Digital smartphone intervention to recognise and manage early warning signs in schizophrenia to prevent relapse: the EMPOWER feasibility cluster RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The EMPOWER feasibility cluster RCT

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Scientific summary

Background

Schizophrenia is a long-term and serious mental illness with a lifetime prevalence rate of 4.0 per 1000 people, and it is estimated to affect 21 million people worldwide. It is one of the top 15 leading global causes of disability, and estimates suggest that around 80% of people with a diagnosis experience a relapse after 5 years. Relapse and associated hospital admissions can be deeply distressing and traumatic for those affected, and the direct treatment costs for people who experience a relapse are three times higher than for those who do not. Additionally, relapse is associated with a lifetime risk of clinical and functional deterioration. There is, therefore, some urgency to develop interventions to identify and respond to valid predictors of relapse in psychosis.

Antipsychotic medication has the strongest evidence for relapse prevention but its benefits are limited by high levels of discontinuation, often associated with common and burdensome side effects. Although there is some evidence for the effectiveness of psychological approaches, their availability is limited and questions have been raised over the supporting evidence. A further approach, known as early warning signs monitoring, is generally achieved by comparing ongoing assessments of potential early signs of relapse against earlier assessments and, where necessary, responding with an appropriate plan for relapse prevention. Although significantly fewer people relapse as a result of early warning signs monitoring, the quality of the supporting evidence makes it impossible to recommend the approach in routine practice. Identifying and responding to early warning signs is constrained by a variety of factors, including the effect of previous negative experiences at times of crisis for service users, fear of relapse, the consequences of help-seeking and a prioritisation of risk within services.

Mobile health technology, and smartphone interventions specifically, offer potential solutions to some of the implementation barriers that have hindered early signs monitoring approaches. Emerging evidence suggests that people with experiences of psychosis are generally comfortable with the application of digital mobile technologies in this context, with studies suggesting good levels of acceptability. Blending peer support with digital interventions has the potential to improve engagement and user experience.

Objectives

The objectives of phase 1 of the study were to conduct task group interviews to explore the acceptability and usability of mobile symptom reporting using smartphones among service users, carers and mental health staff and to identify the incentives and barriers to use by service users and carers and to implementation by mental health staff. We also sought to identify current pathways to relapse identification and prevention with mental health staff. These interviews informed modifications to the EMPOWER app (smartphone application), which then underwent a 5-week beta-testing period with a group of service users.

The purpose of phase 2 was to establish the feasibility of conducting a definitive cluster randomised controlled trial comparing the EMPOWER intervention with treatment as usual. We sought to establish the parameters of the feasibility, acceptability, usability, safety and outcome signals of a mobile and peer-supported intervention as an adjunct to usual care that would be deliverable in the NHS and Australian community mental health service settings.

Methods

In phase 1, task group participants were approached via community mental health services and other groups in Glasgow and Melbourne, with analysis based on the framework approach. Beta testing was conducted with service users over a 5-week period, recruited via task groups and local networks, after which we conducted interviews exploring experiences of beta testing, applying interpretative phenomenological analysis. We utilised normalisation process theory as a framework to understand the work required to optimise the EMPOWER intervention ahead of conducting the feasibility trial.

In phase 2, we evaluated EMPOWER using a multicentre, two-arm, parallel-group cluster randomised controlled trial involving eight purposively selected community mental health services (two in Melbourne and six in Glasgow) with 12-month follow-up. The services were the unit of randomisation (the cluster), with the intervention delivered by the teams to people using services and with outcomes assessed within these clusters. We engaged services likely to have five or more care co-ordinators willing to participate and where potential care co-ordinators had eligible service users on their caseload. Service users were eligible if they were aged > 16 years and had a schizophrenia or related diagnosis, and for whom there was evidence of a relapse within the previous 2 years. Carers of people receiving support from participating services were eligible for inclusion if they were nominated by an eligible service user.

The EMPOWER intervention was designed to enable participants to monitor changes in their well-being on a daily basis using a mobile phone. Participants could use their own mobile phone; if preferred, they were provided with a mobile phone from the study team. A peer support worker was involved in setting up the app and following up people using the app every 2 weeks. Clinical triage of changes in well-being that were suggestive of early signs of relapse was enabled through an algorithm that triggered a check-in prompt that informed a relapse prevention pathway if warranted. The app included messaging, diary and charting functions intended to support self-management.

We used a variety of validated, novel and adapted measures to assess feasibility, acceptability and usability, safety and performance. Carers also completed measures of feasibility. We also assessed the candidate primary outcome of relapse by reviewing electronic patient records with ratings made independent of and blind to allocation to EMPOWER and treatment as usual. We assessed a series of candidate secondary and mechanistic outcomes and completed a health economic evaluation. These were rated independently but not blinded. All outcome measures were administered at baseline and then repeated at 3, 6 and 12 months. A statistical analysis plan and a health economic analysis plan were agreed prior to any analyses.

All analyses were carried out using the intention-to-treat principle with data from all participants included in the analysis, including those who did not complete the intervention.

Results

Phase 1 task groups identified that the EMPOWER intervention made sense to our stakeholder groups and was relevant both to existing mental health services practice and to the concerns and values of service users and carers. We identified barriers to implementation in routine clinical practice, which included worries about additional workload for mental health services and the validity of data. Although service users and carers valued relapse prevention, they also raised concerns around fears of help-seeking and unhelpful service responses in the event of a crisis. We addressed these concerns by reviewing and adapting our approach to the triage of check-in prompts, by reviewing the language we used to describe the intervention and by refining the practices of the peer support workers. Through conducting beta testing, we identified a number of relevant and important technical issues, which were addressed prior to phase 2. Overall, the app was well received by beta testers and was considered to be a useful tool for self-monitoring and recovery.

In phase 2, we were able to recruit our target of 86 service users, of whom 73 were randomised (42 to EMPOWER and 31 to treatment as usual). At 12 months, primary outcome data were collected for 76% of service users in the EMPOWER arm and for 90% in the treatment as usual arm. During the study, seven people withdrew from the EMPOWER arm, two moved out of area and there was one death. There was a clear association between those who withdrew from the EMPOWER arm and low engagement with the app. One person withdrew from the treatment as usual arm. Feasibility data for people using the app suggested that the app was easy to use and had an impact on mental health, but the sharing of early warning signs with carers and care co-ordinators was less frequent. Actual app usage was high, with 91% of users who completed the baseline period meeting our a priori criterion of acceptable engagement (> 33%). The length of time at which 50% of participants no longer meet the intended adherence criterion is hard to predict in this sample (especially in terms of an upper limit) but is likely not to fall below 14 weeks (the lower end of a 95% confidence interval). We supplied 28 mobile phones to service users, six of which were lost or stolen. Across both arms there were 54 adverse events affecting 29 people. Around half were classified as serious adverse events, the vast majority of which were anticipated. There were 13 app-related adverse events affecting 11 people, one of which was serious.

Fewer participants in the EMPOWER arm had a relapse and time to first relapse was longer than in the treatment as usual arm. At 12 months EMPOWER participants were less fearful of having a relapse than those in the treatment as usual arm. These and other secondary and mechanism outcomes offer encouraging signals for a larger study and inform the selection of measures for a definitive trial. Additionally, our health economic analysis suggested that EMPOWER resulted in fewer costs and greater outcomes than treatment as usual in terms of both quality-adjusted life-years and relapses avoided.

Conclusions

We demonstrated the feasibility of recruitment and retention of service user participants into the trial. In addition, the rates of data completeness for candidate primary, secondary and mechanistic outcomes were excellent over the 12 months. However, we did identify problems with the completeness of the health economic measures data. We demonstrated that we can deliver the EMPOWER intervention blending our mobile app with peer support and an algorithm that supports the delivery of tailored messaging and clinical triage of possible early warning signs of relapse. In addition, we learned how to integrate check-in prompts generated by the algorithm into peer support to promote increased awareness and motivation to engage in self-management. It is likely that EMPOWER may reduce relapse over 12 months and reduce fear of relapse. The intervention may improve other outcomes including negative symptoms, depression, personal recovery and self-efficacy. It is unlikely that EMPOWER improves medication adherence. It is likely that overall the costs for the EMPOWER arm are increased but the intervention also results in improved quality-adjusted life-years and reduced relapse. The incremental cost-effectiveness ratio of £3089 per quality-adjusted life-year gained is below the current £20,000 threshold recommended by the National Institute for Health and Care Excellence and there was a 70% probability that EMPOWER is cost-effective from the health-care payer perspective. A further main trial seems merited by these overall findings. We estimate that for a main trial (assuming 90% power and 20% dropout) we would require a sample size of 500 service users to detect a relative risk of 0.7 for reduction of relapse and for continuous variables effect sizes of between 0.3 and 0.4.

Trial registration

This trial is registered as ISRCTN99559262.

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This report

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