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Examining Beating the Blues, comprising of:

“The effectiveness and acceptability of Beating the Blues computerised Cognitive Behaviour Therapy programme: A systematic review”

&


Total word count: 26424

Frances Dreyer
B165196
Doctorate in Clinical Psychology
The University of Edinburgh
August 2022
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Thesis portfolio abstract

Introduction: There is a high prevalence of common mental health disorders globally. Although effective treatments exist, there are several barriers to accessing these interventions. Digital mental health interventions (DMHI) have been developed over the last few decades as a way of addressing these barriers and increasing accessibility to evidence-based therapeutic interventions. Beating the Blues (BtB) is a longstanding computerised Cognitive Behaviour Therapy (cCBT) programme that has been used extensively in the United Kingdom (UK). Although cCBT programmes have been shown to be effective, there are high attrition rates and evidence around acceptability of these programmes is inconclusive. Further research is needed to understand engagement and attrition of DMHI. The COVID-19 pandemic has been a unique context to explore this. In addition to the impacts on mental health, the subsequent restrictions resulted in rapid changes to mental health service delivery and an increased reliance on digital interventions. Given the unprecedented nature of the pandemic, it is unclear how the COVID-19 pandemic impacted mental health as well as engagement and attrition from DMHI. This thesis aimed to explore the existing evidence around BtB in terms of effectiveness and acceptability. It further aimed to evaluate attrition, engagement and clinical effectiveness of BtB and the impacts of COVID-19 on these factors.

Methods: The first chapter of the thesis portfolio involved conducting a systematic review of the evidence for the effectiveness and acceptability of BtB. Publication databases and grey literature were searched, and 23 studies were included. A narrative synthesis was conducted. The second chapter of the thesis portfolio involved conducting an empirical study using routine data from n=4517 referrals to a cCBT service using BtB. The data was statistically analysed to explore associations of uptake, registration, attrition, and clinical effectiveness. The impact of COVID-19 on these variables was examined through grouping the sample pre and during COVID-19.

Main findings: The results of the systematic review indicated that BtB is effective at reducing symptoms of depression and overall psychological distress across contexts, populations and settings. The findings were inconclusive for the treatment of anxiety. There was some limited evidence for the effectiveness of BtB in relation to secondary outcomes measures. The evidence for acceptability of BtB was mixed and the methodologies tended to be less rigorous than effectiveness studies. Variable attrition rates were noted but tended to be higher.
in naturalistic settings than experimental settings. Programme and participant characteristics associated with acceptability were discussed. The results of the empirical research found that BtB was effective at reducing symptoms of anxiety and depression pre and during COVID-19. In line with review findings, the attrition rates were high. Participants had significantly higher baseline levels of depression during COVID-19 and engaged more with the programme during this time than pre COVID-19. Younger age and higher baseline levels of depression significantly predicted attrition. These models, however, had limited predictive power and there are likely to be other unknown factors contributing to engagement and attrition.

Conclusions: The systematic review and empirical research found that BtB is an effective intervention, particularly in relation to treatment of depression. Engagement and attrition, however, pose a barrier to the implementation of these programmes. Strengths and limitations of the review and study were discussed. As a longstanding DMHI, the evidence from BtB has significant implications for informing DMHI research and ongoing clinical practice. There continues to be a lack of consensus around predictors of attrition and how acceptability of DMHI influences engagement and attrition. Further research is needed with use of more nuanced forms of data, to fully understand these factors.
Lay Summary

Many people struggle with feeling anxious or depressed across the world. There are forms of support that help with this, including talking to mental health professionals (i.e. psychological talking therapies). Although these can be very effective, there are many reasons why people might not use these services, for example, finding it difficult to travel to appointments or worrying what others might think of them if they seek this support. As a way of overcoming these difficulties, over the past few decades, online forms of these supports have been developed such as website-based programmes or mobile apps. An example of this includes a programme called Beating the Blues (BtB), which has been frequently used in the United Kingdom (UK). These programmes have helped increase access to mental health support. In addition, the COVID-19 pandemic and the government restrictions that were put in place (such as the ‘stay at home’ guidance) have meant that mental health services have had to change the way they offer support and had to rely more on online forms of therapies.

Although these online programmes are effective, lots of people who use them do not finish the programmes. It is still unclear why. There are also mixed opinions about how people feel about using these online programmes. More research is needed to better understand this. It is also still unclear how the pandemic has impacted mental health and whether it has changed how people use these online programmes.

The first chapter of the thesis aimed to summarise previous studies and evidence for BtB. The second chapter of the thesis used information gathered by a service that uses BtB in the UK, to explore who uses the programme, who does not finish the programme and how helpful the programme is. It also looked at how the pandemic has impacted these factors.

The first chapter reported that BtB is a helpful treatment for people struggling with depression and overall distress. It was not clear if BtB is helpful for treating anxiety. The findings were mixed for how people experienced using the programme: some people found it helpful, enjoyed using it and thought the programme was well designed, whereas other people found it less helpful, did not feel it was relevant and struggled using the programme online. The second chapter reported that BtB was helpful for treating anxiety and depression both before and during the COVID-19 pandemic. Lots of people, however, did not finish the programme. Younger people and those who were more depressed at the start of the programme were more likely to stop using the programme. People who used BtB during
COVID-19 had higher levels of depressive symptoms before using the programme but they were more likely to complete the programme.

The chapters discuss the limitations of these studies and discusses how the study has been helpful and contributed to our understanding of online therapies and COVID-19. The information from this thesis will help services that use online therapies. For example, helping services consider how they can continue researching how people use their services and possible changes they can make to encourage people to use and finish these programmes.
Chapter 1

The effectiveness and acceptability of Beating the Blues computerised Cognitive Behaviour Therapy programme: A systematic review

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Abstract

Background: Digital mental health interventions (DMHI) have been developed as a way of increasing accessibility to evidence-based treatments. Computerised Cognitive Behaviour Therapy (cCBT) has been extensively researched in terms of efficacy and acceptability. Existing reviews have combined findings from various DMHI, making it difficult to draw conclusions about the efficacy and acceptability of individual programmes. Beating the Blues (BtB) is a longstanding cCBT programme that is frequently used. This review aimed to explore the effectiveness and acceptability of BtB specifically.

Methods: a systematic review of evidence from studies examining the effectiveness of BtB (in terms of primary and secondary outcomes) and acceptability of BtB was conducted. Methodological sources of biases in the studies were assessed. A narrative synthesis was used.

Main results: 23 studies were included. BtB is effective for the treatment of depression and overall psychological distress. There was inconsistent evidence for the effectiveness of BtB for the treatment of anxiety. There was limited evidence for effectiveness of BtB in relation to secondary outcomes. The results were mixed for the acceptability of BtB.

Limitations: There was significant heterogeneity in the study contexts, designs and methodologies. The studies consistently lacked a theory driven approach to the research. Studies examining acceptability of BtB were less rigorous than those exploring effectiveness.

Conclusions: BtB is an effective treatment for depression and psychological distress across contexts, populations and settings. More rigorous research is needed to understand acceptability of BtB more fully.

Keywords: Beating the Blues; cCBT; depression; anxiety
Introduction

The prevalence of common mental health disorders such as anxiety and depression is estimated at almost 13% (Institute for Health Metrics and Evaluation, 2020). Despite the strong evidence base for therapeutic interventions, these disorders frequently remain untreated (Kohn et al., 2004; Lubian et al., 2016). This significantly contributes to the global burden of disease (Global Burden of Disease Study 2013 Collaborators, 2015; World Health Organization, 2017). Barriers to seeking mental health treatment include stigma, costs, time associated with attending appointments, service waiting times and motivation to engage with therapy (Andrade et al., 1943; Kaltenthaler et al., 2006). Digital mental health interventions (DMHI) have been developed over the last few decades as a way of addressing these barriers and increasing accessibility, by offering an alternative form of evidence-based service provision (Lattie et al., 2022). Digital mental health encompasses a wide range of interventions including computer-based interventions, apps and telehealth services, typically based on traditional psychological treatments (Lattie et al., 2022). Computerised cognitive behaviour therapy (cCBT) is an example of a frequently used DMHI.

Beating the Blues

Multiple cCBT programmes are currently used in mental health services (Lattie et al., 2022). Beating the Blues (BtB) is an unguided cCBT programme that has been used extensively since it was developed in the United Kingdom (UK) approximately 20 years ago (Proudfoot et al., 2003b). BtB was developed using traditional CBT principles: the short term, structured and present-focused nature of CBT made it particularly appropriate for digital delivery format (Proudfoot et al., 2003b). BtB is structured to include a short introductory video followed by eight sessions, taking approximately 50 minutes to complete. The sessions are designed to be completed on a weekly basis with homework tasks between sessions. BtB developers designed the programme to be user friendly with text supplemented with narrations to provide clear, understandable information and as a way for users to experience a sense empathy. Case studies are used with accompanying videos to help foster motivation, ongoing engagement with the programme and to instil a sense of hope (Proudfoot et al., 2003b).
Effectiveness of Beating the Blues and cCBT
There has been substantial research exploring the effectiveness of cCBT programmes; particularly the effectiveness of BtB, given its longstanding use in the UK. Several randomised controlled trials (RCTs) and naturalistic studies have found that BtB is effective for the treatment of anxiety and depression (for example see Cavanagh et al., 2006a; Grime, 2004; Proudfoot et al., 2003a). Given its effectiveness, BtB was recommended within the National Institute for Health and Care Excellence (NICE) guidelines as a treatment for mild-to-moderate depression (The National Institute for Health and Clinical Excellence, 2006). This was expanded in 2018, however, to include other cCBT recommendations for the treatment of anxiety and depression, given the effectiveness of cCBT programmes more broadly for anxiety and depression (see meta-review evidence from Foroushani et al., 2011; Simmonds-Buckley et al., 2020). These cCBT programmes have been shown to be as effective as traditional therapist led CBT and reduce therapist input (Foroushani et al., 2011).

Within the stepped care approach to mental healthcare, cCBT programmes including BtB, continue to be recommended and used as an effective intervention for mild-to-moderate depression and anxiety in the UK (NHS Education for Scotland, 2015; The National Institute for Health and Clinical Excellence, 2022). This forms part of the continued focus on reshaping mental health service delivery and increasing accessibility to mental health treatments in the UK (Cavanagh et al., 2011). BtB is also used in the United States of America (USA) (Rollman et al., 2020) including within physical healthcare contexts (Gupta et al., 2020). This is in line with alternative cCBT programmes: systematic review evidence reported modest evidence for the effectiveness of cCBT in physical healthcare settings.

Acceptability of Beating the Blues and DMHI
In addition to efficacy, the acceptability of BtB is key to effective implementation and utilization of this intervention. Acceptability is operationalised in multiple ways including: uptake, attrition, facilitators and barriers to adherence, and treatment satisfaction (Treanor et al., 2021). Research examining the acceptability of BtB have reported mixed findings. Some users found BtB acceptable and felt positive about the programme features, viewed it as equivalent to other therapeutic input and were satisfied with the treatment type and experience of using BtB (Cavanagh et al., 2011; Learmonth, 2007; Proudfoot et al., 2003b). Other users, however, have reported reduced acceptability of BtB due to feeling the
programme was irrelevant to their needs, finding the programme demands too high and due to dissatisfaction with the programme features (Learmonth, 2007; Mitchell, 2009; Proudfoot et al., 2003b). These findings are congruent with research exploring acceptability of DMHI more broadly. Factors such as increased autonomy, confidentiality and privacy, convenience, and user friendly formats increased perceived acceptability of the interventions (Treanor et al., 2021); whereas factors such as technical difficulties using the programmes, the impersonal nature of the programmes and feeling as though their needs are not being met by the programmes, have contributed to reduced acceptability of DMHI (Borghouts et al., 2021).

Attrition from interventions can be viewed as a further indicator of poor acceptability. Studies exploring BtB have reported variable attrition rates ranging from as low as 9% (Du et al., 2021) to as high as 86% (Persson, 2018), but the reasons for these variable attrition rates is still not well understood. High rates of attrition are not unique to BtB and have been reported in other DMHI (Karyotaki et al., 2015; Simmonds-Buckley et al., 2020; Van Ballegooijen et al., 2014). Poor adherence to DMHI has been associated with negative perceptions of treatment, low motivation, and personal circumstances (Treanor et al., 2021). Symptom improvement, however, has also been associated with disengagement (Treanor et al., 2021).

Adherence and attrition are key concepts in cCBT including BtB. Improved adherence has been associated with positive expectations of treatment, increased motivation, and satisfaction with treatment (Treanor et al., 2021). Greater adherence with cCBT is also associated with better treatment outcomes (Karyotaki et al., 2017). Thus, the lack of engagement with programmes such as BtB, is likely to limit clinical benefit, regardless of the interventions’ efficacy (Lattie et al., 2022; Treanor et al., 2021). This highlights the importance of investigating acceptability of cCBT, in order to fully understand implementation issues and to maximize the clinical benefits (Treanor et al., 2021).

**Rationale for the current systematic review**

Existing systematic reviews and meta-analyses exploring the effectiveness and acceptability of cCBT interventions have combined findings from various cCBT programmes. This heterogeneity of interventions makes it difficult to draw conclusions about the efficacy and acceptability of individual interventions. Although cCBT programmes are based on the
established principles of CBT (Lattie et al., 2022), the aesthetics, interface, structure and specific content will differ. Research evidence has indicated that programme specific factors can influence engagement with interventions (Kaltenthaler et al., 2006), highlighting the importance of evaluating specific programmes in terms of efficacy and acceptability (Fairburn and Patel, 2017).

There are no known systematic reviews of Beating the Blues specifically, in terms of effectiveness and acceptability. Given the longstanding history and ongoing use of BtB in the UK, there is a large amount of information and data available on the implementation of this programme.

Digital mental health continues to be a priority within mental health policy frameworks (NHS Education for Scotland, 2014; The National Institute for Health and Clinical Excellence, 2022; The Scottish Government, 2017) focussing on the reorganisation of mental health service delivery and increasing accessibility. Synthesizing the evidence of an established cCBT programme has implications for services who continue to use BtB. It can also inform the wider field of DMHI in terms of understanding effectiveness and factors that affect acceptability of programmes delivered in digital formats. This is particularly pertinent given the impacts of the COVID-19 pandemic on the accelerated integration of DMHI into existing services (Inchausti et al., 2020; Lattie et al., 2022; Zhou et al., 2020).

**Aims**

- What is the evidence for the effectiveness of Beating the Blues (BtB) computerised cognitive behaviour therapy programme (cCBt) in terms of primary outcomes, i.e. severity of anxiety or depression?
- What is the evidence for the effectiveness of Beating the Blues cCBT programme in terms of secondary outcomes, for example, quality of life, cost effectiveness and mechanisms of change?
- How acceptable is Beating the Blues to users of the programme in terms of perceptions, satisfaction, attrition and engagement?
- What are the methodological sources of bias in the existing primary literature exploring effectiveness and acceptability of Beating the Blues?
Methodology

Search strategy
The systematic review was conducted in line with PRISMA guidelines (Page et al., 2021) and the protocol was registered with PROSPERO (CRD42022309234). Primary studies were identified through searching the electronic databases PsychINFO, Embase, Global Health, Medline, Cinahl plus, Proquest and Web of Science. The search term “beating the blues” was used. Searches were initially conducted in July 2021 and were repeated in July 2022 to ensure no recent publications were omitted. The initial search returned 223 articles. After initial screening of titles and abstracts, 62 full text articles were screened for eligibility against inclusion and exclusion criteria of the review. 33 articles met criteria, comprising of 21 studies in total. The July 2022 search identified two additional articles. Grey literature was searched using Grey Literature Report, Open Grey and the United Kingdom (UK) Beating the Blues website using the same search term. One additional publication was identified through grey literature but was not accessible despite reasonable attempts made. A total of 35 articles were included in the review, comprising of 23 studies. Results of studies rather than individual papers will be presented. This search process is summarised in the PRISMA flowchart in figure 1 below.
Records identified from databases (n = 233)

Records removed before screening: Duplicate records removed by Covidence (n = 107)

Records screened (n = 126)

Records excluded** (n = 64)

Reports sought for retrieval (n = 1)

Reports not retrieved (n = 1)

Reports assessed for eligibility (n = 61)

Reports excluded: Wrong study design (n = 11) Additional duplicate records (n = 9) Wrong outcomes (n = 5) Wrong intervention (n = 3) etc.

Articles included in review (n = 33) Additional papers included when search updated (n = 2)

Figure 1. PRISMA flowchart summarising search strategy
**Inclusion and exclusion criteria**

Inclusion criteria included: i) studies which used Beating the Blues cCBT programme as an intervention and ii) evaluated the programme in terms of primary outcomes (clinical effectiveness of the programme in terms of symptoms of depression and/or anxiety) and/or secondary outcomes (for example, quality of life, cost effectiveness or mechanisms of change), and/or acceptability (for example, perceptions, satisfaction, uptake and/or attrition). iii) Quantitative and qualitative studies were included. iv) Grey literature was included. v) Studies with or without comparators or control groups were included. vi) All study contexts and settings were included if full inclusion criteria were met.

Exclusion criteria included: i) reviews; ii) case studies; iii) studies where Beating the Blues was not distinguished from other forms of cCBT interventions; and iv) studies not written in or translated to English.

**Data extraction**

**Study characteristics.** The following items were extracted from each full text article: authors, associated study, year of publication, type of publication, study design, study setting, country, mean age of sample, biological sex percentages, diagnoses and sample size.

**Study results.** The following items were extracted from each study: comparator, measures used, primary outcomes, secondary outcomes, measures of effect (where reported) and attrition.

**Quality assessment**

Quality assessment of the included studies was conducted using the Quality Appraisal for Diverse Studies (QuADS) (Harrison et al., 2021). Given the aims of this review and the broad inclusion criteria, a tool that could assess the quality of a diverse group of studies in terms of design and methodologies was required. The QuADS was recently updated from the Quality Assessment Tool for Studies with Diverse Designs (QATSDD), which was originally designed to be used in psychological research (Sirriyeh et al., 2012). The QuADS has good reliability and validity in its application to systematic reviews with studies with diverse designs and methodologies (Harrison et al., 2021). The tool was used to evaluate the following areas: theoretical and conceptual underpinning of the research; research aims;
research setting and target population, study design and sampling, data collection tools and procedure, recruitment, analysis, consideration of relevant stakeholders and acknowledgement of strengths and limitations. It uses a four point scale to rate quality in each area, with higher scores indicating higher quality (Harrison et al., 2021).

The first author quality assessed 100% of the included papers. A second assessor independently assessed a selection of included papers (approximately 25%). Disagreements on ratings were resolved through discussion. There was good reliability between raters (ICC=0.79)(Koo and Li, 2016).

Methods for synthesis

Given the heterogeneity within the designs and methodologies of the studies included in this review, a narrative synthesis was chosen as the most appropriate method to synthesize the results. Given the heterogeneity of outcome measures, a meta-analysis was not performed.

Results

Characteristics of studies

There were 23 included studies (35 papers) representing a total sample size of n=5156 with an individual study range from n=13 (van den Berg et al., 2004) to n=691 (Littlewood et al., 2015). All studies used adult samples with mean ages ranging from M= 24.33 (Mitchell, 2009) to M=74 (Hanna, 2012). The majority of the included studies (14 studies) and total sample had a significantly higher proportion of female participants than male participants. Fifteen studies were conducted in the UK and 8 studies in the USA. Studies were published from 2003 (Proudfoot et al., 2003b), through to 2022 (Stearns-Yoder et al., 2022). Studies conducted in the USA tended to be more recent than those conducted in the UK. Study designs were varied, comprising of randomised controlled trials (RCTS), prospective and retrospective quantitative studies, qualitative studies, pilot studies, and service evaluations. Most studies were disseminated through peer reviewed journal articles but also included grey literature.

For primary outcomes of clinical effectiveness using Beating the Blues, three studies explored depression only as an outcome (Forand et al., 2018; Gupta et al., 2020; Littlewood et al., 2015); whereas 17 studies explored depression and anxiety as an outcome (Boger,
For secondary outcomes, two studies explored cost effectiveness of Beating the Blues (Duarte et al., 2017; McCrone et al., 2004); one study explored quality of life (Jonassaint et al., 2019; Rollman et al., 2020); four studies explored impact of difficulties in terms of work and social adjustment (Cavanagh et al., 2011, 2006b; Proudfoot et al., 2004); one study explored therapeutic alliance (Ormrod et al., 2010); and four studies explored mechanisms of change (Forand et al., 2018; Grime, 2004; Proudfoot et al., 2004, 2003b). Acceptability of Beating the Blues was explored quantitively in ten studies (Boger, 2015; Cavanagh et al., 2011, 2009, 2006b; Johnson and Hinshaw, 2011; Learmonth, 2007; Mitchell, 2009; Mitchell and Dunn, 2007; Pittaway et al., 2009; Proudfoot et al., 2003b, 2004; Stearns-Yoder et al., 2022). It was explored qualitatively in three studies (Du et al., 2021; Hanna, 2012; Jonassaint et al., 2020). Factors associated with uptake, attrition, and engagement were specifically explored in eight studies (Bayliss and Willis, 2010; Fairclough et al., 2020; Johnson and Hinshaw, 2011; Jonassaint et al., 2017; McMurchie et al., 2013; Pittaway et al., 2009; Proudfoot et al., 2004, 2003b).

The majority of the included studies conducted research with adults in generic mental health service contexts such as primary care, secondary care, specialist mental healthcare services or third sector services. Two studies, however, were conducted in older adults mental health services (Fairclough et al., 2020; Hanna, 2012; McMurchie et al., 2013). Other study contexts included education and occupational settings (Grime, 2004; Mitchell, 2009). Several studies were conducted in relation to physical health conditions such as sickle cell disease (Jonassaint et al., 2020), HIV (Gupta et al., 2020), and within substance misuse services (Boger, 2015). Study and participant characteristics are summarised in table 1.
<table>
<thead>
<tr>
<th>Authors and publication year</th>
<th>Associate d study</th>
<th>Type of publication</th>
<th>Study design</th>
<th>Study setting</th>
<th>Country</th>
<th>Sample size</th>
<th>Mean age</th>
<th>Gender/sex</th>
<th>Diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grime 2004</td>
<td>/</td>
<td>Peer reviewed journal article</td>
<td>RCT</td>
<td>Adults experiencing work related stress</td>
<td>UK</td>
<td>n=48 (n=24 per group)</td>
<td>BtB + TAU M=41 (SD = 10.83)</td>
<td>46% Female, 54% Male</td>
<td>Stress/ anxiety/ depression</td>
</tr>
<tr>
<td>Cavanagh et al. 2006</td>
<td>Routine care study</td>
<td>Peer reviewed journal article</td>
<td>Prospective quantitative study</td>
<td>Primary and secondary routine care</td>
<td>UK</td>
<td>n=219</td>
<td>M=43.6 (SD=11.7)</td>
<td>60% Female</td>
<td>Anxiety/depression</td>
</tr>
<tr>
<td>Cavanagh et al. 2011</td>
<td>/</td>
<td>Peer reviewed journal article</td>
<td>Prospective quantitative study</td>
<td>Third sector services</td>
<td>UK</td>
<td>n=510</td>
<td>Modal age range 26-35</td>
<td>68% Female</td>
<td>Anxiety/depression</td>
</tr>
<tr>
<td>Duarte et al. 2017</td>
<td>REEACT trial</td>
<td>Peer reviewed journal article</td>
<td>RCT with qualitative methodology</td>
<td>Primary care</td>
<td>UK</td>
<td>n=691 (n=210 intervention (BtB); n=239 for TAU; n=242 for TAU + MoodGYM)</td>
<td>M=39.86 (SD=12.65)</td>
<td>67% Female</td>
<td>Depression</td>
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<td>Gilbody et al. 2015</td>
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<td>n = 36 patients n=11 healthcare professionals for qualitative feedback</td>
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<td>87% Female</td>
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<td>Littlewood et al. 2015</td>
<td>Older adults study</td>
<td>Doctoral thesis</td>
<td>Qualitative prospective study</td>
<td>Older adult CMHT service</td>
<td>UK</td>
<td>n=20 (n=8 BtB+TAU completers n=5 BtB+TAU)</td>
<td>M=74 (SD=5.2)</td>
<td>70% Female</td>
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<tr>
<td>Study (Year)</td>
<td>Study Design</td>
<td>Study Type</td>
<td>Setting</td>
<td>Sample Size</td>
<td>Intervention</td>
<td>Comparator</td>
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<td>McMurchie et al. 2013</td>
<td>Peer reviewed journal article in Discontinuers</td>
<td>Pilot quantitative prospective study</td>
<td>n=7 TAU</td>
<td>n=58 (n=38 intervention n=20 comparator)</td>
<td>Intervention M=71.58 (SD=4.43) Comparator M=75.55 (SD=6.27)</td>
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<td>Jonassaint et al. 2020</td>
<td>Peer reviewed journal article in Anxiety &amp; Depression</td>
<td>RCT with qualitative methodology</td>
<td>Physical health care in USA</td>
<td>n=30 (intervention n=18 comparator n=12)</td>
<td>M=32.90 (SD=11.10)</td>
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<td>Jonassaint et al. 2017</td>
<td>Minority population study</td>
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<td>Primary care in USA</td>
<td>n=601</td>
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<td>Jonassaint et al. 2019</td>
<td>African American participants: Intervention M=40 (SD=14) Comparator M=39.59 (SD=12.12)</td>
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<td>n=689 (n=590 intervention n=99 comparator)</td>
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<td>Rollman et al. 2018</td>
<td>African American participants:</td>
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<td>n=704 (n=603 intervention n=101 comparator)</td>
<td>M= 47.7 (SD=14.3)</td>
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<td>79.8% Female 20.2% Male</td>
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<td>Journal Methodology</td>
<td>Setting</td>
<td>Country</td>
<td>Sample Size</td>
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<td>Gender</td>
<td>Conditions</td>
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<td>M=25.58 (SD=NR)</td>
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<td>Peer reviewed journal article</td>
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<td>/</td>
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<td>n=54 (n=27 per group)</td>
<td>M=45.1 (SD=10.8)</td>
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<td>Pilot prospective study</td>
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<td>M=44 (SD=11)</td>
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<td>UK</td>
<td>n=13</td>
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<td>Peer reviewed journal article</td>
<td>Prospective beta testing</td>
<td>BtB development</td>
<td>UK</td>
<td>n=20</td>
<td>NR</td>
<td>Completers only: 73% Female 27% Male</td>
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<td>First BtB primary care trial</td>
<td>Peer reviewed journal article</td>
<td>RCT</td>
<td>Primary care</td>
<td>UK</td>
<td>n=138; comparator n=136; comparator n=138</td>
<td>Intervention M=43.6 (SD = 14.4) Comparator M=43.7 (SD=13.7)</td>
<td>Intervention 73% Female 27% Male Comparator: 74% Female 26% Male</td>
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<td>n=167 (intervention n=89; comparator n=78)</td>
<td>Intervention M=43.6 (SD=14.3) Comparator M=43.4 (SD=13.7)</td>
<td>Intervention 73% Female 27% Male Comparator 75% Female 25% Male</td>
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<td>Peer reviewed journal article</td>
<td>eCBT services</td>
<td>UK</td>
<td>n=1158</td>
<td>M=39.99 (SD=14.71)</td>
<td>68% Female, 32% Male</td>
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<td>Doctoral thesis</td>
<td>Peer reviewed journal article</td>
<td>Retrospective study</td>
<td>UK</td>
<td>n=165</td>
<td>M=45 (SD=14.94)</td>
<td>58-63% Female, 25-26% Male</td>
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<td>Pittaway et al. 2009</td>
<td>Peer reviewed journal article</td>
<td>Prospective quantitative study</td>
<td>Primary care</td>
<td>UK</td>
<td>n=100</td>
<td>Modal age 25-44</td>
<td>71% Female, 29% Male</td>
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<td>Forand et al. 2018</td>
<td>Peer reviewed journal article</td>
<td>RCT</td>
<td>Higher education</td>
<td>USA</td>
<td>n=90</td>
<td>Intervention M=33.3 (SD=12.9) Comparator M=32.4 (SD=10.6)</td>
<td>Intervention Female=76% Male = 24% Comparator Female =77% Male = 23%</td>
<td>Depression</td>
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<td>Learmonth &amp; Rai 2008</td>
<td>Specialist CBT service study</td>
<td>Peer reviewed quantitative study</td>
<td>Specialist CBT service</td>
<td>UK</td>
<td>n=104</td>
<td>M=39.5 (SD=11.6)</td>
<td>64% Female, 36% Male</td>
<td>Anxiety/depression</td>
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<tr>
<td>Learmonth et al. 2008</td>
<td>Peer reviewed journal article</td>
<td>Prospective quantitative study</td>
<td>Specialist CBT service</td>
<td>UK</td>
<td>n=555</td>
<td>M=40 (SD=12)</td>
<td>61.3% Female, 38.7% Male</td>
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<tr>
<td>Learmonth 2007</td>
<td>Doctoral thesis</td>
<td>Prospective mixed methodology</td>
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<td>n=590 (BtB intervention n=356; physical co-morbidity BtB group n=100; control n=104)</td>
<td>BtB intervention M=39.2 Physical health BtB M=44.5 Control M=40.4</td>
<td>BtB group 61.2% Female, 38.8% Male Physical health BtB group 61.9% Female, 38.1% Male Control 65.1% Female, 34.9% Male</td>
<td>Depression</td>
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<tr>
<td>Study</td>
<td>Journal Type</td>
<td>Research Design</td>
<td>Setting</td>
<td>Sample Size</td>
<td>Gender</td>
<td>Mental Health</td>
<td>Difficulties</td>
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<td>Boger 2015</td>
<td>Doctoral thesis</td>
<td>Prospective mixed methodology</td>
<td>Substance misuse service</td>
<td>USA</td>
<td>n=181</td>
<td>Females M=44.6 (SD=12.96) Males M=46 (SD=11.73)</td>
<td>73% Female 27% Male</td>
<td>Substance misuse difficulties</td>
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<tr>
<td>Bayliss &amp; Willis 2010</td>
<td>Forum publication</td>
<td>Service evaluation</td>
<td>Specialist CBT service</td>
<td>UK</td>
<td>n=57</td>
<td>Completers M=46.34 (SD=13.04) Non-completers M=42.79 (SD=11.73)</td>
<td>45.61% Female 54.39% Male</td>
<td>Anxiety/depression</td>
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<tr>
<td>Johnson &amp; Hinshaw 2011</td>
<td>Forum publication</td>
<td>Retrospective study</td>
<td>Adult mental health service</td>
<td>UK</td>
<td>n=106</td>
<td>NR</td>
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<td>Fairclough et al. 2020</td>
<td>Forum publication</td>
<td>Service evaluation</td>
<td>Older adults mental health service</td>
<td>UK</td>
<td>n=121</td>
<td>Median age = 70.5</td>
<td>62.8% Female 37.2% Male</td>
<td>Anxiety/depression</td>
<td></td>
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<tr>
<td>Stearns-Yoder et al. 2022</td>
<td>Peer reviewed journal article</td>
<td>Pilot prospective qualitative study</td>
<td>Veteran population</td>
<td>USA</td>
<td>n=49</td>
<td>M=57.1 (SD =9.9)</td>
<td>12% Female 88% Male</td>
<td>Depression</td>
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<tr>
<td>Du et al. 2021</td>
<td>Peer reviewed journal article</td>
<td>Prospective qualitative study</td>
<td>Primary care</td>
<td>UK</td>
<td>n=33</td>
<td>NR</td>
<td>52% Female 48% Male</td>
<td>Anxiety/depression</td>
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</tbody>
</table>

Notes: RCT = randomised controlled trial; CMHT = Community Mental Health Team; NR = Not reported
Quality assessment

No studies were excluded on the basis of poor quality. A summary of quality assessment for included studies is presented in table 2. Although most studies included a relatively thorough presentation of the relevant literature and concepts associated with cCBT and BtB, very few studies integrated theoretical arguments or hypothesized mechanisms of change into their research. Most of the study designs were appropriate to meet the aims of the studies; however, there was significant variability in study design type. The QuADS, however, assessed the design in relation to the individual study’s aims. Thus both an RCT and a service evaluation could score high on the quality assessment, despite the fact that RCT evidence is considered the gold standard for effectiveness studies (Hariton and Locascio, 2018). In relation to sampling, the quality of included studies was variable. Most studies included clear descriptions of inclusion and exclusion criteria. Most of these appeared congruent with other studies; however, some studies included some exclusion criteria which could have resulted in some bias, for example, Ormrod et al. (2010)(Ormrod et al., 2010) described including participants who were confident they would commit to the intervention. Given the known attrition rates in BtB, this is likely to result in issues with generalizability of findings. Many studies did not include power calculations. This may relate to study context: many of the studies were conducted in naturalistic settings, i.e. within mental health services and samples were determined by referrals made to the service. Nevertheless, this highlights an ongoing challenge in psychological research of underpowered research (Maxwell, 2004). In terms of data collection tools, the majority of studies used appropriate tools to address study aims, however, there was significant variability in studies providing sufficient justification for utilization of these tools. Similarly, although most studies appeared to use appropriate forms of data analysis, justification of analytic method was poor, particularly in quantitative studies. Most studies provided good summaries of recruitment data. Consideration of relevant stakeholders (such as consulting with experts by experience), was consistently weak in the included studies: only 3 studies reported this (Boger, 2015; Littlewood et al., 2015; van den Berg et al., 2004). Overall, it is important to note that the QuADS cannot always differentiate between reporting and methodological issues. For example, a study may have conducted a sample size and power analysis but did not report this in publication.
Table 2. Summary of quality assessment using QuADS

<table>
<thead>
<tr>
<th>Authors and publication year</th>
<th>Item 1 Theoretical or conceptual underpinning of research</th>
<th>Item 2 Statement of research aims</th>
<th>Item 3 Clear description of research setting and target population</th>
<th>Item 4 Appropriateness of study design to address aims</th>
<th>Item 5 Appropriateness of sampling</th>
<th>Item 6 Rationality for data collection tools</th>
<th>Item 7 Format and content of data collection tool</th>
<th>Item 8 Description of data collection procedure</th>
<th>Item 9 Recruitment data</th>
<th>Item 10 Justification for analytic method</th>
<th>Item 11 Appropriateness of method of analysis</th>
<th>Item 12 Stakeholder consideration</th>
<th>Item 13 Strengths &amp; limitations discussed</th>
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<td>Grime 2004</td>
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Primary outcomes

A summary of the study results is presented in table 3.

Effectiveness of BtB for depression. Of the 20 studies that explored depression as an outcome, there was significant heterogeneity in depression outcome measures. Most studies used either the Beck Depression Inventory-II (BDI-II) (Beck et al., 1996) (six studies), the Patient Health Questionnaire 9 (PHQ-9) (Kroenke et al., 2001) (seven studies), or the Beating the Blues Subjective Units of Distress (SUDs) for depression (six studies). Other measures used included (one study apiece): Patient-Reported Outcomes Measurement Information System (PROMIS) depression (Cella et al., 2010), the Geriatric Depression Scale (GDS) (Scogin et al., 2000), the Hopkins Symptom Checklist-20 (Williams et al., 2004), the Hamilton Rating Scale for Depression (HRSD) (Hamilton, 1960) and the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983).

Five of six studies using the BDI-II (Learmonth, 2007; Mitchell, 2009; Ormrod et al., 2010; Proudfoot et al., 2004, 2003b) reported statistically significant reductions in BDI-II scores from start to end of treatment, with effect sizes ranging from medium (Learmonth, 2007) to medium-to-large (Mitchell, 2009), where reported. Two of these studies were RCTs involving control group comparisons (Learmonth, 2007; Proudfoot et al., 2004). One of these RCTs found that the improvements in depression were independent of drug treatment, duration of pre-existing illness, and severity of illness (Proudfoot et al., 2004). One study reported that BDI-II scores decreased in magnitude, but this was not statistically significant clinical change (Proudfoot et al., 2003b). This study, however, was conducted with a small sample and constituted beta testing for the Beating the Blues programme.

Five of the seven studies that used PHQ-9 (Cavanagh et al., 2011; Forand et al., 2018; Gupta et al., 2020; Jonassaint et al., 2019, 2017), reported statistically significant reductions in PHQ-9 scores from start to end of treatment, with effect sizes ranging from medium-to-large (Jonassaint et al., 2019) to large (Forand et al., 2018), where reported. Four of these studies were RCTs and two of them reported these changes were maintained at follow up of three and six months (Gupta et al., 2020; Jonassaint et al., 2019). One RCT (Jonassaint et al., 2019); however, found that when compared with the control group, the treatment group had significantly greater improvements at six months but not at one or three months post intervention. Another study noted decreases in mean PHQ-9 scores from start to end of
treatment, but only explored this descriptively (Boger, 2015). One large-scale RCT found that Beating the Blues did not significantly improve PHQ-9 scores when compared with GP care as usual (control) or when compared with another cCBT intervention, MoodGYM (Gilbody et al., 2015).

All six studies using BtB SUDS (Cavanagh et al., 2006b; Cientanni et al., 2019; Fairclough et al., 2020; Johnson and Hinshaw, 2011; Learmonth, 2007; van den Berg et al., 2004) reported a significant reduction in SUDS from start to end of treatment with effect sizes ranging from small (Johnson and Hinshaw, 2011) to medium (Cientanni et al., 2019), where reported. One study found that this was maintained at six month follow up (Cavanagh et al., 2006b). The BtB SUDS, however, is a self-reported level of depression and is not an established measure of depression.

Several other measures of depression were only used in one study, making it difficult to compare these findings. A RCT exploring efficacy of Beating the Blues efficacy within minority populations in the USA, found that there was a statistically significant decrease in PROMIS-depression scores for African American participants from start to end of treatment, when compared with a control group. This was maintained at follow up and a medium effect size was reported. No statistically significant clinical changes to PROMIS-depression scores were observed for white participants (Jonassaint et al., 2019). The sampling process of this study was of lower quality, however, and resulted in significantly unequal sample sizes, which may have influenced findings. In a study exploring the effectiveness of Beating the Blues with older adults (McMurchie et al., 2013), statistically significant reductions in GDS scores were observed from start to end of treatment and were maintained at follow up. These reductions in scores were greater than participants receiving treatment-as-usual. A large effect size was reported. In one RCT (Gupta et al., 2020), the Hopkins Symptom Checklist was used and significant reductions were observed in the intervention group when compared with the control, but only at six month follow up. Another RCT (Forand et al., 2018) used the HRSD and reported significant reductions in HRSD scores in the intervention group when compared with the control. The HADS (HADS) (Zigmond and Snaith, 1983) was used in a trial (Grime, 2004) and significant reductions in level of depression were reported at the end of treatment.
Effectiveness of BtB for anxiety. Of the 17 studies that explored anxiety as an outcome, there was significant heterogeneity in the measures used to measure anxiety. Most studies used either the Beck Anxiety Inventory (BAI) (Beck and Steer, 1993) (five studies), the Generalised Anxiety Disorder Scale 7 (GAD-7) (Spitzer et al., 2006) (four studies), or the Beating the Blue SUDs for anxiety (five studies). Other measures used included (one study apiece): PROMIS anxiety (Cella et al., 2010) and the Geriatric Anxiety Inventory (GAI) (Pachana et al., 2007).

Two of the five studies using the BAI (Learmonth, 2007; Mitchell, 2009) reported statistically significant reductions in anxiety from start to end of treatment with medium effect sizes. One study (Proudfoot et al., 2003b) reported a decrease in magnitude of BAI score but this was not statistically significant (Proudfoot et al., 2003a) of the trial found a statistically significant reduction in BAI score (maintained at follow up); however, in phase two of the trial (Proudfoot et al., 2004) where the study was extended with a larger sample size, this was no longer significant. Another study (Ormrod et al., 2010) found no significant reduction in BAI scores from start to end of treatment and reported that for two participants, there was a significant increase in anxiety.

One of the four studies using GAD-7 (Cavanagh et al., 2011) reported a statistically significant reduction in GAD-7 scores from start to end of treatment with a large effect size. Another study (Boger, 2015) observed mean reductions in GAD-7 scores but only explored this descriptively. Two RCTs found no significant reduction in GAD-7 scores (Jonassaint et al., 2019, 2017).

Four of the five studies using the BtB SUDs for anxiety (Cavanagh et al., 2006b; Cientanni et al., 2019; Johnson and Hinshaw, 2011; van den Berg et al., 2004) reported statistically significant reductions in BtB SUDs for anxiety, with medium effect sizes noted where reported (Cientanni et al., 2019; Johnson and Hinshaw, 2011). One study did not find a significant reduction in SUDs of anxiety (Fairclough et al., 2020). The BtB SUDS, however, is a self-reported measure of anxiety and is not an established, measure of anxiety.

Several other measures of anxiety were only used in one study, making it difficult to compare these findings. A RCT exploring possible differences in Beating the Blues efficacy in minority groups in the USA, the study found that there was a statistically significant decrease
in PROMIS-anxiety scores for African American participants from start to end of treatment, when compared with a control group. This was maintained at follow up and a medium effect size was reported. No statistically significant clinical change to PROMIS-anxiety scores were observed for white participants (Jonassaint et al., 2019). The sampling process of this study was poorer in quality, however, and resulted in significantly unequal sample sizes, which may have influenced findings. In a study exploring the effectiveness of Beating the Blues with older adults (McMurchie et al., 2013), statistically significant reductions in GAI scores were observed from start to end of treatment and were maintained at follow up. These reductions in scores were greater than participants receiving treatment-as-usual. A medium-to-large effect size was reported. A trial (Grime, 2004) using the HADS did not find a significant reduction in level of anxiety post intervention.

**Effectiveness of BtB for psychological distress.** Eight studies used a general measure of distress, the Clinical Outcomes in Routine Evaluation (CORE) (Barkham et al., 2010) or the shorter version, the CORE-10 (Connell and Barkham, 2007). Seven of the eight studies (Cavanagh et al., 2011, 2006b; Cientanni et al., 2019; Fairclough et al., 2020; Johnson and Hinshaw, 2011; Pittaway et al., 2009; van den Berg et al., 2004) reported significant reductions in CORE scores, i.e. psychological distress from start to end of intervention with effect sizes ranging from medium (Johnson and Hinshaw, 2011) to large (Cavanagh et al., 2006b). One of these studies found that although BtB was effective at reducing psychological distress, it was as effective as two other self-guided interventions: Overcoming Workbooks and Living Life to the Full (Pittaway et al., 2009). One of the studies also found that individuals who present with higher levels of psychological distress prior to treatment, who identify with more social groups, who live in less socioeconomically deprived areas and those taking medication, are predictive of greater improvements in psychological distress from start to end of treatment (Cientanni et al., 2019). One RCT (Gilbody et al., 2015) did not find significant reductions in psychological distress when compared with treatment as usual.

**Secondary outcomes**

**Problem impact.** Four studies used the Work and Social Adjustment Scale to (WASA) (Mundt et al., 2002) to measure the impact of anxiety and/or depression on individuals’ work and personal life (Cavanagh et al., 2011, 2006b; Proudfoot et al., 2004, 2003b). All studies reported significant reductions in the impact of participants’ mental health difficulties from
start to end of treatment, with a small-to-medium effect size where reported (Cavanagh et al., 2011). In two of these studies, however, significant reductions were only noted in certain subscales of the WASA: private leisure (Proudfoot et al., 2003b), social sphere and in the work sphere (Proudfoot et al., 2004).

**Cost effectiveness.** Two RCTs explored cost effectiveness of BtB using quality adjusted life years (QALYs) (Duarte et al., 2017; McCrone et al., 2004). One trial (Duarte et al., 2017) found that BtB was not cost effective when compared with GP care as usual and when compared with another free to use cCBT programme, MoodGYM. Another trial (McCrone et al., 2004), however, reported that BtB was cost effective: although BtB was associated with higher costs, it was also associated with lower lost employment days, lower service use at follow-up and higher estimated depression free days.

**Mechanisms of change.** Three studies (Grime, 2004; Proudfoot et al., 2004, 2003b) used the Attributional Style Questionnaire (Peterson et al., 1982) to explore if changes occur to individuals’ explanatory styles i.e. a cognitive mechanism of change. Participants who used BtB had significantly greater reduction in negative attributional style than those in the control groups (Grime, 2004; Proudfoot et al., 2004) and significant increase in positive attributional style (Proudfoot et al., 2004). Another study (Proudfoot et al., 2003b) reported a change in ASQ scores but did not discuss this in terms of positive or negative attributional styles, which limits interpretation of these findings. One RCT used the Competencies of Cognitive Therapy Scale-Self Report (CCTS-SR) to assess the skills learnt in cognitive therapy (Strunk et al., 2014), and the Behavioural Activation for Depression Scale-Short Form (BADs-SF) to assess the skills learnt from behavioural activation theory used in CBT (Manos et al., 2011). Participants who used BtB had significantly improved cognitive and behavioural skills post intervention, when compared with the control group. Large effect sizes were reported. The study noted, however, that cognitive skill change significantly predicted greater change in severity of depression whereas, behavioural skill change did not.

**Additional secondary outcomes.** Several outcome domains were reported in one study only. One study (Ormrod et al., 2010) explored therapeutic alliance through the Agnew Relationship Measure (ARM) (Agnew-Davies et al., 1998). The study reported that the mean item ratings of therapeutic alliance were significantly higher than the neutral midpoint; however, no significant relationship was found between the ARM and depression outcomes.
Two studies explored quality of life (QoL) outcomes. One RCT (Rollman et al., 2018) used the Mental Health Composite from the Short Form Health Survey (SF-12) to assess health related quality of life (Ware, J. et al., 1996) and reported significant improvements post intervention, with a small effect size reported. Another study used the Manchester Short Assessment of Quality of Life scale (MANSA) (Priebe et al., 1999) and reported significant improvements in QoL after BtB intervention (Persson, 2018).

**Acceptability**

*Quantitative measurements of acceptability.* Quantitative measurements of acceptability were heterogenous across the included studies. The majority of studies reported acceptability descriptively rather than statistically. Seven studies used participant feedback forms (Boger, 2015; Cavanagh et al., 2011; Johnson and Hinshaw, 2011; Learmonth, 2007; Mitchell, 2009; Mitchell and Dunn, 2007; Pittaway et al., 2009; Proudfoot et al., 2003b) and five studies (Cavanagh et al., 2009; Learmonth, 2007; Pittaway et al., 2009; Proudfoot et al., 2004; Stearns-Yoder et al., 2022) used ratings of acceptability. Keys areas reported were usefulness, satisfaction, programme features, ease of use, and comparisons to other treatment options. Six studies reported that participants had rated BtB as useful or helpful (Cavanagh et al., 2009; Johnson and Hinshaw, 2011; Learmonth, 2007; Mitchell, 2009; Proudfoot et al., 2003b; Stearns-Yoder et al., 2022). Four studies found that participants were satisfied with BtB (Cavanagh et al., 2011, 2009; Proudfoot et al., 2004; Stearns-Yoder et al., 2022). One of these was a RCT and statistically assessed this, reporting that those receiving BtB had significantly higher satisfaction ratings than those in the control group (Proudfoot et al., 2004). Three studies’ (Jonassaint et al., 2020; Learmonth, 2007; Proudfoot et al., 2003b) reported that BtB programme features increased acceptability including the multimedia features, simplicity of language, structure of BtB, and the empowering nature of using a self-guided programme. Seven studies reported that patients found BtB easy to use, accessible and practical (Boger, 2015; Johnson and Hinshaw, 2011; Jonassaint et al., 2020; Learmonth, 2007; Mitchell, 2009; Pittaway et al., 2009; Stearns-Yoder et al., 2022). Four studies explored comparisons of BtB to other forms of treatments: during early beta-testing for BtB, almost 90% of participants reported BtB was the same or better than previous therapy. A later study (Cavanagh et al., 2009), reported similar findings: 83% of participants who had previous forms of treatment, felt BtB was as good or better than previous treatments. Another study (Pittaway et al., 2009) reported that participants were equally satisfied with BtB when
compared with two alternative forms of self-help (Pittaway et al., 2009). A study in a higher education setting (Mitchell, 2009) reported that approximately 40% of the participants preferred BtB to treatment than usual; whereas only approximately 20% of participants preferred counselling as usual. 40% did not have a preference. Two studies (Pittaway et al., 2009; Stearns-Yoder et al., 2022) reported that users would recommend BtB to others.

Six studies explored reasons for reduced acceptability of BtB. Four studies (Johnson and Hinshaw, 2011; Jonassaint et al., 2020; Learmonth, 2007; Mitchell, 2009) reported that some participants had found BtB unrelatable or irrelevant to their difficulties. (Mitchell, 2009). Five studies (Boger, 2015; Johnson and Hinshaw, 2011; Jonassaint et al., 2020; Learmonth, 2007; Mitchell, 2009; Mitchell and Dunn, 2007) highlighted programme features that contributed to reduced acceptability including finding the pace too slow, programme requirements of reading and typing, a desire for increased clinician support, desire for homework for be reviewed and finding the programme patronising. It is important to note, however, that not all participants completed feedback forms in these studies and completion rate was low, ranging from 14% (Boger, 2015) to 55% (Proudfoot et al., 2003b). Thus, it is unclear whether this was meaningful and indicative of dissatisfaction or not (Mitchell, 2009; Stearns-Yoder et al., 2022). To One study specifically explored predictors of acceptability and found that female participants found BtB more useful and were more satisfied and positive about the programme than male participants (Cavanagh et al., 2009).

**Uptake and attrition.** A further operationalisation of acceptability explores uptake and attrition within studies. Although most of the studies cited uptake and attrition rates, these varied substantially between studies: for example, from 9% (Du et al., 2021) to 86% for attrition (Persson, 2018). Studies conducted on routine data or naturalistic settings tended to report higher rates of attrition (for example see Mitchell 2009, Cientanni 2019, or Boger 2015), whereas experimental studies tended to report lower attrition rates (for example see Jonassaint 2020, Rollman et al. 2020, or McCrone 2004).

Nine studies explicitly explored uptake and attrition as a measurement of acceptability (Bayliss and Willis, 2010; Cavanagh et al., 2011; Fairclough et al., 2020; Johnson and Hinshaw, 2011; Jonassaint et al., 2017; McMurchie et al., 2013; Pittaway et al., 2009; Proudfoot et al., 2004, 2003b). Seven of these explored predictors of uptake and completion. The results were inconsistent. Younger age was a significant predictor of increased uptake in
a study exploring older adult populations (McMurchie et al., 2013) whereas younger adults were significantly less likely to complete the BtB programme than middle aged adults in another study (Pittaway et al., 2009). Three studies (Cavanagh et al., 2011; Johnson and Hinshaw, 2011; Pittaway et al., 2009), however, did not find age as a significant predictor of attrition. Four studies explored baseline symptom severity as predictors: One study (Johnson and Hinshaw, 2011) reported that higher baseline levels of depression and distress were more associated with attrition from BtB. A different study (Cavanagh et al., 2011) found that participants meeting clinical threshold were more likely to commence treatment but this did not predict completion of treatment. Conversely, two studies (Bayliss and Willis, 2010; Pittaway et al., 2009) reported that baseline symptom severity was unrelated to attrition; however, the authors reported that those with longer problem duration were more likely to complete treatment than those with shorter problem duration (Pittaway et al., 2009).

Increased confidence using computers was associated with increased uptake and completion of BtB in older adult populations (Fairclough et al., 2020; McMurchie et al., 2013). In terms of gender, one study reported that male participants were more associated with attrition (Bayliss and Willis, 2010), whereas other studies reported gender did not significantly predict attrition (Cavanagh et al., 2011). Similarly in terms of ethnicity, one trial (Jonassaint et al., 2017) reported that African American participants were significantly less likely than white participants to commence BtB and completed significantly fewer sessions. Another study, however, did not find ethnicity as a significant predictor for uptake or completion (Cavanagh et al., 2011). Only one study reported that self-referrals were associated with increased uptake and completion (Cavanagh et al., 2011).

Three studies (Fairclough et al., 2020; Proudfoot et al., 2004, 2003b) cited reasons for non-completion including: other commitments, travel time to appointments, dissatisfaction with BtB, physical ill health, improvement in symptoms, and difficulties using the programme.

**Qualitative explorations of acceptability.** Three studies conducted qualitative analyses of the acceptability of BtB. Two studies (Du et al., 2021; Jonassaint et al., 2020) used thematic analysis (Braun and Clarke, 2012) and the other study (Hanna, 2012) used Interpretive Phenomenological Approach (IPA) (Smith et al., 2009). A study exploring Scottish primary care patient’s experiences of BtB (Du et al., 2021) found six key themes. The first related to information dissemination of BtB and having little knowledge of it despite referrals to the programme. The second theme focused on expectations and the impact of waiting times. The
third and fourth themes focused on the impact of locations on experiences of using BtB: participants were more positive about using BtB at home and clinic spaces as opposed to public spaces such as libraries. The fifth theme focused on a desire for increased human support when using the programme. The final theme focused on the desire for additional application features to allow for further clarification and feedback.

In a trial exploring the experiences of BtB with participants with sickle cell disease (Jonassaint et al., 2020), three overarching themes with several subthemes were reported. Within the theme of ‘facilitators’, participants spoke of the structure of the programme, practicality, relatability, and positive outcomes from the programme. Within the theme of ‘barriers’, participants spoke of lack of personal factors such as poor concentration and poor literacy levels, and programme specific features such as slow pace, technical difficulties and lack of reminders to complete sessions. In terms of the theme of ‘opportunities’, participants spoke of the possibility of mobile apps for increased convenience, changing the pace of the programme, having progress indicators, and more direct application of skills to difficulties.

A study exploring decision making processes for treatment choice and experiences of using BtB in an older adult population (Hanna, 2012), found five master themes. The first theme focused on the experience of BtB as a process of change in relation to initial uncertain impressions, developing awareness, reinforcing previous treatments, making changes and feeling empowered to move forward. The second theme explored relevance of BtB to older people with participants noting the lack of information relating to physical health issues and feeling it was not particularly relevant for older adult populations. The third theme focused on challenges of using BtB including the discomfort of talking about mental health issues, preferring talking to a person, and coping with technical difficulties. The fourth theme explored motivation to try something new, with participants noting a sense of having nothing to lose by trying BtB and seeing it as an alternative to medication. The final theme focused on barriers to commencing the programme which included lack of confidence using technology, severity of depression, ill physical health and other life events. The authors noted that there appeared to be a bi-directional relationship between the first two themes and that motivation and barriers to uptake directly influenced decision making of continuation and/or uptake of the programme.
<table>
<thead>
<tr>
<th>Author and publication year</th>
<th>Associated study</th>
<th>Comparator</th>
<th>Measures</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
<th>Attrition</th>
<th>Measures of effect</th>
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<tbody>
<tr>
<td>Grime 2004</td>
<td>/</td>
<td>Intervention (BtB + TAU) vs control (TAU)</td>
<td>HADS ASQ</td>
<td>Intervention group ss ↓HADS; ss ↓ASQ when compared with control. Maintained at 1 month follow up but not 4 or 6 month follow up</td>
<td>Reasons given for non-participation included: access problems, preferences for other treatments, time commitment, scepticism about the intervention and employer connection.</td>
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<td></td>
<td>TAU= none /medication /counselling /combination</td>
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<td>BtB + TAU Analysed: n=19</td>
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<td>6 month n=14</td>
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<td>TAU Analysed: n=24</td>
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<td>End of treatment n = 23</td>
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<td>1 month follow up n=19</td>
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<td>6 month n=19</td>
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<tr>
<td>Cavanagh et al 2006</td>
<td>Routine care study</td>
<td>Intervention only (BtB)</td>
<td>BtB SUDS of anxiety and depression GHQ-12 CORE-OM WSA</td>
<td>ss ↓ CORE-OM scores, ss ↓ WSA, ss ↓ BtB SUDS of depression and anxiety post intervention in both primary and secondary care setting.</td>
<td>/</td>
<td>38% attrition from start to end of treatment; 53% attrition at post treatment questionnaire completion; 82% attrition</td>
<td>Cohen’s d=1 post intervention</td>
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</table>

**Table 2. Study results**
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Comparison</th>
<th>Measures</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavanagh et al. 2009</td>
<td>Intervention only (BtB)</td>
<td>CB-OPP, A-CCBTQ, PFQ-CCBT</td>
<td>Greater than neutral midpoint ratings for CB-OPP, A-CCBTQ; PFQ-CCBT when compared with pre-treatment ratings.</td>
<td>/ 38% attrition from start to end of treatment</td>
</tr>
<tr>
<td>Cavanagh et al. 2011</td>
<td>Intervention only (BtB)</td>
<td>PHQ-9, CORE-10, WASA, Patient Experience Questionnaire</td>
<td>Self-referrals ss more likely to commence; complete 2 sessions and complete programme than GP referrals. Meeting clinical threshold at baseline predicted commencement of programme. Lower baseline depression predicted programme completion. ss ↓GAD7, ↓PHQ-9, ↓CORE 10 (↓WASA 6 with effect sizes given.</td>
<td>89% mostly/very satisfied with waiting time. 90% satisfied with overall experience. 93% satisfied with type of treatment received. 10% attrition (start to session 2). 47% attrition (start to end of treatment)</td>
</tr>
<tr>
<td>Duarte et al. 2017</td>
<td>REACT trial</td>
<td>EQ-5D-3L, SF-6D</td>
<td>BtB was not significantly more cost effective than TAU.</td>
<td>/ 24% attrition at 4 months 30% attrition at 12 months</td>
</tr>
<tr>
<td>Gilbody et al. 2015</td>
<td>Intervention (BtB) vs TAU+MoodGYM vs TAU</td>
<td>PHQ-9, SF-46, CORE-OM</td>
<td>No evidence that BtB had additional improvement in PHQ-9 scores when compared with TAU (GP) or MoodGYM. No evidence that BtB had additional improvements in SF-36 or CORE-OM scores compared with TAU (GP)</td>
<td>Odds ratios (CI) BtB vs TAU 4 months = 1.19 (0.75-1.88)</td>
</tr>
<tr>
<td>Study</td>
<td>Age group</td>
<td>Inclusion criteria</td>
<td>Methodology</td>
<td>Findings</td>
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<tr>
<td>-----------------------</td>
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<tr>
<td>Littlewood et al. 2015</td>
<td></td>
<td>See related publications Semi-structured interviews</td>
<td>In addition to results in related publications perceptions of cCBT reported, however, BtB not differentiated from MoodGYM.</td>
<td>/</td>
</tr>
<tr>
<td>Hanna 2012</td>
<td>Older adults study</td>
<td>Sample inclusive of BtB completers &amp; discontinuers and TAU</td>
<td>Semi-structured interviews</td>
<td>Five master themes: 1. BtB as a process of change 2. Relevance of BtB to older people 3. Challenges of using BtB 4. Motivation to try something new 5. Barriers to BtB at uptake</td>
</tr>
</tbody>
</table>

TAU or MoodGYM at any time point.

12 months = 0.77(0.47-1.26)
24 months = 1.00 (0.60-1.68)

BtB vs Moodgym
4 months =0.91(0.62-1.34)
12 months = 0.77(0.50-1.18)
24 months =0.72(0.47-1.11)
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Baseline Measures</th>
<th>Outcome Measures</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>McMurchie et al. 2013</td>
<td>BtB + TAU vs TAU</td>
<td>GDS, GAI, CORE-34</td>
<td>ss ↓ GDS, GAI, CORE-34 post intervention when compared with TAU. Maintained at follow up.</td>
<td>Predictors of uptake included younger age; more years of education; home internet access; and more experience and confidence using computers.</td>
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<td>Intervention 27.3% attrition from start to end of treatment. Comparator 20% attrition from start to end of treatment End of treatment (2 months) GDS d=0.85 GAI d=0.59 CORE d=0.84 Follow up 1 month later (3 month timepoint) GDS d=0.80 GAI d=0.69 CORE d=0.61</td>
</tr>
<tr>
<td>Jonassaint et al. 2020</td>
<td>/</td>
<td>BtB+ care coach support vs TAU</td>
<td>Intervention group had ss ↓ PHQ-9 at 6 month follow up. No changes to TAU. No ss differences at 1 or 3 months. No ss group differences for GAD-7 or BPI at any time points.</td>
<td>Factors facilitated use of BtB: structure, care coach support, simple language, homework activities, practicality. Barriers: not relatable; boring; slow tempo; unable to go at their own pace; typing and reading.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PHQ-9, GAD-7, BPI</td>
<td></td>
<td>10% attrition from study from start to end of treatment Cohen’s d for PHQ-9 at 6 months = -0.652</td>
</tr>
<tr>
<td>Jonassaint et al. 2017</td>
<td>Minority population study</td>
<td>BtB vs BtB + ISG vs TAU (BtB included care manager support)</td>
<td>PHQ-9, GAD-7, PROMIS-Anxiety, PROMISE-Depression, SF-12, HRQoL</td>
<td>No ss differences for PHQ-9 and GAD-7 but African American participants trended towards greater decreases in these scores than white participants. African American participants were significantly less likely than white participants to commence BtB. Of participants who started, African American participants completed less</td>
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<tr>
<td>Study</td>
<td>Intervention/Characteristics</td>
<td>Engagement</td>
<td>Attrition/Outcome</td>
<td>Feedback/Satisfaction</td>
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<tr>
<td>Jonassaint et al. 2019</td>
<td>For white participants: no ss change to PROMIS-anxiety or PROMIS-depression or SF-12 when compared with TAU. For African American patients, BtB was associated with ss ↓ PROMIS-anxiety ↓ PROMIS-depression at 6 month follow up when compared with TAU. No ss changes to SF-12.</td>
<td>/</td>
<td>African American participants vs TAU Cohen’s d</td>
<td>SF-12 (MCS) d=0.25 PROMIS-Anxiety d= -0.54* PROMIS-Depression d= -0.47*</td>
</tr>
<tr>
<td>Rollman et al. 2018</td>
<td>No ss benefit of internet support group i.e. no ss group differences on SF-12 MCS; PROMIS-depression, PROMIS-anxiety for BtB +ISG vs BtB. Engagement: By 6 months, 83.6% of participants with BtB access had completed at least 1 session and 36.7% had completed the programme</td>
<td>14.2% attrition from start to 6n month follow up and 15.8% to 12 month follow up.</td>
<td>6 months for both interventions for SF-12 MCS d=0.02.</td>
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<tr>
<td>Mitchell &amp; Dunn 2007</td>
<td>Higher education study Intervention only (BtB) BDI-II BAI Credibility/expectancy-of-improvement scale Participant feedback form BtB SUDS anxiety/depression Phase 1: ss ↓BDI-II post intervention; no significant reductions in BAI. Positive feedback: skill &amp; strategy acquisition; increased understanding; ease of use. Negative feedback: unrelatable; impersonal</td>
<td>Phase 1 16.67% attrition from start to end of intervention; 66.67% attrition until follow up.</td>
<td>Phase 1 Cohen’s r BDI-II r=0.63 BAI r=-0.37</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Outcome Measures</td>
<td>Results</td>
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<tr>
<td>Mitchell 2009</td>
<td>Phase 2 &amp; combined:</td>
<td>Positive themes:</td>
<td>40% preferred cCBT to TAU; 30% preferred TAU; and 30% were happy with either. 66% would recommend to a friend.</td>
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<td>ss ↓ BDI-II &amp; ↓ BAI</td>
<td>Negative theme:</td>
<td>Positive themes: increased understanding &amp; skill/strategy acquisition</td>
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<td>post intervention.</td>
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<td>Negative theme: difficulty completing homework</td>
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<td>Positive themes: increased understanding &amp; skill/strategy acquisition</td>
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<td>Negative theme: difficulty completing homework</td>
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<td>Combined phases</td>
<td>Positive themes: increased understanding &amp; skill/strategy acquisition</td>
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<td>1&amp;2: TAU; 38.9%</td>
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<td>Negative theme: difficulty completing homework</td>
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<td>happy with either.</td>
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<tr>
<td>Gupta et al. 2020</td>
<td>BtB vs TAU</td>
<td>PHQ-9</td>
<td>37.5% preferred cCBT to TAU; 12.5% preferred TAU; 50% were happy with either.</td>
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<td>SCL-20</td>
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<td>ss ↓ PHQ-9 in both</td>
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<td>groups but greater</td>
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<td>improvements in BtB</td>
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<td>group at week 12</td>
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<td>and at week 24. BtB</td>
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<td>participants had ss</td>
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<td>greater ↓ SCL-20</td>
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<td>than TAU at week 24.</td>
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<td>Ormrod et al. 2010</td>
<td>Intervention only</td>
<td>BDI-II</td>
<td>37% attrition from start to end of intervention</td>
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<td>(BtB)</td>
<td>BAI</td>
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<td>ss ↓ BDI-11. No ss</td>
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<td>changes to BAI.</td>
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<td>Mean item ratings</td>
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<td>26% attrition</td>
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<tr>
<td>Van den Berg 2004</td>
<td>Intervention only (BtB)</td>
<td>GHQ-12, BtB SUDs anxiety/depression, CORE-OM</td>
<td>ss ↓ wellbeing, problems, functioning (CORE-OM), ss ↓ SUDs anxiety/depression for completers</td>
<td>Clinical staff estimated 60-70% referrals would benefit from BtB and in practice, ↓ referrals to CBT waitlist. Informal positive feedback included speed and ease of access.</td>
</tr>
<tr>
<td>Proudfoot et al. 2003a</td>
<td>Intervention only (BtB)</td>
<td>BDI-II, BAI, WSA, ASQ</td>
<td>ss ↓ subscales of private leisure impairment of ↓(WSA) and attributional style ↑(ASQ).</td>
<td>Patient feedback: 100% found BtB helpful, 91% liked multimedia therapeutic features. Of those who had previous therapeutic input, 89% found it the same or better.</td>
</tr>
<tr>
<td>McCrone et al., 2004</td>
<td>First BtB primary care trial</td>
<td>QALY, BDI-II</td>
<td>Estimated depression-free days in 8 months following randomisation based on BDI-II scores</td>
<td>BtB more expensive but more effective than TAU. 81% chance that BtB is cost-effective. Service use: greater use of other services by TAU at follow up. Service costs: Mean service costs was £40 higher for BtB group at follow up but not ss. Lost employment: ss lower lost employment costs for BtB at follow up.</td>
</tr>
<tr>
<td>Author et al. Year</td>
<td>Study Type</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Demographic Predictors</td>
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<tr>
<td>Proudfoot et al. 2003b</td>
<td></td>
<td>BDI-II, BAI, WSA, ASQ</td>
<td>Patient satisfaction survey</td>
<td>ss ↓ BDI-II, ↓ WSA, ↓ ASQ CoNeg, ↑ ASQ CoPos in BtB group when compared with TAU. Greater mean ↓ BAI in BtB group than TAU not ss. No interactions of drug treatment, duration or severity of pre-existing for depression, negative attributional style and social adjustment.</td>
</tr>
<tr>
<td>Cientanni et al. 2019</td>
<td>Mastermind study</td>
<td>GIS CORE-OM, BtB SUDs anxiety/depression</td>
<td></td>
<td>Pre-treatment severity of psychological distress, group identifications, SIMD, ADM use were ss predictors of change in psychological distress. Age and education were ss predictors of pre to mid treatment changes in psychological distress.</td>
</tr>
<tr>
<td>Persson 2018</td>
<td>GIS CORE-OM, BtB SUDs anxiety/depression</td>
<td></td>
<td></td>
<td>Demographic variables did not ss predict treatment outcomes.</td>
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<tr>
<td>Pittaway et al. 2009</td>
<td>Intervention only:</td>
<td>CORE-OM Patient and GP feedback</td>
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<tr>
<td>/</td>
<td>1: BtB</td>
<td>ss ↓ CORE-OM for all groups. No ss group differences.</td>
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<tr>
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<td>2: Overcoming workbooks</td>
<td>No ss associations between age, education, computer literacy, problem duration, length of episode or GP care, medication, suitability of intervention, gender or diagnosis and change to CORE-OM outcomes.</td>
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<td>3: Livinglifetothefull</td>
<td>No ss in GP support between groups.</td>
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</table>

↑ GIS ss predicted ↑ MANSA but did not ss predict functioning or wellbeing (CORE-OM).

↓ CORE-OM ss predicted ↑ MANSA, functioning and wellbeing (↓ CORE-OM subscales).

SIMD ss moderator to functioning when baseline distress was low. Ss mediation relationship between GIS and CORE-OM on satisfaction.

86% found it accessible; 84% found it clear; 73% would recommend to others; 42-46% would consider interventions as an alternative to other forms of treatment. No ss significant differences between interventions.

Age and problem duration ss predicted attrition.

42% attrition from start to end intervention.
<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Intervention (BtB) vs waitlist</th>
<th>Measures</th>
<th>Outcomes</th>
<th>Attrition %</th>
<th>Hedge's g</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forand et al. 2018</td>
<td>/</td>
<td>Intervention (BtB)</td>
<td>PHQ-9, HRSD, CCTS-SR, BADS-SF, MINI600</td>
<td>BtB intervention had ss greater change to cognitive and behavioural skill change when compared with waitlist. Cognitive skills change ss predicted greater change in severity of depression but behaviour activation did not.</td>
<td>29%</td>
<td>Cognitive g = 1.89, Behavioural g = 1.11</td>
<td></td>
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<tr>
<td>Learmonth &amp; Rai 2008</td>
<td>Specialist CBT service study</td>
<td>Intervention only (BtB)</td>
<td>CORE-OM, BDI-II, BAI, SUDS anxiety/depression Qualitative feedback Patient satisfaction feedback</td>
<td>ss ↓ CORE-OM; SUDS anxiety/depression, BDI-II, BAI post intervention. No ss group differences between BtB and those with physical health comorbidities</td>
<td>30%</td>
<td></td>
<td>Helpful aspects: 1) therapeutic features (skill acquisition, agency, identification with case studies) 2) structure (specific media features, implementation and service features); 3) self-determination (self-help structure and increased self-awareness). Areas to improve 1) structure (programme structure, desire of clinician input 2) acceptability (relevancy and identification with BDI-II and BAI)</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Intervention Type</td>
<td>Measures / Additional Details</td>
<td>Findings / Comments</td>
<td>Attrition / Completion Details</td>
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<td>Boger 2015</td>
<td>Intervention only</td>
<td>PHQ-9, GAD7, BtB SUDs</td>
<td>Mean ↓ PHQ-9 and GAD-7.</td>
<td>79% attrition start to end of treatment</td>
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<td>Bayliss &amp; Willis 2010</td>
<td>Intervention only</td>
<td>BtB SUDs</td>
<td>Males were ss more likely to not complete.</td>
<td>40% attrition from start to end intervention</td>
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<td>Johnson &amp; Hinshaw 2011</td>
<td>Intervention only</td>
<td>CORE-OM</td>
<td>ss ↓ CORE-OM; SUDS post intervention. Only SUDs anxiety ss ↓ for those who completed</td>
<td>74.5% attrition from start to end intervention</td>
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<tr>
<td>Reference</td>
<td>Intervention</td>
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<td>Findings</td>
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<td>Fairclough et al. 2020</td>
<td>Intervention only (BiB)</td>
<td>CORE-OM, SUDS depression &amp; problem distress</td>
<td>CORE-OM, SUDS depression &amp; problem distress</td>
<td>Confidence predicted commencement. Reasons for lack of engagement: not right time, lack of confidence, felt better, not interested in cCBT, technological difficulties.</td>
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<tr>
<td>Stearns-Yoder et al. 2022</td>
<td>Intervention only (BiB)</td>
<td>CSQ, IEUQ, IIEQ</td>
<td>Mostly/easy to use, mostly/very good for CBT, mostly/very likely to use again, improved depressive symptoms, 51% felt improved QoL, 72% gained more knowledge.</td>
<td>Most common reasons for attrition were external factors. No one described dissatisfaction with treatment.</td>
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<td>Du et al. 2021</td>
<td>Intervention only (BiB)</td>
<td>Semi-structured interviews</td>
<td>Key themes: 1. Information dissemination</td>
<td>9% attrition from start to end of intervention</td>
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</table>
2. Expectations and impact of waiting for BtB.
3. Impact of locations on experience
4. Home preference
5. Desire for human support
6. Desire for additional application support features

Notes: TAU = Treatment as usual; ss = statistically significant; SIMD = Scottish Index of Multiple Deprivation; ADM = antidepressant medication; QoL = quality of life.
Measures: HADS = Hospital Anxiety and Depression Scale; ASQ = Attributional Style Questionnaire; SUDS = subjective units of distress; GHQ-12 = general health questionnaire; CORE = Clinical Outcomes Routine Measure; WSA= work and social adjustment questionnaire; PHQ-9 = patient health questionnaire; SF-46/SF-12/SF-6D: Short Form Questionnaire; GDS = Geriatric Depression Scale; GAI=Geriatric Anxiety Inventory; GAD-7 = Generalised Anxiety Disorder Assessment; HRQoL= Health Related Quality of Life questionnaire; BDI-II = Beck Depression Inventory; BAI = Beck Anxiety Inventory; SCL 20 = Symptoms Checklist; ARM = Agnew Relationship Measure; QALY = quality adjusted life year; GIS = group identification scale; MANS = Manchester Short Assessment of Quality of Life; HRSD = Hamilton Rating Scale for Depression; CB-OPP = Cognitive Behavioural Opinions about Psychological Problems Questionnaire ; A-CCBTQ = attitudes to CBT Questionnaire; PFQ-CCBT= Patient Feedback Questionnaire for CBT; BPI = brief pain inventory ; CCTs-SR = Competencies of Cognitive Therapy Scale Self Report; BADs-SF = Behavioural Activation for Depression Scale Short Form; MINI600 = Mini-International Neuropsychiatric Diagnostic Interview 6.0.0; IEUQ = Internet Evaluation and Utility Questionnaire; IIEEQ = Internet Impact and Effectiveness Questionnaire.
Discussion

The current review aimed to systematically review and assess the evidence for the effectiveness of BtB in relation to primary and secondary outcomes and the acceptability of BtB.

Overall, the results indicated that BtB is an effective treatment for depression and overall psychological distress. Findings were consistent across ages (adults to older adults) and across contexts including primary, secondary and specialist care services as well as in physical healthcare settings, indicating the versatility of BtB. This is in line with meta-review evidence of cCBT programmes in relation to the treatment of depression (Foroushani et al., 2011). One RCT (Gilbody et al., 2015) in the current review reported conflicting findings that BtB did not significantly reduce level of depression when compared with GP care-as-usual and when compared with another cCBT programme. This trial, however, has received significant criticism (Schröder et al., 2016) including poor adherence to treatment, unusually effective treatment-as-usual and overlap between the treatment and control groups: 19% of the GP treatment-as-usual group accessed cCBT programmes during the trial (Jones et al., 2015). These methodological weaknesses are likely to impact the validity of the findings reported.

Findings were less conclusive for the effectiveness of BtB in treating anxiety. This is in contrast to previous systematic review, meta-analytic and meta-review findings (Foroushani et al., 2011; Griffiths et al., 2010; Simmonds-Buckley et al., 2020). The existing literature argues that cCBT is effective for both anxiety and depression as CBT is a transdiagnostic therapeutic model, focusing on commonalities between anxiety and depressive disorders and focusing on the principles of maintaining factors (Newby et al., 2016). It is important to note, that several of the studies included the current review that did not find any significant reductions in anxiety scores (Jonassaint et al., 2019, 2017; Ormrod et al., 2010; Proudfoot et al., 2003b), had lower quality ratings for sampling (due to recruitment methodology and small sample sizes), which may have impacted the validity of the findings and power associated with the research. This may contribute to the conflicting nature of the current review findings when compared to existing literature. It has been noted, however, that smaller effects have been found for the treatment of anxiety when compared with treatment of depression in previous studies (Newby et al., 2016), but no specific hypotheses were
suggested. This highlights the importance of future BtB research continuing to examine the efficacy of the intervention in relation to anxiety and depression. If differences are evidence, it would be beneficial to consider what factors might affect this.

In terms of secondary outcomes, the results indicated that BtB is effective at reducing the impact of mental health difficulties on individuals’ work, social and personal life although there were few studies exploring this. This is in line with previous research findings of cCBT more broadly (Kaltenthaler et al., 2002; Tumur et al., 2007). Results also indicate some limited support that BtB is effective for improving quality of life, which is in line with previous cCBT research findings (Newby et al., 2016). Review findings also indicated that changes to attributional style as well as cognitive and behavioural skill acquisition may be the mechanism of change for symptom improvement; however, few studies have explored this. Similarly, explorations of mechanisms of change within broader cCBT research are scarce (Mogoașe et al., 2017).

The findings around cost effectiveness were mixed. This is in line with previous systematic review evidence of inconclusive findings for the cost effectiveness of DMHI (Jankovic et al., 2021). Methodological issues and heterogeneity of interventions is likely to have contributed to this (Jankovic et al., 2021). Other evidence, however, has found that telehealth is a cost effective form of healthcare delivery (Eze ID et al., 2020). Within the current review, only two studies have explored cost-effectiveness and the analysis involved making several estimations with authors noting that the results should be interpreted tentatively (McCrone et al., 2004).

There was mixed evidence for the acceptability of BtB. Evidence for the acceptability of BtB included reports of finding it helpful or useful, feeling satisfied with BtB, finding it easy to use or accessible, and perceiving BtB to be as good as other therapy interventions. Evidence for reduced acceptability, however, included finding BtB hard to relate to, irrelevant and feeling dissatisfied with some of the programme features. There were several methodological weaknesses in the study designs to explore acceptability, which are likely to have contributed to the inconclusive findings. The acceptability findings were largely presented descriptively, making it difficult to draw meaningful conclusions. In addition, not all participants completed feedback, correspondingly impacting upon the representativeness of feedback. The overall quality of the methods used to explore acceptability could also have been more rigorous, for
example, using established qualitative data collection and analysis techniques rather than non-standardized feedback forms. However, the pattern of findings around acceptability are consistent with the broader digital mental health research findings (Borghouts et al., 2021; Treanor et al., 2021).

Similarly, findings for attrition and predictors of uptake, adherence and attrition were variable and inconclusive. Variability in attrition rates and inconclusive findings for predictors of adherence and attrition are in line with previous findings from DMH reviews (Karyotaki et al., 2015; Simmonds-Buckley et al., 2020; Treanor et al., 2021; Van Ballegooijen et al., 2014). The concept of attrition, however, is not clearly operationalised in the literature and definitions vary between studies (Fernandez et al., 2015; Self et al., 2005). For example, attrition has been defined to include individuals who do not complete the whole intervention; or those who do not complete a certain number of sessions. It has also been defined according to number of missed appointments or those who have discontinued prior to sufficient clinical change (Fernandez et al., 2015; Richards and Richardson, 2012; Swift and Greenberg, 2012). This variability in definition is reflected in the BtB studies included in this review: some studies used a minimum number of sessions as a way of operationalising attrition (for example see Cavanagh et al., 2011; Cientanni et al., 2019); whereas many other studies used completion of the full intervention as a way of defining completion and attrition (for example see Proudfoot et al., 2003a). There was further significant variability in the reporting of attrition, for example reporting attrition from start-to-end of intervention (for example, see Ormrod et al., 2010); from start of intervention to follow up (for example see Rollman et al., 2018), or reporting a combination of both start-to-end of intervention and follow up (for example see Grime, 2004). Attrition rates also differ at times between the BtB intervention and the specific research study. For example see Jonassaint et al., 2020, where more participants completed the research measures than the BtB intervention (i.e. some participants who disengaged from the programme still completed the research outcome measures). Given this lack of clarity in operationalisation and reporting of attrition, this is likely to contribute to the significant variability in attrition rates, making it difficult to draw meaningful conclusions about attrition. In addition, many studies reported attrition rates, without exploring predictors of explanations for this (for example see Cavanagh et al., 2009; Cavanagh et al., 2006; Gilbody et al., 2015), limiting how meaningful the conclusions regarding attrition can be.
These findings can be compared with face-to-face CBT attrition rates. Meta-analytic evidence indicates that the weighted attrition rate for traditional psychotherapy is 19.7% (Swift and Greenberg, 2012) and is 26.2% for CBT specifically (Fernandez et al., 2015). The findings from the current review indicate that the attrition rates tend to be higher than this. This is in line with previous meta-analytic findings that online CBT has higher attrition rates than face-to-face CBT. For example, Fernandez et al (2015) reported that the weighted attrition rate for online CBT was 34.2%, whereas the weighted attrition rate for face-to-face CBT was 25.1%. Similarly, another large scale meta-analysis found that a 84.7% of the total meta-analysis sample completed the full CBT intervention when it was delivered via face-to-face format, whereas only 65.1% completed the full intervention when the intervention was delivered via the internet (Van Ballegooijen et al., 2014). These studies, however, have also noted that there is significant variability in the attrition rates reported for face-to-face interventions, for example, ranging from 0% to 74.23% attrition, and note that variability in operationalisation of attrition is likely to contribute to this (Swift and Greenberg, 2012). This variability is in line with the current review findings. Thus, it appears that digitally delivered CBT tends to have higher attrition rates than face-to-face CBT, however, there is still significant variability in the attrition rates reported for face-to-face CBT.

**Strengths and limitations**

It is important to note that causality cannot necessarily be inferred in a significant proportion of studies included in this study, given their naturalistic study designs without the use of randomisation and control groups. This can impact on internal validity including selection bias, attrition, confounding variables (such as comorbid medication use or accessing alternative mental health support), and history effects (Behi and Nolan, 1996). That said, seven RCTs identified in the review had more rigorous study designs. However, the consistency of findings across RCTs and non-RCT designs (particularly in relation to depression), bolsters confidence in the causal relationship between BtB and the observed outcome changes. Although RCTs are rigorous in design and reduce threats to internal validity, the clinical benefits observed in RCTs are frequently not generalised into real settings (Mohr et al., 2017), therefore the consistent findings for effectiveness of BtB in naturalistic designs is an important finding. The consistent evidence of BtB for depression and psychological distress across settings, is also supportive of the programme’s overall efficacy within target populations.
Although only BtB interventions were included in the review there was heterogeneity in the study contexts and measures used. This resulted in some difficulties in drawing conclusions when conflicting results were reported, for example, in relation to acceptability and attrition. The advantage, however, was the ability to conclude on effectiveness of BtB, specifically, for the treatment of depression and psychological distress. The evidence was consistent regardless of study context, sample age or measures used.

One weakness of the included studies was the lack of theory underpinning the research. This may speak to some of the broader issues in the DMH literature, particularly the lack of consensus of operationalisation and understanding of concepts such as attrition and acceptability. A further weakness was the lack of rigor applied when exploring acceptability of BtB. Studies focusing on effectiveness were more rigorous in design and methodology. This highlights an ongoing challenge within digital mental health where the emphasis has been on evaluating efficacy of these developed programmes, rather than attempting to understanding the process of implementation and utilization of these programmes within services (Mohr et al., 2017).

**Implications**

There are several implications from the review’s findings. BtB is an effective intervention, particularly for depression, but there is an ongoing issue around attrition. This may be partly due to reduced acceptability of BtB; however, this remains unclear. Given the ongoing relevance and use of cCBT (including BtB) in services and informing systems and policy (The National Institute for Health and Clinical Excellence, 2022; The Scottish Government, 2017) understanding reasons for poor adherence and/or attrition are key. Services using BtB appear to consistently record and evaluate clinical outcomes, yet do not apply the same rigour to measures of satisfaction, acceptability, engagement, and attrition. Established quantitative questionnaires around user satisfaction as well as rigorous qualitative research exploring acceptability should be explored in future research. Some of the variability in the findings around acceptability and predictors of attrition may be explained by contextualised factors, highlighting the need to evaluate these factors at a service level.

Results indicate that some programme features of BtB contribute to acceptability of the programme, for example, its ease of use may improve acceptability. Other programme features, however, may reduce its acceptability, such as perceived lack of relevance. DMHI
including BtB need to develop ways of improving acceptability and adherence to maximise the clinical benefits they can offer. An example of this includes cCBT programme, Silvercloud (Richards et al., 2014), which has released different programme packages targeting specific problems within mental health, chronic health, wellbeing, substance use and context specific packages for higher education settings and families. Creating targeted packages may help address acceptability issues relating to relevance and relatability.

As one of the longstanding cCBT programmes implemented, the extensive evidence available from Beating the Blues, is significant for DMHI at a broader level. The high rates of attrition are not unique to BtB and are an ongoing issue in DMHI (Simmonds-Buckley et al., 2020). This is an ongoing challenge for the development of these interventions: increased clinician support and guidance is associated with greater adherence which maximises clinical impact of these programmes. Equally, unguided DMHI such as BtB, have significant advantages in terms of scalability and increased accessibility (Fairburn and Patel, 2017). Understanding the specific factors associated with reduced adherence and increased attrition for these programmes specifically will help inform the best approach to addressing these barriers, to maximise the clinical impact of DMH programmes.

**Competing interests**

None.
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Chapter 2

Beating the Blues: engagement, attrition and clinical outcomes of a computerised Cognitive Behaviour Therapy programme and the impact of COVID-19

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Abstract

Purpose: Digital Mental Health Interventions (DMHI) have been prioritised to increase accessibility to evidence-based treatments for anxiety and depression. The COVID-19 pandemic significantly impacted mental health and altered mental health service provision through rapid utilisation of DMHI including programmes such as Beating the Blues (BtB). The study aimed to examine engagement, attrition and clinical outcomes of BtB and to explore the impacts of COVID-19 on this.

Method: Routine data was collected from n= 4517 referrals to a cCBT service using BtB, from July 2019 to September 2021. Demographic information, clinical outcome measures, registration, uptake and completion status were recorded. A grouping variable differentiated time of engagement with the programme (pre and during COVID-19 pandemic). Statistical analyses were conducted to explore registration and uptake; to model attrition; to evaluate programme effectiveness; and to explore how the pandemic impacted these variables.

Results: BtB had high uptake but high attrition rates. Associations of uptake and registration were reported. A dosage effect of at least five session was observed to meaningfully benefit from the programme. The programme was effective at reducing symptoms of anxiety and depression. Predictors of attrition included younger age and higher baseline levels of depression. Pre COVID-19 participants had significantly higher baseline levels of depression. BtB was equally effective pre and during the pandemic; however, levels of engagement and completion were higher during COVID-19.

Conclusion: BtB is an effective intervention but high attrition rates are an obstacle to implementation. Strengths, limitations and implications of the findings were discussed.

Keywords: cCBT, COVID-19, anxiety, depression, attrition.
Introduction

Anxiety and depression are common mental health disorders with an estimated global prevalence of almost 13% [1]. Although there is significant evidence for therapeutic interventions such as Cognitive Behaviour Therapy (CBT) as effective treatments for anxiety and depression [2, 3]; there are several barriers to uptake and utilization of these interventions [4]. These barriers include service factors such as insufficient clinician availability given the demand, service costs, waiting times, as well as intrapersonal factors such as motivation to engage with therapy [5]. Digital mental health interventions (DMHI) have been developed over the past few decades as a way of addressing treatment gaps and barriers associated with traditional mental health service provision and providing accessible, evidence-based interventions [4, 6]. Digital mental health includes a variety of interventions including online, mobile and telehealth mental health services [6]. The COVID-19 pandemic resulted in a unique context where accessibility to traditional mental health interventions was reduced yet demand for mental health support increased. DMHI were rapidly expanded, utilized and integrated within services during the COVID-19 and are likely to continue to be an acceptable form of intervention [6].

What is cCBT?

There are a wide variety of internet delivered interventions, including educational and therapeutic interventions. Internet delivered therapeutic interventions are founded on evidence-based face-to-face therapies and aim to produce cognitive, emotional and behavioural changes. They require active engagement from users through activities and homework tasks [7]. Computerised CBT (cCBT) is a frequently used internet delivered therapeutic intervention and may be self-directed or clinician guided, with various levels of support provided [8]. cCBT can be used within clinic or at home settings [9]. There are numerous cCBT programmes used by services within the UK, for example, Beating the Blues [10], MoodGYM [11] and Silvercloud [12].

Beating the Blues

Beating the Blues (BtB) is a self-guided cCBT programme that was developed in early 2000s and has been used extensively within the United Kingdom (UK) [13]. It compromises of eight sessions designed to be completed on a weekly basis. The programme uses traditional
CBT principles and illustrates CBT theory and practice through use of case studies and exercises [13]. BtB was recommended within the National Institute for Health and Care Excellence (NICE) guidelines for mild to moderate depression [14], however, this was later revised to include recommendation of cCBT more broadly. BtB continues to be recommended and used within UK mental health settings [2] as well as in the United States of America (USA), particularly in physical healthcare settings [15, 16].

The evidence base for cCBT

**Efficacy as an intervention.** There is robust systematic review and meta-analytic evidence indicating that cCBT is an effective intervention for mild to moderate anxiety and/or depression [17–22]. There is also evidence that cCBT can improve quality of life and overall wellbeing [23, 24]. Although a significant proportion of the evidence has focused on adult samples, limited evidence reports that cCBT is also effective in adolescent [21] and older adult populations [25].

The findings from a systematic review (see Chapter 1) indicate that the evidence base for the efficacy of BtB is line with the broader cCBT literature. BtB is effective for the treatment of depression and psychological distress (for example, see Cavanagh et al., 2006; Grime, 2004; Proudfoot, Goldberg, et al., 2003). The effectiveness of BtB for the treatment of anxiety is mixed (for example see Cavanagh et al., 2006; Ormrod et al., 2010; Proudfoot et al., 2004); however, methodological weaknesses in the studies may have contributed to this finding. There is some limited evidence that BtB can improve quality of life [30, 31]. The review found that BtB is effective across samples, including with older adult populations [32–34] and in a variety of contexts from mental healthcare settings (for example see Cavanagh et al., 2011) to physical healthcare [15] and higher education [36] settings.

The findings from cCBT studies, however, indicate that clinician supported cCBT programmes tend to have higher effect sizes than self-guided programmes such as BtB [18, 20, 37, 38]. A substantial proportion of these efficacy studies have compared cCBT with waitlist or treatment-as-usual (TAU) [21, 22], however, some studies have found that cCBT can be as effective as therapist led therapeutic interventions [9, 39]; however, this tended to refer to clinician supported cCBT programmes [4]. Factors such as adherence to treatment,
perceived treatment credibility, employment, baseline symptomology and gender have been explored as predictors of clinical outcomes of cCBT [40, 41].

In addition to its efficacy in terms of symptom reduction, acceptability is critical to consider when implementing and maximising the clinical benefit of cCBT programmes. Acceptability has been defined in multiple ways including patient perceptions, attrition rates and uptake rates [42]. The evidence for acceptability of cCBT is mixed and is relatively underexplored. Systematic review evidence indicates that patient perceptions have been positive in relation to viewing cCBT as an acceptable and satisfactory treatment option [42, 43]. These findings should be interpreted cautiously, however, as the samples providing feedback are frequently a subset of the study samples and are not necessarily representative of all those who have used the programmes [42]. Evidence suggests that uptake of cCBT is low and attrition rates are variable [22].

The findings from a systematic review (see Chapter 1) indicate that the acceptability of BtB is line with the broader cCBT literature. The findings are mixed with some studies reporting that participants perceive BtB as acceptable and satisfactory, whereas others have reported reduced acceptability and dissatisfaction with the programme (for example see Cavanagh et al., 2011; Hanna, 2012; Learmonth, 2007; Mitchell, 2009; Proudfoot, Swain, et al., 2003).

**Advantages of cCBT.** In addition to efficacy, cCBT also offers advantages for services and users including ease of rollout, cost effectiveness, and increased service efficiency given the lower clinician input relative to the number of service users that can access therapy at one time, reducing waiting times [9, 45, 46]. Utilization of cCBT can also reduce therapy duration, without impacting negatively on outcomes: cCBT programmes typically constitute six to eight one-hour sessions, whereas 16 to 20 sessions is recommended for face-to-face CBT [47]. Given cCBT is delivered through a designed computer programme, this further ensures that evidence-based interventions are delivered in a standardized and consistent manner [9]. cCBT can increase accessibility and the usual treatment barriers for therapy such as appointment availability, travel time, waiting times and geographical location are significantly reduced [9, 42]. Programmes are designed to be engaging and interactive, which facilitates recording of progress and allows for reminders and prompts to be given for
continued engagement with the programme [9]. Self-guided cCBT programmes can help instil a sense of agency in users of the programme and reduce stigma around accessing mental health support [8]. BtB has several of these key advantages. The programme is time-limited (eight sessions of approximately 50 minutes). The standardized computer format ensures consistency and allows for a multimedia user experience. The programme is online and self-guided, reducing typical treatment barriers of travel, clinician time and service waiting times [13]. A systematic review (see Chapter 1) outlined these advantages in relation to perceived acceptability. Participants who found the programme acceptable noted that it was helpful, easy to use, empowering and felt it was equivalent to other forms of therapy (for example see Learmonth, 2007; Pittaway et al., 2009; Proudfoot, Swain, et al., 2003; Stearns-Yoder et al., 2022).

Limitations. There are, however, several limitations to this body of research evaluation cCBT, including BtB. Methodological weaknesses in many of the studies including failure to include control groups, not controlling for confounding variables (such as medication stabilisation), limited or lack of follow up post intervention and inappropriate statistical treatment of missing data. These methodological weaknesses may impact the validity of the findings [9, 38]. A common finding amongst reviews is that there is significant heterogeneity in the studies in terms of type and length of cCBT programmes used, comparators used, and type of support offered (for example telephone, email, or face-to-face support), which results in difficulties in drawing generalized conclusions about the efficacy of cCBT [17, 18, 38]. Chapter 1 aimed to address this gap by reviewing the BtB evidence specifically. It is also important to acknowledge potential publication bias [50]. Despite these limitations, the weight of evidence supports the efficacy of cCBT as an intervention [50].

There are limitations associated with the delivery and process of using cCBT. The lack of opportunity to develop a genuine therapeutic connection may be problematic, given that the therapeutic relationship is a significant predictor of therapeutic outcome [9]. Using online platforms can pose barriers in relation to developing material that promotes continued engagement, interest and motivation to adhere to the full intervention [9]. Clinician attitudes to cCBT can pose a barrier to effective implementation of cCBT within existing services [9]. Similarly, service users can feel dissatisfied with the lack of support and impersonal nature of cCBT programmes [51]. These are in line with the factors associated with reduced acceptability of BtB: a systematic review (see Chapter 1) highlighted that lack of clinician
support as well as programme features contributed to reduced acceptability of BtB (for example see Learmonth, 2007; Mitchell, 2009).

**cCBT in Scotland.** Within evidence-based guidelines for mental health treatment in the UK, cCBT including BtB is consistently recommended as one of the first lines of treatment for mild-to-moderate anxiety and depression [2, 47, 52]. The Scottish Mental Health Strategy (2017-2027) has identified the need for increased accessibility of psychological support and identified national rollout of cCBT in Scotland as a specific way to address this [53]. This forms part of the stepped care approach taken, to appropriately match level of intervention with need. This is particularly important within NHS Scotland where resources and funding are limited [54]. In a recent report released by the Scottish Government on mental health resources within primary care settings, the progress of the national rollout of cCBT services across Scotland was reported, highlighting that each NHS Scotland health board has a cCBT service integrated within existing mental health services [54].

**Attrition.** The evidence clearly suggests that cCBT including BtB is an effective intervention; however, the success of cCBT services is, to an extent, dependent on service users’ engagement with programmes. The cCBT literature has highlighted that engagement and attrition are significant issues in the implementation of cCBT programmes [8]. When considering attrition, three concepts are important to consider: magnitude, timing and predictors or moderators of attrition [55]. In relation to magnitude of attrition, significant variation of attrition from cCBT is reported [38, 42, 56, 57]. BtB research has similarly reported significant variation in attrition, ranging from 9% [58] to 86% [30]. Attrition rates are reported as highest in self-guided cCBT programmes (such as BtB), followed by clinician support supported cCBT [38] and tend to be lowest in face-to-face CBT [55, 59, 60].

Evidence clearly shows that engagement is positively associated with treatment outcomes [61, 62]. Conversely, disengagement impacts services directly, for example, the costs associated with incomplete therapy, such as clinician and administration time [60]. This also impacts the individuals as they do not engage with the full treatment they were referred for [55]. This in turn is may contribute to the ongoing societal burden of mental health [63].

Predictors of attrition are poorly understood and research findings are mixed both for cCBT broadly [59, 64] as well as for BtB specifically [35, 49, 65, 66]. Several factors such as
gender, treatment expectancy, perceived treatment credibility, type of support offered, treatment demands, age, baseline levels of anxiety and depression, deprivation, education status, marital status and employment status have been explored as predictors of attrition, however, the results have produced mixed findings in relation to the significance of associations and the direction of these relationships [13, 41, 49, 65–71]. Given many studies do not explore reasons for attrition, it is unclear whether individuals discontinue due to perceived improvement symptoms or failure to improve [42]. Similarly, in a systematic review of BtB (see Chapter 1), only seven of the 23 included studies explored predictors of attrition. The limited research in this area makes it difficult to draw meaningful conclusions about predictors of attrition from BtB.

**Criticisms of attrition literature.** One of the main criticisms of attrition research is the lack of consistency in defining and operationalising the interrelated terms of attrition, engagement and adherence [55, 69]. Attrition has been defined in numerous ways including those who either do not complete the full intervention; attend less than a specified number of sessions; have missed more than a certain number of appointments; and who have discontinued prior to achieving a certain level of clinically significant symptom change [55, 60]. Those who fail to commence programmes have, at times, been included in this terminology; however, there are likely to be qualitative differences between those who fail to commence the programmes and those who discontinue after several months of use [69]. This is reflected in the BtB research. For example some studies have used minimum number of sessions to define attrition (see Cavanagh, Seccombe, & Kate;, 2011; Cientanni et al., 2019) whereas others used full intervention completion as a way of operationalising completion and attrition (for example see Proudfoot, Goldberg, et al., 2003). Given this variable definition, it is unsurprising that the findings around magnitude and predictors of attrition are inconsistent. Within the cCBT literature, “adherence” and “engagement” are frequently used interchangeably and have also been defined in various ways including: completing a specified number of sessions (i.e. ‘dose’) [38], number of activated treatment modules [40], and the amount of time spent using the programme [70]. This variability in definitions, methodology and reporting of these concepts is likely to have contributed to the inconsistent findings regarding attrition [55].

**Dosage effects.** A further issue in this area of the research is the timing of attrition. Most current definitions of attrition imply that the full intervention is required for maximal clinical benefit [60]. Studies have explicitly explored the concept of dosage effects within cCBT to
examine if certain quantities of programme exposure are clinically equivalent to completing the full intervention. A study using BtB within NHS Scotland reported that completing at least five of the eight modules constituted sufficient dosage for improvement in clinical outcomes [74]. Similarly, a RCT examining the efficacy of MoodGYM for wellbeing reported that dosage effects were found for individuals completing two or more modules [23]. This concept of dosage has significant clinical implications. Given attrition is high and adherence is low in many cCBT programmes, if dosage effects are relevant, this has implications for how attrition can be meaningfully operationalised. It also has implications for the adjustment and design of cCBT programmes by prioritising sufficient dosage whilst covering the necessary information to help affect change [67, 75].

The COVID-19 pandemic

The growth in digital mental health was accelerated by the COVID-19 pandemic [6]. COVID-19 was declared a pandemic by the World Health Organization (WHO) in March 2020, given its rapid, global spread [76]. In addition to the clear impacts that COVID-19 has had on physical health, COVID-19 and the associated public health strategies have significantly impacted mental health and mental health service provision [77–79].

Impacts on mental health. There are several factors associated with the COVID-19 pandemic which have exacerbated its impact on mental health. COVID-19 presents as a significant health risk to people and those they care about, with resultant increased fear, hypervigilance and anxiety [78, 80, 81]. Significant sense of uncertainty, changes to environment, and loss of control have also been linked to increased generalised anxiety [78]. In the early stages of the pandemic, it was predicted that there would be an increase in prevalence of anxiety, depression, post-traumatic stress disorder (PTSD), acute stress responses and complex grief reactions [53, 58], supported by emerging research on the mental health impacts of COVID-19 in both the early and later stages of the pandemic [79–81, 84–87].

Key responses to the pandemic have included the implementation of national lockdowns; quarantine and shielding measures; and social distancing guidelines, which resulted in significant isolation and reduction of social support [80]. Isolation from social support is a known risk factor for developing mental health disorders such as anxiety and depression [80,
Evidence from a review indicated that being under quarantine is associated with psychological distress, with greater mental health deterioration associated with lengthier quarantine periods [89]. This can be exacerbated by environmental stressors such as overcrowded accommodation and strained relationships [80]. For individuals in the shielding category, however, these impacts of this isolation were heightened and research has indicated that those in the shielding category were more likely to exhibit higher levels of psychological distress [87]. A further consequence of these measures has included reduced income and financial instability, leading to financial related stress and anxiety [80, 82, 84].

**Impacts on service delivery.** In addition to the impacts of COVID-19 on physical and mental health, the pandemic has significantly impacted mental health service delivery. In Scotland, face-to-face mental health service provision was reduced and an increased reliance on remote delivery of health was employed through government guidance [90].

Given the impact of the pandemic on mental health, the need for mental health support during this time was clearly identified; yet the public health responses resulted in significant barriers to accessing the usual supports. This occurred in the context of longstanding, pre-existing barriers to accessing mental health services, thus exacerbating these issues around accessibility [91]. The need for adapting mental health interventions and utilizing accessible forms of remote delivered interventions was critical [77, 91, 92]. Internet delivered interventions such as cCBT offered advantages in the pandemic context due to their effectiveness, accessibility and ease of scalability to meet the demand [77, 88, 91, 93].

**Rationale for the current research**

The emerging evidence indicates that the COVID-19 pandemic and restriction measures have had a significant negative impact on mental health and service provision, and are likely to have an ongoing impact in years to come [82, 83]. Given this need and the subsequent increase in utilization of internet delivered interventions, e-health is likely to be a priority in NHS services moving forward. cCBT is of particular importance given its extensive evidence base as an effective treatment and the Scottish Government’s initiative for national rollout of cCBT to increase accessibility of psychological interventions [53]. BtB as a cCBT programme has been used extensively over the past two decades in the UK [13].
Significant gaps remain in relation to research exploring attrition within cCBT, and BtB specifically. Uptake and attrition are frequently cited in this area of research but are rarely explored further. When predictors of attrition have been explored, the results have been mixed, resulting in difficulties in drawing meaningful conclusions around this. In addition, there has been limited exploration of the timing of attrition. This study aims to directly address these gaps.

The COVID-19 pandemic presents a unique context to explore this. Given the unprecedented nature of a pandemic of this scale and the associated restrictions implemented globally, there is minimal comparison in terms of previous research and literature [80, 83]. The impact and consequences of the lengthy isolation and social distancing guidance; and the extensive period of global uncertainty and fear, remains relatively unknown [80, 83]. Despite the global nature of the pandemic, it has been argued that the impacts of COVID-19 are likely to be experienced differently across countries and within populations, as this is heavily influenced by contextual, social, and environmental factors [79, 83]. This highlights the importance of exploring the impact of COVID-19 on mental health and service provision within communities. This study aims to address these gaps. Understanding uptake and attrition in BtB and how the pandemic has affected this, will have important implications for informing service delivery and facilitating evidence-based decision making at a service level, as well as contributing to the wider gaps in knowledge in the cCBT literature in the UK.

Aims
1. To explore who engages with Beating the Blues in terms of uptake and attrition in terms of age, biological sex, referral source, level of suicidal risk, level of deprivation, and baseline levels of anxiety and depression.
2. To explore the effectiveness of Beating the Blues in terms of clinical outcomes.
3. To explore how the COVID-19 pandemic lockdown impacted upon uptake, attrition and clinical outcomes for Beating the Blues.

Hypotheses
1. No specific hypotheses were used for aim 1 given there was no clear theoretically driven rationale for a hypothesis. The previous evidence in relation to predicting uptake and attrition is mixed and inconclusive, as outlined in the introduction section.
2. It is hypothesized that BtB will significantly reduce PHQ-9 and GAD-7 scores for defined completers. Previous research evidence from this cCBT service [73] has indicated that BtB has been effective at reducing levels of anxiety and depression in participants.

3. No specific hypotheses were used for aim 3. Given the novel, unprecedented nature of the COVID-19 pandemic, the impacts of the pandemic on mental health and mental health service provision is largely unknown.

Methodology

Design
A quasi-experimental design was used with a grouping variable consisting of two levels: pre-COVID-19 lockdown and during COVID-19 lockdown. The dependent variables consisted of clinical outcomes, uptake and attrition. Predictor variables consisted of sample characteristics (demographic variables, level of suicide risk, origin of referral) and clinical outcomes (see below).

Participants and sampling
Participants in this research were service users referred to Beating the Blues (BtB) computerised Cognitive Behaviour Therapy programme (cCBT) provided by an NHS Scotland health board cCBT service. The main referral sources included General Practitioners (GPs) and Mental Health and Wellbeing Services (MHW). A detailed description of the origin of referral is included in the variables section below.

Data was routinely collected data by the service and included all service users referred to the service between July 2019 and September 2021. During this time, n=4517 were referred to Beating the Blues within the health board.

Measures
Clinical outcomes were assessed using two standardized routinely collected through the Beating the Blues programme.

PHQ-9. Level of depression was measured via a standardized measure, the Patient Health Questionnaire-9 (PHQ-9)[94]. The PHQ-9 is a 9-item measure with scores ranging from 0 to 27 with a recommended clinical threshold score of 10 for sensitivity and specificity of
detection of depression. The measure has good construct and criterion validity[95] and reliability, and has been used in both clinical and research settings[94, 96]. Item level data was not available to assess reliability and validity of the measures in the current sample. The PHQ-9 was completed each session by participants.

GAD-7. Level of anxiety was measured via a standardized measure, the Generalised Anxiety Disorder Assessment-7 (GAD-7)[97]. The GAD-7 is a 7-item measure with scores ranging 0 to 21 with a recommended clinical threshold score of 10 for sensitivity and specific of detection of generalised anxiety. This measure demonstrates good internal consistency (Cronbach $\alpha = .92$) and test-retest reliability (intraclass correlation = .83). It also demonstrated good construct validity and factorial validity[97, 98]. Item level data was not available to assess reliability and validity of the measure in the current sample. The GAD-7 was completed each session by participants.

Variables

Demographic variables. Age (measured as a continuous variable) and biological sex (two levels: male or female) were recorded from referral information. Gender identification was not obtained as the variable of biological sex was derived from individuals’ Community Health Index (CHI) numbers. Deprivation was measured through the Scottish Index of Multiple Deprivation (SIMD) 2020[99], a tool designed for identifying relative levels of deprivation in communities across Scotland. It is derived from social and environmental factors associated with areas such as income, employment, education, health, access to services, crime and housing[99]. The SIMD tool ranks communities in Scotland from 1(most deprived) to 6976 (least deprived). In the current study, SIMD was obtained through converting participants postcodes via a SIMD excel syntax. The SIMD index was presented as quintiles (1 to 5).

Level of suicidality. Level of suicidality was measured by the programme each session, through assessing for presence of suicidal thoughts in the last week (binary variable: yes or no). If an individual has experienced suicidal thoughts in the last week, they are asked to rate the frequency of these (4 levels: once, twice, three times, more than three times) and level of suicidal intent from 0 (not very seriously) to 8 (seriously).
**Origin of referral.** Measured as a categorical variable with 6 levels:

- **GP**
- Psychology services (including individuals on the waiting list)
- Mental Health and Wellbeing service
- Patient Assessment and Liaison Mental Health Service (PALMS)
- Third Sector referrals included social prescribing services, housing support services and mental health and wellbeing services.
- ‘Other’ referral sources included Community Mental Health Teams (CMHTs), university, crisis service, medical services (such as diabetes or physiotherapy services), Child and Adolescent Mental Health Services, Health visiting services, nurse led services (for example, Advanced Nurse Practitioners). It also included where the source of referral was unknown or unclear information was provided, for example, Older Adults Service may refer to the CMHT or Psychology Services.

There was no self-referral option. Referral sources were grouped to reduce the number of groups within the variables whilst still capturing the significant sources of referrals to the programme.

**Registration status.** Registration status was measured as a categorical variable with two levels: registered for the programme or did not register for the programme.

**Uptake.** Uptake was measured as a categorical variable with two levels: individuals who registered and commenced the programme (i.e. started module 1.1) and individuals who registered for the programme but did not commence (i.e. did not start module 1.1). Similar operationalisations have been used in community research of another cCBT programme, MoodGYM [100].

**Completion status.** Completion status explored completion and attrition from the programme. This was measured using two approaches: i) as a continuous variable of number of modules completed by participants (from 0 to 32). ii) Participants were subsequently grouped into a categorical variable with three levels:

1. ‘Early non-completers’ denoted participants who commenced the programme but did not complete session one.
2. ‘Non-completers’ denoted participants who commenced the programme but ceased using the programme between session one and the end of session five.

3. ‘Defined completers’ were individuals who completed at least five sessions of the programme. Within the ‘defined completers’, a subgroup of ‘completers’ was defined as participants who completed all eight sessions.

The rationale for grouping this data was to increase sample size of each group and thus increase statistical power associated with the statistical analysis of these groups [101]. Research exploring efficacy and acceptability of cCBT has suggested significant attrition from the programmes [42]. As outlined in the systematic review, reasons for attrition may vary and occur at different stages in using the programme for service users, including that they have gained improvement and do not feel a need to continue with the programme. This highlighted the need to establish whether there was a point at which individuals engaging with Beating the Blues, demonstrate significant improvement clinically equivalent to those who completed the full programme i.e. exploring whether a dosage effect of Beating the Blues exists. Evidence suggests that completion of at least five sessions was equivalent to completing the full eight sessions of the programme in terms of clinical improvement [74].

In the current sample 92.45% of the study sample who commenced the programme did not complete the full eight sessions of the programme. Therefore, dosage effects and definitions of clinically meaningful change were evaluated within the current sample. Results of a repeated measures ANOVA for completers of all eight sessions (n=215) indicated that there was a significant effect of time on severity of anxiety (F (3.91) = 152.30, p <0.001) and severity of depression (F (3.99) = 145.30, p <0.001). The assumption of sphericity was violated, thus Greenhouse-Geisser estimates were used. Pairwise comparisons indicated that in relation to severity of anxiety, the mean GAD7 score for each session was significantly lower than the previous session, indicating continued benefit as sessions progressed. Pairwise comparisons indicated that with severity of depression, the mean PHQ9 scores for each session were lower than the previous sessions and were largely significantly lower. The mean scores for session eight were significantly lower than sessions one to seven, indicating the clinical benefit of completing the full programme. This finding differs from the previous research indicating a dosage effect at five sessions [74]. The current study, however, uses the updated BtB programme whereas this previous research explored a previous version [74]. Similarly, the previous research [74] used BtB self-reported likert ratings of depression and
anxiety, whereas the current study used established, standardised measures of GAD-7 and PHQ-9 to explore possible dosage effects.

Is it important to consider the difference between clinically meaningful change and statistically significant change in severity of anxiety and depression. Validation studies associated with the development of the GAD-7 and PHQ-9 measures indicate that scores of 5, 10, 15 correspond to indicators of mild, moderate and severe presentations, with a score of 10 and above indicating clinical threshold for probable presence of generalised anxiety or depression [95, 97]. There is a lack of consensus in the literature in relation to what clinically meaningful change is and how anxiety or depression remission is defined. Springer et al [102] highlight that remission from anxiety has been defined in various ways, including no longer meeting diagnostic criteria, scoring below the clinical threshold, using a clinical meaningful change, and high end state functioning post intervention. These authors recommended using the definition of scoring below the clinical threshold as a conservative estimate of remission [102]. McMillan et al [103] highlight that defining clinical success for the treatment of depression has similarly been defined in various ways. The study compared the standard clinical threshold with other methods, including defining remission as a score less than 5; defining a non-clinical range as two standard deviations or more from the mean; defining the non-clinical range within two standard deviations of the non-clinical mean and using a threshold score at which the probability of coming from a clinical and non-clinical sample is equal. The results of their analysis indicate that the clinical threshold had good to very good level of agreement with the other definitions of clinical success. Given the consensus from these studies that the clinical thresholds are a valid measure of meaningful clinical change, the current study used the clinical thresholds (i.e. scores of less than or equal to 9) for the GAD-7 and PHQ-9 to indicate meaningful clinical change. The mean GAD-7 and PHQ-9 scores of the completers (n=215) did not fall below 9 until the end of session 5, i.e. indicating that there is a clinically meaningful change in severity of anxiety and depression at the end of session 5. This is in line with the timepoint where a dosage effect was observed in previous service research [74]. This provided the rationale for the ‘defined completer’ variable.

COVID-19 groups. To explore how the COVID-19 lockdown has impacted Beating the Blues in relation to uptake, attrition and outcomes; participants were grouped according to the timeframe in which they engaged with the programme. The COVID-19 lockdown
variable was operationalised according to the change in service delivery of the health board GP surgeries. On 17 March 2020, Scottish Government issued national guidance to all NHS Scotland GPs stating that patients should be triaged by telephone initially as opposed to usual face-to-face appointments[104]. This largely aligns with the ‘delay phase’ of COVID-19 management announced by Scottish Government on 12 March 2020 and the national lockdown announced by the Scottish Government on 23 March 2020. The rationale for aligning this variable with changes to GP service delivery is due to the referral pathway associated with Beating the Blues. Prior research in this cCBT service has indicated that approximately 75-78% of referrals made to Beating the Blues have been from GP surgeries [73, 105]. The cessation of non-essential face to face appointments in GP practices are likely to have impacted referrals to Beating the Blues, thus this timepoint presents as a natural threshold to define the COVID-19 lockdown period. GP surgeries continued to operate in this manner until and beyond September 2021.

The levels of this grouping variable were defined as follows: participants who commenced the programme between, and inclusive of, 1 July 2019 and 17 March 2020 were placed in the pre-COVID-19 lockdown group. In July 2019, Beating the Blues launched an updated programme with amendments to its presentation and the routine measures collected. Routine data collected prior to July 2019 is not comparable to data collected after this timepoint and would not allow for comparative statistical analyses. Participants who commenced the programme after the 17 March 2020 were placed in the during-COVID-19 lockdown group. Commencement of the programme was used to define these groups as this represented intent to engage with the programme. For participants who did not commence the programme, date of registration for the programme was used to determine if they were in the pre-COVID or during COVID-19 group according to the same dates outlined above. Similarly, for participants who did not register for the programme, date of invitation to register for the programme was used to group these participants using the same dates outlined above.

**Treatment**

The treatment procedure followed routine Beating the Blues protocol used by the cCBT service. When individuals are referred to the Beating the Blues service, a referring service is established as a point of contact for any clinical communication required. For example, when an individual commences treatment, when they complete or cease using the service and any
suicide risk alerts. A service point of contract rather than the specific referrer is utilised to ensure urgent information such as suicide alerts is not delayed in being received or actioned if the referring clinician is unavailable.

Once referred, the cCBT service aims to phone the individual within five working days and provide information regarding the programme via a telephone call. Confidentiality and suicide risk alerts are explained at this point. Service users subsequently receive a weblink to activate their account. If this remains inactivated for three weeks, the individual will be prompted by an automated email that provides encouragement to continue and contact the cCBT service if any issues using the programme. If the account remains inactive for a further three weeks, they are discharged from the cCBT service and the referrer is informed. Consent for data storage is covered within the terms and conditions of the Beating the Blues programmes, to which users agree. Data is stored securely in a password protected database within the cCBT service in addition to the Beating the Blues securely stored database.

At the start of the programme, participants are assessed for level of suicidal risk. If a service user responds that they have been experiencing suicidal thoughts in the last week, they are subsequently asked about the frequency of these thoughts (four levels: once, twice, three times, more than three times) and level of intent around these thoughts on a scale from 0 (not very seriously) to 8 (seriously). If an individual reports experiencing suicidal thoughts, cCBT administration staff would contact the referring service and report this information. Any subsequent clinical decisions or interventions regarding the individual’s ongoing care and treatment are made by this referring service. At the start of each session participants complete the PHQ-9, GAD-7, and the two non-standardized measures of anxiety and depression (outlined above). Participants can complete the eight sessions at their own pace. See Table 1 for an outline of the topics covered in each session and module of Beating the Blues [106]. Programme users can contact the cCBT administration team via e-mail or telephone for assistance with using the programme. Clinical advice is not provided, but general encouragement is given and direction to a clinical service may be provided if indicated (for example contacting their GP). An 8B Clinical Psychologist, who is the clinical lead for the service, is also available for advice.
Table 1. Description of the Beating the Blues intervention

<table>
<thead>
<tr>
<th>Session</th>
<th>No. of modules</th>
<th>Content covered</th>
</tr>
</thead>
</table>
| 1       | 3              | • Introduction  
|         |                | • Psycho-education about anxiety and depression  
|         |                | • Defining recovery statements  
|         |                | • Introducing cognitions  
|         |                | • Pleasurable activities  
| 2       | 3              | • Understanding how cognitions impact behaviour and mood  
|         |                | • Goal setting  
|         |                | • Introduction to automatic thought records  
|         |                | • Problem solving  
| 3       | 5              | • Distraction techniques  
|         |                | • Identifying thinking errors  
|         |                | • Problem solving  
| 4       | 5              | • Challenging unhelpful thinking  
|         |                | • Option of: activity scheduling, task breakdown, sleep management or graded exposure  
| 5       | 4              | • Identifying and challenging unhelpful beliefs  
|         |                | • Choosing another option from: activity scheduling, task breakdown, sleep management or graded exposure  
| 6       | 4              | • Understanding attributional styles to improve confidence and self esteem  
|         |                | • Choosing another option from: activity scheduling, task breakdown, sleep management or graded exposure  
| 7       | 4              | • How to change attributional style to improvement confidence and self esteem  
|         |                | • Choosing another option from: activity scheduling, task breakdown, sleep management or graded exposure  
| 8       | 4              | • Review of the program and goals  
|         |                | • Planning for the future  

Procedure
This research used historic, routine quantitative data collected in a cCBT service. Anonymised data was provided to the primary researcher by the cCBT service. The dataset was screened and cleaned for errors, outliers and missing data. Demonstration accounts for
clinicians were deleted from the dataset and duplication of four participant’s data were excluded. Anomalies and errors were cross-referenced with the cCBT administration team using the unique identifier to ensure accurate data was recorded. The data was subsequently coded using SPSS syntax. SPSS statistics version 24 was used for the statistical analysis.

[107]

Statistical Analysis

Data screening. Data was screened for univariate outliers using boxplots. Multivariate outliers were explored using Mahalanobis distance [108]. Where possible outliers were identified, the data was inspected for any errors and extreme scores. No errors or extreme scores were identified and were thus not excluded from any analysis.

Descriptive information. Frequencies and percentages were reported as descriptive statistics of the sample and by grouping variable in relation to the COVID-19 pandemic.

Uptake and registration. Chi square tests of associations and Mann Whitney tests were conducted to explore possible relationships between demographic variables (age, SIMD rank, biological sex, and referral source) and registration and uptake status.

Attrition. The routine data allowed for several ways of modelling attrition. Survival analysis is a group of statistical techniques used to examine time taken for an event to occur [108]. Kaplan Meier survival analysis was used for assessing group differences in survival functions [108] for pre and during COVID-19 in relation to number of modules completed prior to attrition. The assumptions of Kaplan Meier survival analysis were explored and upheld.

Linear regression was used for developing a predictive model of number of modules completed using age, baseline level of anxiety and depression, SIMD rank, COVID-19 group, and biological sex as predictors. In the interests of model parsimony, the baseline clinical measures i.e. baseline level of anxiety and depression were measured using session 1 GAD-7 and PHQ-9 scores respectively. These were used instead of the BtB clinical measures as these are non-standardized and GAD-7 and PHQ-9 have established reliability and validity (outlined in variables section). The assumptions of linear regression were explored: normality was explored using visual methods of Q-Q plots. The variable of number of
modules completed violated the assumption of normality. A log transformation was performed to address this [108] and the assumption of normality was subsequently upheld. The assumption of linearity was explored using visual methods of scatterplots between predictor variables and the dependent variable of number of modules completed. The assumption of linearity was violated. Log and square root transformations of the predictor variables of age, baseline level of anxiety and depression and SIMD were performed [108]. Transformations for baseline PHQ-9 and GAD-7 scores did not improve model fit. Although square root transformations improved model fit for Age and SIMD, these did not significantly change the overall analysis, thus untransformed predictors were used (See Appendix 2 for analyses using transformed variables). Other assumptions of multiple regression were upheld.

Multinomial logistic regression was used to develop a predictive model for completion status (3 levels: early non-completer, non-completer and defined completer). Initial chi square tests of associations were performed to explore which predictors to include, in order to develop a parsimonious model. Chi square tests of association indicated that variables of biological sex, baseline level of anxiety, and baseline level of suicidal risk were not significantly associated with completion status and were thus not included as predictors in the model. Although referral source was significantly associated with completion status, inclusion of this predictor increased the frequency of zero frequency cells and therefore it was not included as a predictor. Age, SIMD, baseline level of depression, and COVID-19 group were included as predictors. The assumptions of a logistic regression were explored. To address a high percentage (67%) of 0% frequency cells, continuous variables were transformed into quartiles reducing percentage of 0% frequency cells to 12.9%. The assumption of the logit was explored using the Bod Tidwell method [108]. This assumption was violated for age but was upheld for the remaining predictors. Further assumptions of logistic regression were upheld.

**Clinical effectiveness.** A repeated measures MANOVA was used to explore clinical efficacy of BtB through exploring changes to GAD-7 scores and PHQ-9 scores from session 1 to 5. The defined completer group was used as opposed to full completers as this resulted in a higher sample size and thus increased power for the analysis. Post hoc testing using univariate repeated measures ANOVA with pairwise comparisons was used to explore where
significant effects were observed. Bonferroni corrections were used to account for multiple testing and inflated type 1 error rate.

Two-way mixed ANOVAs were used to explore possible interaction effects of COVID-19 grouping variable and time on clinical efficacy of the programme, i.e. changes to GAD7 and PHQ9 scores. Bonferroni corrections were used to account for multiple testing and inflated type 1 error rate.

Assumptions of repeated measures MANOVA were upheld, however, the assumption of sphericity was violated for the repeated and two way mixed ANOVAs, thus Greenhouse Geisser estimates were used.

**Power calculation**

A priori power calculations using G*Power [109] were conducted to calculate desired sample size for adequate statistical power. Given that uptake and attrition have not been modelled on this data before and given the novel nature of the COVID-19 pandemic grouping variable in this area of research, no similar research could be used. In order to account for this, a conservative small effect size of $f^2=0.02$ and $f=0.1$ was used. For multiple linear regression, with 5 predictor variables, a standard alpha of 0.05, power of 0.80 and a small effect size of $f^2=0.02$, the total sample size needed was $n=647$.

For a two-way repeated measures ANOVA (within and between interaction), with an alpha=0.05, desired power=0.80, small effect size of $f=0.1$, 2 grouping levels with 8 measurements, and a correlation between repeated measures ranging from 0.3-0.6, the range for total sample size was between $n=112-194$, split across two groups.

**Ethics and Governance**

The study obtained the relevant approval necessary prior to the research commencing. Caldicott governance approval from the health board (see Appendix 3) and the University of Edinburgh Clinical Psychology Department ethics committee (see Appendix 4). The researcher was given access by the NHS cCBT service to the anonymised dataset. Unique ID numbers were used to differentiate responses. As per governance approval, the anonymised
dataset was stored securely in the researcher’s University of Edinburgh’s OneDrive for Business account with the original identifiable dataset remaining on the health board server.

**Results**

**Descriptive statistics**

*Demographic information.* Table 2 reports demographic information for the sample. The mean age of the sample was $M=36.82$ years ($SD=13.86$, range: 16.69 to 94.27). The pre COVID-19 lockdown group was $N= 812$ (28.5%). $N= 2036$ (71.5%) of the sample comprised the during COVID-19 lockdown group.
## Table 2 Descriptive statistics: sample demographics (n= 2848)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Whole sample frequency (%)</th>
<th>Pre COVID-19 lockdown frequency (%)</th>
<th>During COVID-19 lockdown frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biological sex</strong> a</td>
<td>Male</td>
<td>901 (32)</td>
<td>268 (33.5)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1911 (68)</td>
<td>533 (66.5)</td>
</tr>
<tr>
<td><strong>Age</strong> b</td>
<td>16-19</td>
<td>144 (5.1)</td>
<td>29 (3.6)</td>
</tr>
<tr>
<td></td>
<td>20-29</td>
<td>966 (34.5)</td>
<td>293 (36.1)</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
<td>685 (24.5)</td>
<td>198 (24.4)</td>
</tr>
<tr>
<td></td>
<td>40-49</td>
<td>451 (16.1)</td>
<td>128 (15.8)</td>
</tr>
<tr>
<td></td>
<td>50-59</td>
<td>364 (13)</td>
<td>100 (12.3)</td>
</tr>
<tr>
<td></td>
<td>60-69</td>
<td>137 (4.9)</td>
<td>47 (5.8)</td>
</tr>
<tr>
<td></td>
<td>70-79</td>
<td>45 (1.6)</td>
<td>12 (1.5)</td>
</tr>
<tr>
<td></td>
<td>80-89</td>
<td>5 (0.2)</td>
<td>4 (0.5)</td>
</tr>
<tr>
<td></td>
<td>90+</td>
<td>1 (0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Referral source</strong></td>
<td>GP</td>
<td>1483 (52.1)</td>
<td>490 (60.3)</td>
</tr>
<tr>
<td></td>
<td>Mental health and wellbeing</td>
<td>568 (19.9)</td>
<td>165 (20.3)</td>
</tr>
<tr>
<td></td>
<td>Third sector</td>
<td>224 (7.9)</td>
<td>11 (1.4)</td>
</tr>
<tr>
<td></td>
<td>Psychology services</td>
<td>283 (9.9)</td>
<td>102 (12.6)</td>
</tr>
<tr>
<td></td>
<td>Patient Assessment and Liaison Mental Health Service (PALMS)</td>
<td>132 (4.6)</td>
<td>18 (2.2)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>158 (5.5)</td>
<td>26 (3.2)</td>
</tr>
<tr>
<td></td>
<td>SIMD quintile c</td>
<td>1</td>
<td>469 (16.8)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>554 (19.9)</td>
<td>149 (18.7)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>553 (19.9)</td>
<td>156 (19.6)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>726 (26.1)</td>
<td>206 (25.9)</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>483 (17.3)</td>
<td>137 (17.2)</td>
</tr>
</tbody>
</table>

Notes: a biological sex unknown for n=36 for whole sample, n=11 for pre COVID-19 lockdown group, n=25 for during COVID-19 lockdown group; b age unknown for n=50 for whole sample, n=1 for pre COVID-19 lockdown group, n=49 for during COVID-19 lockdown group; c SIMD unknown for n=63 for whole sample, n=17 for pre COVID-19 lockdown group, n=46 for during COVID-19 lockdown group

**Intervention pathway descriptive statistics.** Table 3 contains the descriptive statistics for the completion status of participants by group.
Table 3. Frequencies of completion status per group

<table>
<thead>
<tr>
<th>Completion status group</th>
<th>Whole sample frequencies (%) (n=2848)</th>
<th>Pre COVID-19 lockdown group frequencies (%) (n=812)</th>
<th>During COVID-19 lockdown group frequencies (%) (n=2036)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early non-completer</td>
<td>731 (25.7)</td>
<td>222 (27.3)</td>
<td>509 (25)</td>
</tr>
<tr>
<td>Non-completer</td>
<td>1692 (59.4)</td>
<td>515 (63.4)</td>
<td>1177 (57.8)</td>
</tr>
<tr>
<td>Defined completer</td>
<td>425 (14.9)</td>
<td>75 (9.2)</td>
<td>350 (17.2)</td>
</tr>
<tr>
<td>Subgroup: Completer</td>
<td>215 (7.6)</td>
<td>35 (4.3)</td>
<td>180 (8.8)</td>
</tr>
</tbody>
</table>

Figure 1 depicts referrals, uptake, attrition and completion of the programme. Of those who commenced, 14.92% completed at least 5 sessions of the programme. 7.55% of the sample completed all 8 sessions.
The mean number of modules completed for those who commence the programme was \( M=9.57 \) (SD=9.12), with \( M=7.54 \) (SD=7.86) modules completed in the pre COVID-19 lockdown group and \( M=9.80 \) (SD=9.52) during COVID-19 lockdown. Figure 2 indicates the number of modules completed by participants for the whole sample (n=2848), the pre COVID-19 lockdown group (n=812) and the during COVID-19 lockdown group (n=2036). The line graphs appear to follow a similar trend. Several large peaks occur corresponding to individuals completing sessions one, two and three and subsequently discontinuing with the programme. A further large peak occurs at the end of the programme indicating those who complete the programme. Smaller peaks occur corresponding to the individuals completing sessions four, five, six and seven. This trend appears to indicate that individuals tend to complete a session before discontinuing with the programme rather than discontinuing after a module, i.e. mid-session. This occurred more frequently in the first three sessions and appeared consistent across the two groups.

**Figure 2.** Line graph indicating the number of modules completed by participants per group

**Descriptive statistics of clinical outcomes.** Table 4 reports descriptive statistics for the clinical outcome measures. Figures 3 and 4 indicate line graphs showing the changes in the
GAD-7 and PHQ-9 scores across groups over sessions. The GAD-7 mean score pre intervention indicates a moderate (almost severe) clinical score for severity of anxiety across all groups. There were no significant differences of baseline levels of anxiety between groups (t(2614) = -1.947, p=.052). The PHQ-9 mean score pre intervention indicates a moderately severe clinical score for severity of depression across all groups. A significant difference of baseline levels of depression between groups was observed (t(2618) = -2.846, p=.004), indicating that participants during COVID-19 had higher baseline levels of depression than those pre-COVID-19.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time point</th>
<th>Whole sample Mean (SD)</th>
<th>Pre COVID-19 lockdown group Mean (SD)</th>
<th>During COVID-19 lockdown group Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of anxiety (GAD 7 score)</td>
<td>Session 1</td>
<td>14.10 (4.83)</td>
<td>13.80 (4.93)</td>
<td>14.20 (4.78)</td>
</tr>
<tr>
<td></td>
<td>Session 5</td>
<td>8.45 (5.49)</td>
<td>8.15 (4.97)</td>
<td>8.51 (5.60)</td>
</tr>
<tr>
<td></td>
<td>Session 8</td>
<td>6.10 (5.39)</td>
<td>6.03 (4.90)</td>
<td>6.12 (5.50)</td>
</tr>
<tr>
<td>Severity of depression (PHQ 9 score)</td>
<td>Session 1</td>
<td>16.24 (5.73)</td>
<td>15.73 (5.90)</td>
<td>16.44(5.66)</td>
</tr>
<tr>
<td></td>
<td>Session 5</td>
<td>9.06 (6.40)</td>
<td>8.55 (5.88)</td>
<td>9.16 (6.51)</td>
</tr>
<tr>
<td></td>
<td>Session 8</td>
<td>6.50 (6.27)</td>
<td>6.06 (5.36)</td>
<td>6.58 (6.44)</td>
</tr>
</tbody>
</table>
Figure 3. Line graph showing the changes in the mean GAD7 scores per group across sessions.

Figure 4. Line graph showing the changes in the mean PHQ9 scores per group across sessions.
Table 5 reports descriptive statistics for baseline severity of suicidal thinking for individuals who completed the measures of suicidal risk.

**Table 5. Descriptive statistics of suicidal risk measures**

<table>
<thead>
<tr>
<th>Presence of suicidal thinking in the week prior</th>
<th>Whole sample frequency (%)</th>
<th>Pre COVID-19 lockdown group frequency (%)</th>
<th>During COVID-19 lockdown group frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>2232 (84.6)</td>
<td>657 (85.7)</td>
<td>1575 (84.2)</td>
</tr>
<tr>
<td>Once</td>
<td>167 (6.3)</td>
<td>42 (5.5)</td>
<td>125 (6.7)</td>
</tr>
<tr>
<td>Twice</td>
<td>115 (4.4)</td>
<td>34 (4.2)</td>
<td>81 (4.3)</td>
</tr>
<tr>
<td>Three times</td>
<td>52 (2.0)</td>
<td>16 (2.1)</td>
<td>36 (1.9)</td>
</tr>
<tr>
<td>Three or more times</td>
<td>72 (2.7)</td>
<td>18 (2.3)</td>
<td>54 (2.9)</td>
</tr>
<tr>
<td>Session 5&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>449 (93.7)</td>
<td>91 (96.8)</td>
<td>358 (93)</td>
</tr>
<tr>
<td>Once</td>
<td>13 (2.7)</td>
<td>2 (2.1)</td>
<td>11 (2.9)</td>
</tr>
<tr>
<td>Twice</td>
<td>10 (2.1)</td>
<td>1 (1.1)</td>
<td>9 (2.3)</td>
</tr>
<tr>
<td>Three times</td>
<td>3 (0.6)</td>
<td>0 (0)</td>
<td>3 (0.8)</td>
</tr>
<tr>
<td>Three or more times</td>
<td>4 (0.8)</td>
<td>0 (0)</td>
<td>4 (1.0)</td>
</tr>
<tr>
<td>Session 8&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>226 (95.4)</td>
<td>38 (97.4)</td>
<td>188 (94.9)</td>
</tr>
<tr>
<td>Once</td>
<td>3 (1.3)</td>
<td>0 (0)</td>
<td>3 (1.5)</td>
</tr>
<tr>
<td>Twice</td>
<td>2 (0.8)</td>
<td>1 (2.6)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Three times</td>
<td>3 (1.3)</td>
<td>0 (0)</td>
<td>3 (1.5)</td>
</tr>
<tr>
<td>Three or more times</td>
<td>3 (1.3)</td>
<td>0 (0)</td>
<td>3 (1.5)</td>
</tr>
</tbody>
</table>

<sup>a</sup> = no data for n= 210 for whole sample, n=45 for pre COVID-19 group, n= 165 for during COVID-19 group.

<sup>b</sup> = no data for n = 2369 for whole sample, n=718 for pre COVID-19 group, n= 1651 for during COVID-19 group.

<sup>c</sup> = no data for n = 2611 for whole sample, n=773 for pre COVID-19 group, n= 1838 for during COVID-19 group.

Of those who experienced suicidal thinking in the week prior to session 1, the mean level of intent was M=2.61 (SD = 2.05) for the whole sample (n=404). The mean level of intent for the pre COVID-19 lockdown group (n=106; M=2.40, SD=1.89) and the during COVID-19 lockdown group (n=298;M=2.68, SD=2.10) were not significantly different (t(402) = -1.251, p=.212).

Of those who experienced suicidal thinking in the week prior to session 5, the mean level of intent was M= 1.56 (SD = 1.59) for the whole sample (n=30). The mean level of intent for the pre COVID-19 lockdown group (n=3) was M=0.67, SD=1.16) and M=1.67 SD=1.62 for the during COVID-19 lockdown group (n=27).
Of those who experienced suicidal thinking in the week prior to the final session, the mean level of intent was M= 1.82 (SD = 1.89) for the whole sample (n=11), only one individual responded with a score of 5 for the pre COVID-19 lockdown group (n=1) and M=1.50 (SD=1.65) for the during COVID-19 lockdown group (n=10).

**Registration**

Chi square tests indicate significant associations between biological sex, referral source, COVID-19 lockdown grouping variable and registration status of the sample referred to Beating the Blues.

Results indicated that female participants were more likely to register for the programme than male participants (X² = 39.17 (1), p<.001). There was a significant association between referral source and registration status (X² = 12.73 (5), p=.036). Individuals referred by their GP were significantly more likely not to register for the programme. Individuals referred by Psychology and Mental Health and Wellbeing services were more likely to register for the programme. No significant associations for PALMS, third sector or ‘other’ referral sources were observed. There was a significant association between group and registration status (X²= 6.58 (1), p=.01) indicating that individuals in the pre-COVID-19 lockdown group were more likely to register for the programme than individuals in the during-COVID-19 lockdown group.

There was a significant difference for age in relation to registration status, with individuals who registered for the programme significantly older than those who did not register, U = 1798463.50 (n=4428), p = 0.013. There was also a significant difference for SIMD ranking in relation to registration status, with those who registered for the programme having higher SIMD ranks (i.e less deprived) than those who did not register, U=1711386.50 (n=4413), p <.001. Similarly, when grouped into quintiles, there was a significant association between SIMD and registration status (X² = 21.78 (4), p<.001). Individuals living in the lowest SIMD ranked quintile (i.e. increased deprivation) are less likely to register for the programme than those with lower deprivation.
Uptake

No significant association was found between uptake and biological sex ($X^2 = 2.05$ (1), $p = .152$), nor between uptake and referral source ($X^2 (7) = 4.76$, $p = .446$). A significant association was found between the COVID-19 lockdown group and uptake ($X^2 = 8.86$ (1), $p = .003$), indicating that individuals in the pre-COVID-19 lockdown group who registered for the programme were less likely to commence the programme than individuals in the during COVID-19 lockdown group.

There was no significant group difference of age for uptake ($U=631584$ (n=3272), $p = .124$). There was a significant difference of SIMD ranking for uptake, with those who commenced the programme having higher SIMD rank (i.e. lower deprivation) than those who did not commence the programme, $U=590779.5$ (n=3255), $p = .001$. Similarly, when grouped into quintiles, there was a significant association between SIMD and uptake ($X^2 = 25.09$ (4), $p < .001$). Individuals living in the lowest SIMD ranked quintile (i.e. increased deprivation) were more likely to not commence the programme than those with lower deprivation.

Predicting attrition

Kaplan Meier survival analysis indicated that participants in the pre-COVID-19 group had a median time to attrition of 6 modules 95% CI [5.61; 6.40], similar to participants in the during COVID-19 group (median time to attrition of 6 modules 95% CI [5.85; 6.15]). A similar percentage of censored cases were observed for pre-COVID-19 group (4.3%) and during COVID-19 group (8.8%) relative to group sample sizes. A log rank test was run to determine if there were differences in the survival distribution for the groups. The survival distributions for the groups were statistically significantly different, (Figure 5; $X^2 (1) = 36.39$, $p < .001$), indicating that participants in the pre-COVID-19 group had a lower cumulative survival (i.e. completed less modules) than participants in the during COVID-19 group.
Linear regression was performed exploring the predictors of number of modules completed (Table 6). The overall model was statistically significant $F(8,2449) = 25.69, p<.001$, with an adjusted $R^2=.074$, indicating that 7.4% of the variance in number of modules completed was explained by these predictors. Age ($\beta = .225, p<.001$), baseline level of anxiety ($\beta = .055, p=.026$), baseline level of depression ($\beta = -.101, p<.001$), COVID group ($\beta = .086, p<.001$), and SIMD rank ($\beta = .068, p=.001$) significantly predicted number of modules completed. This indicated that being older, having higher levels of baseline anxiety, having lower levels of baseline depression, using the programme during COVID-19 and having lower levels of deprivation predicted higher number of modules completed. Biological sex ($\beta = .032, p<.106$) and referral source ($\beta = .029, p=.150$) did not significantly predict number of modules completed. Examining part correlations, age uniquely explained 4.8% of the variance in number of modules completed.

Figure 5. Cumulative survival distributions by group
Table 6. Linear regression results showing predictors of number of modules completed

<table>
<thead>
<tr>
<th>Model</th>
<th>95% CI for B</th>
<th>SE B</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of modules completed</td>
<td>B</td>
<td>LL</td>
<td>UL</td>
</tr>
<tr>
<td>Constant</td>
<td>.394**</td>
<td>.296</td>
<td>.492</td>
</tr>
<tr>
<td>Age</td>
<td>.007**</td>
<td>.005</td>
<td>.008</td>
</tr>
<tr>
<td>Biological sex</td>
<td>.028</td>
<td>-.006</td>
<td>.063</td>
</tr>
<tr>
<td>Baseline PHQ-9 score</td>
<td>-.007*</td>
<td>-.011</td>
<td>-.004</td>
</tr>
<tr>
<td>Baseline GAD-7 score</td>
<td>.005*</td>
<td>.001</td>
<td>.009</td>
</tr>
<tr>
<td>Baseline suicidal risk</td>
<td>-.001</td>
<td>-.021</td>
<td>.018</td>
</tr>
<tr>
<td>SIMD rank</td>
<td>1.481e-5**</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>COVID-19 group</td>
<td>.078**</td>
<td>.043</td>
<td>.113</td>
</tr>
<tr>
<td>Referral source</td>
<td>.007</td>
<td>-.003</td>
<td>.017</td>
</tr>
</tbody>
</table>

B = unstandardized regression coefficient; CI = confidence interval; LL = lower limit; UL = upper limit; SE B = standard error of the coefficient; β = standardized coefficient; R² (coefficient of determination) = .278; Δ R² (adjusted R²) = .074; *p<.05 ** p<.001

Multinomial logistic regression was performed to model predictors of completion status (n=160 subpopulation). The model provided a significantly better fit than the null hypothesis, X² (8) = 159.65, p<.001. Likelihoods ratio tests indicated that the model had significantly worse fit if baseline PHQ-9 scores (X² (2) = 25.28, p<.001), age (X² (2) = 89.22, p<.001) and COVID-19 group (X² (2) =35.31, p<.001) were removed from the model. The model fit was not significantly worse; however, if SIMD rank (X² (2) = 5.124 p=.077) was removed.

Parameter estimates are summarised in table 7. For every unit increased in age, the odds of being an early non completer relative to a defined completer changed by a factor of .554, i.e. the odds of being an early non completer decreased as age increased. Similarly, for every unit increase of age, the odds of being a non-completer relative to a defined completer changed by a factor of .728, i.e. the odds of being an early non completer decreased as age increased.

The odds of being an early non completer relative to a defined completer are 2.125 times higher for the pre-COVID-19 group than the during COVID-19 group. Similarly, the odds of being a non-completer relative to a defined completer are 2.234 times higher for the pre-COVID-19 group than the during COVID-19 group, i.e. the odds of being a non-completer is higher pre-COVID-19 than during COVID-19.

For every unit increase in baseline PHQ-9 score, the odds of being an early non-completer relative to a defined completer increased by 1.30. For every unit increase in baseline PHQ-9 score, the odds of being a non-completer relative to a defined completer increased by 1.28, i.e. the odds of being a non-completer increased as baseline PHQ-9 scores increased.
The classification table, however, indicates that the model could accurately predict non completers but very poor at predicting early non completers and defined completers.

### Table 7. Results of a multinomial logistic regression indicating predictors of completion status

<table>
<thead>
<tr>
<th>Completion status</th>
<th>B</th>
<th>SE</th>
<th>Wald</th>
<th>df</th>
<th>Odds Ratio</th>
<th>95% CI for Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LL</td>
</tr>
<tr>
<td>Early non completer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>1.270**</td>
<td>.293</td>
<td>18.736</td>
<td>1</td>
<td>.888</td>
<td>.802 - .984</td>
</tr>
<tr>
<td>SIMD_quintile</td>
<td>-.118*</td>
<td>.052</td>
<td>5.104</td>
<td>1</td>
<td>.888</td>
<td>.802 - .984</td>
</tr>
<tr>
<td>Age_quartile</td>
<td>-.591**</td>
<td>.064</td>
<td>84.330</td>
<td>1</td>
<td>.554</td>
<td>.488 - .628</td>
</tr>
<tr>
<td>Baseline</td>
<td>.261**</td>
<td>.062</td>
<td>17.793</td>
<td>1</td>
<td>1.298</td>
<td>1.150 - 1.465</td>
</tr>
<tr>
<td>PHQ9_quartile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre COVID-19 group</td>
<td>.754***</td>
<td>.168</td>
<td>20.105</td>
<td>1</td>
<td>2.125</td>
<td>1.528 - 2.953</td>
</tr>
<tr>
<td>Non completer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>1.704**</td>
<td>.247</td>
<td>47.582</td>
<td>1</td>
<td>.934</td>
<td>.857 - 1.017</td>
</tr>
<tr>
<td>SIMD_quintile</td>
<td>-.068</td>
<td>.044</td>
<td>2.452</td>
<td>1</td>
<td>.934</td>
<td>.857 - 1.017</td>
</tr>
<tr>
<td>Age_quartile</td>
<td>-.317**</td>
<td>.053</td>
<td>35.546</td>
<td>1</td>
<td>.728</td>
<td>.656 - .808</td>
</tr>
<tr>
<td>Baseline</td>
<td>.244**</td>
<td>.051</td>
<td>23.179</td>
<td>1</td>
<td>1.277</td>
<td>1.156 - 1.410</td>
</tr>
<tr>
<td>PHQ9_quartile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre COVID-19 group</td>
<td>.804**</td>
<td>.144</td>
<td>31.293</td>
<td>1</td>
<td>2.234</td>
<td>1.686 - 2.960</td>
</tr>
</tbody>
</table>

Reference category = defined completer. $B$ = unstandardized regression coefficient; CI = confidence interval; LL = lower limit; UL = upper limit; $SE$ = standard error of the coefficient; *$p<.05$ **$p<.001$

### Clinical effectiveness of BtB

**Overall effectiveness.** The results of a repeated measures MANOVA (n=416) indicated that there was a statistically significant change to the combined PHQ-9 and GAD-7 scores from session 1 to end of session 5, $F(8,3318) = 117.29$, $p < .001$, Wilks’ $\lambda = .608$, partial $\eta^2 = .220$. Post hoc testing using repeated measures ANOVA indicated a significant effect of time on GAD-7 scores, ($F(2.99,1240.69) = 211.06$, $p < .001$) and PHQ-9 scores, ($F(3.07,1275.41) = 209.41$) = 209.20, $p < .001$). Pairwise comparisons indicated significant mean differences between every GAD-7 and PHQ-9 score at each time point indicating a significant decrease in these scores as sessions progressed (Appendix 5).

**Impact of COVID-19 on clinical effectiveness.** A two-way mixed ANOVA (n=417) exploring main and interaction effects between COVID-19 grouping variable and time on the level of anxiety (GAD-7 scores) indicated no statistically significant interaction effect ($F(2.99, 1239.07) = .407$, $p = .804$, partial $\eta^2 = .001$). The main effect of time showed a statistically significant difference in mean GAD-7 scores at each session ($F(2.99,1239.07) =$...
121.51, \( p < .001 \), partial \( \eta^2 = .226 \)) but no statistically significant main effect of COVID-19 grouping variable on GAD-7 scores was observed (\( F(1,415) = .654, \ p = .409 \), partial \( \eta^2 = .002 \)).

A two-way mixed ANOVA (\( n=416 \)) exploring main and interaction effects between COVID-19 grouping variable and time on the level of depression (PHQ-9 scores) indicated statistically significant interaction effect (\( F(3.07, 1272.03) = .117, \ p = .915 \), partial \( \eta^2 < .001 \)). The main effect of time showed a statistically significant difference in mean PHQ-9 scores at each session (\( F(3.07, 1272.03) = 115.60, \ p < .001 \), partial \( \eta^2 = .218 \)) but no statistically significant main effect of COVID-19 grouping variable on PHQ-9 scores was observed (\( F(1,414) = 1.615, \ p = .204 \), partial \( \eta^2 = .004 \)).

**Discussion**

This study aimed to explore engagement with BtB from referral through to completion or point of non-completion. It further aimed to explore effectiveness and attrition and how the COVID-19 pandemic impacted this.

In terms of the characteristics of the sample, more females were referred to BtB than males. This is in line with previous cCBT literature [110] and within broader psychological research which has consistently found that men seek help for mental health less frequently than women [111]. This has been hypothesized to be related to social constructs of masculinity and gender role conflicts [111]. Given the cCBT service does not have a self-referral option, this would require actively engaging in help seeking behaviour including speaking with a healthcare professional about treatment options. This may account for lower rates of male referrals.

The majority of the referrals were from GP surgeries followed by mental health and wellbeing services. The modal age range was 20 to 29 followed by 30 to 39 years of age. These findings are in line with previous findings in this service [105]. It is also in line with referrals to UK based mental health services for mild-to-moderate anxiety and/or depression [112]. There was a relatively even distribution across the SIMD quintiles indicating there was relatively equal representation of levels of deprivation in the sample. Although this study used routinely collected service data, this indicates that this sample is representative of the Scottish population in terms of deprivation.
Close to 15% of the total sample were defined completers (completing at least five sessions) and 7.6% completed all eight sessions. This attrition rate is higher than previous research in the service [73] and higher than previous BtB research (see systematic review chapter). It is, however, in line with naturalistic research exploring adherence to another cCBT programme, MoodGYM: where only 10% of users completed two or more sessions [100]. Consistent with previous BtB research, real-world settings tend to have higher rates of attrition than research and experimental settings [113]. In the current study, the largest attrition occurred in the first three sessions. This is in line with previous BtB research [73]. A similar pattern has been observed in traditional CBT: rates of attrition significantly decrease as sessions progress [55]. In BtB, the reduction in attrition after session three also coincides with the introduction of CBT specific techniques and skills in the programme whereas the initial two sessions focus on psychoeducation and socialization to the CBT model. Early symptom improvement is associated with better adherence in CBT including cCBT [100, 114, 115]. It is possible that if participants engage beyond session three, this is when they may notice the clinical benefit of the CBT techniques employed and may be more likely to adhere to the rest of the programme.

Baseline levels of anxiety and depression were all within the moderately severe clinical range and suicidal risk was low. This indicates that the programme is targeting the appropriate population, albeit at the upper end of this range. Participants using BtB during COVID-19 had significantly higher levels of baseline depression than those using the programme pre-COVID-19. This is in line with evidence from UK longitudinal mental health and wellbeing studies during COVID-19. Rates of depression and suicidal ideation were higher in the initial waves of the pandemic when compared with pre-COVID figures, although these reduced slightly over the initial waves [116]. Rates of depression, defeat and hopelessness, however, increased as the COVID-19 pandemic progressed [117]. Baseline levels of anxiety of the current study’s sample were not significantly different pre or during the COVID-19 pandemic. This was unexpected given the fear and uncertainty associated with the pandemic [78, 80, 81]. Evidence from the UK mental health and wellbeing study indicated that although levels of anxiety were higher than population norms in the early stages of the pandemic, these remained relatively stable as the pandemic progressed [116, 117]. Another UK study examining mental health impacts of COVID-19, reported that levels of anxiety, depression and trauma were higher than pre-pandemic population studies [118]. No group
differences were observed for suicidal risk. This is in contrast with UK based research during the pandemic [116] and may reflect characteristics of those individuals referred to BtB, which is targeted at individuals with mild-to-moderate difficulties with low suicidal risk.

Who engages with the programme?
Almost three quarters of those referred to BtB registered for the programme; and of those almost 86% commenced the programme (i.e. 63% of those originally referred). The operationalisation of uptake and recruitment in cCBT research is variable, making it difficult to compare these results with previous findings. There are indications; however, that this reflects high uptake rates. Systematic review evidence found that uptake of cCBT ranges from 6% to almost 60% [42] with a median value of 38% uptake [119]. Similarly, when compared with a large scale community based evaluation of MoodGYM only 48% registered for the programme and 9.9% commenced [100]. There appears to be higher uptake for users of BtB, but also higher attrition rates, when comparing with existing evidence.

With regards to registration for treatment, participants who were female; older; referred by psychology and mental health and wellbeing services; living in less deprived areas; and those who engaged with BtB pre-COVID-19 were more likely to register for BtB. Conversely, male participants, those referred by GPs and those living in more deprived areas were less likely to register. In terms of uptake, participants who were from less deprived areas and engaged with the programme during COVID-19 were more likely to commence the programme than those from more deprived areas and engaged with the programme pre COVID-19.

Systematic review evidence of cCBT in general has found that female participants are more likely commence and engage with digital mental health interventions than male participants [115]. These gender differences might relate to gender role conflicts in relation to help seeking behaviour [111]. The literature is mixed with regard to age, with some studies reporting better engagement with younger adults, whereas others have reported better engagement with older adults [115].

There is evidence that self-referrals and referrals from mental health professionals were associated with increased uptake and adherence with cCBT [35, 100]. Similarly in
participants in qualitative analyses of BtB, noted that the recommendation of BtB by healthcare professionals they trust impacted their motivation to try BtB [32]. It could be that when referrals are made by psychology or MHW services, this may be from a professional with whom the individual has a trusting relationship. GP contacts with patients are likely to be shorter, which may impact how effectively GPs are able to explain the programme.

The finding that those from more deprived areas are less likely to register or commence with BtB is important. Social deprivation is a risk factor for developing mental health difficulties yet those living in more deprived areas are often faced with inaccessibility to mental health resources [120–123]. This presents as a significant obstacle to the aim of increasing accessibility to evidence based mental healthcare through national rollout of cCBT [53].

**Who disengages from the programme?**
The COVID-19 grouping variable, age and baseline levels of depression consistently predicted attrition. Results consistently indicated that individuals engaging with BtB during COVID-19 completed more of the programme than those engaging with the programme pre COVID-19. Several factors may have contributed to this. Baseline levels of depression were significantly higher for those engaging with the programme during COVID-19. Research indicates there is a complex interplay of severity of symptoms and engagement with digital mental health interventions: severity of symptoms can both decrease capacity to engage with interventions but can also increase motivation to engage with these interventions [115]. In the current study, although the baseline levels were statistically significantly higher than pre-COVID levels, the mean score still fell within the moderate clinical range: perhaps reflecting the optimal conditions for engagement where perceived clinical need was motivating; yet the severity of depression was not debilitating in relation to engaging with the intervention.

In addition, due to COVID-19 restriction guidance to ‘stay at home’ where possible, the pandemic has been associated with increased internet use to complete day-to-day tasks [124]. Confidence using technology and technological difficulties to completing sessions are known barriers to engaging with cCBT [32, 115]. Increased internet use during COVID-19 may have helped address this barrier, leading to higher levels of engagement with BtB. Similarly, another known barrier to cCBT use is difficulty in dedicating time to completing sessions [119]. The ‘stay at home’ COVID-19 guidance and the implementation of schemes including
the Coronavirus Job Retention Scheme in April 2020 resulted in a unique context where the barrier of time may have been less significant. This is reflected in a Scottish study exploring positive impacts of the COVID-19 lockdown: 62% of the sample reported paying more attention to their personal health during this time [125]. There are, however, likely to be many other factors associated with the COVID-19 pandemic that influenced this increased engagement. A UK based study exploring uptake of mental health support during COVID-19 reported that additional factors such as living arrangements, access to social support and coping strategy styles also impacted the level and type of mental health support that individuals engaged with [123]. These factors, however, are unknown in the current sample.

Older participants were more likely to complete more modules and complete the programme than younger participants. This is line with previous meta analytic evidence of self-guided digital interventions [126], although reasons for this were not hypothesized. Some research have reported contradictory results that younger participants engage more with digital mental health interventions, highlighting that increased computer proficiency might account for this [100].

In the current study, lower baseline levels of depression predicted completion. It has been argued that the symptomology of depression, for example, hopelessness, reduced interest, concentration, may directly impact individuals ability to engage with therapeutic interventions [55]; thus, those with more severe levels of depression may be less likely to complete BtB. The existing findings in this area are mixed and it is important to highlight that duration of difficulty may impact this relationship [64]. Duration of difficulties was unknown in the current sample.

Higher baseline levels of anxiety significantly predicted more modules completed. This was not a consistent predictor and is in contrast to previous systematic review findings that lower levels of anxiety predicted increased adherence [127]. It could be hypothesized, however, that the nature of anxiety disorders may result in increased adherence to treatment, for example, due to planning and preparing as coping strategies to manage worry and anxiety. Similarly lower levels of deprivation predicted a higher number of modules completed; however, this was not a consistent predictor. Biological sex and referral source did not significantly predict attrition.
**Is the programme effective?**

The results indicate significant reduction in level of anxiety and depression from sessions one to session five with large effect sizes, indicating that the hypothesis was upheld. This is line with previous findings outlined in the systematic review that BtB is effective for treatment of depression. The systematic review, however, indicated that effectiveness of BtB for treatment of anxiety was mixed and tended to have smaller effect sizes. The results are also in line with effectiveness of other cCBT programmes [9, 128, 129]. No group differences were observed, indicating that the intervention was equally effective pre and during COVID-19. Despite increased baseline levels of depression in participants using BtB during COVID-19, the programme was as effective as usual.

**Limitations**

The study has several limitations. The operationalisation of the COVID-19 grouping variable meant participants were grouped into two discrete groups: pre and during COVID-19 lockdown. In reality this was more nuanced with several ‘waves’ of COVID-19 restrictions where restrictions were lifted and reimposed. Nevertheless, throughout this time, GP practices in the NHS health board continued to operate under COVID-19 guidance [104] using telephone appointment as their routine form of healthcare delivery. Similarly, participants were grouped into the pre and during COVID-19 groups according to when they commenced the programme. This meant that some participants may have commenced the programme pre-COVID-19 but continued to use BtB during COVID-19. This operationalisation was meant to capture individuals’ intent to engage, however, it is important to acknowledge that this could have been operationalised in other ways. Similarly, there were some participants who were referred to BtB prior to September 2021 but may have continued to use the programme beyond the data collection timeframe. This may have resulted in a slightly over-inflated non-completion rate for the descriptive statistics of the during COVID-19 group, however, these numbers were minimal.

There are several threats to internal validity. Confounds, for example, included psychiatric medication use, duration of mental health difficulties and other forms of therapeutic input used concurrently with BtB. These may have influenced changes to clinical outcomes. Similarly, there are extensive factors that may contribute to engagement and attrition to DMHI including user and programme related factors [115]. Many of these were unknown in
the current sample including participant motivation, beliefs about the programme, experience of using the programme, perceived acceptability, and occurrence of unrelated life events.

There were limitations on how engagement could be explored in the research, i.e. through registration and uptake only. One of the opportunities digital mental health presents, is the possibility of extensive routine data capture, for example more nuanced indicators of engagement and adherence including number of site logins and length of use per session [113].

In terms of data analysis, there were several limitations. Causality cannot necessarily be inferred. For example, the results in relation to registration and uptake, represent associations rather than causal relationships between variables. In addition, there were several violations to assumptions of statistical tests. Where possible non-parametric alternatives were used and data transformations were performed. The multinomial logistic regression had poor predictive ability and the linear regression accounted for a small proportion of variance explained. Despite these limitations, the results were consistent across the models of attrition, adding strength to the validity of the findings.

**Strengths**

The study has several strengths. The large sample size resulted in sufficiently powered statistical analyses. Although the study used routine data from a cCBT service, the sample was relatively representative of Scottish population in terms of age ranges, and deprivation, which has implications for the generalizability of the findings. The study used real, service data. Although RCTs are rigorous in design, naturalistic studies are critical for demonstrating effectiveness of therapies in real world settings [130]. The study was also able to model attrition in several ways using both categorical and continuous outcomes. This is in line with the variability in the operationalisation of attrition in the literature [69].

A further strength of this study is the implications of these findings for clinical practice within this cCBT service and wider DMH services. BtB is effective when participants completed at least five sessions. This highlights the need for continued exploration of dosage effects, as this has important implications for the impact attrition rates have and how the clinical impact of DMH programmes is perceived.
Next steps for research and clinical practice

It is important to maximise the data captured through these programmes to understand engagement in a more nuanced manner. For example, website activity, number of times users access the programme, and usage time per session [113]. This data will help inform patterns of engagement and in turn, highlight where services can make changes to improve engagement.

More detailed data is needed to meaningfully understand why attrition occurs. Given the varied and inconclusive findings on the BtB literature in relation to attrition (as outlined in the systematic review), this highlights the need for a local, contextualised understanding. The results of this study have given some indications of what factors might significantly predict attrition in this service, however, the predictive power and variance explained by these models were small. There are likely to be many factors contributing towards attrition from cCBT [115]. As highlighted in a DMH systematic review [127], there are several ways of researching and exploring adherence and attrition, including establishing associations and predictors of adherence and attrition through use of routine data. In addition, post intervention questionnaires can be used to gather user experience and perceptions. Finally, DMHI can actively make changes to the programme or service delivery and explore the impact of this [127]. For example, self-referral options have been proposed to improve recruitment and engagement [131]. Similarly, the systematic review evidence (outlined above) indicates that programme specific factors such as aesthetics may impact acceptability and engagement with the programme. Another study highlighted the importance of receiving adequate information about BtB prior to commencement [132]. Gathering data through these additional lines of enquiry will help provide more meaningful understanding of engagement and attrition in DMHI at a local level.

This study have further contributed to the emerging understanding of the impacts of COVID-19 pandemic on mental health and the role of DMH within this. The results of this study are in line with emerging evidence that the pandemic has negatively impacted mental health. An important finding, however, is the ongoing effectiveness of BtB during the pandemic and the increased engagement during this time. This highlights the importance of DMH as an effective and accessible form of mental health service provision.
Conclusion

BtB is an effective intervention for the treatment of mild-to-moderate depression and anxiety. The programme’s success, however, is not only characterised by effectiveness, but by participants’ engagement with the intervention. Despite the intervention’s clinical effectiveness, attrition rates are high. The study found that several factors predicted attrition from the programme including younger age and higher baseline levels of depression, however, there are many unknown variables which are likely to further impact attrition. This continues to be poorly understood in the literature and requires further continued research to maximise the clinical benefits of programmes such as BtB. Understanding these factors may help services improve uptake, promote continued engagement and reduce attrition rates. An important finding was that users need to complete at least five sessions to experience meaningful clinical change. This challenges the assumption that full interventions are required to benefit from programmes such as BtB. This has important clinical implications for cCBT services, where attrition may be defined in a more meaningful way, if dosage effects were more consistently examined. A final key finding was that BtB continued to be effective during the COVID-19 pandemic, however, users of the programme engaged more with the programme and were more likely to complete the programme during the pandemic. This has significant implications for the ongoing relevance of programmes such as BtB in the UK. It has further contributed to the understanding of the impact of COVID-19 on mental health and mental health service provision.
Box 1. Summary for publication

**Key findings and implications**

- BtB is an effective intervention for mild-to-moderate anxiety and depression when users engage with the programme.
- BtB continued to be effective during COVID-19.
- Younger participants and those with higher levels of baseline depression were less likely to complete the programme.
- Participants using BtB during COVID-19 were more likely to engage with and complete the intervention.
- Further understanding is needed to understand why participants discontinue with cCBT. cCBT services should aim to: i) routinely enquire about attrition and ii) maximise data capture on engagement for example, recording the number of logins.
- Definitions of attrition, adherence and engagement need to be clear and meaningful, i.e, informed by dosage effects when used by services or in research.
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Doctorate in Clinical Psychology

Thesis Research Proposal

(Research 1 Assessment)

This form should be completed and submitted as the assessment for Research 1. It will then be reviewed by a member of the academic team and will receive a grade and detailed feedback. The feedback will include an evaluation of the viability of the project and any recommendations. If there are significant concerns about viability, the project will be flagged to the research director and the research committee will decide whether the project can proceed in its current form.

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Please Note: Whilst this is not an ethics review process, where questions have some similarities to questions contained in the NHS IRAS Research Ethics form, the corresponding IRAS question numbers are given in parentheses. This is intended to facilitate completion of NHS ethics where such approval is needed.
Section 1: Introduction

1.1 Provide a brief critical review of relevant literature, which should clearly demonstrate the rationale and scientific justification for the research

1000 – 1500 words

Relevant to IRAS A12

Introduction

This literature review provides an overview of the research regarding computerised cognitive behaviour therapy and the implications of COVID-19 on mental health and mental health service provision. This highlights current gaps in the research, providing a clear rationale for this proposed research.

Computerised cognitive behaviour therapy

Computerised cognitive behaviour therapy (cCBT) refers to CBT programmes delivered via online platforms and can be self-guided or clinician guided [8]. There is significant research evidence from meta-analyses to suggest that cCBT is an effective psychological intervention for mild to moderate depression and anxiety [17, 43]. There is also research evidence that transdiagnostic cCBT aimed at addressing either mild/moderate depression or anxiety is effective [24]. Meta-analysis evidence further supports that online CBT has similar efficacy in terms of treatment outcomes when compared with face-to-face CBT interventions [39, 43].

In addition to its efficacy, there are significant benefits to cCBT programmes, which include their ease of rollout, increased accessibility and cost-effectiveness. This has important implications for public healthcare systems such as the NHS, where resources and funding are limited [45, 46]. Self-guided cCBT has further significant benefits by instilling a sense of agency in service users and reducing stigma around accessing mental health support [8]. cCBT services have directly assisted with addressing significant barriers to mental health treatment, such as psychology service waiting times [42].

Within evidence-based guidelines for mental health treatment in the UK, cCBT is consistently recommended as one of the first lines of treatment for mild to moderate anxiety and depression [2, 3, 52]. The Scottish Mental Health Strategy has also identified the need for increased accessibility of psychological support and identified national rollout of cCBT in Scotland as a specific way of addressing this [53].

The evidence clearly suggests that cCBT is an effective intervention, however, the sustainability of cCBT services only become viable, if service users engage and complete the programmes. A clear link has been established showing that engagement is positively related with treatment outcomes [61, 62]. Literature has highlighted, however, that engagement and attrition are significant barriers to cCBT programmes [8]. In terms of attrition, this is corroborated in research, although significant variation of attrition rates is reported, ranging from 24% - almost 80% drop out [42, 56, 57]. In line with this, research has also shown that dropout rates are higher in cCBT programmes, compared with face-to-face CBT [59] and particularly with unguided cCBT programmes [38]. Although cCBT research frequently cites dropout rates, reasons for attrition has not been well explored or well understood and this presents as a clear gap in the research [59, 64]. In addition to this, examination of the exposure to cCBT treatment interventions, i.e. the point at which...
service users disengage, also presents as a gap in the research [64]. Engagement with cCBT programmes presents as an additional barrier. A review reported that the average percentage of uptake and engagement with cCBT services was 38% [119]. The understanding of reasons for lack of engagement, however are also poorly understood [119, 133]. This presents as a clear gap in the cCBT research.

**COVID-19**

COVID-19 was declared a pandemic by the World Health Organization (WHO) in March 2020 given its rapid spread globally (WHO, 2020). In addition to the clear impacts the pandemic has had on physical healthcare, this pandemic has had significant impacts on mental health as well as mental health service provision [77]. It is imperative that the impact of COVID-19 on mental health and service provision is understood, in order for an appropriate and effective service response to this increased need [77].

There is some evidence demonstrating the impact of COVID-19 on mental health. Key responses to COVID-19 have included the implementation of national lockdowns and quarantine measures, which result in significant isolation for the general public. Evidence from a review has indicated that being under quarantine is associated with psychological distress, with further mental health deterioration associated with lengthier quarantine durations [89]. Further evidence indicates that isolation from social support can result in an increased risk for developing common mental health disorders such as anxiety and depression [80, 88]. In addition to lockdown and quarantine measures, COVID-19 presents as a significant health risk to individuals and it is reasonable to expect increases in anxiety, fear and psychological distress. This is supported in emerging research evidence exploring the COVID-19 pandemic (see Bareket-Bojmel et al., 2020; Li et al., 2020; Qiu et al., 2020). This is also in line with previous research exploring the impact of other health pandemics (such as the SARS and Ebola health crises) on mental health (see Sim et al., 2010). It is anticipated that the psychological impact of COVID-19 will extend beyond the lockdown period itself [83].

In addition to the impacts of COVID-19 on physical and mental health, the pandemic has also had a significant impact on mental health service delivery. In Scotland, face-to-face mental health service provision was greatly reduced and an increased reliance on remote working was employed according to the government guidance (see Scottish Government, 2020). Given this context of increased barriers to accessing support in a time where the demand for mental health support is likely to increase, internet forms of mental health support such as cCBT are a key resource to employ [88, 91, 135]. Given the recency of the COVID-19 outbreak, the impact of the pandemic on mental health and mental health services remains largely unknown. This includes the impact of COVID-19 on cCBT services and presents as a clear gap in the research.

**Rationale**

The COVID-19 pandemic is having a significantly negative impact on mental health and the effects of this are likely to extend beyond the period of the pandemic. In addition to this, the COVID-19 restrictions on mental health service provision has resulted in an increased reliance on remote and online forms of therapy. Given this, e-health is likely to be a priority in NHS services going forward. cCBT is of particular relevance given its
strong evidence base as an effective treatment and the Scottish Government’s initiative for national rollout of cCBT to assist with improving access to mental health services.

cCBT has received increased attention within psychological research, however, particular gaps still remain. Modelling engagement and attrition within the cCBT services has not been significantly explored. This has further not been explored within NHS Tayside Beating the Blues (a cCBT service). This has been noted in previous research using this service data: Cientanni et al. (2019) highlighted that characteristics of service users who dropped out of treatment was not well understood. In terms of wider literature within cCBT, attrition rates are frequently cited, but exploring the point at which people drop out presents as a further gap in the research. This research will directly address these gaps. In addition to this, the COVID-19 pandemic presents as unique context to explore this within. Given that the effects of COVID-19 on mental health are likely to extend beyond the pandemic, it is imperative that mental health services understand how the pandemic impacts services user’s mental health and their engagement with cCBT services. This will allow for evidence informed decision making with regards to any future service delivery change.

Section 2: Research Questions / Objectives

2.1 What is the principal research question / objective?

The aim of this research is to model engagement, adherence and clinical outcomes on Beating the Blues data.

2.2 What are the secondary research questions / objectives, if applicable?

The secondary aim of this research is to model the impact of the COVID-19 pandemic on engagement, adherence and clinical outcomes on Beating the Blues data by grouping the data into pre-COVID-19 lockdown, during COVID-19 lockdown; and post-COVID-19 lockdown.

Section 3: Methodology

3.1 Give a full summary of your design and methodology

Participants
This research will use routine data collected from service users who are referred to NHS Tayside Beating the Blues service (a cCBT service). The routine data includes demographic information of age and gender (determined from referral information), information regarding level of risk at the start of each session, information regarding level of anxiety and level of depression, engagement with the programme and level of completion of the programme. Please see ‘Measures and variables’ below for operationalisation of these variables.

Design
This research will follow a quasi-experimental design. The quasi experimental variable will be the grouping variable with 3 levels: pre-COVID-19 lockdown; during COVID-19 lockdown and post COVID-19 lockdown. The dependent variables will be engagement, attrition and clinical outcomes. The predictor variables will be the sample characteristics (demographic variables, level of risk, referral origin) and engagement.

**Measures and variables**

**Demographic information:**
- Age: measured a continuous variable.
- Gender: measured as a categorical variable (levels: female, male, non-binary).

**Level of risk:**
- Operationalised as experiencing suicidal thoughts or not in the last week (levels: yes or no). This is assessed at start of each session.
- If answered ‘yes’ to experiencing suicidal thoughts, frequency of thoughts is measured with possible answers ‘once’, ‘twice’, ‘three times’ or ‘more than three times’. Level of intent is assessed from 0 (not very seriously) to 8 (seriously).

**Origin of referrals:**
- Measured as a categorical variable (2 levels: GP surgeries and mental health services).

**Clinical outcomes:**
- Operationalised as level of anxiety, level of depression and perceived benefits from the programme. In the Beating the Blues service, this is measured via 2 standardized measures and 3 unstandardized measures.
- Standardized measures: Level of depression is measured via the Patient Health Questionnaire-9 (PHQ-9), a valid and reliable measure of depression [94]. Level of anxiety is measured via Generalised Anxiety Disorder 7 Item (GAD-7), a valid and reliable measure of anxiety [97]. These are measured at 8 time points (after each session).
- Unstandardized measures: the following question is used to assess anxiety and depression, “In the last 7 days how much have you felt that your stress, tension, anxiety or depression have impacted on your daily activities?” Answered as a discrete variable from 0 (not at all) – 10 (all the time) at the end of each session (8 times). The following 2 questions are used to assess perceived benefits from the programme. After session 1, “In the last 7 days how much have you felt able to manage your negative feelings by using the skills in Beating the Blues”. Answered as a discrete variable from 0 (not at all) – 10 (all the time) at the end of sessions 2-8 (7 times). The second question, “How far are you on the road to recovery?” is measured as a discrete variable from 0 (no progress at all) – 10 (I have achieved this) at the end of each session (i.e. 8 times).

**Engagement**
- Engagement is operationalized as starting and continuing with the Beating the Blues intervention. This will be measured as a continuous variable of the percentage of the programme completed.

**Attrition**
- Operationalised as ceasing the Beating the Blues intervention prior to the planned ending, i.e. before the end of session 8. This will be measured in two ways: firstly, as a categorical variable with 3 levels: completion; non-completion prior to session 4; non-completion after session 4. Secondly, as a continuous variable of point at which a participant drops out (from 0-8).
Grouping variable

- The groups compared will be participants who engaged with NHS Tayside Beating the Blues prior to COVID-19 lockdown, during COVID-19 lockdown and post COVID-19 lockdown. As a research variable, the ‘COVID-19 pandemic’ is being operationalised as the lockdown period defined by time points associated with NHS Tayside GP surgeries ceasing non-essential face-to-face appointments. This largely overlaps with the ‘lockdown’ phase announced by the Scottish Government on 23 March 2020. This operationalisation, however, is argued as being more appropriate given the connection between GP services and referrals to mental health service such as Beating the Blues. Prior research using NHS Scotland Beating the Blues data has indicated that roughly 75-78% of referrals to Beating the Blues came from GP surgeries [73, 105]. The cessation of non-essential services is likely to have an impact on referrals to Beating the Blues service, thus this timepoint presents as a natural threshold to define the ‘COVID-19 lockdown’ period in this research. Given that GP surgeries across NHS Tayside may have closed at slightly different time points, statistical models will be created using the different thresholds to examine if this results in any significant model changes.

The groups will be operationalised and defined as follows:

- During COVID-19 lockdown group: individuals who commenced and completed/failed to complete the service between March 2020 and the future date at which NHS Tayside GP surgeries recommence with non-essential face-to-face appointments, will be included in this group.
- Prior to COVID-19 lockdown: individuals who commenced and completed or failed to complete the service between July 2019 and March 2020 would be included in this group. The rationale for the time period is as follows. In July 2019, the Beating the Blues service was launched with amendments to its presentation of the programme and the routine measures collected. Routine data prior to this time would not be comparable to data after this date and would not allow for comparative statistical analyses. In March 2020, GP surgeries ceased to offer non-essential face-to-face appointments, hence the upper threshold of this time period.
- Post COVID-19 lockdown: individuals who commenced and completed or failed to complete the service from the point at which NHS Tayside GP surgeries re-open for non-essential appointments (i.e. business as usual), until the end of September 2021, would be included in this group.

Procedure

This research plans to use historic and future routine quantitative data collected in the NHS Tayside Beating the Blues service. Given that routine data is being used, participants for this research are service users from the Beating the Blues service. Similarly, given that this research will use routine data, there is no researcher manipulation to variables or data collection, thus the procedure will continue as per Beating the Blues protocol. Participants are referred to the service via their GP surgeries, or mental health services (NHS and third sector). If a referrer is from a mental health service, they may choose to continue to hold the service user on their caseload and would be the point of contact for Beating the Blues in terms of risk alerts. If they refer the service user to Beating the Blues and subsequently discharge from their mental health service, the GP needs to be informed as they would become the point of contact for Beating the Blues risk alerts. Once referred, Beating the
Blues NHS Tayside aim to phone the service user within 5 working days. Administration staff in the Beating the Blues team provide the service user with information regarding the programme via a telephone call. In terms of confidentiality, during this phone call it is explained that if a risk alert regarding suicidal thinking is received, this information would be transferred to the referring mental health professional or referring GP. After this phone call, service users receive a weblink to activate their account. If this remains inactivated after 3 weeks, the service user will be prompted. If the account remains inactive for a further 3 weeks, the service user is discharged from the Beating the Blues service and the referrer is informed. Consent for data storage is covered within the terms and conditions of the Beating the Blues programmes, to which service users agree. Data is stored securely in a password protected database within the NHS Beating the Blues service as well as in a Beating the Blues securely stored database. For research purposes, data extracted from either the NHS database or the Beating the Blues database, will be extracted in an anonymous format with identifiable information removed. At the start of the programme, participants complete the PHQ-9, GAD7, the two unstandardized measures of anxiety and depression (outlined above) and are assessed for risk. If a service user responds that they have been experiencing suicidal thoughts in the last week, they are subsequently asked about the frequency of these thoughts (4 levels: once, twice, three times, more than three times) and level of intent around these thoughts on a scale from 0 (not very seriously) to 8 (seriously). Beating the Blues administration staff then phone the referrer and report this information. The decision regarding whether the service user should continue with Beating the Blues or should be managed under a different service, is made by the referrer.

Participants are able to complete the 8 sessions at their own pace and the clinical outcomes are measured as outlined above in ‘Measures and variables’. Service users are able to contact the Beating the Blues team via e-mail or telephone for assistance with using the programme. Clinical support is not provided. If a service user disengages from the programme and has not logged into the programme for 3 weeks, the administration team from Beating the Blues prompt the service user via e-mail. If the service user does not re-engage within 3 weeks, they are then discharged from the service and the referrer is informed.

Once the appropriate ethical approval has been gained, the routine data will be accessed by the primary researcher and initial screening of the data will commence. This shall include screening for errors, missing data, and outliers. Appropriate statistical techniques shall be utilised at this stage to account for these. This phase would also include assessing whether the assumptions underlying the statistical techniques are upheld or violated. If these are violated, appropriate statistical techniques shall be implemented to correct this. While data collection is ongoing, initial statistical modelling of historic data can occur. At a later stage, when complete data collection has occurred i.e. end of September 2021, subsequent statistical analysis can be performed, and the research dissertation will be reported.

**Ethical considerations**

Several ethical approval applications will be submitted for this research to commence.

1. Ethical approval from the University of Edinburgh School of Health in Social Sciences.
2. NHS ethical approval from the NHS Research and Development Forum via IRAS, as this research involves the data from service users in an NHS mental health service.
3. Caldicott approval as this research will use patient records where patient identifiable information is accessed.

3.2.1 In which aspects of the research process have you actively involved, or will you involve, patients, service users and/or their carers or members of the public? Highlight as appropriate.

<table>
<thead>
<tr>
<th>Design of the research</th>
<th>Analysis of results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of the research</td>
<td>Dissemination of findings</td>
</tr>
<tr>
<td>Undertaking the research</td>
<td>None of the above</td>
</tr>
</tbody>
</table>

3.2.2 Give details of involvement, or if none, please justify the absence of involvement

This project is designed to examine pre-existing data routinely collected from NHS Tayside Beating the Blues service users. All this data is collected online. At present there is no service user or public involvement in this process. The aim would be to disseminate these findings via journal publication and potentially at conferences. See section 8.1 for further details.

3.3 List the principal inclusion and exclusion criteria

Inclusion criteria:
- Individuals referred to NHS Tayside Beating the Blues cCBT programme.
- Standard NHS Tayside Beating the Blues criteria: suspected mild to moderate depression and/or anxiety; 16 years of age or older; understand spoken and written English.
- Participants who have commenced and completed/failed to complete NHS Tayside Beating the Blues programme from July 2019 until September 2021 who fall into one of the grouping levels i.e. pre-COVID-19 lockdown, during COVID-19 lockdown, or post COVID-19 lockdown.

Exclusion criteria:
- Standard NHS Tayside Beating the Blues exclusion criteria: presence of other significant psychological disorders (for example Bipolar Disorder or psychosis) or significant cognitive impairment (for example dementia). This is based on referring clinician’s judgement. Service users must not be presenting as actively suicidal. If an individual is experiencing suicidal thoughts, but does not active plans or intent, they would not be considered actively suicidal. Any active planning or intent and any recent attempts on life would be categorised as actively suicidal. This is based on the referring clinician’s judgement.
- Individuals whose treatment spans more than one grouping variable time period: i.e. if someone commenced Beating the Blues pre-COVID-19 lockdown but completed it during lockdown. This would be excluded on the basis of having discrete groups for statistical analysis techniques proposed.

3.4 How will data be collected?
If quantitative, list proposed measures and justify the use of these measures. If qualitative, explain how data will be collected, giving reasonable detail (don’t just say “by interviews”).

This research will be using quantitative data routinely collected online via the Beating the Blues programme. See ‘Measures and variables’ in section 3.1 for a detailed description of the operationalisation of variables and measures of these. Given that this research will use routine data, there is no researcher manipulation to variables or data collection; thus the procedure will continue as per Beating the Blues protocol (outlined under ‘procedure’ in section 3.1). The routine data will be stored securely within the service and will be extracted anonymously for conducting this research.

**Section 4: Sample Size**

### 4.1 What sample size is needed for the research and how did you determine this?

For quantitative projects, outline the relevant Power calculations and the rationale for assuming given effect sizes. For qualitative projects, outline your reasoning for assuming that this sample size will be sufficient to address the study’s aims. 

*IRAS A59 and IRAS A60*

G*Power [109] was used for a priori sample size calculations in order to achieve adequate power. Given that engagement and attrition have not been modelled on this data before and given that ‘COVID-19 pandemic lockdown’ as a grouping variable is a novel variable in psychological research, there is no similar research to model effect sizes from. To conservatively account for this, a small effect size of $f^2 = 0.02$ and $f = 0.1$ has been used. For multiple linear regression, with 5 predictor variables, a standard alpha of 0.05, power of 0.80, and a small effect size of $f^2 = 0.02$, the total sample size needed is $n = 647$.

For a two way repeated measures ANOVA (within and between interaction), with an alpha of 0.05, desired power of 0.80, a small effect size of $f = 0.1$, 3 grouping levels and 8 measurements, a correlation between repeated measures ranging from 0.3-0.6, a total sample size of $n = 96$-$165$ is needed, relating to $n = 32$ - 55 per group.

### 4.2 Outline reasons for your confidence in being able to achieve a sample of at least this size

E.g. give details of size of known available sample(s), percentage of this type of sample that typically participate in such studies, opinions of relevant individuals working in that area.

NHS Tayside Beating the Blues service provided information regarding past and present referrals to the service. The referrals in 2019 to the service were roughly $n = 2000$. Given this information, it is estimated that the number of referrals to Beating the Blues spanning the ‘pre-COVID-19 lockdown group’ (July 2019 – end of Feb 2020) would be roughly $n=1332$. NHS Tayside Beating the Blues has further confirmed that from beginning of March to end of June 2020, the number of referrals to the service was $n = 548$ (roughly $n=137$ per month). Thus, for the ‘during COVID-19 lockdown’ group currently a potential sample of $n = 548$ exists. It is anticipated that when GP surgeries re-open for business as usual, the referrals to this service should not decrease significantly and are likely to increase. Previous research in this area aligns with these numbers. In a study using Beating the Blues data from 5 NHS Scotland health boards over a 33 month period, $n = 9736$ referrals was reported [73]. Another study involving Beating the Blues data from 4 NHS Scotland health boards over a 25 month period reported $n = 8610$ referrals [105]. Given this information, the primary researcher is confident that achieving the required $n = 647$ for the multiple regressions will be achieved.
When modelling the data with the covariate grouping variable included, participants need to fall into a discrete grouping category and cannot span over two groups. Given this requirement, this will result in the exclusion of some participants. Similarly, when exploring clinical outcome measures over time, service users who have not completed the programme, will be excluded. Given that G*power has reported that a minimum of 32 - 55 participants per group, and given the referral information from Beating the Blues, the primary researcher is confident that this will be attained.

Section 5: Analysis

5.1 Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative methods) by which the data will be evaluated to meet the study objectives

Statistical analysis will be used as the method of analysis for this project. Statistical software programme IBM SPSS Statistics will be used, and consideration will be given to using Statistical software R as a supplementary statistical software package depending on the statistical need.

Proposed statistical analysis to address the main research aim
Initially, the data will be screened for errors, missing data, and outliers. Assumptions of the proposed statistical analyses will be assessed. If there are significant concerns with errors, missing data, outliers or violation of assumptions, appropriate statistical techniques will be implemented to amend this. Alternatively, more appropriate methods of statistical analysis will be considered. Preliminary statistical exploration of demographic data will be performed, including chi square tests of associations.

To explore predictors of engagement with Beating the Blues, multiple regression analysis will be used with engagement as the dependent variable and sample characteristics (demographic variables, level of risk, referral origin) and initial clinical scores (level of anxiety and level of depression) as the predictor variables.

To explore predictors of attrition, logistic regression analysis will be used with attrition status (categorical variable with 3 levels: completed, dropped out prior to session 4, dropped out post session 4) being used as the dependent variable. Sample characteristics (demographic variables, level of risk, referral origin) and level of engagement will be the predictor variables. This will also be explored in an alternative way using survival analysis with ‘point of attrition’ as the continuous dependent variable.

To explore predictors of clinical outcomes, multiple regression analyses will be used with the change scores of level of anxiety and depression as the dependent variables respectively. The sample characteristics (demographic variables, level of risk, referral origin) and level of engagement will be the predictor variables.

Proposed statistical analysis to address the secondary aim
The statistical regression models developed would be extended to include a grouping covariate. This grouping covariate would relate to the grouping variable of pre-COVID-19 lockdown, during COVID-19 lockdown, and post COVID-19 lockdown. In terms of attrition, multiple survival curves could be investigated for comparing attrition across the groups. A two-way repeated measures ANOVA analysis will also be used to compare groups across the clinical outcomes at the three time points, i.e. group (3 levels) and time.
factors (8 time points) as the independent variables and level of anxiety and depression as the dependent variables, respectively. Post-hoc analyses will be conducted to examine where any differences or interactions lie.

Section 6: Project Management / Timetable

6.1 Outline a timetable for completion of key stages of the project

E.g. ethics submission, start and end of data collection, data analysis, completion of systematic review

The following Gantt chart was developed in order to plan for and manage the research project as well as other demands of the DClinPsy course.

| Activity                                      | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr |
|-----------------------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Submit proposal                               | Red |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Ethics (university and NHS)                   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Systematic review                             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Submit systematic review for publication      |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Ongoing routine data collection               |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Data analysis                                 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Thesis write up including drafts of sections and editing |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Thesis final drafts and editing               |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Thesis submission                             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Viva                                          |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Submission for journal dissemination          |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Annual leave                                  |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |

Section 7: Management of Risks to Project

7.1 Summarise the main potential risks to your study, the perceived likelihood of occurrence of these risks and any steps you will or have taken to reduce these risks. Outline how you will respond to identified risks if they should occur

There is a small possibility that the anticipated sample sizes will not be achieved. Given the referrals to Beating the Blues at present and the historic data, this is a very small possibility. If this were to occur, however, ways to manage this statistically would be explored to try and minimise the impact on the power of the statistical analyses.

There is a medium possibility that the COVID-19 pandemic lockdown will continue until September 2021. This is the anticipated data collection completion date. The implications of this include data for the grouping level ‘post-COVID-19 lockdown’ data not being collected. This would result in this group be unavailable for comparison. The plan to
reduce this risk involves planning regular supervision with both the academic and clinical supervisors in order for this potential risk to be identified and discussed at the earliest opportunity. Potential solutions could include extending the data collection period and continuing with preliminary data analysis. Another solution would be considering changes to the project such as removing the third level of the grouping variable. This would still allow for a substantial research dissertation comparing pre and during COVID-19 lockdown impacts on Beating the Blues data.

There is a medium possibility that ethical approval for this research project will be denied, given that this project proposes to use an NHS sample. To reduce the likelihood of this occurring the researcher will prepare the ethical approval application documentation thoroughly in advance (while R1 assignment is being graded) in order for this to be submitted as early as possible. This will allow for additional time if amendments are recommended. In order to aid this process, the researcher will: provide a clear and thorough rationale for using an NHS sample, highlight that no researcher manipulation is occurring (i.e. routine data will be used), and highlight how this explicitly relates to the COVID-19 pandemic and the benefits of conducting this research.

Additional risks to the research also include supervisors and/or primary researchers taking annual leave or becoming ill or unexpectedly unavailable. A Gantt chart has been created (see section 6) to clearly plan how the research will be managed and to allow for some unexpected absences such as illness. Supervision will also be planned in advance to account for annual leave.

A risk to this research is the additional demands of the D ClinPsy training on the primary researcher. The academic submissions have been anticipated and accounted for in the Gantt chart in order for these competing demands to be managed.

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**Section 8: Knowledge Exchange**

**8.1 How do you intend to report and disseminate the results of the study?**

*IRAS A51*

The aim is to disseminate these research findings in a relevant journal. Target journals are:

1. British Journal of Psychiatry
2. British Journal of Clinical Psychology
3. British Journal of Affective Disorders

The aim would also be to disseminate the findings of this research at any relevant conferences. Opportunities for this will be continuously discussed with both the academic and clinical supervisors involved in this research.

**8.2 What are the anticipated benefits or implications of the project?**

*E.g. if this is an NHS project, in what way(s) is the project intended to benefit the NHS?*

This project is likely to have significant benefits to the NHS. This project aims to address a research gap in NHS Tayside Beating the Blues data by exploring attrition and engagement with the service. This project aims to provide information regarding predictors of attrition and engagement. This evidence could help inform any future service delivery considerations or changes.
This project will contribute towards the wider literature on and understanding of cCBT. Given the importance that has been placed on increasing cCBT accessibility within in Scottish policy and national healthcare guidelines, this clearly presents as a key area of psychology research. This project would directly address this.

Similarly, this project has a direct relevance to the COVID-19 pandemic. Given NHS Scotland’s position on primarily focusing on COVID-19 related research, this project falls within this remit. At present, little is known about the impacts of the COVID-19 pandemic on mental health and service delivery. Given that cCBT is an accessible form of mental health care during the COVID-19 pandemic lockdown, it is critical that research explores the impacts of COVID-19 on cCBT services. This project will directly address this. This could help the service understand if the COVID-19 pandemic has impacted engagement, attrition and clinical outcomes of the service. Similarly, this evidence could help inform any future service delivery considerations or changes.

### 8.3 Are the any potential costs for the project?

Outline any potential financial costs to the project, including the justification for the costs (why are these necessary for the research project?) and how funding will be obtained for these costs (how will they be met?) Please separate these into potential costs for the University and potential costs for your NHS Board and note that you should ask your NHS Board to meet stationery, printing, postage and travel costs.

There will be some associated costs for this project. In terms of costs to the University of Edinburgh, SPSS version 25 statistical software package will be used. This is already licensed by the university for students. A licensing code would be needed for this research.

No significant printing or travel is anticipated but it is proposed that NHS Tayside would cover the costs of printing associated with the project and any travel associated with the project.

### Section 9: Any Other Relevant Information

### Section 10: Key References

#### References


44. Learmonth D (2007) The effectiveness and acceptability of a computerised cognitive behavioural therapy programme and the psychometric properties of its service user generated outcome measure. The City University (London) (United Kingdom)


54. The Scottish Government (2022) Resources for Mental Health and Wellbeing in Primary Care Services
<table>
<thead>
<tr>
<th>Reference</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>84. Bareket-Bojmel L, Shahar G, Margalit M (2020)</td>
<td>COVID-19-Related Economic Anxiety Is As High as Health Anxiety: Findings from the USA, the UK, and Israel.</td>
</tr>
<tr>
<td>106.</td>
<td>Beating the Blues (2022) Beating the blues: what happens in an Online CBT Session?</td>
</tr>
<tr>
<td>107.</td>
<td>IBM Corp. (2016) IBM SPSS Statistics for Macintosh, Version 24.0</td>
</tr>
</tbody>
</table>


Section 11: Confirmation of Supervisors’ Approval

“I confirm that both my Academic and Clinical Supervisors have seen and approved this research proposal and have both completed the supervisors’ appraisal forms below.”

Delete as appropriate

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<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Main Academic Supervisor’s Appraisal of Project Risk

**Supervisor’s Name**
Angus MacBeth

**Date**
04/08/2020

**Do you consider that the project should proceed in broadly its current form?**

Delete as appropriate

| Yes | Yes, subject to the revisions outlined below | No |

**Outline the reasons for the above response**

Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks

Project is an hypothesis driven investigation of the impact of Covid-19 on engagement with the BtB CCBT digital platform. It builds on previous empirical research on this platform, and uses a data-driven research design. Project is topical and has clear potential for impact. The data are available for the trainee to use, and the proposed size and scope of analyses are sufficient to meet the demands of the DClin. Project risks have been identified and can be mitigated. I have no substantial concerns over the project.

Clinical Thesis Supervisor’s Appraisal of Project Risk
Do you consider that the project should proceed in broadly its current form?

Yes

Yes, subject to the revisions outlined below

No

Outline the reasons for the above response

Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks.

There are minimal risks attached to this proposal. The data was collected as part of routine ongoing evaluation and audit of the Beating the Blues Service in NHS Tayside Psychological Therapies Service. This Service was well established pre-Covid, continued to be provided during the Covid ‘lock down’ period when GP surgeries reduced face-to-face activity levels and will continue to be offered during the Remobilization period that NHS is currently undergoing. There is a risk that 3 groups of data may not be collected, i.e. pre-Covid, during Covid ‘lock down’, post-Covid ‘lock down’ if a ‘lock down’ period is maintained.

However, even if this scenario transpires this would still provide opportunity of 2 groups i.e. pre Covid -v- during Covid ‘lockdown’. The referral rate identified to date suggests that the proposed study, regardless of what model is tested, is likely to be adequately powered. This is a theoretically sound and clinically relevant proposal.
Examining the impact of the COVID-19 pandemic on engagement, attrition and outcomes of a computerised CBT programme (word count 407)

Computerized cognitive behaviour therapy (cCBT) is a form of therapy that is delivered over the internet, which can either be completed with guidance from a clinician or can be self-guided. cCBT has been included in mental health service provision in the UK as it is an effective therapy and has helped improved access to mental health support. Given the increased use of cCBT, it is important to understand how people use and engage with this treatment and potential reasons for dropping out of these cCBT services. The COVID-19 pandemic is an additional important factor to consider as the pandemic has negatively impacted people’s mental health. The pandemic has also changed the way mental health support can be provided in the UK, for example increased use of online forms of support. The impact of this pandemic on cCBT services and how people will engage with these services, however, remains largely unknown. This is a gap in psychology research that would be helpful to explore.

This research aims to explore this by using data that is collected in a cCBT service: NHS Tayside Beating the Blues. It will explore engagement with the service, dropout rates and how effective the service is. It will also explore how the COVID-19 pandemic impacts engagement, drop out and effectiveness by comparing people who were part of the Beating the Blues programme before, during and after the COVID-19 lockdown.

This research will use information that is collected from people via the Beating the Blues online programme. All of this information will be kept anonymous. The aim will be to have information from at least 647 people who used the service before, during and after the COVID-19 pandemic. The information collected will include information about their characteristics (for example age and gender), and information around their symptoms of anxiety and depression and if they feel the programme is helping. It will also include information relating to how much of the programme they have completed. This information will then be analysed to look at the relationships between these aspects. The results of this research could be helpful to the Beating the Blues service as it will provide information on how people engage with the service and potential reasons for why they drop out. It will also help the service understand if the COVID-19 pandemic changes this in any way.
Appendix 2

The following table shows the analysis output of a linear regression using transformed variables.

\[ F(8,2449) = 26.13, \ p < .001 \text{ with an adjusted } R^2 = .076. \]

**Table A** linear regression results showing predictors of number of modules completed with transformed variables

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<th>SE B</th>
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<th>R²</th>
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\( B = \) unstandardized regression coefficient; CI = confidence interval; LL = lower limit; UL = upper limit; \( SE \ B = \) standard error of the coefficient; \( \beta = \) standardized coefficient; \( R^2 = \) coefficient of determination; \( \Delta R^2 = \) adjusted \( R^2; \ *p < .05 \  **p < .001 \)
Appendix 3

Dear Frances

CALDICOTT APPROVAL – Examining the impact of COVID-19 pandemic on attrition and outcomes of a computerised cognitive behaviour therapy (cCBT) programme

Proposal Sponsor: Professor Kevin Power, Consultant Clinical Psychologist, Direct of NHS Tayside Psychological Therapies Service, NHS Tayside

Data User(s): Frances Dreyer, Chief Investigator/Trainee Clinical Psychologist, NHS Tayside
Dr Angus Macbeth, Academic Supervisor, Senior Lecturer in Clinical Psychology & Research Director of Doctorate in Clinical Psychology

Caldicott approval is given for you to access relevant and proportionate personal data, as described in your recent application and supporting information.

Thank you for your co-operation in providing us with the information required in this process.

Please contact me should any queries arise from the application of this approval.

Yours sincerely

Information Governance
Maryfield House South
Mains Loan
Dundee
DD4 7BT
Tel. 01382 740074
Ext. 70249
www.nhstayside.scot.nhs.uk

Frances Dreyer
Chief Investigator/Trainee Clinical Psychologist
Psychologies Therapies
Ninewells Hospital
Dundee
DD1 9SY

Date 9 March 2021
Our Ref IGTCA8739
Enquiries to Joseph Donnelly
Extension 70249
Email

Everyone has the best care experience possible
Headquarters: Ninewells Hospital & Medical School,
Dundee, DD1 9SY (for mail) DD2 1UB (for Sat Nav)
Chair, Lorna Briste-Stewart
Chief Executive, Grant R Archibald

153
Joseph B. Donnelly
Depute Data Protection Officer

Copy to:  Professor Kevin Power, Consultant Clinical Psychologist, Direct of NHS Tayside Psychological Therapies Service, NHS Tayside
Dr Angus Macbeth, Academic Supervisor, Senior Lecturer in Clinical Psychology & Research Director of Doctorate in Clinical Psychology
Appendix 4

Email from the University of Edinburgh Health in Social Science Ethics committee confirming approval.

Clinical Psychology, F Dreyer

On 19 Mar 2021, at 22:10, CLINICAL PSYCHOLOGY Research Ethics <submitting.ethics@ed.ac.uk> wrote:

Dear Frances,

Thank you for your email and for providing us with all the relevant documents. As your project has been approved Caldicott, we simply need to check and log the application in the Clinical Psychology Ethics Committee database. If you need to make any changes to the protocol these would go through the REC, but I would appreciate if you could also copy University ethics into any correspondence.

Good luck with the project.

Best wishes,

Ingrid

Dr Ingrid Obisuth
Lecturer in Clinical Psychology
Ethics & Integrity Lead
Appendix 5

SPSS output showing the pairwise comparisons for GAD-7 scores and PHQ-9 scores

### Pairwise Comparisons

**Measure:** GAD7

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Based on estimated marginal means

* The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).
**Pairwise Comparisons**

Measure: PHQ9

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Based on estimated marginal means

* The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).