

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

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/06/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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 hospitalisation. 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-hospitalisation. 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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## Contact information

### Type(s)

Scientific

### Contact name

Prof Andrew Gumley

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

### Study type(s)

Prevention

### 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(s)**

1. The proportion of eligible and willing service users who then consent to enter the trial 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

### **Key secondary outcome(s)**

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.

**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).

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

Scotland

Australia

**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

**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)**

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

## Results and Publications

**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**

Date

Date

Peer

Patient-

<b>Output type</b>	<b>Details</b>	<b>created</b>	<b>added</b>	<b>reviewed?</b>	<b>facing?</b>
<a href="#">Results article</a>	qualitative study results	24/10 /2019	29/10 /2019	Yes	No
<a href="#">Results article</a>	qualitative investigation results	12/12 /2019	13/12 /2019	Yes	No
<a href="#">Results article</a>		01/06 /2022	16/05 /2022	Yes	No
<a href="#">Protocol article</a>	process evaluation protocol	10/12 /2019	11/12 /2019	Yes	No
<a href="#">Protocol article</a>	protocol	09/01 /2020	10/01 /2020	Yes	No
<a href="#">Funder report results</a>	results and plain language summary in Health Technology Assessment	01/05 /2022	08/06 /2022	Yes	No
<a href="#">HRA research summary</a>			28/06 /2023	No	No
<a href="#">Study website</a>	Study website	11/11 /2025	11/11 /2025	No	Yes