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Improving Access to Psychological Therapies (IAPT) for People with Bipolar disorder:
Summary of outcomes from the IAPT demonstration site

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ABSTRACT

Access to structured psychological therapy recommended for bipolar disorder (BD) is poor. The UK NHS Improving Access to Psychological Therapies initiative commissioned a demonstration site for BD to explore the outcomes of routine delivery of psychological therapy in clinical practice, which this report summarises.

All clinically diagnosed patients with BD who wanted a psychological intervention and were not in acute mood episode were eligible. Patients were offered a 10-session group intervention (Mood on Track) which delivered NICE congruent care. Outcomes were evaluated using an open (uncontrolled), pre-post design.

Access to psychological therapy increased compared to preceding 6 years by 54%. 202 people began treatment; 81% completed > 5 sessions; median 9 sessions (range 6-11). Pre-post outcomes included personal recovery (primary outcome), quality of life, work and social functioning, mood and anxiety symptoms (secondary outcomes). Personal recovery significantly improved from pre to post-therapy; medium effect-size ($d=.52$). Secondary outcomes all improved (except mania symptoms) with smaller effect sizes ($d=.20-.39$). Patient satisfaction was high. Use of crisis services, and acute admissions were reduced compared to pre-treatment.

It is possible to deliver group psychological therapy for bipolar disorder in a routine NHS setting. Improvements were observed in personal recovery, symptoms and wider functioning with high patient satisfaction and reduced service use.

Highlights

- We summarised outcomes of delivery of psychological therapy for bipolar disorder in clinical practice

- Most people offered therapy accepted and completed it
- Post therapy improvements were found for personal recovery and most secondary functional and symptom outcomes
- It is possible to deliver effective psychological treatment for bipolar disorder in NHS settings

Keywords: Service delivery, psychological treatment, implementation, bipolar disorder

1. Introduction

Bipolar disorder (BD) is a potentially lifelong mental health problem characterised by fluctuating episodes of mania and depression with often extended periods of subsyndromal mood symptoms in between episodes (Goodwin & Jamison, 2007; Merikangas et al., 2007). Many people with BD experience poor clinical outcomes, and low quality of life (IsHak et al., 2012), and are at significant risk for suicide and self-harm (Clements et al., 2015; Clements et al., 2013). Although there is evidence for the efficacy of medication in prophylaxis for bipolar relapse, it is only partially effective (Geddes & Miklowitz, 2013). Thus in 1469 patients in the Systematic Treatment Enhancement Programme for Bipolar Disorder, 416 of the 858 who achieved symptomatic recovery relapsed within 2 years; predominantly with depressive (n=298) rather than manic, or mixed (n=118) episodes. This was despite training all programme clinicians in evidence-based prescribing guidelines (Perlis et al., 2006). In a meta-analysis of the efficacy of lithium therapy for relapse prevention in bipolar disorder, relapse risk was reduced from 60% in controls to 40% in those treated by lithium, over follow up periods varying from 11 months to 4 years (Geddes et al., 2004). Consequently, in many cases BD is only partially treated due to limitations of current medications and/or adherence issues (NICE, 2014a).

Cognitive therapy for bipolar disorder (CT-BD) shares an emphasis on information giving, and linking thoughts, feelings and behaviour to improve adaptive coping with cognitive therapy in general (Lam, Jones, & Hayward, 2010). CT-BD is further informed by vulnerability-stress models of BD, which propose that individuals are vulnerable to circadian disruption, which can lead to early signs and symptoms of mood change. This is based on the instability of model of bipolar disorder, developed by Goodwin and Jamison (1990), which argues that there is a fundamental problem with the modulation of the circadian pacemaker in bipolar disorder, which interacts with social and psychological stressors to cause mood symptoms. This approach is also the cornerstone of Interpersonal and Social Rhythm therapy (Frank et al., 1997). The ways in which such changes are responded to, both cognitively and behaviourally, then influence whether there is further escalation to full episodes of mania or depression (Jones, 2001; Lam et al., 2010). Consequences of mood episodes then create social and functional disturbances, as well as experience of stigma, which in turn increase risks of further mood change (Brohan, Gauci, Sartorius, Thornicroft, & Gamian Europe Study Group, 2011; Gitlin & Miklowitz, 2017). There is increasing evidence for the effectiveness of cognitive therapy and psychoeducation, which both offer evidence based information about BD and work to reduce relapse risk (Oud et al., 2016).

Furthermore, Kessing and colleagues have reported that combining group psychoeducation with optimal pharmacotherapy significantly improved rehospitalisation rates early in the course of bipolar disorder (≤ 3 prior admissions) (Kessing et al., 2013). The same team also explored whether this intervention had differential effects on younger (18-25 year old) vs older (>26 year old) patients. Neither group showed significant differences to controls on hazard ratio for rehospitalisation, although only younger patients experienced a significant reduction in total number of re hospitalisations. Kessing's team concluded that the numerical scale of the point differences in hazard ratio were supportive of further exploration (Kessing et al., 2014). Most of the evidence cited above relates to improving relapse outcomes. Less is known about the impact of such approaches on personal recovery and quality of life, although a recent trial of recovery focused therapy had encouraging results (Jones et al., 2015). As NICE have highlighted, more research is needed in this area, as such outcomes are highly valued by individuals living with BD (NICE, 2014a). Furthermore, the main drivers for the cost of BD are the functional consequences of inadequate treatment including work performance (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008).

Despite evidence for efficacy and cost-effectiveness of psychological therapy highlighted by NICE (NICE, 2014a, 2014b), very few people with severe mental illness are offered it (Haddock et al., 2014; Schizophrenia Commission, 2012). A recent NHS Trust audit specific to BD indicated only 8% of eligible patients were offered BD specific psychological therapy, despite high demand (95% of those offered treatment engaged with it; Dunn & Makin, 2015). The urgent need to improve access to effective psychological interventions for people with BD was recognised by the UK Improving Access to Psychological Therapies (IAPT) initiative, which has already significantly improved access for people with depression and anxiety (Clark, 2011; Gyani, Shafran, Layard, & Clark, 2013). IAPT led a call for demonstration sites to pilot their Severe Mental Illness approach for people with BD, psychosis and personality disorder. Here we summarise uptake and outcomes from the 3 year demonstration site for BD (January 2013 - October 2015), a joint venture between Birmingham and Solihull NHS Foundation trust and the Spectrum Centre for Mental Health, Lancaster University. Implications of findings from this demonstration site are considered in relation to potential for wider national changes in provision of psychological care for BD.

2. Method

2.1. Service context

Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) serves a culturally and socially diverse population of 1.2 million people. It employs over 4,000 staff and provides care for 60,000 service users. In 2015, BSMHFT had 2166 people with a diagnosis of BD. The Bipolar Disorder Service (BDS) provides structured integrated psychological treatment for adults with BD in the Trust. The Spectrum Centre based at Lancaster University is a multidisciplinary centre, which focuses on the development,

evaluation and implementation of effective psychological interventions for bipolar disorder in particular. During the IAPT SMI demonstration site period, the BDS service had 4.4 WTE staff (3 clinical psychologists and 1.4 WTE assistants) to deliver the Mood on Track Intervention. All clinicians who led groups were qualified clinical psychologists who were required to co-facilitate a full Mood on Track intervention before taking on a lead facilitator role. Data collection, analysis and reporting in relation to the demonstration site were registered as an approved audit by BSMHFT (Registration: 1276). All patients provided consent for coded data to be collected and analysed as part of the IAPT Demonstration site evaluation. IAPT funding supported an extra day per week of a clinical psychologist and an additional assistant psychologist in BSMHFT, as well as research psychologist input from the Spectrum Centre to collate and analyse outcome data.

2.2. Referrals

As an IAPT demonstration site, the service for BD was designed for patients who were not in a current acute manic or depressed episode state, but wanted structured psychological help with living with BD. Referrals came from Trust clinicians across BSMHFT including Community Mental Health Teams (CMHTs), Older adult services, Early Intervention services and primary care; these could be requested by the patient (<10 cases) or initiated by the clinician. Clinicians were aware of the MOT programme as it was part of the care pathway for the Trust. Patient awareness, where not prompted by a clinician, was typically through contact with someone who had themselves engaged in the MOT programme. All patients continued to receive usual clinical care from their clinical team whilst waiting for the MOT intervention.

2.3. Assessments

Each person referred was offered an assessment meeting with a trained clinical psychologist from the BDS with the option of bringing a friend or relative. During this assessment the treatment options within BDS were discussed were completed. This assessment was typically conducted 2-3 months after referral and was informed by clinical interview and review of case notes, to confirm the patient was not in an acute episode and that they understood the nature of the Mood on Track intervention. Self-report assessment data were collected for primary and secondary outcomes at baseline assessment (typically collected on the same day of the week 1 session of Mood on Track before the group formally began), mid therapy (week 4-5 depending on whether baseline was completed at initial assessment or in the first therapy session), end of therapy (week 10) and 3 and 6 months post therapy.

2.4. Therapy

The Mood on Track (MOT) psychological intervention offered by BDS following the initial assessment comprised 10-11 group sessions. MOT includes the key elements of

structured psychological therapy for BD indicated by NICE (2014). The original approach was developed by Sandra George (George, 1998) to integrate structured psychological support within a group format and has been updated repeatedly over time by BDS team members. Each session was facilitated by a Clinical Psychologist and co-facilitated, if required, by an Assistant Psychologist. The sessions combined information, with interactive exercises to pinpoint the role of thoughts, feelings and behaviours in depression and mania, and to teach strategies to help individuals to monitor their mood and recognise their own early warning signs. These sessions also reviewed the role of circadian rhythms in regulation of mood and offered strategies to monitor and stabilise their social rhythms. Mindfulness was also addressed in the programme, as well as stress management through the use of mindfulness relaxation techniques. The group MOT sessions also included relapse prevention training to enhance coping responses to early warning signs of mania or depression. Active participant engagement was encouraged including opportunities to discuss and share individual perspectives on each session topic. See Table 1 for a summary of topics covered in each of the 10 sessions.

All MOT therapists received monthly group supervision from a supervisor accredited in Cognitive Behavioural Therapy by the British Association for Behavioural and Cognitive Psychotherapy.

2.5. Measures

IAPT-SMI demonstration sites were tasked with instigating routine assessment and additionally monitoring clinical outcomes, patterns of service use and user perceptions of the service received. The core data set collected for the BD demonstration site is listed below intended to cover neglected personal recovery and quality of life outcomes along with assessment of manic and depressed mood.

2.5.1. Clinical Outcome Measures

2.5.1.1. Bipolar Recovery Questionnaire (BRQ, (Jones, Mulligan, Higginson, Dunn, & Morrison, 2013)

The Bipolar Recovery Questionnaire (BRQ) was developed to provide a quantitative measure of personal recovery in bipolar disorder. Patients consider their experiences in the past week in relation to their mental health and recovery across 36 subjective statements. Patients mark an 'X' at the point on the scale which best describes how much they agree with each statement (from strongly disagree to strongly agree). Higher BRQ scores indicate better personal recovery.

2.5.1.2. Bipolar Quality of Life Scale (QoL-BD, (Michalak & Murray, 2010)

The Brief Bipolar Quality of Life Scale is a 12-item scale used to determine an individual's quality of life over time across physical, sleep, mood, cognition, leisure, social,

spirituality, finance, household, self-esteem, independence and identity domains. Each item is rated from strongly disagree to strongly agree with higher scores reflecting better quality of life.

2.5.1.3. *Internal States Scale (ISS, (Bauer et al., 1991)*

The Internal States Scale (ISS) is a self-report measure used to assess mood states in BD. The Activation (5 items) and Wellbeing (3 items) subscales can be used together to evaluate manic and depressive mood states in individuals with bipolar disorder. Wellbeing above 125 and Activation above 155 indicates mania/hypomania whereas a score of less than 125 on the Wellbeing scale and less than 155 on the Activation scale indicate a depressed state.

2.5.1.4. *Generalised Anxiety Disorder-7 Questionnaire (GAD-7, (Spitzer, Kroenke, Williams, & Lowe, 2006)*

The GAD7 is a 7-item scale measuring generalised anxiety disorder. Patients reported frequency of anxiety problems over the previous 2 weeks on a 4-point scale (0- Not at all to 3- Nearly every day). The total score for the GAD7 for the 7 item questionnaire ranges from 0 to 21. A score of 0-5 represents mild anxiety, 6-10 moderate anxiety, 11-15 moderately severe anxiety and a score of 15-21 represents severe anxiety in a patient.

2.5.1.5. *Patient Health Questionnaire-9 (PHQ-9, (Kroenke, Spitzer, & Williams, 2001)*

The PHQ9 is a 9-item depression self-report scale. Each item was rated on a scale of 0 (not at all) to 3 (nearly every day), in relation to the previous 2 weeks. A score of 0-4 indicates no depression symptoms, 5-9 represents mild depression, 10-14 represents moderate depression, 15-19 moderately severe depression and a score of 20-27 indicates severe depression.

2.5.1.6. *Work and Social Adjustment Scale (WASAS, (Mundt, Marks, Shear, & Greist, 2002)*

The Work and Social Adjustment Scale assesses impairments in ability to carry out day-to-day day tasks including work and leisure activities. Participants responded to five statements on a scale from 0 (not at all) to 8 (very severely) indicating impact on this aspect of their life. A score of 20-40 indicates moderate/ severe psychopathology; 10-20 indicates milder but significant functional impairment, <10 suggests absence of functional impairment.

2.5.2. *Service Use Data*

Service use data was collected from the electronic case record (ECR) system within BSMHFT with respect to crisis/home treatment team contacts and acute mental health admission bed days for 12 months prior to therapy, during the therapy period and post-therapy up to 12 months.

2.5.3. Patient Experience

2.5.3.1. Patient Experience and Choice Questionnaire

This 5-item questionnaire IAPT questionnaire (IAPT, 2011) is rated on a 5-point scale ('At all times' to 'Never') concerning ratings of their treatment experiences. This measure was completed at end of treatment.

2.6. Analyses

Baseline scores (pre-therapy) were paired with the last score available for each patient (post therapy) to create the paired scores consistent with previous IAPT reports (Gyani et al., 2013; Jolley et al., 2015). For example, if the last data point that was recorded was at 6 months follow up, this was used in the analysis, however if this was not available either 3 month follow up, end of treatment or mid therapy data was used. In order to assess the significance of change from pre therapy to post therapy in primary (BRQ) and secondary (QoL-BD, GAD7, PHQ9, WSAS, ISS-W and ISS-A). Given the work of Kessing et al (Kessing et al., 2014), subsidiary analyses were conducted using mixed ANOVAs to test for interaction between age group (18-30 vs ≥ 31 years) and continuous outcomes. We did not split age groups at 25 years, as this led to sample size of only 13-14 in the younger age group compromising power to detect potential interactions, whereas using a cut point at 30 years provided a minimum of 34 younger participants. It was not possible to conduct these analyses on service use variables as cell sizes were too small during treatment and follow-up (cell sizes < 10).

Average number of days per person per month were calculated for crisis/home treatment team (HTT) contacts and occupied bed days (OBD) and compared using the z test (Kirkwood & Sterne, 2003). Service use data compared mean monthly usage in the 12 months prior to treatment with usage during treatment and up to 12 months post treatment.

3. Results

3.1. Demographic characteristics (Table 2)

The sample was predominantly female and middle-aged (over half from the 36-64 age group). The largest ethnic group was White British; ethnic distribution of the sample was in line with the ethnic distribution of the Trust footprint (Solihull Observatory, 2016) for which the predominant grouping is white British with smaller groupings of individuals of Asian or Caribbean ethnic backgrounds.

3.2. Mood and functioning at Baseline (Table 3)

Bipolar Recovery Questionnaire (BRQ) scores were below those in the development study of the measure (Jones, Mulligan, Higginson, Dunn, & Morrison, 2013; 2357.7 s.d. 414) suggesting that personal recovery levels were modest. QoL-BD scores were lower than those in the measure development paper and consistent with pre-intervention levels in a previous online intervention trial indicating modest quality of life (Michalak & Murray, 2010; Todd, Jones, Hart, & Lobban, 2014). GAD7 and PHQ-9 scores respectively suggested that patients are experiencing moderate anxiety and moderate to severe depression (Kroenke et al., 2001; Spitzer et al., 2006). More specifically, for GAD7, n=52 (32%) had mild/no anxiety, n=42 (26%) had moderate, n=30 (18%) had moderate to severe and n=29 (18%) had severe anxiety. For PHQ-9, n=36 (23%) were experiencing no depression, n=38 (24%) mild, n=43 (27%) moderate and n=43 (27%) severe depression. Internal States Scores (ISS) for Wellbeing and Activation indicated scores just below depression and just above hypomania cut offs respectively (Bauer et al., 1991; Bauer, Vojta, Kinosian, Altshuler, & Glick, 2000). ISS cut-offs indicated that n=116 (74%) were not depressed, whilst n=41 (26%) were and n=117 (75%) were not hypomanic, whilst n=40 (25%) were reporting hypomania. Given the discrepancy in depression patterns between ISS and PHQ-9 we also checked which individuals meet depression criteria on both measures; n=27 (17%) of those at baseline met criteria on both measures. WSAS scores at baseline indicated similar functional difficulties to those identified in large study of patients with depression (Mundt et al., 2002). Overall, this data suggests that patients were experiencing significant subsyndromal symptoms and functional difficulties at baseline.

3.3. Assessment and therapy (see Figure 1)

Between 2006-2012, BDS saw 244 patients through to completion at an average rate of 41 per annum. In contrast, over the period January 2013 to October 2015 of IAPT-SMI pilot funding 166 completed treatment, representing a 54% increase to 63 per year.

During the pilot 258 patients were assessed of whom 202 began treatment. Of the individuals who did not start treatment; 21 declined, 10 were deemed unsuitable for the service, 3 were referred elsewhere and reasons were not known for 6. The reasons why people declined treatment were often practical issues such as being unable to arrange time off work, or arranging childcare. Some patients also declined treatment due to concern about the group format, especially those experiencing social anxiety. The waiting time from referral to first treatment session was an average of 256.5 days. Of 202 people who began treatment, 83% completed (>5 sessions), 17% dropped out and 2% were referred to another service. The total number of group (MOT) sessions attended was 1419 across all patients who completed treatment. The median average number of sessions per patient completer was 9 (range 6-10).

3.4. Clinical and Functional Outcomes (see Table 3 and Supplementary Table 1)

3.4.1. Primary outcome

3.4.1.1. Recovery

BRQ scores improved between pre and post therapy, difference was of medium effect size and statistically significant. There was no significant interaction between effect and age group of the patients.

3.4.2. Secondary outcomes

3.4.2.1. Quality of life and function

Quality of life and social functioning as measured by QoL-BD and WASAS respectively improved significantly between pre and post assessments. In contrast to the personal recovery outcomes the effect sizes for both of these differences were small. There was no significant interaction between effect and age group of the patients.

3.4.2.2. Mood and Anxiety Symptoms

All measures of anxiety and low mood improved from pre to post therapy. Differences were significant for anxiety (GAD7) and depression (PHQ9, ISS-Well being). Manic symptoms showed a non-significant trend towards improvement ($p < 0.1$). All effect sizes were small. There was no significant interaction between effects and age group of patients.

3.5. Patient Satisfaction

Patient Experience and Choice Questionnaire data indicated high levels of satisfaction with both the treatment and service in general on completion of MOT from the 98-100 patients who provided data. As this measure was completed by participants during the final few sessions (8-10) of MOT, data was not available for those who completed $>5=$ sessions but ≤ 8 . 99% (n=99) felt that staff listened and treated concerns seriously all or most of the time, 93% (n=99) felt the service helped to address their difficulties all or most of the time, 91% (n=97) felt that they had been involved in making choices about treatment or care all or most of the time, 93% (n=99) felt that they had got the help that mattered to them all or most of the time and 98% (n=100) had confidence in the therapist and their skills all or most of the time.

3.6. Service use (Figures 2A and 2B)

Average service use data (days per month) were available for all patients who completed treatment and who dropped out.

Crisis contacts and acute bed days were significantly lower during treatment and follow-up compared to pre-treatment. The only difference between those completing treatment and those who dropped out was for crisis contacts which were significantly lower for completers at follow-up ($Z = -2.91, p < .05$).

4. Discussion

This paper evaluated, for the first time, the impact on service uptake and outcomes over 3 years of the sole IAPT UK demonstration site for bipolar disorder. This site was already delivering an established service in BSMHFT before IAPT support, which funded an additional MOT group annually as well as collection and analysis of outcome data. Trust sites were accepting of this approach during the demonstration site period. Historically, 5-6 years ago, a number of Trust Consultants not believe or support in non-pharmacological treatment of this type, but by the onset of the demonstration site all clinical teams were willing to refer. The Mood on Track intervention was informed by principles of CBT and psychoeducation, with participants actively encouraged to engage with and debate information provided by facilitators. Similar to Colom & Vieta's group psychoeducation approach (Colom et al., 2003), MOT covers detection of early warning signs and information on how to respond to these as well as ways to manage stress. The interventions differ in that MOT is considerably shorter (10 sessions vs 21 sessions), has less of an emphasis on medication and use of services as the primary responses to early warning sign detection and stronger emphasis on psychological strategies for ongoing management. Findings indicated that the structured approach to delivery and assessment of psychological care was feasible, acceptable and potentially effective. The demonstration site increased treatment completion rates compared to the previous 6-year period, with 81% of those starting treatment completing it. There was also evidence of improvements across a range of outcome measures. Primary outcome of personal recovery improved with a moderate effect size to post therapy. There were also significant improvements in work and social functioning, quality of life, anxiety and depression symptoms. IAPT Patient Experience and Choice Questionnaire results indicated high levels of satisfaction with the service and the care received with 98% reporting confidence in their therapist all or most of the time. Patient satisfaction data, whilst encouraging, should be treated with some caution as data was only available for participants who completed 8 or more sessions. Use of acute services including assertive outreach and hospital admission reduced during and after treatment.

It is difficult to compare outcomes with other research due to the lack of published studies of routine outcomes in response to psychological therapy in BD. Oud et al (Oud et al., 2016) reported on a meta-analysis of all of the structured psychological intervention

data considered for the NICE guideline (2014a). They reported a small effect size for change in depressed mood following group psychological interventions, but this was based on comparison at post treatment with treatment as usual participants and therefore cannot be directly compared. A recent network meta-analysis of psychological therapies for bipolar disorder indicated that combining psychoeducation with CBT was linked to improvements in mania symptoms and functioning with medium and large effects respectively, but no significant impact on depressive symptoms (Chatterton et al., 2017). Colom and Vieta reported sustained effects of group psychoeducation compared to peer support on relapse rate, time to mood episode and hospitalisations (Colom et al., 2009; Colom et al., 2003). When this intervention was delivered in a UK NHS context, outside of a specialist clinic, time to relapse was numerically greater in those receiving group psychoeducation, but this was not statistically significant and there were no differences with respect depression or manic mood symptoms. A significant improvement in interpersonal social functioning was observed but not on other measures of social and occupational functioning (Morriss et al., 2016). Jones et al (2015) obtained a medium effect size for improvement in personal recovery following individual therapy in adults with recent onset bipolar disorder with smaller effects for quality of life and no impact on mood (Jones et al., 2015). Kessing et al's finding of numerically, but not statistically significantly, better outcomes in terms of relapse risk for younger patients led them to argue that the effect of age on treatment outcomes deserved further investigation (Kessing et al., 2014). In the current report there were no significant interactions between membership of young ≤ 30 years or older patient age groups and any of the self-reported outcomes, nor was there a numerical pattern of greater improvement in younger patients. Service use outcomes were not analysed by age as cell sizes for use during and after MOT were too small.

There have been a small number of open trials of structured psychological treatment for bipolar disorder, including evaluations of group CBT, group psychoeducation and a remotely delivered collaborative care approach. Patelis-Siotis reported no effects on mood at post treatment following group CBT, but improvements in functioning and quality of life (medium effects) (Patelis-Siotis et al., 2001). Provencher conducted an implementation study of group psychoeducation reporting post treatment improvements in knowledge about bipolar and depression (large and medium effects respectively) (Provencher et al., 2014). Finally, Bauer and colleagues identified a small, but significant, effect post-treatment for depression and a medium effect on mental health quality of life for their collaborative care intervention delivered by video conferencing (Bauer et al., 2016). A limitation of all of these open trials is the small samples providing data, 22-35 providing outcome data in the Patelis-Siotis study, 47-50 in Provencher and 79 in Bauer. Overall, MOT seems to offer benefits in personal recovery, functional outcomes, service use and, to a less extent, mood. Effect sizes were similar to, or greater than, those observed above. As noted above, for these effects to be directly compared to randomised controlled data a clinical and effectiveness RCT of MOT would be required.

The partnership between BSMHFT and Spectrum was effective in bringing together clinical and academic expertise in bipolar disorder. BSMHFT had an established infrastructure for the referral and assessment of patients with bipolar disorder within the Trust and expertise in the delivery of structured psychological therapy through BDS. Additional support in the identification and selection of standardised outcome measures was an important step in providing more systematic outcome data. The outcome data set was selected in consultation with service users in both BSMHFT and Spectrum including the selection of the BRQ as a measure of recovery as a primary outcome. IAPT funding provided additional clinical time for service delivery and assessment (0.2 WTE clinical psychologist and 1.0 WTE psychological assistant). This allowed extra patients to be assessed and extra groups delivered through the existing care pathway supported at a senior management level by AG as Trust Director of Psychological services. The service delivers psychological care through qualified clinical psychologists supported by assistant psychologists whose duties include assessment data collection. The qualified staff had substantial experience working with individuals with bipolar disorder and the whole clinical team had regular access to clinical supervision throughout the demonstration site period.

The data on feasibility and acceptability are relatively clear from this study. However, this was not an RCT and we do not have data on outcomes for individuals not offered this service, so definitive evaluation of effectiveness was not possible. Assessors were not blind and therefore it is not possible to rule out the impact of non-specific effects outside the intervention on the outcomes measured. There were seven pre- post comparisons, so it is possible that multiple measurement might have yielded false positives. Applying Bonferroni correction would lead to the differences in depression no longer being significant but all other outcomes would stand. Applying the less conservative Glickman approach (Glickman, Rao, & Schultz, 2014) would conclude that depression findings remain significant. Clinical interviews were conducted with patients in advance before starting MOT to confirm they were not in an acute mood episode. Self-report data at baseline indicated 54% were experiencing at least moderate mood symptoms using PHQ-9, however the accuracy of this as a diagnostic tool has been questioned with a number of authors citing evidence of over diagnosis compared with other measures or clinical interview (Jerant et al., 2014; Cameron et al., 2008). Consistent with this using the combined data from ISS and PHQ-9 scores indicated that only 17% of patients met self-report criteria for depression.

Until relatively recently there was limited evidence on the effectiveness of psychological interventions for bipolar disorder. As the recent NICE guidance indicates, this situation has now changed to a significant degree. A current challenge, recognised by NICE and NHS England with the Access and Waiting Times Directive (<https://www.england.nhs.uk/wp-content/uploads/2015/02/mh-access-wait-time-guid.pdf>) is how to increase access to structured psychological care in a systematic manner with routine outcome monitoring in clinical practice. The results of this demonstration site initiative indicate that such delivery is possible, can be integrated with service delivery and

is accepted by patients. Based on this encouraging start it is important that other Trusts with less well established services for bipolar disorder are supported to adopt the successful approach delivered through the demonstration site.

This service provided increased access to structured psychological therapy with benefits to patients in improving personal recovery, clinical outcomes and functioning. This demonstration site therefore provides a potential model for how to deliver psychological care and support in a NICE concordant manner in routine care. Evidence of reduced acute care service use for those offered this service suggests potential cost savings.

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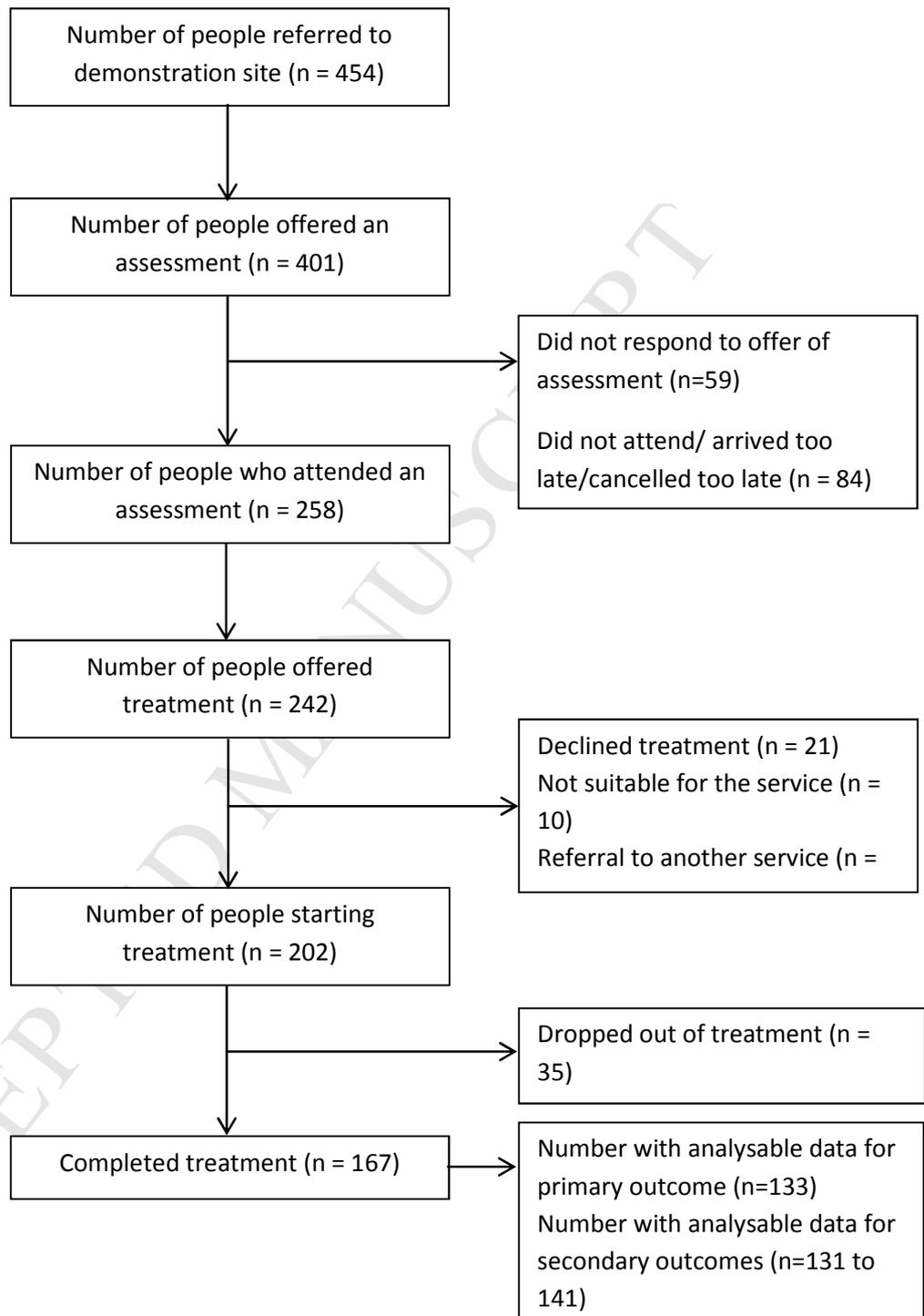
Figure 1 Participant flow through IAPT demonstration site.

Table 1

Mood on Track session content

Session	Session content
1	What is bipolar disorder? Who develops it and how can you recognise and self monitor mood for risk of relapse?
2	Understanding the roles of thoughts, feelings and behaviour in managing mood. What is mania? Early warning signs and the role of thinking in hypomania
3	What is depression? Early signs of depression. The role of thinking in depression. Understanding the role of biological clocks. Managing your social rhythms. Establishing a healthy sleep routine
4	Understanding medication. What it is and how it works. The function of the brain in mood changes. Over the counter medications and substances— what you need to know. The role of self-medication. Pregnancy
5	Understanding the role of stress in bipolar disorder-how to recognise it and the importance of developing effective skills to manage it. Risks associated with bipolar disorder
6	Supporting family members. Introduction to the potential needs of family members and support available
7	Coping with hypomania – understanding the role of stimulation. Managing

8	thinking changes in hypomania. The importance of time management. Discovering strategies to lift your mood. The role of unhelpful thinking in depression – how to recognise it and how to use effective strategies to manage this. Enhancing stimulation to improve your mood. Improving your problem solving skills
9	Mind and Body Stimulation Control. Introduction to and application of mindfulness-based approaches to calming mental and physical stimulation.
10	Putting it altogether and managing special situations. Using the 'On Track Relapse pack'.

ACCEPTED MANUSCRIPT

Table 2

Demographic characteristics of the total sample assessed (n= 258).

Variable	Percentage
Age	
18-25	6%
26-35	32%
36-64	59%
65+	3%
Gender	
Male	32.6%
Female	67.4%
Ethnic Group	
White British	63%
Black- British Caribbean	7%
Asian British- Pakistani	7%
Other ethnic group	20%
Not Stated	3%

Table 3

Baseline and post intervention analyses for clinical outcome measures.

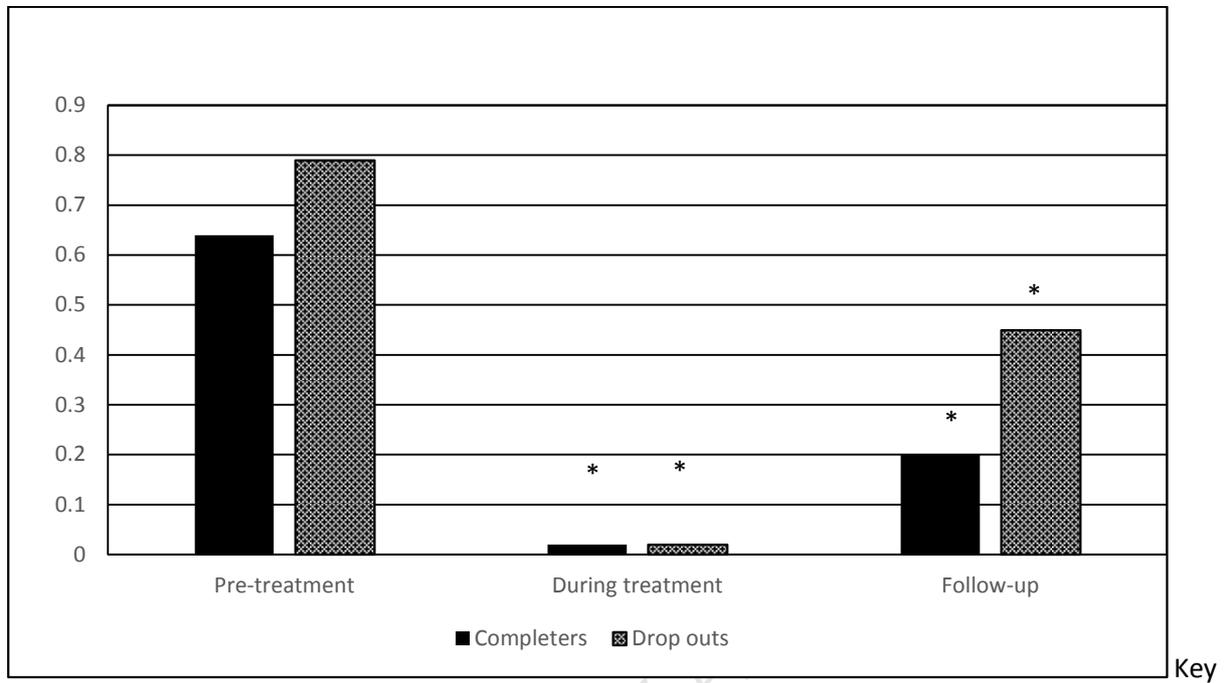
	Number of paired outcomes	Baseline Mean (SD)	Post Score Mean (SD)	Paired t-test
Bipolar Recovery Questionnaire n=153	133	1998.3 (387.2)	2221.0(419.4)	p<.0005, d=.52 ^a
Brief Bipolar Quality of Life Scale n=161	140	35.9 (9.1)	39.4 (10.4)	p<.0005, d=.33 ^b
Generalised Anxiety Disorder- 7 Questionnaire n=162	141	9.1 (6.2)	7.2 (6.2)	p=.001, d=.28 ^c
Patient Health Questionnaire-9 n=160	139	10.9 (7.1)	8.9 (6.8)	p=.011, d=.22 ^d
Work and Social Adjustment Scale n=155	131	18.4(9.0)	14.2 (10.0)	p<.0005, d=.39 ^e
Internal States Scale- Wellbeing n=157	139	138.1 (81.9)	156.6 (78.8)	p=.018, d=.20 ^f
Internal States Scale- Activation n=157	138	155.8 (122.1)	135.1 (110.6)	p=.086, d=.15 ^g

n= number of patients completing measure at baseline

^a t(132)=6.00, ^b t(139)=3.85, ^c t(140)=-3.29, ^d t(138)=-2.59, ^e t(130)=-4.49, ^f t(138)=2.39, ^g t(137)=-1.73

Figure 2A.

Average crisis/home treatment contacts per person per month

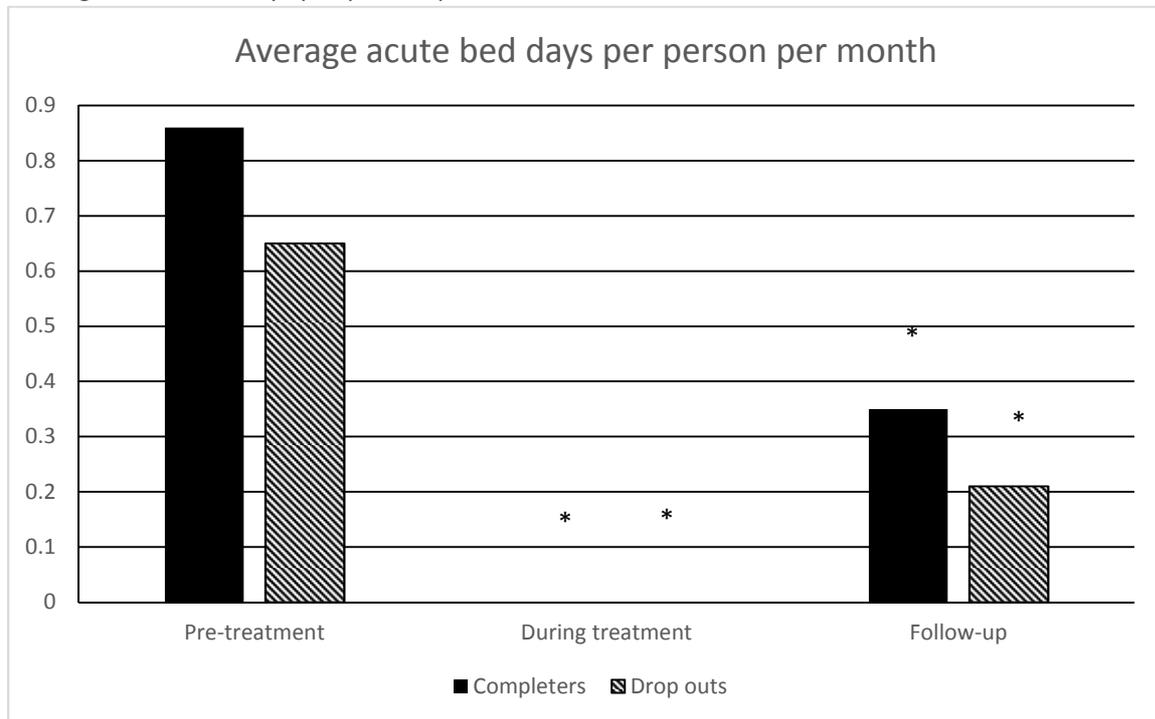


Key:

*Z score significantly different from baseline

Figure 2B.

Average acute bed days per person per month



Key:

*Z score significantly different from baseline