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Research report

Early warning signs checklists for relapse in bipolar depression and mania: Utility, reliability and validity

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ABSTRACT

Background: Recognising early warning signs (EWS) of mood changes is a key part of many effective interventions for people with Bipolar Disorder (BD). This study describes the development of valid and reliable checklists required to assess these signs of depression and mania.

Methods: Checklists of EWS based on previous research and participant feedback were designed for depression and mania and compared with spontaneous reporting of EWS. Psychometric properties and utility were examined in 96 participants with BD.

Results: The majority of participants did not spontaneously monitor EWS regularly prior to use of the checklists. The checklists identified most spontaneously generated EWS and led to a ten fold increase in the identification of EWS for depression and an eight fold increase for mania. The scales were generally reliable over time and responses were not associated with current mood. Frequency of monitoring for EWS correlated positively with social and occupational functioning for depression (beta = 3.80, p = 0.015) and mania (beta = 3.92, p = 0.008).

Limitations: The study is limited by a small sample size and the fact that raters were not blind to measures of mood and function.

Conclusions: EWS checklists are useful and reliable clinical and research tools helping to generate enough EWS for an effective EWS intervention.

1. Introduction

Bipolar Disorder (BD) is a common and severe mental health problem characterised by repeated relapses of mania or depression. Recurrence rates are high at around 50% at one year and 70% at four years (Altshuler et al., 2002; Gitlin et al., 1995; Perlis et al., 2006; Yatham et al., 2009). Surveys of patient organisations in the US and UK reveal a strong wish by patients for both self-help and psychological treatments in addition to pharmacotherapy (Hill et al., 1996; Lish et al., 1994; Morselli et al., 2004). Evidence shows that teaching people to recognise and manage Early Warning Signs (EWS) of relapse can increase time to recurrence, decrease hospitalisation and improve functioning (Morriss et al., 2007). Accurate and early detection of warning signs is crucial to the effectiveness of such interventions. The rationale for EWS interventions relies on sufficient warning signs being detected early enough in the prodromal phase to allow action to be taken to prevent further escalation. Evidence suggests that a minimum of three or four

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early signs can be used but more than six is likely to be necessary for an effective intervention (Morriss, 2004). EWS must be distinguishable from ongoing inter-episode symptoms (which are not specific indicators of relapse), and consistent over subsequent relapses as markers for these events within an individual, resulting in a "relapse signature" (Molnar et al., 1988).

Previous research suggests that 70–80% of people with bipolar disorder can identify one or more prodromal symptoms (Goossens et al., 2010; Jackson et al., 2003) and early symptoms of mania are identified more frequently than early symptoms of depression. Whilst research suggests that there is inter-individual variation, studies have found some consistency between individuals in their reporting of EWS of mania and depression (Goossens et al., 2010; Lam and Wong, 1997; Molnar et al., 1988; Smith and Tarrier, 1992), with the most common EWS for mania being "changes in sleep" and for depression "loss of interest". Smith and Tarrier (1992) asked people to generate their own EWS and found a number of idiosyncratic ones (e.g. 'getting very angry with my ex-wife'; 'increased sensitivity to racism'; 'cutting face') emphasising the need to allow for individuality. However, within each individual, there is evidence for consistency in warning signs over time (Molnar et al., 1988), suggesting that individual "relapse signatures" are applicable to bipolar disorder.

A tool to help people identify their own EWS would be beneficial clinically and key to research aiming to identify mechanisms of effective psychosocial and pharmacological interventions involving the recognition of EWS (Morriss et al., 2007). It is important that this tool is flexible enough to pick up idiosyncratic EWS as well as prompting for more common EWS, and that it can be used by people experiencing mood changes, and those close to them who are often the first to notice early signs.

In this study we report on the development and evaluation of the first EWS checklists for depression and mania. This paper will describe the development of the measures and present data on test–retest reliability, and construct validity. Importantly, clinical utility of the measures as assessed by the extent to which the measures can improve on spontaneous recall of EWS will be reported.

2. Method

2.1. Development of EWS checklists

Two separate two-part measures were developed — one for early signs of depression and one for early signs of mania. The first part (the 'front sheet') asks respondents to spontaneously list their early warning signs, to indicate whether or not they attempt to monitor these signs, and if so how frequently (never, occasionally, fairly regularly, very regularly). The second part is a checklist of 32 items (depression) and 31 items (mania) and respondents indicate for each item whether it is not something they experience (absent) or if it occurs in the relapse process, early, late or not until they are in full relapse. Each item is therefore rated as absent/early/late/full. Early is defined in the instructions as "I DO experience this and it is one of the FIRST things I notice", late is defined as "I DO experience this and it occurs LATER as my mood is becoming lower/higher". Full relapse is defined as "I DO experience this but ONLY when I am having a full relapse". If more than one response is given for an item then it is rated as the earliest answer, as many early signs continue through relapse.

Items for the checklists were derived from reviewing existing literature that reported EWS for depression and mania. More specifically, items for the checklists were taken from Molnar et al. (1988) (depression items = 1,5,9,10,12,14,15,16,17,18,25,28,29,30; mania items = 1,3,6,7,10,13,24,26,28); Smith and Tarrier (1992), (depression items = 1,3,5,9,10,11,12,13,14,16,17,18,19,20,21,22,23,24, 25,26,27,28, mania items = 1,2,3,4,6,8,9,10,11,12,13,14,15, 16,17,18,19,20,21,22,23,24,25); Lam and Wong (1997), (depression items = 2,3,5,8,9,10,15,17,18,19,20,24, mania items = 7,9,15,24,25,29); Wong and Lam (1999), (mania items = 1,6,7,9,10,13,15,19) and Lam et al. (2001), (depression items: 2,3,8,9,10,15,17,18,19,20,24, mania items = 7,9,15,25,26).

The EWS checklist items were initially given by post to a convenience sample of 50 volunteer respondents who declared that they were diagnosed with BD recruited via an advertisement from a national service user charity (MDF: The Bipolar Organisation). The sample were predominantly female (78%) with a mean age of 47 (sd = 9.97). Respondents were asked to complete the checklist, to comment on the relevance and wording of the items, and to add any EWS they experienced that were not included in the checklist. Postal feedback from this phase led to refinements to some of the wording, and some additional items (depression items = 4,6,7,31,32; mania items = 5,27,30,31).

2.1.1. Scoring of checklists

The frequency of monitoring of EWS on the front sheet is scored on a four point scale where never = 1, occasionally = 2, fairly regularly = 3 and very regularly = 4. Similarly, each item on the EWS checklist is scored on a four point scale where absent = 1, early = 2, late = 3 and full relapse = 4.

2.2. Methods of psychometric evaluation and statistical analysis

2.2.1. Participants for psychometric evaluation

The psychometric properties of the EWS checklists were assessed using data from a different sample of participants in a cluster randomised control trial of Enhanced Relapse Prevention (ERP) for bipolar disorder vs. treatment as usual (TAU) (Lobban et al., 2010). Service users in participating Community Mental Health Teams (CMHTs) were invited to take part if they had a lifetime diagnosis of BD I or II, had experienced two or more relapses since their diagnosis, with at least one in the last three years, and did not meet criteria for a major depressive, manic or mixed episode in the four weeks before baseline (assessed using the SCID-LIFE interview (Paykel et al., 2006)). All gave written and verbal informed consent to the study which was also passed by a local research ethics committee. Teams were independently randomised using simple random allocation stratified by site.

Of the total sample (n = 96), 94 (98%) had type I BD and 2 (2%) had type II BD. Sixty five (68%) of the sample was female. The mean age of the sample was 44.0 years (sd = 10.4). Thirty-five (37%) participants were single, 28 (29%) were