An open trial in the NHS of Blues Begone®: A new stand alone computer-based CBT psychotherapy program

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2. An open trial in the NHS of ‘Blues Begone’.

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Abstract

Computer based treatments for depression and anxiety have been available for several years and have demonstrated useful clinical effects (Cavanagh et al, 2006). Most existing computerised CBT products designed to treat depression and anxiety require patients to visit a clinic and require staff input to manage the process which adds to the costs and bottlenecks in delivering a clinically effective treatment with mass availability. Blues Begone® is a new computerised CBT program which has been designed to be completely stand-alone requiring no additional human support. This pilot project provides data from an open trial of Blues Begone® with both primary and secondary care patients. One hundred patients started Blues Begone®, 58% completed the program, 72% (n=42) of completers achieved reliable and clinically significant change with 60% (n=35) considered recovered at the end of the program. This data provides the first demonstration of the potential viability of a genuinely stand alone computer based treatment for depression and anxiety.

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Introduction

Depression and anxiety are common mental health problems and leading sources of disability affecting up to one in six of the population (LSE, 2006; Cassano & Fava, 2002). Cognitive Behavioural Therapy (CBT) is established as an effective, time-limited treatment. CBT is often preferred by patients but there are insufficient resources to deliver treatment in a timely fashion to all who might benefit from it (Roth and Fonagy 2004; Appleby 2004).

Alternatives to face-to-face (FtF) therapy have been developed which have the potential to address some of the current demand for treatment (Proudfoot, et al, 2004). Most existing guided self-help and computerised CBT (cCBT) programs require patients to attend a clinic for treatment; potentially incurring costs, inconvenience and stigma as a result. Additionally, varying degrees of staff input may also be required. There is considerable evidence that people can adequately treat themselves if given the right guidance and materials with which to do it, although the therapeutic factors in effective self-help are not yet well identified (Gellatly et al, 2007). Therefore, two of the challenges for the development of effective interventions are to minimise the use of clinic resources and professional time and to explore the space between the full face-to-face psychological treatments and completely independent stand-alone self-help options.

Blues Begone® (BBG) is a cCBT program that is designed to be used without any additional human support. It offers 30 episodes of cCBT that can be used for between 15 – 40 hours depending upon the level of engagement of the user. BBG assesses each individual and then compiles itself to reflect their needs. Statistically, it is highly unlikely that any two users will ever see exactly the same BBG program. The program learns about the user, talks to them using personalised computer generated voices with context aware messages and feedback

(Self Help Solutions Inc). This paper reports the first open trial of BBG in the UK National Health Service with primary and secondary care patients.

Method

All procedures were approved in advance by an NHS Research Ethics Committee.

The study was conducted in a mixed rural/urban area in the South East of England. Patients were referred directly by their General Practitioner (GP), or other primary or secondary care health professionals to the Blues Begone® 'Active Self-help Clinic'. All patients were sent an appointment letter and invited to attend an assessment meeting lasting approximately 30 minutes. The purpose of the assessment meeting was to determine suitability and to complete the study questionnaires. On completion of treatment patients returned to complete a final set of questionnaires and give comments about their experience. Patient's GP's were kept informed of their progress and patients continued with any drug treatments they may have been receiving.

Participants

Referrals (n = 176) were received between February 2007 and March 2008. N=53 patients (30%) did not respond to the invitation letter, n=123 attended and completed the assessment questionnaires, n=23 were excluded based upon clinical history obtained at interview or failed to meet inclusion criteria. Included patients who started the study (n=100) and therefore yielded at least one data set were given the BBG program to take home and install on their computer. There were n=38 males and n=62 females included aged between 18 and 65. In the early stages of the project patients were invited back to the clinic to complete a

second set of questionnaires mid-way through the program. A total of n=49 patients returned for this mid-term interview. Because of staffing problems this mid-term interview was suspended for a time. See Figure 1) for an illustration of patient recruitment and attrition.

Insert Figure 1) About Here

Study exclusion criteria:

- Aged less than 18 or more than 65 years
- Dependent on alcohol or drugs
- Psychotic
- Learning disability
- Actively suicidal
- Currently receiving face-to-face counselling or therapy
- Poor command of written English or spoken English
- BDI score <11
- No access to a home computer running Windows XP™ or Windows Vista™ operating system.

Measures

Demographic information was collected at screening together with current life problems, psychiatric history, medication and present or past counselling/therapy experience. Outcome measures used were the Beck Depression Inventory-II, (BDI-II) (Beck et al, 1996), the Beck Anxiety Inventory (BAI) (Beck et al, 1988) and the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) (Barkham et al, 2001). BDI-II scores were coded as < 10

normal range, 11 – 19 mild depression, 20 – 28 moderate depression and 29 – 63 severe depression. BAI scores were coded as < 9 normal range, 10 – 19 mild to moderate anxiety, 19 – 29 moderate anxiety and 30 – 63 severe anxiety.

Analysis

Independent sample t-tests were conducted on the total sample of n=100 patients and paired sample t-tests of statistical significance on the n=58 patients who completed BBG. Uncontrolled effect sizes were calculated using the method: mean start – mean end/ SD start (Shapiro et al, 1994; Barkham et al, 2005).

Results

To test for statistically significant differences between pre- and post scores, paired-sample t-tests were conducted. Table 1) presents the means and 95% confidence intervals for patients completing BBG and yielding the final data set. The primary measure of depression used was the BDI-II. Participants had significantly lower difference BDI-II scores at the end of study, $t(57) = 11.4$, $p < .001$, SD = 10.8, pre-post effect size = 1.69, 95 % CI 13.4 – 19.0. There was also a significant reduction in BAI scores $t(57) = 8.0$, $p < .000$, SD = 9.0, ES = 1.0, 95% CI 7.1 – 11.8, and there was also a significant reduction in total CORE-OM score at study end $t(55) = 9.2$, $p < .000$, SD = .79, ES = 1.4, CI .76 – 1.2.

Insert Table I about here

Sex differences from both the beginning and end data were investigated by independent samples t-tests, n=38 males and n=62 females were in the study entry data set. There were no significant sex differences on study entry scores on any measure. However there was a significant difference when BAI final scores were compared because males had significantly greater reductions in anxiety than females, $t(56) = -2.7$, $p < .01$. Mean end score for males ($n = 23$), was 6.1, $SD = 5.5$, the mean end score for females ($n = 35$), was 10.9, ($SD = 8.0$).

This was a semi-naturalistic study which did not seek to interfere with any drug treatments patients were receiving at study entry; 57% of patients were receiving antidepressant or other psychiatric medication at study entry. A between-subjects analysis was performed and no effect of medication could be detected on any of the study measures (all $p > .38$). A more precise analysis was then conducted on the n=58 patients who completed the program ($n = 31$ drug and $n = 27$ no drug) and again no effect of medication could be detected (all $p > .37$).

The question of who uses BBG and improves and who drops out was investigated. The entry scores of those who completed and those who did not were subjected to a between-subjects t-test. There were no significant differences between the groups neither were there sex differences between these groups.

Reliable and clinically significant change

Reliable change was assessed using methods established by Jacobson and Truax (1991). And to place the current data into a comparable context, the reliable and clinically significant benchmarks defined by Westbrook and Kirk, (2005) were also used. These authors

established that reliable change could be considered to have occurred if a change on the BDI-II or BAI had occurred of between 9 – 11 points (averaged to 10 points overall). In addition, clinically significant change had occurred if the patients score was taken from that indicative of a clinical population to below the normative population cut-off. They determined this to be movement to 10 or less BDI points where the score was previously 11 or above. Of the n=58 patients who completed the final set of questionnaires n=42 (72%) achieved a drop in BDI-II scores of ≥ 10 BDI points and n=35 (60%) were considered to be recovered because they dropped to a BDI-II score of 10 or less. For anxiety, n=26 (45%) of patients achieved a BAI reduction of at least 10 points where their score was initially 11 or more BAI points, and n=26 (45%) were considered recovered from as their BAI score was below 11 at completion where it had been 11 or above at the start. Using the same criteria no patients experienced reliable or clinically significant deterioration in symptoms of depression or anxiety

Insert Table 2 about here

Intention to treat analysis

Intention to treat analysis (ITT) using the last observation carried forward method (Shao & Zhong, 2003), is a way of correcting for the potential of clinical trials to overestimate treatment effects. Because of the limited number of data points in this home-based intervention study, ITT presents as a very conservative analysis. Of the n=100 patients in the study, n=58 yielded both beginning and end data and only an additional n=7 yielded mid-point but not end-point data. Therefore the ITT analysis required the scores of the n=36

participants who only attended the initial interview to have their entry scores carried forward. While there is no means of knowing if these n=36 patients actually used BBG or benefited from it, (patients may drop out of trials because they have recovered and see no benefit from going on as well as because of lack of efficacy, difficulty using the product or other reasons), the assumption in this ITT analysis is that they did use it and obtained no benefit at all from it. Table II. Shows the means, standard deviation and 95% confidence intervals for the ITT data. The effect sizes were more modest using this form of analysis, BDI, ES 1.0, CI 7.9 – 12.4, BAI, ES 0.6, CI 4.4 – 7.8, CORE, ES 0.9, CI .44 - .75 but reductions in symptom scores on each of the three scales remained highly significant ($p < .000$).

Discussion

This pilot study demonstrates that Blues Begone® used as a home-based cCBT treatment package with minimal human interaction may yield worthwhile reductions in clinical measures of depression and anxiety. The sample in this study was drawn from primary and secondary care referrals with limited exclusion criteria. Therefore, while all patients suffered from depression as defined by their BDI-II score, many also suffered other co-morbid problems yielding a somewhat heterogeneous patient population. The UK estimate of the prevalence of mixed depression and anxiety is 9.8% (NICE, 2004). The study population also suffered high levels of mixed anxiety and depression with 92% scoring 11 or above on the BAI.

It is of interest to attempt to benchmark the data presented here with data from other relevant research. Westbrook and Kirk (2005) published data on the treatment outcomes of a large

CBT service population. These authors were able to provide BDI and BAI data for a heterogeneous population receiving on average 13 sessions of face-to-face CBT. For patients scoring above the normal clinical cut off at assessment, the BDI entry scores averaged 22.0 with an end score average of 12.4 (mean difference 9.6) with an uncontrolled treatment effect size of 1.15 with 47.9 % reliably improved and 34.5% recovered. The current data compare favourably with those from Westbrook & Kirk (2005), indeed the current study has shown a greater mean difference score arising from treatment with BBG and consequently a larger effect size. For patients assessed with the BAI Westbrook and Kirk (2005) reported a BAI entry score of 17.0, an end score of 10.6 (mean difference 6.4) and an effect size of .54, with 49.5% reliably improved and 31.5% recovered. Again the current data compare favourably with this showing greater mean change on anxiety scores and larger effect size.

Cavanagh et al, (2006) reported an open trial of Beating the Blues (BtB) where the CORE-OM was used as the primary clinical measure. BtB requires patients to attend a clinic for 8 individual one-hour weekly sessions of computer based CBT. Paired data were reported for 104 patients (47%) of those who started the program. CORE-OM scores at intake were 1.88 and at end were 1.27 with a mean difference of 0.61 and a pre-post effect size of 1.0. These data provide a direct comparison between BtB as used in routine care and BBG as used in this pilot study. In the current study, patients using BBG at home without either the on-site location resource or the structure of the weekly meeting with its attendant benefits achieved greater mean change and effect size outcomes than Cavanagh et al's BtB patients.

Finally, Learmonth et al, (2008) have reported work from BtB used in primary and secondary care. These authors reported BDI-II and BAI for 244 and 252 patients respectively collected over a 5 year period. At intake the average BDI-II score was 24.2 and at the end it was 15.8

with a mean change of 8.4 points yielding an effect size of 0.85. For anxiety scores as measured by the BAI the intake score was 20.8 and the end score was 14.9 with a mean difference of 5.9 yielding an effect size of .55. The current data compares favourably with that reported by Learmonth et al, again with apparently greater change over the course of treatment and greater effect sizes attributable to BBG.

This benchmarking exercise allows comparison to be made between different treatment approaches. This is of interest here because BBG was used entirely at home by the patient. There were no more than 2 half-hour interviews, at assessment and mid-way through, which constituted the whole of the pre-completion face-to-face contact. And because of staffing difficulties only n=49 patients received a mid-point interview. This research suggests that given appropriate materials delivered in an appropriate manner, a significant number of patients may be able to treat themselves for common mental health problems such as depression and anxiety. In the current study there was no additive effect detected from taking medication suggesting that as a stand-alone intervention, for some patients, BBG may provide an alternative to either face to face CBT or to a pharmacological intervention with the potential for at least equivalent outcomes as routine care. Future research should be aimed at establishing the efficacy of BBG in RCT conditions with larger samples.

Conflicts of interest

Self Help Solutions Inc. the owners of Blues Begone provided the programs free of charge, Dr David Purves is a co-author of the program and co-owner of Self Help Solutions Inc.

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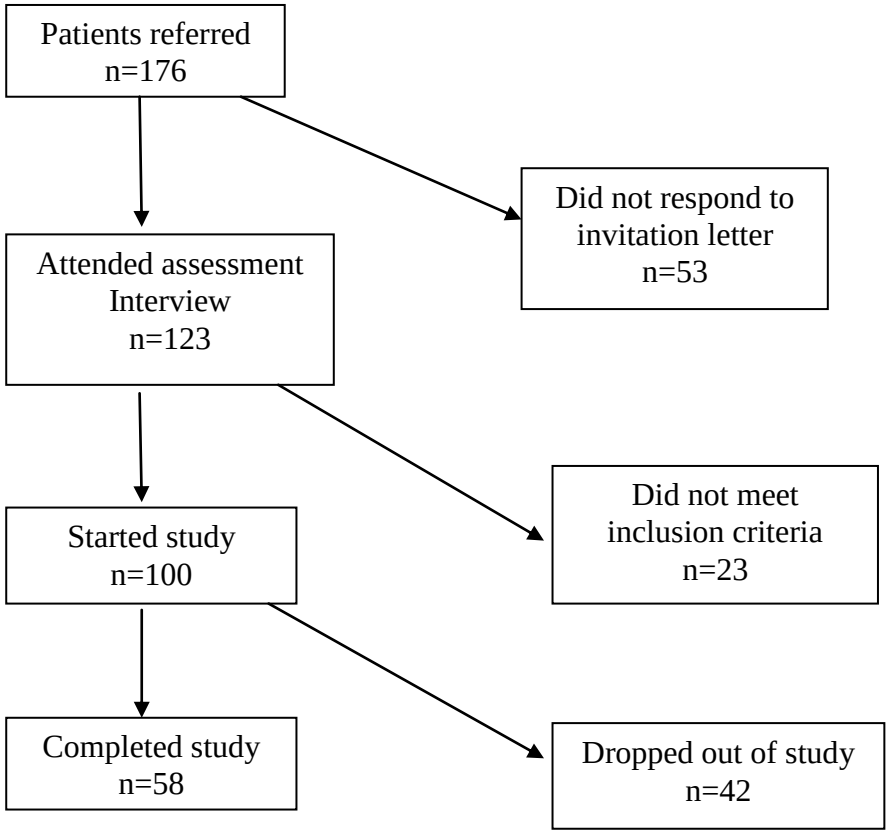
Figure 1). Patient numbers and attrition



17. An open trial in the NHS of ‘Blues Begone’.

Caption for table I. Completers’ means and 95% confidence interval for pre and post BBG for the BDI-II BAI and CORE-OM

18. An open trial in the NHS of ‘Blues Begone’.

Table I.

Outcome measure	Pre-BBG mean (SD)	Post-BBG mean (SD)	Mean difference	95% Confidence interval of the difference	t(p)
BDI-II (n = 58)	27.5	11.5	16.0	13.2 – 18.9	11.3 (< .000)
BAI (n = 58)	18.6	9.0	9.6	7.2 – 12.0	8.1 (<.000)
CORE-OM (n = 55)	1.9	.95	.94	.76 – 1.2	9.2 (<.000)

19. An open trial in the NHS of ‘Blues Begone’.

Table II.

Outcome measure	Pre-BBG mean (SD)	Post-BBG ITT mean (SD)	Mean difference	95% Confidence interval of the difference	t(p)
BDI-II (n = 99)	28.2 (10)	18.0 (12.9)	10.1	7.9 – 12.4	8.9 (< .000)
BAI (n = 100)	20.1 (10.1)	14.0 (10.3)	6.14	4.4 – 7	6.9 (<.000)
CORE-OM (n = 99)	2.0 (.68)	1.4 (.84)	.6	.44 – .75	7.6 (<.000)

20. An open trial in the NHS of ‘Blues Begone’.

Caption for Table II

Intention to treat analysis showing Completers’ means and 95% confidence interval for pre and post BBG for the BDI-II BAI and CORE-OM

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