Helping people to help themselves: the development and evaluation of a non-clinical, peer-supported eTherapy model in the management of anxiety and depression in adults.

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Abbreviations

ACT	Acceptance and Commitment Therapy
AI	Artificial Intelligence
APA	American Psychiatric Association
BA	Behavioural Activation
BDD	Body Dysmorphic Disorder
BFO	Breaking Free Online
BME	Black & Minority Ethnic
BtB™	Beating the Blues
CBT	Cognitive Behavioural Therapy
cCBT	Computerised Cognitive Behavioural Therapy
CMD	Common Mental Disorder
CORE-OM	Clinical Outcomes in Routine Evaluation-Outcome Measure
dCBT	Digital Cognitive Behavioural Therapy
DHTs	Digital Health Technologies
DSM-5®	Diagnostic and Statistical Manual of Mental Disorders 5®
eTC	eTherapy Co-ordinator
GAD	Generalised Anxiety Disorder

GAD-7	Generalised Anxiety Disorder assessment (7 item measure)
GP	General Practitioner
IAB	Impact Assessment Briefing
IAPT	Improving Access to Psychological Therapies
IAPT MDS	Improving Access to Psychological Therapies Minimum Data Set
ICD-10/11	International Classification of Diseases 10^{th}/11^{th} Revision
IPT	Interpersonal Therapy
ISRII	International Society for Research on Internet Interventions
LGBTQQIAAP	Lesbian, Gay, Bisexual, Transgender, Queer, Questioning, Intersex, Allies, Asexual, Pansexual
LLTTF	Living Life to the Full
LOCF	Last Observation Carried Forward
MADD	Mixed Anxiety Depressive Disorder
MDD	Major Depressive Disorder
MDE	Major Depressive Episode
NHS	National Health Service

NICE	National Institute for Health and Care Excellence (formerly National Institute of Clinical Excellence)
OCD	Obsessive Compulsive Disorder
PCTQ-P	Perceptions of Computerized Therapy Questionnaire - Patient Version
PHQ-9	Patient Health Questionnaire (9 item measure)
PTSD	Post-Traumatic Stress Disorder
PWP	Psychological Wellbeing Practitioner
PSW	Peer Support Worker
RCT	Randomised Controlled Trial
SAD	Social Anxiety Disorder
SOP	Service Operating Procedure
TAU	Treatment as Usual
TD-cCBT	Transdiagnostic computerised Cognitive Behavioural Therapy
TS	Third Sector
TSO	Third Sector Organisation
VR	Virtual Reality
WSAS	Work and Social Adjustment Scale
WHO	World Health Organization

Acknowledgements

This thesis has significance in that it completes a period of study commenced many years ago, which was cut short due to the onset of agoraphobia in my early 20s. As a direct consequence, I sadly had to discontinue a PhD level in the field of renal physiology, causing my life to dramatically change course. Unwittingly, I ended up in the field of mental health where I have remained to date, working in senior management roles, though more recently, I have ventured into the clinical world; training in Cognitive Behavioural Therapy (CBT), Compassion Focused Therapy (CFT), Eye Movement Desensitisation and Reprocessing (EMDR) and counselling.

Alongside being Chief Executive of Anxiety UK for over 25 years, I founded the user-led charity, Self Help Services, in 1995, with the aim of providing support for those experiencing anxiety and depression, through provision of accessible, peer-supported services. Throughout my career, I have instigated and overseen the development and delivery of a range of services from peer-led, drop-in support groups, primary care clinical mental health clinics, and regional crisis services – "The Sanctuary," – through to a nationally recognised eTherapy model, which is the subject of this thesis. I am passionate about ensuring that those with anxiety and depression obtain timely and appropriate access to support; something that was not available to me when I first began experiencing agoraphobia.

This thesis would not have been possible without the support and encouragement of my family: Pete, Natalia, and Kingsley. They have consistently motivated me, over the years, to make the best out of my challenges with anxiety; driving me to use this experience for the benefit of others.

Sincere thanks must also be given to my supervisory team, who have been a constant source of guidance, encouragement, and inspiration over the period of study. On this, I would like

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Declaration

This thesis includes a portfolio of publications that have been published in peer-reviewed journals, found in Appendix 1. The author's original contribution, verified by the collaborating authors, can be found in Appendix 2.

Signed:  Date: 26th February 2021

Abstract

eTherapy interventions have widened access to evidence-based psychological therapies, particularly Cognitive Behavioural Therapy (CBT) since their introduction to primary care mental health services over a decade ago. Whilst the effectiveness of eTherapy programmes has been established and, to a degree, the acceptability of eTherapy has been strong, there are a paucity of studies undertaken in real-world settings. Even more scarce is research on service delivery models that utilise non-clinicians and instead, individuals with lived experience of mental health conditions, in the provision of support.

This portfolio of seven published works and thirteen supporting publications - two books, one book chapter, eight papers and two articles - makes a unique contribution to eTherapy literature by detailing the development and evaluation of a non-clinical, peer-supported model of eTherapy in the treatment of adults experiencing anxiety and depression in a real-world setting.

Collectively, the publications provide a body of knowledge that suggest that this novel *model* of pragmatic eTherapy service delivery is effective, acceptable, and capable of generating results equivalent to those generated by low intensity Improving Access to Psychological Therapy (IAPT) services. Furthermore, this *model* supports the widening of access to services and provision of an evidence-based, much-needed treatment for those affected by anxiety and depression, as well as for clients affected by sleep and dual diagnosis issues.

Papers included in the Portfolio of Published Works

Throughout the portfolio, research papers included in the submission will be cited in bold (e.g., **Lidbetter & Bunnell, 2013**) to distinguish such papers from other citations. The research papers listed below can be found in Appendix 1.

(1) Cavanagh, K., Seccombe, N., Lidbetter, N., & Bunnell, D. (2011a). Supported, service-user led, computerised cognitive behavioural therapy (CCBT) self-help clinics. *Journal of Public Mental Health*, 10(4), 225-233.

(2) Cavanagh, K., Seccombe, N., & Lidbetter, N. (2011b). The Implementation of Computerized Cognitive Behavioural therapies in a Service User-Led, Third Sector Self Help clinic. *Behavioural and Cognitive Psychotherapy*, 39(4), 427-442.

(3) Lidbetter, N., & Bunnell, D. (2013). Self Help Services: helping people to help themselves. *Mental Health and Social Inclusion*, 17(2), 76-81.

(4) Elison, S., Ward, J., Davies, G., Lidbetter, N., Hulme, D., & Dagley, M. (2014). An outcomes study of eTherapy for dual diagnosis using Breaking Free Online. *Advances in Dual Diagnosis*, 7(2), 52-62.

(5) Elison, S., Ward, J., Williams, C., Espie, C., Davies, G., Dugdale, S., Ragan, K., Chisnall, L., Lidbetter, N. & Smith, K. (2017). Feasibility of a UK community-based, eTherapy mental health service in Greater Manchester: repeated-measures and between-groups study of 'Living Life to the Full Interactive,' 'Sleepio™' and 'Breaking Free Online' at 'Self Help Services.' *BMJ Open*, 7(7).

(6) Luik, A. I., Bostock, S., Chisnall, L., Kyle, S. D., Lidbetter, N., Baldwin, N., & Espie, C. A. (2017). Treating depression and anxiety with digital cognitive behavioural therapy for insomnia: a real world NHS evaluation using standardized outcome measures. *Behavioural and Cognitive Psychotherapy*, *45*(1), 91-96.

(7) Gellatly, J., Chisnall, L., Seccombe, N., Ragan, K., Lidbetter, N., & Cavanagh, K. (2018). @ Home eTherapy service for people with common mental health problems: an evaluation. *Behavioural and Cognitive Psychotherapy*, 46(1), 115-120.

Supporting articles included in the Portfolio of Published Works

In addition to the seven papers constituting the published works, there are 13 supporting works including papers, a newspaper and magazine article, and two short books that provide additional information on anxiety, eTherapy, and telephone-delivered therapy in the treatment of anxiety and depression. To aid with identification, supporting works appear in bold italics throughout the thesis (e.g., ***Lidbetter, 2020***) and are listed below:

(8) Lidbetter, N., (2003). The stigmatisation of anxiety disorders. In A. Crisp (Ed.). *Every Family in the Land* (pp. 52-53). London: Royal Society of Medicine Press Ltd.

(9) Bee, P. E., Lovell, K., Lidbetter, N., Easton, K., & Gask, L. (2010). You can't get anything perfect: "User perspectives on the delivery of cognitive behavioural therapy by telephone." *Social Science and Medicine*, 71(7), 1308-1315.

(10) Lidbetter, N., & O'Neill, C. (2010). Anxiety: falling between primary and secondary care. *Mental Health Today (Brighton, England)*, 17

(11) Baldwin, D. S., Anderson, I. M., Nutt, D. J., Allgulander, C., Bandelow, B., Den Boer, J. A.., Christmas, D., Davies, S., Fineberg, N., Lidbetter, N., Malizia, A., McCrone, P., Nabarro, P., O'Neill, C., Scott, J., van der Wee, N. & Wittchen, H-U. (2014). Evidence-based pharmacological treatment of anxiety disorders, post-traumatic stress disorder and obsessive-compulsive disorder: A revision of the 2005 guidelines from the British Association for Psychopharmacology. *Journal of Psychopharmacology*, 28(5), 403-439.

(12) Gellatly, J., Bower, P., McMillan, D., Roberts, C., Byford, S., Bee, P., Gilbody, S., Arundel, C., Hardy, G., Barkham, M., Reynolds, S., Gega, L., Mottram, P., Lidbetter, N., Pedley, R., Peckham, E., Connell, J., Molle, J., O'Leary, N & Lovell, K. (2014). Obsessive Compulsive Treatment Efficacy Trial (OCTET) comparing the clinical and cost effectiveness of self-managed therapies: study protocol for a randomised controlled trial. *Trials*, 15(1), 278.

(13) Slawson, N. (2016, 24 May). Nicky Lidbetter: 'My anxiety has been a motivator.' *The Guardian.* Retrieved from https://www.theguardian.com/society/2016/may/24/icky-lidbetter-my-anxiety-has-been-motivator-mental-health

(14) Lovell, K., Bower, P., Gellatly, J., Byford, S., Bee, P., McMillan, D., Arundel, C., Gilbody, S., Gega, L., Hardy, G., Reynolds, S., Barkham, M., Mottram, P., Lidbetter, N., Pedley, R., Molle, J., Peckham, E., Knopp-Hoffer, J., Price, O., Connell, J., Heslin, M., Foley, C., Plummer, F. & Roberts, C. (2017a). Clinical effectiveness, cost-effectiveness and acceptability of low-intensity interventions in the management of obsessive-compulsive disorder: the Obsessive-Compulsive Treatment Efficacy randomised controlled Trial (OCTET). *Health Technology Assessment*, 21(37), 1-132.

(15) Lovell, K., Bower, P., Gellatly, J., Byford, S., Bee, P., McMillan, D., Arundel, C., Gilbody, S., Gega, L., Hardy, G., Reynolds, S., Barkham, M., Mottram, P., Lidbetter, N., Pedley, R., Molle, J., Peckham, E., Knopp-Hoffer, J., Price, O., Connell, J., Heslin, M., Foley, C., Plummer, F & Roberts, C. (2017b). Low-intensity cognitive-behaviour therapy interventions for obsessive-compulsive disorder compared to waiting list for therapist-led cognitive-behaviour therapy: 3-arm randomised controlled trial of clinical effectiveness. *PLoS Medicine*, 14(6), E1002337.

(16) Kenning, C., Blakemore, A., Bower, P., Safari, M., Cuijpers, P., Brown, J. S., Hann, M., Lidbetter, N., Muñoz, R, F. & Waheed, W. (2019). Preventing depression in the community by voluntary sector providers (PERSUADE): intervention development and protocol for a parallel randomised controlled feasibility trial. *BMJ Open*, 9(10), E023791.

(17) Lidbetter, N. (2020a). Understanding Anxiety: An Anxiety UK self help guide. Manchester: Anxiety UK. Retrieved from https://www.anxietyuk.org.uk/products/anxiety-condition/anxiety/new-understanding-anxiety-booklet-instant-download/

(18) Lidbetter, N. (2020b). The Caregivers Guide to Anxiety. Manchester: Anxiety UK. Retrieved from https://www.anxietyuk.org.uk/products/anxiety-condition/anxiety/the-caregivers-guide-to-anxiety-instant-download/

(19) McMillan, D., Bee, P., Lidbetter, N., Lukoseviciute, B. (2020). Telephone therapy is convenient and it works. Let's use it more. Retrieved from https://psyche.co/ideas/telephone-therapy-is-convenient-and-it-works-lets-use-it-more

(20) Rushton, K., Ardern, K., Hopkin, E., Welsh, C., Gellatly, J., Faija, C., Armitage, C., Lidbetter, N., Lovell, K., Bower, P. & Bee, P. (2020). 'I didn't know what to expect': Exploring patient perspectives to identify targets for change to improve telephone-delivered psychological interventions. *BMC Psychiatry*, 20, 1-13.

Introduction

The aim of this thesis is to describe the development and evaluation of a non-clinical, fully peer-supported eTherapy model, referred to hereinafter as the '*model*', in the management of anxiety and depression in adults in the community.

The key objectives were to:

1 Examine the development of the *model*

2 Review and evaluate the clinical effectiveness of the *model*

3 Evaluate the acceptability of the *model*

The thesis is split into 6 sections:

- **Section one** sets the context for the thesis by providing an overview of the definition, prevalence, and treatment in England available through the National Health Service (NHS) for anxiety and depression, including the role of third sector providers in the delivery of IAPT and eTherapy services.

- **Section two** provides an overview of eTherapy in the treatment of anxiety and depression, the evidence base and clinical effectiveness, client acceptability and service delivery models, including peer support in eTherapy.

- **Section three** provides the background and rationale for the published works, thesis aim and objectives, contribution to knowledge made by the included articles and an overview of the non-clinical, peer-supported eTherapy *model*.

- **Section four** provides an overview and critique of the publications individually and by thesis objective.

- **Section five** examines ethical considerations, methodology and limitations, the pragmatic paradigm and personally reflects on the thesis.

- **Section six** summarises key outcomes, makes recommendations for future research and service development, and provides an overall conclusion to the thesis.

Section One: Definition and overview of anxiety and depression

In this section, an overview of anxiety and depression (including common terminology) is provided, along with prevalence rates, treatment options available in England, and the role of the Third Sector (TS) and Third Sector Organisations (TSOs) in the provision of services. This section demonstrates the versatility of, place within current mental health services for, and need for, eTherapy, given the substantial number of individuals affected by anxiety and depression.

1.1 Common mental disorders and terminology

Common mental disorders (CMDs) are depressive and anxiety disorders (McManus, 2016) including Mixed Anxiety Depressive Disorder (MADD), where anxiety and depression are experienced in limited and equal intensity (Kara, 2000).

From hereinafter, the terms 'anxiety' and 'depression' are used instead of CMD. Anxiety means all forms of 'anxiety disorder' including, but not limited to, Generalised Anxiety Disorder (GAD), perinatal anxiety, panic disorder, phobias, Post-Traumatic Stress Disorder (PTSD), and Obsessive-Compulsive Disorder (OCD). Depression means all forms of depressive disorder including Major Depressive Disorder (MDD) and dysthymia. Bipolar and psychotic depression are excluded from the thesis' scope as neither are treated in primary care IAPT services.

1.2 Anxiety

Anxiety is characterised by anticipation about perceived future threats (Craske & Stein, 2016), comprising behavioural, motivational, somatic, affective, and cognitive complexities

(Price, 2003), often leading to persistent impairment in functioning and stigmatisation (Curcio & Corboy, 2020; ***Lidbetter, 2003***). Adults seeking treatment usually have anxiety that interferes with their ability to cope with life events and challenges (Steimer, 2002). Though clinical levels of anxiety can occur at any age, most anxiety disorders begin during childhood, adolescence, and early adulthood (Klein & Pine, 2001).

Craske and Stein (2016), see Table 1, give key signs and symptoms of anxiety. The World Health Organization (WHO) (2017a) define anxiety as a chronic condition comprising psychological, behavioural, and physical symptomatology ***(Lidbetter, 2020a)*** impacting on family and friends, as well as the individual that is directly affected ***(Lidbetter, 2020b).***

There are numerous anxiety disorders ***(Lidbetter, 2020a)*** with similar behavioural manifestations; however, enquiry about cognitions and associated beliefs typically facilitates a definitive diagnosis (Craske & Stein, 2016).

Diagnosis of anxiety in England is made by General Practitioners (GPs) via the Diagnostic and Statistical Manual of Mental Disorders 5® (DSM -5®), American Psychiatric Association [APA] (2013), and the International Classification of Diseases 11th Revision [ICD-11] (WHO, 2018a). Symptom severity is typically measured via the GAD-7 clinical outcome measure (Spitzer, Kroenke, Williams & Lowe, 2006). Whilst diagnosis may help clients gain understanding of their experience, an unintended consequence of diagnostic classification systems is that they do not always reflect lived experience (Hackman et al., 2019).

The IAPT approach itself can be viewed as a medical model of psychological therapy (Binnie, 2015). This reductionist and disablist approach is often viewed as problematic since it views clients as a complicated mixture of anatomical components and physiological systems (Aggleton & Chalmers, 2000); emphasising biochemical dysfunction as the reason behind poor health, focussing on the presence of illness (Jeffery, 2006) and attributing it to a

sole cause within the body (Wade & Halligan, 2017). Those with lived experience of mental health conditions can feel disempowered by the medical model's emphasis on healing from mental health conditions being firmly in the hands of medics, contributing to perceived power imbalances (Gutkin, 2012) as opposed to recovery being something that clients can own and lead on. Additionally, the medical model can result in the medicalisation of human experience and in stigmatisation, discrimination and labelling of those with mental health difficulties (Beresford, Nettle & Perring, 2010). This contrasts with the experiences of many who despite living with anxiety and depression, demonstrate that it is possible to lead a full and meaningful life **(Lidbetter & Bunnell, 2013).**

Though the British Psychological Society's Division of Clinical Psychology (DCP) gave a position statement on the need for a paradigm shift, moving away from diagnosis being based on a disease model to a relational conceptualisation where the role of relationships in shaping experience, behaviour and healing from distress is recognised (Johnstone et al., 2018), medical models of psychological therapy practice still persist (BABCP, 2020). The IAPT paradigm and epistemological framework has been adopted for the purposes of this thesis, as it remains the key initiative through which psychological therapies in England are delivered. Furthermore, whilst the approach has its limitations as detailed above, it was appropriate and relevant to use given the need to demonstrate the meeting of commissioner targets which were quantitative in nature.

Table 1: Key signs and symptoms of anxiety disorders (Craske & Stein, 2016).

Anxiety disorder type	**Key signs and symptoms as per Diagnostic and Statistical Manual of Mental Disorders, 5 - DSM-5® (APA, 2013) and International Classification of Diseases [ICD-10] (WHO, 2017b)**

Separation anxiety disorder	• Marked fear or anxiety about separation from attachment figures to a degree that is developmentally inappropriate • Persistent fear or anxiety about harm coming to attachment figures and events that could lead to loss of, or separation from, them • Reluctance to leave attachment figures • Nightmares and physical symptoms of distress • The symptoms usually develop in childhood, but can develop throughout adulthood as well DSM-5® (APA, 2013) • A four-week duration is required for diagnosis in childhood, whereas a longer duration, typically of at least six months, is required in adulthood DSM-5® (APA, 2013)
Selective or elective mutism	• Consistent failure to speak in specific social situations (e.g., school) where an expectation to speak exists, despite speaking in other situations • Not limited to interactions with adults • Not explained by absence of familiarity with the spoken language • Persists for at least one month (e.g., beyond the first month of school)
Specific phobia	• Marked fear, anxiety, or avoidance of circumscribed objects or situations: DSM-5® (APA, 2013) states that the fears should be out of proportion to the danger posed; ICD-10 (WHO, 2017b) specifies recognition that the symptoms are excessive or unreasonable • Types of specific phobias include animals (e.g., spiders, insects, dogs), the natural environment or natural forces (e.g., heights, storms, water), blood injection injury (e.g., needles, invasive medical

	procedures), situational (e.g., aeroplanes, lifts, enclosed places), and other (e.g., situations that could lead to choking or vomiting; in children, loud sounds, or costumed characters)
Social anxiety disorder (social phobia)	• Marked fear, anxiety, or avoidance of social interactions and situations that involve being scrutinised or being the focus of attention, such as being observed while speaking, eating, or performing in front of others: DSM-5® (APA, 2013) specifies that the fear or anxiety should be out of proportion to the threat posed; ICD-10 (WHO, 2017b) specifies recognition that the symptoms are excessive or unreasonable • Fear negative judgment from others and, in particular, being embarrassed, humiliated, or rejected, or offending others • ICD-10 (WHO, 2017b) specifies physical symptoms and symptoms of blushing, fear of vomiting or urgency, or fear of micturition or defecation • A subset have social anxiety in performance situations only (e.g., performing in front of an audience)
Panic disorder	• Recurrent, unexpected (i.e., without an apparent cue) panic attacks* • DSM-5® (APA, 2013) specifies persistent concern or worry about having more panic attacks or changed behaviour in maladaptive ways (e.g., avoidance of exercise or unfamiliar locations) • Persistent, for at least one month
Agoraphobia	• Marked fear, anxiety, or avoidance of two or more of the following situations: DSM-5® (APA, 2103): public transportation (e.g., travelling in automobiles, buses, trains, ships, aeroplanes), open spaces (e.g., carparks, marketplaces, bridges), enclosed places (e.g., shops,

	theatres, cinemas), queues or crowds, or being outside of home alone; for ICD-10 (WHO, 2017b), the situations are crowds, public places, travelling alone, and travelling away from home: DSM-5® (APA, 2013) specifies that the fear or anxiety should be out of proportion to the threat posed; ICD-10 (WHO, 2017b) specifies recognition that the symptoms are excessive or unreasonable • DSM-5® (APA, 2013) specifies fear that escape might be difficult, or help might not be available in the event of panic-like or other incapacitating or embarrassing symptoms (e.g., incontinence); ICD-10 (WHO, 2017b) lists panic symptoms only
Generalised anxiety disorder	• Marked anxiety and worry, more days than not, about various domains, such as work and school performance, which the individual finds difficult to control, for at least six months • At least three DSM-5® (APA, 2013) or four ICD-10 (WHO, 2017b) physical symptoms: restlessness or feeling keyed up or on edge, easily fatigued, difficulty concentrating, irritability, muscle tension, sleep disturbance (i.e., difficulty falling or staying asleep or unsatisfying sleep), and symptoms of autonomic arousal - ICD-10 (WHO, 2017b)
Anxiety disorders associated with another medical condition	• Marked fear or anxiety that is the direct physiological consequence of another medical disorder
Substance-induced or medication-induced anxiety disorder	• Marked fear or anxiety due to substance intoxication or withdrawal, or due to drug treatment

Illness anxiety disorder (hypochondriasis)†	• Preoccupation with having or acquiring a serious, undiagnosed medical illness • For DSM-5® (APA, 2013) the somatic symptoms are either not present or only mild in intensity (if they are present, the diagnosis of somatic symptom disorder could be applied) • For ICD-10 (WHO, 2017b), preoccupation might be with presumed deformity or disfigurement (body dysmorphic disorder (BDD) in DSM-5® (APA, 2013)

1.3 Depression

Depression is associated with psychological, physical, and behavioural symptoms including fatigue, reduced cognitive functioning, appetite changes, suicidal ideation, feelings of guilt and/or worthlessness, sadness, loss of interest in life and daily activities, and sleep disturbances (APA, 2013).

Depressive disorders are split into two categories (WHO, 2017a):

(1) Major Depressive Disorder (MDD) – includes any number and severity of symptoms detailed above, often categorised by severity and associated with poor physical health outcomes (Knol et al., 2006; Luppino et al., 2010). Negative life events are often followed by depression (Brown & Harris, 1978; Hammen, 2005), suggesting their role in the development of depression (Joormann & Stanton, 2016).

(2) Dysthymia – mild depression which may be chronic or persistent. Symptoms are like those of a depressive episode but of a lesser intensity and lasting longer.

Depression is likely to re-occur following an episode of depression (Solomon, 2000), and is the leading cause of global disability (WHO, 2017a) and a known risk factor for suicide (Gagnon & Oliffe, 2015). It is diagnosed, like anxiety, via the DSM-5® (APA, 2013) or the

International Classification of Diseases, 10th edition (WHO, 1993) with severity of depressive symptoms typically measured using the Patient Health Questionnaire (PHQ-9) clinical outcome measure (Kroenke, Spitzer & Williams, 2001). To obtain a diagnosis of depression, five or more symptoms, including lowered mood, must be experienced (Tolentino & Schmidt, 2018) – see Table 2.

Depression is often considered a heterogeneous diagnosis (National Institute for Clinical Excellence - NICE, 2009) because of frequent co-morbidity with anxiety (Tyrer, 2001) and sedentary behaviour (Zhai, 2015a), over or under sleeping (Zhai, 2015b), and long-term stress (Slavich, 2014) all increasing its risk.

Table 2: Diagnostic criteria for depression (APA, 2013).

Five (or more) of the following symptoms should be present nearly every day during the same two-week period, and one of the symptoms must be either a depressed mood or loss of pleasure/interest in daily activities. Symptoms must also reach clinically significant levels resulting in an adverse impact on an individual's ability to function in work and/or social life.
• Depressed mood • Markedly diminished interest or pleasure in (almost) all activities • Significant weight loss or gain; decrease or increase in appetite • Insomnia or hypersomnia • Psychomotor agitation or retardation • Fatigue or loss of energy • Feelings of worthlessness or excessive or inappropriate guilt • Diminished ability to think or concentrate, or indecisiveness

- Recurrent thoughts of death, suicidal ideation, or a suicide attempt or a specific plan for completing suicide

Diagnosis of depression is challenging (Tyrer, 2009) because of chronicity and severity permeations (Klein, 2008), heterogeneity (Rush, 2007), cultural differences in experience (Haroz et al., 2017), and reliance on clinical judgement (Liu & Jiang, 2016).

ICD-10 (WHO, 2017) and DSM-5® (APA, 2013) categorise depression on the occurrence of a single episode of depression, a major depressive episode – MDE. Recurrent depression is common (Boland & Keller, 2008); defined by DMS-5® (APA, 2013) and ICD-10 (WHO, 2017b) as two or more episodes with at least two months in between each episode, during which the criteria for depression is not met. MDD in DSM-5® (APA, 2013) equates to an individual having had one or more MDE. When anxiety is present, depression is less likely to be detected within primary care (Thompson et al., 2000). Subthreshold depression - when symptoms are insufficient to meet diagnostic criteria - is often observed at community level and is a risk factor for the development of more severe depression ***(Kenning et al., 2019)***.

Late-life depression (adults aged 50-70 years) compared with early-life depression (adults aged 18-49 years) is similar in terms of phenomenology, though older adults are likely to have more somatic symptoms (Hegeman et al., 2012).

1.4 Prevalence of anxiety and depression

Anxiety disorders are common **(**Kessler, Ruscio, Shear & Wittchen, 2009) with a global prevalence of 7.3% (Baxter et al., 2014), and highest prevalence in Euro-Anglo cultures (Baxter, Scott, Vos & Whiteford, 2013); possibly explained by cultural and subsequent

differences in expression (Hofman & Hinton, 2014). Those aged under 35 are more likely to experience anxiety, irrespective of country of origin and culture (Baxter et al., 2013; Somers et al., 2006; Steel et al., 2014), except in Pakistan, where anxiety affects those of middle age more (Mirza & Jenkins, 2004). In the UK, 8.2 million cases of anxiety were reported (Fineberg et al., 2013). Women are twice as likely to be diagnosed with anxiety (Martín-Merino, Ruigómez, Wallander, Johansson, & García-Rodríguez, 2009) and epidemiological surveys suggest a lifetime prevalence of 16.6-21.3% (Kessler et al., 2005; Kessler & Bromet, 2013).

Anxiety in the community is more common than depression (Buszewicz & Chew-Graham, 2011); however, numbers of correct anxiety diagnoses in primary care are low (Fernández et al., 2012; Vermani, Marcus & Katzman, 2011) where there is a high prevalence ranging from 8-20% (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007; Mergl et al., 2007; Qin et al., 2010; Serrano-Blanco et al., 2010).

Depression has a global prevalence of ~4.7% (Ferrari et al., 2013), with 5% of adults in developed countries meeting diagnostic criteria for MDD (Wells & Fisher, 2016).

In the UK, 22.5% of females aged 16 years and over in 2014 showed symptoms of anxiety or depression, compared to 16.8% of males (Evans, 2016), and women are twice as likely to experience depression than men (Kuehner, 2017). This is reflected in services where men are much less likely to access psychological therapy support (Men's Health Forum, 2020).

Both anxiety symptoms and anxiety conditions (Melartin et al., 2002) are prevalent in those experiencing depression, with as many as 80% having symptoms of anxiety and over half having a diagnosable anxiety disorder; demonstrating the high comorbidity in existence between the two conditions (Grobler, 2013).

Finally, anxiety and depression have been linked to reduced quality of life in those with and without additional health problems (Cerne et al., 2013; Comer et al., 2011; Mols, Schoormans, de Hingh, Oerlemans & Husson, 2018; Stevanovic, Jancic & Lakic, 2011), with depression presentations predicted to be the leading cause of disability in countries of high income by 2030 (Mathers, 2005). It is therefore critically important that those affected by anxiety and depression receive treatment in a timely manner, and that treatment options are increased.

1.5 Treatment of anxiety and depression in England

Anxiety and depression are typically diagnosed and treated in primary care (Toft et al., 2005), with most seeking help from their GP (Cape & Parham, 1998), though detection of anxiety is often insufficient (Buszewicz & Chew-Graham, 2011). Only 33% with depression or anxiety receive help in England (McManus et al., 2016), with many not seeking help (Thornicroft, 2007; Wang et al., 2007). Those requiring support over and above what a GP can offer are given low intensity treatments initially (Bennett-Levy et al., 2010), however many with anxiety continue to fall between primary and secondary care, having presentations that are considered too severe for primary care yet not severe enough to warrant access to secondary care services ***(Lidbetter & O'Neill, 2010)***.

NICE guidelines for anxiety and depression (NICE, 2004a, 2004b, 2006, 2009; National Collaborating Centre for Mental Health, NICE & British Psychological Society, 2011) recommend psychological therapies, which, in England, are delivered with other evidence-based treatments, such as pharmacological interventions ***(Baldwin et al., 2014)***, via the stepped care model (Scogin, Hanson & Welsh, 2003; Simon et al., 2001) through IAPT

services - Table 3 (NICE, 2011) - with computerised CBT / eTherapy recommended at Step 2.

Table 3: Stepped-care model: a combined summary for common mental health disorders (NICE, 2011).

Focus of the intervention	Nature of the intervention
Step 3: Persistent subthreshold depressive symptoms or mild to moderate depression that has not responded to a low-intensity intervention; initial presentation of moderate or severe depression; GAD with marked functional impairment or that has not responded to a low-intensity intervention; moderate to severe panic disorder; OCD with moderate or severe functional impairment; PTSD.	**Depression:** CBT, IPT, behavioural activation, behavioural couples' therapy, counselling*, short-term psychodynamic psychotherapy*, antidepressants, combined interventions, collaborative care**, self-help groups. **GAD:** CBT, applied relaxation, drug treatment, combined interventions, self-help groups. **Panic disorder:** CBT, antidepressants, self-help groups. **OCD:** CBT (including ERP), antidepressants, combined interventions and case management, self-help groups. **PTSD:** Trauma-focused CBT, EMDR, drug treatment. **All disorders:** Support groups, befriending, rehabilitation programmes, educational and employment support services; referral for further assessment and interventions.
Step 2: Persistent subthreshold depressive symptoms or mild to moderate depression; GAD; mild to moderate panic disorder; mild to	**Depression:** Individual facilitated self-help, computerised CBT, structured physical activity, group-based peer support (self-help) programmes**, non-directive counselling delivered at home†, antidepressants, self-help groups.

moderate OCD; PTSD (including people with mild to moderate PTSD).	**GAD and panic disorder:** Individual non-facilitated and facilitated self-help, psychoeducational groups, self-help groups. **OCD:** Individual or group CBT (including ERP), self-help groups. **PTSD:** Trauma-focused CBT or EMDR. **All disorders:** Support groups, educational and employment support services; referral for further assessment and interventions.
Step 1: All disorders – known and suspected presentations of common mental health disorders.	**All disorders:** Identification, assessment, psychoeducation, active monitoring; referral for further assessment and interventions.
* Discuss with the person the uncertainty of the effectiveness of counselling and psychodynamic psychotherapy in treating depression. ** For people with depression and a chronic physical health problem. † For women during pregnancy or the postnatal period. CBT, cognitive behavioural therapy; ERP, exposure and response prevention; EMDR, eye movement desensitisation and reprocessing; GAD, generalised anxiety disorder; OCD, obsessive compulsive disorder; IPT, interpersonal therapy; PTSD, post-traumatic stress disorder.	

IAPT services deliver evidence-based interventions (Kendall, Pilling, Glover & Taylor, 2011), specifically, CBT for mild to moderate depression and some forms of anxiety (Clark, 2011), with stepped-care being closely aligned to waiting-list management and cost-effectiveness values (Pickersgill, 2019). Treatment is matched to client need with the least intrusive and effective intervention offered at the earliest point in time, and with each step

having clear eligibility criteria. High intensity treatments are reserved for those with greater symptom severity (Bower & Gilbody, 2005), with 70% (Clark, 2018) treated at low intensity level and typical eligibility criteria for clients being as follows:

- First presentation of the problem
- Presentation is mild/moderate depression/anger/self-esteem/anxiety (including first presentation social anxiety), mild OCD and stress
- Problem is not complex with onset < two years prior to presentation.
- IAPT caseness is met (NHS Digital, 2017) - clients score 10 or more on the PHQ-9 and/or eight or more on GAD-7
- Client scores below 15 on PHQ-9 and GAD-7

Assumptions made regarding numbers of clients benefitting from low intensity interventions (NICE, 2004b) have been questioned (Lovell et al., 2008), though they are considered cheaper to provide, involve less clinician and service input (Van Straten, Hill, Richards & Cuijpers, 2015) with assessments delivered by Psychological Wellbeing Practitioners (PWPs). Some believe that those who do not respond to low intensity interventions may be negatively affected in respect of their attitude to further treatment options (Kellet & Matthews, 2008), and that treatment choice may be perceived to be limited (Lovell & Bee, 2008). Therapy modality, delivery method and service accessibility are important, yet IAPT clients often comment on its inflexibility (Marshall et al., 2016).

Though IAPT focuses on CBT - empirically supported for anxiety and depression (NICE, 2004a; 2004b; 2009) and accepted as a first-line treatment for depression (National Collaborating Centre for Mental Health, 2010) - there is a need for evidence-based psychological therapies to be expanded (Thornicroft, 2018). IAPT has been questioned as to whether it does fully improve access to all psychological therapies as it is more synonymous

with CBT (Binnie, 2015). As such, an illusion has been created regarding the widening of access to all psychological therapies (Mason & Reeves, 2018).

CBT is not for everyone; clients can struggle with the 'homework' element (Omylinska-Thurston, McMeekin, Walton & Proctor, 2019), whilst others find it hard to identify and challenge negative thoughts and feelings (Nilsson, Svensson, Sandell & Clinton, 2007). This is problematic as cognitive restructuring is a key component of the approach (Mansell, 2008). When therapists stick rigidly to a CBT protocol, this can lead to clients feeling misunderstood and invalidated (Bystedt, Rozental, Andersson, Boettcher & Carlbring, 2014); eTherapy, however, can facilitate the delivery of CBT without contamination from such variables (Knowles et al., 2014).

It is often difficult to identify the most appropriate treatment for depression (Cuijpers, 2018) and anxiety; this having been an issue for some time (Paul, 1967). Interpersonal therapy (Churchill, 2010; Cuijpers, 2016), Behavioural Activation (BA) (Ekers, 2008; Shinohara, 2013), problem-solving therapy, (Malouff, 2007), third-wave psychotherapies (Churchill, 2010), and psychodynamic therapy (Leichsenring, 2008) are all effective in the treatment of adult depression (Brettle, 2012; Cuijpers, 2018), with minor differences between modalities in terms of effectiveness for all types of depression (Brettle, 2012). Furthermore, their effects are comparable (Barth, 2013; Palpacuer, 2017). BA, like CBT, has a meta-analytic level of support for its evidence (Butler, 2006; Cuijpers, 2007). Recently, pluralistic approaches encompassing numerous modalities have been said to be essential (British Association for Counselling and Psychotherapy [BACP], 2020), raising questions about the past decade's focus on CBT. There is an also an argument for a broader approach to the management of anxiety and depression to be taken with issues such as nutrition, diet (Anxiety UK, 2020; Terry & Reeves, 2015), and sleep (Cox, Bunmi & Olatunji, 2020) considered in treatment solutions.

The therapeutic relationship, however, is key for outcomes and engagement (Ardito, 2011; Horvath, Del Re, Flückiger & Symonds, 2011), and considered essential for effective therapy (BACP, 2020). Relationship factors, such as empathy and warmth, contribute to outcomes even when therapist contact is limited (as in eTherapy), with good relationship skills generating positive outcomes irrespective of modality (Norcross & Lambert, 2018). Further research on therapist and service variability is required, instead of focusing on modalities (Pybis et al., 2017). Taken together, these variables have the potential to increase patient choice and address the high drop-out rates seen within low intensity IAPT services (Chan & Adams, 2014).

1.6 The role of the Third Sector in the delivery of IAPT services

The TS is known for plugging gaps in statutory services, responding in innovative ways to national policy initiatives, and stepping in when there have been service failures (Newbigging, Mohan, Rees, Harlock & Davis, 2017). TSOs run independently of the state, have social aims, and can access hard to reach populations; successfully engaging communities (Allen, 2011). Government policy has supported provider plurality, however local commissioning strategy determines the extent of TSO commissioning (Allen, 2012) with varied views held by commissioners on this (Baird, 2018.) To secure NHS contracts, TSOs are required to meet specific criteria, particularly regarding IAPT contracts (Sweet, 2019); many report being torn between meeting their original aim versus meeting the demands of delivering contracts (Department of Health, 2016). Some have had to scale up and 'professionalise' when delivering public service contracts (Department of Health, 2016); being forced to act in a more business-like manner (Third Sector, 2020). This has changed organisational dynamics, values, and service delivery (Laurie & Bondi, 2006), leading to notions of constraint, pressure, and uniformity (Boyles & McKinnon Fathi, 2019).

NHS England state that the TS: 'often has an impact well beyond what statutory services alone can achieve (NHS England, 2014, p.14). Furthermore, there is acknowledgment that TSOs typically 'offer a rich range of activities in response to mental health, under the one roof' (NHS England, 2014, p. 14). The sector is renowned for being able to reach under-represented groups, and for its increasing diversity in terms of the make-up of organisations in respect of their size and constitution (Carey & Braunack-Mayer, 2009). Mental health services are no longer solely delivered by the NHS; TSOs now provide such services (Bennion, Hardy, Moore & Millings, 2017). Whilst data from TSOs is included in the IAPT dataset, there is no flag or identifier to distinguish this data from that of other service providers (NHS Digital, 2020). Consequently, there are no reports that state the ratio that TSOs comprise in the dataset regarding their overall contribution to, IAPT.

Self Help Services is a user-led charity established in 1995 by the thesis' author. The charity provides a wide range of inclusive services **(Lidbetter & Bunnell, 2013)** and routinely participates in community research projects such as the PERSUADE trial ***(Kenning et al., 2019)***. It has been commissioned to deliver low intensity IAPT services from the mid-2000s, including eTherapy services **(Cavanagh, Seccombe, Lidbetter & Bunnell, 2011a; Cavanagh, Seccombe & Lidbetter, 2011b)**. Its user-led ethos ensures that peer support is at the heart of its service delivery, whilst innovating and responding to client need for accessible, peer-supported services. In doing this, the charity aligns itself to key policy drivers around clients being in control of their care, that services are focused on client needs and preferences; therefore, facilitating choice (Ormandy & Hulme, 2013).

1.7 Section discussion

IAPT has been the dominant treatment driver for anxiety and depression in England over the past decade. Whilst access to CBT has increased (Moller, Ryan, Rollings & Barkham, 2019),

fewer than one in five individuals in England experiencing anxiety and/or depression are being reached (Clark, 2018). This figure being against a target of at least 1.5 million people by 2020/1 (NHS England, 2019) and rising levels of anxiety and depression in the UK (Sample, 2020). Whilst guidelines recommend treatment is based on the stepped care model, there is limited data available as to how this is implemented in UK routine practice (Richards et al., 2012), and specifically to understand how eTherapy can be successfully implemented in services as an intervention (Drozd, Vaskinn, Bergsund & Haga, 2016; Folker et al., 2018) at low intensity level. New delivery methods and blended approaches are needed to increase access (Brown, 2018), including exploring the TS and its role in delivering services to address population need at primary care level (Chew & Osborne, 2009).

1.8 Section summary

This section provided an overview of anxiety and depression, a summary of treatment available via IAPT - the vehicle through which the majority of the country's primary mental health care service offer is delivered - and an examination of the role of TS providers in the provision of NHS services. The next section examines eTherapy, which is an intervention delivered largely at low intensity level, and the role of peer support in eTherapy service delivery models.

Section Two: eTherapy

This section provides an overview of eTherapy terms, the history and policy context for its role in the treatment of anxiety and depression, its clinical effectiveness, its client acceptability, and an examination of service delivery models, including the role of peer support.

2.1 Definition of eTherapy

The NHS defines digitally enabled therapy as "psychological therapy that is provided online or through mobile applications, with the support of a therapist" (NHS England, 2020a, para 2). In eTherapy, users are guided through content (usually in module format) via text, images, video resources, and sometimes case studies, either interactively or in a non-interactive manner (Rodriguez-Pulido, Castillo & Hamrioui, 2020). Automated feedback processes are used instead of a therapist being present (Marks, Cavanagh & Gega, 2007).

There is no standardised nomenclature to describe eTherapy and so it is defined and categorised in many ways (Bennion et al., 2017), including by the amount of therapist support (Newman et al., 2011) or the way the internet is used to support delivery (Barak, Klein & Proudfoot, 2009). A classification for digital health interventions has recently been constructed, which should support the development of a common, shared language for eTherapy (WHO, 2018b), in the hope that an industry standard will be developed (Borgueta, Purvis & Newman, 2018).

In this thesis, the term eTherapy covers all associated terms (see Table 4) but not interventions delivered solely through mobile phone applications (apps), though it is recognised that some eTherapy programmes are accessible in both standard and app format. Virtual Reality (VR) therapy or interventions not guided by a computer (e.g., psychological

therapy that takes place with a therapist online via videoconferencing facilities or by email or instant messaging or interventions delivered in a group format [e.g., Master Your Mood - MYM (van der Zanden, Kramer, Gerrits & Cuijpers, 2012)]) are excluded.

Table 4: eTherapy terms

iCBT, itherapy, computer-assisted therapy, cybertherapies, cybertherapy, computer-delivered, web-based, electronic CBT (eCBT), computerised Cognitive Behavioural therapy (cCBT), computerised therapy, online CBT, digitally-enabled therapies, computer therapy, digital IAPT, digital psychotherapy, digital cognitive behavioural therapy (dCBT), internet-delivered, internet-administered, internet-guided self-help interventions, computerised psychological therapy, internet-based therapy, internet-based interventions, computer-aided psychotherapy and therapist-guided internet interventions.

2.2 eTherapy in the management of anxiety and depression

An ever-expanding range of computer programs have been developed to support individuals affected by anxiety disorders and depression, typically on the principles of CBT; a structured and directed approach that lends itself to computer-based administration (Anderson, Jacobs & Rothbaum, 2004). However, the assumption in CBT that anxiety and depression stem from faulty attitudes and beliefs has been criticised as being tantamount to blaming clients for their difficulties; failing to take into account that such conditions may instead arise from socio-economic adversity and chronic health difficulties (Knight & Thomas, 2019), and is a limitation of those eTherapy programmes that are entirely CBT-based, of which many are (Simmonds-Buckley et al., 2020). Other modalities have been digitalised including acceptance and commitment therapy - ACT (Pots et al., 2016), BA (Ly et al., 2014), interpersonal psychotherapy - IPT (Donker et al., 2013), mindfulness-based interventions

(Spijkerman, Pots & Bohlmejer, 2016), and problem-solving therapy (Kleiboer et al., 2015). Yet there is gap regarding eTherapy programmes that adopt a pluralistic approach inclusive of all modalities; said to be essential and reflective of clients being unique and needing different things (BACP, 2020).

eTherapy has the potential to offer the same benefits of CBT with less therapist involvement (Kaltenthaler et al., 2002), potentially increasing service capacity (Titov, Andrews & Sachdev, 2010b).

CBT delivered via computer was not used routinely until it was recommended (NICE, 2002), though there was a distinct lack of detail regarding eTherapy implementation and delivery model. Nevertheless, access to CBT was improved within a context of limited therapists, high costs, long waiting times, and clients' reluctance to access therapy. In 2003, the eTherapy programme, Beating the Blues (BtB™) was reported to have positive outcomes in those with anxiety and depression (Proudfoot et al., 2003). However, whilst effective when compared to Treatment as Usual (TAU), in this case, whatever treatment the GP had prescribed, the Randomised Controlled Trial (RCT) was limited by a lack of standard treatment against which to compare BtB™ (Proudfoot et al., 2003). Additionally, as the service was delivered from GP surgeries, with a nurse providing instructions as to how to access sessions, there was no focus on the impact of the nurse's involvement. Furthermore, those not randomised to this arm of the trial did not receive this human interaction; thus, the study (Proudfoot et al., 2003) left unanswered questions as to whether nurse contact alone might have influenced results.

In 2004, a novel interactive self-help clinic was established that clients experiencing anxiety and depression accessed from home, with telephone support as required. The service reported saving clinicians' time through delegating routine aspects of therapy to a computer,

utilising the programme, FearFighter™ (Marks, Kenwright, McDonough, Whittaker & Mataix-Cols, 2004; Schneider, Mataix-Cols, Marks & Bachofen, 2005).

A further appraisal by NICE (2006) recommended BtB™ for mild to moderate depression and FearFighter™ for phobia, panic, and anxiety; and as a result, both programmes became widely available - typically accessed through GP surgeries on a stand-alone, unsupported basis, akin to the earlier model developed by Marks et al. (2004). A summary of the origins of eTherapy is detailed in Table 5 below:

Table 5: eTherapy origins (Andersson, 2018a)

1. The emergence of evidence-based psychological therapies - particularly CBT (Rachman, 2015).
2. Guided self-help literature, with trials reporting evidence for the use of such interventions when supported by clinicians (Clum & Watkins, 2008). Earlier forms of eTherapy were likened to this with online or email support (Marks et al., 2007).
3. Computerised testing and interventions (Marks, Shaw & Parkin, 1998).

A pilot project developed by the thesis' author in the early 2000s delivered through Self Help Services and the National Phobics' Society (now Anxiety UK), provided access to BtB™ on an entirely stand-alone, unsupported basis through the 'computerised cognitive behavioural therapy' - cCBT service, for clients experiencing anxiety and depression. Whilst clients found BtB™ helpful, most needed additional support and guidance, typically delivered by the then eTherapy Co-ordinator (eTC) - an individual with lived experience of anxiety/ depression, akin to a Peer Support Worker (PSW), with whom what amounted to a 'support conversation' would be had at the start and end of sessions. The outcome of this pilot project led directly to the development of a new model of eTherapy service delivery, which

addressed this client need for motivational support, guidance, and contact with a human being who could relate to experiences of living with anxiety and depression. This *model,* a non-clinical, fully peer-supported eTherapy model **(Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017)**, is the main subject of this thesis and is described and explored in greater detail in Section 4 and depicted in Figure 1.

In utilising the lived experience of volunteers and eTCs to provide peer support and thus operating in part as PSWs, the *model* aimed to improve client engagement and reduce drop-out rates in comparison to other non-supported models, as well as by increasing accessibility by delivering the service in the community. The *model* evolved through the work that is contained in the portfolio (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017)** by testing effectiveness and acceptability in a real world setting **(Cavanagh et al., 2011a, b; Elison et al., 2014, 2017; Gellatly et al., 2018; Luik et al., 2017)**, further developing the model into a remote *model* **(Gellatly et al., 2018)**, and by adding different programmes to meet client need **(Elison et al., 2014, 2017; Luik et al., 2017).**

As IAPT grew, focus was placed on widening access to psychological therapies; eTherapy was positioned as being vital to addressing treatment barriers including costs and waiting times (Richards et al., 2018). However, many were cynical; it was not until the *model* was recognised in Manchester as having potential to assist with meeting IAPT access and recovery targets (see Table 6), that the venue *model* (where the service was delivered from venues such as Information Technology (IT) suites located within community centres) was accepted as a credible low intensity intervention **(Cavanagh et al., 2011a, 2011b)**.

In IAPT, recovery is determined by reductions in outcome measures scores (see Table 6). A criticism of the approach is its reliance on the medical model (Binnie, 2015) and failure to

understand symptoms in favour of seeking to suppress or change them (Casement, 2009). Furthermore, there is a lack of focus on the wider domains of recovery (McPherson et al., 2009; Scanlon & Adlam, 2010) which are arguably more meaningful and relevant to those experiencing anxiety and depression than simply a reduction of symptomatology. The reliance on the use of quantitative outcome measures as opposed to holistic, whole-person and specifically, patient-reported outcome measures, as well as those that focus on empowerment, such as the Empowerment Scale (Rogers, Chamberlin, Langer Ellison & Crean, 1997) is also a limitation of the IAPT approach.

Table 6: Key IAPT recovery and associated definitions (**Gellatly et al., 2018**).

IAPT recovery is the percentage of clients who score below the clinical cut-off of >9 on the PHQ-9 and >7 on the GAD-7 after the treatment period over those who scored above the clinical cut-off on the PHQ-9 or GAD-7 before treatment.
Reliable improvement is met if there is a decrease in one or both outcome measures that exceeds the measurement error for that measure (PHQ-9 ≤ 6; GAD-7 ≤ 4) and no increase in the other beyond the error of measurement.
Reliable deterioration is met if there is an increase in one or both scores (PHQ-9 ≤ 6; GAD-7 ≤ 4) that is more than the measurement error.
Reliable recovery is when a client has both reliably improved and recovered.

As leader of Self Help Services, part of my role involved influencing NHS commissioners to fund the *model*. This was achieved by demonstrating its equivalent access and positive outcomes in comparison to standard IAPT recovery rates **(Cavanagh et al., 2011b)**, which led to the commissioning and adoption of the *model* in Greater Manchester and beyond. Whilst the original venue *model* **(Cavanagh et al., 2011a, 2011b)** was found to be effective and acceptable, clients articulated the need for a remote service because of access issues – leading to the @ home/remote *model* being developed a few years later **(Gellatly et al., 2018).**

Many eTherapy programmes exist (see Table 7); differing in disorder specificity, extent of mental health problem addressed (Fairburn & Patel, 2017), and platform design (Hofman, Pollitt, Broeks, Stewart & van Stolk, 2016). Transdiagnostic programmes (TD-cCBT) have also been developed (Newby, Twomey, Li & Andrews, 2016) with greater clinical utility (Fairburn & Patel, 2017). Programmes provide access to therapy content ordinarily delivered face-to-face (Teachman, 2014), with content delivery methods differing (Thew, 2020) and CBT is the most common modality used.

Further developments of the *model* accommodated clients presenting with comorbidity, including substance misuse and sleep difficulties, via the addition of programmes such as Breaking Free Online – BFO (Elison, Humphreys, Ward & Davies, 2013) and Sleepio™ (Espie et al., 2012).

No comprehensive mapping exercise of eTherapy programmes has been undertaken other than an initial mapping exercise by Van Stolk, Hofman, Hafner, and Janta (2014) followed by RAND Europe's review of CCBT tools (Hofman et al, 2016). The latter was limited in that it did not review tools aimed at children, students, or the elderly, and was limited in scope, only focussing on published studies. The Center for Technology and Behavioral Health has also synthesised research on Digital Health Technologies (DHTs) for substance use disorders and co-occurring conditions including mental health issues, listing key eTherapy programmes on their website (Center for Technology and Behavioral Health, 2020).

Table 7: **Key programmes available globally for anxiety and depression.**

eTherapy programme:	**Reference**	**Composition:**	**Country of origin:**	**Suitable for/primary application:**
Beating the Blues*	Proudfoot et al., 2003	Eight module programme	UK	Depression and anxiety

Breaking Free Online*	Elison, et al., 2013	Psychosocial interventions	UK	Substance misuse issues
Calm Tools for Living	Roy-Byrne, et al., 2010	Eight sessions	USA	Anxiety and depression
Deprexis	Meyer et al., 2009	10 module programme	Germany	Depression
FearFighter™*	Marks et al., 2004; Schneider et al., 2005	Nine module programme	UK	Panic and phobias
GET.ON Stress	Ebert et al., 2016	Seven sessions	Germany	Work-related stress
Good Days Ahead	Wright et al., 2005	Six module programme	America	Stress, anxiety and depression
Internet-Based Self-Help Cognitive Behavioural Therapy (icBT) for Depression	Andersson, Bergstrom, Carlbring, Kaldo, & Ekselius, 2005	10-week programme	Sweden	Mild to moderate depression
Living Life to the Full Interactive) (LLTTF)- now known as 'Living Life to the Full Plus' *	Williams, n.d.	On-line, interactive, self-help skills programme comprising modules on areas of life and wellbeing commonly affected by low mood and stress	UK	Low mood, stress, and anxiety
MoodGYM	Christensen, Griffiths & Jorm, 2004	Five interactive modules	Australia	Depression and anxiety
myCompass	Proudfoot et al., 2013	12 modules	Australia	Depression, anxiety, and stress
PAXPD	Ciuca, Berger, Crişan & Miclea, 2018	12-week treatment containing 16 modules	Romania	Panic disorder and anxiety disorders
SilverCloud Health*	Sharry, Davidson, McLoughlin & Doherty, 2013;	Eight-week, condition-specific programmes, marketed under	Ireland and UK	Adults aged 16 and over. Depression, anxiety, phobia,

	Richards et al., 2015	the name 'space from'		panic, social anxiety, health anxiety, OCD, depression and anxiety, GAD, perinatal wellbeing
Sleepio™ *	Espie et al., 2012	Six-week programme with tailored clinical content and up to 12 weeks support via an online community	UK	Insomnia
Smart, Positive, Active, Realistic, X-Factor Thoughts (SPARX)	Fleming, Dixon, Frampton & Merry, 2012	Seven 'provinces' where avatars are used. Modified versions of SPARX have been created such as Rainbow SPARX	New Zealand	Mild to moderate depression in young people aged 12-19 years
The Wellbeing Course	Titov et al., 2011	Transdiagnostic program	Australia	Depression and anxiety disorders
This Way Up - The Panic Program	Wims, Titov & Andrews, 2008 –	Typically, each course comprises six 'lessons' including the 'sadness program', the 'shyness program', and 'the panic program'	Australia	Depression, GAD, mixed anxiety and depression, OCD, social anxiety, post-traumatic stress, health anxiety courses

*indicates an eTherapy programme used in the *model*

Programme format varies; some maintain fidelity with the face-to-face psychotherapy standard of weekly sessions; others adopt a format seen with apps and websites (Ben-Zeev et al., 2015). Most deliver a sequence of modules where evidence-based therapies are

delivered, via the internet, through a device (Wright, Mishkind, Eells & Chan, 2019). Just as session delivery frequency varies, so does programme structure. Some are linear with clients working through an intervention in a methodical, systematic way, others are flexible and unstructured where clients select which parts of the programme they wish to access (Fairburn & Patel, 2017). The number of modules available differs according to the target condition, with anxiety disorders being reported to be lengthier (Hofman et al., 2016). Contact time ranges from < 1.5 hours through to more active involvement by the supporter/clinician, though it remains less than that of face-to-face therapy sessions (Cavanagh, Belnap, Rothenberger, Abebe & Rollman, 2018), with the intensity of support typically low (Hofman et al., 2016). Programmes can also be made available to access in a self-guided manner. The amount of supporter time required to achieve maximum benefit for clients accessing eTherapy is an area requiring further research (Andrews et al., 2018). Holländare et al. (2016) investigated common therapist behaviours in therapist-supported eTherapy via email. Most commonly therapists encouraged, affirmed, guided, and urged clients when sending emails, whilst also providing 'clarification,' 'informing' about module content,' 'emphasising' client responsibility, and self-disclosing.

The extent to which programmes are personalised or tailored differs (Twomey, O'Reilly & Bryne, 2014). The SPARX programme has been adapted for the Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQQIAAP) community (Fleming et al., 2012), and another programme for those with intellectual disabilities has been developed (Cooney, Jackman, Coyle & O'Reilly, 2017). There are no programmes available for clients aged over 65 years (Bennion et al., 2017), though some have been tailored to suit client groups including older adults (Silfvernagel et al., 2012).

A digitally enabled therapy assessment programme (NICE, 2020a) assessing eTherapy programmes for use in IAPT services, and producing an IAPT Assessment Briefing (IAB),

was recently launched. Those programmes receiving positive recommendation are evaluated in practice to obtain real-world activity data, however in contrast to the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), clinicians provide support, maintaining fidelity with the IAPT manual (National Collaborating Centre for Mental Health, 2018). To date, only the Space from Depression (Sharry et al., 2013) has been evaluated in practice, yet many different programmes are offered in IAPT services (Bennion et al., 2017). It is unclear as to the longer-term impact of the IAPT assessment programme on the future use of programmes within services. It may impact on the *model* (**Cavanagh et al., 2011, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), resulting in less choice if only programmes that have been evaluated in practice with an IAB are recommended (NICE, 2019b). Conversely, an evidence standards framework for DHTs developed by NICE (2019a) could lead to greater programme choice if software companies demonstrate compliance and put a case forward for their product to be used with IAPT services, without going through the IAB process. This might result in eTherapy forming a larger part of future IAPT provision in contrast to the small percentage of overall IAPT interactions that it has accounted for (Health and Social Care Information Centre, 2016). This would also contrast with the low uptake seen in some services, which has ultimately resulted in some being terminated (Brown, 2018).

The Topol Review Board, 2019 (Foley & Woollard, 2019) states that eTherapy:

> can provide standalone self-help or be blended with traditional mental health interventions or online peer support networks. Such interventions are already in use and have a significant evidence base. In the future, artificial intelligence (AI) and natural language processing (NLP)-enabled chatbots may facilitate more advanced automated or semi-automated therapeutic tools (Foley & Woollard, 2019, p.5).

IAPT providers are not currently required to submit data on either eTherapy programme or service delivery model deployed; such metrics fall outside of the IAPT Minimum Data Set - IAPT MDS (NHS Digital, 2020) - yet the IAPT manual (National Collaborating Centre for Mental Health, 2018, p.44) states that, in relation to digitally-enabled therapy, it could be 'considered as part of the service model design' and:

> much of the learning that is required to help people deal with emotional difficulties can be achieved by them working through materials on the internet with ongoing contact with a therapist (by telephone, secure messaging and so on) to provide encouragement, clarify misunderstandings and further enhance learning (IAPT manual, p.40).

2.3 eTherapy: clinical effectiveness

Many variables confound eTherapy clinical effectiveness results, including: programme type (transdiagnostic or disorder-specific); target population (community or clinical population); treatment comparisons; whether support is provided versus unguided or automated; who provides the support (clinician/non-clinician); how the service is delivered; the amount of support provided; and method of delivery.

eTherapy research is often focused on individual programmes (Hofman et al., 2016), possibly explained by software companies being keen to establish their programme's efficacy; however, TDcCBT is as effective as disorder-specific programmes (Păsărelu, Andersson, Nordgreen & Dobrean, 2017), and is practical, efficient, and relevant for a range of conditions and multiple comorbidities (Newby et al., 2016).

Meta-analyses have found eTherapy effective for anxiety and depression (Andrews, Cuijpers, Craske, McEvoy & Titov, 2010) and Social Anxiety Disorder - SAD (Kampmann,

Emmelkamp & Morina, 2016) - and systematic reviews report it as being an established treatment for depression, SAD, and panic disorder (Hedman, Ljótsson & Lindefors, 2012).

eTherapy is equally efficacious when compared to face-to-face CBT for SAD, panic disorder, and depression (Andersson et al., 2014; Carlbring, Andersson, Cuijpers, Riper & Hedman-Lagerlöf, 2018). However, an RCT comparing the clinical effectiveness of eTherapy and guided self-help (with support offered by telephone) at low intensity level for OCD, found that neither intervention led to clinically significant benefits (***Gellatly et al., 2014; Lovell et al., 2017a, 2017b***).

Self-guided eTherapy is more effective in treating depression than control conditions (Karyotaki et al., 2017), and eTherapy is clinically effective for anxiety and depression when delivered with minimal clinician guidance (Adelman, Panza, Barley, Bontempo & Bloch, 2014; Andersson & Cuijpers, 2009; Andersson, Cuijpers, Carlbring, Riper & Hedman, 2014; Andrews et al., 2018; Arnberg, Linton, Hultcrantz, Heintz,& Jonsson, 2014; Cuijpers et al., 2009; Olthuis, Watt, Bailey, Hayden & Stewart, 2016; Richards & Richardson, 2012; Titov et al., 2016).

Globally, the International Society for Research on Internet Interventions (ISRII) has debated the role of therapist support (Baumeister, Reichler, Munzinger & Lin, 2014). A number of studies (Campos et al., 2019; Karyotaki et al., 2017) point to the need to investigate supported models of eTherapy as the evidence is mixed. Berger et al. (2011) found that additional support did not lead to better outcomes but observed greater adherence with clients accessing self-guided eTherapy for depression when weekly, short phone calls were provided by an assigned coach (Mohr et al., 2013). Sijbrandij, Kunovski and Cuijpers (2016) found effects were strongest when clients accessing an eTherapy service for PTSD were supported by a therapist; proposing that clinical effectiveness can be improved by increasing the amount of

therapist/clinician support, though the effect size is now believed to be smaller than previously reported (Lorenzo-Luaces, Johns & Keefe, 2018). Other studies report that therapist experience makes no difference to outcomes in the treatment of panic and social anxiety disorder (Klein et al., 2009), though experienced therapists may need less time to support clients (Andersson, Carlbring, Fumark & SOFIE Research Group, 2012).

An RCT on the effectiveness of eTherapy found that the provision of telephone support provided short-term benefits in relation to depression symptoms (Brabyn et al., 2016). Moreover, a Cochrane systematic review (Olthuis et al., 2016) assessing the effects of therapist-supported eTherapy for adults with anxiety disorders, found therapist-supported eTherapy more effective than no treatment (in this case, a waiting list). The professional background of the individual providing support is reported to be of minor importance (Baumeister et al., 2014) with no difference in outcomes found in an RCT comparing the efficacy of clinician- versus technician- (non-clinical) supported treatment for depression (Titov et al., 2010).

No difference between outcomes for clients accessing support via a web forum versus telephone calls was found, indicating that the support method may not make a difference (Titov et al., 2009). However, a meta-analysis of multi-modal CBT (CBT across a variety of delivery formats, including guided self-help CBT, telephone-based cCBT, face-to-face CBT and eTherapy CBT), found eTherapy more effective than no treatment and that practitioner support type may account for differences in results (Twomey, O'Reilly & Byrne, 2015).

Whilst eTherapy is effective in the treatment of anxiety and depression, it is inconclusive as to how long outcomes are maintained, and evidence for its long-term benefit is sparce (Hofman et al., 2016). A recent meta-analysis, however, found eTherapy efficacious and acceptable for people reporting symptoms of anxiety and depression, with benefits maintained for up to 18 months (Andrews et al., 2018); another study reported eTherapy as

effective for SAD compared to CBT group therapy, for as long as up to four years post treatment (Hedman et al., 2014a).

There is limited evidence for the effectiveness of eTherapy in Black and Minority Ethnic (BME) groups aside from the **Cavanagh et al., 2011b** study, with few studies focussing on outcomes and ethnicity/racial differences (Jonassaint et al., 2009).

Clinical effectiveness for eTherapy has been shown to be linked to treatment completion (Hobbs, Mahoney & Andrews, 2018; Karyotaki et al., 2017) with adherence greater in older clients (Hobbs et al., 2018; Mewton, Sachdev & Andrews, 2013) when provided through a GP; suggesting that the views of such healthcare practitioners are held in higher regard by older people and/or more likely to be acted on/listened to. Additionally, a meta-analysis and systematic review found mean study sample age significantly moderated the effectiveness of eTherapy in those with CMDs (Grist & Cavanagh, 2013).

2.4 eTherapy: acceptability

Acceptability was initially studied over a decade ago (Kaltenthaler et al., 2008), though has not been as extensively researched as other areas of eTherapy (Cavanagh et al., 2009), with a heterogeneity of pilot studies and minimal amount of research on public acceptability of the approach (Apolinário-Hagen, Kemper & Stürmer, 2017). Focus has been on improving access, rather than addressing patient experience (Knowles, 2014). Though, more recently, Rost et al. (2017) reported positive experiences in those accessing eTherapy for depression.

eTherapy should not be positioned as a one-size-fits-all approach (Perera-Delcourt & Sharkey, 2019), as personalisation and sensitisation may improve client experience (Knowles, 2014). For some, eTherapy may not be suitable (Rozental et al., 2014) and the

negative effects of the approach need to be researched (Boettcher, Rozental, Andersson & Carlbring, 2014).

Clients find certain CBT techniques in eTherapy programmes helpful, including psychoeducation and cognitive restructuring, as well as supporter interaction. However. the amount of work clients must complete, as well as frustrations with technical issues, can cause hindrance (Burke, Richards & Timulak, 2018).

Perception of eTherapy is important (Batterham et al., 2019) and can be addressed by giving clients enough information on the intervention prior to accessing the service. Positive positioning in this way gives rise to improved treatment outcomes (Cludius, Schroder & Moritz, 2018) – a phenomenon seen in telephone-delivered therapy interventions (***Bee, Lovell, Lidbetter, Easton & Gask, 2010; Rushton et al., 2020***), and something that is often neglected as a treatment response moderator. Addressing this, and the role that professionals and others play in socialising clients to eTherapy, is critical (Schröder et al., 2018). It has also been suggested that positive attitudes towards eTherapy could be improved with certification of programmes by professional psychological bodies, resulting in increased credibility (Klein et al., 2016), though acceptability is rarely measured directly (Kaltenthaler et al., 2008).

Musiat, Goldstone and Tarrier (2014) reported clients being unenthusiastic about eTherapy, but aware of its advantages in terms of accessibility, advising that policy makers must address public perceptions of the approach. Observability is also something that has been reported to be low in eTherapy (Carper, McHugh & Barlow, 2013), and which too may impact on acceptability and explain reported low intentions from clients for future use (Musiat et al., 2014).

It is recognised that eTherapy could pose a challenge in respect of the therapeutic alliance (Cavanagh et al., 2018) since it involves minimal contact (Newman, Szkodny, Llera & Przeworski, 2011). High alliance ratings have, however, been reported, as is also the case for telephone-delivered therapy (***McMillan, Bee, Lidbetter & Lukoseviciute, 2020***), suggesting an alliance is formed (Andersson et al., 2019b) and thought to be important (Nordgreen, Carlbring, Linna & Andersson, 2013; Pihlaja et al., 2018). Furthermore, those supporting and administering the service are likely to influence alliance (Berger, 2017), as does treatment being provided in a user-friendly manner that is not excessively technical, as this promotes greater adherence (Andersson, Carlbring, Berger, Almlöv & Cuijpers, 2009).

Whilst clients are generally positive about eTherapy (Andrews et al., 2018), with acceptability in some client groups being high, for example, those with OCD (Wootton, Titov, Dear, Spence & Kemp, 2011), others prefer to opt for a blended model (Andersson et al., 2019b) of eTherapy and face-to-face therapy; suggesting that some level of human interaction is beneficial.

Supported eTherapy is generally more acceptable (Andersson, 2018a), and therapist contact is believed to be positively linked to treatment adherence and reduction of client frustration regarding technological issues (Rozental, Boettcher, Andersson, Schmidt & Carlbring, 2015). Lack of therapist contact can lead to clients requesting more support (Donkin & Glozier, 2012; Knowles et al., 2015; Rennick-Egglestone et al., 2016; Rost et al., 2017) and improvement in clients with depression where human support was included (Gellatly et al., 2007) has been reported; consistent with earlier research studies on the effectiveness of digital health interventions (Andersson & Cuijpers, 2009, Christensen, Griffiths & Farrer, 2009; Mohr, Cuijpers & Lehman, 2011).

In the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), there is a good degree of human

interaction and contact between clients, eTCs and volunteers, with the service being delivered in the community or remotely, both of which are acceptable and familiar environments to clients.

Whilst eTherapy has been implemented with mixed success (Andersson et al., 2019b), a framework of support like that which is integral to the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) has recently been demonstrated to be acceptable by Richards et al. (2016), where clients identified having a 'supporter' to provide motivation, guidance, and feedback as being what that they liked most. Accessibility (Perera-Delcourt & Sharkey, 2019), convenience (being able to fit therapy into daily routine), anonymity (Beattie, Shaw, Kaur & Kessler, 2009), and flexibility of the approach (Richards et al., 2016 Ritterbrand et al., 2003) are also considered key factors in terms of acceptability.

Though eTherapy is an acceptable, accessible treatment (Brown, 2018), uptake is low with high drop-out rates (Waller & Gilbody, 2009; Rost et al., 2017). Treatment adherence and drop-out is thought to be linked to acceptability (Van Ballegooijen et al., 2014).

2.5 eTherapy: service delivery and peer support

eTherapy can be delivered using different programmes and delivery models, ranging from entirely self-guided, unsupported services through to guided/supported services where varying degrees of support is provided. The recent IAPT evaluation in practice of the Space from Depression programme (NICE, 2020b), where the programme was implemented differently in various services, reported mixed findings; indicating that delivery models are important in terms of outcomes and acceptability. However, studies examining eTherapy when provided as part of a stepped care approach are scarce (Andersson et al., 2019b).

Support can be provided by a range of healthcare professionals from clinicians such as GPs, therapists, and psychologists through to non-clinicians, for example, PSWs.

Peer support has a long history in mental health services where individuals with lived experience have played a critical role in providing support to others similarly affected, informally and through self-help groups (Jackson, 2010) and is at the heart of the service delivery offer at Self Help Services **(Lidbetter & Bunnell, 2013).**

Different terms are used to describe peer support roles (see Table 8), with no formally accepted definition of a PSW (Repper & Carter, 2010).

Table 8: Peer support role terms.

Peer volunteer, peer worker, peer befriender, patient expert, peer visitor, peer support specialist, peer educator, peer role model, peer coach, peer volunteer mentor, peer informant, lay person, peer trainer, peer visitor, peer counsellor, peer broker, peer supporter, consumer advisor, health coach, and peer buddy.

In this thesis, the term 'peer support' covers all terms associated with peer support and 'PSW' for all peer support roles.

Health Education England (2020, para. 1) state that PSWs are:

> people who have lived experience of mental health challenges and choose to support others receiving services. They work towards the individual's wellbeing, giving hope and supporting recovery and their approach is built on shared experiences and empathy and is valued and supported by the NHS.

Peer support can be categorised on the nature of the interaction concerned (Bradstreet, 2006) and has 12 principles (Basset, Faulkner, Repper & Stamou, 2010) - see Table 9 - which risk

being compromised if peer support services are provided by statutory mental health services (Basset et al., 2010).

Table 9: Principles of peer support (Basset et al., 2010).

Mutuality
Solidarity
Synergy
Sharing with safety and trust
Companionship
Hopefulness
Focus on strengths and potential
Equality and empowerment
Being yourself
Independence
Reduction of stigma
Respect and inclusiveness

Peer-supported delivery models may facilitate empowerment by giving PSWs a more active role in their recovery; addressing power imbalances often found in services and moving treatment from being controlled by experts to those with lived experience (Simon & Ludman, 2009; NHS Confederation Mental Health Network, 2013). Additionally, PSWs may act as a channel for relaying the common factors of a therapeutic relationship, instead of clinicians performing this function.

There is high quality evidence for a range of peer support interventions for depression (Bryan & Arkowitz, 2015; Dale, Caramalau, Lindenmeyer & Williams, 2008; Pfeiffer, Heisler, Piette, Rogers & Valenstein, 2011); the purposive use of self-disclosure in peer support can, in general, reframe perspectives, offer coping skills, challenge stigma, establish rapport, and convey empathy and understanding of personal struggle (Marino, Child & Campbell Krasinski, 2016).

Finding ways of providing peer or professional support has been suggested to be critical to seeing the full potential of eTherapy (Knowles, 2014), and research has shown that PSWs offer 'more authentic empathy' (Bailie & Tickle, 2015, p.48).

The PSW role is fulfilled by eTCs, resulting in non-clinical, peer support being fully integrated into the eTherapy *model* operating at Self Help Services; nationally recognised in the field of user and peer-led mental health service provision (**Lidbetter & Bunnell, 2013**). This is discussed as the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) was developed.

Employment of PSWs is key to recovery-focused mental health service delivery (Moll, Holmes, Geronimo & Sherman, 2009). The eTC role is a paid, non-clinical, PSW role which enables those with lived experience of anxiety and depression to gain valuable employment experience. eTCs have responsibility for co-ordination of the eTherapy service and are supported by a small team of volunteers (in the venue *model*). Their role is to provide motivational support, guidance, instruction, encouragement, feedback, and praise; all factors known to be associated with strong perceptions of the therapeutic alliance (Perera-Delcourt & Sharkey, 2019; Schneider, Hadjistavropoulos & Faller, 2016). eTCs also provide guidance regarding homework tasks, this being important since uncompleted homework has been reported to be associated with poorer outcomes in eTherapy treatment of GAD (Paxling et al., 2013). eTCs are appropriately self-disclosing, this being associated with better outcomes in eTherapy for depression in a study where therapists provided support (Holländare et al., 2016). As eTCs appropriately share their experiences of having lived with a mental health condition and of getting to a place where they feel able to enjoy a quality of life that is not adversely affected by anxiety or depression, they are often seen as role models; instilling hope in clients that recovery is possible – this being a phenomenon reported in the peer support literature (Mahlke et al., 2017; Solomon, 2004). Similarly, the sharing of experiences

of coping with anxiety and depression by peer supporters, (in this case eTCs and eTherapy volunteers), has been identified as being something that can lead to clients feeling empowered to take control of their own self-care (Rogers et al., 2007; Solomon, 2004) and is a key component of the *model* as well as the wider charity's service offer.

A decade ago, Self Help Services successfully campaigned to have eTCs (an entirely new role, unique to the *model*, developed under the leadership of the thesis' author), recognised at national level as 'low intensity IAPT workers.' This raised the profile of the eTherapy PSW role and, specifically, that of the eTC. This meant IAPT underspend could be reallocated to eTherapy, enabling Self Help Services to expand its team of eTCs instead of funding clinical roles such as PWPs. This resulted in growth of the charity's eTherapy services and their profile.

Aside from the studies that form the portfolio of works, the integration of peer support with eTherapy is under-investigated. Only one study detailed the development of a peer-support protocol (Ray, Kemp, Hubbard & Cucciare, 2017) and, in general, studies focusing on eTherapy supporter type are few. Whilst Shandley et al. (2008) found eTherapy for panic disorder could be supported by suitably trained health professionals, the study failed to specify whether supporters should be clinically trained. Hollis et al. (2017) report a lack of research detailing levels of human support provided. Mohr et al. (2011) advocated incorporation of mental health clinicians or coaches into eTherapy, seeing this as integral to its success, and Robinson et al. (2010) recommend large scale trials on the clinical effectiveness and acceptability of technician-assisted (non-clinical) eTherapy.

Whilst peer support is a key to the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), by contrast, the IAPT manual (National Collaborating Centre for Mental Health, 2018) recommends that clinicians should support eTherapy stating:

> digitally enabled therapies can achieve comparable outcomes to face-to-face therapy when the same therapy content is delivered in an online format that allows much of the learning to be achieved through patient self-study, reinforced, and supported by a suitably trained clinician (National Collaborating Centre for Mental Health, 2018, p.41).

This recent focus on clinicians has affected the PSW workforce, forcing providers to adopt clinical models; which is at odds with mental health policy's focus on expanding and diversifying peer support in the mental health workforce (Health Education England, 2017).

The portfolio of works contributes to eTherapy knowledge in respect of the integration of non-clinical, peer support and of the effective and acceptable delivery of eTherapy in real-world, community settings.

2.6 Section discussion

Innovative, emerging technologies, such as Artificial Intelligence (AI) and eTherapy, can be used to meaningfully engage clients in online interventions that, in turn, can result in positive health and social outcomes (Vasilica & Ormandy, 2017). eTherapy is effective in the treatment of anxiety and depression (Andrews, Cuijpers, Craske, McEvoy & Titov, 2010), and as effective when compared to face-to-face CBT (Andersson et al., 2014; Andersson, Titov, Dear, Rozental & Carlbring, 2019b; Carlbring, Andersson, Cuijpers, Riper & Hedman-Lagerlöf, 2018).

Programme type is less important in relation to effectiveness, however supported eTherapy appears to be more effective than unsupported eTherapy (Andersson & Cuijper, 2009; Andersson et al., 2019b; Baumeister et al., 2014). Many questions remain, however, regarding support in eTherapy (Andersson & Cuijpers, 2009) and how client improvement

may be impacted by the duration, frequency, and expertise of any human support provided (Cuijpers et al., 2009; Shandley et al., 2008). Furthermore, further research is warranted on the nature of assistance provided (Schneider, Hadjistavropoulos & Faller, 2016).

High drop-out rates are reported in eTherapy (Melville, Casey & Kavanagh, 2010; Rost et al., 2017; Waller & Gilbody, 2009), though positive outcomes are associated with greater treatment adherence (Van Ballegooijen et al., 2014) and, in this regard, acceptability and effectiveness are inextricably linked.

Numerous eTherapy terms and delivery model permeations have presented research challenges; moreover, most research to date has focused on programme effectiveness, as opposed to focusing on moderators and mediators of eTherapy (Andersson et al., 2019b), with research typically being quantitative and of a positivist approach – focussing on effect sizes and statistics instead of client experience and acceptability. There has also been a distinct absence in the literature of descriptions of service delivery models and, to a degree, the implementation of eTherapy within routine care settings (Andersson et al., 2019b). Scalability of eTherapy can, however, be achieved by replacing clinical supporters, and destigmatisation of mental health issues can be addressed by utilisation of peer support in eTherapy delivery models (Wilhelm et al., 2020), as per the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**). Peer and non-clinical support are, however, under-used in eTherapy, despite the mental health workforce being in a declining state (British Medical Association, 2020).

Providers have been encouraged to publish on client experience and acceptance of services (Fleming et al., 2018). Doing so could result in the expansion of peer and non-clinical supported eTherapy services; allowing clinicians to concentrate on other areas of service provision. Further research is needed to identify whether clinician-supported eTherapy is more effective and acceptable than non-clinician supported eTherapy (**Gellatly et al., 2018**).

Overall, eTherapy has unfortunately not received the same amount of focus as other areas of IAPT, where face-to-face delivered low- and high-intensity interventions have been extensively researched. This is despite its undoubted potential to increase access and deliver positive outcomes. Given the scale of the problem of anxiety and depression, it is critical that eTherapy is routinely embedded as a mainstream, low-intensity treatment option.

The portfolio of works demonstrates the unique contribution made to eTherapy literature through demonstrating that an accessible, non-clinical, peer-supported *model* of eTherapy (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) is both effective and acceptable when delivered in a real-world setting as a low-intensity IAPT service for clients experiencing anxiety and depression.

2.7 Section summary

This section has examined eTherapy in the management of anxiety and depression, including clinical effectiveness, acceptability, and service delivery models. The absence of inclusion of peer support in eTherapy service delivery models is detailed with the *model* highlighted as addressing this gap where peer support is both a fundamental and integral component, fulfilled by the eTC role.

This gap is addressed in section three, which offers a rationale for the published works, thesis aim and objectives, and details the unique contribution of the included articles to eTherapy knowledge that collectively describe, review, and evaluate the effectiveness and acceptability of a non-clinical, peer-supported *model* of eTherapy service delivery (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**).

Section Three

This section provides the rationale for the published works, thesis aim and objectives, and details the unique contribution made to eTherapy knowledge achieved collectively through the included articles, as well as providing further detail on the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**).

3.1 Background and rationale for the published works

eTherapy was considered a new concept at the time when the *model* was developed and, whilst its effectiveness had been proven in the treatment of anxiety and depression (Andrews, Cuijpers, Craske, McEvoy & Titov, 2010), little was known about how to successfully implement eTherapy in services (Drozd, Vaskinn, Bergsund & Haga, 2016), and its acceptability was still largely unknown (Cavanagh et al., 2009).

Respondents of a national survey of 500 British Association for Behavioural and Cognitive Psychotherapies (BABCP) accredited CBT therapists in 2004, on the use of eTherapy, said that they would need to learn more about eTherapy before they would use it, and almost half had concerns about the potential increase in its use. Furthermore, respondents also reported a perceived lack of evidence for eTherapy (Whitfield & Williams, 2004), however it was not only CBT therapists who shared these views at the time, but others including NHS commissioners. Given this context, it was necessary to concentrate on quickly building the evidence base for the effectiveness of the *model* to secure a mainstream NHS commission for the service in one geographical area, beyond the initial pilot.

In the early to mid-2000s, providers were routinely required to submit client case vignettes, testimonials, and other monitoring reports to funders and commissioners as part of the terms and conditions of receiving funding. Hence, there was familiarity and adherence with this form of reporting. To ensure consistency with this established norm, the **Cavanagh et al. (2011a)** study was undertaken to describe and share knowledge of the *model*. **Cavanagh et al. (2011a)** also included a range of client case studies; frequently used as a method to undertake qualitative analysis (Stake, 2005; Yin, 2009, 2006) and, in this instance, to illustrate client acceptability as well as reporting on overall experience and onward journey – for example, securing of employment, volunteering opportunities, etc.; all important metrics for commissioners and funders.

Whilst Self Help Services was renowned for treading new ground, (e.g., being commissioned by the NHS to deliver user-led support groups as early as 2000), formal documentation of the unique approach was lacking. **Lidbetter and Bunnell (2013)** recorded this approach by providing a qualitative description of the charity's growth and development, highlighting the importance of lived experience of staff and volunteers in the charity's delivery of non-clinical, peer-supported services.

Whilst **Lidbetter and Bunnell (2013)** and **Cavanagh et al. (2011a)** helped raise the profile of the organisation and its services and, to an extent, qualitatively documented the *model*, it was clear that because of the then country-wide implementation of IAPT, that outcome reporting had shifted from the former qualitative, case-study/vignette methodology to that of a positivist approach with quantitative research favoured where client progress was measured in numbers. Cognisant of this, a quantitative analysis of the *model*, benchmarking outcomes against key IAPT outcomes **(Cavanagh et al., 2011b)**, was undertaken. This demonstrated that the *model* was clinically effective for the first time when delivering BtB™ in the treatment of adults with depression or anxiety within a low-intensity IAPT service, delivered

in the community where over a third of referrals were self-originated. This evidence enabled a mainstream NHS commission for the service and interest outside of Greater Manchester.

By 2012, commissioners were increasingly interested in providers developing services for those with dual diagnosis presentations, as it was expected that this would become one of the biggest issues that the country would face, with suggestions that as many as 75-85% of individuals with substance misuse issues would also experience clinical levels of mental ill health (Weaver et al., 2003). It was important to demonstrate that, in addition to being able to support those with symptoms of anxiety and depression, the *model* could also be used to support those with comorbid substance misuse issues. **Elison et al. (2014)** achieved this by demonstrating that the *model*, when used to deliver BFO, was clinically effective and appropriate for some individuals presenting with dual diagnosis issues, as well as depression and anxiety.

As eTherapy became established as a mainstream intervention, so too followed an expansion in the range and availability of eTherapy programmes (Bennion et al., 2017). Quantitative service evaluations **(Elison et al., 2017**; **Luik et al., 2017**) showed that the *model* could achieve clinically effective results using different programmes; demonstrating versatility and, critically, that programme type affected outcomes less than previously thought. Diversifying the *model* in this way also addressed client desire for greater programme choice, and facilitated tailoring of the service to client presentation, resulting in expansion of the *model's* scope to include clients with sleep difficulties (**Luik et al., 2017**). **Elison et al. (2017)** also provided important evidence for the charity in practice, in respect of programmes, in terms of determining which might be used going forward; an issue of importance since there was considerable variance in their cost as well as addressing comorbidity; an issue affecting many of the clients accessing the charity's services.

Whilst the effectiveness of the remote *model* alongside the venue *model* via a hybrid configuration had been achieved through **Elison et al. (2014**, **2017)** and **Luik et al. (2017)**, the remote *model* had not been the exclusive subject of a quantitatively focused, service evaluation. This was achieved through **Gellatly et al. (2018)**, which demonstrated that the remote *model* could meet IAPT key performance targets and could produce outcomes comparable to other eTherapy services operating in IAPT; enabling the evolved remote *model* to then be widely marketed to NHS commissioners across Greater Manchester and beyond. This was important in practice as the venue *model* was becoming increasing unpopular and costly to operate.

Aside from the Portfolio of Works that describe the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), only two papers have been published on peer-supported eTherapy (de Vares, 2007; Ray et al., 2017); both of which are limited in scope. The former described a protocol for an eTherapy service yet to be established, whilst research undertaken by Ray et al. (2017) was limited to the investigation of possible insertion of peer support into an existing clinical model.

By addressing gaps in the literature on the role of peer support in eTherapy service delivery and of the effectiveness and acceptability of non-clinical, peer-supported eTherapy in real-world settings, this portfolio of work examines the development, effectiveness, and acceptability of the *model* (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) in the management of anxiety and depression in adults, developed at Self Help Services, under the author's direction.

3.2 Thesis aim and objectives

The aim of this thesis is to describe the development and evaluation of a non-clinical, fully peer-supported eTherapy *model* (**Cavanagh et al., 2011a, 2011b; Elison et al, 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) in the management of anxiety and depression in adults.

The key objectives are to:

1 Examine the development of the *model*

2 Review and evaluate the clinical effectiveness of the *model*

3 Evaluate the acceptability of the *model*

3.3 Contribution of included papers

The candidate has made a unique contribution to each of the seven papers under scrutiny, and as a whole – see Table 10.

Table 10: **Details of the published works and the contribution made.**

Study	**Study Objectives**	**Paper overview & contribution to the development of the *model***	**Author contribution**	**Thesis Objectives**
Paper 1: Cavanagh, K., Seccombe, N., Lidbetter, N., & Bunnell, D. (2011a). Supported, service-user led, computerised cognitive behavioural therapy (CCBT)	To describe an innovative, third sector, non-clinical, peer-supported, eTherapy *model* commissioned within Greater Manchester.	This paper described, for the first time, the implementation of, and service delivery model for, the novel, peer-supported venue *model* when operating as a low-intensity IAPT service for anxiety	Conceptualisation of peer-supported eTherapy *model*. Responsible for operational development and implementation of the venue *model*. Agreeing methodological approach to take with partners.	Examine the development of the *model* **(Objective 1)**.

self-help clinics. *Journal of Public Mental Health,* 10(4), 225-233.		and depression in Greater Manchester. The paper demonstrated that the *model* was able to meet a diversity of need and that clients accessing the service are representative of the local population and of clients that access IAPT services instead of the service being supported by clinicians (PWPs) as is typical of eTherapy services delivered through IAPT (Thew, 2020). This paper provided detail on eTherapy client experience by examining the experiences of four clients via case studies that accessed the venue-based *model:* demonstrating its acceptability.	Involved with the preparation, writing and subsequent revisions of the manuscript including decision to include case studies and inclusion of pictorial description of client pathway. Responsible for ensuring overall adherence to service governance regulations. Led on the internal dissemination strategy.	Evaluate the acceptability of the *model* **(Objective 3)**.
<u>Paper 2:</u> Cavanagh, K., Seccombe, N., & Lidbetter, N. (2011b). The Implementation of Computerized Cognitive Behavioural therapies in a Service User-Led, Third Sector Self Help clinic. *Behavioural and Cognitive Psychotherapy*, 39(4), 427-442.	To evidence the implementation of a service user-led, third sector eTherapy clinic via a quantitative service evaluation. To report on uptake and outcomes for the eTherapy programme BtB™ measured using the IAPT Minimum Data Set (IAPT MDS) and Key Performance	This paper benchmarked the venue-based *model's* outcomes when used to deliver BtB™ for outcomes and service uptake including employment status, pre- and post-treatment, and the initial level of unsuitable referrals compared to NHS IAPT demonstration sites, reporting comparable results regarding key	Conceptualisation of the peer-supported eTherapy *model*. Responsible for operational development and implementation of the venue *model*. Agreeing methodological approach to take with partners and the research question. Responsible for ensuring overall adherence to service	Examine the development of the *model* **(Objective 1)** Review and evaluate the clinical effectiveness of the *model* **(Objective 2)**.

	Indicators in relation to extending access to recovery (Department of Health, 2008), when delivered via the *model*. To test the generalisability of BtB™ in terms of previously proven efficacy and effectiveness in NHS services, by studying pre- and post-outcomes when delivered in the community via the venue *model* via a pragmatic study.	outcome measures and recovery rates. This paper demonstrated for the first time, that the peer-supported, eTherapy *model* was effective and capable of meeting IAPT targets, without the involvement of clinicians, - this being a key step towards securing an NHS commission of the service. Furthermore, the paper reported that the *model* was able to deliver three times as many sessions compared to the most engaged IAPT demonstration site; demonstrating acceptability and future potential in terms of client throughput and ability of the service to contribute towards meeting of IAPT prevalence targets. The paper reported on client satisfaction using the IAPT Patient Experience Questionnaire – demonstrating high satisfaction rates. This paper provided evidence of the importance of referral source, and that clients that self-refer are more likely to take up the service and to complete at least two sessions, as well as being	governance regulations. Provided advice and guidance to Data Lead in terms of collection and analysis of data sample. Involved with the preparation, writing and subsequent revisions of the manuscript. Led on the internal dissemination strategy.	Evaluate the acceptability of the *model* **(Objective 3)**.

		significantly more likely to complete the full eTherapy programme. This paper provided important insight into the relationship between adherence, and referral source in the *model*. The paper also reported on ethnicity, caseness, chronic physical health conditions, clinical characteristics upon starting the eTherapy programme (symptom severity), gender, medication, and age and relationship with referral source, likelihood of starting the programme, as well as completion rates – giving new information regarding acceptability as well as reporting high rates of satisfaction.		
<u>Paper 3:</u> Lidbetter, N., & Bunnell, D. (2013). Self Help Services: helping people to help themselves. *Mental Health and Social Inclusion*, 17(2), 76-81.	To describe the growth of the user-led charity, Self Help Services, founded by the thesis' author to becoming a key provider of NHS commissioned, primary care mental health services, including eTherapy services, in the North West of England.	This paper detailed how those with lived experience of mental health difficulties (specifically, anxiety and depression), can be intrinsically and integrally involved in the delivery of NHS commissioned primary care mental health services (specifically, eTherapy services). It detailed the charity's growth	Conceived the idea and led on the design and write up of the manuscript including determining the manuscript's focus, selection of case studies and the inclusion of the 'lessons learned' narrative. Led on the external and internal dissemination strategy.	Examine the development of the *model* **(Objective 1)**.

		and expansion into other areas of service delivery, including differentiation of the eTherapy *model* into new locations, including a Category A prison; demonstrating the versatility of the *model* in terms of where it could be delivered i.e. from venues very different to the community centres where the *model* had originally operated from. The paper provided evidence that personal experiences are 'vital tools' in helping others work through their own difficulties in the eTherapy *model* and that the peer-support element is an integral component of the *model*.		Examine the development of the *model* **(Objective 1)**. Evaluate the acceptability of the *model* **(Objective 3)**.
<u>Paper 4:</u> Elison, S., Ward, J., Davies, G., Lidbetter, N., Hulme, D., & Dagley, M. (2014). An outcomes study of eTherapy for dual diagnosis using Breaking Free Online. *Advances in Dual Diagnosis*, 7(2), 52-62.	To examine outcomes for clients experiencing substance dependency and comorbid mild to moderate mental health problems accessing the dual diagnosis eTherapy programme, Breaking Free Online, via the *model*.	This paper provided evidence of the effectiveness and clinical effectiveness of the Breaking Free Online eTherapy programme for clients experiencing dual diagnosis difficulties, when accessed via a hybrid version of the *mode*l where face-to-face and telephone support are made available, according to client choice. This paper demonstrated the *model's* versatility	Provided approval for the research team to access the database of anonymised clinical data from clients of Self Help Services' that had accessed the *model.* Responsible for ensuring overall adherence to service governance regulations. Provided comments on the manuscript ahead of publication. Led on the internal	Examine the development of the *model* **(Objective 1)**. Review and evaluate the clinical effectiveness of the *model* **(Objective 2)**.

		in supporting a new client group for those first time – those with dual diagnosis issues i.e. anxiety and/or depression as well as substance misuse issues. This was of relevance because of the comorbidity of such issues. Therefore, the paper showed that the *model* had a wider reach than was initially demonstrated in **Cavanagh et al., 2011b.**	dissemination strategy.	
<u>Paper 5:</u> Elison, S., Ward, J., Williams, C., Espie, C., Davies, G., Dugdale, S., … Smith, K. (2017). Feasibility of a UK community-based, eTherapy mental health service in Greater Manchester: repeated-measures and between-groups study of 'Living Life to the Full Interactive,' 'Sleepio™' and 'Breaking Free Online' at 'Self Help Services.' *BMJ Open*, 7(7).	To explore the feasibility and outcomes of the *model* via examination of IAPT outcomes for clients engaging with three different eTherapy programmes through a pre- and post-test service evaluation.	This paper provided further evidence of the effectiveness of three eTherapy programmes when delivered through a hybrid version of the *model* where face-to-face and telephone support were made available, according to client choice. The significance of this was that the paper demonstrated that the *model* could achieve positive outcomes when used to deliver 3 different eTherapy programmes of differing formats and components. Previously effectiveness had only been established in **Cavanagh et al., 2011b** for BtB™ and via **Elison et al., 2014** for BFO.	Provided approval for the research team to access the database of anonymised clinical data from clients of Self Help Services' that had accessed the *model.* Responsible for ensuring overall adherence to service governance regulations. Provided comments on the manuscript ahead of publication. Led on the internal dissemination strategy.	Examine the development of the *model* **(Objective 1)**. Review and evaluate the clinical effectiveness of the *model* **(Objective 2)**.

		This paper therefore demonstrated that the *model* could support client choice regarding eTherapy programme selection – of importance given the emphasis on collaboration as well as the overall ethos of Self Help Services being that of putting clients in control of their treatment, support and ultimately, their recovery.		
<u>Paper 6:</u> Luik, A. I., Bostock, S., Chisnall, L., Kyle, S. D., Lidbetter, N., Baldwin, N., & Espie, C. A. (2017). Treating depression and anxiety with digital cognitive behavioural therapy for insomnia: a real world NHS evaluation using standardized outcome measures. *Behavioural and Cognitive Psychotherapy*, *4 5* (1), 91-96.	To evaluate the implementation of the eTherapy programme, Sleepio™, when delivered via the remote *model* for clients experiencing anxiety and/or depression.	This paper detailed the successful implementation of the remote version of the *model* where clients accessing the eTherapy programme, Sleepio™, are supported entirely via the telephone by non-clinical, peer supporters. The paper demonstrated that the *mode*l achieves a recovery rate greater than the IAPT target recovery and reliable recovery rate and a treatment rate that is above the IAPT average for clients experiencing anxiety and/or depression as well as poor sleep, therefore demonstrating the *model's* versatility both in terms of its composition (the newly evolved	Contributed to the design of the study, leading on the site's strategic delivery of the project including ensuring adherence to service governance regulations. Contributed to the final draft of the manuscript. Played a critical role in the dissemination of the paper to relevant service users and professional populations.	Examine the development of the *model* **(Objective 1)**. Review and evaluate the clinical effectiveness of the *model* **(Objective 2)**.

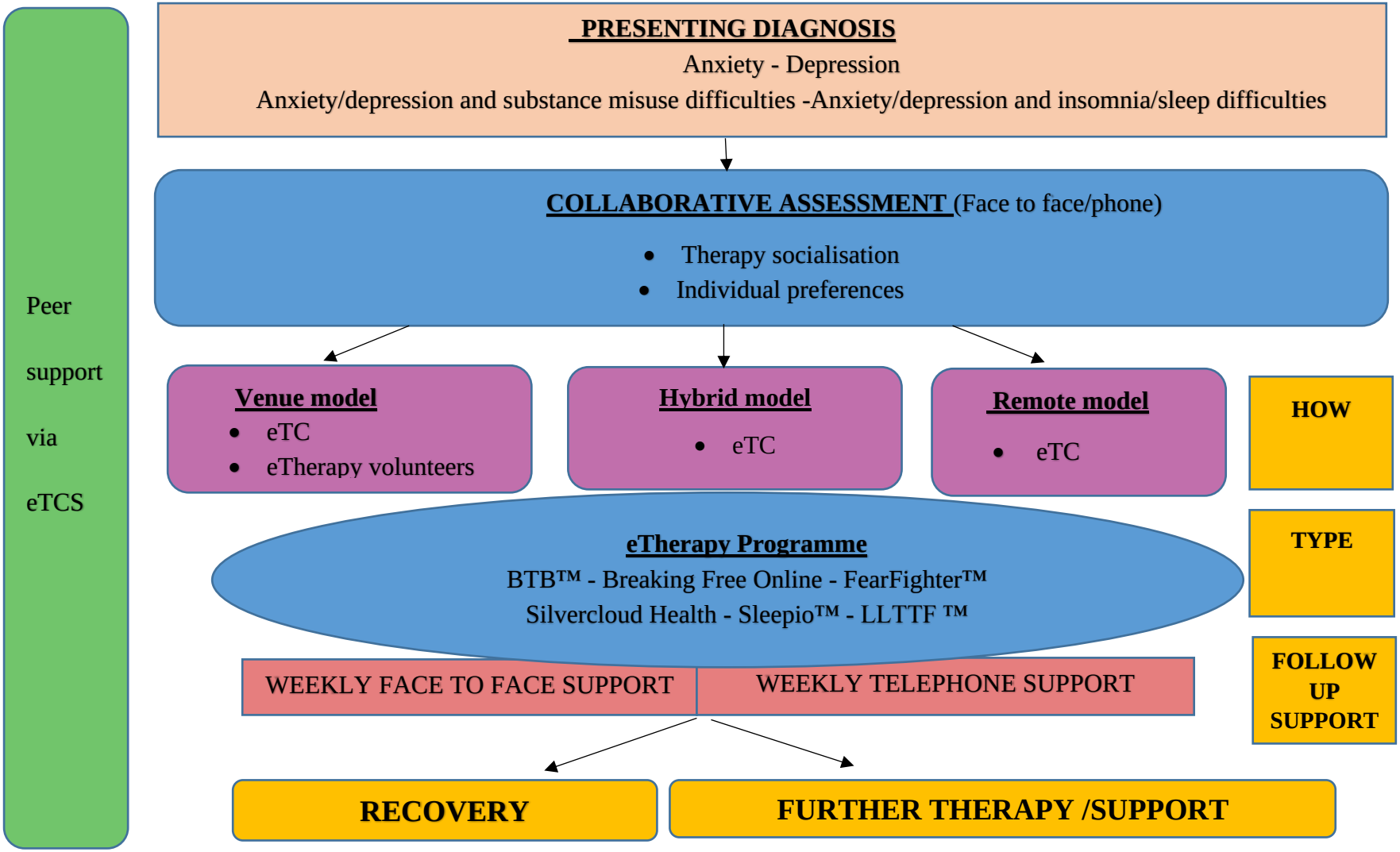
		remote *model*) and of the client groups it can support. i.e. clients with anxiety and/or depression as well as sleep issues. This was of relevance because of the comorbidity of such issues and the bidirectional relationship between sleep and poor mental wellbeing, specifically anxiety, (Alvaro, Roberts & Harris, 2013). Therefore, the paper showed that the *model* had a wider reach than was initially demonstrated in **Cavanagh et al., 2011b** and **Elison et al., 2014, 2017**.		
Paper 7: Gellatly, J., Chisnall, L., Seccombe, N., Ragan, K., Lidbetter, N., & Cavanagh, K. (2018). @ Home eTherapy service for people with common mental health problems: an evaluation. *Behavioural and Cognitive Psychotherapy*, 4 6 (1), 115-120.	To evaluate the implementation of an innovative @ home/remote eTherapy *model* by reporting service outcomes and comparing these with national IAPT service data.	This paper reported on outcomes by providing data from the peer-supported @ home/remote *model*, comparing these against national IAPT outcomes and outlining the *model* where peer support and lived experience is central to this evolved model of eTherapy service delivery. Higher recovery rates are reported than the previous study undertaken on the venue *model* **(Cavanagh et al., 2011b)** which helped build the evidence base for this, the remote version of the	Instigated the research project. Refined aims and objectives of the research ensuring compliance with service governance regulations. Contributed to the preparation, writing and revisions of the manuscript. Played a critical role in the dissemination of the paper to relevant service user and professional populations.	Examine the development of the *model* **(Objective 1)**. Review and evaluate the clinical effectiveness of the *model* **(Objective 2)**.

		*mode*l – needed to secure the future re-commissioning of the service by the NHS. The paper reports on the flexibility of the *model* and the possible contribution that this has in terms of engagement and outcomes and was operationally important since by 2018, many clients were choosing not to access the venue version of the *model*; opting instead for the remote version because of convenience.		

3.4 The non-clinical, peer-supported eTherapy model

The non-clinical, peer-supported eTherapy *model* is depicted in Figure 1, having been developed in all its iterative parts via the portfolio of works (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**).

Figure 1: The non-clinical, peer-supported, eTherapy *model*



Description of the model

The *model* originally operated from community venues with a suitable space (typically IT suites/community cafés, learning zones, schools, and hospitals), where up to four clients at any one time accessed the service via stand-alone PCs/laptops. In the venue *model*, the service is co-ordinated by an eTC (an individual typically with lived experience of a mental health condition who has previously accessed the *model*). eTCs are supported by, on average, three volunteers (individuals with lived experience of a mental health condition, typically anxiety and depression). Both roles are described in Section 2.5.

Referral and assessment

Clients are referred through a variety of means, including GP and self-referral (but must be registered with a GP), and attend an assessment undertaken by the eTC, during which risk and symptom severity is assessed to determine suitability for the service using the PHQ-9 and GAD-7. Confidentiality is discussed as is completion of sessional measures – this being a monitoring and evaluation requirement of the commissioning body. eTCs verify clients do not satisfy any exclusion criteria (see Table 11) and are able to meaningfully engage with programme content.

Table 11: eTherapy service exclusion criteria.

Presence of an organic brain disorder such as dementia
Client is in an acute phase of substance misuse
Client is in an acute phase of psychosis
Client has a moderate to severe learning difficulty
Client has a severe mental illness presentation (e.g., bipolar disorder, schizoaffective disorder, etc.)
Client < 18 years of age

eTherapy programmes available through the *model*

Clients are provided with a description of programmes available, which include BtB™, Sleepio™ (Espie et al., 2012), BFO (Elison et al., 2013), LLTTF™ (Williams, n.d.), FearFighter™ (Marks et al., 2004; Schneider et al., 2005), and Silvercloud Health (Sharry et al., 2013; Richards et al., 2015). Programme availability is dependent on geographical location of the service provided and is collaboratively selected with clients who are then explained how the service works.

When the *model* was first developed, programme access was limited as only a few eTherapy programmes had been recommended by NICE (2002) and approved by NHS commissioners for local use. Today, programme selection is determined by the client's presenting problem and goals, and a much wider selection of programmes are available. The portfolio of works details the development of the evidence base for the *model's* effectiveness and of its acceptability in clients presenting with issues such as insomnia and dual diagnosis issues, using the disorder-specific programmes of Sleepio™ and BFO, respectively.

Client support, eTCs and volunteers

eTCs investigate client computer experience and specific needs via a short, supportive conversation to address any pre-existing anxiety about computer use, as well as to identify the presence of any disabilities that may necessitate adaptations. As eTCS have lived experience of a mental health condition, this experience is deployed to support clients on their road to recovery through offering a personal approach to support and via appropriate self-disclosure. Emphasis is also placed on the availability of eTherapy volunteers (individuals who also have lived experience of a mental health condition) for assistance, peer support and guidance during sessions. Additionally, clients are advised that they may contact the eTC in between sessions if, for example, they struggle with homework. The peer support element of the overall support offer, (visible through the eTCS and volunteers), conveys hope to clients

that it is possible to manage anxiety and depression to a point such that they do not continue to adversely affect daily functioning. At the end of the initial appointment, the client signs a service contract and watches an introductory video for the programme that it has been collaboratively agreed they will undertake, after which, the first session is organised. Thereafter, sessions typically take place on a weekly basis for six to eight weeks on average, though duration varies per programme.

Development of the remote *model*

The *model* was further developed to allow clients to access the service remotely (**Gellatly et al., 2018**); instigated as many clients expressed difficulties accessing the venue *model* due to work and other commitments. This, along with venue hire costs as well as the cost of IT hardware such as laptops etc. (which needed to be typically replenished every three years), gave rise to the development of the remote *model*. In some areas, a hybrid *model* operated, where eTCs assessed clients face-to-face (typically at Self Help Services' community venue); thereafter, clients were supported remotely by telephone by the eTC.

eTCs solely deliver the remote *model*; undertaking weekly support calls of approximately 15-20 minutes, during which programme progress reports (if available) along with goals are reviewed, as well as risk and safeguarding issues identified. The IAPT MDS is completed, and a general discussion takes place focussed on the module undertaken and any challenges encountered, along with enquiry into how clients plan to implement the intervention covered. If risk is identified at any point, a full risk assessment is carried out by the eTC and relevant actions taken, including liaison with the client's GP and/or referral to crisis services. This, and any other actions, are documented (for example, signposting to other resources), and the next support call date confirmed.

Upon completion of therapy, clients are reminded that they may re-access the programme as a self-help aid for a specific period (this varies per programme) and are discharged; with a copy of the discharge report provided to the client's GP.

3.5 Section summary

This section has provided the background to and rationale for the published works, detailed the thesis aim and objectives, and outlined the unique contribution of the published works to eTherapy literature. The *model*, which is the focus of the published works (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**), is described with all its iterations (venue, remote, and hybrid versions).

The next section will provide an overview of the papers that form the portfolio of works, including their strengths and limitations, followed by a critique by thesis objective.

Section Four

4.1 Overview of the publications

An overview of the papers including their strengths and limitations, followed by a critique by thesis objective, is presented in this section.

All studies (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**) describe aspects of the *model* and its development, including the original venue *model*, remote *model*, and the hybrid *model* (Objective 1).

Cavanagh et al. (2011b), **Elison et al. (2014, 2017)**, **Gellatly et al. (2018)** and **Luik et al. (2017)** are all quantitative service evaluations where pre- and post-client outcome data was analysed. The IAPT MDS was collected in full (**Cavanagh et al., 2011b; Gellatly et al., 2018**) for the venue and remote *models* respectively, with outcomes benchmarked against national IAPT outcomes (**Cavanagh et al., 2011b; Gellatly et al., 2018**) to demonstrate effectiveness (objective 2).

Elison et al. (2014, 2017) and **Luik et al. (2017)** demonstrate the effectiveness of the *model* (objective 2) in achieving outcomes for clients with substance misuse issues and insomnia, in addition to anxiety and depression.

Finally, **Cavanagh et al. (2011a)** and **Lidbetter and Bunnell (2013)** are qualitative studies that, as well as describing the *model* (Objective 1), evaluate its acceptability (Objective 3).

4.2 Presentation and critique of the publications

Paper 1: Cavanagh, K., Seccombe, N., Lidbetter, N., & Bunnell, D. (2011a). Supported, service-user led, computerised cognitive behavioural therapy (CCBT) self-help clinics. *Journal of Public Mental Health,* 10(4), 225-233.

This descriptive paper includes four qualitative case studies, and describes the implementation, operational delivery, management, and development of the venue *model* (Objective 1), its impact on the population served (Objective 3) and relevance in terms of UK mental health strategy, which centred on expanding availability and increasing accessibility of evidence-based interventions in the treatment of anxiety and depression.

Cavanagh et al. (2011a) describes the user-led nature of the charity to provide context to the *model* and details funding and commissioning arrangements, along with a description of venues it operated from (Objective 1). Information regarding referral source (to explain the *model's* location in relation to other mental health services) and client pathway including the nature, functions, and duration of touchpoints with eTCs and volunteers and their role is provided (Objective 1). Outcome measures (IAPT MDS) are described, number of clients referred and information on programmes (and their content) available through the *model* at the time: BtB™, LLFT™ and FearFighter™. A summary of the service's key performance indicator, the IAPT recovery rate, is provided with suggestions as to why clients who have accessed the *model* do not meet the criterion for recovery, and what happens in terms of their potential onward pathway. Information regarding programme licenses and implications for the overall cost of delivering the *model* is detailed, with reference made to an accompanying, quantitative evaluation of the same service - **Cavanagh et al. (2011b)**, where outcome data was benchmarked against national IAPT data to demonstrate the *model's* effectiveness when used to deliver BtB™ in a real-world setting.

Four clients provided qualitative feedback on their experience of accessing the *model* as part of the charity's standard service monitoring and evaluation process, where it was routine to

seek views of clients to develop case studies and vignettes for inclusion in reports to funders and for inclusion in other relevant publications (Objective 3), as well as for continuous service improvement purposes. Two clients were male and two female, with half referred by their GP, one via a friend, and another through their psychologist. Client presentations were depression, anxiety, phobias, low mood, and health anxiety; all of which had been experienced for differing durations (range: five months to 30 years). Client age and marital status was provided for only half of the case studies, and medication status detailed in all but one of the case studies. The case studies provided insight into:

- How clients found out about the service
- Referral mechanism
- Conditions(s) that clients were seeking help with
- Accessibility issues
- Client views on the service and the eTherapy programme; what they liked, what could be improved (Objective 3)
- Client onward pathway

The paper reports that the *model* achieves a high throughput of clients with over a third self-referring, with intake and outcome measures suggesting that clients accessing the service are representative of both the local population and IAPT clients accessing services for anxiety and depression, see **Cavanagh et al. (2011b)** for detail. The paper also reports that clients value the service highly, including programmes and support offered via eTCs and volunteers (Objective 3), and that the *model's* ability to meet a diversity of needs is demonstrated, detail also provided in **Cavanagh et al. (2011b)**.

The paper concludes that roll-out of the successful service *model* is highly recommended and is of interest to service users, providers, and commissioners wishing to develop similar

services. Future service and research developments are specified, including examination of the effectiveness of a later iteration - the remote *model* - reported in **Gellatly et al. (2018)**.

The lack of follow-up is a limitation of the study; however, it was not possible to track client progress beyond the point of discharge because of limited resources and the study being a service evaluation (and permission not having been sought at the outset to contact clients post-discharge). A further limitation is the failure to report on uptake by clients of other mental health services and on the utilisation of step-up, step-down, step-sideways, and step-out routes that connect Self Help Services and other TS providers to the NHS and other statutory organisations. Including this information would have given helpful insight as to where the *model* sat within the overall mental health system.

Findings may have been influenced because of the majority of the study's researchers being employed by Self Help Services and therefore being involved, albeit at arm's length, with the development and delivery of the *model*. However, as this was a service evaluation, a realist approach was applicable (Robson & McCartan, 2016), and it was impossible to fully exclude those authors employed by the organisation from involvement in the study. However, the individuals concerned did not directly contact clients selected as case studies, which mitigated against any Hawthorne effect (French, 1953) in terms of client response.

Finally, client outcomes reported via the case studies cannot be solely attributed to the *model* as improvement may have resulted due to other factors including new relationships, changes in personal circumstances, and other external support. Further exploration of these possible external factors via a grounded theory approach utilising structured interviews would have overcome this.

The study's strength is that it provides a robust overview of the *model*, including outlining the client pathway; enabling potential future replication by others (Objective 1), making a unique contribution to eTherapy literature in detailing a novel model of service delivery.

Furthermore, in including heterogeneous case studies, this gives rich insight into client acceptability of the service (Objective 3), though there is lack of consistency in terms of format and information included, which is recommended good practice in case study methodology (Simons, 2009). **Cavanagh et al. (2011a)** also supplies valuable information on referral source and throughput of the service; at the time, this was highly relevant given the focus on IAPT access and uptake (Department of Health, 2012). A decade on, research has shown that GPs are still largely unaware of eTherapy as an intervention (Breedvelt et al., 2019), and so the ability to self-refer remains as important.

In summary**, Cavanagh et al. (2011a)** was the first paper to describe the implementation of, and to provide a service operating procedure for, the venue *model* (Objective 1) when offered as a low-intensity IAPT service for clients experiencing anxiety and depression in a real-world, community setting. In doing so, the paper filled a gap in eTherapy research regarding community-delivered, peer-supported, non-clinical eTherapy models of service delivery.

Paper 2: Cavanagh, K., Seccombe, N., & Lidbetter, N. (2011b). The Implementation of Computerized Cognitive Behavioural therapies in a Service User-Led, Third Sector Self Help clinic. *Behavioural and Cognitive Psychotherapy*, 39(4), 427-442.

This study evaluated the effectiveness of the venue *model* when delivering BtB™ for the first time in a real-world, community setting (Objective 2). It tested the generalisability of findings of an earlier large scale RCT (Proudfoot et al., 2004), and several pragmatic studies undertaken in the NHS (Cavanagh et al., 2006; Learmonth, Trosh, Rai, Sewell & Cavanagh, 2008) where BtB™ was demonstrated to be efficacious and effective. The study was a pragmatic, quantitative service evaluation where data (including pre- and post-clinical outcome measures and other metrics) was retrospectively analysed over a 16-month timeframe (November 2007 - March 2009). This study was required to demonstrate the

effectiveness of the *model* to NHS commissioners to secure mainstream funding for the service and complemented the **Cavanagh et al. (2011a)** qualitative study.

A total of 510 referrals were received during the period, of which 36.7% were self-referrals, 59.7% GP referrals, and 4.1% from other sources, e.g., the local NHS primary care mental health team. Focus was placed on referral source and demographics to enable comparison with IAPT demonstration sites (Clark et al., 2009), as the importance of self-referrals in widening access via the national roll-out of the IAPT scheme had been recognised.

Of the 510 initial referrals, 386 clients accessed the *model* and were screened for suitability by the eTC via an assessment lasting between 30 minutes to an hour, and 351 clients were deemed suitable to access the *model*. All completed a baseline assessment where demographic information was collected, as well as: PHQ-9 and GAD-7 measures; the 10-item Clinical Outcomes in Routine Evaluation Outcome Measure - CORE-OM (Connell & Barkham, 2007); the Work and Social Adjustment Scale - WSAS (Mundt et al., 2002); the IAPT Patient Experience Questionnaire - PEQ (to measure client satisfaction) - (Objective 3); and the Department of Health's Self-Report Questionnaire, which focuses on employment (Department of Health, 2008). CORE-OM (part of IAPT MDS at that time) was included because of its ability to measure symptoms in a broad manner, therefore acting as a general wellbeing measure whilst also allowing for discrimination between clinical and non-clinical populations (Connell & Barkham, 2007). GAD-7 and PHQ-9 were completed sessionally, whilst all other outcome measures were completed at baseline and upon completion of all eight sessions of BtB™. The rationale for using IAPT measures was that these were the measures used by Clark et al. (2009), which reported on experience and outcomes of IAPT services offering low intensity services including clinician-supported eTherapy. In using the same outcome and satisfaction measures, a direct comparison of the *model* with recently established IAPT services could be made.

Chi squared analyses (Pearson's uncorrected) were undertaken to facilitate the exploration of any relationship between two independent variables, in this case referral source (GP or and self-referred groups) and completion of at least two episodes of treatment, uptake, and treatment completion (all eight sessions completed). The decision to choose the variable of completion of a minimum of two sessions by clients was taken as this is the IAPT definition of a completed course of treatment/treatment episode (Moller et al., 2019).

The Chi squared test is a robust statistical test (Cochran, 1952) that is easy to compute, yet provides detailed information. It requires large sample sizes, as per **Cavanagh et al. (2011b)**, as it is sensitive to sample size (McHugh, 2013). This test was also used to examine the relationship between ethnicity (making a comparison between white and BME groups) and referral source, programme uptake, completion of at least two sessions, and of all eight sessions.

When comparing the impact of referral source, self-referrals were more likely to translate into clients that went onto access the service (suggesting greater motivation to access eTherapy), as opposed to GP originated referrals, and were more likely to complete at least two sessions and all eight sessions. There was no difference between white and BME referrals in terms of likelihood to be GP or self-referred, and no difference between white and BME groups regarding uptake or completion of at least two or eight sessions.

Chi squared tests (Pearson's uncorrected) were used to explore the relationship between age and programme uptake, completion of at least two or eight sessions, with no difference found between these variables. Chi squared tests were used to explore the relationship between gender and likelihood of starting the programme, and of completing at least two or all eight sessions, with no difference found. No difference was found when examining the relationship between medication status (comparing those who reported to have taken psychotropic medication with those who had not). When comparing clients with chronic physical health

conditions and those without, when examining the relationship between likelihood to start the programme and of completing at least two or all eight sessions, no differences were found between the groups.

Of those providing baseline data, 246 clients met the criteria for depression and 276 for anxiety caseness criteria (NHS Digital, 2017), with 228 meeting both criteria. Analysis found that clients who met caseness criteria at assessment were more likely to access the *model* than those who did not; however. no difference was found in respect of clients above and below caseness at assessment regarding completing at least two or all eight sessions. No differences between clients who started the programme or not were found at assessment in respect of measures of depression, anxiety, general wellbeing, or work and social adjustment, though those completing all eight sessions appeared to have lower symptom levels and general distress at intake. No differences in functioning or self-impairment were detected between those who failed to complete all eight sessions of the programme.

Outcome data was analysed on an intention-to-treat basis, with all clients opting to access the service undertaking a baseline assessment who had accessed at least two sessions (n=265). This approach is advantageous since it prevents any bias from occurring when incomplete data is related to outcome; of relevance to eTherapy where adherence and completion are reported to be related to outcomes (Van Ballegooijen et al., 2014). This method also provides a conservative estimate of treatment effect (Gupta, 2011).

The study reported large effect sizes for clients who had completed at least two sessions (n=265) in relation to depression and anxiety (d= 0.8 and 0.9 respectively), indicating that the measure of the magnitude of the experiment effect, in this case, BtB™ when delivered via the *model*, was large. Medium effect sizes were found in relation to wellbeing; measured via the CORE-OM and WSAS. Furthermore, following treatment, 142 of 226 clients from the initial intake who had met caseness criteria at baseline for either anxiety or depression or both, no

longer met the caseness clinical cut-off for either depression (measured by PHQ-9) or anxiety (measured by GAD-7). The move from 226 clients meeting caseness at intake to 123 at their final measurement suggested that 50% of clients moved to recovery; demonstrating the *model's* clinical effectiveness when used to deliver BtB™ (Objective 2).

Acceptability and client satisfaction were measured using the PEQ at assessment and end of treatment. Of those that had completed the questionnaire, 89% were happy with the overall experience of using the service, and 93% with the type of treatment received (Objective 3).

Employment data was incomplete, with pre- and post-data available for only 40.4% of clients who had accessed two or more sessions, and with no change in employment status recorded at the final measurement point; though some clients had moved into employment from welfare benefits, whilst others had secured volunteering roles or moved from part- to full-time employment.

Data benchmarked against data reported from IAPT demonstration sites (Clark et al., 2009) revealed more self-referrals and fewer unsuitable referrals, as well as similar proportions of referrals in terms of gender split and over 65s. The finding that self-referrals may result in greater treatment adherence was of importance since many IAPT services report high drop-out rates at step 2 (Chan & Adams, 2014), and adherence is known to be associated with outcome and acceptability (Van Ballegooijen et al., 2014). Similarly, the *model's* higher completion rate of 52% (compared to 37% in Doncaster and 24% in Newham) was viewed favourably by commissioners.

The study found that the *model* delivered three times as many treatment episodes as IAPT demonstration site with the highest level of engagement, with self-referrals being more likely than GP originated referrals to engage and complete the entire programme, and seemingly not impacting on the number of unsuitable referrals. This indicated that clients are likely to do better when accessing a treatment that they have chosen rather than one that has been imposed.

This finding was of interest amongst commissioners with access targets to meet and contrasted with earlier research that indicated that GP referred clients were likely to do better (Mataix-Cols, Cameron, Gega, Kenwright & Marks, 2006). Furthermore, changes in effect size on key IAPT outcome measures and recovery rates for those completing at least two treatment sessions were comparable with IAPT demonstration sites (Objective 2), showing that clinical outcomes achieved by the *model* were comparable to those reported in other low-intensity services (Clark et al., 2009), though clients accessing IAPT demonstration sites had slightly higher symptom severity.

BME clients were just as likely to start, finish, and complete BtB™ via the *model.* Given BME access to IAPT services is a key issue that many have sought to address (Beck, Naz, Brooks & Jankowska, 2019), this was a key finding; demonstrating the utility of the *model* and its role in serving population need (Objectives 1 and 3). Whilst BME referrals were slightly under-represented compared to the population in Manchester, with higher levels of baseline distress, no difference was found regarding access and outcomes.

Client satisfaction rates (Objective 3) were high in clients accessing the *model* (measured by the PEQ), however the views of those who disengaged were not sought; this being an area previously highlighted as necessitating further research (Kaltenthaler et al., 2008), and a limitation of the study. Other limitations included an under-representation of older clients aged over 65, incomplete data collection for employment outcomes, and lack of follow-up data. **Cavanagh et al. (2011b)** is a practice-based study without a control, which is problematic in terms of the internal validity of the study as outcomes could be explained by other variables or may have arisen due to methodological errors (Patino & Ferreira, 2018). This is mitigated by there being evidence of low rates of spontaneous remission in those seeking help with chronic anxiety and mild-moderate depression (Clark et al., 2009; Posternak & Miller, 2001).

Another limitation is that of there being incomplete data; managed by using Last Observation Carried Forward (LOCF) methods. However, such analyses have been criticised for their accuracy (Lachin, 2016), though are believed to represent a conservative approach to responding to the issue of missing data. Data completion issues arose due to eTCs and volunteers failing to be stringent regarding data collection; addressed via the introduction of eTC case management supervision.

Though there are these limitations, **Cavanagh et al. (2011b)** has several strengths. Firstly, it has a large sample size (n=510), rendering the research more efficient with greater reliability of results (Faber & Fonseca, 2014), demonstrating the effectiveness of the *model* (Objective 2). Furthermore, it uses objective data as a strength (Guetterman, 2019), enabling conclusions to be drawn about the sample in terms of intake variables and outcomes. This study provided unique insight into this under-researched area of eTherapy.

In summary, **Cavanagh et al. (2011b)** demonstrated, for the first time, that the *model* provided a statistically and clinically effective low-intensity IAPT service, achieving positive outcomes across a wide range of clients including those from BME communities, accessing the programme, BtB™.

Paper three: Lidbetter, N., & Bunnell, D. (2013). Self Help Services: helping people to help themselves. *Mental Health and Social Inclusion*, 17(2), 76-81.

This paper provides a reflexive, qualitative, subjective overview of the charity, Self Help Services, written by the thesis' author with input from the charity's then Communications Officer. Peer supported and user-led services in the treatment of anxiety and depression were scarce at the time and, societally, it was not accepted that those with lived experience of mental health conditions could develop, lead, and deliver primary mental health services, particularly NHS-funded services. The author's unique contribution includes establishing and

founding a charity that developed and delivered primary care mental health services commissioned by the NHS for the treatment of anxiety and depression (Gamsu, 2011), and identifying the need for and developing, the *model*.

Lidbetter and Bunnell (2013) provides a detailed overview of Self Help Services, its ethos, and services (which included peer-led, drop-in groups, courses, 1:1 psychological therapy services) and eTherapy services, delivered through the *model* (Objective 1). The paper details the development and history of the charity from its inception, whilst giving tips for others interested in developing services using a similar approach, concluding with providing insight into the charity's future potential service provision.

The paper reports some of the learning and challenges experienced in the charity's history, including detailing how the expansion and securing of new services by competitive tender, which entailed the transfer of staff to Self Help Services, had been at odds with the 'grow your own' culture of the organisation and led to roles being filled by staff without lived experience of a mental health difficulty, which had implications for the overall dynamics of the charity, given its user-led ethos.

The paper includes two case studies: one detailing the journey of the charity's then Performance and Informatics manager from an attendee and service user of the charity's drop-in support groups, to becoming an eTC and then Manager of the overall charity's eTherapy services; the other provides an overview of the experience of an eTherapy client who accessed BtB™ via the venue *model*. This case study details the client's satisfaction in terms of the *model's* simplicity and accessibility, highlighting the practical benefit of eTherapy including enabling her to secure employment (Objective 3).

The limitations of **Lidbetter and Bunnell (2013)** are that it is written by the founder of the charity and, therefore, may have been subject to researcher personal bias, including influencing the selection of case studies (Anderson, 2010). Furthermore, there are a small

number of case studies; more case studies would have provided further insight into client experience and would have strengthened the study (Yin, 2009).

Social desirability bias may have taken place, including under-reporting of socially undesirable attitudes and over-reporting of desirable attitudes by case study participants. Paulhus (1984) proposes that social desirability has two components: impression management, where people purposively strive to fit in or please the audience concerned; and self-deception, often unconscious and based on the motivation to maintain a positive self-concept. Both can lead to inaccurate self-reports and erroneous conclusions being made (Latkin, Edwards, Davey-Rothwell & Tobin, 2017).

The strength of **Lidbetter and Bunnell (2013)** include that data collected was based on human experience and, therefore, provides a rich, detailed, subjective perspective of the *model*, supporting transferability to other settings (Anderson, 2010). Furthermore, it provides vital insight and information on challenges encountered within the charity; offering learning that is of value to other organisations wishing to initiate similar services, including the development of a novel model of eTherapy service delivery (Objective 1).

Paper 4: Elison, S., Ward, J., Davies, G., Lidbetter, N., Hulme, D., & Dagley, M. (2014). An outcomes study of eTherapy for dual diagnosis using Breaking Free Online. *Advances in Dual Diagnosis*, 7(2), 52-62.

This pragmatic, quantitative service evaluation where data (baseline and post-treatment clinical outcomes) was analysed, evaluated clinical outcomes (Objective 2) for the first time in clients experiencing dual diagnosis issues (substance misuse and mental health difficulties, in this case, anxiety and/or depression), accessing BFO via either the venue or remote version of the *model*, or a combination of each (Objective 1).

The study was undertaken to demonstrate the effectiveness of the *model* in supporting those with dual diagnosis issues to NHS commissioners, and to augment the small dual diagnosis service delivered at the time, which consisted a community-based, structured dual diagnosis course.

A range of clinical outcome measures were taken: WSAS, GAD-7, PHQ-9, alcohol use via the Alcohol Use Disorders Identification Test - AUDIT (Saunders et al., 1993) -, and drug use via the Drug Use Disorders Identification Test - DUDIT (Berman et al., 2004). The IAPT Phobia Scale (IAPT, 2011), a three-item scale containing single item measures for specific phobia, panic disorder, and social anxiety disorder was also used. Collectively, these measures allowed for analysis of client progress in terms of both substance misuse and anxiety and/or depression.

A total of 74 clients were referred to the service, with follow-up data available for 47. Having determined that the data did not follow a normal distribution using Shapiro-Wilk tests, non-parametric Mann-Whitney U-tests revealed differences between those clients for whom only baseline data was available and those with follow-up data; the former presented with more severe depression and impaired social functioning.

Of clients with follow-up data, 62% were male, 96% were white-British, 29% had not received treatment previously for their presenting problem, and 33% had previously been in treatment for substance use. Alcohol was the main substance of dependence for 78% of clients, 16% were equally split between being dependent on either cannabis, cocaine sulphate, crack cocaine, or heroin, and 6% equally split between being dependent on amphetamines, buprenorphine, or synthetic cannabis.

Periods of engagement varied considerably and was dependent on client perception of need, ranging from 15-154 days, with mean length being 54 days; similar to that taken by clients accessing other programmes typically delivered over a six-week period.

Irrespective of time taken to access the *model*, at discharge, clients completed the same psychometric measures. Statistical regression analysis found the number of days between baseline and discharge assessments did not act as a predictor of change in outcome scores.

Analysis of outcome measures, via the Wilcoxon-signed rank test for those with follow-up data, found statistically significant changes including decreases in scores for social impairment, depression, anxiety (all $p < 0.0001$), drug use ($p = 0.002$), and alcohol dependence ($p = 0.028$), as well as a reduction in scores for the one-item measure for social anxiety ($p = 0.027$). No statistically significant changes were found in the phobia item measure in respect of panic disorder and specific phobia.

Furthermore, large effect sizes were found for reductions in social impairment ($r = 0.68$), depression ($r = 0.59$), and anxiety ($r = 0.63$); medium effect sizes for reductions in alcohol use (0.45), drug use, and social anxiety ($r = 0.32$).

Clinically significant changes were found in clients with follow-up data for those reaching clinical cut-offs for mild, moderate, and severe depression and anxiety; demonstrating that the overall clients meeting clinical cut-offs, in terms of symptom severity, reduced post-treatment. Specifically, clients reaching the clinical cut-off for depression at baseline was 89% and 89% for anxiety, with a total of 74% having moderate to severe depression and 72% moderate to severe anxiety. Post-treatment, 70% remained above the clinical cut-off for depression and 70% above the clinical cut-off for anxiety, with 49% reporting moderate to severe depression and 34% reporting moderate to severe anxiety. Clients that did not reach clinical cut-off for depression increased from 5-14% pre-post treatment assessment, and from 4-14% for anxiety.

Elison et al. (2014) demonstrated that the *model* could, when delivering BFO, generate statistically significant reductions in social impairment, alcohol and drug use, and social anxiety with reductions in depression, anxiety, and social impairment being particularly

robust, as demonstrated through large effect sizes and reductions in alcohol and drug use relatively robust, demonstrated through medium effect sizes. Furthermore, **Elison et al. (2014)** demonstrated that the *model*, when used to deliver BFO, could achieve clinically significant improvements in clients with dual diagnosis presentations in respect of reductions in anxiety and depression symptom severity.

The limitations of **Elison et al. (2014)** include its small sample size (47) and attrition rate; both factors which may impact on the reliability of the statistical outcomes reported (Faber & Fonesca, 2014). Quantitative research is accepted as a paradigm that supports researchers in demonstrating the generalisability and reliability of an intervention (Henn, Weinstein & Foard, 2006), however this is dependent on there being a sufficient sample size. In eTherapy research, small sample sizes are common, and it is recommended that research is conducted with larger sample sizes (Andersson & Cuijpers, 2009; Cuijpers et al., 2009). As the study was undertaken in a real-world setting, however, sample size was determined solely by the number of clients opting to access the service. In terms of attrition, the rate was reported as being 36%; in keeping with eTherapy literature (Eysenbach, 2005), but more favourable than rates reported in other studies (Chistensen et al., 2004a, b; Favolden et al., 2005). This is particularly relevant since this study was not subject to the same environment as that seen in RCTs; being conducted innovatively in a real-world setting. Furthermore, it is likely that the drop-out rate may have been reflective of the level of severity and impairment experienced by those clients accessing the service; it has been reported that higher social impairment and low functioning may affect retention and engagement (Barrett et al., 2008).

A strength of **Elison et al. (2014)** is that it reports on engagement length; seldom addressed in eTherapy research as is similarly the case with studies lacking information on reasons for drop-out (van Ballegooijen, 2014). In giving this information, helpful insight is provided into how engagement length may impact on treatment outcomes.

Previously, BFO had only been positively piloted as a programme to support those with substance misuse issues (Elison et al., 2013). However, **Elison et al. (2014)** found both versions of the *model* (venue and remote), or a combination of each, could achieve clinically significant improvements in clients with dual diagnosis presentations in respect of reductions in anxiety and depression symptom severity (Objective 2). Therefore, this could be used to support clients with dual diagnosis presentations (Objective 1), though it is recognised that the majority of clients had alcohol dependency issues (78%) compared to drug dependency issues (22%). This finding extended the reach of the venue, remote, or a combination of both, *models* to an additional client group and, in doing so, made a unique contribution to eTherapy literature.

Paper 5: Elison, S., Ward, J., Williams, C., Espie, C., Davies, G., Dugdale, S., … Smith, K. (2017). Feasibility of a UK community-based, eTherapy mental health service in Greater Manchester: repeated-measures and between-groups study of 'Living Life to the Full Interactive,' 'Sleepio™' and 'Breaking Free Online' at 'Self Help Services.' *BMJ Open*, 7(7).

This feasibility study ascertained the viability and outcomes of the venue, remote, or combination *model* when used to deliver three different eTherapy programmes: LLTTF™, BFO and Sleepio™; an insomnia for clients experiencing a range of mental health issues including depression anxiety and/or stress, sleep disruption, or problems with alcohol or drugs. The study was a service evaluation that examined the *model's* potential to provide a helpful addition to traditional IAPT service offerings; building on previous effectiveness studies undertaken **(Cavanagh et al., 2011b; Elison et al., 2014)**.

Of 1,786 clients completing a baseline assessment, data was collected from 1,068 clients (59.8%) who had completed one of three eTherapy programmes between 2011 and 2015 accessed via venue, remote, or a combination of the *models*.

Clients were assessed by an eTC on access (via phone or face-to-face), completing a range of standardised psychometric assessments - PHQ-9, GAD-7 and WSAS - to identify main area of difficulty, and were triaged to one of three groups; this allowed them access to the most appropriate programme available.

The breakdown of clients per programme was: 81% - LLTTF™ interactive; 8% Sleepio™; and 11% BFO.

Data analysis undertaken using the Shapiro-Wilks found pre- and post-data for PHQ-9, GAD-7 and WSAS was non-normally distributed (all = $p<0.05$).

Kruskal-Wallis analyses of variance (ANOVA) was deployed to examine baseline differences between the three eTherapy groups in respect of IAPT MDS. Analysis of Covariance (ANCOVA) was used to examine if programme assignment was predictive of the extent of the change in functioning of clients when age and gender were controlled for.

Within-group, repeated-measures Wilcoxon signed-rank ANOVA tests were utilised to examine pre- and post-changes for the same psychometric measures within each of the groups, with Pearson's effect sizes calculated from test statistics using ANOVA and ANCOVA tests, as well as sample size.

A total of 63.6% of the overall sample were female (compared to 40.2% in the group accessing BFO). The mean age of the sample was 37.38 years. Regression analysis of length of time of engagement in treatment found that, whilst engagement varied (4-288 days), it was not associated with the degree of change in symptom severity of depression, anxiety, or social functioning from baseline to post-treatment in LLTTF™ or Sleepio™. However, for clients accessing BFO, the number of days of engagement was associated with the degree of change of scores for depression, anxiety, and social functioning from baseline to post-treatment assessment. Furthermore, the greater the number of days of engagement with BFO, the greater the reduction in scores for depression, anxiety, and social impairment.

Comparison of the three groups, using Kruskal-Wallis ANOVAs on baseline psychometric scores, found some statistically significant differences: the BFO group had significantly higher baseline scores for depression and anxiety than Sleepio™ and LLTTF™ groups. When comparing degrees of psychometric score pre-post change between the three groups whilst controlling for age and gender, ANCOVA revealed no statistically significant differences. Furthermore, comparison of baseline to post-treatment, using Wilcoxon signed-rank tests, found statistically significant reductions in all psychometric measure scores for anxiety, depression, and social functioning for all three groups (p for all groups = <0.0001), with moderate to large effect sizes.

Elison et al. (2017) also reports on the percentages of clients reaching clinical thresholds for mild, moderate, and severe depression and anxiety at baseline and at post-treatment, via Chi-squared analysis, finding that in all the groups, the percentages of clients reaching thresholds for clinically significant depression and anxiety after treatment from baseline significantly reduced. Moreover, the percentages of clients in the moderate and severe categories post-treatment reduced but increased in the minimal and mild categories.

Statistically significant in-group reductions in outcome scores for anxiety, depression, and social functioning were found for all programmes accessed through the *model*. The degree of symptom reduction and of reduction in scores were also found to be comparable across all programmes, with group assignment not being predictive of the degree of change in respect of depression, anxiety, or social functioning between baseline and post-treatment assessment. Although equivalent outcomes were reported, there were statistically significant differences between the groups at baseline assessment in terms of symptom severity with clients that accessed BFO having higher baseline scores for anxiety and depression, and higher scores for anxiety post-treatment. This can be explained by those accessing BFO having more complex issues as it is known that mental health can be impaired by substance use (Buckley, 2006).

The higher rate of anxiety seen post-treatment in clients accessing BFO may be explained by the phenomenon seen in clients in the early stage of substance misuse recovery, where a temporary exacerbation of mental health symptoms can arise (Lubelczyk, 2015; Powell & Taylor, 1992) because of the anti-depressant effects of any substances that were previously taken, no longer being present; this being particularly so with opiates (De Arcos, 2008).

The study's limitations are that there is no data available in respect of those clients who disengaged following the baseline assessment, or why clients did not require treatment. Furthermore, the varying sample size of the groups is problematic as ideally the sample size would have been similar for all groups, thereby allowing optimal performance of equivalence testing between groups (Rusticus & Lovato, 2014). The lack of follow-up data and absence of a control group are also limitations, though recent research has shown that the evaluation of eTherapy as an intervention through RCTs may be subject to methodological limitations because of the personalisation of the approach, which may give rise to enhanced clinical effectiveness (Krebs, Prochaska & Rossi, 2010; Lustria et al., 2013; Noar, Benac & Harris, 2007).

A strength of **Elison et al. (2017)** is its large sample size and use of the IAPT MDS; allowing for future benchmarking against IAPT services. It also reports both statistically and clinically significant findings with reductions in all three groups in the percentages of clients reaching threshold scores for clinically significant anxiety and depression, post-treatment. This is a strength as published research often focusses on the statistical significance whilst failing to determine the clinical importance of results (Nordahl-Hansen, Øien, Volkmar, Shic & Cicchetti, 2018**).** The study also sheds light on attrition, detailing that 38.5% of clients had disengaged/dropped out following baseline assessment, 34.9% had been discharged following baseline assessment because treatment was not required, and 35% had been referred to another more appropriate service, for example, a high-intensity IAPT service.

Elison et al. (2017) makes a unique contribution to eTherapy literature by continuing to build the evidence base for the clinical effectiveness of the remote, venue, or combination of both *models* when used to support those with anxiety and depression (Objective 2) accessing a range of eTherapy programmes.

Paper 6: Luik, A. I., Bostock, S., Chisnall, L., Kyle, S. D., Lidbetter, N., Baldwin, N., & Espie, C. A. (2017). Treating depression and anxiety with digital cognitive behavioural therapy for insomnia: a real world NHS evaluation using standardized outcome measures. *Behavioural and Cognitive Psychotherapy*, *45*(1), 91-96

This study evaluated changes in depression and anxiety in clients with poor sleep, in combination with having symptoms of depression and anxiety. Clients accessed Sleepio™ (a six-session programme) via the remote *model* (Objective 1) between March 2014 and May 2015, with the initial assessment offered either face-to-face or by phone.

The study was a pragmatic, real-world service evaluation of eTherapy within an IAPT programme, where outcomes for clients that had accessed the service were evaluated post-treatment.

Six telephone support calls of between 20-30 minutes long were provided, during which, clients were explained techniques (and suggestions on implementation) with the eTC also determining treatment progress. No clinical input was provided, and clients did not access any other IAPT intervention at the time.

Levels of anxiety and depression were independently measured during each of the calls via GAD-7 and PHQ-9. Insomnia was evaluated at baseline and during the final assessment via the Insomnia Severity Index - ISI (Bastien, Vallières, & Morin, 2001). Clients that did not improve after accessing Sleepio™ through the *model* were referred to other support services.

Additional client data (gender, age, use of sleep medication) was collected and obtained within Sleepio™ itself.

A total of 120 clients received an access code for Sleepio™; of these 98, accessed the service and baseline and post-treatment assessment data was taken. Paired and unpaired T-tests and linear mixed models were used to analyse the data.

The average age of clients was 44.4 years, with 66% female and 14% reported to have taken sleep medication. At baseline, average scores for PHQ-9 were 11, 8.6 for GAD-7, and 18.5 on the ISI. 72% of clients had moderate to severe depressive symptoms (PHQ-9 >9) or moderate to severe anxiety symptoms (GAD-7 >7), and 89% experienced clinical insomnia (ISI >14). Of the 98 clients, 72 (73%) completed treatment, 15 clients completed four to six sessions and 11 dropped out before session four.

Mean PHQ-9 reduced from 10.1 to 4.4 ($p<0.001$), and mean GAD-7 score reduced from 7.7 to 3.7 ($p<0.001$) in clients who completed post-treatment measures and the end of treatment. To account for any missing data, a linear mixed model (n=98, unstructured) was used; the difference before and after treatment remained statistically significant (PHQ-9 $t(74) = 13.7$, $p < 0.001$; GAD-7 $t(84) = 9.4$ $p < 0.001$) with gender, age, or use of sleep medication not reducing these associations.

Baseline depression and anxiety rates were higher in the non-completer group than completers (i.e., those completing all six sessions) for both depressive and anxiety symptoms.

Of the 71 clients who scored above PHQ-9 and GAD-7 threshold for caseness at baseline, 68% moved to recovery when the LOCF was used. Analysis of only complete cases found the recovery rate to be 58% and 65% of the total population scoring below case-level after the treatment period. Additionally, 59% of clients achieved IAPT reliable recovery; this figure decreased to 52% when complete cases were analysed.

Insomnia symptoms significantly decreased (n=71) from an average of 18.3 to 6.6 ($p<0.001$) as measured by the ISI. Furthermore, changes in insomnia symptoms were statistically significantly related to changes seen on the GAD-7 ($r=0.41$, $p<0.001$) and the PHQ-9 ($r=0.32$, $p=0.006$).

Those completing Sleepio™ achieved an IAPT recovery rate of 68%, with a reliable recovery rate of 59%; both being above the IAPT target of ≥ 50% and 43% respectively (NHS Digital, 2020).

Clients who failed to complete treatment had higher baseline levels for anxiety and depression, which could be interpreted that eTherapy is unsuitable for clients with elevated levels of symptom severity, though this is contradicted by Karyotaki et al., 2018 who report clients with severe depression benefit from eTherapy.

The limitation of **Luik et al. (2017)** is its lack of a control arm, though this was not possible due to the research taking place in a real-world setting.

The strengths of the study include that it provided a satisfactory level of detail on Sleepio™, as well as giving information on the treatment pathway and care touchpoints between client and the eTC (Objective 1); assisting with replication, which is something considered to be rare in real-world research (Robson & McCartan, 2016). Furthermore, **Luik et al. (2017)** uses IAPT measures, enabling recovery rates to be benchmarked against national IAPT data (Objective 2). The study also had high completion rates (73%) compared to the average seen in IAPT at the time of 48% (NHS Digital, 2020), supporting the viability of the *model* for clients experiencing poor sleep as well as depression and anxiety.

Luik et al. (2017) contributes to the eTherapy literature by demonstrating that Sleepio™ could be successfully delivered via the remote *model*, with treatment completion rates above the IAPT average and recovery rates higher than IAPT self-help treatment that directly target anxiety and depression. Furthermore, **Luik et al. (2017)** demonstrates that symptoms of

anxiety and depression in clients presenting with these conditions, as well as having problems with sleep, could be alleviated when Sleepio™ is accessed via the *mode*l (this being consistent with the findings of Christensen et al., 2016); demonstrating its effectiveness and versatility (Objectives 1 and 2). Substantial decreases in insomnia symptoms were also reported and correlations found between changes in insomnia and changes in depression and anxiety; suggesting that better sleep might act as a mediator of outcome for depression and anxiety, however further research is required to definitively confirm any associations.

Paper 7: Gellatly, J., Chisnall, L., Seccombe, N., Ragan, K., Lidbetter, N., & Cavanagh, K. (2018). @ Home eTherapy service for people with common mental health problems: an evaluation. *Behavioural and Cognitive Psychotherapy,* 46(1), 115-120.

This study is a pragmatic, retrospective service evaluation that evaluated the implementation of the remote *model* (referred to in the paper as an @ home model) (Objective 1). Furthermore, clinical outcomes achieved were benchmarked against national IAPT service data (Objective 2).

Clients accessing the *model* consented for their anonymised data to be used in routine evaluations, including for this study, and were provided with an assessment as well as between six to 12 20-minute telephone support calls (depending on eTherapy programme accessed). Support calls were made by an eTC who was not formally qualified and had taken part in a two-week induction programme, supported by monthly supervision.

Five programmes were available - Sleepio™, BFO, LLTTF™, Silvercloud Health (Space from Depression), and BtB™ - though not all were available across all the sites where the *model* operated and, therefore, analysis took account of all programmes rather than individual programme outcomes. Clients commenced the most appropriate package available;

determined by their pre-treatment outcome measures and following a collaborative discussion with the eTC.

At every session, PHQ-9, GAD-7 and WSAS were taken. Clients above the clinical cut-off for PHQ-9 and GAD-7 at assessment met caseness. First and last scores were used in the calculation for recovery, reliable improvement, and reliable recovery.

Data were analysed using SPSS (v22), with descriptive statistics presented and inferential statistics used to assess clinical and statistical significance of change on IAPT key measures, using data from the last attended appointment used.

A total of 2,054 clients were referred to the service over 30 months; 66% attended an assessment with 53.4% attending at least two treatment appointments; this being equivalent to completing an IAPT course of treatment (Health and Social Care Information Centre [HSCIC], 2016).

Statistically significant improvements for completers across all programmes combined were found on all outcome measures including PHQ-9, GAD-7, and WSAS, with large pre- to post-treatment effect sizes for changes in symptom severity of depression (Cohen's d= 0.98) and anxiety (d=1.07), with a medium effect size found for functioning (d = 0.53).

At intake, 91.4% of clients met caseness levels for anxiety and depression or both and, of these clients, 61.6% recovered at their final appointment, 56.7% met the criteria for reliable recovery, and 66.2% met criteria for reliable improvement (from start to end of treatment), with only 4.4% having reliably deteriorated.

Most completers were female (57%), aged 45 years or under (79.9%), with more than half being under 36 years of age (57%) and from a white ethnic group (91.2%). A total of 60.6% accessed LLTTF™, 19.1% Silvercloud Health, 4.4% BtB™, 3.6% Sleepio™, and 0.1% BFO.

An independent samples T-test was conducted to compare moving to recovery by clients from caseness, with appointment attendance. A statistically significant difference was found between number of sessions attended for those clients that moved towards recovery (mean = 6.04 sessions, SD =1.8) and those that still met caseness (mean = 4.62 sessions, SD = 2.0), with a large magnitude in the differences of the means (mean difference = 1.42, 95% CI: 1.11 to 1.73), (d=0.937).

Analysed data was also used to benchmark outcomes achieved through the remote *model* against IAPT data (HSCIC, 2016), with 96.3% of clients that finished treatment waiting less than six weeks to enter the service compared to 91.4% within IAPT services nationally (HSCIC, 2016). When comparing caseness at intake against national IAPT, similar numbers were found (91.4% vs 88.6%). Similarly, an equivalent number of referrals completed a programme through the remote *model* (53.4%), when compared to national IAPT service data for clients referred to guided eTherapy (52%). However, on average, almost twice the number of eTherapy appointments were attended (5.6) by clients accessing the remote *model* in this study, compared with that reported in national IAPT services (2.9). This was a positive finding as drop-out rates are known to be an issue in low intensity IAPT services (Chan & Adams, 2014).

Recovery and reliable recovery rates in the study (61.6% and 56.7%) surpassed those in national IAPT services (52.2% and 42.8%), whilst reliable improvement rates were broadly comparable (66.2% and 60.8%). Furthermore, effect sizes determined for PHQ-9 and GAD-7 were found to be equivalent to high performance benchmarks for national services, as detailed in the work undertaken by Delgadillo et al. (2014) where the evaluation of evidence-based intervention measurements in routine practice were explored.

The limitations of **Gellatly et al. (2018)** are that reliable improvement and reliable recovery figures are compared against data from all IAPT referrals, as eTherapy data was not available

from NHS Digital, 2015. Furthermore, the absence of a control (due to the study being a service evaluation) and the lack of follow-up data or information on why clients dropped out of treatment, are additional limitations.

The strength of **Gellatly et al. (2018)** is its large study sample size and its comparison of outcomes for all programmes combined, which gave rise to being able to demonstrate statistically and clinically significant outcomes, which, in turn, demonstrated for the first time the clinical effectiveness of the remote *model*; making a unique contribution to the eTherapy literature. Furthermore, **Gellatly et al. (2018)** provided an appropriate level of detail about the eTC role; emphasising the role of peer support. The study also benchmarked outcomes against national IAPT service data and, when possible, this included comparing data with data from other low intensity eTherapy IAPT services, making for an almost like-for-like comparison.

4.3 Critique of the presented publications by thesis objective

<u>Objective 1:</u> Examine the development of the *model*.

Based on previous experience of developing peer-supported, user-led primary care mental health services, the author led the development and delivery of the *model*. External, credible experts, renowned in the field of eTherapy research, were brought on board with access to research resources and expertise in journal article submissions, and which allowed for an independent evaluation of the *model* to be undertaken. This was necessary as eTherapy was still relatively new and, where available, services operated from settings such as GP surgeries, run by clinicians.

Lidbetter and Bunnell (2013) and **Cavanagh et al. (2011a)** provide qualitative insight into the venue and remote *model* and the 'grow your own' culture of the charity where volunteers

with lived experience of mental ill-health are supported into paid employment to become eTCs. In contrast to research that merely proposed a potential delivery model (De Vares, 2007), or minimally investigated the topic in respect of integrating lived experience into the design of eTherapy services (Ray et al., 2017), or simply focussed on adding lived experience to an existing clinical support offer (Tomasino et al., 2017), **Lidbetter and Bunnell (2013)** and **Cavanagh et al. (2011a)** describe a fully functioning, peer-supported eTherapy *model*.

Furthermore, the portfolio of papers describes the *model* when delivered by a user-led, TSO based in the community; again, addressing a gap in the literature concerning eTherapy delivered in real-world settings; an area requiring further research (Glasgow, Phillips & Sanchez, 2014; Mohr, Cheung, Schueller, Hendricks & Duan, 2013a; Pham, Wiljer & Cafazzo, 2016; So et al., 2013).

Elison et al. (2014, 2017) and **Luik et al. (2017)** detail the expansion of the venue and remote *model* (as well as a combination of each) to being able to support different client groups, including those affected by difficulties such as substance misuse issues (**Elison et al., 2014, 2017)** and insomnia (**Luik et al., 2017)**, in addition to anxiety and depression.

A strength of **Lidbetter and Bunnell (2013)** is that it addresses scalability in providing an overview of both venue and remote *model*, whilst detailing operational and strategic challenges, making a unique contribution to eTherapy literature. A limitation, however, is that it lacks the detail of **Cavanagh et al. (2011a)**, which provides information regarding client-eTC care-pathway touch points. Both studies fail to describe the amount of human support provided with either version of the *model*, though **Cavanagh et al. (2011b)** addresses this by providing information on the venue *model*; giving duration of the initial screening appointment and information on the roles of eTCs and volunteers - explaining that support can range from technical assistance through to supporting clients to get the best out of programmes accessed.

Elison et al. (2014) provides information on the duration and structure of follow-up support, overall length of engagement - known to be important to outcomes (Baumeister et al., 2014) - as well as detailing the method of support (e.g., face-to-face or telephone). **Luik et al. (2017)** also gives an overview of the role of the eTC, the length of the support calls and the nature of the content covered during support interactions; addressing a gap in knowledge in eTherapy literature that is still regarded as under-investigated (Lattie et al., 2019). To enable replication, a comprehensive description of the *model* and of eTherapy programmes would be required. Across the portfolio of works, whilst the *model* is described at overview level, intricate, specific, and particularised detail consistent with a Service Operating Procedure (SOP), for example, was not included. Lack of fine detail regarding eTherapy delivery models and implementation continues to be a common feature of eTherapy research (Hollis et al., 2017), though clearly is a matter of operational significance given it is known that the amount of human support varies according to the type of clinical issue being addressed (Newman et al., 2011), and that implementation of eTherapy continues to be problematic (Thew, 2020).

The limitation of the methods used are that the papers describe the *model* instead of going into a deeper analysis, and lack depth. The overall purpose, however, was to provide an overview of the *model* instead of giving this level of detail that an observational study, for example, would have provided (Pope & Mays, 2006).

<u>Objective 2:</u> Review and examine the clinical effectiveness of the *model*.

The efficacy of eTherapy in the treatment of depression has been demonstrated in a range of RCTs, yet knowledge of how eTherapy works in routine care is scarce (Hedman et al., 2014b). Five papers in the portfolio of works demonstrated the effectiveness of the *model* in a real-world setting when used to deliver a range of eTherapy programmes for those with anxiety and depression, via quantitative retrospective service evaluation (**Cavanagh et al..2011b; Elison et al., 2014, 2017; Luik et al.,2017; Gellatly et al., 2018**). To ensure credibility in

the evaluations, a multi-disciplinary team with a range of academic expertise were brought together to ensure that the evaluations and their findings were as robust as possible. Experts, including statisticians, were brought in for robust statistics support, for example, with credibility in the field of quantitative eTherapy research.

Such quantitative evaluations allowed for the exploration of the implementation of eTherapy and assisted with result interpretation (Oakley, Strange, Bonnell, Allen & Stephenson, 2006), but did not generate generalisable data (Moule et al., 2016). In contrast, the effectiveness of eTherapy in the treatment of anxiety and depression has been demonstrated via meta-analyses of RCTs (Andrews, Cuijpers, Craske, McEvoy & Titov, 2010) and systematic reviews, which report the intervention as being an established treatment for depression, SAD, and panic disorder (Hedman, Ljótsson & Lindefors, 2012). However, it was not possible to conduct studies of these types due to being constrained to undertaking service evaluations; this being a requirement of commissioners.

Furthermore, the efficacy of the *model* was not examined because it was not possible to have a control group (i.e., clients that did not access eTherapy via the *model*) as it would have been unethical to refuse some clients treatment as all had contacted the charity for eTherapy support with anxiety and/or depression. It could, therefore, be argued that some of the observed improvement may have occurred without any intervention having taken place, e.g., natural recovery. The addition of a control group to the studies would have increased the internal validity of the research design, however this was not possible because of funding constraints and due to the studies being service evaluations. Thus, the lack of a control group represents a limitation, however as the studies were carried out in a real-world setting - something that has been called for within the field of eTherapy research (Karyotaki et al., 2017) -, this is a strength as effectiveness research is considered more relevant for providers and commissioners, and to everyday practice (Treweek & Zwarenstein, 2009).

Meta-analyses examine RCTs that typically assess the efficacy and effectiveness of eTherapy by comparing outcomes against a control group or comparison group (for example, face-to-face CBT), via calculation of the standardised mean difference (SMD). SMD was calculated in **Cavanagh et al. (2011b)**, **Elison et al. (2014, 2017)**, **Gellatly et al. (2018)** and **Luik et al. (2017)**; therefore, a robust and validated method was used to determine effectiveness. Furthermore, **Cavanagh et al. (2011b)**, **Elison et al. (2017)** and **Gellatly et al. (2018)** all had large sample sizes with sufficient power, allowing for meaningful detection of difference and the reporting of statistically significant results, which because of their large sample sizes, are likely to result in them being less exposed to bias (Biau, Kernéis & Porcher, 2008).

Cavanagh et al. (2011b) reported large effect sizes for clients completing at least two sessions in respect of depression (d = 0.8) and anxiety (d=0.9). **Gellatly et al. (2018)** reported large effect sizes when comparing pre- and post-treatment data for changes in level of severity of depression using the PHQ-9 (Cohen's d = 0.98) and anxiety using the GAD-7 (d=1.07), where anything over 0.8 is considered a large effect size (Cohen, 2013). **Elison et al. (2017)** reported moderate to large effect sizes for social functioning, anxiety, and depression.

Outcome measures used in the studies were purposefully selected so that the same measures used in IAPT services were used in this quantitative research on the *model* to measure changes in anxiety and depression symptom severity (measured by GAD-7 and PHQ-9) and functioning (measured by the WSAS), and facilitated initial comparison of the *model* with IAPT services (**Cavanagh et al., 2011b**). Following the subsequent commissioning of the *model* as an IAPT service, it then became a requirement of commissioners that the full IAPT MDS was used and hence why in **Luik et al. (2017)** and **Gellatly et al. (2018)** outcome data from the *model* could be directly benchmarked against IAPT service data.

Whilst an intervention may prove effective in terms of its ability to impact on symptom severity reduction (measured by clinical outcome tools such as the GAD-7 and PHQ-9), if

clients are dropping out of the service, this impacts on the effectiveness of the intervention. Attrition is a key issue in eTherapy service delivery and has been widely reported in the literature as needing further attention (Donkin, Christensen & Naismith, 2011; Eysenbach, 2005; Khadjesari et al., 2011; van Balleegooijen et al., 2014). It is thought to be associated with poorer outcomes for clients and is, therefore, important to address (Delgadillo et al., 2014). Attrition was an issue in **Cavanagh et al. (2011b)**, **Elison et al. (2014, 2017)**, **Luik et al. (2017)** and **Gellatly et al. (2018)**, where relatively high numbers of clients failed to complete eTherapy when accessed via the *model*. Whilst this could be a limitation and potentially a negative aspect of the *model*, it could be argued that clients discontinued accessing the service because they had resolved their difficulties and therefore no longer needed support (**Elison et al., 2014**).

The long-term effectiveness of the *model* has not been established yet (though work in this area is ongoing), and is a limitation of **Cavanagh et al. (2011b)**, **Elison et al. (2017)** and **Gellatly et al. (2018)** in that long-term, follow-up monitoring did not take place because outcome measures were only taken pre- and post-clients accessing the *model*, in contrast to other studies where measures were taken at a greater length of time post-treatment (Andrews et al., 2018).

Gellatly et al. (2018) found better recovery outcomes seemed to be associated with clients that attended more treatment appointments, and **Elison et al. (2017)** found length of time of engagement was associated with the degree of change of symptom severity of depression for clients accessing BFO via the *model*; suggesting that engagement is an important consideration and has a role in terms of effectiveness (Donkin et al., 2011).

<u>Objective 3:</u> Evaluate the acceptability of the model.

Three studies evaluated the acceptability using case studies (**Cavanagh et al., 2011a; Lidbetter & Bunnell, 2013**) and via the IAPT PEQ (**Cavanagh et al., 2011b**); a client

satisfaction survey focusing on length of time clients wait for an appointment, overall client experience of using the service, and client satisfaction with treatment type received; administered at baseline and treatment end. In **Cavanagh et al. (2011b)**, 44.9% of clients completed pre- and post-PEQs, with 90% satisfied with their overall experience of the service and 91% satisfied with the treatment received. Using the PEQ measure ensured that client satisfaction was measured via a standardised and well-known tool widely used in IAPT services and, therefore, enabling benchmarking of satisfaction at a later stage if required. Additionally, **Cavanagh et al. (2011b)** reports a high completion rate compared to that seen in the IAPT demonstration sites. Given adherence is likely to be linked to acceptability (Van Ballegooijen et al., 2014), inclusion of this metric was a useful additional measure. Similarly, **Gellatly et al. (2018)** reports twice as many appointments attended compared to national IAPT reported rates; of interest, since engagement is likely to be linked with acceptability (Cavanagh et al., 2018).

The five case studies detailed in **Cavanagh et al. (2011a)** and **Lidbetter and Bunnell (2013)** provide additional helpful insight into client experience, as well as the then eTherapy manager's story of moving from client to service manager. Furthermore, given the heterogenous nature of the case studies, insight is gained into the model's acceptability by providing insight from a range of clients.

Other methods of assessing acceptability in eTherapy research include use of questionnaires (Burke et al., 2018), which do not permit in-depth analysis of patient experience, through to deeper qualitative methodologies such as focus group and interviews, as used by Holst et al. (2017). Due to the pragmatic nature of the studies, however, methods used to assess acceptability were necessarily restricted to those already used in service, e.g., case study testimonials and the PEQ.

Client acceptability in eTherapy is known to be an area requiring further attention (Rost et al., 2017; Wilhelm et al., 2020), along with attrition (Kaltenthaler et al., 2008; Richards & Richardson, 2012; van Ballegooijen et al., 2014; Waller & Gilbody, 2009), though across the body of works, attrition rates were not high. Further understanding of issues underpinning client acceptability could have been gained if the research had also focused on clients failing to complete the full course of eTherapy delivered through the *model*, and reasons for disengagement (Marks et al., 2007); this being a limitation of **Cavanagh et al. (2011b)**, **Elison et al. (2014, 2017)**, **Luik et al. (2017) and Gellatly et al. (2018)**. Within a service evaluation, however, this was not possible for pragmatic reasons.

4.4 Section summary

In this section, the papers comprising the portfolio of works are presented, individually critiqued, and then examined by thesis objective.

Collectively, the body of works makes a unique contribution to eTherapy knowledge by detailing a peer-supported, non-clinical *model* of eTherapy, developed in a user-led organisation, delivered in real-world settings, that is effective and acceptable in the treatment of anxiety and depression in adults. This was specifically achieved through **Cavanagh et al. (2011a, b)** and **Lidbetter and Bunnell (2013)**, where acceptability of the venue *model* was demonstrated in clients with anxiety and depression. **Cavanagh et al. (2011b)**, **Elison et al. (2014)**, **Gellatly et al. (2018)** and **Luik et al. (2017)** showed that the *model* was able to deliver statistically and clinically significant improvements in clients experiencing anxiety and depression, with **Cavanagh et al. (2011b)** demonstrating the pragmatic effectiveness of the venue *model* and **Gellatly et al. (2018)** the remote *model*. Furthermore, **Elison et al. (2014)** demonstrated the effectiveness of the *model* when used to deliver BFO for clients experiencing anxiety and depression as well as drug or alcohol dependency issues, and **Luik**

et al. (2017) demonstrated the effectiveness of the model when used to deliver Sleepio™ in clients experiencing poor sleep and anxiety and depression.

The next section will examine ethical considerations, methodology and limitations, the pragmatic paradigm, and the author's reflections on the journey taken in creating the body of works.

Section Five

In this section, ethical considerations, methodology and limitations, the pragmatic paradigm, and a personal reflection of the thesis, are provided.

5.1 Ethical considerations

Whist undertaking this body of work, several ethical considerations were of relevance, including: the avoidance of harm whilst undertaking real-world research (non-maleficence); coercion of clients to participate; informed consent; having respect for autonomy; protecting and preserving confidentiality (including the safe storage of participant data); and commitment to doing good - beneficence (Beauchamp & Childress, 2008). All are covered by the ethical principles that health researchers use to protect clients from harm, and are distilled down to four rights of subjects considering participation in research, as follows (International Council of Nurses, 2003):

- The right not to be harmed
- The right of full disclosure
- The right of self-determination/to take part or to withdraw at any time
- The right of privacy, anonymity, and confidentiality

The author was mindful of possible ethical issues regarding involvement in the research, whilst at the same time having a commitment to leading the organisation and overseeing its research strategy. This could have potentially given rise to researcher or experimenter bias, which occurs when an individual conducting a research study intentionally or unintentionally influences the results, for example, by asking leading questions, or through poor research design (Galdas, 2017). Bias itself can be defined as:

"any influence that provides a distortion in the results of a study" (Polit & Beck, 2014)

A further consideration is that of clients agreeing to participate in, or respond to, research in a way that they believe would be desired by the researcher; all of which can undermine research findings (Perrier, Etchegary, Palarchio & Snelgrove, 2009). It is accepted that bias is hard to eliminate and exists in all research and across research designs (Smith & Noble, 2014). In respect of this body of works, it is recognised that the author brought her own experiences and beliefs to the work from the outset; specifically, that the *model* could achieve successful outcomes. As a result, researcher bias may have played a role in the selection of the case studies in **Lidbetter and Bunnell (2013)** and **Cavanagh et al. (2011a)**, as it is known that case study research methodologically facilitates bias toward verification where the researcher's views are confirmed (Flyvbjerg, 2006). The effects of researcher bias, however, were mitigated by ensuring that clients were only contacted by staff not directly involved in the research, and that it was made clear that both positive and negative feedback was welcomed. Research bias was also mitigated by bringing in a team of external, respected academics to facilitate independent evaluation of the *model*. It is, however, recognised that there was a conflict-of-interest present (Yanos & Ziedonis, 2006), arising from the opposing agendas inherent to the roles of researcher and Chief Officer and Founder. In the latter role, the author's focus was on growing the organisation and securing commissions for peer-delivered services; fuelled by a fervent desire to promote the efficacy of user-led mental health services. As researcher, the author's goal was to undertake unbiased research to further understanding of the *model* and to test its efficacy; both of which required a neutral stance. Yanos and Ziedonis (2006) state:

> "It has been stated that the field of psychological therapy would stagnate without the involvement of researchers who have direct clinical experience with the health conditions and service systems being studied" (p.249).

Furthermore, the dual role of counsellor-researcher role (whilst not an exact replica of the

relationship of the author-researcher relationship, has similarities), has been reported by Fleet, Burton, Reeves and DasGupta (2018) as being worth the struggle, even though conducting effective and ethical research can be hard.

A further consideration encountered concerned clients completing outcome measures; this aspect of the service explained to clients as being necessary to determine if clients believe that the intervention has been able to effect change, however organisationally, these scales were also used for funding and research purposes (Kewley & McBride, 2013). This issue was addressed in the studies that form the portfolio of works by ensuring that clients were informed, prior to accessing the *model*, that they were required to fill in several questionnaires before, during, and on completion of therapy, and that their questionnaire answers could be published anonymously in internal or external reports, including for the purposes of service evaluations. This was a critical issue to address as those involved in research that are also involved in delivering the service that is the subject of the research, must maintain a balance when working with clients; whilst the research protocol needs to be explained to the client, this cannot be at the expense of impacting on the session/interaction itself (Castonguay et al., 2010).

Respect for autonomy was achieved across the body of works by ensuring that the *model* was delivered in a collaborative, non-hierarchical manner without a 'them and us' relationship; something often seen in services where power is typically held with one partner, usually the healthcare professional (Seale, 2016). Additionally, as clients were supported by volunteers and eTCs (many of whom had themselves accessed the *model* and other services provided by Self Help Services), this helped address power imbalances, with clients being made aware from the outset (through service promotional materials and through disclosure), that those delivering the service had experience of living with a mental health difficulty.

At all times, clients' rights to be self-governing was respected (Bond & Dryden, 2012) by ensuring that clients were fully aware of the right not to be involved in service evaluations, including requesting their anonymised data be excluded from future data analysis. The right for clients to be self-governing is in synergy with the ethos of Self Help Services that was, and still is, that those experiencing anxiety and depression when given appropriate guidance and direction, are in the best position to be able to help themselves. This point was emphasised by the charity's strapline, which at the time was: '*helping people to help themselves*.' This was further demonstrated in the writing up of client case studies, where clients were given the opportunity to read and comment on the definitive version of the case study and request information be removed, as per ethical case study research (Widdowson, 2011).

Clients were also made aware of how to make a complaint about the service and to whom the service provider was accountable. In addition, clients were advised as to what types of information would be disclosed about them, with all information provided in advance of clients accessing the *model*.

It was essential clients were able to make an informed choice regarding their participation in the research. Some may have operated from a belief system where they felt that, if they refused to participate, this may, in some form, negatively affect their care/accessing of the service; a point highlighted by Cleary, Hunt, Robertson and Escott (2009). This issue was overcome by including information about research in the initial client agreement form, which was discussed at assessment to ensure that clients understood their rights in respect of the research. If a client accessed the *model* and then subsequently decided to opt out of participating in any research (including having their data analysed and/or included in future research and service evaluations), this was recorded on the client's record on the service's client management system, and the data excluded from any dataset analyses.

The body of works that form this thesis were service evaluations as defined by the Health Research Authority (2017), therefore approval from an NHS research ethics committee was not required. Additionally, NHS commissioners were routinely informed in advance of the service evaluations being undertaken and did not communicate any further requirements in relation to the studies. Clients accessing the *model* provided advanced consent for their anonymised data to be used by the organisation for routine evaluations (including board reports, service evaluations, publicity, and promotional purposes), and were asked if they were happy to share their experience of accessing the service by way of contributing to an anonymised case study and/or client testimonial.

As Self Help Services was a small organisation at the time when the studies comprising the portfolio of works were undertaken, the organisation did not have a formal research policy in place but followed ethical procedures in line with those of the NHS. The organisation now has a Research and Evaluation Policy and a Privacy Policy (Self Help Services, 2021), which cover procedures regarding ethics, client participation and research.

5.2 Methodology and limitations

All studies were carried out in a real-world setting; important because eTherapy research is not typically undertaken in such environments (Adelman et al., 2014; Karyotaki et al., 2017). Whilst real-world evidence (RWE) is often assigned lower credibility, it is practical in nature, reflecting actual practice being research that focusses on analysis of vast quantities of data that has already been gathered, such as service evaluations (Kim, Lee & Kim, 2018). Real-world studies are likely to provide a more realistic view of outcomes compared to those derived from highly controlled research studies, for example RCTs (**Elison et al., 2014**), because participants are representative of client populations seen in services and do not have to meet strict inclusion and exclusion criteria. Therefore, real-world studies can give

information on utilisation patterns and health outcomes, and when combined with RCTs, provide a fuller view of the pros and cons of an intervention. They can also be used to determine whether results from RCTs are generalisable to real-world client groups and different settings and, therefore, have wider generalisability (Blonde, Khunti, Harris, Meizinger & Skolnik, 2018). As most of the eTherapy programmes delivered through the *model* had already had their efficacy demonstrated via RCTs, further evaluation of their effectiveness was not required. Instead, the objective was to evaluate whether the *model*, when used to deliver eTherapy programmes in a real-world setting, was clinically effective and acceptable in practice. Whilst RCTs are considered the 'gold standard' methodology when examining and evaluating interventions (Hariton & Locascio, 2018), leading psychological therapy professionals, particularly those from counselling backgrounds, are critical of RCTs; although they believe that the method is likely to continue to be the cornerstone of commissioning policy for some time (Cooper & Reeves, 2012). However, as eTherapy is considered a complex, disruptive digital innovation comprising multiple tailorable and modifiable components, RCTs may not be as applicable. A disruptive innovation is one that interferes or disrupts traditional services - in this case, face-to-face delivered psychological therapies, in a way that is not expected - and which leads to services being offered at lower prices or to different client groups, which can then give rise to affordable healthcare (Glabman, 2009).

The Medical Research Council (MRC) proposes that multiple methodologies should be used (including those which examine implementation of interventions in healthcare) when researching complex healthcare interventions such as eTherapy. They have a framework for the development and evaluation of complex healthcare interventions (Craig et al., 2008), which includes piloting, describing, and evaluating, which is consistent with the approach taken when examining, evaluating, and reviewing the *model*. Furthermore, regarding the acceptability of new interventions, the MRC suggests that this can be examined via feasibility

studies as per **Elison et al. (2017)**, to investigate delivery models and client compliance; the latter being issues of importance when considering effectiveness in a broader sense (Craig et al., 2008; Moore et al., 2015).

In the portfolio of works, studies focusing on the effectiveness of the *model* - **Cavanagh et al. (2011b)**, **Elison et al. (2014, 2017)**, **Luik et al. (2017)** and **Gellatly et al. (2018)** - did not compare the intervention with a control group; therefore, there is a possibility that outcomes arose due to other factors, such as clients getting help elsewhere. Control group type is known to significantly mediate effect sizes (Grist & Cavanagh, 2013) and is important to consider; however, this was not possible to implement due to the studies being service evaluations. Service evaluation methodology was chosen because the studies (HRA, 2017):

- Were designed and solely conducted to determine and define current care
- Answered the question of whether the service met the IAPT standard
- Had no randomisation
- Involved an intervention that was already in use and where clients had already made a choice to access the intervention before the service evaluation
- Included analysis of existing data; specifically, pre- and post-data in the quantitative studies

Whilst the *model's* short-term, post-treatment effectiveness was demonstrated, the lack of focus on follow-up, due to service capacity constraints was a common issue and a limitation across many of the studies (**Cavanagh et al., 2011a; 2011b; Elison et al., 2017; Gellatly et al., 2018**), though is an issue commonly reported in eTherapy research (Andersson et al., 2018b).

A further limitation is the lack of focus on clients who dropped out; an issue across the portfolio of works except for **Lidbetter & Bunnell, 2013**. Given relatively high drop out rate has been identified as being a key issue in eTherapy (Schmidt, Forand & Strunk, 2019), it

would have been useful to have looked at this issue further, however due to the studies being service evaluations, this was not possible. Additionally, the issue of drop out is further complicated by there being a lack of an agreed reporting standard regarding completion (Etzelmueller et al., 2020) with much variation existing in terms of what constitutes a completion in eTherapy.

In IAPT, treatment completion/what constitutes a treatment episode, is defined as being receipt of two or more treatment contacts/sessions (Moller et al., 2019) for any intervention including eTherapy. Whilst **Gellatly et al., 2018,** (which focussed on the remote *model),* reported a treatment completion rate of 53.4% based in accord with the IAPT definition of completion, **Cavanagh et al., 2011b,** (which focussed solely on the venue *model),* reported 53% of clients completed all eight sessions of eTherapy. Given the lack of consistent definition of completion across the portfolio of works, it has not been possible to date to determine whether completion rate differs depending on the version of the *model* accessed, however when compared to the overall eTherapy drop out rate reported by Richards and Richardson, 2012 of 57%, the rates reported in **Gellatly et al., 2018** and **Cavanagh et al., 2011b** respectively of 46.6% and 47% compare favourably.

Overall, emphasis on the peer-support element of the *model* was less than would have been optimal because of greater emphasis being placed on programmes and on the reporting of quantitative outcomes. Bias in health research is a key issue to be aware of and, in the case of conflicts of interest, can lead to inferior quality studies (Odierna, Forsyth, White & Bero, 2013); though, in the studies presented in the portfolio, this was hard to completely eliminate. However, declaration/conflicts of interest were acknowledged by relevant authors to ensure transparency in respect of their positions in various eTherapy programme software companies (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Luik et al., 2017**) in keeping with the US (United States) Institute of Medicine (IOM) report's recommendations (Field & Lo, 2009).

Finally, a key area to reflect on is how acceptability and effectiveness were measured. Across the body of works, clinical effectiveness was determined using a positivist, quantitative approach when determining whether symptom severity reduced post treatment (**Cavanagh et al., 2011b, Elison et al., 2014, 2017; Luik et al., 2017; Gellatly et al., 2018**). Benchmarking the *model* against IAPT outcomes was the most applicable standard to compare the *model's* effectiveness against, however the downside to this approach is that a drop in symptom severity may not necessarily mean that clients have recovered from depression/anxiety to the extent that they are no longer adversely affected. Whilst improvement can be examined by numerical analysis to determine changes in depression or anxiety, this is only one way of proving an intervention's effectiveness. Evidence-based healthcare is more encompassing, involving the systematic collection, synthesis, and application of all evidence available, including the views of clients/data subjects and others aside from experts, as well as secondary sources such as opinion pieces and other articles. Rycroft-Malone et al. (2004) describe four main types of evidence that can be used: research, professional knowledge/clinical experience, patient experience and preferences, and local data and information. A more holistic evidence-based approach involving routinely seeking clients' views via focus groups, interviews and examining client-reported, subjective symptoms using tools such as the Psychological Outcome Profiles tool - PSYCHLOPS (Ashworth et al., 2004), which facilitates a client-centred definition of therapy outcome that is client generated - would have been advantageous.

5.3 Pragmatic paradigm

The pragmatic research paradigm has its foundations in the philosophy of pragmatism (Maxcy, 2003) and encompasses a wide range of methods, based on the notion that researchers should adopt the methodological approach that works best for the research

problem that is being investigated (Kaushik & Walsh, 2019). The pragmatist philosophy is underpinned by the belief that knowledge is socially constructed, and that reality is what works. Furthermore, meaning is not something that can be separated from human experience and need, and is dependent on the context (Dillon et al., 2000). The pragmatist paradigm is one that aligns itself to understanding and addressing problems in the real world (Kaushik & Walsh, 2019) and was used throughout the body of works. This meant the author was not committed to any system of research philosophy, and instead was free to choose whichever approach supported an optimal understanding of the research problem (Bryman, 2008; Mertens, 2005 Patton, 1990).

Consequently, five of the papers in the portfolio of works used a quantitative approach; in keeping with the positivist epistemology approach taken by NICE in its recommendation for psychological therapies (Mollon, 2008; Guy, 2012). Two papers were qualitatively focused. Although a quantitative approach is key when benchmarking data against national outcome data such as IAPT, NICE has attracted criticism for being too numbers-driven and for taking a positivist epistemology in its recommendation for psychological therapies (Mollon, 2008; Guy, 2012), with some suggesting that an interpretive paradigm could assist instead with shaping service-based cultures and changing evaluation; giving rise to an overall improvement in the quality of CBT research (Williams, 2015).

Whilst RCTs provide evidence of what works for the average client (McLeod, 2011), this

form of large-scale study does not support identification of subjective issues that, in turn, may also impact and predict outcomes. Positivist paradigms have reigned in eTherapy research at the expense of qualitative research on client experience, acceptability, and real-world delivery models in a wide range of client groups, beyond those typically the subject of research. However, more needs to be known about including what aids and hinders client engagement needed, along with research into the reasons for overall adherence, take-up, dropout, and

completion (Rost et al., 2017). The *model* itself developed directly as a result of client feedback; transforming over time from being available only via the initial community venue-based model **(Cavanagh et al., 2011b)** to accessibly by clients from the comfort of their homes via the remote model **(Gellatly et al., 2018).** This development happened solely because clients said that they didn't want to have to travel to the service, finding this problematic and a barrier. Had the model failed to evolve in this manner, it is likely that eventually clients would have voted with their feet, drop-out rates would have increased, and completion rates would have been adversely affected.

Furthermore, the views of those with lived experience (of critical importance since this provides a qualitative contribution to research, shedding light on issues such as acceptability, accessibility, etc.) are less likely to be the focus of research (Glasby, 2006).

Whilst the body of works includes two qualitative studies (**Lidbetter & Bunnell, 2013; Cavanagh et al., 2011a**) that have case studies that shed some light on acceptability, it is recognised that much more in-depth qualitative research is needed to understand a range of issues, including:

- the mode of delivery of support that clients prefer
- the optimum amount of support required
- who is best placed to provide the support?
- what qualities the supporter should have
- whether is it necessary for the supporter to have received professional training

Gellatly et al. (2018) commented on whether supporters should have professional training, and Cuijpers et al. (2009) stated that all the above were areas that required further focus. A phenomenological approach could be taken in the future to address these issues, as this form of research is concerned with the lived experience of clients and their subjective understandings of their experience. Adopting this type of approach would move beyond

research studies that simply report that clients find the approach acceptable and, instead, to those that provide insight as to why the service is acceptable and the identification of moderators of engagement and outcomes (Grist & Cavanagh, 2013).

The pragmatic paradigm taken across this body of works supports both interpretive and positivist research approaches; supporting the notion that each has their value when investigating the efficacy and acceptability of the *model*. Several studies have called for the pragmatic effectiveness of eTherapy to be further investigated (Adelman et al., 2014; Karyotaki et al., 2017), and there is a growing body of evidence to suggest that real-world studies, as well as RCTs, are needed when evaluating complex interventions such as multi-component interventions where programme and service delivery model are important (Craig, Dieppe & Macintyre, 2008).

5.4 Reflections

As a researcher, it is important to be aware of what is influencing your external and internal responses, as well as knowing what has impacted on the relationship with the research topic and the research subjects; this being the skill of reflexivity (Etherington, 2004).

It is recognised that the studies that form the body of works were driven by the author's desire to firstly prove that a user-led TSO could deliver high quality eTherapy services via the *model* that could achieve comparable outcomes to face-to-face delivered IAPT services, and to be able to demonstrate this to key stakeholders, including commissioners.

The author's firm belief (born out of personal experience of living with anxiety) that it is not necessary for mental health services to always be delivered by professionals, and that those with lived experience of a mental health difficulty are key to effective mental health service delivery when such individuals are provided with appropriate training and support, may have

had an influencing effect that could have affected the studies and the overall direction of travel of the research undertaken. These beliefs and desires were outwardly expressed by the author in conversations with staff and volunteers and through external and internal service promotional materials and may well have been similarly communicated unintentionally by those delivering the service. This may have affected outcomes and results through the concept of insider bias, though was mitigated by bringing in a team of external academics eminent in the field of eTherapy research to facilitate independent evaluation of the *model*. Given the ethos of the charity and its user-led status is something that is overtly celebrated and recognised as a key strength, this could have played a role in terms of bias. Being aware of the existence of this ideology, culture, and the politics (for example, at the time, it was not a widely held view that user-led organisations could deliver clinically effective services), is an essential element of reflexivity, adding validity and rigour by providing information about the context of the location of the data (Etherington, 2004).

As leader of the organisation, the author's role included developing and executing the organisation's strategy and developing the *model* with the goal of getting it commissioned by the NHS on a mainstream basis and accepted as a viable, effective, low-intensity IAPT service. Other key activities undertaken as part of the role were to assist with making decisions regarding selecting the type of research study to undertake, identifying appropriate research partners, assisting with developing the research question(s), agreeing the optimum methodological approach with partners, identifying when research should be carried out and on what to focus, determining data sets, revising manuscripts, and formulating dissemination strategies. Over the years, the author built up research skills, albeit in a non-traditional way without the appropriate language, as a mental health strategist and organisational leader where it was necessary to continuously juggle competing strategic and operational demands, whilst building the evidence base for the *model*.

Looking back, whilst the goal was achieved in getting the *model* successfully mainstreamed across large parts of Greater Manchester (for approaching a decade), forming a key component of low intensity IAPT services in the region, it is without doubt that if there were the opportunity to embark on this path again, things may have been done differently. For example, choosing to work with more independent experts akin to the research on eTherapy undertaken via the independent REAACT trial (Gilbody et al., 2015), and the more recent independent research carried out by Lou et al. (2020). At times it was challenging striking a balance between meeting both research and organisational objectives, versus balancing this with sometimes slightly differing needs or priorities of research partners. For example, the key goal for some of the research partners was to further demonstrate that their company's eTherapy programme was effective, however the author's goal was to show that the *model* was effective in a real-world setting. Gilbody et al. (2015) found that commercially developed cCBT programmes conferred no benefit over a free-to-use product, and one must be cognisant of possible competing agendas, particularly when working with corporates - in this case, software companies - as this may lead to research bias. Across the portfolio of works, this was in part addressed by ensuring that author affiliations and conflicts of interest were routinely declared.

To date, no studies have been undertaken that provide comprehensive operational delivery detail including SOPs for the *model* because of commercial sensitivities, as disclosing such information could have potentially jeopardised the charity's commercial interests at the time. Whilst this is so, this meant that exact replication of the *model* would be difficult, which in turn could be said to affect the verification of the findings by others (Richards et al., 2003).

Finally, allegiance bias, defined as being something that occurs when the results of a study are affected by the researcher's theoretical or treatment preferences (Luborsky, Singer & Luborsky, 1975) in outcomes studies, is something that must be considered. If this bias exists, it could put the validity of outcomes studies into dispute, however, was reduced across the

body of works by involving a variety of people in the studies and where research collaborations between investigators with differing alliances and complementary areas of expertise existed (Leykin & DeRubeis, 2009).

5.5 Section summary

In this section, methodology, limitations, personal reflections, the pragmatic paradigm, and ethical considerations have been examined.

Specifically, researcher bias and the competing agenda between researcher and founder and leader have been discussed, along with the issue of commercial interest. The author's own views on issues such as peer support and their personal investment in the *model* are discussed in relation to the impact this may have had on the studies that form the portfolio of works in respect of allegiance bias.

Respect for client autonomy and their right to self-govern are addressed with recognition that these principles were very much supported by the organisation's ethos and belief that those with lived experience are best placed to support themselves and others, and that a 'them and us' hierarchical service structure is not necessary.

Regarding methodology, service evaluations are discussed along with the value of conducting research in real-world settings (generalisability and ability to provide more realistic outcomes), since this was the approach (and setting) used in most studies that form the portfolio of works. This approach is contrasted with that of RCTs, and an argument is put forward as to why eTherapy as a complex, disruptive innovation is not particularly suited to being researched using this methodology.

The limitations of the methodological stance taken across the portfolio of works is critiqued, including the lack of follow-up data and control group, as well as the absence of focus on participants failing to complete the full eTherapy programme when delivered through the

model. Furthermore, the reliance on numerical data for the reporting on outcomes is discussed, with recognition that evidence-based healthcare is wider than this and therefore use of other outcome measures, particularly patient-reported ones, may have been preferable.

The pragmatic research paradigm is explored, along with a rationale provided as to why it was chosen (freedom for the author to select the most appropriate methodological approaches for the studies that form the portfolio of works) and which resulted in the portfolio comprising five quantitative papers and two papers that are qualitative.

The next section summarises the thesis' key outcomes, whilst also providing recommendations for practice and future research and a conclusion to the thesis.

Section Six

In this concluding section, thesis objectives are revisited and recommendations for practice and future research are provided.

6.1 Key thesis outcomes

The thesis objectives were to:

1. Examine the development of the *model*
2. Review and evaluate the clinical effectiveness of the *model*
3. Evaluate the acceptability of the *model*

Outcomes

The outcomes in terms of meeting the above objectives have been demonstrated through the thesis and achieved through the portfolio of published works.

The development of the *model* has been examined (Objective 1) across the body of works (**Cavanagh et al., 2011a, 2011b; Elison et al., 2014, 2017; Gellatly et al., 2018; Lidbetter & Bunnell, 2013; Luik et al., 2017**). This has included its initial creation and development into further iterations of the remote and hybrid *model*, capable of providing support for clients experiencing anxiety and depression, as well as insomnia and dual diagnosis issues is described.

The effectiveness of the *model* has been reviewed and evaluated (Objective 2) in **Cavanagh et al. (2011b)**, **Elison et al. (2014, 2017)**, **Gellatly et al. (2018)** and **Luik et al. (2017)**, with the finding that it is effective in the treatment of anxiety and depression, and for clients also experiencing sleep (**Luik et al., 2017**) and dual diagnosis issues (**Elison et al., 2014**, **2017**).

The *model's* acceptability has been evaluated (Objective 3) via **Cavanagh et al. (2011a, b)** and **Lidbetter and Bunnell (2013)** and demonstrated to be acceptable, though further research is needed to understand factors that moderate acceptability as well as further examination of those who drop-out. This is particularly important given the link between treatment adherence, acceptability, and effectiveness.

Through the development and publication of the seven focused papers that are presented in this thesis, a unique contribution to eTherapy knowledge has been established through describing the development of a non-clinical peer-supported *model* and demonstrating that, when this is delivered in a real-world setting, it is effective and acceptable in the management of anxiety and depression in adults.

6.2 Recommendations for future research and practice

As a result of the findings from the included articles that form the portfolio of published works, the following recommendations for future research are proposed:

- Examination of client step-up, step-down, step-sideways, and step-out utilisation rates, and how the *model* connects with the NHS, TSO, and statutory providers.
- Research focusing on clients that fail to complete therapy via the *model* and reasons for drop-out; an issue known to impact on the ability to predict the longer-term impact of eTherapy (Waller & Gilbody, 2009). Specifically, it would be helpful to compare drop out rates for different versions of the *model* and to further understand why clients drop out of eTherapy and whether drop out can be predicted so as to inform any future developments to the *model* that may be implemented aimed at addressing engagement and client retention.
- Examination of the optimal nature of client-eTC care pathway touchpoints, duration, nature, and mode of interaction to identify the key ingredients of an effective eTherapy

model (Hollis et al., 2017), including what support involves (Hadjistavropoulos, Schneider, Klassen, Dear & Titov, 2018) and its impact on adherence and therefore effectiveness and acceptability.

- Research focusing on the longer-term follow-up of clients post-discharge, in respect of clinical and employment outcomes in those accessing the *model* when delivered as part of an IAPT, step 2 service.
- The peer-supported *model* should be directly compared with the same intervention supported by a PWP, through an RCT. Research of this nature would provide insight into the impact that the workforce may have on outcomes and is the subject of a current study led by the thesis' author.
- Research into issues that may affect the future scaling up implementation of eTherapy into existing mental health services, to gain a better understanding of how to deliver and integrate eTherapy within mental health and other services (Thew, 2020).

Other recommendations for research arising from this thesis include:

- Investigating the role that the therapeutic relationship plays (Margison et al., 2000) on eTherapy outcomes achieved through the *model*; of interest given it has been reported that a different type of therapeutic relationship develops when those with lived experience deliver services instead of that seen in traditional staff-client relationships (Sweeney et al., 2014).
- Research into client perception of eTherapy using scales such as the Perceptions of Computerized Therapy Questionnaire-Patient Version - PCTQ-P (Carper, McHugh, Murray & Barlow, 2014) - as this would add further understanding of acceptability.
- As technology and AI develops, eTherapy is likely to become more personalised and intuitive (Wright, 2019); in part by incorporating more explicit inclusion of common factors of traditionally delivered therapy (Peck, 2010) and less focus being placed on

therapy modality. In this regard, an evaluation study is currently underway, led by the thesis' author comparing treatment outcomes in clients experiencing anxiety accessing different therapy modalities including clinical hypnotherapy, accessed face-to-face, by telephone and online.

- As blended models become more widespread, results from a largescale stakeholder survey conducted in eight European countries found acceptability was greater when a blend of face-to-face treatment was integrated with eTherapy (Topooco et al., 2017). Therefore, research into outcomes achieved by models that offer a blended approach would too be beneficial.
- Finally, it may also be advantageous to undertake feasibility studies regarding the piloting eTherapy services at high-intensity level for clients experiencing greater symptom severity.

As a result of the findings of the portfolio of works, the following recommendations for practice are being made:

- That the *model*, when used to deliver eTherapy programmes (such as LLTF Children and Young People – CYP), should be piloted in the community.
- That guidelines should be published to increase fidelity to eTherapy delivery models that incorporate client views and experiences (Roddis, Liversedge & Ryder, 2019).
- To develop a standardised training programme for eTherapy supporters (Hadjistavropoulos et al., 2018; Marks & Cavanagh, 2009), as it may not be a matter of who delivers the service but instead the quality of training that eTherapy supporters receive (Thew, 2020).

6.3 Conclusions

This thesis has described the development and evaluation of a non-clinical, fully peer-supported, eTherapy *model*.

The ground-breaking peer-supported *model* pioneered at Self Help Services has been conceptualised, developed, and designed under the author's leadership, for adults experiencing anxiety and depression and additional difficulties with sleep and dual diagnosis issues, when offered as a low-intensity IAPT service. Furthermore, in all its iterations (venue, remote, and hybrid versions), the *model* has been demonstrated to be both effective and acceptable; capable of achieving outcomes equivalent to those reported by IAPT services.

The author instigated and co-instigated, as well as conceptualising research on the *model* via the studies that form the portfolio of works; leading and directing the strategic development, delivery, and evaluation of the *model*. This has included assisting with refining the aims and objectives of the research studies, ensuring compliance with service governance regulations, and playing a critical role in the dissemination of papers to service user and professional populations.

Typically, eTherapy research in regard to the specification, nature, and effectiveness when studied in real-world settings is scarce (Adelman et al., 2014; Karyotaki et al., 2017); however, by contrast, the research represented via the studies that form the portfolio of works, directed by the author, makes a unique contribution to eTherapy literature by providing evidence of the clinical effectiveness and acceptability of a peer-supported *model* of eTherapy when delivered in a real-world setting.

Though roll out of the *model* was originally recommended a decade ago (**Cavanagh et al., 2011a**), peer-supported eTherapy has yet to take its rightful place in the primary care mental health landscape, such that it is widely adopted and incorporated into mainstream practice; a

phenomenon commonplace with disruptive (Barnett et al., 2011) and all innovations (Rogers, 2003), despite its potential being clear (Gretton & Honeyman, 2016).

Given demand for mental health services is expected to rise because of the COVID-19 pandemic (Holmes et al., 2020), never has there been a time when the *model* is more needed, yet its future expansion could be at risk given introduction of guidance that states that the intervention should be supported by clinicians (National Collaborating Centre for Mental Health, 2018). COVID-19 has undoubtedly prompted a radical increase in the delivery of online psychotherapeutic sessions, which contrasts greatly with the former infrequent use of online mental health interventions (Feijt et al., 2020), including eTherapy. It seems unlikely therefore that eTherapy as an intervention will ever return to the former pre-pandemic lower usage levels and as such is likely to form an ever-larger component of the mental health offer available globally.

Finally, it is essential that the potential of those with lived experience of mental health difficulties, such as anxiety and depression, in supporting others is realised in the mental health workforce. Specifically, peer support must be integrally woven into mainstream mental health services such as eTherapy, in the way the *model* facilitates and, in doing so, helping people to help themselves.

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Appendices

Appendix 1

Papers included in the Portfolio of Published Works

Paper One

Cavanagh, K., Seccombe, N., Lidbetter, N., & Bunnell, D. (2011a). Supported, service-user led, computerised cognitive behavioural therapy (CCBT) self-help clinics. *Journal of Public Mental Health,* 10(4), 225-233. https://doi.org/10.1108/17465721111188241

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Paper Two

Cavanagh, K., Seccombe, N., & Lidbetter, N. (2011b). The Implementation of Computerized Cognitive Behavioural therapies in a Service User-Led, Third Sector Self Help clinic. *Behavioural and Cognitive Psychotherapy*, 39(4), 427-442. https://doi.org/10.1017/S1352465810000858

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Paper Three

Lidbetter, N., & Bunnell, D. (2013). Self Help Services: helping people to help themselves. *Mental Health and Social Inclusion*, 17(2), 76-81. https://doi.org/10.1108/20428301311330126

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Paper Four

Elison, S., Ward, J., Davies, G., Lidbetter, N., Hulme, D., & Dagley, M. (2014). An outcomes study of eTherapy for dual diagnosis using Breaking Free Online. *Advances in Dual Diagnosis*, 7(2), 52-62. https://doi.org/10.1108/ADD-11-2013-0025

Paper Five

BMJ Open

Feasibility of a UK community-based, eTherapy mental health service in Greater Manchester: repeated-measures and between-groups study of 'Living Life to the Full Interactive', 'Sleepio' and 'Breaking Free Online' at 'Self Help Services'

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ABSTRACT

Objectives There is increasing evidence to support the effectiveness of eTherapies for mental health, although limited data have been reported from community-based services. Therefore, this service evaluation reports on feasibility and outcomes from an eTherapy mental health service.

Setting 'Self Help Services', an Increasing Access to Psychological Therapies (IAPT) eTherapy service in Greater Manchester.

Participants 1068 service users referred to the service for secondary care for their mental health difficulties.

Interventions Participants were triaged into one of three eTherapy programmes: 'Living Life to the Full Interactive' for low mood, stress and anxiety; 'Sleepio' for insomnia; and 'Breaking Free Online' for substance misuse, depending on clinical need.

Primary outcomes measures Standardised psychometric assessments of depression, anxiety and social functioning, collected as part of the IAPT Minimum Data Set, were conducted at baseline and post-treatment.

Results Data indicated baseline differences, with the Breaking Free Online group having higher scores for depression and anxiety than the Living Life to the Full Interactive (depression CI 1.27 to 3.21, p<0.0001; anxiety CI 0.77 to 1.72, p<0.0001) and Sleepio (depression CI 1.19 to 4.52, p<0.0001; anxiety CI 2.16 to 5.23, p<0.0001) groups. Promising improvements in mental health scores were found within all three groups (all p<0.0001), as were significant reductions in numbers of service users reaching clinical threshold scores for mental health difficulties (p<0.0001). Number of days of engagement was not related to change from baseline for the Living Life to the Full or Sleepio programmes but was associated with degree of change for Breaking Free Online.

Conclusion Data presented provide evidence for feasibility of this eTherapy delivery model in supporting service users with a range of mental health difficulties and suggest that eTherapies may be a useful addition to treatment offering in community-based services.

Strengths and limitations of this study

- Large sample size
- Data from community-based mental health service and service users
- High ecological validity
- Examines feasibility of a novel treatment modality within a community-based mental health service
- Outcomes have implications for reducing waiting list times for mental health services
- Unequal sample sizes across three eTherapy groups
- Lack of control/comparison group
- Lack of randomisation to treatment arms
- Lack of longer-term follow-up data

INTRODUCTION

For individuals in the UK with mental health difficulties, waiting list times remain a significant barrier to accessing psychosocial support.[1] Data indicate that since the 2008 recession, funding for mental health provision in some regions of the UK has been cut by as much as 32%,[2] a trend that has occurred alongside increasing prevalence of common mental health difficulties such as anxiety and depression[3] and increased demand for mental health service.[4] Despite the introduction of the Increasing Access to Psychological Therapies (IAPT) programme in England, which was intended to alleviate pressures on primary mental health services,[5] as many as 1 in 10

patients may still be waiting for over a year for face-to-face psychosocial treatment.[6] The IAPT approach is designed to widen access to lower-intensity interventions for mild to moderate depression and anxiety, which are delivered by specially trained Psychological Wellbeing Practitioners (PWPs). These PWPs work alongside higher-intensity mental health professionals such as high-intensity therapists and Clinical Psychologists, who provide support to individuals with more complex needs.[7] Although the IAPT approach has reduced waiting list times within primary mental health services, IAPT services themselves are now facing significant oversubscription.[6]

One possible solution to the growing issue of waiting lists in mental health services are 'computer-assisted therapies' (CATs) or 'eTherapies.' These therapies deliver evidence-based psychosocial interventions and behavioural change techniques through digital technologies such as web and mobile applications. Such interventions have the potential to deliver highly individualised treatment, by tailoring intervention content to the specific needs of the individual, and there is now a growing literature demonstrating the clinical and cost-effectiveness of tailorable eTherapy programmes for the treatment of a wide range of health difficulties.[8 9]

Three examples of such eTherapy programmes are 'Living Life to the Full Interactive' (www.llttf.com/),[10 11] a programme for low mood, stress and anxiety, and depression associated with physical health problems; 'Sleepio' (www.sleepio.com),[12–15] a sleep improvement programme; and 'Breaking Free Online' (www.breakingfreeonline.com),[16–20] a programme that helps people overcome substance misuse difficulties. All three of these programmes have been delivered to service users via an innovative eTherapy service in Greater Manchester, 'Self Help Services', a service-user-led mental health charity that provides primary care mental health services across the north of England. A number of National Health Service (NHS) Trusts have commissioned services provided by the charity as part of the IAPT initiative, and therefore, this study reports on the feasibility of the delivery of these three eTherapies by Self Help Services in community-based mental health treatment settings, via the use of clinical outcomes data collected for service evaluation purposes in the IAPT Minimum Data Set.

Advantages and disadvantages of delivering eTherapies for mental health

There are a number of advantages to providing eTherapies, such as significantly reducing waiting times within healthcare services and being more cost-effective than one-to-one therapy, given that multiple users can access an eTherapy simultaneously.[21–23] Providing interventions as eTherapy also ensures optimal treatment fidelity as therapeutic techniques are delivered using a computer in a highly standardised manner,[21 24] without the human-related variance in delivery often seen in traditional human-facilitated interventions.[21 25] However, despite these advantages of delivering eTherapies, there are still some limitations with the approach. Some studies have demonstrated adherence to be low, with numbers of service users dropping out of treatment being high.[27–29] Additionally, when such interventions are provided with minimal or no practitioner support, there is little opportunity for a positive therapeutic alliance to be built between the service user and and a practitioner, which may reduce effectiveness.[30 31]

The introduction of digital health interventions such as eTherapies into existing healthcare systems is also often perceived as 'disruptive', meaning it can take considerable time for such innovations to be implemented and incorporated into standard practice.[32–34] Additionally, research has demonstrated that information technology infrastructure within NHS mental health services may be inadequate for the effective delivery of eTherapies.[35 36] Nevertheless, a recent report by the King's Fund highlighted the potential of eTherapies as part of effective practice,[37] with some eTherapy programmes having been demonstrated to be tailorable to the need of the individual and clinically effective, with the National Institute for Health and Care Excellence now recommending such approaches for anxiety and depression.[38] This is due to the fact that despite difficulties with implementation, some eTherapies have crossed the divide between research-based innovation and implementation in clinical settings, including those eTherapies delivered at Self Help Services, namely Living Life to the Full Interactive, Sleepio and Breaking Free Online.

Mental health eTherapy provision at Self Help Services

Living Life to the Full Interactive[10 11] is a licensed eTherapy programme demonstrated as being effective in helping people cope with low mood, stress and anxiety via the inclusion of techniques informed by cognitive behaviour therapy (CBT) principles.[39 40] The programme is an online interactive self-help skills package, comprising a number of modules covering areas of life and well-being commonly affected by low mood and stress. It uses both interactive text and video formats to accommodate different learning styles and provides psychoeducation alongside more practical CBT techniques such as relaxation and guidance on how to make life changes.

Sleepio is an online sleep improvement programme demonstrated as being effective in helping people with insomnia,[12–15] which can be used as a self-help programme. It comprises intervention techniques informed by CBT principles and provides users with 6 weeks of access to tailored clinical content, and 12 weeks of support from an online community. The programme includes 10 online tools and a 'library' of articles written by sleep experts, in addition to a personal 12-week sleep diary. Users are encouraged to log on once a week for a personalised 20 min session with an avatar that guides them through a personalised programme.

Breaking Free Online is an online treatment programme that has a growing evidence base to support its effectiveness in helping people overcome difficulties

with alcohol and drugs,[16–20] which can be delivered as CAT or self-help, and targets 39 different substances, including alcohol. The programme provides multiple interactive psychosocial interventions, drawing on CBT, mindfulness and relapse prevention techniques, via a six-domain biopsychosocial model, the Lifestyle Balance Model,[41] which conceptualises various aspects of functioning associated with substance misuse and comorbid mental health difficulties.

Although the three eTherapy programmes provided by Self Help Services each have different primary clinical targets, they all contain cognitive-behavioural interventions that are likely to be generally helpful to individuals in addressing underlying anxiogenic or depressogenic thinking and unhelpful behaviour patterns. For example, Living Life to the Full Interactive was developed specifically for individuals experiencing low mood, stress and anxiety but contains clinical techniques that could also be effective for addressing associated issues such as poor sleep. Additionally, previous research conducted at Self Help Services with individuals using Breaking Free Online for their substance misuse demonstrated significant improvements in depression (r=0.59), anxiety (r=0.63) and general social functioning (r=0.68).[16] Additionally, outcomes studies of Sleepio indicate that as well as resulting in improved sleep for users, the programme also facilitates general improvements in mental health (d=−0.33)[42] and workplace functioning (d=0.77).[12]

Aims of the study

Over the past 4 years, Living Life to the Full Interactive, Sleepio and Breaking Free Online have been delivered to service users via the novel eTherapy delivery model developed by Self Help Services, which has provided an additional, digital treatment modality within the Greater Manchester IAPT service provision. Therefore, this service evaluation sought to explore feasibility and outcomes of the Self Help Services eTherapy delivery model and its potential to provide a useful addition to traditional IAPT treatment offerings. This is done via examination of psychosocial outcomes for service users engaging with each of the three eTherapy programmes using the IAPT Minimum Data Set, which is intended to facilitate service evaluation and development, and measures depression, anxiety and social functioning.

Guidance from the Medical Research Council (MRC) recommends that alongside examining clinical effectiveness of complex interventions via randomised controlled trials (RCTs), feasibility studies allow examination of acceptability of a new intervention, service user compliance and different delivery approaches. These are all important considerations that can impact on recruitment and retention of service users and, ultimately, clinical outcomes.[43 44] Additionally, the MRC framework recommends that feasibility and piloting work be conducted, both within research and community-based treatment delivery settings, in order to contribute to further development of clinical content of such interventions, and development of appropriate delivery models within the healthcare system. In this way, this service evaluation takes a pragmatic approach by examining feasibility of delivering eTherapies in a community mental health service, using clinical outcomes data from service users, as opposed to data collected within the highly controlled context of a research study such as a clinical trial, where ecological validity may be low.[45 46]

METHOD

Design

This study had a pre-test post-test design, using standardised psychometric assessments from the IAPT Minimum Data Set, to examine mental health and social functioning outcomes, in three separate groups of service users accessing different eTherapy treatment programmes in a community-based mental health service.

Participants

Participants were 1068 service users receiving support for a range of mental-health-related issues from Self Help Services, an eTherapy service, between 2011 and 2015. Inclusion criteria included any service user over the age of 18 years accessing one of the three eTherapy programmes provided by Self Help Services (Living Life to the Full Interactive, Sleepio or Breaking Free Online), who had completed their eTherapy treatment period, provided post-treatment assessment data and consented for their anonymised data to be used for service evaluation purposes at the start of their treatment. Self Help Services provides services across Greater Manchester and some areas of Liverpool, including self-help and peer support groups, face-to-face counselling and a mental health crisis centre, alongside access to a eTherapies.

Services users had either been referred to Self Help Services by a healthcare practitioner or self-referred. On entering the service, they completed an initial assessment comprising a battery of standardised psychometric assessments, which forms the IAPT Minimum Data Set, and a consultation with a Self Help Services practitioner to establish their principal area of difficulty: depression, anxiety and/or stress, sleep disruption or problems with alcohol or drugs. These initial assessments were conducted either face to face or via telephone depending on the service users' preference. Practitioners were all trained to provide guidance and support to service users using the eTherapy programmes, with some practitioners also having lived experience of mental health difficulties. Following a collaborative discussion between the service user and practitioner, service users were triaged into the most appropriate of the three eTherapies and supported in setting up an account on the relevant programme.

Procedure

Service users entered the service and were evaluated as above during a 4-year period between 2011 and 2015. Primary outcome measures came from the Minimum Data Set of standardised psychometric assessments completed

in NHS IAPT services throughout England to facilitate service evaluation, and included:

A. The Patient Health Questionnaire (PHQ-9)[47]: This nine-item scale measures levels of depression and contains validated clinical norms, with a possible score range of 0–27. Internal reliability of the PHQ-9 has been found to be excellent (α=0.89), with test–retest reliability also being excellent (r=0.84). Score ranges for severity of depression are: 0–4, 'minimal'; 5–9, 'mild'; 10–14, 'moderate'; 15–19, 'moderately severe'; 20–27 'severe.'
B. The General Anxiety Disorder Scale (GAD-7)[48]: This seven-item scale measures levels of anxiety and also contains validated clinical norms and has a possible score range of 0–21. Factor analyses revealed the GAD-7 to have a one-dimensional factor structure with item factor loadings ranging between 0.69 and 0.81, with internal consistency being excellent (α=0.92). Score ranges for severity of anxiety are: 0–4, 'minimal'; 5–9, 'mild'; 10–14, 'moderate'; 15–21, 'severe.'
C. The Work and Social Adjustment Scale (WASA)[49]: This five-item scale measures levels of social impairment and has a possible score range of 0–40. Cronbach's α measure of internal scale consistency ranged from 0.70 to 0.94, with test–retest correlation being 0.73.

This baseline assessment was completed with a total of 1787 service users. Once the baseline assessment had been completed, service users were triaged into the most appropriate eTherapy programme and provided with full access. They were then followed up with a telephone call once a week from the service coordinator and were offered the opportunity to come into the service for face-to-face support if required. Then, following a period of engagement with the eTherapy programme each service user was triaged into, each service user was contacted to arrange a time to complete the last treatment session, during which the same measures were completed a second time as part of a post-treatment assessment. Of the 1786 service users completing the baseline assessment, a total of 1068 (59.8%) started treatment and provided post-treatment assessment data, with 719 (40.2%) completing the baseline assessment but not completing treatment and providing post-treatment assessment. Reasons for service users not completing treatment and providing post-treatment data were: 216 (38.5%) disengaged/dropped out from the service following baseline assessment, 251 (34.9%) were discharged from the service following baseline assessment because treatment was not required; and 252 (35%) were referred to another service, for example, higher-intensity IAPT or non-IAPT services. Comparisons between those service users providing post-treatment assessment data and those who did not, indicated no significant baseline differences between the groups in terms of psychometric assessment scores (PHQ-9, p=0.234; GAD-7, p=0.061; WASA, p=0.54).

Data analyses

Shapiro-Wilk tests revealed data from the main outcomes measures (PHQ-9, GAD-7, WASA), both at baseline and post-treatment, to be non-normally distributed (all $p<0.05$); therefore non-parametric tests were run to analyse data. Two main sets of analyses were conducted. Kruskal-Wallis analyses of variance (ANOVA) were conducted to examine baseline differences between the three eTherapy groups on the mental health and social functioning assessment contained within the IAPT Minimum Data Set. Analyses of covariance (ANCOVA) were also conducted to examine whether eTherapy group assignment was predictive of the extent to which scores for post-treatment mental health and social functioning differed from baseline scores, that is, the degree of change in functioning, whilst controlling for the participant characteristics of age and gender. Additionally, separate within-group, repeated-measures Wilcoxon signed-rank ANOVA tests were conducted to examine changes in the same psychometric outcomes from baseline to post-treatment assessment within each of the three eTherapy groups. Pearson's effect sizes (r) were calculated using test statistics from ANOVA and ANCOVA tests run in SPSS (Z) and sample size (n) using the following formula[50]:

$$r = \frac{Z}{\sqrt{n}}$$

RESULTS

Clinical outcomes data from a total of 1068 service users from the Self Help Services eTherapy service were included in the analyses, with 866 (81%) having accessed Living Life to the Full Interactive, 85 (8%) having accessed Sleepio and 117 (11%) having accessed Breaking Free Online. Across the entire sample, 679 (63.6%) were female; by group, 572 (66.1%) of those allocated to Living Life to the Full Interactive were female, compared with 60 (70.6%) to Sleepio and 47 (40.2%) of Breaking Free Online users. Across the whole sample, mean age was 37.38 years (range 16–79 years; SD, 11.98), with a mean age of 36.11 years (range 16–73 years; SD, 11.51) for Living Life to the Full Interactive users, 45.21 years (range 20–79 years; SD, 15.04) for Sleepio users, and 41.21 years (range 19–60 years; SD, 9.80) for Breaking Free Online users.

Time periods of engagement with the service varied, with some service users engaging in treatment for longer periods than others, depending on their need. Engagement periods for the whole sample ranged from 4 days to 288 days (0.64–41.14 weeks), with a median engagement treatment period of 62.39 days (IQR=40.18). For each individual eTherapy group, engagement periods were as follows: for Living Life to the Full Interactive users, 4–288 days (0.64–41.14 weeks) with a median of 66.29 days (IQR=43.06); for Sleepio users, 29–148 days (4.19–21.08 weeks) with a median of 66.35 days (IQR=39.06);

Table 1 Comparison of baseline psychometric outcomes for the three eTherapy programmes

	Breaking Free Online mean (SD)	Living Life to the Full Interactive mean (SD)	Sleepio mean (SD)	Z	p Value	r
PHQ-9 baseline	14.20 (6.43)	11.89 (4.77)	11.34 (5.12)	12.00	<0.0001	0.36
GAD-7 baseline	12.18 (5.75)	11.32 (3.98)	8.49 (5.00)	9.80	<0.0001	0.31
WASAS baseline	16.84 (9.74)	16.14 (7.91)	15.65 (9.12)	0.56	0.569	0.00

and for Breaking Free Online users, 6–205 days (0.92–29.35 weeks) with a median of 58.29 days (IQR=48.64). At the end of each service user's period of engagement with the service, the same battery of assessment measures was completed at point of discharge, which was between 4 days and 288 days following the baseline assessment.

When the three eTherapy groups were compared using Kruskal-Wallis ANOVAs on their psychometric assessment scores for mental health and social functioning at baseline, some significant differences between the groups were found (table 1). The Breaking Free Online group was found to have significantly higher scores on the PHQ-9 assessment for baseline depression (Breaking Free Online mean=14.20) than the other two eTherapy groups (Living Life to the Full Interactive mean=11.89, CI 1.27 to 3.21, p<0.0001; Sleepio mean=11.34; CI 1.19 to 4.52, p<0.0001). The Breaking Free Online group was also found to have significantly higher scores at baseline on the GAD-7 assessment for anxiety than the other two eTherapy groups (Breaking Free Online mean=12.18; Living Life to the Full Interactive mean=11.32, CI. 077 to 1.72, p<0.0001; Sleepio mean=8.49, CI 2.16 to 5.23, p<0.0001).

In addition to comparing the three eTherapy groups at baseline, degrees of psychometric score change from baseline to post-treatment were also compared across the three eTherapy groups, with baseline scores on each of the psychometric assessments being regressed against post-treatment scores, while controlling for age and gender. ANCOVAs revealed no significant differences between the groups in terms of degree of change in any of the baseline psychometric assessments including the following: PHQ-9 F=2.373, p=0.094; GAD-7 F=3.239, p=0.052; WASAS F=0.164, p=0.848. Additionally, when outcomes from baseline to post-treatment were compared within each of the three eTherapy groups, using Wilcoxon signed-rank tests, significant reductions in scores on PHQ-9, GAD-7 and WASAS were found within all three groups, with p values across all three eTherapy groups being <0.0001. In addition to conducting these Wilcoxon analyses, effect sizes were calculated. In all three eTherapy groups and for each of the psychometric assessments, effect sizes were in the moderate to large range. See table 2 for full details of these within-group analyses.

Given that service users accessed each eTherapy programme for varying lengths of time (4–288 days), regression analyses were conducted to examine whether number of days engaging with each programme was associated with degree of change in depression, anxiety and social functioning from baseline to post-treatment assessment. These regression analyses revealed that length of period of engagement (in days) was not related to degree of change from baseline for service users accessing either the Living Life to the Full Interactive or Sleepio groups. However, number of days of engagement was associated with degree of change in scores for depression, anxiety and social functioning from baseline to post-treatment assessment for those service users accessing Breaking Free Online. For Breaking Free Online users, the greater the number of days of engagement with the programme, the greater the reduction in scores for depression,anxiety and social impairment (table 3).

Alongside statistically significant within-group changes in scores on PHQ-9, GAD-7 and WASAS (table 2), the percentages of service users reaching clinical thresholds scores for mild, moderate and severe depression and anxiety at baseline were compared with the percentages reaching each threshold at post-treatment (see tables 4 and 5). Chi-square analyses demonstrated that within each of the three eTherapy groups, the percentages of service users reaching threshold scores for clinically relevant depression and anxiety (a score of 5≤) after treatment reduced significantly from baseline: Living Life to the Full Interactive (PHQ-9 χ^2=260.30, p<0.0001; GAD-7 χ^2=105.44, p<0.0001), Breaking Free Online (PHQ-9 χ^2=68.77, p<0.0001; GAD-7 χ^2=45.88, p<0.0001), Sleepio (PHQ-9 χ^2=57.24, p<0.0001; GAD-7 χ^2=44.23, p<0.0001). Specifically, the percentages of service users

Table 2 Within-group comparison for each of the three eTherapy groups on baseline and post-treatment psychometrics assessment scores

		Z	p Value	r
PHQ-9	Breaking Free Online	−6.771	<0.0001	0.63
	Living Life to the Full Interactive	−21.450	<0.0001	0.73
	Sleepio	−7.226	<0.0001	0.78
GAD-7	Breaking Free Online	−6.449	<0.0001	0.60
	Living Life to the Full Interactive	−21.463	<0.0001	0.73
	Sleepio	−6.365	<0.0001	0.69
WASAS	Breaking Free Online	−5.558	<0.0001	0.51
	Living Life to the Full Interactive	−13.729	<0.0001	0.47
	Sleepio	−4.967	<0.0001	0.54

Table 3 Regression analyses demonstrating associations between number of days of engagement with each eTherapy programme and degree of change in psychometric scores

		F	β	p	95% CI
Breaking Free Online	**PHQ-9**	**34.387**	**−0.341**	**<0.0001**	**−0.214 to 0.039**
	GAD-7	**28.396**	**−0.330**	**<0.0001**	**−0.193 to 0.027**
	WASAS	**26.648**	**−0.190**	**0.020**	**−0.170 to 0.176**
Living Life to the Full Interactive	PHQ-9	168.814	−0.038	0.185	−0.039 to 0.013
	GAD-7	95.392	−0.041	0.178	−0.036 to 0.016
	WASAS	127.071	−0.021	0.475	−0.037 to 0.058
Sleepio	PHQ-9	31.996	−0.130	0.129	−0.065 to 0.056
	GAD-7	40.010	−0.138	0.083	−0.060 to 0.047
	WASAS	30.856	−0.050	0.556	−0.147 to 0.097

in the minimal and mild categories of symptom severity increased after treatment, while the percentages of service users in the categories between moderate and severe symptom severity decreased (see tables 4 and 5 for score ranges for each severity category).

DISCUSSION

Given that eTherapy is still a relatively novel treatment modality within the UK mental health sector, this service evaluation explored the feasibility of a novel treatment delivery model developed by one of the UK's only eTherapy mental health services: Self Help Services. This service evaluation used outcomes from community-based service users receiving treatment via three eTherapy programmes provided by Self Help Services: Living Life to the Full Interactive for low mood, stress and anxiety; Sleepio for insomnia; and Breaking Free Online for substance misuse. Statistically significant within-group reductions in scores for anxiety, depression and social impairment were demonstrated for each of the three eTherapy programmes. Additionally, regardless of eTherapy group allocation, degrees of reduction in mental health scores were comparable across each of the three eTherapy programmes, (table 1) with eTherapy group assignment not being predictive of degree of change in depression, anxiety or social functioning scores between baseline and post-treatment assessment.

Despite the equivalent outcomes across the three eTherapy groups, there were some significant differences between the groups in terms of scores on the assessment measures and hence the severity of their mental health difficulties. The Breaking Free Online group was found to have significantly higher baseline scores for depression and anxiety than the Living Life to the Full Interactive and Sleepio groups, and significantly higher scores for anxiety at post-treatment assessment. These findings may make sense, as the Breaking Free Online group may have presented with more complex difficulties than the Living Life to the Full Interactive and Sleepio groups, given the extent to which substance use can impair mental health[51 52] and the often chaotic lifestyle that is common for individuals with drug and alcohol difficulties.[41 53] The significantly higher post-treatment anxiety for the Breaking Free Online group may also be explained by the fact that, in the early stages of substance misuse recovery, many individuals may experience a temporary worsening of mental health symptoms[54 55] when the anti-depressant effects of previously consumed drugs are removed, particularly in the case of opiates.[56]

When clinical threshold scores for depression and anxiety were examined, there were reductions across all three groups in percentages of service users reaching threshold scores for clinically significant anxiety and depression at post-treatment assessment. These findings reinforce the statistically significant reductions in scores for mental health found across the three eTherapy groups. Moreover, it is important to note that anxiety and depression scores reduced in association with all programmes, despite these symptoms not being the principal clinical targets of the Breaking Free Online and Sleepio programmes.

Table 4 Changes in percentages of service users reaching clinical threshold scores for depression by eTherapy group

	PHQ-9 baseline threshold (%)			PHQ-9 post-treatment threshold (%)		
PHQ-9 score thresholds	**Breaking Free Online**	**Living Life to the Full Interactive**	**Sleepio**	**Breaking Free Online**	**Living Life to the Full Interactive**	**Sleepio**
Minimal (range 0–4)	7.7	6.9	10.6	37.6	40.5	42.4
Mild (range 5–9)	21.4	23.1	20	15.4	33.5	38.7
Moderate (range 10–14)	20.5	40.3	44.7	22.2	15.5	11.8
Moderately severe (range 15–19)	26.5	24.2	18.8	11.1	7.8	2.4
Severe (range 20–27)	23.9	5.5	5.9	13.7	2.7	4.7

Table 5 Changes in percentages of service users reaching clinical threshold scores for anxiety by eTherapy group

	GAD-7 baseline threshold (%)			GAD-7 post-treatment threshold (%)		
GAD-7 thresholds	Breaking Free Online	Living Life to the Full Interactive	Sleepio	Breaking Free Online	Living Life to the Full Interactive	Sleepio
Minimal (range 0–4)	11.1	3.6	27.1	38.5	43.3	58.9
Mild (range 5–9)	26.5	41.1	43.4	28.2	37.9	23.5
Moderate (range 10–14)	28.2	40.2	20	15.4	11.3	14.1
Severe (range 15–21)	34.2	15.1	10.6	17.9	7.5	3.5

The findings from this service evaluation would appear to support the feasibility and effectiveness of eTherapy programme delivery in mental health services, and would appear to support findings from previous research, including outcomes studies demonstrating effectiveness of each of the three eTherapy programmes,[10 11 13 14 16 17] and findings related to delivery of eTherapies more generally. For example, eTherapies have been demonstrated as being useful additions to adult mental health services,[58] services for children and young people[57 58] and also treatment provision delivered by social care workers.[59] However, some authors have advised caution around the potential of eTherapies, as many may not be grounded in psychological theory and may lack a solid evidence base.[60] Additionally, in some cases, during the development process, the challenges of implementation and uptake may not have been adequately considered, meaning that some eTherapies may not fulfil their promise of widening access to treatment.[61] However, despite this caution, a recent survey of NHS mental health services showed that the provision of eTherapies is an emerging and growing trend, meaning that it is becoming increasingly important to put structures in place to ensure that only evidence-based eTherapies are commissioned and delivered.[62]

Limitations to the study

Although the findings from this study are promising, there are a number of limitations that merit discussion. Firstly, the sample sizes across the three programmes varied, with the Living Life to the Full Interactive group (n=866) being considerably larger than the Sleepio and Breaking Free Online groups (n=85 and n=117, respectively). However, given that Self Help Services is an eTherapy service for individuals with mental health problems that are common among the general population, it is unsurprising that Living Life to the Full Interactive is accessed by more service users, as it is the only eTherapy programme of the three included in this service evaluation that is designed specifically for addressing mental health difficulties, such as low mood, stress and anxiety. Additionally, Living Life to the Full Interactive is a more established programme and has been provided in mental health services for a number of years, in contrast to Sleepio and Breaking Free Online, which are still relatively new eTherapy programmes.

Further limitations are the lack of follow-up data from participants and the fact that the study did not include randomisation and control groups. However, although methodologies such as RCTs are an important part of the development and evaluation process for complex interventions,[14 63 64] there is now a growing literature to suggest that additional methodologies, employed alongside RCTs, may be required for evaluating complex, multi-component interventions such as eTherapies for mental-health-related conditions.[44 65–68] When eTherapies are evaluated via RCT designs, there may be some methodological limitations due to the tailorability of these programmes, which though may enhance clinical effectiveness,[69–71] may result in within-group variation in terms of the personalised sets of intervention strategies that each user may complete.

This study was also restricted to analyses of data routinely collected for service evaluation purposes at IAPT services via the Minimum Data Set, meaning that the authors were not able to make decisions around which psychometric measures should be used. It may be that there are limitations with the psychometric properties of the measures that have been selected for inclusion in the Minimum Data Set, and therefore, other measures may be more appropriate. Additionally, some data that would have been informative were not available in the Minimum Data Set, such as around severity of insomnia for the Sleepio group and severity of substance dependence and substance consumption for the Breaking Free Online group. The Minimum Data Set also does not record whether service users have received face-to-face or telephone support during each contact with Self Help Services, and some information was not available around reasons for service users disengaging with the service or, reasons why service users engaged with each of the programme for the time periods they did. For example, it would have been informative to understand service user satisfaction with each programme, or why they stopped using each one.

An additional factor that could be viewed as a limitation is that service users engaged with the eTherapy programmes for varying lengths of time, between 4 days and 288 days. However, eTherapy programmes are designed to offer such patient-centred flexibility, with this being associated with their potential to be clinically effective.[21] Additionally, regression analyses revealed that number of days of engagement did not appear to be associated with degree of change in scores for depression, anxiety and social impairment, from baseline to treatment assessment, for

the Living Life to the Full Interactive and Sleepio users. However, there did appear to be a significant association between number of days of engagement with Breaking Free Online and degree of improvement in depression, anxiety and social impairment from baseline to post-treatment assessment. This may be explained by the fact that the Breaking Free Online group had more severe mental health problems at baseline and were being treated for a particularly challenging mental-health-related condition, that being substance misuse and comorbid mental health difficulties.

Finally, just over 40% of service users who initially engaged with the service did not provide post-treatment data, although for the majority of these service users, they were either discharged due to the service not being required or were referred to more appropriate services. Attrition is common in eTherapies[29 72 73] with this now a focus for research in the digital health sector more generally. The problem of attrition may also be an issue in mental health interventions,[74 75] with drop-out from psychological therapies being associated with poorer outcome for service users.[76]

Implications of the findings

The data presented here demonstrate that the Self Help Services eTherapy model may have the potential to inform future mental health service delivery, given the encouraging clinical outcomes reported and the potential cost-effectiveness of such an approach. In addition, as there are now significant and lengthening waiting lists—even for IAPT services that were originally intended to reduce waiting times for mental health services[6]—widening service provision to incorporate eTherapies may increase access to evidence-based psychosocial treatment for large numbers of people who could benefit from it.

PWPs, who are trained specifically to deliver lower-intensity interventions within IAPT services, may be ideally placed to incorporate the delivery of eTherapies into their current roles. This is because they are trained to conduct assessments, build a therapeutic alliance with service users, work collaboratively with them to identify areas in which they wish to see change, deliver assisted self-help and provide information about other services that may be beneficial to each individual service user's recovery.[77] By expanding their therapeutic repertoire to include the provision of eTherapies, PWPs would be able to deliver comprehensive, evidence-based programmes that are highly standardised and not subject to the variation in fidelity of delivery that is common to more traditional psychosocial interventions,[25] given that all clinical content is delivered via the computer.[78]

Clearly, it is important to provide access to psychosocial interventions to address the increasingly pressing issue of waiting times for mental health services and to ensure these interventions are effective and evidence based. This service evaluation has demonstrated that evidence-based eTherapy programmes can be effective, using clinical outcomes data from service users in a community-based mental health service, as opposed to data from a highly controlled study, enhancing ecological validity and generalisability of findings. Future research is planned to explore the longer-term clinical outcomes of providing eTherapies as part of an IAPT stepped-care model and potential waiting list time and cost implications of such a service.

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Contributors SE led on study design, data analyses, literature review and drafting the manuscript. JW developed the Breaking Free Online treatment programme and co-wrote the manuscript. CW developed the Living Life to the Full interactive treatment programme and provided comments on the manuscript. CE developed the Sleepio treatment programme and provided comments on the manuscript. GD developed the Breaking Free Online treatment programme and provided comments on the manuscript. SD assisted with literature review and data analyses. KR provided support to service users in accessing the three eTherapy programmes, collected outcomes data and assisted with access to the data. LC provided support to service users in accessing the three eTherapy programmes and collected outcomes data. NL provide permissions for accessing the data, organised access to the data and provided comments on the manuscript. KS extracted data for analyses and provided these to the lead author.

Competing interests SE, GD and SD are employed by Breaking Free Group, where the Breaking Free Online programme was developed. JW and GD are authors of the Breaking Free Online programme. JW is founder and a director and shareholder of Breaking Free Group. CW is President of BABCP, the lead body for CBT in the UK, and is also author of Living Life to the Full interactive as well as a range of other CBT-based resources that address anxiety, depression and other disorders, which are available commercially. He receives royalties for these and is shareholder and director of a company that commercialises these resources. CE is co-founder and CMO of Big Health Ltd (Sleepio), where he is a shareholder and receives remuneration from the company.

Patient consent Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

Ethics approval This was a service evaluation using existing, non-identifiable service user data from Self Help Services, which were fully anonymised by Self Help Services before being provided to the lead author for analyses, and so external ethical approval was not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Paper Six

Luik, A. I., Bostock, S., Chisnall, L., Kyle, S. D., Lidbetter, N., Baldwin, N., & Espie, C. A. (2017). Treating depression and anxiety with digital cognitive behavioural therapy for insomnia: a real world NHS evaluation using standardized outcome measures. *Behavioural and Cognitive Psychotherapy*, *45*(1), 91-96. https://doi.org/10.1017/s1352465816000369

Article removed due to copyright restrictions.

Paper Seven

Gellatly, J., Chisnall, L., Seccombe, N., Ragan, K., Lidbetter, N., & Cavanagh, K. (2018). @ Home eTherapy service for people with common mental health problems: an evaluation. *Behavioural and Cognitive Psychotherapy*, 46(1), 115-120 https://doi.org/10.1017/S1352465817000297

Appendix 2

Letters from collaborating authors confirming contribution

UNIVERSITY OF SUSSEX

21st October 2020

This letter is to confirm the contribution of Nicky Lidbetter to the following paper:

Cavanagh, K., Seccombe, N., Lidbetter, N., & Bunnell, D. (2011). Supported, service-user led, computerised cognitive behavioural therapy (CCBT) self-help clinics. Journal of Public Mental Health, 10(4).
https://doi.org/10.1108/17465721111188241

This paper documents the delivery of supported, service-user led, computerised CBT in self-help clinics. It describes the ground-breaking delivery model pioneered by Self Help Services under Nicky's leadership and summarises relevant outcome data. Nicky was involved in the preparation, writing and revisions of the manuscript.

Yours sincerely

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UNIVERSITY OF SUSSEX

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Yours sincerely

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BREAKING FREE™

Thursday 22nd October 2020

Dear Sir/Madam,

I am writing to you to confirm that in her role as CEO of 'Self-Help Services', Nicky provided approval for the Breaking Free Group research team to access a database containing anonymised clinical data from service users at Self-Help Services. This was done in order to facilitate the publication of two studies – references for these studies are listed below. Nicky also provided comments on draft manuscripts outlining the findings of these studies, ahead of their submission for publication in the journals *Advances in Dual Diagnosis* and *BMJ Open*.

Elison, S., Ward, J., Davies, G., Lidbetter, N., Dagley, M., & Hulme, D. (2014). An outcomes study of eTherapy for dual diagnosis using Breaking Free Online. *Advances in Dual Diagnosis, 7*(2), 52-62.

Elison, S., Ward, J., Williams, C., Espie, C., Davies, G., Dugdale, S., Ragan, K., Chisnall, L., Lidbetter, N., & Smith, K. (2017). Feasibility of a UK community-based, eTherapy mental health service in Greater Manchester: repeated-measures and between-groups study of 'Living Life to the Full Interactive', 'Sleepio' and 'Breaking Free Online' at 'Self Help Services'. *BMJ Open, 7*(7), 1-10.

Your faithfully,

Dr Sarah Elison-Davies, PhD

Research Director, Breaking Free Group

NUFFIELD DEPARTMENT OF
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Professor of Sleep Medicine
Senior Research Fellow, Somerville College

Our ref: CE/ts

15th September 2020

To whom it may concern:

Dear Sir/Madam

Treating Depression and Anxiety with Digital Cognitive Behavioural Therapy for Insomnia: A Real World NHS Evaluation Using Standardized Outcome Measures

I am writing to confirm that Nicola Lidbetter contributed to the design of the study; leading on the site's strategic delivery of the project at Self Help Services. Nicola also contributed to the final draft of the manuscript and played a critical role in the dissemination of the paper to relevant service user and professional populations.

Yours faithfully

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21st October 2020

eTherapy peer-reviewed paper contribution

Gellatly, J., Chisnall, L., Seccombe, N., Ragan, K., Lidbetter, N., & Cavanagh, K. (2017). @Home eTherapy Service for People with Common Mental Health Problems: an Evaluation. *Behavioural and Cognitive Psychotherapy*. https://doi.org/10.1017/S1352465817000297

I am writing with respect to the peer-reviewed journal article above, and specifically the contributions that were made by Nicola Lidbetter.

The piece of work conducted was evaluative and was instigated by Nicola who worked closely with myself, other University academics and the eTherapy team to refine aims and objectives of the research, ensuring compliance with service governance regulations. Nicola contributed to the preparation, writing and revisions of the manuscript. She also played a critical role in dissemination of the paper to relevant service user and professional populations.

I would be pleased to provide any further information if required.

Dr Judith Gellatly
Programme Manager/Research Fellow
The University of Manchester