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The Morita Trial

Submission date	Recruitment status	[X] Prospectively registered
13/07/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/07/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
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. The aim of this initial study is to find out whether it is an effective depression and anxiety treatment for people here. We also need to speak with patients and therapists to find out what they think about Morita Therapy.

Who can participate?
Adults currently experiencing depression, whether they are taking anti-depressant medication or not, and whether they have received psychotherapy in the past or not.

What does the study involve?
People will contact us to let us know that they are interested in taking part and we will speak to them over the phone to answer any questions they may have and to see if they are likely to be eligible. If so, we will arrange an assessment appointment with them to confirm if they eligible. If so, we will let the participant's GP know re participation
Participants are randomly allocated to one of two groups: Morita Therapy group or usual care group.
The decision about whether they receive Morita Therapy or usual care is made completely by chance. Half of our participants will receive Morita Therapy and half will receive usual care. Participants who are allocated to Morita Therapy will receive between eight and twelve individual sessions of one hour duration with a trained therapist once a week, spread over eight to twelve weeks. The therapist will see participants face to face and help them to complete a daily diary between sessions. 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 the patient to understand these behaviours and how they can be unhelpful, and helps to shift the patient's focus from overcoming symptoms to undertaking action which allows them to live a fulfilling life. 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 the participant will not receive any treatment through the study itself but there will be no restrictions placed on the care or treatment they may wish to access elsewhere. Once participants have been allocated to Morita Therapy or usual care, they may be invited to a more in-depth interview about why they have chosen to take part. We will also meet every participant again for a follow-up appointment four months after the assessment, to complete a number of questionnaires. For participants who are allocated to Morita Therapy, once they have attended all their treatment sessions we will also invite them to take part in a more in-depth interview about their views of Morita therapy and experiences of taking part in the study.

What are the possible benefits and risks of participating?
We are not aware of any side effects, disadvantages or risks of taking part in this research. If any relevant new information comes to light which may affect a participant's decision to take part in the study we will tell them.

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 difficulties such as depression and anxiety. Therefore, we hope that the participants who receive Morita Therapy will find the treatment helpful. However, we cannot guarantee that they will benefit from the treatment. The information we get from this study may help us to treat future patients with depression and anxiety better, and/or offer them more choices in the treatments available to them.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2014 to October 2017.
It is anticipated that recruitment will start in September 2015 and that we will be recruiting our final participants in June 2016. Participants will be enrolled on the study for a period of 5 to 6 months.

Who is funding the study?
Funded by a University of Exeter Medical School PhD fellowship awarded to the Chief Investigator, Holly Sugg.

Who is the main contact?
Holly Sugg
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
T540019495

Study information

Scientific Title
Morita therapy for depression and anxiety: a feasibility and pilot study

Study objectives
1. What are the estimated between-group differences (and 95% confidence intervals) in patient-related outcomes following Morita Therapy and primary care as usual? (Note: it is recognised that the study is not formally powered to undertake inferential assessment of between (or within) group differences and no p-values will be calculated).
2. How acceptable is Morita Therapy to patients and therapists?
3. How do patients' views about Morita Therapy relate to the variability in the number of treatment sessions they attend?
4. What is the variance in patient-related outcomes following Morita Therapy and primary care as usual, and how do they correlate with patients' baseline scores?
5. What proportion of patients approached to take part will agree to do so?
6. What proportion of patients who agree to take part in Morita Therapy will adhere to a pre-defined per-protocol dose of Morita Therapy?
7. What proportion of patients who agree to take part will remain in the trial at 4 month follow-up?
8. What are participants' reasons for volunteering to be part of a research trial?
9. Why do participants choose to take part in a trial of Morita Therapy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority, NRES Committee South West - Frenchay, 06/07/2015, ref: 15/SW/0103

Study design
We will undertake a mixed-methods single-centre study incorporating exploratory and explanatory sequential components in an embedded multiphase design. Semi-structured qualitative interviews with patients and therapists will be embedded within a pilot randomised controlled trial of Morita Therapy versus primary care as usual for people with depression, with or without anxiety disorders.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
People with current DSM Major Depressive Disorder, with or without DSM Anxiety Disorders

Interventions
1. Morita Therapy: Morita Therapy will be delivered at the University of Exeter's Mood Disorders Centre AccEPT Clinic: www.exeter.ac.uk/moooddisorders/acceptclinic/. Morita Therapy is a novel and sustainable psychotherapy for various mental health issues developed by Dr Shoma Morita in 1919 and widely practiced in Japan. The underlying premise of Morita Therapy is that symptoms of depression and anxiety are part of the natural ecology of the human experience. Morita Therapy helps patients to re-orientate themselves in the natural world and takes a restorative approach to potentiate the individual’s natural capacity for health. Morita Therapists help patients to move away from symptom preoccupation and combat, which interferes in this natural recovery process, towards focusing on constructive action and meaningful living. Morita Therapy will consist of eight to twelve one hour individual face to face sessions following a therapy protocol developed prior to the trial.

Participants in the Morita Therapy arm will be asked not to engage in other psychological therapies during the course of their treatment, although they will be free to access any other care and medication as usual in liaison with their GP.

2. Primary Care as Usual: Participants in the control arm will be able to access the routine care offered to patients with depression and anxiety through their GP surgery or elsewhere. The study will not place restrictions on the treatment options available to these participants.

Intervention Type
Behavioural

Primary outcome measure

Quantitative data will be collected at baseline assessment and follow-up, four months post baseline assessment. Given this is a feasibility study with a range of different aims, we plan to collect a variety of data: severity of depressive symptoms (9 item version of the Patient Health Questionnaire: PHQ-9 (Kroenke et al., 2001)), severity of generalised anxiety symptoms (7 item Generalised Anxiety Disorder questionnaire: GAD-7 (Spitzer et al., 2006)), quality of life (Short Form 36 Health Survey Questionnaire: SF-36 (Ware et al., 2000); Work and Social Adjustment Scale: WSAS (Mundt et al., 2002)), and attitudes (The Morita Attitudinal Scale for Arugamama: MASA (Richards et al., 2011)). For participants in the Morita Therapy arm, the therapists will also inform the study researcher of the number of Morita Therapy sessions completed by patients. Data on participants' use of services will also be collected at four month follow-up in order to characterise primary care as usual and calculate the cost of Morita Therapy for any definitive trial.

During pre-treatment qualitative interviews, we will explore participants' journeys to becoming involved in the Morita trial and their reasons for wanting to be involved in the study in terms of both the type of research being conducted and the type of treatment being tested. During post-treatment qualitative interviews on the acceptability of Morita Therapy, we will explore interviewees' views and experiences of Morita Therapy; potential barriers to/facilitating factors in engaging in Morita Therapy; and the feasibility and appropriateness of the trial procedures and measures.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
22/09/2014

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Current DSM Major Depressive Disorder (people may take part whether they are in receipt of anti-depressant medication or not)

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

72

Total final enrolment
68

Key exclusion criteria
1. Cognitive impairment
2. Alcohol or drug dependence
3. Psychosis/psychotic symptoms and/or mania
4. Demonstration of any risk to self or others that would require management by specialist mental health or other services
5. Current receipt of psychological therapy

Date of first enrolment
01/09/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
University of Exeter Medical School
St Luke's Campus
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Sponsor information

Organisation
University of Exeter

Sponsor details
Innovation Centre Phase 2
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Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
University/education

Funder Name
University of Exeter Medical School

Results and Publications

Publication and dissemination plan
We intend to publish the protocol for this research in an Open Access journal and, for consenting participants, to store anonymised research data and outputs in the University of Exeter's Open Research Exeter repository in order to facilitate open access to, and the impact of, our research.

We will disseminate the results of this study in a full internal report and we aim to publish our results in a peer reviewed scientific journal. The results will primarily be of interest to those who experience mental health difficulties, and those who provide and use services for patients with depression and anxiety. There is much interest in alternative therapeutic and psychotherapeutic approaches to psychopathology so that patients in the UK have a choice of interventions for depression and anxiety, and this study begins the assessment of Morita Therapy as one such potential choice alternative.

The main output from this study will be the information required to design and seek funding to conduct a fully powered definitive randomised controlled trial of Morita Therapy and primary care as usual for depression and anxiety. The pilot study will ensure that the larger trial can be planned effectively and efficiently, and successfully delivered, or will determine that it is not feasible to run such a trial. In addition, the development of a qualitative framework and materials such as the topic guides in this study would set the basis for the implementation of qualitative methods embedded in a definitive randomised controlled trial. On aiming to design a definitive randomised controlled trial, we intend in the long-term to contribute to guidelines for the treatment of depression and anxiety (e.g. NICE and other clinical guidelines).

Our advisory group, comprising members of the University of Exeter Medical School Peninsula Public Involvement Group, will disseminate the results of the study to the public and patients using accessible channels and their own conference and group meetings. The advisory group will also be consulted on the development of a summary sheet explaining the results of the study

and their implications in lay terms, to be sent to former trial participants via post or email, depending on participant preference. We will also publish the results in lay networks accessible to mental health service users and their carers.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/03/2016		Yes	No
Results article	results	10/08/2018		Yes	No
Results article	qualitative study results	29/05/2019	01/05/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		08/01/2020	18/08/2023	Yes	No