Mental health and mobile phones – EMPOWER Study

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#EMPOWERApp
Plan

• Digital Health in Psychosis – update on evidence

• EMPOWER – a cluster randomised controlled trial

• Planning implementation before doing a trial
We have a new vocabulary of digital health, e-health and m-health. Many have proposed that new and emerging digital technologies will:

- Facilitate self management
- Reduce stigmatization
- Offer faster, easier, and more cost-effective access to help
- Provide a more neutral space to connect

As a consequence, digital health care “has the potential to support shared decision making, service user empowerment, and self-management”

van der Krieke et al. 2014
Over promised, over-sold and underperforming?

- Wykes & Brown 2015 J Ment Health 25:1–4

- Raised a number of issues including
  - Skills and access to the internet – particularly older adults
  - The reality of digital empowerment and choice – what do do with data
  - Self monitoring and where is this taking us – potential for adverse events
  - Adherence to digital interventions – motivation for use
  - Reciprocity – responses by services
  - User involvement - design
  - Benefits – focus so far on feasibility / acceptability
Adherence

• Killikelly et al. 2017 JMIR Mhealth 5:e94

• 20 studies included: 6 RCTs; 7 feasibility and acceptability studies; and 7 observational studies.

• Percentage of intervention completed 83.4% (range = 70.7-98.0%) P

• Percentage completing the intervention 74.3% (range = 28-100%)

• Adherence was greater in studies with:
  • Higher levels of social support and
  • Service user involvement in the development of the intervention.
  • Studies of shorter duration.
Mobile Phone Ownership


- Fifteen studies reporting data from 12 independent samples (US, UK, Canada, India: n = 3227).
- Overall mobile phone ownership rate was 66.4% (95% CI = 54.1%–77.6%)
- Increasing since 2007, and the rate among patients surveyed in the last 2 years was 81.4% (n = 454).
  - 60.2% of service users in favoured using mobile phones for tracking/monitoring their mental health,
  - 56.1% for receiving information about physical or mental health
  - 55.5% for appointment/medication reminders via text, and
  - 51.1% for facilitating contact with health professionals.
Smartphone Apps

- Firth & Torous 2015 Journal of Medical Internet Research mHealth 3:e102

- Identified 7 eligible studies reporting data from 5 independent trials
- All examined feasibility, and one assessed the preliminary efficacy.
- Study lengths varied between 6 and 130 days.
- Overall retention was 92% (95% CI 82-98%).
- Participants used the apps on 86.5 - 94% of days and on average, 3.94 times per day
- Furthermore, participants responded to 71.9% of automated prompts (95% CI 65.7-77.8%).
- Participants reported a range of potential benefits from the various interventions, and user experience was largely positive.
- No paper reported any adverse outcomes or cases of app use increasing paranoia or exacerbating psychosis.
Find out more - https://empowerstudy.net
• **Early signs Monitoring to Prevent relapse and PrOmote Wellbeing, Engagement and Recovery**

• Our aim is to build a complex intervention (MRC Framework) that:
  • enhances recognition of early warning signs;
  • provides a stepped care pathway;
  • may trigger a relapse prevention strategy which can be stepped up to a whole team response.
Trial registration

- **ISRCTN**: 99559262

- **Funders**:  
  - National Institute for Health Research – Health Technology Agency (UK)  
  - NHS Greater Glasgow & Clyde  
  - National Health and Medical Research Council (Australia)

- **Medical Device Regulation**:  
  - Medicines and Healthcare Products Regulatory Authority (MHRA)
Our approach

• Relationships are at the centre of relapse and recovery.
• Fear of relapse can strain relationships, communication and decision making.
• We hope that digital technology will empower people with lived experience to:
  • track and observe changes in their own wellbeing,
  • develop a positive awareness of the “ebb and flow” of feelings in daily life
  • maintain their own data,
  • access wellbeing resources, and
  • share data to access support
Something’s not quite right

Relationships

Feelings: Fear, anxiety, shame
Behaviours: Avoidance, hypervigilance, over positive

I’ll let everyone down

Feelings: Concern, suspiciousness
Behaviours: Increased monitoring, risk oriented

Something’s not quite right

What might happen?

I could end up back in hospital

Service provider

Service recipient

Relationships
EMPOWER Aims

• To enhance and tailor our mobile phone software application (App) to deliver EWS monitoring, self-management interventions and access to a relapse prevention pathway which is firmly embedded in whole team protocols and action;

• To determine rates of eligibility, consent and recruitment of potentially eligible participants (service users, carers and care co-ordinators) to the study;

• To assess the performance and safety of the EMPOWER Medical Device;

• To assess the feasibility, acceptability, and usability of the intervention including feedback on suggested enhancements from consumers, peer support workers and clinicians;

• To assess primary and secondary outcomes in order to determine preliminary signals of efficacy of the EMPOWER Relapse Prevention Intervention as a basis for the estimation of sample size requirements of a future definitive trial,

• To undertake a qualitative analysis of relapses to refine intervention in the main trial, and

• To establish the study parameters and data gathering frameworks required for a co-ordinated health economic evaluation of a full trial across the UK and Australia.
EMPOWER is a multicentre, two arm, parallel groups Cluster Randomised Controlled Trial involving eight purposively selected Community Mental Health Services (CMHS) (2 in Melbourne and 6 in Glasgow) with 12-month follow-up.

The CMHS will be the unit of randomisation (the cluster), with the relapse prevention pathway provided by the teams to individual service users and with outcomes assessed within these clusters.

The study will take place in NHS Greater Glasgow & Clyde and NorthWestern Mental Health, Melbourne.
Eligibility

• Teams (n=8), Service Users (up to 120) and Carers

• Service users from participating CMHS are eligible for inclusion if:
  • they are adults (age 16+);
  • in contact with a local community based services;
  • who have either
    • been admitted to a psychiatric in-patient service at least once in the previous two years for a relapse of psychosis;
    • or received crisis intervention (e.g. via a crisis intervention service; re-engaged with a CMHS) in the previous two years for a relapse of psychosis;
  • a diagnosis of Schizophrenia-related disorder (DSM-5).
What is the EMPOWER App?

Supported mobile phone App:
- Monitoring mental health and wellbeing
- Supports self management
- Peer Supported
- Informs early intervention via clinician triage
- Stepped care response

#EMPOWERApp
The EMPOWER System

- Server and database
- Notifications and messages
- Mobile application
- Question responses
- Alert handling info
- Researcher interface
- Alert emails to research team

#EMPOWERApp
The App
Question time

- Mood
- Hope
- Anxiety
- Self-esteem/identity
- Connectedness
- Sleep
- Fear of recurrence
- Coping
- Personalised

Psychosis symptoms

I have felt upbeat about the future

Not at all
Very much

Next
Suspicious thoughts are common. In one recent study, 70% of people said that they had, at some time, experienced the feeling that people were deliberately trying to harm them or upset them in some way and 80% felt strangers were looking at them critically.
Functions

How are you feeling?

I feel...

because...

I've got to do this talk today so nerves are an issue

How am I feeling?

Last 30 Days

01/6/14-30/6/14

#EMPOWERApp
Planning to make a difference?

• Developing an implementation theory can help predict the uptake of digital technologies from research into every day life. Not only “does it work” – but “why would people use it?” (Grant et al., 2013).

• Important to consider how staff interact with intervention - not only service users (Thornicroft & Slade, 2014).

• Family and friends are large source of support in psychosis – even if person lives alone (Understanding Psychosis Report, 2014).

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Study Aims – Staff, Carers and Service Users

• Prior to starting the Cluster RCT, we explored the following in our task groups:

• to identify current perceptions and usage of Early Warning Signs in practice.
• evaluate the coherence of symptom monitoring using a smartphone. Does it make sense?
• identify incentives and barriers to implementation
Participants

- Total participants = 142
- 81 mental health staff participants –
  - 13 Task Groups (9 in Glasgow, UK and 6 in Melbourne, Australia)
- 23 service user participants –
  - 7 Task Groups (3 in Glasgow, UK and 4 in Melbourne, Australia).
- 38 carer participants –
  - 5 Task Groups (2 in Glasgow, UK and 3 in Melbourne, Australia).
Findings - EWS

• There was a shared understanding by the three stakeholder groups of early warning signs in terms of their function to prevent relapse.

• There was also a shared emphasis on the importance of relationships as a context for staying well.

• Early warning signs were closely linked to the appraisal of risk.

• For each stakeholder there were important differences in the way that risk was experienced and expressed, thus acting as an important block to help seeking and help providing.
“she’s had a couple of fairly minor relapses but in the past they would have been kept secret, they would have escalated she would have been detained and would all have been mayhem for months”

Participant 1, Mental Health Centre 1, 139-141

EWS discussions related to professional role. Relapse threatens service user mental wellbeing (staff perceptions of their responsibility) and also takes up staff resources. “Mayhem”.

Non disclosure to staff limits information available to make clinical decisions – relying on information gleamed from relationship / case notes.
“We hate hospital, but we also want to be as honest as we can and often we want to be able to manage our own symptoms too. We don’t want to be medicated up to our eyeballs”

Participant 5, Service User Group 5, 148-150

EWS constructed as threatening because response from services can be misattuned. Service users report their self-management expertise can be disregarded during this time.
Early Warning Signs as risk - Carers

“my daughter is so badly traumatised by her experience... and what happened in hospital that she would do almost anything to hide her symptoms so she wouldn't need to go through that again and as someone who protects her I would obviously within reason I would want to protect her”

Participant 1, Carer Group 2, 9-13

Carers described EWS as threatening to their family relationships if contacting services resulted in their loved ones perceiving their actions as harmful. Carers find themselves in the middle.

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Findings – Making Sense

• Broad consensus that EMPOWER has value in encouraging more attuned responses to changes in mental states.

• Shared agreement that current system comprises is mainly “risks” based. Perception that digital technologies could help negotiate these.
“So if you're monitoring yourself every day, you realise a regular pattern. And if it stoops down all the time, you really realise that you urgently need help.” (Participant 2, Service User Group 2, 566-567)

• Service users reported having access to their own early signs data made sense as a way to encourage learning and help-seeking when there has been a significant change in well-being.
Making Sense to Staff

“You see where the stressors are, what times, what the patterns are, the patterns would be so clear.”

Participant 1, Centre 2, 514-515

• Staff reported that EMPOWER made sense to them as an EWS management tool that could increase the information available to them for making decisions.
“could see that being a big big benefit especially for us - being able to access like a source of content that you know is coming from the right sort of people rather than just entrepreneurs looking for a fast £1.79 off an app site”

Participant 2, Carer Group 1, 136-141

- Carers reported the app made sense as a trustworthy source of information on managing EWS for the family unit.
Developing an implementation theory

- Implementation needs to take account of interpersonal context of EWS and distinctive perspectives on risk.
- EWS tend to emphasise role dependent ‘risk’ as a means of preventing or avoiding a threatening experience (i.e. relapse).
- EMPOWER App emphasises the ‘ebb and flow’ of emotions and psychotic experiences in daily life.
- Placing data in hands of service users as a means of promoting autonomy, learning and attunement to own experiences.
- Peer Support Workers provide an additional source of support in making sense of own data and app content. Emphasising exploration, curiosity and recovery focus.
Developing an implementation theory

- EMPOWER Algorithm based on user’s own ‘ebb and flow’ allows calculation of changes in wellbeing to guide wellbeing messages.
- Algorithm also enables larger changes to be viewed on a ‘researcher interface’ to enable assessment of possible early signs.
- Ability to trigger a relapse prevention pathway enables early engagement of keyworkers.
Thank you

• Participants contributing to planning implementation
• Participants contributing to the EMPOWER website and messages survey
• EMPOWER Glasgow
  • Simon Bradstreet, Andrea Clark, Claire Matrunola, Alison Wilson Kay, Helen Whitehill, Jayne Artis, Davy Thomson, Steph Allan
• EMPOWER Melbourne
  • John Farhall, John Gleeson, Maria Lambrou
• EMPOWER Manchester
  • Matt Machin, Bill Spence and John Ainsworth