly with the approach, alongside holding a commitment to both the research team and the testing of new treatments within their roles in a research clinic. Such therapeutic allegiance (Luborsky, Singer and Luborsky, 1975) may effect treatment delivery and thus influence outcomes, adherence and patients' views (Falkenström, Markowitz, Jonker et al., 2013; McLeod, 2009). As it cannot be assumed that therapists with such allegiance and commitment may be relied upon moving forwards, this raises an issue for any future testing and implementation of Morita Therapy. In this vein, one objective of a large-scale trial may be to train therapists without this degree of therapeutic allegiance, to inform an assessment of the potential for the wider implementation of Morita Therapy in the UK.

8.3.4 Overall thesis

A strength of this overall thesis was embedding the work within the MRC framework (Craig et al., 2008). Throughout the studies an iterative and flexible approach towards assessing and optimising intervention feasibility and acceptability has been engaged in and, through responding to the feasibility study findings on acceptability and its relationship to adherence, this iterative and patient-centred process can be continued in the future development and evaluation of Morita Therapy. Furthermore, in the development and testing of Morita Therapy, the principles of care laid out in the forthcoming NICE guidelines for depression (Section 1.4, In Consultation) have been observed: a thorough treatment protocol was developed and followed; frameworks for assessing therapist competence and adherence which included monitoring of

audio-recordings were included; therapists received regular high-quality supervision; and participant treatment adherence was evaluated.

Patient and public involvement (PPI)

It is acknowledged that a greater utilisation of PPI may have strengthened this thesis and, through the completion of this thesis, an awareness of PPI as good practice has been obtained. Within the optimisation study, the involvement of potential patients with experience of depression as participants was prioritised over PPI as this was considered to provide the greatest potential value in optimising an approach which was unfamiliar to patients and distinct from current treatments. Whilst PPI informed the development of participant materials, given that prior to this thesis no one had received Morita Therapy within the UK, the opportunities for PPI engagement in the feasibility study were somewhat limited and perhaps not given due attention. Since undertaking the trial one participant who received Morita Therapy has been involved in the dissemination of results, and if the trial were to be conducted again the incorporation of a steering group comprising PPI representatives with experience as service users, if not as Morita Therapy recipients, is recommended.

8.3.5 Alternative methodological approaches

Despite the aforementioned strengths of the methods employed in this thesis, alternative approaches may have provided other insights and benefits. For example, an alternative design for the feasibility study is a non-randomised comparative trial: if all participants had received Morita Therapy, qualitative data could have been collected from an increased number and potentially wider range of participants, potentially generating new or different results. However, this approach would not have allowed the procedural uncertainties associated with conducting a large-scale RCT to be addressed.

From an epistemological perspective, within this thesis an evidence-based research paradigm informed by a Western scientific epistemology and coherent with a biomedical theory of disease (McKenzie, 2012; Tonelli and Callahan, 2001) has been applied to a therapy based on an Eastern epistemology and

theory of disease. Thus, the methods are aligned with a realist and reductionist approach which prioritises (and deems possible) objective, empirical, statistical evidence; whereas the therapy has a holistic focus on the embodied experiences of the individual and a vitalistic perspective (the notion that living systems possess a nonphysical and non-measurable life force, i.e. 'desire for life' in Morita Therapy) (Barry, 2006; Coulter and Willis, 2004; Jagtenberg et al., 2006; McKenzie, 2012; Shea, 2006; Tonelli and Callahan, 2001). This arguably produces an "internal inconsistency" (Tonelli and Callahan, 2001) (p.1218) between the therapy and research method: some authors claim that the philosophy and methods of complementary and alternative medicine, consistent with those of Morita Therapy, are incompatible with those of evidence-based medicine (EBM) (Jagtenberg et al., 2006; Keshet, 2009; Quah, 2003; Tonelli and Callahan, 2001). Indeed, some authors argue that the application of EBM to such approaches necessitates the medicalisation of the approach, thereby robbing it of its essential, alternative philosophy (Barry, 2006; Churchill, 1999).

Thus, it is arguable that alternative methods are more consistent with the philosophy underpinning Morita Therapy (Verhoef, Lewith, Ritenbaugh et al., 2005): for example, embodied and inter-subjective data would be more accepted within anthropological approaches (Barry, 2006). Case studies may also prioritise each participants' unique phenomenological experience and allow for a richer exploration of the ways in which different aspects of the patient, treatment and context relate to each other (McLeod, 2008; Verhoef et al., 2005; Williams and Garner, 2002). This method is commensurate with the Japanese research tradition: case studies are typically preferred by Japanese Morita therapists for allowing an appreciation of each unique case (Ishiyama, 1988a). Thus, such methods would have also aligned this study more closely with the Japanese culture of research, potentially facilitating stronger relationships between Japanese and UK Morita Therapy researchers. However, given the limitations discussed in Chapter Three, case studies would not have been deemed credible within the dominant Western research paradigm, and even some Japanese Morita therapists advocate the investigation of Morita Therapy using more experimental methods; indeed, the lack of such research has likely contributed towards the lack of international recognition of the approach to date (Ishiyama, 1988a; Ishiyama, 1994).

Additionally, the theory and methods of Morita Therapy centre on phenomena which are not easily subjected to measurement, presenting another difficulty from an EBM perspective (Coulter and Willis, 2004; McKenzie, 2012; Tonelli and Callahan, 2001; von Peter, 2013): vitalism ('desire for life'), experience and embodiment are all deemed essential in the healing process. It might be argued that qualitative interviews, as per the feasibility study, are ill-equipped to explore such features. Such methods rely on verbalisation and thus intellectualisation which, particularly from an Eastern perspective, are inaccurately discriminative and unable to convey the truth of experiences: putting experiences into words changes them through the processes of introspection and self-reflection (processes Morita Therapy deliberately attempts to reduce) (Blocker and Starling, 2010; Chang and Rhee, 2005; Kapleau, 2000; Watts, 1961). Whilst such methods may capture participants' cognitive understandings of Morita Therapy, they are less able to capture their internalisation of the principles, intuitive sense (if any) of accepting oneself as part of nature, or changes arising from the embodied self (von Peter, 2013).

Even expressing such notions using the English language, as opposed to Japanese, constrains them: there may exist some dissonance between concepts relevant to Morita Therapy and the culturally constituted narratives available within the UK. For example, the English definition of the term 'nature' lends itself to literal expressions of *being in* nature, perhaps as a means to improve mood (as at times expressed by participants), with the opportunity for articulating a sense of *being of* nature limited by a lack of equivalent term for the Japanese *kācho fugetsu* ("oneness with nature" (Ogawa, 2007) (p.46)) (Davidson, 2001; Watts, 2012); similarly, an equivalent concept for *kappatsu* ('spontaneity'; 'responsiveness to the environment'; "going with the flow" (Ogawa, 2007) (p.67)) does not exist in English, and is thus an inevitably challenging concept for UK participants to express (and, perhaps, understand).

Alternative qualitative methods may have facilitated a better understanding of at least some of these components. For example, an analysis of participants' diary accounts using discourse analysis (Brown and Yule, 1983) might allow for a more direct exploration of participants' experiences and the ways in which they relate to themselves, others and nature, as well as capturing changes over

time. Indeed, Japanese Morita therapists have used diaries to help understand patients' perception of daily events and subjective processes of change (Ishiyama, 1988a). Whilst observation and the analysis of verbal and visual data (for example, therapy sessions) through methods such as ethnographic content analysis (Altheide, 1987) may also be similarly informative, they are also subject to the constraints of language discussed.

In addition, the choice of feasibility study outcome measures was informed by the way in which effectiveness is constructed within the Western biomedical model (Barry, 2006): in order to be of relevance in the UK, it is necessary to show that Morita Therapy reduces symptoms. Whilst Morita therapists do seek to relieve suffering, and consider symptoms to reduce as a by-product of therapy, Morita Therapy is not intended to be curative in that, within the philosophy underpinning it, symptoms are not medicalised. Indeed, this seeking of a cure, or resistance to suffering, is the very mechanism of psychopathology in Morita Therapy (Fujita, 1986; Morita et al., 1998; Ogawa, 2013).

Finally, whilst EBM prefers one form of medical knowledge, provided by experimental research (Tonelli and Callahan, 2001), given the results of this feasibility study it appears that it has been possible for a (potentially) effective treatment to be developed in Japan through rationalism, clinical observation and case studies: such methods clearly can produce valid and meaningful knowledge (Tonelli and Callahan, 2001). However, as noted, to establish Morita Therapy in an evidence-based culture, it is necessary to follow the methods deemed legitimate within that culture: to address bias, generalisability and proof of efficacy, despite the aforementioned tension with the philosophy underpinning the treatment (Tonelli and Callahan, 2001).

Furthermore, the feasibility study methods have not overlooked the importance of outcomes aside from reducing symptoms, nor of participants' subjective perspectives by reducing all data to quantitative averages: outcomes included attitudes and quality of life; qualitative and mixed methods were utilised to understand individuals' subjective meanings and views, and how these relate to treatment engagement and outcomes, including illuminating the role of participants' expectations (Verhoef, Casebeer and Hilsden, 2002; Verhoef et al., 2005; Williams and Garner, 2002). Thus, efforts have been made, whilst

working within the EBM model, to embrace the value of different forms of knowledge and means of knowledge generation.

8.4 Future research directions

8.4.1 A fully-powered evaluation of Morita Therapy

The feasibility study specified three 'criteria for success' to be met in order to deem a large-scale trial feasible, and to determine whether protocol modification and/or close monitoring during such a trial would be required (Thabane et al., 2010). Each criterion will now be considered in turn.

Criterion (1): recruitment and retention

"A sufficient number of participants to populate a fully-powered trial are likely to be recruited and retained, i.e. we recruit at the rate anticipated in the pilot trial (12% of those invited) and experience an attrition rate no higher than 20% of those randomised".

The attrition rate was 6%, thus fulfilling this standard. It was possible to recruit close to target (68/72) with a randomisation rate from GP invite of 5.1% and 33/68 of participants recruited through other sources such as flyers and email circulations to former participants. It was also necessary to extend the recruitment period, albeit by only one month and in order to accommodate a lull in recruitment over the Christmas period, which could be accounted for in any future trial planning. One additional Practice was also recruited to undertake record searches, and three more record searches were undertaken than originally anticipated (i.e. 27 rather than 24). Whilst the rate of randomisation from GP invite alone was lower than anticipated on the basis of other depression trials (Richards et al., 2016; Richards et al., 2013), 5.1% is slightly higher than that found in alternative trials in the field (e.g. 2.2% (Kuyken et al., 2015); 4.4% (Wiles et al., 2013)).

The impact of this recruitment data on the feasibility of a large-scale trial is tied to the sample size required. To recruit 266 participants (see below), it is anticipated that 5216 patients would need to be invited via GP record search; thus, based on the pilot data, 51 average sized Practices would need to

participate. As per the current study, additional participants may also be identified through advertising and approaching former trial participants. The procedures may also be amended to improve the recruitment rate. For example, telephone reminders to non-responding patients invited via record search may be incorporated, as a particularly successful method for increasing recruitment (Harris, Carey, Victor et al., 2008; Nystuen and Hagen, 2004; Treweek et al., 2010), although data on the feasibility of such a method was not collected as part of the current study. In addition, further PPI could be utilised in this area to better understand how to recruit participants.

Related to the recruitment rate, the rate of GP exclusions (28%) was comparable to that found in other depression trials (averaging 31%) (Kuyken et al., 2015; Richards et al., 2013; Wiles et al., 2013). In a large-scale trial, incorporation of methods to record reasons other than the study exclusion criteria which GPs have for excluding patients (accounting for 29% of exclusions in the current study) might facilitate an assessment of external validity (Jenkinson, Winder, Sugg et al., 2014). To the same end, potential participants who chose not to opt-in to the study may also be asked to provide the study team with sufficient information to enable the characterisation of non-responders and thus an assessment of the generalisability of findings (Moran and Whitman, 2014).

Criterion (2): treatment adherence

"The levels of engagement with and adherence to Morita Therapy are likely to be on par with other NIHR mental health trials i.e. at least 65% of participants allocated to Morita Therapy attend at least 40% of treatment sessions".

No participants declined to start Morita Therapy and 70.6% of Morita Therapy patients attended ≥five sessions, corresponding to 40% of the maximum available twelve sessions. This is comparable to adherence to psychological therapies in similar trials (e.g. Richards et al., 2016) and fulfils this criterion.

Criterion (3): acceptability

"It is likely that a Morita Therapy outpatient protocol can be produced which is acceptable to patients and therapists, and deliverable by therapists, as defined by responses to qualitative interviewing".

Whilst highlighting the importance of participants' identification with the Morita Therapy principles in light of their expectations and understandings of treatment, and ability to commit to the practical elements of the approach, the qualitative data indicated that Morita Therapy was broadly acceptable to therapists and acceptable to many participants. In the context of the treatment adherence data and the impact of Morita Therapy indicated by many participants, it is suggested that the views of a minority of participants who found Morita Therapy less acceptable should not prevent the conduct of a large-scale trial using the UK Morita Therapy outpatient protocol, and that this criterion has been met.

However, therapist data and some participant data did highlight several minor ways in which the therapy protocol and practice of Morita Therapy might still be improved in order to enhance acceptability and facilitate therapists' delivery of treatment (Table 30, overleaf), which may be incorporated for a large-scale trial. The potential for more major modifications to the therapy protocol, in response to the typologies of acceptability, adherence and outcomes identified through the mixed methods analysis, is discussed in section 8.4.2.

Table 30. Possible modifications to the UK Morita Therapy outpatient protocol in response to qualitative data

Qualitative data	Suggested action/ modification to protocol
Participants • Diaries described as cumbersome • Unclear/ vague instructions for diary completion • Difficulties following and recalling content of therapy sessions	• Reduce size of diary, with two pages to be completed per day • Provide therapists with additional guidance for explaining the diary to patients • Provide session summary handouts; ensure regular patient input is sought during sessions
Therapists • Preference for more flexible number of therapy sessions to ensure objectives of treatment phases can be met • Challenges of not being provided with a patient 'problem statement' at the start of treatment • Difficulties critically engaging patients with diary comments • Difficulties identifying indicators of therapeutic progress • Difficulties distinguishing between phases two, three and four • Seeking additional guidance for managing patients' cognitive discrepancies between the 'ideal' and 'real', and for working with 'unrealistic' desires • Suggested summary sheet describing Morita Therapy overall; addition of diary examples and further clinical examples of manifestations of the vicious cycle and options for conveying fears and desires as two sides of the same coin	• Consider extending the maximum number of sessions from twelve to fourteen (though note implications for follow-up time point in a future trial) • Consider whether provision of more detail on how patients perceive their difficulties is consistent with the non-symptom focus of Morita Therapy • Consider means to engage patients e.g. example questions to ask them • Include more clinical illustrations/ examples; incorporate section for recording the duration of rest in the diary; consider tools for assessing patients' internalisation of principles • Clarify purpose of each phase and constituent activities • Consider whether more direct discussion and verbal challenging of these components is consistent with the experiential nature of Morita Therapy; clarify if not • Include as suggested

Sample size for a large-scale trial

Pilot trial data were also collected on the variability in outcomes and correlation between baseline and follow-up scores. Alongside data on the minimum clinically important difference (MCID) on the primary outcome measure in a future trial (PHQ-9), this data can be used to inform an estimate of the sample size required for a fully-powered evaluation designed to assess whether Morita Therapy plus TAU is superior to TAU alone.

The published PHQ-9 MCID is 2.59 to 5.00 (Löwe et al., 2004). Estimating a between-group difference corresponding to the lowest MCID (2.59) and using a 90% power level allows for the most conservative estimate of the required sample size: taking a higher MCID value and/or lower power level (e.g. 80%) would reduce the number of participants required. Thus, to provide 90% power to detect a between-group difference of 2.59 based on a two-sided 5% significance level, using the PHQ-9 standard deviation (6.4) and taking account of the correlation between baseline and follow-up PHQ-9 scores (0.42) found in the pilot trial, 133 participants per group would be required. Whilst the pilot data suggests that the retention rate will be between 88.3% and 99.7%, this calculation allows for 20% attrition.

Applying the pilot recruitment rate from GP invite alone (5.1%), it is subsequently estimated that 5216 potential participants would need to be invited to participate in order to recruit to target using GP record searches as the only recruitment method (Figure 18, overleaf). As these calculations assume recruitment via GP record searches alone, Figure 18 includes a level of attrition between opt-in and randomisation that is higher than that experienced in the pilot trial (as higher proportions of eligibility were found for those opting into the study via sources other than GP invite).

Figure 18. Estimated recruitment and retention in a fully-powered superiority trial of Morita Therapy plus TAU versus TAU alone to achieve a target sample size of n=266 via GP record search only
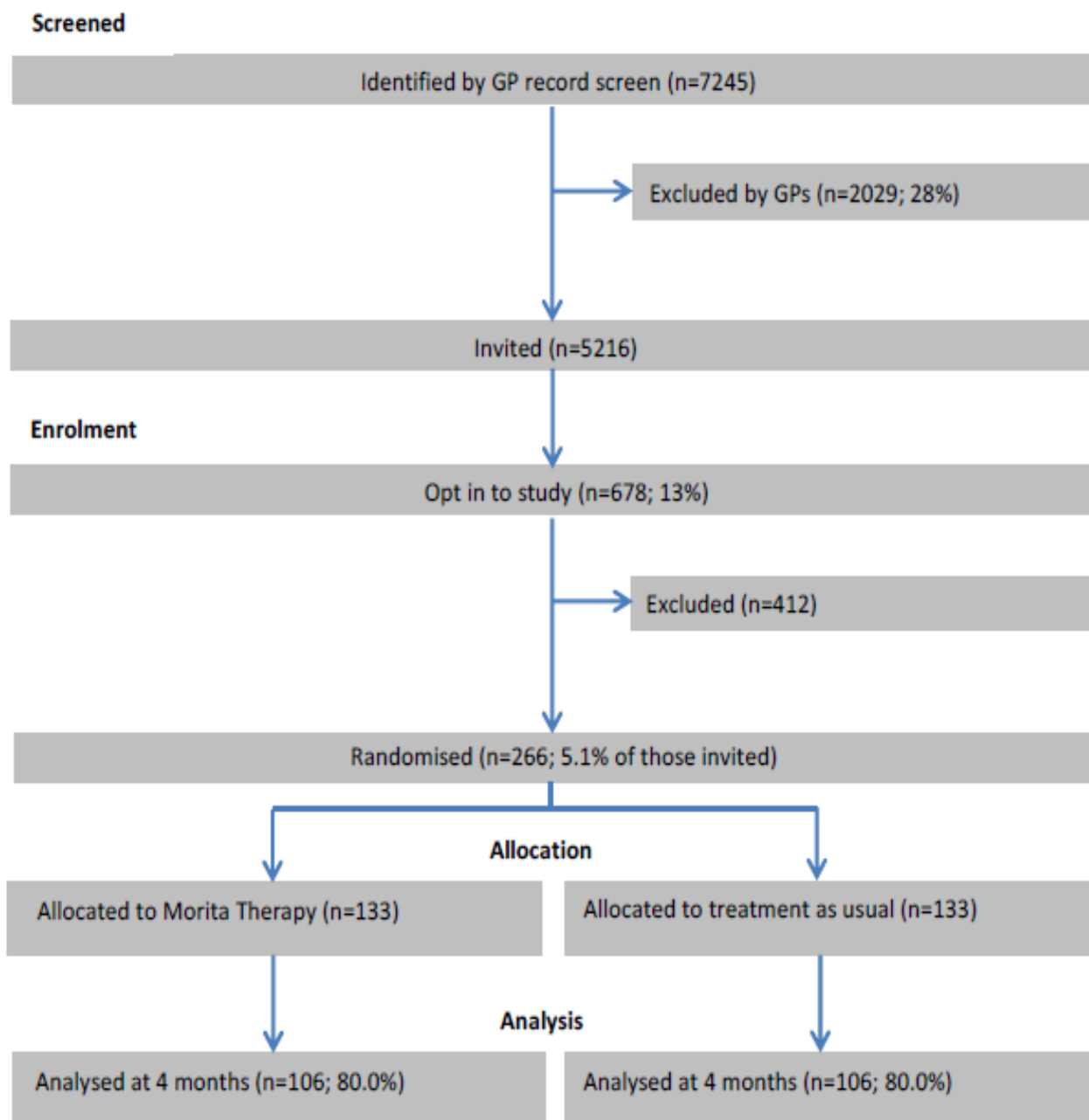
The potential value of Morita Therapy

In addition to data pertaining to the feasibility and acceptability of Morita Therapy, the findings of the feasibility study also provide information on the potential value of Morita Therapy as a treatment for depression and anxiety. Whilst the study was insufficiently powered to enable inferential statements to be made, the observed differences between groups on the PHQ-9 (the primary

outcome in a large-scale trial) showed that depressive symptoms reduced from baseline to follow-up by an average of 5.5 points more in the Morita Therapy group compared to TAU alone (95% confidence intervals from 2.9 to 8.1). This (and, indeed, the lower margin of error) exceeds the PHQ-9 MCID and, although requiring caution in interpretation in light of the small sample size and related risk of overestimating the treatment effect (Conn, Algase, Rawl et al., 2010; Nagendran, Pereira, Kiew et al., 2016; Thabane et al., 2010), does provide evidence of the *possible* effect of Morita Therapy plus TAU compared to TAU alone (Robb, 2013).

Similarly, 66.7% of Morita Therapy participants achieved remission in their depressive symptoms at follow-up: a figure similar to or exceeding remission rates for current NICE recommended treatments for depression (around one half to two thirds of patients – see Chapter One). Furthermore, the qualitative accounts of many participants highlight the distinctiveness and value of Morita Therapy in comparison to other available treatments (participant qualitative theme five, constituent theme (a): a preferable alternative), supporting the argument set forward at the beginning of this thesis that Morita Therapy has the potential to provide patients with a meaningfully distinct treatment alternative, thus facilitating true patient choice as enshrined in the forthcoming NICE guidelines for depression (In Consultation). All such factors support the potential value of Morita Therapy and of continuing research in this area.

8.4.2 Investigating potential moderators in Morita Therapy

Whilst the quantitative findings suggest that, on a population level, Morita Therapy may be equivalent in effectiveness to other psychological therapies, the qualitative and mixed methods findings provide early indications of who might benefit most from Morita Therapy on an individual level. Thus, potential moderators of acceptability, adherence to treatment and whether or not patients demonstrate a clinical response to treatment were suggested.

The qualitative findings first highlighted (1) the importance of patients coming to treatment with expectations and understandings which allow them to identify with the principles of Morita Therapy and understand the purpose of the treatment; (2) the challenges of translating the principles into a process which is

feasible for patients to engage with. The mixed methods analysis advanced these findings through techniques which suggested that (1) the extent to which participants identify with the principles and consider them acceptable (or, in contrast, hold incompatible expectations and understandings of treatment) is a factor in treatment adherence which also appears strongly associated with treatment outcomes, largely regardless of treatment adherence: participants who described strongly identifying with the principles typically responded to treatment in anywhere between two and twelve sessions; (2) the acceptability of the practice and process of Morita Therapy, and whether related challenges are experienced in the context of demanding personal circumstances, appears strongly related to treatment adherence: participants who experienced more practical challenges generally attended fewer treatment sessions.

Overall, the findings suggest that patients with incompatible expectations of treatment may be unlikely to benefit from Morita Therapy, and patients with demanding personal circumstances may be unlikely to remain in treatment. Whilst generated from a relatively small dataset, these findings provide tentative insights which have possible implications in terms of both the nature of Morita Therapy and the nature of research in the field in the future. Potential options and considerations are outlined below.

Assessment of moderators within a process evaluation

To improve our understanding of the role of patients' personal circumstances, expectations and readiness to identify with the Morita Therapy principles, such data might be collected as part of a large-scale trial of Morita Therapy. Any such trial should incorporate a process evaluation (Moore, Audrey, Barker et al., 2015a) to investigate the mechanisms of change in Morita Therapy and the influence of context on outcomes. Analyses to investigate the relationship between the potential moderators, adherence and outcomes may be incorporated.

The means of collecting such data on moderators require consideration. It may be possible to identify or develop questionnaires which capture patients' relevant expectations, values and circumstances. Such questionnaires might be used as stand-alone measures of possible moderators, or may be used to

map participants' responses onto the typologies identified in the feasibility study. Alternatively, pre-treatment qualitative interviews might allow exploration of participants' more implicit expectations and values, if deemed necessary to identify to which typology participants belong. A key consideration includes the (possible) need for participants to understand a sufficient amount about Morita Therapy in order to provide the required information, which may potentially be provided to participants via written material or during an orientation session. Whichever methods are selected, it is important to ensure that all measures are applied equally to both Morita Therapy and TAU participants in order to avoid performance bias (Higgins and Altman, 2008), unless an orientation session which is *part* of the Morita Therapy treatment is developed, and thus to consider the potential burden placed upon TAU participants who do not proceed to receive treatment following the collection of this data.

Development of a 'low-intensity' option

The findings might inform further development of the UK Morita Therapy outpatient protocol in an effort to overcome the practical challenges of engaging with treatment, and thus improve treatment adherence, for people for whom engaging in the process is unfeasible in the context of their personal circumstances. Given that such participants in the current study all highly identified with the Morita Therapy principles, were keen to continue treatment had it not been for their personal circumstances, and showed improvements in treatment outcomes, there seems potential value in developing a form of 'low-intensity' Morita Therapy, in a similar vein to the low-intensity versions of Cognitive Behavioural Therapy (CBT) developed to improve access to evidence-based therapies by reducing the commitment required in traditional CBT to one based more on briefer self-help interventions with remote therapist support (Bennett-Levy, Richards, Farrand et al., 2010). Such an option might allow relevant patients to continue attending therapy sessions without engaging in the full therapy process, and thus potentially gain increased benefits from treatment.

Whilst the qualitative data highlighted the importance of the experiential process in Morita Therapy, particularly in terms of the lessons learned from rest, therapists suggested that some patients might benefit from talking with their

therapist about the principles of the approach alone. Furthermore, participants fitting this typology within the current study all benefitted from treatment after only engagement in a (typically limited) amount of rest. Thus, there may be scope to a) curtail the amount of rest participants undertake, to save time; b) provide a safe space for participants to undertake rest in the therapy room, where relevant; and/or c) consider whether the subsequent treatment phases might be removed or reduced. Any such changes to the UK Morita Therapy outpatient protocol would need to be subjected to further assessment of feasibility and acceptability, and exactly who such an approach would be suitable for requires further definition.

A possible clinical algorithm

Based on the current study findings; potentially the findings of further research into moderators of acceptability, adherence and outcomes in Morita Therapy; and possible modifications to the UK Morita Therapy outpatient protocol (as detailed above), it may be possible in the future to develop a clinical algorithm for delivering Morita Therapy (Figure 19, overleaf). Thus, patients with expectations of treatment which are incompatible with Morita Therapy (and who may therefore be less likely to benefit from treatment) might be advised of alternative treatment approaches better suited to them; patients for whom engagement with the full process of Morita Therapy is unfeasible despite identification with the principles (and who may therefore be less likely to remain in treatment) might be offered the 'low-intensity' version.

Figure 19 overleaf

Figure 19. Potential Morita Therapy clinical algorithm based on possible moderators of acceptability, adherence and outcomes
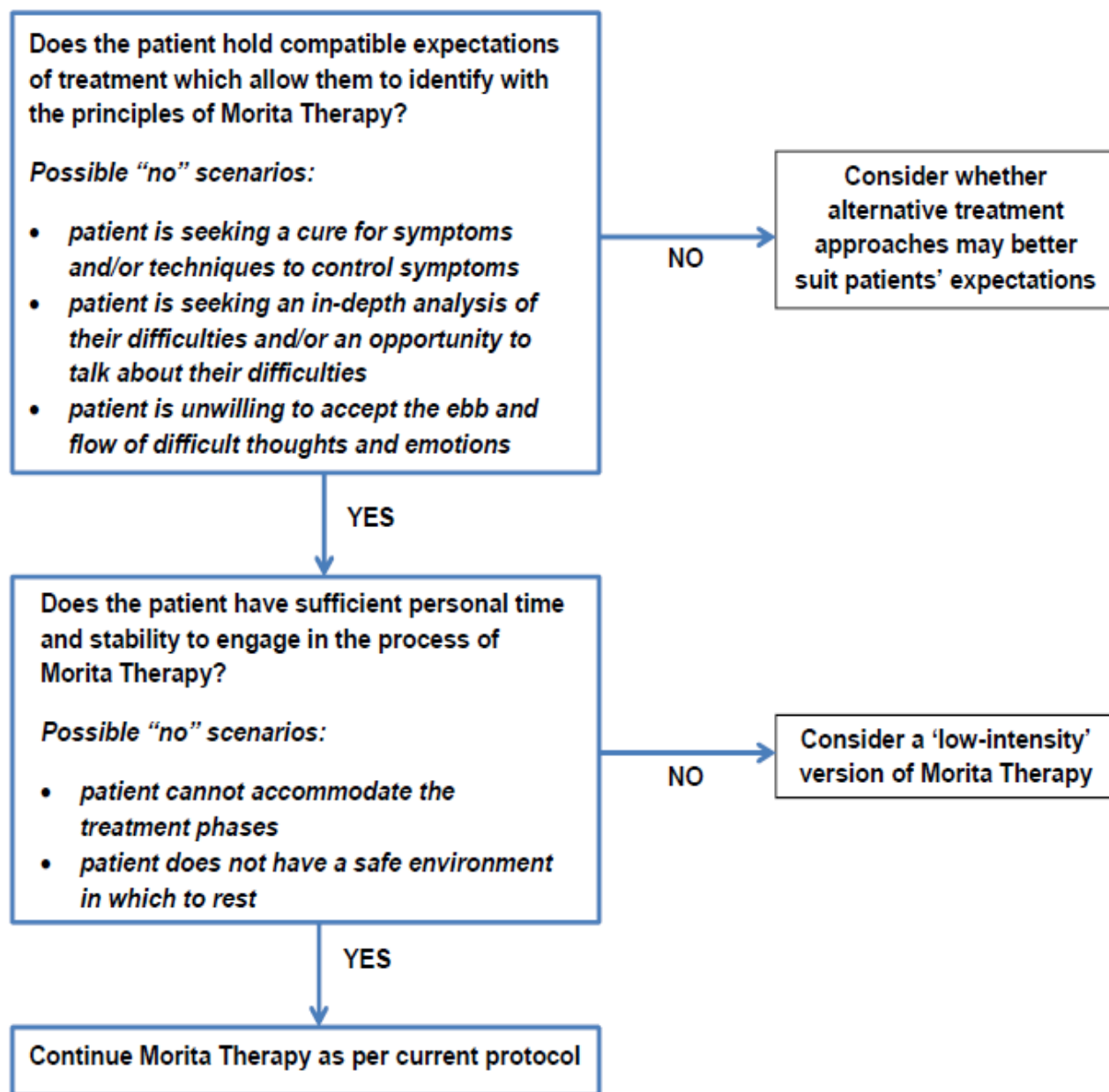
A patient preference trial

The current results highlight the potential importance of patients' expectations of and hopes for treatment in relation to treatment outcomes. Similar results have been found with regards to other psychological therapies. For example, in a trial of CBT versus psychodynamic therapy, among patients who had not found therapy helpful, those who received CBT described dissatisfaction with not being able to talk more extensively about their emotions and relationships (i.e. a more psychodynamic approach), and those who received psychodynamic

therapy described dissatisfaction with not being offered structured problem-solving (i.e. a more CBT approach) (Nilsson, Svensson, Sandell et al., 2007). As per the current study, such accounts illustrate the ways in which different patients construct 'helpful' treatment in different ways, and suggest the importance of patients' expectations of and hopes for treatment in relation to the effectiveness of the approach (McLeod, 2011; Nilsson et al., 2007).

To further such findings and test them in relation to different treatments, patient preference trials may be undertaken (Howard and Thornicroft, 2006). As per the comprehensive cohort design (Olschewski and Scheurlen, 1985), such trials may compare two treatments, allowing participants with strong preferences to select their preferred treatment whilst others are randomised, thus enabling investigation of the influence of preferences on intervention effectiveness. However, it should be kept in mind that important differences between preference and randomised participants may compromise the value of such a trial (von Essen, 2015).

Furthermore, in the qualitative findings of the current study (and potentially those of Nilsson et al. (2007)), participants' expectations of and hopes for treatment were fairly implicit: for example, some claimed to find elements of Morita Therapy, such as 'living with' difficulties, appealing and yet, in their criticisms of the approach, revealed their desire for techniques to remove their difficulties. Thus, whether such participants have prior identifiable 'preferences' for treatment which might be accounted for within a preference trial is questionable.

Towards the individualisation of treatment

The current results have potential value in the field of individualising treatment, or matched care. As noted in the introduction, research on the effectiveness of current psychotherapies reveals that they are broadly equally effective on a population level (McLeod, 2011; Stiles et al., 1986) and the current findings regarding remission rates in Morita Therapy are compatible with this. However, on an individual level, treatment effectiveness varies; thus, it is argued that research should focus on which treatments are effective for which patients (Cuijpers and Christensen, 2017; Kiesler, 1966; Paul, 1967; Stiles et al., 1986).

However, there is currently little evidence to guide such treatment choice (Cuijpers, 2014; Cuijpers and Christensen, 2017; Goddard, Wingrove and Moran, 2015; NICE, 2009). Progress has been made with the development of a method for integrating predictive information that, applied retrospectively, allowed for the identification of an optimal treatment for patients that would have led to superior clinical outcomes (the Personalised Advantage Index), although this method requires further evaluation (DeRubeis et al., 2014; Huibers, Cohen, Lemmens et al., 2015). If the results of further research corroborate the relationship proposed by this study (and other research (e.g. Nilsson et al. (2007)) between expectations of treatment/ ability to identify with the underlying principles of an approach and outcomes, it may ultimately be possible to include an assessment of such factors within this clinical algorithm. Furthermore, the current findings suggest value in using mixed methods (as discussed in section 8.2.2), in addition or as an alternative to these currently purely quantitative techniques, in order to relate information on outcomes directly to participants' views and experiences, and potentially incorporate such findings into a future model of individualisation in depression treatment.

8.4.3 Exploring the Morita Therapy diaries

As Morita Therapy is a complex intervention with multiple components (Craig et al., 2008) future research may focus on discerning which of these components, whether comprising common or specific therapeutic factors (Luborsky et al., 2002; Rosenzweig, 1936), are the 'active ingredients' of Morita Therapy (Campbell et al., 2000). In terms of specific therapeutic factors, Morita Therapy includes both theoretical and operational components which are distinct from other psychological treatments and therefore of particular interest. One such distinctive and potentially important component is the patients' completion of daily diaries, in which therapists provide comments for patients to reflect on (see Appendix XI for an example diary page).

Diaries have formed a fundamental feature of Morita Therapy since the original inpatient treatment approach, in which diaries provided the main method of communication between therapist and patient (Kora, 1995; LeVine, 1998). The qualitative findings of the feasibility study indicate a role for the diaries in highlighting the transient nature of emotions and 'making participants think', and

other research suggests that diaries (whilst different in nature from the Morita Therapy diaries) may facilitate psychological recovery (Aitken, Rattray, Hull et al., 2013). Further research, such as a component study (Simon, Bosworth and Unger, 2001) or process evaluation within a large-scale trial (Moore et al., 2015a), may therefore be undertaken to investigate the role of the diaries as a potentially important mechanism of change in Morita Therapy.

Furthermore, completed diaries from the feasibility study may provide a rich source of data for additional analyses. As noted (section 8.3.5), methods such as discourse analysis (Brown and Yule, 1983) and ethnographic content analysis (Altheide, 1987) may be utilised to explore features of Morita Therapy which are difficult to capture within qualitative interviews, and an analysis of participants' diary accounts in terms of both their style and content might illuminate any changes experienced by participants over time: how participants position themselves in relation to nature; any shift from internal to external attentional fixation, or from 'self'-orientation towards 'action'-orientation. Additionally, an analysis of therapists' comments might be informative in terms of understanding how therapists are implementing Morita Therapy, particularly the distinctive and defining elements of the approach such as Fumon (inattention to symptoms), and methods such as conversation analysis (Sacks, 1992) may illuminate how therapist comments interact with participants' diary entries and any changes they indicate (McCabe, Skelton, Heath et al., 2002).

8.4.4 Other possible research directions: treatment-resistant depression

Whilst the current study was designed to investigate the feasibility and acceptability of Morita Therapy for patients suffering with depression, the findings also provide some early and tentative insights into the potential value of Morita Therapy for patients suffering with treatment-resistant depression (TRD) more specifically (those who do not respond to NICE recommended first-line treatments). Whilst much of the disease burden of depression is attributable to TRD (Greden, 2001; Malhi et al., 2005), there is currently little evidence to guide the management of these patients (Stimpson, Agrawal and Lewis, 2002) and few alternatives aside from combining psychotherapy with medication, augmenting medication or trying another NICE recommended psychotherapy (NICE, In Consultation). However, as an example of one such option, one

recent large-scale trial showed only 55% of non-responders to ADM alone responded to CBT as an adjunct to ADM, with only 40% achieving remission (Wiles et al., 2013).

Thus, there is an absence of a specific and effective pathway within the NICE guidelines to be followed for those with TRD. In this context, it makes sense to test treatments which offer patients, for whom establish treatments have failed, a fundamentally different way of approaching mental health. As such, Morita Therapy, in light of the distinctive philosophical underpinnings of the approach, might offer a meaningful *alternative* for these patients. This is supported by elements of the qualitative data within the current feasibility study (i.e. participant theme five, constituent theme (a): a preferable alternative), in which many participants who had received other treatments referred to their preference for Morita Therapy and valued the distinctive focus of the approach (on allowing as opposed to controlling symptoms) in contrast to their previous experiences of treatment. Although further feasibility work would need to be undertaken with this specific population, there are therefore signals within the current study which support the potential value of Morita Therapy in this field.

8.4.5 Improving quality and methodological rigour

Whilst the current feasibility study has provided sufficient data to enable the evaluation of Morita Therapy in the UK to proceed, these findings relate only to one patient condition within one culture. In order to advance the wider assessment of the effectiveness of Morita Therapy, the scoping and systematic review findings suggest that the quality and methodological rigour of studies in the field should be improved. More experimental studies which ensure internal validity should be conducted to enable researchers to establish whether a causal relationship between Morita Therapy and outcomes exists (Burns et al., 2011), and studies making inferential statements about effectiveness should be sufficiently powered to do so, ensuring external validity and the precision of results (Higgins et al., 2011). Those which are insufficiently powered should take care in interpreting results with caution and reporting confidence intervals to enable the precision of results to be taken into account.

8.4.6 Standardising and reporting of Morita Therapy

The scoping and systematic review demonstrated much variation and little transparency in the implementation of Morita Therapy. Further research in the field would be facilitated by sufficient standardisation of Morita Therapy (whilst allowing therapists to respond to individual patients) and adequate reporting of implemented interventions, to enable replication and comparisons to be made across studies. To this end, the Morita Therapy field may benefit from the application of standard health services research methods and tools which provide frameworks for the development and reporting of interventions (e.g. Craig et al., 2008; Hoffmann, Glasziou, Boutron et al., 2014).

8.5 Clinical implications

This thesis was undertaken primarily to inform the conduct, design and development of a fully-powered evaluation of Morita Therapy. However, the study findings may also be of immediate interest to patients, clinicians and health service providers.

As per the comments above, Morita therapists, who typically report their own studies, may wish to consider the use of less 'biased' and more transparent data collection and reporting procedures, and standard outcome measures, to improve the methodological rigour of studies and potential to replicate and compare them. Clinicians may also be interested in the views of (potential) patients and therapists about Morita Therapy, particularly as an approach which contrasts with typical Western treatments. Morita therapists in particular may be interested to know that, during the optimisation study, it was considered more appropriate for a UK population to shift the approach towards the original four-phased Morita Therapy model, including rest, and away from a counselling-based model alone. Such findings, alongside the views of participants who then received this version of Morita Therapy, suggest Morita Therapy may not require as much modification to achieve cultural accommodation in the West as many authors have previously deemed necessary, yet not empirically tested (Ishiyama, 1994; Ogawa, 2013; Ohara, 1990; Reynolds, 1989; Reynolds, 1995a; Tanaka-Matsumi, 2011; Tseng, 1999).

Finally, the feasibility study findings on the relationship between patients' expectations and understandings of treatment and treatment adherence/outcomes may be of immediate interest to clinicians who, whilst not currently in a position to offer Morita Therapy specifically, may wish to take such factors into account in deciding between current treatment options. This is both supported by, and in a position to further develop, the forthcoming NICE guidelines for depression (In Consultation) which, whilst stressing that patient preferences be taken into account, provide little guidance for doing so and do not necessarily incorporate the more implicit expectations and understandings of treatment suggested as important by the current qualitative and mixed methods results.

8.6 Personal learning

Completing this thesis has provided an invaluable learning experience. I have had the opportunity to consolidate my skills in time management, independent working and problem-solving through applying these to the management of a large-scale research project. I have learned that, whilst research is at times invigorating and highly rewarding, it can also be laborious and monotonous. This process has reaffirmed for me the importance of dedication and perseverance, particularly in the context of the demands and stress of trial management and recruitment.

Furthermore, whilst I appreciate that there are always more skills and knowledge to be gained, I have learned to trust in my own abilities and instincts in the interpretation of research: if something appears interesting or important to me, it generally is to others too. I have also gained insights into the challenges of managing other staff members which have highlighted the importance of both working with a team on which one can rely, and adapting my own working practices in order to respond to the needs and abilities of other team members. I will take this learning forwards in the development of my leadership skills and ability to delegate work effectively.

My work with participants during assessments and qualitative interviews has also provided valuable insights. I have come to appreciate the challenges and importance, for both parties, of clearly establishing appropriate boundaries: the

tension between being an approachable and patient researcher who builds necessary trust and rapport, and not being considered a therapist or support system for participants. I now have a heightened awareness of what might be 'taken for granted' knowledge for those with a scientific background, which I will heed in future work with participants. I have also learned the emotional impact that such research can have on the researcher, in terms of communicating in-depth with participants experiencing depression, and the associated feelings of empathy and responsibility. Moving forwards, I will hold more realistic expectations around this personal toll, ensuring for example that an appropriate limit is placed on the number of participant appointments scheduled per day.

The research topic has also provided a philosophical perspective which has helped me to examine my own assumptions and understandings of the world. Through learning about Morita Therapy and its foundations, my understanding of depression and traditional Eastern and Western approaches towards mental health has changed and grown; my assumptions about what constitutes 'effective' treatment, and the ways in which notions of 'control' may or may not be helpful, have been re-evaluated. As well as my outlook having changed, my awareness of how one's outlook is culturally situated has been heightened: I am more able to appreciate that no one is a 'value-free', independent and objective being; that differing viewpoints may be equally valid.

In the future I hope to maintain and build upon these insights by developing my skills in critical engagement and self-reflection: continuing to question and challenge my own and others' perspectives; remaining aware of and open to alternatives. Similarly, I have also gained significant value from working with two supervisors with different backgrounds, perspectives, and priorities. Whilst at times balancing these perspectives can be challenging, this experience has been invaluable in teaching me different ways of approaching and interpreting research, and I will seek to develop interdisciplinary collaborations which facilitate this stimulating and reflective way of working in the future.

Finally, in attempting to balance due respect for the origins of Morita Therapy and the Japanese tradition with applying methods and developing a treatment which are acceptable in the UK, I have gained insights into the importance of cultural sensitivity and ways in which this might be fostered which I will take with

me, particularly in attempts to strengthen communication and collaboration with members of the Japanese Society for Morita Therapy in the future.

8.7 Conclusions

This thesis encompassed a scoping and systematic review, intervention optimisation study and mixed methods feasibility study to optimise and investigate the feasibility and acceptability of Morita Therapy as a treatment for depression and anxiety in the UK.

In light of the lack of UK-based research and relevant unbiased randomised controlled trials (RCTs) highlighted within the review, a fully-powered UK-based RCT is required to establish whether Morita Therapy plus treatment as usual (TAU) is superior to TAU alone in the treatment of depression and anxiety in a UK population. The results of this thesis support the feasibility and acceptability of conducting such a trial. Thus, patients in the UK are able to accept the premise of Morita Therapy and find the approach beneficial, and a definitive RCT may be planned for with minor modifications to the pilot trial protocols. Future research may also build upon the insights obtained within this thesis regarding potential moderators of acceptability, treatment adherence and outcomes in Morita Therapy.

Morita Therapy for Depression and Anxiety:

Intervention Optimisation and Feasibility Study

Volume 2 of 2

Submitted by Holly Victoria Rose Sugg to the University of Exeter

as a thesis for the degree of

Doctor of Philosophy in Medical Studies

In November 2017

This thesis is available for Library use on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

I certify that all material in this thesis which is not my own work has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

Signature: …………………………………………………………………………

Appendices

- Appendix I: Summary tables of papers included in the scoping and systematic review
- Appendix II: Intervention optimisation study management and data collection
- Appendix III: Published paper from the intervention optimisation study
- Appendix IV: The UK Morita Therapy Outpatient Protocol
- Appendix V: Intervention optimisation study data analysis
- Appendix VI: Morita Therapist Training Programme
- Appendix VII: Published protocol paper for the feasibility study
- Appendix VIII: Feasibility study recruitment
- Appendix IX: Feasibility study management and data collection
- Appendix X: Feasibility study qualitative data analysis
- Appendix XI: Example page of therapeutic diary

Appendix I: Summary tables of papers included in the scoping and systematic review

Table 1 Non-randomised comparative studies (n=2)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Wang et al. (2000)	China	Patients (n not provided), mean age 40.3 (SD 7.8, range 22-57)	Chronic schizophrenia	Original inpatient Morita Therapy, plus pharmacotherapy; duration 12 months (n=60)	Quantitative. Post measures. Follow-up (2 years). Control group 1: non-Morita Therapy (n/ further details not provided); control group 2: individuals with no history of psychosis (n=60).	SPA-4 series analyser for bone mineral content
Hanson (2002) (thesis – not published)	USA	Patients (n=80), mean age 32.5 years (range 18-47)	Depression or dysthymia	Outpatient counselling; duration 8 weeks	Quantitative. Pre/post measures. Control group 1: dietary brain-chemistry treatment (n=20); control group 2: combined Morita psychotherapy and Brain-Chemistry treatment (n=20); control group 3: no treatment (n=20).	Standard outcome measures: depression; global symptom severity; global functioning

Table 2 Before-and-after studies (n=6)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Jiangbo (2000)	China	Patients (n=6), mean age 33.7 years (SD 17.1)	Obsessional neurosis	Home care by family/partners trained in Morita Therapy theory and ideas; mean duration 72.2 days (SD 24.6)	Quantitative. Pre/post measures. No control.	Morita Therapy 3 point rating scale: (A) complete cure (complete disappearance of observable symptoms with or without occasional subjective complaints); (B) improvement (some reductions in symptoms and subjective complaints); (D) no improvement Author-developed outcome measure: obsessional behaviour/ideas, insight, personality, pain, anxiety; effect on family life, social activities, work/study
Mingyi et al. (2000)	China	Patients (n=21), mean age 40.4 years (range 30-54)	Cardiac neurosis	Group Morita Therapy; 5 sessions over 5 weeks	Quantitative. Pre/post measures. No control.	Standard outcome measure: anxiety Author-developed outcome measure: cardiac symptoms
Kuroki et al. (2000)	Japan	Adolescents (n=20), age not provided	Social phobia and/or avoidant personality disorder	Modified inpatient Morita Therapy, plus medication; duration undefined	Quantitative. Pre/post measures. Follow-up (2 and 5 years post-treatment). No control.	Job/school status
Donahue (1988) (thesis – not published)	Canada	Adolescents (n=12), age range 13-17 years	Shyness	Group Morita-based counselling; 4 sessions over 4 weeks	Quantitative. Repeated measures administered bi-weekly throughout study period of 14 weeks. No control.	Standard outcome measure: shyness Author-developed outcome measure: anxiety intensity; difficulty in taking action; level of confidence; degree of emotional disturbance; anxiety acceptance; problem severity; coping effectiveness Extent of behaviour change

Continued overleaf

Table 2 Before-and-after studies (continued)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Ishiyama (1991)	Canada	Patients (n=5), mean age 27.6 years (range 20-34)	Social anxiety	Outpatient counselling; 3 sessions	Quantitative and qualitative. Repeated measures administered at intervals of 5-10 days as well as immediately before and after each therapy session. Pre/post auxiliary measures. Follow-up approximately 1.5 months post-treatment. No control.	Standard outcome measure: problem severity (primary); social avoidance/ distress (auxiliary); neurotic symptoms (auxiliary) Author-developed outcome measure (primary): interpretation of anxiety; coping effectiveness Qualitative follow-up interviews (no further details provided)
Tiancheng (2000)	China	Patients (n=32), mean age 38.7 years (SD 9.6, range 18-58)	Neurosis with no response to medication	Outpatient counselling plus withdrawal of medication within 2 weeks; duration 8 weeks	Quantitative. Repeated measures administered pre-treatment, fourth week of treatment and eighth week of treatment. No control.	Standard outcome measure: global symptom severity Clinical opinion

Table 3 Cross-sectional observational studies (n=5)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Hasegawa (1990)	Japan	Members (n=1085), age not provided	Neurotic subtype of shinkeishitsu who are still functioning at work, school or home	Seikatsu-no Hakkenkai self-help group; ongoing	Quantitative. Time point undefined.	Undefined
Zhen-tao et al. (1990)	China	Patients (n=102), mean age 26.5 years (range teens-60s)	Social phobia (n=24), obsessive compulsive disorder (n=23), somatoform disorder (n=19), generalised anxiety (n=7), phobia (n=7), adjustment disorder with anxiety (n=6)	Outpatient counselling; weekly sessions for first month then biweekly for average of 11.2 weeks	Quantitative. Time point undefined.	Morita Therapy 4 point rating scale: (A) complete cure (complete disappearance of observable symptoms and subjective complaints); (B) improvement (disappearance of observable symptoms with occasional subjective complaints); (C) limited improvement (some reductions in both symptoms and subjective complaints); (D) no improvement
Suzuki et al. (1982)	Japan	Patients (n=1287), mean age at admission 26 years	Shinkeishitsu: hypochondriacal neurosis (n=154), anxiety neurosis (n=122), obsessive neurosis (n=436), depressive neurosis (n=123)	Original inpatient Morita Therapy; duration 25 days to 6 months	Quantitative. Follow-up survey at least 2 years (average 6.3) after discharge.	Life table analysis
Suzuki and Suzuki (1981)	Japan	Patients (n=1287), mean age at admission 26 years	Shinkeishitsu: clearly shinkeishitsu (n=1044); closely related (n=243): severe compulsive behaviour (n=57), depersonalisation (n=13), depressive neurosis (n=173)	Original inpatient Morita Therapy; duration 25 days to 6 months	Quantitative. Follow-up survey at least 2 years (average 6.3) after discharge.	Morita Therapy 4 point rating scale: (A) complete cure (complete disappearance of observable symptoms and subjective complaints); (B) improvement (disappearance of observable symptoms with occasional subjective complaints); (C) limited improvement (some reductions in both symptoms and subjective complaints); (D) no improvement

Continued overleaf

Table 3 Cross-sectional observational studies (continued)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Ashizawa et al. (2000)	Japan	Patients (n=13), age not provided	Chronic pain	Group Morita Therapy; duration 2 years	Quantitative. Follow-up survey administered to patients attending the party celebrating the 100th meeting of the group. Only analysis undertaken was to explore correlations between questionnaire items.	Author-developed outcome measure: degree of improvement in chronic pain; satisfaction with life; effect of treatment

Table 4 Case studies (n=26)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Chang (2011)	Japan	Patients (n=3), aged: (1) not provided; (2) not provided; (3) 19 years	(1) Neurasthenia; (2) Neurasthenia; (3) Anxiety (fear of gaze)	Original inpatient Morita Therapy; duration undefined	Qualitative	Clinical opinion
LeVine (1993a)	Australia	Single patient, aged 27 years	Bulimia nervosa	Outpatient counselling; 5 sessions over 4 weeks	Quantitative and qualitative. Pre/post measures. Follow-up (2 months post-treatment).	Standard outcome measure: presence of eating disorders Patient self-report
Alfonso (1992)	Canada	Single patient, aged 27 years	Social anxiety	Outpatient counselling; duration undefined	Qualitative. Follow-ups (face-to-face at 3 weeks; via phone at 8 weeks/ 2 years post-treatment).	Clinical opinion
Tateno et al. (2015)	Japan	Patients (n=2), aged: (1) 30 years; (2) 29 years	Obsessive-Compulsive Disorder (OCD)	Original inpatient Morita Therapy; duration up to 5 months	Quantitative and qualitative. Pre/post measures.	Standard outcome measure: obsessive compulsive symptoms Clinician opinion
Ogawa (2013)	Not provided	Patients (n=3), aged: (1) 30 years; (2) 25 years; (3) not provided	(1) Obsessive Compulsive disorder; (2) Social anxiety disorder; (3) Chronic anxiety	(1) outpatient counselling (6 sessions over 12 weeks); (2) original inpatient Morita Therapy, duration undefined; (3) outpatient counselling (10 sessions)	Qualitative	Clinical opinion
Alfonso and Guthrie (1990)	Canada	Single patient, aged 28 years	Shinkeishitsu	Outpatient counselling; duration undefined	Qualitative	Clinical opinion
France et al. (1995)	Canada	Single patient, aged 35 years	Stress	Letter therapy process; duration 5 months	Qualitative	Clinical opinion

Continued overleaf

Table 4 Case studies (continued)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Itoh et al. (2000)	Japan	Single patient, aged 53 years	Psycho-physiological insomnia	Outpatient counselling, plus medication and sleep hygiene education; duration undefined	Qualitative	Clinical opinion
Jamieson (1990)	Canada	University students (n=2), age not provided	None (presumed to potentially exhibit Shinkeishitsu traits)	Use of Morita techniques in University counselling; duration undefined	Qualitative	Patient self-report
Kurokawa (2006)	Japan	Single patient, aged 43 years	Panic disorder	Form of outpatient Morita Therapy termed Walking Training therapy; duration 6.5 years at present (ongoing)	Qualitative	Clinical opinion
LeVine (1991)	Australia	Single patient, aged 26 years	Bisexual patient in the 'coming out' process	Outpatient counselling; 7 sessions	Qualitative	Clinical opinion
Moriyama (2000)	Japan	Single patient, aged 39 years	Phantom bite syndrome	Outpatient counselling; duration undefined	Qualitative	Clinical opinion
Morley (1990)	Canada	Single patient, aged 40 years	Socially avoidant borderline personality	Outpatient counselling; duration undefined	Qualitative	Clinical opinion
Nakamura (2016)	Japan	Single patient, aged 25 years	Social anxiety	Original inpatient Morita Therapy; duration undefined	Qualitative	Clinical opinion
Shioji et al. (2000)	Japan	Single patient, aged 29 years	Social phobia	Original inpatient Morita Therapy; duration 101 days	Qualitative	Clinical opinion

Continued overleaf

Table 4 Case studies (continued)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Tamai and Tashiro (1989)	Japan	Single patient, aged 18 years	Shinkeishitsu	Outpatient counselling; duration 19 weeks with regular follow-ups over 8 months	Qualitative. Follow-ups (undefined time points).	Clinical opinion
Tamai et al. (1991)	Japan	Single patient, aged 26 years	Borderline personality disorder	Original inpatient Morita Therapy; duration 70 days	Qualitative	Clinical opinion
Terada et al. (2000)	Japan	School teachers (n=5), aged: (1) 31; (2) 49; (3) 51; (4) 40; (5) 41	Nervous disorder	Original inpatient Morita Therapy; duration 3-4 months	Qualitative	Clinical opinion
Ishiyama (1983)	Canada	Single patient, aged 40 years	Test anxiety	Outpatient counselling; 1 session	Qualitative. Follow-ups (6 and 12 months).	Clinical opinion Patient self-report (follow-up interview)
Ishiyama (1986b)	Canada	Single patient, aged 35 years	Death-anxiety with paroxysmal anxiety reactions	Outpatient counselling; 1 session	Qualitative. Follow-ups (6, 12, 18 and 40 months).	Clinical opinion Patient self-report (follow-up interview)
Kelly (1993)	Canada	Single patient, aged 45 years	Survivor of incestuous childhood sexual abuse	Outpatient counselling; duration 6 months	Quantitative and qualitative. Pre/post measures. Follow-up (4 months).	Standard outcome measure: personality; self-concept Patient self-report
Tashiro et al. (1993)	Japan	Single patient, aged 18 years	Specific phobia (emitting an offensive bodily odour)	Outpatient counselling; duration 18 months to date	Quantitative and qualitative. Pre/current (18 month) measures (treatment ongoing).	Undefined outcome measure: nature of inner conflicts Clinician opinion
Kondo (1953)	Japan	Single patient, aged 27 years	Homophobia and feeling of inferiority	Original inpatient Morita Therapy; duration undefined	Qualitative	Patient self-report (diary excerpt)

Continued overleaf

Table 4 Case studies (continued)

Author(s)/ Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Reynolds (1982)	Not provided	Patients (n=3), aged: (1) 17 years; (2) 19 years; (3) 27 years	Shinkeishitsu	Inpatient Morita Therapy; no further details provided	Qualitative	Patient self-report (diary excerpt)
Chang (1974)	Japan	Single patient, aged 33 years	Shinkeishitsu	Original inpatient Morita Therapy; duration undefined	Qualitative	Patient self-report (diary excerpt)
Ishiyama (1986a)	Canada	Single patient, aged 42 years	Social anxiety (fear of speaking in groups; fear of approaching strangers)	Outpatient counselling; 3 sessions	Quantitative and qualitative. Measures weekly plus immediately before/ after each session. Follow-ups (14, 18 and 28 weeks post-baseline).	Author-developed outcome measure: anxiety acceptance; problem severity; coping effectiveness Patient self-report

Table 5 Systematic/ narrative reviews (n=4)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Minami (2011a)\n\n(thesis – not published)	Japan; China	Various	Anxiety disorder (n=270); schizophrenia (n=86); mood disorder (n=34); somatoform disorder (n=24); eating disorder (n=2); adjustment disorder (n=7); pain disorder (n=4); sleep disorder (n=1); substance abuse disorder (n=1); personality disorder (n=1); other subclinical issues (n=40)	Outpatient counselling; original inpatient Morita Therapy; modified inpatient Morita Therapy (excluding bed rest); durations varied	Quantitative and qualitative. Author searched the latest ten volumes of the Japanese Journal of Morita Therapy, from 2006 to 2010 (current). All articles were included except socio-historical and theoretical/conceptual articles which contained no efficacy data.	Standard outcome measures: various Clinical opinion Patient self-report
Nakamoto (2010)\n\n(thesis – not published)	Japan; China; Australia; USA	Various	Depression; obsessive compulsive disorder; Taijin Kyofusho; neurotic disorder; social phobia; anxiety; social withdrawal; bulimia nervosa; panic disorder; somatoform disorder; schizophrenia; dysthymia; borderline personality disorder; phobia; post-traumatic stress disorder; other	Inpatient Morita Therapy; outpatient counselling; self-help group; patients treated at school or welfare counselling centres; patients treated by non-mental health professionals such as dentists employing Morita Therapy techniques; durations undefined	Quantitative and qualitative. Authors searched Psycinfo and The Japanese Journal of Morita Therapy published from 1990 to 2008. Only articles which clearly demonstrated the effectiveness of Morita Therapy were included.	Standard outcome measures: various Clinical opinion

Continued overleaf

Table 5 Systematic/ narrative reviews (continued)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Wu et al. (2015)	China	Patients (n=449), aged 16-60	Anxiety disorder	Morita therapy defined as any care practice defined as Morita therapy by the carers and involving at least two of the four phases. Duration of included interventions varied from 6 weeks to 12 months.	Quantitative. Authors searched Cochrane Collaboration Depression, Anxiety and Neurosis Group's Specialised Register (CCDANCTR), Dissertation Abstracts International (DAI), Chongqing VIP Database, Wanfang Database, China Hospital Knowledge Database, China Biology Medicine disc, Cochrane Central Register of Controlled Trials (CENTRAL), World Health Organization International Clinical Trials Registry Platform (ICTRP) and Sagace. All relevant randomised controlled trials comparing Morita Therapy with any other treatment for anxiety disorders were included.	Standard outcome measure: global symptom severity
He and Li (2007)	China	Patients (n=1123), aged 15-65	Schizophrenia and schizophrenia-like disorders such as schizophreniform disorder, delusional disorder or schizoaffective disorder	Morita Therapy defined as any care practice defined as Morita by the carers and involving at least two of the four phases. Duration of included interventions varied from 6 weeks to 10 months.	Quantitative. Authors searched the Cochrane Schizophrenia Groups Trials Register, the Chongqing VIP Database, and the Wanfang Database for all relevant references (July 2008). All randomised clinical trials comparing Morita Therapy with any other treatment were included.	Standard outcome measures: symptom severity; negative symptoms; activities of daily living; psychiatric rehabilitation

Table 6 Secondary reports (n=7)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Maeda and Nathan (1999)	Japan	Various	Taijin Kyofusho (fear of interpersonal relations)	Undefined	Quantitative. Methods undefined. No control.	Undefined
Kitanishi and Mori (1995)	Japan	Various	Shinkeishitsu; Taijin Kyofusho; delusional-type neurosis; obsessive-compulsive neurosis; depression; bipolar II; dysthymia; schizophrenia; borderline personality; psychosomatic illness	Undefined	Quantitative. Methods undefined. No control.	Undefined
Fujita (1986)	Japan	Various	Shinkeishitsu	Inpatient Morita Therapy; Morita-based group therapy; some undefined; durations undefined	Quantitative. Follow-up survey. Time point undefined.	Morita Therapy rating scale (undefined)
Gibson (1974)	Japan	Various	Shinkeishitsu; some not provided	Various: inpatient Morita Therapy; outpatient counselling; durations undefined	Quantitative. Measures/ time points unclear. No control.	Undefined
Ishiyama (1988a)	Japan	Various	Shinkeishitsu; phobic-obsessive disorder; some not provided	Inpatient Morita Therapy; outpatient counselling; Morita-based group therapy; some undefined; durations undefined	Quantitative and qualitative. Varied measures/ time points. No control.	Standard outcome measures: various Morita Therapy rating scale (3 and 4 point) Clinical opinion

Continued overleaf

Table 6 Secondary reports (continued)

Author(s) / Year	Country	Sample	Patient diagnosis/ condition	Intervention summary	Research methods	Outcome measures
Reynolds (1976)	Japan	Various	Shinkeishitsu; neurosis; some not provided	Various: inpatient Morita Therapy; Morita-based group therapy; self-help group; some undefined; durations undefined	Quantitative and qualitative. Varied measures/ time points. One study employed non-directive therapy as control.	Standard outcome measures: various Morita Therapy 3 point rating scale: (A) complete cure (complete disappearance of observable symptoms with or without occasional subjective complaints); (B) improvement (some reductions in symptoms and subjective complaints); (D) no improvement Clinical opinion Urine specimen tests
Wei (2005) as reported by De Silva et al. (2013)	China	Patients (n=104), age not provided	Post-schizophrenic depression	Inpatient Morita Therapy, plus antidepressant medication; duration 12 weeks	Quantitative. Pre/post measures. Control: inpatient treatment as usual and antidepressants.	Standard outcome measure: social disability

Appendix II: Intervention optimisation study management and data collection

This appendix provides a copy of supporting documents used during the management of and data collection for the intervention optimisation study, specifically:

- University of Exeter Medical School ethics approval letter
- Summary of core Morita Therapy principles
- Topic guide for potential patients
- Topic guide for therapists (round 1)
- Topic guide for therapists (round 2)

University of Exeter Medical School ethics approval letter

UNIVERSITY OF | **MEDICAL**
EXETER | **SCHOOL**

Our Ref: PF/CB/15/02/066

24 February 2015

Miss Holly Sugg
PhD Student
University of Exeter Medical School
University of Exeter
Haighton Building
St. Luke's Campus
Heavitree Road
EXETER
EX1 2LU

Please reply to:
Peta Foxall, PhD
Chair, UEMS Research Ethics Committee
University of Exeter Medical School
c/o Carol Barkle
Administrator to UEMS REC
Knowledge Spa
Royal Cornwall Hospital
TRURO
Cornwall
TR1 3HD
Tel: 01872 256460
Fax: 01872 256401
Email: *c.barkle@exeter.ac.uk*

Dear Miss Sugg

Application Number : 15/02/066
Project Title : Developing the Morita therapy protocol for a UK population and clinicians: A Qualitative Study

Thank you for submitting the above application, which was considered by the University of Exeter Medical School Research Ethics Committee at its meeting on 12th February 2015.

As you are aware, the Committee agreed that this was an excellent study raising no ethical concerns and approved your application unanimously. Members commended you on submitting a well written application. I have pleasure in enclosing your Certificate of Approval.

Good luck with your study.

Yours sincerely

Peta Foxall, PhD
Chair
University of Exeter Medical School Research Ethics Committee

University of Exeter Medical School Knowledge Spa Royal Cornwall Hospital Truro Cornwall TR1 3HD UK
Tel +44 (0)1872 256460 Fax +44 (0)1872 256401 Email : c.barkle@exeter.ac.uk

Dean **Professor Steve Thornton**
Associate Dean for Cornwall **Dr Nicki Saulsbury**

Summary of core Morita Therapy principles

Principles of Morita Therapy

Desire for life and the naturalness of emotion

Within Morita therapy is the idea that everyone has basic desires to be alive and to live well, called 'desire for life'. Our fears and other unpleasant symptoms are seen to reflect such desires, as if they were two sides of the same coin. For example, if someone experiences social anxiety, this reflects a desire to be accepted by others. These dual feelings always exist together, it is not possible to experience only one side of emotions: one cannot know happiness without having felt sadness, and vice versa. Morita therapy therefore teaches that distress and undesired feelings are a normal, inevitable and uncontrollable consequence of human desire, result from our experiences and are not problematic in themselves.

The vicious cycle

What is problematic is a loss of balance between the two sides of the coin, whereby too much attention and effort is directed towards the 'unpleasant' side. This creates a vicious cycle in which symptoms are exacerbated. Thus, in Morita therapy, suffering does not indicate a deficit, but an excess of: attention placed on symptoms; judgement of certain emotions as 'good' or acceptable and others as 'bad' or unacceptable; engagement in unrealistic and perfectionist thinking, such as believing one should or deserves to feel differently; and, crucially, self-defeating attempts to control or fight otherwise uncontrollable emotions.

The mind's natural healing capacity

Not only do the characteristics of the vicious cycle exacerbate symptoms, they also interfere in the mind's natural capacity to heal and restore itself. If emotions are left to run their natural course, without such interference and the resulting aggravation, the mind can recover in the same way that the body recovers from a wound or the flu. An aim of Morita therapy is therefore to accept our experiences of who we are and how we feel without such attempts to manipulate them, and to engage in sufficient rest to allow this natural recovery process to take form. With enough time spent resting without fighting symptoms, the desire for life will naturally re-surface in the form of boredom and desire to take small actions.

The focus on action

The focus is then shifted from changing emotion to action, which one does have control over. Morita therapists promote spontaneous activity in line with the natural impulses surfacing during rest. This desire for life is translated into small and achievable goals, cultivating the ability to take action whilst experiencing symptoms. The ultimate aim is to be able to take the action that needs to be taken in order to live a productive life. Thus, Morita Therapy does not offer skills to control or eliminate symptoms, but instead encourages realistic and constructive ways of living in spite of symptoms. With new experiences paving the way for new emotions, symptoms are found to reduce as a by-product of this shift in attention and efforts from symptom combat to constructive living.

Acceptance and obedience to nature

The underlying premise of Morita Therapy is to bring patients back in touch with the natural world. Morita therapy often draws on natural metaphors, comparing the experience of human emotion to changes in the seasons or the weather, in teaching awareness of what is natural and out of our control. By cultivating an awareness of one's place within nature as a whole, attempts to control emotions are relinquished and instead patients accept that their feelings adjust in accordance with external circumstances. Patients are helped to accept, honour and ultimately obey the rhythms of the natural environment, including one's own emotional fluctuations. As such, the 'self' is decentralised. One moves from being feeling-centred to being purpose-centred, from focusing on subjective experiences to focusing on external reality, and from reflecting on and evaluating oneself to accepting oneself as embedded within nature.

Holly Sugg
Professor David Richards

Topic guide for potential patients

Morita Trial Qualitative Interview Topic Guide

Phase one (participants)

Introduction

Thank you very much for meeting with me today. We really appreciate your time. Once I've explained the study to you and answered any questions you may have, the interview itself should last about one hour so we should be finished by…. Is that going to be ok for you?

So I'm a PhD student at the University of Exeter Medical School working with Professor Dave Richards. As I mentioned in your invitation, I'd like to find out what you think about a therapy for depression which is called Morita therapy and is quite new to the UK. This is so that we can make sure as far as possible that the therapy will be appropriate for people and will be understood by people in the ways that we hope, before we move onto trialling the therapy here.

I appreciate that you may not have heard anything about this therapy before now so in order to find out your views of it I have written a flyer explaining some of the theory and principles of MT and we can discuss your thoughts are about that. Then I will play some recordings of the therapy being delivered in practice, to show some real life attempts to try and implement some of those MT principles which I will have explained.

So when we're listening to those recordings, I'm interested in what you think of the approach, what messages you think the therapist is trying to convey, whether you think something is unclear or doesn't make sense, and how you might feel if you were receiving therapy in that way. I'm also really interested in what principles of MT you think the therapist is trying to implement in the recording. I'll ask you to listen to the recording whilst being in charge of pausing it, so that if anything comes to mind whilst you're listening to it you can pause it and tell me there and then so that I can capture your initial reaction. Does that sound ok?

I just want to make clear that this is not in any way a test of your understanding, but rather a test of the therapy so please do be as critical as you like and if there is something you don't understand that's exactly the kind of information it is important for us to capture so please don't feel there is a right answer that we're looking for. The recordings are not perfect attempts to implement the principles and sometimes the message seems to be communicated better than others, so I'm just interested in what you think he's trying to convey and perhaps if you have any suggestions for how he might have done that better. Also, if you have nothing to say or add that's really important for us to know too so a non-answer is still a completely valid response.

The recordings are of a therapist called Masa and his client Kitima. I should just note that Kitima has given permission for us to use these recordings in this way. Before starting a recording I'll give you some context about what they're talking about, and then once we've finished a recording I'll ask you some specific questions about it before moving onto the next one. Some of the clips are drawn together from different moments in therapy so if the

conversation doesn't seem to flow quite right that's probably why! There are 5 recordings in total but if we're running out of time we don't have to listen to them all, and you can let me know at any time if you'd like to stop the interview.

Just to confirm that everything you say is kept strictly confidential, but the one exception to that is if you tell me anything which makes me think you may be at risk of harming yourself or someone else in which case I will need to follow our protocols for reporting that. Is that OK?

I have a CONSENT FORM here for us to complete before we start. The main things on there are whether you happy for our interview to be audio-recorded? I'll let you know when I start recording. When I transcribe the interview I will take out any information that might identify you personally. And for my write up if I include any direct quotes I can either label them as anonymous or replace your first name with a pseudonym if there's a particular name you would like to choose?

I'll also be taking some notes during the interview. There is also an option to receive a summary of the results of our study once we have finished the trial if you would like to, so I can send those by email or by post if you prefer (get address if via post and interviewing at St Luke's).

Before I start can I also just CONFIRM/ COLLECT DEMOGRAPHIC AND BACKGROUND INFORMATION.

Is there anything that you would like to ask before we begin?

As we go through the questions, if anything is unclear, please do ask me to explain.

Ready to begin?

I'm going to **start recording now**.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

Ask them to confirm that the study has been explained to them and they have given their consent to participate.

Morita therapy explanation:

Morita therapy is a talking therapy for various mental health issues including depression and anxiety, which has roots in Zen Buddhist philosophy and has been developed and practiced for a long time in Japan and somewhat elsewhere but has not been tried in the UK before. Later this year I will be running a pilot trial where the therapy will be delivered here, on a face to face and one to one basis, for a one hour session per week over 8 to 12 weeks. The treatment is quite flexible, so rather than having a strict manual of what will be covered in each session, the therapist responds directly to what the patient presents with at the time.

CHECK READ PAGE AT HOME – IF NOT, READ OUT OR ASK PARTICIPANT TO READ TO THEMSELVES

- What are your thoughts on what you've heard of the approach so far?

- *Is there anything you particularly like or dislike about it?*
- *What stands out about the approach to you?*
- *How do you think you might feel about receiving that type of therapy?*
- In what ways do you think the approach sounds distinctive or different to other therapies you may be aware of?

Now that we've discussed some of the principles of MT, I'll move onto the recordings to show some examples of a therapist trying to implement those in practice.

General probes:

- What is your initial reaction to that clip?
- What's your interpretation of what the therapist was saying?
  - How well do you think he was getting that message across?
  - Do you have any suggestions for how he might have communicated that better?
- Do you think there are any distinctive principles of MT which were demonstrated in that clip? What do you think those were?
- What did you think about the approach of the therapist?
- If you had been the patient in that scenario, how do you think you would have felt?

Clip 1: Diary

Context: they are talking about her completing a therapeutic diary – show example

- What is your understanding of the purpose of the diary?
- Do you think it is clear what is expected from the client?
- How easy or difficult do you think it would be for you to complete something like that?

Clip 2: Positive reinterpretation/ judgement towards symptoms/ touch of vicious cycle

Context: talking about the anxiety she suffers from and how she wants to have no worry at all

- What did you think about the idea that anxiety and fear show desire to be safe and caring?
- How helpful was the metaphor about the feelings being two sides of the same coin in explaining this idea?

Clip 3: Naturalness/ baby metaphor/ touch of vicious cycle and Fumon approach

Context: follows on from their discussions about anxiety

- What do you think of the idea that anxiety is natural and healthy? How do you think you would feel if a therapist approached your difficulties in this way?
- What did you think of the way the therapist tried to get this idea across? e.g. saying that he doesn't see an anxious person, he just sees a human?
- What did you think of his reaction to her saying that she thought other people were more stable and able to manage anxiety better?

Clip 4: Control/ anxious action taking

Context: they have labelled the inner self-critical voice the 'dictator' which they refer to

- How helpful did you find the therapist's explanation that "You can't control that certain feelings are coming but you can control what you do with them?" How would you feel if a therapist approached your difficulties in this way?
- What do you think the therapist is trying to achieve by pointing out all the actions she has been able to do?

Clip 5: Rest/ marathon metaphor

Context: talking about her not being able to study and write enough

- What did you think about the therapist saying that he was giving her a "job to rest"? How would you feel about a therapist approaching you in that way?
- How helpful do you think the approach and the metaphor about running a marathon was in encouraging rest and relaxation?
- This wasn't referred to specifically but how would you feel about being asked to draw up and commit to a schedule of rest for yourself?

Concluding questions:

- Overall, what did you think of the approach?
- Are there any things that stand out on reflection? Why?
- Do you think you would like to be involved in that type of therapy?
- Do you have any thoughts about the principles you read through compared to hearing some of those put into practice – did they seem to relate well to each other/ anything surprising hearing them in practice?
- What are the main ways in which you think MT is distinctive or different to other types of therapy you may know of?
- Is there anything else that you would like to add?

FINISH

Finally, are there any other comments that you would like to make about taking part?

Thank you.

Stop recording and tell them that the recorder has been switched off.

Explain that they will receive a short summary of results after the pilot study if they have agreed to this on the consent form.

Topic guide for therapists (round 1)

Morita Trial Qualitative Interview Topic Guide

Phase one (therapists)

Introduction

Thank you very much for meeting with me today. We really appreciate your time. Once I've explained the study to you and answered any questions you may have, the interview itself should last about one hour so we should be finished by…. Is that going to be ok for you?

So I'm a PhD student at the University of Exeter Medical School working with Professor Dave Richards. As I mentioned in your invitation, I'd like to find out what you think about a therapy for depression which is called Morita therapy and is quite new to the UK. This is so that we can make sure as far as possible that the therapy will be appropriate for people and will be understood by people in the ways that we hope, before we move onto trialling the therapy here.

I appreciate that you may not have heard anything about this therapy before now so in order to find out your views of it I have written a flyer explaining some of the theory and principles of MT and we can discuss your thoughts are about that. Then I will play some recordings of the therapy being delivered in practice, to show some real life attempts to try and implement some of those MT principles which I will have explained.

So when we're listening to those recordings, I'm interested in what you think of the approach, what messages you think the therapist is trying to convey, whether you think something is unclear or doesn't make sense, and how you might feel if you were asked to deliver therapy in that way. I'm also really interested in what principles of MT you think the therapist is trying to implement in the recording. I'll ask you to listen to the recording whilst being in charge of pausing it, so that if anything comes to mind whilst you're listening to it you can pause it and tell me there and then so that I can capture your initial reaction. Does that sound ok?

I just want to make clear that this is not in any way a test of your understanding, but rather a test of the therapy so please do be as critical as you like and if there is something you don't understand that's exactly the kind of information it is important for us to capture so please don't feel there is a right answer that we're looking for. The recordings are not perfect attempts to implement the principles and sometimes the message seems to be communicated better than others, so I'm just interested in what you think he's trying to convey and perhaps if you have any suggestions for how he might have done that better. Also, if you have nothing to say or add that's really important for us to know too so a non-answer is still a completely valid response.

The recordings are of a therapist called Masa and his client Kitima. I should just note that Kitima has given permission for us to use these recordings in this way. Before starting a recording I'll give you some context about what they're talking about, and then once we've finished a recording I'll ask you some specific questions about it before moving onto the next one. Some of the clips are drawn together from different moments in therapy so if the conversation doesn't seem to flow quite right that's probably why! There are 5 recordings in

total but if we're running out of time we don't have to listen to them all, and you can let me know at any time if you'd like to stop the interview.

Just to confirm that everything you say is kept strictly confidential, if you're happy for me to record the interview I will remove any identifiable information when I transcribe it.

I have a CONSENT FORM here for us to complete before we start. For my write up if I include any direct quotes I can either label them as anonymous or replace your first name with a pseudonym if there's a particular name you would like to choose?

I'll also be taking some notes during the interview. There is also an option to receive a summary of the results of our study once we have finished the trial if you would like to, so I can send those by email or by post if you prefer (get address if via post and interviewing at St Luke's).

Before I start can I also just CONFIRM/ COLLECT DEMOGRAPHIC AND BACKGROUND INFORMATION.

Is there anything that you would like to ask before we begin?

As we go through the questions, if anything is unclear, please do ask me to explain.

Ready to begin?

I'm going to **start recording now**.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

Ask them to confirm that the study has been explained to them and they have given their consent to participate.

Morita therapy explanation:

Morita therapy is a talking therapy for various mental health issues including depression and anxiety, which has roots in Zen Buddhist philosophy and has been developed and practiced for a long time in Japan and somewhat elsewhere but has not been tried in the UK before. Later this year I will be running a pilot trial where the therapy will be delivered here, on a face to face and one to one basis, for a one hour session per week over 8 to 12 weeks. The treatment is quite flexible, so rather than having a strict manual of what will be covered in each session, the therapist responds directly to what the patient presents with at the time.

CHECK READ PAGE AT HOME – IF NOT, READ OUT OR ASK PARTICIPANT TO READ TO THEMSELVES

- What are your thoughts on what you've heard of the approach so far?
- *Is there anything you particularly like or dislike about it?*
- *What stands out about the approach to you?*
- *How do you think you might feel about delivering that type of therapy?*
- In what ways do you think the approach sounds distinctive or different to other therapies you may be aware of?

Now that we've discussed some of the principles of MT, I'll move onto the recordings to show some examples of a therapist trying to implement those in practice.

General probes:

- What is your initial reaction to that clip?
- Do you think there are any distinctive principles of MT which were demonstrated in that clip? What do you think those were?
- What did you think about the approach of the therapist?
  - How would you feel approaching a client in that way?
- Would you want to do anything differently?
- What's your interpretation of what the therapist was saying or what message he was trying to convey?
  - How well do you think he was getting that message across?
  - Do you have any suggestions for how he might have communicated that better?

Clip 1: Diary

Context: they are talking about her completing a therapeutic diary – show example

- What is your understanding of the purpose of the diary?
- In writing comments, what do you think you'd be trying to achieve in terms of the principles we discussed?
- Do you think it is clear what is expected from the client?
- How would you feel about asking a client to make that commitment and explaining the purpose of it to them?
- Does this sound similar to something you might do in other treatments?
  - How is it different to a diary in other treatments?

Clip 2: Positive reinterpretation/ judgement towards symptoms/ touch of vicious cycle

Context: talking about the anxiety she suffers from and how she wants to have no worry at all

- What did you think about the idea that anxiety and fear show desire to be safe and caring?
- How helpful do you think metaphors and his choice of metaphors are?

Clip 3: Naturalness/ baby metaphor/ touch of vicious cycle and Fumon approach

Context: follows on from their discussions about anxiety

- What did you think of the way the therapist tried to get this idea across? e.g. saying that he doesn't see an anxious person, he just sees a human?
- What did you think of his reaction to her saying that she thought other people were more stable and able to manage anxiety better?

Clip 4: Control/ anxious action taking

Context: dictator = inner self-critical voice

- How helpful did you find the therapist's explanation that "You can't control that certain feelings are coming but you can control what you do with them?" How would you feel approaching a client's difficulties in this way?
- What do you think the therapist is trying to achieve by pointing out all the actions she has been able to do?

Clip 5: Rest/ marathon metaphor

Context: talking about her not being able to study and write enough

- What did you think about the therapist saying that he was giving her a "job to rest"? How would you feel approaching a client in this way?
- How helpful do you think the approach and the metaphor about running a marathon was in encouraging rest and relaxation?
- This wasn't referred to specifically but how would you feel about asking a client to draw up and commit to a schedule of rest to be shared with you as a therapist?

Concluding questions:

- Overall, what did you think of the approach?
- Are there any things that stand out on reflection? Why?
- Do you think you would like to be involved in delivering that type of therapy?
  - Where do you think you would need more guidance in particular?
- Do you have any thoughts about the principles you read through compared to hearing some of those put into practice – did they seem to relate well to each other/ anything surprising hearing them in practice?
- What are the main ways in which you think MT is distinctive or different to other types of therapy you may know of?
- What did you think about his use and choice of metaphors?
- A lot of the focus in the clips was on anxiety, how do you see this relating to depression?
- Is there anything else that you would like to add?

FINISH

Finally, are there any other comments that you would like to make about taking part?

Thank you.

Stop recording and tell them that the recorder has been switched off.

Topic guide for therapists (round 2)

Morita Trial Qualitative Interview Topic Guide

Phase one Round Two

Introduction

Thank you very much for meeting with me today. We really appreciate your time. Once I've explained the study to you and answered any questions you may have, the interview itself should last about one hour so we should be finished by…. Is that going to be ok for you?

So I'm a PhD student at the University of Exeter Medical School working with Professor Dave Richards. We're running a pilot trial later this year where we will be testing a psychotherapy called Morita Therapy. Morita Therapy is new to the UK, so I'm also holding interviews with therapists and potential patients to help us develop the treatment and the manual itself and make sure it is suitable for the people who will be delivering and receiving the treatment here.

The purpose of today's interview is to look specifically at the draft therapy manual so that I can find out what your views are on that in terms of how comprehensive the manual is, how user-friendly it is, and things like that. Does that sound ok?

So just to be clear that this is not in any way a test of your understanding, but rather a test of the therapy and the manual so please do be as critical as you like and if there is something you don't understand that's exactly the kind of information it is important for us to capture so please don't feel there is a right answer that we're looking for.

Just to confirm that everything you say is kept strictly confidential, if you're happy for me to record the interview I will remove any identifiable information when I transcribe it.

I have a CONSENT FORM here for us to complete before we start. For my write up if I include any direct quotes I can either label them as anonymous or replace your first name with a pseudonym if there's a particular name you would like to choose?

I'll also be taking some notes during the interview. There is also an option to receive a summary of the results of our study once we have finished the trial if you would like to, so I can send those by email or by post if you prefer (get address if via post and interviewing at Uni).

Before I start can I also just CONFIRM/ COLLECT DEMOGRAPHIC AND BACKGROUND INFORMATION.

Is there anything that you would like to ask before we begin?

As we go through the questions, if anything is unclear, please do ask me to explain.

Ready to begin?

I'm going to **start recording now**.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

Ask them to confirm that the study has been explained to them and they have given their consent to participate.

So I sent you the draft therapy protocol over email, did you have a chance to read through that before today?

- What were your first impressions of the protocol?
- How much understanding of Morita Therapy itself were you able to gain from the protocol?
    - Do you have any comments about the approach itself?
- Generally, how much understanding did you feel you were able to gain in terms of how Morita Therapy should be delivered by a therapist?
    - In what ways would you need more guidance as a therapist?
    - Did you feel there were any gaps or lack of detail in any particular areas?
    - Was there anything in that didn't make sense or you found confusing?
- How user-friendly do you think the protocol is?
    - What are your thoughts on the overall structure, like the order of the sections?
    - How easy or difficult do you think it would be to use and navigate through the protocol in practice whilst seeing patients?
- How does the protocol compare to something you may use for a different therapy?
    - Are there any ways in which those manuals were more helpful or easier to understand?
- In terms of the phases of treatment, how operationalisable do you think these are?
    - Is it clear when to move from one phase to the next?
- Is there anything that stands out as being an area to pay particular attention to during therapist training or as suggestions for additional reading?
- Do you have any other suggestions for improving the protocol?
- Is there anything else that you would like to add?

FINISH

Finally, are there any other comments that you would like to make about taking part?

Thank you.

Stop recording and tell them that the recorder has been switched off.

Appendix III: Published paper from the intervention optimisation study

METHODOLOGY   **Open Access**

Optimising the acceptability and feasibility of novel complex interventions: an iterative, person-based approach to developing the UK Morita therapy outpatient protocol

Holly Victoria Rose Sugg[*], David A. Richards and Julia Frost

Abstract

Background: The aim of this paper is to showcase best practice in intervention development by illustrating a systematic, iterative, person-based approach to optimising intervention acceptability and feasibility, as applied to the cross-cultural adaptation of Morita therapy for depression and anxiety.

Methods: We developed the UK Morita therapy outpatient protocol over four stages integrating literature synthesis and qualitative research. Firstly, we conducted in-depth interviews combining qualitative and cognitive interviewing techniques, utilising vignettes of Morita therapy being delivered and analysed using Framework analysis to investigate potential patients and therapists' perceptions of Morita therapy. Secondly, we developed qualitative themes into recommendations for optimising Morita therapy and synthesised Morita therapy literature in line with these to develop a draft protocol. Thirdly, we conducted repeat interviews with therapists to investigate their views of the protocol. Finally, we responded to these qualitative themes through protocol modification and tailoring our therapist training programme.

Results: As a consequence of literature describing Morita therapy and participants' perceptions of the approach, we developed both a therapy protocol and therapist training programme which were fit for purpose in proceeding to a UK-based Morita therapy feasibility study. As per our key qualitative findings and resulting recommendations, we structured our protocol according to the four-phased model of Morita therapy, included detailed guidance and warning points, and supported therapists in managing patients' expectations of the approach.

Conclusions: Our systematic approach towards optimising intervention acceptability and feasibility prioritises the perspectives of those who will deliver and receive the intervention. Thus, we both showcase best practice in intervention development and demonstrate the application of this process to the careful cross-cultural adaptation of an intervention in which balancing both optimisation of and adherence to the approach are key. This presentation of a generalisable process in a transparent and replicable manner will be of interest to those both developing and evaluating complex interventions in the future.

Keywords: Intervention development, Qualitative research, Person-based approach, Morita therapy, Feasibility study, Depression, Mental health, Protocol

* Correspondence: h.v.s.sugg@exeter.ac.uk
Complex Interventions Research Group, University of Exeter Medical School,
University of Exeter, Room 1.33 South Cloisters, St Luke's Campus, Exeter EX1
2LU, UK

APPENDIX III

Sugg et al. Pilot and Feasibility Studies (2017) 3:37

Page 2 of 11

Background

Clinical depression and generalised anxiety disorder (GAD) are the two most common mental health disorders [1], with one in six people in the UK experiencing such a disorder each year [2]. Many patients are refractory to available interventions [3] such as medication and cognitive behavioural therapy (CBT), with depression and anxiety remaining chronic disorders [1]. Thus, it is important to develop and test new treatments in order to treat a wider range of patients [4] and provide patients with choice alternatives.

Morita therapy

Morita therapy [5] was developed in Japan in 1919 and originally used in inpatient settings for particular psychological problems, including GAD [6]. The approach is now applied in a variety of ways to a wide range of conditions, including depression, and practiced in countries including North America, Australia, China, Russia and Rwanda [6].

Morita therapy is a holistic approach aiming to improve everyday functioning rather than targeting specific symptoms [6]. Through conceptualising unpleasant emotions as part of the natural ecology of human experience, Morita therapy seeks to re-orientate patients in the natural world and potentiate their natural healing capacity. Morita therapists help patients to move away from symptom preoccupation and combat, which are considered to exacerbate symptoms and interfere with this natural recovery process [7]. By helping patients to accept symptoms as natural features of human emotion which ebb and flow as a matter of course, Morita therapy is in sharp contrast to the focus of established western approaches on symptom reduction and control. In Morita therapy, patients are taught to live with, rather than be without, unpleasant emotions.

Morita therapy in the UK: the need for an intervention development process

Morita therapy is little known in the UK: neither empirical investigation nor research exploring stakeholders' views has been undertaken with this population. In line with the Medical Research Council framework for the development and evaluation of complex interventions [8], the authors are currently undertaking a Morita therapy feasibility study to begin such investigations [9]. However, in the absence of research exploring the cross-cultural transferability of Morita therapy, and in the context of multiple possible methods of operationalisation, prior to such a trial, an intervention development process was required to design a comprehensive UK Morita therapy outpatient protocol.

The purpose of this paper is to illustrate an in-depth, iterative, qualitative approach to intervention development, demonstrating best practice in applying the Medical Research Council framework for developing interventions [8] and reflecting the 'person-based approach' [10] to optimising intervention acceptability and feasibility prior to a full feasibility study, as applied to the UK Morita therapy outpatient protocol. By alternating and integrating literature synthesis and qualitative research in the cross-cultural adaptation of Morita therapy, our approach prioritises the perspectives of those who will deliver and receive the intervention, whilst ensuring adherence to its core features. This process was essential to proceeding to the feasibility study with a treatment which is both true to the essence of Morita therapy and appropriate, accessible, understandable and deliverable for the target population, particularly in the context of the aforementioned contrast between Morita therapy and established western approaches.

Study objective

To develop a deliverable and acceptable Morita therapy outpatient protocol for a UK clinical population.

Research questions

1. Stage one: What are the views and understandings of potential patients and therapists about Morita therapy?
2. Stage two: What can the English-language literature on Morita therapy contribute to the development of an optimal draft protocol?
3. Stage three: What are therapists' views of Morita therapy, focusing on operationalisability and the accessibility of the draft protocol?
4. Stage four: How should the protocol be optimised and on what should a therapist training programme focus?

Methods/design

Study design

Corresponding to the person-based approach's intervention development phase [10], we developed the protocol over four stages combining exploratory and explanatory components. Stage one involved in-depth exploratory interviews combining qualitative and cognitive interviewing [11] to investigate participants' views and understandings of Morita therapy. In stage two, we developed qualitative themes into recommendations for optimising Morita therapy and synthesised Morita therapy literature in line with these to develop a draft protocol. Stage three involved repeat in-depth explanatory interviews with therapists, to investigate how they related to the intervention content and protocol format. In stage four, we responded to these qualitative themes through protocol modification and tailoring the focus of our therapist training programme.

381

APPENDIX III

Sugg et al. Pilot and Feasibility Studies (2017) 3:37

Page 3 of 11

Assumptions

We adopted pragmatism as the underlying research paradigm: we approached our study objective from a pluralistic perspective, combined deductive and inductive modes of reasoning, and allowed for a singular view and multiple views of reality in interpreting our findings [12].

Qualitative interviews: participants and recruitment

To reflect the feasibility study's proposed population [9] and account for factors deemed potentially relevant in forming views of Morita therapy [10], we purposively sampled participants aged ≥ 18 with self-reported experience of depression, whether current or historic, and a range of previous therapy experience (potential patient sub-group) and therapists trained in complex psychological interventions such as CBT (therapist sub-group).

We recruited potential patients by email circulation to our research centre's former participants who had consented to such contact and therapists by email circulation to current or former therapists in our centre.

Procedure

Interviews were held at University of Exeter premises or the participant's home and lasted between 45 and 130 min. Interviews combined qualitative techniques with those of cognitive interviewing [11], a method widely used when seeking an understanding of the cognitive processes involved in task completion [13] and recommended to capture participants' immediate reactions to each intervention element [14].

Stage one Interviews explored perceptions of Morita therapy in principle and practice. Prior to interview, we emailed participants a written summary of core Morita therapy principles on which to provide feedback. In line with prior research investigating novel interventions [15, 16], we then employed the vignette method to elicit views and understandings of the approach in practice, playing five audio-recording clips of the counselling-based modal model ranging from 3 to 5 min and each capturing a core element of the approach. We employed a variation of the think aloud technique [11], inviting participants to voice their thoughts during or after each vignette, according to their preference. At the end of each vignette, we used the open question 'what are your thoughts on that?' to allow flexibility and enable us to capture spontaneous responses [14].

Our topic guide was based on Morita therapy literature, the vignettes' content and prior research addressing similar questions [16]. We included focussed questions to ensure discussion of each intervention element [14] as well as probing further into individual responses to investigate meanings, both exploring views on our pre-defined topics of interest and eliciting participants' own themes [17]. Furthermore, we engaged in hypothesis testing as deemed appropriate, exploring the value of alternative explanations of concepts when misunderstanding of the vignettes was indicated.

Qualitative data analysis Interviews were recorded, transcribed verbatim, managed within NVivo10 [18] and analysed using Framework analysis to allow for both inductive and deductive approaches [19], a method suitable for both data collected via cognitive interviewing [20] and health services research [21].

We used a combination of two approaches, namely Framework analysis and constant comparative analysis to analyse the data. Familiarisation with the data was achieved through producing and reading transcripts. We developed a thematic framework during preliminary analysis and subsequently as batches of transcripts were analysed, iteratively combining our topic guide with the overall narratives in context. Using this framework, we coded transcripts at the individual level and analysed them thematically across the whole dataset as well as in the context of each interview using a constant comparison approach [22], whereby each piece of data (e.g. one statement or theme) was compared with others for similarities and differences [23]. We thus formulated explanations, explored negative cases and provided explanations of variance [24]; ensuring perspectives which diverged from dominant themes were not overlooked [25]. To identify any sub-group differences, we undertook stage one analysis for potential patients first and subsequently for therapists. Given the resulting convergence of views within similar thematic frameworks, we developed analytic matrices [23] including all participants, allowing within and across case analyses, the exploration of relationships between themes and further refinement of themes through author discussions.

Stage two In developing the draft protocol, we reviewed the English-language literature on the practice of Morita therapy to guide us in implementing the approach, most notably, Morita et al. 1998 [5]; Ogawa 2013 [6]; Nakamura et al. 2010 [7]; Ishiyama 2011 [26]; Ogawa 2007 [27]; LeVine 1993 [28]; LeVine, in press [29]; and personal communications: Minami, M. Through this process, we ensured adherence to the fundamental, defining features of Morita therapy (Table 1), considered akin to 'guiding principles' [14] which were essential to include in our protocol and formed the basis of the intervention.

In response to our stage one findings, we also developed recommendations for optimising elements of Morita therapy for which multiple options were available in the literature and selected from the literature the delivery options considered most likely to address the

Table 1 Key principles and practices of Morita therapy

	Term	Definition
Key principles	Natural world	Morita therapy conceptualises unpleasant thoughts and emotions as part of the natural ecology of the human experience. It draws upon the natural world, the place of humans within it, to emphasise that symptoms are not subject to the patient's control and will naturally pass with time.
	Acceptance and allowance	All emotions and thoughts are accepted as they are. Attempts to control or resist symptoms are considered to exacerbate them; therapists thus help patients to move away from symptom preoccupation and combat and towards acceptance and a focus on action. Thus, the objectives of therapy are to shift attention and perspective, rather than controlling or 'fixing' symptoms.
	Rest	Morita therapy seeks to potentiate patients' natural healing capacities, in contrast to resisting and exacerbating symptoms. Patients sit with their thoughts and emotions as they are, to learn how they naturally ebb and flow with time if attempts to control or remove them are not made and to build a natural desire to take action.
	Action-taking with symptoms	Patients learn to undertake purposeful and necessary action, with or without their symptoms. Morita therapy thus aims to improve everyday functioning in spite of symptoms, with symptoms reducing as a by-product of moving from a mood-oriented to a purpose-oriented and action-based lifestyle.
Key practices	Positive reinterpretation technique	Therapists 'positively reinterpret' symptoms as desires by seeing these as two sides of the same coin. For example, in Morita therapy, social anxiety represents a desire to be accepted by others. This technique aids acceptance of symptoms as natural and inevitable.
	Normalisation technique	Therapists label thoughts and emotions as 'unpleasant' and 'pleasant' but not 'good' or 'bad'. They emphasise that all emotions are natural, or normal, and will ebb and flow on their own so long as attempts are not made to control or resist them.
	Fumon (inattention to symptoms)	Therapists, in an effort to shift patients' attention away from symptom preoccupation and combat, will not focus on discussion or analysis of patients' symptoms or their causes but rather will 'steer' the conversation towards action-taking and the external environment.
	Diaries	Patients complete daily diaries on which therapists provide comments which facilitate an acceptance of internal states and refocus attention on action and the external environment.
	Four-phased model	In traditional inpatient Morita therapy, rest and action-taking are structured within four phases: (1) complete bed rest; (2) light repetitive activities; (3) more challenging activities; and (4) social reintegration. The process is understood to aid experiential acceptance of the natural ebb and flow of thoughts and emotions, to re-orientate patients in nature and to refocus attention from internal to external states.

issues raised. In addition, we included in the protocol specific stage one interview findings to address concerns and confusions, stress potentially valuable features and guide therapists in applying techniques.

Stage three To review the draft protocol, we repeated interviews with the therapists from stage one, to enable them to reflect on the development of the approach and how well the protocol addressed their previous issues, plus an additional therapist recruited in the manner described, to capture the views of a therapist naïve to Morita therapy. Having emailed the protocol to therapists to read prior to their interview, we discussed their thoughts on the protocol and, to elicit views on all components, reviewed each protocol section in turn. Our topic guide was based on the draft protocol and stage one findings, with a focus on the extent of understanding obtained from the protocol, operationalising the therapy, protocol usability and accessibility, and areas on which to focus training.

Stage four In amending the protocol in response to stage three, we re-referred to the Morita therapy

literature to seek further guidance and ensure changes were grounded in the treatment's fundamental features. Stage three findings also enabled us to tailor our therapist training programme by highlighting key issues and content to focus on.

Results

We interviewed ten potential patients. All reported experience of depression; six had experience of psychotherapy and four did not (Table 2). The majority were female ($n = 8$, 80%); ages ranged from 22 to 63 years. We interviewed four therapists in stage one and five in stage three. All were trained in CBT and a mixture of other treatments such as behavioural activation; ages ranged from 43 to 63 years.

Stage one

Participants' perspectives could be understood within three key themes: translating principles into practice, respecting the individual and shifting the understanding framework. Each key theme encompassed a number of constituent themes (Fig. 1: stage one themes and constituent themes).

Table 2 Participant characteristics

Characteristics	Potential patients (n = 10)		Therapists (stage 1) (n = 4)		Therapists (stage 3) (n = 5)	
	n	%	n	%	n	%
Sex						
Male	2	20	2	50	2	40
Female	8	80	2	50	3	60
Age (in years)						
18–30	2	20	0	0	0	0
30–50	4	40	2	50	3	60
50–70	4	40	2	50	2	40
Nationality						
British	10	100	4	100	5	100
Highest level of education						
< A-levels	1	10	0	0	0	0
A-levels	2	20	0	0	0	0
University degree	5	50	1	25	1	20
Post-graduate diploma	0		1	25	2	40
Post-graduate degree	1	10	1	25	1	20
Doctoral degree	1	10	1	25	1	20
Mental health problem						
Depression	10	100	N/A		N/A	
Anxiety	8	80	N/A		N/A	
Previous therapy experience						
None	4	40	N/A		N/A	
Cognitive behavioural therapy	4	40	N/A		N/A	
Mindfulness-based cognitive therapy	3	30	N/A		N/A	
Behavioural activation	1	10	N/A		N/A	
Interpersonal psychotherapy	1	10	N/A		N/A	
Area(s) of clinical training						
Cognitive behavioural therapy	N/A		4	100	5	100
Behavioural activation	N/A		4	100	4	80
Eye movement desensitisation and reprocessing	N/A		1	25	2	40
Interpersonal psychotherapy	N/A		1	25	1	20
Dialectical behaviour therapy	N/A		1	25	1	20

N/A not applicable

In accordance with the objective of this paper to demonstrate the development of our protocol rather than presenting qualitative findings, we provide an exemplar of coded data for theme 1 (Table 3) to illustrate our analytical process, as opposed to including participant data for each theme.

Translating principles into practice illustrates participants' responses to the written therapy principles and how these relate to the practice of therapy as demonstrated within the vignettes.

Generally, the principles of Morita therapy resonated positively. However, there was a lack of apparent translation of these into the vignettes and a sense of unmet expectations in practice. Of particular note was an absence of reference to the natural world and confusion caused by the presentation of 'rest'. This perpetuated a lack of clarity regarding the purpose of rest and the treatment overall. Participants also demonstrated misunderstanding of messages conveyed in the vignettes, especially 'positive reinterpretation' (Table 1), indicating a need for increased clarity and specificity. Participants, whilst acknowledging the value of features such as diaries, rest and action-taking, also noted challenges around committing to these in practice.

Respecting the individual illustrates the extent to which Morita therapy was considered to be a well explained, individualised and collaborative approach.

The therapy process and intended outcomes were not considered clear from the vignettes, with mixed views on the acceptability of this: those with therapy experience generally expressed a need for full disclosure of rationale. Participants also expressed preferences for increased collaboration, such as seeking patient feedback, and more in-depth and personalised exploration and explanation of patients' individual experiences and difficulties, particularly in relation to the normalisation technique (Table 1).

Shifting the understanding framework reflects how distinctive Morita therapy was considered to be and the extent to which it met participants' expectations of effective therapy.

Overall, therapists acknowledged Morita therapy as a novel approach with a distinctive philosophical framework. Potential patients were less likely to note this, tending to interpret Morita therapy through the lens of other treatments and attempting to 'fit' the approach to those, generating some inaccurate assumptions. Potential patients also expressed tension between accepting unpleasant emotions, as per the premise of Morita therapy, and seeking techniques to change them. Thus, despite positive views of the holistic approach towards living well *with* symptoms, participants struggled to adopt this approach in considering the value of the overall therapy. Potential patients (especially those with therapy experience) focused more narrowly on mood-orientated goals, interpreting the features of therapy only as possible means of achieving the end of symptom reduction. However, therapists and treatment naïve potential patients often valued how the therapy provided insight, shifted attention, and potentially changed one's relationship to emotions without changing emotions themselves.

In summary

Our findings indicated that the core Morita therapy features were largely acceptable to participants, albeit
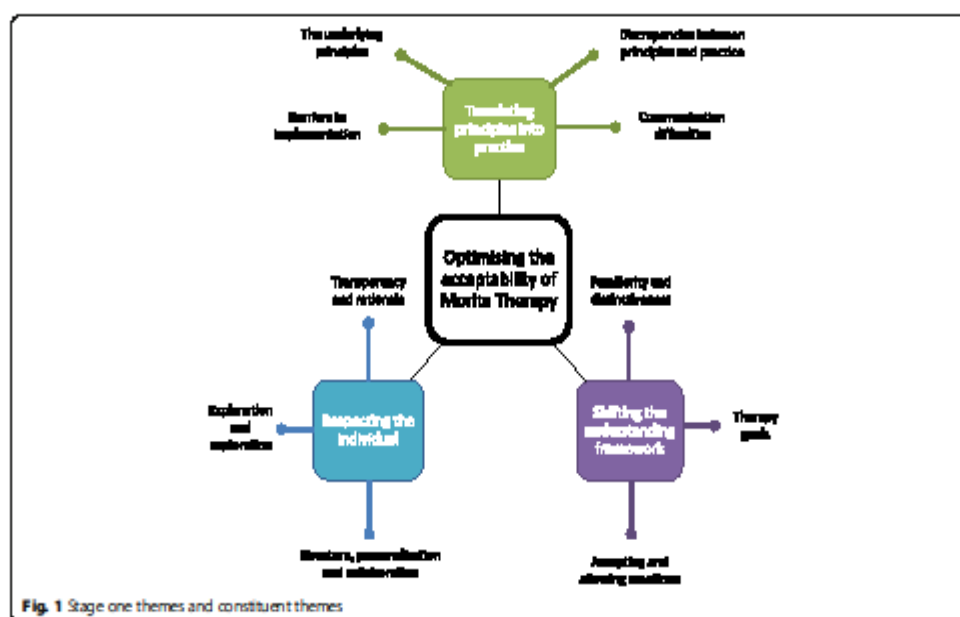
Fig. 1 Stage one themes and constituent themes

with potential for improvement in how these are conveyed and structured in order to enhance the relevance, comprehensibility and appeal of the approach.

Stage two

The Morita therapy literature demonstrated a range of potential methods for implementing, communicating and structuring the key features of Morita therapy, which were thus open to tailoring to the target population. Overall, the delivery options fall along a spectrum (personal communications: Minami, M) from prescriptive inpatient settings adhering to a four-phased experiential structure [5] to exploratory outpatient counselling methods with no such structure, such as the active counselling method [26] and modal model (personal communications: Minami, M), which apply and extend the guidelines for outpatient Morita therapy [7].

In selecting from these options during the development of our therapy protocol, we shifted our approach along the spectrum of treatment modes from the counselling-based method alone (as presented in the vignettes) towards the traditional experiential four-phased approach (Table 1). This addressed our stage one findings by strengthening the core components and overarching structure of the approach, reinforcing the process and purpose of therapy, and balancing otherwise somewhat paradoxical features such as rest and action-taking within a clearly defined structure.

To address the challenges highlighted by participants in relation to completing diaries and rest, we stressed the need for an individualised, flexible and reassuring approach to identifying patients' concerns and capabilities. As indicated necessary by our qualitative results, we stressed the importance of delivering therapy in a personalised, collaborative and well explained manner. We provided clear guidance and warning points on implementing techniques such as positive reinterpretation and normalisation, to address the misunderstandings and concerns raised.

One key qualitative message was that care would be required in explaining the purpose of therapy and managing the ways in which it may differ from patients' preconceptions and prior experiences. Thus, one protocol inclusion is a managing patients' expectations section, intended to facilitate a shift in patients' understanding frameworks from the beginning of treatment, and ensure provision of the desired level of transparency and rationale.

We have selected the rest phase to illustrate how we developed the protocol (Table 4) and Additional file 1 provides further details of the ways in which our qualitative themes were refined into recommendations and subsequently informed our protocol development.

Stage three

Therapists' perspectives in the context of the draft protocol could be understood within two key themes: addressing insecurities and enhancing operationalisability and accessibility. Each key theme encompassed a number

385

Table 3 Exemplar of coded data: stage one theme one (translating principles into practice)

Constituent theme and elements	Participant responses
The underlying principles	
Learning to live with symptoms	'I like that it's about acceptance and accepting um the bad feelings you have rather than um fighting them all the time...yeah sort of living in spite of rather than trying to get rid of um, because it doesn't work...it's realistic.' (Grace, potential patient)
Connecting to the natural world	'That greater sense of being one with it all... I think that's a very positive thing because it diffuses one's own emotion...it puts what you are going through in context and that's what this seemed to me in a way, um rather than being the centre of our universe as it were, we are part of it.' (Claire, potential patient)
Viewing all emotions as natural phenomena	'It's a compassionate way of looking at yourself and what you've experienced as opposed to you shouldn't be feeling like this.' (Nicola, potential patient)
The vicious cycle of symptom aggravation	'It does get into a cycle...you always tend to lean towards the, it, it almost feels easier to feel sad...and you do generally go over and over and over the unpleasant things.' (Sarah, potential patient)
Rest	'Giving yourself a bit of space...healing space, because I don't always think there's that in other kinds of therapies, there's not that kind of re-charging space, um yeah, that's nice.' (Grace, potential patient)
Discrepancies between principles and practice	
Connection to the natural world	'I liked the nature thing, but I didn't hear that brought in.' (Beth, potential patient)
Rest	'I suppose what I construed from what I read is it's more like actually if you don't feel able then rest should be the mainstay of what you're doing, rather than an hour in your day or a few minutes in your marathon...so I, yeah, I guess I feel kind of slightly less clear about the use of that sort of natural healing.' (Hayley, therapist)
Resulting confusion	'I don't think that that [vignettes] matched this [summary of principles] at all, um really, so I'm going away from this...still wondering what Morita Therapy is.' (Estelle, potential patient)
Communication difficulties	
Confusion in positive reinterpretation	'My question to him would be if they're flip sides then are they equal, so am I supposed to be worrying and enjoying something equal at the same time because I would disagree with that...I would say most of the time you should be looking at the positive and focusing on that...not you should be half worrying and half doing this' (Beth, potential patient)
	'I remember somebody saying to me once nothing is either good or bad, it's the way we react to it....somebody could get that impression...What I was going through with my parents...I'd be very interested to see how anybody could reframe for me in an acceptable way.' (Claire, potential patient)
Barriers to implementation	
Diaries	'I've always struggled with er sort of self-reflection in terms of writing... I think sometimes if it's been a bad day, it kind of just all comes out and then I read it the next day and I just, it just looks like a load of rubbish... That's, that's the one thing that puts me off about doing it.' (Mark, potential patient)
Action-taking	'I find my depression and anxiety um quite paralysing, so saying about be anxious but get on with doing something, I find that I can't' (David, potential patient)
Rest	'Actually just saying hey just rest, I don't find that very helpful because I need some order and structure and I think okay if I'm gonna rest at this point, who's gonna clean the fish tank out, who's gonna cook dinner, what do I do.' (Sarah, potential patient)
Balancing action-taking and rest	'Um dealing a little bit with this like paradox with action and also inaction, which is new... What are the parameters of rest, how is it structured...I'd like a little bit more structure around once you got to action.' (Paul, therapist)

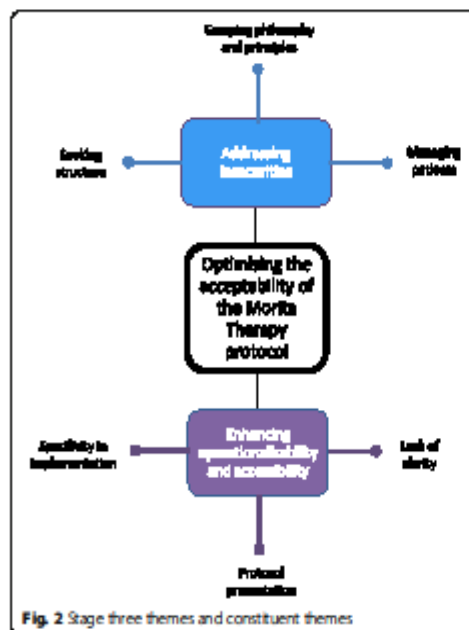Note: Names changed to pseudonyms to protect confidentiality

of constituent themes (Fig. 2: stage three themes and constituent themes).

Addressing insecurities illustrates the concerns therapists expressed around orientating to and delivering therapy.

Therapists noted that the protocol provided much understanding and addressed many issues previously raised. However, considering the approach novel and only deliverable from a thorough grounding in the principles, they demonstrated a lack of confidence and noted the need to emphasise key principles to adhere to. They sought to simplify the approach, understand it in terms of more familiar therapies and, despite acknowledgement of the potential incompatibility with Morita therapy, enhance its structure through clearly defined timeframes and content outlines for each therapy session.

Although acknowledging the usefulness of the guidance on managing expectations, therapists expressed trepidation around this, stressing the importance of role playing during

Fig. 2 Stage three themes and constituent themes

and areas in which they felt more guidance, clarity or specificity was required.

Overall, therapists considered the protocol thorough, understandable and user-friendly. However, further clarity was required, especially in balancing features such as direction with collaboration, and Fumon (inattention to symptoms, Table 1) with empathy. Therapists appreciated the current inclusion of stage one interview findings and desired more verbatim clinical illustrations to guide them in implementing techniques, choosing appropriate activities and commenting on diaries. Noting the subtlety of the indicators of therapeutic progress, therapists suggested value in delineating these clearly in line with treatment objectives and illustrative examples.

Therapists queried whether they should use Japanese terms, desired a glossary of these, and noted the lack of explicit specification of the number and spacing of therapy sessions. Furthermore, they considered the protocol somewhat difficult to digest, indicating the value of additional summaries and crib sheets, and of further compartmentalisation through bullet points and highlighting of key interview findings.

Summary

Our findings indicated that the protocol required improvements in format to enhance ease of use; additional guidance, specificity or clarity to address the issues raised.

Stage four

To optimise the protocol in response to our stage three findings, we added verbatim illustrations where available from the literature and, to provide precision in assessing indicators of progress, re-structured the protocol to link these explicitly to key objectives and examples. To adhere to Morita therapy practice, we did not provide session content outlines and clarified that all patients

training, seeking examples of managing typical patient responses and desiring a pre-treatment patient summary sheet. Therapists often noted concerns around implementing rest and doubts as to the rationale for this. Accordingly, they desired more clearly defined instructions for instigating rest and flexibility around engagement with rest dependent on patient presentation and preference.

Enhancing operationalisability and accessibility illustrates therapists' suggestions for improving protocol presentation

Table 4 Exemplar of therapy protocol development: stage two (the rest phase)

Stage two: development of the draft protocol	We developed each of the four phases of Morita therapy into separate sections following our decision, on the basis of our qualitative findings, to structure the therapy according to this model
	To produce the rest phase section, we amalgamated the Morita therapy literature on engaging in rest to provide an overview and general guidance for preparing patients for rest (personal communications: Minami, M), specific instructions for developing an appropriate schedule and environment for rest ([5, 7, 27, 28, 30]; personal communications: Minami, M) and guidance on the indicators of progress during rest (personal communications Minami, M)
	In incorporating our qualitative findings, we included potential patients' feedback on their fears of and barriers to rest
	To guide therapists in addressing such issues, we provided guidance on stressing the importance of and rationale for rest, drawing on physical health and natural metaphors in explaining rest, and exploring and tackling feelings of guilt around taking rest, as suggested valuable from our qualitative themes
	In order to address the misinterpretations of the meaning and nature of rest encountered in our interviews, we provided warning points for these potential misinterpretations as well as clear guidance on managing patients' expectations of the purpose and likely experience of rest
	We included specific instructions for the conditions for taking rest to further assuage doubts around the meaning of rest in Morita therapy

APPENDIX III

Sugg et al. Pilot and Feasibility Studies (2017) 3:37

Page 9 of 11

should partake in rest. We added guidance on balancing direction with collaboration, specified the number and spacing of therapy sessions, added a glossary of Japanese terms noting no requirement to use these during treatment and clarified the types of/conditions for patient activities.

In amending the protocol presentation, we added summaries and concise guidance; deconstructed guidance into bullet points and tables; delineated key features, tips, techniques and warning points in boxes; and incorporated colour and bold text to enhance accessibility. We developed one-page summary sheets to simplify key concepts, techniques and phases of treatment alongside their purpose, conditions and indicators of progress. We developed a pre-treatment patient handout, to begin expectation management at the earliest opportunity.

We have illustrated our continued development of the therapy protocol using the rest phase section (Table 5).

In tailoring our therapist training programme, we maintained a focus on grounding in the key principles to enhance therapists' confidence. We focused role plays on implementing and balancing therapeutic techniques, managing patient expectations and responses, delivering rationale, guiding patients through treatment phases and identifying suitable and personalised activities for patients. In the absence of diary illustrations in the literature, we incorporated commenting on mock diaries and discussions around key principles to adhere to in doing so.

Discussion

The overall aim of this paper is to showcase best practice in intervention development through describing a systematic, iterative, person-based approach to optimising intervention feasibility and acceptability, illustrated by its application to the development of the UK Morita therapy outpatient protocol. We have presented examples of how qualitative findings were integrated with Morita therapy literature in order to sensitively adapt the intervention across cultures whilst carefully ensuring adherence to its fundamental features.

Our first stage utilised in-depth exploratory qualitative interviews, drawing on techniques of cognitive interviewing [11] and vignettes of therapy delivery in order to explore potential patients' and therapists' perspectives of Morita therapy in principle and practice. Our findings demonstrated that the core features were acceptable for participants whilst highlighting the potential for improvement in their implementation, for which scope for tailoring the approach was available. Secondly, we synthesised the Morita therapy literature whilst accounting for and incorporating our qualitative findings and resulting recommendations for optimising the intervention.

Our third stage utilised in-depth explanatory repeat qualitative interviews with therapists, aided by the draft protocol itself, to investigate responses to the resulting intervention content, reflect on the intervention development and explore views on protocol presentation. Our findings indicated that the draft protocol addressed many of the issues previously raised, providing comprehensive and understandable guidance, whilst highlighting requirements for further guidance and improved accessibility. Finally, we re-examined the Morita therapy literature to assist us in addressing these issues, improving the protocol presentation and tailoring the focus of our therapist training programme. As such, we developed a therapy protocol and training programme which were fit for purpose in proceeding to a UK-based Morita therapy feasibility study.

Table 5 Exemplar of therapy protocol development: stage four (the rest phase)

Stage four: modification of the draft protocol	• We edited the rest phase section to ensure the guidance was concise and increase the use of bullet points
	• We deconstructed key features of rest (analogies to physical health, tackling guilt), tips for explaining rest (using metaphors to describe the rationale, experience and nature of rest), techniques for preparing for rest (silent sitting) and warning points (e.g. potential misinterpretations of the meaning of rest) into boxes of different colour to aid ease of use
	• We delineated the indicators of progress in a table relating each to a conceptual objective, means of assessment and verbatim examples of patients demonstrating the indicator as identified from a further review of the literature (personal communications: Minami, M)
	• We developed a summary sheet for negotiating and engaging in the rest phase (guidelines, purposes and indicators of progress) to provide simplified and accessible key guidance to refer to during a therapy session
	• The pre-treatment patient handout was made suitable to be provided to patients' significant others when embarking on the rest phase, to provide additional support for patients during this phase and thus ease therapists' concerns in this area
	• As well as clarifying the instructions to provide to patients entering the rest phase, we clarified that all patients, regardless of presentation, should engage in as much rest as possible, in order to address confusion around assessing this and stress that, in the event of patients' reluctance to engage in rest, reiterating the importance of and rationale for rest should be prioritised over missing this phase
	• Thus, whilst acknowledging and addressing the challenges of the rest phase for both patients and therapists, we adhered to the literature which deems rest, or at least silent sitting, fundamental to Morita therapy [5, 7, 28]

APPENDIX III

Limitations

HVRS, who conducted all interviews, was also involved in the protocol development process. Thus, particularly in the repeat interviews, although questions were posed to deliberately elicit negative views, participants may have been reluctant to express criticism of the draft protocol. However, participants did freely indicate ways in which the protocol was currently confusing, insufficient or inaccessible. In addition, in the absence of vignettes demonstrating a variety of treatment models, we were unable to elicit participants' views on all available options so as to elect a favoured approach and instead used their feedback on the modal model to guide us in positioning our version of therapy along the available spectrum. Furthermore, although our sample was diverse in age, gender and therapy experience and may well represent those most likely to be interested in receiving Morita therapy, certain sectors of the UK population such as ethnic minority groups were clearly underrepresented.

Conclusions

This process has enabled us to proceed to the feasibility study [9] with a therapy protocol which, whilst adhering to the essence of Morita therapy, has enhanced acceptability and feasibility for a UK population, thus maximising the likelihood of a successful outcome in this study [10]. During the feasibility study we are continuing our assessment of intervention acceptability through post-treatment qualitative interviews and a mixed method analysis exploring the relationship between participants' views, therapist fidelity to the protocol and patient adherence to treatment. Further intervention modifications may well be suggested by such findings, enabling us to continue this iterative process of optimising the approach for a UK population in preparing for the first large-scale evaluation of Morita therapy in the UK.

We showcase best practice in intervention development by transparently illustrating a systematic approach which prioritises the perspectives of those who will both deliver and receive the intervention and integrates user feedback with literature synthesis in an iterative, thorough and replicable design. In line with the person-based approach to enhancing the acceptability and feasibility of interventions, we have thus grounded our development process in 'a sensitive awareness of the perspective and lives of the people who will use [it]' ([10] p.1), utilising both written materials and vignettes of therapy delivery in order to elicit views on every intervention element and repeating interviews to check acceptability and accessibility. Without undertaking this study, we would not have understood the expectations, understandings and needs of stakeholders and the ways in which these may shape their delivery of and engagement with the intervention. Whilst this was key in the specific cross-cultural adaptation of a novel intervention, we present a generalisable approach to optimising interventions which is likely to be relevant and interesting to others in both the development and evaluation of complex interventions.

References

1. Andrews G, Sanderson K, Slade T, Issakidis C. Why does the burden of disease persist? Relating the burden of anxiety and depression to effectiveness of treatment. Bull World Health Organ. 2000;78:446–54.
2. Mental Health Foundation. https://www.mentalhealth.org.uk/sites/default/files/fundamental-facts-about-mental-health-2016.pdf. Accessed 22 Dec 2014.
3. Rush AJ, Fava M, Wisniewski SR, Lavori PW, Trivedi MH, Sackeim HA, et al. Sequenced treatment alternatives to relieve depression (STAR*D): rationale and design. Control Clin Trials. 2004;25:119–42.
4. Hollon SD, Munoz RF, Barlow DH, Beardslee WR, Bell CC, Bernal G, et al. Psychosocial intervention development for the prevention and treatment of depression: promoting innovation and increasing access. Biol Psychiatry. 2002;52:610–30.
5. Morita M, Kondo A, LeVine P. Morita therapy and the true nature of anxiety-based disorders. New York: State University of New York Press; 1998.
6. Ogawa B. Desire for life: the practitioner's introduction to Morita therapy for the treatment of anxiety disorders. Indiana: XLibris Publ; 2013.
7. Nakamura K, Kitanishi K, Maruyama S, Ishiyama FI, Ito K, Tatematsu K, et al. Guidelines for practising outpatient morita therapy. Japanese Society for Morita Therapy. Tokyo; 2010.
8. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J 2008;337:979–83.
9. Sugg HV, Richards DA, Frost J. Morita therapy for depression and anxiety (Morita trial): study protocol for a pilot randomised controlled trial. Trials. 2016;17(1):1.
10. Yardley L, Ainsworth B, Arden-Close E, Muller I. The person-based approach to enhancing the acceptability and feasibility of interventions. Pilot Feasibility Stud. 2015;1(1):1.
11. Willis GB. Cognitive interviewing: a "how to" guide. Meeting of the American Statistical Association; 1999.
12. Borglin G. The value of mixed methods for researching complex interventions. In: Richards DA, Hallberg IR, editors. Complex interventions in health: an overview of research methods. Oxon: Routledge; 2015. p. 29–45.
13. Zhelev Z, Garside R, Hyde C. A qualitative study into the difficulties experienced by healthcare decision makers when reading a Cochrane diagnostic test accuracy review. Syst Rev. 2013;2:32.
14. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: Application to digital health-related behavior change interventions. J Med Internet Res. 2015;17(1):e30. doi:10.2196/jmir.4055.
15. Johnson M, Newton P, Jiwa M, Goyder E. Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. Health Expect. 2005;8:324–33.
16. Richards DA, Lankshear AJ, Fletcher J, Rogers A, Barkham M, Bower P, Gask L, Gilbody S, Lovell K. Developing a U.K. protocol for collaborative care: a qualitative study. Gen Hosp Psychiatry. 2006;28:296–305.
17. Taylor M. Interviewing. In: Holloway I, editor. Qualitative research in health care. Maidenhead: Open University Press; 2011. p. 29–55.
18. QSR International: NVivo 10 for windows. www.qsrinternational.com/products_nvivo.aspx. Accessed 14 June 2016.
19. Ritchie J, Spencer L, O'Connor W. Qualitative research practice: a guide for social science students and researchers. London: Sage; 2003.
20. Collins D. Cognitive interviewing practice. London, California, New Delhi, Singapore SAGE Publications; 2014.
21. Green J, Thorogood N. Qualitative methods for health research. 2nd ed. London, California, New Delhi, Singapore: Sage; 2009.
22. Thorne S. Data analysis in qualitative research. Evid Based Nurs. 2000;3:68–70.
23. Miles MB, Huberman AM. Qualitative data analysis: an expanded sourcebook. London: Sage; 1994.
24. Dingwall R, Murphy E, Watson P, Greatbatch D, Parker S. Catching goldfish: quality in qualitative research. J Health Serv Res Policy. 1998;3(3):167–72.
25. Yardley L. Demonstrating validity in qualitative psychology. In: Smith JA, editor. Qualitative psychology. 2nd ed. London: Sage; 2008.
26. Ishiyama I. Introduction to Morita therapy. Paper presented at the In Holstebroand Vejle (HOLD FAST) Denmark 2011. http://vholderfast.nu/wp-content/uploads/2011/06/Slides-fra-kursus-i-Morita-terapi.pdf. Accessed 14 June 2016.
27. Ogawa B. A river to live by: the 12 life principles of Morita therapy. Philadelphia: XLibris/Random House; 2007.
28. LeVine P. Morita-based therapy and its use across cultures in the treatment of bulimia nervosa. J Couns Dev. 1993;72(1):82–90.
29. LeVine P. Classic Morita therapy: consciousness, nature and trauma. USA: State University of New York Press. In press
30. LeVine P. Morita therapy and its divergence from existential therapy: a proposal for adopting a Morita-based philosophy for use in counselling and psychotherapy. International Bulletin of Morita Therapy. 1993;3(1):4–6. cited in Ogawa B. Desire For Life: The Practitioner's Introduction to Morita Therapy for the Treatment of Anxiety Disorders. Indiana: XLibris Publ; 2013

Appendix IV: The UK Morita Therapy Outpatient Protocol

Appendix IV of this thesis has been embargoed by the author due to commercial sensitivities and to protect ongoing research which the author hopes to publish in the future.

Appendix V: Intervention optimisation study data analysis

This appendix provides examples of the analytic process in the development of themes on potential patients' and therapists' views and understandings of Morita Therapy.

1. List of initial codes following first-cycle descriptive coding

Positive links to nature
Taking nature literally
Nature not coming through in practice
De-centralising the self and being part of something bigger
Challenges/ barriers to action-taking
Positive responses to action-taking
Action as "constructive"
Rest as appealing/ helpful
Mind's natural healing capacity
Rest as distinctive
Permission and guilt around rest
Concerns/ challenges of rest
    Depression/ rumination/ unhelpful avoidance
    Practical
    Cultural
What is rest? Purpose/definition
Balancing rest with action
Instructions for rest
Marathon metaphor
Purpose of/ instructions for diaries
Inaccurate assumptions regarding diaries
Therapist comments/ exchange of diaries
Struggle/ challenges of diaries
Suggested changes to diaries
Naturalness of emotion
Normalisation as validating/ reassuring
Normalising versus trivialising
Healthy versus unhealthy levels of distress
Explaining differences between people/ causes of difficulties
Positive reinterpretation creating positive slant/ stressing attributes
Coin metaphor
Overgeneralisation in positive reinterpretation
Disagreement and confusion in positive reinterpretation
Holistic/ person-centred/ non-diagnostic
Gentle/ kind/ compassionate
Fluidity and lack of structure
Providing rationale and explanation
Personalisation
Collaboration
Directive versus non-directive
Subtle/ implicit approach

Fumon – dangers
Communication difficulties/ lack of clarity
Resonation of/ identification with underlying principles
The vicious cycle
Principles versus vignettes
Acceptance/ relinquishing control/ not fighting
    Where are the tools?
    Balance/ keeping on an even keel
Paradigm shift
Managing expectations
Comparisons to other treatments
    CBT
    MBCT
    Other
    Distinctiveness
Constructive/ realistic approach
Enabling understanding
Application to depression
Metaphors and analogies
Supporting the therapists

2. Initial impressions of striking/ important elements of the data for answering the research questions

Principles versus clips

- o Participants typically identify with principles
- o Some unsuccessful communication/ translation into practice
- o Participants demonstrate acceptance of inability to control thoughts/ emotions in principle but still seek coping mechanisms and manipulation of thoughts/ emotions in practice.
  - ▪ A lack of this and the exploration/explanation of difficulties is potentially perceived as undermining the severity of symptoms
- Potential challenges with implementation – diaries/ rest/ action-taking
- Thoughts/ difficulties around tone/ style of practice
- Paradigm shift/ distinctive elements of therapy
  - o Preparing patients for the approach/ managing expectations
  - o Similarities/ differences to other treatments

3. Codes categorised into initial thematic framework following second cycle pattern coding

1. Key components: Nature/ action-taking/ rest/ diaries

De-centralising the self
    Naturalness of emotions
    Challenges/ barriers
    Action as "constructive"
    Permission and guilt in rest
    Meaning and purpose of rest/ diaries

2. Therapist techniques

Fumon - dangers
    Metaphors and analogies
    Normalisation
        Allowing negative emotions
        Trivialising and healthy vs unhealthy levels
        Explaining differences between people/ causes of difficulties
    Positive reinterpretation
        Lack of clarity/ communication difficulties
            Overgeneralisation
            Reframing emotions not situations
    Disagreement
    Positive responses

3. Structure and style

Providing rationale and explanation
    Conversational/ lack of structure
    Collaboration
    Personalisation
    Subtle/ implicit approach

4. Underlying approach

Anti-diagnostic
    Constructive, realistic and pragmatic
    Holistic and spiritual

5. Therapy goals

Acceptance
    Seeking tools/ management/ balance
    Insight and enabling understanding

6. Other

Resonation of/ identification with underlying principles
    The vicious cycle
    Principles versus vignettes
    Paradigm shift
    Comparisons to other treatments
    General confusion/ lack of clarity

4. Modified thematic framework following review and refinement of coded data during continued second cycle pattern coding

1. Therapy in practice

Challenges/ barriers to implementation
    Confusion/ communication difficulties
        Positive reinterpretation
    Lack of depth and explanation
        Fumon
        Normalisation

2. Structure and style

Providing rationale and explanation
    Conversational/ lack of structure
    Collaboration
    Personalisation

3. Underlying principles and approach

Resonation of/ identification with underlying principles
    Discrepancies between principles and vignettes
    Anti-diagnostic, holistic and spiritual
    Paradigm shift
    Comparisons to other treatments

4. Therapy goals

Acceptance and allowance
    Seeking tools
    Insight and enabling understanding

5. Example framework matrix ('structure and style')

	Providing rationale and explanation	Conversational/ lack of structure	Collaboration	Personalisation
TH 02				
		Seems to be some CBT structure without as much structure. Some background philosophy similar to GAD model but without the same structure - emphasis less on diagram, more on metaphor. Seems to evolve without a clear pathway.	Background feels similar to person-centred therapy. Explored fact she needed a rest well i.e. collaboratively - but then told her what she needed to do, and would have been better to let her answer that question herself. Therapist was overwhelming/ overlabouring - better to stick with one example and explore that with the patient.	Therapist says a lot without checking patient's understanding or taking examples from them. Liked when illustrations of the two sides of the coin were drawn from patient herself - could do more of that. Liked when therapist stayed with what the patient was saying and reflected that back to her.
TH 03	May need to deal with people feeling that their questions aren't being addressed (e.g. Fumon) - suggests giving education upfront around how focusing on gaining a deeper understanding can perpetuate problems = good quote - managing expectations from start. The approach is subtle - sometimes directive and sometimes the principles are interwoven implicitly – "will be a skill to develop".	DIARY - less structured than CBT. Liberating to have a more fluid therapy (but feels like a novice).	How directive is it? Compared to CBT (collaboratively working), is MT steering more didactically? How much does patient determine how much rest they need? In some instances, more directive than would have expected, and yet very subtle in other instances. Conversation around action quite directed by therapist.	Repetitive - should elicit more from patient - e.g. what do you think value/ function of worry is? Keen to personalise nature metaphors in practice so they feel most pertinent to the patient.
TH 04	People need to understand upfront: new approach which may appear counter to expectations. Suggests may need more preamble around explaining the purpose of		Interpreted as Wise Sage/ Guru (culturally defined?) giving out wisdom and not deviating from principles, rather than Western treatment which is more	Hard to make a connection for the individual patient when it's a very directive/ guru driven approach.
TH 01				

	therapist comments in DIARY.		collaborative/ seeking permission. Didn't check patient's understanding/ interpretation well - this is directive, not patient-centred/ collaborative working. ACTION - therapist not as directive as behaviour therapist here. MT is appealing in that sense - this is more of a reflective piece between therapist/patient. REST - therapist is being more directive here, which is distinctive to other treatments.	
PT 10: no therapy experience	"Therapist obviously knows something I don't" - but she is open to this.	More 'open' than other treatments - not text book, step by step instructions (positive point).		
PT 09: no therapy experience but strong positive views re: CBT	DIARY explanation needs more - likes to know why she's doing something/ to have an end goal for more motivation. If you're not using goals (e.g. to feel better), better to be upfront about that rather than just ignoring them - therapy shouldn't be doing things the patient is not aware of. REST - needs more explanation to know why you're doing it/ assurance that it works.	"Wishy washy" - not concrete enough/ not clear enough what to do or take away from the session. It's like a friendly chat - hard to identify therapist and patient - seems to go easily. Worried that people won't see markers and progress strictly laid out and so won't see the point.	It's like a lecture - I'm telling you this rather than you telling me something. Not the feedback you usually hear in therapy.	More personalised metaphors would help. Therapy shouldn't only use abstract metaphors - should relate directly to patient.

PT 04: no therapy experience	DIARY - unsure of purpose but does not think it necessary to know more as then you second guess/ get ahead of yourself. Subtlety - it's like e-learning: getting somebody to learn something without knowing they've learned it.	Doesn't feel like therapy, feels like "good advice". This is positive as he would feel some resistance to something which feels like therapy.		Got the tone right - more personal than previous therapies - not one size fits all.
PT 01: no therapy experience		Friendly way of talking about it - more conversational and reflective rather than homework-based. More personable rather than scripted according to the therapist's plan.	Re: Giving the patient a job to REST - being made to do something by someone else as opposed to giving it to yourself means you're more likely to do it.	Liked discussion around ACTION as patient was talking - it was about the individual patient rather than a "story or quip". More personable/ reactionary towards the patient rather than covering the therapist's plan, as in other treatments.
PT 08: therapy experience	DIARY - comfortable with explanation given - bullet points are sufficient.	No strict structure is a positive.	Likes that it's person-centred.	
PT 07: therapy experience	DAIRY - purpose not very clear - should have explained more e.g. why they're doing it and how long it will be for - too open-ended. Generally, should have explained the 'plan' more.	CBT is more structured - MT is open-ended.	Re: Giving the patient a job to REST - saying 'listen to me' - would be better if the patient "owned" the job herself.	Repeated the same ground a lot - not much to make the patient think/ didn't explore her particular anxieties enough/ not opening her up to the possibilities. Metaphors = frustrating as not engaging enough for the person.
PT 06: therapy experience	DIARY - needs more information as can be threatening - explain why they're doing it and why it will help the patient. Generally - need to understand why you're doing things to be respectful. And can note that some things may not make sense but that there is a reason for it (even if you don't explain the reason). REST - should explain why it may be difficult (e.g. conditioned not to rest) and that it is important/ should assure them			Didn't paint a full picture - repetitive without eliciting from the patient what would happen if she didn't worry/ didn't unpack what worry meant to her - superficial/ didn't get to know patient/ didn't allow enough space for patient - imposing and disrespectful. Discussion around ACTION was better as actually focused on what the patient did.

	that it has a basis in something that works and suggest they have faith in the process.			
PT 05: therapy experience	DIARY - would probably want to know more about why they're doing it but if told they don't need to know they would accept that.			
PT 03: therapy experience			ACTION - less imposed by therapist than in BA (positive point). Gentle approach - didn't push the patient too much.	
PT 02: therapy experience	Generally - Not sure more explanation is necessary as don't want to be second guessing. But would find it helpful to have the background info (explanation of principles) to give context to what he is saying generally/ to explain why some questions are not being addressed (e.g. Fumon). Appreciates some people may be able to trust process and may be distracted by too much info/ others may need more info to focus on principles.			Types of ACTION are not set in stone so can be personalised (positive point).

6. Final themes following within-case and cross-case analysis using framework matrices, as informed by initial impressions of/ insights into the most important and striking elements of the data

1. Translating principles into practice

The underlying principles
    Discrepancies between principles and practice
    Barriers to implementation
    Communication difficulties

2. Respecting the individual

Transparency and rationale
    Explanation and exploration
    Structure, personalisation and collaboration

3. Shifting the understanding framework

Familiarity and distinctiveness
    Accepting and allowing emotions
    Therapy goals

Appendix VI: Morita Therapist Training Programme

<u>Morita Therapist Training Programme</u>

(1) Discussion: Morita Therapy principles

- Nature
  - o The natural healing capacity of the mind – law of emotion
  - o The ebb and flow of emotions as a natural phenomenon
- Vicious cycle
  - o Preserving energy
  - o Two sides of the coin
  - o Desire for life
- Doing rather than introspecting
- Looking out rather than looking in
- Fumon – selective reinforcement
  - o Acknowledge negative experiences but do not explore content
  - o Promoting good behaviour rather than eradicating bad behaviour
- Purpose orientated living rather than mood orientated living
- Rest
  - o Rest when you are ill
  - o Priming principle – you need to go through this phase in order to stop fighting/ come back into line with the natural world
  - o 'Riding the storm' (sitting with/ endurance) rather than 'sunbathing' (relaxing)
- Emerging desire for life
  - o The person will take the right kind of action from within
- Acceptance (of 'first-level' emotions)
- Experiential learning (through 4 phases)
  - o Re-programming your relationship with your emotions (and the world)
- NB: Goals
  - o Always break goals into small steps
  - o Help people to create the (intrapersonal) conditions in which they may achieve their goals
  - o Optimising their potential to achieve whatever is meaningful to them

(2) Discussion: Operationalising the principles: the vehicles

- **Nature** as the 'golden thread'
  - o Try 'nature dots'
  - o Check in every session: 'how have I brought this in?'
  - o At the end of treatment: consider with the patient how they will maintain this sense of being part of/ connected to the natural world
    - Not focusing on the way they feel
    - Activities which provide space to look outwards

- **Diaries**
  - o Selective reinforcement
  - o Reframing as desire

- o Noting experiences of the law of emotion
- o Ask patients to write about their day (whatever seems important to them) rather than what they did/thought/felt
- o Be clear on the Fumon approach first
- o Exchange:
    - When they hand in their newly completed diary, be thankful and scan for risk issues/ completeness but do not discuss content
    - When you hand back their diary with your comments on, ask them to quickly look over your comments and reflect on these/ raise any issues they may have

- **The rest phase**
    - o In the inpatient setting, patients would rest for a week
    - o The purposes of rest are:
        - To experience the ebb and flow of emotions. Thus, habituation is presumably one of the key goals of rest. Whether or not multiple 30 minute bouts of rest would be sufficient to achieve habituation is unclear.
        - Removing patients from unhelpful expectations/ routines
        - A return to natural biorhythms/ Allowing recovery from fatigue
            - The emergence of a desire to move on – boredom and attention turning outwards following saturation
    - o The general indicator of progress in the rest phase is the drive to action – as long as this drive is coming from the right place (from interest/ curiosity/ boredom NOT mood driven i.e. to escape unpleasant emotions)
    - o The therapist may wish to send a letter to the patient's GP to advise them that they will be engaging in rest and may require a sick note
    - o If the patient absolutely cannot commit to rest, return to the key principles: explore in what ways they may be helped to become more outward looking/ part of nature – could try 30 minute bouts of rest/ could try attention focused activities

- **The action phases**/ connecting people with the natural world
    - o Use ways of connecting to nature that make sense for the individual e.g. if someone already visits the gym, suggest exercising in a park.
    - o Not all activities need to be nature orientated – the priority is for people to move their attention outwards, so anything they already do which fits this criterion may be used.

- NB: Praise – try to resist this! Paying attention (selectively) should be reinforcement enough
- NB: Empathy – go easy on empathising with difficult feelings. Empathise with difficult situations, and naturalise difficult feelings as a result of these

(3) Guidelines: ROLE PLAY EACH SESSION

(3)(a) Session 1: Introducing the therapy

1. Acknowledge they are part of a research project they volunteered for
2. Briefly introduce history of Morita Therapy
   a. Over 90 years of practice
   b. Originally from Japan and now used somewhat elsewhere e.g. Canada/ Australia
   c. Do not move into Morita principles yet
3. Acknowledge that Morita Therapy is a treatment for mood and anxiety problems
   a. Ask patients to explain a little about why they are seeking therapy
   b. Gather enough information to elicit examples for illustrating desire for life and ways in which they are caught in the vicious cycle (e.g. "do you find yourself preoccupied with those feelings?"/ "do you find yourself doing more or less of anything when you feel that way?")
4. Reframe their issues through an explanation of Morita Therapy principles
   a. Use their own examples
   b. Nature
      i. We're not above/ separate to nature: as a natural organism we're subject to forces/ changes that we cannot control – as with trees/ weather
      ii. Ebb and flow of emotions is one such natural phenomenon: there will always be storms but we can learn how to better weather these so we don't make them worse or delay their subsiding
   c. Stress that emotions are neither good nor bad *but* they are pleasant and unpleasant – use this to help ensure they sense an understanding of their suffering
   d. Not a therapy for treating symptoms but for helping to change their relationship to their symptoms so that they spend less time labelling/fighting them
   e. Vicious cycle: exacerbating unpleasant feelings
      i. Inward vs outward focus
      ii. Desire for life: will emerge and manifest itself in small signs that they want to DO things
      iii. Mind's capacity for restoration/ rejuvenation if given the right conditions (although this is not *permanent* healing – the scab will 'heal' but we may be left with a scar and will certainly be wounded again during our lives)
   f. Check in on the patient's understanding of these principles
5. Explain the four phases of treatment
   a. Note that this is a treatment where you will help them to understand the principles of Morita Therapy and change their relationship to emotions by experiencing certain things, rather than a treatment aimed at intellectual understanding of the principles
   b. Use inpatient model to help explain what each phase is supposed to achieve i.e. experiencing the flow of emotions, turning attention

from inwards to outwards and moving to a more action-oriented way of living

    i. Explain that the treatment is like a training program where we create slightly artificial circumstances in order to achieve these purposes

c. Phase one: stress that rest/ inaction, or at least the purpose of rest (experiencing the ebb and flow of emotions), is essential – we will need to find a way for them to experience this somehow, and we think rest is the best way to achieve this

    i. 'During this phase, it is important to dedicate as much time as possible to 'sitting with' your thoughts and feelings – how can we maximise this amount of time for you? Who do we need to involve/ talk to?'

d. Phase two provides an opportunity to look outwards in detail – concentrate on what things smell, feel, look etc. like, find small tasks which involve repetitive movements e.g. knitting/ drawing, and focus on things they enjoy doing

e. Phase three involves more complicated and demanding activities e.g. things in the garden/ more strenuous exercise

f. Phase four involves more social activities

g. Stress that this is a gradual process of re-engagement in which there is a breadth of options for activities which will be driven by their desires and signs that they are ready to move on (i.e. nothing too intimidating/ forced)

6. Explain techniques you'll be using

a. Fumon: Explain upfront that emotions will be used as cues for discussions of desire, action, attitude and acceptance but we will not disentangle and analyse emotions – prepare patients to allow for less empathy/ acknowledgement of he negative

    i. Acknowledge importance of emotions and that you understand how they feel, but be clear that this therapy will not focus on those emotions and will instead help draw their attention to when they are looking outwards

    ii. Explain that spending time focusing on emotions will not improve how they feel and will feed into the vicious cycle

        1. 'It is not that I don't think those feelings are important or understand how difficult they are but because I don't want to reinforce that vicious cycle – I'll be picking up on when you focus your attention outwards rather than inwards

b. Diaries

    i. Explain that this is not a structured diary but rather they will be asked to write a page every day about their day

    ii. Stress that they should write about whatever they like but reiterate that we will not focus on their emotions

    iii. Explain that the diaries will be exchanged so that you may comment on their previous week and that you will have a quick chat at the start of each session in case there's anything in your comments that they want to mention or don't understand

7. Consider with the patient whether they should bring a significant other to session 2 to help arrange rest

(3)(b) Providing diary guidance (and responses during therapy sessions)

ACTIVITY: trainees to take example diary entries away, provide comments and bring them to the next session for discussion

1. Reinforce actions (especially 'in spite of the way you were feeling…')
2. Interpret negative emotions as desires for life
3. Note when making a connection with the natural world
4. Reinforce their acknowledge of/ insight into the vicious cycle (and if they break out of it)
5. Note when they are experiencing the natural ebb and flow of emotions
6. Note when they are looking outwards generally e.g. responding to the external environment
- NB: adapt comments to reflect the phase they are in so that you reinforce appropriate (in)action for the phase e.g. 'this sounds like a really suitable activity for this time'
- NB: avoid emotionally loaded language
- NB: keep language personalised e.g. 'you are…'
- NB: consider using metaphors to illustrate the nature of their experiences

(3)(c) Session 2: Negotiating rest

- Remember: 3 rationales for rest:
  - Experiencing the ebb and flow of emotions
  - Allowing recovery from fatigue
  - Removing patients from unhelpful expectations/ routines
    - Purpose one is fundamental and relevant to all patients. The other two purposes are more dependent on patient presentation.
1. Cover purpose two/three: prescribe and permit rest (including sleep)
   a. As part of the natural world we cannot resist this need
   b. If we take a break from unhelpful situations/ patterns/ expectations and also from fighting how we think/ feel, we can conserve energy
2. Cover purpose one: 'you will find that your emotions naturally go up and down – sometimes you may sleep, sometimes you may feel peaceful and other times you will feel distress and emotional turmoil' (make sure patients are aware that this is to be expected and will happen by itself)
   a. This will provide an opportunity for you to experience the ebb and flow of thoughts and feelings over time
   b. Don't focus on making yourself feel better or trying to change your thoughts/feelings – just be with it and observe what happens
   c. Use the boat/stormy sea metaphor and scab metaphor (the itch will go away – we don't normally give ourselves the opportunity for things to change naturally because we quickly jump to trying to force change)
3. Facilitate rest
   a. How are we going to make this work for you, to ensure you get these experiences?
   b. Stress the importance of this phase: you have a serious condition and this is part of your treatment which requires an investment from you which will hopefully pay off in the long term (what you have been doing so far has not been helping!)

     c. Be clear that this is radical – it is not what they would normally be doing

     d. Consider if it is possible to be signed off work for a week – what would they do if they were physically ill?

4. What are the challenges/ barriers they envisage?
   a. Make sure they are aware that it will be challenging
   b. Explore how to create a resting space in which they feel safe
   c. Use the diary as a container for their experiences and observations
5. Specify the conditions/ practicalities
   a. In silence with no distractions etc.
   b. Tend to basic needs
6. Make an individualised aide-memoire with the patient outlining what they should be doing and the purpose of this – something which might mimic a reassuring therapist presence

(3)(d) Session 3

1. Return the diary with your comments on to the patient for the first time
   a. Ask them what sense they make of those comments/ what messages they take from them
   b. Ask them if they can see how the comments reflect some of the principles of Morita Therapy
      i. If they cannot, explain your comments in terms of the principles
2. Ask how they have got on with establishing rest this week
   a. Explore how much/ how they set it up etc. (give sufficient attention to this to reflect the value of rest)
3. Prescribe rest for a further week
   a. If it seems that patients require further concentrated rest, consider taking further time off work
      i. If patients have only experienced distress and no ups and downs, reassure them that we are expecting that this will be difficult, they are in the early stages and they are still taking the (in)action that they need to take
   b. If it seems that patients have experienced a reasonable amount of rest, are showing some indicators of progress and have learned appropriate lessons (i.e. how emotions ebb and flow), discuss moving onto smaller periods of rest, fitting around their work
   c. This provides you with an opportunity to review their diary data from the rest period before considering moving onto phase two

(3)(e) Negotiating further phases

- Always bear in mind the *purpose* of the phase and then consider how this can be achieved
- Be prescriptive in terms of the conditions/ criteria that activities need to fulfil i.e. looking outwards
   a. If there are no such activities patients can think of in phase two, suggest observation of nature to see what might capture their attention

    b. For phase two, avoid reactive/ automatic activities or 'mind' orientated activities e.g. Sudoku/ crosswords
- Use active therapeutics
  - a. Phase two: explore and observe outside/ pick up leaves etc. and study those – demonstrate to patients the level of observation and detailed attention paying we would like them to engage in
  - b. Phase three: take patients to the community garden etc. – they should now be observing for useful tasks they could complete
- Both observe and enquire about the indicators of progress to reassure you that it is time to move on
  - a. Also consider the overall indicators of progress on p. 82 of the protocol – "do you look at your emotions any differently now?"

(3)(f) Ending a session

- Ask the patient what they are taking away from the session
- Confirm with them which phase you are in and what (in)action they will be taking this week
  - o Ensure they are planning to write in their diary, and to reflect on the comments you have made in their diary from the previous week

(4) Arrange supervision slots

(5) Additional reading

- MORITA, S., KONDO, A. & LEVINE, P. (1998) Morita therapy and the true nature of anxiety-based disorders (Shinkeishitsu). New York, NY: State University of New York Press.
- OGAWA, B. (2013) Desire For Life: The Practitioner's Introduction to Morita Therapy. Indiana: Xlibris Corporation.

Appendix VII: Published protocol paper for the feasibility study

STUDY PROTOCOL　　　　　　　　　　　　　　　　　　**Open Access**

Morita therapy for depression and anxiety (Morita Trial): study protocol for a pilot randomised controlled trial

Holly Victoria Rose Sugg*, David A. Richards and Julia Frost

Abstract

Background: Morita Therapy, a psychological therapy for common mental health problems, is in sharp contrast to established western psychotherapeutic approaches in teaching that undesired symptoms are natural features of human emotion rather than something to control or eliminate. The approach is widely practiced in Japan, but untested and little known in the UK. A clinical trial of Morita Therapy is required to establish the effectiveness of Morita Therapy for a UK population. However, a number of methodological, procedural and clinical uncertainties associated with such a trial first require addressing.

Methods/Design: The Morita Trial is a mixed methods study addressing the uncertainties associated with an evaluation of Morita Therapy compared with treatment as usual for depression and anxiety. We will undertake a pilot randomised controlled trial with embedded qualitative study. Sixty participants with major depressive disorder, with or without anxiety disorders, will be recruited predominantly from General Practice record searches and randomised to receive Morita Therapy plus treatment as usual or treatment as usual alone. Morita Therapy will be delivered by accredited psychological therapists. We will collect quantitative data on depressive symptoms, general anxiety, attitudes and quality of life at baseline and four month follow-up to inform future sample size calculations; and rates of recruitment, retention and treatment adherence to assess feasibility. We will undertake qualitative interviews in parallel with the trial, to explore people's views of Morita Therapy. We will conduct separate and integrated analyses on the quantitative and qualitative data.

Discussion: The outcomes of this study will prepare the ground for the design and conduct of a fully-powered evaluation of Morita Therapy plus treatment as usual versus treatment as usual alone, or inform a conclusion that such a trial is not feasible and/or appropriate. We will obtain a more comprehensive understanding of these issues than would be possible from either a quantitative or qualitative approach alone.

Trial registration: Current Controlled Trials ISRCTN17544090 registered on 23 July 2015.

Keywords: Morita therapy, Major depressive disorder, Mixed methods, Feasibility study

Background

Clinical depression and generalised anxiety disorder are the two most common mental health disorders [1], with one in six people in the UK experiencing such a disorder each year [2]. Together, depression and anxiety are estimated to cost the UK economy £17bn in lost output and direct health care costs annually, with a £9bn impact on the Exchequer through benefit payments and lost tax receipts [3].

Depression accounts for the greatest burden of disease among all mental health problems, and is the second-highest among all general health problems [4]. The lifetime prevalence of depression has been estimated at 16.2 %, and rates of co-morbidity and risk for suicide are high [5–7]. Depression is also recurrent, with over three quarters of people who recover from one episode experiencing at least one more [8].

* Correspondence: h.v.s.sugg@exeter.ac.uk
Complex Interventions Research Group, University of Exeter, University of Exeter Medical School, South Cloisters, St Luke's Campus, Exeter EX1 2 LU, UK

Generalised Anxiety Disorder (GAD) affects between 2–5 % of the UK population at any one time, and accounts for up to 30 % of the mental health problems presented to General Practitioners (GPs) [2]. The lifetime prevalence of GAD has been estimated at 5.7 % [9]. Furthermore, the comorbidity between anxiety and depression make a strong contribution to the total disability attributed to mental disorders [1].

Medication and Cognitive Behavioural Therapy have the strongest evidence-base for treating these conditions, and are each recommended by the National Institute for Health and Care Excellence (NICE) [10, 11]. However, many patients are refractory to such interventions [12], with both depression and anxiety remaining chronic disorders despite treatment [1]. Recovery is only reached by 55–56 % of people receiving treatment through the large-scale UK initiative to provide NICE recommended psychological therapies ('Improving Access to Psychological Therapies' (IAPT)) [13, 14], thereby increasing the risk of future relapse and the maintenance of recurring and chronic problems [15].

Thus, it is important to develop and test new potentially effective treatments for depression and anxiety in order to treat a wider range of patients [15] and provide patients in the UK with choice alternatives.

Morita Therapy

Morita Therapy is a psychotherapy developed in Japan by Dr Shoma Morita in 1919 [16] used for the treatment of common mental health problems. Morita Therapy was originally developed in inpatient settings for patients with particular psychological problems, including but not limited to GAD [17]. More recently, Morita Therapy has been applied to a wider range of conditions, including depression, and guidelines for practicing outpatient Morita Therapy have been developed [17]. Morita Therapy is now widely practiced in Japan, and has branches in various other countries including North America, Australia, China, Russia and Rwanda [18].

Morita Therapy is a holistic approach, aiming to improve functioning in everyday life, rather than an approach targeting specific symptoms [18]. The underlying premise is that unpleasant symptoms are part of the natural ecology of the human experience. Morita Therapy thus helps patients to re-orientate themselves in the natural world and takes a restorative approach to potentiate their natural healing capacity. Morita therapists help patients to move away from symptom preoccupation and combat, which it is conceptualised both interfere with this natural recovery process and lead to preoccupation with and worsening of symptoms [17]. By helping patients to accept that undesired symptoms are natural features of human emotion rather than something to control or eliminate, and that emotions ebb and flow as

a matter of course and can be lived with, Morita Therapy is in sharp contrast to established western psychotherapeutic approaches with their focus on symptom elimination. In Morita Therapy, patients are taught to live with, rather than be without, unpleasant emotions.

Uncertainties: The need for a mixed methods feasibility study

As with the development of many other treatments to date [15], initial evidence for Morita Therapy's efficacy is largely based on case studies, predominantly conducted in Japan. A narrative review of forty-nine such studies and four quasi-experimental studies indicated that Morita Therapy has been reported as effective for a diverse range of issues, but that further work is required to both standardise its delivery and investigate its efficacy in controlled trials (personal communications: Minami, M).

Furthermore, Morita Therapy is currently little known in the UK. Thus, evidence of the efficacy of Morita Therapy based on truly experimental studies, and evidence of the effectiveness of Morita Therapy specifically for a UK population, has not yet been established. Whilst a fully-powered UK randomised controlled trial (RCT) of Morita Therapy versus treatment as usual is needed to establish the effects of Morita Therapy, a number of clinical, procedural and methodological uncertainties currently prevent us moving immediately to such a trial.

With respect to clinical uncertainties, the operationalisability of the UK Morita Therapy outpatient protocol, and the acceptability of both the protocol specifically and Morita Therapy in general, is unknown. Gathering data on these uncertainties is essential to ensure that the treatment administered in a large-scale trial is deliverable by therapists, and acceptable to both therapists and patients.

With respect to procedural uncertainties, information is required on the likely rates of recruitment to and retention in a trial of Morita Therapy, and of treatment adherence, in order to assess the feasibility of a trial and inform the required sample size. With respect to methodological uncertainties, estimates of the variance in participant outcomes and information on how these correlate with baseline scores are also required to inform future sample size calculations.

In line with the Medical Research Council (MRC) framework for the development and evaluation of complex interventions [19], all such uncertainties are appropriate to address within a pilot trial and feasibility study [20]. In order to both collect the required quantitative data and understand people's views of Morita Therapy, qualitative work will be embedded in a pilot randomised controlled trial of Morita Therapy compared to treatment as usual, and merged with quantitative data on treatment adherence to potentially help explain variability in participants' therapeutic engagement.

Study purpose

The purpose of this study is to prepare the ground for the design and conduct of a fully-powered RCT of Morita Therapy plus treatment as usual versus treatment as usual alone, or to conclude that such a trial is not appropriate and/or feasible.

Research questions

1. What proportion of participants approached to take part in the trial will agree to do so?
2. What proportion of participants who agree to take part in the trial will remain in the trial at four month follow-up?
3. What proportion of participants who agree to take part in Morita Therapy will adhere to a pre-defined per-protocol dose of Morita Therapy?
4. What is the variance in participant outcomes following Morita Therapy plus treatment as usual and treatment as usual alone, and how do they correlate with participants' baseline scores?
5. What are the estimated between-group differences (and 95 % confidence intervals) in participant outcomes following Morita Therapy plus treatment as usual and treatment as usual alone?
6. How acceptable is Morita Therapy to participants and therapists?
7. How do participants' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?

Criteria for success

The criteria to be met in order to deem a fully-powered RCT feasible as is [20] are:

1. A sufficient number of participants to populate a fully-powered trial are likely to be recruited and retained, i.e. we recruit at the rate anticipated in the pilot trial (12 % of those invited) and experience an attrition rate no higher than 20 % of those randomised, in line with our other National Institute of Health Research (NIHR) mental health trials [21–23]. We will consider whether protocol modification or close monitoring during a fully-powered RCT will address any failure to meet these criteria [20].
2. The levels of engagement with and adherence to Morita Therapy are likely to be on par with our other NIHR mental health trials [23], i.e. at least 65 % of patients allocated to Morita Therapy attend at least 40 % of treatment sessions. Any failure to meet this criterion will be considered in the light of participants' views on the acceptability of Morita Therapy in order to determine whether protocol

modification or close monitoring are sufficient to deem a fully-powered RCT feasible [20].

3. It is likely that a Morita Therapy outpatient protocol can be produced which is acceptable to patients and therapists, and deliverable by therapists, as defined by responses to qualitative interviewing.

Methods/Design

Study design

We will incorporate exploratory and explanatory components in a mixed methods embedded design [24]. Thus, we will embed semi-structured qualitative interviews within a pilot randomised controlled trial of Morita Therapy plus treatment as usual versus treatment as usual alone for people with depression, with or without anxiety disorders. We will give quantitative and qualitative components equal priority and mix them interactively at the design level within a program-objective framework [24]. For these two components, we will collect data concurrently and analyse data simultaneously. We will use quantitative data to assess the feasibility of trial recruitment, retention and treatment adherence, and to inform any future sample size calculations. We will collect qualitative data on participants' and therapists' views of Morita Therapy. By merging qualitative and quantitative data, we aim to explain variability in participants' treatment adherence and develop a richer understanding of the feasibility, acceptability and appropriateness of Morita Therapy (Table 1).

Philosophical assumptions

Our decision to use a mixed methods design is driven by the primary importance we give to addressing the uncertainties associated with running a fully-powered RCT. Thus, we are guided by a pragmatic philosophy: we prioritise our research objectives and the methods which will lead to the best evidence with regards to those objectives [25]. Consistent with a pragmatic worldview, we will also approach the objectives from a pluralistic perspective, combine deductive and inductive modes of reasoning, and allow for a singular view and multiple views of reality in how we come to understand and interpret our findings [25].

Pilot Randomised Controlled Trial

Sample size

A conventional power calculation is inappropriate for the purpose of a pilot trial [20]. Instead, we have calculated the sample size in order to provide useful information about the aspects of the study being assessed for feasibility [20]. Thus, we have constructed confidence intervals based on certain criteria for success [20], specifically: recruiting at a rate of 12 % of those invited and experiencing an attrition rate no higher than 20 % of those randomised. We expect to invite a total of 570 participants to

Table 1 World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	Current Controlled Trials database
	ISRCTN17544090
Date of registration in primary registry	23-Jul-15
Secondary identifying numbers	N/A
Source(s) of monetary or material support	University of Exeter Medical School, UK
Primary sponsor	University of Exeter, UK
Secondary sponsor(s)	N/A
Contact for public queries	Holly Victoria Rose Sugg
	University of Exeter Medical School, UK
	h.v.s.sugg@exeter.ac.uk
Contact for scientific queries	Holly Victoria Rose Sugg
	University of Exeter Medical School, UK
	h.v.s.sugg@exeter.ac.uk
Public title	The Morita Trial
Scientific title	Morita Therapy for Depression and Anxiety: A Feasibility and Pilot Study
Countries of recruitment	UK
Health condition(s) or problem(s) studied	Depression
Intervention(s)	Morita Therapy
	Treatment as usual
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years;
	Sexes eligible for study: both;
	Accepts healthy volunteers: no
	Inclusion criteria: adult patient (≥18 years), current DSM Major Depressive Disorder
	Exclusion criteria: cognitive impairment, bipolar disorder or psychosis/psychotic symptoms, substance dependence, acute suicidal risk, current psychological therapy
Study type	Interventional
	Allocation: randomized intervention model
	Primary purpose: treatment
	Phase II
Date of first enrolment	Sep-15
Target sample size	72
Recruitment status	Recruiting
Primary outcome(s)	Depressive symptoms, generalised anxiety symptoms, quality of life, attitudes (at four-month follow-up); qualitative exploration of acceptability.
Key secondary outcomes	N/A

participate in the trial. Thus, we expect to recruit 72 participants into the trial, and follow-up 60 participants (30 in each trial arm).

Inviting 570 participants is sufficient to estimate a participation rate (as percentage of subjects invited) of 10 % with a margin of error of +/− 2.46 %, or to estimate a participation rate of 12 % with a margin of error of +/− 2.67 %, or to estimate a participation rate of 15 % with a margin of error of +/− 2.93 %, based on 95 % confidence intervals. Recruiting 72 participants is sufficient to estimate a follow-up rate (as percentage of participants randomised) of 80 % with a margin of error of +/− 9.24 %, or to estimate a follow-up rate of 85 % with a margin of error of +/− 8.25 %, based on 95 % confidence intervals.

In addition, we will calculate the standard deviation of participant outcomes and the correlation between baseline and four month follow-up scores, which can be used to refine future sample size calculations to incorporate the additional precision obtained from adjusting for baseline scores when comparing outcome scores between the trial arms. 30 participants in each group is sufficient to estimate: (i) the standard deviation of continuous outcomes to within 22 % of their true value based on the upper limit of the 95 % confidence interval; (ii) a Pearson's correlation coefficient between baseline and follow-up scores with a margin of error of +/− 0.1 if the true correlation is 0.8, or with a margin of error of +/− .14 if the true correlation is 0.7, or with a margin of error of +/− 0.17 if the true correlation is 0.6.

30 participants per group is also in line with the general rule of thumb for using pilot studies to reliably estimate variance for participant outcomes [26]. With these factors in mind, we consider 60 participants at follow-up to be both sufficient to provide useful information and reasonable to recruit for within the constraints of our pilot trial and have, therefore, selected 72 as our target sample size, inflating our sample by 20 % to take account of predicted attrition.

Participant inclusion criteria
Eligible participants will be aged 18 or over with Diagnostic and Statistical Manual of Mental Disorders (DSM) Major Depressive Disorder, with or without accompanying DSM anxiety disorder(s).

Participant exclusion criteria
Given the exploratory nature of this trial (and any fully-powered evaluation), and thus the requirement for reasonable internal validity with a homogenous and tightly defined population, we will identify and exclude people who are cognitively impaired, have bipolar disorder or psychosis/psychotic symptoms, or are substance dependent. Cognitive impairment will be determined using the Mini-Cog, whereby a score of 0, or 1–2 with an abnormal clock-face, would indicate sufficient cognitive impairment to be excluded [27]. Bipolar disorder,

psychosis and substance dependence will be established according to the DSM.

We will also exclude participants whose risk of suicide is sufficiently acute to demand immediate management by a specialist mental health crisis team, and those who are currently in receipt of psychological therapy. Psychological therapy includes any formal standard course of psychological (talking) therapy, such as Cognitive Behavioural Therapy. Ad hoc contact with a therapist or counsellor will not be considered to meet this exclusion criterion. Participants will be eligible regardless of whether they are in receipt of antidepressant medication or have received psychological therapy in the past.

Participant identification and recruitment

Our main method of recruitment will be through searches of General Practice records, conducted by Practice staff. We will recruit six GP Practices in Devon. All GP Practices who are able to access the University of Exeter's Mood Disorders Centre (MDC) Accessing Evidence-Based Psychological Therapies (AccEPT) Clinic (those within the National Health Service Northern, Eastern and Western Devon Clinical Commissioning Group) will be eligible.

Practice record searches will be limited to patients aged 18 or over and seen within the past three months for depression. The resulting patient names will be screened by the GP with whom the patient is registered for any patients known to meet exclusion criteria or for whom the GP considers the trial unsuitable. The remaining patients will be sent invitations to participate in the trial by Practice staff.

We will also place adverts on websites of the University of Exeter Medical School and AccEPT Clinic, place leaflets

in the waiting rooms of consenting Devon General Practices and circulate an email invitation to former MDC participants who have consented to such contact. All invitations and adverts will include a study summary sheet [see Additional file 1] and permission to contact form [see Additional file 2] (Figs. 1 and 2).

Screening and baseline

We will telephone all people who return their permission to contact form to the study team to assess possible eligibility using a standard two-question case-finding instrument for depression [28] and arrange baseline interviews with potentially eligible and willing participants who will be sent a confirmation letter and full participant information leaflet [see Additional file 3]. We will hold baseline interviews at University of Exeter premises or the participant's home, depending on participant preference. At interview, we will explain the study in full and assess eligibility according to the Mini-Cog [27] (to screen for cognitive impairment) and standard clinical interview (Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Clinical Trials Version [29]). If eligible and once fully informed, participants will be asked to complete a consent form [see Additional file 4] and entered into the trial. Ineligible participants will be returned to the care of their GP.

Randomisation, allocation concealment and blinding

We will allocate participants in a 1:1 ratio to either Morita Therapy plus treatment as usual or treatment as usual alone, stratified according to their symptom severity on the nine item version of the Patient Health Questionnaire (PHQ-9) [30], specifically whether they score below 19 or

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) diagram describing flow of participants through the study
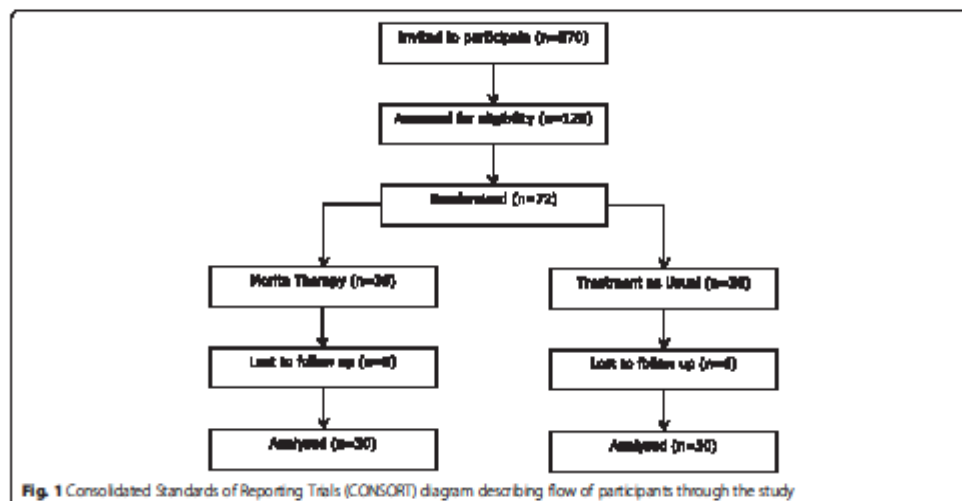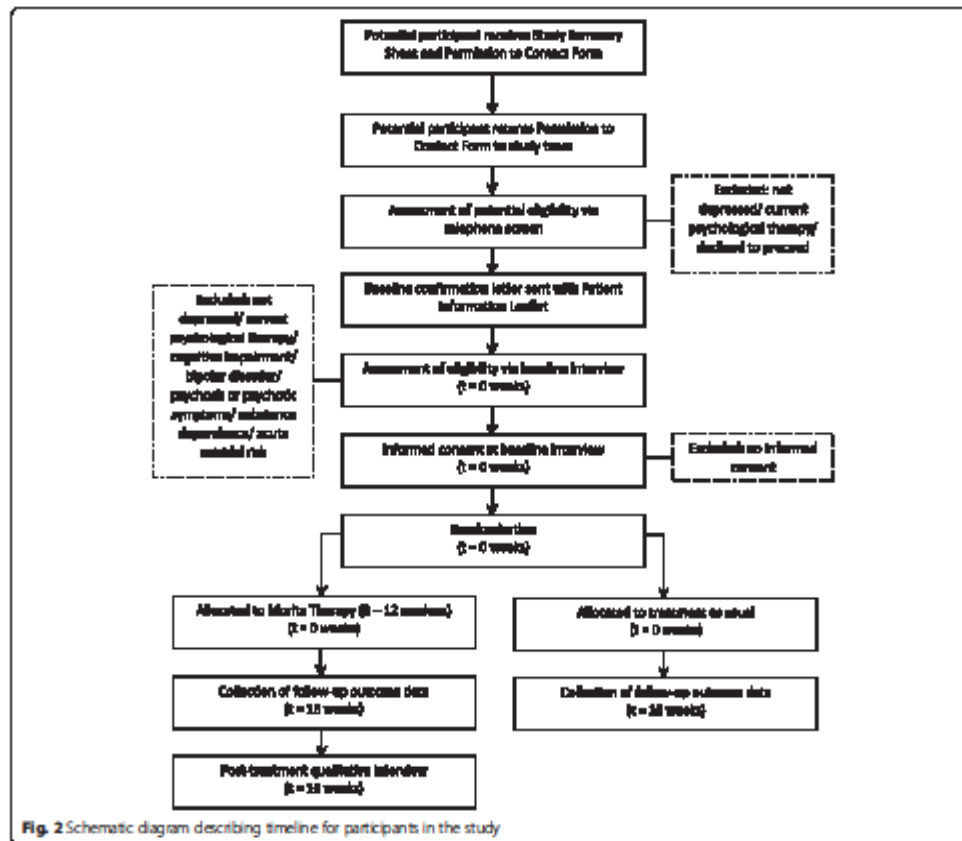
Fig. 2 Schematic diagram describing timeline for participants in the study

19 and above, given that a score of 19 is the median score of depressed participants in our previous research [21, 23]. Allocation will be minimised to maximise the likelihood of balance in the stratification variable across the two trial arms. To ensure allocation concealment, we will undertake randomisation through the use of an externally administered, password-protected randomisation website independently developed and maintained by the Exeter Clinical Trials Unit.

The researchers will not be blinded to allocation due to the different pathways to be followed for each trial arm. Baseline and follow-up data will be self-reported and the risk of bias related to lack of blinding will be both minimal and tolerable.

Trial interventions

Morita Therapy plus treatment as usual We will ask participants in the Morita Therapy plus treatment as usual trial arm not to engage in other formal courses of psychological therapy elsewhere during the course of their treatment. Otherwise, these participants will be free to access any other usual care and medication in liaison with their GP.

Morita Therapy will consist of eight to twelve one hour face-to-face weekly sessions and be delivered at the University of Exeter's MDC AccEPT clinic [31] by two research therapists trained in Morita Therapy and experienced in both the delivery of complex psychological interventions and adopting different modes of treatment, including experimental treatments. Therapist training took place over 6 months and included background reading, attending presentations, involvement in the development and review of the UK Morita Therapy outpatient protocol, and practical training led by DAR, a clinically qualified academic and 10 year member of the Japanese Society for Morita Therapy. Practical training was experiential, involving role plays, diary examples, additional reading and peer support.

APPENDIX VII

The therapists are not accredited as there is no accreditation process for Morita Therapy within the UK.

Therapists will follow the UK Morita Therapy outpatient protocol developed by the study researchers from multiple sources of literature on the delivery and practice of Morita Therapy [16–18, 32–35] and by considering the views of potential participants and therapists about Morita Therapy, as explored in qualitative interviews, in order to enhance the suitability of Morita Therapy for a UK population. DAR will provide fortnightly supervision of cases together with advice and support. A qualitative checklist highlighting the key components of Morita Therapy will be used as an aide memoir to structure supervision discussions and the assessment of adherence and fidelity. With the patient's consent, all therapy sessions will be audio recorded. We will use the first two recordings for each therapist to confirm their adherence to the Morita Therapy outpatient protocol and a further 10 %, stratified by length of time in treatment, to evaluate fidelity to the protocol, which will inform therapist supervision.

During therapy, patients will progress through four stages of rest and increasing action taking in order to address fatigue, expand peripheral attention and move from a mood-oriented to purpose-oriented and action-based lifestyle. Therapists will aid patients in re-appraising their symptoms as part of the natural ecology of human experience; recognising the vicious cycle of symptom aggravation created by fixation on symptoms, contradictions between reality and the ideal, and attempts to fight or control otherwise inevitable emotions; and moving from a position of preoccupation with symptoms to the acceptance of spontaneous affective experiences. Therapists will continually reinforce the patient's shift from self-reflection towards a focus on constructive action and the external environment. Throughout therapy, patients will also complete a daily diary for therapists to comment on, to increase communication and the opportunity for therapist reinforcement.

Treatment as usual alone

We have selected treatment as usual as our trial comparator as a reflection of the trial comparator which would be selected for a fully-powered RCT, in which our key interest would be whether Morita Therapy plus treatment as usual has superior or equivalent effectiveness to current clinical practice in the UK, in which people have access to GP care and a range of other treatments. Thus, a large scale RCT would be a pragmatic trial embedded within the healthcare environment in which Morita Therapy would be delivered, seeking to establish whether Morita Therapy could be useful in addition to the options currently available to depressed patients in the UK.

Thus, in this pilot trial we will replicate 'treatment as usual' by making no specific patient-level recommendation or requirement to alter the usual treatment received by depressed patients in the UK, and the study will not place any restrictions on the treatment options available to these participants. GPs will treat and refer participants as would be their normal practice and participants in this trial arm are free to access any other care and services, including formal courses of psychological therapy such as Cognitive Behavioural Therapy. All participants, irrespective of their allocation, are free to choose whether they take antidepressant medication or not. We will record the treatments received in the course of participants' treatment as usual.

Outcomes

Given this is a feasibility study with a range of different aims, there is no single primary outcome measure. Rather, we will collect a variety of data at baseline interview and four months post-randomisation: severity of depressive symptoms (PHQ-9 [30]), severity of generalised anxiety symptoms (seven item Generalised Anxiety Disorder questionnaire: GAD-7 [36]), quality of life (Short Form 36 Health Survey Questionnaire: SF-36 [37]; Work and Social Adjustment Scale: WSAS [38]), and attitudes (The Morita Attitudinal Scale for Arugamama: MASA [39]). At four months post-randomisation, we anticipate that treatment for participants in the Morita Therapy plus treatment as usual trial arm will be complete. We will hold follow-ups at University of Exeter premises or the participant's home, depending on participant preference, and apply all research measures to both groups of participants equally.

We will also collect data on the flow of participants through the trial. For participants in the Morita Therapy plus treatment as usual trial arm, therapists will also inform the researcher of the number of therapy sessions attended and the reason for ending treatment. We will not conduct an economic evaluation as part of this pilot trial, although at follow-up we will incorporate methods for collecting data on participants' use of health and social care services as used in our recent mental health trials [23] (whereby we will establish the rates and nature of hospital visits; use of community, social and complementary services; and use of psychotropic medication since baseline assessment), in order to characterise treatment as usual and calculate the cost of each trial arm for a large-scale RCT.

Semi-structured Interviews
Sample and setting

We will invite all participants who are allocated to Morita Therapy plus treatment as usual for a post-treatment

APPENDIX VII

semi-structured interview, thus selecting as diverse a sample as possible within this pilot trial. This will provide a maximum of 30 participants (all those retained in the Morita Therapy trial arm). We will also invite the two therapists providing Morita Therapy to interview. We will hold participant interviews at University of Exeter premises or the participant's home, depending on participant preference. Therapist interviews will be conducted at the AccEPT Clinic.

Recruitment

We will explain the purpose and content of the interview to participants in the participant information leaflet, and determine their consent to participate at baseline interview. We will send therapists an interviewee information leaflet explaining the interview prior to a pre-trial meeting, and establish their consent to participate during this meeting. Upon completion of Morita Therapy (delivery, for therapists), we will contact participants to establish whether they are still willing to be interviewed, remind them of what will be involved and answer any questions. For willing participants, we will arrange an interview no sooner than 48 hours later and send an interview confirmation letter explaining the opportunity to rearrange or cancel the interview at any time.

Interview process and questions

We will undertake semi-structured interviews to allow participants to describe their views of Morita Therapy. This method will enable us to investigate the meaning of participants' responses, both exploring views on our pre-defined topics of interest and eliciting more detail on any emerging themes [40]. Interviews are expected to last up to one hour and will be audio-recorded with the participant's consent. The interviewer will also take field notes during and after the interview.

We will follow topic guides established on the basis of our recent mental health trials addressing similar research questions [21, 23, 41] (which ask about participants' views and experiences of treatment, any barriers to treatment, and the impact of treatment) and existing Morita Therapy literature. To explore the acceptability of Morita Therapy, we will ask participants to describe their understanding of Morita Therapy, explore their views and experiences of Morita Therapy and investigate potential barriers to/facilitating factors in engaging with Morita Therapy. In particular, we will explore participant's views and experiences of the defining features of Morita Therapy in practice, such as the four stages and daily diaries. To explore the feasibility and appropriateness of our trial procedures, we will explore participants' views on the support provided throughout the trial; procedures for recruitment, monitoring and data collection; and use of the MASA questionnaire. We aim to identify both procedures that facilitated

the efficient running of the trial and any considered problematic.

Analysis

We will first analyse the quantitative and qualitative data separately before integrating both types of information in a mixed methods analysis.

Quantitative analysis

Following double data entry into STATA v.11 [42], we will analyse recruitment, retention, treatment adherence and estimates of the participant-related data to inform the feasibility of and sample size calculation for a fully-powered trial. Thus, we will emphasise quantification and estimation rather than hypothesis testing. All analyses will be on an intention to treat basis and we will not impute missing data, although we will report outcome data that are missing in each trial arm and the reasons for missing data where possible.

We will use count data with calculated estimated margins of error, expressed as a percentage of both the total number of participants invited and in relation to the preceding step in recruitment, to quantify the flow of the participants through the trial. For each trial arm, we will quantify the number of participants who withdrew, could not be contacted or did not provide follow-up data for another reason. We will also express data as a percentage of the total number of participants in each trial arm. We will follow CONSORT guidelines, including the forthcoming pilot and feasibility extension [43], in reporting all data including the number of participants exiting the trial at each step and from whom we are unable to collect follow-up data. Descriptive statistics will also be used to describe the number of Morita Therapy sessions attended by participants allocated to Morita Therapy plus treatment as usual.

To measure the variance in participant outcomes, we will estimate the standard deviation around the mean PHQ-9, GAD-7, SF-36, WSAS and MASA scores at baseline and four months for both groups. We will also estimate the correlation between participants' scores on these measures at baseline and at four months, which can be used to refine the sample size calculation for any fully-powered evaluation. Although we do not have the power to make inferential statements on between (or within) group differences and as such no p values will be calculated, we will also calculate and report the observed differences between Morita Therapy plus treatment as usual and treatment as usual alone on the mean changes in these measures from baseline to four month follow-up, and the 95 % confidence intervals around these figures.

APPENDIX VII

Qualitative analysis

With participants' permission, we will record and transcribe interviews verbatim. We will use NVivo10 [44] to organise the data and conduct a systematic analysis of interviews and field notes, using Framework analysis [45] to allow for the combination of both inductive and deductive approaches in the development of analytic categories. In line with this, an initial thematic framework will be developed as preliminary analysis is undertaken and subsequently as batches of transcriptions are analysed, iteratively combining our topic guide and the overall impression of the narratives in context. Using this framework, transcripts will be coded at the level of individual participants and then analysed thematically across the whole dataset as well as in the context of each participant's interview using a constant comparison approach [46], whereby each piece of data (e.g. one statement or one theme) is compared with others for similarities and differences [47]. As we formulate explanations in this way, negative cases will be explored and explanations of variance provided [48], thus incorporating all observations relevant to our research question. Data collection and analysis will be iterative: we will amend our interviewing style to respond to emerging themes and explore deviant cases further in subsequent interviews as appropriate.

Mixed methods analysis

Our mixed methods analysis will be guided by both the nature of the quantitative and qualitative data that we ultimately obtain and the inferences that arise from our separate analysis of each [41]. Thus, the analysis we eventually undertake may differ to the analysis we propose [41]. Analytical techniques have been proposed below based on the methods summarised by Creswell and Plano Clark [24].

To explore how the qualitative data on the acceptability of Morita Therapy explains the quantitative findings on treatment adherence, we will merge these two types of data. Firstly, we will develop typologies of participants' different views on the acceptability of Morita Therapy from the qualitative data, and for each typology we will present data on treatment adherence for participants to whom the typology applies [41]. Alongside this, we will also present data on fidelity to the therapy protocol if the qualitative data relates to particular sections of the protocol or stages of therapy. This will allow us to explore whether any issues with the acceptability of Morita Therapy relate to the treatment itself or the therapists' delivery of treatment and thus aid us in identifying any 'fatal flaws' [49] of Morita Therapy requiring refinement in the future. Secondly, we will identify categories of participants defined by their treatment adherence and explore similar and different views on acceptability within and between categories [41].

We will consider the use of joint displays to summarise the quantitative data in relation to the qualitative themes for both of these purposes [41]. We will also integrate data on acceptability and treatment adherence in a case-oriented merged analysis display that will position cases (participants) on a scale of treatment adherence along with their qualitative data on acceptability [41].

Ethical issues

We will conduct this trial in such a way as to protect the human rights and dignity of the participants, as reflected in the Helsinki Declaration [50]. The study has received ethical approval from the National Research Ethics Service South West – Frenchay (reference 15/SW/0103) and governance assurance from the National Health Service Research and Development Directorate (reference CG/JL), and has been approved by the University of Exeter Medical School following independent peer review.

Participants will not receive any financial inducement to participate. We will conform to Good Clinical Practice Guidelines, data protection and freedom of information acts. All data will be stored securely and anonymised wherever possible. All identifiable participant information will be stored separately to questionnaire data which will be coded by a trial ID number only. No published material will contain identifiable participant information.

Informed consent and withdrawal

The study researchers will be fully trained and supervised by senior academic and clinically qualified staff. All our information leaflets and consent forms have been produced using the current Health Research Authority's online guidance for writing such documents [51], and are based on similar materials used in our other mental health trials as informed by Patient and Public Involvement.

Informed consent will be determined by a two phase process. Potential participants will receive a study summary sheet and a form on which to complete their contact details and confirm their permission for a researcher to contact them. We will telephone those who return this form to us, to assess their potential eligibility and answer any questions. For those who are eligible and willing, we will send a participant information leaflet and arrange a baseline interview at least 48 hours later, to allow the participant time to reflect on their decision to participate and change their mind if they so wish. Full informed consent will only be obtained at this interview where the information leaflet will be fully explained and the opportunity to ask questions given.

Consent to participate in the qualitative interview is optional; participants may participate in the pilot RCT only. We will explain the purpose and content of the interview in the participant information leaflet

APPENDIX VII

(or interviewee information sheet, for therapists), and note that a decision not to be interviewed will not affect participation in the trial. At baseline interview (for participants) and the pre-trial meeting (for therapists), we will answer any questions, explain the opportunity to stop and/or withdraw from the interview at any time and clarify steps to maintain confidentiality. We will ask willing participants to indicate their decision on a consent from. Consent for audio recording of the interview and/or therapy sessions is also optional.

We will treat informed consent as an ongoing process whereby participants may withdraw their consent to participate at any time, and set up communication and recording systems to enable us to monitor and act on such wishes. When obtaining consent, we will advise participants of this fact and that they may be asked to give a reason for their withdrawal but will not have to provide one. Participants allocated to Morita Therapy plus treatment as usual may withdraw from therapy and continue their involvement in the trial through participation in the follow-up and qualitative interview if they wish.

Should it come to our attention that a participant loses capacity to consent during the study according to the Mental Capacity Act 2005 [52], we will withdraw them from the study as per information provided to participants in the participant information leaflet. Within this leaflet, we will also inform participants that if they should withdraw or be withdrawn from the study, we will retain any data already provided to be used confidentially in relation to the purpose for which consent was sought.

Anticipated risks and benefits
No treatment will be withheld from participants taking part in this trial. All participants will remain under the care of their GP and will have access to primary care services in the usual way. Participants allocated to treatment as usual alone will be returned to the care of their GP with no restrictions placed on treatment options. Participants allocated to Morita Therapy plus treatment as usual will be asked not to engage in other formal courses of psychological therapy during their treatment, as it is not considered good practice to engage in more than one psychological therapy at once. Should participants in this trial arm wish to engage in other psychological therapy elsewhere, a discussion will be held with their therapist to establish which therapy option is in the participant's best interests.

Participants allocated to Morita Therapy plus treatment as usual will take part in an alternative therapeutic approach to psychopathology which is widely practiced in Japan and somewhat elsewhere. Morita Therapy has been practiced since the 1920s and is not known to be associated with any risks to patients. It is possible that participation in therapy focused on psychopathology may cause distress to some participants, however participants in the Morita Therapy trial arm will receive an intensive level of monitoring so that any worsening or at suicidal risk will be identified and directed to appropriate care. Similarly, we will address any impact of potentially distressing questions within our assessment and outcome measures by following our protocols for responding to risk and directing participants to appropriate care. Additionally, we will report any serious adverse events reported to a therapist or researcher which are thought to be treatment related to the trial sponsor, Research Ethics Committee and independent oversight clinician (see section on study oversight).

The patient information leaflet will explain that participants allocated to Morita Therapy plus treatment as usual will no longer be offered such therapy once they have received a full "dose" (up to twelve sessions), but will be referred back to their GP with whom they could consider access to other treatments. We will ensure participants are reminded of these factors throughout the trial.

The University of Exeter has insurance to cover the potential legal liability for any harm to participants arising from the management of this trial. We will also provide potential participants with information about the possible benefits and risks of taking part in the trial in the participant information leaflet, and give them the opportunity to discuss this issue with us before consenting. We will inform participants in writing if new information comes to light which may affect their willingness to participate in the trial.

Managing risk of suicide
Inherent in the nature of the population under scrutiny is the risk of suicide. We will follow good clinical practice in monitoring for suicide risk during all appointments and explain to participants that we will contact their GP or specialist if deemed necessary in line with our risk protocol. If an acute risk is present, we will seek advice from the participant's GP (or the duty GP) immediately and/or follow locally established suicide management plans. All clinicians and researchers will be familiar with established risk protocols used in our previous research trials and/or within the AccEPT Clinic, specifically trained in risk assessment and supervised by experienced clinicians. We will put in place systems to ensure that senior academic and clinically qualified staff are notified should there be any risk to a participant's safety.

Patient and public involvement
We have developed the patient materials on the basis of both consultation with a Public and Patient Involvement Expert and similar materials used in our other mental health trials which received feedback from Public and

417

APPENDIX VII

Patient Involvement groups such as the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South West Peninsula (PenCLAHRC) [53] Patient and Public Involvement Group (PenPIG). This feedback has helped us to ensure that our research respects the rights, safety and dignity of participants. Ensuring that our research materials are sensitive and consistent with the views of people with depression will also aid us in recruitment and participants' engagement in and openness during interviews.

Following completion of the pilot trial, to ensure that our results reach our former trial participants and people with mental health issues in a way that is meaningful and accessible, we will establish an advisory group comprising members of PenPIG and follow national good practice guidance for researchers on public involvement in research and the paying of representatives [53]. The group will be involved in the dissemination of the results to the public and patients using accessible channels and their own conference and group meetings. Training in presentation skills will be arranged for members of the group should they consider this helpful. We will also consult the advisory group on the development of a summary sheet explaining the results of the study and their implications in lay terms, to be sent to consenting former trial participants.

Dissemination protocol
In addition to the above details on the dissemination of results to the public and former trial participants, we will disseminate the results of this study in a full internal report and intend to publish our results in a peer reviewed scientific journal. Authors will be those considered to have made a substantive intellectual contribution to the study. The main output from this study will be the information required to design and seek funding to conduct a definitive trial of Morita Therapy. Thus, in the long term we aim to contribute to national guidelines for the treatment of depression and anxiety.

The investigators and relevant authorities will have access to the trial dataset. Furthermore, we will store anonymised research data and outputs in the University of Exeter's Open Research Exeter repository [54] in order to facilitate open access to, and the impact of, our research.

Study oversight
This research forms part of the first author and Chief Investigator's (HVRS) PhD programme of studies for which she is supervised by DAR and JF. Trial conduct will be discussed between the Chief Investigator and her supervisors at monthly supervision meetings.

Although the convention of a formal Data Monitoring and Ethics Committee is not appropriate for the scale of this study, an independent clinician will act in this capacity in order to review serious adverse events which are thought to be treatment related, and any substantive protocol amendments. All such amendments will be communicated to the relevant authorities as deemed necessary.

Forecast execution dates
The preparatory period started in October 2014. Recruitment is running from September 2015 for approximately ten months. Follow-up and qualitative data will be collected from January 2016 to November 2016. Data analysis and reporting are expected to take another nine months. The total duration of the study will be 24 months.

Discussion
By preparing the ground for the design and conduct of a large-scale RCT, this study will contribute important information towards the development and subsequent evaluation of Morita Therapy for the treatment of depression and anxiety for the first time in the UK. One strength of our study design is that the proposed methods are appropriate for undertaking a feasibility study [41]. Our study purpose and research questions are in line with the National Institute for Health Research Trials and Studies' definition of a feasibility study [55] endorsed by Arain and colleagues [56]. We have calculated the RCT sample size based on the key feasibility objectives around recruitment and retention rates, and will calculate the variance in participant outcomes and their correlation with baseline scores to inform future sample size calculations. We will also calculate the observed differences between Morita Therapy plus treatment as usual and treatment as usual alone on the mean changes in outcome measures, although we will not make inferential statements or evaluate these outcomes. Rather than identifying a primary outcome measure, we have designed both the pilot trial and qualitative interviews to allow us to test the uncertainties associated with designing and running a large-scale fully-powered RCT of Morita Therapy plus treatment as usual versus treatment as usual alone.

To embrace the complexity of developing and evaluating interventions and provide a comprehensive understanding of the intervention in question, no one method will suffice [25]. Thus, a further strength of this study is our explicit commitment to a mixed methods approach and transparent description of the way in which quantitative and qualitative components will be integrated [41, 57]. We have carefully considered guidance on maximising the impact of qualitative research in feasibility studies

[49] and described our proposal in line with recommendations for Good Reporting of a Mixed Methods Study [57], which we will continue to follow in our future reporting. Our embedded mixed methods design reflects key decisions we have reached on the levels of interaction, priority, timing and procedures in the mixing of the quantitative and qualitative components [24, 41]. Thus, we will interactively mix the two components before final interpretation, at both the design and analysis levels, by embedding qualitative interviews within the pilot RCT in a program-objective framework; give the two components equal priority; undertake the pilot trial and qualitative interviews concurrently; and analyse data from the two components simultaneously.

We have specified research question seven to frame the integration of results from the quantitative and qualitative strands, to help explain variability in treatment adherence and thus facilitate a more complex picture of the acceptability of Morita Therapy [24]. By qualitatively exploring the acceptability of both Morita Therapy and our trial procedures, and integrating the qualitative and quantitative data, we will facilitate both the interpretation of our pilot trial findings and the feasibility and/or efficiency of any large-scale RCT, thus allowing us to optimise both our intervention and trial conduct in the future [58]. The integration of quantitative and qualitative methods will enable us to address both exploratory and explanatory research questions simultaneously, and help to reduce the limitations of each individual method whilst retaining their strengths [25]. Ultimately, by implementing an embedded mixed methods design, this study will better prepare the ground for a large-scale fully-powered RCT of Morita Therapy plus treatment as usual versus treatment as usual alone than would be possible from either a quantitative or qualitative approach alone [25, 41].

Trial status

Recruitment commenced in September 2015 and is ongoing.

Additional files

Additional file 1: Study Summary Sheet. (PDF 222 kb)

Additional file 2: Permission to contact form. (PDF 160 kb)

Additional file 3: Participant Information Leaflet. (PDF 766 kb)

Additional file 4: Model Consent Form. (PDF 246 kb)

Abbreviations

GAD: Generalised Anxiety Disorder; GPs: General Practitioners; NICE: National Institute for Health and Care Excellence; IAPT: Improving Access to Psychological Therapies; RCT: Randomised Controlled Trial; MRC: Medical Research Council; NIHR: National Institute for Health Research; DSM: Diagnostic and Statistical Manual of Mental Disorders; MDC: Mood Disorders Centre; AccEPT: Accessing Evidence Based Psychological Therapies; PHQ-9: nine item version of the Patient Health Questionnaire; GAD-7: seven item Generalised Anxiety Disorder questionnaire; SF-36: Short Form 36 Health Survey Questionnaire; WSAS: Work and Social Adjustment Scale; MASA: The Morita Attitudinal Scale for Arugamama; CLAHRC: National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care; PenCLAHRC: National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care South West Peninsula; PenPIG: National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care South West Peninsula Patient and Public Involvement Group.

References
1. Andrews G, Sanderson K, Slade T, Issakidis C. Why does the burden of disease persist? Relating the burden of anxiety and depression to effectiveness of treatment. Bull World Health Organ. 2000;78:446–54.
2. Mental Health Foundation. http://www.mentalhealth.org.uk/help-information/mental-health-statistics/anxiety-statistics/. Accessed 22 Dec 2014.
3. Layard R. The depression report: A new deal for depression and anxiety disorders, (No. 15). Centre for Economic Performance, LSE; 2006.
4. Ferrari AJ, Charlson FJ, Norman RE, Patten SB, Freedman G, Murray CJ, et al. Burden of depressive disorders by country, sex, age, and year: findings from the global burden of disease study 2010. PLoS Med. 2013;10(11):e1001547.
5. Andrews G, Henderson S, Hall W. Prevalence, comorbidity, disability and service utilisation. Overview of the Australian National Mental Health Survey. Br J Psychiatry. 2001;178:145–53.
6. Kessler RC, Berglund P, Demler O, Jin R, Koretz D, Merikangas KR, et al. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). Jama. 2003;289:3095–105.

7. O'Brien M, Singleton N, Bumpstead R, Office For National Statistics LSSD. Psychiatric morbidity among adults living in private households, 2000. London (United Kingdom): The Stationery Office; 2001.

8. Keller MB. Long-term treatment of recurrent and chronic depression. J Clin Psychiatry. 2001;62:3–5.

9. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2005;62:593–602.

10. National Institute for Health and Clinical Excellence. Depression: Management of depression in primary and secondary care, National Institute for Health and Clinical Excellence; 2009.

11. National Collaborating Centre for Mental Health. Generalised Anxiety Disorder in Adults: Management in Primary, Secondary and Community Care, Leicester and London, The British Psychological Society and the Royal College of Psychiatrists (NICE Clinical Guidelines, No. 113); 2011.

12. Rush AJ, Fava M, Wisniewski SR, Lavori PW, Trivedi MH, Sackeim HA, et al. Sequenced treatment alternatives to relieve depression (STAR*D): rationale and design. Control Clin Trials. 2004;25:119–42.

13. IAPT: Improving access to psychological therapies. www.iapt.nhs.uk. Accessed 22 Dec 2014.

14. Clark DM, Layard R, Smithies R, Richards DA, Suckling R, Wright B. Improving access to psychological therapy: Initial evaluation of two UK demonstration sites. Behav Res Ther. 2009;47:910–20.

15. Hollon SD, Munoz RF, Barlow DH, Beardslee WR, Bell CC, Bernal G, et al. Psychosocial intervention development for the prevention and treatment of depression: promoting innovation and increasing access. Biol Psychiatry. 2002;52:610–30.

16. Morita M, Kondo A, LeVine P. Morita Therapy and the True Nature of Anxiety-Based Disorders. Albany: State University of New York Press; 1998.

17. Nakamura K, Kitanishi K, Maruyama S, Ishiyama FI, Ito K, Tatematsu K, et al. Guidelines for practising outpatient morita therapy. Tokyo: Japanese Society for Morita Therapy; 2010.

18. Ogawa B. Desire For Life: The Practitioner's Introduction to Morita Therapy for the Treatment of Anxiety Disorders. Indiana: XLibris Publ; 2013.

19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J. 2008;337:a1655.

20. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10:1.

21. Richards DA, Hill JJ, Gask L, Lovell K, Chew-Graham C, Bower P, et al. Clinical effectiveness of collaborative care for depression in UK primary care (CADET): cluster randomised controlled trial. Br Med J. 2013;347:f4913.

22. Wiles N, Thomas L, Abel A, Ridgway N, Turner N, Campbell J, et al. Cognitive behavioural therapy as an adjunct to pharmacotherapy for primary care based patients with treatment resistant depression: results of the CoBalT randomised controlled trial. Lancet. 2013;381:375–84.

23. Rhodes S, Richards DA, Ekers D, McMillan D, Byford S, Farrand PA, et al. Cost and outcome of behavioural activation versus cognitive behaviour therapy for depression (COBRA): study protocol for a randomised controlled trial. Trials. 2014;15:29.

24. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 2nd ed. Thousan Oaks: Sage Publications, Inc; 2011.

25. Borglin G. The value of mixed methods for researching complex interventions. In Richards DA, Hallberg IR, editors. Complex Interventions in Health: An overview of research methods. Oxon: Routledge; 2015. p. 29–45.

26. Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995;14:1933–40.

27. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The Mini-Cog: a cognitive 'Vital signs' measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry. 2000;15:1021–7.

28. Whooley MA, Avins AL, Miranda J, Browner WS. Case-finding instruments for depression. J Gen Intern Med. 1996;12:439–45.

29. First MB, Williams JBW, Spitzer RL, Gibbon M. Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Clinical Trials Version (SCID-CT). New York: Biometrics Research, New York State Psychiatric Institute; 2007.

30. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16:606–13.

31. Mood Disorders Centre AccEPT Clinic (Accessing Evidenced Based Psychological Therapies). https://www.exeter.ac.uk/mooddisorders/acceptclinic/. Accessed 22 Dec 2014.

32. Ishiyama I. Introduction to Morita Therapy. Paper presented at the In Holstebroand Vejle (HOLD FAST) Denmark. 2011. http://vlholderfast.nu/wp-content/uploads/2011/06/Slides-fra-kursus-i-Morita-terapi.pdf. Accessed 30 Jun 2015.

33. LeVine P. Morita-Based Therapy and Its Use Across Cultures in the Treatment of Bulimia Nervosa. J Counsel Dev. 1993;72(1):82–90.

34. LeVine P. Classic Morita Therapy: Consciousness, Nature and Trauma, State University of New York Press, USA. (In Press)

35. Ogawa B. A River to Live By: The 12 Life Principles of Morita Therapy. Philadelphia: Xlibris/Random House; 2007.

36. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166:1092–7.

37. Ware JE, Kosinski M, Dewey JE, Gandek B. SF-36 health survey: manual and interpretation guide. Lincoln: Quality Metric Inc; 2000.

38. Mundt JC, Marks IM, Shear MK, Greist JM. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. Br J Psychiatry. 2002;180:461–4.

39. Richards DA, Mullan EG, Ishiyama FI, Nakamura K. Developing an Outcome Framework for Measuring the Impact of Morita Therapy: A Report from a Consensus Development Process. J Morita Ther. 2011;22:165–73.

40. Taylor M. Interviewing. In: Holloway I, editor. Qualitative Research in Health Care. Maidenhead: Open University Press; 2011. p. 29–55.

41. Hill JJ, Kuyken W, Richards DA. Developing stepped care treatment for depression (STEPS): study protocol for a pilot randomised controlled trial. Trials. 2014;15:452.

42. STATA: Data Analysis and Statistical Software. http://www.stata.com/. Accessed 25 Sep 2015.

43. Lancaster GA. Pilot and feasibility studies come of age! Pilot Feasibility Stud. 2015;1(1):1.

44. QSR International: NVivo 10 for windows. www.qsrinternational.com/products_nvivo.aspx. Accessed 25 Sep 2015.

45. Ritchie J, Spencer L, O'Connor W. Qualitative research practice: A guide for social science students and researchers. London: Sage; 2003.

46. Thorne S. Data analysis in qualitative research. Evid Based Nurs. 2000;3:68–70.

47. Miles MB, Huberman AM. Qualitative data analysis: An expanded sourcebook. London: Sage; 1994.

48. Dingwall R, Murphy E, Watson P, Greatbatch D, Parker S. Catching goldfish: quality in qualitative research. J Health Serv Res Policy. 1998;3(3):167–72.

49. O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. Pilot Feasibility Stud. 2015;1:32.

50. World Medical Association. World Medical Association Declaration of Helsinki. Ethical principles for edical research involving human subjects. Bull World Health Organ. 2001;79:373.

51. Medical Research Council/ NHS Health Research Authority Consent and Participant Information Sheet Preparation Guidance. http://www.hra-decisiontools.org.uk/consent/. Accessed 22 Dec 2014.

52. Department of Health. Mental Capacity Act. London: HMSO; 2005.

53. NHS National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care South West Peninsula. http://clahrc-peninsula.nihr.ac.uk/. Accessed 22 Dec 2014.

54. Open Research Exeter (ORE). https://ore.exeter.ac.uk/repository/. Accessed 16 Nov 2015.

55. The National Institute for Health Research Evaluation Trials and Studies Coordinating Centre (NETSCC) glossary. The National Institute for Health Research Evaluation Trials and Studies Coordinating Centre (NETSCC) Q8 glossary. http://www.netscc.ac.uk/glossary/. Accessed 25 Sep 2015.

56. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010;10:67.

57. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. J Health Serv Res Policy. 2008;13:92–8.

58. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J. What can qualitative research do for randomised controlled trials? A systematic mapping review. British Medical Journal Open. 2013, 3. doi: 10.1136/bmjopen-2013-002889

Appendix VIII: Feasibility study recruitment

This appendix provides a copy of supporting documents used for feasibility study recruitment, specifically:

- Study summary sheet
- Permission to contact form
- Participant Information Leaflet
- Consent form
- Clinical Information Form
- Patient Details Form

Study summary sheet

Morita
The Morita
Therapy Trial

Patient Summary Information Leaflet

The Morita Trial (Morita Therapy for Depression and Anxiety:
A Feasibility and Pilot Study)

This is a very short summary of our study. **It asks you to consider taking part in our research and for your permission for a researcher to contact you about the study.**

Introduction. We are carrying out a study at the University of Exeter Medical School to help develop a large trial of Morita therapy, a new treatment for depression and anxiety. We are writing to you because your GP surgery has agreed to help us with this by sending information to you after you visited your GP reporting symptoms that are experienced by many people with depression.

What is the treatment that is being tested? This study will provide us with the information we need to investigate the effects of Morita therapy. Morita therapy is a treatment for mental health problems which is widely practiced in Japan but little known in the UK. Ultimately, we would like to carry out a large trial to find out whether Morita therapy is effective for people here who experience depression and anxiety. Before we can do this, we need to carry out a small trial to develop the treatment and test our procedures. We also want to know if Morita therapy is acceptable to patients and to clinicians.

What will happen if I take part? If you would like to take part, a researcher will speak with you to see if you are eligible for the study and to explain it in more detail. If you are eligible and agree to take part you will receive either Morita therapy or the usual care which is available to you from your GP and elsewhere.

This study is a randomised controlled trial which means that the decision about whether you would receive Morita therapy or not is made completely by chance. Half of our participants will receive Morita therapy and half will receive usual care. We will meet with

Study Summary Sheet v1.0 08 JAN 2015

422

everyone who would like to take part to find out if they are eligible and to fill in some questionnaires. Four months later, we will also meet again with everyone who takes part in the study to fill in the questionnaires again.

Morita therapy will involve between eight and twelve face to face sessions over eight to twelve weeks, a one hour session per week. The treatment will be delivered by a trained therapist at the University of Exeter's AccEPT Clinic. Everyone who receives Morita therapy will also be invited to an interview after they have completed treatment to find out their views of Morita therapy and their experiences of taking part in the trial, if they would like to.

At the end of the trial, we will look at how many people took part and filled in our questionnaires. We will also use the information people provide to work out how big a large trial needs to be, and to see whether Morita therapy is acceptable to patients and therapists.

Will my taking part in this study be kept confidential? We will keep all of the information that we collect about you during the course of the research strictly confidential within the study team.

What should I do now? If you are interested in the study and are happy for a researcher to contact you to discuss whether or not you would like to take part, you should **complete the enclosed 'Permission for Researcher to Contact' form and return it to the study researcher in the freepost envelope enclosed.** Someone working on the study will then contact you with more information about this study and arrange a time to meet you and answer any questions you may have.

Meanwhile, if you would like to find out more, you can contact the Morita Trial researcher Holly on 01392 727412 or at h.v.s.sugg@exeter.ac.uk.

Thank you for reading this and for considering taking part in this study.

EXETER | MEDICAL SCHOOL
UNIVERSITY OF

Study Summary Sheet v1.0 08 JAN 2015

Permission to contact form

Morita
The Morita
Therapy Trial

'Permission for Researcher to Contact' Form

**The Morita Trial (Morita Therapy for Depression and Anxiety:
A Feasibility and Pilot Study)**

I confirm that I have read and understand the summary sheet for the above study and I am happy for a researcher to contact me to discuss whether or not I would like to take part. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

Name...
(Please print name)

Address..

....

....

Signature...

Name of GP and Surgery:...

Telephone contact details:

Day.. May we leave a voice mail message? Y / N

Evening.. May we leave a voice mail message? Y / N

Mobile... May we leave a voice mail message? Y / N

When is the best week day/ time of day to get hold of you? ....

Email address...

Please return to:

Holly Sugg, Morita Trial Study Researcher
University of Exeter Medical School
South Cloisters, St Luke's Campus
Heavitree Road
Exeter EX1 2LU

Email: h.v.s.sugg@exeter.ac.uk   Office telephone: 01392 727412

EXETER | MEDICAL SCHOOL

Permission to Contact Form v1.0 07 JAN 2015

Participant Information Leaflet

Participant Information Leaflet

The Morita Trial (Morita Therapy for Depression and Anxiety: A Feasibility and Pilot Study)

Thank you for returning your permission to contact form for this research study. Before you decide whether you want to take part or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Depression and anxiety cause misery to many people and are major health problems in the UK. Although some current treatments are effective for some people, they do not work for everybody and it is important to develop new therapies so as to offer people a choice of treatments which may suit them. One possible treatment for depression and anxiety is called Morita therapy. Although this treatment is widely used in Japan, we do not know if it is effective for and acceptable to patients and clinicians in the UK. By carrying out a large clinical trial to assess the outcomes of Morita therapy, we hope to find out whether it is an effective depression and anxiety treatment for people here. However, before we can do this, we need to test the treatment and our procedures in a small trial. We also need to speak with patients and therapists to find out what they think about Morita therapy.

Why have I been invited and will the study be suitable for me?

Either your GP surgery or local Improving Access to Psychological Therapies (IAPT) service is taking part in this trial and sent you a letter asking you to consider taking part because you reported symptoms that are experienced by many people with depression

which we are treating in this study, or you have contacted us in response to one of our adverts for the study online or in your GP waiting room. This information sheet is for you to keep, if you decide to take part one of our research team will go through the information sheet with you and answer any questions you have. You will also be asked some questions by the researcher to see if you are eligible to be included in the study. You may take part whether you are taking medication or not, and whether you have tried therapy in the past or not. <u>However, if you are currently receiving another psychological therapy you will not be able to take part in this study.</u>

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. If you do decide to take part, you will still be still free to withdraw at any time and without giving a reason. A decision to withdraw or not to take part will not affect the care you receive in any way.

What is being tested?

We are running a small clinical trial to compare Morita therapy for depression and anxiety with usual care. We are intending to carry out a large trial to test Morita therapy but before we can do this, we need to find out how big such a trial needs to be and how many people we need to approach to take part. We also need to know what patients and therapists think about Morita therapy. A small trial will allow us to develop the treatment and our trial methods, and we will use qualitative interviews to find out if Morita therapy is acceptable to people.

Morita therapy is based on the idea that symptoms of depression and anxiety are a natural part of peoples' experience, but that responses to these feelings can make them worse. In particular, focusing too much on trying to change unpleasant feelings can actually fuel them, like being caught in a vicious cycle. The therapist helps you to understand these behaviours and how they can be unhelpful. As opposed to current therapies such as Cognitive Behavioural therapy, the aim is therefore to focus on how to live constructively in spite of symptoms, rather than focusing on changing thoughts and feelings.

Usual care means you will not receive any treatment through the study itself but there will be no restrictions placed on the care or treatment you may wish to access

elsewhere. You will be returned to the care of your GP and may discuss treatment options with them.

What will happen if I take part?

Thank you for speaking with us over the phone and arranging to meet with us to find out if you are eligible to take part in the study. You can ask us about the study at any time. If we confirm at our meeting that you are eligible and you agree to take part you will receive Morita therapy or usual care. However, if after you have spoken with the researcher and answered some questions it is found that you are not eligible to take part, we are really sorry if it causes you disappointment and thank you for your interest and time that you have given. If you are not eligible to take part we would refer you back to your GP to continue treatment in the normal way.

If you are eligible to take part we need to explain that this study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about whether you receive Morita therapy or usual care is made completely by chance. In this trial half of our participants will receive Morita therapy and half will receive usual care. We will allocate you to either Morita therapy or usual care by assigning you a personal identification number, known only to the research team, which will be entered into a secure computer system that picks the numbers at random and allocates them to one of the options at random. We will let your GP know that you are participating in this study.

If you are allocated to Morita therapy, you will receive between eight and twelve sessions of one hour duration with a trained therapist once a week, spread over eight to twelve weeks. The therapist will see you face to face and help you to complete a daily diary between sessions which outlines your daily activities. If you are allocated to usual care, we will let your GP know and you will be free to access any other treatments which you can discuss with your GP.

Once you have been allocated to Morita therapy or usual care, you may be invited to a more in-depth interview about why you have chosen to take part in the trial. We will also meet you again for a follow-up appointment with a researcher four months after our first meeting, to complete a number of questionnaires. If you are allocated to Morita therapy, once you have attended all the treatment sessions we will also invite you to take part in a more in-depth interview about your views of Morita therapy and

experiences of taking part in the trial. Overall, your involvement in the study will be for a maximum of five months although the research study will last for two years.

What information do you need from me?

At our arranged meeting we will find out more about you. We will need to ask about your current and past mental health as well as your life more generally. We will ask you some questions about how you have been feeling recently and there will be a few questionnaires that we would like you to fill out. You will also be able to ask any questions you may have about the study. This meeting will take about two hours. We expect that the follow-up appointment will take no more than around one hour and we will collect some more questionnaires from you at this appointment.

We are interested in finding out about why people have volunteered to take part in the trial. Therefore, we may ask you to attend a more in-depth interview of up to one hour after we have seen you for our first meeting. We are also interested in finding out what people think of Morita therapy and their experiences of taking part in the trial. Therefore, we will ask people who are allocated to receive Morita therapy to attend a more in-depth interview of around one hour after they have completed treatment. We would like to audio record these interviews if you are happy for us to. The interviews would be conducted over the phone or face to face at your home. Alternatively, if you cannot speak on the phone or meet a study researcher at your home, we will arrange to meet with you at the University of Exeter. There is a separate part to the consent form to allow you to give your consent for these interviews, and you do not have to agree to it if you do not want to.   If you choose not to take part in the interviews, you can still take part in the trial and it will not affect the standard of care you receive. If you agree, the recordings will be anonymously transcribed (typed up word for word, with any information which may identify you or your family or friends removed) before being destroyed.

Will I have to do anything differently?

No, there are no restrictions in your lifestyle from taking part in this research. You should continue to follow the advice of your GP if they remain involved in your care.

Will I be paid to take part?

No. We cannot pay people to attend appointments with their therapist and we will not reimburse travel expenses for these. Occasionally, it may be necessary for people to attend additional interviews with a study researcher at the University of Exeter for which we will pay travel expenses.

What happens when the research study stops?

We will encourage you to continue to see your GP who will treat you as s/he feels is best for you and with your agreement.

Are there any side effects, disadvantages and risks of taking part?

We are not aware of any side effects, disadvantages or risks to you of taking part in this research. If any relevant new information comes to light which may affect you or your decision to take part in the trial we will inform you of this.

What are the possible benefits of taking part?

Many people in Japan and other countries have found Morita therapy helpful and it has been shown to have a positive effect for some people with mental health problems such as depression and anxiety. If you are allocated to receive Morita therapy, we hope that the treatment you are given will help you. However, we cannot guarantee that you will benefit from the treatment. The information we get from this study may help us to treat future patients with depression and anxiety better.

What will happen to the results of this study?

We will send you a summary of the results of the study if you would like us to. We intend to publish the results of this study. Any presentations and publications will not identify you personally. We hope to use the information from this study to design a large trial of Morita therapy and potentially help us to treat future patients better.

What if something goes wrong or I have a complaint?

We do not expect any harm coming to you from being in this study. However, if you wished to complain, or had any concerns about any aspect of the way you have been approached or were treated during the course of this study, the normal National Health

Service complaints mechanisms are available to you through the Patient Advice and Liaison Service (PALS) on 0800 0730741. Alternatively, if you are randomised to receive Morita therapy, you may prefer to raise the matter with the Mood Disorders Centre AccEPT Clinic. Written complaints should be sent to the AccEPT clinic complaints manager at: Washington Singer Laboratories, School of Psychology, University of Exeter, Perry Road, Exeter, EX4 4QG. If you are eligible, agree to take part, randomised to Morita therapy and are unhappy with the care or treatment you receive, you can also raise the matter (in writing or by speaking) with your clinic therapist.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Any personal details, such as name and address, that we collect from you will be stored securely for five years and accessed only by the study team. Any information about you that is collected from the questionnaires or interviews will be stored indefinitely on the University of Exeter's open access repository (Open Research Exeter) in order to support other research in the future. These will have all personal details removed so that you cannot be recognised from them.

As your GP may be involved in your treatment, s/he will be informed of your progress as part of the research study. Should your condition worsen to a point where it is felt by either a researcher or a clinician that you may be a danger to yourself or others, your GP will be informed of this; with or without your permission. However, this is the only time we would ever break confidentially.

In the unlikely event that you become unable to consent to taking part during the study, we will withdraw you from the study. We will retain any data which you have already given us but will only use this confidentially and in line with the consent you have already given us.

Who is organising and funding the research?

The study researcher is funded by the University of Exeter Medical School who also sponsor this research. This is not a commercially funded industry study. This means that your GP surgery and the Exeter Depression and Anxiety Service who may have invited you to express your interest in the study, and the research team, will not receive any extra money for conducting this study.

Who has reviewed the study?

All research involving NHS patients is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights well-being and dignity. The study has been reviewed and given a favourable opinion by the South West - Frenchay Research Ethics Committee.

Further Information – Next Steps

Please look at the 'Participant Flow Chart' on the next page which sets out the assessment and treatment process in a way which we hope you find helpful. During our arranged meeting you will have the chance to ask questions and we will ask you for more information to find out if you are eligible. If you are eligible and want to take part, we will ask you to sign a form to say so and then get you to fill out some questionnaires about yourself.

Contact for Further Information

If you need further information or have any questions, please contact:

Holly Sugg, Morita Trial Researcher
University of Exeter Medical School
Room 1.33, South Cloisters
St Luke's Campus
Heavitree Road
Exeter EX1 2LU

Email: h.v.s.sugg@exeter.ac.uk
Office telephone: 01392 727412

Thank you for reading this and for considering taking part in this study.

Morita Trial Participant Flow Chart

You expressed your interest in taking part in a trial of a treatment called Morita therapy

↓

You have spoken to the study researcher who has arranged an assessment meeting with you to find out if you are eligible to take part in the study

↓

At the assessment the study will be explained to you fully and you can ask any questions you may have. You will be asked some questions to see if you are eligible

↓

If you are eligible and happy to proceed you will be asked to provide your consent to take part in the study

If after the assessment you are found not to be eligible to enter into the study, we are very sorry and thank you very much for your interest in the Morita Trial. You will return to the usual care of your GP

↓

If you are enrolled into the trial your details will be entered onto a secure computer that picks at random whether you will receive Morita therapy or treatment as usual

↓

You may be invited to an interview about why you chose to take part

↓

Morita therapy involves between 8 and 12 one hour one-to-one sessions with a therapist on a weekly basis

Treatment as usual means you will not receive treatment in the study but may access treatment elsewhere as normal

↓

There will be a follow-up appointment at 4 months

↓

You will be invited to an interview after you finish Morita therapy

↓

Thank you. You have completed your involvement in the Morita Trial and we thank you for your participation. You will return to the usual care of your GP and will be sent a summary of the results of the Morita studies if you would like to

Consent form

Morita
The Morita
Therapy Trust

The Morita Trial (Morita Therapy for Depression and Anxiety: A Feasibility and Pilot Study)

CONSENT FORM

This consent form is in two parts. You do not have to sign both parts.

Part 1 on page 1: This is about your general participation in the study. Please initial the boxes and sign if you agree to take part.

Part 2 on Page 2 is optional – you can choose if you wish to take part or not: This is about whether you agree to being interviewed by a study researcher about your reasons for taking part in the trial and, if you receive Morita therapy, your views of the therapy. This also asks whether you agree to your Morita therapy sessions being audio-recorded, if you receive Morita therapy in the study.

PART 1: MAIN STUDY	Please initial box
1. I confirm that I have read and understand the information leaflet (dated 26/05/15 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree to my GP being informed of my participation in this study and updated with information from this study relevant to my medical care.	
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	
5. I understand that the data collected for this study which may identify me personally will be retained securely for up to five years, even if I decide to withdraw from the study, and that it will be accessed by the study researchers only.	
5. I understand that the data collected for this study will be anonymised (the information which may identify me personally will be removed) and will be stored indefinitely in Open Research Exeter in order to support other research in the future.	
6. I agree to take part in the above study.	
7. I would like to receive a summary of results of the Morita therapy studies via [email] or [post] (please delete as appropriate, and delete both if you do not wish to receive a summary)	

When you have initialled the boxes above, please write your name and sign and date below.

_____   _____   _____
Name of Participant *(BLOCK CAPITALS)*   **Date**   **Signature**

TO BE COMPLETED BY THE RESEARCHER:
I have explained the study to the above patient and he/she has indicated his/her willingness to take part in the study"

_____   _____   _____
Name of Researcher *(BLOCK CAPITALS)*   **Date**   **Signature**

I copy for patient, 1 copy for researcher, 1 copy for GP

EXETER | MEDICAL SCHOOL

Morita Trial Participant Consent form v1.0 – 06 JAN 2015

Morita
The Morita
Therapy Trial

The Morita Trial (Morita Therapy for Depression and Anxiety: A Feasibility and Pilot Study)

PART 2: INTERVIEWS AND AUDIO-RECORDING (OPTIONAL)

This section is optional.

You can choose if you wish to be interviewed and/or have your Morita therapy sessions audio-recorded or not.

Your decision will not affect your participation in the main part of the study.

This consent form is about whether you agree or not to being interviewed and your interviews being audio-recorded. It also asks you whether you agree to your Morita therapy sessions being audio-recorded or not if you receive Morita therapy through the study, and how you are happy for us to use these recordings. Please note that if you agree either of these, your data will be retained and shared in accordance with the consent form for the main study.

Please only initial the boxes that you wish to consent to. Thank you.

	Please initial box
1. I am willing for my Morita therapy sessions to be audio recorded for clinical purposes.	
2. I am willing for my therapy session recordings to be retained for research purposes.	
3. I am willing for my therapy session recordings to be retained for training purposes.	
4. I am willing to be interviewed.	
5. I am willing for the interviews to be audio recorded for research purposes only and I understand that the recordings will be deleted once transcribed.	
6. I am willing for publications and presentations to include direct quotations from me which will be made anonymous.	

When you have initialled the boxes above, please write your name and sign and date below.

_____   _____   _____

Name of Participant *(BLOCK CAPITALS)*   **Date**   **Signature**

TO BE COMPLETED BY THE RESEARCHER:

I have explained the additional part of study to the above patient and he/she has indicated which parts apply.

_____   _____   _____

Name of Researcher *(BLOCK CAPITALS)*   **Date**   **Signature**

I copy for patient, 1 copy for researcher, 1 copy for GP

EXETER | MEDICAL SCHOOL
UNIVERSITY OF

Morita Trial Participant Consent form v1.0 – 06 JAN 2015

Clinical Information Form

Trial ID	
Date of baseline assessment	
SCID major depressive disorder (symptoms present most of the day nearly every day for at least two weeks within past month)	Depressed or down - Loss of interest or pleasure - Change in appetite/ weight (gain or loss?) - Change in sleep (insomnia or hypersomnia?) - Psychomotor change (agitation or retardation?) - Fatigue/ loss of energy - Feelings of worthlessness/ guilt - Trouble concentrating/ indecisiveness - Recurrent thoughts of death - Number of episodes: Age of onset: Notes:
SCID anxiety disorders	Panic disorder (lifetime) - Panic disorder (current) - Panic disorder with agoraphobia (lifetime) - Panic disorder with agoraphobia (current) - Agoraphobia without panic disorder (lifetime) - Agoraphobia without panic disorder (current) - Social phobia (lifetime) - Social phobia (current) - Specific phobia (lifetime) - Specific phobia (current) - Define specific phobia: OCD (lifetime) - OCD (current) - PTSD (lifetime) - PTSD (current) - GAD (6 months preceding MDD) - Notes:
Baseline PHQ-9 score	
Baseline PHQ-9 Question 9 (risk) score	
	P.T.O.

Baseline GAD-7 score	
Baseline Work and Social Adjustment score	436
Current anti-depressant use	
Any other notes/ issues for the therapist	

Patient Details Form

Name	
DoB	
Address	
Phone number	
Okay to leave message?	
Mobile number	
Okay to leave message?	
Email address	
GP name	
GP Practice	
Ethnicity	
Preferred days/ times for therapy	
Preferred gender for therapist	
Consent to audio record therapy sessions?	
Follow-up date	

Appendix IX: Feasibility study management and data collection

This appendix provides a copy of supporting documents used during the management of and data collection for the feasibility study, specifically:

- Therapist fidelity checklist
- Topic guide for participants
- Topic guide for therapists
- Risk protocol
- Serious Adverse Events reporting form
- Letters:
    - National Research Ethics Committee South West – Frenchay (ethics approval)
    - Devon Partnership NHS Trust (governance assurance)

Therapist fidelity checklist

Morita Therapy: Therapist Fidelity Record

Session 1: Introducing Therapy

Therapist name:_____   Patient Trial
ID:_____

Date of session:_____   Session number: 1

	Tick if completed
1. Acknowledgement that participant is part of a research project	
2. Introduction to the history of Morita Therapy	
3. Information gathering on why the patient is seeking treatment	
a. Elicit examples of possible desire for life	
b. Elicit examples of the vicious cycle	
4. Explanation of principles	
a. Use of patient's own examples	
b. Nature	
c. Emotions as pleasant/unpleasant but neither good/bad	
d. Therapy for changing relationship to emotions, not emotions themselves	
e. Vicious cycle	
f. Inward vs outward focus	
g. Desire for life	
h. Mind's capacity for rejuvenation in right circumstances	
i. Check in on patient's understanding of principles	
5. Explanation of four phases	
a. Experiential treatment	
b. Rest as an opportunity to experience the ebb and flow of emotions	
c. Phase two as an opportunity to look outwards in detail	
d. Phase three involving more complicated/ demanding activities	
e. Phase four involving more social activities	
f. Gradual process of re-engagement with breadth of options	
6. Explanation of techniques	
a. Fumon: emotions will be used as cues for discussions but we will not disentangle and focus on emotions	
i. Acknowledgement of importance of emotions	
b. Diaries	
i. Maximum one page per day	
ii. Patient should 'just write'	
iii. No right or wrong	
iv. Exchange process	
v. Patient given diary to complete over next week	
7. Consideration of whether the patient should bring a significant other to session 2 to prepare for rest phase	

Morita Therapy: Therapist Fidelity Record

Session 2: Preparing for Rest

Therapist name:_____ Patient Trial
ID:_____

Date of session:_____ Session number: 2

	Tick if completed
1. Explanation of rationale for rest	
a. Allow recovery from fatigue: as part of the natural world we cannot resist this need	
b. Remove patient from unhelpful expectations/ routines/ patterns including fighting how they feel	
c. Experience the ebb and flow of emotions	
i. Patient will find that their emotions go up and down and that they may experience distress which is natural	
ii. Patient should not focus on trying to change their thoughts/ feelings but be with them and observe how they flow over time	
iii. Metaphor use – stormy sea/ scab	
2. Facilitation of rest	
a. Ensuring that the patient has a way to get these experiences – the longer the rest, the better	
b. Stressing of the importance of this phase as an investment	
c. Clarity that this is radical – not their normal experience of rest	
d. For working patients, consideration of whether they may be signed off for one week	
3. Exploration of challenges/ barriers to rest	
a. Ensuring the patient is aware that rest will be challenging	
b. Exploration of how to create a safe space	
c. Advice given to patients to use the diary as a container for their experiences	
d. Addressing any guilt the patient expresses	
4. Specification of the conditions for rest	
a. In silence with no distractions etc.	
b. Tend to basic needs	
5. Production of aide-memoir with patient which they take away	

Morita Therapy: Therapist Fidelity Record

Session 3 onwards

Therapist name:_____   Patient Trial
ID:_____

Date of session:_____   Session
number:_____

Phase (1: rest/2: light activities/ 3: heavy activities/ 4: social reintegration):
_____

PRINCIPLES/ STANCE

		Tick if completed
ESSENTIAL	1. Fumon	
	2. Reference to the natural world	
	3. Interpretation of negative emotions as desires for life	
AS APPROPRIATE	4. Use of metaphor	
	5. Explanation of/ reinforcement of patient's insight into the vicious cycle	
	6. Reference to accepting the natural ebb and flow of emotions	
	7. Reinforcement of emerging desire for life	
	8. Reinforcement of outward focus	
	9. Reinforcement of action	

OPERATIONALISATION

		Tick if completed
	1. Diary exchange	
	a. Patient asked to review comments and feedback	
	b. Patient asked if they can see how the comments reflect Morita Therapy principles	
	2. Review of how the patient got on with the phase over the previous week	
	3. Enquiry into indicators of progress for the current phase	
	4. Negotiation of the next phase (see overleaf) *if appropriate*	
	5. Check on what patient is taking away from the session	
	6. Confirmation with patient which phase they are in/ what (in)action they will take this week	
	a. Ensuring patient is planning to complete diary	

P.T.O.

		Tick if completed
PHASE 1	1. Exploration of how (much) rest was set up – sufficient attention given to reflect value of rest	
	2. Prescription of rest for additional week *if appropriate (essential for session 3)*	
	a. Where indicators of progress present in session 3, discussion of moving onto smaller periods of rest	
	3. For patients who have experienced a lot of distress, provision of reassurance that this is expected/ early stages	
PHASE 2	1. Explanation of the purpose *when negotiating phase*	
	a. Experience the ebb and flow of emotions if left alone	
	b. Increase focus outwards	
	c. Connect with nature	
	d. Channel and fuel desires	
	2. Facilitation of the patient's identification of activities which meet the criteria	
	a. Engagement with nature	
	b. Observation and use of senses	
	c. Light and repetitive tasks using hands	
	d. Absorbing activities	
	e. Enjoyable activities	
	3. Use of active therapeutics *if appropriate* e.g. moving outside to observe/ explore	
PHASE 3	1. Explanation of the purpose *when negotiating phase*	
	a. Increase focus outwards	
	b. Connect with nature	
	c. Channel and fuel desires	
	d. Try to experience the self in the moment and as part of their body	
	2. Facilitation of the patient's identification of activities which meet the criteria	
	a. Engagement with nature	
	b. Concrete and functional tasks in which the patient can succeed	
	c. Attending to what is significant in their environment – what requires their attention	
	d. Small steps	
	e. Tasks involving whole body movements	
	3. Use of active therapeutics *if appropriate* e.g. use of community garden	
PHASE 4	1. Explanation of the purpose *when negotiating phase*	
	a. Reintegrate the patient back into their real life in society	
	b. Anxious action-taking to develop an action/purpose-based rather than mood-oriented lifestyle	
	2. Facilitation of the patient's identification of activities which meet the criteria	
	a. Small steps/ cumulative efforts	
	b. Tasks of everyday living	

Topic guide for participants

Morita Trial Qualitative Interview Topic Guide

PARTICIPANTS

Introduction

Thank you very much for meeting with me today. We really appreciate your time. Once I've explained this part of the study to you and answered any questions you may have, the interview itself should last about one hour so we should be finished by…. Is that going to be ok for you?

You may remember that we'd like to know what you think about the treatment you've received as part of this study. We'd also like to hear your views of how we have set up and run the study so I'll be asking you some questions about that, too.

Compared with when I last met with you, this interview will be a bit different. We'd like to know what you think about things. This means that I will ask you questions for you to tell me your views and opinions – how things have been from your perspective. Sometimes, I might follow up something you say with a few more questions to make sure that I fully understand it.

IF CONSENTED TO AUDIO RECORDING: Before we begin, are you still happy for our interview to be audio-recorded? I'll let you know when I start recording.

IF DID NOT CONSENT TO AUDIO RECORDING: Can I just check whether you're happy for me to audio-record the interview? When I transcribe the interview I will take out any information that might identify you personally. (IF NO, TAKE NOTES INSTEAD/ IF YES, ASK THEM TO RE-INITIAL THE RELEVANT PART OF THE CONSENT FORM AND PUT THE DATE NEXT TO THE CHANGE)

I will take some notes as we talk instead, but please be assured that I am still listening.

You may remember that everything you say is kept strictly confidential with one exception and that's if you tell me anything which makes me think you may be at risk of harming yourself or someone else. Is that OK?

And for my write up if I include any direct quotes from you I can either label them as anonymous or replace your first name with a pseudonym if there's a particular name you would like to choose? (ADD CHOSEN PSEUDONYM OR "ANONYMOUS" TO INTERVIEW NOTES AT THE END OF THE TOPIC GUIDE)

Is there anything that you would like to ask before we begin?

As we go through the questions, if anything is unclear, please do ask me to explain.

Ready to begin?

I'm going to start recording now.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

Ask them to confirm that the study has been explained to them and they have given their consent to participate.

1. **Thoughts and feelings before treatment**
   Can you tell me a bit about what led you to take part in this trial?

   Probe areas:

   -Was there anything about Morita Therapy in particular

   -Why are they involved in this trial in particular

   -What did they expect from treatment

   -Were there any problems with which they particularly wanted help? What were they?
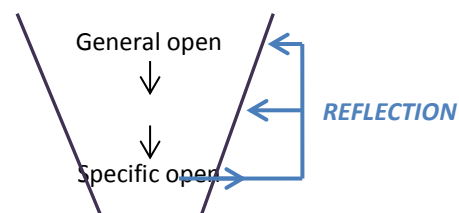
2. **Understanding/ Experiences of treatment**
   Having now attended Morita Therapy, please can you describe to me your understanding of what Morita therapy is?

   Probe area:

   -Understanding of the goals of Morita Therapy

   <u>Please tell me about your experiences of receiving treatment</u>.

   Probe areas:

   -Length of therapy sessions, total length of treatment, way in which therapy was ended

   -What it felt like receiving treatment

   -Anything in particular that they liked or found helpful

   -Anything they didn't like or found less helpful

   -How could the treatment have been improved

   -How well the therapy helped them with the problems they wanted to work on

   *-To what extent did therapy match their **expectations** – why (not)/ how (not)/ in what ways*

   *-How they found the experience of completing a daily **diary**, and the written comments*
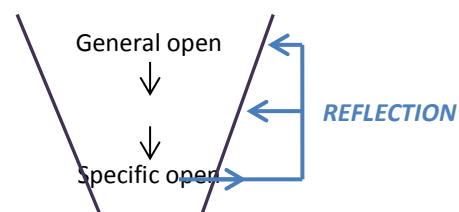
*-What is their view of the different **phases** of Morita Therapy, especially the rest phase (including directions received/ preparing for rest with the therapist)*

*-What are their thoughts/ feelings about the **style of the therapist** (including their explanation of how/why they would not be paying particular attention to emotions, and how this was experienced in practice)*

*-What is their view of the concept of '**desire for life**' – how this was explained/ the examples used and how relevant it was for them*

*-What is their view of the **vicious cycle** and how this does or does not relate to them*

*-How did they feel about the idea of **accepting the natural ebb and flow** of emotions and how this was put across to them*

*-What is their view of the **connection to natural world/** how this was put into practice for them in a literal sense*

*-What is their view of the use of **metaphors**? Any that stick in their mind as particularly helpful or unhelpful*

*-What is their view of the amount of **explanation and rationale** that was given for the therapy as a whole, and anything they were asked to do (diary/ each phase)*

3. **Barriers to treatment**
   We are interested in reasons why people might decide to attend some or all of their therapy sessions. Please could you tell me about your reasons for deciding to continue with or stop therapy? (If relevant: Why did you decline treatment/ stop early?)

   Probe areas:

   -Personal contextual factors

   -Specific therapy factors

   -Therapeutic relationship factors (including therapist style)

   -Stages or exercises i.e. diary writing/ particular phases found difficult?

   -Anything (else) that could have been done to overcome these difficulties

General open
↓
Specific open

REFLECTION
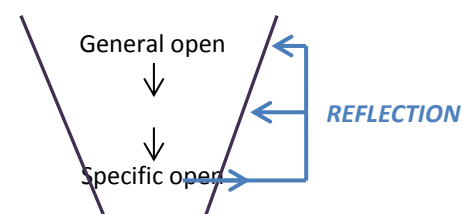
4. **Active treatment components/ mechanisms**
   We are interested in the ways in which treatment may have brought about changes for you, particularly in terms of anything you may have learned from the treatment. Please can you tell me about any changes that happened for you during treatment?

   Probe areas:

   -Anything they learned during treatment

   -'What was it about treatment that changed that for you?'

   -'What impact has this change had for you?'

General open
↓
Specific open

REFLECTION
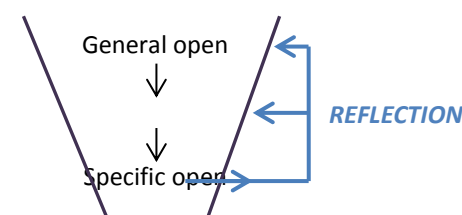
5. Experiences of the trial

Your views and opinions of the trial itself are also important to us. How did you feel about taking part in a research trial?

Do you have any views or comments on how we have set up and run the trial?

Probe areas:

-When did they decide to take part in the study

-What did they think of the written information they received

-How did they feel about how long it took for us to contact them after they returned their form

-How did they feel about the process of being randomised to either Morita therapy or TAU

-What did they think of how long it took the clinic team to contact them after their baseline

-How easy was it to schedule therapy appointments

-How well were their questions or concerns during the study addressed

-What could have been done to improve the running of the study

General open ↓ ↓ Specific open → *REFLECTION*
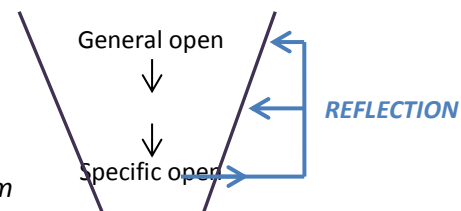
6. Experiences of the MASA questionnaire

We are interested in your experiences completing one of the questionnaires in particular, the MASA (give example). Do you have any comments on this?

Probe areas:

-Anything they didn't like

-Anything they didn't understand

-Relevance to them/ their experience of therapy/ the impact therapy had on them

General open ↓ ↓ Specific open → *REFLECTION*
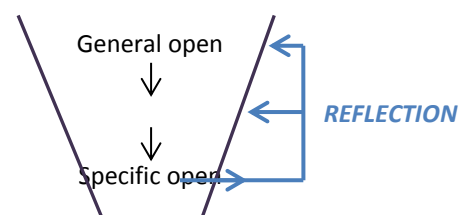
Finally, are there any other comments that you would like to make about taking part?

FINISH

Thank you.

Stop recording and tell the patient that the recorder has been switched off.

Explain that the patient will receive a short summary of the results of the interviews once completed (if they have agreed to this on the consent form)

Topic guide for therapists

Morita
The Morita
Therapy Trial

Morita Trial Qualitative Interview Topic Guide

THERAPISTS

Introduction

Thank you very much for meeting with me today. I really appreciate your time. Once I've explained the study to you and answered any questions you may have, the interview itself should last about one hour so we should be finished by…. Is that going to be ok for you?

As you know, I would like to find out what you think about the therapy you've delivered as part of this study. I'd also like to hear your views of how we have set up and run the Morita Trial so I'll be asking you some questions about that too. I have broad questions that will help structure the interview but I will also be led by what you say. Sometimes I might follow up something you tell me with more questions to help me understand it in full.

Is that OK?

Before we begin, I would like to acknowledge that it may sometimes be difficult for you to provide honest feedback. However, it is important for me to understand what did and didn't work well. The information you provide will be used to help develop a large clinical trial on Morita therapy. Everything you say is kept strictly confidential.

And for my write up, if I include any direct quotes from you, I can either label them as anonymous or replace your first name with a pseudonym if there's a particular name you would like to choose? (ADD CHOSEN PSEUDONYM OR "ANONYMOUS" TO INTERVIEW NOTES AT THE END OF THE TOPIC GUIDE)

I will not, without your permission, include a quote that would directly identify you by something you said. However, because a very small number of therapists have been involved in the Morita Trial, it may be possible for a reader who is familiar with the project to attribute quotes and/or views, to you or your colleagues.

Do you have any concerns?

IF CONSENTED TO AUDIO RECORDING: Before we begin, are you still happy for our interview to be audio-recorded? I'll let you know when I start recording.

IF DID NOT CONSENT TO AUDIO RECORDING: Can I just check whether you're happy for me to audio-record the interview? When I transcribe the interview I will take out any information that might identify you personally.   (IF NO, TAKE NOTES INSTEAD/ IF YES, ASK THEM TO RE-

INITIAL THE RELEVANT PART OF THE CONSENT FORM AND PUT THE DATE NEXT TO THE CHANGE)

I will take some notes as we talk instead, but please be assured that I am still listening.

Is there anything that you would like to ask before we begin?

As we go through the interview, if any of my questions are unclear, please do ask me to explain.

Ready to begin?

I'm going to start recording now.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

Ask them to confirm that the study has been explained to them and they have given their consent to participate.

1. **Understanding of Morita therapy**
   To help me understand what you think of Morita therapy, I would like to know how you define it. Please describe Morita therapy to me.
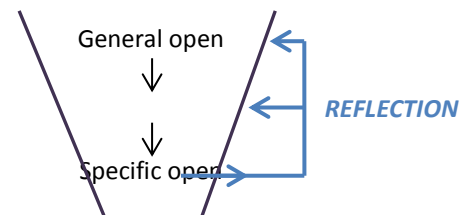
2. **Experiences of Morita therapy**
   I would now like to ask you about the therapy you have implemented as part of this study. First, please tell me what you thought of Morita therapy.

   Probe areas:

   -The frequency and length of each session/ total duration of treatment

   -What they thought about the diary writing

   *-How they expected patients to benefit from Morita therapy*

   -Any patients or circumstances where Morita therapy felt inappropriate and how they handled that

   -Patients for whom Morita therapy worked especially well or not and why

   -Reasons why patients declined Morita therapy or dropped out early and how they felt about this

   -Ways in which Morita therapy and how it was delivered could be improved
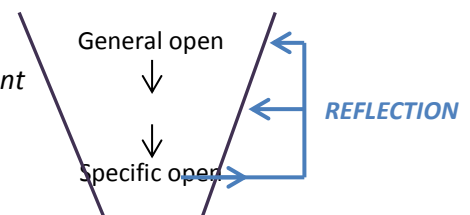
-How they felt about the criteria for ending treatment and implementing this in practice

-What, if any, support they wanted to offer upon ending treatment

-DIARIES (how often returned/ completed)

-Phases especially REST

-Use of FUMON and ACCEPTANCE of emotions

-Connection to NATURE

-DESIRE FOR LIFE/ Reinterpreting fears as desires

-Vicious cycle

3. Mechanisms of change

We are interested in the ways in which Morita Therapy may have brought changes about for patients, especially in terms of things they may have learnt from treatment. Please can you tell me what you think the changes were that Morita Therapy brought about for patients?

Probe areas:

-What impact do you think this has for patients?

-What was it about Morita Therapy that you think may have brought about these changes?

General open

↓

↓

Specific open

REFLECTION
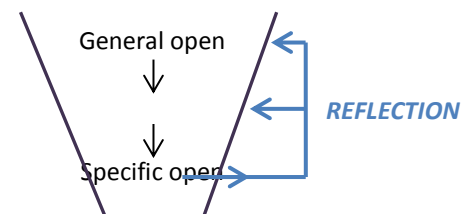
4. Orientation towards Morita Therapy

We are interested in your views of Morita Therapy and how this has impacted upon you. Can you tell me about your views and experiences of delivering Morita Therapy?

Probe areas:

-Any impact on them personally

-Any impact on views of mental health/ other approaches to treatment

-Any impact on their worldview

General open

↓

↓

Specific open

REFLECTION

5. The therapy protocol

We are also interested in your experiences using the Morita therapy protocol. Please could you tell me what you thought of the protocol?

Probe areas:

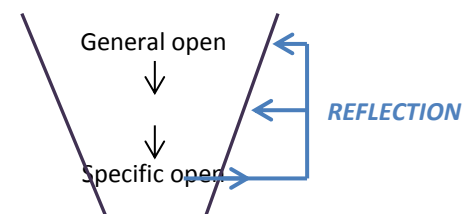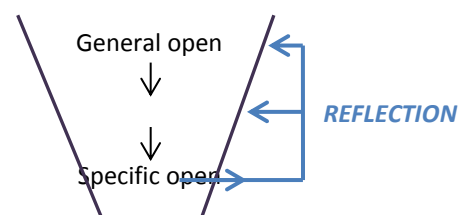- *How user friendly and understandable*

- *How helpful during treatment sessions*

- *Any impact they found from changes made to the protocol during the intervention optimisation study*

- *Ways in which the current version could be improved*

- *Views on using the protocol as part of training new therapists*

General open

↓

Specific open

REFLECTION

Please tell me about anything else that feels important to feedback on your experience of Morita therapy

6. Feasibility and appropriateness of trial procedures

Your views and opinions of how this study has been set up and run are also important to us. Please can you tell me your thoughts on taking part in this study?

Probe areas:

- *What they thought of the Morita therapy orientation meeting*

- *How well details of new patients were passed on/ comments on the patient information received from me from baseline assessment*

General open

↓

Specific open

REFLECTION

- *Problems scheduling therapy sessions*

- *Views and experiences of record keeping and file management including copying of diaries*

- *How they felt about SAE and risk procedures*

- *Views on DNA protocol and letters to people who withdrew from therapy*

- *How they felt about clinical supervision*

- *What might be done to improve how the study is run*
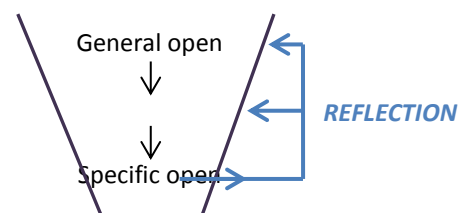
Please tell me about anything else that feels important to feedback on the set up and running of the Morita Trial

FINISH

Finally, are there any other comments that you would like to make about taking part?

Risk protocol

PROTOCOL FOR ASSESSING, REPORTING AND MONITORING RISK

Amended from the COBRA Protocol for assessing, reporting and monitoring risk v.2.2 120313

1. Policy Statement

GPs are responsible for the ongoing clinical care of Morita trial participants. Therefore, all trial staff directly involved with research participants have a duty of care to ensure that participants' GPs are aware of any risk to participants or from participants to others, including suicidal thoughts expressed by participants.

Researchers must initiate the risk protocol each time a participant expresses suicidal thoughts, thoughts of self-harm or thoughts of harm to others. This may be as a result of responses to questionnaire items or the participant may disclose information during an interview that leads the researcher to believe that there are thoughts of suicide or harm to self or others. In both instances, the researcher should initiate the risk protocol and notify their first supervisor.

2. Principles

The following principles and procedures govern risk assessment, reporting and monitoring for the Morita Trial.

The Morita trial excludes participants at baseline interview who demonstrate any risk to self or others that would require management by specialist mental health or other services. However, included participants might develop such risk during the trial and must be assisted accordingly.

The first supervisor has overall responsibility for risk assessment and management for the Morita trial. The first supervisor must ensure that any research personnel involved with the Morita trial are adequately qualified and trained on risk assessment prior to any patient contact in which risk could be disclosed, and that these personnel receive support and supervision around risk issues during their involvement with the trial.

All cases where significant risk is identified by researchers will be managed according to the Morita risk protocol and discussed with the first supervisor. All assessment reports and correspondence relating to risk sent by research staff will be checked by the first supervisor before they are sent.

3.   Procedures for research personnel

All researchers will be made familiar with the protocol and new staff who will be involved in assessing/treating patients will be familiarised as part of their induction/training. Risk assessment should therefore be conducted following appropriate training and with appropriate supervision.

The first supervisor is responsible for ensuring that appropriate cover is arranged for any risk issues that might arise in their absence when away from research sites. This will entail a person being named as responsible for overseeing risk assessments in their absence and contact details being shared with Morita trial staff.

Whenever any significant risk is identified (during an interview or through reviewing patient reported outcome measures) a **risk assessment form (appendix A) should be completed and (counter-) signed by the first supervisor**. If at all possible this should be done at the time of the assessment, or as soon afterwards as possible. Research staff should seek supervision the same working day that they receive any information regarding risk and ensure management of the information has been handed over to the first supervisor.

All contact with patients/GPs and any other professionals around risk should be documented in writing in the participant's file. Contact with the patient's GP, duty GP or other emergency service should be instigated according to the level of risk identified having followed the Morita risk policy. As specified in the policy, contact may be by telephone, or if by fax a phone call to the GP Surgery made to ensure receipt of the fax.

Many of the Morita questionnaires (e.g. PHQ-9) include questions about suicide risk. Morita trial staff should always respond to any identified risk (as specified below) via these measures, and a risk assessment in line with this protocol should be completed.

A score of 1 or more on the PHQ-9 item 9 requires further assessment.

All personnel working on the Morita trial should also ensure they ascertain whether participants represent a risk to themselves or others through neglect or active harm and whether participants are themselves at risk of being harmed by others. The same process is to be followed in any instance of risk and **supervision from the first supervisor should be obtained immediately in the case of significant risk and within the same day for less immediate concerns.**

4. Questions To Ask & Protocol If Risk Has Been Identified For Morita trial Patients

THOUGHTS

"I see that you've said / you mentioned that……... These are thoughts / feelings that people suffering from depression often have, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

1   Do you know how you would kill yourself?   Yes / No

If **yes** – details

---

2   Have you made any actual plans to end your life?   Yes / No

If **yes** – details

ACTIONS

3   Have you made any actual preparations to kill yourself?   Yes / No

If **yes** – details

---

4   Have you ever attempted suicide in the past?   Yes / No

If **yes** – details

PREVENTION

5   Is there anything stopping you killing or harming yourself
at the moment?   Yes / No

If **yes** – details

---

6   Do you feel that there is any immediate danger that you
will harm or kill yourself?   Yes / No

If **yes -** details:

FOLLOW-UP FROM PREVIOUS CONTACT

7   **If Action B was enacted at previous assessment and level B risk is identified at current assessment**: Last time we met I suggested that you spoke to your GP about these thoughts, and I also wrote to your GP about this. Have you been able to speak with your GP about these thoughts since we last met?   Yes / No

To be used following any indication of risk from questionnaire items, responses to interview questions or any other sources. <u>Look at answers from the sheet to determine level of risk, A B or C:</u>

Actions by Morita trial Staff member	*Tell Participant*

All answers 'no' apart from Q5 'yes':

A
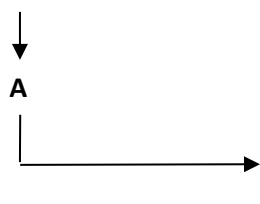
I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) <u>I would advise you to make an appointment to see your GP to talk about these feelings.</u>

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6

B1
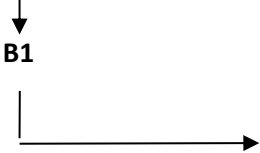
Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. <u>I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.</u>

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 **and** 'no' to Q7

B2

I think it's important that your GP knows how difficult things are for you right now. <u>I will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings.</u> N.B: telephone call to GP to be followed up by letter. The letter should include the statement "the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan."

Scoring 'no' to Q5 or 'yes' to Q6

C Actively Suicidal
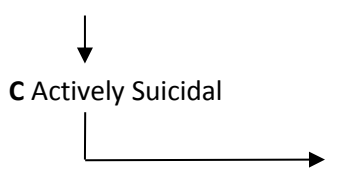
I am very concerned about your safety at this moment, <u>I am going to make some telephone calls to your GP/ Care Co-ordinator / Crisis Management team/the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.</u>

<u>Action to take in the case of immediate risk</u>:
Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up**. Follow your chain of supervisory contact in order to involve supervisory clinician right away. Then (with supervisor if possible) follow the chain of contact below:

1. **GP/out-of-hours GP**; if not
2. **Crisis team;** if not
3. **Clinician accompanies to A&E**; if not (or interview is over telephone)
4. **Call ambulance.**

Appendix A: Morita Risk Assessment Form

Date risk protocol enacted:	**Participant ID:**
Time Point: Telephone screen / Baseline / 4 month / other, please specify:	
Risk protocol has identified level of risk as: A B1 B2 C	

Suicide Risk Information:
Report which questionnaire and the score that gave cause for concern and attach copy of risk assessment. Include whether the participant has reported any of the following:
 	
• Current suicidal ideation
• Suicide plans
• Active preparations to commit suicide
 	
    • Protective factors or lack of them
    • Regular contact with GP?	

Clinical supervisor contacted: Y / N **Date:** **Name of supervisor:**	
Actions taken:	
Additional relevant information:	

Researcher Name:	Date:	Signature:
Clinical Supervisor Name:	Date:	Signature:

Appendix B: GP Risk Letter

Surgery Address

Date

Dear Dr_____

POTENTIAL RISK TO PATIENT

Re: Participant Name_____ DOB_____

As you know, <u>PATIENT NAME</u>, is taking part in the Morita trial comparing Morita therapy with primary care as usual for the treatment of Depression and Anxiety. As part of the trial, the Morita trial researcher interviews patients on a number of occasions to assess their health, during which we assess risk, including risk to self and others and suicide risk.

During the interview we conducted on <u>DATE</u> <u>PATIENT NAME</u> reported ……………………………………………………………………. (DETAILS OF PARTICIPANT'S THOUGHTS, PLANS ACTIONS).

As a consequence of this we instigated the Morita risk policy. We …………………………………………………………………………… (DETAILS OF ACTIONS TAKEN).

The Morita trial's clinical and research procedures do not provide participants with services to manage significant risk to self or others, including suicidal intentions. Clinical management of all patients in the Morita trial remains the responsibility of their GP. Of course, as part of our study protocol we have a duty to inform you of these disclosures and our actions in response to them so that you can take account of them in your clinical management of this patient. We trust that the above information will be of value to you in doing so.

Yours sincerely,

Site Researcher   Supervised by Professor David Richards
Cc: Participant

Action to take in the case of immediate risk:
Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up**.

1. Contact your supervisor AS SOON AS POSSIBLE:
    1. Prof Dave Richards – 07930 393456
    2. Holly Sugg – 07803 706516

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding Morita risk protocol"

2. Then follow the chain of contact below:

5. Participant's GP

Inform the receptionist that you need to speak to the GP and that it is urgent because it is about risk to their patient. If the GP is unavailable at the moment, ask when they are likely to be available. Ask the receptionist to ask the GP to call you back and make sure they pass on the message that this is urgent/ related to their patient being at risk.

"Hello, my name is_____, I'm one of the researchers working on the Morita Therapy trial at the University of Exeter's Medical School. I'm ringing because I'm with your patient _____ for an appointment at the moment and I'm very concerned about their safety. I have run through our suicide risk protocol with them and they have told me that _____ (briefly detail thoughts/ plans and the fact that they have nothing stopping them from harming themselves and/ or they have said that they are in immediate danger of harming themselves). Because I am a researcher and not a clinician, and to ensure their safety, I need to make sure they are seen by an appropriate clinician as soon as possible. Is it possible for yourself or a colleague of yours to meet with them here (*University premises or patient's home*)? …. I will stay [on the phone] with them until you arrive. (*if not and you are with the participant in person*: Is it possible for me to accompany them to your Practice so that I can stay with them until someone is able to meet with them for an appointment?)"

6. If participant's GP not available: **Out-of-hours/ Duty GP**

If the receptionist tells you that the GP is not in that day, ask for whoever the duty GP is/ if it is out of hours, speak with the out of hours GP. Use the same script as above.

7. If no GP available: **Crisis team:**

- Depending on where your appointment is being held (or the location of the participant if on the phone), contact the **Mental Wellbeing and Access Team** on:
    - Exeter: 01392 207799
    - Mid, Tiverton: 01884 235710/ Crediton: 01363 778600
    - East, Exmouth: 01395 280300/ Honiton: 01404 540100
    - Teignbridge (e.g. Dawlish): 01803 290782
    - North Devon (e.g. South Molton): Barnstaple: 01271 378781/ Bideford: 01237 472379

- Out of hours or where you cannot get hold of the Mental Wellbeing and Access team, contact

the **Crisis Resolution Team**:
  - o Wonford House (Exeter, East and Mid Devon): 01392 208540 or 07968845048
  - o Teignbridge (e.g. Dawlish): 01392 388266 or 01626 357351 or 01626 357327
  - o North Devon (e.g. South Molton): 01271 311835 or 0845 6000 388

"Hello, my name is _____, I'm a researcher working at the University of Exeter. I am currently in an appointment with a participant and I have become very concerned for their safety. I have run through our suicide risk protocol with them and they have told me that _____ (briefly detail thoughts/ plans and the fact that they have nothing stopping them from harming themselves and/ or they have said that they are in immediate danger of harming themselves). Because I am a researcher and not a clinician, and to ensure their safety, I need to make sure they are seen by an appropriate clinician as soon as possible but I'm not able to reach a GP at their Practice at the moment. Is it possible for a clinician within your service to meet with them here (*University premises or patient's home*)? …. I will stay [on the phone] with them until you arrive"

8. If GP/ Crisis team unavailable and you're with the participant in person: **Accompany to A&E** (if at all possible this should be done by Dave, not you)

"Hello, I'm a researcher working at the University of Exeter. I have come here with a participant because I am very concerned for their safety. According to what they have told me they are in immediate danger of harming themselves. Please can you arrange for them to be seen by a clinician to ensure their safety?"

Stay with participant until they are seen by a clinician.

9. If GP/ Crisis team unavailable and you're on the phone with the participant: **Call ambulance.**

"Hello, I'm a researcher working at the University of Exeter. I am currently with a participant and have become very concerned for their safety. According to what they have told me they are in immediate danger of harming themselves. …"

Stay with participant [on the phone] until the ambulance arrives.

Serious Adverse Events reporting form

Date of incident:	Participant ID:

Details of incident: Outcome:

Please indicate type (tick all that apply):				
Fatality:	☐	Persistent or significant disability or incapacity: ☐		
Life-threatening:	☐			
Hospitalisation or prolongation of hospitalisation:	☐	Congenital anomaly or birth defect: ☐		
		Other: ☐		

Additional relevant information:

Action taken by research team (if any):

Name of Therapist / Researcher (BLOCK CAPITALS)**:**	**Date:**	**Signature:**
Name of Researcher / Chief Investigator (BLOCK CAPITALS)**:**	**Date:**	**Signature:**

1. **Details of Primary Supervisor**

Name:	Prof David A Richards
Address:	University of Exeter Medical School Haighton Building University of Exeter St Luke's Campus Heavitree Exeter EX1 2LU
Telephone:	01392 724615
Email:	D.A.Richards@exeter.ac.uk

2. **Details of Study**

Full title of study:	Morita Therapy for Depression and Anxiety: A feasibility and pilot study
Name of main REC:	
REC reference:	
Research sponsor:	
Sponsor's reference for this report (if applicable):	

3. **Type of Event**

Please categorise this event, ticking all appropriate options:

Fatality:	☐	Life threatening:	☐	Hospitalisation or prolongation of hospitalisation:	☐
Persistent or significant disability or incapacity:	☐	Congenital anomaly or birth defect:	☐	Other:	☐

4. Circumstances of the Event

Date of event:	
Location of event:	
Describe the circumstances of the event (attach further details if required):	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Name of Chief Investigator: (BLOCK CAPITALS)	
Date of submission:	
Signature:	

6. Acknowledgement of Receipt by REC

INSERT NAME OF ETHICS COMMITTEE acknowledges receipt of the above.

Name: (BLOCK CAPITALS)	
Position on REC:	
Date:	
Signature:	

Signed original to be sent back to the Chief Investigator; copy to be kept for information by REC.

Ethics approval letter: National Research Ethics Committee South West – Frenchay

NHS

Health Research Authority

NRES Committee South West - Frenchay

Level 3, Block B
Whitefriars
Lewins Mead,
Bristol BS1 2NT
Email: nrescommittee.southwest-frenchay@nhs.net

Telephone: 0117 342 1335
Fax:0117 342 0445

28 May 2015

Miss Holly V. R. Sugg
PhD Student, Complex Interventions Research Group
University of Exeter
University of Exeter Medical School
Haighton Building, St Luke's Campus
Exeter
EX1 2LU

Dear Miss Sugg

Study title:	**Morita Therapy for Depression and Anxiety: A Feasibility and Pilot Study**
REC reference:	15/SW/0103
Protocol number:	N/A
IRAS project ID:	173077

Thank you for your letter (undated) responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Naazneen Nathoo, nrescommittee.southwest-frenchay@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

A Research Ethics Committee established by the Health Research Authority

Confirmation of ethical opinion

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

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.
Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

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

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

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [Appendix 11. Online advert]	1	08 January 2015
Copies of advertisement materials for research participants [Appendix 12. Flyer]	1	08 January 2015
Copies of advertisement materials for research participants [Appendix 13. Morita leaflet]	1	08 January 2015
Covering letter on headed paper [Letter of response to provisional opinion]	1	26 May 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Appendix 25. Public Liability Insurance Certificate]	1	19 March 2015
GP/consultant information sheets or letters [Appendix 22. Letter informing GP of patient's participation]	1	03 March 2015
Interview schedules or topic guides for participants [Appendix 5. Qualitative topic guide - pre-treatment]	1	20 February 2015
Interview schedules or topic guides for participants [Appendix 6. Qualitative topic guide - post-treatment - participants]	1	08 January 2015
Interview schedules or topic guides for participants [Appendix 7. Qualitative topic guide - post-treatment - therapists]	1	08 January 2015
IRAS Checklist XML [Checklist_24032015]		24 March 2015
IRAS Checklist XML [Checklist_26052015]		26 May 2015
Letter from sponsor [Appendix 27. Letter confirming sponsorship]	1	19 March 2015
Letters of invitation to participant [Appendix 8. Letter from GP to potential participant]	1	07 January 2015
Letters of invitation to participant [Appendix 14. Email for circulation]	1	08 January 2015
Letters of invitation to participant [Appendix 15. Letter from IAPT to potential participant]	1	08 January 2015

Non-validated questionnaire [Appendix 4. The Morita Attitudinal Scale for Arugamama]	1	15 August 2013
Other [Appendix 10. Permission for researcher to contact form]	1	07 January 2015
Other [Appendix 17. Telephone screen]	1	01 March 2015
Other [Appendix 26. Professional Indemnity Insurance Certificate]	1	19 March 2015
Other [Appendix 3. Frost CV]	1	01 March 2015
Other [Minami CV]	1	26 May 2015
Participant consent form [Appendix 19. Consent form - participants]	1	06 January 2015
Participant consent form [Appendix 21. Consent form - therapists]	1	06 January 2015
Participant information sheet (PIS) [Appendix 9. Study summary sheet]	1	08 January 2015
Participant information sheet (PIS) [Appendix 16. Study summary sheet - IAPT version]	1	08 January 2015
Participant information sheet (PIS) [Appendix 20. Interviewee information leaflet]	1	08 January 2015
Participant information sheet (PIS) [Appendix 18. Patient Information Leaflet]	2	26 May 2015
REC Application Form [REC_Form_24032015]		24 March 2015
Referee's report or other scientific critique report [Appendix 23. Scientific critique report]	1	05 February 2015
Referee's report or other scientific critique report [Appendix 24. Response to scientific critique report]	1	19 February 2015
Research protocol or project proposal [Research protocol]	1	01 March 2015
Summary CV for Chief Investigator (CI) [Appendix 1. Sugg CV]	1	01 March 2015
Summary CV for student [Appendix 1. Sugg CV]	1	01 March 2015
Summary CV for supervisor (student research) [Appendix 2. Richards CV]	1	01 March 2015
Validated questionnaire [PHQ9 questionnaire]	1	26 May 2015
Validated questionnaire [GAD7 questionnaire]	1	26 May 2015
Validated questionnaire [SF-36 questionnaire]	1	26 May 2015
Validated questionnaire [WSAS questionnaire]	1	26 May 2015

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

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

HRA Training

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

15/SW/0103	Please quote this number on all correspondence

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

Yours sincerely

pp. **Mr Peter Jones**
    Chair

Email:nrescommittee.southwest-frenchay@nhs.net

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

A Research Ethics Committee established by the Health Research Authority

Copy to: **Mrs Gail M. Seymour**

A Research Ethics Committee established by the Health Research Authority

Governance assurance letter: Devon Partnership NHS Trust

Miss Holly Sugg
PhD Student
Complex Interventions Research Group
University of Exeter
Haighton Building
St Luke's Campus
Exeter
EX1 2LU

Royal Devon and Exeter
Hospital (Wonford)
Barrack Road
Exeter
EX2 5DW

Tel: 01392 411611
RESEARCH AND DEVELOPMENT DIRECTORATE
Direct Dial: 01392 406933
Direct Fax: 01392 403012
Email: rde-tr.Research@nhs.net
Ref: CG/JL

Date: 4 August 2015

Dear Miss Sugg

Study Title: Morita therapy for depression and anxiety: A feasibility and pilot study

Researcher Name: Holly Sugg   **MREC Ref:** 15/SW/0103

Thank you for submitting your study documents to the Royal Devon & Exeter NHS Foundation Trust for review. We can confirm that the research satisfies our checks and has the following:

- Ethics Approval dated 28/05/2015 from NRES Committee South West - Frenchay
- Sponsorship from the University of Exeter
- Research protocol
- Participant Information Sheet and Consent
- Peer review

This assurance is for research based on the documents provided by the researcher and does not take into account any alterations to the research after the date of this letter.

Research Governance

I would like to take this opportunity to remind you of your responsibilities as a Principal Investigator.

These are:
1. Research procedures must be carried out in line with Good Clinical Practice and the Research Governance Framework for Health and Social Services, which details the responsibilities for everyone involved in research.
2. The Data Protection Act 1998 requires you to follow the eight principles of 'good information handling'.
3. To provide information when requested for research governance monitoring and auditing purposes.
4. You must be aware of, and comply with, Health and Safety standards in relation to your research.

Research Assurance Letter
V2.0 15/04/13

This letter is not an approval letter for the research to take place, but provides assurance that the study has been reviewed and has been approved by ethics.

It is advised that you, as the researcher, obtain written approval from each site you wish to involve in your study.

Yours sincerely

Chris Gardner
R&D Directorate Manager

Cc: Gail Seymour

Appendix X: Feasibility study qualitative data analysis

This appendix provides a copy of supporting documents used for the analysis of embedded qualitative interviews in the feasibility study, specifically:

- Sample participant field note
- Transcription template

Finally, examples of the analytic process in the development of themes on the acceptability of Morita Therapy to participants are included.

APPENDIX X

Sample participant field note

INTERVIEW NOTES	TRIAL ID M733
	DATE 18/08/16
	LOCATION St Luke?
	PSEUDONYM [illegible]

Respondent characteristics (pre (and post if obtained) PHQ-9 and GAD-7 scores; demographics; number of sessions attended; reason for ending treatment; last phase engaged in)

Pre PHQ = 12 / Post = 1   Pre GAD7 = 10 / Post = 1
Therapist = Pete
Completed treatment at 9 sessions / Social reintegration phase

Main themes on Morita therapy (session length, mode, number & total time in therapy; content; diary writing; ending treatment)

overall message: accepting etc & plan / it's ok to be with emotions /
    letting go of what you cannot control → changing expectations
→ Accepting emotion & focusing on changing response i.e. taking action
    you need to take despite emotion
"Worked"! Diary + phases + nature = especially helpful

Main themes on barriers to therapy

No weekend appts
Difficult to access building after hours
    Rest was hard (but necessary to break through)

Awkward at first as different
to preconceived ideas of
"therapy"

Main themes on mechanisms of change

Making sense of emotions / life through nature
Taking the action which needs to be taken
Acceptance - learning it's okay to allow & be with difficult emotions

Changing attitude /
expectations

Main themes on trial methods and procedures

None - all okay

Anything not asked that would have liked to in hindsight

None

Thoughts, new hypotheses

When people do 'get it', it's a v. simple & generalisable message -
going with the flow / accepting what you cannot control

Directions / questions for next interview

Comments about the contact
How did it go? How did I feel during? Rapport? Anything about the environment or events before or during the interview which may have influenced how it went?

Comfortable / good rapport

Transcription template

<u>Morita Trial Standard Operating Procedure: Transcription</u>

Interviews should be transcribed verbatim i.e. written down word for word (including "ums" etc.), using the template transcript below.

Formatting: The template transcript (see below) has been formatted so that each exchange of conversation is labelled by the identifier for the person (participant, interviewer) who is speaking. Insert what the person says on the line below their identifier. Interviewer and participant identifiers have been formatted as 'heading levels'; what people say must be formatted as 'normal' text. Insert a line break after what someone says and the next identifier. The start of the transcript is labelled by the participant's identifier – this label is formatted as normal text. The end of the transcript is demarcated by, "END OF TRANSCRIPT" – this has been written as normal text. All formatting should be left as is.

Identifiers: The interviewer is Holly Sugg, identifier I-HS. Participant identifiers contain two pieces of information and they are written in the form: MT-XX. The digits of the participant's trial ID number should replace the XX. As an example, the identifier for the participant with trial ID number MT01 would be 'MT-01'. The participant's trial ID number can be obtained from the name of the recording (which are in the format ID number _date of interview_interviewer's initials _post treatment interview_recording]

File labels: Please save transcripts in the form: ID number _date of interview_interviewer's initials _post treatment interview_transcript E.G. MT01_08.04.15_HS_post treatment interview_transcript.

Identifiable participant information: No identifiable data should be recorded. Where the participant reveals identifiable data during the interview (such as the name of the street they or a family member lives on), refer to the transcription conventions below. If the participant states a name and you are unsure who they are referring to and thus what information to place within brackets, please enter the name into the transcript but highlight it in yellow and alert me to it.

Transcription conventions:

{ } Interviewer and participant talk at same time (place both sections of speech in their own brackets)
[ ] non-verbal utterances e.g. laughter, and to **indicate removal of identifiable information** (e.g. [cough] or [participant's home town])
Xxx unintelligible (please try to decipher speech if at all possible)
(…) significant pause (2 or more seconds)
- abrupt cut off or self-interruption
<u>Underlining</u> indicates emphasis on the word

Template transcript

MT-XX

I-HS
Insert text here and continue on a new line as required.
Insert a blank line between the end of this text and the patient's identifier. Ensure that the blank line is formatted as normal text.
Repeat below.

MT-XX
Replace XX with the digits of the participant's trial ID number.
Insert text here and continue on a new line as required.
Insert a blank line between the end of this text and the interviewer's identifier. Ensure that the blank line is formatted as normal text.
Repeat below.

I-HS

MT-XX

I-HS

MT-XX

I-HS

MT-XX

I-HS

MT-XX

I-HS

END OF INTERVIEW

Examples of the analytic process in the development of themes on the acceptability of Morita Therapy to participants
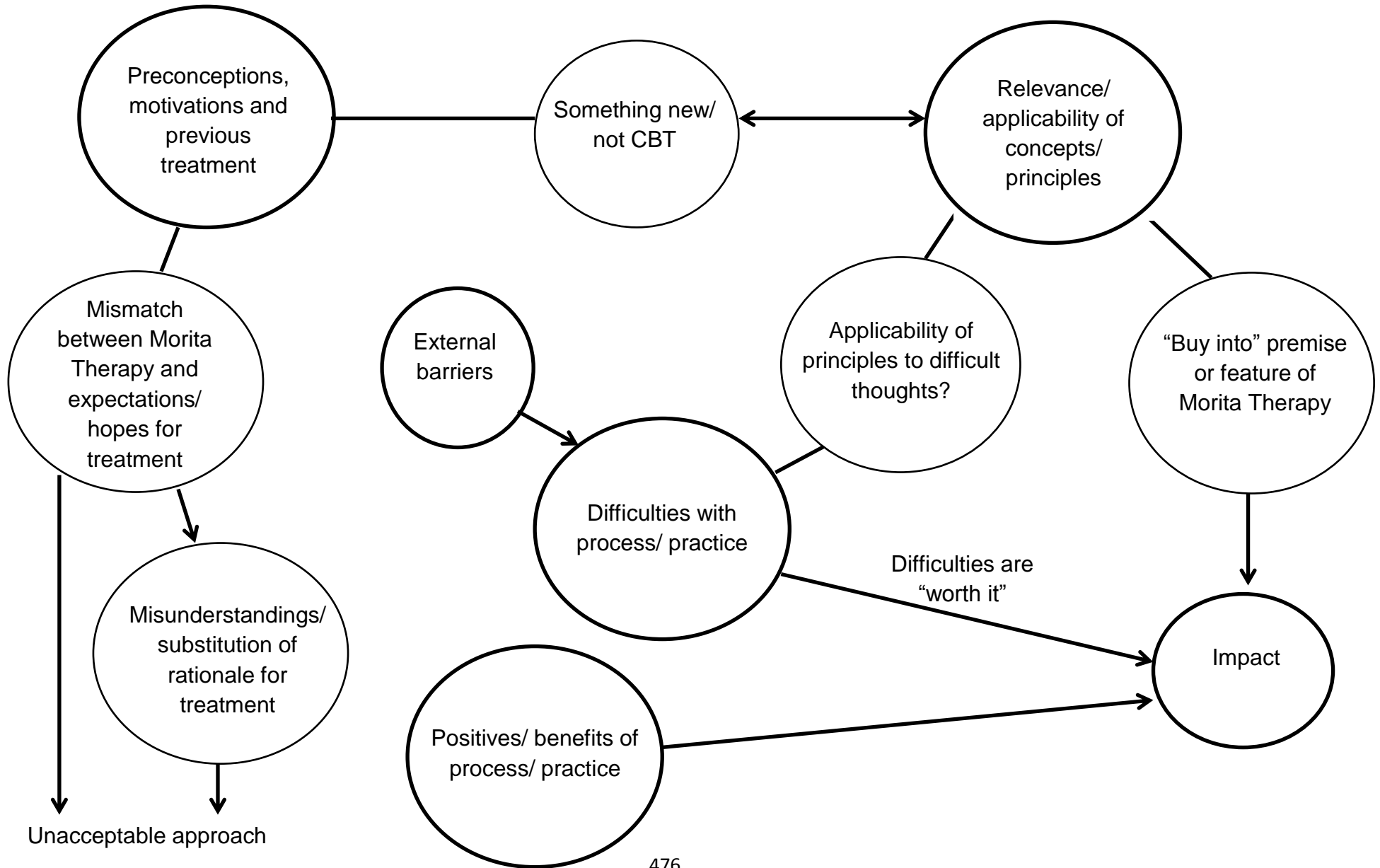
1. List of initial codes following first-cycle descriptive coding

Expectations and hopes for treatment
Seeking someone to talk to and understand
Seeking something new
Seeking tools and techniques
Comparisons to other therapies
Suits their previous approach
Understanding purpose and rationale
Misunderstandings
Accepting, allowing and being with
Learning everything passes
Learning what you can't control
Losing attachment to emotions
Normalising emotions
The ebb and flow of emotions
Vicious cycle
Authentic self
Desires and values
Nature - general
Nature - enjoyment
Conceptualising the self as part of nature
Understanding through nature
Understanding through metaphors
Refocusing attention
Taking action
Applying the principles
Not connecting to the principles
Interpretation of meaning of phases
Experiences of rest
Rest – fear
Rest - time difficulties
Experiences of phase 2
Experiences of phase 3
Experiences of phase 4
Diary as difficult
Diary as helpful
Fumon
Holistic
Aspects of therapy working together
Instinctive/ experiential changes
Structure
Natural, gradual, gentle progression
Small steps and goals
Making you think
Barriers to treatment
Pressure

Relationship with therapist
Support system
Dealing with difficult thoughts
Impact of treatment
Impact - confidence
Impact - less criticism
Thinking differently
Coping with and managing emotions
Longer term solution
Ongoing process
Ending treatment
Session structure and number
Risk protocol
AccEPT Clinic/ building issues
Trial management
Randomisation
The MASA questionnaire

2. Initial mind map/ development of a thematic map

Preconceptions, motivations and previous treatment

Something new/ not CBT

Relevance/ applicability of concepts/ principles

Mismatch between Morita Therapy and expectations/ hopes for treatment

External barriers

Applicability of principles to difficult thoughts?

"Buy into" premise or feature of Morita Therapy

Difficulties with process/ practice

Misunderstandings/ substitution of rationale for treatment

Difficulties are "worth it"

Impact

Positives/ benefits of process/ practice
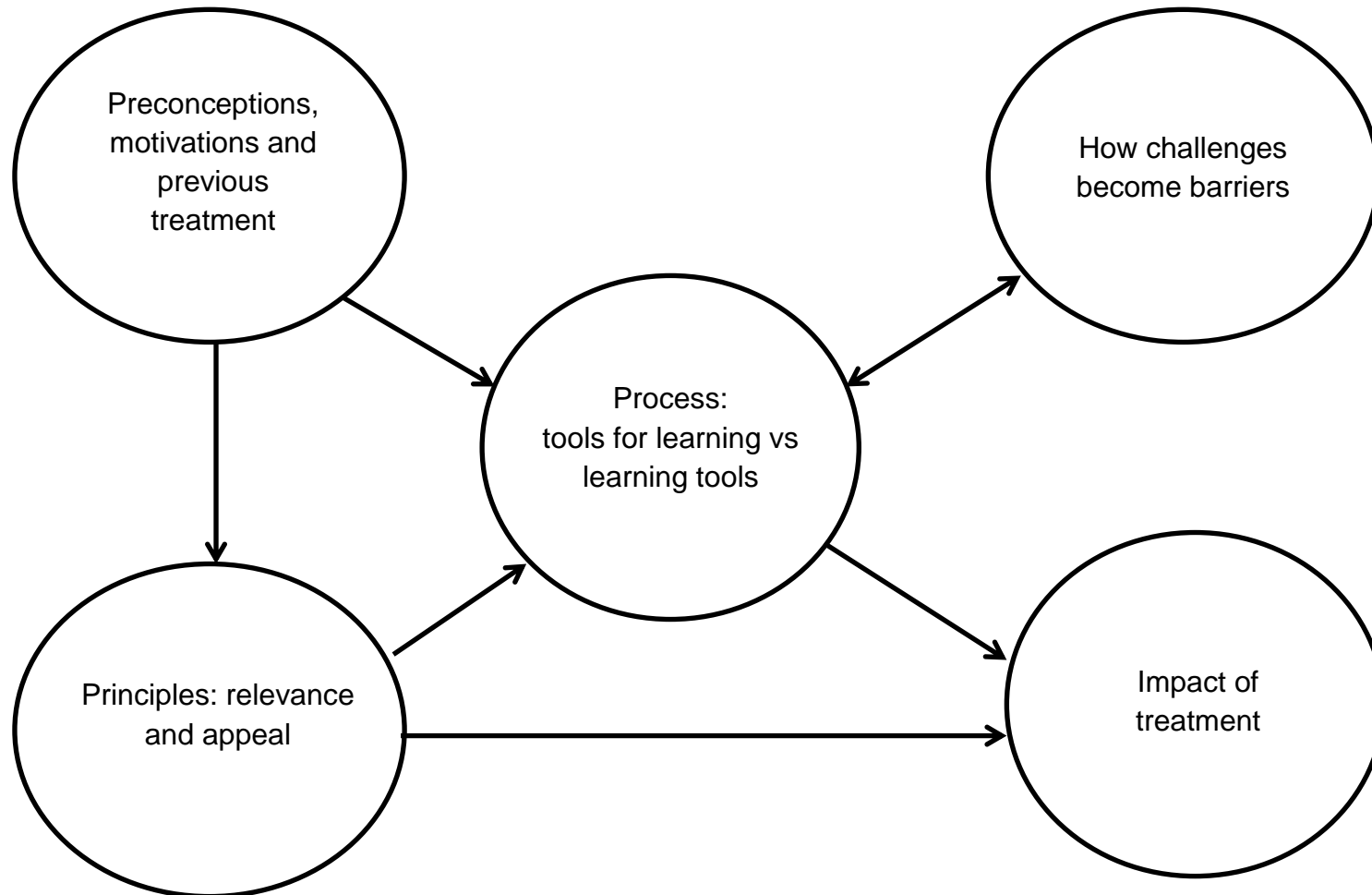
Unacceptable approach

476

3. Codes categorised into initial thematic framework following second cycle pattern coding

1. Preconceptions, motivations and previous treatment
A welcome change to CBT and counselling
Seeking something new
Compatible expectations
Incompatible expectations
2. Principles: relevance and appeal
Accepting, allowing and being with
Normalising emotions
Nature
Taking action
Values, desires and authentic self
Vicious cycle
Exceptions: not connecting to principles
Applicability to difficult thoughts
3. The process of Morita Therapy: Tools for learning vs learning tools
Seeking tools and techniques
Selecting ongoing resources
Mechanisms for accepting and learning
Mechanisms to enable action
Mechanisms to increase awareness of the vicious cycle
Mechanisms to re-focus attention
Making you think
Holistic approach
Natural, gradual, gentle progression
Small steps and goals
Instinctive/ experiential changes
4. How challenges become barriers
Pressure and burden
Time difficulties
Personal circumstances
Guidance and rationale
Misunderstanding
Support and opinions of others
Reluctance to stop "doing"
Discomfort in facing oneself and one's emotions
Relationship with therapist
5. Impact of treatment
Accepting, allowing and normalising
Acceptance of self and others
Breaking the vicious cycle
Empowerment
Action and purpose-oriented living
Continued practice and ongoing process
Symptoms and mood
Work, social and family life
6. Trial and measures

AccEPT clinic/ building issues
Trial management
Randomisation
Impact of trial
The MASA questionnaire

4. Modified thematic map

5. Modified thematic framework following review and refinement of coded data during continued second cycle pattern coding

1. Managing incompatible expectations, motivations and understandings
Unmet expectations
Seeking techniques and cures
Misunderstanding and substitution of rationale
Applicability to difficult thoughts
Incompatibility with Fumon
Creating pressure
2. The principles of Morita Therapy: receptivity and relevance
Readiness to accept
Identification with the vicious cycle
Connection to nature
Seeking an action-focus
Working with the authentic self
Exceptions: disconnect with principles
3. Approaching Morita Therapy as a process
Holistic approach
Natural and gentle progression
Trusting the process
Experience over intellect
Making you think
Mechanisms for accepting and learning
Mechanisms to for transition and refocusing attention
4. Facilitating the process: (overcoming) challenges and barriers
Fear and discomfort
Needing safety and support from others
Providing guidance and reassurance
Therapy as onerous
5. The value and impact of Morita Therapy
A preferable alternative
The value of acceptance
Breaking the vicious cycle
Empowerment and liberation
Engagement with life and action
Discovering joy
Effect on mood and symptoms
Wider impact
6. Trial and measures
The AccEPT Clinic
Trial management
Randomisation
The MASA questionnaire

6. Example framework matrix (theme two: the principles of Morita Therapy: receptivity and relevance)

	FINAL CONSTITUENT THEME: READINESS TO ACCEPT		FINAL CONSTITUENT THEME: ATTRACTION TO THE FEATURES OF MORITA THERAPY			INCORPORATED INTO THEME ONE/ EXAMPLES OF EXCEPTIONS TO THESE CONSTITUENT THEMES
	Readiness to accept	**Identification with the vicious cycle**	**Connection to nature**	**Seeking an action-focus**	**Working with the authentic self**	**Exceptions: Disconnect with principles**
MT16 : completed_ improved	CBT focused on trying to change thoughts - the Morita focus on accepting feelings felt easier to understand and connect with		Attracted to the connection to nature - using nature to help/ relating how you're feeling to natural patterns		Looking at what he wants to achieve and building around that worked for him	
MT33: completed_ improved	Felt able to accept that he gets depressed/ has good and bad days - resonated to look at this within the ebb and flow of nature		Already enjoyed the outdoors so using the weather as a metaphor worked for him			
MT43: completed_ improved	Appreciated that Morita Therapy is not a cure, it's about being with and allowing unpleasant emotions as natural - she likes that anxiety is natural/ part of who she is		Interested pre-treatment in the natural world element/ reconnecting to nature	Liked that it's about action, it's very practical - she understands that she can't change thoughts	Connected to the concept of the authentic self - thinking about how she could get back to aspects of herself she had lost	

MT45: completed_ improved	Had read about allowing anxiety/giving up the struggle - this resonated with him. Attracted to Morita Therapy because it's about treating anxiety like any other emotion - wanted reinforcement of the fact that you can't cure it. CBT helps you understand but MT gives extra element of not treating anxiety as bad or wrong	Already understood he had a need to fix himself and engaged in a vicious cycle of rumination/analysis (which CBT fed). Would not have taken part if it had been about challenging thoughts as he considered this another battle		Was already doing things despite anxiety - doesn't avoid things. "So that's why I actually - if I was designing a therapy, I would probably come up with something similar to Morita."		Connection to nature did not resonate with him in terms of appreciating/enjoying the natural world
MT55: completed_ improved	Expectations here were not to be cured. Teaching you how to live with it is much more sensible than the impression the NHS gave which was that she would be cured - that made her feel worse	The vicious cycle made sense - the concept made a big impact/ resonated	She was "into" the natural world already e.g. gardening/ Greenpeace - easy to get into this aspect			
MT63 : completed_ improved	Attracted to Morita Therapy as way of understanding symptoms as natural parts of human experience and not catastrophising them. Wanted to live with it, not manage it like CBT		Attracted to Morita Therapy as a way of getting back to nature and realising these are natural experiences		The concept of fears and desires is useful in making her look at things differently	
MT58: completed_no improvement		"Picking the scab" made a big impact because she knew she did that - the idea of 'shoulds' being unhelpful resonated			Looking at the flip side of difficulties resonated for her - she could really identify desires	

MT37: over 5_improved	Morita Therapy appealed in comparison to other approaches as she was already aware some things cannot be changed					
MT19: over 5_no improvement			Happy about connection to the natural world because he enjoys being in nature already			Whilst understood principle of ebb and flow of emotions, could not "feel the flow" as he is "a logician, not emotional person" - focus of Morita Therapy seemed to be on emotions, not thoughts, thus not relevant to him
MT28: over 5_no improvement						Wanted to eliminate unpleasant thoughts and break the vicious cycle by force, thus doesn't really understand the Morita concept of a the vicious cycle
MT51: over 5_no improvement			Liked idea of being part of nature			Didn't relate to seeing emotions like seasons/ the weather - they are more difficult to deal with than that

MT15: under 5_improved	Drawn to the idea of accepting difficulties because in her past experience they have come and gone, as per the premise of Morita Therapy	Could relate pre-treatment to principles around not pushing things away because they tend to come back - that's what's happened throughout her life. Had always kept herself busy/ distracted self and self-harmed - helpful to see it within the vicious cycle			Found the concept of fears and desires helpful because previously these things had always been seen as "bad" - this provided a very different way of looking at it	
MT50: under 5_improved	Liked idea you cannot stop thoughts and feelings, in contrast to counselling	Felt talking about problems with a counsellor just highlights them and worsens them - the Morita Therapy approach is more valuable	Looking at ways you could "connect" resonated with her - connecting with nature/ thoughts and feelings as part of a circle - considered this a nice way of coming to terms with your feelings. Already found being in nature helpful - often inspired her	Part of what she sought was to get back into the world and do something. Liked the practical element of taking small steps towards goals	Attracted to the idea of being nurtured slowly to get back to your values/ tap into the authentic self. Wanted to be true to her values - been looking for this for 20 years. Morita Therapy highlighted and supported what she had already begun	
MT54: under 5_improved						

MT17: under 5_no improvement	Living with it and getting on with things appealed to her - she knew from experience that depression comes and goes. The CBT approach of changing negative thoughts to positive thoughts created an internal battle - acceptance felt a better way for her to deal with it			Liked the focus on doing things as opposed to thoughts		
MT61: under 5_no improvement						Wasn't sure that going through the process without fighting it was "him" - likes to find solutions/ not on board with the idea that if you go through the bad you will get to good. Plus felt nature doesn't have a brain, it just happens - does not see humans like this

7. Final themes following within-case and cross-case analysis using framework matrices

1. The impact of incompatible expectations and understandings

Seeking a solution for symptoms
    Exploring and expressing the self
    Failing at the wrong job: the substitution of rationale

2. Identifying with the principles of Morita Therapy: receptivity and relevance
Readiness to accept   Attraction to the features of Morita Therapy
3. Approaching and understanding Morita Therapy as a process

Allowing a natural progression
    Mechanisms: transition and learning
    Ownership of responsibility: making <u>you</u> think

4. Facilitating the process: (overcoming) challenges and barriers

Fear and discomfort
    Safety and support from others
    Providing guidance and reassurance
    Burden and commitment

5. The value and impact of Morita Therapy

A preferable alternative
    Relinquishing control: the value of acceptance
    Transformation: from dwelling to doing
    Empowerment and liberation
    Effect on mood and symptoms

6. Trial and measures

The AccEPT Clinic
    Trial management
    Randomisation
    The MASA questionnaire

Appendix XI: Example page of therapeutic diary

Date:	
Patient's notes	Therapist's notes

References

ABRAHAM, C., DENFORD, S., SMITH, J. R., DEAN, S., GREAVES, C., LLOYD, J., TARRANT, M., WHITE, M. P. & WYATT, K. (2015) Designing interventions to change health-related behaviour. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 103-110.

ADAMS, J. (2000) General practitioners, complementary therapies and evidence-based medicine: the defence of clinical autonomy. *Complementary Therapies in Medicine.* 8(4), pp. 248-252.

AITKEN, L. M., RATTRAY, J., HULL, A., KENARDY, J. A., LE BROCQUE, R. & ULLMAN, A. J. (2013) The use of diaries in psychological recovery from intensive care. *Critical Care.* 17(6), 253.

ALFONSO, V. (1992) Brief Morita intervention with a socially anxious client: A case study. *International Bulletin of Morita Therapy.* 5(1-2), pp. 26-34.

ALFONSO, V. & GUTHRIE, K. (1990) Courage to be and to do: Use of a narrative as a vehicle for taking action. *International Bulletin of Morita Therapy.* 3(2), pp. 104-111.

ALONSO, J., ANGERMEYER, M., BERNERT, S., BRUFFAERTS, R., BRUGHA, T., BRYSON, H., GIROLAMO, G. D., GRAAF, R., DEMYTTENAERE, K. & GASQUET, I. (2004) 12-Month comorbidity patterns and associated factors in Europe: results from the European Study of the Epidemiology of Mental Disorders (ESEMeD) project. *Acta Psychiatrica Scandinavica.* 109(s420), pp. 28-37. doi: 10.1111/j.1600-0047.2004.00328.x

ALTHEIDE, D. L. (1987) Reflections: Ethnographic content analysis. *Qualitative sociology.* 10(1), pp. 65-77.

AMERICAN PSYCHIATRIC ASSOCIATION. (2000) *Diagnostic and statistical manual of mental disorders DSM-IV-TR.* 4th ed., text revision. Washington, DC: American Psychiatric Association.

AMERICAN PSYCHIATRIC ASSOCIATION. (2013) *Diagnostic and statistical manual of mental disorders (DSM-5®).* 5th ed. Washington, DC: American Psychiatric Association.

AMICK, H. R., GARTLEHNER, G., GAYNES, B. N., FORNERIS, C., ASHER, G. N., MORGAN, L. C., COKER-SCHWIMMER, E., BOLAND, E., LUX, L. J. & GAYLORD, S. (2015) Comparative benefits and harms of second generation antidepressants and cognitive behavioral therapies in initial treatment of major depressive disorder: systematic review and meta-analysis. *BMJ.* 351(h6019. doi: 10.1136/bmj.h6019

ANDERSON, L. M., PETTICREW, M., CHANDLER, J., GRIMSHAW, J., TUGWELL, P., O'NEILL, J., WELCH, V., SQUIRES, J., CHURCHILL, R. & SHEMILT, I. (2013) Introducing a series of methodological articles on considering complexity in systematic reviews of interventions. *Journal of Clinical Epidemiology.* 66(11), pp. 1205-1208. doi: 10.1016/j.jclinepi.2013.07.005

ANDREWS, G., HENDERSON, S. & HALL, W. (2001) Prevalence, comorbidity, disability and service utilisation Overview of the Australian National Mental Health Survey. *BJPsych.* 178(2), 145-153.

ANDREWS, G., SANDERSON, K., SLADE, T. & ISSAKIDIS, C. (2000) Why does the burden of disease persist? Relating the burden of anxiety and depression to effectiveness of treatment. *Bulletin of the World Health Organization.* 78(4), 446-454. doi: 10.1590/S0042-96862000000400006

ANDREWS, G., SLADE, T. & ISSAKIDIS, C. (2002) Deconstructing current comorbidity: data from the Australian National Survey of Mental Health and Well-being. *The British Journal of Psychiatry.* 181(4), pp. 306-314. doi: 10.1192/bjp.181.4.306

APOSHYAN, H. M. (1995) *The efficacy of Morita therapy applied in a group modality for socially phobic adults: An outcome study.* PhD, University of Oregon.

ARAIN, M., CAMPBELL, M. J., COOPER, C. L. & LANCASTER, G. A. (2010) What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol.* 10(1), 67. doi: 10.1186/1471-2288-10-67

REFERENCES

ARKSEY, H. & O'MALLEY, L. (2005) Scoping studies: towards a methodological framework. *International Journal of Social Research Methodology*. 8(1), pp. 19-32. doi: 10.1080/1364557032000119616

ASHIZAWA, T., ANAZAWA, T. & HONMA, M. (2000) Morita Therapeutic Approach to Chronic Pain in Combination with Group Psychotherapy. *Journal of Morita Therapy.* 11(1), pp. 233-235.

BACKMAN, C. L. & HARRIS, S. R. (1999) Case studies, single-subject research, and N of 1 randomised trials: comparisons and contrasts. *American Journal of Physical Medicine & Rehabilitation.* 78(2), pp. 170-176.

BAKX, K. (1991) The 'eclipse'of folk medicine in western society. *Sociology of Health & Illness*. 13(1), pp. 20-38. doi: 10.1111/1467-9566.ep11340307

BARBOUR, R. S. (1999) The case for combining qualitative and quantitative approaches in health services research. *Journal of Health Services Research & Policy*. 4(1), pp. 39-43. doi: 10.1177/135581969900400110

BARBOUR, R. S. (2001) Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ.* 322(7294), pp. 1115-1117.

BARRY, C. A. (2006) The role of evidence in alternative medicine: Contrasting biomedical and anthropological approaches. *Social science & medicine*. 62(11), pp. 2646-2657. doi: 10.1016/j.socscimed.2005.11.025

BARTHOLOMEW, J. R. (1989) *The formation of science in Japan: Building a research tradition.* New Haven, London: Yale University Press.

BARTON, S. (2000) Which clinical studies provide the best evidence? *BMJ*. 321(pp. 255-256. doi: 10.1136/bmj.321.7256.255

BECK, A. T., STEER, R. A. & BROWN, G. K. (1996) *Beck Depression Inventory Manual.* San Antonio, TX: The Psychological Corporation.

BECK, J. S. (2011) *Cognitive behavior therapy: Basics and beyond.* New York, London: Guilford Press.

BENNETT-LEVY, J., RICHARDS, D., FARRAND, P., CHRISTENSEN, H., GRIFFITHS, K., KAVANAGH, D., KLEIN, B., LAU, M. A., PROUDFOOT, J., RITTERBAND, L., WHITE, J. & WILLIAMS, C. (2010) *Oxford Guide to Low Intensity CBT Interventions.* Oxford, New York: Oxford University Press.

BERLINER, H. S. & SALMON, J. W. (1980) The holistic alternative to scientific medicine: History and analysis. *International Journal of Health Services.* 10(1), pp. 133-147.

BEUTLER, L. E., ENGLE, D., MOHR, D., DALDRUP, R. J., BERGAN, J., MEREDITH, K. & MERRY, W. (1991) Predictors of differential response to cognitive, experiential, and self-directed psychotherapeutic procedures. *Journal of Consulting and Clinical Psychology.* 59(2), pp. 333-340.

BHANDARI, M., ZLOWODZKI, M. & COLE, P. A. (2004) From eminence-based practice to evidence-based practice: a paradigm shift. *Minnesota Medicine.* 87(4), pp. 51-54.

BLATT, S. & FELSEN, I. (1993) Different kinds of folks may need different kinds of strokes: The effect of patients' characteristics on therapeutic process and outcome. *Psychotherapy Research.* 3(4), pp. 245-259.

BLOCKER, H. G. & STARLING, C. L. (2010) *Japanese philosophy.* New York, NY: State University of New York Press.

BLOOM, D., CAFIERO, E., JANÉ-LLOPIS, E. & ET AL. (2011) The Global Economic Burden of Noncommunicable Diseases (World Economic Forum, Geneva).

BOEIJE, H. R., DRABBLE, S. J. & O'CATHAIN, A. (2015) Methodological challenges of mixed methods intervention evaluations. *Methodology*. 11(4), pp. 119-125. doi: 10.1027/1614-2241/a000101

BORGLIN, G. (2015) The value of mixed methods for researching complex interventions. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 29-45.

REFERENCES

BORSON, S., SCANLAN, J., BRUSH, M., VITALIANO, P. & DOKMAK, A. (2000) The Mini-Cog: a cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. *Int. J. Geriatr. Psychiatry.* 15(11), pp. 1021-27.

BOTHWELL, L. E., GREENE, J. A., PODOLSKY, S. H. & JONES, D. S. (2016) Assessing the gold standard—lessons from the history of RCTs. *The New England Journal of Medicine.* 374(22), pp. 2175-2181. doi: 10.1056/NEJMms1604593

BOWEN, G. A. (2008) Naturalistic inquiry and the saturation concept: a research note. *Qualitative research.* 8(1), pp. 137-152.

BRADLEY, E. H., CURRY, L. A. & DEVERS, K. J. (2007) Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Services Research.* 42(4), pp. 1758-1772. doi: 10.1111/j.1475-6773.2006.00684.x

BRAUN, V. & CLARKE, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology.* 3(2), pp. 77-101.

BRAZIER, C. (2003) *Buddhist psychology. Liberate your mind, embrace your life.* London: Robinson.

BRAZIER, D. (2012) *Zen Therapy: A Buddhist approach to psychotherapy.* London: Constable & Robinson.

BRITTEN, N. (1995) Qualitative research: qualitative interviews in medical research. *BMJ.* 311(6999), pp. 251-253. doi: 10.1136/bmj.311.6999.251

BRITTEN, N. (2010) Qualitative research and the take-up of evidence-based practice. *Journal of Research in Nursing.* 15(6), pp. 537-544.

BROWN, G. & YULE, G. (1983) *Discourse analysis.* Cambridge: Cambridge University Press.

BROWNE, R. H. (1995) On the use of a pilot sample for sample size determination. *Statistics in Medicine.* 14(17), 1933-1940. doi: 10.1002/sim.4780141709

BRYMAN, A. (2016) *Social research methods.* 5th ed. Oxford: Oxford University Press.

BUETOW, S., UPSHUR, R., MILES, A. & LOUGHLIN, M. (2006) Taking stock of evidence-based medicine: opportunities for its continuing evolution. *Journal of Evaluation in Clinical Practice.* 12(4), pp. 399-404.

BUHSE, S. & MUHLHAUSER, I. (2015) Development of complex interventions: Outcome modeling. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 96-102.

BURNS, P. B., ROHRICH, R. J. & CHUNG, K. C. (2011) The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery.* 128(1), pp. 305-310. doi: 10.1097/PRS.0b013e318219c171

BURSTON, D. (2003) Existentialism, humanism and psychotherapy. *Existential Analysis.* 14(2), pp. 309-319.

BUSFIELD, J. (2001a) Introduction: Rethinking the sociology of mental health. In: BUSFIELD, J., ed., *Rethinking the sociology of mental health.* Oxford, Massachusetts: Blackwell, pp. pp. 1-16.

BUSFIELD, J. (2001b) *Rethinking the sociology of mental health.* Oxford, Massachusetts: Blackwell.

CAMPBELL, M., FITZPATRICK, R., HAINES, A. & KINMONTH, A. L. (2000) Framework for design and evaluation of complex interventions to improve health. *BMJ.* 321(7262), pp. 694-696.

CARLETON, J. A. (2002) Body, Self And Soul: The Evolution Of A Wholistic Psychotherapy. *JISHIM.* 2(pp. 30-39.

CASSELL, E. J. (2004) *The Nature of Suffering and the Goals of Medicine.* 2nd ed. New York: Oxford University Press.

CENTRE FOR REVIEWS AND DISSEMINATION (CRD). (2001) *Undertaking systematic reviews of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews.* 2nd ed. York: NHS Centre for Reviews and Dissemination, University of York.

REFERENCES

CENTRE FOR REVIEWS AND DISSEMINATION (CRD). (2009) *Systematic reviews: CRD's guidance for undertaking reviews in health care.* York: NHS Centre for Reviews and Dissemination, University of York.

CHALMERS, I. & GLASZIOU, P. (2009) Avoidable waste in the production and reporting of research evidence. *Obstetrics & Gynecology*. 114(6), pp. 1341-1345. doi: 10.1097/AOG.0b013e3181c3020d

CHANG, S. C. (1974) Morita therapy. *American Journal of Psychotherapy.* 28(2), pp. 208-221.

CHANG, S. C. (2011) Psychotherapy and Culture. Morita Therapy: an illustration. *World Cultural Psychiatry Research Review.* 6(2), pp. 135-145.

CHANG, S. C. & RHEE, D.-S. (2005) Buddhist Teaching: Relation to Healing. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. pp. 156-165.

CHEN, S. Q. (2000) The Comparative Analysis of Morita Therapy for Schizophrenia Patients in Recovery Period. *Journal of Morita Therapy.* 11(1), pp. 293-295.

CHEN, Y. C. (2001) Chinese values, health and nursing. *Journal of Advanced Nursing*. 36(2), pp. 270-273. doi: 10.1046/j.1365-2648.2001.01968.x

CHIBA, K. (2010) *Japanese women, class and the tea ceremony: The voices of tea practitioners in Northern Japan.* Oxon, New York: Routledge.

CHURCHILL, W. (1999) Implications of evidence based medicine for complementary & alternative medicine. *Journal of Chinese Medicine.* 59(pp. 32-35.

CLARITY INFORMATICS. (2014) *Quality Improvement – A Clinical Analysis*. [online]. Available from: https://clarity.co.uk/quality-improvement-a-clinical-analysis/ [Accessed 10 Nov 2016].

CLARK, A. M. (2013) What are the components of complex interventions in healthcare? Theorizing approaches to parts, powers and the whole intervention. *Social Science & Medicine*. 93(pp. 185-193. doi: 10.1016/j.socscimed.2012.03.035

CLARK, D. M., LAYARD, R., SMITHIES, R., RICHARDS, D. A., SUCKLING, R. & WRIGHT, B. (2009) Improving access to psychological therapy: Initial evaluation of two UK demonstration sites. *Behaviour Research and Therapy*. 47(11), pp. 910-920. doi: 10.1016/j.brat.2009.07.010

CODAY, M., BOUTIN-FOSTER, C., SHER, T. G., TENNANT, J., GREANEY, M. L., SAUNDERS, S. D. & SOMES, G. W. (2005) Strategies for retaining study participants in behavioral intervention trials: retention experiences of the NIH Behavior Change Consortium. *Annals of Behavioral Medicine*. 29(2), pp. 55-65. doi: 10.1207/s15324796abm2902s_9

COHEN, J. (1988) *Statistical Power Analysis for the Behavioral Sciences.* Hillsdale: Lawrance Erlbaum.

COLLINS, D. (2014) *Cognitive Interviewing Practice.* London, California, New Delhi, Singapore: Sage.

COLLINS, R. & MACMAHON, S. (2001) Reliable assessment of the effects of treatment on mortality and major morbidity, I: clinical trials. *The Lancet*. 357(9253), pp. 373-380. doi: 10.1016/S0140-6736(00)03651-5

COMMUNITY & MENTAL HEALTH TEAM. (2016) *Improving Access to Psychological Therapies (IAPT). Executive Summary (May 2016).* NHS DIGITAL (GOVERNMENT STATISTICAL SERVICE), Available from: https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwj0o_vjmuvWAhXMiRoKHYagBZAQFggtMAE&url=https%3A%2F%2Fdigital.nhs.uk%2Fmedia%2F29276%2FImproving-Access-to-Psychological-Therapies-Executive-Summary-May-2016%2FAny%2FIAPT-month-May-2016-exec-sum&usg=AOvVaw3PdUxE3Y7Zlf1Nl6jFz6eF [Accessed 12 Feb 2017].

CONN, V. S., ALGASE, D. L., RAWL, S. M., ZERWIC, J. J. & WYMAN, J. F. (2010) Publishing pilot intervention work. *Western Journal of Nursing Research*. 32(8), pp. 994-1010. doi: 10.1177/0193945910367229

REFERENCES

COOK, D. J., GUYATT, G. H., LAUPACIS, A. & SACKETT, D. L. (1992) Rules of evidence and clinical recommendations on the use of antithrombotic agents. *CHEST Journal*. 102(4_Supplement), pp. 305S-311S. doi: 10.1378/chest.95.2_Supplement.2S

COULTER, I. D. & WILLIS, E. M. (2004) The rise and rise of complementary and alternative medicine: a sociological perspective. *Medical Journal of Australia.* 180(11), pp. 587-590.

CRAIB, I. (2002) *The importance of disappointment.* London, New York: Routledge.

CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I. & PETTICREW, M. (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 337(p. a1655. doi: 10.1136/bmj.a1655

CRAIG, P. & PETTICREW, M. (2013) Developing and evaluating complex interventions: reflections on the 2008 MRC guidance. *International Journal of Nursing Studies*. 50(5), pp. 585-587. doi: 10.1016/j.ijnurstu.2012.09.009

CREEL, H. G. (1956) What is Taoism? *Journal of the American Oriental Society*. 76(3), pp. 139-152. doi: 10.2307/596285

CRESWELL, J. W. & PLANO CLARK, V. L. (2007) *Designing and conducting mixed methods research.* Thousand Oaks: Sage.

CROTTY, M. (2003) *The foundations of social research: Meaning and perspective in the research process.* Thousand Oaks, CA: Sage Publications.

CROWDER, D. J. (2016) Using Morita methods as an alternative to Brief Solution Focused counselling. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 12. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

CRUZ, L. (2015) Self-Reflexivity as an Ethical Instrument to Give Full Play to Our Explicit and Implicit Subjectivity as Qualitative Researchers. *The Qualitative Report.* 20(10), pp. 1723-1735.

CUIJPERS, P. (2014) Personalized treatment for functional outcome in depression. *Medicographia.* 36(4), pp. 476-481.

CUIJPERS, P., ANDERSSON, G., DONKER, T. & VAN STRATEN, A. (2011) Psychological treatment of depression: results of a series of meta-analyses. *Nordic Journal of Psychiatry*. 65(6), pp. 354-364. doi: 10.3109/08039488.2011.596570

CUIJPERS, P. & CHRISTENSEN, H. (2017) Are personalised treatments of adult depression finally within reach? *Epidemiology and Psychiatric Sciences*. 26(1), pp. 40-42. doi: 10.1017/S204579601600007X

CUIJPERS, P., REYNOLDS, C. F., DONKER, T., LI, J., ANDERSSON, G. & BEEKMAN, A. (2012) Personalized treatment of adult depression: medication, psychotherapy, or both? A systematic review. *Depression and Anxiety*. 29(10), pp. 855-864. doi: 10.1002/da.21985

CUIJPERS, P., SIJBRANDIJ, M., KOOLE, S. L., ANDERSSON, G., BEEKMAN, A. T. & REYNOLDS, C. F. (2013) The efficacy of psychotherapy and pharmacotherapy in treating depressive and anxiety disorders: A meta-analysis of direct comparisons. *World Psychiatry*. 12(2), pp. 137-148. doi: 10.1002/wps.20038

CULLUM, N. & DUMVILLE, J. (2015) Systematic Reviews of the Effects of Interventions. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 57-65.

DAMSCHRODER, L. J., ARON, D. C., KEITH, R. E., KIRSH, S. R., ALEXANDER, J. A. & LOWERY, J. C. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*. 4(1), p. 50. doi: 10.1186/1748-5908-4-50

REFERENCES

DAS-MUNSHI, J., GOLDBERG, D., BEBBINGTON, P. E., BHUGRA, D. K., BRUGHA, T. S., DEWEY, M. E., JENKINS, R., STEWART, R. & PRINCE, M. (2008) Public health significance of mixed anxiety and depression: beyond current classification. *BJPsych*. 192(3), 171-177. doi: 10.1192/bjp.bp.107.036707

DATTA, J. & PETTICREW, M. (2013) Challenges to evaluating complex interventions: a content analysis of published papers. *BMC Public Health*. 13(1), p. 568. doi: 10.1186/1471-2458-13-568

DAVIDSON, J. (2001) A phenomenology of fear: Merleau-Ponty and agoraphobic life-worlds. In: BUSFIELD, J., ed., *Rethinking the sociology of mental health.* Oxford, Massachusetts: Blackwell, pp. 95-114.

DAVIS, R. J. & IKENO, O. (2002) *The Japanese Mind: Understanding Contemporary Japanese Culture.* Tokoyo: Tuttle Publishing.

DE SILVA, M. J., COOPER, S., LI, H. L., LUND, C. & PATEL, V. (2013) Effect of psychosocial interventions on social functioning in depression and schizophrenia: Meta-analysis. *The British Journal of Psychiatry*. 202(4), pp. 253-260. doi: 10.1192/bjp.bp.112.118018

DENFORD, S., ABRAHAM, C., SMITH, J., LLOYD, J. J., WHITE, M., TARRANT, M., WYATT, K., GREAVES, C. & DEAN, S. (2015) Designing and evaluating behavior change interventions to promote health. In: REYNOLDS, K. J. & BRANSCOMBE, N. R., ed., *Psychology of Change: Life Contexts, Experiences, and Identities.* New York, Hove: Psychology Press, pp. 151-169.

DEPARTMENT OF HEALTH. (2005) *Mental Capacity Act.* London: HMSO.

DEPRESSION GUIDELINE PANEL. (1993) *Clinical practice guideline. Number 5. Depression in primary care.* Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research.

DEROGATIS, L. R. (1996) *SCL-90-R: Symptom Checklist-90-R: administration, scoring, and procedures manual.* NCS Pearson.

DERUBEIS, R. J., COHEN, Z. D., FORAND, N. R., FOURNIER, J. C., GELFAND, L. A. & LORENZO-LUACES, L. (2014) The Personalized Advantage Index: translating research on prediction into individualized treatment recommendations. A demonstration. *PLOS ONE*. 9(1), p. e83875. doi: 10.1371/journal.pone.0083875

DERUBEIS, R. J., HOLLON, S. D., AMSTERDAM, J. D., SHELTON, R. C., YOUNG, P. R., SALOMON, R. M., O'REARDON, J. P., LOVETT, M. L., GLADIS, M. M. & BROWN, L. L. (2005) Cognitive therapy vs medications in the treatment of moderate to severe depression. *Arch Gen Psychiatry*. 62(4), 409-416. doi: 10.1001/archpsyc.62.4.409

DEVOS, G. (1980) Afterword. In: REYNOLDS, D. K., ed., *The quiet therapies: Japanese Pathways to Personal Growth.* Honolulu, HI: University Press of Hawaii, pp. 113-132.

DINGWALL, R., MURPHY, E., WATSON, P., GREATBATCH, D. & PARKER, S. (1998) Catching goldfish: quality in qualitative research. *Journal of Health Services Research & Policy*. 3(3), pp. 167-172. doi: 10.1177/135581969800300308

DISC BV. (2016) *EndNote X7.7 for Mac and Windows*. [online]. RESEARCHSOFTWARE.com. Available from: https://researchsoftware.com/newsletter/endnote-x77-mac-and-windows-now-available [Accessed 13 Mar 2017].

DODD, S., WHITE, I. R. & WILLIAMSON, P. (2012) Nonadherence to treatment protocol in published randomised controlled trials: a review. *Trials*. 13(1), p. 84. doi: 10.1186/1745-6215-13-84

DOGHERTY, E. J. & ESTABROOKS, C. A. (2015) Why do barriers and facilitators matter? In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 273-281.

DONAHUE, P. (1988) *Efficacy study of brief Morita Therapy with shy adolescents.* MA, The University of British Columbia.

DOYLE, L., BRADY, A.-M. & BYRNE, G. (2009) An overview of mixed methods research. *Journal of Research in Nursing*. 14(2), pp. 175-185. doi: 10.1177/1744987108093962

REFERENCES

DUGAS, M. J., BRILLON, P., SAVARD, P., TURCOTTE, J., GAUDET, A., LADOUCEUR, R., LEBLANC, R. & GERVAIS, N. J. (2010) A randomized clinical trial of cognitive-behavioral therapy and applied relaxation for adults with generalized anxiety disorder. *Behavior Therapy*. 41(1), pp. 46-58. doi: 10.1016/j.beth.2008.12.004

EATON, W. W., SHAO, H., NESTADT, G., LEE, B. H., BIENVENU, O. J. & ZANDI, P. (2008) Population-based study of first onset and chronicity in major depressive disorder. *Archives of General Psychiatry*. 65(5), pp. 513-520. doi: 10.1001/archpsyc.65.5.513

ECCLES, M., GRIMSHAW, J., CAMPBELL, M. & RAMSAY, C. (2003) Research designs for studies evaluating the effectiveness of change and improvement strategies. *Quality and Safety in Health Care*. 12(1), pp. 47-52. doi: 10.1136/qhc.12.1.47

ECCLES, M. P. & MITTMAN, B. S. (2006) Welcome to implementation science. *Implementation Science*. 1(1), p. 1. doi: 10.1186/1748-5908-1-1

EDWARDS, A., ELWYN, G., WOOD, F., ATWELL, C., PRIOR, L. & HOUSTON, H. (2005) Shared decision making and risk communication in practice. *British Journal of General Practice.* 55(510), pp. 6-13.

EGNEW, T. R. (2005) The meaning of healing: transcending suffering. *The Annals of Family Medicine*. 3(3), pp. 255-262. doi: 10.1370/afm.313

ELDRIDGE, S. M., CHAN, C. L., CAMPBELL, M. J., BOND, C. M., HOPEWELL, S., THABANE, L. & LANCASTER, G. A. (2016) CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies*. 2(1), p. 64. doi: 10.1186/s40814-016-0105-8

ELLWOOD, R. S. & PILGRIM, R. (2016) *Japanese religion: A cultural perspective.* 2nd ed. Oxon, New York: Routledge.

ERICSSON, K. A. & SIMON, H. A. (1998) How to study thinking in everyday life: Contrasting think-aloud protocols with descriptions and explanations of thinking. *Mind, Culture, and Activity*. 5(3), pp. 178-186. doi: 10.1207/s15327884mca0503_3

ETHERINGTON, K. (2007) Ethical research in reflexive relationships. *Qualitative Inquiry*. 13(5), pp. 599-616. doi: 10.1177/1077800407301175

EVANS, I., THORNTON, H., CHALMERS, I. & GLASZIOU, P. (2011) *Testing treatments: Better research for better healthcare.* 2nd ed. London: Pinter & Martin Ltd.

FAES, M. C., REELICK, M. F., ESSELINK, R. A. & RIKKERT, M. G. O. (2010) Developing and evaluating complex healthcare interventions in geriatrics: the use of the medical research council framework exemplified on a complex fall prevention intervention. *Journal of the American Geriatrics Society*. 58(11), pp. 2212-2221. doi: 10.1111/j.1532-5415.2010.03108.x

FALKENSTRÖM, F., MARKOWITZ, J. C., JONKER, H., PHILIPS, B. & HOLMQVIST, R. (2013) Can psychotherapists function as their own controls? Meta-analysis of the "crossed therapist" design in comparative psychotherapy trials. *Journal of Clinical Psychiatry*. 74(5), pp. 482-491. doi: 10.4088/JCP.12r07848

FEELEY, N., COSSETTE, S., CÔTÉ, J., HÉON, M., STREMLER, R., MARTORELLA, G. & PURDEN, M. (2009) The importance of piloting an RCT intervention. *Canadian Journal of Nursing Research.* 41(2), pp. 84-99.

FETTERS, M. D. & FRESHWATER, D. (2015) The 1+ 1= 3 Integration Challenge. *Journal of Mixed Methods Research*. 9(2), pp. 115-117. doi: 10.1177/1558689815581222

FIELD, A. & HOLE, G. (2003) *How to design and report experiments.* London, Thousand Oaks, New Delhi: Sage.

FINLAY, L. (2002) Negotiating the swamp: the opportunity and challenge of reflexivity in research practice. *Qualitative Research.* 2(2), pp. 209-230.

FIRST, M. B., WILLIAMS, J. B. W., SPITZER, R. L. & GIBBON, M. (2007) *Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Clinical Trials Version (SCID-CT).* New York, NY: Biometrics Research, New York State Psychiatric Institute.

FISHER, P. & WARD, A. (1994) Complementary medicine in Europe. *BMJ.* 309(6947), pp. 107-111.

REFERENCES

FITZPATRICK, R. & BOULTON, M. (1996) Qualitative research in health care: I. The scope and validity of methods. *Journal of Evaluation in Clinical Practice*. 2(2), pp. 123-130. doi: 10.1111/j.1365-2753.1996.tb00036.x

FLORA, C. (2009) The pursuit of happiness. *Psychology today*. 1.(Available from: http://blogs.jefftwp.org/wordpress/rzegas/files/2014/03/pursuit-of-happiness.doc [Accessed 12 Dec 2016]

FOURNIER, J. C., DERUBEIS, R. J., SHELTON, R. C., HOLLON, S. D., AMSTERDAM, J. D. & GALLOP, R. (2009) Prediction of response to medication and cognitive therapy in the treatment of moderate to severe depression. *Journal of Consulting and Clinical Psychology*. 77(4), p. 775-787. doi: 10.1037/a0015401

FRANCE, M. H., CADIEAX, J. & ALLEN, G. E. (1995) Letter Therapy: A Model for Enhancing Counselling Intervention. *Journal of Counseling & Development*. 73(3), pp. 317-318. doi: 10.1002/j.1556-6676.1995.tb01755.x

FUJITA, C. (1986) *Morita therapy: A psychotherapeutic system for neurosis.* Tokyo, New York: Igaku-Shoin Medical Pub.

FUKUI, T. & RAHMAN, M. (2002) Contribution of research in basic and clinical sciences in Japan. *Internal Medicine*. 41(8), pp. 626-628. doi: 10.2169/internalmedicine.41.626

GABBAY, J. & LE MAY, A. (2004) Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ*. 329(7473), p. 1013. doi: 10.1136/bmj.329.7473.1013

GALE, N. K., HEATH, G., CAMERON, E., RASHID, S. & REDWOOD, S. (2013) Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*. 13(1), p. 117. doi: 10.1186/1471-2288-13-117

GASKELL, G. (2000) Individual and Group Interviewing. In: BAUER, M. & GASKELL, G., ed., *Qualitative Researching with Text, Image, and Sound: A Practical Handbook.* London: Sage Publications, pp. pp. 38-56.

GAUDIANO, B. A. (2008) Cognitive-behavioral therapies: Achievements and challenges. *Evidence-based Mental Health*. 11(1), p. 5. doi: 10.1136/ebmh.11.1.5

GIANGREGORIO, L. M. & THABANE, L. (2015) Pilot studies and feasibility studies for complex interventions: An introduction. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 127-135.

GIBSON, H. (1974) Morita therapy and behaviour therapy. *Behaviour Research and Therapy*. 12(4), pp. 347-353. doi: 10.1016/0005-7967(74)90009-6

GILTROW, J., GOODING, R., BURGOYNE, D. & SAWATSKY, M. (2005) *Academic writing: An introduction.* Peterborough: Broadview Press.

GLASER, B. & STRAUSS, G. (1967) *The discovery of grounded theory: Strategies for qualitative work.* New York: Aldine Publishing Company.

GLOGOWSKA, M. (2015) Paradigms, pragmatism and possibilities: mixed-methods research in speech and language therapy. *International Journal of Language & Communication Disorders.* 0(0), pp. 1-10.

GODDARD, E., WINGROVE, J. & MORAN, P. (2015) The impact of comorbid personality difficulties on response to IAPT treatment for depression and anxiety. *Behaviour Research and Therapy*. 73(pp. 1-7. doi: 10.1016/j.brat.2015.07.006

GOODMAN, W. K., PRICE, L. H., RASMUSSEN, S. A., MAZURE, C., FLEISCHMANN, R. L., HILL, C. L., HENINGER, G. R. & CHARNEY, D. S. (1989) The Yale-Brown obsessive compulsive scale: I. Development, use, and reliability. *Archives of General Psychiatry*. 46(11), pp. 1006-1011. doi: 10.1001/archpsyc.1989.01810110048007

GRAVEL, K., LÉGARÉ, F. & GRAHAM, I. D. (2006) Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. *Implementation Science*. 1(1), p. 16. doi: 10.1186/1748-5908-1-16

GREDEN, J. F. (2001) The burden of disease for treatment-resistant depression. *Journal of Clinical Psychiatry.* 62(pp. 26-31.

REFERENCES

GREEN, A. R., CARRILLO, J. E. & BETANCOURT, J. R. (2002) Why the disease-based model of medicine fails our patients. *Western Journal of Medicine.* 176(2), pp. 141-143.

GREEN, J. & THOROGOOD, N. (2014) *Qualitative methods for health research.* London, California, New Delhi, Singapore: Sage.

GRIFFITHS, P. & NORMAN, I. (2012) Qualitative or quantitative? Developing and evaluating complex interventions: time to end the paradigm wars. *International Journal of Nursing Studies*. doi: 10.1016/j.ijnurstu.2012.09.008

GROL, R. & GRIMSHAW, J. (2003) From best evidence to best practice: effective implementation of change in patients' care. *The Lancet*. 362(9391), pp. 1225-1230. doi: 10.1016/S0140-6736(03)14546-1

GROL, R., WENSING, M., ECCLES, M. & DAVIS, D. (2013) *Improving patient care: the implementation of change in health care.* 2nd ed. Chichester: John Wiley & Sons.

GUEST, G., BUNCE, A. & JOHNSON, L. (2006) How many interviews are enough? An experiment with data saturation and variability. *Field Methods.* 18(1), pp. 59-82.

GUETTERMAN, T. C., FETTERS, M. D. & CRESWELL, J. W. (2015) Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *The Annals of Family Medicine*. 13(6), pp. 554-561. doi: 10.1370/afm.1865

GUYATT, G., RENNIE, D., MEADE, M. O. & COOK, D. J. (2002) *Users' guides to the medical literature: a manual for evidence-based clinical practice.* Chicago, IL: AMA press.

HALL, J. (2011a) The Applicability of Psychologies Developed within One Set of Cultures to Other Cultures: Workin in Cross-cultural and International Settings. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc., pp. 93-102.

HALL, J. (2011b) Responding to Psychological Need: The Impact of Values, Evidence, Need and Policy on the Practice of Applied Psychologists in Health Care. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc, pp. 3-24.

HALLBERG, I. R. (2015) Introduction to Section 3. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 185-190.

HAMILTON, M. (1959) The assessment of anxiety states by rating. *British Journal of Medical Psychology*. 32(1), pp. 50-55. doi: 10.1111/j.2044-8341.1959.tb00467.x

HANSON, L. M. (2002) *The efficacy of three treatments for depression: Morita psychotherapy, dietary brain-chemistry treatment, and the combination of morita psychotherapy/brain-chemistry treatment as compared to no-treatment control.* PhD, Seton Hall University.

HARRIS, T. J., CAREY, I. M., VICTOR, C. R., ADAMS, R. & COOK, D. G. (2008) Optimising recruitment into a study of physical activity in older people: a randomised controlled trial of different approaches. *Age and Ageing*. 37(6), 659-665. doi: 10.1093/ageing/afn159

HARWOOD, D., HAWTON, K., HOPE, T. & JACOBY, R. (2001) Psychiatric disorder and personality factors associated with suicide in older people: a descriptive and case-control study. *International journal of geriatric psychiatry.* 16(2), pp. 155-165.

HASEGAWA, Y. (1990) Hakkenkai's method of studying Morita theory: A group learning approach to overcoming neurosis. *International Bulletin of Morita Therapy.* 3(1), pp. 26-34.

HASHI, H. (2013) Morita Therapy as a "conceptus cosmicus" for psychosis influenced by Zen Buddhism. *Biocosmology - Neo-aristotelism.* 3(4), pp. 629-641.

HASHIMOTO, K. (2016) The importance of inquiring into negative feelings in outpatient Morita Therapy. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 15. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healt

REFERENCES

hservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

HAWE, P., SHIELL, A., RILEY, T. & GOLD, L. (2004) Methods for exploring implementation variation and local context within a cluster randomised community intervention trial. *Journal of Epidemiology and Community Health*. 58(9), pp. 788-793. doi: 10.1136/jech.2003.014415

HAY, M. C., WEISNER, T. S., SUBRAMANIAN, S., DUAN, N., NIEDZINSKI, E. J. & KRAVITZ, R. L. (2008) Harnessing experience: exploring the gap between evidence-based medicine and clinical practice. *Journal of Evaluation in Clinical Practice.* 14(5), pp. 707-713.

HAYES, S. C., STROSAHL, K. D. & WILSON, K. G. (1999) *Acceptance and commitment therapy: An experiential approach to behavior change.* New York, NY: Guilford Press.

HAYS, P. A. & IWAMASA, G. Y. (2006) *Culturally responsive cognitive-behavioral therapy: Assessment, practice, and supervision.* Washington, DC: American Psychological Association.

HE, Y. & LI, C. (2007) Morita therapy for schizophrenia. *Cochrane Libr*. doi: 10.1002/14651858.CD006346

HELLAWELL, D. (2006) Inside–out: analysis of the insider–outsider concept as a heuristic device to develop reflexivity in students doing qualitative research. *Teaching in Higher Education.* 11(4), pp. 483-494.

HIGGINS, J. & ALTMAN, D. (2008) Assessing risk of bias in included studies. *Cochrane handbook for systematic reviews of interventions.* 5(2), 187-242.

HIGGINS, J. P., ALTMAN, D. G., GØTZSCHE, P. C., JÜNI, P., MOHER, D., OXMAN, A. D., SAVOVIĆ, J., SCHULZ, K. F., WEEKS, L. & STERNE, J. A. (2011) The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 343(p. d5928. doi: 10.1136/bmj.d5928

HIGGINS, J. P. & GREEN, S. (2011) *Cochrane handbook for systematic reviews of interventions.* Vol. 4. Wiley Online Library.

HILL, J. J., KUYKEN, W. & RICHARDS, D. A. (2014) Developing stepped care treatment for depression (STEPS): study protocol for a pilot randomised controlled trial. *Trials*. 15(1), p. 452. doi: 10.1186/1745-6215-15-452

HINOGUCHI, J. (2016) What should the Morita therapist keep in mind in the process of outpatient treatment with Morita Therapy? In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 14. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

HIRAKI, N. (2011) Creating Modern Nation and the Development of Helping Profession in Japan. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc., pp. 179-190.

HOFFMANN, T. C., GLASZIOU, P. P., BOUTRON, I., MILNE, R., PERERA, R., MOHER, D., ALTMAN, D. G., BARBOUR, V., MACDONALD, H. & JOHNSTON, M. (2014) Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 348(p. g1687. doi: 10.1136/bmj.g1687

HOFMANN, S. G. (2008) Acceptance and Commitment Therapy: new wave or morita therapy? *Clinical Psychology: Science and Practice*. 15(4), pp. 280-285. doi: 10.1111/j.1468-2850.2008.00138.x

HOLAWAY, R. M., RODEBAUGH, T. L. & HEIMBERG, R. G. (2006) The epidemiology of worry and generalized anxiety disorder. In: DAVEY, G. C. & WELLS, A., ed., *Worry and its psychological disorders: Theory, assessment and treatment.* Chichester: John Wiley & Sons, pp. 3-20.

HOLLON, S. D., MUÑOZ, R. F., BARLOW, D. H., BEARDSLEE, W. R., BELL, C. C., BERNAL, G., CLARKE, G. N., PATT FRANCIOSI, L., KAZDIN, A. E., KOHN, L., LINEHAN, M. M.,

REFERENCES

MARKOWITZ, J. C., MIKLOWITZ, D. J., PERSONS, J. B., NIEDEREHE, G. & SOMMERS, D. (2002) Psychosocial intervention development for the prevention and treatment of depression: promoting innovation and inreasing access. *Biol Psychiatry*. 52(6), 610-630. doi: 10.1016/S0006-3223(02)01384-7

HOSOYA, R. (2016) Outpatient Morita Therapy for an atopic dermatitis patient - A study on the significance of assisting animals. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 20. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

HOU, D., SONG, S., CUI, Y. & MENG, F. (2000) Clinical Comparison Study on Neurosis Treated by Morita Therapy and Chinese Acupuncture. *Journal of Morita Therapy.* 11(1), pp. 266-269.

HOUGHTON, C., CASEY, D., SHAW, D. & MURPHY, K. (2013) Rigour in qualitative case-study research. *Nurse Researcher.* 20(4), pp. 12-17.

HOWARD, L. & THORNICROFT, G. (2006) Patient preference randomised controlled trials in mental health research. *The British Journal of Psychiatry*. 188(4), pp. 303-304. doi: 10.1192/bjp.188.4.303

HU, H.-L. & ALLEN, W. C. (2005) *Taoism.* Philadelphia, PA: Chelsea House Publishers.

HUCKVALE, K. (2016) Act, Be, Change & Do: Art psychotherapy and Morita in assertive outreach and outpatient settings. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 15. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

HUIBERS, M. J., COHEN, Z. D., LEMMENS, L. H., ARNTZ, A., PEETERS, F. P., CUIJPERS, P. & DERUBEIS, R. J. (2015) Predicting optimal outcomes in cognitive therapy or interpersonal psychotherapy for depressed individuals using the personalized advantage index approach. *PLOS ONE*. 10(11), p. e0140771. doi: 10.1371/journal.pone.0140771

HUNOT, V., CHURCHILL, R., SILVA DE LIMA, M. & TEIXEIRA, V. (2007) Psychological therapies for generalised anxiety disorder. *Cochrane Database of Systematic Reviews*. 1(doi: 10.1002/14651858.CD001848.pub3

HUNT, J. R. & WHITE, E. (1998) Retaining and tracking cohort study members. *Epidemiologic Reviews.* 20(1), pp. 57-70.

IAPT. (2012) *IAPT three-year report. The first million patients.* London: DEPARTMENT OF HEALTH, Available from: https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjVr7WulPXWAhXIzRoKHcspCJEQFggoMAA&url=https%3A%2F%2Fwww.uea.ac.uk%2Fdocuments%2F246046%2F11919343%2FIAPT%2B3%2Byear%2Breport.%2BThe%2Bfirst%2Bmillion%2Bpatiets.pdf%2F0e0469ff-0884-4203-99de-4b61601e69dd&usg=AOvVaw1NhSugavF4mlvy9cRizLwq [Accessed 01 Aug 2017].

INOUE, N., JUN, E., MIZUE, M. & SATOSHI, I. (2003) *Shinto: a short history.* London, New York: Routledge.

ISAACS, D. & FITZGERALD, D. (1999) Seven alternatives to evidence based medicine. *BMJ*. 319(7225), p. 1618. doi: 10.1136/bmj.319.7225.1618

ISHIDA, S. (2016) Outpatient Morita Therapy for Occlusal Discomfort Syndrome following depression. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 13. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healt

REFERENCES

hservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

ISHIYAMA, F. (1983) A case of severe test anxiety treated in Morita therapy: Acceptance of anxiety and not fighting it. *Canadian Counsellor.* 17(4), pp. 172-174.

ISHIYAMA, F. (1986a) Brief Morita therapy for social anxiety: A single-case study of therapeutic changes. *Canadian Journal of Counselling.* 20(1), pp. 56-65.

ISHIYAMA, F. (1986b) Positive reinterpretation of fear of death: A Japanese (Morita) psychotherapy approach to anxiety treatment. *Psychotherapy: Theory, Research, Practice, Training.* 23(4), pp. 556-562.

ISHIYAMA, F. (1988a) Current status of Morita therapy research: An overview of research methods, instruments, and results. *International Bulletin of Morita Therapy.* 1(2), pp. 58-84.

ISHIYAMA, F. (1991) A Japanese reframing technique for brief social anxiety treatment: An exploratory study of cognitive and therapeutic effects of Morita therapy. *Journal of Cognitive Psychotherapy.* 5(1), pp. 55-70.

ISHIYAMA, I. (1986c) Morita therapy: Its basic features and cognitive intervention for anxiety treatment. *Psychotherapy: Theory, Research, Practice, Training.* 23(3), pp. 375-381.

ISHIYAMA, I. (1987) Use of Morita therapy in shyness counseling in the West: Promoting clients' self-acceptance and action taking. *Journal of Counseling & Development.* 65(10), pp. 547-551.

ISHIYAMA, I. (1988b) Morita therapy: A treatment of dogmatic self-containment in anxious and nervous clients. *Psychotherapy Patient.* 4(3-4), pp. 243-262.

ISHIYAMA, I. (1994) Cross-cultural issues in introducing Morita therapy to the West. *Journal of Morita Therapy.* 5(1), pp. 57-60.

ISHIYAMA, I. (2011) Introduction to Morita Therapy. In: ISHIYAMA, I., ed. *Holstebroand and Vejle (HOLD FAST) conference.* Denmark, 9-11 May 2011. Holstebroand and Vejle. Available from: http://viholderfast.nu/wp-content/uploads/2011/06/Slides-fra-kursus-i-Morita-terapi.pdf [Accessed 14 Oct 2014].

ITOH, H., YAMADERA, W., SASAKI, M. & USHIJIMA, S. (2000) Morita Therapy and Sleep Hygiene. *Journal of Morita Therapy.* 11(1), pp. 172-175.

JAGTENBERG, T., EVANS, S., GRANT, A., HOWDEN, I., LEWIS, M. & SINGER, J. (2006) Evidence-based medicine and naturopathy. *Journal of Alternative & Complementary Medicine*. 12(3), pp. 323-328. doi: 10.1089/acm.2006.12.323

JAMIESON, J. (1990) An application of Morita techniques in a university counseling center setting. *International Bulletin of Morita Therapy.* 3(2), pp. 118-123.

JAPANESE LITERATURE. (undated) *Shinto*. [online]. Blog Spot. Available from: http://napajlit.blogspot.co.uk/2009/10/shinto.html [Accessed 11 Jan 2017].

JARRETT, R. & RUSH, J. A. (1994) Short-term psychotherapy of depressive disorders: current status and future directions. *Psychiatry.* 57(2), 115-132.

JENKINSON, C. E., WINDER, R. E., SUGG, H. V., ROBERTS, M. J., RIDGWAY, N., KUYKEN, W., WILES, N., KESSLER, D. & CAMPBELL, J. (2014) Why do GPs exclude patients from participating in research? An exploration of adherence to and divergence from trial criteria. *Family Practice*. 31(3), pp. 364-370. doi: 10.1093/fampra/cmu005

JERAY, K. J. & TANNER, S. L. (2012) Pilot randomized trials: is there a need? *JBJS*. 94(Supplement_1), pp. 15-18. doi: 10.2106/JBJS.L.00180

JIANGBO, L. (2000) Trying out a Household Morita Therapy like Hospitalisation for Treating Obsessional Neurosis. *Journal of Morita Therapy.* 11(1), pp. 154-157.

JOHNSON, M., NEWTON, P., JIWA, M. & GOYDER, E. (2005) Meeting the educational needs of people at risk of diabetes-related amputation: a vignette study with patients and professionals. *Health Expectations*. 8(4), pp. 324-333. doi: 10.1111/j.1369-7625.2005.00344.x

REFERENCES

JOHNSON, R. B. & ONWUEGBUZIE, A. J. (2004) Mixed methods research: A research paradigm whose time has come. *Educational Researcher*. 33(7), pp. 14-26. doi: 10.3102/0013189X033007014

KAPLEAU, P. (2000) *The Three Pillars of Zen: Teaching, Practice and Experience.* New York, NY: Anchor Books.

KASPER, S., SCHINDLER, S. & NEUMEISTER, A. (1996) Risk of suicide in depression and its implication for psychopharmacological treatment. *International Clinical Psychopharmacology.* 11(2), pp. 71-79.

KELLER, M. B. (2001) Long-term treatment of recurrent and chronic depression. *J Clin Psychiatry.* 62(Supplement_24), 3-5.

KELLY, M., MORGAN, A., ELLIS, S., YOUNGER, T., HUNTLEY, J. & SWANN, C. (2010) Evidence based public health: a review of the experience of the National Institute of Health and Clinical Excellence (NICE) of developing public health guidance in England. *Social Science & Medicine*. 71(6), pp. 1056-1062. doi: 10.1016/j.socscimed.2010.06.032

KELLY, P. (1993) Integrating Morita therapy in the treatment of incest. *International Bulletin of Morita Therapy.* 6(1-2), pp. 59-68.

KESHET, Y. (2009) The untenable boundaries of biomedical knowledge: epistemologies and rhetoric strategies in the debate over evaluating complementary and alternative medicine. *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*. 13(2), pp. 131-155. doi: 10.1177/1363459308099681

KESSLER, R., VAN LOO, H., WARDENAAR, K., BOSSARTE, R., BRENNER, L., EBERT, D., DE JONGE, P., NIERENBERG, A., ROSELLINI, A. & SAMPSON, N. (2017) Using patient self-reports to study heterogeneity of treatment effects in major depressive disorder. *Epidemiology and Psychiatric Sciences*. 26(1), pp. 22-36. doi: 10.1017/S2045796016000020

KESSLER, R. C., BERGLUND, P., DEMLER, O., JIN, R., KORETZ, D., MERIKANGAS, K. R., RUSH, A. J., WALTERS, E. E. & WANG, P. S. (2003) The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). *JAMA*. 289(23), 3095-3105. doi: 10.1001/jama.289.23.3095

KESSLER, R. C., BERGLUND, P., DEMLER, O., JIN, R., MERIKANGAS, K. R. & WALTERS, E. E. (2005a) Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*. 62(6), 593-602. doi: 10.1001/archpsyc.62.6.593

KESSLER, R. C., CHIU, W. T., DEMLER, O. & WALTERS, E. E. (2005b) Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*. 62(6), pp. 617-627. doi: 10.1001/archpsyc.62.6.617

KIESLER, D. J. (1966) Some myths of psychotherapy research and the search for a paradigm. *Psychological Bulletin.* 65(2), pp. 110-136.

KITANISHI, K. (1992) Morita therapy: Its theory and practice in Japan. *International Bulletin of Morita Therapy.* 5(1-2), pp. 3-9.

KITANISHI, K. (2005) The Philosophical Background of Morita Therapy: Its Application to Therapy. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 169-185.

KITANISHI, K. (2016) Personal communication to HOLLY SUGG, 02 Sept.

KITANISHI, K. & MORI, A. (1995) Morita therapy: 1919 to 1995. *Psychiatry and Clinical Neurosciences.* 49(5-6), pp. 245-254.

KITANISHI, K., NAKAMURA, K., MIYAKE, Y., HASHIMOTO, K. & KUBOTA, M. (2002) Diagnostic consideration of Morita shinkeishitsu and DSM-III-R. *Psychiatry and Clinical Neurosciences.* 56(6), pp. 603-608.

KITZINGER, J. (1994) The methodology of focus groups: the importance of interaction between research participants. *Sociology of Health & Illness*. 16(1), pp. 103-121. doi: 10.1111/1467-9566.ep11347023

REFERENCES

KJOLHEDE, B. (2000) Afterword. In: KAPLEAU, P., ed., *The Three Pillars of Zen: Teaching, Practice and Enlightenment.* New York: Anchor Books, pp. 375-389.

KNOBLAUCH, D. L. (1985) Applying Taoist thought to counseling and psychotherapy. *American Mental Health Counselors Association Journal.* 7(2), pp. 52-63.

KOBAYASHI, M. (2016) Making Morita Therapy familiar for use in clinics and everyday life: An attempt to create "Mild Morita" based on clinical practice. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 17. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healt hservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_f inal.pdf [Accessed 17 Jan 2017].

KONDO, A. (1953) Morita therapy: a Japanese therapy for neurosis. *American Journal of Psychoanalysis.* 13(1), pp. 31-37.

KONDO, A. (1975) Morita therapy: Its sociohistorical context. In: ARIETI, S. & CHRZANOWSKI, G., ed., *New dimensions in psychiatry: A world view.* New York, London, Sydney, Toronto: John Wiley & Sons, pp. 239-260.

KONDO, A. (1992) A Zen perspective on the concept of self and human nature. *International Bulletin of Morita Therapy.* 5(1-2), pp. 46-49.

KONDO, A. (1998) Translator's preface. In: MORITA, S., KONDO, A. & LEVINE, P., ed., *Morita therapy and the true nature of anxiety-based disorders (Shinkeishitsu).* New York, NY: State University of New York Press, pp. xi-xii.

KORA, T. (1995) *How to Live Well: Secrets of Using Neurosis.* New York, NY: State University of New York Press.

KRAEMER, H. C. (2013) Discovering, comparing, and combining moderators of treatment on outcome after randomized clinical trials: a parametric approach. *Statistics in Medicine*. 32(11), pp. 1964-1973. doi: 10.1002/sim.5734

KRECH, G. (2014) *The Art of Taking Action: Lessons from Japanese Psychology.* Monkton, VT: ToDo Institute.

KROENKE, K., SPITZER, R. L. & WILLIAMS, J. B. (2001) The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med*. 16(9), 606-613. doi: 10.1046/j.1525-1497.2001.016009606.x

KUMASAKA, Y. (1965) Discussion. *International Journal of Psychiatry.* 1(4), pp. 641-642.

KUPFER, D. J. (1991) Long-term treatment of depression. *Journal of Clinical Psychiatry.* 52(Supplement), pp. 28-34.

KUROKAWA, N. (2006) Morita therapy in psychosomatic medicine. *International Congress Series*. 1287(pp. 313-315. doi: 10.1016/j.ics.2005.12.040

KUROKI, T., TATEBAYASHI, H. & TASHIRO, N. (2000) Five-Year Follow-up of Adolescent Patients with Social Withdrawal Following Morita Therapy at the Current Clinical Setting. *Journal of Morita Therapy.* 11(1), pp. 126-129.

KUYKEN, W., HAYES, R., BARRETT, B., BYNG, R., DALGLEISH, T., KESSLER, D., LEWIS, G., WATKINS, E., BREJCHA, C. & CARDY, J. (2015) Effectiveness and cost-effectiveness of mindfulness-based cognitive therapy compared with maintenance antidepressant treatment in the prevention of depressive relapse or recurrence (PREVENT): a randomised controlled trial. *Lancet*. 386(9988), 63-73. doi: 10.1016/S0140-6736(14)62222-4

LAMB, S. & ALTMAN, D. G. (2015) Individually and Cluster-Randomized Trials. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 191-199.

LANCASTER, G. A., DODD, S. & WILLIAMSON, P. R. (2004) Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice.* 10(2), pp. 307-312.

LAU, D. C. (1979) Introduction. *Confucius: The Analects.* Penguin Books, pp.

REFERENCES

LAYARD, R. (2006) *The depression report: A new deal for depression and anxiety disorders.* No. 15. Centre for Economic Performance, LSE.

LEGGETT, J. (1997) Medical scientism: good practice or fatal error? *Journal of the Royal Society of Medicine.* 90(2), pp. 97-101.

LEVAC, D., COLQUHOUN, H. & O'BRIEN, K. K. (2010) Scoping studies: advancing the methodology. *Implementation Science.* 5(1), p. 69. doi: 10.1186/1748-5908-5-69

LEVINE, P. (1991) Applications of Morita therapy for clients with a bisexual orientation during the coming-out process. *International Bulletin of Morita Therapy.* 4(1-2), pp. 3-14.

LEVINE, P. (1993a) Morita-based therapy and its use across cultures in the treatment of bulimia nervosa. *Journal of Counseling & Development.* 72(1), pp. 82-90. doi: 10.1002/j.1556-6676.1993.tb02282.x

LEVINE, P. (1993b) Morita Therapy and its divergence from Existential Therapy: A proposal for adopting a Morita-based philosophy for use in counselling and psychotherapy. *International Bulletin of Morita Therapy.* 6(1), pp. 47-58.

LEVINE, P. (1998) Editor's Introduction. In: MORITA, S., KONDO, A. & LEVINE, P., ed., *Morita therapy and the true nature of anxiety-based disorders (Shinkeishitsu).* New York, NY: State University of New York Press, pp. xvii-xxvii.

LEVINE, P. (2016a) Classic Morita Therapy: Advancing Consciousness in Psychotherapy. *Psychotherapy and Counselling Journal of Australia.* 4(1),

LEVINE, P. (2016b) Q & A Session: How is outpatient therapy informed by residential Morita therapy for treating cruelty-based trauma? In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 20. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

LEVINE, P. (In press) *Classic Morita Therapy: Consciousness, Zen, Justice and Trauma.* State University of New York Press.

LEWIN, S., GLENTON, C. & OXMAN, A. D. (2009) Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ.* 339(p. b3496. doi: 10.1136/bmj.b3496

LEWINSOHN, P. M., BIGLAN, A. & ZEISS, A. M. (1976) Behavioral treatment of depression. *The behavioral management of anxiety, depression and pain.* pp. 91-146.

LI, S., MARQUART, J. M. & ZERCHER, C. (2000) Conceptual issues and analytic strategies in mixed-method studies of preschool inclusion. *Journal of Early Intervention.* 23(2), pp. 116-132. doi: 10.1177/105381510002300206

LIBERATI, A., ALTMAN, D. G., TETZLAFF, J., MULROW, C., GØTZSCHE, P. C., IOANNIDIS, J. P., CLARKE, M., DEVEREAUX, P. J., KLEIJNEN, J. & MOHER, D. (2009) The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Annals of internal medicine.* 151(4), W-65-W-94.

LILIENFELD, S. O., RITSCHEL, L. A., LYNN, S. J., CAUTIN, R. L. & LATZMAN, R. D. (2013) Why many clinical psychologists are resistant to evidence-based practice: Root causes and constructive remedies. *Clinical Psychology Review.* 33(7), pp. 883-900. doi: 10.1016/j.cpr.2012.09.008

LOVELL, K., BOWER, P., RICHARDS, D., BARKHAM, M., SIBBALD, B., ROBERTS, C., DAVIES, L., ROGERS, A., GELLATLY, J. & HENNESSY, S. (2008) Developing guided self-help for depression using the Medical Research Council complex interventions framework: a description of the modelling phase and results of an exploratory randomised controlled trial. *BMC Psychiatry.* 8(1), p. 91. doi: 10.1186/1471-244X-8-91

LÖWE, B., UNÜTZER, J., CALLAHAN, C. M., PERKINS, A. J. & KROENKE, K. (2004) Monitoring depression treatment outcomes with the patient health questionnaire-9. *Medical Care.* 42(12), 1194-1201.

REFERENCES

LUBORSKY, L., ROSENTHAL, R., DIGUER, L., ANDRUSYNA, T. P., BERMAN, J. S., LEVITT, J. T., SELIGMAN, D. A. & KRAUSE, E. D. (2002) The dodo bird verdict is alive and well—mostly. *Clinical Psychology: Science and Practice*. 9(1), pp. 2-12. doi: 10.1093/clipsy.9.1.2

LUBORSKY, L., SINGER, B. & LUBORSKY, L. (1975) Comparative studies of psychotherapies: is it true that everyone has won and all must have prizes? *Archives of General Psychiatry.* 32(8), pp. 995-1008.

LUTY, S. E., CARTER, J. D., MCKENZIE, J. M., RAE, A. M., FRAMPTON, C. M., MULDER, R. T. & JOYCE, P. R. (2007) Randomised controlled trial of interpersonal psychotherapy and cognitive–behavioural therapy for depression. *BJPsych*. 190(6), 496-502. doi: 10.1192/bjp.bp.106.024729

MADDEN, M. & SPEED, E. (2017) Beware Zombies and Unicorns: Toward critical patient and public involvement in health research in a neoliberal context. *Frontiers in Sociology*. 2(7), doi: 10.3389/fsoc.2017.00007

MAEDA, F. & NATHAN, J. H. (1999) Understanding Taijin kyofusho through its treatment, Morita therapy. *Journal of Psychosomatic Research.* 46(6), pp. 525-530.

MALHI, G., PARKER, G., CRAWFORD, J., WILHELM, K. & MITCHELL, P. (2005) Treatment-resistant depression: resistant to definition? *Acta Psychiatrica Scandinavica*. 112(4), pp. 302-309. doi: 10.1111/j.1600-0447.2005.00602.x

MARCUS, M., YASAMY, M. T., VAN OMMEREN, M., CHISHOLM, D. & SAXENA, S. (2012) Depression: A global public health concern. *WHO Department of Mental Health and Substance Abuse.* 1(6-8.

MARSHALL, M. N. (1996) Sampling for qualitative research. *Family practice.* 13(6), pp. 522-526.

MASON, M. (2010) Sample size and saturation in PhD studies using qualitative interviews. *Forum: qualitative social research*. 11(3), doi: 10.17169/fqs-11.3.1428

MATESZ, D. (1990) Morita and Buddhism: On the nature of suffering. *International Bulletin of Morita Therapy.* 3(1), pp. 14-25.

MCCABE, R., SKELTON, J., HEATH, C., BURNS, T. & PRIEBE, S. (2002) Engagement of patients with psychosis in the consultation: conversation analytic study. Commentary: Understanding conversation. *Bmj.* 325(7373), 1148-1151.

MCDONALD, A. M., KNIGHT, R. C., CAMPBELL, M. K., ENTWISTLE, V. A., GRANT, A. M., COOK, J. A., ELBOURNE, D. R., FRANCIS, D., GARCIA, J. & ROBERTS, I. (2006) What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials*. 7(1), p. 9. doi: 0.1186/1745-6215-7-9

MCENTARFFER, R. (2003) *Strengths-based mentoring in teacher education: A mixed methods Study (master's thesis).* University of Nebraska-Lincoln, Lincoln, NE.

MCKENZIE, B. A. (2012) Is complementary and alternative medicine compatible with evidence-based medicine? *Journal of the American Veterinary Medical Association*. 241(4), pp. 421-426. doi: 10.2460/javma.241.4.421

MCLEOD, B. D. (2009) Understanding why therapy allegiance is linked to clinical outcomes. *Clinical Psychology: Science and Practice*. 16(1), pp. 69-72. doi: 10.1111/j.1468-2850.2009.01145.x

MCLEOD, J. (2011) *Qualitative research in counselling and psychotherapy.* 2nd ed. Los Angeles, London, New Delhi, Singapore, Washington DC: Sage.

MCLEOD, S. A. (2008) *Case study method*. [online]. Simply Psychology. Available from: www.simplypsychology.org/case-study.html [Accessed 20 Oct 2017].

MCMANUS, S., BEBBINGTON, P., JENKINS, R. & BRUGHA, T. (2016) *Mental health and wellbeing in England: Adult Psychiatric Morbidity Survey 2014.* Leeds: NHS DIGITAL, 39-40. Available from: http://digital.nhs.uk/catalogue/PUB21748 [Accessed 18 Aug 2017].

MEDICAL RESEARCH COUNCIL. (2000) *A framework for development and evaluation of RCTs for complex interventions to improve health.* London: MRC.

REFERENCES

MENDLINGER, S. & CWIKEL, J. (2008) Spiraling between qualitative and quantitative data on women's health behaviors: a double helix model for mixed methods. *Qualitative Health Research.* 18(2), pp. 280-293.

MERCER, J. R. (2015) *Zen In classic Morita therapy: a heuristic inquiry.* PhD, University of Melbourne.

MESSER, S. B. & WAMPOLD, B. E. (2002) Let's face facts: Common factors are more potent than specific therapy ingredients. *Clinical Psychology: Science and Practice*. 9(1), pp. 21-25. doi: 10.1093/clipsy.9.1.21

MEYER, G. & KOPKE, S. (2015) Introduction to Section 1. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 53-56.

MILES, A. (2009a) Complexity in medicine and healthcare: people and systems, theory and practice. *Journal of Evaluation in Clinical Practice.* 15(3), pp. 409-410.

MILES, A. (2009b) On a Medicine of the Whole Person: away from scientistic reductionism and towards the embrace of the complex in clinical practice. *Journal of Evaluation in Clinical Practice.* 15(6), pp. 941-949.

MILES, M. B. & HUBERMAN, A. M. (1994) *Qualitative data analysis: An expanded sourcebook.* Thousand Oaks, London, New Delhi: Sage.

MILES, M. B., HUBERMAN, A. M. & SALDANA, J. (2014) *Qualitative data analysis: A methods sourcebook.* 3rd ed. Los Angeles, London, New Delhi, Singapore: Sage.

MINAMI, M. (2011a) Systematic Review and Critique of Methodological Approaches Employed in Evaluating the Effectiveness of Morita Therapy: A Preliminary Analysis. *Unpublished*.

MINAMI, M. (2011b) Systematic Review and Critique of Methodological Approaches Employed in Evaluating the Effectiveness of Morita Therapy: A Preliminary Analysis. *Unpublished.*

MINAMI, M. (2013) Morita Therapy Treatment Protocol. *Unpublished*.

MINAMI, M. (2016) Morita Therapy and psychosocial reconcilliation. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 16. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

MINGYI, Q., CHENGJUN, K., ZHONGTANG, X., GUOHUA, X., ZIAN, L., XIN, F., HUILAN, W. & HUIFANG, W. (2000) Morita Group Therapy for Cardiac Neurotic Patients. *Journal of Morita Therapy.* 11(1), pp. 224-228.

MITTE, K. (2005) Meta-analysis of cognitive-behavioral treatments for generalized anxiety disorder: a comparison with pharmacotherapy. *Psychological Bulletin.* 131(5), pp. 785-795.

MOFFITT, T. E., CASPI, A., TAYLOR, A., KOKAUA, J., MILNE, B., POLANCZYK, G. & POULTON, R. (2010) How common are common mental disorders? Evidence that lifetime prevalence rates are doubled by prospective versus retrospective ascertainment. *Psychological Medicine.* 40(6), pp. 899-909.

MONTORI, V. M. & GUYATT, G. H. (2008) Progress in evidence-based medicine. *JAMA*. 300(15), pp. 1814-1816. doi: 10.1001/jama.300.15.1814

MOORE, G., AUDREY, S., BARKER, M., BOND, L., BONELL, C., HARDEMAN, W., MOORE, L., O'CATHAIN, A., TINATI, T., WIGHT, D. E. & BAIRD, J. (2015a) Process evaluations of complex interventions: A summary of Medical Research Council guidance. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 222-231.

MOORE, G. F., AUDREY, S., BARKER, M., BOND, L., BONELL, C., HARDEMAN, W., MOORE, L., O'CATHAIN, A., TINATI, T. & WIGHT, D. (2015b) Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 350(p. h1258. doi: 10.1136/bmj.h1258

REFERENCES

MORAN, V. H. & WHITMAN, D. (2014) Recruitment and Retention. In: WALKER, D.-M., ed., *An Introduction to Health Services Research.* London, Thousand Oaks, New Delhi, Singapore: Sage, pp. 285-302.

MORGAN, D. L. (2007) Paradigms lost and pragmatism regained methodological implications of combining qualitative and quantitative methods. *Journal of Mixed Methods Research*. 1(1), pp. 48-76. doi: 10.1177/2345678906292462

MORITA, S., KONDO, A. & LEVINE, P. (1998) *Morita therapy and the true nature of anxiety-based disorders (Shinkeishitsu).* New York, NY: State University of New York Press.

MORIYAMA, N. (2000) Phantom Bite Syndrome Successfully Treated with Morita Therapy. *Journal of Morita Therapy.* 11(1), pp. 236-239.

MORLEY, N. (1990) The application of Morita techniques to a borderline personality in an outpatient service. *International Bulletin of Morita Therapy.* 3(2), pp. 112-117.

MORSE, J. M. (1995) *The significance of saturation.* Thousand Oaks, CA: Sage.

MORTON, W. S. & OLENIK, J. K. (2004) *Japan: Its History and Culture.* 4th ed. New York, Chicago, San Francisco, Lisbon, London, Madrid, Mexico City, Milan, New Delhi, San Juan, Seoul, Singapore, Sydney, Toronto: McGraw Hill Professional.

MULROW, C. & OXMAN, A. (1997) *Cochrane Collaboration Handbook (database on disk and CDROM).* Oxford: The Cochrane Library, The Cochrane Collaboration.

MUNDT, J. C., MARKS, I. M., SHEAR, M. K. & GREIST, J. M. (2002) The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *BJPsych*. 180(5), 461-464. doi: 10.1192/bjp.180.5.461

MURASE, T. & JOHNSON, F. (1974) Naikan, Morita, and western psychotherapy: A comparison. *Archives of General Psychiatry*. 31(1), pp. 121-128. doi: 10.1001/archpsyc.1974.01760130091016

MURRAY, J. W. & ISHIYAMA, I. (2016) Morita therapy-based group program for persons with chronic pain who are unemployed. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 17. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

NAGENDRAN, M., PEREIRA, T. V., KIEW, G., ALTMAN, D. G., MARUTHAPPU, M., IOANNIDIS, J. P. & MCCULLOCH, P. (2016) Very large treatment effects in randomised trials as an empirical marker to indicate whether subsequent trials are necessary: meta-epidemiological assessment. *BMJ*. 355(p. i5432. doi: 10.1136/bmj.i5432

NAKAMOTO, T. (2010) *Comparing and contrasting Morita therapy with Western therapies.* PsyD, Alliant International University.

NAKAMURA, K. (2016) *Common Language for Psychotherapy procedures: Morita Therapy*. [online]. COMMON LANGUAGE for PSYCHOTHERAPY (clp) PROCEDURES. Available from: http://www.commonlanguagepsychotherapy.org/fileadmin/user_upload/Accepted_procedures/morita.pdf [Accessed 10 Jan 2017].

NAKAMURA, K., KITANISHI, K., MARUYAMA, S., ISHIYAMA, F. I., ITO, K., TATEMATSU, K., KUROKI, T., KUBOTA, M., HASHIMOTO, K. & ICHIKAWA, M. (2010) *Guidelines for practising outpatient morita therapy.* Tokyo: Japanese Society for Morita Therapy.

NATIONAL COLLABORATING CENTRE FOR MENTAL HEALTH. (2011) *Generalised Anxiety Disorder in Adults: Management in Primary, Secondary and Community Care.* Leicester, London: The British Psychological Society and the Royal College of Psychiatrists (NICE Clinical Guidelines, No. 113).

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE. (2012) *Methods for development of NICE public health guidance (third edition).* London: NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE, Available from: https://www.nice.org.uk/process/pmg4/chapter/introduction [Accessed 18 Oct 2016].

REFERENCES

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE). (2009) *Depression in adults: recognition and management.* [online]. Available from: https://www.nice.org.uk/guidance/cg90/chapter/1-Guidance#step-3-persistent-subthreshold-depressive-symptoms-or-mild-to-moderate-depression-with-inadequate [Accessed 21 Feb 2017].

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE). (In Consultation) *Depression in adults: treatment and management: Draft guidance consultation*. [online]. Available from: https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0725/consultation/html-content [Accessed 01 Sep 2017].

NEWMAN, M. G., CASTONGUAY, L. G., BORKOVEC, T. D., FISHER, A. J., BOSWELL, J. F., SZKODNY, L. E. & NORDBERG, S. S. (2011) A randomized controlled trial of cognitive-behavioral therapy for generalized anxiety disorder with integrated techniques from emotion-focused and interpersonal therapies. *Journal of Consulting and Clinical Psychology.* 79(2), pp. 171-181.

NHS ENGLAND. (undated) *Adult Improving Access to Psychological Therapies programme*. [online]. Available from: https://www.england.nhs.uk/mental-health/adults/iapt/ [Accessed 21 Feb 2017].

NICHOL, A., BAILEY, M. & COOPER, D. (2010) Challenging issues in randomised controlled trials. *Injury*. 41(p. S20-S23. doi: 10.1016/j.injury.2010.03.033

NIIMURA, H., KITANISHI, K. & MASAFUMI, M. (2016) Appropriate rest and behavioural intervention in the convalescent stage of depression. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 12. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

NILSSON, T., SVENSSON, M., SANDELL, R. & CLINTON, D. (2007) Patients' experiences of change in cognitive–behavioral therapy and psychodynamic therapy: a qualitative comparative study. *Psychotherapy Research*. 17(5), pp. 553-566. doi: 10.1080/10503300601139988

NISHIZONO, M. (2005) Culture, Psychopathology, and Psychotherapy: Changes Observed in Japan. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 40-54.

NORBURY, P. (2011) *Japan-Culture Smart!: The Essential Guide to Customs & Culture.* London: Kuperard.

NYSTUEN, P. & HAGEN, K. B. (2004) Telephone reminders are effective in recruiting nonresponding patients to randomized controlled trials. *J Clin Epidemiology*. 57(8), 773-776. doi: 10.1016/j.jclinepi.2003.12.015

O'BRIEN, M., SINGLETON, N., BUMPSTEAD, R. & OFFICE FOR NATIONAL STATISTICS, L. S. S. D. (2001) *Psychiatric morbidity among adults living in private households, 2000.* London: The Stationery Office.

O'CATHAIN, A., HODDINOTT, P., LEWIN, S., THOMAS, K. J., YOUNG, B., ADAMSON, J., JANSEN, Y. J., MILLS, N., MOORE, G. & DONOVAN, J. L. (2015) Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and Feasibility Studies*. 1(1), p. 32. doi: 10.1186/s40814-015-0026-y

O'CATHAIN, A., MURPHY, E. & NICHOLL, J. (2007a) Integration and publications as indicators of" yield" from mixed methods studies. *Journal of Mixed Methods Research*. 1(2), pp. 147-163. doi: 10.1177/1558689806299094

O'CATHAIN, A., MURPHY, E. & NICHOLL, J. (2007b) Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. *BMC Health Services Research*. 7(1), p. 85. doi: 10.1186/1472-6963-7-85

O'CATHAIN, A., MURPHY, E. & NICHOLL, J. (2008) The quality of mixed methods studies in health services research. *Journal of Health Services Research & Policy*. 13(2), pp. 92-98. doi: 10.1258/jhsrp.2007.007074

REFERENCES

O'CATHAIN, A. & THOMAS, K. (2006) Combining qualitative and quantitative methods. In: POPE, C. & MAYS, N., ed., *Qualitative Research in Health Care.* 3rd ed. Oxford: Blackwell Publishing, pp. 102-111.

OAKLEY, A., STRANGE, V., BONELL, C., ALLEN, E. & STEPHENSON, J. (2006) Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 332(7538), pp. 413-416. doi: 10.1136/bmj.332.7538.413

OFFICE. (undated) *Excel*. [online]. Available from: https://products.office.com/en-gb/excel [Accessed 13 Mar 2017].

OGAWA, B. (2007) *A river to live by: the 12 life principles of Morita therapy.* Philadelphia, PA: Xlibris/ Random House.

OGAWA, B. (2013) *Desire For Life: The Practitioner's Introduction to Morita Therapy.* Indiana: Xlibris Corporation.

OGAWA, B. K. (1988) Counseling victims of sexual assault. *International Bulletin of Morita Therapy.* 1(1), pp. 19-25.

OGILVIE, D., MITCHELL, R., MUTRIE, N., PETTICREW, M. & PLATT, S. (2006) Evaluating health effects of transport interventions: methodologic case study. *American Journal of Preventive Medicine*. 31(2), pp. 118-126. doi: 10.1016/j.amepre.2006.03.030

OGRISSEG, J. F. (1999) *Communication apprehension and Morita therapy: Evaluation of a brief Morita therapy workshop against a stress management education workshop.* PhD, Bowling Green State University.

OHARA, K. (1990) Creativity and experiential understanding in Morita Therapy. *International Bulletin of Morita Therapy.* 3(1), pp. 61-63.

OHARA, K. & REYNOLDS, D. (1968) Changing methods in Morita psychotherapy. *International Journal of Social Psychiatry*. 14(4), pp. 305-310. doi: 10.1177/002076406801400409

OLSCHEWSKI, M. & SCHEURLEN, H. (1985) Comprehensive Cohort Study: an alternative to randomized consent design in a breast preservation trial. *Methods Archive.* 24(3), pp. 131-134.

ONG, B. N. (1993) *The Practice of Health Services Research.* London: Chapman & Hall.

ONWUEGBUZIE, A. J. & COLLINS, K. M. (2007) A typology of mixed methods sampling designs in social science research. *The Qualitative Report.* 12(2), pp. 281-316.

ONWUEGBUZIE, A. J., JOHNSON, R. B. & COLLINS, K. M. (2009) Call for mixed analysis: A philosophical framework for combining qualitative and quantitative approaches. *International Journal of Multiple Research Approaches*. 3(2), pp. 114-139. doi: 10.5172/mra.3.2.114

OXMAN, A. D. & GUYATT, G. H. (1993) The Science of Reviewing Research. *Annals of the New York Academy of Sciences*. 703(1), pp. 125-134. doi: 10.1111/j.1749-6632.1993.tb26342.x

PARKINSON, S., EATOUGH, V., HOLMES, J., STAPLEY, E. & MIDGLEY, N. (2016) Framework analysis: A worked example of a study exploring young people's experiences of depression. *Qualitative Research in Psychology*. 13(2), pp. 109-129. doi: 10.1080/14780887.2015.1119228

PARTRIDGE, N. & SCADDING, J. (2004) The James Lind Alliance: patients and clinicians should jointly identify their priorities for clinical trials. *The Lancet.* 364(9449), pp. 1923-1924.

PAUL, G. L. (1967) Strategy of outcome research in psychotherapy. *Journal of Consulting Psychology.* 31(2), pp. 109-118.

PAWSON, R. (2002) Evidence-based policy: in search of a method. *Evaluation*. 8(2), pp. 157-181. doi: 10.1177/1358902002008002512

PAYNE, K. & THOMPSON, A. J. (2015) Economic evaluations of complex interventions. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 248-258.

PEDERSON, P. S. (1977) Asian personality theory. In: CORSINI, R. J., ed., *Current Personality Theories.* Itasca, IL: F. E. Peacock Publishers, pp. 367-397.

REFERENCES

PETTICREW, M., CUMMINS, S., FERRELL, C., FINDLAY, A., HIGGINS, C., HOY, C., KEARNS, A. & SPARKS, L. (2005) Natural experiments: an underused tool for public health? *Public Health*. 119(9), pp. 751-757. doi: 10.1016/j.puhe.2004.11.008

PHAM, M., RAJIC, A., GREIG, J., SARGEANT, J., PAPADOPOULOS, A. & MCEWEN, S. (2014) A scoping review of scoping reviews: advancing the approach and enhancing the consistency. *Research Synthesis Methods*. 5(4), pp. 371-385. doi: 10.1002/jrsm.1123

POPE, C. (2003) Resisting evidence: the study of evidence-based medicine as a contemporary social movement. *Health:*. 7(3), pp. 267-282.

POPE, C. & MAYS, N. (2006a) Qualitative methods in health research. In: POPE, C. & MAYS, N., ed., *Qualitative Research in Health Care.* 3rd ed. Oxford: Blackwell Publishing, pp. 1-11.

POPE, C. & MAYS, N. (2006b) *Qualitative research in health care.* 3rd ed. Oxford: Blackwell Publishing.

PRESSLEY, M. & AFFLERBACH, P. (1995) *Verbal protocols of reading: The nature of constructively responsive reading.* New York, London: Routledge.

QIYI, M. & XIONGWEI, Z. (2000) The Study on Efficacy of Using Morita Therapy to Treat Obsessive-Compulsive Disorder and Follow-up. *Journal of Morita Therapy.* 11(1), pp. 148-151.

QSR INTERNATIONAL. (undated) *NVIVO: THE #1 SOFTWARE FOR QUALITATIVE DATA ANALYSIS*. [online]. Available from: http://www.qsrinternational.com/nvivo-product [Accessed 21 Feb 2017].

QUAH, S. R. (2003) Traditional healing systems and the ethos of science. *Social Science & Medicine*. 57(10), pp. 1997-2012. doi: 10.1016/S0277-9536(03)00078-9

RAWLINS, M. (2008) De testimonio: on the evidence for decisions about the use of therapeutic interventions. *Clinical Medicine*. 8(6), pp. 579-588. doi: 10.7861/clinmedicine.8-6-579

REYNOLDS, D. K. (1976) *Morita psychotherapy.* Berkley, Los Angeles, London: University of California Press.

REYNOLDS, D. K. (1982) *The quiet therapies: Japanese pathways to personal growth.* Honolulu, HI: The University Press of Hawaii.

REYNOLDS, D. K. (1989) *Flowing bridges, quiet waters: Japanese psychotherapies, Morita and Naikan.* New York, NY: State University of New York Press.

REYNOLDS, D. K. (1995a) Foreword. In: KORA, T., ed., *How to Live Well: Secrets of Using Neurosis.* New York, NY: State University of New York Press, pp. vii-ix.

REYNOLDS, D. K. (1995b) *A handbook for constructive living.* New York, NY: William Morrow & Co.

REYNOLDS, S., TAYLOR, E. & SHAPIRO, D. (1993) Session impact and outcome in stress management training. *Journal of community & applied social psychology.* 3(4), 325-337.

RHODES, S., RICHARDS, D. A., EKERS, D., MCMILLAN, D., BYFORD, S., FARRAND, P. A., GILBODY, S., HOLLON, S. D., KUYKEN, W. & MARTELL, C. (2014) Cost and outcome of behavioural activation versus cognitive behaviour therapy for depression (COBRA): study protocol for a randomised controlled trial. *Trials*. 15(1), 29. doi: 10.1186/1745-6215-15-29

RHYNER, B. (1987) Morita therapy, Mitchell's Rest Treatment and Otto Binswanger's "geregelte Lebensfuhrung": A methodological comparison. *Psychologia: An International Journal of Psychology in the Orient.* 30(2), pp. 70-74.

RICHARDS, D. A. (2015a) The complex interventions framework. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 1-15.

RICHARDS, D. A. (2015b) The critical importance of patient and public involvement for research into complex interventions. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 46-50.

REFERENCES

RICHARDS, D. A. (2015c) Introduction to Section 2. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 53-56.

RICHARDS, D. A., ed. (2016) *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century,* Exeter, 1-2 Sept 2016. University of Exeter. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

RICHARDS, D. A., EKERS, D., MCMILLAN, D., TAYLOR, R. S., BYFORD, S., WARREN, F. C., BARRETT, B., FARRAND, P. A., GILBODY, S. & KUYKEN, W. (2016) Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. *Lancet.* 388(10047), 871-880. doi: 10.1016/S0140-6736(16)31140-0

RICHARDS, D. A., HILL, J. J., GASK, L., LOVELL, K., CHEW-GRAHAM, C., BOWER, P., CAPE, J., PILLING, S., ARAYA, R. & KESSLER, D. (2013) Clinical effectiveness of collaborative care for depression in UK primary care (CADET): cluster randomised controlled trial. *BMJ.* 347(f4913. doi: 10.1136/bmj.f4913

RICHARDS, D. A., LANKSHEAR, A. J., FLETCHER, J., ROGERS, A., BARKHAM, M., BOWER, P., GASK, L., GILBODY, S. & LOVELL, K. (2006) Developing a UK protocol for collaborative care: a qualitative study. *General Hospital Psychiatry.* 28(4), pp. 296-305. doi: 10.1016/j.genhosppsych.2006.03.005

RICHARDS, D. A., MULLAN, E. G., ISHIYAMA, F. I. & NAKAMURA, K. (2011) Developing an Outcome Framework for Measuring the Impact of Morita Therapy: A Report from a Consensus Development Process. *Journal of Morita Therapy.* 22(2), 165-173.

RIFKIN, A. (2007) Randomized controlled trials and psychotherapy research. *American Journal of Psychiatry.* 164(1), pp. 7-8.

RITCHIE, J., LEWIS, J., NICHOLLS, C. M. & ORMSTON, R. (2013) *Qualitative research practice: A guide for social science students and researchers.* 2nd ed. Los Angeles, London, New Delhi, Singapore: Sage.

ROBB, S. L. (2013) The power of the pilot. *Journal of Music Therapy.* 50(1), 3-5.

ROBERTSON, M. & WALTER, G. (2013) *Ethics and mental health: the patient, profession and community.* Boca Raton, FL: CRC Press.

ROBINSON, K. A., DENNISON, C. R., WAYMAN, D. M., PRONOVOST, P. J. & NEEDHAM, D. M. (2007) Systematic review identifies number of strategies important for retaining study participants. *Journal of Clinical Epidemiology.* 60(8), pp.757-e1. doi: 10.1016/j.jclinepi.2006.11.023

ROEMER, L. & ORSILLO, S. M. (2002) Expanding our conceptualization of and treatment for generalized anxiety disorder: Integrating mindfulness/acceptance-based approaches with existing cognitive-behavioral models. *Clinical Psychology: Science and Practice.* 9(1), pp. 54-68. doi: 10.1093/clipsy.9.1.54

ROSENTHAL, M. H. (2003) The challenge of comorbid disorders in patients with depression. *Journal of the American Osteopathic Association.* 103(8 Suppl 4), pp. S10-5.

ROSENZWEIG, S. (1936) Some implicit common factors in diverse methods of psychotherapy. *American Journal of Orthopsychiatry.* 6(3), pp. 412-415.

RUSH, A. J., FAVA, M., WISNIEWSKI, S. R., LAVORI, P. W., TRIVEDI, M. H., SACKEIM, H. A., THASE, M. E., NIERENBERG, A. A., QUITKIN, F. M., KASHNER, T. M., KUPFER, D. J., ROSENBAUM, J. F., ALPERT, J., STEWART, J. W., MCGRATH, P. J., BIGGS, M. M., SHORES-WILSON, K., LEBOWITZ, B. D., RITZ, L., NIEDEREHE, G. & FOR THE, S. D. I. G. (2004) Sequenced treatment alternatives to relieve depression (STAR*D): rationale and design. *Controlled Clinical Trials.* 25(1), 119-142. doi: 10.1016/s0197-2456(03)00112-0

RUSH, B. A. (2000) *Zen and the therapeutic relationship.* PsyD, Pepperdine University.

REFERENCES

RUSSELL, J. G. (1989) Anxiety disorders in Japan: A Review of The Japanese literature on Shinkeishitsu and taijinkyōfushī. *Culture, Medicine and Psychiatry.* 13(4), pp. 391-403.

RYCHETNIK, L., FROMMER, M., HAWE, P. & SHIELL, A. (2002) Criteria for evaluating evidence on public health interventions. *Journal of Epidemiology and Community Health*. 56(2), pp. 119-127. doi: 10.1136/jech.56.2.119

SACKETT, D. L., ROSENBERG, W. M., GRAY, J. M., HAYNES, R. B. & RICHARDSON, W. S. (1996) Evidence based medicine: what it is and what it isn't. *BMJ*. 312(7023), pp. 71-72. doi: 10.1136/bmj.312.7023.71

SACKETT, D. L. & WENNBERG, J. E. (1997) Choosing the best research design for each question. *BMJ.* 315(7123), p. 1636.

SACKS, H. (1992) *Lectures on conversation, volumes I and II. Edited by G. Jefferson with Introduction by EA Schegloff.* Oxford: Blackwell.

SANSOM, G. B. (1978) *Japan: a short cultural history.* Stanford, CA: Stanford University Press.

SATO, T. (2011) Rises and Falls of Clinical Psychology in Japan: A Perspective on the Status of Japanese Clinical Psychology. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc., pp. 161-178.

SCHULZ, K. F., CHALMERS, I., HAYES, R. J. & ALTMAN, D. G. (1995) Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA*. 273(5), pp. 408-412. doi: 10.1001/jama.1995.03520290060030

SCOTT, J. G., WARBER, S. L., DIEPPE, P., JONES, D. & STANGE, K. C. (2017) Healing journey: a qualitative analysis of the healing experiences of Americans suffering from trauma and illness. *BMJ Open*. 7(8), e016771. doi: 10.1136/bmjopen-2017-016771

SEERS, K. (2007) Evaluating complex interventions. *Worldviews on Evidence-Based Nursing*. 4(2), pp. 67-68. doi: 10.1111/j.1741-6787.2007.00083.x

SEGAL, Z., WILLIAMS, J. & TEASDALE, J. (2002) *Mindfulness-based cognitive therapy for depression: A new approach to relapse prevention.* 2nd ed. New York, NY: Guilford Press.

SEMENOVA, N. (2016) The principles of Morita Therapy: Implications for psychoeducation. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 20. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

SERMEUS, W. (2015) Modelling process and outcomes in complex interventions. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 111-120.

SHEA, J. L. (2006) Applying evidence-based medicine to traditional Chinese medicine: debate and strategy. *Journal of Alternative & Complementary Medicine*. 12(3), pp. 255-263. doi: 10.1089/acm.2006.12.255

SHIMOYAMA, H. (2011) Clinical Psychology in Japan: Toward Integration Inside and Recognition from Outside. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc., pp. 56-68.

SHIOJI, R., NAKAMURA, K. & USHIJIMA, S. (2000) The Treatment Process of Social Phobia by Morita Therapy. *Journal of Morita Therapy.* 11(1), pp. 240-243.

SILCOCKS, P. & GHEORGHE, A. (2014) Clinical Trials. In: WALKER, D.-M., ed., *An Introduction to Health Services Research.* London, Thousand Oaks, New Delhi, Singapore: Sage, pp. 159-178.

SIMON, T., BOSWORTH, K. & UNGER, J. (2001) Component studies. *Handbook of program development for health behavior research and practice.* Thousand Oaks, CA: SAGE Publications, Inc., pp. 320-344.

REFERENCES

SKELLY, A. C. & CHAPMAN, J. (2011) Evidence-based medicine (EBM): origins and modern application to spine care. *Evidence-based Spine-care Journal*. 2(1), pp. 11-16. doi: 10.1055/s-0030-1267081

SKOLARUS, T. A. & SALES, A. E. (2015) Implementation issues: Towards a systematic and stepwise approach. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 265-272.

SMITH, H. (2000) Foreword. In: KAPLEAU, P., ed., *The Three Pillars of Zen: Teaching, Practice and Enlightenment.* New York: Anchor Books, pp. xi-xiv.

SOMEYA, T. & TAKAHASHI, M. (2001) Is DSM widely accepted by Japanese clinicians? *Psychiatry and Clinical Neurosciences*. 55(5), pp. 437-450. doi: 10.1046/j.1440-1819.2001.00888.x

SPATES, C. R., TATENO, A., NAKAMURA, K., SEIM, R. W. & SHEERIN, C. M. (2011) The experiential therapy of Shoma Morita: A comparison to contemporary congnitive behavior therapies. *Annals of Psychotherapy & Integrative Health.* 14(1), pp. 14-25.

SPENCER, L., RITCHIE, J., O'CONNOR, W., MORRELL, G. & ORMSTON, R. (2014) Analysis in practice. In: RITCHIE, J., LEWIS, J., MCNAUGHTON NICHOLLS, C. & ORMSTON, R., ed., *Qualitative research practice: A guide for social science students & researchers.* 2nd ed. London, Thousand Oaks, New Delhi, Singapore: Sage, pp. 295-346.

SPIELMANS, G. I., BERMAN, M. I. & USITALO, A. N. (2011) Psychotherapy versus second-generation antidepressants in the treatment of depression: a meta-analysis. *Journal of Nervous and Mental Disease.* 199(3), pp. 142-149.

SPITZER, R. L., KROENKE, K., WILLIAMS, J. B. & LÖWE, B. (2006) A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 166(10), 1092-1097. doi: 10.1001/archinte.166.10.1092

SPRING, B. (2007) Evidence-based practice in clinical psychology: what it is, why it matters; what you need to know. *Journal of Clinical Psychology*. 63(7), pp. 611-631. doi: 10.1002/jclp.20373

STALEY, K. (2009) *Exploring Impact: Public involvement in NHS, public health and social care research.* Eastleigh: INVOLVE, National Institute for Health Research.

STANISZEWSKA, S., BRETT, J., MOCKFORD, C. & BARBER, R. (2011) The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *International Journal of Technology Assessment in Health Care*. 27(4), pp. 391-399. doi: 10.1017/S0266462311000481

STANLEY, M. A., WILSON, N. L., NOVY, D. M., RHOADES, H. M., WAGENER, P. D., GREISINGER, A. J., CULLY, J. A. & KUNIK, M. E. (2009) Cognitive behavior therapy for generalized anxiety disorder among older adults in primary care: a randomized clinical trial. *JAMA*. 301(14), pp. 1460-1467. doi: 10.1001/jama.2009.458

STANSFELD, S., CLARK, C., BEBBINGTON, P., KING, M., JENKINS, R. & HINCHLIFFE, S. (2014) Chapter 2: Common mental disorders. In: MCMANUS, S., BEBBINGTON, P., JENKINS, R. & BRUGHA, T., ed., *Mental health and wellbeing in England: Adult Psychiatric Morbidity Survey 2014.* Leeds: NHS Digital, pp. 1-32.

STATACORP. (2015) *Stata Statistical Software.* Release 14. College Station, TX: StataCorp LP.

STETLER, C. B., LEGRO, M. W., WALLACE, C. M., BOWMAN, C., GUIHAN, M., HAGEDORN, H., KIMMEL, B., SHARP, N. D. & SMITH, J. L. (2006) The role of formative evaluation in implementation research and the QUERI experience. *Journal of General Internal Medicine*. 21(S2), pp. S1-S8. doi: 10.1111/j.1525-1497.2006.00355.x

STILES, W. B., SHAPIRO, D. A. & ELLIOTT, R. (1986) Are all psychotherapies equivalent? *American Psychologist.* 41(2), pp. 165-180.

STIMPSON, N., AGRAWAL, N. & LEWIS, G. (2002) Randomised controlled trials investigating pharmacological and psychological interventions for treatment-refractory depression. *The British Journal of Psychiatry.* 181(4), pp. 284-294.

REFERENCES

SUGG, H. V. R., RICHARDS, D. A. & FROST, J. (2016) Morita therapy for depression and anxiety (Morita Trial): study protocol for a pilot randomised controlled trial. *Trials*. 17(1), 161. doi: 10.1186/s13063-016-1279-3

SUGG, H. V. R., RICHARDS, D. A. & FROST, J. (2017) Optimising the acceptability and feasibility of novel complex interventions: an iterative, person-based approach to developing the UK Morita therapy outpatient protocol. *Pilot Feasibility Stud*. 3(1), 37. doi: 10.1186/s40814-017-0181-4

SUZUKI, D. T. (1961) *Essays in Zen Buddhism.* New York, NY: Grove Press.

SUZUKI, D. T. (2010) *Zen and Japanese culture.* 2nd ed. Princeton, Oxford: Princeton University Press.

SUZUKI, D. T., FROMM, E. & DE MARTINO, R. (1960) Zen Buddhism and psychoanalysis. *Philosophy East and West.* 15(1), pp. 81-82.

SUZUKI, T., KATAOKA, H. & KARASAWA, O. (1982) On the long-term development of shinkeishitsu-neurotics treated by Morita therapy. A statistical quantitative analysis. *Psychiatria Clinica.* 15(3), pp. 145-152.

SUZUKI, T. & SUZUKI, R. (1981) The effectiveness of in-patient morita therapy. *Psychiatric Quarterly.* 53(3), pp. 203-213.

TALLON, D., CHARD, J. & DIEPPE, P. (2000) Relation between agendas of the research community and the research consumer. *The Lancet*. 355(9220), pp. 2037-2040. doi: 10.1016/S0140-6736(00)02351-5

TAMAI, K., TAKEICHI, M. & TASHIRO, N. (1991) Morita therapy for treating borderline personality disorder: The utility of treatment structuredness and limit-setting. *International Bulletin of Morita Therapy.* 4(1-2), pp. 32-41.

TAMAI, K. & TASHIRO, N. (1989) A model of conflict-focused outpatient Morita therapy. *International Bulletin of Morita Therapy.* 2(2), pp. 57-68.

TANAKA-MATSUMI, J. (2011) Cultural Differences and the Practice of Clinical Psychology in Japan and the United States: Cross-cultural Professional Experiences. In: SHIMOYAMA, H., ed., *An International Comparison of Clinical Psychology in Practice: West Meets East.* Tokyo: Kazama Shobo Inc., pp. 145-158.

TASHAKKORI, A. & CRESWELL, J. W. (2007) Editorial: The new era of mixed methods. *Journal of Mixed Methods Research*. 1(1), pp. 3-7. doi: 10.1177/2345678906293042

TASHIRO, N., TAMAI, K. & NAKAO, H. (1993) A theoretical view of modified Morita therapy for neurotic patients. *International Bulletin of Morita Therapy.* 6(1-2), pp. 18-29.

TATEMATSU, K. (2000) Morita Therapy and Pharmacotherapy for Panic Disorder. *Journal of Morita Therapy.* 11(1), pp. 229-232.

TATENO, A., YANO, K., KAWAKAMI, M., IMAMURA, Y. & NAKAMURA, K. (2015) Obsessive-Compulsive Disorder cases with a Good Prognosis which Underwent CBT and Morita Therapy. *Family Medicine & Medical Science Research*. 4(3), doi: 10.4172/2327-4972.1000172

TATENO, A. N., KEI; NAKAYAMA, KAZUHIKI. (2014) Comparative Study of Outpatient Morita Therapy and 'Acceptance and Commitment Therapy' for Patients with OCD. *Annals of Psychotherapy & Integrative Health.* 1-17.

TAUB, N., DOUIRI, A. & WALKER, D.-M. (2014) Sampling. In: WALKER, D.-M., ed., *An Introduction to Health Services Research.* London, Thousand Oaks, New Delhi, Singapore: Sage, pp. 267-283.

TAYLOR, M. (2011) Interviewing. In: HOLLOWAY, I., ed., *Qualitative Research in Health Care.* Maidenhead: Open University Press, pp. 29-55.

TEDDLIE, C. & TASHAKKORI, A. (2009) *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences.* Thousand Oaks, New Delhi, London, Singapore: Sage.

TEDDLIE, C. & YU, F. (2007) Mixed methods sampling: A typology with examples. *Journal of Mixed Methods Research*. 1(1), pp. 77-100. doi: 10.1177/2345678906292430

REFERENCES

TERADA, H., OCHIAI, M., OHTA, D., YOSHIDA, K. & OHARA, K. (2000) The Neurotics among Teachers Treated by the Morita Therapy with Hospitalisation. *Journal of Morita Therapy.* 11(1), pp. 209-213.

THABANE, L., MA, J., CHU, R., CHENG, J., ISMAILA, A., RIOS, L. P., ROBSON, R., THABANE, M., GIANGREGORIO, L. & GOLDSMITH, C. H. (2010) A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 10(1), 1. doi: 10.1186/1471-2288-10-1

THE NATIONAL INSTITUTE FOR HEALTH RESEARCH EVALUATION TRIALS AND STUDIES. (2015) *The National Institute for Health Research Evaluation Trials and Studies Coordinating Centre (NETSCC) glossary*. [online]. National Institute for Health Research. Available from: http://www.netscc.ac.uk/glossary/ [Accessed 25 Sep 2015].

THORNE, S. (2000) Data analysis in qualitative research. *Evidence based Nursing*. 3(3), pp. 68-70. doi: 10.1136/ebn.3.3.68

TIANCHENG, W. (2000) The Efficacy of Morita Therapy in Neurotic Outpatients of No Effect with Drugs. *Journal of Morita Therapy.* 11(1), pp. 296-300.

TOKI, S. (2016) Is Morita Therapy effective for the treatment of and recovery from schizophrenia? In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 21. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healt hservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_f inal.pdf [Accessed 17 Jan 2017].

TONELLI, M. R. & CALLAHAN, T. C. (2001) Why Alternative Medicine Cannot Be Evidence-based. *Academic Medicine.* 76(12), pp. 1213-1220.

TORGERSON, D. J. & TORGERSON, C. J. (2008) *Designing randomised trials in health, education and the social sciences: an introduction.* Hampshire, New York: Palgrave Macmillan.

TREWEEK, S., MITCHELL, E., PITKETHLY, M., COOK, J., KJELDSTRØM, M., JOHANSEN, M., TASKILA, T. K., SULLIVAN, F., WILSON, S. & JACKSON, C. (2010) Strategies to improve recruitment to randomised controlled trials. *Cochrane Database Syst Rev*. 4(4), doi: 10.1002/14651858.MR000013.pub4

TSENG, W.-S. (1999) Culture and psychotherapy: Review and practical guidelines. *Transcultural Psychiatry*. 36(2), pp. 131-179. doi: 10.1177/136346159903600201

TSENG, W. S. (2005) Integration and Application for Therapy. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 265-279.

TSENG, W. S., CHANG, S. C. & NISHIZONO, M. (2005) Asian Culture and Psychotherapy: An Overview. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 1-18.

TURNER III, D. W. (2010) Qualitative interview design: A practical guide for novice investigators. *The Qualitative Report.* 15(3), pp. 754-750.

UNIVERSITY OF EXETER MEDICAL SCHOOL. *Introduction to The Third Gap*. [online]. Available from: http://medicine.exeter.ac.uk/research/healthresearch/thethirdgap/ [Accessed 6th Oct 2017].

VAN ACHTERBERG, T. (2015) Introduction to Section 4. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 261-264.

VANDENBROUCKE, J. (2013) Thalidomide: an unanticipated adverse effect. *JLL Bulletin: Commentaries on the history of treatment evaluation*. Available from: http://www.jameslindlibrary.org/articles/thalidomide-an-unanticipated-adverse-effect/ [Accessed 01 Oct 2016]

VERHOEF, M. J., CASEBEER, A. L. & HILSDEN, R. J. (2002) Assessing efficacy of complementary medicine: adding qualitative research methods to the" Gold Standard". *The Journal of Alternative & Complementary Medicine.* 8(3), pp. 275-281.

REFERENCES

VERHOEF, M. J., LEWITH, G., RITENBAUGH, C., BOON, H., FLEISHMAN, S. & LEIS, A. (2005) Complementary and alternative medicine whole systems research: beyond identification of inadequacies of the RCT. *Complementary Therapies in Medicine*. 13(3), pp. 206-212. doi: :10.1016/j.ctim.2005.05.001

VICKERS, A. J. (2014) Clinical trials in crisis: four simple methodologic fixes. *Clinical Trials*. 11(6), pp. 615-621. doi: 10.1177/1740774514553681

VICTORA, C. G., HABICHT, J.-P. & BRYCE, J. (2004) Evidence-based public health: moving beyond randomized trials. *American Journal of Public Health.* 94(3), pp. 400-405.

VON ESSEN, L. (2015) Non-standard and preference designs. In: RICHARDS, D. A. & HALLBERG, I. R., ed., *Complex Interventions in Health: An overview of research methods.* Oxon, New York: Routledge, pp. 207-212.

VON PETER, S. (2013) Exploring embodied perspectives of change within a psychiatric context: Some preliminary remarks from a psychiatrist. *Subjectivity.* 6(2), 212-224.

WALSH, R. (1989) Asian psychotherapies. In: CORSINI, R. J. & WEDDING, D., ed., *Current Psychotherapies.* 4th ed. Itasca, IL: F. E. Peacock Publishers, pp. 547-559.

WAMPOLD, B. E., MINAMI, T., BASKIN, T. W. & TIERNEY, S. C. (2002) A meta-(re) analysis of the effects of cognitive therapy versus 'other therapies' for depression. *Journal of Affective Disorders*. 68(2), pp. 159-165. doi: 10.1016/S0165-0327(00)00287-1

WANG, X., MA, W., SUN, H., JIANG, T., LU, Q., ZHANG, X., LI, Y., LAN, B. & LEE, Z. (2000) Controlled Study of Bone Mineral Content and Morita Therapy in Chronic Schizophrenics. *Journal of Morita Therapy.* 11(1), pp. 289-292.

WARE, J., KOSINSKI, M., BJORNER, J. B., TURNER-BOWKER, D. M., GANDEK, B. & MARUISH, M. E. (2008) *SF-36v2 health survey: Administration guide for clinical trial investigators.* Lincoln, RI: QualityMetric.

WARE, J. E., KOSINSKI, M., DEWEY, J. E. & GANDEK, B. (2000) *SF-36 health survey: manual and interpretation guide.* Boston, MA: Quality Metric Inc.

WATSON, D. & FRIEND, R. (1969) Measurement of social-evaluative anxiety. *Journal of Consulting and Clinical Psychology.* 33(4), pp. 448-457.

WATTS, A. (1961) *Psychotherapy, east and west.* New York, NY: Ballatine Books, Inc.

WATTS, A. W. (2012) *Nature, man and woman.* New York, NY: Vintage Books, Random House, Inc.

WEI, Q. (2005) Effect of new Morita therapy plus antipsychotic drugs in ameliorating post-schizophrenia depression. *Zhongguo Linchuang Kangfu.* 9(32), pp. 72-75.

WESTEN, D. & MORRISON, K. (2001) A multidimensional meta-analysis of treatments for depression, panic, and generalized anxiety disorder: an empirical examination of the status of empirically supported therapies. *J Consult Clin Psychol.* 69(6), 875-899.

WESTRA, H. A., ARKOWITZ, H. & DOZOIS, D. J. (2009) Adding a motivational interviewing pretreatment to cognitive behavioral therapy for generalized anxiety disorder: A preliminary randomized controlled trial. *Journal of Anxiety Disorders*. 23(8), pp. 1106-1117. doi: 10.1016/j.janxdis.2009.07.014

WHITEFORD, H., HARRIS, M., MCKEON, G., BAXTER, A., PENNELL, C., BARENDREGT, J. & WANG, J. (2013) Estimating remission from untreated major depression: a systematic review and meta-analysis. *Psychological Medicine*. 43(08), pp. 1569-1585. doi: 10.1017/S0033291712001717Published

WHOOLEY, M. A., AVINS, A. L., MIRANDA, J. & BROWNER, W. S. (1997) Case-finding instruments for depression. *Journal of General Internal Medicine*. 12(7), pp. 439-445. doi: 10.1046/j.1525-1497.1997.00076.x

WILES, N., THOMAS, L., ABEL, A., RIDGWAY, N., TURNER, N., CAMPBELL, J., GARLAND, A., HOLLINGHURST, S., JERROM, B. & KESSLER, D. (2013) Cognitive behavioural therapy as an adjunct to pharmacotherapy for primary care based patients with treatment resistant depression: results of the CoBalT randomised controlled trial. *Lancet*. 381(9864), 375-384. doi: 10.1016/S0140-6736(12)61552-9

REFERENCES

WILLIAMS, D. & GARNER, J. (2002) The case against 'the evidence': a different perspective on evidence-based medicine. *The British Journal of Psychiatry*. 180(1), pp. 8-12. doi: 10.1192/bjp.180.1.8

WILLIAMS, S. J. (2001) Reason, emotion and embodiment: is 'mental' health a contradiction in terms? In: BUSFIELD, J., ed., *Rethinking the sociology of mental health.* Oxford, Massachusetts: Blackwell, pp. 17-38.

WILLIS, G. B. (1999) *Cognitive interviewing: A "how to" guide.* Research Triangle Park, NC: Research Triangle Institute.

WISDOM, J. P., CAVALERI, M. A., ONWUEGBUZIE, A. J. & GREEN, C. A. (2012) Methodological reporting in qualitative, quantitative, and mixed methods health services research articles. *Health Services Research*. 47(2), pp. 721-745. doi: 10.1111/j.1475-6773.2011.01344.x

WITTCHEN, H. U. (2002) Generalized anxiety disorder: prevalence, burden, and cost to society. *Depress Anxiety*. 16(4), 162-171. doi: 10.1002/da.10065

WITTINK, M. N., BARG, F. K. & GALLO, J. J. (2006) Unwritten rules of talking to doctors about depression: integrating qualitative and quantitative methods. *The Annals of Family Medicine*. 4(4), pp. 302-309. doi: 10.1370/afm.558

WOLFF, N. (2001) Randomised trials of socially complex interventions: promise or peril? *Journal of Health Services Research & Policy.* 6(2), pp. 123-126.

WOOD, A. M., WHITE, I. R. & THOMPSON, S. G. (2004) Are missing outcome data adequately handled? A review of published randomized controlled trials in major medical journals. *Clinical Trials*. 1(4), pp. 368-376. doi: 10.1191/1740774504cn032oa

WORLD HEALTH ORGANIZATION. (1992) *The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines.* Geneva: World Health Organization.

WORLD HEALTH ORGANIZATION. (2017) *The 11th Revision of the International Classification of Diseases (ICD-11) is due by 2018!* [online]. Available from: http://www.who.int/classifications/icd/revision/en/ [Accessed 6th Nov 2017].

WORLD MEDICAL ASSOCIATION. (2001) World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. *Bulletin of the World Health Organization.* 79(4), p. 373-374.

WU, H., YU, D., HE, Y., WANG, J., XIAO, Z. & LI, C. (2015) Morita therapy for anxiety disorders in adults. *Cochrane Database Syst Rev*. 2), doi: 10.1002/14651858.CD008619.pub2

WU, W. (1998) Social disability screening schedule-Chinese version. *Handbook of rating scales in psychiatry.* pp. 163-166.

YAMADA, H. (2016) The emergence of J-Mindfulness - A new strategy of Morita therapy. In: RICHARDS, D. A., ed. *The 9th International Congress of Morita Therapy: Sustainable Psychotherapies for the 21st Century.* Exeter, 1-2 Sept 2016. University of Exeter, p. 13. Available from: http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/research/healthservicesresearch/docs/complexinterventions/Morita_Congress_programme_leaflet_final.pdf [Accessed 17 Jan 2017].

YAN, H. (2005) Confucian Thought: Implications for Psychotherapy. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 129-141.

YARDLEY, L. (2008) Demonstrating validity in qualitative psychology. *Qualitative psychology: A practical guide to research methods.* 2(235-251.

YARDLEY, L., AINSWORTH, B., ARDEN-CLOSE, E. & MULLER, I. (2015a) The person-based approach to enhancing the acceptability and feasibility of interventions. *Pilot and Feasibility Studies*. 1(1), p. 37. doi: 10.1186/s40814-015-0033-z

YARDLEY, L., MORRISON, L., BRADBURY, K. & MULLER, I. (2015b) The person-based approach to intervention development: application to digital health-related behavior change interventions. *Journal of Medical Internet Research*. 17(1), e30. doi: 10.2196/jmir.4055

REFERENCES

YOKOTA, T., KOJIMA, S., YAMAUCHI, H. & HATORI, M. (2005) Evidence-based medicine in Japan. *The Lancet*. 366(9480), p. 122. doi: 10.1016/S0140-6736(05)66869-9

YOO, J., MIYAMOTO, Y., RIGOTTI, A. & RYFF, C. D. (2017) Linking positive affect to blood lipids: A cultural perspective. *Psychological Science*. 28(10), pp. 1468-1477. doi: 10.1177/0956797617713309

YOUNG, D., TSENG, W. S. & ZHOU, L. (2005) Daoist Philosophy: Application in Psychotherapy. In: TSENG, W. S., CHANG, S. C. & NISHIZONO, M., ed., *Asian culture and psychotherapy.* Honolulu, HI: University of Hawaii Press, pp. 142-155.

ZHELEV, Z., GARSIDE, R. & HYDE, C. (2013) A qualitative study into the difficulties experienced by healthcare decision makers when reading a Cochrane diagnostic test accuracy review. *Systematic Reviews.* 2(1), p. 32. doi: 10.1186/2046-4053-2-32

ZHEN-TAO, L., TAO-TSON, Z., JI-UIN, L. & WAN-BIN, T. (1990) Is Morita therapy for patients with shinkeishitsu symptoms or shinkeishitsu personality characteristics? A clinical study in China. *International Bulletin of Morita Therapy.* 3(2), pp. 85-91.