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Feasibility randomised controlled trial of 'On the Road to Recovery'

Submission date
26/05/2017

Recruitment status
No longer recruiting

Registration date
27/07/2017

Overall study status
Completed

Last Edited
17/07/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
'On the Road to Recovery' (OTRTR) is a brief low intensity group psychological therapy that aims to improve patients' insight into their mental disorder and develop adaptive coping skills to manage their distress. OTRTR is currently delivered in forensic mental health services in Scotland to forensic patients. However, to date its effectiveness or safety has not been evaluated. The ultimate aim is to evaluate OTRTR in a large study. This small study will assist in the planning of a subsequent larger study. The aim of this study is to determine the feasibility of conducting a large study of OTRTR therapy alongside treatment as usual compared to treatment as usual alone for forensic mental health patients.

Who can participate?
Patients aged between 18 to 65 receiving treatment under the Mental Health (Care and Treatment) (Scotland) Act 2003 at a participating site

What does the study involve?
Participation in this study lasts about 25 weeks. Participants first have an appointment with the researcher where they complete questionnaires and answer questions relating to their mental health, coping strategies, and self-esteem. Then the participants are randomly allocated to one of two groups. One group attends weekly OTRTR sessions either in group or on an individual basis for 12 weeks. The other group continues their usual treatments and activities during this 12-week period with the option to attend OTRTR sessions after the study ends. All participants complete two brief measures on a weekly basis during the 12-week treatment phase. After the 12 weeks, all participants attend a second appointment with the researcher where they complete the same assessments as the first appointment. After 3 months participants are asked to attend a third appointment where they complete the same assessments as previously. Finally, all participants are offered the option of participating in an interview where they are asked for their views and experiences of taking part in the study.

What are the possible benefits and risks of participating?
Participants who attend OTRTR sessions may benefit from improved understanding of their mental health and improved coping strategies which they could use to manage difficult emotions and/or experiences. By participating, all participants assist in determining the best way

to evaluate the OTRTR therapy in the future, which would help to improve psychological treatments for other forensic mental health patients. Risks of participating include that the participants may find discussing their mental health and experiences, or the questions asked at the research appointments, upsetting.

Where is the study run from?
The State Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2017 to September 2018

Who is funding the study?
Forensic Mental Health Services Managed Care Network (UK)

Who is the main contact?
Mrs Lindsey Gilling McIntosh
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol V1.0; 30/03/2017

Study information

Scientific Title
Multi-site feasibility randomised controlled trial of the ‘On the Road to Recovery’ psychological therapy for forensic inpatients

Study objectives
This is a feasibility study with aims relating to the feasibility and acceptability of key trial procedures which would inform the design of a future definitive randomised controlled trial of the On the Road to Recovery therapy. As a feasibility study, this study was not designed to test hypotheses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Lothian Research Ethics Committee 01, 15/05/2017, ref: 17/SS/0064

Study design
Multi-centre parallel-group feasibility randomised outcome blinded evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patients receiving treatment under Mental Health (Care and Treatment) (Scotland) Act 2003 at forensic mental health services in Scotland

Interventions
Participants will be randomly assigned to 12 weeks of either 'On the Road to Recovery' or treatment as usual with a 1:1 allocation ratio and varying block size (4 or 6), using a computer generated randomisation schedule stratified by site and assessed treatment need at baseline.

On the Road to Recovery (OTRTR): A brief, low intensity psychosocial intervention which aims to improve patients' insight into their mental health problems and develop coping strategies to help manage distress. Approximately 12 weeks of 1.5-2 hour sessions, delivered in small groups or on an individual basis.

Treatment as usual (TAU): Participants randomised to TAU will engage in treatment as usual including psychological therapies, with the exception that they do not attend OTRTR sessions. TAU participants will be advised they will be offered the OTRTR therapy at a later stage.

Intervention Type
Other

Primary outcome measure
Primary study outcomes relate to the feasibility and acceptability of key trial procedures
1. Number of eligible participants identified over the study period, indexed by the total number of participants identified across sites who meet eligibility criteria.
2. Rate of recruitment into the trial, measured in two ways: the proportion of eligible participants who consent to participate, and the number of participants enrolled into the study each month during the recruitment period
3. Adherence to randomization procedure: the number of instances where the actual treatment allocation differed from assigned allocation, measured after all participants have been randomised
4. Overall completion rate of OTRTR therapy and average number of sessions attended (in proportion to number of sessions offered). Participants will be considered to have completed OTRTR if they attended at least 80% of the offered sessions. Measured at post treatment timepoint, T2
5. Reasons for study drop-out. Participants will have the option to provide a reason for why they wish to discontinue to the study, collected by the researcher at the time of exit from the study
6. Overall completion rate of primary clinical outcome measures weekly during treatment phase. The proportion of BIS and CSQ forms completed as intended each week during the treatment phase (between T1 and T2)
7. Completion rate of standardized recording forms by OTRTR therapy facilitators based on therapy content delivered, measured by proportion of complete forms at post treatment timepoint, T2
8. Number of participants lost to follow up and reasons, measured at post treatment timepoint T2 and 3-month follow up T3
9. Safety of OTRTR, measured using descriptive statistics for frequency of observed adverse events (AEs) and serious adverse events (SAEs) across treatment conditions. The incident rate of SAEs for study participants is also compared to the rate observed for each participant in the 12 weeks prior to enrolment in the study. This reference data will be requested from the local site clinical effectiveness departments or equivalents following study completion. An AE is considered to have occurred if either of the following takes place: a participant is removed from the study at the request of their responsible medical officer (RMO) due to significant deterioration in the patient's mental state and/or behaviour, and a participant's global CORE-34-OM score (indexes overall psychiatric distress) increases from the previous assessment to an extent that is both clinically significant and reliable (as defined in Evans et al., 2002). An SAE is considered to have occurred if a participant commits an act of violence resulting in injury to another person, commits serious self-harm, attempted suicide, or suicide
10. Average duration (in minutes) of assessments at baseline (T1), post-treatment (T2), and 3-month follow up (T3)
11. Acceptability of the OTRTR programme and trial for participants, assessed in optional post-study interview analysed using thematic analysis

Secondary outcome measures
Secondary outcomes relate to estimating the therapeutic effects on the following outcomes. All clinical outcomes will be measured at baseline (T1), post intervention (T2), and 3-month follow

up (T3). Effect sizes will be calculated by comparing group means at T2 covarying for T1 differences; repeated using T3 means to estimate maintenance of therapeutic effects. Change in institution-recorded incidents of aggression and violence, as well as institutional privileges will be analysed using descriptive statistics only.

Primary clinical outcomes:
1. Insight into mental disorder, measured using the Birchwood Insight Scale (Birchwood et al., 1994)
2. Use of adaptive coping skills, measured using the Coping Styles Questionnaire (Roger et al., 1993)

Secondary clinical outcomes:
3. Self-rated psychological distress, measured using the Clinical Outcomes in Routine Evaluation (Evans et al., 2000)
4. Self esteem, measured using the Rosenberg Self Esteem Scale (Rosenberg, 1965)
5. Recovery progress, measured using the Questionnaire on the Process of Recovery (Neil et al., 2009)
6. Psychiatric symptom severity, measured using the Brief Psychiatric Rating Scale (Overall & Gorham, 1962)
7. Institution-recorded incidents of physical aggression and violence. The number of incidents of violence/aggression during the study treatment phase and 3-month follow up period will be compared across treatment groups. This information will be requested from the local site clinical effectiveness department (or local equivalent) as participants complete the 3-month follow up period
8. Institutional privileges (e.g. grounds access, unsupervised phone calls, patient outings). Changes in institutional privileges (e.g. increased grounds access, unsupervised phone calls, patient outings) will be measured for all participants during the study at T2 and T3. This information will be collected from the local site clinical effectiveness department (or local equivalent) as participants complete T3

Overall study start date
01/07/2017

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Males and females aged between 18 to 65 years
2. Proficient in English
3. Viewed by their Responsible Medical Officer (RMO) as capable of providing informed consent and well enough to participate in the study
4. Receiving treatment under the Mental Health (Care and Treatment) (Scotland) Act 2003 at a participating site

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Diagnosis of learning disability
2. Viewed by their Responsible Medical Officer (RMO) as incapable of providing informed consent or too unwell to participate in the study
3. Completed either module of the 'On the Road to Recovery' program ('Awareness and Recovery' and 'Looking After Yourself') in the previous three years

Date of first enrolment
01/09/2017

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The State Hospital
Lampits Road
Carstairs, Lanarkshire
United Kingdom
ML11 8RP

Sponsor information

Organisation
The State Hospitals Board for Scotland

Sponsor details
Lampits Road
Carstairs

Scotland
United Kingdom
ML11 8RP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04za2st18

Funder(s)

Funder type
Government

Funder Name
Forensic Mental Health Services Managed Care Network

Results and Publications

Publication and dissemination plan
Trial results will be communicated in conference presentations, peer-reviewed journal publications and a PhD dissertation. Consistent with the University of Edinburgh Open Access policy, findings will either be published in Open Access journals or a copy of the publication will be deposited in an Open Access Repository. Results will be disseminated in manner that maintains the confidentiality of individual participants. A summary of the results will be provided to any participants who are interested to know the outcome of the study.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Lindsey Gilling McIntosh (l.m.gilling-mcintosh@sms.ed.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/07/2018		Yes	No
HRA research summary			28/06/2023	No	No