Links between participant demographic and clinical characteristics and patterns of usage in research trials of self-management psychoeducation interventions for bipolar disorder.

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I declare that this thesis is my own work and has not been submitted for the award of a higher degree elsewhere.

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Abstract

Bipolar Disorder (BD) is a complex mood disorder that is often treated pharmacologically to reduce patient symptoms and the risk of relapse. Medication though is only partially effective, with most individuals continuing to experience on-going symptoms. This has resulted in interest in the benefits of psychological approaches delivered as adjuncts to pharmacotherapies. Psychoeducation (PE) is an example of a psychological approach which has been demonstrated to be effective in BD, reducing the number of patient relapses, with positive outcomes being linked to increased levels of intervention usage. However, individuals with BD have been demonstrated to have high rates of intervention non-usage. This study investigated participant demographic and clinical characteristics, to discover if they correlated with usage levels in PE interventions for BD when delivered by digital or face-to-face modalities.

A quantitative systematic literature review of 39 studies examined the clinical and demographic characteristics of participants in adjunctive PE interventions for BD. This was to determine if these characteristics differed between users of individual, group and online delivery modalities. An empirical study, consisting of a secondary analysis of 3 studies, delivered by two online and one group modality was also conducted. Measures of demographic and clinical characteristics were extracted and used to examine predictors of PE intervention usage for BD via the number of sessions attended.

The literature review showed that numbers of female participants in PE interventions were significantly higher than males across all delivery modalities. In the online studies, higher levels of regular commitments due to work, family and other responsibilities, were significantly associated with greater intervention usage. In the empirical study, increased usage of group PE was linked to increasing age and higher levels of education. No significant correlations were observed in the online studies.

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List of abbreviations

ANOVA	Analysis of Variance
APA	American Psychiatric Association
AR	Adjusted Residuals
BAP	British Association for Psychopharmacology
BD	Bipolar disorder
BP I	Bipolar I
BP II	Bipolar II
CBT	Cognitive Behavioural Therapy
CM	Co-Morbidity
DALY	Disability Adjusted Life Years
DSM	Diagnostic and Statistical Manual of Mental Disorders
DV	Dependent Variable
ERP	Enhanced Relapse Protection
FFT	Family-Focused Therapy
FHMREC	Faculty of Health and Medicine Research Ethics Committee
GBD	Global Burden of Disease
HBM	Health Belief Model
IBM	International Business Machines
IBPI	Integrated Bipolar Parenting Intervention
ICD	International Classification of Diseases
IHME	Institute for Health Metrics and Evaluation
IPSRT	Interpersonal and social rhythm therapy
IQR	Inter Quartile Range
IV	Independent Variable
NAMI	National Association of Mental Illness
NIMH	National Institute of Mental Health
MAR	Missing at Random
LD	Listwise Deletion
MH	Mental Health
ML	Maximum Likelihood
MMAT	Mixed Methods Appraisal Tool
NNT	Number Needed to Treat
NNH	Number Needed to Harm

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PARADES	Psychoeducation, Anxiety, Relapse, Advance Directive Evaluation and Suicidality
PBC	Perceived Behavioural Control
PE	Psychoeducation
PRISMA	Preferred Reporting Items for Systematic reviews and Meta Analyses
PS	Psychosocial
QoL	Quality of Life
RCT	Randomised Controlled Trial
SA	Secondary Analysis
SCID	Structured Clinical Interview for DSM
SPSS	Statistics Package for the Social Sciences
SRM	Self-Regulation Model
TAU	Treatment as Usual
TPB	Theory of Planned Behaviour
TTM	Trans Theoretical Model
UK	United Kingdom
USA	United States of America
WHO	World Health Organization
WLC	Wait List Condition

1 Introduction

The current understanding of bipolar disorder (BD) indicates that, for some patients, medication alone is not a solution and that for the majority, outcomes will be unfavourable (Reinares, Sanchez-Moreno, & Fountoulakis, 2014). Even during periods of remission, many individuals continue to encounter residual sub-syndromal symptoms, such as, mood instability and problems with day-to-day functioning (Grunze & Born, 2020). Poor adherence to medication is also often experienced, with this being a barrier to treatment and associated with worsened patient outcomes (Barbeito et al., 2014; Vieta, 2005).

In addition, a significant body of research has indicated psychosocial (PS) factors, such as life stress events and childhood trauma, are influential in the course of BD (Alloy, Abramson, et al., 2005) and that they play an important role in whether at-risk individuals develop this condition. As a result, many clinicians have sort alternative interventions to improve condition outcomes (Fountoulakis, 2015). This has resulted in the development of a number of PS interventions and a body of evidence supporting the thesis that, when delivered adjunctively to pharmacotherapies, PS interventions for BD are useful in the reduction of BD symptoms and in the improving of psychosocial functioning and medication adherence (Richardson, 2010). As a result, PS interventions are now recognised as being important components in the treatment of BD. Of these, group psychoeducation (PE) is recommended by the National Institute for Health & Care Excellence (NICE) for individuals with BD (National Institute for Health and Care Excellence, 2020). However, in order to get the best results from a PE intervention, a patient needs to experience sufficient exposure to its therapeutic content, a situation which is often difficult to achieve (Donkin et al., 2013; Rakofsky, Levy, & Dunlop, 2011; Stulz, Lutz, Kopta, & Manami, 2013). This is because, in common with other mental health (MH) interventions, patient usage levels of PE interventions can be low (Waller & Gilbody, 2009), with factors intrinsic to the intervention itself (Eysenbach, 2005), as well as the demographic and clinical characteristics of the users, being cited as being influential in a patient's usage level of an intervention (Gaudiano, Weinstock, & Miller, 2008; Okasha et al., 2020).

This thesis examines, via a systematic quantitative literature review, if the demographic and clinical characteristics of participants in PE interventions for BD differ between the delivery modalities of face to face, group and online. An empirical secondary analysis of PE trial data then investigates if these characteristics were related to levels of intervention usage across the delivery modalities of group and online.

This chapter begins by exploring the diagnostic categories and prevalence of BD, before proceeding to examine the shortcomings associated with pharmacological treatment alone. It then discusses the societal, individual and familial burdens associated with the condition, before considering the use of PS interventions for BD when delivered adjunctively to pharmacotherapies. It concludes with a discussion of patient adherence in MH interventions and how factors intrinsic to these interventions, coupled with participant demographic and clinical characteristics, may influence levels of intervention usage.

1.1 Bipolar Disorder: Characterisation, Prevalence, Treatment and Impact.

BD is one of the most severe and persistent mental illnesses. It is a chronic condition, characterised by episodes of depression and periods of elevated and/or irritable mood (mania or hypomania), which cause extreme fluctuations in a individuals mood, energy, and ability to function (National Institute of Mental Health, 2020). The Diagnostic and Statistical Manual of Mental Disorders V includes criteria for 7 types[1] of BD (DSM-5;(American Psychiatric Association, 2013)). Of these Bipolar disorder type-I, Bipolar disorder type-II and Cyclothymia are the most common. Type I can exist both with and without psychotic episodes and is differentiated from type II by the presence of mania. Type II has a milder form of mood elevation, involving episodes of hypomania [2] that are mixed with periods of depression. Cyclothymia is characterized by brief periods of hypomanic symptoms, which are mixed with short periods of depression that do not meet the criteria for full hypomanic or full depressive episodes. The lifetime prevalence rate for BD-I, from epidemiological studies reporting in Europe, has been estimated at 0.1% to 2.4% (Faravelli, Degl'Innocenti, Aiazzi, Incerpi, & Pallanti, 1990; Pini et al.,

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[1] These are Bipolar Disorder type-I, Bipolar Disorder type-II, Cyclothymia, Substance-Induced Bipolar Disorder, Bipolar Disorder Associated with Another Medical Condition, Other Specified Bipolar and Related Disorder and Unspecified Bipolar and Related Disorder.

[2] Hypomania is a mood state characterized by persistent disinhibition and mood elevation (euphoria), with an individual behaving in a manner that is noticeably different from the person's typical behaviour when in a non-depressed state. Potential secondary characteristics may include restlessness, extreme talkativeness, increased distractibility, a reduced need for sleep and an intense focus on a single activity (Smith & Ghaemi, 2006).

2005; Regeer et al., 2004; Szádóczky, Papp, Vitrai, Ríhmer, & Füredi, 1998), and in the United States of America (USA) at 1.0%, with 12 month prevalence being estimated at 1.6% (Merikangas et al., 2007; Szádóczky et al., 1998). For BD-II European estimates are between 0.2 and 2.0% (Faravelli et al., 1990), with a cross-national epidemiological study of 11 countries indicating a prevalence rate of 0.4% (Merikangas & Lamers, 2012).

The primary treatment of BD is pharmacological (Geddes & Miklowitz, 2013), with medication having the aim of returning the patient to symptomatic recovery and stable mood, reducing sub-threshold symptoms and preventing relapses. Nevertheless, despite many pharmacological interventions being available (Fountoulakis et al., 2012; Grunze et al., 2013; Nivoli et al., 2013), the use of pharmacotherapy is often ineffective in the treatment of the depressive phase of BD (Muneer, 2016). Consequently, this phase of the condition can often be prolonged, poorly controlled and may persist as major depressive episodes or mixed affective presentations. In addition, most patients continue to experience on-going sub-syndromal symptoms, and poor levels of functional recovery. This, coupled with significant side effects from medication, including toxicity, weight gain, tremors and nausea, can lead to a reduced quality of life (QoL) throughout a patient’s life (Magalhães, Dodd, Nierenberg, & Berk, 2012; Reinares et al., 2013; Rosa et al., 2011; Tohen et al., 2000).

BD is also associated with cognitive, physical, and behavioural symptoms (Anderson, Haddad, & Scott, 2012; Lewandowski, Cohen, & Öngur, 2011) and a high prevalence of psychiatric and medical comorbidities (Dervaux &

Laqueille, 2016; Parker, 2010). As a result, the average life expectancy of an individual with BD is shortened by approximately 15 years (Harrison, Geddes, & Tunbridge, 2018), due to a combination of approximately 10% of BD patients dying by suicide, health problems linked to drug treatment and an elevated mortality rate from natural causes (Harrison et al., 2018). The incidence and morbidity of BD has also been shown to differ with ethnicity, with incidence rates in the combined black and minority ethnic groups, in the UK cities of London, Nottingham and Bristol, being significantly higher than those of comparison white groups (Lloyd et al., 2005).

As well as the psychological burdens and negative health outcomes BD imposes on those who experience it, it has also been shown to create substantial financial burdens for society (McCrone, Dhanasiri, & Patel, 2008). The World Health Organization (WHO) mental health survey, based on findings from the Global Burden of Disease (GBD) Study (Institute for Health Metrics and Evaluation (IHME), 2018), has shown that BD is the second most common MH reason for absence from work. The GBD data also estimates that the incidence of BD has increased by 47.74%, from 3.06 million in 1990 to 4.53 million in 2017, with the disability-adjusted life years (DALYs) increasing by 54.4%, from 6.02 million in 1990 to 9.29 million in 2017. Nonetheless, it must be considered that the increases in these figures could be ‘real’, be linked to changes in diagnostic practice or be a combination of both of these factors.

In the UK, the estimated number of individuals with BD, in 2007, was 1.14 million people, with the mean service cost per individual per year being estimated at £1,424 (McCrone et al., 2008). This is a figure which produces a total annual service cost of an estimated £1.6 billion. In addition, future projections of the number of UK residents that may experience BD have estimated that by 2026 this figure will have risen to 1.23 million. When factoring in lost employment costs, the total estimated figure for 2007 was £5.2 billion, with a projected total cost to the economy of £8.2 billion in 2026 (McCrone et al.). It must also be noted that these costs included the expense of losing talented people from the work place and did not allow for the fact that in BD, individuals who receive optimal treatment, can often return to the workplace (National Institute for Health and Care Excellence, 2020). As a result of this, these figures must be considered to be worst case.

In addition to the societal financial burdens, BD has major implications for the families of those that experience BD. For these families effects can include economic difficulties and emotional reactions to the illness, the stress of coping with disturbed behaviour, the disruption of household routine and the restriction of social activities (World Health Organization, 2013). The literature also suggests that family stress can play an important role in the course of BD, with expressed emotion (EE) being employed as a common index of this. This is a measure of negative attitudes, manifesting as criticism, hostility, and emotional overinvolvement, demonstrated by family members toward a person with a mental disorder. Whilst EE, and levels of caregiver burden in BD (Ogilvie, Morant, & Goodwin, 2005), have been largely neglected in the literature, several studies have demonstrated that high levels in relatives are associated with increased risks of mood relapse and delays in recovery amongst adults with BD (Ogilvie et al., 2005).

1.2 Psychosocial interventions for BD

Over the last one hundred years the theoretical perspective on BD has oscillated between biological and psychological conceptualisations and, despite the early work performed by Kraepelin (1921), who emphasized the psychosocial context of the disorder, over the last century BD has come to be considered as a genetically influenced, biological illness. A position which was reinforced by family, twin & adoption studies, which accentuated the genetic aspects of its transmission Goodwin and Jamison (2007), as well as pharmacotherapy trials, that demonstrated the usefulness of lithium and anticonvulsive medications in the controlling of its cycling (Keck & McElroy, 1996). During this period BD was ascribed many names: manisch-depressives irresein[3] (Kraepelin, 1899), manic-depressive reaction (American Psychiatric Association, 1952), manic depressive illness (American Psychiatric Association, 1968) and finally, Bipolar disorder (American Psychiatric Association, 1980). However, towards the end of the twentieth century the popularity of the biomedical model began to wane with Engel (1977, p. 130) describing, and criticizing, it as:

> “The dominant model of disease today is biomedical, with molecular biology its basic scientific discipline. It assumes diseases to be fully accounted for by deviations from the norm of measurable biological (somatic) variables. It leaves no room within its framework for the social, psychological, and behavioural dimensions of illness. The

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[3] Manic-depressive insanity.

> biomedical model not only requires that disease be dealt with as an entity independent of social behaviour, but it also demands that behavioural aberrations be explained on the basis of disordered somatic (biochemical or neurophysiological) processes”.
>
> (Engel, 1977, p. 130)

This, coupled with the acknowledgement that the 1980’s models of genetic and biological processes were unable to fully account for the observed differences in the expression, timing, and polarity of BD symptoms (Alloy, Abramson, et al., 2005; O’Connell, 1986), led to a resurgence of interest in the role of PS processes. As a result, a 1990 National Institute of Mental Health (NIMH) workshop report (Prien & Potter, 1990) called for an exploration of the influence PS processes may have on the course of BD. This report also called for the development of PS interventions, designed to be delivered as adjuncts to pharmacotherapy, which led to the accumulation of a body of evidence indicating that psychosocial and environmental context was important in the etiology and expression of BD (Alloy, Reilly-Harrington, Fresco, & Flannery-Schroeder, 2005; Johnson & Kizer, 2002). This included life events, where there is strong evidence that periods of high stress precede BD onset or recurrence (Alloy, Reilly-Harrington, et al., 2005; Johnson & Kizer, 2002) and social support from family and friends, where there is substantial, but less strong evidence that negative interpersonal factors, like high EE are associated with an increased likelihood of poorer outcomes (Johnson, Meyer, Winett, & Small, 2000; Rosenfarb et al., 2001). Conversely, positive support from other individuals has been associated with improved outcomes.

In addition, other researchers (Aas et al., 2016) have observed that childhood traumatic events have been consistently linked to the clinical characteristics of BD. These include an earlier age of onset (Garno, Goldberg, Ramirez, & Ritzler, 2005), rapid condition cycling (Garno et al., 2005), psychotic features (Bebbington et al., 2004; Shevlin, Dorahy, & Adamson, 2007), a higher number of episodes across the patient's lifetime (Weber et al., 2008) and increased suicidal ideation and attempts (Álvarez et al., 2011). However, it must be emphasised that the quality of these specific studies was reported as being variable due to small sample sizes (n=<100) and the omission of a structured clinical interview for diagnosis (Daruy-Filho, Brietzke, Lafer, & Grassi-Oliveira, 2011). A later, larger study (n = 587) which addressed these potential biases, confirmed that trauma at a young age was indeed associated with an earlier age of onset, increased risk of at least one suicide attempt, rapid cycling, substance abuse and an increased number of (lifetime) episodes (Etain et al., 2013).

These factors, coupled with controversy regarding the effectiveness of the pharmacological treatment of BD depression (Hlastala et al., 1997), have provided a strong rationale for the development and use of adjunctive psychological interventions, designed to enhance the effectiveness of medication. Accordingly, when combined with the appropriate pharmacotherapies, a growing body of evidence has shown, that psychosocial (PS) interventions can enhance clinical outcomes for BD in a cost-effective manner. Other studies have demonstrated the benefits of employing PS interventions for the treatment of BD to include: i).Increased medication compliance (Depp, Moore, Patterson, Lebowitz, & Jeste, 2008), ii). Improved detection of the early signs of recurrence (Miziou et al., 2015), iii). The learning of skills aimed at the reduction of stressors which contribute to the risk of recurrence (Miziou et al., 2015), iv). Improvements in family and interpersonal skills and increases in levels of functioning and ability to work (Kurdal, Tanriverdi, & Savas, 2014), v). Learning of the skills and lifestyle adjustments that are required in order that sufferers can effectively manage their condition (Miziou et al., 2015), vi). Support from others and exchange of shared experiences (Morriss et al., 2016), vii). Education of patients and their families to encourage collaboration in treatment (Bond, 2014), viii). Improvement in the identification and management of the adverse effects of BD medication that may limit its usage and acceptance (Bond, 2014), ix). Reductions in the numbers of hospitalization periods (Miziou et al., 2015).

As a result of these benefits, a range of PS interventions, designed to be delivered as adjuncts to pharmacological therapies have been developed for the treatment of BD. These include Enhanced Relapse Prevention/Individual Psychoeducation (PE) (Lobban et al., 2010), Cognitive Behavioural Therapy (CBT,(Lam, McCrone, Wright, & Kerr, 2005), Group Psychoeducation (Castle et al., 2010; Colom, Vieta, Martinez-Aran, et al., 2003) and Family-Focused Therapy (FFT) (Miklowitz, George, Richards, Simoneau, & Suddath, 2003). These interventions can be delivered by delivery modalities (Depp et al., 2008) such as, face-to-face, group and online.

Notwithstanding their differing theoretical positions, all of these interventions have common features and aims, and include:

- An understanding of the nature of BD
- Being taught how to identify the main symptoms of BD and the early signs of relapse and prodromal symptoms.
- The planning of coping strategies for identified early warning symptoms, mood instabilities and situations which might trigger changes in mood and activity levels.
- Planning for emergencies: Developing a plan for ‘staying-well’ and a crisis plan.

(National Institute for Health and Care Excellence, 2020)

There is a good evidence base for the efficacy of CBT and FFT in BD treatment (Novick & Swartz, 2019). In the UK NICE (National Institute for Health and Care Excellence) has recommended that all individuals who experience BD should be offered the option of a manualised, evidence-based psychological therapy for the treatment of BD (National Institute for Health and Care Excellence, 2020). As a result of this, individuals with BD are given the opportunity to collaborate with a therapist to discover the lifestyle adjustments and skills they need to make to manage their condition and to become active participants in their treatment process. Other research studies have demonstrated that PS interventions, which teach individuals with BD how to detect the signs of relapse and how to modify their behaviours to prevent full-blown episodes, are also efficacious (Morriss, Faizal, et al., 2007). These have been demonstrated to reduce levels of patient morbidity and the number of hospitalisations experienced (Goldberg & Ernst, 2002; Miziou et al., 2015; Oud et al., 2016; Salcedo et al., 2016; Swartz & Swanson, 2014). However, not all PS studies have reported positive outcomes, with some finding limited evidence regarding the impact of PS interventions on patient functioning (Bond & Anderson, 2015; de Azevedo Cardoso et al., 2014; de Barros Pellegrinelli et al., 2013; Gumus, Buzlu, & Cakir, 2015; Morriss et al., 2016).

1.3 Adherence to mental health interventions

> "Incidentally, it's easy to write prescriptions, but difficult to
> come to an understanding with people".
>
> (Kafka, 2009, p. 140)

Whilst PS interventions are efficacious, levels of participant usage are, in common with the usage of MH interventions in general, a problem (Chakrabarti, 2016; Jawad, Watson, Haddad, Talbot, & McAllister-Williams, 2018). This was evidenced by a non-concurrent prospective study (historical cohort) of individuals who experienced schizophrenia, affective psychoses, depression and alcohol dependence. In this study (n=295) 116 did not complete treatment[4], with a dropout rate of 39.2% (Melo & Guimarães, 2005). In addition, a systematic review of 19 online and face-to-face psychological interventions, for panic disorder and post-traumatic stress disorder (PTSD), found that participant usage of these interventions ranged from 2% to 83% of the total number of sessions available, with a median of 19% and a weighted average of 31% (Melville, Casey, & Kavanagh, 2010). In the specific case of

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[4] Which was defined as those who came to the initial interview (first consultation) but did not return to the intervention during the study.

BD several reviews, have concluded that, on average, approximately 40% to 50% of patients with BD (range 9%-66%) did not take their medications regularly (Berk et al., 2010; Colom, Vieta, Tacchi, Sanchez-Moreno, & Scott, 2005; Goodwin & Jamison, 2007; Leclerc, Mansur, & Brietzke, 2013; Perlick, Rosenheck, Kaczynski, & Kozma, 2004), rates which were approximately the same whether patients are taking mood stabilizers or antipsychotics. These are levels of usage which, drawing on adherence models in the medication literature, would be considered to be sub-optimal (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008).

As a result of low levels of intervention usage, across MH interventions in general, Eysenbach (2005) proposed that interventions may have intrinsic features which influence how frequently and consistently patients / participants use them. These features, which Eysenbach termed ‘structural’, included:

- The degree to which an intervention is considered superior to another.
- The degree to which an intervention is seen as being consistent with existing values, including the past experiences and perceived needs of users.
- The complexity of the intervention.
- The trialability of an intervention, can the user test it?
- How observable the results are to others?
- The side effects, if any, of the intervention

As a result, Eysenbach (2005) considered the manner by which an intervention gains acceptability and, in an effort to explain participant discontinuation in studies and interventions, created the diffusion of innovation reversed theory. This theory, based upon Rogers (2003) theory of the 'diffusion of innovations', suggests that an intervention trial usually brings an 'innovation' to its participants[5]. After its conception, that innovation spreads, albeit slowly at first, though the work of social change agents[6], who, if the intervention is viewed positively, actively promote it to others. Therefore, as every intervention type has features which are unique to its design, these will influence how it is viewed and promoted. These may include participant expectations, ease of enrolment, ease of dropout, usability, adjunct personal contact, financial commitment, workload, competing events, experience and efficacy. Although Eysenbach originally wrote in the context of online interventions, Roger's theory on the diffusion of innovations, as the process by which an innovation is communicated over time, among the members of a particular social system, can be considered to apply to any intervention. In his article, Eysenbach differentiates online trials from RCT drug trials, for example, by stating that attrition levels in RCTs are much less than in online interventions. However, other researchers (Christensen & Mackinnon, 2006) have since challenged this, indicating that retention rates are often comparable across both types of trial and that Eysenbach's assertion regarding these differences was overstated. Thus, Eysenbach's theory can be applied to other interventions, such as PE, when delivered by modalities such as face to face, group or online. Consequently, if an intervention is viewed

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[5] Here Rogers (2003) defines diffusion as the process by which an innovation spreads and innovation as an intervention perceived as new by the participant/patient.

[6] A change agent, or agent of change, is someone who promotes and enables change to happen within a group or population.

positively by its users, the speed with which knowledge of it diffuses through society will increase as more individuals hear about it and adopt it. This continues until a saturation level is reached, at which point, all who are going to adopt it will have done so (Eysenbach, 2005).

The ‘reversed’ term in the theory’s name comes about from the actions of individuals, who may have enrolled in a trial and then discontinued its usage before completion, due to features which they considered to be negative. At the onset of a trial, the population would, usually, consist of 100% intent-to-use participants, all of which would have completed informed consent and have agreed to participate in the study. If these individuals then later considered some aspect of the trial to be negative, then over time some may have decided to discontinue the intervention, in a reversal of the adoption process described above.

More recently the issues of adherence to and usage levels of interventions has fallen under the purview of the field of ‘implementation science’, which typically focusses on the rates and quality of use of an evidence-based intervention. It can be defined as “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality and effectiveness of health services” (Eccles & Mittman, 2006, p. 1). It has the aim of identifying and, if necessary, changing patient, provider and system behaviours (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015), to increase usage, acceptance and availability of interventions. It also aims to facilitate the translation of evidence-based research into the clinical healthcare environment (theory into practice). Here, an intervention strategy is differentiated from the intervention itself by being “an integrated set, bundle, or package of discreet implementation interventions selected to address specific identified barriers to [the] implementation’s success” (Bauer et al., 2015, p. 4).

With regard to the individual factors which may influence a participant’s usage levels of an intervention, previous research has indicated that the personal demographic and clinical factors of the users themselves may be influential in this process (Chakrabarti, 2016). Some examples are provided in Table 1.1.

Table 1:1

Possible demographic and clinical characteristics which may influence intervention usage levels in BD

Category	Factor	Finding correlated with poor adherence / usage	
Patient Factors			
	Age	Younger age	(Edlund et al., 2002; Fornaro et al., 2021; Graff, Griffin, & Weiss, 2008; Henzen, Moeglin, Giannakopoulos, & Sentissi, 2016; Nicholas et al., 2010; O’Brien, Fahmy, & Singh, 2009; Olfson et al., 2009; Perlick et al., 2004)
	Gender	Male gender	(Bauer et al., 2019; Perlick et al., 2004)
	Ethnicity	Minority ethnicity	(Fischer et al., 2008; Memon et al., 2016; Morris et al., 2020; O’Brien et al., 2009; Olfson et al., 2009; Perlick et al., 2004; Strakowski et al., 1998)

	Education Level	Lower levels of education	(Graff et al., 2008; Olfson et al., 2009), gender (Connell, Grant, & Mullin, 2006; Graff et al., 2008; Nicholas et al., 2010; Olfson et al., 2009)
	Employment	Reduced usage in unemployed participants	(de Graaf, van Dorsselaer, Tuithof, & ten Have, 2013; Graff et al., 2008)
	Not in a relationship	Being single	(Minamisawa, Narumoto, Yokota, & Fukui, 2016; Olfson et al., 2009).
	Poor treatment alliance	Poor relationship with and mistrust of clinicians	(Busby & Sajatovic, 2010; Cochean & Gitlin, 1988; Levin et al., 2016)
	Influencing from others	Negative influences from others	(Cochean & Gitlin, 1988; Levin et al., 2016)
Clinical Factors			
	Severity of illness	More severe	(Perlick et al., 2004)
	Previous levels of adherence	History of non-attendance	(Scott & Pope, 2002)
	Substance Abuse	Present as comorbid condition	(Fornaro et al., 2021; O'Brien et al., 2009; Olfson et al., 2009; Strakowski, 2000)
	Condition Duration	Longer duration	(Fornaro et al., 2021; Moon et al., 2012)
	Condition Severity	More severe	(Christensen, 2009; Schimmelmann, Conus, Schacht, McGorry, & Lambert, 2006).
	Number of previous episodes	More previous episodes	(Leclerc et al., 2013; Perlick et al., 2004)

Consideration must also be given to the fact that the nature of drug use, treatment usage, and outcomes in BD is complex, variable and individual to the patient or participant (Gaudiano, Weinstock, & Miller, 2011). As a result of this, the evidence for these variables is either often limited, or in some cases, contradictory.

1.4 Chapter summary

BD is one of the most severe and persistent mental illnesses, with medication and PS interventions representing the clinical mainstays of its management. Nonetheless, adherence to these treatment regimens is a common problem, with many individuals not adhering to their medication protocols and ceasing to use prescribed psychological interventions before their intended completion. As a result, various aspects of these interventions, as well as the clinical and demographic characteristics of those who use them, have been suggested as influencers of intervention usage levels.

Chapter 2 provides background information and expands upon the summary provided in Chapter 1. It begins with a brief discussion of the history of BD, before examining the classification of mental disorders and the use of the DSM vs. ICD. It continues with an examination of the aetiology and treatment of BD, before appraising the terms engagement, adherence and usage and discussing the relationship between levels of intervention usage and outcomes in BD. It concludes by defining and examining PE and its delivery modalities for BD.

2 Background

2.1 A (Brief) History of Bipolar Disorder

Bipolar Disorder (BD) is one of the earliest described medical conditions, with records extending back to the second century AD. Aretaeus of Cappadocia, a medical philosopher, was the first to record the symptoms of mania and depression, and to note that they could be linked to each other, when he described melancholia and mania as two aspects of the same disease.

This work went largely unnoticed until 1621 when Robert Burton wrote ‘The Anatomy of Melancholia’, a book which focused on melancholia [depression]. (Abraham, 1911; Burton, 1932). Later in the 17th Century Theophilus Bonet published ‘Sepuchretum’ in which he linked mania and melancholia in a condition called “Manico-melancholicus”. This was an important step in diagnosing BD, as prior to this, mania and melancholia were more often considered to be separate disorders.

Over two hundred years later, in 1854, Jules Falret devised the term "Folie circulaire" (circular insanity) and established a link between depression and suicide (Falret, 1854). He also found a difference between periods of depression and elevated moods, and in 1875, his findings were described as ‘Manic-Depressive Psychosis’. He was the first to describe that the condition seemed to be observed more frequently in certain families, thereby recognizing that a familial link may be present.

Francois Baillarger (1809-1890) was instrumental in distinguishing bipolar disorder from schizophrenia and, by separately characterising the depressive and manic phases of the condition “Folie à double forme” (dual-form insanity), allowed BD to receive its own classification from other mental disorders of the time (Baillarger, 1854; Khouzam & Singh, 2006).

In 1913, Emil Kraepelin, a German neuropsychiatrist, recorded thorough accounts of manic-depressive insanity as a continuum of mixed and rapid cycling subtypes (Kraepelin, 1899) and by the 1930s, Kraepelin's understanding of BD was commonly accepted. However, despite Falret’s earlier description of a genetic-link, it wasn’t until Kleist published an article in The Journal of Nervous and Mental Diseases (1952), that the Kraepelinian model was contested. Kleist proposed that both bipolar and monopolar psychoses and mania and depression were separate conditions and that bipolar psychosis was a particular affiliation of both (Angst, 2002).

In the 1950’s Karl Leonhard refined Kliest’s clinical descriptions and produced a differentiated classification system for the psychoses but his work was largely ignored by American psychiatry, until it was translated into English in 1979, and gained the attention of the diagnostically oriented psychiatry department at Washington University (Carroll, 1998). Leonhard was the first to use the term bipolar for disorders which comprised of both manic and depressive symptoms.

In terms of the classification of BD, the American Psychiatric Association (APA) published the first edition of its Diagnostic and Statistical Manual of Mental Disorders (DSM-I) in 1952 and, in the 1960’s, proposed a differentiation between major depression and manic-depression (American Psychiatric Association, 1968). In 1980, with the publication of the third edition of the DSM (DSM-III), the term 'manic-depressive disorder' was replaced with 'bipolar disorder' (American Psychiatric Association, 1980; Leonhard & Beckmann, 1999). The definition of BD was expanded further with the publication of the DSM-IV (American Psychiatric Association, 1994), where it was now classified as a heterogeneous group of mood disorders including Bipolar I, Bipolar II, Mixed episodes and a separate diagnostic subcategory of Cyclothymic disorder. The inclusion of cyclothymia in the DSM was important as it allowed the inclusion of individuals who experienced numerous periods of depression and hypomania, but did not fulfil the diagnostic criteria of having major depressive and hypomanic episodes, to receive treatment.

More recent changes to the concept of BD have been to define a group of disorders which are characterized by recurrent episodes of major depression, but with varying aspects of hypomanic features, and to define a bipolar spectrum of disorders (Merikangas et al., 2007). Other developments have included the extension of BD to include conditions that were historically considered to represent personality disorders, including borderline disorder (Gunderson & Elliott, 1985). More controversially, proposals have also been made to extend the diagnosis of BD into juvenile populations, including prepubertal children, despite many descriptive differences between juvenile and episodic adult forms of the disorder existing (Papolos & Papolos, 2006).

In addition, others have considered that definitions at the earliest indications of BD may assist in distinguishing its presentation from other adult mental illnesses, and would support long-term clinical planning and interventions (Salvatore et al., 2014). Challenges for the 21st century include the resolution of the controversies about what constitutes a 'disorder', where is the appropriate place to draw a line between 'normality' and abnormal psychological status and the provision of optimised interventions and treatments for a growing range of types and ages of BD patients.

2.2 The classification of mental disorders

The taxonomy of mental disorders represents an important aspect of psychiatry for clinicians and researchers. This is because it facilitates the exchange of ideas and experiences and, using operational definitions[7], allows for more consistent measures and agreement regarding the value of specific treatments. It also enables a more consistent epidemiological approach to be applied to psychiatric research.

For clinicians, the introduction of operational definitions allowed treatment practices to be homogenised and provided a guide for teaching. For researchers, who use mental disorder classifications to identify homogeneous groups of patient populations, it allows for the determination of their characteristics and the identification of possible determinants of mental illness and outcomes. These taxonomies are guided by two manuals, either the International Classification of Diseases (ICD-11) (World Health Organization,

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[7] An operational definition is the statement of the procedures the researcher is going to use to measure a specific variable.

1992) or the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 2013). Both are important, not because they were developed to classify diseases in the conventional medical sense, but because they describe syndromes[8] without aetiological implication. This is important, as psychiatric diagnoses are dependent on empirically observed symptoms and signs which are not the definition of a disease. In the case of MH conditions this is essential, as the etiology of psychiatric disorders is not clearly known.

2.3 Why use the DSM as a research tool?

Since the publication of the DSM-III (American Psychiatric Association, 1980), the DSM has used operational criteria, derived from the Feighner diagnostic criteria (1972), to improve its reliability[9] and to ensure that different groups of researchers are studying the same disorder. It also provides increased standardisation of diagnoses and improved inter-rater reliability. As a result, the DSM is commonly used in BD research. By informing the operationalisation of conditions, and subsequently the inclusion and exclusion criteria of a project, the DSM can also determine how that research is conducted via its influencing of the eligibility and classification of individuals for research projects.

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[8] A group of symptoms which consistently occur together, or a condition characterized by a set of associated symptoms.

[9] The consistency of a measure and whether the results can be reproduced under the same conditions.

By employing the DSM and the Structured Clinical Interview for DSM [10] (SCID), researchers can identify those participants who may be suitable for enrolment in their research or, in the event of them not meeting these requirements, serving as controls. Any participants presenting with other disorders may, as appropriate, be excluded from the study. However, it has been argued that using the DSM in this manner allows it to construct both pathology and normalcy (O'Reilly & Lester, 2016) for the purposes of research. This has created an area of contention, as some argue that the DSM labels are a collection of symptoms which do not represent a real disorder (Michael, 2016). Others claim that being designed purely as a diagnostic tool, the consideration of different disorders as distinct entities (Casey et al., 2013), through the use of diagnostic criteria and checklists, provides a 'common language' for researchers and clinicians.

In this thesis the DSM was used throughout. In the empirical (secondary analysis) study it was used to guide the study's design and the criteria for the included studies and, in the case of the systematic quantitative literature review, the design of the inclusion and exclusion criteria.

2.4 Aetiology of Bipolar Disorder

The exact cause of BD is unknown, but there is a growing research base that has identified several factors which may contribute to the risk of developing the condition, such as: biological differences, genetics and environmental

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[10] An interview document that takes approximately three hours to complete and offers an assessment of an individual in relation to all DSM disorders. It allows researchers to know which, if any, DSM specified pathologies are present in a participant.

factors. In the case of genetics, having family members with the condition, increases the risk, but the extent to which this reflects genetic vs environmental factors is disputed (Aldinger & Schulze, 2017). Evidence from epidemiological and twin studies have shown the effects of genetic factors in influencing an individual's susceptibility to BD. For those with a familial relation with BD the lifetime risks are, for a first degree relative 5–10% and for a monozygotic co-twin 40–70%, compared to an unrelated member of the general population with a risk factor of 0·5–1·5% (Fusar-Poli, Howes, Bechdolf, & Borgwardt, 2012). The current evidence indicates that susceptibility levels to BD may be influenced by several different genes, with these only exhibiting a small effect with inheritable factors being considered to play a small role in contributing to condition onset (Kerner, 2014).

Whilst there is evidence that BD can run in families (Purse & Gans, 2020), it must also be considered that many individuals who experience BD do not have relatives with this condition. A situation which implies that despite BD sometimes recurring in families, it may not necessarily have been genetically inherited. This is because, as well as genetics, families share many other common and shared factors, including those which are socially and psychologically based, which may also be influential in the pathogenesis of BD.

Some have linked abnormal levels of a number of neurotransmitters to the etiology of BD research which has largely been based on observations of patient responses to psychoactive agents such as the blood pressure drug

Reserpine[11] and drugs of abuse such as, cocaine[12] (Ayano, 2016). In the case of Reserpine, which depletes catecholamines[13] from nerve terminals, this was noted incidentally to cause depression, which led to the 'catecholamine hypothesis' (Schildkraut, 1965). This maintains that an increase in epinephrine and nor-epinephrine causes mania and a decrease in epinephrine and nor epinephrine causes depression. In addition, drugs used to treat depression or for abuse (e.g., cocaine) increase levels of monoamines[14], including serotonin, norepinephrine, or dopamine. As these neurotransmitters can potentially trigger mania, they have been implicated in its etiology.

When considering the environmental, non-inheritable, non-neuro-chemical factors of BD, a diathesis-stress model[15] is often considered (Monroe & Simons, 1991). In this model, where someone may genetically inherit a greater likelihood of the disorder but require some sort of mental trauma to activate it, a variety of critical risk factors have been identified (Ayano, 2016). In studies of life-events, across childhood and adulthood, it has been observed that individuals have often experienced negative events prior to

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[11] Which depletes catecholamines from nerve terminals and was noted [incidentally] to cause depression. This led to the catecholamine hypothesis which posits that an increase in epinephrine and nor-epinephrine causes mania and a decrease in epinephrine and nor-epinephrine causes depression.

[12] Cocaine increases levels of monoamines, including serotonin, nor-epinephrine, and dopamine, all of which can trigger episodes of mania, thereby potentially implicating all of these neurotransmitters in the etiology of BD.

[13] Catecholamines are hormones made by the adrenal glands, such as, dopamine; norepinephrine; and epinephrine. The adrenal glands send catecholamines into the blood when an individual is physically or emotionally stressed.

[14] Monoamines refer to the particular neurotransmitters' dopamine, noradrenaline and serotonin. They are neurotransmitters and neuromodulators which function as psychostimulants. Examples are dopamine, norepinephrine and serotonin.

[15] The diathesis–stress model is a psychological theory that attempts to explain a disorder as the result of an interaction between a specific vulnerability, the diathesis, and a stress caused by life experiences.

condition first onset or recurrences of BD episodes. These events have also been found to precede episodes of mania, hypomania and depression, with between 20 to 66% of patients suffering one or more negative events in the 1 – 3 months prior to the onset of a mood episode (Ayano, 2016). As a result, psychosocial stressors are considered as being a major cause of relapse in BD (Johnson, 2005; Johnson et al., 2008).

Another risk factor is trauma experienced during childhood, with many studies showing associations between childhood trauma and BD susceptibility and/or severity (Aas et al., 2016; Daruy-Filho et al., 2011; Etain, Henry, Bellivier, Mathieu, & Leboyer, 2008; Fisher & Hosang, 2010). These traumas, which may include sexual or physical abuse, neglect or an unstable home environment such as one which has the presence of domestic violence and/or high expressed emotion (EE;(Maniglio, 2013)), appear to be highly correlated with the presence of BD. Nonetheless, it must be stressed that the specific role of each trauma subtype (emotional, physical or sexual) remain subjects of debate (Aas et al., 2016).

2.5 The treatment of bipolar disorder

A comprehensive treatment plan for BD generally has two aims. The first is condition stabilisation, with the aim of bringing a patient to a symptomatic recovery with euthymic (stable) mood. The second is condition maintenance, in which the goals are relapse prevention, reduction of subthreshold symptoms, and enhanced social and occupational functioning. However, for most patients this is seldom achieved with medication alone and, because of this, treatment guidelines are increasingly suggesting that, for optimum management, pharmacotherapy for BD should be integrated with adjunctive PS interventions (Goodwin et al., 2016). The aims of these interventions include a provisioning of information to patients in regard to strategies for stress management and the identification of the early signs of recurrence (Miklowitz & Scott, 2009). As PS treatments are delivered as adjuncts to pharmacotherapies, these interventions also emphasise the importance of adherence to medication. As a result of this, the UK NICE guideline CG185 (2014, p. 264) states:

> “[Clinicians should] *offer a structured psychological intervention (individual, group or family), which has been designed for BD and has a published evidence-based manual describing how it should be delivered, to prevent relapse or for people who have some persisting symptoms between episodes of mania or bipolar depression.”*

NICE also recommends the need for clinicians to foster collaborative relationships between the patient, their carers and families to keep them fully informed at every stage of the assessment, diagnosis and treatment.

In the category of psychological interventions for BD several specific adjunctive psychotherapies have been developed. These include Cognitive Behavioural Therapy (CBT;(Lam, Hayward, Watkins, Wright, & Sham, 2005)), Family-Focused Therapy (FFT,(Miklowitz et al., 2003)) and Psychoeducation (PE) (Castle et al., 2010; Colom, Vieta, Reinares, et al., 2003). Regarding the efficacy of these interventions, different theories exist with regard to their mechanism of operation. These include the improvement of treatment adherence (Depp et al., 2008; Gaudiano et al., 2008), the stabilisation of biological rhythms through the improvement of lifestyle, food intake and social zeitgebers (Walker, Walton, DeVries, & Nelson, 2020), as well as the changing of dysfunctional attitudes (Atuk & Richardson, 2020; Bond, 2014), the improving of family interactions (Miklowitz & Johnson, 2009) and the improving of an individuals' ability to identify the signs of relapse early (Miklowitz & Scott, 2009).

When a patient has been returned to a euthymic state, they may have long periods of recovery and remission and may be symptomatic for approximately 50% of the time (Judd et al., 2003; Judd et al., 2002). However, even during these periods of remission, levels of PS functioning has been shown to continue to be impaired (Rosa et al., 2012) and for this to persist beyond symptomatic recovery. As a result, many patients continue to experience subsyndromal symptoms even during remission (Judd et al., 2003; Judd et al., 2002). Because of this, and the life-long relapsing-remitting nature of BD, many patients often continue to receive medication and PS interventions for the long-term prophylaxis of BD.

In environments where PS interventions are not available, it has been demonstrated that routine care can be improved by the provision of educational information regarding the nature of BD, identification of the signs of relapse, and practical advice on what patients should do if emergent symptoms are observed (Taylor & Goodwin, 2006).

2.6 Engagement, adherence and usage

Over the last ten years the term ‘user engagement’ has become a phrase used to cover a wide range of concepts, such as an intervention’s usability, acceptability, feasibility and satisfaction, all of which are measured with usage metrics (O’Brien & Cairns, 2016, pp. 2,179). These have included, in the case of face-to-face interventions, the number of sessions attended, and for online interventions, the number of logins made, or number of modules visited (Fleming et al., 2018; Fletcher, Foley, & Murray, 2018). Despite this, across the literature, there is little consensus on a definition of the term ‘engagement’ (Fletcher et al., 2018). Some have viewed it as being synonymous with adherence and the opposite of intervention attrition or dropout (Doherty, Coyle, & Sharry, 2012). Others, have considered it to be more than a measure of usage or attendance, and have incorporated levels of active participation which can be assessed behaviourally, cognitively, and affectively (Graffigna, Barello, Bonanomi, & Lozza, 2015). One useful definition of the term ‘adherence’ comes from NICE who defined it to be ‘the extent to which the patient’s behaviour matches the agreed recommendations of the prescriber’ (National Institute for Health and Care Excellence, 2009). Using this definition adherence may apply to any health care intervention. It must also be considered that adherence is not a unitary or steady state phenomenon and an individual who is adherent to an intervention at one point in time may become non-adherent at another.

Throughout this thesis, the concept of engagement was equated to intervention usage, and was operationalised in terms of the number of intervention sessions attended or, for online studies, the number of modules accessed. For online studies the number of modules accessed was chosen over number of logins made, as module completion has been found to be the metric most related to positive outcomes in psychological health interventions (Donkin et al., 2011). It is also recognised that other factors, such as emotional involvement and behavioural and cognitive factors may influence a participants usage level of an intervention (Smith & Gallicano, 2015).

2.7 The importance of increased intervention usage levels in BD

Medication non-adherence is a widespread problem in BD (Chakrabarti, 2016) with the literature reporting rates which, on average, indicate that about 40% to 50% of patients with BD (range 9%-66%) do not take their medication regularly (Berk et al., 2010; Colom et al., 2005; Goodwin & Jamison, 2007; Lingam & Scott, 2002; Miasso, do Carmo, & Tirapelli, 2012; Montes, Maurino, de Dios, & Medina, 2013). In PS interventions usage levels are also variable, with a review of 10 self-guided internet-based interventions for depression (n=2705) showing that for online interventions 40% of participants ceased usage before completing 25% of the modules. In addition, 59% ceased usage before the completion of half of the modules, 70% ceased usage before completion of 75% of modules and 17% completed all available treatment modules (Karyotaki et al., 2015). In the case of group interventions for BD, an RCT (Morriss et al., 2016), which examined a PE (n=153) intervention and peer support group (n=151) respectively, found that the median number of sessions attended in the PE group was 14 out of 21 with an interquartile range (IQR) of 3 to 18. In this group 13% did not attend any sessions, 29% dropped out before the completion of 25% of the sessions, 37% dropped out before the completion of 50% of the sessions, 56% dropped out before the completion of 75% of the sessions and 44% completed between 75-100% of the sessions. Finally, in the case of individual face-to-face interventions a review of 54 studies (n=5852) reported non-attendance levels of 20% in research studies and 18% under clinical conditions (Cooper & Conklin, 2015).

These levels of non-usage are important in pharmacological interventions for BD, where non-adherence to medication regimens has been associated with poor outcomes, increased risk of relapse, re-hospitalization and suicide (Berk et al., 2010; Colom et al., 2005). It is also one of the potential reasons why these interventions may not be as effective in community settings as they are in efficacy studies[16], giving rise to the so called "Efficacy-effectiveness gap" (Nordon et al., 2016).

Usage levels are also important in the case of PS interventions where studies, across a range of MH conditions, have explored the relationship between levels of psychological intervention usage and outcomes (Donkin & Glozier, 2012; Donkin et al., 2013; Stulz et al., 2013). These have indicated that increased exposure to the therapeutic content of a PS intervention is influential in producing positive outcomes, improved Quality of Life (QoL), increased adherence to medication, reduced stigmatization and reduced functional impairment. These are important factors which are associated with decreasing the burden of BD on the individual, the family and society as a

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[16] Treatment adherence is also believed to be the most important barrier in translating the levels of efficacy observed in research settings compared to clinical practice. Here interventions that may be efficacious in both acute and long-term treatments and trials for BD, present as being less impressive in day-to-day practice.

whole (Christensen, Griffiths, Mackinnon, & Brittliffe, 2006; Donkin et al., 2011; Rakofsky et al., 2011; Stulz et al., 2013).

2.8 BD patients, a common diagnosis but differing levels of intervention usage.

Whilst BD patients share a common diagnosis, they differ in their demographic and clinical characteristics, personal attitudes and beliefs about their prescribed interventions, as well as in their personal experiences of their illness. This includes condition severity, the type and amount of medication side effects and their relationships with clinicians (Chakrabarti, 2016). Consequently, the factors which may influence their levels of intervention usage are individual, with these, potentially, including gender, age, condition severity, length of condition, personal worldviews, number of comorbidities, level of education, self-image, peer-grouping and being in a relationship, to name but a few (Berk et al., 2010). In addition, evidence indicates that a significant level of non-adherence to both medication and PS interventions is ‘rational’ and involves deliberate decisions. Here the patient may make a decision, to adjust or discontinue intervention usage, due to its adverse effects (Wroe, 2002). The factors which have been implicated in these decisions include, in the case of pharmacotherapies, the participants perceived effectiveness of the medication on outcomes and the number and severity of side-effects[17] (Laba, Brien, & Jan, 2012). As a result, many BD sufferers, who consider their medication to be ineffectual or as having too many side effects, choose to manage their condition without drugs (Cappleman, Smith, & Lobban, 2014). In the case of PS interventions, identified barriers to intervention usage are considered to include psychological barriers (stigma and isolation) and comorbid conditions (Parker, 2010), lack of condition knowledge (diagnosis, treatments & causes), behavioural barriers (attitude, lifestyle and condition-based issues) and physical health barriers (Goldsmith, Pellmar, Kleinman, & Bunney, 2002). Other barriers to usage have been associated with family and community issues and include a lack of social support, a limited understanding of BD, misinformation about medication and stressful personal relationships. In addition, for some BD sufferers, limited income and housing options also pose barriers to their management of BD (Blixen, Perzynski, Bukach, Howland, & Sajatovic, 2016).

These approaches concur with the use of the Self-Regulation Model (SRM) (Leventhal & Steele, 1984), as applied to MH by Lobban et al. (2003). This suggests that an individual's ways of responding to a health condition may be influenced by their own unique beliefs, in relation to their personal identity and the nature, cause, consequences and effects of their condition.

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[17] These are of importance to patients as, even with treatment, about 37% will relapse into depression or mania within 1 year, and 60% within 2 years (Gitlin, Swendsen, Heller, & Hammen, 1995). From the perspective of side-effects however, some highly efficacious BD agents have been demonstrated to be as likely to yield adverse effects for patients as they are therapeutic benefits. However, despite this, they may still be the intervention of choice in more severe cases of BD. This is because, whilst the United States Food and Drug Administration (FDA) and the British Association for Psychopharmacology (BAP) approved pharmacotherapies for BD all have single-digit numbers for needed to treat (NNT) figures (i.e., > 10% advantage over placebo), their needed to harm (NNH) figures may vary widely (Ketter, Citrome, Wang, Culver, & Srivastava, 2011; Srivastava & Ketter, 2011).

Conversely, specific interventions and treatment effects, which are perceived by the patient as decreasing debilitating symptoms and/or having less side effects are more likely to be adhered to. For example, in the case of patients who feel more affected by depressive than manic symptoms, it has been observed that patients have indicated a greater likelihood of using interventions which reduce their depressive symptoms (Johnson et al., 2007; Sajatovic, Jenkins, Cassidy, & Muzina, 2008).

2.9 Personal recovery and the BD journey

Historically, a decision to be non-compliant with medication or non-adherent to treatment has been considered to be the result of a lack of insight on the part of the patient (Yen et al., 2005) with this being associated with the extent to which a patient agrees with the clinician’s definition of the nature of their experiences (Chakrabarti, 2014). Therefore, more insight is associated with increased adherence to treatment and better outcomes, whilst impairments of executive functions and memory and higher severity of psychotic symptoms, are associated with ‘impairments’ of insight and less intervention usage (Latalova, 2011).

When considered from a personal rather than clinical perspective, a decision not to use medication can be linked to the patient having a personal model and/or a set of experiences, which are different to, but as valid as, those of their clinician. This could include an awareness of the real risks of long-term medication usage and personal experiences of the limited efficacy of a particular intervention (Yen et al., 2005).

As a result, many patients and clinicians now refer to the concept of personal recovery (PR) in BD (Tse et al., 2019). PR is distinct from clinical recovery, which focuses solely on symptom reduction, and is regarded as referring to the process of an individual's psychological adaptation to a disorder rather than a sole focus on the reduction of psychiatric symptoms and functional deficits (Leamy, Bird, Boutillier, Williams, & Slade, 2011; Murray et al., 2011). It allows patients to emphasize the importance of functional outcomes, such as employment, engagement in meaningful activities and discovering meaning and purpose in life. This was highlighted by a UK study which examined what the process of recovery meant to individuals with BD. Through in-depth interviews with 12 people, a theme emerged which indicated that, to the patients, recovery was not just about the absence of symptoms and that it required them to make sense of knowledge about BD, from multiple sources. In addition, it highlighted that patients often wanted to be 'allowed' to take responsibility for their own wellness (Todd, Jones, & Lobban, 2011). In this study, the concept of recovery was measured by the bipolar recovery questionnaire (BRQ), a quantitative questionnaire designed to capture personal understanding of self and symptoms, the role of the individual and sense of personal agency in the process of recovery and developing meaning through active engagement in the social and occupational world (Jones, Mulligan, Higginson, Dunn, & Morrison, 2013). As such, a patient's perspective on their quality of life (QoL) can be considered to be a view of where they are at the moment and PR to be the recovery trajectory they consider themselves to be on. As a result, at a specific moment in time, it is possible for an individual who experiences BD to have a low QoL, but to still consider that they are on the right recovery path which will take them to where they want to be in the future.

The significance of the PR journey has also been recognised by the Department of Health (DoH) which promotes a focus on the importance of supporting people to live the lives they want to live alongside their bipolar experiences. It also allows for the consideration of personal experiences in the improvement of the outcomes of mental health interventions (Department of Health, 2011).

The change of clinical perspectives to include PR, with its focus on the individual, has been described as a ‘humanistic paradigm shift’ in MH treatment (Wand, 2015). As a result, over the last decade, there has been a growing consensus that the assessment and treatment of symptoms alone does not capture either clients’ or therapists’ aims in BD and that outcome measures should be augmented with more ‘personal’ factors (Murray et al., 2017). The commonly recognised components of PR include connectedness, hope and optimism, identity, meaning in life and empowerment (Leamy et al., 2011). All of these factors, coupled with calls for the aims of PS interventions to be more congruent with those of humanistic values (Jones et al., 2013), have focussed interest on outcome measures and the subjective experiences of the individual. Of these, QoL measures have received the most research attention (Murray & Michalak, 2012) and represent the sum of a person's physical, emotional, social, occupational and spiritual well-being (Michalak, Yatham, & Lam, 2005).

2.10 The economic burden of BD to society

There are also large economic costs associated with mental health (MH) as 94% of severe MH service users in the UK have a diagnosis of either schizophrenia or BD (Reilly et al., 2012). A cost which is exacerbated by the fact that, despite medication being the mainstay of treatment for BD (Geddes & Miklowitz, 2013), many patients do not respond adequately to pharmacotherapy. This is illustrated by the previously discussed situation where patients do not respond to medication, and may experience prolonged, poorly controlled and persistent major depressive episodes, mixed affective presentations and increased relapse rates. As a result of ineffective responses to medication, relapse rates of up to 40% in the first year, 60% in the second year and 73% over more than five years have been observed (Gitlin et al., 1995; Keller, 2015). This is not only of importance from an economic perspective but also from that of the individual, as the more relapses an individual has the greater is the probability of future relapses and reduced clinical outcomes (Maj, Pirozzi, Magliano, & Bartoli, 2002). Therefore, interventions which produce reductions in the frequency of relapses, improve intervention and medication adherence and facilitate reductions in the required intensity of community crisis services, can generate recurrent savings in clinical treatment expenditure (McCrone et al., 2008)[18]. In a recent review of the costs of poor medication adherence, the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM) study examined the costs of patient adherence to health services (Hong, Reed, Novick, Haro, & Aguado,

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[18] Some of the evidence included in this review has been criticised for being of low quality, due to small sample sizes, single-centre trials, high heterogeneity and a lack of controls for the clustering effect of group treatments in its analysis.

2011). In this study, non-adherence to medication was operationalised as never taking medication to taking it 50% of the time, which was compared to adherence, defined as medication being taken 50% to 100% of the time. Over 21 months, the clinical costs derived from UK unit costs[19] applied to European resource usage data, showed that the non-adherent patients exhibited poorer outcomes which translated into higher treatment costs. Over the duration of the study the costs for non-adherent patients, were found to be £10,231 compared to £7379 ($p<0.05$) for each adherent patient, with the difference being mainly due to a x2 increase in inpatient costs (£4796 vs. £2150).

2.11 Psychosocial interventions for BD

The inability of pharmacological interventions alone to address all of a patient's needs, coupled with increased treatment costs due to poor responses, has resulted in the need for and development of effective and affordable adjunctive interventions. These PS interventions are more tailored to the requirements of the individual patient and can address stress factors which may contribute to relapse vulnerability (Catala-Lopez, Genova-Maleras, Vieta, & Tabares-Seisdedos, 2013; Johnson, 2005), as well as providing a focus on the importance of intervention usage and adherence. As a result, several PS interventions, designed to be delivered adjunctively to pharmacotherapies, have been developed, with the goal of filling the above therapeutic 'gaps' and improving BD outcomes (Miziou et al., 2015).

To appreciate the rationale for these interventions, it is necessary to view BD in the context of the theoretical models which relate to its course and etiology.

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[19] In this study UK unit costs were used because of their quality and availability.

For example, in the stress-diathesis model it is believed that PS stress is transformed, in a genetically predisposed individual, into low grade-affective symptoms, which may then become the prodromes of a major episode of mania or depression (Kemner et al., 2015). In Lam's model of BD, an individual's extreme goals of perfectionism and achievement are responded to in ways which lead to increased levels of mood changes as well as, episodes where excitement and anxiety are transformed into mania or hypomania (Jones, Sellwood, & McGovern, 2005; Lam, Wong, & Sham, 2001). Other research has shown that relapse and poor outcomes are associated with life events and family environments. Although, in this case, where high expressed emotion (EE) is prevalent, modification of these environments and subsequent reduction in the levels of EE through psychotherapy, may translate in the BD patient to a reduction in the numbers of relapses experienced, along with improved symptom control (Johnson & Roberts, 1995; Mansell, Colom, & Scott, 2005).

2.12 Development of PS interventions

PS interventions for BD were developed from the translation of basic science on BD into the clinical arena and have given rise to several forms of intervention such as, CBT, FFT, PE and Inter Personal and Social Rhythm Therapy[20] (IPT) (Nusslock, 2009). For example, in the case of CBT, this was

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[20] Interpersonal and Social Rhythm Therapy (IPSRT) stresses the link between how a person's mood affects their life and how they relate to others in the world, the "interpersonal" component. The 'social' component focuses on stabilizing a person's daily, circadian, rhythms and creating a daily routine, as individuals with BD tend to live less regimented lives. IPSRT draws upon principles from interpersonal psychotherapy (IPT; American Psychological Association, 2014) an evidence-based treatment for depression (Ehlers, Frank, & Kupfer, 1988).

applied to BD via research that indicated that the logic of cognitive vulnerability-stress theories of unipolar depression would extend to bipolar episodes and symptoms (Abramson, Metalsky, & Alloy, 1989; Alloy, Reilly-Harrington, Fresco, Whitehouse, & Zechmeister, 1999). In the case of, IPT, a form of psychotherapy that focusses on relationships with others and considers interpersonal relationships to be at the centre of psychological problems, this took its structure from CBT, which is time-limited and utilises structured interviews and assessment tools. In general, IPT is differentiated from CBT by its focus on patients feelings, whereas CBT focuses on cognitions with strong associated affects. (Lipsitz & Markowitz, 2013). FFT was developed from observations that life events such as levels of familial EE (Miklowitz, Goldstein, Nuechterlein, Snyder, & Mintz, 1988), low parental warmth (Geller et al., 2002) and social support (Johnson, Winett, Meyer, Greenhouse, & Miller, 1999) may influence the course and onset of BD. Finally, in the 1980’s, PE was conceived as composite of numerous therapeutic elements within a complex family therapy intervention. Since this time it has evolved into an independent therapeutic program, with a didactic focus on the communication of key information which relates to BD condition management, delivered within a cognitive-behavioural framework (Bäuml, Froböse, Kraemer, Rentrop, & Pitschel-Walz, 2006).

2.13 Knowledge gaps regarding the characteristics of individuals who utilise PS interventions for BD treatment

Despite PS interventions being recognized as effective interventions in the adjunctive treatment of BD, little research has been conducted into the characteristics of those individuals who utilise them. One study which did examine this was conducted by Klein & Cook (2010), who examined the demographic characteristics of individuals who used interventions, delivered via the internet and by traditional face-to-face modalities, with their results indicating that there were no significant differences between the demographic characteristics of the two groups. However, they did observe that the level of an individual’s perceived stigma was higher in the online group along with a belief that chance determined an individual’s MH status. In addition, Crisp (2014) observed a perception that clinicians have little effect on an individual’s MH. Another study (Donkin et al., 2012) identified the characteristics associated with the self-selection of eligible trial participants, recruited from a community health cohort, into a randomized controlled trial of an online depression treatment, as a method of identifying sampling bias in the study. Their results indicated that having a higher level of education and a prior diagnosis of depression were associated with involvement. However, there have been no studies, to the best of the author’s knowledge, which have specifically targeted PE interventions for individuals with BD. Because of this, there exists a gap in the literature, in relation to the demographic and clinical characteristics of individuals who have participated in research studies relating to PE interventions for BD. An improved understanding of these characteristics would add to the knowledge base in regard to the ‘types’ of individuals who use PE treatments for BD. This would enable researchers and practitioners to better understand the requirements of those individuals and to gain insight into how they make decisions about their treatment options. It would also facilitate clinicians in more accurately targeting differing delivery modalities of PE interventions to their patients and, by better aligning the prescribed delivery modalities with the requirements of the individual, make them a better fit for their lifestyles and preferences. By prescribing interventions which were more congruent with an individual’s lifestyle and requirements, usage levels and exposure to the therapeutic content of an intervention could be increased, with subsequent improvements in patient clinical outcomes and their QoL.

Psychoeducation for BD

PE for BD is a PS intervention which didactically provides patients with the information they need to manage their condition and its treatment. Its primary goals are to deliver information based behavioural training, which is directed at adjusting a patient’s lifestyle and their strategies for coping with BD, see Table 2:1. It focusses on the enhancement of condition awareness, encouraging intervention adherence, early detection of prodromal symptoms and relapses and the avoidance of harmful factors such as sleep deprivation and substance abuse.

Table 2:1

Content of the psychoeducation programme (Barcelona Bipolar Disorders Programme, The Barcelona Bipolar Clinic)

Programme sessions
Introduction
What is bipolar illness?
Causal and triggering factors
Symptoms (I): mania and hypomania
Symptoms (II): depression and mixed episodes
Course and outcome
Treatment (I): mood stabilisers
Treatment (II): antimanic agents
Treatment (III): antidepressants
Serum levels: lithium, carbamazepine and valproate
Pregnancy and genetic counselling
Psychopharmacology vs alternative therapies
Risks associated with treatment withdrawal
Alcohol and street drugs: risks in bipolar illness
Early detection of manic and hypomanic episodes
Early detection of depressive and mixed episodes
What to do when a new phase is detected?
Regularity
Stress management techniques
Problem-solving techniques
Final session

*Taken from (Colom, Vieta, Martinez-Aran, et al., 2003)

2.14 A definition of PE for BD

Across the literature there are many definitions of PE, with these ranging from education or training of a person with a psychiatric disorder that serve the goals of treatment and rehabilitation (Goldman, 1988) to Any structured group or individual program that addresses an illness from a multi-dimensional viewpoint including familial, social, biological and pharmacological perspectives, as well as providing service users and carers with information support and management strategies (National Institute for Health and Care Excellence, 2020). In this thesis the definition of PE to be employed is:

> “An intervention with systematic, structured and didactic[21] knowledge transfer for an illness [BD] and its treatment, integrating emotional and motivational aspects to enable patients to cope with the illness and to improve its treatment adherence, efficacy and QoL”.
>
> (Ekhtiari, Rezapour, Aupperle, & Paulus, 2017, p. 239).

In this definition, the use of the didactic transfer of knowledge allows for information regarding the etiology of BD, the treatment process, possible adverse effects of prescribed medications, coping strategies, relapse prevention and life skills training (Colom & Vieta, 2006) to be delivered. It is this [didactic] nature of the knowledge transfer in PE which is employed to differentiate it from other PS interventions, such as CBT, where Socratic questioning affords the therapist and client the same opportunities, revealing what clients already know but may have forgotten or not yet considered (Braun, Strunk, Sasso, & Cooper, 2015)

By being a structured learning method, which has been developed over the last four decades, PE *presents* patients with the information they require to manage their condition and directs them in learning the techniques they require for self-monitoring. In addition, through the identification of the early warning signs of relapse, it teaches the strategies which may prevent the progression of a relapse into a full-blown episode (Bond & Anderson, 2015; de

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[21] The didactic method is a teaching method which follows a consistent scientific approach or educational style to present information to students. This contrasts with the Socratic method, which is a dialogue between individuals based on asking and answering questions with the aim of stimulating critical thinking and drawing out ideas and underlying presuppositions.

Barros Pellegrinelli et al., 2013; Miziou et al., 2015; National Institute for Health and Care Excellence, 2020; Oud et al., 2016; Salcedo et al., 2016). It has also been shown to be effective in promoting medication adherence (Chatterton et al., 2017).

2.15 Delivery modalities of PE for BD

PE interventions can be delivered to patients face-to-face, in either an individual, group or family setting, or more recently via the internet, where a user interacts with an online device such as a computer, tablet or smart phone. The therapeutic media may be presented to the participant in a variety of ways including written, audio, video or interactively. Some interventions may also utilise more than one form of presentation method to increase the impact and retention of material.

Group PE

Group PE is an effective adjunct to pharmacotherapies for BD, with evidence indicating that it is associated, in a 5-year follow-up, with longer times to relapse, fewer episodes, less days hospitalized, and less time acutely ill than the control group (Colom et al., 2009). It has also been shown to improve medication adherence (Rahmani, Ebrahimi, Ranjbar, Razavi, & Asghari, 2016). However, it should be noted that not all studies have shown a significant overall effect on relapse levels (Morriss et al., 2016). Group PE has also been demonstrated to be particularly effective in deferring manic relapse, possibly by promoting patient improvements in medication adherence and by providing them with the ability to identify prodromal symptoms early and to seek prompt medical intervention (Bond & Anderson, 2015).

Individual PE

Individual PE sessions are usually prepared in accordance with the literature using the group PE approach (Colom & Vieta, 2006; Miklowitz & Goldstein, 1997). Sessions typically last 50 minutes and employ the delivery of information via face to face and audio-visual presentations. Role-playing and feedback stages are sometimes employed to ensure patient comprehension.

Online PE

In the case of online delivery there has been, over the last 20 years, a rapid growth in the number of interventions which target MH conditions in the community (Batterham & Calear, 2017). During this time a considerable body of evidence has been accumulated in regard to their efficacy in relation to depression (Batterham et al., 2015), anxiety (Cuijpers et al., 2009) and substance abuse (Rooke, Thorsteinsson, Karpin, Copeland, & Allsop, 2010; Van Spijker, Van Straten, & Kerkhof, 2014). As is the case with group deliveries, the content of these sessions are typically prepared in accordance with the literature using the group PE approach (Colom & Vieta, 2006; Miklowitz & Goldstein, 1997). Online sessions can be delivered by 2 different methods, both of which differ in some aspects of their delivery from the original Colom & Vieta (2006) group psychoeducation intervention, which was delivered over 21 sessions of 2 hours duration. In the case of interventions which are delivered by a video link, these often have fewer sessions and are of a shorter duration, lasting approximately 50 minutes (Rueter, 2021), with these interventions being similar to individual face-to-face sessions. Modules which are delivered via a website do not generally follow the Colom & Vieta delivery format and are often delivered in fewer and shorter sessions, although the content is usually still inspired by Colom & Vieta's original program. In this case, the therapeutic content is delivered to the patient in the form of website based interactive modules. In this context, and whilst the content of the modules are 'modelled' on group interventions, it is worth considering that differences will exist between a 'typical' online session and those delivered via a face-to-face video link.

Regarding intervention delivery, if consideration is given to the general use of the internet, then much of the content viewed is found to be of very limited duration. For example, a typical YouTube video lasts less than 4 minutes (Huppertz, 2019), and users typically spend no more than 70 seconds on 80% of web pages (Liu, White, & Dumais, 2010). As a result, some non-MH studies have indicated that users may have a preference for online, modular, sessions which are much shorter, approx. 20 minutes or less, than the traditional 50 minutes sessions in individual face-to-face and video linked therapy sessions (McClay, Waters, Schmidt, & Williams, 2016). This consideration was supported by an online study of PE trials for BD where participant usage times, median[minutes] (min-max), ranged from, 2 (0-40) to 14.5 (0-2150) (Lobban et al., 2017). Others, in a study designed to assess which usage metrics were associated with improved outcomes in an online depression treatment trial, found average usage time, per log-in, to be 17.3 minutes (SD ±10.5) (Donkin et al., 2013).

Despite fewer barriers to online therapies being reported, others have indicated that the majority of participants still express a preference for face-to-face interventions (Casey, Wright, & Clough, 2014). Amongst these individuals it was observed that there were no differences between their perceptions of barriers to internet and face-to-face treatment in relation to stigma, lack of motivation, emotional concerns, negative evaluations of therapy, misfit of therapy to needs and availability of services (Casey et al., 2014). Finally, other factors, such as, older age, being female, being separated or divorced, having higher levels of education and a history of depression have, in a study on depression, been cited as being associated with increased usage levels in online interventions (Crisp, 2014).

Family PE

BD poses specific issues for the family environment, with issues being dependent upon the stage of the condition and its presenting symptomatology, as well as the patient’s role in the family. As a result, within the family environment, many carers have confusion and a lack of awareness in relation to how they can deal with the disruptive behaviours which may result from living with a BD individual. A consequence of this is that they can feel overwhelmed by the number of unanswered questions regarding how they should deal with their afflicted relatives (Palli, Kontoangelos, Richardson, & Economou, 2015). Other concerns often relate to how, and if, they should accept disruptive behaviours, how to differentiate any deliberate ‘behaviours’ from those caused by BD, how to deal with intervention non-compliance and how to identify the early symptoms of condition recurrence (Madianos et al., 2004). Importantly, these factors have been identified as being sources of significant PS distress for the sufferers’ relatives / caregivers which have often led to marital and family collapse and the causing of further PS stress (Grover, Nehra, & Thakur, 2017). PE for family groups has shown improvements in condition knowledge, a reduction in the subjective and objective burdens reported and a significant reduction in the degree of EE exhibited (Honig, Hofman, Rozendaal, & Dingemans, 1997).

2.16 The effectiveness of PE for BD

PE has been confirmed to be effective in assisting individuals with BD in identifying the early signs of relapse and teaching them to implement behavioural measures to prevent full-blown episodes (Miziou et al., 2015; Oud et al., 2016; Salcedo et al., 2016; Swartz & Swanson, 2014). In addition, studies (Bond & Anderson, 2015; Colom et al., 2009; González Isasi, Echeburúa, Limiñana, & González-Pinto, 2014) have confirmed, via long term follow-ups, that PE confers a long-lasting prophylactic effect on patients. This has been observed in terms of longer times free from hospitalization and reduced numbers of days of patient hospitalisation (Buizza et al., 2019).

Non-adherence to medication and other interventions, such as PE, are particularly prevalent in BD patients, with at least one in three patients not taking more than 70% of their prescribed medication (Beynon, Soares-Weiser, Woolacott, Duffy, & Geddes, 2008). As a result, increasing adherence to medication is a common therapeutic target in PE, particularly as non-adherence is associated with higher relapse rates, increased levels of hospitalization, and increased health care costs (Depp et al., 2008). However, whilst PE for BD has, generally, been shown to support relapse prevention in BD, the evidence for its effects on treatment and medication adherence are not consistent in the literature and the way in which it improves outcomes is unclear (Sajatovic, Chen, Dines, & Shirley, 2007). For PE interventions to be effective in increasing intervention adherence and, subsequently positive clinical outcomes, patients need to be exposed to the therapeutic content of that intervention, with this being achieved in the manner which the designers of the intervention intended. Unfortunately, this is often not the case, as was illustrated by a review of internet based interventions (Waller & Gilbody, 2009) which indicated that the median proportion of users that completed all of the available modules was 56%.

The limited amount of literature that has focussed on PE interventions for BD has mostly examined dropout attrition, recording the number of users that have not completed a trial or have not provided follow-up data. Whilst this gives an indication of the overall usage of an intervention it provides only a limited subset of data in relation to how users use that intervention. It also gives no indications as to when or how often, the individual sessions are engaged with. The potential importance of these factors was demonstrated by Donkin (2013), who, in a systematic review of online interventions for depression, determined that the metrics of total time online and the number of intervention log-ins, were not consistently related to improvements in positive clinical outcomes. In this case, consistent improvements were shown to be related to the number of modules completed. Donkin (2013) also highlighted the importance of users using an intervention as it was designed to be used and made an important differentiation between the terms usage and adherence. In their study, usage referred to the number of times the modules had been accessed by an individual. Adherence referred to the manner of the intervention usage and if it matched the way in which it was intended to be used. For example, a user could complete a set of 10 modules in one session and have a 100% usage figure, but, if these modules were designed to be completed weekly, they would only be 10% adherent, needing to do 1 a week for 10 weeks to be 100% adherent. Using this definition made the term adherence a subcategory of usage as it now included temporality.

When contemplating the relationship between levels of intervention usage and improvements in outcomes, this must be considered to be a complex cause-and-effect relationship where usage patterns may potentially be influenced by other factors. These may include changes in a user’s health or sociodemographic and clinical factors, which could prompt changes in an their usage of an intervention and its associated outcomes (Christensen, 2009). As a result, the dose-response relationship between outcomes and intervention usage may not be linear and may exhibit a curvilinear response, where a saturation point is reached and no further benefits are obtained (Donkin et al., 2013).

2.17 What factors mediate change in PE?

Although PE has been shown to be effective in the treatment of BD, there is a general lack of clarity in relation to the way it may mediate patient change. All forms of PE aim to improve the self-efficacy and self-regulation of patients, which is achieved by didactically teaching them the knowledge and skills they require to manage their health and regulate their moods and cognitions. Group PE interventions may also have the additional therapeutic factors of improved social contact and opportunities for shared peer support and learning (Cook et al., 2012; Lobban et al., 2020). In the case of some internet-based PE interventions similar opportunities have been provided via moderated forums and on-line chat facilities (Naslund, 2016). Miklowitz & Scott (2009) also considered, in a study of depression and psychosis, that a large percentage of the observed variance in patient outcomes could be explained by the therapeutic alliance formed between the clinician/group and the patient. This study also reported on other potential mediators as detailed in Table 2:2. It should be noted, that in this study Miklowitz was not reporting on formal evaluations of medication.

Table 2:2

*Potential mediators of the effects of adjunctive psychotherapy on illness outcomes in bipolar disorder**

Acquiring emotional self-regulation skills
Acquiring balanced and less pessimistic attitudes toward the self in relation to the illness
Improving family relationships and communication
Improving social skills
Decreasing self-stigmatization and increasing acceptance of the disorder
Increasing external social and treatment supports
Enhancing medication adherence
Stabilizing sleep ⁄ wake cycles and other daily routines
Improving ability to identify and intervene early with relapses

Note* (Miklowitz & Scott, 2009)

2.18 Conclusions

BD is a recurrent and chronic disorder with significant morbidity and mortality, the treatment of which is primarily pharmacological. However, the limited understanding of how affective behaviour is regulated has presented an obstacle to the discovery and development of more effective pharmacology. As a result of this, pharmacological treatment has remained suboptimal (Vieta et al., 2013) with medication side effects and a lack of efficacy reducing patient adherence.

Regarding its etiology, BD has been shown to be influenced by an interplay between genetic, social, familial and psychological factors with recent years seeing psychosocial factors being increasingly implicated as risk factors for its onset, course, and expression. As a result of this, psychological interventions have become increasingly recognized as essential components for the condition’s management. Studies have also shown that PS interventions, when delivered as adjuncts to pharmacotherapy, are beneficial in achieving some of the long-term needs of treatment, needs which can be unmet if treatment is performed with pharmacotherapy alone. PE for BD is a PS intervention which didactically provides patients with the information they need to manage their condition and its treatment. This has been shown to be effective in the treatment of BD, although there is a general lack of clarity in relation to the way it may mediate patient change.

Within the literature, there is considerable confusion regarding the terminology used to describe a participant’s usage of an intervention with the terms engagement and adherence often being used synonymously and as the opposite of intervention attrition or dropout. The level of intervention usage is of particular importance in PE interventions for BD, as several studies have indicated increased levels of exposure to the therapeutic content of the intervention to be influential in the production of positive patient outcomes, improved QoL and reduced stigmatization and functional impairment.

Chapter 3 opens with the research questions and aims of this study, followed by a discussion of the choice of theoretical framework selected to underpin this thesis. It continues with an exploration of the chosen methodology, theoretical framework and philosophical paradigm before concluding with the author's critical reflections regarding these processes.

3 Research Objectives & Methodology

3.1 Introduction

This chapter presents the research question and the aims of the empirical study, before discussing the choice of theoretical framework and the philosophical positioning of this thesis. It then discusses the use of a secondary analysis (SA) and its inherent challenges, before moving on to examine the selection of variables and techniques employed for data preparation. This is followed by the analysis plan. The chapter closes with an examination of the ethical considerations and the researcher's critical reflections.

3.2 The research question

> *Are the demographic and clinical characteristics of individuals linked to patterns of usage in research trials of self-management PE interventions for BD, when delivered by the modalities of group and online?*

3.3 Research aims

The aim of this empirical study was to evaluate whether the clinical and demographic characteristics of participants with BD, were associated with levels of PE intervention usage, across the delivery modalities of group and online.

3.4 Methodology

The theoretical framework

The health and well-being of individuals are shaped, across their lifespan, not only by their physical characteristics but also by their lifestyle choices. They are also influenced by the effects of an accumulated set of personal experiences from a combination of sociological, demographic, and epidemiological factors. Collectively these are known as the Social Determinants of Health (SDoH;(Marmot, Wilkinson, & Oxford Scholarship, 2006)) and are comprised of the non-medical factors that influence health outcomes. They represent the conditions into which individuals are born, grow, live, work and age and are recognised as being key mediating mechanisms associated with both health and life expectancy at the population and individual levels (Short & Mollborn, 2015). Research has indicated that the many SDoH factors, which include age, educational attainment, employment, socio-economic status and social inclusion, can be more important than health care or lifestyle choices in the influencing of an individual’s health (Booske, Athens, KIndig, Park, & Remington, 2010). By focussing on these factors, the SDoH do not deny that medical care influences health but indicate that it is not the only influence. As such, it does not conflict with biological or psychosocial approaches to healthcare, but allows for an interplay between complex dynamic systems, at both the population and individual levels.

As this work aimed to investigate if a participant's clinical and demographic characteristics influenced their levels of PE intervention usage, across differing delivery modalities, several of the SDoH variables were of interest (Leclerc et al., 2013). This was particularly so when the author was assessing the suitability of various theoretical models to highlight the boundaries of the research project, both in terms of the theories and the constructs that would be studied and measured.

Whilst researching suitable theoretical models to underpin this work, several models were identified which shared the approach of highlighting how a set of personal, demographic and clinical factors may shape an individual's usage of an intervention. Of these, the most referenced were: the Social Cognitive Theory (SCT;(Bandura, 1977a, 1977b)), the Health Belief Model (HBM;(Rosenstock, 1974)) the Theory of Reasoned Action (TRA;(Ajzen, 1980; Ajzen & Fishbein, 1975)), the Theory of Planned Behaviour (TPB;(Ajzen, 1991; Azjen, 1985)), the Self-Regulation Model (SRM;(Leventhal, Hudson, & Robitaille, 1997)) and the Transtheoretical or 'Stages of Change' model (TTM;(Prochaska & Velicer, 1997). All of these were considered as possible theoretical frameworks for this work, as they all had the aim of explaining an individual's behavioural intentions towards a specific health intervention. However, the HBM was finally chosen as it was differentiated from the others by the inclusion of factors which focussed on a participant's perception of a condition's severity. This was important as the inclusion of condition severity allowed the effect of how ill an individual was to be factored into any resulting model. From a clinical perspective, this was also of note as a longer duration of BD has been associated with clinical progression and neurobiological changes over the course of the illness[22]. The inclusion of condition severity also allowed for the inclusion of a temporal dimension[23] and an appreciation that BD is not a singular 'event' but a long-term recurrent condition.

Choosing the HBM as a guiding theoretical framework also allowed aspects of cognitive theory to be incorporated alongside the SDoH. This was because social processes, within which the HBM is grounded (Rosenstock, 1966), are important in the maintenance of an individual's mental health (MH) (Lund et al., 2018). In addition, social and familial support has been demonstrated to impact upon MH, with discrimination and stigmatisation leading to stress and increased levels of mental ill-health (Ibanez & Manes, 2012). In this context, it was considered that personal-cognitive[24] factors, in the form of social cognitive skills (SCS), were important, due to their influence on emotional and social cue perception and MH wellbeing (Ibanez & Manes, 2012). In the case of the SDoH, these factors were considered to be relational-contextual[25], with negative and positive factors influencing an individual's MH (Santamaría-

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[22] Although the development of BD is heterogeneous, there is evidence of clinical progression over time and an association with an increasing number of affective episodes and increasing duration and severity of episodes (Kessing et al., 2017).

[23] Through the concept of the 'stages of change' the TTM also has a temporal dimension and implies that change is not a singular 'event'. However, this model was rejected as a possible framework due to its focus on the process of change (Prochaska & Velicer, 1997).

[24] Cognition is usually used to refer to the mental processes involved in gaining knowledge and comprehension. Social cognition examines the links between cognitive tendencies and social behaviour and personal cognition examines links between cognitive tendencies and personality processes.

[25] This refers to the depth of relationship an individual has with another person and how communication is adapted based on that relationship.

García et al., 2020). Another important aspect of the HBM is that SCS and the SDoH appear to be interlinked (Armitage & Conner, 2000), with an SDoH vulnerability being associated with poor SCS and vice versa (Twenge, Baumeister, DeWall, Ciarocco, & Bartels, 2007). As the HBM is grounded in a SCS perspective, this coupled with its ability to include participant demographic and clinical characteristics via the SDoH, made it an appropriate model to guide this study.

The Health Belief Model

The HBM has been successfully employed in the study of physical health behaviours in relation to the control of blood pressure, cancer screening and weight management, as well as in numerous, cross-sectional (Nobiling & Maykrantz, 2017; O'Connor, Martin, Weeks, & Ong, 2014; Saleeby, 2000; Waite & Killian, 2008) and longitudinal mental health (MH) studies (Henshaw & Freedman-Doan, 2009). It hypothesises that an individual is more likely to engage with, or participate in a health behaviour if: i) they perceive that they could be susceptible to the condition or illness that the intervention addresses (perceived susceptibility); ii) if they consider the consequences of that condition to be serious (perceived severity); iii) if they are confident that the intervention will be effective in treating the condition (perceived benefits) and iv) if they consider that there will be few barriers to utilising the intervention (perceived barriers). In this model, see Figure 3.1, modifying factors, on the left of the diagram, affect an individual's beliefs about a condition or intervention. The resultant of which then interacts with their individual behaviours to produce an action or inaction regarding a health intervention.

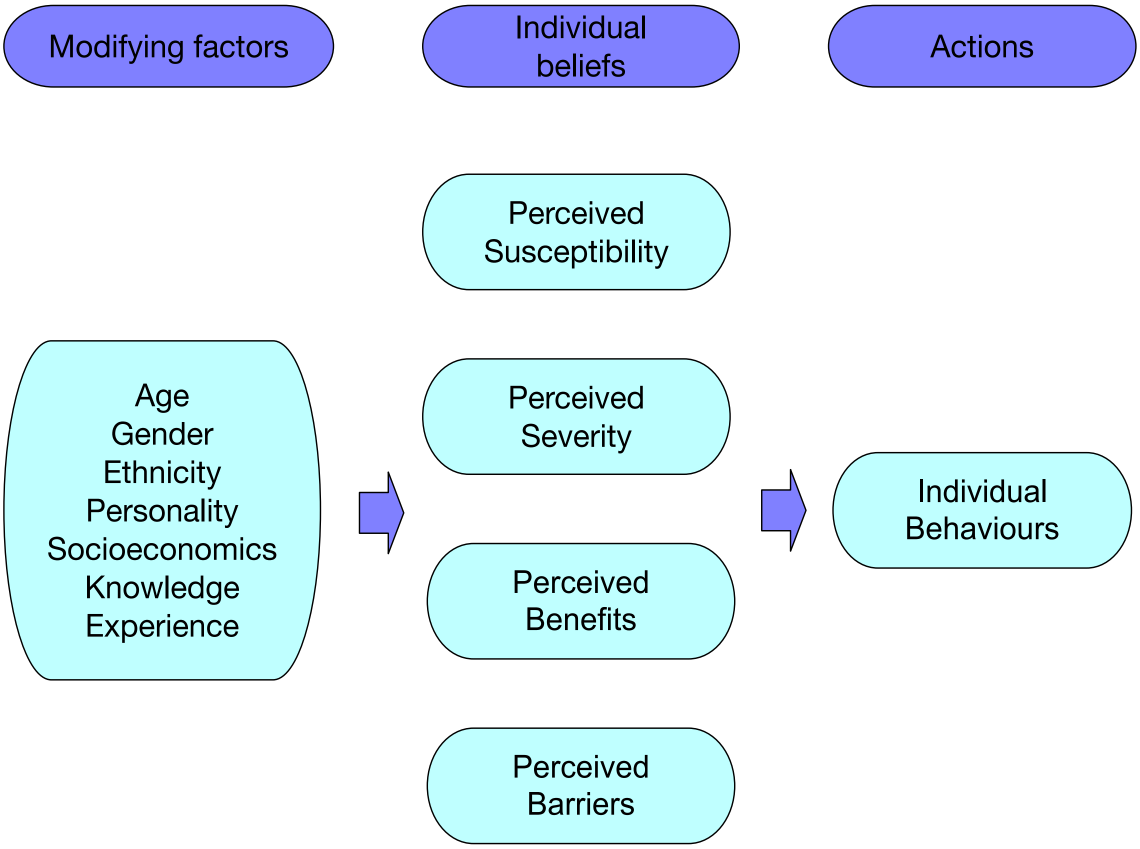

Figure 3:1

Diagram of the HBM adapted from (Glanz, Barbara, & Viswanath, 2008, p. 49)

The original HBM model did not allow for the consideration of a participant's perceptions of 'self-efficacy'. As a result of this, Rosenstock, Strecher, and Becker (1988), added this to the HBM to allow an individual's personal expectations, in regard to their ability to influence outcomes, to be included in the model. The inclusion of this concept, defined here as the belief that an individual can successfully execute a behaviour required to produce a desired outcome, also added an overlap with social cognitive theory (Bandura, 1977a, 1977b). Here, self-efficacy is considered to provide a foundation for an individuals' motivation, well-being, and personal accomplishment. This is an important factor because, unless an individual believes that their actions can produce the outcomes they desire, they have little incentive to act or to persevere in the face of difficulties. Others, (Henshaw & Freedman-Doan, 2009) noted that the fear of psychological treatments was absent from the HBM, an emotional component which may be an important factor in the prediction of health-related behaviours (Glanz et al., 2008). As a result of this, Henshaw and Freedman-Doan (2009), in their theoretical review of the use of the HBM, as a framework for predicting help-seeking behaviour in MH interventions, further amended the HBM model, see Figure 3:2.

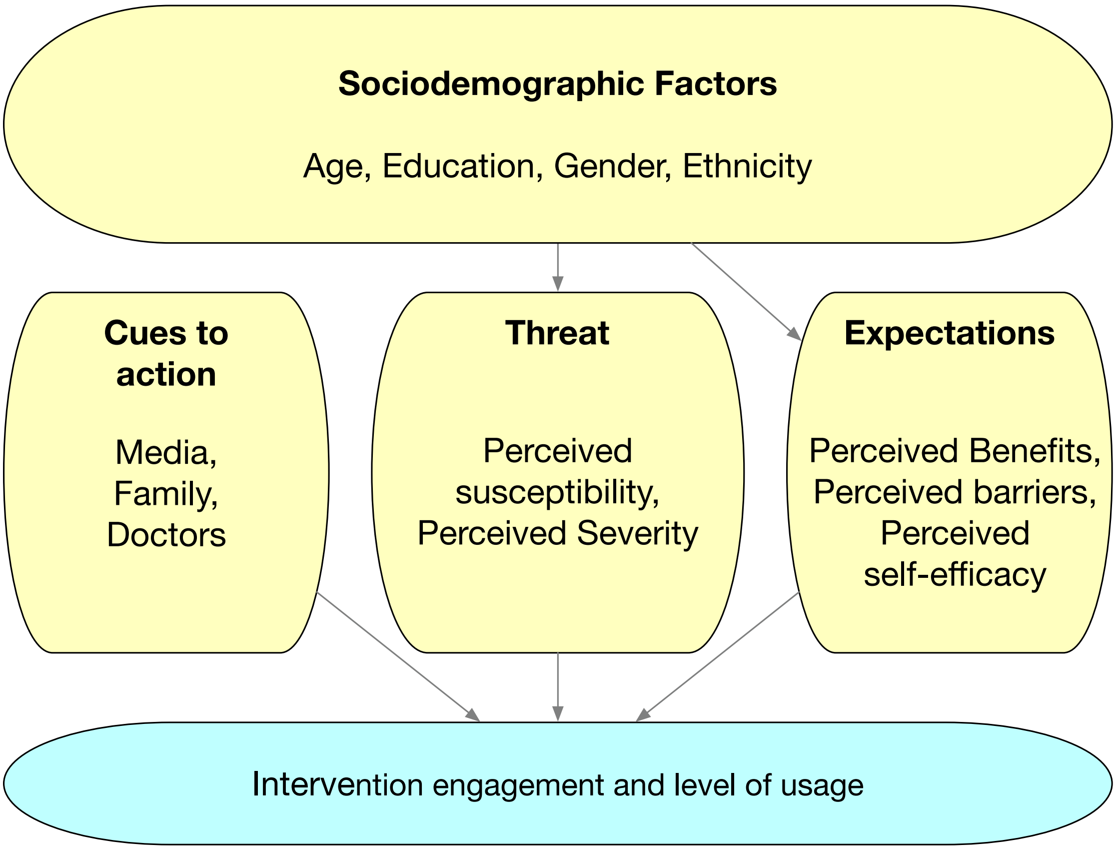

Figure 3:2

The health belief model after Henshaw and Freedman-Doan (2009)

This amended model now focussed on three composite variables which were considered to impact on treatment usage; i.) Threat, comprising of the severity of and susceptibility to the condition; ii.) Expectations, comprising of the benefits and barriers to treatment, and iii.) Cues to action, representing any influences that brought the condition to the attention of the individual. Henshaw and Freedman-Doan (2009) also suggested that sociodemographic factors such as, age, education level, gender and ethnicity, may influence the factors of threat and expectations and subsequently, intervention usage.

In the case of interventions for anxiety disorders, the use of the HBM has been supported by studies, which have indicated that up to 51% of the variance in intention to seek help was accounted for by the HBM variables (Langley, Wootton, & Grieve, 2018; Ogden, 2003). In addition, its use has been supported by other studies which, whilst not explicitly citing the HBM by name, have investigated the same constructs. For example, Constantine et al (2004), investigated, across a spectrum of MH conditions, the perceived barriers to treatment, the severity of symptoms and the benefits of treatment in various ethnic populations. They found that what may be viewed as normal or abnormal in one culture may be different in another and that some individuals may attribute the cause of a MH issue to social factors. They also observed that some cultures were more likely to use informal resources, such as, family members and friends before accessing formal MH services, whereas others may prefer to speak with pastors or members of the clergy about their MH concerns (Constantine et al., 2004). Schnittker (2000), using data from the General Social Survey (GSS;(Arbor, 2016)), investigated MH stigmatisation across a spectrum of MH disorders and the creation of barriers to treatment in groups of different ethnicities. He found that the beliefs of African Americans, regarding the causes of mental illness, were incompatible with the models employed by community health services and that, as a result, they tended to have more negative attitudes than White Americans' toward MH interventions. Nonetheless, it is not known if different conceptions of the etiology of MH illnesses are held between African Americans and American Whites, or if those beliefs may be at the core of observed differences in attitude towards professional help-seeking. Overall, the HBM has been demonstrated to be a useful framework for guiding MH research across a variety of MH populations (Henshaw & Freedman-Doan, 2009).

Despite its extensive use as an explanatory framework, the HBM does have limitations, with a key factor being its lack of consideration of feelings and emotion as an influencer on health intervention usage and behaviours (McCaul & Mullens, 2003). In addition, its variables have often exhibited low predictive capabilities ($R^2 < 0.21$ on average) and, individually, small effect sizes (Orji, Vassileva, & Mandryk, 2012). Most notably, it lacks clear rules for the combination of and the relationships between the variables (Champion & Skinner, 2008). A situation which has resulted in the literature being unclear if the HBM constructs have comparable levels of effect (parallel mediation; (Champion & Skinner, 2008)), if some act in a sequential or serial manner (serial mediation; (Janz & Becker, 1984)) or if they are hierarchically structured so that some moderate the effects of others (moderated mediation; see (Champion & Skinner, 2008). No investigations could be identified which had investigated this in the context of MH disorders, however, in a study by Jones et al (2015), a statistical evaluation (N=1377) which investigated HBM variable ordering in a vaccine campaign, it was demonstrated that "the indirect effect of exposure on usage through perceived barriers and seriousness was moderated by self-efficacy (moderated mediation)" Jones et al (2015, p. 566).

In addition, “perceived barriers and benefits were also observed to form a serial mediation chain” (Jones et al., 2015, p. 566). This indicated that the ordering of the HBM variables may be complex. It may also explain the variability demonstrated in the results obtained for its efficacy in previous studies. Other studies have shown an individual’s level of self-efficacy to be linked to socioeconomic and educational factors such as family income and academic achievement (Seyedi-Andi, Bakouei, Adib Rad, Khafri, & Salavati, 2021).

In light of these observations, the HBM was reformulated following the work of Montgomery (2002), who considered the main HBM constructs of perceived seriousness, susceptibility and barriers and benefits to be broad enough to encompass the various factors related to BD, the amendments presented by Henshaw and Freedman-Doan (2009) and the mediation proposed by Jones et al (2015). This resulted in the conceptual model in Figure 3:3.

In this model, each of the factors discussed have been categorised into one of the four constructs of the HBM. Here, the demographic and clinical characteristics of an individual are considered to be ‘modifying factors’, which influence all of these constructs and may contribute to the participants’ intervention usage decisions. As the aim of this study was to investigate the effects of a participant’s demographic and clinical characteristics on the usage levels of PE interventions for BD, across the delivery modalities of online and group, this model was useful in highlighting how these characteristics may be influential.

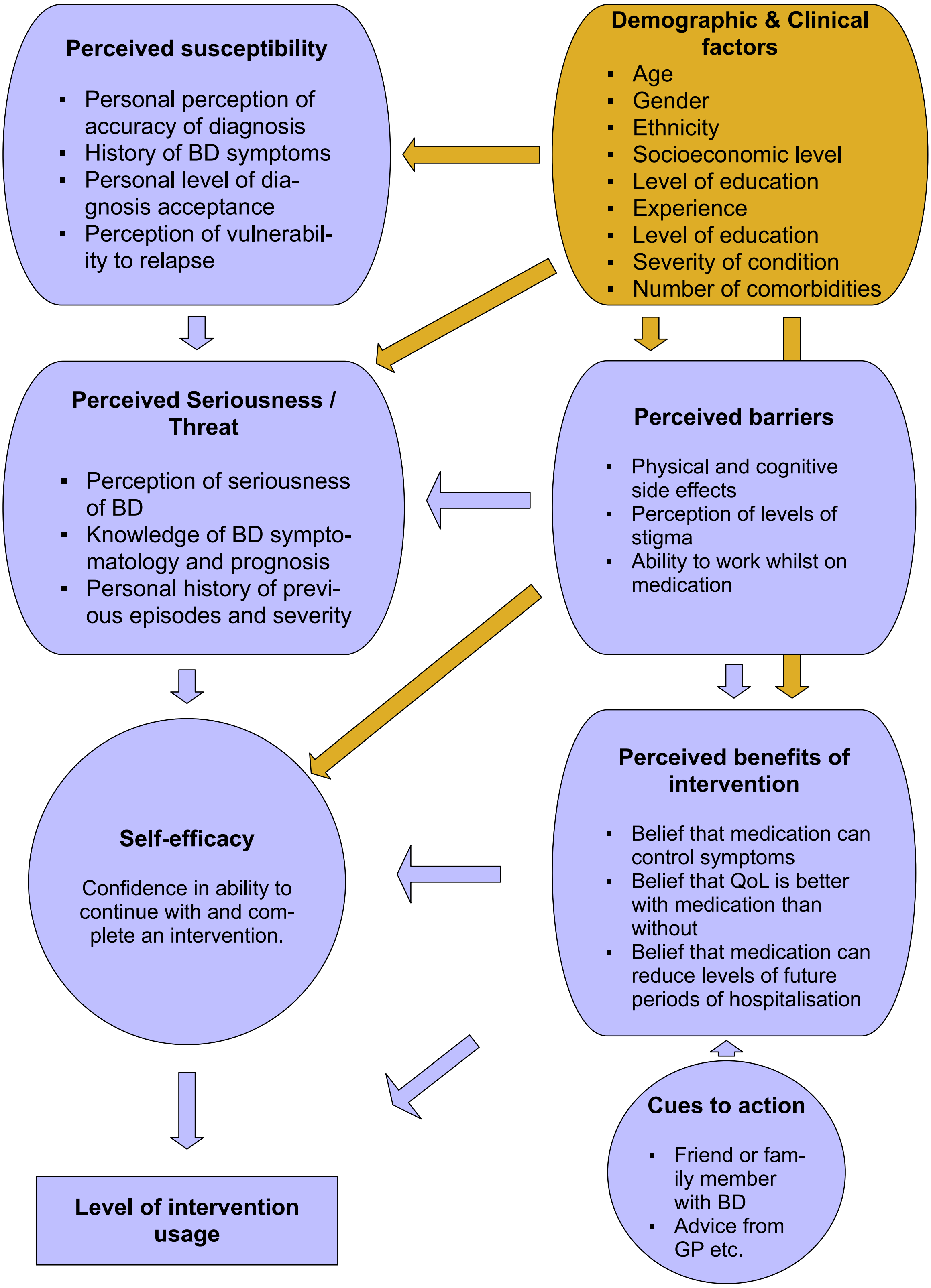

Figure 3:3

HBM model reformulated as a predictor of BD intervention usage

The chosen philosophical paradigm

As the purpose of research is to develop new knowledge it was important that the researcher was able to reflect on the methods used when theorizing about and framing existing knowledge (i.e., their epistemologies and methodologies), as well as the processes that could be employed to build upon that knowledge (i.e., the methods). These reflections facilitated a better alignment between the research questions and the theory and methodology and enabled the identification of opportunities which allowed the researcher to expand upon the questions that could be asked. As a result of this, it was considered that a discussion of the epistemological, ontological and axiological positioning of this work was important despite its quantitative approach.

> “The belief about the nature of the world (ontology) adopted by an enquirer will affect their belief about the nature of knowledge in that world (epistemology) which in turn will influence the enquirer’s belief as to how that knowledge can be uncovered (methodology)”.
>
> (Taylor & Edgar, 1996, pp. 211-227)

In research, a paradigm represents a conceptual framework or worldview and is comprised of a set of assumptions and beliefs made about that world and the individuals within it. These assumptions consist of four related components: ontology, epistemology, methodology and methods, with these being used to guide a researcher’s practice and suppositions about the generation of knowledge (Polit & Beck, 2012).

As such, a paradigm underpins a research approach by focussing, primarily, on the nature of reality, knowledge and existence (Polit & Beck, 2012). There are many paradigms, all of which influence the nature of the research question, how the research is conducted and the knowledge which may be generated (Kelly & Millar, 2018). Fundamentally there are two principal paradigms, the positivist and interpretivist, both of which have their own unique ontological and epistemological perspectives (Polit & Beck, 2012).

In the case of the positivist paradigm, which is generally associated with quantitative research, it is assumed that reality exists independently of the observer and that a cause-effect relationship exists between phenomena, a relationship which, once established, is replicable and can be predicted with confidence in the future. It is guided by the principles of objectivity, knowability and deductive logic, with the researcher remaining separate from the research participants. In addition, it considers that science should be value-free and that researchers should abandon their pre-existing preconceptions and biases in the search for an objective, empirical and knowable truth (Ryan, 2018). In contrast to this perspective, the interpretivist paradigm, which is generally associated with qualitative research, maintains that individuals are complex entities and that different individuals experience and comprehend the same reality in very different ways (Ryan, 2018). Accordingly, interpretive researchers assume that access to reality is only achieved through social constructions such as language, consciousness and shared meanings (Myers, 2009). As a result of this, for an interpretivist, the truth is a construct of which there are many alternatives and subjectivity is unavoidable.

In this thesis, the aim was to generate explanatory associations and to identify potential causal relationships between the demographic and clinical characteristics of individuals with the levels of intervention usage. This aim, which restricted the study to data collection and analysis in an objective manner, dictated the use of a positivist paradigm.

Such a paradigm assumes that reality is objective, independent of human behaviour and is concrete. A perspective which, whilst valuing external validity[26], reliability[27] and representativeness[28], does not allow for the influence of the researcher's background or of imperfect perceptions and measurements (Pham, 2018). As a result, and because of a belief that the influence of the researcher's background and imperfect perceptions were important, it was decided a post-positivist (PP) paradigm was more appropriate to guide this thesis.

The PP paradigm differs from positivism by maintaining that whilst reality is knowable, it is only imperfectly accessible (Miller, 2005) and, whilst existing on a continuum between the quantitative and qualitative paradigms, it aims to maintain the perspectives of objectivity, reliability, validity, generalisability[29] and reproducibility[30]. However, in the case of PP, these terms may have different meanings to those used in positivism; i) Objectivity, for the positivist

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[26] The degree to which the conclusions of a study will relate to others in other places and at other times.

[27] The consistency of the results obtained.

[28] Indicating a small sample, obtained from a larger group, that was representative of the larger group, such that an assumption could be made that the results would have been very similar to the larger group if that had been tested.

[29] Findings are applicable to the greater population.

[30] Results will be the same in similar studies with similar contexts.

is something which can be assumed, but for the PP it is more of an ideal than an inherent characteristic of the scientific method. Because of this, the PP researcher must be aware of any values and biases which may compromise the neutrality of their research (Phoenix et al., 2013); ii) Reliability is not rejected in PP and it is recognised that the methods employed should be systematic, well-documented and designed to include subjectivities to establish dependability; iii) Validity, in the case of PP, relates to the epistemology of positivism and the researcher strives to isolate their variables with the aim of producing a conclusion that is free of context. As a result, experiments and quantitative models are the preferred methods for observing and reporting results with the aim of rejecting any rival plausible explanations; iv) With regard to reproducibility, the PP researcher aims to ensure that the operationalisation of variables, the instruments employed and the data analysis methods used are defined to enable repeatability. Nevertheless, as access to reality is considered to be imperfect in this paradigm, simple replications can be more complex to achieve; v) Finally, by virtue of having a critical realist ontology and recognising the validity of both quantitative and qualitative methodologies, PP aims to retain precision while recognising the importance of generalisability.

By positioning itself within a critical realist ontology and an objectivist epistemology, post-positivism allows for the recognition that all observation is fallible, has errors and that all theory is revisable (Trochim, 2020). By rejecting our ability to know reality with certainty, it believes the aim of science is to get as close as is possible to reality, even though that goal can never be completely achieved (Trochim, 2020). Epistemologically speaking the positioning of PP is objectivist and proposes that reality exists independently of the individual. The objectivity of this position supports outcomes which are reliable and possess good external validity (Moon & Blackman, 2017).

For a description of the paradigm chosen for a research project to be complete an axiological commitment has to be made (Lincoln & Guba, 1985). Here axiology refers to the study of values, in the sense of what’s good (or bad) and what is considered worthy. Axiological thinking was incorporated in this work by the consideration of ‘what ought to be’ (Kivunja & Kuyini, 2017) and by asking questions such as, ‘what values guided the researcher?’ and ‘what was needed to be done to respect the participants’ rights and privacy?’

The adoption of an axiological position was important because of its influence on a number of aspects of the research process. These included: the development of the research question, the choice of a research paradigm and theoretical framework, decisions on the main methods of data collection and data analysis and the choice of how to present results (Aldawod & Day, 2017). It also illustrated the assumptions made regarding the congruence of the ontological and epistemological positions adopted. This is illustrated in Figure 3:4.

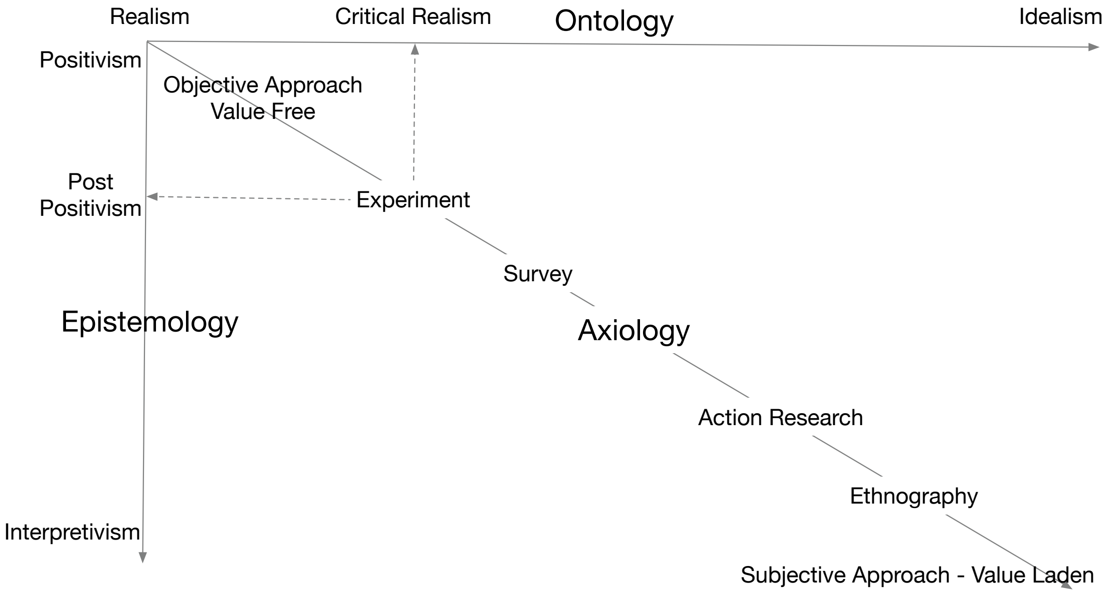

Figure 3:4

Mapping of the research positioning (Source: Sexton, 2003)

The nature of this study, with its aim of correlating the demographic and clinical characteristics of participants with intervention usage levels, coupled with the researchers' quantitative background, led to the choice of using a quantitative correlational methodology. This was an approach which was congruent with the PP paradigm and, whilst the use of a PP positioning does not dictate a quantitative approach, it allowed for the acceptance of a multimethodological spectrum, extending along a continuum between the quantitative and qualitative paradigms.

By using this framework to inform the comprehension, interpretation, and research practice of this work, it allowed the philosophical positioning to be finalised. This was described as: a post-positivist philosophical paradigm, coupled with a critical realist ontology, objectivist epistemology, quantitative experimental methodology and, an axiology which emphasises the researcher’s acceptance that their values and beliefs may have influenced their research.

Chapter Four is a quantitative systematic literature review. This aims to identify if and how participant demographic and clinical characteristics differed between previous research studies into psychoeducational interventions for bipolar disorder, when delivered by individual, group and online delivery modalities. It also investigates the recruitment methods employed in these studies, with the aim of identifying if those methods may have influenced the demographics and clinical characteristics of those who participated. The chapter includes a quality assessment of the included studies and discusses the existing literature, in relation to the factors which may influence a participant’s choice of intervention modality.

4 A Systematic Quantitative Literature Review

4.1 Introduction

Bipolar Disorder (BD) is a chronic, recurrent condition that exhibits high relapse rates, morbidities and psychosocial impairments. It is, primarily, treated with medication. Whilst there are a range of pharmacological interventions available to treat the condition (Fountoulakis et al., 2012), pharmacotherapy alone does not, for a significant number of patients, guarantee the absence of relapses and morbidity (Vieta et al., 2013). In addition, a patients' level of psychosocial (PS) functioning[31] is regularly reduced, even during periods of remission (Rosa et al., 2010), with longitudinal studies highlighting that the probability of functional recovery after an episode is less likely than is syndromal recovery[32] (Rosa et al., 2011). Nonetheless, despite their shortcomings, pharmacological interventions still represent the mainstay of BD treatment.

Other research has demonstrated socio-environmental factors to be stressors which are associated with remission-relapse cycles and treatment non-

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[31] The ability to perform daily living activities and to engage in relationships with other people in ways that are gratifying to the BD patient and others and meet the demands of the community in which the individual lives.

[32] No longer fulfilling the formal criteria of a mood episode.

adherence in BD (Berk et al., 2010). As a result, PS interventions, designed to be delivered as adjuncts to pharmacological interventions have been developed. These can be delivered by a variety of modalities, including individual, group and online (Reinares et al., 2014). These include, Cognitive Behavioural Therapy (CBT), Family Focused Therapy (FFT) and Psychoeducation (PE), all of which have all been demonstrated to reduce the levels of PS disability associated with BD (Depp et al., 2008). Of these interventions, PE is one of the more [clinically] popular for BD, and is directed at adjusting a patient's lifestyle and BD coping strategies (Colom, Vieta, Martinez-Aran, et al., 2003). By didactically delivering information based behavioural training, PE is designed to adjust a patient's lifestyle and their condition coping strategies (Rostami, Habibnezhad, & Zarei, 2012). This includes the enhancement of condition awareness, the encouragement of intervention adherence, early detection of prodromal symptoms and relapses and the avoidance of harmful factors such as sleep deprivation and substance abuse, factors which if unaddressed, reduce the likelihood of positive clinical outcomes (Bonnín et al., 2019).

Usage levels for pharmacological and PS interventions for BD have been shown to be highly variable (Donkin et al., 2013) with approximately 21% to 50% of BD patients not adhering to their recommended treatment programmes. This is a factor which adds to the burden of illness and also impairs condition positive outcomes (Buckley, Foster, & Patel, 2009). As a result, studies across a range of conditions have explored the relationship between the effects of levels of intervention usage and positive patient outcomes (Barkham et al., 1996; Donkin et al., 2013; Hansen, Lambert, &

Forman, 2002). In these studies, it has been observed that increases in the level of exposure to the therapeutic content of a PE intervention were correlated with increased positive clinical outcomes, improved Quality of Life (QoL), reduced stigmatization and reduced functional impairment (Christensen, 2004; Christensen et al., 2006; Donkin et al., 2011; Rakofsky et al., 2011; Stulz et al., 2013).

Whilst the current literature supports the use of PE interventions, as adjuncts to pharmacological interventions for the treatment of BD (National Institute for Health and Care Excellence, 2020), it is unclear as to which BD patients, in terms of their demographic and clinical characteristics, are most likely to use a specific modality of delivery (Christensen & Petrie, 2013). As a result, increasing the knowledge of patient preferences in regard to treatment modalities, and being able to incorporate this into the clinical decision-making process, may be a step towards improving treatment adherence, decreasing dropout and increasing overall usage of BD interventions (Swift, Callahan, & Vollmer, 2011; Whiteford et al., 2013).

Variables which may affect levels of intervention usage

The literature indicates, across a range of MH conditions, that being female (Liddon, Kingerlee, & Barry, 2018) and having higher levels of education (Webelhorst, Jepsen, & Rummel-Kluge, 2020) are associated with increased levels of intervention engagement. In contrast to this, younger age has been shown to be associated with non-adherence and reduced intervention usage (Lange et al., 2003; Nicholas et al., 2010). Being male has also been associated with lower levels of participation in interventions for anxiety and depression (Titov, Andrews, Kemp, & Robinson, 2010), a result which may be influenced by females being overrepresented in health, medical and psychosocial research, particularly where online recruitment methods have been employed (Thornton et al., 2016; Whitaker, Stevelink, & Fear, 2017). Other studies, across a range of MH conditions that have investigated mental ill health in adolescent boys and young adult men, have shown that this age bracket and gender tend to disconnect from health-care services during adolescence and that this “marks the beginning of a progression of health care disengagement and the creation of associated barriers to care…” (Rice, Purcell, & McGorry, 2018, p. 509). Males have also been demonstrated to have a preference for online interventions (Bradford & Rickwood, 2014).

In a long-term study of BD patients receiving planned outpatient maintenance treatment, Moon (2012) identified that the number of past psychotic symptoms, longer illness duration, the number of past psychiatric diagnoses and other axis I disorders, significantly increased the level of intervention dropout and therefore reduced usage levels in BD patients.

With regard to the effects of employment status on intervention usage, Titov et al (2010), in a study of depression and anxiety, did not observe differences in employment status between users of outpatient clinics and an intervention delivered online. Similarly, de Graaf (2013), in an epidemiological study of the sociodemographic and psychiatric predictors of attrition, did not find usage to be associated with employment status. However, having experienced higher levels of education was an indicator of increased levels of intervention adherence and, subsequently, increased usage levels of an intervention (de Graaf et al., 2013).

Possible impact of recruitment methods

As the focus of this quantitative literature review was on the demographic and clinical characteristics of the study participants, the methods of recruitment employed in the included studies were also of interest, due their potential for biasing the datasets. For example, in the case of online recruitment, recruitment rates for women have been indicated to be 10 percentage points higher when compared to men. In the case of young adults, Facebook has been shown to be the most effective recruitment method with 30.6% of those invited being recruited to studies. Other online recruitment methods, such as e-mail and WhatsApp have also been shown to yield similar recruitment levels (24.9%) (Blumenberg et al., 2019).

Despite Facebook being the most effective recruitment method it is not without problems, and it has been shown to invite individuals who are more highly educated, wealthier and younger to participate in studies (Blumenberg et al., 2019). In the case of e-mail as a recruitment medium, this has been shown to be more effective in the recruitment of older participants who are less likely to be users of Facebook (Nolte, Shauver, & Chung, 2015).

Due to the above, the recruitment methods employed in the studies included in this review had the potential to produce a biased sample in terms of the sociodemographic characteristics of their participants and, because of this, it was important to know the recruitment methods which had been employed.

4.2 Aims

As observed previously, there is evidence that factors such as gender, age, level of education, past psychotic symptoms, longer illness duration, past psychiatric diagnoses, employment status, number of co-morbidities and the presence of other axis I disorders, are related to the usage levels of therapeutic interventions across a range of MH conditions. As a result of this, and consistent with the post positivist paradigm adopted, this quantitative systematic review of the literature, guided by the HBM, aimed to identify if participant demographic and clinical characteristics differed between the delivery modalities of individual, group and online.

4.3 Objectives

To explore if the demographic and clinical characteristics of study participants differed between the delivery modalities of individual, group and online. In addition, recruitment methods to the included research trials of PE interventions for BD were investigated, to observe if the methods employed influenced the demographics and clinical characteristics of those who participated.

4.4 Research questions

Do the demographic or clinical characteristics of participants in evaluations of adjunctive PE interventions for BD differ between the delivery modalities of individual, group and online?

Do the recruitment methods employed in research trials of PE interventions for BD influence the demographics and clinical characteristics of those who participated.

4.5 Methods

This quantitative systematic literature review was guided by the Cochrane Collaboration's handbook (2019) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA] checklist (Moher, Liberati, Tetzlaff, & Altman, 2009). Titles and abstracts in Academic Search Ultimate, CINHAL, Medline, PsycArticles, PsycInfo, Embase, PubMed and the Cochrane databases were systematically searched on 20th September 2019. Each database was searched for English language articles, as the reviewing of non-English language journals was beyond the expertise of the researcher and the financial and time constraints of this PhD. As a result of this, it is possible that language bias (Higgins et al., 2019) was introduced into the quantitative systematic review. This was defined by Cochrane as a situation where, depending on the nature of the results, findings from a study are more likely to be published in a certain language (Higgins et al., 2019). An example of this is where statistically significant results are more frequently published in English language journals and results, which do not achieve statistical significance, are more likely to be published in low impact, national journals (Egger, Schneider, Junker, Lengeler, & Antes, 1997). For this reason, researchers whose work is not in English and whose results do not reach significance, may decide to publish in a national, non-English, journal rather than not to publish at all or to be rejected from an English language journal. The omission of non-English journals from the literature review may therefore have resulted in a reduction in the precision of the results and introduced English-language bias.

More recent studies have indicated that the effect of language bias may have decreased over the last 10 years, due to a reported decline in the number of published non-English language articles (Higgins & Green, 2017).This was highlighted by Ramirez-Castaneda (2020) who identified that 98% of science papers are now being published in English. In a review of the effects of restricting evidence to English language medical publications, Nussbaumer-Streit et al (2020) have suggested that the exclusion of non-English language articles does *not* introduce bias into analyses of specific systematic reviews and that it does not [markedly] alter pooled effect estimates and study conclusions. However, these observations only apply to current research and as this review is of previously published articles consideration must be given to the publication dates of the included studies. These ranged from 1999 to 2017 (Mean=2011.49, SD=4.25). Whilst the effect of language bias may have been decreasing for the last 10 years (Higgins & Green, 2017) it would have been more prevalent at the time the included studies were published and because of this the results of this review may include some language bias.

The search was also augmented by a manual search using reference lists of related papers, e-mails to researchers, and Google Scholar internet searches. The following search criteria were employed (Key words in italics), see Appendix A.

(*Bipolar* OR *manic depression* OR *mania OR hypomania OR hypomanic*)

AND

(*education* OR *psychoeducation* OR *Relapse Prevention*).

To ensure comprehensiveness and reduce selection bias (Ahmed, Sutton, & Riley, 2012), the final list of included studies was screened by, Prof. Steven Jones, a clinical expert in this field. Articles nominated for inclusion in the review were divided into 3 discrete categories covering the delivery modalities of Individual, Group and Online.

Inclusion criteria

Studies were included if (1). All participants were aged ≥18 years and had a diagnosis of BD of Type I or II as classified by the DSM. (2). The studies must have provided quantitative usage, demographic and clinical participant data. (3). All data must have been from primary research. (4). Studies must have been in English and be peer reviewed. (5). The intervention must have been intended for individuals[33] diagnosed with BD, for personal condition management. (6). Interventions must have been explicitly described as being PE. If this was not the case then the interventions therapeutic content must have been delivered in a didactic manner and have contained sufficient 'common and specific elements', as defined by Miklowitz (2008). In this study, which was designed to indicate the benefits of various adjunctive psychosocial interventions for BD, Miklowitz et al (2008) investigated whether different forms of psychotherapy consisted of overlapping and/or modality-specific components. They identified five categories of active psychosocial treatment across 14 trials: cognitive-behavioural therapy (CBT; 4 studies), family psychoeducation (5 studies), interpersonal and social rhythm therapy (IPSRT; 2 studies), individual psychoeducation (3 studies), and group psychoeducation

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[33] This excluded family interventions.

(5 studies). Within these studies the frequency of 17 treatment strategies in the active and TAU conditions were identified. The authors, Miklowitz et al (2008), also identified that active modalities were differentiated from TAU by more frequent use of problem-solving and the presentation of components to enhance the patients' ability to cope with stigma. In the case of specific delivery modalities, they observed that these could be distinguished from each other and from TAU by the degree to which specific strategies were emphasized. Miklowitz et al (2008) identified that ‘common’ treatment components, which characterized the active interventions when compared to TAU, were about problem-solving, community functioning and the use of strategies to cope with the stigma of mental illness. They also illustrated that most psychosocial interventions for BD attempt to enhance pharmacotherapies by teaching coping skills for managing psychosocial stressors, condition recurrence, and the social stigma of the disorder. In the case of ‘specific’ elements, group interventions had an emphasis on relapse prevention and individual PE, the importance of medication adherence. Individual PE also had a decreased focus on the regulation of daily routines and interpersonal focussing.

These were operationalized as those delivery modalities which contained the ‘common elements’ and ‘specific’ elements. For group interventions, these had an emphasis on relapse prevention and for individual PE there was an emphasis on medication adherence. These are summarised in Table 4.1 below.

Table 4:1

Distinguishing features of psychosocial interventions

Intervention Type	Distinguishing Factors
CBT	Cognitive restructuring (+) Self-rated mood charts (+)
Family	Communication training (+) Self-rated mood charts (-)
Interpersonal	Tracking and regularization of sleep/wake cycles (+) Use of written psychoeducational materials (-)
Group PE	Relapse prevention (+)
Individual Psychoeducation	Encouraging medication adherence (+) Regulating daily routines (-) Interpersonal focus (-)

Note: A plus sign (+) indicates that greater use of the ingredient characterized the modality, A minus sign (-) indicates that lower use of that ingredient characterized the modality. Adapted from (Common and specific elements of psychosocial treatments for bipolar disorder: a survey of clinicians participating in randomized trials. Miklowitz et al., 2008, p. 13).

Exclusion criteria

Studies were excluded if (1). They were a sub-analysis or a continuation of other included works, see appendix B. (2). The mode of intervention was family based. (3). They were systematic reviews or meta-analyses. (4). The study was unpublished. A full listing of all studies included is detailed in Appendix F.

Publication relevance was assessed against the predetermined inclusion and exclusion criteria by the author and a fellow PhD student (DT) who independently screened all titles and abstracts. Full-text manuscripts were obtained for all studies entering the review, with any uncertainties being resolved by the author and the fellow student, who formed a consensus from examination of the full text. In the event this was not resolved a third reviewer, another PhD student (BA), was asked to give the casting vote. In this event, Miklowitz (2008) criteria of common or core components was applied to determine suitability, see Appendix B.

Quality appraisal

To enable the reviewers to critically access the studies, all were screened using quality assessment templates, see Appendices C & D. The methodological quality was assessed using the Mixed Methods Appraisal Tool (MMAT) (Pluye et al., 2011; Scott et al., 2014). This tool consists of 2 initial screening questions, used to exclude non-empirical studies from the appraisal stage and 4 questions which related to specific study designs. In the 2018 description of the MMAT, the use of a descriptive summary of results is encouraged for the assessment of the quality of the included studies, but a ‘quality score’ is also acceptable as an indicator of the overall quality of included studies (Pluye, 2019). Overall quality was assessed by totalling the number of Yes responses, relevant to the included study designs, to give a final overall percentage score ranging from 0 to 100%.

RCT’s were appraised for a clear description of the randomization process, allocation concealment, the completeness of outcome data and study attrition levels. Other quantitative methodologies were assessed to ensure the sampling strategies employed were relevant to the research question, the representativeness of the population under study, outcome measurements and study response rates.

Study quality was rated as good, fair or poor, according to the extent to which the studies satisfied the MMAT criteria. Whilst ratings are by their nature subjective, the minimum criteria for each rating was defined as follows (Hong et al., 2018; Pluye, 2019):

- Good quality: Study must satisfy at least three of the MMAT criteria.
- Fair Quality: Study must satisfy two of the MMAT criteria.
- Poor quality: Study satisfies one or less of the MMAT criteria.

Data extraction

The variables detailed in Table 4:2 were extracted directly from the studies to a data extraction template, see Appendix E, and then transferred to an Excel spreadsheet.

Table 4:2

Demographic and Clinical variables extracted from included articles

Publication Details	
	Title
	First Author
	Year of Publication
Methodological Variables	
	Methodological Quality
	Recruitment method
Demographic Variables	
	Age
	Gender
	Relationship type
	Employment type
	Years of Education (Range / Mean)
	Ethnicity
	No of Children
	Socioeconomic Status
	Economic Indicators
	Income
	Accommodation Type
	Geographic Location
Clinical Variables	
	Diagnosis
	Age of First Onset
	Mean Age at diagnosis
	No of Manic Episodes
	No of Previous Episodes
	Alcohol Abuse / Dependency
	Substance Abuse / Dependency
	Duration of illness
	No of Hospitalizations (Last year/ 5 years)
	Family member with BD?
	Psychotic features

Attempted Suicide
Axis I/II co-morbidity
Hamilton Depression Score (HAM-D)
Bech Depression Inventory (BDI)
Young Mania Rating Scale (YMRS)
Montgomery-Asberg Depression Scale (MADRS)
The Clinician-Administered Rating Scale for Mania (CARS-M)
Center for Epidemiologic Studies Depression Scale (CES-D)
The State-Trait Anxiety Inventory (STAI)
The Mood Disorder Questionnaire (MDQ)
WHO QoL
Personal and social performance scale (PSP)
Multidimensional scale of independent functioning
Currently taking medication?
No of prescribed drugs
Medication Type
Comorbid clinical anxiety

For comparison, each of the examined variables had to be present in each of the three of the datasets from the delivery modalities of face-to-face, group and online. If any variable was missing from one of more of the datasets it was excluded from further analysis. This resulted in the final variable list for analysis as detailed in Table 4:3.

Table 4:3

Demographic and Clinical variables employed for participant comparison

Demographic Variables		Operationalisation of variable
	Age	Scale variable
	Gender	Nominal, dichotomous variable with two options: male / female
	In/out of relationship – Relationship proxy	Nominal, dichotomous variable with two options: In/Out of relationship
	In/out of structured activity – Employment proxy	Nominal, dichotomous variable with two options: In/Out of structured activity
	Years of Education (Years)	Scale variable
Clinical Variables		
	Diagnosis	Nominal, dichotomous variable with two options: BPI versus BPII
	Age of First Onset	Scale variable

Due to the diverse range of categories employed across the included articles for the variable's 'employment' and 'marital status', these were difficult to compare. As a result, a decision was made to dichotomise these variables as, given the available categories, this allowed for the comparison and analysis of these variables. The dichotomised variables were named ‘in or out of structured activity[34]’ and ‘in or out of a relationship’.

Data synthesis

All scale variables were analysed via ‘boxplot charts’, in the IBM Statistical Package for the Social Sciences (SPSS) (v25) and screened to identify the presence of outliers, see Appendix J.

Due to large variations in sample sizes across the included studies, a decision was made to weight the computed mean data values by the size of the respective samples (Borman, Hewes, Overman, & Brown, 2003), see Appendix H. This was done because it was recognised that each size of study, if unweighted, would have made a different contribution to the total picture and, that because of this, would have created bias. By applying a weighting factor, the aim was to prevent larger studies having an undue influence on the statistical results. Another reason for weighting was that bigger studies more closely approximate the population of interest and have less variability and smaller standard errors[35] than small studies. Smaller studies also increase the variance and add noise to the study. So, by weighting the noise was reduced.

Weighted means were calculated using:

$$\overline{x} = \frac{\sum_{i=1}^{n} \omega_i x_i}{\sum_{i=1}^{n} \omega_i}$$

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[34] Here ‘Structured employment’ means having employment or responsibilities, such as being a homemaker or childcare, which imposes regularity and structure to the participants activities.

[35] Which represent the amount of sampling variability.

this was implemented in the data as:

$$\overline{x} = \frac{\omega_1 x_1 + \omega_2 x_2 + \cdots + \omega_n x_n}{\omega_1 + \omega_2 + \cdots + \omega_n}$$

Some of the included papers provided median data instead of a mean value. In these cases it was assumed that, if the sample size exceeded 25, the median value was the best estimator of the mean (Hozo, Djulbegovic, & Hozo, 2005).

In the case of pooled variances these were calculated as shown below:

$$S_{Pooled} = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2 + \cdots + (n_k - 1)s_k^2}{n_1 + n_2 + \cdots + n_k - k}}$$

Comparative analyses were performed between the 3 intervention modalities with ordinal variables being assessed using one-way ANOVAs. The unit of analysis was the publication. Differences between samples in categorical variables were assessed using chi-square tests. A two-tailed *p*<.05 was considered significant throughout. Adjusted residuals (AR) were employed to identify the variables with largest influence in chi-square calculations. In the case of the ANOVAs, post hoc Games-Howell (nonparametric) tests[36], were conducted to determine if there were any statistically significant differences

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[36] This test was chosen, over Tukey's test, because it did not assume homogeneity of variances or equal sample sizes (Newsom, 2020).

between the means of the three included datasets. Analyses were conducted using SPSS V25.0.

4.6 Results

A total of 2374 abstracts were retrieved and screened from eight electronic databases. After the removal of duplicates, 2212 records remained as potentially relevant. Seven citations were retrieved from hand searching reference lists. Following removals, due to unclear descriptions of intervention modality or for being a pharmaceutical intervention or qualitative study, 131 abstracts were shortlisted for review and were assessed for inclusion against the inclusion and exclusion criteria by the author and an independent reviewer. After excluding 93 of these, the reviewers independently performed quality assessments on the 38 papers remaining, see Appendix F. In the case of one publication by Cakir and Gümüş (2015) two investigations were reported in the same article, with one detailing an individual intervention and the other a group intervention, because of this the appropriate articles were included in both the individual and online data. The 39 studies were then categorised by delivery modality as either individual (n=8), group (n=19), or online (n=12), see Prisma diagram, Figure 4:1.

Data was analysed from 5270 participants with BD. Thirty-five studies employed an RCT design, 2 a pre-test/post-test approach, 1 a feasibility study, comprising of a single-blind trial and 1 reported usage of an intervention. The mean age of the participants was 39.75 (SD=9.36) years, with a mean age of BD onset of 23.81 (SD=8.98) years and a mean length of education of 11.55 (SD=2.94) years. Female gender accounted for 65% of the total participants, see Table 4:4, 4.5 and 4.6.

All included studies, across the 3 intervention modalities, presented with similar quality profiles, Appendix D. In the case of the RCT’s the main concerns were, inadequate descriptions of the randomisation process and allocation concealment and 60% of all studies exhibiting dropout levels which were >20%. All studies had clear quantitative research questions and the collected data was relevant in addressing the specific research questions asked.

Average quality scores for individual and group interventions were similar with 62.5% and 63% being of high quality, 12.5% and 16% medium and 25% and 21% low quality respectively. In the case of the online interventions 77% were of high quality with 8% being medium and 15% low. The majority of all included studies in each category described their intervention in detail, reported main outcomes and had comparable groups at baseline.

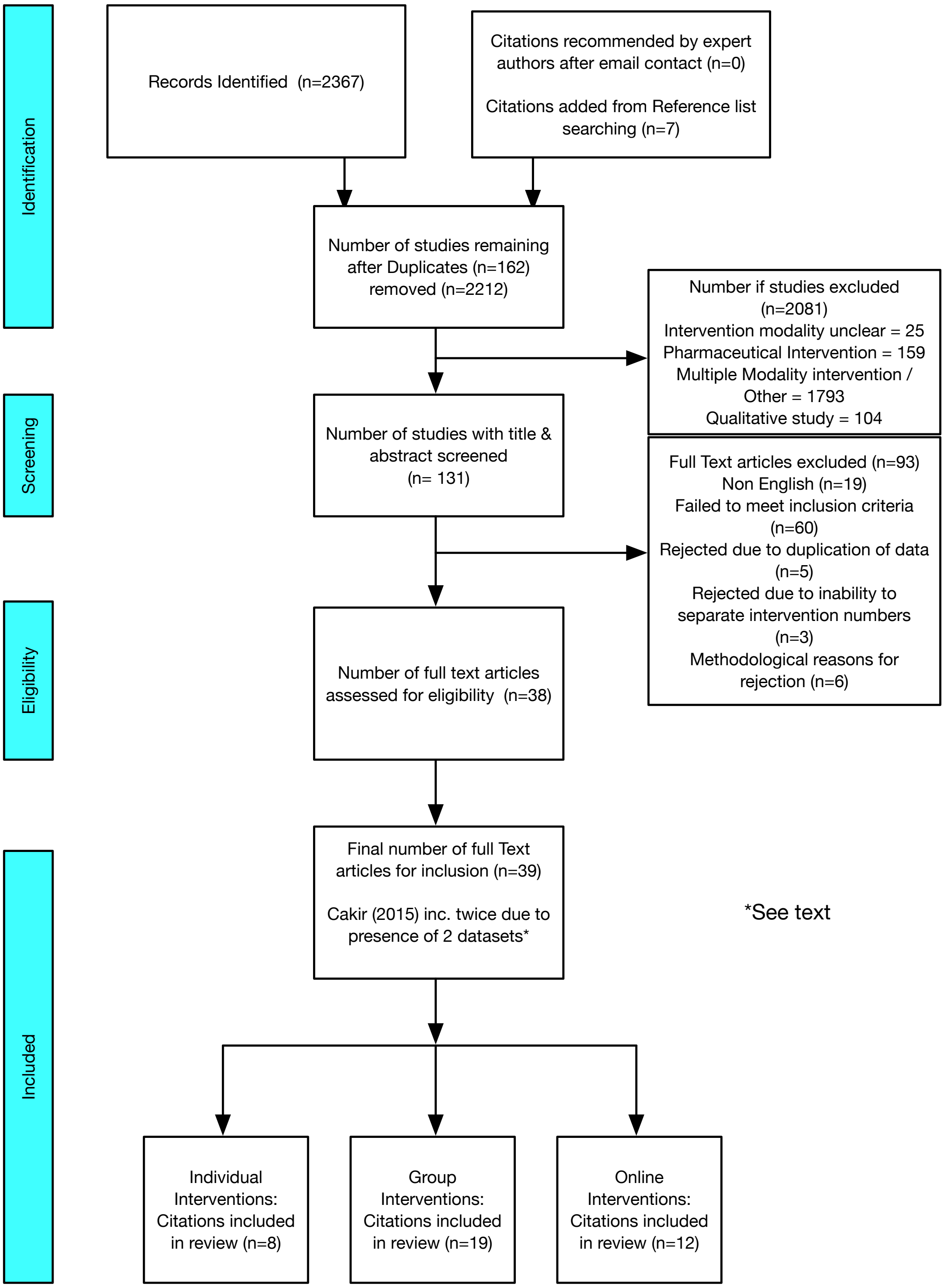

Figure 4:1

Prisma pathway of citation screening for inclusion in analysis

Table 4:4

Key features and quality assessments of Individual delivery articles (sorted by publication date)

Study	Design	Sample Size (n)	Study Population	Comparison condition	No of sessions (n)	Data quality score (0–100%)	Recruitment Method[1]
Perry (1999)	RCT	TAU=35 INT=35	Outpatients	TAU	7-12	75	M
Dogan (2003)	RCT	TAU=12 INT=14	Inpatients	TAU	2	25	M
Zaretsky (2008)	Pilot RCT[2]	PE=39 PE+CBT=40	Patients / Outpatients	TAU	7	25	M
Lobban (2010)	Cluster RCT	TAU=40 ERP=56	Service Users	TAU	6	100	M
Javadpour (2013)	RCT	PE= 45 PE+CBT=41	Outpatients	TAU	8	75	M
Cardoso (2014)	RCT	TAU=29 INT=32	Outpatients	TAU	6	75	M
Cakir (2015)	RCT	PE=93	Outpatients	TAU	4	25	M
Gumus (2015)	Controlled expt	TAU=41 INT=37	Outpatients	TAU	4	100	M

Note 1: M=Medical Source, F=Flyers, O=Online. 2=Functional Remediation, 3=Waitlist control
Note 2: Whilst it was appreciated that a pilot RCT would be underpowered in relation to the measurement of outcomes. This study was included as participant demographics and clinical outcomes were the variables of interest and not the studies outcomes.

Table 4:5

Key features and quality assessments of group delivery articles (sorted by publication date)

Study	Design	Sample Size (n)	Study Population	Comparison condition	No of sessions (n)	Data quality score (0–100%)	Recruitment Method[1]
Colom (2003)	RCT	TAU=25 INT=25	Outpatients	TAU	20	100	M
Colom (2003)	RCT	TAU=60 INT=60	Outpatients	TAU	20	100	M
Simon (2006)	RCT	TAU=229 INT=212	Outpatients	TAU	5	75	M
Soares (2009)	Repeated measures	INT=5 PE=5	Outpatients	Pretest–posttest	6	100	M
Castle (2010)	RCT	Control=42 Exp=42	Outpatients	Control	15	100	M
D'Souza (2010)	RCT	TAU=31 INT=27	Outpatients	TAU	12	50	M

Even (2010)	Pretest–posttest	PE=50	Outpatients	Pretest–posttest	5	100	M
Eker (2012)	Controlled experiment	TAU=35 INT=36	Outpatients	TAU	6	100	M
Parikh (2012)	RCT	PE=109 CBT=95	Outpatients	CBT	6/20	50	F/M
Candini (2013)	Pragmatic RCT	TAU=45 INT=57	Outpatients	TAU	21	100	M
Pellegrinelli (2013)	RCT	TAU=23 INT=32	Outpatients	TAU	16	25	M
Torrent (2013)	RCT	TAU=80 FR=77[2] PE=82	Outpatients	TAU	0/21/21	100	M
Van Dijk (2013)	RCT	TAU=12 INT=12	Outpatients	TAU	12	50	M
Cuhadar (2014)	Controlled expt	TAU=23 INT=24	Outpatients	TAU	7	100	Not specified
González Isasi (2014)	RCT	PE=20 PE+CBT=20	Outpatients	TAU	13/21	25	M
Kurdal (2014)	Pretest–posttest	Control=40 Exp=40	Outpatients	Control	21	100	M
Cakir (2015)	RCT	PE=173	Outpatients	TAU	6	25	M
Morriss, R. (2016)	RCT	Peer =151 PE=153	Outpatients	Peer group	21	100	F/M
Grabski (2017)	Controlled experiment	TAU=20 INT=20	Outpatients	TAU	8	100	M

Note 1: M=Medical Source, F=Flyers, O=Online. 2=Functional Remediation, 3=Waitlist control

Table 4:6

Key features and quality assessments of online delivery articles (sorted by publication date)

Study	Design	Sample Size (n)	Study Population	Comparison condition	No of sessions (n)	Data quality score (0–100%)	Recruitment Method[1]
Barnes (2007)	RCT	N=299	Outpatients	Control	21	75	O/F/M
Proudfoot (2007)	Usage Reports	N=540	Bipolar sufferers	NA	9	100	O/F/M
Nicholas (2010)	RCT	TAU=117 INT1=120 INT2=121	Outpatients	TAU	8	50	O/F/M
Smith (2011)	RCT	TAU=26 INT=24	Outpatients	TAU	8	75	F/M

Proudfoot (2012)	RCT	PE + Peer=134 Control=139 PE=139	Outpatients	PE + Peer	8	75	F/M
Todd (2014)	RCT	WLC^{3}=61 INT=61	Self-Report diagnosis	WLC	10	75	O/F
Barnes (2015)	RCT	TAU=120 INT=113	Outpatients	TAU	20	75	O
Depp (2015)	RCT	INT1=51 INT2=53	Support Grp Outpatients	INT2	4	75	O/F/M
Hidalgo-Mazzei (2016)	Feasibility study	N=49	Outpatients	NA	daily	100	M
Lauder (2015)	RCT	PE=71 PE+CBT=59	Outpatients	PE + CBT	5	75	F
Lobban (2015)	RCT	WLC=49 INT=47	Bipolar sufferers	WLC	9	75	O/F/M
Jones (2017)	RCT	WLC=50 INT=47	Bipolar diagnosis	WLC	10	100	M

Note 1: M=Medical Source, F=Flyers, O=Online. 2=Functional Remediation, 3=Waitlist control

Individual (face-to-face) PE

There were 8 studies included which assessed individual PE. In total they involved 588 participants, 57% of which were female, with a mean age of 38.65 years (SD=9.19). The average number of sessions which were offered was 6.25 (SD=2.8) with the number of available sessions ranging from 2 to 12, Table 4:4. All participants were recruited to the studies via referrals from medical sources. The focus of these interventions included: the causes and symptoms of BD, the side effects of medication, condition management and the identification of the symptoms of relapse.

Results across this category were inconsistent, with one of the studies observing that the time to relapse was no different between the individual PE and the treatment as usual (TAU) arms (Lobban et al., 2010), one finding improvements in the time to manic relapse but not in depressive relapse[37] (Perry, Tarrier, Morriss, McCarthy, & Limb, 1999), two finding reduced severity of relapse (Gumus et al., 2015; Javadpour, Hedayati, Dehbozorgi, & Azizi, 2013) and three in which participants reported an improved QoL (de Azevedo Cardoso et al., 2014; Dogan & Sabanciogullari, 2003; Javadpour et al., 2013). In the case of the Zaretsky study (Zaretsky, Lancee, Miller, Harris, & Parikh, 2008), CBT, in addition to PE, was demonstrated to reduce subsyndromal depression by 50% when compared to PE alone. In addition, Cakir (2015) found that patients with BD were less willing to attend and continue group PE interventions than individual PE.

Out of the 8 studies 5 were identified as being of high quality. Most of the studies (5) indicated that participant withdrawal rates were greater than 20% with 2 not reporting this data. Only the study by Gumus (2015) reported withdrawal rates at 4.88%. The lack of the reporting of dropout levels was the main factor for studies not achieving the highest quality score. Two of the studies (Cakir & Gümüş, 2015; Dogan & Sabanciogullari, 2003) were of low quality as they did not report on either their processes of randomisation or allocation concealment. Finally, the RCT by Zaretsky (2008) was of medium quality due to dropout levels >20% and no report of the method of allocation concealment.

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[37] 25th centile time to first manic relapse was 65 weeks in the experimental group and 17 weeks in the control group. In contrast the 25th centile time to first depressive relapse was 21 weeks in the experimental group and 26 weeks in the control group, but this was not significant p=0.19.

Group based PE

There were 19 studies included which assessed group-based PE. In total these involved 2192 participants, 63% of which were female, with a mean age of 42.53 years (SD=10.33). The average number of sessions which were conducted was 13.13 (SD=6.87) with the number of sessions offered ranging from 5 to 21, see Table 4.5. The interventions contained topics relating to BD and the self-management of symptoms and were facilitated by a health-care professional, see Table 4:5.

Results across this category showed that group PE was effective in reducing the time to relapse (Castle et al., 2010; Colom, Vieta, Martinez-Aran, et al., 2003; D'Souza, Piskulic, & Sundram, 2010; Morriss et al., 2016) and in improving patients treatment adherence (Eker & Harkin, 2012). On the other hand, in the Morriss study (2016), the time to next bipolar episode did not differ between groups. In addition, the number of hospitalisations (Van Dijk, Jeffrey, & Katz, 2013) and the mean number of days in hospital were reduced in participants who received a group-based PE intervention (Candini et al., 2013; Even et al., 2010; González Isasi et al., 2014). The number of total recurrences and the number of depressive episodes were also significantly lower in PE patients (Colom, Vieta, Reinares, et al., 2003).

Group interventions had higher attrition rates (20.2%) than the individual face to face interventions (9.7%) but these results were not significantly different, *p*=0.15, (Cakir & Gümüş, 2015). PE also reduced reported patient stigmatisation and alienation (Çuhadar & Çam, 2014), as well as producing statistically significant positive changes in the participants' internal locus of health control, problem-solving and sense of self-efficacy (Even et al., 2010; Grabski, Maczka, Filar, Dudek, & Gierowski, 2017). Parikh (2012) observed that both the control and the PE groups had similar outcomes with respect to the reduction of symptom burden and the likelihood of relapse. One study demonstrated that a PE intervention significantly reduced the mean level of mania symptoms and the time with significant mania symptoms (Simon, Ludman, Bauer, Unutzer, & Operskalski, 2006). However, in this study, there were no significant intervention effects on the mean level of depressive symptoms or the time with significant depressive symptoms.

Some studies reported contradictory results, with Pellegrinelli (2013) finding no significant differences between the intervention and control groups with regard to levels of functioning, whilst Kurdal (2014) and Torrent (2013), found that PE groups scored significantly higher ($p < .05$).

Out of the 19 studies, 11 were identified as being of high quality, with 4 having participant withdrawal rates less than 20%. The studies for group-based PE, which were rated as being of the highest quality, were the RCTs by Castle (2010), Morriss (2016) and, the experimental pre-test post-test by Even (2010), the controlled experiment by Grabski (2017) and the exploratory study by Soares (1997). The RCTs received high-quality scores due to their clear descriptions of randomisation techniques and allocation concealment, coupled with a low dropout rate (<20%). In the case of the other studies, high quality scores were due to having relevant sampling strategies, a representative sample of the population under study, appropriate measurements and an acceptable response rate (>60%).

Online PE

There were 12 studies included which assessed internet-based PE. They included 2490 participants, of which 70% were female, with a mean age of 44.29 years (SD=10.69). The average number of modules available within each study was 9.75 (SD=5.54) with the number of modules offered ranging from 4 to 21, see Table 4:6.

Two of these studies indicated improvements in participant mood symptoms and well-being (Lauder et al., 2014; Todd, Jones, Hart, & Lobban, 2014), with two others producing inconsistent results for the effects of gender and age (Nicholas et al., 2010; Proudfoot, 2007). QoL also reported inconsistently, with Todd (2014) and Nicholas (2010) et al reporting improvements in QoL, whilst Smith et al (2011) reported no difference between the active and control arms. Recurrence of illness (Barnes, Hadzi-Pavlovic, Wilhelm, & Mitchell, 2015) and illness perception (Proudfoot et al., 2012) also reported with no difference between the active and control arms. In the case of clinical outcomes, Lobban et al (2017) described that participants experienced a more positive model of BD at both 24 and 48-week follow-up with low relapse rates (<15%), but reported no evidence of improved clinical outcomes. Retention and usage levels were found to be high (Hidalgo-Mazzei et al., 2016; Jones et al., 2017; Nicholas et al., 2010). One study indicated that more data were required for an assessment of symptomatic improvements over time (Depp et al., 2015).

In this group ten of the studies were of high quality and 2 were of medium quality (Barnes, Harvey, Mitchell, Smith, & Wilhelm, 2007; Nicholas et al., 2010). 10 studies also had dropout levels >20% which was the main factor for not achieving the highest quality score. This applied to all studies with the exception of Barnes (2007) and Jones (2017). The quality of the studies in this group was, on average, the highest amongst the three delivery modalities examined. The studies were also the most recently published.

Recruitment Methods

A range of recruitment methods were employed in the included studies across the three analysed modalities, see appendix G, these included clinician recruitment (medical), online and advertising with posters and flyers. Across the delivery modalities it was observed that individual face-to-face interventions had recruited exclusively from the medical route, via outpatients' clinics, whilst the group interventions had used the medical route with the addition of advertising flyers. In the case of online studies recruitment was predominantly via the online route. See Table 4:7 for summary data. None of the included studies reported controlling for any biases which may have been introduced into their samples by the choice of recruitment methods.

Table 4:7

Recruitment methods

Recruitment Type (%)	Intervention modalities (% within each modality)		
	Individual	Group	Online
Medical	100	84	16
Medical + Flyers	-	10	17
Online only	-	-	17
Online + Flyers	-	-	17
Online + Flyers + Med	-	-	33
Flyer only	-	-	-
Not Specified	-	6	-

Comparison of intervention groups

To assist with the interpretability of the results Table 4:8 presents categorical variables as percentages due to the use of weighted data. Full information supporting this table is presented in Appendix I.

Table 4:8

Participant data comparing all intervention groups (Weighted Data)

Grouping \ Intervention	Individual	Group	Online	F Statistic / (Chi-square)	P Value	Effect Size Cohens d / (Cramer's V)
Gender (Female), %	57	63	72	(8.05)	0.018[a]	(.11)[c]
Age Mean Years, (SD)	41.54 (11.25)	41.74 (11.28)	39.35(11.43)	0.50	0.61	.21[d]
Relationship Status (In Relationship) %	45	39	46	(2.22)	.33	(.07)
Structured Activity, % (In Structured Activity)	46	52	70	(24.88)	<.00001[b]	(.12)
Length of Education, Mean (SD), Years	11.97(3.24)	11.76(3.53)	14.59(2.37)	0.25	0.80	.80
Diagnosis BP1, %	88	78	83	(4.10)	0.13	(.23)
Age of first Onset, Mean (SD), Years	20.12 (6.37)	24.77 (8.71)	21.66 (12.34)	0.24	0.79	.31

Notes: *a – Number of females in online interventions had adjusted residuals of 2.7*
b – Number of individuals with Structured Activities in online interventions had adjusted residuals of 4.9
c –Small effect<=0.2, 0.2<Medium effect<0.5, Large effect>.5
d -Weak effect<=0.2, 0.2<Moderate<0.6, Strong>=0.6

When comparing between the intervention delivery modalities, differences were observed in gender distribution (X^2 = 8.05, *p*< .02), see Table 4.7. There was also an overrepresentation of female participants in the online intervention when compared to other modalities.

Comparison between delivery modalities also showed differences in structured activity (X^2 = 24.88, *p*< 0.00), with individuals who had structured activities, when compared to those who did not, having a higher representation in online interventions, see Table 4:8.

In the case of the variables relationship status (X^2=2.22, p<=.33, d=.07) and level of education (F=.25, p<=0.80, d=.80) neither was significant, but their effect sizes were of note being very small and large respectively. These are discussed below as a large effect size indicates that there is stronger relationship between the two variables. Here it is possible that the non-significance of the results for level of education, which exhibited a large effect size and, in the case of relationship status, which exhibited a small effect size, may indicate that the sample size was not large enough for the results to reach significance.

The clinical characteristics of diagnosis, age of first onset, age and relationship status also exhibited no significant differences between the differing delivery modalities, see Table 4:8.

4.7 Discussion

The objective of this quantitative systematic literature review was to assess if differences existed in the demographic and/or clinical characteristics of participants who participated in PE interventions for BD, when these interventions were delivered by the modalities of individual, group and online. Participant clinical and demographic characteristics and recruitment methods were analysed to assess if they influenced the individuals who participated. Results indicated that both gender and the presence of structured activities were significantly associated with the choice of intervention delivery modality. Another variable of note, whilst not giving a significant result, was level of education (Cohens d=.80).

Gender

The results for female gender were significant (p=.018) with a small effect size (d=.11). The observation that more females participated in all intervention types was in agreement with Titov (2010) and Crisp and Griffith (2014), who found higher numbers of females to be both online users and outpatient attendees in studies of depression. The results also corresponded with other studies that observed women to be more likely to have been treated for a MH problem than men (29% compared to 17%), have an increased likelihood of exhibiting help-seeking behaviours than men (Liddon et al., 2018) and being more likely to report or seek help for symptoms of common MH problems (Singleton, Lewis, & UK Statistics Authority, 2003).

The methods of recruitment may also have influenced the relative percentages of male and female participants, because the online interventions recruited more via the internet than the individual or group interventions. This is an important distinction, as studies have shown that, whilst internet recruitment via Facebook and websites are successful in recruiting from hard to reach populations, with the results being representative of the control or comparison demographic, there is often an over representation of young white women (Whitaker et al., 2017).

Structured activities

The data indicated that levels of structured activity, which were approximately equal within the individual and group interventions, were significantly associated with usage of online interventions. This result concurred with other findings, where patients who have days which are structured, due to work, family and other commitments, reporting that flexibility in time and location of intervention use are practical advantages of online interventions (Beattie, Shaw, Kaur, & Kessler, 2009).

Relationship status

The result for the variable relationship status was not significant and exhibited a small effect size (Cramer's V=.07). This indicated that there was a small relationship between Relationship Status and a preference for a delivery modality. In addition, the observations of being in or out of a relationship in the existing literature is mixed and inconclusive. Olfson (2009) found, across a range of interventions, that, when compared to separated, divorced, or widowed patients, patients that were married were significantly more likely to dropout from mental health care interventions. In contrast to this, Minamisawa et al (2016) observed that patients were more likely to drop out of treatment if they were divorced or widowed (relative to being single or married). This observation concurs with social solitude being reported as a determinant of intervention dropout in previous studies (Rossi et al., 2002), where it can be assumed that patients without family support might have difficulties in daily life. These difficulties may include making visits to hospitals or clinics or participating in online treatment interventions.

Level of education

Whilst results for the level of education experienced by the participants was not statistically significant the variable exhibited a large effect size (d=.80) with individuals with the longest periods of education showing a preference for online interventions. This was a result which was congruent with the majority of the literature, which has indicated that increased amounts of education are associated with an increased likelihood of receiving psychological treatment and psychoeducation for BD (Karanti et al., 2021). The level of education has also been shown to be related to the expectations of patients and their abilities to demand a specific treatment which may drive differences in preferences for psychological treatments and delivery modalities (Weitoft, Rosén, Ericsson, & Ljung, 2008). Educational level might also be associated with the severity or type of illness, which may warrant treatment with different interventions and delivery modalities. For example, higher educational level has been shown to be a proxy for cognitive reserve[38], which has been associated with the course of and functional outcomes in bipolar disorder (Anaya et al., 2016).

Age, diagnosis and age of first onset

The data indicated that participant age, diagnosis and age of first onset were not significantly associated with intervention delivery modality with all three variables exhibiting moderate effect sizes.

Recruitment methods

In the case of recruitment methods, individual and group interventions recruited, predominantly, from hospital units and outpatient departments, with online interventions, as discussed, recruiting via the internet. As a result of

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[38] Cognitive reserve (CR) is a concept that was postulated as a protective factor for some clinical symptoms after the observation that there is not a direct relationship between the degree of brain damage and its clinical manifestation.

these differences, the sampled populations may have been biased. In the case of internet recruitment this may have been by a potential over representation of young white women (Whitaker et al., 2017). This concern was also supported by Thornton et al (2016) who reported, in a systematic review of studies which used the internet (Facebook) for recruitment, that only 36% studies reported their participants to be representative of the demographics of the group of interest from the wider population. However, the same review also highlighted that traditional recruitment routes have similar issues with representativeness, so that this limitation was not specific to this form of recruitment. In this study the characteristics which were identified as being most frequently imbalanced included gender, age and level of education, with participants who had experienced higher education tending to be overrepresented.

Limitations

This review provides the first quantitative systematic assessment of the differences in participant demographic and clinical characteristics between the delivery modalities of individual, group and online in adjunctive PE interventions for BD. Its strengths include: the searching of eight electronic databases; the manual searching of the reference lists of related papers and the quality assessment of the identified studies by two independent researchers using the MMAT checklist.

The analysis may have benefitted from the inclusion of the grey literature. This was omitted from the search strategies because much of it was very specific to certain geographical regions, and it was often not included in online databases. In addition, there was less consistency in how this research was conducted and the data analysed. Despite this, it is recognised that by its exclusion, the included publications were unlikely to reflect the complete works in this field.

Whilst there was a considerable literature in relation to individual, group and particularly online interventions for depression and anxiety, literature for psychoeducational interventions in BD was found to be more limited. Within the studies that were selected for inclusion, heterogeneity existed between the variables recorded. This was primarily due to the way the variables had been operationalized.

Improving practice / services

Learning more about how the clinical and demographic characteristics of patients and participants may influence the usage of an intervention is important. From the perspective of clinical services, the dissemination of and the informing of clinicians of the results of this quantitative literature review may result in the better tailoring of specific delivery modalities of PE interventions to patients. By providing delivery formats which better fit with patient preferences and lifestyles, usage of these interventions may be increased along with patient exposure to the interventions therapeutic content. This has been shown to be important in the case of PE interventions where studies have indicated increased exposure to the therapeutic content of an intervention to be influential in the production of positive outcomes (Donkin & Glozier, 2012; Donkin et al., 2013; Stulz et al., 2013).

Implications for further research

More in-depth quantitative studies need to be conducted, across all modes of PE delivery for BD, to further establish if specific delivery modalities are preferred by patients with specific demographic and clinical characteristics. This would enable these delivery modalities to be explored further and better targeted at patients, to increase their usage rates.

Whilst quantitative studies can facilitate an understanding and categorising of ‘who’ prefers which delivery format for an intervention, the use of additional qualitative studies would be required to understand ‘why’. Future studies could also facilitate an assessment of the acceptability and reach of these interventions within the BD community, and an understanding of the personal impact of PE from the perspective of the patient. In order to assess if participant usage levels were influenced by the recruitment methods employed, it is suggested that future studies could review the expressed preferences of participants, or conduct a three armed patient preference trial (Torgerson & Sibbald, 1998). This would recruit across several recruitment platforms, to provide an assessment of the influence of the differing recruitment methods.

4.8 Conclusions

This review was the first, to the author’s knowledge, to appraise the data from studies of PE interventions for BD and to evaluate if the demographic and clinical characteristics of the participants differed between the delivery modalities of individual, group and online. It also illustrated that many studies which involved PE for BD were focused on group interventions, with a smaller number of studies examining face-to-face and online interventions.

The main findings of the literature review were that female participants and those with higher levels of structured activities were more likely to engage with online interventions. A larger percentage of female participants took part across all delivery modalities. age of first onset, age and diagnosis type did not have a significant effect on the participants choice of delivery modality, but all exhibited medium effect sizes, with individuals who had a later age of first onset being more likely to engage with group delivery modalities. The variable relationship status was not significant and yielded a small effect size. Finally, there were indications that participants who had received higher levels of education were more likely to participate with online interventions. This variable, whilst not significant, exhibited a large effect size and was congruent with the majority of the literature.

Chapter 5 presents the method employed for the empirical study. It opens with a discussion of the type of analysis chosen, before proceeding to discuss the process of secondary analysis and the specific challenges this presented. It continues with descriptions of the processes employed for the selection of included studies and the variables chosen to be studied, before discussing the methods of data preparation and analysis.

5 Empirical Study Method

The quantitative systematic review of the literature in Chapter 4 showed that differences existed in the demographic and clinical characteristics of individuals who participated in psychoeducational interventions (PE) for bipolar disorder (BD), delivered by differing delivery modalities.

The main findings of the literature review were that females and individuals with higher levels of structured activities were more likely to engage with online interventions. Across all modalities a larger percentage of females took part. Regarding clinical factors age of first onset, age and diagnosis type did not have a significant effect on the choice of delivery modality, but all exhibited medium effect sizes. Individuals who had a later age of first onset were more likely to engage with group delivery modalities.

This empirical study, a quantitative secondary analysis of an existing data set using a correlational approach, was guided by a post-positivist paradigm which employed the Health Belief Model (HBM) as a theoretical framework. This was used to answer the research question, "*Are the demographic and clinical characteristics of individuals linked to patterns of usage in research trials of self-management PE interventions for BD, when delivered by the modalities of group and online?*"

The chapter begins by examining the choice of data collection methods, the study selection criteria and any ethical issues which are associated with the use of a secondary analysis (SA). It continues with a discussion on how the HBM, modified for use with BD intervention usage (see section 3.4.2), guided the study and informed the selection of the independent variables (IV). It then continues with a discussion of how the datasets were cleaned, before concluding with a discussion of the operationalisation of the dependent variable (DV) and the methods of data analysis employed.

5.1 The choice of the data collection method

The chosen research question presented the author with two data collection options. The first of which was to conduct individual PE investigations delivered by group and online delivery modalities and the second was to employ a secondary data analysis. Given the limited time and financial resources of this doctoral research, a decision was made that option one, with the need to conduct multiple separate studies was impractical[39]. It was also considered that the secondary analysis option could provide larger and higher-quality datasets, with more precise estimates of relevant participant relationships. As a result of this, a decision was made to proceed with a secondary data analysis.

Study selection criteria

There are no biological markers for bipolar disorder and its diagnosis is based on a review of symptoms and their potential medical explanations. To improve

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[39] It may also have been unethical, if, due to these constraints, the studies had been too small and underpowered to produce valid results.

diagnostic accuracy, several structured clinical interviews, have been created and tested to assess BD in adults. These interviews are superior to clinical interviews, which are less-structured, in the derivation of reliable psychiatric diagnoses (Ventura, Liberman, Green, Shaner, & Mintz, 1998). This is because they facilitate symptom reporting, while systematically probing indicators and behaviours that clinicians may overlook (Levis et al., 2019) thereby reducing diagnostic variability (Weinstein, Noam, Grimes, & Schwab-Stone, 1989).

The most common of these interviews are:

- Structured Clinical Interview for *DSM* (SCID)
- Schedule for affective Disorders and Schizophrenia (SADS)
- Composite International Diagnostic Interview (CIDI)
- Mini International Neuropsychiatric Interview (MINI)

Of these the two most often used are the Structured Clinical Interview for the *DSM* (SCID) and the Schedule for Affective Disorders and Schizophrenia (SADS). The SCID and the SADS both provide interview probes, symptom thresholds and information about exclusion criteria (i.e. medical or pharmacological conditions that may induce mania), but differ in the criteria they are designed to assess. The SCID is designed to help assess diagnoses according to the *DSM*, whereas the SADS is designed to assess diagnoses according to the Research Diagnostic Criteria (RDC;Spitzer, Endicott, & Robins, 1978).

For a diagnostic assessment procedure to be useful in clinical practice it needs to yield information that is reliable across raters, is valid, and is clinically meaningful (Drill, Nakash, DeFife, & Westen, 2015). To this end, structured diagnostic interviews such as the SCID involve the questioning of patients or research participants in relation to specific diagnostic criteria. Within the interview, structured questions follow directly from the DSM and correspond to symptoms for each diagnosis.

The Schedule for Affective Disorders and Schizophrenia (SADS) is a collection of psychiatric diagnostic criteria and symptom rating scales (Endicott & Spitzer, 1978). The SADS assesses the subject's current condition of illness, as well as their level of psychopathology and functioning. It has demonstrated good to excellent reliability for both symptoms and diagnoses, being organized into two parts and 8 scales: Depressive mood and ideation; Endogenous features; Depressive--associated features; Suicidal ideation and behaviour; Anxiety; Manic syndrome; Delusions--Hallucinations; and Formal thought disorder. There are three versions of the schedule, the regular SADS, the lifetime version (SADS-L) and a version for measuring change in symptomology (SADS-C).

The World Health Organisation (WHO) Composite International Diagnostic Interview version 3.0 (CIDI) (Kessler & Ustün, 2004) is a fully structured lay-administered diagnostic interview where DSM criteria are employed to define mania, hypomania and major depressive episodes. Individual-level CIDI-SCID concordance has been found to be excellent for any bipolar spectrum disorder, with good CIDI-SCID concordance for lifetime diagnoses of most anxiety disorders, substance use disorders, and major depressive disorder (Kessler et al., 2006). The CIDI is mainly used in epidemiological surveys (Kessler & Zhao, 1999).

Finally, The Mini International Neuropsychiatric Interview (MINI) is a brief structured diagnostic interview for the major psychiatric disorders. Validation and reliability studies have compared the MINI to the SCID-P and the CIDI to SCID (Kessler et al., 2006; Sheehan et al., 1997). The standard MINI assesses the 17 most common disorders in mental health. However, in relation to MINI/SCID concordance, as depressive symptom severity increased, the probability of diagnosis increases more for the MINI than for the CIDI and the likelihood of classification increased less for the CIDI and MINI than for the SCID (Levis et al., 2019; Wu, Levis, Ioannidis, Benedetti, & Thombs, 2020).

Whilst all of these interviews standardise the collection of information by asking structured questions (Farmer & Chapman, 2002) they have been shown to exhibit lower than ideal validity and clinician preference (Drill et al., 2015). As a result of this, the process employed by many clinicians to make a final diagnostic decision may differ considerably from the methods used in structured interviews (Westen, 1997). Many clinicians have also reported that they do not exclusively rely on the asking of direct questions to identify specific diagnostic criteria (Nakash & Alegría, 2013).

These structured interviews were all considered as possible bipolar disorder diagnostic tools for this empirical study. However, when preliminary searches were conducted, the studies which had used the MINI, CIDI, or SADS-L had not reported quantitative participant intervention usage data. In the case of the SCID, three studies were identified which had reported this variable.

Whilst it was unfortunate that no quantitative usage data was identified in studies which had used the MINI, CIDI, or SADS-L an advantage was that by using only one diagnostic tool, the potential for previous researchers to introduce variability and inconsistency in their diagnoses was reduced. In addition, as the onset and trajectory of BD can be influenced by social and environmental factors, if a clinician uses more than one assessment tool, or one that differs in the amount to which it asks about these factors (e.g., triggers), then it may provide conflicting evidence in relation to diagnosis and treatment. This is especially so in the case for disorders, such as BD, where external events are known to have a considerable impact (Newson, Hunter, & Thiagarajan, 2020).

The inclusion criteria were: i). Participants must have been aged ≥18 years and had a diagnosis of BD of Type I or II as classified by the DSM IV or 5 (American Psychiatric Association, 1994, 2013). ii). Studies must have recorded quantitative intervention usage data. iii). Studies must have been PE based. iv). Studies must have been written in English and have been peer reviewed.

The exclusion criteria were: i). Studies were a sub-analysis or a continuation of other included works. ii). The mode of intervention was family based. iii). Studies were systematic reviews or meta-analyses. iv). Studies comprised of non-randomised and non-controlled designs or recorded only qualitative data.

To identify suitable studies, the papers retrieved for the quantitative systematic literature review, covering the period 1974 to 2018 and matching the criteria described above, were reviewed. From these, seven studies

(Colom, Vieta, Martinez-Aran, et al., 2003; Colom, Vieta, Reinares, et al., 2003; González Isasi et al., 2014; Jones et al., 2017; Lobban et al., 2017; Morriss et al., 2016; Simon et al., 2006) were identified which concurred with the inclusion and exclusion criteria. These generally used similar measures to collect data and good homogeneity was observed between them regarding [the majority of] the categorisations employed for the recorded independent variables. However, only three of these studies had published the participants usage levels of the intervention (Jones et al., 2017; Lobban et al., 2017; Morriss et al., 2016). To increase the number of available studies, emails were sent to the contact addresses of the lead authors of the other 4 studies. This was to inquire if usage level data was available and if the authors would make it available for this study. Unfortunately, none of these emails received responses. This resulted in only three studies above being suitable for inclusion in this study. As a result of the limited number of available studies, an *a priori* power calculation was not conducted. This was because only three studies were identified that included usage data, no more data was available, and the number of participants could not be increased.

Whilst the limited number of studies was disappointing, from a pragmatic perspective this was also convenient, as the author’s supervisor had been author or co-author on these works and had good knowledge of the recorded data and methods employed.

5.2 Studies included for analysis

The included PARADES psychoeducation study (Morriss et al., 2016), was identified to provide data for group interventions. ERPOnline (Lobban et al.,

2017) and IBPI (Jones et al., 2017) provided data for online interventions. All articles were published between 2016 and 2017 and originated in research groups at Lancaster University in the UK.

Critique of included studies

1. Clinical effectiveness and acceptability of structured group psychoeducation versus optimised unstructured peer support for patients with remitted bipolar disorder (PARADES): a pragmatic, multicentre, observer-blind, randomised controlled superiority trial (Morriss et al., 2016).

The PARADES pragmatic, multicentre, parallel-group, observer-blind, randomised controlled superiority trial was designed to independently examine the clinical effectiveness of structured group PE versus unstructured peer support for the time to next bipolar episode. The primary outcome measure was time to next bipolar episode. This was based on the SCID Longitudinal Interval Follow-up Evaluation (LIFE) (First, Spitzer, Gibbon, & Endicott, 1997; Paykel, Abbott, Morriss, Hayhurst, & Scott, 2006), which was done every 16 weeks for 96 weeks. Secondary outcome measures were time to next mania-type episode (mania, hypomania, or mixed affective episode) and time to next depressive episode (First et al., 2004; Scott et al., 2006), assessment of mean weekly symptoms of mania-type symptoms and depression symptoms using the LIFE (First et al., 1997; Scott et al., 2006), assessment of function with the Social Adjustment Scale (SAS) (Morriss, Scott, et al., 2007), Social and Occupational Functioning Assessment Scale (SOFAS); (Goldman, Skodol, & Lave, 1992), observer-rated and self-rated measures of mood (17 item GRID-Hamilton Depression Rating Scale (Williams, Kobak, & Bech, 2008), Bech-Rafaelsen Mania Scale (Licht & Jensen, 1997), Hospital Anxiety and

Depression Scale (Zigmond & Snaith, 1983) and self-rated overall mental and physical health (Short Form [SF]-12 mental and physical component scores) (Ware, Kosinski, & Keller, 1996).

The study was conducted across eight community sites in two regions of the UK, with participants being recruited via secondary care referral and randomly assigned to either 21 2-hour weekly sessions of structured group PE or 21 2-hour weekly sessions of optimised unstructured group peer support.

Results indicated that, whilst structured group psychoeducation was no more clinically effective than similarly intensive unstructured peer support, it was more acceptable to, and improved outcomes in participants with fewer previous BD episodes. Limitations included a low rate of completion of self-rated symptomatic and functional outcomes, the moderate reliability of the assessment of mania symptoms, no formal rating of blinding and the absence of recorded treatment sessions to ensure fidelity to treatment. Finally, this study did not include a treatment-as-usual control group which meant that this study could only inform about the relative merits of the two intervention groups.

2. Assessing feasibility and acceptability of web-based enhanced relapse prevention for bipolar disorder (ERPonline): A randomized controlled trial (Lobban et al., 2017).

The ERPONline study was a single-blind, parallel, primarily online RCT conducted over 48 weeks. It compared ERPonline plus usual treatment with waitlist (WL) control plus usual treatment for individuals with BD. Its objective was to test the feasibility of a randomized controlled trial (RCT) in evaluating a Web-based enhanced relapse prevention intervention (ERPonline). Other objectives included an assessment of the acceptability of ERPonline for people with BD via (1) ERPonline website usage, (2) number and type of adverse events associated with use of the website, and (3) detailed feedback from participants about their experiences of ERPonline to inform future developments. Process and clinical outcomes were assessed to identify those remotely collected measures which were sensitive to change and to explore potential positive and negative impacts of the intervention.

Results indicated that acceptability was high for ERPonline, with data highlighting the importance of the relationship that the users have with Web-based interventions. There was no evidence of ERPonline impacting on clinical outcomes or medication adherence, but relapse rates across both arms were low (15%) and the sample remained high functioning throughout.

Limitations were, despite 280 site registrations, only 145 people consented, and due to ineligibility and drop out, only 96 were randomized. During the trial, there was higher dropout in the ERPonline arm, and survey responses were incomplete for feedback on trial participation (22/49 in WL group, 45%) and for feedback on the ERPonline intervention (17/47 in ERPonline arm, 36%). The bias in responders may have skewed the nature of the feedback, which overall, was very positive.

3. Web-based Integrated Bipolar Parenting Intervention for parents with bipolar disorder (IBPI): A randomized controlled pilot trial (Jones et al., 2017).

The IBPI study was an evaluation of a web-based single-blind randomised controlled trial self-help parenting intervention based on the Triple P-Positive Parenting Programme adapted for bipolar parents. The Triple P intervention was delivered, along with a tip sheet on detecting and coping with mood swings, in addition to treatment as usual (TAU). It was compared with TAU alone. A primary aim of this study was to determine if there was a demand for interventions of this type for this patient group. An additional aim was to determine the effect sizes, for perceived parenting and child behaviour outcomes, to inform a future definitive trial. Where participants were assigned to the waiting list condition, they received the intervention after the active treatment group. Parents reported on their perceptions of parenting behaviour and child behaviour problems at baseline and at 16, 24, 36 and 48 weeks.

Results indicated that it was possible to deliver a web-based parenting approach to bipolar parents and that this approach impacted on both child behaviour and perceived parenting practices. Parents in the intervention group reported improvements in both child behaviour problems and problematic perceived parenting when compared to controls. Statistical comparisons indicated no significant demographic differences for parents or children with respect to group or completer status. Whilst the limited sample sizes of this pilot would have reduced the power to detect differences, improvements with moderate to large effect sizes were obtained in both perceived parenting behaviour and child behaviour problems.

Limitations included: the participant parents being a self-selecting group which may, have been unrepresentative of the general population in their levels of motivation and readiness to change and completer controls having a higher ratio of boys to girls. There was also a higher rate of contact with professional carers for child problems in the treatment arm. Finally, 38% of the sample were lost to follow-up, with more lost from the intervention group when compared to the control (57% vs. 20%). As with the PARADES psychoeducation and ERPOnline studies, it was not possible in the IBPI study to ask participants that had dropped out of the study for their reasons for doing so, as they had stopped responding to communications from the trial teams. Consequently, it was not possible to rule out the possibility that some participants in these studies dropped out because they found aspects of the intervention unhelpful.

Overall sample sizes for the three studies ranged from 96 to 304, with a median sample size of 97 (M=165, SD=119.80). The intended duration of therapy (in weeks) was, 21 sessions for the group study, and, in the case of the online interventions, the number of available modules ranged from 10 to 12 (M=11, SD=1.41). For both online studies, assessed outcomes included recruitment and usage, levels of intervention use, adverse events, and participant feedback.

5.3 Secondary Analysis

A secondary analysis (SA) involves the use of existing data, collected for the purposes of a prior study, to pursue a research interest which is distinct from that of the original work. This may be a new research question or an alternative perspective on an original question (Hinds, Vogel, & Clarke-Steffen, 2013). Consequently, it differs from systematic reviews and meta-analyses, which aim to compile and assess evidence in relation to a common concern or area of practice (Popay, Rogers, & Williams, 1998).

Whilst being a flexible approach, it is still an empirical methodology and applies the same basic research principles as studies that collect primary data. As a result, it has procedural and evaluative steps which need to be followed: research questions are formulated, literature reviews are performed, the research design is devised, inclusion criteria are established and data is collected, analysed and the findings reported (Miller & Brewer, 2003).

Employing a SA for this study presented challenges which were specific to this method. For example, one anticipated difficulty with this strategy had been observed whilst conducting the literature review. This was in relation to the levels of heterogeneity which had been observed between the categories employed to record specific variables. To conduct an empirical analysis, the included studies would need to provide a more homogeneous set of categories for these variables, with data being recorded using the same or a similar instrument. In addition, as the data had been collected by third parties, it was essential that, before use, it was checked for validity and errors, as well as being evaluated for methodological rigour.

In the case of potential sources of bias, two areas were of particular interest: sampling bias and measurement bias, both of which, if unaddressed, could have compromised the generalizability of the original studies and reduced confidence in their findings.

The included studies in the SA were selected using specific inclusion and exclusion criteria. These were defined *a priori,* made as specific as possible and were based upon the chosen theoretical framework, the Health Belief Model (HBM). The goal of which was to minimize the number of subjective decisions made, by the researcher, in regard to study inclusion and to reduce the number of random errors made in study selection (McDonagh, Peterson, & Raina, 2013).

Another issue with the use of a SA involved any variables in the original data set(s) that were not appropriate for use in their original form, due to them being measured on different scales or categories across studies. In these situations, the variables were examined for commonalities and if possible were ‘transformed’ into comparable categories via dichotomisation. If such conversions were not practicable or possible, then the data was excluded from the analysis. Whilst this process allowed for comparison of these variables, it was acknowledged that the process of dichotomization involves the loss of some data resolution and can introduce potential measurement errors amongst any variables which need to be dichotomised (McCullagh, 1980; Whittaker & Agresti, 1985). Dichotomisation also reduces the statistical power (Altman & Royston, 2006) of the study.

In addition, as the generalisability of a SA can be affected by both the original research and the inclusion criteria employed, it was necessary to be well acquainted with the original methods used to acquire the primary samples, as well as being clear about the requirements of the SA. For example, if some of the primary subjects proved to not be suitable for inclusion and a subset of the sample had to be created in the analysis, then this would have affected how representative the sample was of the original study.

To evaluate the circumstances in which the studies were conducted, the context of the data collection in the original studies was examined by asking questions such as, under what circumstances was the data collected? and what was the research burden that was placed upon the participants? This was important to the external validity of the SA as, for example, a participant who has a particularly long questionnaire to complete, may have exercised little care in its completion or may have withdrawn from the study.

Finally, access was needed to the included studies original documentation, data and published results, to allow for the identification of any other limitations. This also allowed for the re-calculation of the descriptive statistics of these studies and for these results to be matched to those published, enabling it to be confirmed that the data being analysed was the same as that which had been published.

5.4 Ethical considerations

Concerns regarding privacy and confidentiality are the among the most often raised objections to SA, although some authors have considered that it is “likely that this obstacle is cited much more frequently than is warranted” (Hedrick, 1988, p. 124). Nonetheless, informed consent cannot be presumed and, because of this, judgements had to be made in regard to whether the re-use of data violated any agreements that were made between the original participants and the primary researchers (Heaton, 1998; Thome, 2012), see Appendix K. Additional judgements were also made regarding the fit between the original and the secondary research questions and whether the new questions shifted the focus of the research too far from that of the original included studies (Long-Sutehall, Sque, & Addington-Hall, 2010). As a result, the researcher had to be ‘ethically aware’ and ensure that all decisions made considered the wellbeing of the original participants and were within the context of the original studies (Grinyer, 2009).

5.5 Demographic & Clinical variables selected for analysis

Whilst the literature contains empirical research relating to the effects of participant demographic and clinical characteristics on usage levels of interventions for mental health conditions in general, little is known in relation to these characteristics and their effects on the usage of PE for BD. As a result, decisions regarding which variables were to be analysed were informed by the modified HBM model and previous research into BD intervention usage. The HBM guided the types of demographic and clinical variables which might influence its four factors of perceived susceptibility, seriousness, benefits and barriers, whilst the previous research, across a range of MH conditions, highlighted specific variables of interest and the effects they might have on intervention usage.

In the case of adherence to BD interventions, the literature indicates that certain demographic correlates have emerged as most likely determinants of usage (Basco & Smith, 2009; Colom et al., 2005; Lingam & Scott, 2002; Perlick et al., 2004). These include, younger age (Edlund et al., 2002; Fornaro et al., 2021; Graff et al., 2008; Henzen et al., 2016; Nicholas et al., 2010; O'Brien et al., 2009; Olfson et al., 2009), ethnicity (Fischer et al., 2008; Memon et al., 2016; Morris et al., 2020; O'Brien et al., 2009; Olfson et al., 2009), level of education (Graff et al., 2008; Olfson et al., 2009), gender (Connell et al., 2006; Graff et al., 2008; Nicholas et al., 2010; Olfson et al., 2009), employment status (de Graaf et al., 2013; Graff et al., 2008) and marital status (Minamisawa et al., 2016; Olfson et al., 2009). The evidence presented in the literature for the variables for age, level of education and ethnicity is consistent, whilst that pertaining to the effects of gender, employment status and marital status is more mixed.

In the case of the clinical variables, the presence of comorbid conditions, particularly substance abuse disorders, have emerged as consistent correlates of non-adherence to pharmacological interventions across a range of MH interventions (O'Brien et al., 2009; Olfson et al., 2009). In addition, the length of time since condition onset (Moon et al., 2012) has been associated with levels of intervention usage in BD but contradictory results have been presented for condition severity (Christensen, 2009; Schimmelmann et al., 2006). As a result of these inconsistencies, candidate variables were divided into two categories: primary variables, Table 5:1, which were consistently supported by previous research, and subsidiary variables, Table 5:2, the evidence base for which was sometimes contradictory.

5.6 Data preparation

Once access had been given to the selected studies, a comprehensive assessment of their data was begun. In addition, protocols, procedures, instruments and variable listings were obtained from the original authors. Descriptive statistics were then calculated for all relevant variables, both to gain familiarity with the data and to ensure the datasets under investigation were the same ones that that been referenced in the original publications.

Table 5:1

Previous research supporting the selection of variables to be analysed

Variable	Citations	Title	Summary	Rationale
Age	Edlund et al., 2002	Dropping Out of Mental Health Treatment: Patterns and Predictors Among Epidemiological Survey Respondents in the United States and Ontario	Subjects were drawn from respondents to community epidemiological surveys carried out in representative samples of the US and Ontario populations. Dropouts were those who had left mental health treatment during the prior year for reasons other than symptom improvement. The surveys also assessed potential dropout correlates: sociodemographic characteristics, attitudes about mental health care, disorder type, provider type, and treatment received.	Age and insurance were the only individually significant predictors, with the highest dropout rates among the young and those without insurance.
	Henzen, Moeglin, Giannakopoulos, & Sentissi, 2016	Determinants of dropout in a community based mental health crisis centre	The aim of this naturalistic descriptive cohort study was to identify the demographic, patient and care-related predictive factors of dropout in a community-based psychiatric crisis centre. 245 consecutive outpatients were included followed-up for 4 to 6 weeks of intensive outpatient psychiatric treatment. Logistic regression models were built to examine the association between dropout and demographic, care and patient-related variables.	Among patient-related variables, younger age raised the risk of dropout (OR = .96; 95 %; p = .002; 95 % CI [.94, .99]).
	O'Brien, Fahmy, & Singh, 2009	Disengagement from mental health services: A literature review	This paper reviews the literature on disengagement from mental health services. It examined how the terms engagement and disengagement were defined, what proportion of patients disengage from services, and what sociodemographic variables predicted disengagement. Both engagement and disengagement appear to be poorly conceptualised, with a lack of consensus on accepted and agreed definitions. Rates of disengagement from mental health services varied from 4 to 46%, depending on the study setting, service type and definition of engagement used.	Young people seemed to be more likely to dropout and miss appointments.
	Nicholas et al. 2010	The ins and outs of an online bipolar education program: A study of program attrition	As part of an ongoing RCT evaluating an online PE program for people newly diagnosed with BD, a qualitative study to identify participants' reasons for nonadherence to, and attrition from an online intervention, as well as a quantitative study investigating predictors of attrition was undertaken. 370 participants were randomly allocated to 1 of 2 active interventions or an attention control condition.	Multiple regression analysis revealed that young age (P= .004) was a significant predictor of attrition (F = 8.08, P< .001).
	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Younger age significantly predicted dropout among patients.
	Graff, Griffin, & Weiss, 2008	Predictors of dropout from group therapy among patients with bipolar and substance use disorders	Using binary and multivariate analyses, baseline data were analysed as part of a randomized controlled trial of integrated group therapy for bipolar and substance use disorders. Patients included 25 women and 36 men, 18–65 years old (mean = 38.3±11.1), and primarily white (92%). They were well-educated (49% graduated from college), yet (54%) were currently unemployed, and 40% had an annual household income under US$ 35,000. Most were unmarried (54% never, 16% divorced, and 2% widowed.)	19.7% of participants failed to complete the group therapy. These were younger (31.5°±11.5 vs. 40.0°±10.4; t(59) = 2.47, p = .02).
Level of education	Graff et al., 2008	Predictors of dropout from group therapy among patients with bipolar and substance use disorders	Using binary and multivariate analyses, baseline data were analysed as part of a randomized controlled trial of integrated group therapy for bipolar and substance use disorders. Patients included 25 women and 36 men, 18–65 years old (mean = 38.3±11.1), and primarily white (92%). They were well-educated (49% graduated from college), yet (54%) were currently unemployed, and 40% had an annual household income under US$ 35,000. Most were unmarried (54% never, 16% divorced, and 2% widowed.)	19.7% of participants failed to complete the group therapy. These were less likely to be college educated (16.7% vs. 57.1%; $\chi^2(1) = 6.32$, p < .02).

	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Low education (0–15 years) was associated with increased odds of dropout from treatment with mental health professionals other than psychiatrists (OR: 1.9, 1,1–3.4).
Ethnicity	O'Brien et al., 2009	Disengagement from mental health services: A literature review	This paper reviewed the literature on disengagement from mental health services. It examined how the terms engagement and disengagement were defined, what proportion of patients disengage from services, and what sociodemographic variables predicted disengagement. Both engagement and disengagement appear to be poorly conceptualised, with a lack of consensus on accepted and agreed definitions. Rates of disengagement from mental health services varied from 4 to 46%, depending on the study setting, service type and definition of engagement used.	The available evidence showed that approximately 30% of patients with mental health problems drop out of contact with services. Associations with disengagement were complex, encompassing sociodemographic variables such as young age and ethnicity.
	Fischer et al., 2008	Longitudinal Patterns of Health System Retention Among Veterans with Schizophrenia or Bipolar Disorder	Data from the VHA National Psychosis Registry data relating to 164,150 veterans with schizophrenia or BD was analysed to identify the characteristics associated with 5 years patterns of intervention survival. Most cohort members (63%) survived the period with no break in VHA healthcare lasting over 12 months. Inconsistent utilization was associated with younger age, no service-connected disability, and less physical comorbidity, regardless of diagnosis. The influence of gender and ethnicity on attrition varied by diagnosis.	Being non-Hispanic Black (OR 1.45, CI 1.4–1.5), of other ethnicity (OR 1.31, CI 1.13–1.51) or of unknown ethnicity (OR 3.13, CI 2.96–3.31) were associated with increased likelihood of a gap in intervention utilisation.
	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Although patient race-ethnicity did not significantly predict dropout from other provider groups in the overall model, several associations between patient race-ethnicity and intervention dropout were evident among patients.
Condition comorbidity	O'Brien et al., 2009	Disengagement from mental health services: A literature review	This paper reviewed the literature on disengagement from mental health services. It examined how the terms engagement and disengagement were defined, what proportion of patients disengage from services, and what sociodemographic variables predicted disengagement. Both engagement and disengagement appear to be poorly conceptualised, with a lack of consensus on accepted and agreed definitions. Rates of disengagement from mental health services varied from 4 to 46%, depending on the study setting, service type and definition of engagement used.	Although a few studies have reported high engagement rates a figure of approximately 30% seems to represent the proportion of patients disengaging from the majority of services studied.
	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Patients who met criteria for ≥2 classes of psychiatric disorders were at significantly elevated risk of dropout from general medical treatment overall (OR: 1.5, 95% CI: 1.0–2.3) and before the third visit (OR: 1.7, 95% CI:1.1–2.7). Psychiatric comorbidity was associated with reduced dropout, however, from psychiatric treatment after ≥3 visits (OR:.5, 95% CI:.0–.8).

Table 5:2

Previous research with mixed evidence for variables to be analysed

Variable	Citations	Title	Summary	Rationale
Gender	Nicholas et al. 2010	The ins and outs of an online Bipolar education program: A study of program attrition	As part of an ongoing RCT evaluating an online PE program for people newly diagnosed with BD, a qualitative study to identify participants' reasons for nonadherence to, and attrition from an online intervention, as well as a quantitative study investigating predictors of attrition was undertaken. 370 participants were randomly allocated to 1 of 2 active interventions or an attention control condition.	Being male was indicative of increased dropout and less usage.
	Connell, Grant, & Mullin, 2006	Client initiated termination of therapy at NHS primary care counselling services.	The main aim of this paper was to provide estimated benchmarks for unplanned endings for primary care counselling services using data drawn from the CORE National Research Database. Due to the problem of missing data, benchmarks were provided for 'declared' therapy endings and 'estimated' therapy endings. 'Declared' therapy endings are where the practitioner provided data; 'estimated' therapy endings took into account missing data where clients were more likely to have had an unplanned rather than a planned ending to therapy.	Found no difference in gender dropout rates.
	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Found no difference in gender dropout rates.
	Graff et al., 2008	Predictors of dropout from group therapy among patients with bipolar and substance use disorders	Using binary and multivariate analyses, baseline data were analysed as part of a randomized controlled trial of integrated group therapy for bipolar and substance use disorders. Patients included 25 women and 36 men, 18–65 years old (mean = 38.3±11.1), and primarily white (92%). They were well-educated (49% graduated from college), yet (54%) were currently unemployed, and 40% had an annual household income under US$ 35,000. Most were unmarried (54% never, 16% divorced, and 2% widowed.)	Found no difference in gender dropout rates.
Employment[1]	Graff et al., 2008	Predictors of dropout from group therapy among patients with bipolar and substance use disorders	Using binary and multivariate analyses, baseline data were analysed as part of a randomized controlled trial of integrated group therapy for bipolar and substance use disorders. Patients included 25 women and 36 men, 18–65 years old (mean = 38.3±11.1), and primarily white (92%). They were well-educated (49% graduated from college), yet (54%) were currently unemployed, and 40% had an annual household income under US$ 35,000. Most were unmarried (54% never, 16% divorced, and 2% widowed.)	Levels of employment made no difference to usage.
	de Graaf et al., 2013	Sociodemographic and psychiatric predictors of attrition in a prospective psychiatric epidemiological study among the general population. Result of the Netherlands Mental Health Survey and Incidence Study-2	In prospective psychiatric epidemiological studies, attrition at follow-up can be selective, and can bias the research findings. Therefore, knowledge of predictors of attrition and of its different types (noncontact, refusal, inability to participate) is of importance. By means of regression analyses, predictors of attrition were studied in the first 3-year follow-up of the second Netherlands Mental Health Survey and Incidence Study (NEMESIS-2), a prospective psychiatric epidemiological study among 6646 subjects of the general population aged 18–64 years. Baseline sociodemographic characteristics, physical health, mental disorders and their clinical characteristics, and experience with the previous interview were studied as predictors of attrition and of its different types.	Observed that increased levels of employment led to less usage.

Length of Time Since First Diagnosis	Moon et al., 2012	Dropout rate and associated factors in patients with bipolar disorders	The study participants were 275 patients with DSM-IV bipolar disorders, receiving planned maintenance treatment between January 2005 and December 2007. The rates of dropout in patients were prospectively examined for 3 years. The factors affecting the dropouts were analysed using a Cox regression model. The dropout rates were 10.9%, 20.4%, 24.7%, 33.8%, 44.0%, and 50.2% at 1, 3, 6, 12, 24, and 36 months after treatment entry, respectively. Past psychotic symptoms (HR 0.523, 95% CI 0.339–0.807), longer illness duration (HR 0.975, 95% CI 0.955–0.966), past psychiatric diagnoses (bipolar disorder, HR 0.242, 95% CI 0.120–0.490; other axis I disorders 0.434, 95% CI 0.268–0.701), and a past history of dropouts (HR 1.746, 95% CI 1.028–2.965) significantly influenced the time to dropout in bipolar patients.	Longer illness duration (HR 0.975, 95% CI 0.955–0.966) was associated with reduced usage.
Marital status	Olfson et al., 2009	Dropout from Outpatient Mental Health Care in the United States	Data came from the National Comorbidity Survey Replication (NCS-R), a nationally representative household survey. Respondents in MH treatment in the12 months (n=1,664) before interview were asked about dropout. This was defined as quitting treatment before the provider wanted. Cross-tabulation and discrete-time survival analyses were used to identify predictors.	Found being married was associated with *increased* levels of intervention dropout.
	Minamisawa, Narumoto, Yokota, & Fukui, 2016	Evaluation of factors associated with psychiatric patient dropout at a university outpatient clinic in Japan.	Patient dropout from treatment can lead to a deterioration in clinical condition, thereby increasing the need for more intensive therapy that incurs substantial social and economic losses. The aim of this study was to identify factors related to psychiatric patient dropout at a university outpatient clinic in Japan. A retrospective examination of 1626 patients who were diagnosed with either a mood disorder (International Classification of Diseases, 10th revision, code: F3) or an anxiety disorder (F4), between April 2010 and March 2013 was conducted. The baseline characteristics of the patients, treating psychiatrist experience in years, and sex concordance between the patients and their treating psychiatrists were analysed using Cox regression models.	Found being married was indicative of *reduced* dropout.
Severity of Health Problem	Christensen, 2009	Adherence in Internet Interventions for Anxiety and Depression: Systematic Review	The aims of this paper were to review the adherence literature, a range of mental health disorders, with respect to internet interventions and to investigate the rates of dropout and compliance in RCTs of anxiety and depression studies. A systematic review of RCTs using Internet interventions for anxiety and depression was conducted, and data was collected on dropout and adherence, predictors of adherence, and reasons for dropout. Relative to reported rates of dropout from open access sites, the present study found that the rates of attrition in RCTs were lower, ranging from approximately 1 - 50%. Predictors of adherence included disease severity, treatment length, and chronicity. Very few studies formally examined reasons for dropout.	Dropout rate decreased with increased severity of health condition.
	Schimmelmann, Conus, Schacht, McGorry, & Lambert, 2006	Predictors of Service Disengagement in First-Admitted Adolescents with Psychosis	The aim of this study was to assess the risks and predictors of service disengagement in adolescents with first-episode psychosis receiving their first treatment. The Early Psychosis Prevention and Intervention Centre (EPPIC) admitted 157 adolescents, ages 15 to 18, with first-episode psychosis from January 1998 to December 2000. Treatment at EPPIC spanned an average of 18 months. Data were collected from (n=134) patients' charts using a standardized questionnaire. Baseline and treatment predictors of service disengagement were examined via Cox proportional hazards model. The results indicated that the Kaplan-Meier 18-month risk of service disengagement was 0.28. A lower severity of illness at baseline (hazard ratio [HR] = 0.2; 95% confidence interval [CI] 0.1Y0.4), living without family during treatment (HR = 4.8; 95% CI 2.1Y11.2), and persistent substance use during treatment (HR = 2.6; 95% CI 1.1Y5.9) contributed significantly to predicting service disengagement.	Schimmelman et al. found the dropout rate increased in patients with a lower severity of illness.

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[1] In contrast to these results, the literature review found, under the category of 'Structured Activity', employment to be a significant factor in the prediction of the delivery modality used.

Proxy and Dichotomised variables

One of the problems with secondary data analysis relates to the use of categorical variables and that the included studies may have employed differing categories in their analyses. In this study, the included datasets were examined to observe how the categories had been recorded in each of the included studies to see if they were comparable. If they did differ they were then recategorized or dichotomised and transformed into another variable.

An examination of the included studies indicated that the variables level of Education (Table 5.3), types of employment (Table 5.4), ethnicity (Table 5.5) and marital status (Table 5.6) had differing categories between the selected studies. To make them comparable, it was decided to dichotomise these variables for the purposes of data analysis.

Table 5:3

Variations in Coding Between Levels of Education in the Included Studies

Level of Education					
ERPOnline		IBPI		PARADES	
Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables
No formal education		<= Year 6		<= Year 6	
CSE/O Level/GCSE	School	Year 7-11 without GCSE	School	Year 7-11 without GCSE	School
		GCSE		GCSE	
A Level		Further Education without completing		Further Education without completing	
Degree		Further Education completed		Further Education completed	
Post Graduate diploma	FE/HE	Higher Education without completing	FE/HE	Higher Education without completing	FE/HE
PhD		Higher Education completed		Higher Education completed	
		Post Grad without completing		Post Grad without completing	
		Post Grad completed		Post Grad completed	

Table 5:4

Variations in Coding between Employment Types in the included studies

Employment type					
ERPOnline		IBPI		PARADES	
Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables
Full Time Part Time	In employment	Full Time Part Time Self Employed	In employment	Full Time Part Time Self Employed	In employment
Voluntary Work Housewife/Husband Student Unemployed Retired	Out of employment	Voluntary Work Unemployed Sick/Disability Retired Student	Out of employment	Voluntary Work Unemployed Sick/Disability Retired Student	Out of employment

Table 5:5

Variations in coding between ethnicity in the included studies

Ethnicity					
ERPOnline		IBPI		PARADES	
Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables
White British	White British	White British White Irish	White British	White British	White British
Other Black British Caribbean Asian British Indian Other Mixed African Other Black Pakistani Other Asian Other not listed	Other	Other White Pakistani Other Mixed Other	Other	Chinese British Mixed White Black Caribbean Mixed Other White Other Black British Black Caribbean Black African Black Other Asian Indian Asian Pakistani	Other

Table 5:6

Variations in Coding between Marital Status in the included studies

Marital Status					
ERPOnline		IBPI		PARADES	
Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables	Original Variables	Dichotomised Variables
Not recorded	Not recorded	Single Married Cohabiting	In relationship	Married	In relationship
		Civil Partnership Separated Divorced Widowed	Out of relationship	Widowed Divorced Separated Never Married	Out of relationship

In the case of the variable number of comorbidities, a decision was made to categorise and dichotomise this variable. This decision was made because, if the presence of one or more comorbidities influenced the usage levels of interventions, this would be more instructive than would be an assessment of the effect of increasing numbers of CMs. This was particularly so as most participants had 0 or 1 CM. The variable number of CMs was dichotomised into 2 values. These were ‘no CMs’ and ‘1 or more CMs’, see Table 5.7 below.

Final list of included independent variables (IV)

The final list of variables included in the analysis is detailed in Table 5:7 below.

Table 5.7

Demographic and Clinical variables employed for participant comparison

Demographic Variables		Operationalisation of variable
	Age	Scale variable
	Gender	Nominal, dichotomous variable with two options: male / female
	In/out of relationship – Relationship proxy	Nominal, dichotomous variable with two options: In/Out of relationship
	In/out of structured activity – Employment proxy	Nominal, dichotomous variable with two options: In/Out of structured activity
	Years of education (Categorical data - Years)	Nominal, dichotomous variable with two options: School / HE or FE
	Ethnicity	Nominal, dichotomous variable with two options: White British or Other
Clinical Variables		
	Diagnosis	Nominal, dichotomous variable with two options: BPI versus BPII
	Age of first onset	Scale variable
	Presence (or absence) of comorbidities	Nominal, categorical variable with two categories: No CMs and >=1 CM.

Operationalisation of intervention usage (Dependent Variable)

Usage analyses of interventions frequently utilise variables such as, in the case of online interventions, the number of user log-ins, total time spent using an intervention, the number of pages or modules accessed and, for group interventions, the number of sessions attended (Miller et al., 2019). In this work, due to differences between the studies, where one was a group intervention and the others were online interventions, the term usage needed to be operationalized in two different ways. In the case of the online interventions, it was operationalized as the *number of modules completed*, which have been shown to correlate with outcomes in interventions that targeted depression (Andersson et al., 2005; de Graaf et al., 2009; Meyer et al., 2009; Spek et al., 2008; Spek et al., 2007) and anxiety conditions (Carlbring et al., 2005; Furmark et al., 2009; Titov, Andrews, Choi, Schwencke, & Mahoney, 2008; Titov, Andrews, & Schwencke, 2008; Van Spijker et al., 2014). In the case of group interventions, this was operationalized as the *number* of *sessions* attended[40].

5.7 Data Analysis

All data was screened for normality, outliers and the presence of missing values before analysis. To assess the homogeneity of the data a graphical examination was conducted in SPSS by plotting the variables on boxplots, histograms and Q-Q plots[41] (Coakes & Steed, 2007, p. 31). In the case of problematic data values, which deviated so much from the other observations that they aroused suspicion, these were designated as outliers (Hawkins, 1980). Outliers were operationalized as any data points found outside either the 3rd quartile + 1.5*interquartile range or 1st quartile – 1.5*interquartile range[42] (Starnes & Tabor, 2018), see Figure 5:1.

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[40] Using the variable usage in this manner made the implicit assumption that all of participants had completed each session they had attended. However, contact with the original researchers indicated the validity of this assumption, as those participants who had attended specific sessions had been recorded as staying to the end.

[41] To examine the deviations of the cumulative probabilities of the data from that expected from a theoretical normal distribution. In the case of a perfectly normal variable, the observed data points fell exactly on the line of theoretical normality, with any deviation from this line indicating a deviation from normality.

[42] The interquartile range was calculated by taking the difference between the 75th and 25th percentile in the row labelled Tukey's Hinges in the SPSS output.

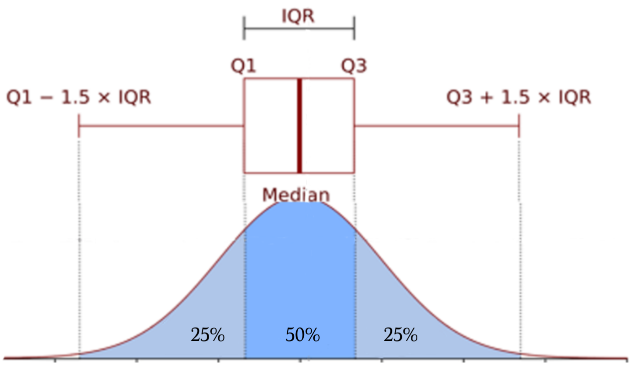

Figure 5:1

Operationalisation of outliers

Outliers were removed from the dataset due to their effect of increasing the error variance and reducing the power of the statistical tests (Moore, Notz, & Fligner, 2013). In addition, if they were non-randomly distributed, they could influence the skew and kurtosis of the variables and decrease normality, altering the likelihood of a Type I or Type II error being made. Finally, they could also seriously bias or influence estimates that may be of substantive interest, see Appendix J.

For the analyses, participants with complete data on all relevant variables, see Table 6.2, were included. In the cases of IBPI (Jones et al., 2017) and ERPOnline (Lobban et al., 2017), the original researchers assumed that any missing data was missing at random (MAR) and estimated parameters were based on maximum likelihood (ML) imputation. For the PARADES study (Morriss et al., 2016), to enable all participants with outcome data to be included in the analyses, missing baseline response values were imputed using simple (deterministic) imputation. Whilst the number of missing values in the data was found to be small, the small size of the online intervention datasets meant that a decision was made to employ pairwise deletion (PD) in the empirical study. This was to minimize the loss of data that would occur in listwise deletion (LD) and to maximize the data available on an analysis-by-analysis basis.

It was also anticipated that, because of the nature of some of the clinical variables, a positive or right skew would be seen. This was because, in the case of the number of past episodes or number of comorbidities, more individuals will have experienced a lower number of these events than a higher number. To assess these variables their histograms were reviewed and, if skewed, consideration was given to the application of a mathematical transformation (square root or logarithmic). However, as transformed data is more difficult to interpret (Lee, 2020) and whilst accepting that transformations can resolve issues with outliers and remedy failures of normality, linearity, and homoscedasticity, Tabachnick and Fidell (2001) do not recommend their use. Other studies have indicated the Pearson correlation to be insensitive to violations of the basic assumption of normality and that a failure to meet those basic assumptions has little effect upon the obtained distributions of the resulting correlation coefficients (Havlicek & Peterson, 1976). As a result of this, a decision was made to not transform the variable number of past episodes and to test the data with both parametric (Pearson's correlation[43]) and non-parametric (Spearman's correlation[44]) tests, to observe if data skew was influencing the results.

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[43] Pearson correlation evaluates the linear relationship between two continuous variables.

[44] Spearman correlation evaluates the monotonic relationship between variables and is based on the ranked values for each variable rather than the raw data.

The aim of this study was to answer the research question of "*Are the demographic and clinical characteristics of individuals linked to patterns of usage in research trials of self-management PE interventions for BD, when delivered by the modalities of group and online?"* To answer this question, the association between the candidate predictors (IV's) and the number of sessions/modules attended/used (DV) was evaluated using bivariate (Pearson) and Spearman's correlations for each study. Checks were made for the presence of multicollinearity and then, for any predictors which had exhibited significant correlations ($p<.05$) with the DV, a regression analysis was applied to determine the contribution these predictors had made in terms of explaining the DV. All variables were examined for effect size, as this indicated the size of the relationship between the two variables. It is also independent of sample size[45]. In the event of non-significant results, a variable with a large, or small, effect size may indicate that the sample size was not large enough to reach significance.

As it was necessary to operationalise the DV of intervention attendance in [two] different ways, a decision was made to compare results between the included studies via a narrative discussion.

5.8 Ethical approval

Ethical approval was obtained for this PhD project from the Lancaster University Faculty of Health and Medicine Research Ethics Committee (FHMREC) on 19th June 2018 (FHMREC Reference: FHMREC17097).

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[45] A test of significance "confounds" the size of the effect with sample size, whereas effect size separates the two and just looks at how big the actual difference is regardless of the sample size.

Ethical considerations are detailed in Appendix K and a copy of the approval letter is attached to the thesis as Appendix L.

5.9 Summary

This chapter has examined the choice of data collection methods, the study selection criteria and the ethical issues associated with the use of a SA. It has also discussed how the IVs were selected for analysis, the cleaning of the datasets and the operationalisation of the DV and the methods of data analysis. Chapter 6 will discuss the results from this analysis.

6 Results

6.1 Introduction

The purpose of this quantitative correlational study was to understand how the levels of intervention usage, across the delivery modalities of group and online, in psychoeducational (PE) research studies for bipolar disorder (BD), were related to the demographic and clinical characteristics of the participants. This chapter presents the results from the secondary analyses of the PARADES group intervention (Morriss et al., 2016) and the IBPI (Jones et al., 2017) and ERPOnline (Lobban et al., 2017) online interventions. Throughout the chapter the results are categorised by the intervention modality.

The chapter begins with a descriptive statistic used to assess participant data for the presence of any outlying data that could affect the data analysis. It continues with the descriptive statistics that were used to identify the characteristics of the datasets, before concluding with inferential analyses which were conducted to answer the research question. The inferential statistics consisted of Pearson and Spearman's correlations, which were used to measure the associations between each independent variable (IV) and the dependent variable (DV). In addition, regression analyses, where appropriate, were used to assess the prediction of intervention usage by any IV's which had exhibited significant correlations with the DV. The chapter concludes with a summary of the results.

6.2 Results

The datasets analysed included participants with data in the relevant variables. Any participants with missing data were excluded via pairwise deletion in SPSS. The initial exploratory analyses, conducted to evaluate the distribution of these variables, showed that the variables number of past episodes and number of modules completed, contained some outliers which were skewing the data (see Table 6:1). After reviewing these cases with the respective principal investigators (PI) of the studies, a total of 16 data points were excluded from analysis and flagged as outliers. The final sample was composed of 242 participants.

Table 6:1

Outliers

Study	Number of outliers	Variable	Range
PARADES	3	Number of past episodes	100-214
IBPI	4	Number of past episodes	114-180
ERPOnline	3	Number of modules completed	1386-3203
	6	Number of past episodes	129-198

The demographic characteristics assessed were gender, ethnicity and level of education. No differences were observed in terms of gender distribution (*p*>.05) between the participants from the three studies. Regarding participant age, post-hoc comparisons indicated that the age of the participants in the ERPOnline study was significantly younger than those from the PARADES study (Table 6.2).

Table 6:2

Descriptive Statistics

	Parades (n=150)	ERPOnline (n=47)	IBPI (n=45)	*F, Kruskal-Wallis* or Chi-Square
Age at Interview, mean (SD)	43.80(11.32)[a]	39.75(11.12)	37.05(6.02)	7.70***
Female, n (%)	88(60)	19(60)	33(77)	4.29
White British ethnicity, n (%)	135(92)	23(74)	37(88)	8.79***
In further or higher education, n (%)	96(65)	31(97)	36(84)	16.32***
In FT or PT employment, n (%)	35(26)	22(69)	29(67)	34.37***
Age of first onset, years (SD)	28.08(12.38)	21.68(11.62)[c]	28.05(8.24)	3.93***
Individuals with absence of Comorbidities, n, (%)	71 (52)	16 (47)	14 (42)	1.04
No of past episodes, mean (SD)	23.65 (17.61)	23.03(25.53)	22.23(18.99)	
No of past episodes, median (IQR)	20(21.5)	15(24)	16(22)	2.17[b]

Note: **p*<.05, ***p*<.01, ****p*<.001. [a]Average age of PARADES study was significantly higher than average age of IBPI. [b]Kruskal-Wallis test. [c]ERPOnline Age of first onset was significantly lower than Parades or IBPI.

In terms of ethnicity, participants in ERPOnline were less likely to be White British than in PARADES or IBPI.

Regarding education, fewer participants in the PARADES (group) intervention had studied at further or higher levels than in the IBPI or ERPOnline studies.

In the case of the clinical characteristics, the participants in the PARADES (group) and IBPI (Online) interventions were of older age at condition onset than those in the ERPOnline study. As a result, participants in these groups had experienced BD for 7 and 9 years less than the participants in the ERPOnline study respectively.

Correlation analyses

To evaluate the relationship between the demographic and clinical variables and levels of intervention usage, bivariate Pearson correlations (parametric) and Spearman's rank-order correlations (non-parametric), were conducted for both delivery modalities. In the case of the group intervention the dependant variable (DV) was measured by the number of sessions attended and, for the online interventions, the number of modules used, see Table 6:3 and Table 6:4.

Both Pearson and Spearman's' correlation coefficients gave significant correlation values for age at Interview and level of education in the PARADES study. Differences in the value of the correlation results were expected due to the differing assumptions made by the two tests in relation to the data[46].

Regression Analyses

PARADES psychoeducation study (Group intervention)

When entered in a regression simultaneously, age and level of education explained 8% of the total observed variance (F(2,144) = 6.74, p<.002), see Table 6.5. Age was a significant predictor of intervention usage (p<.04), with a unit increase in age being associated with a .16 increase in the number of sessions attended. Age also significantly and uniquely explained 5% of the variance. When level of education was entered into the model, it was also a significant predictor of attendance (p=.011), with a unit increase being

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[46] In the case of Spearman's' correlation, the variables tend to move in the same/opposite direction but not necessarily at a constant rate as would be expected in a linear relationship.

associated with a 3.3x increase in the number of sessions attended. It explained 4% of the total shared variance.

IBPI & ERPOnline

No regression analyses were conducted for the online studies due to there being no significant correlations with the number of modules completed, see section 6.2.1.

Table 6:3

Pearson correlation with Intervention Usage Levels

		Age at interview	Education Level (Stat. only or FE/HE)	Ethnicity (White Brit/ other)	No of CMs (0 or <=1)	Gender (F)	Employed (FT, PT / Other)	No of past episodes	Age at first MDE, Manic or Hypo episode
PARADES*	Correlation	.208**	.178**	-.073	-.117	.028	.035	-.114	.089
	N	147	147	146	137	147	133	137	141
IBPI*	Correlation	.062	-.263	.191	-.004	.014	-.121	-.008	.074
	N	35	35	35	28	35	35	33	35
ERPOnline*	Correlation	-.211	.163	-.230	.271	.087	-.213	-.154	-.163
	N	35	35	34	35	35	35	34	33

Notes: * After exclusion of outliers and missing data, ** Correlation is significant at the .05 level

Table 6:4

Spearman's correlation with Intervention Usage Levels

		Age at interview	Education Level (Stat. only or FE/HE)	Ethnicity (White Brit/ other)	No of CMs (0 or <=1)	Gender (F)	Employed (FT, PT / Other)	No of past episodes	Age at first MDE, Manic or Hypo episode
PARADES*	Correlation	.220**	.117**	-.075	-.136	.007	.034	-.081	.010
	N	147	147	146	137	147	133	137	141
IBPI*	Correlation	.110	-.128	.137	-.104	.094	-.017	-.153	.132
	N	35	35	35	28	35	35	33	35
ERPOnline*	Correlation	-.148	.282	-.206	.166	.007	-.221	-.031	-.075
	N	35	35	34	35	35	35	34	33

Notes: * After exclusion of outliers and missing data, ** Correlation is significant at the .05 level

Table 6.5

Multiple Regression Results for Number of Sessions Attended (PARADES)

No of sessions attended	B	95% Confidence Interval for B		SE	β	P Value	% Shared variance explained	R^2	Adjusted R^2
		LL	UL						
Model								.086	.073
Constant	2.5	-2.8	7.9	2.7	-	-	-		
Age	.16	.05	.27	.05	.23	.004*	4.3		
Education	3.4	.79	5.9	1.3	.21	.011*	4.2		

Note: * p<.05

For the PARADES study age and level of education were significantly and positively associated with the number of sessions attended, *p*<.05. Thus, the number of sessions attended increased with age and level of education. These predictors were uniquely associated with 5% and 4% of the shared variance respectively.

In the case of the IBPI and ERPOnline (Online interventions), no significant correlations were observed between the number of modules completed (DV), and any of the analysed variables. This may in part have been linked with the smaller number of participants in these studies, when compared to those in the PARADES psychoeducation study. As a result, it was not possible to be definitive about the null findings observed. However, this study gives some indications of the relationships which may be expected in future studies.

Age

When the association between age and usage levels were considered, the non-significant Pearson correlation for age in ERPONline ($r_{pearson}$ =-.211, $r_{spearman}$=-.148), indicated that the older individuals in this study used this digital intervention *less* than younger participants. In the case of the significant PARADES psychoeducation ($r_{pearson}$ =.208, $r_{spearman}$=.220), and non-significant IBPI studies ($r_{pearson}$ =.062, $r_{spearman}$=.110), older participants used these interventions more than younger participants.

Level of education

The data obtained from the variable level of education was inconclusive, with the (significant) PARADES ($r_{pearson}$=.178, $r_{spearman}$=.117) and (non-significant) ERPOnline ($r_{pearson}$ =.163, $r_{spearman}$=.282) results indicating that increased use of an intervention was associated with increased education. The results for the IBPI study ($r_{pearson}$=-.263, $r_{spearman}$=-.128) indicated that usage of the intervention decreased as the level of education increased.

Presence of Comorbidities

This variable was not significant across all three studies and exhibited small effect sizes in the PARADES ($r_{pearson}$=-.117, $r_{spearman}$=-.136) and IBPI ($r_{pearson}$=-.004, $r_{spearman}$=-.104) studies. These studies also indicated that, as the absence/presence of comorbidities increased, from zero to one or more, the usage of the interventions decreased. In the case of the ERPOnline study the (Pearson) effect size was of a medium magnitude ($r_{pearson}$=.271, $r_{spearman}$=.166) and the results indicated that, as the absence/presence of comorbidities increased, the usage of the intervention increased.

Gender

No significant results were observed for gender and intervention usage across any of the included studies with all reporting small effect sizes (PARADES psychoeducation ($r_{pearson}$=.028, $r_{spearman}$=.007), IBPI ($r_{pearson}$=.014, $r_{spearman}$=.094) and ERPOnline ($r_{pearson}$=.087, $r_{spearman}$=.007) These results indicated that participants in the included studies were equally likely to use the intervention types regardless of their gender.

Employment

In the case of employment this variable was not statistically significant in any of the studies and exhibited small effect sizes in the PARADES psychoeducation ($r_{pearson}$=.035, $r_{spearman}$=.034) and IBPI ($r_{pearson}$=-.121, $r_{spearman}$=-.017) studies. In the ERPOnline study it exhibited a medium effect size ($r_{pearson}$=-.213, $r_{spearman}$=-.221). Surprisingly, and in contradistinction to the majority of the literature, it also indicated that when employment was present the usage of the online IBPI and ERPOnline interventions decreased.

Age of first onset

The variable age of first onset was not significant in either Pearson or Spearman correlations across any of the analysed studies, but the Pearson effect sizes were similar between PARADES ($r_{pearson}$=.089, $r_{spearman}$=.010) and IBPI ($r_{pearson}$=.074, $r_{spearman}$=.132). This indicated that increased use of an intervention was associated with a later age of BD onset, although effect sizes were small. In the case of the ERPOnline study effect sizes were larger

($r_{pearson}$=-.163, $r_{spearman}$=-.075) and indicated that as the age of first onset increased the intervention was used less.

Number of past episodes

No significant correlations were observed for the variable number of past episodes and intervention usage across any of the included studies, with all reporting small (Pearson) effect sizes (PARADES psychoeducation ($r_{pearson}$=-.114, $r_{spearman}$=-.081) IBPI ($r_{pearson}$=-.008, $r_{spearman}$=-.153) and ERPOnline ($r_{pearson}$=-.154, $r_{spearman}$=-.031). Results indicated that as the number of past episodes increased, participants in the included studies were less likely to use the intervention types.

Ethnicity

No significant results were observed for ethnicity and intervention usage across any of the included studies. The results for the PARADES psychoeducation ($r_{pearson}$=-.073, $r_{spearman}$=-.075) and IBPI ($r_{pearson}$=.191, $r_{spearman}$=.137) studies reported small effect sizes and the ERPOnline ($r_{pearson}$=-.230, $r_{spearman}$=-.206) study a medium effect size. These results were consistent with the literature, where health disparities between individuals of white and non-white ancestry are well documented. In this case, an examination of the ethnicity data from the three included studies[47] indicated that the number of participants of non-white origin was very low and that these

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[47] In the IBPI study active intervention participants arm 87% of participants were white British, 6.4% were white Irish or white other and 6.4% were Pakistani or from another ethnic group. In the PARADES psychoeducation and ERPOnline studies 92% of participants in the active intervention arm were white.

correlations were not very meaningful, making it difficult to draw any conclusions from the data.

Summary

The results of this analysis indicated that, in the case of the PARADES group study, the variables age and level of education were significantly correlated with increased intervention usage. These variables, when entered together into a regression model, were both observed to be significant predictors of levels of session attendance. Gender, ethnicity, employment, number of past episodes and the presence or absence of comorbidities had no statistically significant effect on the number of sessions attended.

In the case of the online interventions, none of the variables investigated exhibited significant correlations with the number of intervention modules accessed.

In Chapter 7, these results will be discussed in terms of the extent literature with recommendations being made for future research.

7 Discussion

7.1 Introduction

This PhD has examined the effects of participant demographic and clinical characteristics on the usage levels of psychoeducational interventions for bipolar disorder, when delivered by the modalities of group and online. Its main objectives were to:

i). Use a quantitative systematic literature review, to identify if the demographic and clinical characteristics of participants in research studies of psychoeducation (PE) for bipolar disorder (BD) differed between the delivery modalities of individual, group and online.

ii). Use a quantitative correlational study, to explore which participant characteristics were associated with participant usage levels of PE group or digital interventions for BD.

The aim of PE interventions for BD is to educate individuals about their condition, via the didactic teaching of information. This typically focusses on information about BD and its treatment, medication adherence, early recognition and management of the symptoms of relapse, coping strategies and the promotion of lifestyle regularity (Rouget, 2007). Other issues frequently presented include recurrence rates, medication side effects, the dangers of BD and substance abuse and the importance of maintaining daily routines as well as, suicide risks and social problems associated with the condition (Bond & Anderson, 2015; Jones, 2004). PE interventions for BD can be delivered by differing modalities with these including individual, group, and online.

Usage levels of PE interventions for BD, regardless of their delivery modality, are often very variable (Donkin et al., 2011). This is important as increased levels of participant usage of these interventions has been linked to increased positive clinical outcomes, via the maximising of participant exposure to the interventions therapeutic content. As a result of this, an understanding of the factors which may influence these levels is important.

This PhD was the first quantitative correlational study of secondary data to investigate whether the demographic and clinical characteristics of participants were associated with differing levels of intervention usage in PE research studies, delivered by group and online delivery modalities, for BD. It was guided by philosophical positioning of post positivism and the theoretical framework of the Health Belief Model (HBM). Consistent with this paradigm, it included an element of researcher interpretation (Putnam, 1981). This was in terms of the decisions made, to make the independent variables, levels of education, types of employment, ethnicity and marital status compatible for analysis across the included studies, see section 5.7.1. In addition, due to the differing nature of the group and online interventions, the dependent variable usage was operationalised in two different ways. In the case of the group intervention, it was operationalized as the *number* of *sessions* attended and in the online intervention as the *number of modules completed*.

7.2 Findings from the quantitative systematic literature review

The results from the quantitative systematic literature review indicated that a larger percentage of females participated across the investigated delivery modalities of face to face, group and online. There were also indications that individuals with higher levels of structured activities were more likely to engage with online interventions. Regarding clinical factors, age of first onset, age and diagnosis type did not have a significant effect on the choice of delivery modality, but all exhibited medium effect sizes. Individuals who had a later age of first onset being more likely to engage with group delivery modalities. The variable relationship status was not significant and yielded a small effect size. Finally, there were indications that participants who had received higher levels of education were more likely to participate with online interventions. Whilst this variable was not significant, it exhibited a large effect size and was congruent with the majority of the literature.

In the case of the recruitment methods used, it was observed that individual and group interventions recruited, predominantly, from hospital units and outpatient departments, with online interventions recruiting via the internet. As a result of these differences, the sampled populations may have been biased, as internet recruitment has been shown to have the potential to over represent young white women (Whitaker et al., 2017). Individuals who had experienced higher levels of education were also overrepresented.

7.3 Findings from the secondary data analysis

Results from the PARADES study indicated that the variables age and level of education were significantly correlated with increased levels of intervention usage. This indicated that participants attended more group sessions as either their age and/or level of education increased. However, the effect sizes associated with these effects were relatively small, with the value of R^2 for the overall model being 8% with an $R^2_{adjusted}$ of 7%. Age individually accounted for 5% of the shared variance and education 4%.

Age

The finding that age had a positive correlation with group intervention usage, and that older individuals used the PARADES psychoeducation group intervention *more* than younger participants was consistent with the literature (Fornaro et al., 2021). In a retrospective longitudinal follow-up study, Fornaro (2021) followed up 131 outpatients over 6 months: 78 with major depressive disorder (MDD), and 53 with BD. In this study, younger age was observed to predict premature attrition and less usage of an intervention significantly and positively. The likelihood of younger participants using an intervention less also concurred with age as a modifying factor in the HBM. As previously discussed, this model proposes that individuals weigh the benefits of and barriers to an intervention and, if they perceive the benefits to outweigh their perception of these barriers, they are then more likely to decide to use that intervention. This was supported by the observations of Greene (2018) who, in a study which investigated participant readiness to seek formal mental health services, across a range of mental health conditions, found that the perception of barriers to accessing a MH service was significantly greater in younger participants, aged 25 to 39, than it was in participants aged 40 to 70 years.

The results for the online studies were mixed, with the non-significant result obtained from the ERPOnline study, indicating that increasing participant age, correlated with a decreased use of the intervention. This was in agreement with Bauer et al (2018) who demonstrated that the internet and online interventions are used less frequently by older adults, with 47% of older adults using the Internet against 87% of younger adults. However, the IBPI study indicated that intervention usage increased with increasing age, albeit with a small effect size. This observation concurred with other studies of BD individuals which have shown small differences, with regard to age, between completers and non-completers of an intervention (Depp et al., 2015; Hidalgo-Mazzei, 2016). Given these differences, both within the literature and within this study, it is apparent that more research is needed to understand these results.

Whilst the effects of age are important considerations in the dissemination of online and group PE interventions for BD, it is important to ensure that the type of intervention prescribed does not exacerbate health disparities based on age.

Level of education

Participants who had experienced longer periods of education also exhibited significantly higher levels of intervention usage in the PARADES study, an observation which was consistent with previous research (Karanti et al., 2021). In the case of the ERPOnline study, non-significant correlation results also indicated that increased use of this intervention was associated with increased levels of education. However, the IBPI result, indicated that intervention usage decreased with increasing levels of education.

In the case of less educated individuals, previous research has suggested that lower levels of intervention usage may be due to the effects that PE interventions have on the HBM construct of self-efficacy, with this corresponding to a reduction in a participant's perception of their ability to effect personal change (Reinwand et al., 2015). One hypothesis for this is linked, across a range of mental health conditions, to the lifestyles of lower educated individuals (Cowell, 2006; Vlismas, Stavrinos, Panagiotakos, Semba, & Bloem, 2009). This assumes that these individuals may start an intervention with the aim of changing their health behaviours but, upon receiving information from the intervention tutor, in regard to the extent of the required changes, may feel overwhelmed (Crutzen & Ruiter, 2015). This may then decrease their self-efficacy, their capacity for change and their motivation to continue to participate in the intervention, with this resulting in lower usage levels. Alternatively, others investigating PE intervention usage for anxiety and depression, have proposed that less educated participants may be less likely to believe that they *can* change their behaviour and thus, may perceive the recommendations suggested by an intervention as being less feasible, causing them to use the intervention less (Christensen, 2009; Eysenbach, 2005). From the perspective of the intervention itself, the content may not be appropriate for all individuals, with some individuals, who may have experienced less education, potentially finding the content inaccessible and subsequently using the intervention less. Interestingly, in the quantitative systematic literature review, the levels of education for users of both group and individual interventions were similar but lower than that observed in online intervention users, although this result was not significant. However, the IBPI study results indicated that usage levels decreased with increasing amounts of education.

Regarding the observed correlation values, the Pearson results between PARADES and ERPOnline were similar, whilst Spearman results were not. This may have been because of the skew in the data due to the distribution of individuals who had experienced higher education. In the Parades study 65% of the participants had experienced higher education, in IBPI 84% and in ERPOnline 97%. These were compared to a UK average of 42% graduates (Office for National Statistics, National Records of Scotland, & Northern Ireland Statistics and Research Agency, 2016).

Whilst the IBPI study results indicated increased levels of education to be associated with decreased usage of interventions and differed from those results obtained for the PARADES psychoeducation and IBPI studies, the balance of evidence in the literature is that increasing levels of education are linked to increased intervention usage and attendance. As was the case with age, more research is needed to understand how consistent these results are and why there may be exceptions.

Presence of comorbidities

The variable presence of comorbidities was non-significant across all three studies with the ERPOnline study indicating, albeit with a small effect size, that the presence of one or more comorbidities increased the level of intervention usage, a result which differed from most of the literature. In the case of the PARADES psychoeducation and IBPI studies the results for the presence of comorbidities were in agreement with the literature, and highlighted that individuals, with one or more comorbidities, were less likely to engage with therapeutic interventions (Miklowitz, 2009).

Unfortunately, in the datasets analysed, the types of comorbid condition were not available, only the number. However, in the wider literature, the most cited overrepresented comorbid conditions in individuals with BD were, anxiety disorders, impulse-control disorders, and drug and alcohol problems (Parker, 2010). In the case of anxiety disorders, these are highly comorbid with BD, and exhibit a 93% lifetime prevalence (McIntyre et al., 2006) and a 50% prevalence over a 12-month period (Spoorthy, Chakrabarti, & Grover, 2019). This has resulted in others arguing[48], Schlembach et al (2016), in agreement with the Health Belief Model, that the presence of comorbidities may impact on a participant’s confidence to engage with interventions. This may include, for some people, a fear of both the practical and psychological aspects of attending (Goffman, 1971).

The presence of comorbid conditions has also been demonstrated to correlate with many adverse consequences in BD patients (Parker, 2010). These include a negative impact on aspects of the presentation and course of the condition, as well as poorer clinical outcomes, reduced levels of general functioning, reduced social cognition and Quality of Life (Lahera et al., 2012; Spoorthy et al., 2019). In the case of social cognition, it has been observed, in

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[48] While physical barriers to the use of public and private transportation have been well researched, research into barriers for individuals with mental health conditions is still scarce.

a cross-sectional study, that lower functioning individuals with BD exhibit significant social cognition deficits in both the verbal (Faux pas test) and nonverbal tests (recognizing facial emotion), when compared with the higher functioning patients (Lahera et al., 2012). In this study, Lahera et al. (2012) have suggested that the presence of persistent mood swings may alter the mechanisms of social understanding. If this is the case, then social cognition, as influenced by numbers of comorbid conditions, may play a significant role in a patient's level of global functioning, along with demographic, clinical, and other cognitive factors. They also observed significant differences between high and low functioning groups[49] in terms of educational levels, with high functioning correlating with increased educational level.

In sum, the presence of comorbid conditions may make it difficult for some BD participants to engage with PE sessions, particularly those activities which may increase patient anxieties such as, leaving their homes to attend a face-to-face therapeutic session (Thomas, Nisha, & Varghese, 2016).

Returning to the ERPOnline study, which indicated that the presence of one or more comorbidities increased the level of intervention usage, this result highlights the need for more research to be conducted on online intervention usage to assess the [non] concordance of the results.

Gender

The lack of significant results and small effect sizes, for the variable gender indicated that male and female participants in the included studies were

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[49] These groups did not differ in terms of clinical variables

equally likely to use the intervention types. However, it should be noted that, the literature contains relatively little research on the differences in treatment and service use between men and women with bipolar disorder (Cunningham et al., 2020).

Employment

In the case of employment this variable was not statistically significant across any of the analysed studies. It also exhibited small effect sizes in both the PARADES psychoeducation and IBPI studies and a medium effect size in the ERPOnline study. In the case of the ERPOnline and IBPI online studies, the result indicated that individuals, who had days which were structured due to employment commitments, utilised online interventions less. This was in contradistinction to the literature and the literature review, which indicated that patients, who have structured activities, utilise online interventions more (Beattie et al., 2009). The results here indicated that as the amount of structured activities increased, intervention usage decreased. Despite this result, the balance of evidence in the literature is that increased levels of structured activities are linked to increased online intervention usage and attendance. This notwithstanding, further research is clearly needed to understand these results and why there may be exceptions.

Age of first onset

Results for the correlation of age of first onset and intervention usage were mixed and exhibited small effect sizes across all the investigated studies. In the PARADES psychoeducation and IBPI studies, a later age of first onset was associated with an increased usage of the interventions. This finding concurred with the literature, where studies have shown adults with later-onset BD appearing to have reduced risks of recurrence and decreased functional impairment when compared to individuals with earlier condition onset (Berk et al., 2014). In contradistinction to the above, the ERPOnline study indicated that intervention usage decreased with increasing age of first onset, although this was with a small effect size. This result again illustrates the need for further research on online PE interventions in order that an understanding for the differences in these results can be obtained.

Number of past episodes

The number of past episodes was non-significant and exhibited a small effect size across all three studies. As the Number of Past Episodes increased, the usage of all interventions decreased. This was in agreement with the literature where patients, with increasing numbers of past episodes, have been shown to demonstrate more numerous hospitalizations (Goldberg & Ernst, 2002), increased disability rates (Magalhães et al., 2012), impaired levels of cognitive functioning (Lewandowski et al., 2011), social difficulties (Magalhães et al., 2012) and a reduction in their Quality of Life (Magalhães et al., 2012; Peters, West, Eisner, Baek, & Deckersbach, 2016). This may be because, as the number of past episodes increases, residual effects may reduce an individual’s physical and cognitive capacities and, subsequently, their ability to participate in PE and other interventions.

Ethnicity

The results for ethnicity and intervention usage were non-significant across all three studies. The effect sizes were small for the PARADES psychoeducation group intervention and the IBPI study and of medium size for the ERPOnline study. These results indicated that individuals of non-British ethnicity were less likely to use the PARADES psychoeducation and ERPOnline interventions but were more likely to use the IBPI intervention than were those participants of British origin. However, ethnic diversity was very low across the studies so that these correlations were not very meaningful.

7.4 Summary

In the case of the online studies no significant correlations were observed. In the group intervention PARADES age and level of education were positively correlated with intervention usage but exhibited small effect sizes.

8 Conclusions

8.1 Contributions to knowledge

This study adds to the existing body of knowledge by demonstrating that participant demographic and clinical factors are correlated, in group PE interventions for bipolar disorder, with participant levels of usage. In this study, the observed variables of age and level of education explained 8% of the shared variance of usage. As a result, whilst the investigated variables are important, this implied that there are other variables and relationships between them, which may further influence participant usage levels.

In the case of the effects observed for the online studies, the results were not definitive. A result which may have been due to the limited number of participants in these studies. As the observed effect sizes were small, more research is needed to provide conclusive data about the size of these relationships. In addition, future research could aim to understand if any other factors were important in influencing the levels of participant usage.

8.2 Summary of findings

The findings of this quantitative correlational post-positivist study, which was guided by the Health Belief Model (HBM), suggested, in the case of the group intervention PARADES (Morriss et al., 2016), that older individuals with more education were more likely to attend a higher number of group therapy sessions. In the case of the digital interventions, IBPI (Jones et al., 2017) and ERPOnline (Lobban et al., 2017), no statistically significant results were obtained. However, this result may have been due to these studies having insufficient power to detect the effects of participant demographic and clinical characteristics on differing levels of intervention usage. These findings are novel and represent, to the best of the author’s knowledge, the only quantitative research to investigate the effects of participant demographic and clinical factors on usage patterns in psychoeducational interventions (PE) for bipolar disorder (BD), when delivered by group and online modalities.

8.3 Strengths and limitations

A strength of this secondary analysis of an existing data set, using a correlational analytic approach, was that it provided the first quantitative assessment of how the demographic and clinical characteristics of individuals with BD may influence patterns of PE intervention usage. Another strength was that the included studies utilised a clinical sample of individuals with BD, all of whom had taken part in a Structured Clinical Interview for Diagnosis interview (SCID; First et al., 1997) to confirm their diagnosis. The use of structured interviews for condition diagnosis was also an asset of the recruitment and selection processes employed in the original studies. In addition, all participants were currently euthymic which, when the original data had been collected, had helped to ensure that their questionnaire responses were not simply a function of a current high or low mood episodes.

A limitation of this work was the limited number of studies which had recorded intervention usage data. In addition, no effect sizes had previously been calculated to guide sample sizes. As a result, the only way to get an indication of the effect sizes between the participant demographics and clinical characteristics was to use the datasets that were available.

Another consideration was that the empirical study relied on the data logs from previous studies to measure participant usage levels in the online PE interventions for BD. Whilst this data was objective and provided good insight into usage levels and patterns, it was influenced by several assumptions made by the researcher. For example, when the usage data showed improbably long or short visits to the webpages, assumptions had to be made that the participants had either, opened a web page and then left it open for a long time, or had been quickly distracted and moved onto something else. As a result, and in common with digital studies generally, judgements had to be made in relation to some of the visits to the websites, to exclude these outlying session durations. This also supported the researcher's choice of a post-positivist paradigm, as these decisions influenced exclusions. In addition, whilst the researcher still believes that a quantitative approach was the right choice for this study, quantitative methods alone were unable to capture participant perceptions and experiences (Short et al., 2018). An increased understanding of the research problems could have been achieved if this quantitative approach had been supplemented with a qualitative, or mixed methods approach. This would have permitted the inclusion of personal, subjective factors which could then have been triangulated with the quantitative results. This would have enhanced the validity of any inferences made and enabled a richer and more informed picture of the factors which influence the individual's intervention usage to be presented.

8.4 Future research: directions and recommendations

The starting point for this analysis was to use a complex model, the Health Belief Model (HBM), to guide the research in terms of the selection of candidate variables. But upon reflection, a learning point from my thesis has been that a complex model of 'cause and effect' relationships may not be able to be modelled with a linear regression model alone. This was chosen due to the limited number of available samples.

As a result, future research will need to consider that the relationship between the independent variable(s) and the dependent variable 'usage' may exhibit a curvilinear and not a linear relationship. If this is the case, then the use of linear regression alone would result in a poorly fitting model. In this eventuality a polynomial regression of the form:

$$Y = \beta_0 + \beta_1 X + \beta_2 X^2 + \ldots + \beta_h X^h + \varepsilon$$

may have to be considered for analysis. Here, as the value of h is increased, the model would, potentially, be better able to fit nonlinear relationships. This form of regression would also be suited to the analysis of more moderators and predictors (symptoms, psychosocial, clinical, neurocognitive and delivery factors) of intervention usage and could be used for multiple predictor variables. However, this would create interaction terms within the model which would become extremely complex if more than a few variables were used. A useful approach may be to use model evaluation to model the data with both linear and curvilinear models. A series of fit indices could then be calculated and tested to observe which model better captured the structure of the data with the best overall goodness of fit[50].

Other factors to be considered include:

i). The identification of more moderators and predictors (symptoms, psychosocial, clinical, neurocognitive and delivery factors) of intervention usage, with the aim of better informing the development of PE approaches for BD treatment and increasing participant usage.

ii). Regarding the issue of low recruitment levels amongst ethnic minorities, future research studies need to continue to strive to increase the number of people from ethnic minorities. This is to ensure sample profiles are in proportion to the 14% ethnic minority observed across England and Wales (Office for National Statistics et al., 2016). In addition, studies including large urban areas need to consider that in cities this figure may be much higher. For example, in the case of London the representative percentage would be 55% (Office for National Statistics et al., 2016).

A consideration for increasing the number of ethnic minority participants is to ensure that research studies include culturally sensitive adaptions[51] of PE interventions, with multiple versions of the same study materials, being targeted at multiple ethnic groups and cultures. This could be achieved by considering how the cultural aspects of the content of research materials,

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[50] This is used mainly in structural equation modelling, but Empirical Quantile Mapping (EQM) is basically a collection of regressions.

[51] Cultural adaptation refers to the systematic modification of an evidence-based treatment (EBT) or intervention protocol to consider language, culture, and context in such a way that is compatible with the clients' cultural patterns, meaning, and values.

such as translations, cultural appropriateness and functional, conceptual and linguistic equivalence, may affect intervention participation and usage levels, similar to the work of Husain et al (2017). This could then enable researchers to achieve levels of ethnic minority participance which was proportional to that observed in society.

iii). In the case of the online studies, where none of the clinical or demographic variables significantly correlated with levels of intervention module usage, it would be useful if any future [online] PE studies for BD were to record participant session and/or module usage. This would then enable future investigations to be based on a larger dataset and allow the results to be better generalised to the BD population.

vi). Finally, the results of this study have raised some concerns with the author about health inequalities, regarding the effects of age of a participant. Results indicated that younger individuals were less likely to complete a prescribed group intervention, a result which could result in their exclusion from group PE interventions for BD. For this reason, it is important that future research focusses on understanding why these groups find attendance challenging, in order that solutions can be investigated.

8.5 Dissemination

A review article, based on the first four chapters of this thesis, is currently being prepared for publication, along with a second based on the remaining chapters regarding the empirical secondary analysis. In addition to the academic dimension, my hope is that the results of this study will reach mental health professionals and policy makers, in order to increase their awareness of the effects that an individual’s demographic and clinical characteristics can have on usage levels of PE interventions for BD.

8.6 Final words

This study explored differences exhibited in the usage levels of PE interventions, for individuals who experience BD, when those interventions were delivered by the modalities of group or online. To quantitatively identify the variables which influenced usage, the constructs of the Health Belief Model were employed to provide a theoretical framework for this work.

An understanding of the effect that the demographic and clinical characteristics of participants have on their usage levels of PE interventions for BD across different delivery modalities is important. This is because an understanding of the effects of these can be employed to improve the levels of participant intervention usage. Thus, it is hoped, that by optimising the exposure a participant receives to the therapeutic content of a PE intervention for BD, positive outcomes may be improved in the research and clinical environments.

9 Reflections upon my learning

Walford (2001) describes current research interests to be the result of complex interactions between various prior interests and accidents of personal histories. In my case, the path that led me to writing this thesis was no different and represented a convergence of aspects of my early careers as an Electronics Engineer and later as a psychotherapist. These were both professional roles and were focused upon personal growth and development through learning and reflection (Fook, Royes, & White, 2017), processes which continued in the context of my PhD, with this thesis representing and reflecting many aspects of my personal learning journey (Forman & Cazden, 1985). When thinking about this journey, I found Gibbs' reflective cycle (Gibbs, 1988) to be a useful model to support to my experiential learning. In this model Gibbs considers the reflective cycle to be a continuous, repeated, cycle of improvement, but it can also be used to reflect on a standalone experience. It asks what happened (description), thoughts and feelings about the experience (feelings), what was good and what was bad about it (evaluation), how sense was made of what happened (analysis), and what was learnt, or could have done better or differently (conclusion) (Gurney, 2013). This is the framework I have applied to my reflections regarding the process of this PhD.

Following my career change 15 years ago I found myself missing some of the quantitative aspects which had previously been present in my work. These were reflections which, along with my interest and work with individuals with BD, led me to investigate and begin the PhD research process. When I reflect upon how that process went, I consider that at the onset my secondary analytic skills were limited but, as I became more practiced and experienced, they greatly improved. An added benefit has been that I have also improved how I manage personal anxiety, time management, teamworking skills and management of work relationships. These represented personal factors and aspects of the PhD process, which illustrated that my PhD was not just about the chosen subject, but equally about how those processes developed me as a researcher and individual. Some facets that I didn't expect were the intensity with which the PhD was 'with me' at nearly every moment and how my own biases, opinions and life experiences could permeate my research and influence the decisions I made[52]. Another factor of importance was that this study was conducted part-time as a distance / blended learning doctorate. The upshot of which was that sometimes I came to feel, due to limited access to on-campus study[53] and primarily online interactions with colleagues or academics (Albion, 2005), that motivation, independent working and limited

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[52] I initially worked in medical engineering and hold a Bachelor of Science in Electronic Engineering and a Master of Science in Medical Electronics and Physics. Later I became a psychotherapist, with a Master of Arts from the Tavistock and Portman NHS clinic. The research question for this thesis originated from my work for Mind, the mental health charity. This was as a result of, whilst providing counselling and PS interventions for individuals with BD, my observations that differing modalities of intervention had variations in usage across geographical areas which exhibited differing levels of average socioeconomic status and education.

[53] Lancaster University did provide access to annual academies which helped considerably with this aspect.

social interaction were challenging issues. Another important factor at the onset of this process was my naivety regarding how busy supervisors are and, despite the establishment of a regular and very productive student-supervision relationship, I initially, found the accessibility and availability of my supervisors to be factors which further affected my motivation and anxiety (Griffiths & Griffiths, 2007; Lin, 2008). Whilst I have developed a very good personal relationship with my supervisors, I have, on occasions, felt that I may have ‘missed out’ on the opportunity of physically working within the Faculty of Health and Medicine and gaining from practical observations and interactions on ‘how research is conducted’. That said, I feel, given the effects of the global pandemic and social isolation requirements I may have ended up having a similar experience to those researchers who intended to be on-campus but had to work from home.

When considering what I have learnt from my PhD, the most important factors were to stay organised, be confident and not to blindly accept something because it had been published. For me staying organised included keeping records of everything I had discussed with my supervisors and peers, as well as, having three Microsoft word documents, that I kept regularly updated. One of these I started in my first year, one in my second year and the final one in my fourth year. The first document kept a list of all the articles that I had read, tagged by keyword with their published abstracts. I found this to be very useful in finding key points when I was unsure of which article related to a specific area or section of the thesis. The second was my research diary, which allowed me to keep track of my research ideas and items suggested in supervision. When I had a promising idea, I made a note of it in this document and over time, this document assisted in informing my research directions and decisions. In hindsight, I should have started keeping this diary earlier in the PhD process, probably at the very beginning as it was so useful. The third was my analysis diary. This was a document which contained all my workings, ideas and the SPSS scripts that were used in the analysis of the data. I found this to be invaluable, especially when I needed to go back and to re-run previous calculations.

Regarding personal confidence, one of my first considerations, when starting the secondary analysis, was to ensure that the data which had been supplied to me by authors was the same as that which had been published. To confirm this, I re-processed the raw data and then compared the results to the variable values as presented in the original articles. On several occasions I found that the data I had produced did not correspond with that which had been published. Although I considered that the published data *could* have contained misprints, my first thought was that I had been performing the calculations incorrectly. At this point I contacted the original authors, and they were able to confirm that the differences were indeed misprints. This illustrated to me just how important it was to be able to have a reliable dialogue with the original authors, particularly when conducting a secondary analysis of data, as well as having more confidence in my own work.

For me learning is “the way in which I [individuals] acquire, interpret, reorganize, change or assimilate, a related cluster of information, skills, and feelings. It is also primary to the way in which I [people] construct meaning in my [their] personal and organizational life” (Matthews, 1999, p. 19). It is a journey without end and because of this, I continue to develop my analytic skills, my work role(s) and my acquiring of relevant qualifications. In terms of the transtheoretical model, cited earlier in this thesis, my personal development is ongoing, and I am moving up through the spiral of the models' stages as opportunities continue to arise.

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11 Appendices

Appendix A

Search Parameters

#	Search Terms	Search Options
S1	DE ”Bipolar Disorder”	Search Modes: Find all my search terms
S2	TI (Bipolar OR “manic depress*” OR mania *OR hypomania OR hypomanic*) OR AB (Bipolar OR “manic depress*” OR mania *OR hypomania OR hypomanic*)	Search Modes: Find all my search terms
S3	S1 OR S2	Search Modes: Find all my search terms
S4	((DE “Education”) OR DE(“Psychoeducation”)) OR (DE ”Relapse Prevention”)	Search Modes: Find all my search terms
S5	TI (education OR psych?education OR “Relapse Prevention”) OR AB (education OR psych?education OR “Relapse Prevention”)	Search Modes: Find all my search terms
S6	S4 OR S5	Search Modes: Find all my search terms
S7	S3 AND S6	Search Modes: Find all my search terms
S8	S3 AND S6	Search Modes: Find all my search terms Narrow by Subject Age: Adulthood
S9	S3 AND S6	Search Modes: Find all my search terms Narrow by Subject Age: Adulthood Narrow by Language: English

Appendix B

Articles excluded for methodological reasons

Article Details	Reason for rejection
Colom, F., et al. (2009). "Group psychoeducation for stabilised bipolar disorders: 5-year outcome of a randomised clinical trial." Br J Psychiatry 194(3): 260-265.	Data duplication as this was a continuation study of Colom, F., et al. (2003). "A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission." Arch Gen Psychiatry 60(4): 402-407.
Colom, F., Vieta, E., Sanchez-Moreno, J., Martinez-Aran, A., Torrent, C., Reinares, M., Goikolea, J., Benabarre, A. & Comes, M. 2004. Psychoeducation in bipolar patients with comorbid personality disorders. *Bipolar Disord,* 6**,** 294-298.	Data duplication as this was a sub analysis of Colom, F., et al. (2003). "A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission." Arch Gen Psychiatry 60(4): 402-407.
Parikh, S. V., et al. (2013) Psychosocial interventions for bipolar disorder and coping style modification: similar clinical outcomes, similar mechanisms? Canadian journal of psychiatry. Revue canadienne de psychiatrie 58, 482-486.	Data was from subgroup of Parikh, S. V., et al. (2012). "A randomized controlled trial of psychoeducation or cognitive-behavioral therapy in bipolar disorder: a Canadian Network for Mood and Anxiety treatments (CANMAT) study [CME]." J Clin Psychiatry 73(6): 803-810
Kallestad, H., et al. (2016) The long-term outcomes of an effectiveness trial of group versus individual psychoeducation for bipolar disorders. Journal of Affective Disorders 202, 32-38 DOI: 10.1016/j.jad.2016.05.043.	Participant preferences for group or individual interventions could not be identified due to both group and individual being conducted concurrently.
Rea, M. M., et al. (2003). "Family-focused treatment versus individual treatment for bipolar disorder: Results of a randomized clinical trial." Journal of Consulting and Clinical Psychology 71(3): 482-492.	Participant preferences for individual treatment could not be identified due to both modalities being conducted concurrently
Faria, A. D., et al. (2014). "The influence of psychoeducation on regulating biological rhythm in a sample of patients with bipolar II disorder: a randomized clinical trial." Psychology Research and Behavior Management 7: 167-174.	Rejected as this study appears to contain the same participant data as Cardoso Tde, A., et al. (2014). "Brief psychoeducation for bipolar disorder: impact on quality of life in young adults in a 6-month follow-up of a randomized controlled trial." Psychiatry Res 220(3): 896-902.

Appendix C

MMAT methodological quality criteria

PART I. MMAT criteria & one-page template (to be included in appraisal forms)

Types of mixed methods study components or primary studies	**Methodological quality criteria (see tutorial for definitions and examples)**	**Responses**			
		Yes	No	Can't tell	Comments
Screening questions (for all types)	• Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)?				
	• Do the collected data allow address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).				
	Further appraisal may be not feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.				
1. Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?				
	1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)?				
	1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected?				
	1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?				
2. Quantitative randomized controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)?				
	2.2. Is there a clear description of the allocation concealment (or blinding when applicable)?				
	2.3. Are there complete outcome data (80% or above)?				
	2.4. Is there low withdrawal/drop-out (below 20%)?				
3. Quantitative non-randomized	3.1. Are participants (organizations) recruited in a way that minimizes selection bias?				
	3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?				
	3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups?				
	3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?				
4. Quantitative descriptive	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?				
	4.2. Is the sample representative of the population understudy?				
	4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)?				
	4.4. Is there an acceptable response rate (60% or above)?				
5. Mixed methods	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?				
	5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)?				
	5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design?				
	Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4, or 4.1 to 4.4), must be also applied.				

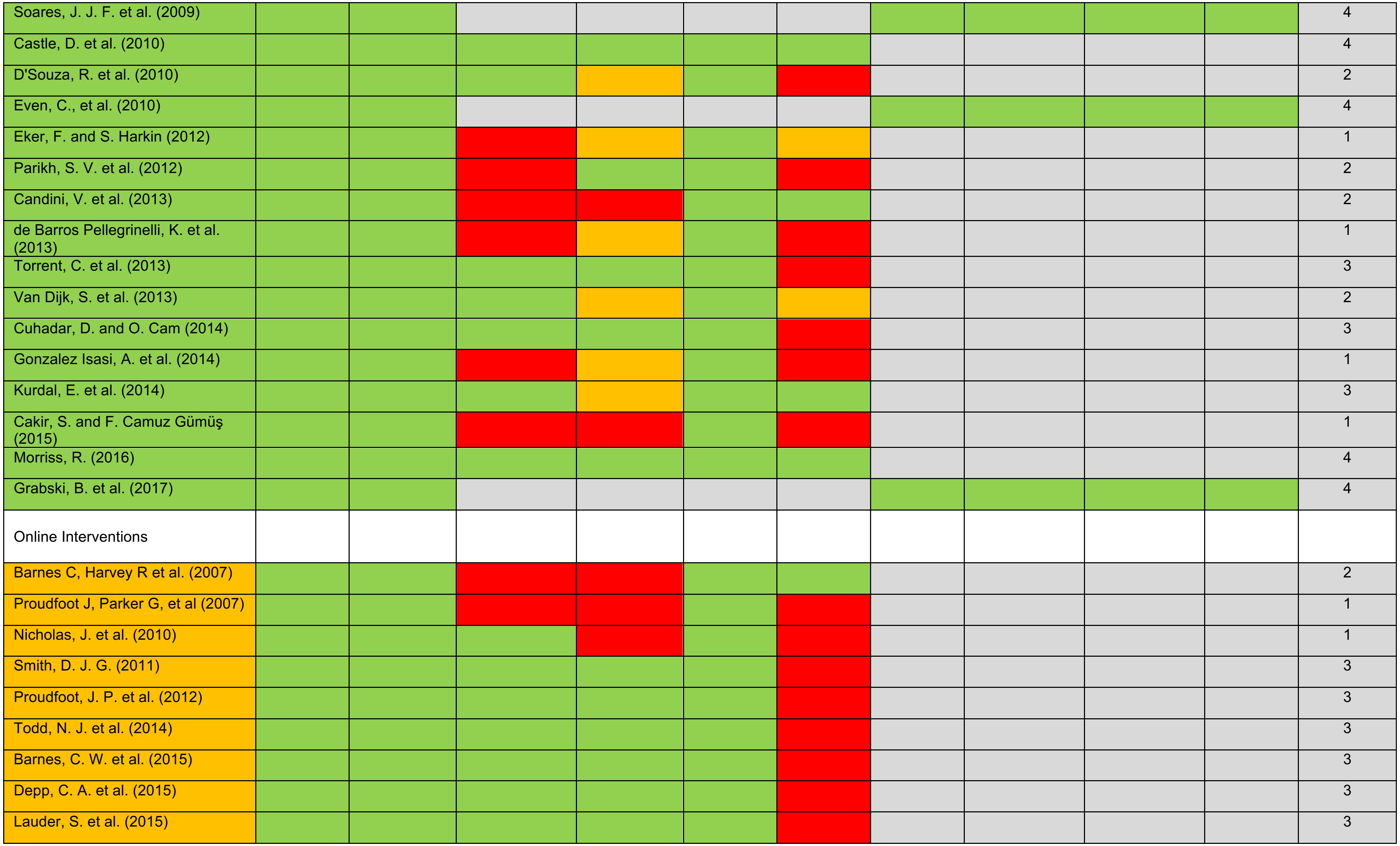
*These two items are not considered as double-barreled items since in mixed methods research, (1) there may be research questions (quantitative research) or research objectives (qualitative research), and (2) data may be integrated, and/or qualitative findings and quantitative results can be integrated.

Appendix D

MMAT quantitative methodological quality assessment of included studies

🟩 = Yes
🟧 = Cannot tell
🟥 = No
⬜ = Not Applicable

	Screening questions		RCT questions				Quantitative descriptive questions				Quality Score
Author, Title & Journal details*	Are there clear quantitative research questions?	Do the collected data address the research question?	Is there a clear description of the randomization process?	Is there a clear description of the allocation concealment ?	Are there complete outcome data (above 80%)	Is there a low withdrawal /drop-out (below 20%)?	Is sampling strategy relevant to address research question?	Is the sample representative of population under study?	Are the measurements appropriate?	Is there an acceptable response rate (>60%)?	1 to 4 points (3-4 = High 2 =Medium 1=Low)
Individual interventions											
Perry, A., et al. (1999)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Dogan, S. and S. Sabanciogullari (2003)	🟩	🟩	🟥	🟥	🟩	🟥	⬜	⬜	⬜	⬜	1
Zaretsky, A. (2008)	🟩	🟩	🟩	🟥	🟩	🟥	⬜	⬜	⬜	⬜	2
Lobban et al. (2010)	🟩	🟩	🟩	🟩	🟩	🟧	⬜	⬜	⬜	⬜	3
Javadpour, A. et al. (2013)	🟩	🟩	🟩	🟩	🟩	🟧	⬜	⬜	⬜	⬜	3
Cardoso Tde, A. et al. (2014)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Cakir, S. and F. C. Gümüş (2015)	🟩	🟩	🟥	🟥	🟩	🟥	⬜	⬜	⬜	⬜	1
Gumus, F. et al. (2015)	🟩	🟩	🟩	🟩	🟩	🟩	⬜	⬜	⬜	⬜	4
Group interventions											
Colom, F., Goikolea, J. M., Benabarre. (2003)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Colom, F., Vieta, E., Reinares, M.,Torrent, C. (2003)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Simon, G. E. et al. (2006)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3



Soares, J. J. F. et al. (2009)	🟩	🟩	⬜	⬜	⬜	⬜	🟩	🟩	🟩	🟩	4
Castle, D. et al. (2010)	🟩	🟩	🟩	🟩	🟩	🟩	⬜	⬜	⬜	⬜	4
D'Souza, R. et al. (2010)	🟩	🟩	🟩	🟧	🟩	🟥	⬜	⬜	⬜	⬜	2
Even, C., et al. (2010)	🟩	🟩	⬜	⬜	⬜	⬜	🟩	🟩	🟩	🟩	4
Eker, F. and S. Harkin (2012)	🟩	🟩	🟥	🟧	🟩	🟧	⬜	⬜	⬜	⬜	1
Parikh, S. V. et al. (2012)	🟩	🟩	🟥	🟩	🟩	🟥	⬜	⬜	⬜	⬜	2
Candini, V. et al. (2013)	🟩	🟩	🟥	🟥	🟩	🟩	⬜	⬜	⬜	⬜	2
de Barros Pellegrinelli, K. et al. (2013)	🟩	🟩	🟥	🟧	🟩	🟥	⬜	⬜	⬜	⬜	1
Torrent, C. et al. (2013)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Van Dijk, S. et al. (2013)	🟩	🟩	🟩	🟧	🟩	🟧	⬜	⬜	⬜	⬜	2
Cuhadar, D. and O. Cam (2014)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Gonzalez Isasi, A. et al. (2014)	🟩	🟩	🟥	🟧	🟩	🟥	⬜	⬜	⬜	⬜	1
Kurdal, E. et al. (2014)	🟩	🟩	🟩	🟧	🟩	🟩	⬜	⬜	⬜	⬜	3
Cakir, S. and F. Camuz Gümüş (2015)	🟩	🟩	🟥	🟥	🟩	🟥	⬜	⬜	⬜	⬜	1
Morriss, R. (2016)	🟩	🟩	🟩	🟩	🟩	🟩	⬜	⬜	⬜	⬜	4
Grabski, B. et al. (2017)	🟩	🟩	⬜	⬜	⬜	⬜	🟩	🟩	🟩	🟩	4
Online Interventions											
Barnes C, Harvey R et al. (2007)	🟩	🟩	🟥	🟥	🟩	🟩	⬜	⬜	⬜	⬜	2
Proudfoot J, Parker G, et al (2007)	🟩	🟩	🟥	🟥	🟩	🟥	⬜	⬜	⬜	⬜	1
Nicholas, J. et al. (2010)	🟩	🟩	🟩	🟥	🟩	🟥	⬜	⬜	⬜	⬜	1
Smith, D. J. G. (2011)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Proudfoot, J. P. et al. (2012)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Todd, N. J. et al. (2014)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Barnes, C. W. et al. (2015)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Depp, C. A. et al. (2015)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3
Lauder, S. et al. (2015)	🟩	🟩	🟩	🟩	🟩	🟥	⬜	⬜	⬜	⬜	3

Lobban, F., et al. (2015)	🟩	🟩	🟩	🟩	🟩	🟥					3
Hidalgo-Mazzei, D., et al. (2016)	🟩	🟩					🟩	🟩	🟩	🟩	4
Jones, S. et al. (2017)	🟩	🟩	🟩	🟩	🟩	🟩					4

Note: *= Arranged by date of publication

Appendix E

Data extraction template for literature review

Screening Section

Review Title	
Study ID *(Surname and Year)*	
Name of review author completing this form	
Date form completed	
Name of review author checking the data extracted to this form	
Other information and notes Author contact details for study	
Further information required	
Correspondence with authors successful or not; what information was received and when	
Will any additional unpublished data supplied by the authors be included in the review?	
If so, note that the study will include unpublished data.	
Notes:	

Inclusion criteria

Age >=18	
Diagnosis of BPD	
Data from primary research	
Study in English	
Peer reviewed	
Able to give informed consent	
Intervention described as Psychoeducational or contained sufficient ‘common and specific elements’*.	
Notes: *as defined by Miklowitz (2008)	

Exclusion criteria

Study was sub-analysis or a continuation of other works	
Mode of intervention was family based	
Study was a systematic review or meta-analysis	
Comprised of non-randomized and non-controlled designs	
Recorded only qualitative data	
Study was unpublished	
Notes:	

Available variables

Methodological Variables		
	Methodological Quality	
	Recruitment method	
Demographic Variables		
	Age	
	Gender	

	Relationship type	
	Employment type	
	Years of Education (Range / Mean)	
	Ethnicity	
	No of Children	
	Socioeconomic Status	
	Economic Indicators	
	Income	
	Accommodation Type	
	Geographic Location	
Clinical Variables		
	Diagnosis	
	Age of First Onset	
	Mean Age at diagnosis	
	No of Manic Episodes	
	No of Previous Episodes	
	Alcohol Abuse / Dependency	
	Substance Abuse / Dependency	
	Duration of illness	
	No of Hospitalizations (Last year/ 5 years)	
	Family member with BD?	
	Psychotic features	
	Attempted Suicide	
	Axis I/II co-morbidity	
	Hamilton Depression Score (HAM-D)	
	Bech Depression Inventory (BDI)	
	Young Mania Rating Scale (YMRS)	
	Montgomery-Asberg Depression Scale (MADRS)	
	The Clinician-Administered Rating Scale for Mania (CARS-M)	
	Center for Epidemiologic Studies Depression Scale (CES-D)	
	The State-Trait Anxiety Inventory (STAI)	
	The Mood Disorder Questionnaire (MDQ)	
	WHO QoL	
	Personal and social performance scale (PSP)	
	Multidimensional scale of independent functioning	
	Currently taking medication?	
	No of prescribed drugs	
	Medication Type	
	Comorbid clinical anxiety	

	Inc.	Exc.
Include or exclude study?		

Study Data Extraction

	Int.	TAU
Number of participants		
Age of group Years, Mean, (SD)		
Mean age of all participants Years, Mean, (SD)		
Gender (Male, Number, %)		

Category of study (Individual/Group/Online)	

Relationship Status (Number of individuals in each category)

	Intervention Category	
	Int.	TAU
Never in Relationship		
With Partner		
Married		
Divorced/ Separated		
Other		

Employment Status (Number of individuals in each category)

	Intervention Category	
	Int.	TAU
Employed Full time		
Employed Part time		
Unemployed		
In full time education		
Homemaker		
Retired		
Other		

Length of education (Years)

	Intervention Category			
	Int.		TAU	
	Mean	(SD)	Mean	(SD)
Years in Education				

Diagnosis (Number of individuals in each category)

	Intervention Category	
	Int.	TAU
Bipolar I		
Bipolar II		
Other		

Age of first onset (Number of individuals in each category)

	Mean	(SD)
Experimental group		
TAU/ control group		
Note: If sample size exceeds 25, and only median value is given, then the median is the best estimator of the mean Hozo (2014).		

Recruitment Methods to study

Online	
Flyers/Newspaper Advert	
Medical route (clinic/hospital recommendation)	
Not specified	

Appendix F

List of included studies*

Individual interventions
Perry, A., et al. (1999). Randomised controlled trial of efficacy of teaching patients with bipolar disorder to identify early symptoms of relapse and obtain treatment. *BMJ* 318(7177): 149-153.
Dogan, S. and S. Sabanciogullari (2003). The effects of patient education in lithium therapy on quality of life and compliance. *Archives Of Psychiatric Nursing* 17(6): 6.
Zaretsky, A. (2008). Is Cognitive-Behavioural Therapy More Effective Than Psychoeducation in Bipolar Disorder? *The Canadian Journal of Psychiatry* 53(7).
Lobban, F. et al (2010). Enhanced relapse prevention for bipolar disorder by community mental health teams: cluster feasibility randomised trial. *The British Journal of Psychiatry*, 196(1), 59-63.
Javadpour, A., et al. (2013). The impact of a simple individual psycho-education program on quality of life, rate of relapse and medication adherence in bipolar disorder patients. *Asian Journal of Psychiatry* 6(3): 208-213.
Cardoso Tde, A., et al. (2014). Brief psychoeducation for bipolar disorder: impact on quality of life in young adults in a 6-month follow-up of a randomized controlled trial. *Psychiatry Research*, 220(3): 896-902.
Cakir, S. and F. Camuz Gümüş (2015). Individual or Group Psychoeducation: Motivation and Continuation of Patients with Bipolar Disorders. *International Journal of Mental Health* 44(4): 263-268 (Individual intervention data)
Gumus, F., et al. (2015). Effectiveness of Individual Psychoeducation on Recurrence in Bipolar Disorder; A Controlled Study. *Archives of Psychiatric Nursing*, 29(3): 174-179.
Group interventions
Colom, F., Vieta, E., Martinez-Aran, A., Reinares, M., Goikolea, J. M., Benabarre, A., . . . Corominas, J. (2003). A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission. *Archives of General Psychiatry*, 60(4), 402-407.
Colom, F., et al. (2003). Psychoeducation efficacy in bipolar disorders: beyond compliance enhancement. *Journal of Clinical Psychiatry* 64(9): 1101-1105.
Simon, G. E., et al. (2006). Long-term effectiveness and cost of a systematic care program for bipolar disorder. *Archives of*

General Psychiatry, 63(5): 500-508.
Soares, J. J. F., et al. (2009). Psychoeducation for patients with bipolar disorder: An exploratory study. *Nordic Journal of Psychiatry* 51(6): 439-446.
Castle, D., et al. (2010). Group-based psychosocial intervention for bipolar disorder: randomised controlled trial. *The British Journal of Psychiatry*, 196(5): 383-388.
D'Souza, R., et al. (2010). A brief dyadic group-based psychoeducation program improves relapse rates in recently remitted bipolar disorder: a pilot randomised controlled trial. *Journal of Affective Disorders*, 120(1-3): 272-276
Even, C., et al. (2010). Psychoeducation for patients with bipolar disorder receiving lithium: Short and long-term impact on locus of control and knowledge about lithium. *Journal of Affective Disorders*, 123(1-3): 299-302
Eker, F. and S. Harkin (2012). Effectiveness of six-week psychoeducation program on adherence of patients with bipolar affective disorder. *Journal of Affective Disorders*,138(3): 409-416.
Parikh, S. V., et al. (2012). A randomized controlled trial of psychoeducation or cognitive-behavioral therapy in bipolar disorder: a Canadian Network for Mood and Anxiety treatments (CANMAT) study [CME]. *The Journal of Clinical Psychiatry*, 73(6): 803-810
Candini, V., et al. (2013). Is structured group psychoeducation for bipolar patients effective in ordinary mental health services? A controlled trial in Italy. *Journal of Affective Disorders*, 151(1): 149-155.
de Barros Pellegrinelli, K., et al. (2013). Efficacy of psychoeducation on symptomatic and functional recovery in bipolar disorder. *Acta Psychiatrica Scandinavica*, 127(2): 153-158.
Torrent, C., et al. (2013). Efficacy of functional remediation in bipolar disorder: a multicenter randomized controlled study. *American Journal of Psychiatry* 170(8): 852-859.
Van Dijk, S., et al. (2013). A randomized, controlled, pilot study of dialectical behaviour therapy skills in a psychoeducational group for individuals with bipolar disorder. *Journal of Affective Disorders*, 145(3): 386-393.
Cuhadar, D. and O. Cam (2014). Effectiveness of Psychoeducation in Reducing Internalized Stigmatization in Patients with Bipolar Disorder. *Archives of Psychiatric Nursing*, 28(1): 62-66.
Gonzalez Isasi, A., et al. (2014). Psychoeducation and cognitive-behavioral therapy for patients with refractory bipolar disorder: a 5-year controlled clinical trial. *European Psychiatry*, 29(3): 134-141.
Kurdal, E., et al. (2014). The Effect of Psychoeducation on the Functioning Level of Patients with Bipolar Disorder. *Western Journal of Nursing Research*, 36(3): 312-328.
Cakir, S. and F. Camuz Gümüş (2015). Individual or Group Psychoeducation: Motivation and Continuation of Patients with Bipolar Disorders. *International Journal of Mental Health* 44(4): 263-268 (Group intervention data)
Richard Morriss et al (2016). Clinical effectiveness and acceptability of structured group psychoeducation versus optimised

unstructured peer support for patients with remitted bipolar disorder (PARADES): a pragmatic, multicentre, observer-blind, randomised controlled superiority trial, *Lancet Psychiatry*, 3(11), 1029-1038.
Grabski, B., et al. (2017) Group psychoeducation in bipolar disorder and its influence on the cognitive representation of illness and basic personality dimensions: a control group study. *Archives of Psychiatry and Psychotherapy* 18, 18-26.
Online Interventions
Barnes C, Harvey R, Mitchell P, Smith M, Wilhelm K. (2007) Evaluation of an online relapse prevention program for bipolar disorder — an overview of the aims and methodology of a randomized controlled trial. *Disease Management and Health Outcomes*;15(4):215–24
Proudfoot, J. P., Hyett, G., Manicavasagar, M., Smith, V., Grdovic, M., & Greenfield, L. (2007). Next generation of self-management education: Web-based bipolar disorder program. *The Australian and New Zealand Journal of Psychiatry*, 41(11), 903-909.
Nicholas, J., et al. (2010). The ins and outs of an online bipolar education program: a study of program attrition. *Journal of Medical Internet Research*, 12(5): e57.
Smith, D. J. G. (2011). "Beating Bipolar Exploratory trial of a novel internet-based psychoeducational treatment for bipolar disorder." *Bipolar Disorders* 13(5-6): 571-577.
Proudfoot, J., Parker, G., Manicavasagar, V., Hadzi-Pavlovic, D., Whitton, A., Nicholas, J., . . . Burckhardt, R. (2012). Effects of adjunctive peer support on perceptions of illness control and understanding in an online psychoeducation program for bipolar disorder: A randomised controlled trial. *Journal of Affective Disorders*, 142(1-3),
Todd, N. J., Jones, S. H., Hart, A., & Lobban, F. A. (2014). A web-based self-management intervention for bipolar disorder ‘living with bipolar’: a feasibility randomised controlled trial. *Journal of Affective Disorders*, 169, 21-29.
Barnes, C. W., et al. (2015) A web-based preventive intervention program for bipolar disorder: outcome of a 12-months randomized controlled trial. *Journal of Affective Disorders* 174, 485-492
Depp, C. A., et al. (2015) Augmenting psychoeducation with a mobile intervention for bipolar disorder: a randomized controlled trial. *Journal of Affective Disorders* 174, 23-30
Lauder, S., et al. (2015). A randomized head-to-head trial of MoodSwings.net.au: an Internet based self-help program for bipolar disorder. *Journal of Affective Disorders* 171: 13-21.
Lobban, F., et al. (2015) Assessing feasibility and acceptability of web-based enhanced relapse prevention for bipolar disorder (ERPonline): A randomised controlled trial. *Journal of Medical Internet Research*, 2017 Vol 19, issue 3
Hidalgo-Mazzei, D., et al. (2016). Psychoeducation in bipolar disorder with a SIMPLe smartphone application: Feasibility,

acceptability and satisfaction. *Journal of Affective Disorders* 200: 58-66.
Jones, S., et al. (2017). Web-based integrated bipolar parenting intervention for parents with bipolar disorder - a randomised controlled pilot trial. *Journal of Child Psychology and Psychiatry*.

Notes: * = Arranged by publication date.

Appendix G

Recruitment methods/sources of included studies

Author, Title & Journal details*	Recruitment Criteria			
	Online	Flyers / Newspapers	Medical	Not Specified
Individual interventions				
Perry, A., et al. (1999)			Y	
Dogan, S. and S. Sabanciogullari (2003)			Y	
Zaretsky, A. (2008)			Y	
Lobban et al. (2010)			Y	
Javadpour, A. et al. (2013)			Y	
Cardoso Tde, A. et al. (2014)			Y	
Cakir, S. and F. Camuz Gümüş (2015)			Y	
Gumus, F. et al. (2015)			Y	
Group interventions				
Colom, F., Vieta, E., Martinez-Aran, A., Reinares, M., Goikolea, J. M., Benabarre, A., . . . Corominas, J. (2003)			Y	
Colom, F., Vieta, E., Reinares, M., Martinez-Aran, A., Torrent, (2003)			Y	
Simon, G. E. et al. (2006)			Y	
Soares, J. J. F. et al. (2009)			Y	
Castle, D. et al. (2010)			Y	
D'Souza, R. et al. (2010)			Y	
Even, C., et al. (2010)			Y	
Eker, F. and S. Harkin (2012)			Y	
Parikh, S. V. et al. (2012)		Y	Y	
Candini, V. et al. (2013)			Y	
de Barros Pellegrinelli, K. et al. (2013)			Y	
Torrent, C. et al. (2013)			Y	
Van Dijk, S. et al. (2013)			Y	
Cuhadar, D. and O. Cam (2014)				Y
Gonzalez Isasi, A. et al. (2014)			Y	
Kurdal, E. et al. (2014)			Y	
Cakir, S. and F. Camuz Gümüş (2015)			Y	
Morriss, R. (2016)		Y	Y	

Grabski, B. et al. (2017)			Y	
Online Interventions				
Barnes C, Harvey R et al. (2007)	Y	Y	Y	
Proudfoot J, Parker G, et al (2007)	Y	Y	Y	
Nicholas, J. et al. (2010)	Y	Y	Y	
Smith, D. J. G. (2011)		Y	Y	
Proudfoot, J. P. et al. (2012)		Y	Y	
Todd, N. J. et al. (2014)	Y	Y		
Barnes, C. W. et al. (2015)		Y		
Depp, C. A. et al. (2015)	Y	Y	Y	
Lauder, S. et al. (2015)	Y			
Lobban, F., et al. (2015)	Y	Y	Y	
Hidalgo-Mazzei, D., et al. (2016)			Y	
Jones, S. et al. (2017)			Y	
Note: * = Arranged by publication date				

Appendix H

Formulae for calculation of weighted mean values and pooled standard deviations

Weighted mean

$$\overline{x} = \frac{\sum_{i=1}^{n} \omega_i x_i}{\sum_{i=1}^{n} \omega_i}$$

which was implemented as:

$$\overline{x} = \frac{\omega_1 x_1 + \omega_2 x_2 + \cdots + \omega_n x_n}{\omega_1 + \omega_2 + \cdots + \omega_n}$$

In the event that the included papers provided median data instead of the mean, it was assumed that as soon as the sample size exceeded 25 the median value would be the best estimator of the mean as described by Hozo (2005).

Pooled variances

These were calculated as below:

$$S_{Pooled} = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2 + \cdots + (n_k - 1)s_k^2}{n_1 + n_2 + \cdots + n_k - k}}$$

Appendix I

Participant data comparing all intervention groups (Weighted Data)

Participant data comparing all intervention groups (Weighted Data)

Grouping \ Intervention	Individual	Group	Online	F Statistic / (Chi Square)	P Value	Effect Size Cohens d / (Cramer's V)
Gender (Female), n (%)	45.79(57.54)	138.22(63.31)	230(71.87)	(8.05)	0.018[a]	(.11)
Age Mean (SD), Years	41.54 (11.25)	41.74 (11.28)	39.35(11.43)	0.50	0.61	.21
Relationship Status (In Relationship) n (%)	35.59(44.91)	67.58(39.27)	124.4(46.44)	(2.22)	.33	(.07)
Structured Activity, n (%) (In Structured Activity)	36.95 (46.49)	157.06 (51.81)	178.78 (70.10)	(24.88)	<.00001[b]	(.12)
Length of Education, Mean (SD), Years	11.97(3.24)	11.76(3.53)	14.59(2.37)	0.25	0.80	.80
Diagnosis BP1, n (%)	73.01(86.70)	102.40(64.27)	146.7(82.54)	(21.24)	<.00001[b]	(.23)
Age of first Onset, Mean (SD), Years	20.12 (6.37)	24.77 (8.71)	21.66 (12.34)	0.24	0.79	.31

Notes: *a – Number of females in online interventions had adjusted residuals of 2.7*
b – Number of individuals with Structured Activities in online interventions had adjusted residuals of 4.9
c –Small effect<=0.2, 0.2<Medium effect<0.5, 0.5<Large effect
d -Weak effect<=0.2, 0.2<Moderate<0.6, Strong<=0.6

Appendix J

Definition of outliers

Outliers in the data were defined as datapoints that lay an abnormal distance from other values in a random sample from a population. In this case, this definition left it to the researcher to decide what would be considered abnormal. In order to identify any abnormal observations, it was necessary to characterize the normal observations. To characterise the data, it was graphed and analysed for important features such as, the mean, the SD and its overall shape. It was also examined for any unusual observations that were a long way from the mass of data by employing a box plot.

The box plot was useful for describing the behaviour of the data in the middle as well as at the ends of the distributions. It used the median and the lower and upper quartiles (defined as the 25th and 75th percentiles). If the lower quartile was Q1 and the upper quartile was Q3, then the difference (Q3 - Q1) was the interquartile range (IQ). The boxplots were created in SPSS by drawing a box between the upper and lower quartiles. A solid line was drawn across the box to locate the position of the median. Fences were then constructed to identify any extreme values residing at the tails of the distribution:

1. lower inner fence: Q1 - 1.5*IQ
2. upper inner fence: Q3 + 1.5*IQ
3. lower outer fence: Q1 - 3*IQ
4. upper outer fence: Q3 + 3*IQ

Any points which existed beyond the inner fence, on either side of the median, were considered to be mild outliers and any points which existed beyond the outer fence were considered to be extreme outliers, see Figure J:1 below.

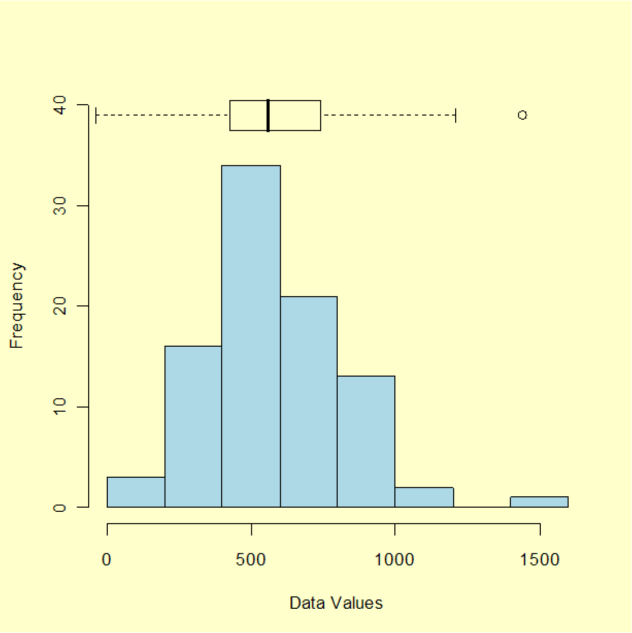


Figure J:1

Example histogram with an overlaid box plot

Appendix K

Ethical considerations

This research project was authorised by Lancaster University ethics department on the 19th of June 2018, see Appendix L. Access to the studies which were to provide the secondary data was granted during October 2018.

Appendix K.1: Informed consent

In order for a participant to participate in a research study the researcher has to ensure that the individual has the mental capacity to volunteer, that they are free of coercion or undue influence, understand the purpose, risks and benefits of the work and that they consent to participate (Brakewood & Poldrack, 2013). However, in the case of a secondary analysis of data, as in this work, this will be more nuanced and may not be possible. It would be ethically unacceptable to approach previous participants ‘out of the blue’ and equally unacceptable for their data to be utilized without their consent. As well as ethical issues there are also practical problems involved such as the inability to trace participants who may have moved to a new house or changed their telephone number. It is also a possibility that a participant may have died. In this case, contact from a researcher could cause distress for the participant’s relatives, if they were to receive a request for the further use of their data (Grinyer, 2009).

In order to mitigate these situations this research draws upon on the fundamental concepts underlying human subject research, which were laid out in the Ethical Principles and Guidelines for the Protection of Human Subjects Research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), better known as the Belmont Report. This states that for data to be shared for the purpose of a [secondary] analysis its usage must align with the reports three core principles, respect for persons, beneficence and justice. To apply these principles, the Belmont report defines three strategies – obtaining informed consent, balancing risk and benefit and selecting subjects appropriately. Strategies which can be consistent with the core principles and still support the sharing of primary data in a secondary analytic environment.

There were a variety of options for the type of consent which may have been appropriate for the original research, with some researchers anticipating that the data might be reused and shared with researchers in a future analysis. In these cases, the informed consent may have included an option whereby the participants agreed to further, future analysis. In these cases further informed consent or a waiver was not required for the data to be reanalysed. This was the case of the studies used here and are detailed for the included studies below:

ERPOnline

> I understand that my medical notes and records will be made available to responsible individuals from Cumbria Partnership NHS Foundation Trust, Lancaster University, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records and to collect, store, analyse and publish information obtained from my participation in this study.

Parades

> I understand that my medical notes and records will be made available to responsible individuals from MMHSC, Lancaster University, the research group and regulatory authorities where relevant. I give permission for these individuals to have access to my records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.

IBPI

> I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Spectrum Centre, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my records.

Another ethical aspect which was considered was that, as the participants in the original studies had agreed to their data being analysed both in the original study and after, it was acceptable to allow an analysis of their data which was unforeseeable at the time of the original study. However, it is arguable that the participants did not agree to their data being used in any unrelated type of study and, to treat their data with respect, the subject of the secondary analysis needed to be congruent with the aim of the original studies, as was the case in this research.

Appendix K.2: Risk Reduction

Beneficence is an obligation to minimise harm to a participant and to maximise the benefits from a study (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). In the case of a secondary analysis, the main risk to the participants was that of a breach of their confidentiality may have occurred (Brakewood & Poldrack, 2013). The best way to minimize this risk was to ensure that the data was no longer identifiable. To ensure this was the case, the data provided to this research was checked to ensure that all identifying information had been removed prior to the start of its analysis. To ensure that all identifying data had been removed the dataset were compared against the 18 unique identifiers detailed in the U.S. Health Insurance Portability and Accountability Act (HIPAA) (United States, 2004), see Table K:1.

Table K:1.

The 18 unique identifiers defined in the HIPAA

Name / Initials
Geographic subdivisions smaller than a state
All elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, and date of death and all ages over 89 and all elements of dates (including year) indicative of such age (except that such ages and elements may be aggregated into a single category of age 90 or older)
Telephone numbers
Fax numbers
Electronic mail addresses
Social security numbers
Medical record numbers
Health Insurance numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs)
Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
Full face photographic images and any comparable images
Any other unique identifying number, characteristic, or code (excluding a random identifier code for the subject that is not related to or derived from any existing identifier).

Once any identifying data had been removed, the principle of beneficence was applied via the security and data protection measures employed by the researcher. To ensure that risks to the privacy and confidentiality of the participants was maintained, strong procedures were employed to protect and restrict access. This was ensured by storing all data on an encrypted storage drive at Lancaster University and, when in the process of being analysed, on a secure, encrypted Solid State Drive (SSD) on a MacBook.

Appendix K.3: Participant selection

The ‘Justice’ section of the Belmont report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978) ensures that participants are treated fairly and are not excluded from research. Within this concept lies the principle of appropriate representation, with this applying to classes of people rather than to individuals. If particular individuals in a class had not been recruited as research subjects then this would then be a violation of the principle of distributive justice, as described in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). However, examination of the included studies exhibited no exclusion or underrepresentation of specific classes of subjects by gender or ethnicity.

Appendix L

Ethics approval letter

Lancaster University

Applicant: Russell Baker
Supervisors: Steve Jones and Guillermo Perez-Algorta
Department: Health Research
FHMREC Reference: FHMREC17097

19 June 2018

Dear Russell,

Re: Are the demographic and clinical characteristics of individuals linked to patterns of usage and adherence in research trials of self-management psychoeducation interventions for bipolar disorder?

Thank you for submitting your research ethics application for the above project for review by the **Faculty of Health and Medicine Research Ethics Committee (FHMREC)**. The application was recommended for approval by FHMREC, and on behalf of the Chair of the Committee, I can confirm that approval has been granted for this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer at the email address below (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information.

Tel:- 01542 592838
Email:- fhmresearchsupport@lancaster.ac.uk

Yours sincerely,

Dr Diane Hopkins
Research Integrity and Governance Officer, Secretary to FHMREC.