A randomised controlled trial of a worry intervention for individuals with persistent persecutory delusions

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**Abstract**

Recent research has shown that worry is associated with distressing paranoia. Therefore, the aim was to target worry in a therapeutic intervention for individuals with delusions. It was predicted that a worry intervention would reduce levels of worry and paranoia distress. Twenty-four individuals with persistent persecutory delusions and high levels of worry were randomly assigned to receive a four session cognitive-behavioural worry intervention (W-CBT) or treatment as usual (TAU). The worry intervention was specifically designed not to target the content of delusions. In this open-label evaluation, assessments of worry and paranoia were conducted at baseline, at one month (end of treatment) and at two months. The worry intervention achieved a statistically significant reduction in worry which was maintained at two month follow up. A significant reduction in delusional distress was also reported. There was an indication that the worry intervention may also reduce the frequency of paranoid thoughts but this was not statistically significant. In the first trial specifically for persecutory delusions, a brief worry intervention was shown to have benefits. The results support a causal role for worry in paranoid experience.

1. Introduction

Developments in the understanding of persecutory delusions have the potential to lead to improvements in treatments. Worry, defined as ‘a chain of thoughts and images, negatively affect-laden and relatively uncontrollable’ (Borkovec, Wilkinson, Folensbee, & Lerman, 1983), is a factor that has recently been implicated in paranoid experience. Clinical levels of worry are present in almost two-thirds of individuals with persecutory delusions and the presence of worry is associated with more distressing delusional experience (Bassett, Sperling, & Freeman, 2009; Freeman & Garety, 1999; Morrison & Wells, 2007; Startup, Freeman, & Garety, 2007). A catastrophising worry style predicts the occurrence of non-clinical paranoia and the persistence of persecutory delusions (Freeman et al., 2008; Startup et al., 2007). Emphasis is placed on the importance of worry in a cognitive model of persecutory delusions (Freeman, 2007; Freeman & Freeman, 2008). The intriguing implication is that treatment of worry in individuals with persecutory delusions will also lessen paranoia.

Worry has been successfully targeted in people with generalised anxiety disorder using cognitive-behavioural interventions (see review by Covin, Ouimet, Seeds, & Dozois, 2008). We aimed to examine in a small pilot study whether a brief cognitive-behavioural worry intervention has the potential to be effective at reducing levels of worry and delusional distress in individuals with persecutory delusions and clinically significant levels of worry. The main prediction was that the worry intervention would reduce both worry and paranoia distress compared with treatment as usual. A secondary hypothesis was that the worry intervention would reduce the overall occurrence of delusional thoughts. Strengthening the support for the causal role of worry, it was also predicted that changes in worry would be associated with changes in paranoia.

2. Method

2.1. Participants

The patients with persecutory delusions were recruited from the South London and Maudsley NHS Foundation Trust. The inclusion criteria were: a current persecutory delusion as defined by Freeman and Garety (2000); the delusion had persisted at least six months; a current clinical diagnosis of schizophrenia, schizoaffective disorder or delusional disorder; a clinically significant level of worry, as indicated by scores of 45 or more on the PSWQ (Behar, Alcaine, Zuellig, & Borkovec, 2003; Startup & Erickson, 2006); and aged...
between 18 and 65. Criteria for exclusion from the trial were: a primary diagnosis of alcohol or substance dependency; organic syndrome or learning disability; a command of spoken English inadequate for engaging in psychological therapy; judged as unable to give informed consent; and currently engaged in any other individual CBT.

2.2. Design

Participants were randomly allocated to one of two conditions: a four session worry reduction intervention and treatment as usual (W-CBT), or treatment as usual (TAU). Participants meeting the entry criteria were randomly allocated to each condition in a 1:1 ratio using randomised permuted blocks varying from two to four (carried out by a researcher independent of the team). Random allocation followed completion of the baseline assessment (a sealed envelope was opened). Data were collected at three time points: at baseline assessment before randomisation, at one month from randomisation and at two months from randomisation. The assessments were carried out by the therapist (CF) and were, therefore, not blind. Ethical approval for the study was obtained from the Joint South London and Maudsley and the Institute of Psychiatry NHS Research Ethics Committee. Data collection was carried out from June 2007 to April 2008.

2.3. Treatment and control conditions

Participants in the W-CBT arm of the trial were offered four sessions over one month. The worry reduction strategies included were (i) indicated in the literature to be effective at reducing worry, either alone or in conjunction with other anxiety management strategies; (ii) did not challenge or review the delusion itself; and (iii) had been used by the authors in clinical practice. Key influences were Borkovec, Ray, and Stober (1998), Butler, Gelder, Hibbert, Cullington, and Klimes (1987), Dugas and Ladouceur (1998), Leahy (2006), and Wells (1997). The main techniques were psychoeduction about worry, reviewing of positive and negative beliefs about worry, increasing awareness of the initiation of worry and identification of individual triggers, learning to ‘let go’ of worry, use of worry periods, substituting problem-solving in place of worry, and relaxation exercises. A simple individualised formulation of each person’s worry was developed and homework between sessions was agreed. Written information was provided in the form of a leaflet called ‘Winning against Worry’. The therapy was provided by the first author under the supervision of the two other clinical psychologists.

TAU consisted of standard care, delivered according to national and local service protocols and guidelines. During hospitalisation, TAU usually involves prescription of anti-psychotic medication, occupational therapy activities and exercise groups. Following discharge, the level of TAU varies according to the needs of the individual. However, this usually consists of prescription of anti-psychotic medication, visits from a community mental health worker and monthly outpatient appointments with a psychiatrist.

2.4. Outcome measures

2.4.1. Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990)

The PSWQ is the most established worry questionnaire. It is designed to capture the generality, excessiveness and uncontrollability of worry. Respondents are asked to indicate how typical sixteen statements are of them on a five-point scale, ranging from “not at all typical of me” to “very typical of me”. A high score represents a greater degree of worry. The PSWQ has demonstrated sensitivity to change across both 6-week and 12-week therapeutic interventions for GAD (Borkovec & Costello, 1993).

2.4.2. Psychotic Symptoms Rating Scale: Delusions Subscale (PSYRATS; Haddock, McCarron, Tarrier, & Faragher, 1999)

The PSYRATS, increasingly used in psychosis research (e.g. Lewis et al., 2002), provides a multi-dimensional interviewer rating of delusional beliefs. Each of the six items are rated on a five-point ordinal scale (0–4) and concern the past week. Items on the PSYRATS relating to preoccupation, duration, conviction and disruption load onto Factor 1, labelled ‘cognitive interpretation’, and items relating to amount and intensity of distress load onto Factor 2, labelled ‘emotional impact’. The factor structure was confirmed in a study of over two hundred and fifty individuals presenting with acute first episodes of schizophrenia (Drake, Haddock, Tarrier, Bentall, & Lewis, 2007).

2.4.3. Green et al. Paranoid Thought Scales (GPTS, Green et al., 2008)

The GPTS comprises two 16-item scales: Part A, which assesses social ideas of reference, and Part B, which assesses ideas of persecution. Respondents are asked to indicate on a five-point scale from one (not at all) to five (totally) how often they have experienced each paranoid thought over the past month. Higher scores represent a greater degree of delusional ideation. Within the GPTS are eight-item subscales of conviction, preoccupation, and distress. Convergent validity of the GPTS with the Paranoia Scale (Fenigstein & Vanable, 1992) and the Psychotic Symptoms Rating Scale (Haddock et al., 1999) has been shown.

2.5. Intellectual functioning

2.5.1. Wechsler Test of Adult Reading (WTAR; Wechsler, 2001)

The WTAR was used as an assessment of premorbid intellectual functioning and consists of 50 words with irregular pronunciations which the participant is required to read aloud.

2.6. Statistical analysis

The outcomes (PSWQ, PSYRATS, GPTS) at one month and two months post-randomisation were modelled by the use of multilevel linear regression. Multilevel linear regression was used as the data produced were longitudinal in nature, and participants were included as a random effect. An advantage of this approach is that it can easily be used if any data are missing and, therefore, provides a way to achieve a fully multilevel analysis of repeated measures with incomplete data (Van Der Leeden, 1998). The models include the respective baseline measurement to control for pre-treatment differences, treatment group (represented by one dummy variable), time (since the one month assessment), and a treatment time interaction term as an explanatory variable. As an interaction term was fitted in all models, the coefficient of the treatment group represented the mean difference between the treatment groups at the one month assessment adjusting for any baseline differences. The models were fitted in Stata (version 10) (Stata Corporation, 2007) using the xtmixed command. In all the analyses, a multilevel model with random intercepts was applied as it was deemed a more appropriate fit than a random coefficient model due to reduced standard errors of within and between patient variance in comparison to the random coefficient model. A full analysis set of participants was used following ICH topic E9. Randomised participants were excluded from the full analyses set if they provided no data post-randomisation. The association between change in worry and in paranoia was examined using Kendall’s tau; this non-parametric measure was used because Kendall’s tau is more robust
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