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CARMS v1: Cognitive approaches to combatting suicidality

Submission date	Recruitment status	[_] Prospectively registered
05/06/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Around 6% of people with psychosis die by suicide. Many more think about suicide. Talking therapies, for people with psychosis, focus mainly on treating symptoms and this does not stop people from having suicidal thoughts or making suicide attempts. A new psychological therapy called CARMS, Cognitive AppRoaches to coMbatting Suicidality, which specifically targets suicidal thoughts and behaviours has been developed. Many people with psychosis feel isolated, unable to cope emotionally, nor able to deal with their problems. Feelings of being hopeless, being trapped and/or feeling defeated often can occur, and all of these feelings can be precursors to suicide. CARMS aims to help people find ways of dealing with these sorts of negative perceptions and feelings. The aim of this study is to assess whether CARMS is effective in reducing suicidal thoughts and behaviours in people experiencing psychosis and how well it works in practice in the NHS.

Who can participate?
Adults aged 18 and older who are diagnosed with psychosis, have felt suicidal in the past three months and who are under the care of a mental health services clinical team (i.e., community or inpatient mental health care teams) with a care coordinator.
(updated 12/07/2019, previously: Adults aged 18 and older who are diagnosed with psychosis and have felt suicidal in the past three months.)

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive their usual treatment. Those in the second group receive 24 weekly sessions of CARMs therapy as well as their usual treatment. This involves 50 minutes of treatments over six months that are recovery focused, structured and socio-cognitive based. The aim of this therapy is to modify negative thoughts and improve the feeling of defeat and hopelessness. Participants are assessed for their suicidal thoughts and behaviours, appraisals of social isolation, emotion regulation, problem solving, perceptions of being defeated, trapped and hopeless prior to treatment and six and 12 months after treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their psychosis and suicidal symptoms. There are no notable risks, however talking about feelings may upset participants.

Where is the study run from?
This study is being run by the University of Manchester (UK) and takes place in four NHS Trusts in the UK.

When is the study starting and how long is it expected to run for?
January 2017 to September 2022

Who is funding the study?
The Efficacy and Mechanism Evaluation (EME) programme, an MRC and NIHR partnership
(updated 12/07/2019, previously: National Institute for Health Research (UK))

Who is the main contact?
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(updated 18/11/2020, previously: Miss Charlotte Huggett, charlotte.huggett@manchester.ac.uk)

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03114917

Integrated Research Application System (IRAS)
201644

Central Portfolio Management System (CPMS)
33661

Study information

Scientific Title
A psychological intervention for suicide applied to patients with psychosis: the CARMS trial (Cognitive AppRoaches to coMbatting Suicidality)

Acronym
CARMS v1

Study objectives
The aim of this study is to assess whether CARMS is effective in reducing suicidal thoughts and behaviours in people experiencing psychosis and how well it works in practice in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – GM South, 02/05/2017, ref: 17/NW/0089

Study design
Randomised; Both; Design type: Treatment, Screening, Prevention, Psychological & Behavioural, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychosis

Interventions

Participants are randomly allocated to one of two arms: treatment as usual and treatment as usual plus CARMS (Cognitive AppRoaches to coMbatting Suicidality) Therapy.

Treatment as usual arm (TAU): Participants allocated to TAU receive their usual care and treatment from mental health services.

CARMs therapy plus TAU arm: Participants allocated to the CARMS therapy + TAU arm receive their usual care and treatment from mental health services along with CARMS therapy. The CARMS therapy comprises of 24 sessions, each up to 50 minutes long over a six month period. The investigators' psychological therapy is a recovery-focused, structured, time-limited, socio-cognitive intervention. It is based upon the investigators' recently developed treatment manual and pilot RCTs in the community and in prison. The intervention modifies negative appraisals of emotional regulation, social support, and interpersonal problem-solving. As a consequence, perceptions of defeat, entrapment, and hopelessness will be improved indirectly. In addition, perceptions of defeat, entrapment, and hopelessness will be worked on directly during the therapy.

Participants are assessed for their suicidal thoughts and behaviours, appraisals of social isolation, emotion regulation, problem solving, perceptions of being defeated, trapped and hopeless at baseline and six and 12 months after treatment.

Intervention Type
Behavioural

Primary outcome(s)
Frequency of suicidal ideation is measured using the Adult Suicide Ideation Questionnaire score at baseline, six and 12 months.

Key secondary outcome(s))
1. Suicide risk is measured using the Suicide Probability Scale score at baseline, six and 12 months
2. Thoughts, attitudes and intentions regarding suicide is measured using the Beck Scale for Suicidal ideation score at baseline, six and 12 months
3. Frequency of suicidal thoughts, plans and acts are measured using a clinical interview at baseline, six and 12 months
4. Frequency of suicide attempts are measured using medical records at baseline, six and 12 months
5. Emotional dysregulation are measured using the Emotional Regulation Scale score at baseline, six and 12 months
6. Individual social problem-solving skills are measured using the Social Problem-Solving Inventory score at baseline, six and 12 months
7. Individual's appraisals of social support are measured using the Social Support Appraisals Scale score at baseline, six and 12 months
8. Hopelessness (feelings about the future, loss of motivation, and expectations) is measured using the Beck Hopelessness Scale score at baseline, six and 12 months
9. Feelings of defeat and feeling trapped are measured using the Defeat and Entrapment scale scores at baseline, six and 12 months
10. Symptom severity of individual's experiencing Schizophrenia is measured using the Positive and Negative Syndrome Scale score at baselines, six and 12 months
11. Psychosis symptoms are measured using the Psychotic Symptoms Ratings Scale (PSYRATS) score at baseline, six and 12 months
12. Personal and social functioning in individual's experiencing Schizophrenia is measured using

the Personal and Social Performance Scale score at baseline, six and 12 months
13. Symptoms of depression in individual's experiencing Schizophrenia are measured using the Calgary Depression Scale score at baseline, six and 12 months
14. Frequency and type of substance misuse over 3 months are measured using clinical interviews at baseline, six and 12 months 15. Drug 'abuse' is measured using the drug use (self-reported) DAST score at baseline, six and 12 months
16. Alcohol use is measured using the alcohol use (self-reported) AUDIT score at baseline, six and 12 months
17. Individual's reasons for using alcohol and drugs respectively are measured using the Reasons for substance Use Scale - Alcohol and Drugs scores at baseline, six and 12 months
18. Insomnia is measured using the Sleep Condition Indicator (SCI) score at baseline, six and 12 months
19. Current medication for mental health problems (information regarding which anti-psychotic medication, if the medication is atypical, and the dosage will be collected from medical records) as prescribed at baseline
20. Client-therapist therapeutic alliance from the participant's and the therapist's perspective is measured using the Working Alliance Inventory - short form score at baseline, six and 12 months
21. Health outcomes are measured using the EQ-5D score at baseline and 12 months
22. Use of services are measured using the Client Service Use Receipt Inventory at baseline and 12 months

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/05/2020:

1. ICD-10 diagnosis of psychosis
2. Suicidality in the past three months
3. In contact with mental health services and under the care of a mental health services clinical team (e.g., community or inpatient mental health care teams) with a care coordinator
4. Aged 18 or over
5. English-speaking (hence, not needing an interpreter)
6. Able to give informed consent as assessed by either a responsible clinician or by trial RAs following the British Psychological Society's guidelines on gaining informed consent

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Previous inclusion criteria:

1. ICD-10 diagnosis of psychosis
2. Suicidality in the past three months
3. In contact with mental health services and under the care of a mental health services clinical team (e.g., community mental health care teams) with a care coordinator
4. Aged 18 or over
5. English-speaking (hence, not needing an interpreter)
6. Able to give informed consent as assessed by either a responsible clinician or by trial RAs following the British Psychological Society's guidelines on gaining informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current inclusion criteria as of 05/05/2020:

1. Dementia, or an organic brain disorder
2. Unable to complete assessments due to language barriers
3. Currently taking part in a clinical trial

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Previous exclusion criteria:

1. Dementia, or an organic brain disorder
2. Unable to complete assessments due to language barriers

Date of first enrolment
19/05/2017

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Oxford Road
Manchester
United Kingdom
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Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation programme, a Medical Research Council and National Institute for Health Research partnership

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2025	27/01/2025	Yes	No
Protocol article	protocol	16/06/2020	18/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study results	24/11/2023	27/11/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes