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Population-based Outreach Services to Reduce Homelessness among Veterans with serious mental illness (SMI)

Submission date
11/04/2013

Recruitment status
No longer recruiting

Registration date
30/04/2013

Overall study status
Completed

Last Edited
11/07/2018

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
Homelessness disproportionately affects Veterans with serious mental illness (SMI, e.g., schizophrenia, bipolar disorder). Many Veterans with SMI are at risk of homelessness because of substance use, unstable employment, and incarceration, and are disproportionately represented among Veterans who are chronically homeless. Moreover, Veterans with SMI who drop out of Veterans Affairs (VA) care are more likely to die than those engaged in VA care. A recent VA quality improvement project involving outreach to this population found that Veterans with SMI who reengaged in VA care had a 12-fold decreased risk of mortality compared to Veterans who were not brought back into care. The VA National Center on Homelessness among Veterans has sought to adapt this approach to reengage Veterans who are homeless or are risk of homelessness, starting with the most vulnerable groups (e.g., SMI). In addition, the VA Office of Mental Health Services recommended that the program be implemented in concert with ongoing recovery-oriented initiatives in the VA. This study seeks to test the effectiveness of two different program implementation frameworks to enhance the adoption of a national outreach program for Veterans. Specifically, the study will compare the effectiveness of using Enhanced REP compared to standard REP to enhance the uptake the national Re-Engage directive to implement brief care management program for patients with serious mental illness who have dropped out of care.

Who can participate?
The study includes all VA facilities in the United States and Puerto Rico with Veterans who were directed to implement Re-Engage, with the adaptive implementation intervention phases focusing on facilities that that did not initially implement Re-Engage in response to standard REP alone.

What does the study involve?
This is a four phase study.
Phase 1 Initial Run-in (01/01/2012 - 08/31/13): All VA facilities received standard REP implementation support through national trainings, standardized implementation materials, and technical support. VA administrative databases identified 2738 Veterans with SMI lost to follow-

up and lists were disseminated to 158 sites for local recovery coordinators to attempt to reach and re-engage these Veterans in VA healthcare services. All outreach activities were documented on a VA intranet web site to monitor program process and provide feedback reports to regional leaders on a periodic basis.
Phase II (09/01/12 - 03/01/2013): Start of the adaptive treatment design where facilities who did not adequately implement Re-Engage (defined as documented less 80% of the disposition of Veterans lost-to follow-up for a facility) were randomly allocated by geographic region and VA regional network affiliation to receive either Enhanced REP (Facilitation consultations) or continued receipt of standard REP with passive technical assistance and usual feedback reports.
Phase III (03/01/2013 - 08/31/2013): Facilities that were initially randomized to Enhanced REP will return to receiving standard REP support, and facilities initially randomized to receive standard REP and that had not successfully implemented Re-Engage as of the end of Phase II will received Enhanced REP for the next 6 months.
Phase IV - Follow-up (8/31/2013 - 8/31/2014): Outcome monitoring at 18 and 24 months.

What are the possible benefits and risks of participating?
Knowledge gained from this study has the potential to help improve the dissemination and delivery through evaluation of the effectiveness of Faciliation as an program implementation strategy. Moreover, this program will potentially benefit the delivery of VA clinical care services for vulnerable groups of Veterans who could benefit from the application of population-based panel management and brief care management services as found in Re-Engage. There are no known risks to participating sites or Veterans.

Where is the study run from?
The study is run from the Center for Clinical Management Research at the Ann Arbor VA with the support of VA Mental Health Services and the VA Serious Mental Illness Treatment Resource & Evaluation Center.

When is the study starting and how long is it expected to run for?
January 2012 to August 2013.

Who is funding the study?
VA Health Services Research and Development (HSR&D), USA

Who is the main contact?
Principle Investigator: Dr. Amy M. Kilbourne, PhD, MPH (amykilbo@umich.edu)
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Study website
http://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141701267

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VA Health Services Research & Development SDR 11-232

Study information

Scientific Title
Population-based Outreach Services to Reduce Homelessness among Veterans with SMI: a four-phase, clustered randomized trial

Study objectives
The primary implementation outcome is program uptake of the VA Re-Engage clinical outreach program, defined as the percentage of Veterans' with SMI lost to care with an updated documentation of their clinical status, which is a central component of Re-Engage population management. The primary hypothesis is that among facilities not initially responding to use of the Centers for Disease Control and Prevention's Replicating Effective Program (REP) to guide Re-Engage implementation activities, the addition of Facilitation (Enhanced REP) will be associated with increased percentages of documented updates to Veterans' clinical status at 6, 12, 18, and 24 months after program implementation at sites receiving Facilitation versus those continuing to receive standard REP technical assistance. Secondary outcomes include facilities' percentage of Veterans who were provided brief care management, defined as 1) percentage contacted or 2) percentage returning to VA care. Additionally, we seek to explore whether among facilities that initially did not respond to standard REP, the immediate addition of Facilitation (Enhanced REP) is associated with better outcomes than receiving Facilitation after a six month delay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ann Arbor VA Institutional Review Board, 01/02/2012

Study design

Four-phase clustered randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not applicable. The focus of this study is on site-level implementation factors. Patients are identified as part of VA routine care for outreach contacts.

Health condition(s) or problem(s) studied
Serious mental illnesses including schizophrenia, bipolar disorder, and schizoaffective disorder.

Interventions
Standard REP included the initial Implementation phase of Re-Engage, specifically:
1. Training providers in how to conduct the program
2. Technical assistance provided by research staff through regularly scheduled national phone calls and in response to specific requests from providers via email or phone to answer questions, provide information, troubleshoot various aspects of the treatment and its implementation
3. Evaluation of program outcomes provided on an ongoing basis to regional leadership and partners
4. Ongoing partnership support between policy makers and researchers, and
5. Feedback and refinement of processes as needed.

Enhanced REP included the addition of External Facilitation (EF), which has been defined as a process of interactive problem-solving and support that occurs in the context of a recognized need for improvement and a supportive interpersonal relationship.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The percentage of Veterans on each VA facility's outreach list whose clinical status has been updated in the Re-Engage web-based clinical registry assessed at the end the 6 month run-in period prior to randomization (08/31/2012) and 12, 18, and 24 months.

Secondary outcome measures
Assessed at 6, 12, 18, and 24 months:
1. The percentage of Veterans that the LRCs successfully contacted among those who were on their lists and still alive and able to be contacted directly

2. The percentage of Veterans who were contacted who re-engaged in VA healthcare services
3. All cause mortality for Veterans based on level of outreach (not contacted, contacted, contacted and re-engaged)
4. Health care utilization including number and length of inpatient hospitalizations, outpatient visits, and emergency department visits as well as use of recovery-oriented VA mental health, housing, and employment services. External Facilitation was delivered via telephone contacts for six months. Individual semi-structured calls with stakeholders lasted about 30 minutes and occurred approximately one to three times per month for each facility to accomplish the following steps: 1) gather information; 2) offer ongoing partnership support; 3) garner regional and local leadership support; 4) identify barriers and facilitators at each site; 5) collaboratively develop action plans; 6) link to resources; and 7) provide feedback on implementation progress.

Overall study start date
01/09/2011

Completion date
31/08/2015

Eligibility

Key inclusion criteria
A VA facility was eligible for the current trial if it was included in the national VA Re-Engage program. VA facilities were included in the national Re-Engage program if they were:
1. Within the 50 United States or Puerto Rico
2. Were required, per VA policy to have a mental health provider who filled the role of a Local Recovery Coordinator
3. Had at least one Veteran with serious mental illness who was lost to care (i.e., had been seen at the facility in Fiscal Year 2008 or Fiscal Year 2009, but had no subsequent outpatient visits or an inpatient stay of less than 2 days as of January 2012). There were a total of 158 facilities eligible for Re-Engage, of which 139 were medical centers (i.e., with hospital beds) and 19 were community-based outpatient clinics.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2,738 Veterans were initially identified for Re-Engage services and will be the basis for outcome measurement in this study.

Key exclusion criteria
Sites were not eligible for Re-Engage if they were not required to have a Local Recovery Coordinator or acting point of contact for mental health recovery services.

Date of first enrolment

01/09/2011

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
United States of America

Study participating centre
VA Center for Clinical Management Research
Ann Arbor
United States of America
48109

Sponsor information

Organisation
VA Health Services Research & Development (USA)

Sponsor details
810 Vermont Avenue, NW
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Sponsor type
Government

Website
http://www.hsrd.research.va.gov/about/default.cfm

ROR
https://ror.org/011qyt180

Funder(s)

Funder type
Government

Funder Name

Department of Veterans Affairs, Veterans Health Administration, Health Service Research and Development Service (SDR 11-232) (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	20/11/2013		Yes	No
Results article	results	28/12/2014		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	09/07/2018		Yes	No