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Morita Therapy for depression (Morita Trial): a pilot randomised controlled trial

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ABSTRACT

Objective To address uncertainties prior to conducting a fully powered randomised controlled trial of Morita Therapy plus treatment as usual (TAU) versus TAU alone, or to determine that such a trial is not appropriate and/or feasible.

Design Pilot parallel group randomised controlled feasibility trial.

Setting and participants Participants aged ≥18 years with Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV major depressive disorder, with or without DSM-IV anxiety disorder(s), recruited from general practice record searches in Devon, UK.

Interventions We randomised participants on a 1:1 basis stratified by symptom severity, concealing allocation using a secure independent web-based system, to receive TAU (control) or 8–12 sessions of Morita Therapy, a Japanese psychological therapy, plus TAU (intervention).

Outcomes Rates of recruitment, retention and treatment adherence; variance and estimated between-group differences in follow-up scores (on the Patient Health Questionnaire 9 (PHQ-9) (depressive symptoms); Generalised Anxiety Disorder Questionnaire 7 (anxiety symptoms); Short Form 36 Health Survey Questionnaire/Work and Social Adjustment Scale (quality of life); Morita Attitudinal Scale for Arugamama (attitudes)) and their correlation with baseline scores.

Results We recruited 68 participants, 5.1% (95% CI 3.4% to 6.6%) of those invited (34 control; 34 intervention); 64/68 (94%; 95% CI 88.3% to 99.7%) provided 4-month follow-up data. Participants had a mean age of 49 years and mean PHQ-9 score of 16.8; 61% were female. Twenty-four of 34 (70.6%) adhered to the minimum treatment dose. The follow-up PHQ-9 (future primary outcome measure) pooled SD was 6.4 (95% CI 5.5 to 7.8); the magnitude of correlation between baseline and follow-up PHQ-9 scores was 0.42 (95% CI 0.19 to 0.61). Of the participants, 66.7% and 30.0% recovered in the intervention and control groups, respectively; 66.7% and 13.3% responded to treatment in the intervention and control groups, respectively.

Conclusions A large-scale trial of Morita Therapy would require 133 participants per group and is feasible with minor modifications to the pilot trial protocol. Morita Therapy shows promise in treating depression and may provide patients with a distinct alternative to current treatments.

Trial registration number ISRCTN17544090; Pre-results.

Strengths and limitations of this study

- This is the first randomised controlled trial of Morita Therapy for depression in English-speaking countries.
- Our pilot trial used mixed methods to address the procedural, methodological and clinical uncertainties associated with a large-scale trial.
- Criteria for success were specified a priori.
- The patients, clinicians and researchers were not blinded to group allocation, although self-report measures were used to reduce detection bias.

INTRODUCTION AND OBJECTIVES

Globally, depression is the leading cause of disability, affecting 350 million people worldwide.[1] In the UK, depression has a lifetime prevalence of 16.2%.[2] For individuals, depression is often chronic and recurrent, and rates of comorbidity and risk for suicide are high.[2–5] Furthermore, the comorbidity between depression and anxiety disorders, such as generalised anxiety disorder (GAD), makes a strong contribution to the total disability attributed to mental disorders.[6–8] Overall, the cost of depression and anxiety in the UK is significant at an annual rate of £17 billion in lost output and direct healthcare costs.[9]

Medication and cognitive behavioural therapy (CBT) have the strongest evidence base for treating depression, each being recommended by the National Institute for Health and Care Excellence (NICE).[10] However, many people are resistant to such interventions.[11] Indeed, current treatments appear to have had little impact on the prevalence of common mental disorders in the UK, and depression remains a chronic disorder despite the available interventions.[6 12] Recovery (defined as Patient Health Questionnaire 9 (PHQ-9)[13] score <10) is reached by fewer than 50% of patients who complete a NICE recommended psychological therapy within the 'Improving Access to Psychological Therapies' service, thereby increasing patients' risk of future relapses and the maintenance of chronic and recurring problems.[14–16] Similarly, studies suggest that between a third and half of depressed patients treated with psychotherapy or antidepressant medication do not respond to treatment (typically defined as a 50% reduction in

symptoms).[17–23] Thus, there is scope to develop and test new potentially effective treatments for depression.

Morita Therapy is a Japanese psychotherapy developed by Dr Shōma Morita in 1919, and informed by Zen Buddhist principles.[24 25] It is a holistic approach aiming to improve everyday functioning rather than targeting specific symptoms.[26] Through conceptualising unpleasant emotions as part of the natural ecology of human experience, Morita Therapy seeks to reorientate 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.[27] By helping patients to accept symptoms 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.[28] In Morita Therapy, patients are taught to live with, rather than be without, their symptoms.

While other psychological therapies (such as Acceptance and Commitment Therapy[29]) also foster patients' acceptance of symptoms, through Morita's four experiential stages of rest and increasing action-taking, acceptance has a uniquely active, spontaneous and paradoxical quality: it cannot be brought about by deliberate cognitive reappraisal or meditative exercises (as per other approaches), but only through everyday behavioural experience.[26 30 31] Indeed, according to Morita's unique method of shifting patients' attention away from self-reflection and immersing them in their environments, any efforts to consciously accept symptoms are considered counterproductive: maintaining focus on and therefore exacerbating symptoms.[26 31] Thus, Morita Therapy is a unique psychotherapy with the potential to provide patients in the UK with a distinct and meaningful alternative to current treatment options.

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, and is considered a potentially pan-diagnostic approach given the absence of symptom focus.[26] The approach is practised in Japan and applied to a limited degree in countries including Australia, China, North America, Russia and Rwanda.[26] Initial evidence for the efficacy of Morita Therapy is largely based on case studies, predominantly conducted in Japan[32] (Minami, M. 2011). A limited number of randomised controlled trials (RCTs) in China and the USA provide mixed evidence for the effectiveness of inpatient Morita Therapy for postschizophrenic depression[33] and inpatient/outpatient Morita Therapy for anxiety.[34–38] However, to our knowledge, outpatient Morita Therapy for depression has not been tested using a randomised controlled design. Furthermore, no RCTs of any form of Morita Therapy for depression have been undertaken in English-speaking countries, and Morita Therapy is untested within the UK. Although a fully powered RCT is clearly required to establish the effectiveness of Morita Therapy, given the novelty of Morita Therapy in the UK a number of clinical, methodological and procedural uncertainties[39] prevented us from immediately undertaking such a trial.

Here, we report the results of a pilot RCT, comprising part of a mixed-methods programme of research undertaken to prepare for the design and conduct of a fully powered RCT of outpatient Morita Therapy plus treatment as usual (TAU) versus TAU alone for the treatment of depression, or to determine that such a trial is not appropriate and/or feasible. Our pilot RCT was designed to address the uncertainties associated with conducting a definitive trial by gathering information on: (1) Likely rates of recruitment, retention and treatment adherence. (2) Variance in participant outcomes and how these correlate with baseline scores, in order to inform future sample size calculations. It follows on from a programme of work conducted with patients and therapists to develop our Morita Therapy clinical protocol.[40] Findings from qualitative and mixed-methods work undertaken alongside the trial, to explore the acceptability of Morita Therapy and how this relates to treatment adherence, are reported elsewhere.

Research questions

1. What proportion of participants approached to take part in a trial of Morita Therapy for depression will agree to do so?
2. What proportion of participants who agree to take part in the trial will remain in the trial at 4-month follow-up?
3. What proportion of participants who agree to take part in Morita Therapy will adhere to a predefined per-protocol dose of Morita Therapy?
4. What is the variance in participant outcomes (depressive symptoms; anxiety symptoms; quality of life; attitudes towards symptoms) 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% CIs) in participant outcomes (depressive symptoms; anxiety symptoms; quality of life; attitudes towards symptoms) following Morita Therapy plus TAU and TAU alone?

METHODS

Trial design

The Morita Trial was a mixed-methods feasibility study encompassing a pilot trial and embedded qualitative interviews. The trial, reported here, used a parallel group randomised controlled design.

Participants

We recruited people aged ≥18 years with Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)[41] Major Depressive Disorder, with or without DSM-IV anxiety disorder(s), assessed using standard clinical interview (Structured Clinical Interview for DSM-IV-TR (text revision) Axis Disorders, Clinical Trials Version[42] (SCID)).

We excluded people who were cognitively impaired, had bipolar disorder or psychosis/psychotic symptoms, were substance-dependent, were currently in receipt of psychological therapy, and those whose risk of suicide was sufficiently acute to demand immediate management by a specialist mental health crisis team.

We recruited participants through record searches at eight general practices in Devon, UK, to identify potential participants from depression read codes. Practice staff contacted potentially eligible patients to seek permission for researcher contact. Advertisements were also placed on the websites of the University of Exeter Medical School and Mood Disorders Centre (MDC) Accessing Evidence-Based Psychological Therapies (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. People who responded to these invitations/advertisements were interviewed by the study team who provided detailed information on the study, assessed eligibility and took informed written consent. The protocol has been published previously[43] (see online supplementary file 1).

Interventions

Morita Therapy plus TAU

Participants allocated to the intervention group were asked not to engage in other formal courses of psychological therapy during the course of their treatment. Otherwise, they were free to access any other usual care and medication in liaison with their GP.

Morita Therapy consisted of 8–12 1 hour face-to-face weekly sessions delivered at the University of Exeter's MDC AccEPT clinic (http://www.exeter.ac.uk/mood-disorders/acceptclinic/) by two professionally accredited research therapists experienced in the delivery of psychological interventions, including experimental treatments. Therapists were trained in Morita Therapy over 6 months. Training included background reading, attending presentations, involvement in the development of the UK Morita Therapy outpatient protocol,[40] and practical training led by the second author (DAR), a clinically qualified academic with 10 years membership of the Japanese Society for Morita Therapy. Practical training was experiential: role plays, diary examples, additional reading and peer support as per a tailored therapist training programme developed by the study team.[40]

Therapists followed the UK Morita Therapy outpatient protocol developed by the study team.[40] 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 fidelity. With the patient's consent, all therapy sessions were audio-recorded for use in supervision.

During therapy, patients progressed through Morita Therapy's four phases 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 aided patients in reappraising 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 wrote comments to increase communication and the opportunity for therapeutic reinforcement.

TAU alone

For the control group, no intervention (nor 'waiting-list' option) was offered by the study team. No specific recommendation or requirement to alter the usual treatment received by depressed patients in the UK was made, and no restrictions were placed on the treatment options available to these participants. General practitioners (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 CBT.

All participants, irrespective of their allocation, were free to choose whether or not to take antidepressant medication. For all participants, we informed their GP of their participation in the study and group allocation.

Outcomes

We collected demographic data including SCID diagnoses at baseline assessment. We collected the following self-reported data at baseline and 4 months post-baseline: severity of depressive symptoms (PHQ-9); severity of generalised anxiety symptoms (GAD Questionnaire 7 (GAD-7)[44]); quality of life (Short Form 36 Health Survey Questionnaire (SF-36)[45] and Work and Social Adjustment Scale (WSAS)[46]). We measured participants' attitudes towards themselves and their symptoms using a questionnaire developed for Morita Therapy specific outcomes (Morita Attitudinal Scale for Arugamama (MASA)[47]).

We collected data 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.

Trial success criteria

We defined criteria which should be met in order to determine if a fully powered trial would be feasible or not.[39 43] These were:

1. Participant recruitment and retention: we can recruit and retain sufficient participants to populate

a fully powered trial, that is, at a recruitment rate of 12% of those invited and an attrition rate no higher than 20% of those randomised, in line with other UK National Institute for Health Research (NIHR) mental health trials.[22 48]

2. Participants will engage with and adhere to Morita Therapy at a rate on a par with other UK NIHR mental health trials,[22] that is, at least 65% of participants allocated to Morita Therapy attend the per-protocol minimum of at least 5 sessions out of a maximum of 12 available sessions.

In terms of decision making against these criteria, should we have fallen below any of these rates in our pilot trial we would consider whether protocol modification or close monitoring during a fully powered RCT would address any failure to meet these criteria, or decide that a fully powered trial would not be feasible.[39]

Sample size

A conventional power calculation is inappropriate for the purpose of a pilot trial.[39] However, informed by our criteria above and guidance on using pilot studies to reliably estimate variance for participant outcomes,[39 49] we aimed to invite 570 potential participants, recruit 72 participants and follow up 60 participants (30 in each arm). These figures were sufficient to estimate (1) Participation rates (as percentage of subjects invited) of 10% with a margin of error of ±2.46%, 12% with a margin of error of ±2.67% or 15% with a margin of error of ±2.93%, based on 95% CIs. (2) 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% CIs. (3) The SD of continuous outcomes to within 22% of their true value based on the upper limit of the 95% CI. (4) 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, ±0.14 if the true correlation is 0.7 or ±0.17 if the true correlation is 0.6.

Randomisation

We randomised participants in a 1:1 ratio to the intervention or control arm using a computer-generated random allocation sequence at the Exeter Clinical Trials Unit (ExeCTU). We stratified randomisation according to participants' symptom severity on PHQ-9 and minimised allocation to balance the stratification variable across the two arms. To ensure allocation concealment, we randomised using an externally administered, password-protected randomisation website independently developed and maintained by ExeCTU. Allocation occurred on completion of eligible participants' baseline assessment. Subsequently, the study researchers informed the participant and their GP, via a standard letter, of the outcome and, for those randomised to the intervention group, passed participant details to the clinic to arrange treatment.

It was not possible to blind participants or clinicians to group allocation due to the nature of the intervention. The study researchers were not blinded to group allocation due to resource limitations. However, baseline and follow-up data were self-reported and all research measures were applied equally to both groups to reduce potential detection bias.

Statistical methods

We undertook all analyses on an intention-to-treat basis and did not impute missing data. We applied pairwise deletion to each measure in order to maximise the data available. Where a questionnaire item was missing (which occurred only at follow-up), pairwise deletion was applied to that follow-up measure for that participant. We reported recruitment, retention, treatment adherence and baseline characteristics using descriptive statistics: means and SDs for continuous variables; numbers and percentages for categorical variables. We reported the SDs of the outcome measures (all continuous) with 95% CI for each trial arm at baseline and 4 months. We estimated the correlations between participants' scores on these measures at baseline and 4 months to inform the sample size calculation for a fully powered trial. Although insufficiently powered to make inferential statements or calculate P values, we reported the observed differences between the intervention and control groups on the mean changes in these measures (with 95% CI), as well as proportions of participants recovering (follow-up PHQ-9 and GAD-7 scores<10[13 44]) and responding to treatment (≥50% reduction in PHQ-9 and GAD-7 scores from baseline to follow-up) in each trial arm.

Patient and public involvement

The Morita Trial follows on from an iterative programme of work conducted to develop our Morita Therapy clinical protocol, whereby we optimised Morita Therapy according to the views of potential patients and therapists.[40] The patient materials were developed on the basis of 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 (eg, PenPIG http://clahrc-peninsula.nihr.ac.uk/). A former trial participant, who expressed an interest in supporting our research and will be involved in the further dissemination of results, has co-written a summary sheet explaining our results in lay terms which has been sent to consenting former trial participants.

RESULTS

Participant flow

Participant flow through the trial is summarised in figure 1.

We randomised 68 participants into the trial between October 2015 and September 2016: 34 (50%) to each trial arm. One hundred and forty-six potential participants gave permission for study researcher contact ('opted in'). We excluded 55/140 (39.3%) of those who could be contacted for telephone screen (24 did not meet inclusion

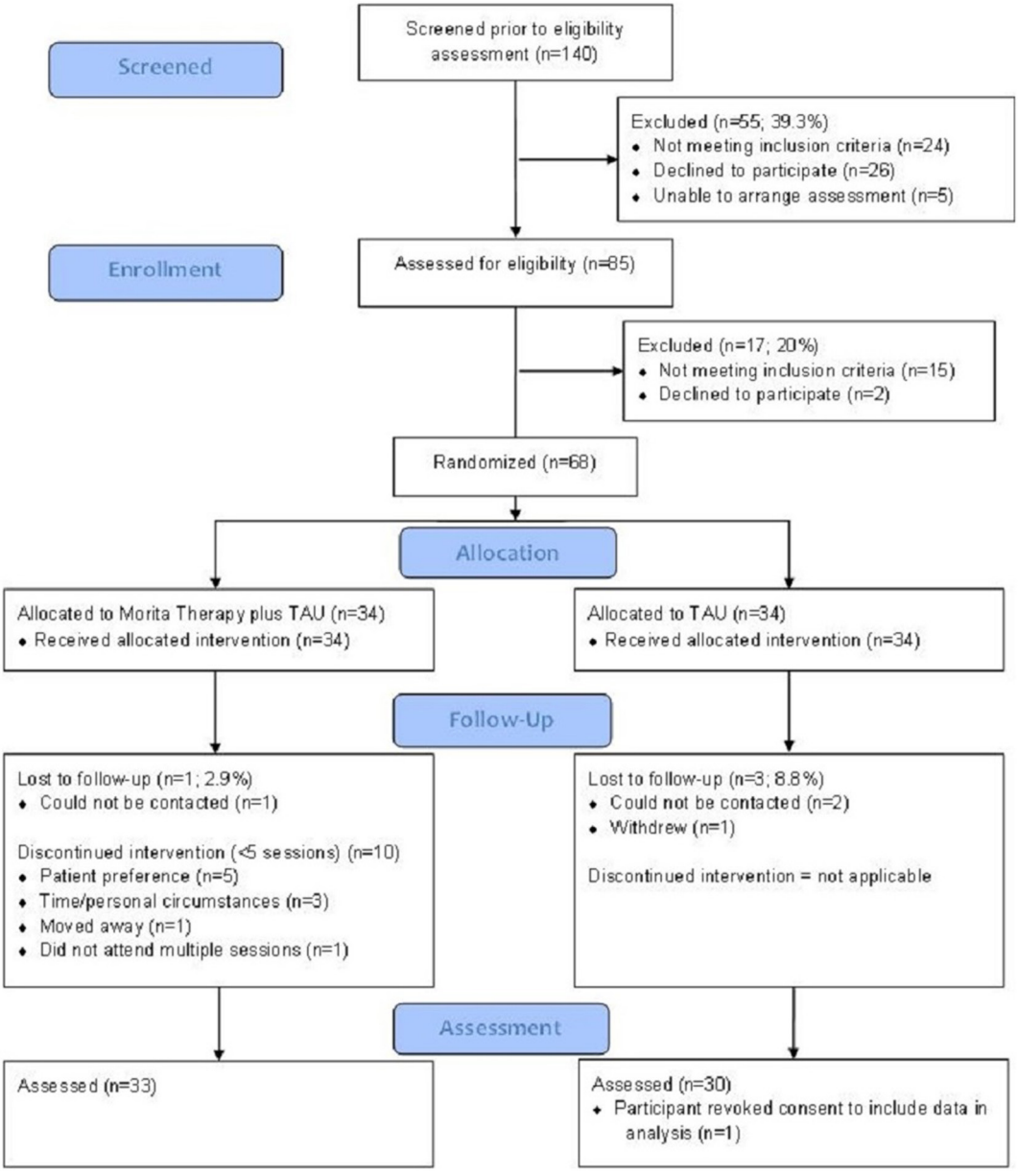

Figure 1 Consolidated Standards of Reporting Trials diagram. TAU, treatment as ususal.

criteria; 26 declined to participate; 5 were unable to arrange a baseline assessment) and 17/85 (20%) of those who attended baseline interview (15 did not meet inclusion criteria; 2 declined to participate). We randomised 68/146 (46.6%) of those who opted into the study. The 690 study invitations sent to potentially eligible patients identified via GP record search resulted in 35 participants randomised into the trial, a rate of 5.1% (95% CI 3.4% to 6.6%), with an additional 33 participants recruited from alternative sources such as advertising.

From January 2016 to January 2017, we collected 4-month follow-up data from 64/68 (94%) participants (95% CI 88.3% to 99.7%): 33/34 (97%) in the intervention arm and 31/34 (91%) in the control arm. In the intervention arm, one participant could not be contacted for follow-up; in the control arm, two participants could not be contacted for follow-up and one withdrew on the basis that they had not received active treatment. An additional control participant, after attending follow-up, revoked consent for his data to be included in the trial. Thus, while this participant is included within the participant flow figures, his data have not been included in the analysis of baseline characteristics or outcomes.

Baseline data

Baseline characteristics are summarised in table 1.

Receipt of Morita Therapy

No participant in the intervention group declined to start Morita Therapy and 24/34 (70.6%) adhered to a per-protocol minimum (at least five 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

Table 1 Participant baseline characteristics

	Intervention (n=34)	Control (n=33*)	Total (n=67)
Gender			
Female	22 (64.7)	19 (57.6)	41 (61.2)
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)
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)
GAD-7 (anxiety) score			
Mean (SD)	13.3 (4.8)	12.2 (4.0)	12.7 (4.4)
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)

Continued

Table 1 Continued

	Intervention (n=34)	Control (n=33*)	Total (n=67)
Eye movement desensitisation 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.
*Thirty-four participants were randomised into the control arm, with 33 participants' characteristics included due to 1 participant revoking consent to include data.
Percentages may not always total 100 due to rounding.
GAD-7, Generalised Anxiety Disorder Questionnaire 7; SCID, Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders IV-TR (text revision) Axis Disorders, Clinical Trials Version; PHQ-9, Patient Health Questionnaire 9.

was 9.8 (range 5–14; SD 2.5) and 2.6 (range 1–4; SD 1.0), respectively.

Outcomes and estimation

The SD of the outcomes at baseline and follow-up by trial arm, with 95% CI, are reported in table 2. At follow-up, the pooled SD around the mean PHQ-9 score (the primary outcome in any definitive trial) was 6.4% (95% CI 5.5% to 7.8%). The correlations between baseline and 4-month scores by trial arm, with 95% CI, are reported in table 3.

Outcomes in the intervention and control arms at baseline and follow-up, with observed between-group differences in changes from baseline to follow-up (with 95% CI), are summarised in table 2. Depressive symptoms reduced from baseline to follow-up by an average of 9 PHQ-9 points in the intervention group and an average of 3.5 PHQ-9 points in the control group.

Proportions of recovery and response on the PHQ-9 (depressive symptoms) and GAD-7 (anxiety symptoms) by trial arm are summarised in table 4. At follow-up, 22/33 participants in the intervention group (66.7%) scored below the threshold for moderate depression (PHQ-9 <10) with 9/30 controls (30.0%) similarly recovering. Depressive symptoms reduced by ≥50% from baseline to follow-up for 22/33 participants in the intervention group (66.7%) and 4/30 controls (13.3%).

Service use

Participants' use of health services (in addition to Morita Therapy) since baseline assessment is presented in table 5. These data were collected in order to characterise TAU in preparation for costing a large-scale trial. Service use was comparable across the two arms with the exception of psychological therapy and counselling, which were proscribed in the Morita Therapy arm (0% in the Morita Therapy arm; 26% (n=8) in TAU). Compared with 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).

DISCUSSION

In this pilot RCT we have demonstrated that it is possible to recruit UK-based people with depression into a trial of Morita Therapy, and to retain them at 4-month follow-up at a rate which is equivalent to or exceeds that found in other trials in the field.[22 48 50 51] Participants' adherence to the minimum dose of Morita Therapy was on a par with other psychological therapies in similar trials.[22] Furthermore, depressive symptoms reduced from baseline to follow-up by an average of 9 PHQ-9 points in the intervention group and 3.5 points in the control group: a between-group difference exceeding the PHQ-9 minimum clinically important difference (MCID).[52] Rates of recovery and response to Morita Therapy (66.7%) were at least as good as those achieved by leading evidence-based psychological therapies.[14 15 17–23]

Strengths and limitations

A key strength of this trial is that it represents the first study of Morita Therapy in the UK and the first RCT of Morita Therapy for depression within English-speaking countries. While the findings are consistent with previous studies which suggest possible benefits of Morita Therapy[32 38 53] (Minami, M. 2011), this study provides a valuable contribution in terms of applying Morita Therapy to a UK population, and by employing a rigorous methodology in preparation for a fully powered trial. The methods used were suitable for a feasibility study: the study purpose and research questions accorded with the NIHR Evaluation Trials and Studies' definition of a feasibility study,[54] endorsed by Arain *et al*;[55] the trial was designed to address key uncertainties associated with a large-scale trial; criteria for success were specified a priori.[39]

Due to resource limitations, the study researchers were not blinded to group allocation. While 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[56 57] and blinding of study researchers would be ensured in any future definitive trial.

Implications and future research

We can now estimate the parameters necessary in order to design a fully powered trial based on the 95% CIs around our current data: we estimate that (1) The randomisation rate (as percentage of patients invited via GP record searches alone) would be between 3.4% and 6.6%. (2)

Table 2 Treatment outcomes at baseline and 4-month follow-up with variability and between-group differences

Outcome measure	Participants	Baseline				Four months				Change from baseline to 4 months			Between-group difference	
		n	Mean	SD	95% CI*	n	Mean	SD	95% CI*	n	Mean	SD	Mean	95% CI†
PHQ-9	All	67	16.8	4.6	3.9 to 5.6	63	10.3	6.4	5.5 to 7.8	63	−6.3	5.8	−5.5	−8.1 to −2.9
	Intervention	34	17.4	4.7	3.8 to 6.2	33	8.4	6.5	5.2 to 8.6	33	−9.0	5.9		
	Control	33	16.1	4.5	3.6 to 6.0	30	12.4	5.7	4.6 to 7.7	30	−3.5	4.2		
GAD-7	All	67	12.7	4.4	3.8 to 5.3	62	7.7	5.0	4.3 to 6.1	62	−5.0	5.2	−3.3	−5.8 to −0.7
	Intervention	34	13.3	4.8	3.9 to 6.4	32	6.8	5.2	4.2 to 7.0	32	−6.6	5.6		
	Control	33	12.2	4.0	3.2 to 5.3	30	8.7	4.7	3.7 to 6.3	30	−3.3	4.3		
WSAS	All	67	22.4	7.6	6.5 to 9.2	62	15.7	10.5	8.9 to 12.7	62	−6.8	8.8	−5.9	−10.1 to −1.7
	Intervention	34	22.7	7.9	6.3 to 10.3	32	13.5	11.0	8.9 to 14.7	32	−9.7	9.7		
	Control	33	22.1	7.4	6.0 to 9.8	30	18.0	9.4	7.5 to 12.7	30	−3.7	6.5		
MASA	All	67	76.8	26.5	22.6 to 31.9	62	103.5	36.3	30.9 to 44.2	62	25.3	30.6	15.5	0.4 to 30.7
	Intervention	34	80.7	29.3	23.6 to 38.5	32	114.4	40.3	32.3 to 53.6	32	32.8	37.2		
	Control	33	72.7	23.0	18.5 to 30.5	30	91.8	27.7	22.1 to 37.3	30	17.2	19.0		
SF-36 PCS	All	67	50.9	11.5	9.8 to 13.9	63	49.4	12.0	10.2 to 14.6	63	−1.9	7.5	0.6	−3.2 to 4.4
	Intervention	34	49.6	12.3	10.0 to 16.2	33	47.9	13.0	10.5 to 17.2	33	−1.7	6.6		
	Control	33	52.2	10.6	8.5 to 14.0	30	51.1	10.8	8.6 to 14.5	30	−2.2	8.5		
SF-36 MCS	All	67	24.4	7.8	6.6 to 9.3	63	35.2	12.4	10.5 to 15.0	63	10.8	11.5	8.1	2.7 to 13.6
	Intervention	34	25.0	8.8	7.1 to 11.6	33	39.8	11.9	9.6 to 15.7	33	14.7	11.3		
	Control	33	23.8	6.6	5.3 to 8.7	30	30.1	11.0	8.8 to 14.8	30	6.6	10.3		

*95% CIs around the SD.
†95% CIs around the mean between-group difference.
GAD-7, Generalised Anxiety Disorder Questionnaire 7; MASA, Morita Attitudinal Scale for Arugamama; MCS, Mental Component Score; PCS, Physical Component Score; PHQ-9, Patient Health Questionnaire 9; SF-36, Short Form 36 Health Survey Questionnaire; WSAS, Work and Social Adjustment Scale.

Table 3 Correlation between participant scores at baseline and 4 months

Association	Participants	n	Spearman's ρ	95% CI around Spearman's ρ
PHQ-9 at baseline and 4 months	All	63	0.42	0.19 to 0.61
	Intervention	33	0.37	0.04 to 0.64
	Control	30	0.71	0.47 to 0.85
GAD-7 at baseline and 4 months	All	62	0.40	0.17 to 0.59
	Intervention	32	0.40	0.07 to 0.66
	Control	30	0.51	0.18 to 0.73
WSAS at baseline and 4 months	All	62	0.52	0.31 to 0.68
	Intervention	32	0.45	0.12 to 0.69
	Control	30	0.76	0.55 to 0.88
MASA at baseline and 4 months	All	62	0.58	0.39 to 0.73
	Intervention	32	0.45	0.12 to 0.69
	Control	30	0.73	0.50 to 0.86
SF-36 PCS at baseline and 4 months	All	63	0.68	0.52 to 0.80
	Intervention	33	0.78	0.59 to 0.88
	Control	30	0.58	0.27 to 0.78
SF-36 MCS at baseline and 4 months	All	63	0.42	0.20 to 0.61
	Intervention	33	0.43	0.10 to 0.67
	Control	30	0.39	0.04 to 0.66

GAD-7, Generalised Anxiety Disorder Questionnaire 7; MASA, Morita Attitudinal Scale for Arugamama; MCS, Mental Component Score; PCS, Physical Component Score; PHQ-9, Patient Health Questionnaire 9; SF-36, Short Form 36 Health Survey Questionnaire; WSAS, Work and Social Adjustment Scale.

The retention rate would be between 88.3% and 99.7%. (3) The pooled SD on the PHQ-9 (the primary outcome measure in a definitive trial) score at follow-up would be between 5.5 and 7.8. Using our pilot trial data alongside the most conservative estimate of the between-group difference based on the published PHQ-9 MCID (2.59),[52] we also estimate that 133 participants per group would be required to provide 90% power based on a two-sided 5% significance level and allowing for 20% attrition. Our previous experience leads us to assert that we could reasonably expect to recruit such numbers into a future trial.

We specified two criteria for success[39] for proceeding to a fully powered trial. Our pilot trial attrition rate of 6% fulfils the specified standard (no higher than 20%), as does the treatment adherence rate of 70.6% (at least 65%). While the recruitment rate from GP record searches alone (5.1%) was lower than anticipated, this is slightly higher than that found in other trials in the field.[50 51] To recruit 266 participants into a fully powered trial, based on our pilot data 51 average-sized general practices would need to participate in record searches. This could be achieved in a similar time frame to the pilot trial by conducting the trial over three sites (as opposed to one site) and with an increased workforce to recruit participants. Recruitment might also be maximised by identifying additional participants through advertising and using research registers (as per our

Table 4 Proportions of recovery and response at 4-month follow-up

Outcome measure	Participants	n	Recovery: n (%) scoring <10 at follow-up	Response: n (%) showing 50% reduction	n (%) either showing 50% reduction or scoring <10 at follow-up
PHQ-9	All	63	31 (49.2)	26 (41.3)	32 (50.8)
	Intervention	33	22 (66.7)	22 (66.7)	23 (69.7)
	Control	30	9 (30.0)	4 (13.3)	9 (30.0)
GAD-7	All	62	40 (64.5)	27 (43.5)	40 (64.5)
	Intervention	32	24 (75.0)	17 (53.1)	24 (75.0)
	Control	30	16 (53.3)	10 (33.3)	16 (53.3)

GAD-7, Generalised Anxiety Disorder Questionnaire 7; PHQ-9, Patient Health Questionnaire 9.

Table 5 Service use at 4-month follow-up

Service	Participants	n	%	Number of 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

A&E, accident and emergency; GP, general practitioner; TAU, treatment as usual.

current study) and by modifying the pilot trial protocol to include measures known to improve recruitment rates, such as telephone reminders to non-responding patients invited via GP record search.[58–60] We therefore anticipate that a sufficient number of participants to populate a fully powered trial can be recruited, although with additional procedures, and conclude that a fully powered trial is feasible with minor modifications to the pilot trial protocol in relation to our recruitment activities.

The level of participant adherence to Morita Therapy suggests that it is as acceptable to participants as other psychological treatments.[22] While it is not the purpose of this paper to assess the effectiveness of Morita Therapy and the study was not powered to enable inferential statements to be made, our findings also suggest promising possible effects of Morita Therapy plus TAU versus TAU alone.[61] The observed between-group difference in reduction in depressive symptoms (PHQ-9) from baseline to follow-up, and indeed the lower margin of error on this figure, exceeds the PHQ-9 MCID. Furthermore, the rates of recovery and treatment response found in this study are comparable to or exceed those found for current NICE-recommended treatments for depression.[14 15 17–23] While these findings suggest that Morita Therapy may be equivalent in effectiveness to other psychological therapies, supporting the potential value of Morita Therapy as a treatment for depression, our qualitative and mixed-methods findings (reported elsewhere) provide early indications of which patients might benefit most from Morita Therapy, which will be incorporated into a process evaluation in a fully powered trial.[62]

In line with this, given that treatment effectiveness varies at an individual if not population level, it is argued that research should focus on matching patient characteristics to treatment type.[63–66] In order to facilitate such work, it makes sense to test treatments which are qualitatively distinct from current options. Given the contrast between Morita Therapy and established Western approaches,[28] Morita Therapy may prove a valuable addition to current treatment options by providing a meaningful alternative which may be particularly suited to patients for whom current treatments are not suitable. As such, Morita Therapy may facilitate both true patient choice (as enshrined in the forthcoming NICE guidelines for depression[67]) and the future 'matching' of patients to treatments, and potentially provide patients for whom current NICE-recommended therapies have failed a qualitatively different approach towards mental health.

CONCLUSIONS

We have determined that it is feasible to conduct a large-scale trial of Morita Therapy with minor modifications to the pilot trial protocol in order to maximise recruitment. Our findings indicate that Morita Therapy shows promise in the treatment of depression, supporting the potential of Morita Therapy to provide patients in the UK with a distinct and meaningful alternative to current treatment options.

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Contributors DAR proposed the study; HVRS as chief investigator and study researcher designed the study with the involvement of DAR and JF; HVRS drafted the study protocol and materials and obtained National Health Service ethical approval and research and development governance assurance; HVRS was responsible for project management, data collection and analysis; HVRS and DAR developed the UK Morita Therapy outpatient protocol; DAR supervised the study therapists. HVRS drafted the manuscript. All other authors contributed to editing of the final manuscript. All authors read and approved the final manuscript.

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