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Effects of a cognitive skills program for offenders with serious mental illness

Submission date
16/12/2013

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The current study aims to examine a population of Mentally Disordered Offenders (MDOs) at a closed custody facility that offers many treatment opportunities to offenders having a variety of mental health issues. The objective of the study is to find out the effectiveness of Reasoning and Rehabilitation 2 (R&R2), a program that targets antisocial attitudes, on violence and future criminal involvement. The study will also find out the effect of participation in the program on self-report and doctor-rated scales that measure antisocial attitudes.

Who can participate?
Any male resident age 18 or over in the Secure Treatment Unit at Brockville Mental Health Centre and who has a diagnosis of a serious mental illness can take part in this study.

What does the study involve?
The effectiveness of the R&R2 program will be tested by comparing residents who complete the program with residents who do not participate in any programming and with residents who participate in Treatment as Usual (TAU). Programs offered through the TAU stream are focused on addressing mental health concerns and specific treatment targets such as sexual offending, domestic violence, anger, trauma, and substance abuse. Participants with stays less than 1.5 months will not participate in any programming due to time constraints. The remainder of eligible participants will be randomly allocated to receive either the R&R2 group, or groups offered through TAU. Residents who are not allocated to the R&R2 group will not be permitted to attend the group for the duration of the study.

What are the possible benefits and risks of participating?
There are no direct benefits to participants for participating in the study. However, the study will produce data that tell us how effective the R&R2 program is, potentially benefitting many future residents. The study does not present a risk to participants. The same quality of care is offered whether or not a resident chooses to participate in the study. Participants are free to withdraw from the study at any time without penalty.

Where is the study run from?
Brockville Mental Health Centre, Canada.

When is the study starting and how long is it expected to run for?
Participant recruitment is expected to start after January 2014 and will continue for approximately 2 years.

Who is funding the study?
Royal Ottawa Health Care Group (Canada).

Who is the main contact?
Dr Drew Kingston
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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
N/A

Study information

Scientific Title
Effects of a cognitive skills program versus no treatment for offenders with serious mental illness: a randomized controlled trial

Study objectives
1. Mentally Disordered Offenders (MDOs) randomized to receive Reasoning and Rehabilitation 2 (R&R2), compared to the other treatment groups, will show greater improvements on intermediate outcomes that measure relevant constructs, such as antisocial attitudes.
2. MDOs randomized to receive R&R2, compared to the other treatment groups, will show a

reduction in the number of incidents of violence and antisocial behavior occurring during treatment (i.e., institutional violence) and during the 12-month follow-up period.
3. Treatment engagement will be significantly associated with the degree of change noted on self-report and clinician-rated measures.
4. Individuals who were more engaged in treatment will show lower levels of violence and antisociality in the institution and in the community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Royal Ottawa Health Care Group Research Ethics Board (reference number 2013028)
2. Ministry of Community Safety and Correctional Services

Study design
Randomized Control Trial (Single Site)

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Forensic mental health patients: verbal aggression and violence

Interventions
1. Reasoning and Rehabilitation 2: Short Version for Adults (R&R2; Ross, Hilborn, & Liddle, 2007) -14 session skill-based program targeting antisocial attitudes
2. Treatment as Usual (TAU) - includes various programs that target anger, trauma, sexual offending, and substance abuse
3. Control Group - no treatment

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Official recidivism data (charges and convictions): These are officially recorded and made available by our partner, the Ministry of Community Safety and Correctional Services. Recidivism data will be first collected at the 1-year follow-up period.

Secondary outcome measures
1. Institutional Misconducts (Verbal aggression and violence): A research assistant who is blind to group assignment will be reviewing the 'OTIS Client Profile' of each participant in the study. The OTIS Client Profile provides information on each occurrence of an institutional misconduct for the present booking period, as well as historical misconducts including the date of the occurrence, what the incident was (e.g. assault, threat), and the penalty given for the misconduct. The research assistant will take note of all of the information provided on any institutional misconducts. The research assistant will also gather information on institutional misconducts from the electronic information management system (eIMS) to corroborate information from the OTIS Profiles and to note any relevant additional information.
2. Pre-Post measures of antisocial attitudes: Pre-post measures include self-report questionnaires tapping into antisocial attitudes and clinician rated measures of risk to re-offend. These measures will be administered at baseline (pre-treatment) and after the final session (post-treatment). Other measures (e.g., group engagement) will be administered at post-treatment only.

Overall study start date
01/01/2014

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Has a primary clinical diagnosis of a serious mental illness (SMI)
2. Has a history of violence
3. Is proficient in the English language

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
108

Key exclusion criteria
1. Has previously participated in the R&R2 program, or similar
2. Is actively psychotic
3. Has a significant cognitive impairment

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
Canada

Study participating centre
1804 Highway 2 East
Brockville
Canada
K6V 5W7

Sponsor information

Organisation
Royal Ottawa Health Care Group (Canada)

Sponsor details
Secure Treatment Unit
1804 Highway 2 East
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Sponsor type
Hospital/treatment centre

Website
http://www.theroyal.ca/

ROR
https://ror.org/056vnsb08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Ottawa Health Care Group (Canada) (Brockville Mental Health Centre, Secure Treatment Unit)

Results and Publications

Publication and dissemination plan
The study was submitted for publication to Criminal Behavior and Mental Health on 11/12/2017.

Intention to publish date
11/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/01/2018	15/02/2018	No	No