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*Beating the Blues: Computerised Cognitive Behaviour Therapy
for the treatment of depression and anxiety with older people*

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ABSTRACT

Introduction

With increasing longevity the population of the world is becoming older and there are growing numbers of people over the age of 65 years. This has implications for services providing psychological treatment to older people as there is likely to be an increasing demand for evidenced-based treatments such as Cognitive Behaviour Therapy (CBT) in the coming years. There are, however, relatively few clinical psychologists specialising in working with older people and therefore additional ways of dealing with the growing demands are essential. Computerised Cognitive Behaviour Therapy (CCBT) offers one potential option and NICE recommends *Beating the Blues (BTB)* as the most clinically and cost-effective package for treating depression. However, no study to date has explored the use of *BTB* with older people.

Objective

The objective of the study was to address this gap in the literature and had the following aims: 1) to explore the uptake rate of *BTB* with older people; 2) to explore the characteristics of older people opting to receive *BTB*; 3) to explore the drop-out rate from *BTB* with older people; and 4) to determine if *BTB* was effective in reducing symptoms of depression and anxiety in older people experiencing these difficulties. The findings were compared to previous research on *BTB* with younger adults.

Methodology

A between-groups, repeated measures design (with assessment time as the repeated measure) was used. Participants were given a free choice of receiving *BTB* plus treatment as usual (BTB+TAU) or treatment as usual alone (TAU). Treatment as

usual was provided by clinicians from older people community mental health teams (e.g. psychiatric nurses) and the only constraint that was placed in this was that no face-to-face psychological therapy from an accredited therapist could be provided. The participants opting to receive *BTB* also completed eight sessions of *BTB* on a weekly basis. All participants completed a range of outcome measures prior to commencing treatment (pre), after eight weeks (post) and after a further 4 weeks (one month follow-up).

Results & Discussion

The results indicated that 56.9 per cent of the participants opted to receive *BTB* and they reported having significantly more experience and confidence using a computer than those who declined *BTB*. It was also found that 72.7 per cent of older people completed all eight sessions of *BTB* (27.3 per cent discontinuation rate). This was comparable to what has been found in previous studies of *BTB* with younger adults. A two (treatment group) x three (time) repeated measures ANOVA revealed that, in comparison to the TAU group, the *BTB*+TAU group showed statistically significant greater improvements on measures of depression and anxiety by the end of treatment. This was maintained at one month follow-up. Furthermore, in comparison to the TAU group the *BTB* had a higher percentage of participants who met criteria for clinically significant improvement by the end of treatment and at one-month follow-up. The results suggest that *BTB* is an acceptable and effective treatment for older people experiencing depression and anxiety and the implications of these findings are discussed.

CHAPTER 1 – INTRODUCTION

1.1 CONTEXT

1.1.1 Changing Demographics of the Population

Much coverage has been given to the fact that life expectancies have greatly increased over the last six decades (United Nations, 2010). As illustrated in Table 1.1, the increase in longevity since the 1950's has been a global trend that is predicted to show a similar pattern over the next 60 years and beyond (United Nations, 2010).

Table 1.1 Life expectancy (in years) by year, gender and region

REGION	YEAR							
	1950-1955		2005-2010		2060-2065		2095-2100	
	Male	Female	Male	Female	Male	Female	Male	Female
United Kingdom	66.7	71.8	77.4	81.7	83.8	88.1	87.3	91.6
North America	65.8	71.7	75.6	80.7	82.4	87.4	85.9	91.0
Europe	62.0	68.0	71.4	79.3	80.8	86.4	84.7	90.1
Oceania	58.2	63.1	74.3	79.0	81.7	86.0	84.6	88.9
South America	50.2	53.8	69.5	76.5	78.3	84.1	81.6	87.2
Asia	42.8	43.1	67.2	70.9	76.3	80.6	79.8	83.9
Africa	36.9	39.5	54.0	56.3	69.3	73.7	75.0	79.2
World	46.7	48.7	65.7	70.1	75.2	79.9	79.0	83.3

Source: United Nations (2010)

One of the impacts of increased longevity has been that the world's population has become increasingly older over the last 60 years, with a large rise in the proportion of people who are over the age of 65 years. Table 1.2 summarises the percentage of the population that are over the age of 65 years by different regions of the world and highlights the world wide population of older people¹ is expected to show an increase over the next 60 years from just over 525 million to just under 2 billion by 2070 (United Nations, 2010).

¹ An older person in the remainder of this study refers to an individual(s) over the age of 65 years unless otherwise stated.

Table 1.2 Projected percentage of the population over 65 years by year and region

REGION	YEAR			
	1950	2010	2070	2100
United Kingdom	10.8	16.6	25.8	27.7
North America	8.2	13.2	22.9	26.0
Europe	8.2	16.2	26.5	27.0
Oceania	7.4	10.7	20.9	24.9
South America	3.5	7.1	25.9	28.8
Asia	4.1	6.7	22.9	25.9
Africa	3.3	3.5	9.6	15
World	5.2	7.6	19.5	22.3
More Developed	7.9	15.9	25.7	27.0
Less Developed	3.9	5.8	18.5	21.6
Least Developed	3.3	3.4	10.6	15.7

Source: United Nations (2010)

Table 1.2 also highlights that the growth in the ageing population is most apparent in developed parts of the world (although it is also occurring in less developed regions). More developed regions often have low fertility rates combined with the greatest life expectancies and it is this combination that gives rise to the most rapidly aging populations (United Nations, 2010). At present the UK has the 11th fastest growing aging population in the world, and apart from Japan, the next 20 fastest growing aging populations are within Europe, whilst the USA is placed at 32 (United Nations, 2010). With the first of the ‘baby boomer’ cohort² now reaching the age of 65 years this is likely to further increase the percentage of the population of older people in the coming years.

It is also evident that the largest and most rapid increases in the age demographics are within the ‘oldest old’ sections of society (i.e. people over the age of 80 years) where a five fold increase is expected by the year 2070 (United Nations, 2010). Furthermore,

² ‘Baby boomers’ is the term often used for individuals born in the years shortly following the 2nd world war, when there was a significant peak in birth rates amongst many nations

the number of people aged 100 years and over is predicted to show approximately an eighteen fold increase by 2070 (United Nations, 2010).

Laidlaw and Pachana (2009) highlight the importance of the changing age demographics of the population in relation to clinicians who provide treatment to older people who are experiencing psychological problems, such as depression and anxiety. Consistent with Laidlaw and Baikie (2007) and Knight *et al* (2009), Laidlaw and Pachana (2009) note that with increasing numbers of older people who are living longer, and with the first 'baby boomers' turning 65 in 2011, this may translate into a large increase in the number of older people with depression and anxiety in the coming years. Knight *et al* (2009) also suggests that newer cohorts of older people may be more receptive to receiving input from mental health services than previous cohorts of older people. All these factors may therefore lead to an increase in the demand for treatments for these disorders amongst older people.

1.1.2 Prevalence Rates of Anxiety and Depression in Older People

Depression has consistently been found to be one of the most common psychological difficulties older people can experience (Blazer, 1994; Blazer, 2002; Djernes, 2006; Steffens *et al*, 2009; Blazer, 2010a) and it frequently occurs with co-morbid symptoms of anxiety (Shaub & Lindeen, 2000, Kvaal *et al*, 2008; Van der Weele, 2008, Kessler *et al*, 2010), so much so that it has been argued that whenever symptoms of anxiety are present in an older person, an assessment for depression should also be conducted (Katona, 1997).

The Household Psychiatric Morbidity Surveys (Singelton *et al*, 2001; McManus *et al* 2009) were commissioned by the Department of Health, the Scottish Executive and the National Assembly for Wales to obtain detailed information about the prevalence of different psychiatric disorders found in individuals living in households in Great Britain. The surveys, which utilised the Clinical Interview Schedule – Revised (CIS-R) to obtain an ICD-10 diagnosis, found that the combination of both depression and anxiety in older people (and younger adults) has consistently been identified as the most prevalent category of psychological disorders. (Singelton *et al*, 2001; McManus *et al*, 2009). The results of these two surveys are summarised in Table 1.3.

Table 1.3 Prevalence of psychological disorders by age category

Study	Depressive Episode	Generalised Anxiety Disorder	Mixed Depression & Anxiety Disorder
Singelton <i>et al</i> (2001)			
70-74 years	1.1%	2.3%	5.5%
65-69 years	0.6%	2.6%	6.0%
16-64years	2.8%	4.5%	9.0%
McManus <i>et al</i> (2009)			
75+ years	1.5%	2.6%	5.9%
65-74 years	1.0%	3.3%	6.4%
16-64 years	2.6%	4.7%	9.7%

As can also be seen from Table 1.3, the Psychiatric Morbidity Surveys indicate that, in comparison to younger adults, older people show lower prevalence rates for all the psychological disorders highlighted. Similar prevalence rates for these psychological disorders in older people, and similar findings of lower prevalence rates of DSM-IV defined major depressive episode in older people compared to younger adults, has also been found in the USA (Kessler *et al*, 2010).

A limitation of the studies by Singelton *et al* (2001), McManus *et al* (2009) and Kessler *et al* (2010) is that they do not include any older people living in nursing homes, where significantly higher prevalence rates of depression have been found (Jongenelis *et al*, 2004). A review of the literature by Jongenelis *et al* (2003), for example, found prevalence rates of 6-26 per cent for major depression, 11-50 per cent for minor depression and 30-48 per cent for sub-clinical depressive symptoms found in older people residing in nursing homes. In a more recent study, Gaboda *et al* (2011) found that 51.8 per cent of residents across 5445 nursing homes in the USA were diagnosed with depression. Such findings would suggest that the prevalence rates of anxiety and depression found in the household surveys by Singelton *et al* (2001), McManus *et al* (2009) and Kessler (2010) may be underestimates of the overall prevalence of these disorders amongst all older people.

A review of the epidemiology of depression in older people living in the community, including studies from Europe, Australia, North America and Asia (Beekman *et al* 1999), has suggested that an important factor that must be considered when exploring the prevalence rates of depression in older people is the different methodologies used to assess depression across different studies. For example, some studies included in the review by Beekman *et al* (1999) used the DSM diagnostic criteria to identify cases of depression (Pahkala *et al*, 1995) whilst others use clinical cut-offs on assessment scales for depression (Lauritzen *et al*, 1996). The different methodologies used in different studies often results in variations in the 'levels of caseness' of depression explored in different studies (i.e. some examined clinically diagnosed major depressive disorder, whilst others examined sub-threshold symptoms of depression). As a result of this, there was significant variation in the prevalence rates of depression

found across the 34 studies included in the review by Beekman *et al* (1999) (ranging from 0.4 per cent to 35 per cent). However, Beekman *et al* (1999) argued that this variation diminishes when studies are grouped together by ‘caseness’ and they conclude that whilst clinically diagnosed major depressive disorder may be relatively rare in older people (1.8 per cent), when all depressive syndromes deemed to be clinically relevant are taken together it yields a prevalence rate of 13.5 per cent.

A weakness of the review by Beekman *et al* (1999) is that it included studies with an age inclusion criteria below the age of 65 years (as low as 55 years) and excluded studies exploring “the oldest age groups” (p 307). It did not, however, report what the criteria for defining the oldest age groups were. In addition, in line with the discussion above, the authors, conclude that as the studies included in their review did not include the oldest age groups or individuals living in nursing homes the “true prevalence of depression in the elderly is likely to be somewhat higher” (p 307).

A more recent study by McDougall *et al* (2007) explored the prevalence of different levels of caseness of depression in older people throughout England and Wales, ranging from sub-clinical depression to case-level depression. The study used the GMS-AGECAT system, which, depending on the responses of the individuals, generates a diagnosis of depression at differing levels of increasing severity, with level zero indicating no or very few symptoms of depression, level one and two indicating sub-clinical depression of different severity and level three and four indicating case level depression of different severity (a further psychotic subtype can also be obtained). The results of an initial analysis, which excluded individuals with dementia, found that overall the prevalence rate of case-level clinical depression was

8.7 per cent, whilst a lower prevalence of 2.7 per cent was found for severe case-levels of depression. It was also apparent in this study that there were significant differences in the prevalence rates of depression found in the different regions that were sampled. For example, a prevalence rate of 3.5 per cent was found in Cambridgeshire, whilst a rate of 14.8 per cent was found in Newcastle.

This variation in the prevalence of depression found in older people across different regions of the UK would indicate that, in addition to the methodological differences between studies, the variation may also be accounted for by population differences across regions. Indeed, the study by McDougall *et al* (2007) found an association between higher prevalence rates of depression and higher social deprivation, greater functional disability and more medical co-morbidity, which have all been factors associated with depression in older people in a number of other studies (Cole & Dendukuri 2000; Blazer & Hybels, 2005). Even greater variation in the prevalence rates of depression may also be found when exploring rates in different countries. In line with this, a recent study across the USA (Steffens *et al*, 2009), found a total prevalence rate of 10.94 per cent (including older people with minor depression, major depression and those who were receiving medication for treating depression). This finding is slightly higher than what was found in the UK (McDougall *et al*, 2007) and in the Psychiatric Morbidity Surveys (Singelton *et al* 2000; McMannus *et al* 2009), but slightly lower than the overall prevalence rates found in an earlier review including studies from many regions of the world (Beekman *et al* 1999)

The variation in results found in studies exploring the prevalence of depression in older people is likely to be a result of a combination of different methodologies (i.e.

different diagnostic methods used between studies, such as clinically diagnosed major depressive disorder or clinical cut-off scores on screening measures for depression), different samples of patients examined (i.e. community, nursing home, outpatients) and different areas of the world (where factors such as levels of deprivation may vary) (Djernes, 2006). Despite this variation in prevalence rates found between studies, Djernes (2006) suggests that whilst symptoms of depression, (which are clinically relevant and which could benefit from treatment), are arguably less prevalent in older people compared to younger adults, it is still a common problem affecting a significant number of older people.

An important point to make at this stage is that whilst depression may affect a number of older people it is by no means an inevitable consequence of old age and the vast majority of older people do not experience depression. Indeed, a recent study by Carstensen *et al* (2011) suggests that emotional well-being improves from early adulthood into old age, which they state “flies in the face of stereotypes of ageing...where old age is viewed as a time of loss and sadness by younger people” (p21). Woods (2008) also discusses this issue, which he states has been referred to as the “well-being paradox” (p44), whereby despite the challenges that old age can bring (such as multiple losses, relative poverty, reduced independence, and increased physical health problems), older people often maintain greater life satisfaction and well-being than younger age cohorts. In light of these findings, different mechanisms and models have been proposed to account for the fact that older people may be more able than younger age cohorts to deal with the psychological stressors they often face (e.g. Blazer, 2010b, Carstensen *et al*, 2011)

Despite the findings of Carstensen *et al* (2011), it is important to acknowledge that the individuals who are experiencing psychological distress still account for a significant number of older people. Based on the evidence outlined above an estimate would be that at approximately 5-10 per cent of older people experience symptoms of depression and anxiety to the extent that they are likely to have a detrimental impact upon their wellbeing. Assuming that these prevalence rates do not decrease over the coming years in parallel with the projections for the increasing numbers of older people, this is likely to produce an overall increase in the numbers of older people experiencing these disorders.

1.1.3 Impact of Depression and Anxiety in Older People

1.1.3.1 Quality of Life, Mortality and Suicide

It is clear, based on the diagnostic criteria for depression and anxiety, that both these disorders are subjectively unpleasant experiences, which can have a detrimental effect upon older people's functioning and quality of life (Doraiswamy *et al*, 2001; Wetherell *et al*, 2004; Van der Weele, 2008). Unutzer *et al* (2000), for example, found that depression was the third leading cause of reduced quality of life in older people, with only arthritis and heart disease having a greater association with reduced quality of life. Similarly, Bourland *et al* (2000) found that, in comparison to control participants without anxiety, older people diagnosed with generalised anxiety disorder reported significant reductions in their quality of life.

In addition to the unpleasant nature of depression and anxiety, and the impact these disorder can have on quality of life, there is also evidence to suggest they are also associated with increased mortality in older people. For example, Schoevers *et al*

(2009), in a prospective study of 3746 older people who were assessed as not having dementia at baseline, found that both moderate and severe depression was associated with increased mortality after 10 years. Furthermore, they found a 'dose response relationship' whereby increased severity and duration of depression at baseline was associated with greater mortality risk, with chronic depression increasing mortality by 41 per cent (Shoevers *et al*, 2009). The authors argue that their findings were independent of other factors which they included in their analysis, such as a range of sociodemographic variables, levels of physical ill health and declines in intellectual functioning characteristic of the onset of dementia. Similar findings were reported in a study by Van der Weele *et al* (2008), which examined a sample of individuals over the age of 90 years. The results indicated that the presence of depression and depression co-morbid with anxiety at baseline increased the risk of mortality by 20 per cent after an average of 3.3 years.

The results of Shoevers *et al* (2009) and Van der Weele (2008) should, however, be treated with a degree of caution as, because of the correlational nature of the studies, it was not possible to infer any causal mechanisms that may account for the results. Nevertheless, these studies, along with a number of others which have documented similar findings of increased mortality in older people with depression and anxiety (Pennix *et al*, 2001; Schulz *et al*, 2002; Ryan *et al* 2008; Peters *et al*, 2010; Hamer *et al* 2011), highlight a further negative aspect of these disorders for older people.

A possible factor that may in part account for the increase in mortality found in older people who have depression relates to suicide. It is often reported older people have high completed suicide rates across many countries of the world and that older people,

particularly older males, are at greater risk of committing suicide than any other age group (O’Connell *et al*, 2004; Duberstein & Heisel, 2008; Conwell, 2009; Erlangsen *et al*, 2011). Duberstein and Heisel (2008), for example, cite evidence that whilst the ratio of non-lethal suicide attempts to completed suicide is 20:1 in younger adults, the figure rises to 4:1 in older people. In line with these findings, the most recent Centres for Disease Control and Prevention figures from the USA (CDC, 2007) indicate that whilst women show a peak in rates of suicide in their 40’s and then lower rates from their 60’s onwards, rates of completed suicide in males increase with age, with the highest rates found in males aged 75 years and above. This is summarised in Table 1.4:

Table 1.4 Rates of suicide (per 100 000) by age and gender

Age Category (Years)	Males	Females
15 – 19	11.03	2.48
20 – 24	20.64	3.89
25 – 29	20.43	4.69
30 – 34	21.31	5.39
35 – 39	22.34	6.35
40 – 44	25.62	8.28
45 – 49	27.01	8.75
50 – 54	27.09	8.84
55 – 59	25.04	8.00
60 – 64	23.34	6.54
65 – 69	22.43	4.48
70 – 74	22.54	3.88
75 – 79	32.49	4.01
80 – 84	35.29	3.51
85 +	45.35	3.20
Overall rate for all ages		11.47

Source: Centres for Disease Control and Prevention (2007)

As can be seen from Table 1.4, there is over a three fold increase from the national average in suicide rates in males over the age of 75 years. Despite these findings, a different pattern has emerged in the UK whereby it has been reported that older people show comparably lower rates of suicide than younger adults, with the highest

prevalence found within the age cohort of 25-34 years (Shah and Coupe, 2009). In addition, a review by Shah (2007), which explored rates of suicide across 62 countries, found that only 25 countries had higher rates of suicide in older males compared to younger males, and 27 countries had higher rates in older females compared to younger females.

Despite the variation between countries in the rates of suicide amongst older people, and differences in the trends in the rates found across different age groups, it is clear that with the overall numbers of older people projected to increase in the coming years this may translate into an increase in the number of suicides within this age group (Conwell, 2009). This increase is important in relation to depression as it is widely reported that there is a high prevalence of this disorder in older people who commit suicide (Conwell *et al*, 2002; O'Connell *et al*, 2004; Hawton & van Heerengen, 2009, Wiktorsson *et al* 2010). Wiktorsson *et al* (2010) argue that if efforts are not made to improve the provision of treatments for older people experiencing depression then the increasing numbers of older people in the population could lead to a large overall rise in the number of suicides. Given the HEAT target set by the Scottish Executive Health Department to reducing suicide rates in Scotland by 20 per cent by the year 2013 (SEHD, 2006), the importance of providing effective treatments for older people experiencing depression is clear. Indeed, O'Connell *et al* (2004) argue that if psychiatric illnesses were 'eliminated' (i.e. completely treated and the person no longer experiences any symptoms), then 74 per cent of suicides in older people could be prevented.

1.1.3.2 Physical Health

In terms of physical health, older people are at greater risk of experiencing certain acute illnesses such as stroke (Feigin *et al*, 2002). It is evident, however, that with the increase in life expectancy, older people are increasingly likely to have developed at least one chronic physical health condition, such as arthritis, hypertension, heart disease, etc. For example, The General Lifestyle Survey (ONS, 2009) highlighted 58 per cent of people aged 65-74 years and 66 per cent of people aged 75 years and above reported suffering from at least one longstanding physical illness. These were significantly higher rates than found in younger age cohorts. Furthermore, this survey found that, in comparison to younger age cohorts, older people were more likely to have consulted their GP within the previous two weeks, had a higher average number of GP consultations within the previous year, were more likely to have attended a hospital outpatient appointment and were more likely to have been admitted as an inpatient to a general hospital.

The high prevalence of physical health conditions in older people is particularly important when considered together with anxiety and depression, as there is evidence to suggest that these disorders can lead to an exacerbation in the pain, distress and disability associated with physical health problems, as well as having a negative impact in terms of treatment outcomes for such problems (Mousavvii *et al*, 2007). For example, a number of studies have consistently shown that individuals diagnosed with depression following a stroke exhibited slower recovery times, increased functional impairment, reduced quality of life and increased mortality, when compared to those who were not diagnosed with depression (Parikh *et al*, 1990; Ramasubbu *et al*, 1998; Kauhanen *et al*, 1999; Williams *et al*, 2004; Samakouri *et al*, 2011).

Similarly, a systematic review of the literature by Lichtman *et al* (2008) suggested that there has been a consistent finding of a reciprocal relationship between depression and coronary heart disease (CHD). They highlighted that not only is there a much higher prevalence rate of depression in individuals with CHD, but that the presence of depression increases mortality rates and reduces factors such as adherence to medications and cardiac rehabilitation programmes, which can have an adverse affect on the persons functioning.

In addition, Lin *et al* (2003) highlight that one third of people over the age of 65 years have a diagnosis of osteoarthritis and individuals who also have co-morbid depression often report significantly more pain and functional impairment as a result of their arthritis, compared to those without depression. Similar findings were reported in a more recent study by Kojima *et al* (2009), which found severity of depression, as assessed by the Beck Depression Inventory, was positively correlated with the perceived levels of pain reported by individuals with rheumatoid arthritis. Similarly, Morris *et al* (2011), in an 18 year follow-up study, found that depression was associated with increases in functional disability and self-reported poor physical health in individuals with rheumatoid arthritis.

A number of studies have also shown a range of negative consequences of late life anxiety disorders upon physical wellbeing including: increased physical disability, reduction in activities, decreased sense of wellbeing and over- use of medical services (Roberts *et al*, 2001; Lenze *et al*, 2001; Wetherell *et al* 2004; Brenes *et al*, 2005). Falling is a common problem amongst older people and can lead to extensive physical disability and increases in the likelihood of admission to a nursing home (Rubenstein,

2006). There is evidence to suggest that anxiety is a risk factor that can increase an older person's likelihood of falling and that one of the sequelae of this is a loss of independence as a result of increased anxiety levels (Chang *et al*, 2004).

The studies mentioned above highlight that the presence of depression and anxiety may have a significant adverse effect on the physical health and wellbeing of an older person as well as significantly reducing their quality of life. The fact that depression and anxiety can interact with factors such as adherence to treatment and the duration of hospital admission times also has financial and resource implications (Hosaka *et al*, 1999). Indeed, Katon (2003) highlight the large increase in medical costs associated with under-treated depression in older people.

1.1.4 Conclusion

It is widely recognised that there can be a number of challenges in aging (Laidlaw & McAlpine, 2008; Laidlaw & Pachana, 2009). Older people can be at greater risk of reduced physical health functioning, reduced independence and multiple losses and bereavements. These are all factors which may increase the risk of an older person becoming depressed and anxious. Indeed, due to the challenges which older people can face, in the past some have falsely assumed that depression and anxiety are 'normal reactions' to becoming old (Blanchard, 1996; Unutzer *et al*, 1999; Neiremberg, 2001). This is clearly not the case, as anxiety and depression are not inevitable consequences of the ageing process (Laidlaw & Pachana, 2009). Carstensen (2011), for example, highlighted that improved emotional well-being is associated with greater age and models have been proposed to help understand how many older people learn to adapt to and deal with these challenges and 'age successfully' (Woods,

2008). However, it is also clearly the case that a significant proportion of older people develop depression and anxiety that is clinically significant and which would benefit from treatment.

With the evidence demonstrating a demographic shift towards an ageing population across the world it could be argued that it is essential that there is an increased focus on the treatment of psychological problems, such as anxiety and depression, for older people. At a basic level, assuming the prevalence rates of anxiety and depression remain stable, the increase in the population of older people would suggest that there is going to be a corresponding increase in the number of older people with depression and anxiety and, in turn, an increase in the demand for treatments of such difficulties amongst this population.

In addition, it is evident that the largest increases in the population are amongst the 'oldest old' (i.e. those above 85 years: United Nations, 2010). There is evidence to suggest that increasing age increases the chances of developing chronic physical health problems, which given the aging demographic would suggest there is likely to be an increase in the numbers of people within this age cohort living for longer with physical health problems (ONS, 2009). It has also been recognised that the prevalence of depression is increased in people with chronic medical problems. Given the evidence to suggest that depression and anxiety reduces an individual's ability to cope with physical health problems, increases their use of health care services and increases their morbidity and mortality, this group of people will potentially be most in need of treatments.

1.2. TREATMENT FOR DEPRESSION AND ANXIETY IN OLDER PEOPLE

1.2.1 Introduction to Treatments

Based on the information outlined in the previous sections, the development of effective treatments for depression and anxiety in older people is essential. Although in comparison to adults of working age the overall number of treatment outcome studies is relatively small with older people (Cuijpers *et al*, 2009), it has been consistently demonstrated that both psychological and pharmacological treatments for depression and anxiety are effective with both age groups (Stanley *et al*, 1996; Gerson *et al*, 1999; Wilson *et al* 2001; Kapczinski *et al* 2003; Ayers *et al*, 2007; Hunot *et al*, 2007; Wilson *et al*, 2008; Stanley *et al*, 2009; Serfaty *et al*, 2009). Studies which have directly compared psychological and pharmacological treatments suggest that they both produce equal benefits in the short-term, whilst psychological treatments such as Cognitive Behaviour Therapy (CBT) often produce greater benefits at longer-term follow-up (DeRubesis *et al*, 1999; Bortollotti *et al*, 2008). This has been a consistent finding in both adults of working age and older people (Pinquart *et al*, 2006; Laidlaw *et al*, 2008), highlighting the importance of psychological treatments in both these populations.

It has also been suggested that the effect sizes produced in meta-analyses of psychological treatments for depression in older people are broadly equivalent to those found in meta-analysis with adults of working age (Scogin & McElreath, 1994; Cuijpers *et al* 1998; Pinquart *et al*, 2006), which would suggest such treatments produce equal benefits in both age groups. The most recent meta-analysis exploring psychological treatments for depression in older people by Cuijpers *et al* (2009) directly compared studies with older people to younger adults. This meta-analysis

examined 112 studies of which 20 were with older people and 92 were with adults of working age. The results indicated that there was no significant difference in the effect size produced by studies with older people ($d = .74$) compared to those with younger adults ($d = .67$), with both age cohorts showing moderate to large effect sizes in favour of psychological treatments over control conditions. These findings of large effect sizes and no significant differences between the two age cohorts were maintained when the authors excluded certain studies from the analysis; including removing outlier studies (i.e. studies with effect sizes greater than 2.0); excluding studies of specific populations that would limit if all older people or all younger adults could participate (i.e. student cohorts, women with postpartum depression and depression as a result of a specific medical condition); and when an individual study yielded several effect sizes only the smallest one was included.

Despite these findings, a limitation of the results was that the authors only included pre-post treatment comparisons and no results regarding follow-up were analysed, which means no conclusions can be drawn regarding the differential effect of psychological treatments between younger and older people at longer term follow-up. Cuijpers *et al* (2009) also highlight there were a number of differences between the studies with older people compared to those with younger adults. For example, whilst CBT was the most common psychological intervention used in both age groups (42.3 per cent in older people and 48.6 per cent in younger adults), in comparison to younger adults, few studies with older people examined interpersonal psychotherapy (three older people studies versus nine younger adults studies), problem-solving therapy (three older people studies versus eleven younger adults studies), supportive therapy (zero older people studies versus eleven younger adults studies) and

behavioural activation treatments (one older people studies compared to nine younger adults studies). In contrast a number of outcome trials with older people examined life review therapies (five studies), which was not examined in any with younger adults. When the authors only included studies examining CBT in their analysis the results again indicated that studies with younger adults and studies with older people had moderate effect sizes in favour of CBT over control conditions ($d = .68$ and $d = .65$ respectively), with no significant differences between the two groups.

Cuijpers *et al* (2009) also highlight some limitations in the evidence-base for psychological treatments for depression in older people that emerged from their meta-analysis. For example, they suggest that only one study (3.8 per cent of the total older people studies) with older people compared to 31 studies with younger adults (21.5 per cent of the total younger adult's studies) recruited participants from a clinical sample. This finding could potentially over-inflate the effect sizes found in studies with older people, if it is assumed that (in comparison to participants from a clinical sample) those recruited from a non-clinical sample may respond more favourably to treatment. Some evidence for this assumption was indeed found by Cuijpers *et al* (2009), whereby studies recruiting participants from clinical samples had lower effect sizes than other studies with participants who were not recruited from a clinical sample (Cuijpers *et al*, 2009). A related limitation was that although studies with severe depression in younger adults were not as common as those with mild-moderate depression, no studies explored severe depression in older people. A further limitation of the results found in the meta-analysis was that the mean age of older people across all the included studies was 69.28 years, which means conclusions

cannot be drawn regarding the effectiveness of psychological treatments for depression in 'older-old' age cohorts.

Despite the limitations of the meta-analysis by Cuijpers *et al* (2009), the authors conclude that, whilst more research is required exploring psychological treatments with older people, (particularly with 'older old' participants and with individuals recruited from a clinical sample), at present the evidence suggests that psychological treatments (and in particular CBT) are equally effective in older people as well as younger adults (Cuijpers *et al*, 2009).

Table 1.6 provides a brief summary of the main conclusions of other meta-analyses that have examined psychological treatments for depression with older people over the years. A theme that has emerged from these studies has been that CBT appears to be the form of psychological treatment that has been the most systematically evaluated in the published literature. A consistent limitation of each of these meta-analyses has been that, the relatively small number of studies exploring alternative psychological treatments with older people, compared to younger adults, makes it difficult to draw any firm conclusions about CBT's relative efficacy, when compared to other psychological treatments with older people (Koder *et al*, 1996; Wilson *et al*, 2008).

The finding of CBT being the most empirically evaluated psychological treatment for depression in older people is borne out in a recent meta-analysis by Wilson *et al* (2008), which evaluated the evidence from randomised control trials of psychological treatments using the Cochrane Review inclusion criteria.

Table 1.5 Summary of meta-analyses examining psychological treatments for depression with older people.

Study	Main Conclusions
Scogin <i>et al</i> (1994)	Psychological treatments for depression in older people are effective in comparison to no treatment or placebo control conditions. The effect sizes produced are comparable to those found in studies with younger age groups. A limitation is that too few older people studies exist to allow a comparison between the relative efficacies of different types of treatment for depression with this age group.
Koder <i>et al</i> (1996)	CBT is an effective treatment for depression in older people in comparison to no treatment or placebo conditions. A limitation is that there are not enough studies of sufficient quality to allow a comparison of CBTs efficacy relative to other psychological treatments for depression in older people.
Engels <i>et al</i> (1997)	Psychological treatments are effective for treating depression in older people and Cognitive and Behavioural treatments appear to be the most effective psychological treatments. Individual therapy appears to be more effective than group therapy for treating depression in older people
McCusker <i>et al</i> (1998)	Pharmacological and psychological treatments (such as cognitive and behavioural therapies) are moderately effective in treating depression in older people, compared to no treatment/placebo controls. A limitation was that only a small number of studies, in some cases only one, of certain treatments were identified.
Cuijpers (1998)	The effect sizes of psychological interventions for treating depression in older people are large in community samples and are comparable to those found in younger populations. A limitation was that participants in the identified studies often were not recruited from clinical samples and the authors suggest more research is required with these populations.
Gerson <i>et al</i> (1999)	A significantly greater amount of research has focused on pharmacological treatments for depression in older people than on psychological treatments. Both, however, are effective in treating depression in older people. Too little data is available to allow a direct comparison between the relative efficacies of different treatments for depression in older people.
Pinquart <i>et al</i> (2001)	Psychological treatments are more effective in comparison to control conditions in treating depression in older people. CBT, Psychodynamic and Supportive Therapies appear to be the most effective psychological treatments for older people.
Pinquart (2006)	Psychological and pharmacological treatments are both efficacious in treating depression in older people, with some evidence that psychological treatments are more effective with patients with milder levels of depression. Very few studies have directly compared psychological and pharmacological treatments to control conditions in older people to draw firm conclusions about their relative efficacy.
Cuijpers (2006)	“There is no doubt psychological treatments are effective in treating depression in older people” (p 1146) and the obtained effect sizes are comparable to those found in meta-analyses with younger adults.
Wilson <i>et al</i> (2008)	There is a paucity of RCTs exploring psychological treatments, of adequate quality and sample size with older people experiencing depression. CBT appears to be effective in comparison to waiting list controls but too little data exists to draw conclusions about its efficacy relative to other treatments.
Cuijpers <i>et al</i> (2009)	Psychological treatments for depression are equally effective for older people as it is for younger adults. There is, however, relatively little research with older people than with younger adults, particularly with severe levels of depression and from clinical samples.

In this study, the authors classified different treatments into Cognitive Behavioural Therapy (CBT), Interpersonal Psychotherapy (IPT), Psychodynamic Therapy and

Supportive/Counselling Therapies. The aim of the analysis was to firstly examine the effectiveness of the different psychological treatments to waiting list or standard care control groups. The second aim was to explore the relative effectiveness of different types of psychological treatments. In conducting their analysis the authors pooled the results from studies utilising the same outcome measures using weighted mean differences. When different outcome measures were employed between studies the authors pooled the results using the standardised mean difference.

Of the 82 studies identified only 12 met the inclusion criteria and of these only nine were available for inclusion in the meta-analysis as the authors reported being “unable to obtain suitable usable data” (p5) for three studies. Furthermore, the results indicated that, in terms of psychological treatments, only studies utilising CBT and psychodynamic therapy, as the primary treatment, could be identified, although three ‘active comparator’ control treatments including; reminiscence, visual imagery and education were also included .

In terms of the main analysis, only five studies, all of which used CBT, compared this psychological treatment to waiting list/no active treatment control conditions. No other studies were identified that compared other forms of psychological treatment to waiting list controls. The results of these five studies, all of which used the HRDS to assess treatment outcome, showed that CBT was significantly better than waiting list controls at reducing symptoms of depression. It was, however, identified by Wilson *et al* (2008) that only one of these studies examined clinical response (i.e. how many participants clinically improved following treatment), and no significant differences

were found between the CBT and a placebo drug group that was used as a non-active control condition in this study.

It was also identified that three trials compared CBT to psychodynamic therapy and no significant difference was found between these two treatment modalities in terms of reductions in psychopathology or clinical response to treatment. Similarly, in a subgroup analysis of three CBT studies that compared CBT to active control conditions (i.e. reminiscence, visual imagery and education), no significant differences were found between these treatment conditions in terms of reductions in psychopathology as assessed by the GDS, although a significant difference was found on the HDRS in favour of CBT.

Based on the results of their meta-analysis, Wilson *et al* (2008) conclude that there is a relative lack of high quality research that has explored psychotherapeutic treatments, other than CBT, which they state is more effective than waiting list controls. An important point to make in this regard is that the types of treatment that were categorised as CBT within this study were heterogeneous and included, for example, bibliotherapy and problem-solving therapy. The authors also highlight the lack of research that has focused on outcomes such as quality of life following treatment.

In terms of anxiety disorders, Ayers *et al* (2007) highlight that whilst the amount of research generally on psychological treatments is smaller with older people than adults of working age, studies focusing on the treatment of anxiety with older people lags even further behind. Ayers *et al* (2007) conducted a review which identified 17 studies that have examined psychotherapeutic evidence based treatments (EBTs) for treating anxiety disorders in older people. The results of this review suggest that four

types of EBTs were found to be effective in treating anxiety disorders, namely: CBT, cognitive therapy³, relaxation training and supportive therapy. The results also suggested that CBT was the most common therapeutic approach, being used in nine studies, whilst a further three studies used Cognitive Therapy. The authors conclude that all the treatments reviewed are effective in treating anxiety in older people, with CBT having the most significant evidence-base. Ayers *et al* (2007) also suggest that the results of the studies that were included in their review are not as strong as the results found in studies exploring the effectiveness of psychological treatments in younger adults. It is, however, unclear as to how they reached this conclusion as they did not employ any statistical analysis to examine the results from the studies included in their review, (for example, using meta-analytic techniques). Such an approach would allow a comparison with meta-analyses undertaken with younger adults.

This latter issue is addressed in a more recent meta-analysis (Hendricks *et al*, 2008) which examined the effectiveness of CBT in treating anxiety disorders in older people. The results indicated that seven studies, with a total of nine comparison conditions, met the inclusion criteria (four comparisons between CBT and waiting list controls and five comparisons between CBT and active control conditions). The pooled standardised mean difference (SMD), calculated by the authors, suggested that in comparison to both waiting list and active control conditions, CBT was more effective (SMD = -.44 and SMD = -.51 respectively). An interesting aspect of these results is that CBT appeared to be more effective when compared to an active control than when compared to a waiting list control. The authors report an expectation that

³ The authors differentiated CBT from Cognitive Therapy, whereby CBT was defined as also incorporating relaxation training components into the treatment whilst Cognitive Therapy did not.

as participants who were in an active control condition also received some form of treatment, the relative efficacy of CBT would not be as great in comparison to a waiting list control condition. However, Hendricks *et al* (2008) suggest that the opposite pattern that they found was likely the result of two studies, which compared CBT to an active control, having a very large effect in favour of CBT. The authors also suggest the relative small number of studies included in the analysis meant the results were more sensitive to the effects from single studies. Despite the limitations produced by the small number of available studies for analysis, on the basis of their results Hendricks *et al* (2008) conclude that CBT is an effective treatment for anxiety in older people. There were, however, some additional limitations of this study particularly as the majority of the included studies only involved patients with generalised anxiety disorder (GAD), meaning these findings may not be applicable to other anxiety disorders. Furthermore, data regarding longer term follow-up were not included in their meta-analysis, meaning that conclusions regarding the long-term benefits of CBT for treating anxiety in older people cannot be drawn from this study.

Wolitzky-Taylor *et al* (2010) also highlight that the magnitude of the effect sizes obtained in the meta-analysis by Hendricks *et al* (2008) are smaller than what has been observed in published meta-analysis exploring CBT for anxiety in younger adults (e.g. Western *et al*, 2001). Wolitzky-Taylor *et al* (2010) suggest that whilst CBT appears to be effective in treating anxiety, particularly GAD, in older people, these benefits may be improved by designing treatment protocols to make them more specific to the issues that can arise with older people.

1.2.2 CBT Development and Use with Older People

As alluded to in the previous section, CBT has been the most evaluated psychological treatment for depression and anxiety in older people. CBT was first developed by Beck (Beck, 1976). At its most basic level CBT developed from a cognitive model that proposed emotional disorders, such as depression and anxiety, arise from dysfunctional information processing, which in-turn has a maintenance effect on these disorders (Beck, 1976). CBT uses different cognitive and behavioural techniques to target and correct this dysfunctional information processing and change unhelpful behaviours, which in-turn is proposed to produce symptomatic reduction.

More specifically, the premise of CBT is that through early developmental experiences an individual develops underlying beliefs and assumptions that guide their thinking, behaviour and the way they interpret themselves and events in their world (Beck, 1976). In the case of emotional disorders the person may hold dysfunctional beliefs and assumptions about themselves and the world, which can be activated through situational events and subsequently cause the individual to develop symptoms of emotional disorders. The result of this is the person thinks and behaves in a way that maintains their symptoms. An example may be a child who is harshly treated and criticised by their parents, with little explicit signs that they are loved, may grow up with an underlying belief that they are worthless and unlovable. They may manage this by developing the assumption that to be worthy and loved they should always make sure they please others so they are liked and can therefore avoid any criticism. A subsequent event such as a divorce may then trigger a pattern of thinking and behaving such as believing this situation shows they are truly worthless and unlovable and they therefore may subsequently avoid social contact, assuming that

others also see them as worthless. They may subsequently interpret other events as reinforcing the belief that they are unlovable and worthless. This pattern of thinking and behaving subsequently maintains the emotional distress they experience. A more detailed description of the initial development of the model of CBT can be found in Beck (1976).

CBT has now been widely investigated and applied to a range of emotional disorders with a vast body of evidence demonstrating its efficacy (Bisson, 2007; Hunot, *et al* 2007; Wilson *et al*, 2008; Eccleston *et al*, 2009; Hay *et al*, 2009; NICE, 2010). Over the years the way the initial model has been applied has developed and has varied in terms of how it is used with different problems and populations (e.g. Hawton *et al*, 1989; Wells, 1997; Laidlaw *et al*, 2003). It could be argued that CBT does not form an individual specific treatment in itself but rather a range of different therapeutic techniques. A commonality amongst all the approaches of CBT is that it is present-focused, targeting the symptoms and difficulties the person is currently experiencing. It is also highly structured, with clear procedures for how the different skills and techniques of CBT are provided to patients to help them manage their symptoms. The emphasis of treatment is on helping the patient to identify their dysfunctional patterns of thinking and behaving. This is then changed through techniques that show the person that such thoughts are not fixed, but rather are hypotheses to be tested empirically and subsequently changed to more adaptive, helpful and realistic thoughts and behaviours.

A detailed description of the treatments can be found in Beck *et al* (1979) for depression and Wells (1997) for anxiety disorders. Laidlaw *et al* (2003) provide a

detailed description of how CBT can be used for treating depression and anxiety with older people. This is also described more recently in Laidlaw and Thompson (2008) and Laidlaw and McAlpine (2008).

A randomised controlled trial by Laidlaw *et al* (2008) aimed to explore the efficacy of CBT, using a treatment manual that made specific modifications to CBT for use with older people, in line with what is outlined in Laidlaw *et al* (2003). This treatment manual is described fully in Thompson *et al* (2000). This study randomly allocated 40 participants to either CBT or treatment as usual (TAU) delivered by a GP, which was described by the authors as “generally (comprising) pharmacotherapy” (p 843) as indicated by the fact that 80 per cent of participants in the TAU group were provided with antidepressants. It was, however, also apparent that 50 per cent of participants in the TAU group were also referred to a psychiatrist, community psychiatric nurse or district/practice nurse for treatment, which could suggest pharmacotherapy was not the sole treatment provided in the TAU condition.

The results of this study indicated that both treatment groups achieved statistically significant improvements on a range of outcome measures relating to depression, functioning and quality of life by the end of treatment. These improvements were maintained by six month follow-up. An initial analysis did not reveal any statistically significant greater benefit for CBT over TAU, with the exception that when baseline characteristics were controlled for, hopelessness was significantly more reduced in the CBT group than the TAU group by the 6 month follow-up point.

However, when the authors controlled for whether or not the participants were married, the results indicated that, in comparison to TAU, those in the CBT group had statistically greater improvements by the end of treatment and by six month follow-up on a range of outcome measures, whereby those who were living alone showed greater improvements than those living with a spouse. Laidlaw *et al* (2008) suggest that this finding may have been the result of those living alone having more time to complete homework tasks. Furthermore, the author's cite evidence suggesting that some older people in long-term marriages often have an affectively neutral interactional style, which a depressed person may experience as isolating. They therefore suggest levels of intimacy within a marriage are an important consideration in terms of the support it will provide, rather than the actual existence of a marriage. Despite these suggestions, Laidlaw *et al* (2008) do not provide any evidence from their study that would lead to such conclusions (i.e. they did not report on homework completion rates or the levels of intimacy within the marriages of the participants). An alternative explanation for their findings could be that those who were living alone were more socially isolated and therefore benefited more from the non-specific aspects of CBT, such as the increased contact and interaction with other people. A control condition that provided attention and interaction, but no specific treatment, would be required to analyse this hypothesis further.

A further methodological weakness of this study was that it was evident that there was a wide range in the number of CBT sessions that participants received (i.e. between two and 17, with a mean of eight sessions). Laidlaw *et al* (2008) do not, however, report how much this variation was a result of the planned discontinuation of CBT, or early drop-out from treatment, as the authors did not set a minimum or maximum

number of treatment sessions. Furthermore, they did not include the number of CBT sessions received by participants as a factor in their analysis. In relation to this, although an intention-to-treat analysis was performed (using last observation carried forward) it was not clear as to the number of participants where this was applicable (i.e. the number of drop-outs). Despite these limitations, Laidlaw *et al* (2008) conclude that their results highlight that CBT poses an effective and acceptable alternative to pharmacotherapy in the treatment of late life depression.

A more recent and larger scale study of 204 participants with depression by Serfaty *et al* (2009) addressed some of the limitations of the study by Laidlaw *et al* (2008) and used the same CBT treatment manual modified for older people. This study compared the effectiveness of CBT, TAU and a talking control condition (TC) offered over the course of four months with a maximum of 12 treatment sessions in the CBT and TC conditions. In the TC condition participants received sessions with a therapist who was instructed to provide interest and warmth towards the participant, but not to engage in any specific therapeutic techniques (such as challenging dysfunctional thoughts or giving any form of advice).

The results of this study showed that, in comparison to the TAU and TC condition, those who received CBT showed statistically significant greater improvements in their symptoms of depression over the course of treatment, which were maintained at a 10 month follow-up point. The authors conclude that their results highlight the direct effect of CBT in treating depression in older people and challenges any assumptions that all older people require and want is “company and a friendly ear” (p 1138).

Furthermore, as all participants in this study were provided with treatment as usual, with no significant difference in the number of participants between each treatment group receiving concurrent antidepressant medication, this study has a degree of external validity, in terms of the combination of treatments that occur in typical clinical practice. Indeed, Laidlaw *et al* (2008) highlight that a factor that limited participation in their study was that some potential participants at recruitment were receiving antidepressants and some may have withheld consent to participate, due to the possibility of not being able to receive antidepressants. An interesting finding in the study by Serfaty *et al* (2009) was that only one fifth of participants who received antidepressants were prescribed a therapeutic dose, highlighting the importance of alternative non-pharmacological treatments for depression in older people.

1.2.3 Myths Surrounding Psychological Treatment with Older People

Despite the findings indicating equality in the efficacy of psychological treatments, and in particular CBT, between adults of working age and older people, there is evidence to suggest that older people often do not receive psychological treatments. Wei *et al* (2005), for example, found that only 25 per cent of older people with depression were provided with a psychological treatment and of these only 33 per cent remained in consistent treatment. Evidence also suggests that the percentage of older people receiving psychological treatment for depression and anxiety disorders is below what would be expected based on the prevalence rates for this population (Department of Health, 2011).

This finding is of particular significance given the evidence to suggest that the main alternative form of treatment (pharmacotherapy) is often prescribed at sub-therapeutic

levels with older people due to factors such as concerns regarding poly-pharmacy and side-effects and the interaction such medications can have on physical health problems (McDonald, 1986; Crawford *et al*, 1998; Serfaty *et al*, 2009).

Laidlaw *et al* (2003) highlight a number of ‘myths’ that surround psychological treatment with older people, which may influence whether or not they receive it. These myths follow two main themes with the first being ‘older people will not benefit from psychological treatment’. As mentioned above, despite there being relatively fewer studies with older people than adults of working age, the evidence suggests psychological treatments are equally effective in both age groups. This suggests it is inappropriate to deny older people psychological treatment on the assumption they will not benefit from it.

The second theme relates to an assumption that ‘older people will not want psychological treatment’. A number of studies have, however, debunked the myth that older people prefer not to receive psychological treatments. Rokke and Scogin (1995), for example, compared older and younger adults’ attitudes to mental health services and treatments for mental health problems. The results indicated that, in comparison to younger adults, older people expressed more positive attitudes towards mental health professionals and both age groups gave equally positive ratings regarding the acceptability and credibility of CBT as a psychological treatment. Similarly, Landreville *et al* (2001) found that when given vignettes describing patients with depression and three different treatment options (Cognitive Bibliotherapy (CB), Antidepressant Medication (AM) and CBT) older people rated CB and CBT as being more acceptable for treating mild to moderate depression than AM. Furthermore,

CBT was rated by older people as being more acceptable than CB and AM for treating severe depression. These studies therefore indicate a preference for psychological rather than pharmacological treatments amongst older people. A potential weakness of these studies is that they do not take into account patients preferences in relation to combined treatments.

This issue was, however, addressed in a more recent study by Hanson and Scogin (2008), which compared older peoples preferences for CBT, Antidepressant Medication (AM) and combined CBT and AM (CBT+AM) for treating depression. The results indicated that, in relation to the general acceptability of the various treatment options, older people viewed CBT+AM to be a more preferable treatment than CBT or AM alone. However, when asked to consider possible negative aspects of the treatments, older people rated CBT as being preferable to either CBT+AM or AM. These studies further emphasise the importance of psychological therapies as an important treatment option for older people.

1.2.4 Conclusion

The above section highlights that CBT is an effective and acceptable treatment for depression and anxiety in older people. However, despite a range of initiatives to increase access to psychological therapies such as CBT across the UK (DOH, 2011), there is growing evidence to suggest that older people are under-represented in services providing such treatment. For example, a recent report by the Department of Health (DOH, 2011) and a previous study by Clark *et al* (2009) suggested that at present older people account for only 4 per cent of individuals who are treated within services created to increase access to psychological therapies in England and Wales.

These studies suggested that, based on the prevalence rates of depression and anxiety, the expected rate of use of such services by older people should be 12 per cent. Similarly, Boddington (2011) proposes an 'equality of access score (EOA)' which involves dividing the percentage of older people seen in a service by the percentage of older people (relative to adults of working age) in a population, multiplied by 100. An EOA score of 100 would indicate older people gaining equal access to psychological treatment as adults of working age. Boddington (2011) examines EOA scores across five services from England and Scotland and highlights the range of EOA scores from 15.3 to 48, with the highest score still remaining "disappointingly low" (p11) and providing further evidence that older people are not accessing psychological treatments. A study by Todman *et al* (2011) also highlighted that in a six month period GPs only made nine referrals to a clinical psychology service for older people. Furthermore, in a qualitative analysis Todman *et al* (2011) found that GPs, despite recognising depression and anxiety as problems for older people, which could benefit from psychological treatment, were reluctant to make referrals for such treatment due to perceptions of long waiting times and a lack of locally available resources (i.e. patients may have to travel long distances for treatment, which may be a particular issue with older people ,who may be less mobile).

A further factor that may account for low rates of older people accessing psychological treatment may relate to the number of clinicians specialising in providing psychological treatments to older people, whereby a lack of trained therapists in general has been highlighted as a factor limiting access to psychological treatment in people of all ages (Layard *et al*, 2006; Shafran *et al*, 2009; Andrews & Titov, 2009). Indeed, Boddington (2011) found higher EOA scores in psychology

services that have appointed more staff with a special interest in treating older people or services with clear pathways to specialist older people psychology services. Wells *et al* (2010) suggest that 19 wte applied psychologists are required for every 100 000 of the population. However, across Scotland there are currently only 0.6 wte applied psychologists per 100 000 of the population specialising in working with older people (Wells *et al*, 2010). This indicates that the lack of available therapists is a particular issue with older people.

All the studies mentioned above recommended that older people need to have better access to psychological therapies. Whilst increasing the numbers of clinicians specialising in providing psychological treatments for older people would be a welcome addition to achieving this, in the current economic climate the possibility of this happening to the levels required may not be realistic. Therefore, alternative and innovative methods of increasing the provision of psychological treatments are also required.

1.3 COMPUTERISED COGNITIVE BEHAVIOUR THERAPY (CCBT)

1.3.1 Introduction to CCBT

The preceding sections highlight CBT as an effective treatment for dealing with the high prevalence of depression and anxiety in older people. It has also been highlighted that there are a number of potential difficulties in patients being able to access this type of treatment. One of the factors that limits access and is relevant to all age groups relates to the lack of trained therapists. This may be a particular issue in relation to older people, where in comparison to adult services, there are less available specialist clinicians working with older people relative to the size of this population (Wells *et*

al, 2010). There has therefore been a focus on the development of alternative ways of delivering CBT from the traditional face-to-face method, which (due to its typical requirements of 6-20 sessions lasting 45-60 minutes, with one therapist per patient per session) has been described as “labour-intensive” (Van Den Berg *et al*, 2004). Alternative, less labour-intensive methods, potentially offer the opportunity to deliver CBT to larger numbers of patients, but are only viable if they are found to be effective and acceptable to patients. Such treatments also fit in with matched models of care advocated by the NICE guidelines for the treatment of depression (NICE, 2009), whereby individuals with less severe levels of depression should first be provided with ‘low intensity treatments’ and those failing to respond to these treatments (or with more severe levels of depression) can be provided with ‘high intensity treatments’.

A recent innovation in terms of alternative methods for delivering CBT has been the development of Computerised Cognitive Behaviour Therapy (CCBT). Cavanagh and Shapiro (2004) highlight that for a number of years attempts have been made to transfer the “key ingredients” of psychological treatment into computer programs that deliver such treatment and do not require (or significantly reduce the need for) the presence of a trained clinician to deliver the treatment. Proudfoot *et al* (2003a) argue that CBT, which has an emphasis on short-term treatment that is present-focused, structured, involving psychoeducation and clear procedures for patients being taught skills to manage their symptoms, lends itself well to having some of the key features of the treatment replicated and delivered in a computer program. Furthermore, Cavanagh and Shapiro (2004) suggest that recent developments in multimedia technology also means that some of the non-specific therapeutic features of CBT,

which have been identified as important factors that influences outcomes from CBT, can be much more effectively replicated by contemporary computer technology. These components include: the therapeutic alliance, empathy, communicating hope for improvement, increasing patient motivation and providing feedback on homework tasks. Cavanagh and Shapiro (2004) suggest that the features of the latest CCBT packages allow these aspects to be incorporated. Proudfoot *et al* (2003a), suggest that it was the lack of emphasis on incorporating such therapeutic features and instead focusing simply on “transposing words from a treatment manual to a computer screen” that meant previous attempts at delivering computerised therapy failed.

A number of different CCBT packages have now been developed and potentially offer one method of increasing access to psychological therapies. Within matched care models of service delivery, as advocated by NICE, CCBT packages are often described as ‘low intensity’ treatments. The programs primarily have an emphasis on self-help whereby patients independently complete the sessions contained in the computer programs with much more limited contact with a therapist. Such packages can therefore be offered to a large number of patients as a first line treatment, whilst significantly reducing the requirement of a therapist to be available. Following completion of the CCBT program, only those subsequently requiring more intensive treatment are referred on to higher intensity treatments (e.g. face-to-face CBT).

1.3.2 Examples of CCBT Packages

A number of different CCBT packages have now been developed. Some packages have been designed to be used as an adjunct to face-to-face treatment (e.g. *Good Days Ahead: The Multi-media Program for Cognitive Therapy* (Wright *et al*, 2002)). This

program, therefore, does not directly fit in with a stepped-care model to improve access to psychological treatments.

Three systematic reviews of the literature (Kaltenthaler *et al*, 2004; Kaltenthaler *et al*, 2006; Kaltenthaler *et al*, 2008) on the use of CCBT have identified seven different software packages for the treatment of depression and anxiety. These include *Beating the Blues* (Proudfoot *et al*, 2003a); *Overcoming Depression: A Five Areas Approach* (Whitfield *et al*, 2006); *FearFighter* (Shaw *et al*, 1999); *MoodGym* (Christensen *et al*, 2004); *Overcoming Depression on the Internet* (Clarke *et al*, 2005); *COPE* (Osgood-Hynes *et al*, 1998); and *BTSteps* (Griest *et al*, 2002). Each of the cited papers provides a description of the packages in more detail.

The Technology Appraisal Guidelines on the use of CCBT (NICE, 2006) reviewed the evidence for the range of CCBT packages available for the treatment of depression and anxiety in terms of their clinical and cost-effectiveness. *Beating the Blues (BTB)* was the only package that was recommended, as both a clinical and cost-effective intervention for the treatment of depression, whilst *Fearfighter* was recommended as an effective package for treating phobias. It was concluded that the other packages reviewed did not yet have a sufficiently established evidence-base for supporting their use. These recommendations were maintained in the NICE guidelines for depression (NICE, 2010). A limitation of the reviews of CCBT mentioned above, which the authors have highlighted, has been that there are relatively few outcome studies of sufficient quality at present to draw any firm conclusions about the efficacy of other CCBT packages. For example the NICE guidelines on depression identified only seven studies of CCBT and they recommend that further research is required.

1.3.3 Review of Evidence for *Beating the Blues*

A review of the literature was conducted to identify the evidence-base of studies purporting to show the effectiveness of *BTB* and to identify gaps in the literature. The criteria for inclusion in the review were kept broad; all randomised control trials and non-comparator open trials of *BTB*, which reported outcome data on participants symptoms of depression or anxiety were included. The studies were identified through 4 different means. Initially, searches were made of several electronic literature databases including: Medline; PsycINFO; the Cochrane Database; and PsycARTICLES. Search items included combinations of the following disorder and intervention terms, using truncated versions and different spellings: anxiety or depression with; cognitive therapy, or behaviour therapy, or, CBT, or psychotherapy, or intervention, or treatment; with computer or computerised or internet. These searches were supplemented by using 'Beating the Blues' as a search term. Secondly, the developers of *BTB* (Ultrasia) were contacted to request a reference list of all the *BTB* studies that, to their knowledge, had been completed or were ongoing. Thirdly, the reference sections of the systematic reviews and meta-analysis of CCBT, cited in section 1.3.2, were inspected, together with the reference lists of initially identified studies, to locate possible additional papers for inclusion in the review. Lastly, individuals who had previously conducted research on *BTB* and individuals with expertise in the field of CBT were contacted regarding their knowledge of previous, recently completed and ongoing studies of *BTB*. All identified studies were cross referenced.

The abstracts of all the identified studies were initially evaluated to determine whether each study met the inclusion criteria. When it was clear from the abstract that a study

did not meet the inclusion criteria (e.g. it was clear it was not reporting on the outcome of receiving BTB) it was removed from further analysis. Whenever any doubt arose from the initial review of the abstract as to whether the study met the inclusion criteria the full text was obtained to complete a fuller evaluation. The full text of all the remaining studies were subsequently evaluated to determine whether each study met the inclusion criteria. A total of 11 studies were identified (three RCTs and eight other studies). These are critically evaluated below.

1.3.3.1 Evidence from Randomised Controlled Trials (RCTs)

An initial beta test by Proudfoot *et al* (2003a) demonstrated that, for a sample of 20 participant's experiencing depression, *BTB* produced significant reductions by the end of the treatment on measures of depression, anxiety and work and social adjustment. Although there were a number of limitations in this pilot study, such as a lack of a control group and a drop out rate of over 50 per cent, with no intention-to-treat (ITT) analysis being performed, the authors conclude that participant feedback about *BTB* was positive and the results were promising enough to evaluate *BTB* further in a larger scale RCT. The first RCT of *BTB* was conducted by Proudfoot *et al* (2003b). In this study, 167 patients attending their GP were recruited and randomly allocated to either *BTB* (N = 89) or GP treatment as usual (TAU, N = 78). Patients suffering from anxiety and/or depression, as assessed by the Computerised Clinical Interview Schedule – Revised (CIS – R, patients scoring > 12) were included. Patients in the *BTB* group received eight sessions of *BTB* and were also provided with GP treatment as usual. The only constraint that was placed on the treatment as usual the *BTB* group could receive was that no “face-to-face counselling or psychological intervention” (p 219) could be provided. The provision of psychotropic medication was not

randomised between the two groups in the study. No constraints were placed on the treatment participants in the TAU group received and in addition to medication this included “discussions with GP, provision of practical/social help and referral to specialist mental health professionals” (Proudfoot *et al*, 2003b p 219).

The results of the study indicated that at the post-treatment assessment point those in the *BTB* group showed significantly greater improvements than the TAU group on measures of depression, anxiety and work and social adjustment (Proudfoot *et al* 2003b). These improvements were maintained at one, three, and six month follow-up points and the authors argue that these findings were independent of the duration and severity of illness prior to treatment and whether or not participants received psychotropic medication. The authors highlight that a weakness of their study was that the sample size did not allow more definitive conclusions to be drawn about these latter factors.

A subsequent study by Proudfoot and colleagues (Proudfoot *et al*, 2004) continued their previous research whereby a further 105 patients were randomised to *BTB* (N = 55) or TAU (N = 50). The results of this second study of 105 patients replicated the findings of the initial study by Proudfoot *et al* (2003b), whereby in comparison to the TAU group those receiving *BTB* showed significantly greater reductions on measures of depression, anxiety and work and social adjustment. The authors subsequently combined the sample of this second study with the participants in the initial study by Proudfoot *et al*, (2003b). The authors argue that this larger sample allowed them to demonstrate more robustly that the results were independent of whether patients received medication and of the duration or severity of symptoms prior to beginning

treatment. A limitation of these two studies was they did not report effect sizes or provide an analysis of the clinical significance of their findings (e.g. the percentage of patients in each group meeting criteria for clinically significant improvements) as this has been advocated as more meaningful when drawing conclusions about the relevance of a treatment to actual practice (Jacobson and Truax, 1991).

A further weakness of both these studies is that although they evaluated the acceptability of the *BTB* treatment and concluded it was an acceptable treatment, this was based only on rates of drop-out and self-reports of satisfaction with treatment. This latter factor was however only with patients who had not dropped out of the study, which may provide biased results. Uptake of treatment would also be an important factor determining the acceptability of a treatment, although this was not addressed by Proudfoot *et al* (2003b) or Proudfoot *et al* (2004). It was evident in the study by Proudfoot *et al* (2003b) that of the 167 individuals recruited to the study a further 100 refused to participate, giving a refusal rate of 41 per cent. It is feasible that the possibility of randomisation to *BTB* contributed to the refusal of these individuals to take part in the study and would indicate it being an unacceptable treatment for a significant proportion of patients, limiting whether the results can be generalised to the wider population. An alternative explanation could be that individuals refusing to participate would not wish to take part in any study regardless of the treatment. Based on the results provided, it was not possible to draw any conclusions about reasons for non-participation.

A further weakness of these two studies is that, although they report the inclusion criteria in terms of age as being 18-75 years, they only report the mean and standard

deviations of the samples age (*BTB* = 43.7 (SD – 14.7) and TAU = 45.7 (SD – 14.1). This would therefore exclude a significant proportion of older people (those over 75) and based on the mean and standard deviation of the samples age, older people overall may have been under represented. This makes it difficult to determine if these results can be generalised to older people.

Grime (2004) conducted an RCT exploring the effectiveness of *BTB* plus ‘Conventional Care’ (*BTB*) to ‘Conventional Care’ alone (CC) in the treatment of work related stress, anxiety and depression. This study also aimed to evaluate the rate of uptake into the study and the reasons given by individuals for non-participation. Participants were included if they had 10 or more cumulative day’s absence from work as a result of stress, anxiety or depression, and scored above 4 on the GHQ-12.

The results indicated that of the 155 patients approached about taking part and meeting the inclusion criteria, only 48 agreed to participate (30.9 per cent uptake rate), with 24 in the *BTB* group and 24 in the CC group. Of the 107 people who declined to participate, 60 provided reasons for this. It was apparent that the primary reasons for non-participation related to difficulties in meeting the demands of the study itself, irrespective of what the treatment consisted of. For example, twenty participants reported that it would be too difficult to travel to the location where the *BTB* sessions took place, thirteen reported they would be unable to take time off work to participate, and thirteen were unhappy that their employer would be aware of their participation. A minority reported reasons relating to negative perceptions about *BTB*. For example, twelve individuals reported that they did not think the *BTB* treatment would help and four reported disliking computers. Overall, the results indicated that a

negative perception of the *BTB* treatment itself did not form the main reason why such a large proportion of patients declined to take part. The other reasons are, however, important factors that would have to be considered in terms of the utility of the *BTB* treatment in actual clinical practice.

In terms of drop-out, 16 (66.7 per cent) participants in the *BTB* group completed all eight sessions, whilst eight (33.3 per cent) dropped-out, although 4 of the drop-outs completed the post-treatment outcome questionnaires. No participants in the CC group dropped-out by the post-treatment assessment point. No analysis was made regarding factors that may have influenced drop-out from *BTB*.

In terms of outcome, the results indicated that in comparison to the CC group those in the *BTB* group showed statistically significant reductions in depression scores on the Hospital Anxiety and Depression Scale (HADS) and on the Attribution Style Questionnaire by the end of the eight-week treatment, which indicated a significantly greater improvement in their symptomatology. At the one month follow-up, participants in the *BTB* group also showed statistically significant greater reductions in anxiety as well as depression on the HADS than the CC group. At the three and six month follow-up points there were no statistically significant differences on any of the measures between the *BTB* group and the CC group, although the author highlights that due to study attrition in the two groups by these assessment points too small a sample was available to detect a statistically significant difference. As with the earlier RCTs by Proudfoot *et al* (2003b) and Proudfoot *et al* (2004), this study did not report effect sizes and there was no analysis of the clinical significance of participant

outcome, reducing the conclusions that can be drawn in terms of the importance of the statistical findings to actual clinical practice.

There are also a number of methodological weaknesses in this study. The analysis did not employ an ITT analysis (i.e. four participants in the *BTB* group who started the treatment but did not complete post-treatment outcome measures were not included in the analysis). Although this was a relatively small number, these participants may have shown a large deterioration in their symptoms (which could have explained their withdrawal) which may have reduced the magnitude of change found in the *BTB* group. This, therefore, does not take into account the impact of treatment drop-out on the overall effectiveness of *BTB*.

Furthermore, a major confounding factor relates to the conventional care both groups received as part of the study. It was apparent that those in the *BTB* also received active psychological treatments in addition to *BTB* as part of their conventional care. For example, 11 participants in the *BTB* group received face-to-face psychological treatment, such as Solution-Focused Therapy, whilst 12 in the CC group received such a treatment. In addition, four participants in the *BTB* group were provided with “other care” as part of their conventional treatment, although it was not specified what this consisted of. Although it was approximately equal in terms of the *number of participants* receiving such conventional care between the two groups, it was not reported *how much* treatment each participant received (i.e. how many sessions had been attended). It would be possible that those in the *BTB* group attended a greater number of face-to-face conventional care treatment appointments than the CC group,

which may account for the changes between the two groups, rather than specifically the *BTB* treatment as being the variable producing changes.

A further limitation of the study was that the age range of the participants was not reported but only the mean and standard deviations (*BTB* = 41 (SD = 10.83) and *CC* = 37 (SD = 8.27). Taking into account the mean ages, and as this study was based within a work place occupational health department it could be surmised that older people may not have been included in this study, making it difficult to generalise these findings to older people.

1.3.3.2 Evidence from Non Randomised Controlled Trials

A study by Van Den Berg *et al* (2004) described the implementation of *BTB* within a community mental health team (CMHT). This study explored the effectiveness of *BTB* within the everyday practice of the CMHT, whereby the results of the Clinical Outcomes in Routine Evaluation questionnaire (CORE) were compared pre-treatment and post-treatment amongst a cohort of 13 participants receiving *BTB*.

It was not possible to evaluate the rate of uptake from *BTB* in this study, as they did not report exact figures relating to how many were offered *BTB*. The authors, however, state 60-70 per cent of their referrals may benefit from *BTB*, whilst of these about 50 per cent agreed to start *BTB*. There was an indication that 115 patients had used *BTB* within the service but it seemed that the 13 who actually participated in the study were included on the basis that they were the only ones that had completed pre- and post-CORE measures. The authors also report approximately 45 per cent of patients drop-out of *BTB*, although this was not evaluated in any detail. In terms of

treatment outcome, the results suggested that, in comparison to the start of treatment there was a statistically significant reduction in scores on the CORE by the end of treatment (effect size, = 1.1)⁴. These results were not, however, maintained in a sub-sample of nine participants who completed a six month follow-up assessment.

These results should, however, be treated with caution as it was a small sample and there was no control condition. In relation to this, the authors did not report on the effects of any concurrent psychotropic medications or face-to-face psychological treatments participants may have been receiving, meaning it is difficult to establish the extent to which the results are attributable to *BTB*. In addition, the study did not include any specific standardised assessment of depression and anxiety with this cohort, making it difficult to generalise these findings to these specific problems. A further weakness was that the age of the participants was not included, making it difficult to draw any conclusions about whether these results can be generalised to older people.

Hunt *et al* (2006) examined the integration of *BTB* into a stepped care, primary care mental health service. A total of 54 participants were reported to have completed *BTB* and (in comparison to the start of treatment) by the end of treatment there was a significant reduction in participants scores on measures of depression and social adjustment. The authors also argue that the vast majority of participants found *BTB* to be “enjoyable, easy and pleasant to access and helpful in overcoming their depression” (p34).

⁴ It was noted that the method used for calculating the effect size was not described.

Cavanagh *et al* (2006) examined the effectiveness of *BTB* in routine primary and secondary care practice. This was conducted in eight general practices, two community mental health teams and one primary care clinical psychology service all of which had incorporated *BTB* into their respective services. A total of 219 participants commenced *BTB* during the time frame of the study, with an age range of 16 – 70 years. Participants were included in the study if: 1) they were referred to any of the eleven services for the treatment of depression and/or anxiety; 2) if they were assessed as likely to benefit from *BTB*; and 3) if they scored four or above on the General Health Questionnaire (GHQ – 12). The study used the Clinical Outcomes in Routine Evaluation (CORE) and the Work and Social Adjustment Scale (WSA) prior to treatment, post-treatment and at six month follow-up, to assess the effectiveness of the *BTB*.

It was not reported how many patients who were offered *BTB* declined to receive this treatment, meaning it was not possible to evaluate the uptake of *BTB* in this sample. Of the 219 patients who commenced *BTB*, 135 (61.6 per cent) completed all eight sessions (38.4 per cent dropped-out) and of these treatment completers, 104 completed the post-treatment outcome measures with a further 40 completing the six month follow-up outcome measures. The results showed no significant differences between those who completed treatment and those who dropped out on a range of demographic variables (e.g. age, gender, computer experience etc) or illness variables (e.g. scores at pre-treatment on the CORE or WSA).

In terms of the effectiveness of the treatment, the results of those completing all eight sessions and the post-treatment outcome measures showed statistically and clinically

significant reductions on both the CORE (effect size = 1)⁵ and WSA (effect size = 0.5). The authors also completed an intent-to-treat (ITT) analysis using the last observation carried forward method (LOCF) to take into account the effects of individuals dropping out of the study. Whilst this more conservative method of analysis produced an expected reduction in the effect sizes of the *BTB* treatment, the results still showed a statistically significant reduction in patients scores on the CORE (effect size = 0.5) and WSA (effect size = 0.26) between the start and end of treatment. These improvements were maintained at six month follow-up in the sub-sample of 40 patients who completed these follow-up measures.

These latter results have to be treated with caution as not only was there a relatively large attrition rate in the numbers of participants completing the six month follow-up measures, but the authors also did not examine any subsequent treatment that was received during this follow-up period that could potentially account for the maintenance of improvements. In relation to this, the authors did not report on any psychotropic medications or concomitant psychological treatment participants may have been taking throughout the study, which could be significant confounding factors influencing the results. This weakness is further highlighted by the lack of a control group, making it difficult to determine how much the results were attributable specifically to *BTB*.

A further weakness of this study was that it did not employ any specific standardised measures for depression and anxiety, making it difficult to generalise the findings to these specific problems. Cavanagh *et al* (2006), however, argue that the use of the

⁵ Effect sizes were calculated by the authors using Mean (start) – Mean (end) / SD (start).

CORE allows benchmarking of the results of their study to the national database of CORE outcomes for primary and secondary care psychological therapies services in the UK (Barkham *et al* 2005). Cavanagh *et al* (2006) suggest that their results show a pre-post effect size smaller than what is typically found in primary care services, but larger than what has been found in secondary care services. They also suggest the drop-out rates for *BTB* in their study are similar to what is found in face-to-face psychological treatments. Despite the limitations of the study, Cavanagh *et al* (2006) therefore concluded that their pragmatic study suggests that *BTB* is a useful first line treatment for common mental health problems, such as anxiety and depression, in everyday clinical practice. Of note, however, is the fact that the mean age of participants was 43 years (SD = 11.7), which suggests that a significant proportion of older people (i.e. those over 70 years) were excluded from the study and the minority aged 65-70 years that were included may have been under-represented. This makes it difficult to generalise the findings to older people.

A study by Mitchell and Dunn (2007) examined the use of *BTB* in a sample of 12 higher education students experiencing symptoms of depression as assessed by scoring above twelve and above on the Beck Depression Inventory (BDI). The authors state that everyone who met the inclusion/exclusion criteria agreed to start *BTB*, suggesting a 100 per cent uptake rate, although the 12 who were recruited represents a relatively small number. The results indicated 10 participants completed all eight sessions (83.3 per cent), whilst two (16.7 per cent) dropped out after sessions three and four, respectively. Due to the small numbers, no detailed analysis was reported regarding factors that influenced drop-out, other than one participant expressing a wish for face-to-face treatment. In terms of outcome, only eight

participants completed pre-treatment and post-treatment outcome measures. These eight participants showed a statistically significant reduction in their symptoms of depression by the end of treatment, as assessed by the BDI (effect size $r = 0.63$). There was, however, no significant difference in anxiety as assessed by the Beck Anxiety Inventory (BAI).

These findings should, however, be treated with caution, particularly as: 1) it was a relatively small sample; 2) only the results of those completing all eight sessions and the post-treatment outcome measures were analysed (representing only 66.7 per cent of the initial sample recruited); 3) there was no control group against which to compare the results of the treatment; and 4) no longer term follow-up data were reported. Despite these weaknesses, the authors conclude that *BTB* was an effective as well as a credible and acceptable treatment for this small sample of participants (Mitchell & Dunn, 2007).

Learmonth and Rai (2007) examined the effectiveness of *BTB* in treating individuals with symptoms of depression and co-morbid physical health problems, such as Irritable Bowel Syndrome, headaches and Chronic Fatigue Syndrome. The results indicate that, in comparison to a waiting list control group, patients with and without physical co-morbidities showed equally greater reductions in symptoms of depression after completing *BTB*. A further study by Learmonth and Rai (2008) explored the use of *BTB* with 104 patients who had been referred to a specialist CBT service for the treatment of chronic depression and/or anxiety (median duration 5 – 10 years), but were currently held on a waiting list for face-to-face treatment. No assessment was made regarding the participants levels of symptomatology for inclusion/exclusion

from the study but they were excluded if they were actively suicidal, had a primary diagnosis of obsessive compulsive disorder, had drug or alcohol dependence, cognitive impairment, were ambivalent about treatment, or were currently receiving face-to face psychological treatment.

Learmonth and Rai (2008) do not report in detail the uptake of *BTB* and factors that may influence this, but they do suggest 75 per cent of patients agreed to start *BTB* suggesting this was the uptake rate. Of these 104 participants, 71 (68.3 per cent) completed all eight sessions of *BTB*, whilst 31 (31.7 per cent) dropped out of treatment after completing a mean of 3.8 sessions. There were no significant differences between completers and those who dropped-out with regard to age, gender or pre-treatment scores on the CORE. No other factors in terms of drop-out were explored.

In terms of outcome, those who completed all eight sessions showed a statistically significant improvement by the end of treatment on the CORE questionnaire (effect size = 1.26). The authors also used an ITT analysis using the LOCF method to take into account those who had dropped out of treatment. This analysis also produced a statistically significant pre/post reduction on the CORE by the end of treatment (effect size = 0.82). The authors conclude that, as almost 50 per cent of those completing *BTB* also met criteria for clinically significant improvement, their findings suggest *BTB* has the potential as an initial treatment option that patients can quickly access.

There were, however, a number of weaknesses in the study, including the lack of a control group, meaning that other factors that may contribute to the results cannot be

ruled out. The authors argue that spontaneous recovery or benefits from psychotropic medication would be unlikely in their sample, as many had been waiting for several months prior to commencement in the study and reported a chronic duration of symptoms. However, the study, did not include a minimum level of symptomatology required for inclusion in the study suggesting that some could have already remitted but were still keen to take part in the study. The study also did not employ a standardised measure of depression or anxiety in their assessment of treatment outcome, making it difficult to generalise the findings to these specific problems. Lastly, the study reported the age range of participants was 19 – 70 years old (Mean 39, SD = 11.6). This suggests a significant proportion of older people (those over the age of 70 years) were not included in the study, and those between the age of 65-70 years that were included, were in the minority. Clearly this makes it difficult to generalise the findings of this study to older people.

A naturalistic study by Learmonth *et al* (2008) reported the results of 555 patients aged between 18-70 years who were referred, over a 60 month period, to a specialist CBT centre for the treatment of anxiety and/or depression. Patients who were on the services waiting list (reported to be 12-18 months from referral to treatment) for face-to-face CBT were assessed by a CBT therapist and offered the opportunity to use *BTB* whilst waiting for face-to-face treatment. Participants were included if they were assessed as likely to benefit from *BTB* and were excluded if they were actively suicidal, had a primary diagnosis of obsessive-compulsive disorder, had drug or alcohol dependence or cognitive impairment, or were currently receiving face-to-face psychological treatment. Participants completed the *BTB* sessions on a computer at

the specialist CBT centre and were assessed again by a CBT therapist 6-8 weeks after completing *BTB* and offered further treatment if required.

The results indicated that 829 patients were offered *BTB* and 555 agreed to participate, giving an uptake of 67 per cent. Of those who started *BTB*, 394 (71 per cent) completed all eight sessions with 161 (29 per cent) dropping out after a mean of 3.5 sessions. No significant differences were found between those who completed all eight sessions and those who dropped out, in terms of demographic details, anxiety and depression severity, or duration prior to starting *BTB*. In terms of clinical outcome, the results indicated that those completing all eight *BTB* sessions showed statistically significant reductions by the end of treatment in their symptoms of depression and anxiety, as assessed by the Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI), with effect sizes of 0.85 and 0.55 respectively.

An ITT analysis, incorporating those who dropped out of treatment, using LOCF again showed statistically significant reductions by the end of treatment on the BDI and BAI, although the effect sizes had reduced to 0.72 and 0.5 respectively. Furthermore, the authors report that 21 per cent of participants in the ITT sample achieved a clinically significant improvement in their symptoms of depression and 19 per cent achieved this in their symptoms of anxiety. The percentage of participants achieving clinically significant improvement was elevated to 23 per cent and 26 per cent for anxiety and depression, respectively, in the completers sample. Lastly, the results indicated that of those completing *BTB* 21 per cent required follow-up, face-to-face psychological treatment, whilst 95.5 per cent of those dropping-out required this. The authors, however, argue that the mean number of further face-to-face sessions

after starting *BTB* was 3.5, which they suggest is smaller than the 15 sessions their service typically provides.

There were, however, a number of methodological weaknesses in the study. Firstly, although 555 participants were recruited and started *BTB*, it appeared that data relating to depression and anxiety symptoms from only 241 and 252 participants respectively were entered into the completer analysis, whilst a significantly higher number of participants (394) were reported to have completed the treatment. Similarly, in their ITT analysis, only data relating to depression and anxiety symptoms for 298 and 301 respectively were included, rather than the 555 which should have been included in an ITT analysis. It was not made clear in the report what happened to these lost data in both their completer and ITT analysis, which could call into question the validity of the results of the study (i.e. it is possible that all of the participants who did not have outcome data entered into the analysis significantly deteriorated in terms of their symptoms).

A further weakness is the lack of a control group, which makes it difficult to conclude that the results can be attributed to the *BTB* treatment rather than other external factors. Related to this point, although an exclusion criterion was that participants were not receiving concurrent face-to-face psychological treatment at the start of the study, the authors made no mention about concurrent psychotropic medication usage, which could have been a significant confounding factor influencing the results (i.e. it is possible participants improved as a result of their GP prescribing antidepressants and this accounted for the results). Similarly, it was clear that 22.4 per cent of completers and 95.5 per cent of non-completers were subsequently offered face-to-

face psychological treatment. However, it was not clear whether or not participants had started this prior to the post-*BTB* assessment, which took place up to two months after completing *BTB*. It is possible participants may have begun face-to-face treatment by the post-*BTB* assessment, which may have also confounded the results. A final limitation of the study was that although the age range of participants was 18-70 years, the mean was 40 years (SD = 12), suggesting that a significant proportion of older people were excluded (those over 70 years) and that those who were included may have been under-represented. This makes it difficult to generalise these findings to older people.

A recent naturalistic study by Cavanagh *et al* (2011) explored the use of *BTB* in a service-user led self-help clinic, which accepted both primary care and self-referrals for anxiety and/or depression. During the 16 month timeframe of the study, 510 referrals were received and if individuals were assessed as being suitable they were offered *BTB* within seven days at a community venue. It was not made clear what the inclusion/exclusion criteria were, or how participants were assessed as “being suitable”, but it was reported that five referrals were deemed unsuitable. A further 78 potential participants (15.3 per cent) did not attend the initial assessment interview.

The results indicated that of the 432 individuals who attended an initial appointment with the service, 295 were considered appropriate and went on to complete initial outcome measures and start the first session of *BTB*, giving an uptake rate for *BTB* of 68.2 per cent. Of these patients 265 (89.8 per cent) completed at least two sessions of *BTB* whilst 156 (52.9 per cent) went on to complete the full eight sessions (47.1 per cent dropped out). The results indicated that those who had referred themselves were

significantly more likely to start *BTB*, complete at least two sessions, and go on to complete the full eight sessions, when compared to those referred by a primary care service. The results also indicated no significant differences in terms of uptake or drop-out from *BTB* in terms of gender, ethnic group, use of psychotropic medication, presence of chronic physical health problems, or age. The results also found no significant difference in terms of uptake regarding baseline levels of depression, anxiety, general well-being or work and social adjustment. However, intake level of symptomatology was found to be significantly lower in those completing the full eight sessions compared to those who dropped out early.

In terms of outcome, an ITT analysis using LOCF for participants completing at least two sessions of *BTB* found statistically significant reductions in symptoms of depression (effect size = 0.8), anxiety (effect size = 0.9), work and social adjustment (effect size = 0.4) and on the CORE (effect size = 0.6) questionnaire by the end of treatment (Cavanagh *et al*, 2011). In addition, the authors suggest following treatment 50 per cent of the sample no longer met ‘casesness’ for either depression or anxiety (as assessed by scoring below clinical cut-offs on self-report measures of depression and anxiety). The authors argue their results are comparable to the outcomes found in two IAPT self-help services and conclude that their study supports the use of *BTB* and the development of further service-user led self-help services for treating common mental health problems.

There were, however, methodological weaknesses in this study, which means the authors conclusions should be treated with a degree of caution. The lack of a control group, for example, means that is difficult to conclude how much of the results can be

attributable to *BTB* rather than other external factors. The authors argue that spontaneous recovery is not likely and therefore downplay this limitation. However, they did not report on, or take into account, the possibility of the effects of other treatments participants could potentially be receiving, such as the effect of concurrent medication and psychological treatment. There was also no longer-term follow-up data reported, which means it is not possible to draw any conclusions regarding the sustainability of the results. In addition, only two participants in the study were over the age of 65 years, which limits the extent to which the results can be generalised to older people.

1.4.4.3. Summary of Evidence for BTB

The use of *BTB* has been supported by three RCTs and eight pragmatic studies of its use in routine clinical practice, all of which have been critically evaluated above. An aspect of the eight pragmatic studies that were reviewed has been that, whilst the results have consistently suggested that participants who received *BTB* showed significant reductions in their psychopathology by the end of treatment, only one study (Learnmonth and Rai, 2007) utilised a control group. Therefore, this limits any conclusions that can be drawn about the extent to which the findings in these studies were a direct result of participants receiving *BTB* (i.e. other factors that were not controlled for may have also influenced the results).

The three RCTs, which were reviewed (Proudfoot *et al*, 2003b, Proudfoot *et al*, 2004 , and Grime, 2004) have also consistently found that, in comparison to treatment as usual (the control group used in these studies), participants who also received *BTB* (the intervention group used in these studies) showed significantly greater reductions

in their symptoms of anxiety and/or depression by the end of treatment. The use of random allocation of participants to either the intervention or the control group in these three studies allows stronger conclusions to be drawn about the beneficial effects of receiving *BTB*. However, as discussed above, the study by Grime (2004), in particular, had other confounding variables, which may have also influenced the results (e.g. participants in the *BTB* group were also provided with face-to-face psychological treatment).

In addition, despite the evidence purporting to the beneficial impact of *BTB* for depression and anxiety, only four of the eleven studies that were reviewed reported on the clinical significance of the obtained results (Cavanagh *et al*, 2006; Cavanagh *et al*, 2011; Learmonth and Rai, 2008); Learmonth *et al*, 2008) with none of the RCTs discussing this issue. This limits the conclusions that can be drawn about the clinical effectiveness of *BTB*, which has implications in terms of its viability for use in actual practice.

One of the major limitations of all the studies that were included in the review was the apparent lack of older people who participated. Some studies (Grime, 2004; Mitchel & Dunn, 2007) were specifically targeting populations that would be unlikely to include older people (i.e. they specifically targeted working age adults and students respectively), whilst all the others studies either imposed an upper age limit of 70 years or did not report on the age of participants. Although these studies could have potentially included some older people (e.g. those aged between 65-69 years), based on the mean ages of participants that were reported, it appeared that older people appeared to be underrepresented. It was certainly apparent that none of the included

studies focused solely on older people. This means that any conclusions about whether the findings can be generalised to older people should be treated with caution.

Given the lack of research that has focused the use of *BTB* with older people, not only are questions raised about whether it is an effective treatment for this population an important initial question would also be: is it an acceptable and therefore feasible treatment for older people? Indeed, Elsegood and Powell (2008) have suggested that the lack of research focusing on the use of *BTB* with older people has been in part a result of assumptions that older people will not accept this treatment. The exploration of the acceptability of CCBT has been highlighted as an area in need of further research by Kaltenthaler *et al* (2008) and given the issues raised by Elsegood and Powell (2008) this would appear to be a pertinent area in relation to older people in particular.

1.4 SUMMARY AND CONCLUSION

The discussion in the sections above have highlighted that depression and anxiety are prevalent psychological problems amongst older people. With the aging population there is the potential that the demand for treatments for these disorders will increase amongst older people in the coming years. Psychological treatments, particularly CBT, have been found to be effective for older people and the evidence suggests that they find such treatments acceptable. Despite these facts, services specialising in the psychological treatment of older people are significantly under-resourced, and at present there is unlikely to be adequate staffing levels to meet the increasing demand

associated with an ageing population. CCBT offers one potential method to begin to help address this issue.

1.5 RATIONALE OF CURRENT STUDY

Despite evidence purporting to the acceptability and effectiveness of *BTB* with adults of working age, as discussed above, it appears that no study to date has specifically explored the use of *BTB* solely with older people in actual practice. It is therefore not possible at present to generalise the findings relating to the use of *BTB* to older people. Furthermore, the lack of research focusing on *BTB* with older people raises important, initial questions, about whether this will be an acceptable, and therefore viable, treatment for older people. The current study will therefore go towards beginning to address these major gaps in the literature and will be the first study, to the best of the author's knowledge, to explore the acceptability and feasibility of *BTB* in actual practice with older people experiencing depression and anxiety.

The specific focus on older people in the current study, combined with the previous research with adults of working age, will also contribute to one of the research recommendations outlined in the NICE guidelines on the use of CCBT (NICE, 2006): that future research should explore whether such packages can be used effectively by people of all ages. The study will help inform whether *BTB*, in its present format, offers one potential option to help address the psychological needs of older people in the context of under-resourced older people mental health services.

As highlighted previously, treatment acceptability is one of the major factors that will influence whether or not it is viable in actual clinical practice (Kaltenthaler *et al*,

2008). It could be argued that other factors, such as the cost-effectiveness of *BTB*, or process issues relating to patients experience of using the treatment, would also be important areas relating to the viability of its use in actual practice. However, Elsegood and Powell (2008) have highlighted that examining the acceptability of *BTB* may be particularly relevant with older people and an important first step in determining the treatments viability with older people. For example, they have suggested that older people have often been excluded from studies of CCBT in the past specifically because it has been assumed that they will find this treatment unacceptable. It could be argued that exploring the acceptability of *BTB* to older people is, therefore, an important first step to establish as, regardless as to whether the treatment is clinically and cost effective, it will not be viable if they do not accept this treatment.

As described in the above sections, similar assumptions about finding treatments unacceptable were once falsely held regarding face-to-face psychological treatments with older people. In a small pilot study Elsegood and Powell (2008) found that the majority of the older people they surveyed would be willing to try CCBT, even if they had no previous experience of using computers (although no participant was actually required to go on and use the treatment) Their small study, therefore, begins to challenge the viewpoint that older people will not accept CCBT packages such as *BTB*. Whilst Elsegood and Powell (2008) provided some evidence in the form of a small survey that older people will accept *BTB*, the current study will be the first study to examine the acceptability of *BTB* to older people in actual practice (i.e. participants will be required to go on and use the treatment). The focus of the current study on the acceptability of *BTB* for older people was also chosen as this is often

regarded as one of the first steps in determining the utility of a treatment in actual practice i.e. regardless of how clinically and cost effective a treatment is found to be in a clinical trial, unless it is acceptable to patients it will not be viable for use in actual practice (Kaltenthaler *et al*, 2008).

The current study will also meet a research recommendation described by Kaltenthaler *et al* (2006). These authors suggest that future research should explore patients' preferences with regard to the uptake of *BTB*, as this is a key factor determining a treatments' acceptability (Kaltenthaler *et al*, 2008). Kaltenthaler *et al* (2006) suggest that the acceptability of *BTB* should be explored with, for example, patient preference trials. In the current study, participants will be given a free choice about the treatment they receive as part of the study: *BTB* in addition to treatment as usual or just treatment as usual alone. A similar methodology has been used for exploring the acceptability of group versus face-to-face CBT for treating anxiety in adults of working age (Sharp *et al*, 2004).

This design will allow an examination of the rate of uptake of this treatment when given a free choice. The study will also explore some of the participant characteristics that may influence the uptake of *BTB* amongst an older people population. An alternative design, such as a RCT, would limit the possibility of these aims being explored. For example, patients who have a strong preference not to receive *BTB* may be unlikely to participate in a RCT. It would also be difficult to separate these individuals from those who would be reluctant to participate in any study, regardless of the treatment, which is a confounding factor when exploring the uptake rate of a treatment if an RCT is employed. This has been a weakness of previous studies

which have examined the acceptability of *BTB* in terms of uptake, as it has not been possible to determine if patients declining to receive *BTB* did so as a result of not wanting to receive this treatment, or not wanting to participate in any study regardless of the treatment.

The current study will also examine drop-out from *BTB*, which is another factor reflecting the acceptability of a treatment (Kaltenthaler *et al*, 2008). No study to date has explored the rate of drop-out from *BTB* amongst an older people population. The rates of drop-out will be discussed in terms of the findings from previous research that has examined *BTB* in adults of working age.

The study will also meet one of the research recommendations outlined in the Health Technology Assessment on the use of *BTB*, which states that future research should be carried out by third-party researchers (i.e. independent of the developers of the packages: Kaltenthaler *et al*, 2006). No researcher in the current study had any connection with the development of *BTB* and there were no vested interests or conflicts of interest.

1.6 AIMS & HYPOTHESES

The primary aim of the study was to examine the acceptability and feasibility of the use of *BTB* for treating depression and anxiety with older people. A secondary aim was to begin to examine whether *BTB* is effective for treating depression and anxiety, with this population. With regard to this secondary aim the study should be considered primarily a pilot study, and not a controlled effectiveness trial, whereby any results in relation to treatment outcome have to be interpreted with caution in

terms of being able to draw conclusions about the effectiveness of *BTB*. This is discussed further below. Specific aims were examined with both descriptive statistics for explorative aims and inferential statistics for specific hypotheses that were tested.

1.6.1 Primary aims and hypothesis

Primary Aim 1: The first specific aim of the study is to examine the acceptability of *BTB* to older people, seeking treatment for depression and anxiety, indexed by the rate of uptake of this treatment. As an initial step the response rate of study participation (i.e. the percentage agreeing to take part in the study versus the percentage that declined) will be calculated. The uptake rate of *BTB* will subsequently be calculated by determining the percentage of participants who, when given a free choice, opted to receiving *BTB* plus treatment as usual versus the percentage who opted for treatment as usual alone. This aim will be examined using descriptive statistics, which will be reported in comparison to the descriptive statistics for the uptake rates for *BTB* reported in previous research with other populations.

Primary Aim 2: The second aim of the study was to examine the acceptability of *BTB* to older people in terms of rates of drop-out from treatment. This will be calculated by determining the percentage of participants who completed all eight sessions of *BTB* and the percentage who discontinued treatment prior to session eight. The mean number of sessions completed by all participants using *BTB* and the mean number of sessions completed by those who discontinued treatment will also be calculated. This aim will be examined using descriptive statistics, which will be reported in comparison to the descriptive statistics for the drop-out rates found in previous research with other populations.

Primary Aim 3: The third aim of the study was to examine differences in the characteristics of participants who opted to receive *BTB* to those who declined this treatment. The purpose of this aim was to identify some of the characteristics that may influence whether or not older people accept this treatment, for example, their reported levels of confidence in using a computer. This third aim was examined using inferential statistics and the hypothesis was as follows:

Hypothesis: Based on the research discussed in the introduction, relating to factors that have previously been found to influence older people's use of computer technology, it was hypothesised that, in comparison to the TAU group, those in the BTB+TAU group would report significantly greater levels of confidence and experience in using a computer. The null hypothesis is that there will be no significant differences between the two groups in their reported confidence and experience in using a computer. In addition, other factors that will also be tested with inferential statistics include; examining whether the two treatment groups significantly differed on a range of demographic variables collected including; age, years of education, the number of reported co-morbid physical health problems, their gender, whether they were taking psychotropic medication, the duration of their current episode and their social deprivation category. It was hypothesised that there would be no significant differences between the two groups on these variables, with the null hypothesis being that the two groups would significantly differ on one or more of these variables

1.6.2 Secondary aims and hypotheses

The secondary aim of the study was to begin to begin to examine how effective *BTB* is at treating symptoms of depression and anxiety in older people when they are given

a free choice about whether or not they wish to receive this treatment. Given the methodology used within the current study (i.e. patients being given a free choice about which treatment group they were part of, rather than being randomly allocated to treatment) interpretation of the results in relation to this aim have to be treated with caution. The purpose of examining treatment outcome across the two groups was, therefore, done in the context of a pilot study primarily to explore the acceptability and feasibility of using *BTB* with older people. It should, therefore, not be interpreted in the context of a controlled treatment outcome study with the main purpose of determining the treatments effectiveness.

Secondary hypothesis A: Based on previous research examining the effectiveness of *BTB* with other populations, it was hypothesised that when participants are given a free choice about whether they receive *BTB* (plus treatment as usual: *BTB+TAU*) or treatment as usual alone (*TAU*), those in the *BTB+TAU* group will show significantly greater reductions on measures of depression and anxiety than the *TAU* group, by the end of treatment and at a one month follow-up point. The null hypothesis is that there will be no significant differences between the two groups on measures of depression and anxiety following treatment. As described previously, interpretation of the results in relation to this hypothesis have to be treated with caution due to the design of the current study, which should be regarded as a pilot study focused on examining the acceptability and feasibility of *BTB*, rather than a controlled effectiveness study.

Secondary Hypothesis B: A further hypothesis in relation to treatment outcome was that; following treatment and at one month follow-up, in comparison to the *TAU* group, a significantly greater proportion of participants in the *BTB+TAU* group will

meet criteria for clinically significant improvement on measures of depression and anxiety. The null hypothesis is that there will be no significant difference between the two groups by the end of treatment and at one month follow-up, in terms of those meeting criteria for clinically significant improvement. The same cautions, in terms of interpreting the results in relation to this hypothesis, as described for hypothesis 2 should also be applied here.

CHAPTER 2 –METHODOLOGY

2.1 ETHICS

Prior to the commencement of the study an application for ethical review by the local area NHS Research Ethics Committee (REC) was submitted through the Integrated Research Application System (IRAS). In addition, a submission was also made to the local area NHS Research and Development (R&D) Office for approval. Following attendance at the REC meeting the study was granted a favourable ethical opinion and was approved by the local area R&D office (see Appendices 1 & 2).

2.2 DESIGN

2.2.1 Study Design

The study utilised a 2 (treatment group) x 3 (time), between groups design with time as a repeated measure. Participants were able to self-select, which of the two treatment groups they wished to be part of: *Beating the Blues (BTB)* plus treatment as usual (BTB+TAU) or treatment as usual alone (TAU). Section 2.4 provides details of the treatments. Participants were not asked to indicate their choice until they had been given full details of the study and the *BTB* treatment and were aware of what the two treatment options would comprise. All participants were assessed using a range of outcome measures at pre-treatment (week 0), post-treatment (week 8) and one month follow-up (week 12) assessment points.

2.2.2 Design Considerations

When designing the study, there were different potential options available. A randomised control trial (RCT), in which participants are randomly allocated to different treatment arms of a study, is often considered the ‘gold standard’ of

treatment outcome research. One of the primary reasons for this is that confounding variables are equally distributed between the different groups, therefore reducing the impact of unsystematic variation. The use of randomisation means that the impact these confounds have upon the systematic variation, produced by the independent variable that is manipulated, is reduced and therefore a more sensitive measure of the experimental manipulation can be obtained (Field, 2009).

One of the disadvantages of an RCT in terms of examining the acceptability and feasibility of a treatment is that it may not account for the impact of participants preferences have upon their participation and treatment outcome (Torgerson & Sibald, 1998). For example, if participants have a strong preference to receive a particular treatment but are not randomised to this they may be ambivalent about the treatment they do receive. This has been referred to as “resentful demoralisation”, which has been suggested to have a negative effect upon factors such as participant’s adherence to the treatment (or control condition) to which they are allocated to (Janevic *et al*, 2003). It has also been suggested that this can create a “negative placebo effect”, which may in-turn adversely affect participants overall treatment outcome (Janevic *et al*, 2003). In extreme circumstances individuals with preferences regarding which treatment they receive may refuse to participate at all in an RCT, and the absence of such participants reduces how much the results can be generalised to the wider population (Torgerson and Sibald 1998).

In contrast, the opposite pattern can also occur whereby some participants may have such a strong preference for a treatment that they are allocated to that it may improve their outcome and make it difficult to generalise the findings to the wider population

who do not have as strong a preference (Torgerson & Sibald, 1998). In studies of psychological treatment the impact of participant preference is particularly important, as it is often difficult to blind participants to the treatment they are receiving.

Participant preference is particularly important in the context of the current study whereby it has been highlighted that relatively little is known about the acceptability of *BTB*, particularly with older people, where it has been assumed older people will prefer not to receive it and therefore will not accept it (Kaltenthaler *et al*, 2008). The use of an RCT at this stage, without initial research to inform its feasibility with older people, may limit the numbers of older people who agree to participate in such a study. The acceptability of *BTB* to older people is therefore a key area in determining the treatments feasibility in practice for this population and an area that requires research. The uptake of a treatment is a particularly important factor when considering its acceptability (Kaltenthaler *et al*, 2008). Consequently, one of the aims of the study was to explore the acceptability of *BTB* in terms of the number of participants who wished to receive this treatment (the *BTB*+TAU group), compared to the number who were prepared to participate in the study but did not wish to receive *BTB* (the TAU group). As Kaltenthaler *et al* (2008) highlight, the refusal to take part in a trial exploring CCBT may suggest a reluctance to take part in any study, rather than a specific aversion to CCBT itself. Although asking patients about their reasons for non-participation in an RCT can also help answer this question, this creates an ethical issue as it is a specific requirement that potential participants do not have to give a reason for not wishing to participate in a research study.

The use of allowing participants to self-select which of the two treatment arms of the study they wished to be allocated to helps avoid some of the issues outlined above. This design was chosen for the current study and it allowed an examination of the number of participants who agreed to take part in the study (and the number who declined), and the number who subsequently accepted the *BTB* treatment compared to the number that did not. A similar methodology has been used for exploring the acceptability of group versus face-to-face CBT for treating anxiety in adults of working age (Sharp *et al*, 2004). This methodology also arguably has a greater degree of external validity in comparison to an RCT as it is more reflective of what would typically occur in routine clinical practice (i.e. patients are generally provided with treatments they opt to receive). It should, however, be noted that due to the fact that participants were not randomly allocated to the treatment arms of the study this introduces a source of bias, which means the TAU condition may not fully control for the *BTB*+TAU group (i.e. as participants in the *BTB*+TAU may have a strong preference for *BTB* this may influence the treatment outcome). This in turn potentially means that conclusions regarding the direct efficacy of *BTB* should be treated with a degree of caution.

The use of placing participants in the treatment group they have chosen is in line with the research recommendations made by Kaltenthaler *et al* (2006) in their Health Technology Assessment of CCBT. These authors state that the preference of patients should be built into the design of future studies in order to gain a better understanding of how acceptable the treatment is to prospective patients.

2.3 PARTICIPANTS

2.3.1 Participant Recruitment

Individuals who were referred to an NHS regions older people secondary care mental health services for the treatment of depression and/or anxiety were recruited for the study. A number of promotional and training sessions were completed with potential referrers prior to the start of the study. An initial session involved the researcher attending a meeting with each of the 11 older people mental health service multidisciplinary teams (MDT's) throughout the region from which participants were to be recruited. The purpose of this was to provide a presentation giving an overview of the study, the main aims of the study, the inclusion/exclusion criteria, information about the *BTB* treatment, and to answer any initial questions clinicians had.

Following this, clinicians from each of the MDT's were invited to attend an hour long training session on *BTB*. At these training sessions clinicians were provided with a standard demonstration video prepared by the developers of *BTB*, which gave an overview of the content of *BTB* and demonstrated what the treatment looks like when it is being used. They were also provided with written materials used routinely within the department, which gave details of the content of each session (see Appendix 3)

Subsequent to the training session the researcher attended a further meeting with each of the MDT's, to reinforce information regarding the details of the study and to provide clinicians with referrals packs so they could begin to refer patients to the study, as well as answering any further questions they may have had.

Upon commencement of the study the researcher sent an update email to each clinician within the MDT's approximately every 12 weeks to provide a brief summary of the number of referrals that had been received and to highlight that the study was still recruiting participants and new referrals would be welcomed. After approximately six months of the study commencing the researcher attended a further meeting with each of the MDT's to provide a face-to-face update of the study, remind the clinicians of the aims of the study and the referral procedure and to encourage any patient meeting the inclusion/exclusion criteria to be approached about possible participation and if appropriate to refer them.

2.3.2 Inclusion and Exclusion Criteria

Individuals were included in the study if they met the following inclusion and exclusion criteria:

Inclusion Criteria

- Individuals aged 65 years and over (no upper age limit) seeking treatment from secondary care mental health services for depression and/or anxiety.
- Individuals currently presenting with at least a mild level of depression and/or anxiety, as measured by the Hospital Anxiety and Depression Scale (HADS). Participants were included if they scored 8 or above on either the depression or anxiety sub-scale of the HADS.

Exclusion Criteria

- Individuals who were currently presenting with acute psychotic symptomatology.

- Individuals with a diagnosis of a dementia or who were currently being actively investigated for possible dementia (i.e. were awaiting a neuropsychological assessment or brain scan).
- Individuals who were unable to read English or follow verbal instructions.
- Individuals who were currently presenting with active suicidal ideation.
- Individuals who were currently receiving a formalised psychological treatment, such as CBT, from an accredited therapist.
- Individuals who had current difficulties with alcohol or drug dependence.

2.4 TREATMENTS

2.4.1 *Beating the Blues (BTB)*

BTB was developed by Ultrasis UK Ltd and was first fully described and empirically evaluated in a pilot study by Proudfoot *et al* (2003a). *BTB* is described as an interactive, multimedia computer package which teaches practical skills, based on Cognitive Behaviour Therapy (CBT), to help manage symptoms of depression and anxiety (Proudfoot *et al*, 2003a). The package comprises eight sessions, completed on a weekly basis, with each session lasting approximately 45 – 60 minutes. Each session includes video clips, case vignettes, animations and interactive tasks designed to provide the user with the skills to understand and manage symptoms of depression and anxiety. A summary of the content of each of the sessions, which has been provided by the developers of *BTB*, is provided in Appendix 3. A brief overview of the structure of *BTB* is illustrated in Figure 2.1.

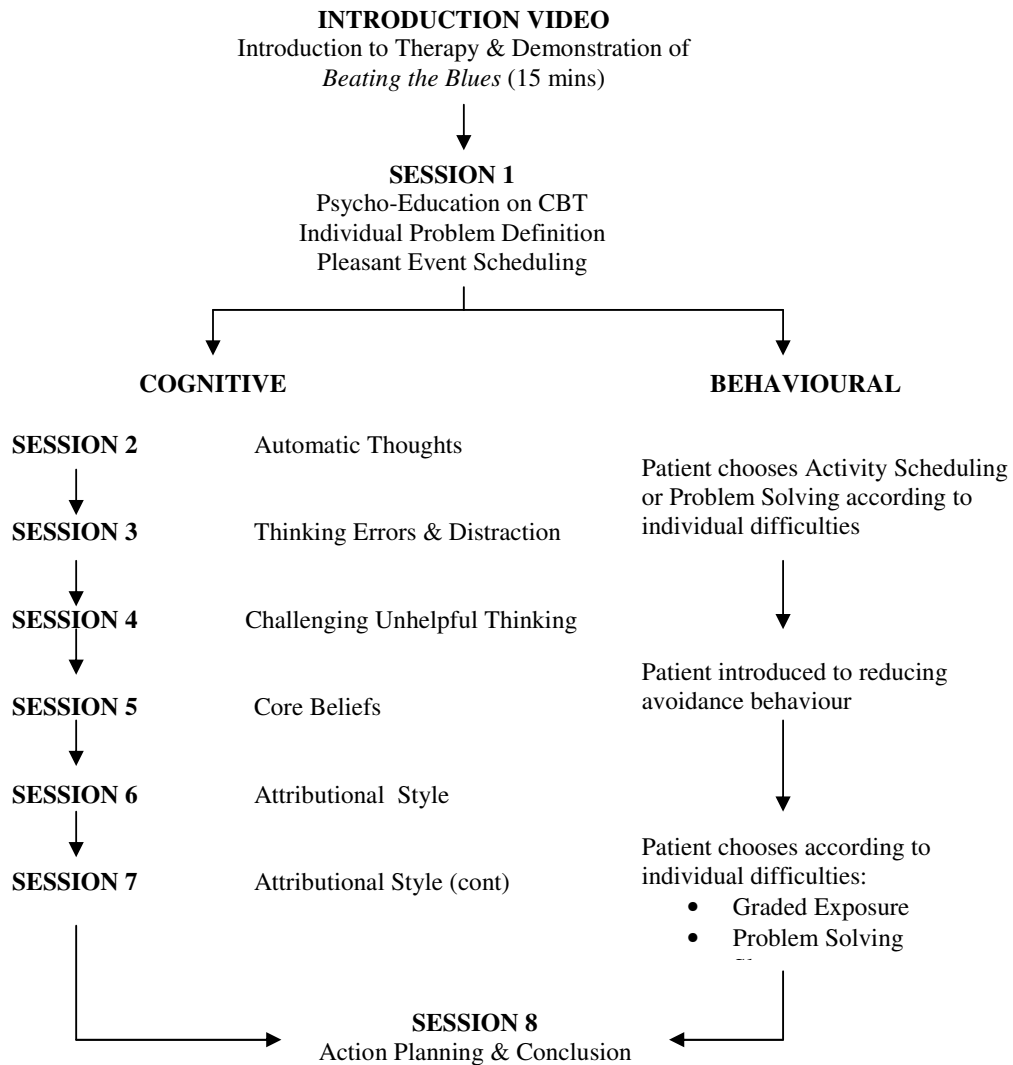


Figure 2.1 Overview of the Structure of *BTB* (adapted from Proudfoot *et al*, 2003a)

A homework task is assigned to the participant at the end of each session, to be completed prior to the next session. This is designed to help facilitate users' learning of the cognitive-behavioural techniques (Proudfoot *et al*, 2003a). These tasks include mood monitoring, activity scheduling, thought monitoring and challenging, as well as relaxation techniques. At the start of each session the participant provides a rating on a 0-8 point Likert scale in terms of how depressed and anxious they have felt over the last week and if they have had any feelings of suicide. This information is generated

into a progress report that is provided to the researcher. If the participant indicates they have felt suicidal an email alert is sent to the researcher, so the participant can be immediately contacted and provided with support if indicated.

Proudfoot *et al* (2003a) also highlight that a number of features were incorporated into the program to enhance not only its direct therapeutic procedures but also to make it user-friendly for patients. The authors suggest that video vignettes of case study ‘patients’⁶, whose progress can be watched over the course of each of the sessions, were incorporated to increase participants interest and motivation in using the program. The authors also argue that the case studies serve a number of other therapeutic functions, such as presenting models of the cognitive-behavioural techniques which users can observe to help their own understanding and learning. The patients in the case studies are also designed to communicate hope for improvement to users, by allowing them to see that other people go through similar experiences and learn how to manage their difficulties. All these non-specific therapeutic factors are interwoven with the specific cognitive-behavioural strategies outlined in Figure 2.1 (Proudfoot *et al*, 2003a).

2.4.2 Treatment as Usual

Within the context of the current study no constraints were placed on what was provided as treatment as usual (TAU), with the exception that participants could not be receiving a formalised face-to-face psychological treatment from an accredited therapist (as per the inclusion/exclusion criteria). The clinician from the participant’s direct care team who referred the participant to the study was instructed to provide

⁶ Case study ‘patients’ are actors’ role playing a patient.

whatever treatment felt necessary as part of the participant's normal, routine care and treatment. This could include no direct treatment if this was what was deemed appropriate for the participant by their clinician.

Prior to commencement of the study clinicians from the MDT's were consulted regarding the types of treatment they would typically use with patients. Based on the information that was provided, treatment as usual was hypothesised to typically consist of: 1) outpatient assessment/review appointment with a psychiatrist; 2) psychotropic medication prescribed/reviewed; 3) social support/advice; 4) relaxation training; 5) attendance at day hospital; and 6) referral to another specialist (e.g. a clinical psychologist). Information regarding the treatment as usual that was provided was gathered from clinicians from the referring MDT's at the end of the study. Participants were also asked about the treatment as usual they received, including whether they continued to be prescribed or had been commenced on psychotropic medication at the end of the study. The adherence to the exclusion criteria, with regard to point six listed above, was evaluated through monitoring of incoming referrals to the older people clinical psychology services throughout the region (adherence to this exclusion criteria was high in the study: see section 3.4.2, p 112).

2.5 MATERIALS

2.5.1 Referral Pack

Referral packs containing all the relevant information (e.g. details of the study and the inclusion/exclusion criteria) and the forms required to make referrals were provided to each of the MDTs from which participants were to be recruited. This included the following:

2.5.1.1 Participant Information Sheet

All potential participants who were approached about their possible participation in the study were provided with a Participant Information Sheet (see Appendix 4). This provided information about the study, what the aims were, and what participation would entail. It also contained contact details for the researcher and an independent advisor should they have any initial questions.

2.5.1.2 Consent Form 1

This form was completed by all the potential participants who agreed to be referred about their possible participation in the study (see appendix 5). It was made clear in the Participant Information Sheet and by the clinician from the potential participant's MDT that completion of this form did not mean they were consenting to take part in the study. They were advised they were only consenting to be contacted by the researcher to arrange an initial recruitment meeting in which they would have information on the study clarified before deciding if they wished to participate. The consent form contained a section to provide the contact details for the potential participant and the referrer.

2.5.1.3 The Hospital Anxiety and Depression Scale (HADS)

To confirm eligibility to take part in the study the HADS was used to screen for the presence of symptoms of depression and anxiety. This self-report measure has been used extensively for this purpose and is reported to have been used in 747 published studies and has been found to be a valid and reliable tool for identifying the presence and severity of depression and anxiety (Bjelland, 2002). The HADS is also recommended by the British Psychological Society (BPS) as one of the most effective

self-report measures for screening for the presence of depression and anxiety in older people above the age of 65 years (BPS, 2004).

The HADS comprises two distinct scales for depression and anxiety. Each scale has seven questions relating to different symptoms, which the patient answers by choosing an option between 0 and 3, based on the severity/intensity/frequency with which they have experienced the symptoms. The total score possible for each scale is 21. A score of 0 to 7 on either of the scales is rated as being within the "normal" range. Patients scoring 8 to 10 on either scale are rated as having "mild" difficulties, those scoring 11 to 15 are rated as having "moderate" difficulties and those scoring 16 to 21 are rated as having "severe" difficulties. Patients scoring 8 or above on either of the two HADS scales were eligible for participation in the present study.

2.5.1.4 Recruitment Questionnaire

This consisted of three questions: 1) the potential participant's date of birth; 2) the first four digits of their postcode; and 3) whether they agreed to be referred for an initial recruitment meeting with the researcher (see Appendix 6). This form was completed by the clinicians from potential participant's direct care team. It allowed the monitoring of the total number of potential participants approached about the study and how many subsequently agreed/declined to be referred for an initial recruitment meeting.

2.5.2 Outcome Measures

Participants who agreed to take part in the study in both the BTB+TAU group and the TAU group completed the same battery of self-report questionnaires to assess their

symptoms of depression and anxiety prior to treatment, after the completion of treatment and at one month follow-up. They also completed a consent form for taking part in the study (see appendix 7). The following measures were used:

2.5.2.1 The Clinical Outcomes in Routine Evaluation (CORE-34).

The CORE-34 is a self-report measure that was developed for use throughout the UK to be used in routine practice for evaluating outcomes for psychological therapies (see Appendix 8). It consists of thirty-four questions that are rated on a 0 – 4 point Likert scale. The results of the CORE-34 are separated into four domains relating to wellbeing, problems/symptoms, life functioning and risk. A total composite domain score can also be obtained. The CORE-34 has been reported to be a valid and reliable assessment for measuring outcomes from psychological treatment (Evans *et al*, 2000). For example, Evans *et al* (2000) reported Cronbach's alpha coefficients of .94 for the total domain and Cronbach alpha coefficients ranging from .79 to .90 for the four sub-domains, highlighting the internal consistency of the measure. In addition, these authors reported test-retest reliability coefficients ranging from .87 to .90 for each of the domains. Evans *et al* (2000) suggest that the CORE demonstrates good convergent validity of the CORE with strong correlations between it and a number of other measures of psychopathology e.g. BDI (.85), BAI (.65) and SCL-90-R (.88). Furthermore, Evans *et al* (2000) found significant differences between a clinical and non-clinical sample of participants on their CORE scores, providing evidence that it was a valid and reliable measure for differentiating these two samples. Since 2001 the CORE has been used in 450 services in the UK and data have been collated for 300 000 patients. The CORE is recommended by the BPS (BPS, 2004) as an assessment tool for use with older people. It has also been used in a number of previous studies of

BTB (e.g. Learmonth & Rai, 2008), which have demonstrated an improvement in scores over the course of treatment.

2.5.2.2 *The Geriatric Depression Scale (GDS)*

The GDS is a self-report measure designed specifically for use with older people (see Appendix 9). It contains 30 questions relating to symptoms of depression, to which the patient answers “yes” or “no”, depending on whether or not the symptom has been present over the previous week. The questionnaire is scored out of a possible 30, with a score of 0 – 9 being classified as in the "normal" range, a score of 10 – 19 being classified as "mild depression" and a score of 20 – 30 being classified as "severe depression". The GDS has been shown to be a valid and reliable measure for detecting the presence of and severity of depression in people 65 years and above (Yesavage *et al*, 1983). For example, Yesavage *et al*, (1983) found Cronbach alpha coefficients of .94 and split-half reliability coefficients of .94, demonstrating the internal consistency of the GDS. The authors also found test-retest reliability coefficients of .85 for the GDS. Yesavage *et al* (1983) also suggest the GDS is a valid and reliable measure for differentiating between clinical and non-clinical samples as they found significant differences between participants scores on the GDS from each of these two groups. Lastly the authors found significant correlations between participants scores on the GDS and other measures of depression such as the Zung Self Rated Depression Scale (.84) and the Hamilton Rating of Depression Scale (.83). The GDS is reported to be one of the most widely used assessments for detecting and rating the severity of depression with older people in a range of different settings (Montorio & Izal, 1996). A review by the BPS (2004) of all the assessment tools routinely used with older people recommended the use of the GDS as a valid and reliable assessment tool that

can be used before and after treatment to assess older people's progress after receiving treatment.

2.5.2.3 *The Geriatric Anxiety Inventory (GAI)*

The Geriatric Anxiety Inventory is a self-report measure designed specifically for use with people over the age of 65 years (see Appendix 10). It contains 20 questions relating to symptoms of anxiety, to which the patient answers "yes" or "no", depending on whether or not the symptom has been present over the previous week. The questionnaire is scored out of 20, with a score of 0 – 8 being classified as in the "normal" range and a score of 8 and above being indicative of the presence of an anxiety disorder. The GAI has been shown to be a valid and reliable measure for detecting the presence of anxiety in older people in a range of settings (Pachana *et al*, 2007). For example, Pachana *et al* (2007) found Cronbach alpha coefficients of .91 highlighting the internal consistency of the GAI. The authors also found test-retest reliability coefficients of .91. Furthermore, they found that the GAI was significantly correlated with other measures of anxiety, such as the Beck Anxiety Inventory (.63), State Trait Anxiety Inventory (.80) and the Penn State Worry Questionnaire (.70). Lastly, the GAI was found to differentiate between clinical participants experiencing anxiety and non-clinical control participants, with significant differences between the two groups in their scores on the GAI. It has been recommended as an appropriate measure for assessing the severity of anxiety in older people and can be used to monitor any changes in patient's symptoms after receiving treatment (Smith *et al*, 2008).

2.5.2.4 Demographics Questionnaire

A demographics questionnaire was completed by all participants taking part in the study (see Appendix 11). This included a section relating to participants' experience and confidence in using a computer.

2.6 PROCEDURE.

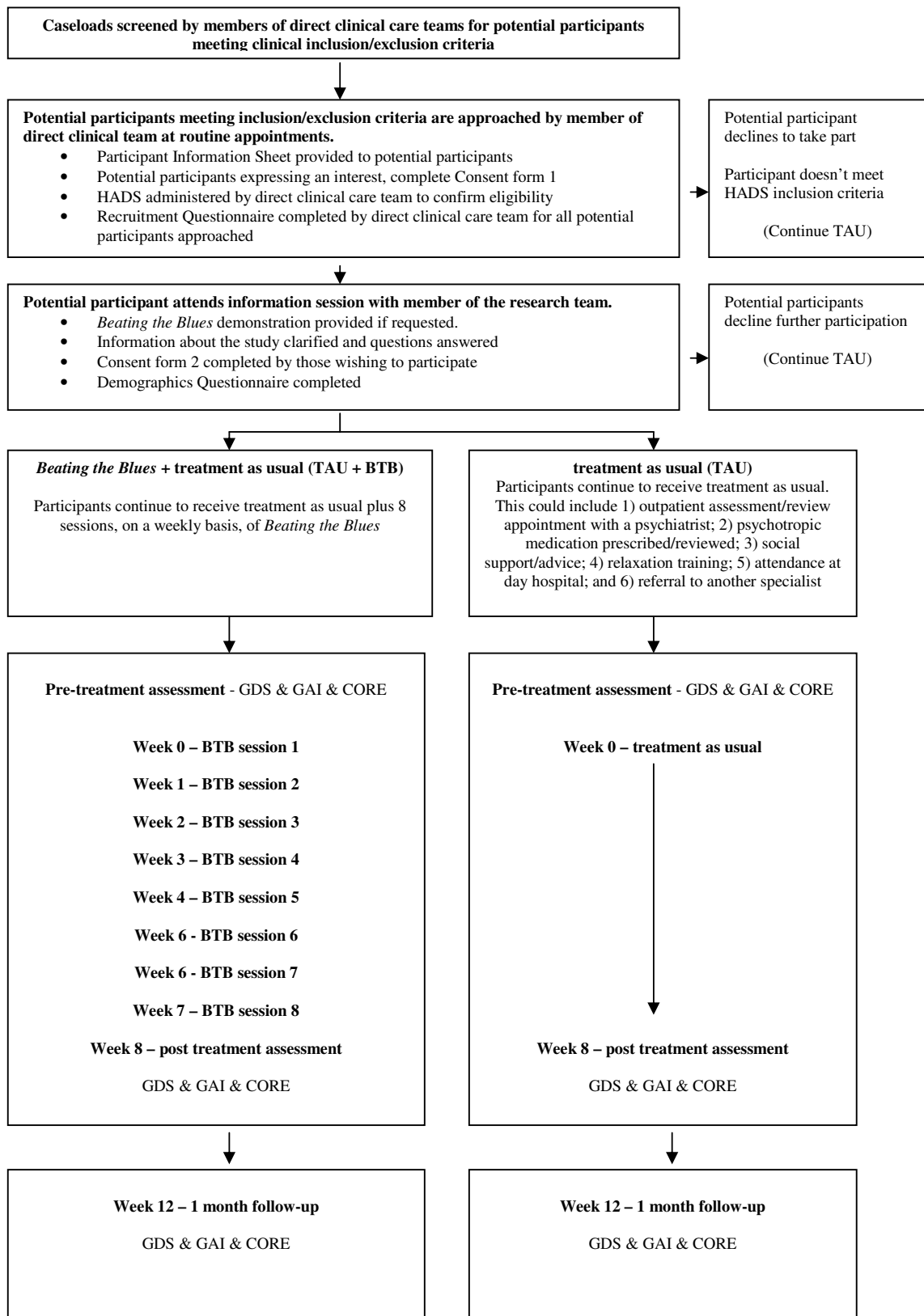
The procedure for the study is illustrated schematically in Figure 2.2

2.6.1 Initial Approach to Potential Participants

Prior to the commencement of the study (and throughout the running of the study) the researcher liaised closely with clinicians from the MDT's regarding details of the study, including, for example, the inclusion/exclusion criteria. Potential participants were known to the clinicians from the MDTs, who were able to assess whether they met the inclusion/exclusion criteria and had access to their medical records to confirm any details.

Potential participants meeting the inclusion/exclusion criteria were approached by a clinician from the MDT at a routine appointment about their interest in finding out about the study. These clinicians had been provided with referral packs described in the Materials section above. Potential participants were offered the Participant Information Sheet by their clinician and were supported in reading and understanding this. The contact details of the Chief Investigator (the researcher) and an Independent Advisor were also provided if they had any initial questions.

Figure 2.2 Overview of Study Procedure.



Potential participants who expressed an initial interest in taking part in the study were asked to sign Consent Form 1 to allow their contact details to be provided to the researcher. They were also asked to complete the HADS questionnaire to confirm whether or not they met the inclusion criteria. It was made clear in the Participant Information Sheet and by the clinician from their direct care team that they could take more time to consider the information further before deciding if they wished to have their contact details provided to the researcher. It was also emphasised that by signing Consent Form 1 they were not agreeing to participate in the study, but just to be contacted to arrange a meeting with the researcher.

Those potential participants who did not wish to participate or who scored below the inclusion criteria cut off on both the HADS scales were excluded from the study and continued to receive their treatment as usual (i.e. whatever treatment they normally receive as part of their normal routine care).

Clinicians from the direct care team completed the Recruitment Questionnaire for all potential participants approached to take part (including those who did not wish to be referred), which was returned to the researcher in stamped address envelopes. This allowed an examination of the number of patients initially approached to take part in the study and the number agreeing/declining to be referred.

2.6.2 Initial Recruitment Meeting

For participants who agreed to be referred, an initial recruitment meeting was arranged with the researcher. At this meeting information relating to what was involved in taking part in the study was clarified and the potential participant had the

opportunity to have any questions answered. Potential participants were also offered the opportunity to view a standard video demonstration of *BTB*. Potential participants were then asked whether they wished to take part in the study. It was also made clear that they could take more time to consider their decision if required.

2.6.3 Allocation to Group, Assessment & Treatment

Participants were allocated to the treatment as usual group (TAU) or the *BTB* plus treatment as usual group (BTB+TAU), based on their choice.

2.6.3.1 Treatment as Usual (TAU)

Throughout their participation in the study all participants in this group continued with their treatment as usual (i.e. whatever treatment they had already been receiving as part of their normal, routine care and treatment, as detailed above in section 2.4.2, (p 82). At week 0 participants attended a session with the researcher to complete the GDS, the GAI and CORE-34 pre-treatment measures. They were again contacted at week eight and week by the researcher to complete the post-treatment and one month follow-up measures. In the interim period between the initial session with the researcher and the subsequent follow-up points with the researcher, participants continued to receive treatment as usual, which, based on information gathered from clinicians prior to the study was hypothesised to include: 1) outpatient assessment/review appointment with a psychiatrist; 2) psychotropic medication prescribed/reviewed; 3) social support/advice; 4) relaxation training; 5) attendance at day hospital; and 6) referral to another specialist. At the end of the study the clinician who referred the participant was contacted to gather information regarding the

number of treatment as usual sessions that had been provided and the primary content of treatment as usual.

2.6.3.2 BTB plus Treatment as Usual (BTB + TAU)

Participants in this group followed the same procedure as to what is detailed in the TAU section above (2.6.3.1). In addition, at week 0 participants in the BTB+TAU group completed their first *BTB* session. Participants were given the option of completing their *BTB* sessions at home, if they had access to a computer with a broadband connection. Alternatively, participants were able to attend one of several sites in the community that were already established for the use of *BTB* by patients from the NHS region where the study was being conducted. These sites included a primary care Psychological Therapies Service Department and local pharmacies and libraries. The researcher was present throughout the whole of session one of *BTB* to support the participant in the technical use of the program. No specific guidance was provided regarding answering particular questions on the computer program or completing specific tasks set by the program.

Participants subsequently completed the remaining seven sessions independently on a weekly basis. If participants were completing the sessions at home they were asked to contact a member of the research team each week by telephone to ‘book’ when they were planning to do each of their sessions. They also had the contact numbers of the researcher and who they could contact if they had any specific problems with using the program (e.g. if they forgot their password, etc). Participants completing their sessions in the community booked each of their sessions with a member of staff at these sites. Members of staff at each of these sites were trained in using *BTB* and

could provide any technical assistance to participants if this was required. No help or support was provided regarding completing the actual content of the *BTB* sessions. If a participant did not attend an appointment or did not complete a home session when they had booked it they were contacted by telephone by the researcher to ascertain if they wished to discontinue *BTB*, or if they had forgotten. Those who had simply forgotten were encouraged to book and complete the session at a time later in the week.

2.7 POWER CALCULATION & SAMPLE SIZE

G*Power 3 (Faul *et al*, 2007) was used prior to the start of the study to estimate the sample size required to detect a statistically significant differences between the two groups. The purpose of this was to avoid making a Type II error and incorrectly accepting the null hypothesis that there are no significant differences between the two groups by the end of treatment, as a result of too small a sample size. Previous research comparing *Beating the Blues* plus treatment as usual to treatment as usual alone has found effect sizes of 0.63 (Proudfoot *et al* 2004 (analysis combined with Proudfoot *et al*, 2003b)) and 0.85 (Grime, 2004). Using the more conservative effect size of 0.63, for the current study a sample size of 64 (32 per group) was calculated to be required to detect a significant difference between the groups at .80 power and with an alpha of 0.05.

CHAPTER 3 – RESULTS

In this chapter the methods used to examine the obtained data prior to conducting the statistical analysis for the primary aims and hypothesis of the study are initially described. An analysis of the results in terms of the primary aims and hypothesis of the study is presented in sequence in section 3.2. This is followed by an analysis of the secondary aims and hypotheses of the study in section 3.3.

3.1 DATA ANALYSIS

3.1.1 Analysis of Assumptions

Prior to conducting the statistical analyses it is necessary to determine if the obtained data violated/satisfied the assumptions of parametric statistical analysis. The data were therefore first examined to check the normality of the distributions. Field (2009) suggests that the values of skew and kurtosis, which determine the normality of a distribution, can be divided by their respective standard error (SE) to produce a z-score. These z-scores can then be compared to the z-scores produced by a normal distribution to determine if the obtained data are normally distributed (i.e. it can be determined whether the obtained z-scores significantly differ to those produced by a normal distribution). Field (2009) states that obtained z-scores greater than 1.96 are significant at $p < .05$, z-scores greater than 2.58 are significant at $p < .01$ and z-scores greater than 3.29 are significant at $p < .001$, and therefore violate the assumptions of normality.

In addition, the Kolmogorov-Smirnov test can be used to determine whether the distributions of the obtained data are significantly different from a normally distributed set of data with the same mean and standard deviation (SD) as the obtained

data set (Field, 2009). If the Kolmogorov-Smirnov test is significant (i.e. $p < .05$) this indicates the obtained data significantly differs from a normal distribution and violates the assumption of normality. Field (2009) also highlights that if the research questions of a study involve exploring differences between two or more groups then the normality of the distributions within each of these groups is more important than the normality of sample as a whole (i.e. both groups combined). When conducting the analysis of normality the output was therefore split between the two groups in the current study. The results are summarised in Table 3.1 below, which shows the obtained z-scores and results from the Kolmogorov-Smirnov (KS) tests, with significant findings highlighted in red.

Table 3.1 Examination of normality of baseline outcome and demographic variables

Variable	Condition	Mean (SD)	Median	Skew (SE)	Z	Kurtosis (SE)	Z	KS	p
Age	BTB+TAU	71.58 (4.43)	71	.48 (.41)	1.16	-.46 (.80)	-0.57	.10	.20
	TAU	75.55 (6.27)	75	.41 (.51)	0.80	-.42 (.99)	-0.42	.15	.20
Education	BTB+TAU	11.70 (2.56)	10	.97 (.41)	2.37	-.43 (.80)	-0.53	.32	<.000
	TAU	10.25 (1.88)	10	2.46 (.52)	4.81	5.66 (.99)	5.70	.40	<.000
Health	BTB+TAU	2.45 (1.46)	2	.160 (.41)	0.39	-.63 (.80)	-0.78	.14	.088
	TAU	2.45 (1.50)	2	.36 (.51)	0.71	.25 (.99)	0.24	.17	.143
Experience	BTB+TAU	4.67 (2.70)	5	-.40 (.41)	-0.98	-.62 (.80)	-0.77	.13	.172
	TAU	1.40 (2.83)	0	1.93 (.51)	3.77	2.46 (.99)	2.47	.44	<.000
Confidence	BTB+TAU	5.33 (2.70)	6	-.57 (.41)	-1.39	-.45 (.80)	-0.56	.15	.065
	TAU	1.30 (2.65)	0	2.07 (.51)	4.04	3.42 (.99)	3.45	.44	<.000
GDS	BTB+TAU	21.09 (5.47)	20	-.20 (.41)	-0.48	-.81 (.80)	1.01	.15	.064
	TAU	20.95 (6.03)	23	-.66 (.51)	-1.28	-.52 (.99)	-0.52	.19	.171
GAI	BTB+TAU	13.48 (6.01)	15	-.65 (.41)	-1.58	-.82 (.80)	-1.03	.15	.056
	TAU	14.15 (5.537)	16.5	-.51 (.51)	-0.99	-1.21 (.99)	-1.27	.11	.250
CORETotal	BTB+TAU	52.30 (18.14)	49	.09 (.41)	0.21	-.39 (.80)	-0.48	.13	.200
	TAU	49.50 (16.89)	48	-.17 (.51)	-0.33	-.39 (.99)	-0.38	.10	.200
CORE-W	BTB+TAU	8.76 (3.08)	8	.40 (.41)	0.97	-.12 (.80)	0.14	.14	.087
	TAU	8.10 (3.24)	7.5	.10 (.51)	0.28	-1.80 (.99)	-0.17	.13	.200
CORE-R	BTB+TAU	1.79 (2.42)	1	1.63 (.41)	3.98	2.78 (.80)	3.48	.26	<.000
	TAU	0.60 (1.04)	0	1.54 (.51)	3.01	1.04 (.99)	1.04	.42	<.000
CORE-F	BTB+TAU	17.12 (6.99)	16	.57 (.41)	1.40	.86 (.80)	1.07	.15	.068
	TAU	17.05 (6.85)	16	.91 (.51)	1.77	1.86 (.99)	1.87	.13	.200
CORE-P	BTB+TAU	24.39 (9.41)	24	-.08 (.41)	-0.20	-.60 (.80)	-0.75	.73	.200
	TAU	23.80 (10.11)	25.5	-.61 (.51)	-1.19	.22 (.99)	0.21	.12	.200

As can be seen from Table 3.1, three demographic variables violated the assumptions of normality (number of years of education in both treatment groups and confidence and experience in using a computer in the TAU group). As these variables were to undergo statistical analysis to explore differences between the two treatment groups, non-parametric tests were used for these variables (the Mann-Whitney U test).

As can also be seen from Table 3.1, in terms of the outcome measures that were used in relation to the secondary aims of the study, the only variable that violated the assumptions of normality was the risk sub-scale of the CORE-34 (CORE-R). Given the nature of the questions that make up this sub-scale and the exclusion criteria for the study, whereby individuals who were expressing active suicidal ideation were excluded, it is perhaps unavoidable that the data skewed towards low responses on this sub-scale. As this variable violated the assumption of normality, and as it was not a specific target for treatment, this variable was not examined further in the final analysis.

3.1.3 Statistics

Means and standard deviations (SD) were calculated for all continuous variables and numbers and percentages were calculated for categorical data. Comparisons between the two treatment groups in terms of demographic variables, pre-treatment scores on outcome measures and study completion/drop-out rates were made with independent t-tests (or Mann-Whitney U tests for variables where the data violated assumptions of normality), for continuous data and Chi-square tests for categorical data. The statistics used for the secondary aim of the study are described in section 3.3.1.

3.2 DESCRIPTION & ANALYSIS OF FINAL STUDY SAMPLE

3.2.1 Rates of Recruitment and Uptake of Treatment – Primary Aim 1

Figure 3.1 shows diagrammatically the flow of patients through the study from the initial approach regarding their possible participation to the completion of one month follow-up assessment measures. This provides an overview of the rate of uptake and drop-out from the respective treatment conditions.

3.2.1.1 Overall Recruitment to Study

A total of 77 patients were approached about their possible participation in the study. Fifty-eight (75.3 per cent) subsequently agreed to be referred to the study, whilst 19 (24.7 per cent) declined. All 58 individuals who were referred subsequently agreed to participate in the study and met the inclusion/exclusion criteria. An analysis of differences between patients who agreed to participate and those who declined (i.e. who did not wish to be referred to the study) in terms of age and Deprivation Category (DepCat) are provided in Table 3.2.

As can be seen from Table 3.2, those who declined to be referred to the study (non-participants) were older (mean (SD) = 78.32 (7.17)) than those who agreed to participate (mean (SD) = 73.43 (5.88)) and this difference was statistically significant ($t(75) = 2.97, p < .01$). As the mean age of participants was 73.08 years this indicates those in the ‘oldest-old’ age category were under-represented in the current study, despite no upper age limit being imposed. This is reflected in other studies that have explored psychological treatments for depression in older people (Cuijpers *et al*, 2009).

Table 3.2 also shows that there was no significant difference between participants and non-participants in terms of DepCat classification ($\chi^2 (2) = .398, p = .53$ ns). The majority of both participants and non-participants were in the I-III classification, which indicates that most of the individuals approached about participation came from less socially deprived areas.

Table 3.2 Characteristics of participants vs. non-participants

Variable	Study Participants N = 58		Non-participants N = 19		Summary Statistics		
	Mean	SD	Mean	SD	t	d.f.	p
Age	73.43	5.88	78.32	7.17	2.97	75	< .01
	N	%	N	%	χ^2	d.f.	p
DepCat							
I - III	35	60.3	13	68.4			
IV-VII	23	39.7	6	31.6			
					.398	2	.53 (ns)

3.2.1.2 Allocation to Treatment Group – Rates of Uptake of BTB

Of the 58 participants recruited to the study 38 (65.5 per cent) indicated a preference to receive *BTB* and were allocated to the BTB+TAU group. The remaining 20 (34.5 per cent) participants indicated that they did not wish to receive *BTB* and were allocated to the TAU group. A description of the demographic characteristics of the two groups of participants is provided in Table 3.3, including an analysis of differences between the two groups. After group allocation, five participants in the BTB+TAU group did not attend for their first *BTB* session and did not complete any of the pre-treatment assessment measures. Two of these participants reported significant physical health problems diagnosed after they were allocated to treatment, which they felt would render them unable to participate in the study. One participant

was unknowingly also referred for individual face-to-face psychological therapy by a different referrer and this participant indicated a preference to begin this rather than continue in the study. Two participants did not provide any reasons for dropping-out of the study prior to the first *BTB* session. These five participants were excluded from subsequent treatment outcome analyses, as they had not completed any pre-treatment assessment measures, had not completed any *BTB* sessions and had indicated they did not wish to continue to participate in the study. From the total number of participants recruited to the study (58), the total number who opted for *BTB* and then started the first session was 33, resulting in an uptake rate of 56.9 per cent.

3.2.2 Analysis of Differences in Demographic Characteristics – Primary Aim 2

As can be seen from Table 3.3 there were significant differences between the two treatment groups on the following variables; age ($t(51) = 2.70, p < .01$), years of education (Mann-Whitney $U = 198, p < .01$), self reported confidence in using a computer (Mann-Whitney $U = 101, p < .001$), self reported experience with using a computer (Mann-Whitney $U = 135, p < .001$) and whether or not they had access to the internet at home ($\chi^2(1) = 7.92, p < .01$). Analysis of the means of the two groups on each of these variables highlights that in comparison to the TAU group the *BTB+TAU* group were younger, had more years of education, were more likely to have access to the internet at home and reported having more experience and confidence in using a computer.

Table 3.3 Demographic characteristics of study participants

Variable	BTB+TAU N = 33		TAU N = 20		Comparison		
	Mean	SD	Mean	SD			
Age	71.58	4.43	75.55	6.27	$t(51) = 2.70, p < .01$		
Years of Education	11.70	2.56	10.25	1.88	Mann-Whitney U = 198, $p < .01$		
Number of Co-morbid Physical Illnesses	2.45	1.46	2.45	1.50	$t(51) = .01, p = .991$ (ns)		
Self Reported Confidence Using Computers (0-9 scale)	5.33	2.70	1.30	2.65	Mann-Whitney U = 101, $p < .001$		
Self Reported Experience Using Computers (0-9 scale)	4.67	2.67	1.40	2.83	Mann-Whitney U = 135, $p < .001$		
	<i>N</i>	%	<i>N</i>	%	χ^2	d.f.	<i>p</i>
Gender:							
Male	8	24.2	6	30.0			
Female	25	75.8	14	70.0			
					.21	1	.645 (ns)
Access to Internet at Home:							
Yes	23	69.7	6	30.0			
No	10	30.3	14	70.0			
					7.92	1	< .01
Currently Taking Psychotropic Medication:							
Yes	26	78.8	19	95			
No	7	21.2	1	5			
					2.55	1	.234 (ns)*
Previous Psychiatric History:							
Yes	23	69.7	15	75.0			
No	10	30.3	5	25.0			
					.17	1	.678 (ns)
Duration of Current Treatment Episode:							
1-3 Months	4	12.1	3	15			
4-12 Months	16	48.5	8	40			
>12 Months	13	39.4	9	45			
					.49	1	.795 (ns)*
Deprivation Category (DepCat):							
I-III	20	60.6	11	55.0			
IV-VII	13	39.4	9	45.0			
					.16	1	.688 (ns)

*Fisher's exact test statistic was used due to expected frequencies < 5 in the sample

In contrast, the groups did not significantly differ in terms of the number of co-morbid physical health problems they reported ($t(51) = .01, p = .991$ (ns)) and whether they were taking psychotropic medication at the start of their participation in the study ($\chi^2(1) = 2.55, p = .234$ (ns)). Nor did they significantly differ regarding whether they had a previous psychiatric history, for which they had received treatment, prior to their current episode of treatment ($\chi^2(1) = .17, p = .678$ (ns)). There were also no significant differences between the two groups regarding the duration of their current episode of treatment ($\chi^2(1) = .49, p = .795$ (ns)) and their DepCat classification ($\chi^2(1) = .16, p = .688$ (ns)). In addition, the groups did not significantly differ in terms of the number of males and females in each group ($\chi^2(1) = .21, p = .645$ (ns)). Overall, however, there was a higher proportion of females than males in both groups. However, this imbalance is reflective of the overall population of the region from which participants were recruited, whereby the population of females over the age of 65 years is 66 per cent compared 34 per cent who are male (NHS, 2007).

3.2.3 Study Attrition Rates – Primary Aim 3

3.2.3.1 BTB+TAU Group

A total of nine (27.3 per cent) participants who began *BTB* subsequently discontinued the *BTB* treatment (treatment discontinuers) prior to the final session, whilst 24 (72.7 per cent) completed the full course of eight sessions. Of the nine participants who discontinued *BTB*, seven completed post-treatment assessment measures to assess their treatment outcome. The remaining two participants (study drop-outs) who did not complete post-treatment assessment measures had these values replaced using the LOCF method to enable an intention-to-treat analysis.

A total of 28 (84.8 per cent) participants in the BTB+TAU group completed the one month follow-up assessment measures. The five participants (which included the two participants who did not complete the post treatment assessment measures) who did not complete the one month follow-up assessment measures had these values replaced using LOCF to enable intention-to-treat analysis. A summary of participants reasons for discontinuing *BTB* are summarised in Table 3.4. Although participants were not required to give a reason for dropping out, many spontaneously gave a reason.

Table 3.4 Reasons provided for discontinuing *BTB*

Reason Provided by Participants	<i>N</i>	<i>BTB</i> session when discontinued
Found <i>BTB</i> unhelpful	1	4
Found computer hardware too difficult to use	1	1
Offered opportunity of face-to-face counselling	1	5
Physical health significantly deteriorated	2	1 & 4
Personal computer malfunction	1	6
Felt better and did not wish to continue	1	4
Difficulties concentrating due to anxiety	1	4
No reason provided	1	1
Total	9	-

3.2.3.2 TAU Group

Of the 20 participants who were allocated to TAU and who completed the pre-treatment assessment measures, three (15 per cent) subsequently dropped-out of the study by the post treatment assessment point (i.e. they declined to complete the post-treatment outcome measures). An additional two patients subsequently dropped-out of the study by the one month follow-up point. It was not possible to obtain detailed information about the reasons for dropping-out of the study for this group due to the nature of their participation, which involved completing a series of questionnaires (as well as continuing with treatment as usual). When they were contacted, the participants who dropped out from this group at the post-treatment and one-month follow-up indicated they no longer wished to complete the outcome questionnaires.

3.2.3.3 Differences in Study Attrition Rates by Treatment Group

Table 3.5 shows an analysis of differences between the two treatment groups in terms of those who remained enrolled in the study and completed outcome measures (including those who discontinued *BTB* but completed assessment questionnaires) and those who dropped out of the study. As can be seen in Table 3.5, there was no significant difference between the BTB+TAU group and the TAU group in terms of the number of participants dropping out of the study by the post-treatment or one month follow-up assessment points (post treatment assessment point, $\chi^2(1) = 2.41, p = .135$ ns; one month follow up assessment point, $\chi^2(1) = 1.67, p = .173$ ns).

Table 3.5 Analysis of outcome measure completion and study drop-out rates

Variable	BTB+TAU N = 33		TAU N = 20		Summary Statistics		
	N	%	N	%	χ^2	d.f.	p
Post Treatment							
Outcome Measure Completers	31	93.9	16	80.0	2.41	1	.135* (ns)
Study Drop-outs	2	6.1	4	20.0			
One Month Follow-up							
Outcome Measure Completers	28	84.8	14	70	1.67	1	.173 (ns)
Study Drop-outs	5	15.2	6	30			

* Fisher's exact test statistic was used due to expected frequencies < 5 in the sample

A further analysis of differences in the drop-out rate between the two groups, which placed all *BTB* treatment discontinuers within the drop-out category, is illustrated in Table 3.6. This highlights that a higher percentage of individuals in the BTB+TAU discontinued *BTB*, in comparison to the percentage that dropped out the study from the TAU group (27.3 per cent discontinue *BTB* in the BTB+TAU group vs. 20 per

cent drop out in the TAU group). This difference was not, however, statistically significant $\chi^2 (1) = .356, p = .744$ ns.

Table 3.6 Analysis of study completers and study drop-out rates

Variable	BTB+TAU N = 33		TAU N = 20		Summary Statistics		
	N	%	N	%	χ^2	d.f.	p
Study Completers	24	72.7	16	80.0			
BTB discontinuers & Study Dropouts	9	27.3	4	20.0			
					.356	1	.744* (ns)

* Fisher's exact test statistic was used due to expected frequencies < 5 in the sample

3.3 SECONDARY AIM – Examination of treatment outcome

3.3.1 Statistics & Assumptions

Assumptions of parametric statistics relevant to the analysis being conducted for the secondary aim are homogeneity of variance and sphericity. An examination of the homogeneity of variance between the BTB+TAU group and the TAU group was therefore conducted using a series of Levene's test. For all the outcome measures undergoing this analysis, with the exception of the risk sub-scale of the CORE-34, Levene's tests were non-significant indicating that the data did not violate this assumption. When conducting repeated measures ANOVAs, sphericity was examined using Mauchley's test and corrections were made if this was significant. When sphericity estimates are .75 and less, the Greenhouse-Geisser correction is used, when they are greater than .75 then the Huynh-Feldt correction should be applied (Field, 2009). It is stated in the relevant sections below when these corrections were used when repeated measures ANOVAs were performed.

Outcome from treatment was analysed using a series of 3 (Time) x 2 (Treatment Group) ANOVAs with time as the repeated measure. All analyses were intention-to-treat. Post treatment and one month follow-up effect sizes were calculated between the two groups using Cohen's *d* (Cohen, 1988)⁷. An examination of the clinical significance of the results was also made using criteria set out by Jacobson and Truax (1991), which is described in greater detail in section 3.4.2.

3.3.2 Missing Data & Intention-to-Treat Analysis

Participants who discontinued treatment (e.g. if they stopped *BTB* before the last session) prior to the post-treatment assessment point were offered the opportunity to complete the post-treatment and one month follow-up outcome measures. Participants who agreed to complete these outcome measures were referred to as “treatment discontinuers”. Participants who discontinued treatment and then subsequently declined to complete post-treatment and one month follow-up outcome measures were referred to as “study drop-outs”.

An analysis of the rates of discontinuers and drop-outs between the two treatment groups is described in more detail in section 3.2. An Intention-to-Treat (ITT) analysis was used when conducting all the statistical analyses exploring the outcome from the two treatment conditions. This is a more conservative approach, whereby all the individuals who begin treatment, including those who subsequently discontinue or drop-out, are entered into the data analysis. An alternative method of only including those who complete the full course of treatment may bias the results in favour of a

⁷ Cohen's *d* is derived from the following formula: $\text{Mean (TAU)} - \text{Mean (BTB+TAU)} / \text{Standard Deviation (pooled)}$ and applying a correction for the sample size. Cohen's *d* effect sizes of 0.80 and above are large, 0.50 to 0.80 are moderate and lower effect sizes are regarded as small (Cohen, 1977).

treatment condition, as it does not take into account the impact of those stopping treatment early on the overall effectiveness of the treatment.

In order to complete an ITT analysis, it was necessary to employ a method of replacing the data that was missing as a result of study drop-outs. Carpenter *et al* (2002) highlight four options that are available for this:

1. *Deletion of study-drop outs from the data analysis*

When using this method, all data completed by participants who drop-out of the study is removed from the analysis. This is a much less conservative method, as it produces a completer analysis rather than an ITT analysis and does not take into account the impact of those dropping out on a treatments overall effectiveness.

2. *Last Observation Carried Forward (LOCF)*

When using this method, participants' last recorded score on an outcome measure is carried forward and used to replace the missing values for when the measure would have been completed if they had not dropped out. This method is conservative, in that the use of the last observation is not intended to inflate or deflate outcome scores for either treatment group.

3. *Design and build a statistical model to replace missing data*

This method uses the obtained data to determine a statistical model for the drop-out process. This is most useful with large samples and in studies where drop-out is considered a non-random event. Given that the sample size is relatively small in the current study, there would be insufficient numbers to give any resulting model sufficient precision to detect non-random drop-outs.

4. *Replacing missing data for study drop-outs with the group mean*

In this method the measures that are missing as a result of drop-out are replaced with the group mean. This can have the effect of either inflating or deflating outcome scores depending on the group means.

Based on the evidence outlined above, only options two and four were possible in the current study. Option one produces a completer analysis and therefore does not account for the impact of those dropping out of treatment. The sample size was too small to consider option three as a possibility. Option two was chosen over option four as the former was more conservative based on the obtained group means.

3.3.3 Analysis of Treatment Outcome over Time by Treatment Group

Table 3.7 summarises the means and standard deviations for all the outcome measures completed by the two treatment groups. As an initial step in the analysis independent t-tests were conducted between the two treatment groups on all the pre-treatment outcome measures to determine if there were any significant differences between the two treatment groups prior to commencing treatment. Results of these t-tests indicated that participants scores on the outcome measures did not significantly differ between the two treatment groups at the pre-treatment assessment point: GDS: $t(51) = .08, p = .93$ (ns); GAI: $t(51) = .40, p = .68$ (ns); CORE-Total: $t(51) = .56, p = .57$ (ns); CORE-F: $t(51) = .04, p = .97$ (ns); CORE-P: $t(51) = .22, p = .83$ (ns); CORE-W: $t(51) = .74, p = .46$ (ns). This suggests both treatment groups had equivalent levels of psychopathology, as assessed by each of the outcome measures, prior to the start of treatment.

Table 3.7 Means and standard deviations (SD) of self-report outcome measures

Outcome Measure	BTB+TAU (N=33)		TAU (N=20)	
	Mean	SD	Mean	SD
Geriatric Depression Scale				
Pre-treatment	21.09	5.47	20.95	6.03
Post-treatment	12.88	8.92	19.70	6.60
One Month Follow-up	12.91	8.26	19.30	7.83
Geriatric Anxiety Inventory				
Pre-treatment	13.48	6.01	14.15	5.53
Post-treatment	8.70	5.94	12.05	5.46
One Month Follow-up	8.52	6.36	12.75	5.95
CORE - Total				
Pre-treatment	52.30	18.14	49.50	16.89
Post-treatment	37.33	17.82	51.75	16.66
One Month Follow-up	34.82	20.46	47.05	20.08
CORE - W				
Pre-treatment	8.76	3.08	8.10	3.24
Post-treatment	6.58	3.87	8.50	3.67
One Month Follow-up	6.24	4.66	8.60	3.93
CORE - P				
Pre-treatment	24.39	9.41	23.80	10.11
Post-treatment	17.09	7.70	25.00	9.14
One Month Follow-up	16.48	9.51	22.10	10.34
CORE - R				
Pre-treatment	1.79	2.42	.60	1.05
Post-treatment	.88	1.51	.35	.99
One Month Follow-up	.85	1.56	.55	1.37
CORE - F				
Pre-treatment	17.12	6.99	17.05	6.85
Post-treatment	12.03	7.05	17.90	6.34
One Month Follow-up	11.36	7.85	15.60	5.42

A series of 2 (Treatment Group) x 3 (Time) ANOVAs, with time as the repeated measure were conducted in order to examine the two treatment group's outcome over time, for each of the outcome measures listed in Table 3.7, for each of the outcome measures listed in Table 3.7.

Mauchley's test of sphericity was significant for the GDS ($\chi^2 (2) = 18.09, p < .001$) and as the sphericity measure was $< .75$ the Greenhouse-Geisser correction was used to adjust the degrees of freedom (df). Similarly, Mauchley's tests of sphericity for the CORE-Total was significant ($\chi^2 (2) = 7.81, p = < .05$) and as the sphericity measure was $> .75$ the Huynh-Feldt correction was used to adjust the degrees of freedom (d.f.). Mauchley's test was not significant for the GAI, the CORE-P, the CORE-F and the CORE-W. Therefore, no corrections were required for each of these measures⁸. The results of the repeated measures ANOVA are summarised in Table 3.8.

Table 3.8 highlights that there was a significant main effect of time (GDS: $F (1.53, 78.24) = 28.60, p < .001$; GAI: $F (2, 102) = 21.69, p < .001$; CORE-Total: $F (1.84, 93.81) = 17.24, p < .001$; CORE-W: $F (2, 102) = 3.09, p < .01$; CORE-P: $F (2, 102) = 15.02, p < .001$ and CORE-F: $F (2, 102) = 10.81, p < .001$) for all the outcome measures. This suggests that when the two treatment groups (i.e. BTB+TAU vs. TAU) are not considered, there was a significant reduction in all of the outcome measures over the course of treatment. Pairwise comparisons revealed that for each of the outcome measures there was a significant reduction between the pre-treatment and the post-treatment assessment points, and the pre-treatment and one month follow-up assessment points. There was, however, no significant difference between the post-treatment and one month follow-up assessment points on any outcome measure.

⁸ When the Greenhouse-Geisser and the Huynh-Feldt corrections were not applied to the GDS and CORE-total it did not affect whether or not the data reached statistical significance.

Table 3.8 Repeated measures ANOVA of time (pre-treatment, post-treatment, one month follow-up) by Group (BTB+TAU, TAU).

	Time (d.f.)		Time X Group (d.f.)		Group (d.f.)	
	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
GDS	28.60 (1.53, 78.24)	< .001	14.02 (1.53, 78.24)	< .001	5.17 (1, 51)	< .05
GAI	21.69 (2, 102)	< .001	5.09 (2, 102)	< .01	3.17 (1, 51)	.08 ns
CORE-total	17.24 (1.84, 93.81)	< .001	14.88 (1.84, 93.81)	< .001	2.79 (1, 51)	.10 ns
CORE-W	3.09 (2, 102)	< .01	6.75 (2, 102)	< .01	1.60 (1, 51)	.21 ns
CORE-P	15.02 (2, 102)	< .001	12.29 (2, 102)	< .001	3.67 (1, 51)	.06 ns
CORE-F	10.81 (2, 102)	< .001	7.76 (2, 102)	< .01	3.16 (1, 51)	.08 ns

Table 3.7 also shows there was a significant main effect of group for the GDS ($F(1, 51) = 5.17, p < .05$). For all the other outcome measures the main effect of group was non-significant (GAI: $F(1, 51) = 3.17, p = .08$ (ns); CORE-Total: $F(1, 51) = 2.79, p = .10$ (ns); CORE-W: $F(1, 51) = 1.60, p = .21$ (ns); CORE-P: $F(1, 51) = 3.67, p = .06$ ns; CORE-F: $F(1, 51) = 3.16, p = .08$ (ns)). This indicates that if time of assessment is not taken into account (i.e. pre, post, one month follow-up) then there were no significant differences between the two treatment groups on the outcome measures with the exception of the GDS. Analysis of the means indicates those in the BTB+TAU had significantly lower scores on the GDS than the TAU group when time of assessment is not considered.

Table 3.8 also highlights the significant time x group interactions for the GDS ($F(1.53, 78.24) = 14.02, p < .001$) the GAI ($F(2, 102) = 5.09, p < .01$) the CORE-Total ($F(1.84, 93.81) = 14.88, p < .001$) the CORE-W ($F(2, 102) = 6.75, p < .01$), the

CORE-P ($F(2, 102) = 12.29, p < .001$) and the CORE-F ($F(2, 102) = 7.76, p < .01$). These results suggest that for each of the outcome measures there was a significant difference in how the two treatment groups responded over time. These interactions are illustrated graphically in Figures 3.2, 3.3 and 3.4.

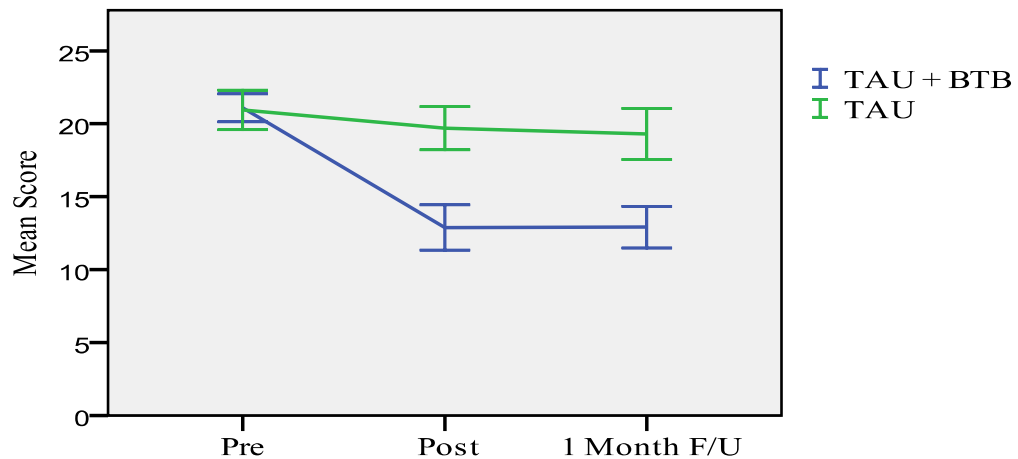


Figure 3.2 Mean GDS scores by treatment group over time

As there are only two treatment groups in the current study, *post hoc* tests to evaluate the interaction between treatment group and time were not produced by SPSS. As only one t-test is required to evaluate differences between the two treatment groups at the different assessment time points, this does not inflate the familywise error rate (Field, 2009). Therefore, independent t-tests were used to explore the interactions illustrated in Table 3.8.

For the GDS, independent t-tests showed a statistically significant difference between the BTB+TAU and the TAU group by the post treatment assessment point ($t(51) = 2.96, p < .01$) with the BTB+TAU group having significantly lower scores than the TAU group on the GDS. Effect sizes in favour of BTB+TAU over TAU by the end of

treatment were large ($d = .85$). These results suggest that, in comparison to the TAU group, the BTB+TAU group showed significantly greater improvements in their symptoms of depression by the end of treatment. Furthermore, these improvements were maintained by the one month follow-up point ($t(51) = 2.78, p < .01$). Effect sizes in favour of BTB+TAU over TAU at the one month follow-up point on the GDS were moderate ($d = .80$). As described previously, due to the design of the current study, interpretation of these results in terms of drawing any conclusions about the effectiveness of *BTB*, have to be treated with caution.

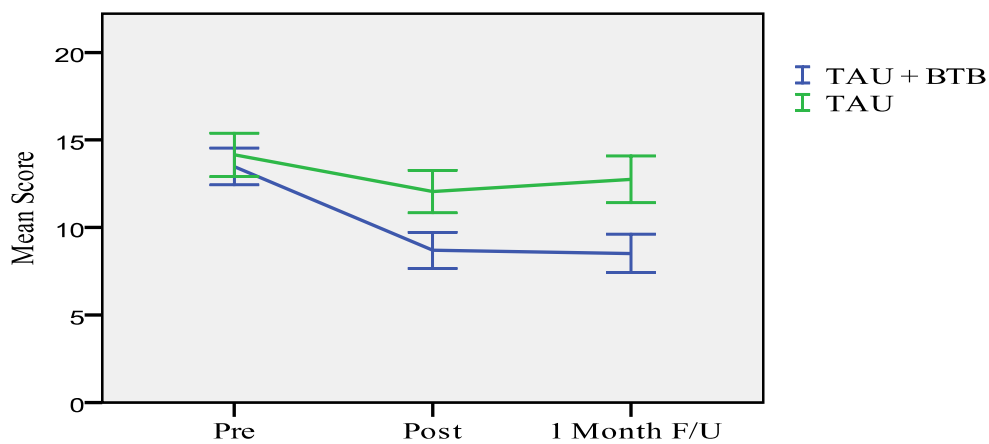


Figure 3.3 Mean GAI scores by treatment group over time

Independent t-tests on the GAI showed a significant difference between the BTB+TAU and the TAU group by the post treatment assessment point ($t(51) = 2.05, p < .05$) with the BTB+TAU group having significantly lower scores than the TAU group on the GAI. Effect sizes in favour of BTB+TAU over TAU at the end of treatment were moderate ($d = .59$). These results suggest that, in comparison to the TAU group, the BTB+TAU group showed significantly greater improvements in their symptoms of anxiety by the end of treatment. These improvements were maintained

by the one month follow-up point ($t(51) = 2.40, p < .05$). Effect sizes in favour of BTB+TAU over TAU on the GAI at the one month follow-up were moderate ($d = .69$). As described previously, due to the design of the current study, interpretation of these results in terms of drawing conclusions about the effectiveness of *BTB*, have to be treated with caution.

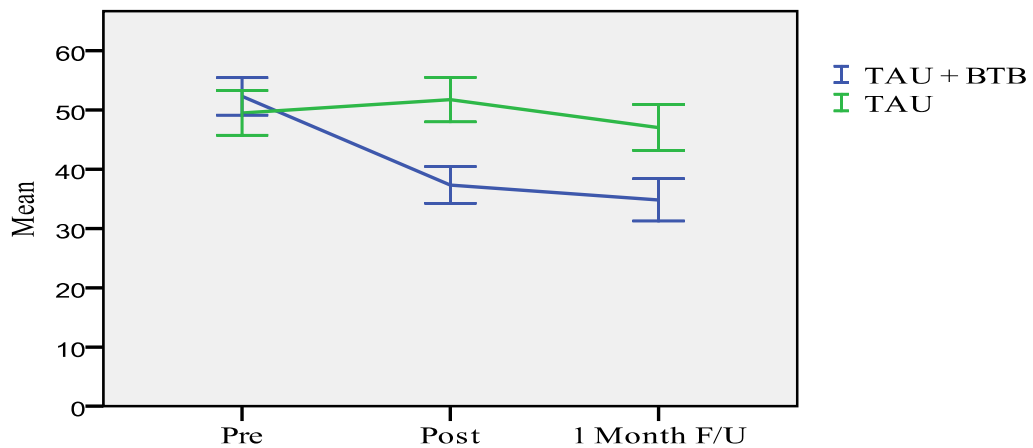


Figure 3.4 Mean CORE-total scores by treatment group over time

Independent t-tests on the CORE-Total showed a significant difference between the BTB+TAU and the TAU group by the post-treatment assessment point ($t(51) = 2.92, p < .01$) with the BTB+TAU group having significantly lower scores than the TAU group on the CORE-Total. Effect sizes in favour of BTB+TAU over TAU at the end of treatment were large ($d = .84$). This suggests that, in comparison to the TAU group, the BTB+TAU group showed significantly greater improvements in their symptoms over the course of treatment. These improvements were maintained by the one month follow-up point ($t(51) = 2.23, p < .05$). Effect sizes in favour of BTB+TAU over TAU on the CORE-Total at the one month follow-up were moderate ($d = .61$). As described previously, due to the design of the current study,

interpretation of these results in terms of drawing conclusions about the effectiveness of *BTB*, have to be treated with caution.

For the CORE-P subscale there was a significant difference between the TAU and BTB+TAU group by the end of treatment ($t(51) = 3.37, p < .001$) and at the one month follow-up assessment point ($t(51) = 2.01, p < .05$), indicating (in comparison to the TAU group) the BTB+TAU group showed significantly greater improvements over the course of treatment and at one month follow-up. A similar pattern was found with the CORE-F subscale, whereby there was a significant difference between the TAU and BTB+TAU group by the end of treatment ($t(51) = 3.37, p < .001$) and at the one month follow-up assessment point ($t(51) = 2.01, p < .05$), indicating that in comparison to the TAU group, the BTB+TAU group showed significantly greater improvements over the course of treatment and at one month follow-up. There were, however, no significant differences between the two treatment groups on the CORE-W subscale at the post-treatment ($t(51) = 1.78, p = .08$ ns) and the one month follow-up assessment points ($t(51) = 1.89, p = .065$ ns).

3.3.3.1 Multivariate Analysis

Due to the fact that several separate ANOVAs were conducted for each of the dependent variables (DV's) used in the study, this can potentially inflate the familywise error rate, particularly if there is a partial overlap in the underlying construct being examined by each of the DV's (Field, 2009). The use of Multivariate Analysis of Variance (MANOVA) helps reduce this by incorporating several dependent variables, which may share an association with each other, into a new overall dependent variable(s), that takes into account the participants scores on a

combination of dependent variables. Two MANOVAs were therefore conducted: firstly by incorporating the GDS, GAI and CORE-total scores to give an overall assessment of mood; and secondly by combining the subscales of the CORE (rather than separate ANOVAs for each subscale).

The results of the MANOVAs showed that there was a significant difference between the TAU group and the BTB+TAU group in terms of an overall assessment of their mood (GDS, GAI and CORE-total composite) with the BTB+TAU group having significantly lower scores ($F(3, 49) = 3.14, p < .05$; Pillai's Trace = .16) by the end of treatment. The same pattern of results was observed for the MANOVA incorporating the subscales of the CORE ($F(4, 49) = 5.19, p < .001$; Pillai's Trace = .30). These results appear to lend additional support to the main treatment effects reported in section 3.3.1.

3.3.4 Examination of Clinically Significant Improvement

The results thus far have been examined in terms of their statistical significance. However, Jacobson and Truax (1991) suggest statistical tests are used primarily to determine if a treatment effect actually exists (i.e. if the results are statistically significant in favour of a particular treatment it can be inferred that the findings are produced by the treatment, as opposed to by chance). However, Jacobson and Truax (1991) argue that statistically significant findings in favour of a particular treatment have little to do with the clinical significance of the treatment (i.e. the size and importance of what the treatment does in actual practice). These authors describe an example to illustrate this point, whereby a treatment for obesity results in a mean weight loss of 2lb; whilst a control condition results in a mean weight loss of 0lb.

Statistical analysis shows these results are significant in favour of the obesity treatment. However, the clinical significance of losing 2lb from a treatment can be questioned.

Jacobson and Truax (1991) therefore argue that following statistical examination, further analysis of outcome data is required in order to determine the clinical significance of any treatment effects. The most conservative method proposed by Jacobson and Truax (1991) is to assess whether a participant's outcome by the end of treatment is two standard deviations from the mean (in the direction of improvement) of the 'dysfunctional population' (i.e. the treatment group prior to starting treatment. This method was therefore used to determine the number of participants within each treatment group who did or did not meet clinically significant improvement criteria by the end of treatment and at one month follow-up). The methods outlined by Jacobson and Truax (1991) were also used in other studies of *BTB* to determine the clinical significance of the treatment (e.g. Cavanagh et al, 2006; Learmonth and Rai, 2008; Learmonth et al, 2008). The results are summarised in Table 3.8.

As can be seen from Table 3.8, in comparison to the TAU group, a significantly greater number of participants in the BTB+TAU group met criteria for clinically significant improvement on the GDS by the post treatment assessment point ($\chi^2(1) = 5.30, p < .05$) and by the one month follow-up assessment point ($\chi^2(1) = 7.18, p < .01$). Similarly, in comparison to the TAU group a higher percentage of participants in the BTB+TAU group met criteria for clinically significant improvement on the GAI and the CORE-Total, but these differences were not statistically significant. As described previously, due to the design of the current study, interpretation of these

results in terms of drawing conclusions about the effectiveness of *BTB*, have to be treated with caution.

Table 3.8 Number and percentage of participants who meeting criteria for clinically significant improvement by post treatment and one month follow-up

	BTB+TAU		TAU		Summary Statistics		
	Yes (%)	No (%)	Yes (%)	No (%)	χ^2	d.f.	<i>p</i>
By Post-Treatment							
GDS	13 (39.4)	20 (60.6)	2 (10)	18 (90)	5.30	1	.021
GAI	6 (18.2)	27 (81.8)	0 (0)	20 (100)	4.10*	1	.072 ns
CORE-T	5 (15.2)	28 (84.8)	0 (0)	20 (100)	3.34*	1	.144 ns
By 1 month F/U							
GDS	14 (42.4)	19 (57.6)	2 (10)	18 (90)	7.18	1	.007
GAI	9 (27.3)	24 (72.7)	1 (5)	19 (90)	4.03*	1	.070 ns
CORE-T	6 (18.2)	27 (81.8)	1 (5)	19 (90)	1.88*	1	.233 ns

*Fisher's exact test statistic was used due to expected frequencies < 5

3.4 EXAMINATION OF TAU RECEIVED BY PARTICIPANTS

3.4.1 Psychotropic Medication

A high percentage of participants (85 per cent) reported being prescribed psychotropic medication as part of the treatment as usual they were receiving at the start of the study. In terms of the classifications of psychotropic medication that was prescribed to participants, the majority reported receiving antidepressant medication (86.7 per cent). Twenty-four percent of participants were also prescribed benzodiazepine medication. There were no significant differences between the BTB+TAU group and the TAU groups in terms of the percentage of participants who were receiving psychotropic medication at the start of the study ($\chi^2 (1) = 2.55, p = .234$ (ns)). All participants reported being prescribed psychotropic medication for at least a month prior to the start of the study.

As the study was not primarily concerned with the specific effectiveness of psychotropic medications, specific details about the dosages or the prescription protocols were not collected as this was beyond the scope of what was possible in the study. Similarly, it was beyond the scope of the study to accurately assess participant adherence to medication or collect accurate details regarding changes in the prescribed dosage of medication. Information was, however, collected regarding whether participants continued to be prescribed and whether they reported continuing to take psychotropic medication. This revealed all participants who were prescribed psychotropic medication at the start of the study continued to take this by the end of the study. One participant who was not prescribed psychotropic medication at the start of the study reported being commenced on this by the end of the study. This participant was within the BTB+TAU group. They discontinued *BTB* after session four and overall had a poor treatment response in terms of reductions in their scores on the outcome measures.

3.4.2 Psychological Treatment

An exclusion criterion for the study was that participants should not be receiving face-to-face psychological therapy from an accredited therapist during their participation. Overall this was adhered to well, as monitored through examining incoming referrals to the clinical psychology department where participants would have been referred. However, two participants in the BTB+TAU group were referred for face-to-face psychological therapy. Both participants discontinued *BTB* (at session four and five respectively) before they were referred for face-to-face treatment. They had not received any face-to-face treatment sessions by the end of treatment assessment point.

Both participants reported receiving one assessment session by the one-month follow-up point.

3.4.3 Other Treatment as Usual Received

In terms of the other treatment as usual that was received by participants this tended to vary, which may have been the result of limited constraints being placed on this condition. An in-depth analysis of the additional treatment as usual that was received was limited by the information that was possible to obtain from the clinicians providing this treatment. As described in the previous sections, a high percentage of participants in both groups received psychotropic medications but did not receive active psychological therapy from an accredited therapist as part of their treatment as usual. These two aspects could be monitored accurately by examining the incoming referrals to the clinical psychology service that participants would have been referred to, and asking what medication they were prescribed at the end of treatment. In addition, 14 participants (11 in the TAU group and 3 in the BTB+TAU group) attended a day hospital. The primary purpose of this was reported as providing social support and advice regarding managing their difficulties. Six participants had contact with a psychiatrist (2 in the TAU group and 4 in the BTB+TAU group) at outpatient clinics with the primary purpose of reviewing medication. Lastly, 23 participants received contact with a Community Psychiatric Nurse, Support Worker or Care Manager. The primary purpose of these contacts was reported as social support and advice regarding managing their difficulties, including in some instances the provision of relaxation techniques.

CHAPTER 4 – DISCUSSION

4.1 RESEARCH OVERVIEW

Although a number of studies (Proudfoot *et al*, 2003b; Proudfoot *et al*, 2004; Grime, 2004; Cavanagh *et al*, 2006; Mitchell & Dunn, 2007; Learmonth & Rai, 2008; Learmonth *et al*, 2008; Cavanagh *et al*, 2011) have suggested that *Beating the Blues (BTB)* is an effective treatment for depression and anxiety with adults of working age, until now no study has examined the use of this treatment with older people in actual routine practice (but see Elsegood & Powell, 2008). The main purpose of conducting the current study was to begin to address this gap in the literature, with the primary focus on determining the acceptability and feasibility of the use of *BTB* with older people as well as beginning to tentatively examine whether it is an effective treatment for this population. The design of the study, however, means that interpretation of the results in relation to this latter area should be treated with a degree of caution. This is discussed further below. Specific aims of the study were to explore the acceptability of *BTB* with older people in terms of the rate of uptake of the treatment, determine some of the participant characteristics that influence the uptake of *BTB* with older people, explore the acceptability of *BTB* with older people in terms of the treatment discontinuation rate and finally to make an initial evaluation of whether *BTB* is an effective treatment in reducing symptoms of depression and anxiety in older people. Due to the design of the study, which was a pilot study primarily to examine the acceptability and feasibility of *BTB* with older people, any conclusions with regard to the treatments effectiveness should be treated with caution.

It was found that, when given a free choice of whether or not they wished to receive *BTB*, just over half the participants in the study (56.9 per cent) opted to receive this

treatment and completed at least one session (see Figure 3.1, page 101). It was also found that in comparison to those who declined to receive *BTB*, participants who agreed to receive this treatment reported having significantly more experience and confidence with using computers and were more likely to have the internet at home. They were also significantly younger (71.58 years vs. 75.55 years) and significantly more educated (11.70 years of education vs. 10.25 years of education). However, based on the mean values, the clinical importance of these latter two findings may be relatively small.

Participants who opted for *BTB* did not, however, appear to be any less ‘ill’ than those who declined *BTB* (i.e. participants in both groups did not significantly differ in terms of: 1) their psychiatric history; 2) the duration of their current episode; 3) whether they were currently taking psychotropic medication; 4) the number of co-morbid physical illnesses they reported; and 5) the severity of their symptoms of depression and anxiety prior to starting the study).

In terms of the rate of discontinuing *BTB* before the last session (27.3 per cent) the findings are similar to what has been found in previous research of *BTB* with adults of working age. (see section 4.3 below).

In terms of treatment outcome, the results indicated that, in comparison to the TAU group, those in the *BTB*+TAU had significantly greater reductions in their symptoms of depression and anxiety over the course of treatment and after a one month follow-up. This could suggest *BTB* (combined with treatment as usual) may be more efficacious than treatment as usual alone in reducing symptoms of depression and

anxiety in older people. Such a conclusion should, however, be treated with a degree of caution due to the methodology used in the current study, which did not randomly allocate participants to the treatment groups. The fact that participants were able to choose which treatment group they wished to be part of may suggest that the participants in the BTB+TAU group were highly motivated and keen to receive this treatment. It could be argued that this may have facilitated their treatment outcome (in comparison to the impact *BTB* would have when there was an even number of participants who were not as motivated to use this treatment). This potentially limits the extent to which the findings can be generalised to the wider population (i.e. including individuals who may not be as motivated to receive this treatment) and means any conclusions made about the effectiveness of *BTB* should be treated with caution.

In addition, compared to those in the TAU group, significantly more participants (39 per cent) in the BTB+TAU group showed clinically significant reductions in their symptoms of depression as measured by the GDS by the end of treatment and after one month follow-up. There were also more participants in the BTB+TAU group compared to the TAU group who reported clinically significant improvements in their symptoms of anxiety as measured by the GAI at the end of treatment and at one month follow-up, although the difference in the numbers of participants achieving clinically significant improvements between the two groups was not statistically significant. A similar pattern was found on the CORE-total.

All these findings are discussed in greater detail below with reference to the results from previous research. Each of the aims of the study will be discussed in sequence

and the clinical relevance of the findings will be highlighted together with the implications for future research and service provision. The strengths and limitations of the study will also be discussed.

4.2 UPTAKE OF *BTB* WITH OLDER PEOPLE

4.2.1 Context

The first aim of the study was to explore the acceptability of *BTB* to older people in terms of the number of participants who, when given a free choice, firstly agreed to take part in the study and then subsequently opted to receive *BTB*, relative to those who agreed to take part but declined to receive *BTB*. A similar methodology has been used for exploring the acceptability and effectiveness of group versus face-to-face CBT for treating anxiety in adults of working age (Sharp *et al*, 2004). This has also been advocated as a methodology that should be incorporated into future studies of CCBT to explore its acceptability (Kaltenthaler *et al*, 2006).

Kaltenthaler *et al* (2008) highlight that there has been a lack of research that has focused on the acceptability of CCBT and what little there has been has often involved satisfaction surveys (often with participants who have completed the full course of treatment). It could be argued that any findings using this method may be biased as they may not take into account the views of those dropping out of treatment, or the individuals who refused to participate at all. The current study therefore contributes to the limited evidence base on the acceptability of *BTB* and is the first to explore this specifically with older people in actual practice.

Kaltenthaler *et al* (2008) also argue that the first step in evaluating the acceptability of CCBT should be to explore the rate of uptake of this treatment. More specifically, the reason for this is that even if a treatment is found to be effective in reducing a particular problem, if no one accepts it when it is offered it is likely to have little clinical use. Kaltenthaler *et al* (2008) define the rate of uptake as the percentage of individuals who agree to begin CCBT relative to the total number of individuals who are approached and who decline. This approach to exploring the acceptability of *BTB* is particularly important with regard to the viability of *BTB* with older people, where previously a common assumption has been that older people will not accept CCBT packages such as *BTB*, despite some limited evidence to the contrary (Elsegood & Powel, 2008).

An important point in relation to the uptake rate as an index of a treatments acceptability is that the uptake rate in an RCT may be confounded by the fact that participants do not receive a choice regarding the treatment they receive. The rate of uptake in an RCT is therefore defined by the number of individuals agreeing to participate in the study relative to the number who decline to participate. However, it has been highlighted that refusal to participate in a study may be a reflection of a reluctance to participate in any study, regardless of the treatment, rather than finding a specific treatment unacceptable (Kaltenthaler *et al*, 2008). Refusal to participate in an RCT could also potentially be a result of an individual finding the control condition unacceptable, rather than finding the specific treatment under investigation unacceptable. Exploring the rate of uptake in an RCT can therefore potentially under-represent the uptake rate of a treatment in actual practice, unless specific reasons for non-participation are explored. This has rarely been reported in previous research of

BTB. The only study of *BTB* that specifically discusses this issue is Grime (2004), where it was found that some individuals refused to participate in the study, as their employer would have to be informed they were taking part. It could be argued that such a reason for non-participation is not about finding *BTB* unacceptable *per se*, but rather finding the conditions of the study unacceptable. The detailed exploration of reasons for non-participation, however, raises ethical and practical issues as it is an ethical requirement that individuals do not have to give reasons for non-participation, and they may be reluctant to provide any reasons. Indeed, Grime (2004) found that only 42 per cent of non-participants gave reasons for not wishing to take part, which may therefore bias any conclusions that can be drawn from using this method.

4.2.2 Uptake Rates of *BTB*

The current study found that, in terms of the total number who agreed to participate in the study, 65.5 per cent opted to receive *BTB*. However, it was evident that five of these participants dropped out of the study prior to attending their first session of *BTB* (and without completing any treatment outcome measures). These individuals were removed from any subsequent treatment outcome analysis. A more conservative analysis of the uptake rate, which includes only those who attended at least one session of *BTB*, indicated that 56.9 per cent was therefore found with older people in the current study. This is compared to what has been found in previous research of *BTB* with adults of working age in Table 4.1.

As can be seen from Table 4.1, the uptake rate of 56.9 per cent found in the current study is lower than what is found in previous studies, with only Grime (2004) reporting a lower uptake rate (30.9 per cent). As discussed previously, the low uptake

rate found in the study by Grime (2004) may have been in part a result of some potential participants finding the conditions of the study unacceptable.

Table 4.1 Uptake rates of *BTB*

Study	Total Approached & Eligible for <i>BTB</i>	Total Starting <i>BTB</i> / Participating in RCT	Uptake Rate
Proudfoot <i>et al</i> (2004)*	406	274 (146 <i>BTB</i>)	67.5%
Grime (2004)	155	48 (24 <i>BTB</i>)	30.9%
Van den Berg <i>et al</i> (2004)	not reported	13	not reported
Cavanagh <i>et al</i> (2006)	not reported	219	not reported
Mitchell & Dunn (2007)	12	12	100%
Learmonth & Rai (2008)	not reported	104	75%**
Learmonth <i>et al</i> (2008)	829	555	67%
Cavanagh <i>et al</i> (2011)	432	295	68.2%
Current study	58	33	56.9%

*this included data from Proudfoot *et al* (2003b) as Proudfoot *et al* (2004) was a combined analysis.

**This uptake rate was reported as an approximation by Learmonth & Rai (2008) but they did not state exactly how many individuals were offered *BTB*

A discussion of participant characteristics that may influence the rate of uptake of *BTB* found in the current study is presented in section 4.2.4. Despite a lower uptake rate of *BTB* in the current study compared to previous research on *BTB*, the uptake rate found in the current study is, however, comparable to a recent RCT exploring face-to-face CBT for treating depression in older people where an uptake rate of 55.5 per cent was found (Laidlaw *et al*, 2008).

4.2.3 Participant Characteristics Influencing Uptake of *BTB*

The second aim of the study was to explore the characteristics of participants that influence whether or not they opted to receive *BTB*. Previous research on *BTB* has been limited in terms of evaluating the characteristics of individuals that may influence whether or not participants agree to start *BTB*. Cavanagh *et al* (2011) explored this in a population of working age adults by comparing the ethnicity, age, gender, current use of psychotropic medication, presence of chronic physical health

conditions and pre-treatment severity of depression, anxiety and general wellbeing, in those who met their study inclusion criteria and started *BTB*, to those who met the inclusion criteria but opted not to complete any *BTB* treatment sessions. The results indicated that there were no significant differences between the two groups on any of these characteristics. They did, however, find a significant difference in terms of clinical ‘caseness’, whereby individuals who scored above clinical cut-offs on the outcome measures were more likely to start *BTB* than those who scored below these cut-offs (Cavanagh *et al*, 2011).

Grime (2004) also reported on the age and gender characteristics of working age adults who declined to participate in an RCT of *BTB* with adults of working age, but did not compare these characteristics to those who did agree to participate. Grime (2004) did, however, describe some of the reasons individuals gave for not wishing to participate and highlights that only a minority declined to participate due to a specific reluctance regarding using *BTB* itself (e.g. disliking computers or thinking *BTB* would be unhelpful). The primary reasons for non-participation were reported to relate more to individuals feeling they could not take time off work to travel to appointments and feeling anxious about their employer finding out about their participation or being unsupportive. The full extent of these findings should be treated with caution, as reasons from only 42 per cent of non-participants were obtained, which could potentially mean other reasons for non-participation were not identified. Nevertheless, many of the findings that were reported for non-participation would be less applicable to older people (i.e. being unable to take time off work).

In the current study, as described previously, it was found that in comparison to those who declined to receive *BTB*, participants who agreed to receive this treatment reported having more experience and confidence with using computers and were more likely to have the internet at home. They were also significantly younger (71.58 years vs. 75.55 years) and significantly more educated (11.70 years of education vs. 10.25 years of education). These findings are fairly consistent with what would be expected and the clinical importance of the latter two findings may be relatively minor, due to relatively small differences between the actual mean values.

These findings can help inform the types of patients who are currently more likely to accept *BTB*, but more importantly highlight areas that could be targeted to help increase the likelihood of individuals who may benefit from *BTB* being willing to try it. This could potentially help bring the uptake rate with older people more in line with what has been found with younger age cohorts. For example, it was evident that overall, individuals with lower reported levels of confidence in using a computer were less likely to accept *BTB*. A future expansion could be to develop a computer skills training course to help increase older people's confidence and experience in using a computer prior to *BTB* being offered. A potential barrier may be that individuals who are inexperienced and lack confidence may be reluctant to try such a course. However, a qualitative study by the Office of Communications (Ofcom, 2006), which explored older peoples use of computer technology and the internet, highlighted that the majority of older people who did not use computers were classified as 'disengaged' rather than 'rejecters' (i.e. the disengaged non-users would be willing to learn to use computer technology given the right circumstances and if the correct support was provided, as opposed to the 'rejecters' who had no wish at all to learn

such skills). This study highlighted that computer training courses designed and run by older people could potentially help other older people who have little computer experience become more engaged. It could also be argued that this will become less and less of an issue in the coming years, as larger cohorts of individuals who are experienced in using a computer will reach the age of 65 years. In line with this, data from the Office for National Statistics (Randall, 2010) suggests that the number of older people who have access to an internet connection in their home has risen by 26 per cent in the year 2000 to 2008. This may be assisted further by UK government initiatives to increase individuals having access to the internet and computer technology (Lane, 2010; Scottish Government, 2011), with a specific focus on marginalised groups such as older people.

A further important finding in relation to the characteristics of the participants who opted for *BTB* were not, however, any less 'ill' than those who declined *BTB* (i.e. participants in both groups did not significantly differ in terms of: 1) their psychiatric history; 2) the duration of their current episode; 3) whether they were currently taking psychotropic medication; 4) the number of co-morbid physical illnesses they reported; and 5) the severity of their symptoms of depression and anxiety at the start of the study as assessed by their scores on the outcome measures prior to starting treatment. These findings challenge any assumptions that older people with, for example, more physical health problems will be reluctant to try new treatments such as *BTB*. An argument could also be made that it is older individuals who may have more physical health conditions that may make them less mobile than younger populations, where treatments such as *BTB*, which can be done over the internet in their own home, may be most accessible. The findings that those declining *BTB* were no more ill than those

accepting *BTB* is also in line with the findings from study by the Office of Communications (2006), which found individuals who did not use computer technology were no more ill than those who did use it.

An important point to make is that although the current study identified a profile of some of the characteristics that may influence whether older people opt to receive *BTB*, this is by no means exhaustive. Future research could explore other characteristics that may influence the uptake of *BTB*, such as perceptions about the credibility of the treatment or individuals' expectations for how much they perceive it would help treat their symptoms of depression and anxiety, which have been factors associated with uptake and outcome from CCBT (de Graff *et al*, 2009). In addition, the characteristics found in the current study should not be used as exclusion criteria for denying the option of receiving *BTB* to individuals deviating from these characteristics. Indeed, it was found that a minority of individuals with no experience or confidence in using a computer and with no access to the internet at home still opted to receive *BTB* and completed all eight sessions. This could indicate another underlying characteristic that is an important mediating factor that influences whether older people accept *BTB*. A further area that could be explored is whether levels of self-efficacy play a role in influencing the acceptability of *BTB*. At present the obtained profile can be useful for identifying some of the targets for intervention that may improve the acceptability of *BTB* to older people.

4.3 RATES OF DISCONTINUATION OF *BTB*

The third aim of the study was to explore the discontinuation rate of *BTB* with older people as this is another aspect that relates to the acceptability of a treatment

(Kaltenthaler *et al*, 2008). Of the 33 participants who started *BTB* nine participants subsequently discontinued using the program before the eighth session, giving a discontinuation rate of 27.3 per cent. Table 4.2 summarises the discontinuation rates, together with the mean number of sessions that were completed prior to discontinuation, for the other studies that have examined *BTB* with adults of working age to allow a comparison with the current study.

Table 4.2 Discontinuation rates of *BTB*

Study	Discontinuation Rate	Mean number of sessions completed prior to discontinuation
Proudfoot <i>et al</i> (2004)*	27.4%	not reported
Grime (2004)	33.3%	3.1
Van den Berg <i>et al</i> (2004)	0%**	not reported
Cavanagh <i>et al</i> (2006)	38.4%	not reported
Mitchell & Dunn (2007)	16.7%	3.5
Learmonth & Rai (2008)	31.7%	3.8
Learmonth <i>et al</i> (2008)	29%	3.5
Cavanagh <i>et al</i> (2011)	47.1%	not reported
Current study	27.3%	3.3

*this included data from Proudfoot *et al* (2003b) as Proudfoot *et al* (2004) was a combined analysis.

**This should be treated with caution as the authors only reported on a cohort of 12 participants who had completed all 8 sessions of *BTB*

As can be seen from Table 4.2, the discontinuation rate found in the current study is comparable to what has been found in previous studies of *BTB*. If the study by Van den Berg *et al* (2004) is not included, the mean discontinuation rate for the studies reporting on this issue is 31.9 per cent. The rate found in the current study is slightly below this at 27.3 per cent.

It was also evident that the average number of sessions at which participants drop-out is between the third and fourth session. It could also be argued that the modal number of sessions at which participants discontinue *BTB* would also be helpful to analyse. In the current study the modal session at which participants discontinued was session

four. It was not, however, possible to calculate the modal value at which participants discontinued *BTB* in any of the other studies listed in Table 4.2. It may be helpful to explore further in future research the sessions at which participants discontinue *BTB*, for example, to examine whether or not there are particular aspects of the program that increases the likelihood of discontinuing (e.g. is there particular aspects at session 3 - 4 that some participants find off putting). This could potentially be undertaken with qualitative methods to try and gain more in-depth information about participants reasons for discontinuing *BTB*.

Within the current study it was evident that there was a range of reasons participants gave for discontinuing *BTB*, with all but two participants reporting a different reason (see Table 3.4, p 94). It was, however, noted that only one participant who discontinued *BTB* reported that they found *BTB* unhelpful and another reported that the computer was too difficult to use. The reasons provided by participants do, however, need to be treated with a degree of caution, as a detailed exploration of the reasons for discontinuing treatment was beyond the scope of the current study. It was also an ethical requirement that participants did not have to provide reasons for discontinuing, although in the current study many participants spontaneously provided brief reasons for discontinuing *BTB*. Kaltenthaler *et al* (2008) have advocated that future research should use detailed qualitative methodologies to explore factors such as participants experience of using *BTB* and factors that relate to discontinuing treatment early, as there is a paucity of information about this. The current study provides some initial relevant information with older people. Ethical approval has been obtained for a follow-up study that will use qualitative methods to explore these

factors in more detail with participants from the current study, as well as reasons that may have influenced their decision as to whether or not to opt for *BTB*.

It was also apparent in the current study that a higher percentage of participants in the BTB+TAU group discontinued *BTB* than the percentage of participants in the TAU group who dropped out of the study. The differences were not, however, statistically significant.

4.4 TREATMENT OUTCOME – Secondary aim

The secondary aim of the study was to begin to tentatively explore the effectiveness of *BTB* for treating symptoms of depression and anxiety in older people, with the caution that the study was primarily a pilot study and not a controlled effectiveness study. The results showed that, in comparison to the TAU group, the BTB+TAU group had statistically, and clinically significant, greater improvements in symptoms of depression and anxiety by the end of treatment and at one month follow-up. The results also suggested that there were not significant differences found between the two groups in the content or amount of treatment as usual that was received (e.g. in comparison to the TAU group the BTB+TAU did not have a higher proportion of participants who were prescribed psychotropic medication). This limits the extent to which the significant differences found between the two groups, in terms of treatment outcome, could be accounted for by differences in the treatment as usual that was received. However, given the fact that participants were not randomly allocated to the treatment groups, combined with the non-specific and variable nature of treatment as usual, any interpretation about the extent to which the significant differences in symptoms of depression and anxiety between the two groups are attributable to *BTB*,

rather than also being influenced by other factors, should be treated with caution. This issue is discussed further in the strengths and limitations section below.

In addition, there did not appear to be any evidence suggesting that the TAU group was any more ‘unwell’ than the BTB+TAU group at the start of the study, as indexed by no significant differences between the two groups on pre-treatment levels of symptomatology, previous psychiatric history, use of concurrent psychotropic medication, number of co-morbid physical health problems and duration of current episode of illness.

Table 4.3 summarises the main findings reported in previous studies of *BTB* with adults of working age in terms of the treatment effect sizes and percentages of participants meeting criteria for clinically significant improvement.⁹ This allows a comparison of the treatment effects found in the current study to previous research on *BTB*. As can be seen from Table 4.3, uncontrolled effect sizes and *BTB* compared to treatment as usual effect sizes ranged from .62 to .85 in favour of *BTB* for treating depression. This suggests *BTB* has a moderate to large treatment effect on symptoms of depression. The effect size of .80 in the current study is comparable to what has been found in the previous studies of *BTB* listed in Table 4.3 and suggests that it is no less effective with older people than with adults of working age for treating depression. A similar pattern can also be seen in terms of effect *BTB* has upon the CORE-total.

⁹ All effect sizes and clinically significant improvement percentages were based on ITT samples (rather than completers samples when both were reported) at the end of treatment, to facilitate comparison with the current study.

Effect sizes on measures of anxiety were generally smaller across the previous studies of *BTB* listed in Table 4.3 that reported this, ranging from .37 to .90. The effect size in the current study of .59 compares favourably to the previous studies with younger adults (Proudfoot *et al*, 2003b; Proudfoot *et al*, 2004; Grime, 2004; Mitchell & Dunn, 2007; Learmonth *et al*, 2008; Cavanagh *et al*, 2011). The fact that *BTB* appears to have less of an effect upon anxiety is possibly a reflection of the content of the program, which may be more targeted towards the treatment of symptoms of depression rather than anxiety.

As highlighted in Table 4.3, an analysis of clinically significant improvements has only been made in four previous studies of *BTB* (Cavanagh *et al*, 2006; Learmonth & Rai; 2008; Learmonth *et al*, 2008; Cavanagh *et al*, 2008) and only the latter two studies report this specifically in relation to depression. The findings of clinically significant improvements in symptoms of depression in 39.4 per cent of participants in the current study compares favourably to the 21 per cent reported by Learmonth *et al* (2008) but is slightly below the 50 per cent reported by Cavanagh *et al* (2011). The fact that approximately 40 per cent of the sample in the current study met criteria for clinically significant improvements in their symptoms of depression, as measured by the GDS, by the end of treatment and at one month follow-up highlights the potential clinical impact this treatment may offer in actual clinical practice.

The results of the current study do, however, highlight that a majority of participants did not meet criteria for clinically significant improvements on measures of depression. An important aspect in relation to this is that the *BTB* package that was used was in no way modified or adapted for use with older people. Laidlaw and

Table 4.3 Summary of results from previous research on *BTB*¹⁰

Study	Index	Effect Size	% of participants achieving clinically significant improvement
Proudfoot <i>et al</i> (2004)*	Depression (BDI)	.62	not reported
	Anxiety (BAI)	.38	not reported
	CORE-Total	na	not reported
Grime (2004)	Depression (HADS)	.85	not reported
	Anxiety (HADS)	.43	not reported
	CORE-Total	na	not reported
Van den Berg <i>et al</i> (2004)	Depression	na	na
	Anxiety	na	na
	CORE-Total	1.1	not reported
Cavanagh <i>et al</i> (2006)	Depression	na	na
	Anxiety	na	na
	CORE-Total	.50	38%
Mitchell & Dunn (2007)	Depression (BDI)	.67	not reported
	Anxiety (BAI)	.37	not reported
	CORE-Total	na	na
Learmonth & Rai (2008)	Depression	na	na
	Anxiety	na	na
	CORE-Total	.82	48.6%
Learmonth <i>et al</i> (2008)	Depression (BDI)	.72	21%
	Anxiety (BAI)	.55	19%
	CORE-Total	na	na
Cavanagh <i>et al</i> (2011)	Depression (PHQ-9)	.80	50%
	Anxiety (GAD-7)	.90	50%
	CORE-Total	.60	not reported
Current study	Depression (GDS)	.80	39.4%
	Anxiety (GAI)	.59	18.2%
	CORE-Total	.84	15.2%

*this included data from Proudfoot *et al* (2003b) as Proudfoot *et al* (2004) was a combined analysis.

McAlpine (2008) highlight that there “remains a persistent question regarding the issue of modification and adaptation of CBT with older people” (p 251), despite a number of meta-analyses suggesting it is an equally efficacious treatment for

¹⁰ The effect sizes for Proudfoot *et al* (2004) and Grime (2004) were not reported in the respective papers but were calculated using Cohen’s *d* (Mean (treatment) – Mean (control) / SD (pooled)) as per the method used in the current study. The remainder of the studies, which did not employ a control condition, reported calculating their uncontrolled effect sizes by: Mean (pre) – Mean (post) / SD (start).

depression in older people as it is for younger adults. Indeed, as discussed above the current study produced outcomes with older people that are comparable to studies of BTB with younger adults. Laidlaw and McAlpine (2008) suggest that despite such findings “it is interesting to speculate whether outcome could be enhanced if modifications, which take into account gerontological models of aging, are incorporated” (p 251). These authors, however, highlight that older people represent a heterogeneous group and that modifications to an already efficacious treatment should be based on need rather than age. However, they also suggest that conceptual modifications, rather than procedural modifications, that take into account the aging process may help enhance outcomes from CBT with older people. Laidlaw and McAlpine (2008) suggest six conceptual issues that can be incorporation into the basic model of CBT that may enhance its use with older people including “1) incorporation of a comprehensive conceptualisation framework; 2) understanding the different time-frame older people operate within; 3) achieving goal-focussed optimized coping with loss experiences; 4) focussing on maintenance rather than cause in treatment; 5) understanding differences between generations (cohort); and 6) the assessment of suitability” (p 252).

Somewhat paradoxically to the arguments made by Laidlaw and McAlpine (2008) described above, it was evident that as the version of *BTB* used in the current study was not adapted for use with older people (e.g. only one of the case study video vignettes used to illustrate key points in the treatment involves an older person). This leads to a hypothesis as to whether adapting the current version of *BTB* to include more vignettes specifically with older people would be helpful in further facilitating outcomes. Although this veers more towards a procedural change than a conceptual

change, (which Laidlaw and McAlpine (2008) argue are not necessarily required in using CBT with older people), it was something that a number of the participants in the current study commented upon. It is possible that having a greater range of case study vignettes including a larger number of older people, incorporating differing older people age cohorts, may be more reflective of the heterogeneous nature of older people. This could potentially help illustrate some of the conceptual issues outlined by Laidlaw and McAlpine (2008). For example, it may allow different cohorts of older people and their differences to be more effectively incorporated into the treatment.

In terms of the CORE-total and GAI, a smaller percentage of participants receiving *BTB* met clinically significant improvement criteria for these (15.2 and 18.2 per cent respectively), in comparison to the percentage meeting clinically significant improvement criteria on the GDS (39.4 per cent). This may lend further support to the suggestion that *BTB* is not as effective in treating symptoms of anxiety, compared to depression, particularly in older people as such disparities between the clinical impact of *BTB* on depression and anxiety were not found in two other studies which reported this with adults of working age (Cavanagh *et al*, 2011; Learmonth *et al*, 2008).

However, of note, within the current study there were relatively large standard deviations on the CORE-total, which meant the criteria for reaching clinically significant improvement on this measure was very conservative. Similarly, the criterion for meeting clinically significant improvement on the GAI was extremely conservative and was well below the clinical cut-off defined by the developers of this measure for differentiating individuals within the normal range and clinical range (i.e. some individuals moved from above the clinical cut-off range at the start of treatment

to below this by the end of treatment and were within the normal range on this measure but still did not reach criteria for clinically significant improvement). This could suggest that some participants in the current study may have reported anxiety symptoms on the GAI within the normal range by the end of treatment but may not have reached criteria for clinically significant improvement, which may attenuate the findings in terms of the number of participants achieving clinically significant change on the GAI.

4.5 STUDY STRENGTHS AND LIMITATIONS

Despite the findings outlined above, there were a number of limitations in the current study that should be noted. An argument could be made that as the study did not employ an RCT, which is often classed as the ‘gold standard’ of treatment outcome research, this could reduce the extent to which the results can be attributable to *BTB* as the lack of randomisation may have meant confounding variables were not evenly distributed between the two groups. For example, it was evident that there were significant differences between the two groups in terms of participants’ age and years of education, with the BTB+TAU group being significantly younger and more educated. Similarly, in comparison to the TAU group, the BTB+TAU group reported being significantly more confident and experienced in using a computer. Given that patients were also able to self-select which treatment group they wished to be part of, it could be argued that, although it was not directly measured in the current study, those participants who actively opted (as opposed to being randomly allocated) to receive *BTB* were highly motivated about using this treatment. All of these factors could have potentially facilitated the outcomes obtained by participants in the BTB+TAU group (i.e. as opposed to what would be found in groups comprising of

randomly and evenly distributed participants in terms of their experience and confidence in using a computer and their motivation in using *BTB*). This means any conclusions about the effectiveness of *BTB* in the current study have to be treated with caution.

There was, however, some evidence to suggest that some important factors that could have affected outcome were evenly distributed between the two groups. For example, there were no significant differences between the groups on baseline levels of anxiety or depression, the reported duration of their current episode, the number of reported physical health problems, the use of psychotropic medication etc.

As the group receiving *BTB* in the current study reported significantly higher confidence and experience in using a computer than those who declined *BTB*, this may limit the extent to which the findings can, at present, be generalised to those reporting low-levels of confidence and experience with using a computer. As noted previously, the methodology and design of the current study limits any conclusions that can be drawn about the effectiveness of *BTB* with older people. However, as the use of *BTB* with older people is an emerging research area the current study was an important initial step in providing some evidence towards demonstrating the acceptability and feasibility of the use of this treatment with older people. Future research could explore more rigorously the effectiveness of *BTB*, for example using an RCT, given that the results of the current study would lend support to the feasibility of this. As mentioned previously, future areas of development could also explore interventions to increase older peoples confidence in using computers and then evaluate if this increases the uptake of *BTB* and subsequently leads to the same

levels of improvements in those who initially reporting low levels of confidence in using a computer.

Despite the potential for the design of the current study to include participants who had a strong preference to receive *BTB* being allocated to this treatment condition, which may facilitate the obtained outcome in favour of this treatment, the use rather than an RCT has a number of advantages in terms of the other aims of the study. It allowed an understanding of the percentage of older people who are likely to accept *BTB* when given a free choice about whether to receive it, which is more reflective of what would occur in actual practice. It also allowed a pragmatic evaluation of how acceptable this treatment is likely to be with older people in terms of the discontinuation rate and the clinical outcome achieved. As these areas were unknown prior to this study the feasibility of an RCT was unknown (i.e. it was not clear if older people would agree to be randomised to *BTB*). The current study could therefore be considered as a pilot study, demonstrating the acceptability and feasibility of the use of *BTB* with older people, that provides support for a larger scale RCT to be conducted. This would help identify if the results of the current study can be generalised to wider populations of older people and would allow firmer conclusions to be made regarding the efficacy of the treatment with older people. This could stratify allocation to treatment groups based on the levels of reported experience and confidence in using a computer. A future RCT could also employ additional control conditions that test non-specific aspects of the *BTB* treatment, such as the use of a potentially enjoyable computer program. Alternatively, it could explore the differential impact of another treatment patients are likely to have the option to receive in actual clinical practice i.e. face-to-face psychological treatment.

In relation to the previous point regarding the feasibility of an RCT, the current study was relatively small in scale in terms of the number of participants (i.e. only 58 participants were recruited). However, the obtained effect sizes were moderate to large, in line with previous research comparing *BTB* to treatment as usual with younger adults and meta-analyses of psychological treatments with older people. In addition, the significant findings obtained suggest that a type II error was avoided (*post hoc* power = .87 for depression and .65 for anxiety). The relatively small numbers recruited is also reflective of a number of other published studies evaluating psychological treatments with older people. For example, Laidlaw *et al* (2008) recruited 40 participants for their RCT examining face-to-face CBT with older people. Furthermore, a meta-analysis of 25 published studies examining psychological treatments for depression in older people (Cuijpers *et al*, 2006) highlighted that 14 of these studies has sample sizes that were smaller than the current study. However, it should be noted that many of these studies employed a range of designs, had different study durations, recruited participants with differing levels of severity and some were multi-site. This means that drawing direct comparisons, in terms of the number of recruited participants, should be treated with a degree of caution.

One of the major limitations of the current study was that longer-term follow-ups were not obtained, meaning no conclusions can be drawn regarding the long-term benefits of receiving *BTB*. Within the constraints of the time frame of the current study it was only possible to obtain one month follow-ups and the findings suggested that *BTB* treatment benefits were maintained. Ethical approval has, however, been obtained for longer-term follow-ups and this is in the process of being completed at present.

It could be argued that the use of clinical cut-off scores for inclusion into the study (rather than diagnostic criteria) was a limitation of the study, as this potentially created a more heterogeneous sample. This could mean that the findings are limited in terms of the specific diagnostic categories to which the results apply. However, the use of clinical cut-offs as inclusion criteria has been widely used in previous research of *BTB*, with only Proudfoot *et al* (2003b) and Proudfoot *et al* (2004) using diagnostic criteria. It was evident in the current study that all participants scored above the clinical cut-offs on measures of depression, with the pre-treatment mean score in both groups being just within the 'severe' range. Similarly, the majority of participants scored above the clinical cut-off on the anxiety measure, with the pre-treatment mean in both groups being within the 'clinical' range, suggesting high levels of symptomatology in both groups with a high degree of co-morbidity. The use of clinical-cut offs on measures of symptomatology is reflective of what would typically occur in everyday practice and is in line with the goals of the primary purpose of CBT for older people as advocated by Laidlaw and Thompson (2008), which is symptom reduction.

Another limitation of the study relates to the mean age of those participating in the study, which was 73.43 years with a range of 65 to 83 years. This means that older people within the 'oldest-old' age cohorts were not included in the study, despite no upper age limit being imposed. This limits the extent to which the results of the current study can be generalised to older age cohorts of older people. However, this is reflective of a number of other studies examining psychological treatments with older people, where there is less evidence with 'older old' age groups (Cuijpers *et al*, 2009).

Cuijpers *et al* (2009), for example, in their meta-analysis, highlight that the mean age of participants in 20 studies examining psychological treatment for depression in older people was 69.28 years. Although these authors highlight some individual studies reported a mean age of up to 81.4 years they suggest the majority of the studies (15 of the 20) included in their analysis reported mean ages of less than 70 years. This trend has been reduced to a certain extent by two recent RCTs exploring CBT for treating depression in older people, whereby Laidlaw *et al* (2009) reported 50 per cent of their participants were over 75 years (mean = 74 years) and Serfaty *et al* (2009) reported the mean age of their participants as 74.1 years. Within the current study it was evident that those who declined to participate were significantly older (mean = 78.32 years, range = 68 to 88 years) than those who participated. This may suggest that 'older old' age cohorts at present may be less likely to take part in a research study exploring *BTB* than younger old people. Within the current study it was not possible to examine reasons for non-participation in the study, which may have helped inform why older old people did not wish to take part. It may be helpful for future research to specifically explore the attitudes of older old age cohorts toward *BTB*, which may help inform areas that could be targeted to help increase the likelihood of these individuals taking part in such research.

A final limitation of the current study to note here was that it did not specifically explore participant satisfaction with using *BTB*, other than through indexes of this (i.e. the uptake rate, the discontinuation rate and the reasons for discontinuing). One method that could have been used was to employ a satisfaction survey. A potential weakness of this method is that the findings can be biased, as those dropping-out due to dissatisfaction may be unlikely to respond to any such questionnaires. It could also

be argued that more rich and detailed information can be obtained regarding satisfaction with *BTB*, as well as a number of other factors associated with the experience of using the program using qualitative methods (i.e. through interviewing participants). A study is currently being undertaken using this method with participants from the current study.

4.6 FUTURE RESEARCH

Throughout the previous sections a number of areas for future research have been mentioned, for example, introducing an initial basic computer skills training course to examine if this will increase the uptake rate of *BTB* with older people and exploring participants outcome at longer term follow-up, to gain a better understanding of any enduring benefits of the program.

A particular area that would be a welcome addition to the literature on *BTB* would be to use qualitative methods to gain a more in-depth understanding of a number of factors associated with the use of *BTB* with older people. In particular, a greater understanding of the factors that influence the decision-making process of older people (in terms of whether or not they opt to receive *BTB*) would be helpful, in terms of making adaptations that may increase the acceptability of the treatment. Similarly, a greater understanding of the factors that influence older people deciding to discontinue treatment (as well as the overall experience of using *BTB*), may also help inform how the program can be improved, which may in turn improve its efficacy. A follow-up qualitative study to explore each of these areas is currently being undertaken with participants from the current study, including those who opted not to

receive *BTB*, those who did opt to receive it but discontinued, and those who completed all eight sessions.

It may also be helpful for future research to use qualitative methods to explore the attitudes of clinicians who work with older people towards *BTB*. Anecdotal evidence from the current study has suggested that a minority of clinicians did not approach any patients about their possible participation. Some limited research had been conducted on this and has suggested that clinicians often have much poorer attitudes towards CCBT than patients, although no study has explored this with reference specifically to older people. A greater understanding of the factors that may prevent clinicians from offering older people the chance to use *BTB* may help provide areas for intervention that may help to reduce any barriers to accessing this treatment.

Given the promising findings of the current study, which could be regarded as a pilot study that has provided initial evidence regarding the effectiveness of *BTB* and has demonstrated the feasibility of its use with older people, a larger scale RCT would be welcome to examine in greater detail the efficacy of *BTB* with older people. In order to complete this an application for a Chief Scientific Office grant is in the early stages of development.

4.7 CONCLUSION

Despite some of the limitations of the current research, by exploring *BTB* with a clinical population of older people experiencing depression and anxiety, it was the first study to begin to address a major gap in the literature. The findings of the study provide some initial evidence to suggest that *BTB* is an acceptable and feasible

treatment for use with older people. The findings of the study also indicate that, in comparison to those who chose not to receive *BTB*, participants who used *BTB* obtained both statistically and clinically significant reductions in their symptoms of depression by the end of treatment and at one month follow-up. Although conclusions about these latter findings have to be treated with caution, with more research being required to further develop these initial findings, *BTB* appears to offer one potential treatment option to help address the fact that with an aging population there is likely to be an increase in demand upon under-resourced services to provide psychological treatments for older people experiencing depression and anxiety.

An important final point to make is that although there is growing evidence for the use of self-help treatments such as *BTB*, such treatments are advocated to be employed within matched care-service models (i.e. as first line treatments with patients with appropriate levels of difficulties). The importance of adequately trained clinicians, such as clinical psychologists, (who in addition to direct therapeutic skills have advanced training in research, evaluation of services and treatments, and supervision and training of other clinicians), are still extremely important within stepped/matched care service models and cannot be replaced with computer packages. Specialist older people clinical psychologists are small in number relative to other services, such as adult mental health, and nationally are well below what is stated to be required, based on the size of the population (Wells *et al*, 2010). The introduction of *BTB* to older people services can help ensure older people can be provided with an evidence-based psychological treatment in the context of increased demands for such services. However, the provision of adequate numbers of clinical psychologists specialising in working with older people is essential.

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