Reducing relapse and suicide in bipolar disorder: practical clinical approaches to identifying risk, reducing harm and engaging service users in planning and delivery of care – the PARADES (Psychoeducation, Anxiety, Relapse, Advance Directive Evaluation and Suicidality) programme

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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 PARADES programme

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Scientific summary

Background

Bipolar disorder (BD) is a potentially life-long condition characterised by recurrent episodes of mania and depression and by significant mood problems between mood episodes. This condition costs the English economy £5.2B annually, largely as a result of incomplete recovery after inadequate treatment. The importance of improving mental health recovery is emphasised in the UK government's *No Health Without Mental Health* document (HM Government. *No Health Without Mental Health*. London: Department of Health; 2011) and, more recently, in NHS England's call to action on parity of esteem for mental health. (NHS England. A Call to Action: Achieving Parity of Esteem. London: NHS England; 2014.)

Rationale and objectives

The programme contains a series of linked studies to help reduce harm and improve outcomes for people living with BD across five workstreams (WSs), as follows.

Pragmatic randomised controlled trial of group psychoeducation versus group peer support in the maintenance of bipolar disorder

The National Institute for Health and Care Excellence (NICE) guidelines for BD recommend structured psychological treatment delivered by experienced therapists. NICE's recommendation may be facilitated by group psychoeducation (PEd) delivered by care co-ordinators without extensive training in psychological therapy. Pilot work prior to this programme on group PEd, delivered by a clinician and an expert patient, supported its feasibility. The objectives of this stream were to evaluate whether or not group PEd is feasible and sustainable across different NHS sites and to evaluate whether or not group PEd is clinically effective and cost-effective compared with group peer support (PS).

Psychological treatment of anxiety in bipolar disorder

Anxiety disorders respond to individual cognitive–behavioural therapy (CBT) group CBT and supported self-help. Despite the efficacy of such approaches, current approaches to BD do not include therapy for anxiety symptoms despite the high rates of comorbid anxiety disorders in those with BD. The objectives of this stream were to understand the impact of, and what psychological help is required for, anxiety in bipolar disorder (AIBD) and to develop and evaluate the feasibility of CBT-informed, time-limited therapy for people with anxiety and BD.

Psychological treatment of comorbid alcohol use in bipolar disorder

Alcohol and substance use disorders are amenable to treatment with motivational interviewing (MI) and CBT. Despite the high prevalence of such comorbid problems in BD (in particular cannabis and alcohol use disorders), and their association with worse clinical outcomes, there has been little progress in developing integrated psychological interventions. The objectives of this stream were to explore the reasons for and impacts of cannabis and alcohol use in BD, and to develop and evaluate the feasibility of MI-CBT for alcohol use in those with BD.

Suicidal behaviour in bipolar disorder

Despite the prevalence of self-harm and suicide in BD, and the Department of Health's emphasis on reducing these problems, research in BD in this area has been limited. No studies have examined how risk factors combine, and few have investigated the role of clinical management in BD. The objectives of this stream were to understand the risk of suicide in BD in NHS service settings, to understand the demographic-, clinical- and management-related risk factors for suicidal behaviour and to understand how these risk factors link together in self-harm or suicide in BD.

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Is the Mental Capacity Act 2005 changing clinical practice for patients with bipolar disorder?

Patients with BD, especially those requiring inpatient treatment, often lose mental capacity in acute episodes. The Mental Capacity Act 2005 (MCA) (Department of Constitutional Affairs. *Mental Capacity Act 2005*. London: Department of Constitutional Affairs, HMSO; 2005) could be used to design care plans that help individuals with BD to ensure that they receive the treatment they want and avoid treatments they find unhelpful in acute episodes. There are also concerns about capacity assessment in BD, and ethical and practical issues about its implementation in a condition in which severe harm can arise but capacity loss may be brief. The objectives of this stream were to determine whether or not people living with BD are making use of the MCA, to determine whether or not the MCA promotes joint care planning in the event of capacity being lost and to examine the barriers and drivers at service user (SU) and staff levels to use of the MCA in general.

Methods

Pragmatic randomised controlled trial of group psychoeducation versus group peer support in the maintenance of bipolar disorder

A single-blind randomised controlled trial (RCT) compared the clinical effectiveness and cost-effectiveness of 21 weekly bipolar group PEd sessions delivered by two health professionals and a SU facilitator, plus treatment as usual (TAU), with group PS sessions delivered in the same way.

The trial was in two centres in England (East Midlands and North West). Patients were individually randomised to one of the two interventions with stratification by clinical site and minimisation in terms of their number of previous episodes.

The primary outcome measure was time to next bipolar episode using 16-weekly the Structured Clinical Interview for the *Diagnostic and Statistical Manual of Mental Disorders* longitudinal interval follow-up evaluation interviews.

A Cox proportional hazards model was fitted to the primary outcome measure. Longitudinal statistical models were fitted across follow-up time points to the secondary outcome scale data. Qualitative interviews were used to investigate the experiences of the group. A cost-effectiveness analysis was used to compare the relative costs and outcomes of the bipolar group PEd intervention with those of the bipolar PS control group.

Psychological treatment of anxiety in bipolar disorder

Phase 1

Semistructured interviews were carried out with individuals with BD and experience of anxiety symptoms to understand how they experienced anxiety and discover their preferred type of psychological treatment.

Phase 2

Focus groups were run to inform the development and delivery of the therapy to be trialled in phase 3.

Phase 3

A single-blind RCT was conducted to determine the feasibility and acceptability of the AIBD intervention compared with TAU. We also conducted a preliminary analysis of anxiety and mood outcomes.

Psychological treatment of comorbid alcohol use in bipolar disorder

Phase 1

Q-Sort methodology was used to explore experiences and consequences of substance use in those with BD.

Phase 2

Focus group meetings were held to inform the planned intervention.

Phase 3

A single-blind RCT was conducted to determine the feasibility and acceptability of the integrated intervention compared with TAU. We also conducted a preliminary analysis of alcohol and mood.

Suicidal behaviour in bipolar disorder

Phase 1

Phase 1 used data from a large national case series of individuals with BD who died by suicide to explore the overall characteristics of suicide in BD.

Phase 2

Phase 2 used a smaller case–control data set of current and recent inpatients to systematically compare the characteristics identified in phase 1.

Phase 3

Phase 3 used a cohort design to explore the characteristics of people with BD who self-harm.

Phase 4

Phase 4 used qualitative methods to further explore factors found to be important in the previous studies, how these and other factors are experienced on an individual level, and the role of Mental Health Services (MHS) in the prevention of suicidal behaviour in those with BD.

Is the Mental Capacity Act 2005 changing clinical practice for patients with bipolar disorder?

This WS included a:

1. national postal survey of psychiatrists in England and Wales, which covered experiences of receiving and applying MCA training
2. national postal survey of SUs with BD recruited through a SU organisation (Bipolar UK, previously Manic Depression Fellowship – the BiPolar Organisation) to explore the application of the MCA and related advance directives from a patient perspective
3. qualitative study of SUs and psychiatrists to examine, in greater detail, the issues faced by participants in advance planning.

Key findings

Pragmatic randomised controlled trial of group psychoeducation versus group peer support in the maintenance of bipolar disorder

Psychoeducation and PS are feasible to deliver in routine NHS care across inner-city, urban and rural clinical sites across two regions of England. Overall, the PEd and PS groups did not differ in terms of the primary outcome variable, namely time to the next bipolar relapse. However, there was evidence of a large effect favouring PEd over PS in delaying time to relapse (hazard ratio 0.28, 95% confidence interval 0.12 to 0.68) in the 13% (39/304) of participants with fewer than eight previous bipolar episodes.

There was a 35% probability of PEd being cost-effective, compared with PS, if decision-makers are willing to pay £30,000 to gain 1 quality-adjusted life-year.

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Psychological treatment of anxiety in bipolar disorder

Phase 1
Participants highlighted the importance of a flexible integrated psychological approach to anxiety problems in the context of BD.

Phase 2
Focus groups indicated the importance of enhancing behavioural and cognitive self-management in flexible and collaborative sessions with high-quality support materials.

Phase 3
The AIBD intervention is feasible and is acceptable to, and valued by, participants, although the clinical outcomes were not significantly different from those of TAU.

Psychological treatment of comorbid alcohol use in bipolar disorder

Phase 1
There were indications that the reasons for substance use, and the after-effects of such use, differed between cannabis and alcohol users, with more negative effects in the latter group.

Phase 2
Focus groups highlighted the importance of therapy being non-judgemental, collaborative and normalising. Flexibility, setting and timing for sessions and very clear information on confidentiality were emphasised as enhancing engagement.

Phase 3
Motivational interviewing-CBT was feasible and was acceptable to and valued by participants. Clinical outcomes did not differ significantly between the trial arms.

Suicidal behaviour in bipolar disorder

Phase 1
Ten per cent of psychiatric patients who died by suicide had a primary diagnosis of BD. This group were more likely than those with schizophrenia or depression to be female, be aged > 45 years and have had a diagnosis for > 5 years.

Phase 2
Higher rates of depression, previous self-harm, adverse life events and comorbid alcohol and/or personality disorders were reported in individuals with BD who died by suicide than in those who did not.

Phase 3
A comparison of participants with BD who self-harmed with those who did not showed that the former group included more women in late middle age, higher levels of contact with MHS and a higher incidence of sleep disturbance and unemployment/long-term sickness.

Phase 4
Qualitative interviews with SUs with BD who had self-harmed and with the relatives of SUs who had died by suicide indicated that both groups prioritised fast access to good-quality mental health care.

Is the Mental Capacity Act 2005 changing clinical practice for patients with bipolar disorder?
Around 50% of psychiatrists surveyed indicated that they would not discuss advance directives to refuse treatment and the majority felt that the MCA had not increased advance planning in BD. SUs regard

advance planning as important but the MCA has only rarely been used. Both groups indicated that lack of support for advance planning was a factor, even for those individuals who were aware of the possibility of doing this.

Conclusions

The findings from the Psychoeducation, Anxiety, Relapse, Advance Directive Evaluation and Suicidality programme have a number of important implications for both clinical practice and further research in BD.

Clinical practice implications

1. If NHS trusts are looking to implement either group PEd or PS, then group PEd appears more acceptable, and there are some clinical benefits, especially for people early in the course of their BD. There is a demand for improved psychological therapy for people with BD with anxiety and/or alcohol comorbidities, which needs to be delivered with due recognition of the bipolar experiences people have. However, it may be less cost-effective to implement group PEd than PS in the NHS. The extent to which either intervention could be cost-effective will depend, in part, on the initial set-up and implementation costs.
2. The risk of suicide and self-harm is high compared with the general population, and illness/treatment factors are important.
3. Implementation of the MCA and use of advance planning in BD is poor and requires improved information sharing with SUs.

Research implications

1. Further research is required to evaluate individual versus group PEd early in the course of BD delivered in person and/or through the internet or video conferencing.
2. Definitive trials of integrated approaches to comorbid anxiety and alcohol use are suggested by the present research, although with alterations to the current interventions required.
3. The persistence over time and age of suicide and self-harm risk in BD highlights the importance of developing interventions to reduce this risk. An exploration of optimal mechanisms to improve their implementation and support by psychiatrists is warranted.

Trial registration

The trial entitled 'Group psychoeducation versus group support using expert patients and clinical staff in the management of bipolar disorder' is registered as the International Standard Randomised Controlled Trial Number (ISRCTN)62761948.

The trial entitled 'Evaluating the feasibility and acceptability of a time limited anxiety in bipolar disorder' is registered as ISRCTN84288072.

The trial entitled 'Integrated psychological therapy for people with bipolar disorder (BD) and co-morbid alcohol use: a feasibility randomised trial' is registered as ISRCTN14774583.

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