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A pilot study to investigate the feasibility and acceptability of a cognitive behavioural suicide prevention therapy for people in acute psychiatric wards.

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
22/04/2015

Overall study status
Completed

Last Edited
17/05/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Suicide is a major cause of preventable death with patients in acute psychiatric wards being oat particularly high risk. Many patients experience repeated episodes of suicidal behaviour causing great mental distress and heavy use of NHS services. However there is little research investigating treatments that work in helping patients address issues that lead to suicide. This study investigates issues concerning the introduction of cognitive behavioural therapy (CBT) for suicide prevention for patients in acute psychiatric wards who are a very high risk group in a setting where use of psychological therapies is uncommon and requires evaluation.

Who can participate?
Adult (aged between18-65) inpatients on an acute psychiatric ward.

What does the study involve?
Researchers first observe ward life and investigate “usual patient journeys” to identify best ways of introducing the new therapy. Participants are then randomly allocated into one of two groups. Those in group 1 receive their usual treatment. Those in group 2 receive their usual treatment and cognitive behavioural suicide prevention therapy (CBSP). Ward staff and patients are asked about their views before and after introduction of the new therapy. Participants also complete questionnaires to identify how they feel (mood, suicidal ideas, functioning and general wellbeing). These assessments are made before treatment begins, after 6 weeks and then after 6 months. Staff and patients are interviewed to give their views of the new therapy, how it fits into ward routines, whether they like the therapy and if they feel any benefits or otherwise. We also identify costs of NHS treatment for both groups and make comparisons.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Manchester Mental Health & Social Care Trust (UK)

When is the study starting and how long is it expected to run for?
May 2014 to December 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Sarah Jones.

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Jones

Contact details
Manchester Mental Health & Social Care Trust
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Additional identifiers

Protocol serial number
15409

Study information

Scientific Title
A pilot study to investigate the feasibility and acceptability of a cognitive behavioural suicide prevention therapy for people in acute psychiatric wards: a randomised controlled trial

Acronym
INSITE Phase 2

Study objectives
This feasibility study investigates issues concerning the introduction of cognitive behavioural therapy (CBT) for suicide prevention for patients in acute psychiatric wards who are a very high risk group in a setting where use of psychological therapies is uncommon and requires evaluation.

Ethics approval required

Old ethics approval format

Ethics approval(s)
First MREC approval date 21/08/2013, ref: 13/NW/0504MHRNB;

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Suicide and self-harm; Disease: Suicide and self harm

Interventions
Pilot study to investigate the feasibility of cognitive behavioural suicide prevention therapy (CBSP). Participants will be randomly allocated to two treatment arms - treatment as usual or treatment as usual plus CBSP Intervention.
Follow Up Length: 5 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome(s)
The Suicidal Behaviours Questionnaire – revised (SBQ-R); Timepoint(s): Baseline, 6 week follow up, 6 month follow up

Key secondary outcome(s)
1. Basic Emotions Scale (BES; Power, 2006); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
2. Beck Scale for Suicidal Ideation (BSS; Beck & Steer, 1991); Timepoint(s): Baseline, 6 week follow up and 6 month follow up
3. Calgary Depression Scale (Addington et al, 1990); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
4. Coping in Stressful Situations (Endler & Parker, 1990); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
5. EG-5D (Euroqol Group, 1990); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
6. Personal and Social Performance Scale (Morosoni et al 2000); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
7. Positive and Negative Syndrome Scale (PANSS; Kay, Opler & Fiszbein, 1987); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
8. Psychotic Symptoms Rating Scale (Haddock et al, 1999); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
9. Sleep Condition Indicator (SCI; Espie et al, 2013); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
10. The Beck Hopelessness Scale (BHS; Beck, 1988); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
11. The Defeat Scale (Gilbert & Allan, 1998); Timepoint(s): Baseline, 6 week follow up, 6 month

follow up
12. The Difficulties in Emotional Regulation Scale (Gratz & Roemer, 2004); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
13. The Entrapment Scale (Gilbert & Allan, 1998); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
14. The Forms of Self Criticising/Attacking & Self Reassuring Scale; Timepoint(s): Baseline, 6 week follow up, 6 month follow up
15. The Implicit Beliefs About Emotions Scale (IBES; Tamir et al 2004); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
16. The Self Concept Questionnaire (Robson, 1989); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
17. The Suicide Probability Scale (SPS; Cull & Gill 1988); Timepoint(s): Baseline, 6 week follow up, 6 month follow up
18. The World Health Organisation Quality of Life Assessment , brief version (WHOQOL-BREF; Skevington, L; Timepoint(s): Baseline, 6 week follow up, 6 month follow up
19. Views on Inpatient Care (VOICE; Evans et al, 2012); Timepoint(s): Baseline, 6 week/6 month follow up (dependent on hospital admission dates
20. Views on Therapeutic Environments (VOTE; Laker et al, 2012); Timepoint(s): Baseline, 6 week /6 month follow up (depending on hospital admission dates)
21. Working Alliance Inventory (Horvath, 1992); Timepoint(s): Taken at 2 time points during course of therapy

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Inpatients on an acute psychiatric ward
2. Adults aged 18-65 years
3. Mental capacity to provide informed consent
4. Positive risk of suicide verified SBQ-R

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
51

Key exclusion criteria
Planned discharge within next 7 days.

Date of first enrolment
01/05/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Mental Health & Social Care Trust
Rawnsley Building
Manchester Royal Infirmary
Oxford Road
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Sponsor information

Organisation
Manchester Mental Health & Social Care Trust (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2019	17/05/2023	Yes	No
Protocol article	protocol	11/02/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative results	16/10/2018		Yes	No