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Early signs monitoring to prevent relapse and promote wellbeing, engagement and recovery

Submission date
04/12/2015

Recruitment status
No longer recruiting

Registration date
21/12/2015

Overall study status
Completed

Last Edited
08/06/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Schizophrenia is a serious mental health problem that affects how a person thinks, feels and behaves. Schizophrenia is usually treated with a combination of therapy and medication, which is able to control the symptoms, allowing the sufferer to function in their day-to-day life (remission). Relapse (reemergence of symptoms) in schizophrenia is a major cause of distress and disability amongst patients and their families. It can often be predicted by early warning signs (EWS) such as feelings of anxiety, depression and suspiciousness (paranoia). Studies have shown that treatment programs focusing on addressing EWS when they appear can help to enhance recovery and lower the risks of relapse requiring hosptialisation. Currently, the quality of evidence for this is poor, and so it has not yet been possible to test whether programs such as these would work in routine practice. EMPOWER is a new program which uses digital smartphone technology for the monitoring of EWS, encouraging patients to seek help and minimizing the risk of “false alarms”. The aim of this study is to refine this approach in order to develop a practical program for use in the mental health services.

Who can participate?
Schizophrenic adult service users (patients) of community mental health teams (CMHTs) who are in contact with a local community based services, have been admitted to a psychiatric in-patient service in the last two years for a relapse and are able to consent to take part. Carers who are nominated by service users and mental health staff within the participating CMHTs are also included.

What does the study involve?
Community mental health teams are randomly allocated to one of two groups. Those in the first group take part in the EMPOWER program. This involves three main levels of stepped care: smartphone based EWS monitoring, personalised self-management support (delivered through smartphones) and the activation of a relapse prevention pathway in the mental health services. The EMPOWER smartphone app allows service users, their nominated carer and their care coordinator to agree on and personalise the frequency settings (number of EWS alerts per day /week), thresholds for increasing the frequency of monitoring and delivery of motivational self-management messages and thresholds for activating the relapse prevention pathway. Those in the second group continue to receive treatment as usual, with no access to the EMPOWER

program. At the start of the study, and then again after 3, 6 and 12 months, service users, carers and mental health staff complete a number of questionnaires in order to find out the rate of relapse and pattern of recovery of the patients.

What are the possible benefits and risks of participating?
Participants who take part in the EMPOWER intervention may benefit from improved mental wellbeing and a reduced risk of relapse and re-hosptialisation. Risks of participating include the possibility that discussing past experiences of relapse could be upsetting for participants, affecting their mood and anxiety levels.

Where is the study run from?
1. NHS Greater Glasgow & Clyde (UK)
2. NorthWestern Mental Health Services (Australia)

When is the study starting and how long is it expected to run for?
March 2016 to August 2019
(updated 12/06/2019, previously: September 2018)

Who is funding the study?
1. National Institute for Health Research (UK)
2. National Health and Research Council (Australia)

Who is the main contact?
Professor Andrew Gumley
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Study website
https://empowerstudy.net/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA 13/154/04

Study information

Scientific Title
Early signs Monitoring to Prevent relapse and prOmote Wellbeing, Engagement and Recovery: a mixed methods study

Acronym
EMPOWER

Study objectives
The overall objective of this study is to evaluate the novel EMPOWER intervention in terms of relapse prevention in individuals with chronic schizophrenia by:
1. Completing an evaluation of the system for a self-initiated and self-managed EWS using real time sampling methods
2. Examining the feasibility of EMPOWER through a 15-month pilot cluster randomised trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 16/03/2016, ref: 16/WS/0042

Study design
Mixed methods study comprising a qualitative investigation and a cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

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
Schizophrenia

Interventions
Participating CMHTs will be randomized to the EMPOWER Relapse Prevention Intervention or to continue their Treatment as Usual approach to care.

EMPOWER Relapse Prevention involves Mental Health Staff, Service Users and their carers. Mental health staff will receive training and ongoing support to emphasise:
1. Therapeutic alliance
2. Barriers to help-seeking
3. Developing an individualised formulation of risk of relapse
4. Developing a collaborative relapse prevention plan.
Service users will receive have access to the EMPOWER App for 12-months. A Peer Support Worker will meet with service users, carers and their key-workers to introduce the service users (and their nominated carers) to the App and the handset use. EMPOWER will be developed as a flexible user-led Early Warning Signs (EWS) monitoring tool that incorporates flexibility to tailor frequency of EWS monitoring, delivery of personalised self management messages directly to service users, flexibility to reduce numbers of items included in EWS, development of a user interface enabling service users to interact with and analyse their own data and ability for service users to send their data via email notification to their case coordinator and nominated carer.

Treatment as Usual will be delivered by adult Community Mental Health Teams, which largely involve regular, fortnightly, follow-up with a care coordinator and regular review by a psychiatrist. We will assess relevant policies governing delivery of routine care, service utilisation, documentation of care plans and crisis intervention plans (including advance statements, early signs indicator forms and relapse prevention plans).

Intervention Type
Behavioural

Primary outcome measure
1. The proportion of eligible and willing service users who then consent to enter the trial at at the end of the recruitment period
2. The proportion of service users continuing in the study at 3, 6 and 12 months
3. The proportion of service users completing >33% EWS datasets at 3, 6 and 12 months
4. The number of times data are accessed and number of times data shared by service users with mental health staff and their carers at 3, 6 and 12 months
5. The self-reported acceptability and usability of EMPOWER using a purposely developed questionnaire which will be derived from existing measures at 3, 6 and 12 months
6. The number of times mental health staff discuss service users' EWS data at 3, 6 and 12 months
7. The number of times service users has seek help from mental health staff at 3, 6 and 12-months
8. The number of times service users has activate the relapse prevention pathway at 3, 6 and 12 months

9. The number of times EMPOWER triggers a change in management (e.g. appointment brought forward, medication change) at 3, 6 and 12 months
10. Fear of Relapse is measured using the Fear of Recurrence Scale at 3, 6 and 12 months
11. Total number serious adverse events (relapse, rehospitalisation, suicide and attempted suicide) are recorded at 3, 6 and 12 months

Secondary outcome measures
Service Users Participants:
1. Rate of relapse observed between the two treatment conditions over 12 months
2. Patterns of recovery (Questionnaire for Personal Recovery), empowerment (The Empowerment Rating Scale) and coercion (MacArthur Perceived Coercions Scale) are measured at 3, 6 and 12 months
3. Patterns of interpersonal support are measured using the Sources of Support Scale and Perceived Criticism Scale at 3, 6 and 12 months
4. Functioning is measured using the Psychosis Attachment Measure at 3, 6 and 12 months
5. Patterns of service engagement are determined using the Working Alliance Inventory and Service Attachment Questionnaire at 3, 6 and 12 months
6. Patterns of psychiatric recovery are determined using the Positive and Negative Syndrome Scale and Calgary Depression Scale at 3, 6 and 12 months
7. Patterns of emotional recovery are determined using the Fear of Recurrence Scale, Hospital Anxiety and Depression Scale and Personal Beliefs about Illness - Revised questionnaires at 3, 6, and 12 months
8. Patterns of substance use are determined using the Time Line Follow Back for drugs and alcohol, Alcohol Use Disorder Identification Test, the Drug Abuse Screening Test (DAST) and the Cannabis User Disorders Identification Test - Revised questionnaires at 3, 6, and 12-months

Carer Participants:
Patterns of carer burden and distress are evaluated using the Involvement Evaluation Questionnaire at 3, 6 and 12-months.

Mental Health Staff:
Patterns of therapeutic alliance/service engagement are evaluated using the Service Engagement Scale and Working Alliance Scale at 3, 6 and 12 months.

Overall study start date
01/03/2016

Completion date
31/08/2019

Eligibility

Key inclusion criteria
Service users of participating CMHT's:
1. Aged 16 years or over
2. In contact with a local community based services
3. Have been admitted to a psychiatric in-patient service at least once in the previous two years for a relapse of psychosis
4. A diagnosis of schizophrenia spectrum disorder (DSM-V)
5. Able to provide informed consent as adjudged by the care co-ordinator or if in doubt the responsible consultant.

Carers who are nominated by eligible service users who provide informed consent will also be approached for their inclusion in the study. Service users can also nominate proxy-carers if they do not have a trusted other (e.g., care co-ordinator, keyworker, support worker).

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
86

Total final enrolment
149

Key exclusion criteria
Participants who do not meet the inclusion criteria.

Date of first enrolment
01/05/2016

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Australia

Scotland

United Kingdom

Study participating centre
NHS Greater Glasgow & Clyde
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre

NorthWestern Mental Health Services
35 Johnstone Street
Broadmeadows
Victoria
Melbourne
Australia
VIC 3047

Sponsor information

Organisation
NHS Greater Glasgow & Clyde

Sponsor details
NHS Greater Glasgow and Clyde Research and Development Central Office
The Tennent Institute, 1st Floor
Western Infirmary General
38 Church Street
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Scotland
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G11 6NT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

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

Funder Name
National Health and Medical Research Council

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
Our strategy for Knowledge Exchange and Impact means that we are ensuring service user and carer involvement from the outset of the study (for audit criteria see Ruppertsberg et al., 2014). This is reflected in a number of design features of the protocol.
1. The Scottish Recovery Network (www.scottishrecovery.net/) are active collaborators on the project proposal and have actively been involved in the design of the EMPOWER Relapse Prevention Intervention (led by their Director Simon Bradstreet). A key impact of this early involvement has been to ensure that service users retain control of their data and can be empowered to make decisions to activate different stages of the relapse prevention pathway and share their data with carers and case coordinators.
2. In addition, the SRN will employ the Research Assistant evaluating the outcomes of the C-RCT and a Peer Support Worker who will engage with and support service user participants randomized to the EMPOWER Relapse Prevention Intervention. The main beneficiaries of the intervention are service users with a diagnosis of schizophrenia and their carers. At the outset of the study we will involve these stakeholders in evaluating the acceptability and usability of ambulant symptom recording using mobile phones and identifying key of incentives and barriers to use.
3. Our strategy for Knowledge Exchange and Impact also means that we are ensuring the involvement of professional care staff from the outset of the study. This is reflected in our work packages that explore the acceptability and usability of ambulant symptom recording using mobile phones amongst professional care staff, identify incentives and barriers to implementation by NHS Teams and identification existing relapse prevention pathways.
4. In addition, our use of a Cluster Randomised Controlled Trial design maximises our ability to learn how to implement the EMPOWER Relapse Prevention Intervention into routine care. Our

inclusion of sites spanning the United Kingdom and Australia maximises the portability of this intervention across different health systems.
5. We will work with and seek feedback from a Trial Steering Group following each WP phase. This will enable us to report transparently achievement of milestones and inform the next step of project development. The Trial Steering Group will comprise stakeholders including clinical academic, health service managers and clinicians, and service user and carers.
6. We will organize a number of events for carers, service users and professional staff in Glasgow, Edinburgh, Manchester and Birmingham to identify and share key learning experiences arising from the study and to facilitate scoping and engagement of stakeholders participating in the main study.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	qualitative study results	24/10/2019	29/10/2019	Yes	No
Protocol article	process evaluation protocol	10/12/2019	11/12/2019	Yes	No
Results article	qualitative investigation results	12/12/2019	13/12/2019	Yes	No
Protocol article	protocol	09/01/2020	10/01/2020	Yes	No
Results article		01/06/2022	16/05/2022	Yes	No
Funder report results	results and plain language summary in Health Technology Assessment	01/05/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No