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**Doctoral Thesis:**

**Managing Bipolar Moods Without Medication: A Qualitative Investigation**

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# Word Counts

| | Main Text | Appendices (including abstract, tables, figures and references) | Total |
|---|---|---|---|
| Thesis abstract | 300 | | 300 |
| Literature Review | 7,379 | 9,781 | 17,160 |
| Research paper | 7,860 | 4,156 | 12,016 |
| Critical Review | 3,548 | 426 | 3,974 |
| Ethics Section | 4,528 | 2,326 | 6,854 |
| **Total** | 23,615 | 16,689 | 40,304 |

**Abstract**

This thesis begins with a literature review examining whether family interventions for people diagnosed with Bipolar Disorder (BD) lead to better outcomes for their relatives, who often exhibit greater service utilisation and greater distress than the general population. Following a systematic search of the quantitative literature, ten papers were identified, analysed for relevant data, and assessed for their methodological rigour. Results indicated that family interventions may improve relatives' feelings of carer burden and psychological distress, but that these conclusions must be treated with caution given methodological issues in the evidence base. Suggestions are made as to which type of family intervention clinicians should consider offering, and which priorities future researchers in this area may wish to address.

Decisions not to use medication among people diagnosed with BD are often viewed as indicative of a 'lack of insight' into the nature of bipolar moods and medication. However, research has not examined the individual's experiences once they decide to manage bipolar moods without medication. The empirical paper presented here seeks to elucidate the processes by which people manage bipolar moods without medication by using grounded theory methods. Ten participants were interviewed and a model developed from their data. This model suggests participants engaged in a complex decision-making process as to how to manage their moods, frequently with reference to beliefs they held about themselves and their mood, suggesting that the 'lack of insight' model may be inadequate for understanding the processes involved in managing bipolar moods without medication. On the basis of the model developed from the data, suggestions are made regarding clinical interventions and future research. There then follows a critical appraisal of the work conducted in the empirical paper, focussing on challenges in the area of recruitment, in the hope that reflections provided will aid future researchers in this area.

**Declaration**


This thesis records work undertaken for the Doctorate in Clinical Psychology at the Division of Health Research at Lancaster University from December 2012 to May 2014.

The work presented here is the author's own, expect where due reference is made. The work has not been submitted for the award of a higher degree elsewhere

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Signature:


Date:

**Acknowledgements**

I would like to thank the participants who gave their time to participate in this research, and for making the process of carrying out this project fascinating and engaging. I would also like to thank my supervisors, Dr Ian Smith and Dr Fiona Lobban, for their guidance with the many different elements of this project, and for their ongoing encouragement and enthusiasm with the topic.

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Finally, thanks must go to my coursemates, who have been an invaluable source of support (and laughter) over the course of this project, and to my friends, who have tolerated me through particularly disconcerting bouts of 'thesis brain'. And particular thanks must go to my long-suffering friend and housemate Alison, who will just be glad when every available surface in our house is no longer covered in papers about bipolar disorder and grounded theory.

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Manage Bipolar Moods**

**Section One: Literature Review**

**Relatives' Outcomes Following Family Intervention for People Diagnosed With Bipolar**

**Disorder: A Systematic Review**

**Word Count: 7,540**

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Prepared in accordance with the Guidelines for Authors of *Journal of Affective Disorders*[1]

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[1] See Appendix A.

**Abstract**

**Objective.** Relatives of people diagnosed with Bipolar Disorder (BD) show clinically significant levels of distress more frequently than the general population, and are more likely to use mental health services. Family interventions have the potential to improve outcomes for relatives, but to date no authors have systematically reviewed the evidence for improvements in relatives' outcomes following family interventions for people diagnosed with BD.

**Methods.** The electronic databases AMED, CINAHL, EMBASE, Medline and PsycINFO were searched for relevant articles according to pre-defined inclusion criteria. References of relevant papers and reviews were also hand-searched. Included papers were quality assessed using the Clinical Trials Assessment Measure tool (CTAM).

**Results.** 10 studies met inclusion criteria, and 3 met CTAM criteria for adequate methodology, a proportion comparable to trials of individual psychological therapies for psychosis (Wykes et al., 2008) and higher than that for family interventions in psychosis (Lobban et al., 2013a). There was evidence for improvements in carer burden, maintained 2 years after intervention, and improvements in psychological distress, maintained 1 year after intervention. However these results must be viewed with caution due to issues with the handling of participant attrition and lack of evidence for improvements being the result of any specific intervention components. Future researchers may wish to consider using intention-to-treat analyses and the use of active control groups to address these issues.

**Limitations.** The review only included evidence from studies in English and at present does not include reliability checks for CTAM scores.


*Key Words: Bipolar Disorder; Relatives; Family intervention; Outcome; Systematic review*

Bipolar Disorder (BD) is the term often used to conceptualise mood states that fluctuate between extreme highs ('manic episodes') and lows ('depressive episodes') (American Psychiatric Association, 2013; World Health Organisation, 1992).  Following a long period of emphasis on biomedical factors, research has recently begun to address the psychosocial variables that may influence outcomes for people diagnosed with bipolar disorder (BD) (Alloy et al., 2006).  Miklowitz and Johnson (2009) suggest that factors linked to family relationships may interact with personality variables, life events and biological factors in determining vulnerability to problematic mood experiences.  Consistent with this, there is growing evidence to support the effectiveness of clinical interventions involving the families of people diagnosed with BD (Morris & Miklowitz, 2006).  These are often referred to as family interventions, defined by Lobban et al. (2013) as professional input aimed at "reducing distress and improving wellbeing for all family members" (p. 372) based on psychosocial models.

Studies evaluating the effectiveness of family interventions routinely collect data on outcomes for the individual diagnosed with BD (Justo et al., 2009), though fewer researchers evaluate the impact of such interventions on family members of the diagnosed individual (Reinares et al., 2002).  This is surprising given the recent increase in research examining the possible consequences for relatives involved in caring for someone diagnosed with BD (Steele et al., 2010).  Informal caregivers have played a growing role in the support of those diagnosed with BD since the move away from institutionalised care in the latter half of the 20th Century (Harvey et al., 2008).  The role of informal caregiver is usually assumed by spouses or family members (Schulze & Rossler, 2005) who are often  given little information about what to expect or how to go about providing care for their relative (Doornbos, 2002). Carers of people diagnosed with BD have reported struggling to cope with the impact of problems such as their relative's reckless spending and violence (Dore & Romans, 2001),

suicide attempts (Chessick et al. 2007), strain on their relationships and feelings of

helplessness (Bauer et al., 2011), as well as experiencing a lack of involvement with mental

health care teams (Highet et al., 2004).  Research suggests that issues such as these may have

a negative impact on the carers' quality of life (Zendjidjian et al., 2012) leading to high

incidences of clinically significant distress and levels of service utilisation significantly

higher than those seen in the general population (Steele et al., 2010).

Many researchers adopt the concept of caregiver burden to conceptualise the impact

on family carers of people diagnosed with BD  (Vella & Pai, 2012), with  several authors

suggesting such carers experience high levels of burden (Maji et al., 2012; Reinares et al.,

2004; Van der Voort et al., 2007).  Caregiver burden is often separated into 'subjective

burden' and 'objective burden' (Cuijpers & Stam, 2000), with objective burden being

characterised by the behaviours of the individual being cared for and the observable effect

that this may have on the carer (e.g. disruptions to the carer's sleep or them struggling with

finances), while subjective burden characterises how these difficulties are experienced by the

carer (e.g. subjective experiences of anxiety, low mood, anger etc.).

 Negative outcomes for family caregivers may also lead to negative outcomes for

those they are caring for (Perlick et al., 2010).  Higher caregiver scores on measures of

burden have been linked to an increased risk of individuals with BD experiencing a further

major mood episode, regardless of the person with BD's recent history of mood episodes

(Perlick et al., 2001).  Furthermore, difficulties in family relationships may lead to people

diagnosed with BD experiencing a lack of social support (Miklowitz, 2007), which has been

found to predict subsequent episodes of depressed mood (Johnson et al., 2003).

Perlick et al. (2004) found that the degree of difficulty experienced by relatives in

managing the demands of caring predicted higher levels of emotional over-involvement (e.g.

over-protectiveness, high levels of self-sacrifice, over-stated emotional responses) in carers'

relationships with their relative diagnosed with BD.  Emotional over-involvement is one component of the concept of expressed emotion (EE), which refers to family members' attitudes to a relative experiencing problems with mental or emotional wellbeing, and has been found to predict recurrence of mood episodes in people diagnosed with BD, particularly episodes of depression (Miklowitz & Johnson, 2009).  Findings such as those by Perlick et al. suggest that difficulties caring for individuals diagnosed with BD may lead to emotional over-involvement, although Miklowitz (2004) recommends caution in interpreting such findings as evidence of a direct causal relationship.  Miklowitz suggests that the relationship between EE and outcome in those diagnosed with BD is likely to be bidirectional, and that difficulties arising from having a family member diagnosed with BD may exacerbate previously-existing negative communication patterns and ways of interacting.

In summary, research findings consistently suggest a high prevalence of distress and difficulty among family carers of people diagnosed with BD, and seeking to address this may have positive effects on the person diagnosed with BD and their relatives.

**Family Interventions for People Diagnosed with BD**

In a Cochrane Review of seven randomised control trials (RCTs) Justo et al. (2009) stated that there was insufficient evidence to conclude whether or not family interventions were effective in producing positive outcomes for people diagnosed with BD, due to the small number of studies using an RCT design, and the heterogeneous nature of the interventions assessed.  Miklowitz and Scott (2009) systematically reviewed the outcome of all types of psychosocial intervention on individuals diagnosed with BD and concluded that, whilst there was evidence for the effectiveness of psychosocial interventions (including family intervention) as an adjunct to pharmacotherapy, little was known about which are the effective elements of these interventions, who they work best for, their adverse effects, or their cost-effectiveness.  Fiorillo et al. (2013) are more optimistic in their recent review of the

literature on family intervention for people diagnosed with BD, stating the available evidence

suggests that "supportive family intervention should be an integral part of optimal

management of bipolar disorder" (p.134).  However, the more positive tone of this conclusion

may be due to Fiorillo et al. reporting studies' positive findings without consideration of the

methodological limitations taken into account by Justo et al. and Miklowitz and Scott.

Reinares et al. (2002) reviewed studies focussing on the impact of family

interventions for people diagnosed with BD, and concluded that they may be of benefit both

for individuals with a BD diagnosis and for their families.  However, this conclusion is based

on only two papers that reported outcomes for family members following family intervention

(Clarkin et al., 1990; Van Gent & Zwart, 1991).  The authors also comment that the evidence

is limited by methodological issues such as lack of control groups, and lack of controls for

factors such as life events and psychiatric diagnoses in family members.  More recently,

Fiorillo et al. (2013) examined the impact of family intervention on relatives' outcomes as

part of a wider review of family intervention for people diagnosed with BD, and state that

family interventions consistently "improve coping strategies and increase knowledge about

bipolar disorder and early warning signs" (p. 138).  However, Fiorillo et al.'s conclusions

may again be questioned due to their lack of consideration of studies' methodological issues,

such as the utilisation of questionnaire measures with no demonstrated psychometric

properties (e.g. Ruffolo et al., 2011) or research designs that do not include a comparison

group of any sort (e.g. Jonsson et al., 2011).

This review assesses the impact of family interventions for people diagnosed with BD

and their relatives, specifically focussing on relatives' outcomes. This review updates the

findings of Reinares et al.'s (2002) and Fiorillo et al (2013), whilst also addressing some of

their methodological flaws.  Specifically, neither of these reviews provide information about

a systematic search strategy or any inclusion criteria, meaning their searches cannot be

replicated and it is unclear to the reader why they have included some papers but not others (e.g. Fiorillo et al. omit Miller et al.'s (2008) RCT that measures distress levels of relatives). Further, the methodological quality of studies is not formally assessed or taken into account in the interpretation of findings.  A more rigorous review of this area is timely given that the UK's National Institute for Health and Care Excellence (NICE) have released a draft update of their guideline *The management of bipolar disorder in adults, children and adolescents in primary and secondary care* for consulation (NICE, 2014).  The draft suggests clinicians should consider offering psychosocial interventions for relatives of people diagnosed with BD.  A rigorous review of the literature in this area may provide clinicians with more explicit guidance as to which interventions they should consider offering.

The question this review aims to address is:
"What is the evidence that family intervention for people diagnosed with BD affects outcomes for family members of the diagnosed individual?"

The methodological quality of the included studies will be assessed and taken into consideration when interpreting findings. This study also aims to identify which specific outcomes for relatives show the most evidence for improvement following family intervention, and which are the most effective elements of family intervention in improving relatives' outcomes.

## Method

### Search Strategy

The electronic databases AMED (Allied and Complementary Medicine Database), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Embase, Medline and PsycINFO were searched electronically for papers up to and including 14/05/14.  Search terms used are shown in Table 1, and concentrated on four key categories: terms for bipolar; terms for relatives; intervention terms; and outcome terms.  The whole texts of entries were

searched. Titles of articles were inspected, and if a title indicated an article might be relevant the abstract was read. If the abstract indicated the article might meet inclusion criteria, the full text of the article was retrieved in order to ascertain whether it met inclusion criteria. A flowchart documenting this process is detailed in Figure 1.

**Insert Table 1**

In addition, the reference lists of included papers were hand searched for further relevant papers. The reference lists of relevant review articles found during this search process were also inspected for this same purpose. These review articles were: Reinares et al. (2002); Justo et al. (2007); Lucksted et al. (2013); and Fiorillo et al. (2013). A further review article (Dixon et al., 2001) was obtained during this process, and its reference list was also hand-searched. This process uncovered no additional papers.

**Inclusion Criteria**

Studies met criteria for inclusion in the study if they:

- Evaluated an intervention involving relatives of adults diagnosed with BD;

- Reported outcomes using measures that had been investigated for their psychometric properties in peer-reviewed research;

- Evaluated the intervention over at least two different time points (e.g. pre- and post-measures);

- Reported inferential statistics for the intervention under evaluation;

- Published in English in a peer-reviewed journal.

**Insert Figure 1**

Once full texts were retrieved, studies only using measures where psychometric properties had not been investigated were excluded due to the difficulties in interpreting resulting findings (n=3: Fitzgerald, 1972; Davenport, 1977; Ruffolo et al., 2011). Studies only reporting descriptive statistics were also excluded (n=1; Bland & Harrison, 2000), again

due to difficulties in interpreting the generalizability of such data. Pilot studies based on data also reported in later studies were also excluded (n=1: Honig et al., 1995). Papers were not automatically excluded if they investigated interventions designed for people with a range of diagnoses, or for a combination of adults and children- however to meet inclusion criteria such studies had to show results and inferential statistics specifically for families of adults diagnosed with BD, as opposed to only displaying aggregated data for all families regardless of family member diagnosis. Five studies were excluded as they only presented aggregated data for family members of individuals with a range of diagnoses (Anderson et al., 1986; Dixon et al., 2004; Lucksted et al., 2013; Mueser & Fox 2002; Sherman et al., 2006), while one study was excluded due to aggregating data for families of children and adults diagnosed with BD (Eisner & Johnson, 2008). Two studies met all other inclusion criteria but upon inspection of the full text measured relatives' outcome variables at only one time point (Miklowitz et al., 2000; Uebelacker et al., 2006).

**Assessment of Quality**

The methodological quality of papers included in the review was assessed using the Clinical Trial Assessment Measure (CTAM; see Appendix B) (Tarrier & Wykes, 2004). The CTAM was chosen to assess quality as it is based on Moher et al.'s (2001) CONSORT (Consolidated Standards Of Reporting Trials) framework for ensuring and assessing quality in controlled trials of clinical interventions. The CTAM rates papers according to six areas: recruitment, allocation, measurement of outcome, control groups, description of the intervention, and methods of analysis. Although a total score can be computed by allocating differential weightings to specific areas of the CTAM, a sum of the scores given for the six different areas may also be used to indicate a paper's overall quality (Lobban et al., 2013a). Wykes et al. (2008) suggest that a sum CTAM score of 65 is indicative of adequate methodological rigour- however, this cut-off point seems to have been chosen arbitrarily

rather than being based on any validated norms, and so was not used here to guide inclusion criteria. The CTAM was instead used to provide criteria for systematically assessing the methodological quality of studies published in this area. Included papers' CTAM scores are displayed in Table 2.

**Analysis**

The heterogeneity of the interventions and measures employed within the included studies indicated meta-analytic methods would not be appropriate (Bailar, 1995). Studies were therefore analysed by narrative means in the areas of: sample characteristics; CTAM scores; intervention characteristics; recruitment and retention; and relatives' outcomes.

## Results

The studies included in this review are listed in Table 2, along with details as to the numbers of relatives who participated, their control conditions, CTAM score, the focus of the study, and outcomes measured. All but one of the studies focussed exclusively on interventions aimed at people diagnosed with BD and their families: Clarkin et al. (1990) evaluated family therapy with people diagnosed with BD and people diagnosed with unipolar depression, but present separate data for the two groups. The effect of intervention on relatives' outcomes was the primary focus in three of the studies (Honig et al., 1997; Jonsson et al., 2011; Madigan et al., 2012).

## Insert Table 2

**Sample Characteristics**

The number of relatives included across the 10 studies could not be computed as two studies (Clarkin et al., 1990; Miller et al., 2008) did not report the total number of relatives who participated in their interventions. Across the eight remaining, 349 relatives participated in total. Given that Clarkin et al. (1990) and Miller et al.'s (2008) samples included, respectively, 21 and 92 people diagnosed with BD, it can be inferred that at least 113

additional relatives participated across these two studies, bringing the overall number of

relatives participating in the 10 studies up to at least 462.

Three studies did not describe the age of relatives who participated (Clarkin et al.,

1990; Miller et al., 2008; Reinares et al., 2004), and five did not provide specific details as to

the nature of the relationship between the relative(s) attending the intervention and the

individual diagnosed with BD (Clarkin et al., 1990; Honig et al. 1997; Miller et al., 2008;

Reinares et al., 2004; Simoneau et al., 1999).  Across the seven studies that detailed the

proportion of their sample who were parents of an individual diagnosed with BD, parents

comprised 36.4% of the sample.  Authors did not consistently report the number of other

relatives who participated in their study, although these are most frequently reported as being

partners, adult children and siblings.

**Methodological Quality**

All studies were assigned a total CTAM score out of 100 (see Table 3).  CTAM

scores ranged from 21 to 69 (mean=47.4; SD=19.9; median=57.5).  Only three studies (Miller

et al., 2008; Perlick et al., 2010; Simoneau et al., 1999) met Wkyes et al.'s (2008) cut-off of

65, denoting an adequate methodology.

As shown in Table 3, the studies included in this review tended to score low on the

CTAM's "analysis" subscale, where eight studies attained no more than five points out of 15

(the exceptions being Miller et al., 2008, who scored 11; and Van Gent and Zwart, 1991, who

scored 0).  These eight studies lost marks on the "analysis" subscale for not including all

participants as randomised (e.g. by using intention-to-treat analyses) and for not investigating

drop-outs when attrition rates exceeded 15%.  The studies also tended to score low on the

"active treatment" subscale, where only three studies scored above three points out of 11.

The remaining seven studies either provided very little detail as to interventions being

evaluated (Madigan et al., 2011; Miller et al., 2008; Reinares et al., 2004), or described the

intervention but did not use a manual (Bernhard et al., 2006; Honig et al., 1997; Jonsson et al., 2011; Van Gent & Zwart, 1991).  Only two studies (Perlick et al., 2010; Simoneau et al., 1999) used manualised interventions where therapist adherence was assessed as part of the study design.

**Insert Table 3**

**Interventions Evaluated**

Six distinct types of intervention were evaluated across the 10 studies: five studies used multi-family psychoeducation for groups of relatives only (Bernhard et al., 2006; Jonsson et al., 2011; Madigan et al., 2012; Reinares et al., 2004; Van Gent & Zwart, 1991); two studies used multi-family psychoeducation groups including groups of relatives and individuals diagnosed with BD (Honig et al., 1997; Miller et al., 2008); one study (Simoneau et al., 1999) investigated Family-Focussed Therapy (FFT), with another (Perlick et al., 2010) investigating Family-Focussed Therapy Health Promoting Intervention (FFT-HPI), a therapy based on FFT; one study (Clarkin et al., 1990) evaluated Inpatient Family Intervention (IFI); and one study (Miller et al., 2008) evaluated Problem Centred Systems of the Family (PCSTF).

Of the papers reporting multi-family psychoeducation for groups of relatives only, two (Bernhard et al., 2006; Jonsson et al., 2011) explicitly state that the intervention is based on cognitive-behavioural principles, one (Madigan et al., 2012) states the intervention is based on Miklowitz's (2002) self-help manual for carers, while the remaining two (Reinares et al., 2004; Van Gent & Zwart, 1991) do not refer to the programmes under investigation being based on any specific theoretical orientation or pre-existing programs.  Of the two papers evaluating multi-family psychoeducation for groups of individuals diagnosed with BD and their relatives, Honig et al. (1997) state their programme was based on similar educational interventions used for families of people diagnosed with schizophrenia, while

Miller et al. (2008) state their intervention was based on a psychoeducational program for relatives of people diagnosed with depression.

Clarkin et al. (1990) evaluated IFI, a programme manualised by Clarkin et al. (1981) based on the family accepting the needs of the individual diagnosed with BD, identifying potential triggers for problems with their mood, and planning strategies to address these problems in future.  IFI is used with individual families, as is FFT (Simoneau et al., 1999) and FFT-HPI.  FFT and FFT-HPI are both based on a manualised behavioural approach to family therapy (Miklowitz & Goldstein, 1997; Miklowitz, 2008) that emphasises education about BD, along with training in communication and problem-solving skills, with FFT-HPI featuring additional material exploring ways of coping for carers.  Miller et al. (2008) evaluated PCSTF, an approach that focusses on working with individual families to develop problem-solving techniques for specific issues (Ryan et al., 2005).  Madigan et al. (2012) compared their psychoeducational group intervention with a solution-focussed group programme, as well as a Treatment as Usual (TAU) condition, but give few details as to what this intervention entailed.  Interventions evaluated across the 10 studies comprised differing numbers of sessions, ranging from two workshops of four hours' duration (Bernhard et al., 2006) to 20 sessions of FFT (Simoneau et al., 1999).

**Recruitment and Retention**

Madigan et al. (2012) were the only authors to include data detailing how many relatives were offered the opportunity to participate in their trial, and how many accepted.  Of the 165 relatives who were assessed as being eligible for the trial, 118 refused.  The most common reasons for refusal were a lack of involvement with the relatives' illness (n=43), the intervention not being relevant "as duration of illness prolonged" (n=31), though it is unclear what this means within the context of the study, and the relatives seeking longer term support (n=15).

The proportion of relatives completing interventions following group allocation was not always clear from the data presented. In the four studies that reported this, completion rates ranged from 76% (Jonsson et al., 2011) to 100% (Bernhard et al., 2006; Van Gent & Zwart, 1991). All but one of the papers where intervention completion rates could be calculated reported on the outcome of brief psychoeducational interventions. The exception was Perlick et al.'s (2010) study, wherein 96% of participants allocated to the 15 session FFT-HPI intervention completed the programme.

Retention to studies at follow-up was also not always clear, in two cases (Clarkin et al., 1990; Simoneau et al., 1999) because studies reported number of families who dropped out of follow-ups rather than reporting the number of individual relatives. One study (Van Gent & Zwart, 1991) did not mention retention to the trial over the course of its six month follow-up. Of the remaining studies four studies (Bernhard et al., 2006; Jonsson et al., 2011; Madigan et al., 2012; Miller et al., 2008) that reported on follow-ups, the mean retention to the trial at follow-up was 49% (median= 71%, range= 18.4% to 76%). Bernhard et al (2006) recorded the lowest retention rate, even though their follow-up period (1 year) was the shortest. This may be due to their psychoeducation intervention comprising fewer sessions than the other interventions (two sessions in total), perhaps influencing participants' motivation to respond to follow-ups. Other interventions followed-up participants at 2 years (Jonsson et al., 2011; Madigan et al., 2012) and 2 years 4 months (Miller et al., 2008). No study dealt with drop-outs from their trial by using intention-to-treat (ITT) analyses to impute missing data, potentially raising questions as to whether the final samples in studies using follow-up data were representative of the original sample as a whole.

**Outcomes**

The outcomes measured in the studies included in this review can be divided into three categories: carer burden; family interactions; and carer distress. Other outcomes only included in one study were also considered.

**Carer burden.** Of the five studies that investigated the effect of family interventions on carer burden, four reported that the intervention had a significant positive effect on this variable. Bernhard et al. (2006) found that subjective burden among relatives, as measured by Benazon and Coyne's (2000) scale designed for those living with individual diagnosed with depression, reduced significantly between baseline and assessment at post-intervention ($p = .02$) and 1 year ($p =.03$) as a result of their brief psychoeducational intervention. However, conclusions that can be drawn from these results are limited due to the lack of a control group. In the RCT of their 12-session psychoeducational programme , Reinares et al. (2004) found that relatives assigned to a TAU control condition (pharmacological treatment alone) showed significantly higher post-intervention scores on the Social Behaviour Assessment Scale's (SBAS) 'subjective burden' scale than those who had completed a relatives-only psychoeducation group ($t = 2.12$, $p =.40$). Calculation of effect sizes from Reinares et al.'s data reveals a medium effect ($d =.57$) according to Cohen (1992). Perlick et al. (2010) compared FFT-HPI with a health education intervention and found that a model regressing changes in subjective burden (measured by the SBAS) scores onto treatment allocation explained a significant amount of variation in the data, in favour of the FFT-HPI group ($F= 7.51$, $p =.009$) and carried a large effect size ($d =1.23$). Perlick et al.'s data included pre- and post-intervention scores but did not include longer-term follow-up. Another RCT by Madigan et al. (2012) measured burden using the Involvement Evaluation Questionnaire (IEQ), and found a significant difference in overall caregiver burden between TAU (care from a local multi-disciplinary team) and psychoeducation conditions, with lower scores in the latter, at both 1 year ($z =5.31$, $p <.001$) and 2 years ($z =3.334$, $p <.001$) after the

intervention, with no such differences present at baseline.  However, there was no significant difference at either of these time points between psychoeducation and another condition where family members were assigned to a solution-focussed group intervention.

Two studies found no evidence of an effect of intervention on family burden at any time point.  Of these two studies, Clarkin et al.'s (1990) reporting of attrition throughout their study of IFI makes it unclear whether their null findings may be related to levels of drop-out as the study progressed.  The meaning of Jonsson et al.'s (2011) negative findings with regards to their 10-session psychoeducation group are difficult to interpret as their study did not feature a comparison group of any sort.

**Family interactions.**  Four studies reported outcomes relating to family members' styles of interaction.  Two of these report outcomes for Expressed Emotion (EE).  Bernhard et al. (2006) found a significant positive effect of intervention on EE score when comparing baseline and 1 year follow-up, as measured by Feinstein et al.'s (1989) family questionnaire, for relatives who had participated in their psychoeducational workshops ($p =.004$).  However, once more the conclusions that can be drawn from this are limited due to the lack of a control group.  Honig et al. (1997) reported on levels of EE scores on the Five-Minute Speech Sample (FMSS) among relatives and found that a statistically significant number of people ($p <.03$) changed from high EE to low EE in their psychoeducation group, whereas this change did not occur for any high EE relatives in their group of waiting list controls.  However, problems with the FMSS's reliability (Hooley & Parker, 2006) could have led Honig et al. to classify some of their sample as 'low expressed emotion' incorrectly.  The fact that most researchers in this area have found that family psychoeducation has no effect on relatives' expressed emotion (Eisner & Johnson, 2008) further suggests that Honig et al.'s findings may have been an effect of their choice of outcome measure.

Two studies used alternative measures of family members' interactional styles.   Van Gent and Zwart (1991) measured interactional problem solving using Lange's (1983) questionnaire and found no difference between partners who had completed psychoeducation and waiting list controls.  Simoneau et al. (1999) used the Category System for Partner Interactions (KPI) to measure changes in the communication patterns of people diagnosed with BD and their relatives over the course of FFT.  Although people diagnosed with BD showed increases in positive non-verbal behaviours after FFT, there was no difference in positive or negative verbal or non-verbal interactions displayed by relatives.

**Carers' psychological difficulties.**  Four studies employed measures of relatives' psychological distress, two of which focussed on depression.  Bernhard et al. (2006) found that relatives' scores on the Beck Depression Inventory (BDI) did not reduce significantly after their brief psychoeducational intervention, but did show a significant reduction at 1 year follow-up (p=.013).  However, as noted above, conclusions that can be drawn from this study are limited due to the lack of a control group.  Perlick et al. (2010) found a significant reduction in relatives' scores on the Quick Inventory of Depressive Symptomology (QIDS-C) following FFT-HPI in comparison to the observed QIDS-C changes for relatives who completed a health education intervention ($F$=4.64, $p$ =.037), recording a medium effect size ($d$ =0.5).  Perlick et al. also found that changes in QIDS-C scores were significantly predicted by the interaction between experimental group and changes in avoidant styles of coping, as measured using items from the Ways of Coping Questionnaire (WCQ) ($F$=4.01, $p$ =.014). No such interaction was found for participants assigned to a Health Education group.  This indicates that FFT-HPI decreased feelings of depression for caregivers through the mechanism of changing avoidant coping strategies.

Two studies measured overall psychological distress.  Madigan et al. (2012) found a significant difference between scores on the General Health Questionnaire 12 (GHQ12) for

relatives who had completed psychoeducation compared to those in the TAU group at 1 year follow-up ($z =1.95$, $p =.025$) but not at 2 years, with lower scores for those in the psychoeducation condition.  However, when comparing GHQ12 scores of participants who had been assigned to psychoeducation with scores of those who had been assigned to the group solution-focussed intervention, there were no significant differences at either 1 year or 2 year follow up.  Drawing conclusions from this data is difficult, as the authors did not specify whether they had scored the GHQ12 bi-modally or using a 4 point Likert scale (Schmitz et al., 1999), so the potential maximum GHQ12 score for participants is unclear and therefore readers cannot interpret changes in the mean scores for the two groups.  Miller et al. (2008), compared relatives' overall psychological distress scores on the Symptom Checklist 90 Revised (SCL-90-R) across TAU, psychoeducation, and PCSTF conditions, and found no significant differences between relatives in these conditions at any time point.

**Variables included in only one study.**  Studies included in the review also measured a number of other variables, each of which was only measured in one study.   Jonsson et al. (2011) measured general coping behaviour using the Jalowiec Coping Scale-40 and found significant reductions between baseline and follow-up at 6 months ($z =-2.763$, $p =.006$) and 2 years ($z =-3.253$, $p =.001$) following psychoeducation.  Although the authors cite a significant positive interaction of time on outcome ($x^2=10.203$, $p =.006$) as support for the effectiveness of their intervention, this analysis is based on pre-post comparisons with the same group of participants due to a lack of control group.  These findings may therefore be attributable to a maturation effect rather than the intervention.

Perlick et al. (2010) found that compared to relatives receiving a health education intervention, relatives receiving FFT-HPI showed significant reductions in health risk behaviours post-intervention compared to pre-intervention scores ($F=5.11$, $p =.029$). Madigan et al. (2012) found a significant increase in caregiver quality of life for participants

in their psychoeducation group compared to those in their TAU group at 1 year- and 2 year-follow up (1 year: $z =3.81$, $p <.001$; 2 year: $z =3.71$, $p <.001$), though there were no significant differences between relatives' scores in the psychoeducation group and their solution-focussed group at either of these time points.

A number of variables were only measured in one study with no significant findings. Clarkin et al. (1990) measured family attitude and did not record significant findings, although any interpretation here is limited as it is unknown how many relatives of people diagnosed with BD responded. This is possibly a low number due to the high drop-out rates recorded in the sample as a whole. Jonsson et al. (2011) found no significant changes in social functioning and capacity to manage stress following psychoeducation, though again this study used no control group. These authors also found no significant differences between baseline and later measurements of relatives' capacity to manage stress and their social functioning. Madigan et al. (2012) found no significant differences in Global Assessment of Functioning between either of their intervention groups (psychoeducation and a solution-focussed group) and TAU over a period of 2 years, and Reinares et al. (2004) found no significant interaction between group and relatives' perceptions of the family environment when comparing psychoeducation and TAU.

## Discussion

This paper aimed to review the current research regarding whether family interventions for people with BD affect relatives' outcomes. The strongest evidence in this area is for multi-family psychoeducation group for relatives only (Madigan et al., 2012; Reinares et al., 2004) and Perlick et al.'s (2010) FFT-HPI. Multi-family psychoeducation may reduce relatives' levels of carer burden and increases relatives' quality of life scores for at least 2-years after intervention, and may reduce relatives' levels of psychological distress for at least 1-year after intervention. FFT-HPI may reduce relatives' levels of carer burden,

feelings of depression and destructive coping behaviours, but there is currently no evidence

for these benefits being maintained at follow-up.

These findings are based on an additional seven studies to those included in Reinares

et al.'s (2002) review in this area, including four RCTs, which has enabled more specific

conclusions to be drawn regarding specific interventions and their potential benefits.  These

conclusions are also notably more cautious than those of Fiorillo et al.'s (2013) review, which

stated "family psychoeducational interventions reduce subjective burden on relatives,

improve coping strategies and increase knowledge about bipolar disorder and early warning

signs" (p. 138).  A likely reason for the different conclusions reached in the current review is

that a more stringent approach has been taken to setting inclusion criteria and assessing

included studies' methodological quality.  The current review excludes papers that did not

use tools with assessed psychometric properties, while Fiorillo et al.'s review included papers

(e.g. Ruffolo et al., 2011) using unstandardized assessments of knowledge about BD, leading

the authors to endorse the impact of family interventions on relatives' knowledge, claims for

which the present review finds no evidence.  Fiorillo et al.'s review also seems to give equal

weight to the findings of each included study, whereas the present review places more

emphasis on forming conclusions based on studies with stronger methodologies.  This may

have led to Fiorillo et al.'s conclusion about family intervention improving relatives' coping

strategies, which is not supported here due to the only available evidence coming from

Jonsson et al.'s (2011) study, which did not use a control group.  Furthermore, the present

review provides more specific conclusions that Fiorillo et al.'s as to which interventions show

strongest evidence for improving relatives' outcomes.

**Methodological Limitations**

This review aimed to interpret the evidence in this area based on an assessment of

studies' methodological quality.  Using Wykes et al.'s (2008) CTAM cut-off of 65, drawn

from their review of CBT for psychosis, 30% of the papers in this review met criteria to denote 'adequate' methodology.  This is comparable to the figure from Wykes et al.'s review of 39.4% meeting this criteria, but compares less favourably to 41.6% in Gooding and Tarrier's (2009) review of CBT for gambling, 55.6% in van der Gaag et al.'s (2014) review of CBT for auditory hallucinations and delusions, and 70% in van der Gaag's et al.'s (2013) review of interventions to prevent first-episodes of psychosis.  The 30% of papers in the current review that obtained a CTAM score denoting adequate methodology is somewhat better than the 22% that did so in Lobban et al.'s (2013a) similar review of relatives' outcomes following family intervention in psychosis.  However, Lobban et al.'s review included 53 papers, whereas the smaller number of papers in this review means that there are only three studies with adequate methodology from which one can draw conclusions.  Readers should therefore bear in mind that any conclusions drawn from such a small pool of methodologically sound studies will necessarily be tentative, and should be treated with caution.

Examination of the CTAM subscales where studies received low marks highlights the caveats that readers should bear in mind when interpreting the above conclusions.  One common methodological shortcoming of included studies highlighted by the CTAM's 'analysis' subscale is that studies providing follow-up data recorded high drop-out rates, but excluded these participants from analysis rather than using techniques such as ITT analyses to impute their outcomes and ensure they were included as randomised.  Failure to use such techniques may lead to final samples that are unrepresentative of the sample originally recruited, and that may have limited generalizability.  This is particularly relevant to conclusions relating to long-term follow-up of improvements in participants' caregiver burden, self-esteem and quality of life following multi-family psychoeducation, which are based on Madigan et al.'s (2012) RCT.  Madigan et al. recorded an attrition rate of 34%, yet

used no ITT analysis. This suggests that evidence regarding the long-term effects of multi-family psychoeducation on relatives' outcomes may be biased by not including data from people who dropped out of the trial, impeding generalizability, and conclusions drawn from this evidence should therefore be treated with caution.

Papers in this review also scored low marks on the CTAM's 'active treatment' subscale (discussed below). Studies assessing the impact of family intervention in psychosis on relatives' outcomes in Lobban et al.'s (2013a) review also tended to score low marks on the same areas of the 'analysis' and 'active treatment' subscales, suggesting more thoroughly defined intervention protocols and appropriate handling of data missing through attrition are important methodological issues that future researchers in this areashould take care to address.

**Key Elements of Family Intervention**

This review also aimed to ascertain the key elements of family intervention in BD that impact relatives' outcomes. However it was difficult to ascertain which aspects of interventions were most effective due to the lack of information provided about intervention components, as reflected by studies' low scores on the CTAM's 'active treatment' subscale, in part due to the fact that little specific information was given as to the theoretical basis or content of interventions . This made it difficult to compare studies and attempt to ascertain which elements of an intervention have been key to its efficacy or effectiveness. For example, Reinares et al. (2004) and Madigan et al. (2012) both conducted RCTs of multi-family psychoeducation for groups of relatives. However, Reinares et al. provide no detail as to the theoretical bases of their intervention, and although topics for each session are outlined there is no indication as to how these topics were addressed. Similarly, Madigan et al. state that their intervention is based on Miklowitz's (2002) self-help text about BD, but provide no

detail as to how this was adapted into a group psychoeducational programme specifically for relatives.

The comparison conditions used by authors pose further problems in assessing which elements of interventions were most effective. The majority of authors used waiting list controls or TAU as comparison conditions for their interventions. One exception was Perlick et al. (2010), who compared FFT-HPI with a health education programme. However this programme was didactic in nature and featured little opportunity for participants to share their own experiences or relate these experiences to the material being presented. This raises the possibility that relatives' gains following FFT-HPI may have been an effect of having a space in which to share their experiences and feel listened to, rather than specific features of the FFT-HPI programme per se. In the one study that used a more active comparison, Madigan et al. (2012) compared their psychoeducation programme with a group intervention based on solution-focussed principles (George et al., 2006; Sharry, 2007) and found no significant differences between relatives in the two conditions on variables including carer burden, quality of life and general distress levels. This raises the possibility that positive effects of interventions on relatives' outcomes may have been due to non-specific factors rather than specific features of the interventions under investigation. Such non-specific factors may include being listened to by an attentive therapist in interventions such as FFT or FFT-HPI. If taking part in multi-family group interventions, non-specific factors may include relatives meeting other individuals who share similar problems to their own and having their problems listened to by a group of peers (Diefenbeck et al., 2014). It is therefore unclear whether improvements in relatives' outcomes are the result of any specific intervention component, or whether they are attributable to more general supportive factors.

**Limitations of This Review**

Although this review is the most rigorous to have taken place on the topic of relatives' outcomes following family intervention for people diagnosed with BD, readers should still be mindful of limitations.  Only papers published in English-language journals were considered for inclusion.  The exclusion of data from papers not written in English may therefore have influenced the results of the analysis.

It was also not possible to employ reliability checks for papers' CTAM scores in time for this paper's submission.  However, a researcher with specific interest in statistics and clinical trials has agreed to provide these checks in advance of this papers' submission to its target journal.

**Clinical Implications**

From the draft of NICE's (2014) revised guidance for clinicians working with people diagnosed with BD and their relatives, it seems likely the final revised guidelines will recommend clinicians offer psychosocial interventions to relatives.  On the basis of current evidence, this review indicates that clinicians might consider multi-family psychoeducation as an intervention of choice in order to provide more positive outcomes for relatives of people diagnosed with BD, particularly if targeting reductions in carer burden and general distress, as this is the only intervention with any evidence for gains being maintained over the course of 1-2 years.  There is only evidence for these groups being effective in improving outcomes when they comprise carers alone, without the individual diagnosed with BD.  Where relatives present with harmful coping behaviours, clinicians may wish to offer FFT-HPI in order to address this alongside carers' feelings of burden and depression.  However, in making this choice clinicians should be aware that there is no evidence as yet of gains following FFT-HPI being maintained beyond the end of the intervention.

However, clinicians may wish to base this decision on other clinical considerations.  Whether an individual diagnosed with BD is included in family intervention may depend on

individual family's preferences and circumstances: families may have their own thoughts as to whether the diagnosed individual should be included, and formulations developed between families and clinicians may also indicate whether a whole-family or relatives-only approach will be most helpful.  Furthermore, multi-family psychoeducation groups may not be practicable for clinicians serving smaller communities, which may have a lower number of families where an individual has been diagnosed with BD.  This may leave clinicians with no option but to work with individual families rather than being able to provide multi-family psychoeducation groups.  Clinicians may wish to use FFT (Miklowitz, 2008) as a framework for doing so.  Although the only paper in this review that evaluated FFT (Simoneau et al., 1999) found that it had no effect on relatives' positive communication levels, FFT forms the basis for Perlick et al.'s (2010) FFT-HPI, which was found to decrease post-intervention levels of carer burden and depression.

**Implications for Future Research**

Studies' scores on the CTAM's sub-scales indicate that future research in this area should address recurring limitations relating to the handling of missing of data (e.g. by using ITT analyses), inadequate description of intervention protocols, and lack of quality assessments to ensure intervention protocols are adhered to.  Future studies should also attempt to compare interventions against other similar evidence-based programmes in order to ascertain which specific intervention components are most effective.  Researchers should also use comparison conditions other than TAU in order to indicate whether psychosocial interventions result in benefits above and beyond those that may be gained through supportive interventions (e.g. by outcomes following interventions to those observed following supportive counselling or attending support groups).

Furthermore, relatives themselves should be involved in future research from the planning phase.  Consulting with relatives as to their preferences regarding intervention

format and content may facilitate engagement with the research process and improve trials'

retention rates. The promising results from an RCT exploring the feasibility of an

intervention aimed at relatives of people diagnosed with psychosis (Lobban et al, 2013b),

where relatives were involved in the development and evaluation of the intervention, suggests

that such involvement may also have a positive impact on intervention efficacy.

### Highlights

- Research on relatives' outcomes following family intervention was reviewed

- Family intervention may reduce carer distress and carer burden

- However, this may be due to non-specific effects of interventions

- Future research should address methodological issues affecting most studies in this area

- Clinicians may need to adapt interventions to fit their routine practice

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Table 1.  Search terms for electronic search of databases

| Field/Category[1] | Search Terms Used |
|---|---|
| Bipolar | Bipolar OR manic OR mania OR hypomani* |
| Family | Carer* OR caregiver* OR "care giver*" family OR relative* OR partner* OR spouse* OR husband* OR wife OR wives OR "significant other*" OR mother* OR father* OR son* OR daughter* OR sibling* OR parent* OR couple* OR marital |
| Intervention | Intervention OR psychoeducation OR therapy OR training OR CBT OR treatment |
| Outcome | distress OR burden OR wellbeing OR symptoms OR coping OR attitudes OR "expressed emotion" OR attribution* OR "locus of control" OR communication OR conflict OR stress OR hope OR "quality of life" OR health OR strain OR "interpersonal relations*" OR "family relations*" OR "relationship quality" OR "relationship satisfaction" OR resourcefulness OR resilience OR stigma OR support OR impact OR adjustment |

[1]All fields were connected with the Boolean operator 'AND' when entering them into database search engines.

Table 2.  Properties of Studies Included in the Review

| Authors | Location | N | Comparison | Intervention | Primary Focus | CTAM Score (Max=100) | Family Outcomes Measured | Summary of Main Findings on Family Outcome |
|---|---|---|---|---|---|---|---|---|
| Bernhard et al., 2006 | Germany | 49 | None | 2x 4hr multi-family group psychoeducation (relatives only) | Effectiveness of psychoeducation on service user and family outcomes | 21 | Objective burden; Subjective burden; Expressed emotion; Depression; | Relatives displayed less symptom-related burden post-intervention and at follow up; Expressed emotion reduced at follow-up |
| Clarkin et al., 1990 | USA | Unclear exactly how many relatives returned data | TAU (medication review) | IFI (inpatient family intervention) | Effectiveness of family intervention on patient and family variables, compared to lithium treatment alone | 58 | Family attitudes to treatment, social support and the service user; Family burden | No significant findings at 6 month or 18 month follow-up |
| Honig et al., 1997 | Netherlands | 52 | Waiting list control | 6x2hr group psychoeducation (people with BD diagnosis and their relatives) | Effect of psychoeducation on relatives' levels of expressed emotion | 31 | Expressed emotion | Significant effect of intervention on reduction of expressed emotion |
| Jonsson et al. , 2011 | Sweden | 34 | None | 10x90 minute education sessions multifamily group psychoeducation (relative only) | Effect of intervention on long-term family outcome | 21 | Impact of caring; Coping behaviour; Social function; Ability to manage stress | Significant difference in coping behaviour between baseline and T3, and baseline and T5. Decrease significant over time |
| Madigan et al., 2012 | Republic of Ireland | 47 | TAU (MDT care)/ 5 sessions of solution-focussed group therapy | Condition one: 5x2hr multifamily group psychoeducation (relatives only); Condition two: 5 sessions of solution-focussed group therapy | Effectiveness of psychoeducation on family and patient variables compared to solution-focussed intervention and TAU, over period of 2 years | 58 | Carer burden; Carer distress | Significant differences between psychoeducation and control on carer burden at year 1 and year 2, and on carer distress at year 1 |

| Authors | Location | N | Comparison | Intervention | Primary Focus | CTAM Score (Max=100) | Family Outcomes Measured | Summary of Main Findings on Family Outcome |
|---|---|---|---|---|---|---|---|---|
| Miller et al., 2008 | USA | Not described | TAU (medication review) | 10-15 sessions of PCSF (Problem-Centred Systems of the Family); 6 sessions of psychoeducation | Effectiveness of intervention on patient variables, as moderated by family functioning | 69 | Carer psychiatric symptoms | No significant difference in carer psychiatric symptoms between baseline and later measures for either condition |
| Perlick et al., 2010 | USA | 43 | Standard health education programme | 12-15 sessions of FFT-HPI (Family Focused Therapy-Health Promoting Intervention) | Effectiveness of psychoeducational program compared to control; Mediators of change | 66 | Carer depressive symptoms; Health behaviour; Carer burden; Coping | Significant effect of treatment group on carer depression, health behaviour, and burden scores; Reduction in avoidant coping mediates depression scores in intervention group |
| Reinares et al., 2004 | Spain | 45 | TAU (medication review) | 12x90 min sessions of psychoeducation | Effectiveness of intervention for caregivers vs TAU | 57 | Carer burden; Family relationships | Significant decrease in subjective burden and attributions of patient responsibility for intervention group, but not for TAU group |
| Simoneau et al., 1999 | USA | 52 | TAU (medication review, 2 psychoeducation sessions, crisis management) | 21 sessions of FFT (Family-Focussed Therapy) | Effect of FFT on family communication compared to TAU | 66 | Family communication | Significant increase in non-verbal positive behaviour for patients but not relatives in FFT group |
| Van Gent & Zwart, 1991 | Netherlands | 26 | Control group-receiving no described intervention | 5 sessions of multifamily psychoeducation group (for partners only) | Effect of psychoeducation on patient wellbeing | 27 | Interactional problem-solving | No significant difference in interactional problem-solving between treatment and controls |

Note: CTAM= Clinical Trials Assessment Measure; MDT= Multi-Disciplinary Team; TAU= Treatment as Usual

Table 3.  CTAM Scores for Studies Included in the Review

| Study | Sample (10[1]) | Allocation (16) | Assessment (32) | Control (16) | Analysis (15) | Treatment (11) |
|---|---|---|---|---|---|---|
| Bernhard et al, 2006 | 7 | 0 | 6 | 0 | 5 | 3 |
| Clarkin et al., 1990 | 2 | 13 | 26 | 6 | 5 | 6 |
| Honig et al., 1997 | 7 | 0 | 6 | 10 | 5 | 3 |
| Josson et al., 2011 | 7 | 0 | 6 | 0 | 5 | 3 |
| Madigan et al., 2011 | 2 | 16 | 19 | 16 | 5 | 0 |
| Miller et al., 2008 | 2 | 10 | 29 | 16 | 11 | 0 |
| Perlick et al., 2010 | 2 | 16 | 22 | 10 | 5 | 11 |
| Reinares et al., 2004 | 7 | 10 | 29 | 6 | 5 | 0 |
| Simoneau et al., 1999 | 2 | 13 | 29 | 6 | 5 | 11 |
| Van Gent & Zwart, 1991 | 2 | 10 | 6 | 6 | 0 | 3 |
| **Total** | 40 | 89 | 178 | 76 | 51 | 40 |
| **Average score across all studies** | 4 | 8.9 | 17.8 | 7.6 | 5.1 | 4 |
| **Percentage of total points obtained** | 40 | 55.6 | 55.6 | 47.5 | 34 | 36.4 |

[1]Figures in brackets represent the maximum achievable score on that subscale.

Fig 1. Flowchart of systematic literature search

```
┌─────────────────────────┐                    ┌─────────────────┐
│ Articles titles returned │                    │    Excluded     │
│ by search strategy       │ ─────────────────> │                 │
│                          │                    │    N=3,422      │
│       N=3,508            │                    │                 │
└─────────────────────────┘                    └─────────────────┘
            │
            v
┌─────────────────────────┐                    ┌─────────────────┐
│    Abstracts read        │                    │    Excluded     │
│                          │ ─────────────────> │                 │
│       N= 86              │                    │     N=50        │
└─────────────────────────┘                    └─────────────────┘
            │
            v
┌─────────────────────────┐     ┌──────────────────────────────────────────┐
│   Full texts retrieved   │     │ Excluded N= 26                            │
│                          │ ──> │                                           │
│       N= 36              │     │ Reasons:                                  │
└─────────────────────────┘     │   • No measurement of relatives' outcome  │
            │                    │     (N=7)                                 │
            v                    │   • Review article (N=5)                  │
┌─────────────────────────┐     │   • Family variable only measured at one  │
│ Papers included in review│     │     time point (N=2)                      │
│                          │     │   • No standardised outcome measure used  │
│       N= 10              │     │     (N=3)                                 │
└─────────────────────────┘     │   • No inferential statistics (N=1)       │
            ^                    │   • Results reported in later paper (N=1) │
            │                    │   • Aggregates results of adults and      │
┌─────────────────────────┐     │     children (N=1)                        │
│ References of included   │     │   • Aggregates bipolar with other         │
│ papers and relevant      │     │     diagnoses (N=2)                       │
│ review articles          │     │   • No intervention (N=1)                 │
│ hand-searched for        │     └──────────────────────────────────────────┘
│ additional studies       │
│                          │
│       N=0                │
└─────────────────────────┘
```

**Appendix A:**

**Instructions for Authors for *Journal of Affective Disorders***

## Guide for Authors

### Description

*The Journal of Affective Disorders* publishes papers concerned with **affective disorders** in the widest sense:**depression, mania, anxiety and panic**. It is interdisciplinary and aims to bring together different approaches for a diverse readership. High quality papers will be accepted dealing with any aspect of affective disorders, including biochemistry, pharmacology, endocrinology, genetics, statistics, epidemiology, psychodynamics, classification, clinical studies and studies of all types of treatment.

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**Copy of Clinical Trials Assessment Measure (CTAM)**

**Clinical Trials AssessmentMeasure (CTAM)**

Sample—two questions: maximum score = 10

Q1: is the sample a convenience sample (score 2) or a geographic cohort (score 5), highly selective sample, e.g., volunteers (score 0) **Score:**

(*Convenience sample*—e.g., clinic attenders, referred patients or *Geographic cohort*—all patients eligible in a particular area)

Q2: is the sample size greater than 27 participants in each treatment group (score 5) or based on described and adequate power calculations (score 5) **Score:**

**Sample Score:**

Allocation—three questions: maximum score = 16

Q3: is there true random allocation or minimisation allocation to treatment groups (if yes score 10) **Score:**

Q4: is the process of randomisation described (score 3) **Score:**

Q5: is the process of randomisation carried out independently from the trial research team (score 3) **Score:**

**Allocation Score:**

Assessment (for the main outcome)—five questions: maximum score = 32

Q6: are the assessments carried out by independent assessors and not therapists (score 10) **Score:**

Q7: are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms (score 3) **Score:**

Q8: are assessments carried out blind (masked) to treatment group allocation (score 10) **Score:**

Q9: are the methods of rater blinding adequately described (score 3) **Score:**

Q10: is rater blinding verified (score 3) **Score:**

**Assessment Score:**

Control groups—one question: maximum score = 16

Q11: TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)

**Control Groups Score:**

Analysis—two questions: maximum score = 15

Q12: the analysis is appropriate to the design and the type of outcome measure (score 5) **Score:**

Q13: the analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4) **Score:**

**Analysis Score:**

Active treatment—three questions: maximum score = 11

Q14: was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3) **Score:**

Q15: was adherence to the treatment protocol or treatment quality assessed (score 5) **Score:**

**Active Treatment Score:**

where the criterion is not reached for any question score = 0

Total score:  maximum score = 100

**Section Two: Empirical Paper**

**Managing Bipolar Moods Without Medication: A Qualitative Investigation**

**Word Count: 8,000**

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[2] See Appendix A.

## Abstract

**Objectives:** Although many people diagnosed with Bipolar Disorder (BD) choose to manage their moods without medication at some point, their experiences have not been researched. This paper aims to explore the psychological and social processes by which people manage bipolar moods without medication.

**Methods:** Ten participants diagnosed with BD who manage their moods without medication were interviewed. Analysis of their accounts using grounded theory methods led to developing of a model of their perception of the processes involved in managing moods without medication.

**Results:** Participants engaged in a repeated evaluative process around which strategies to use in order to manage their moods, where their intentions and actions were influenced by their perceptions of themselves as people and the personal meaning they placed on bipolar moods. Different obstacles to implementing intentions presented themselves to participants as their mood varied.

**Conclusions:** The complexity of the processes described by participants suggests traditional models of explaining non-adherence may not capture the extent of some individual's experiences. Understanding the processes involved in not using medication for bipolar moods may inform the development of future psychosocial interventions for those who make this choice. Services should place more emphasis on non-medication approaches in order to make services acceptable for such individuals.

**Limitations.** Findings relate specifically to these participants' perceptions of the processes involved in managing their moods. Future research should ascertain the extent to which such processes may apply to others who make this choice, and which factors predict better outcome when managing bipolar moods without medication.

*Key Words:* Bipolar disorder; medication; self-management; qualitative research

Bipolar Disorder (BD) is a term used to describe experiences of mood fluctuating between extreme low and high states (American Psychiatric Association, 2013; World Health Organisation, 1992). During periods of elevated mood individuals may experience high levels of physical and mental energy, agitation, increases in goal-orientated behaviour, and increased engagement in pleasurable and risky activities. Extreme periods of elevated mood can also be associated with unusual experiences such as seeing or hearing stimuli others can't perceive, or unusual beliefs about oneself or others (often characterised as delusions). During low mood episodes, individuals commonly experience 'dysphoria'- problematic feelings of anxiety, guilt and depression (Mansell & Pedley, 2008). As noted in publications such as the British Psychological Society's (BPS) *Understanding Bipolar Disorder* (2010), the reliability and validity of BD as a construct may be limited, and not all who experience bipolar moods understand these moods as a disorder. This paper therefore avoids using the language of disorder where at all possible.

**Medication for Bipolar Moods**

Guidance for professionals working with those who experience bipolar moods focusses largely on medication. The UK's National Institute for Clinical Excellence (NICE) states that "the treatment of bipolar disorder is based primarily on psychotropic medication to reduce the severity of symptoms, stabilise mood and prevent relapse" (NICE, 2006, p.20). Similarly, the American Psychiatric Association's (APA's) guidance (2002) concentrates almost exclusively on the role of medication in its treatment recommendations. Both guidelines suggest that lithium, valproate or an antipsychotic should be used in the management of acute episodes of mania, and longer-term as prophylactic agentsmedication should be used long-term as a prophylactic. Despite the centrality of medication to current clinical guidance, it is estimated that up to 64% of people diagnosed with bipolar disorder will stop taking medication prescribed for their mood at some point (Leclerc et al., 2013).

Authors such as Yen et al. (2005) and Yatalova (2012) frame the decision not to take medication as 'non-adherence' and suggest this is frequently a result of an individual's 'lack of insight' into the nature of their problems, which the authors see as indicative of psychiatric illness.  Clatworthy et al. (2007) and Clatworthy et al. (2009) also suggest that such decisions can be understood as the result of incorrect beliefs about the safety and effectiveness of medication.  However, such arguments ignore evidence that medication will not be effective for everyone diagnosed with BD, and may cause significant side effects, suggesting that decisions not to take medication might also be carefully thought-through and based on personal negative experiences.  Indeed, the safety and effectiveness of psychiatric medications have been a source of recent academic debate (Moncrieff, 2013; Whitaker, 2010).

In relation to medication's efficacy, Ketter et al. (2011) reviewed studies reporting Number Needed to Treat (NNT) analyses for bipolar mood medications.  NNT analyses are frequently used in the psychiatric literature, and represent the number of individuals in a trial who receive a medication before a clinically significant improvement is seen in one person more than in a placebo control group, (i.e. the ratio of people who do not show clinically significant improvement from a medication for every one who does).  Ketter et al.'s review found NNT ratios ranging from 7 to 9 for the most frequently prescribed drugs.  It would therefore seem from the clinical trials Ketter et al. reviewed that for every one person who benefits from a medication, 7 to 9 people do not.  Such data therefore undermine the assumption that decisions not to use medication are indicative of a lack of insight or mistaken beliefs about medication's effectiveness.

The severe side-effects that can result from medication for bipolar moods also suggest that for some individuals non-adherence may be related to legitimate health concerns. Lithium may lead to tremors in up to 65% of people who take it, with the likelihood of this

increasing when it is used with other psychiatric medications (Grandjean & Aubry, 2009).

Newer atypical antipsychotic medications may still lead to increased fatigue, difficulties

concentrating, and sedation (Serretti et al., 2013).  Furthermore, medications prescribed for

bipolar moods may lead to more serious life-threatening complications, with lithium carrying

risk of kidney failure (Markowitz, 2000), and evidence suggesting that antipsychotics may

reduce life expectancy through increasing risk of cardiovascular problems (Weinmann et al.,

2009).

**Managing Bipolar Moods**

In this paper I use the term 'managing bipolar moods'  to refer to the ways in which

individuals attempt to make the most of their lives while living with the effects of their

moods.  This is adapted from Davidson's (2005) definition of 'self-management' in

schizophrenia- "making the most of our lives despite our condition" (Davidson, 2005, p.27).

I altered the negative connotations from the latter half of Davidson's definition (changing

"despite our condition" to "living with the effects of moods") in an attempt to reflect the

possibility that not all individuals negative meanings to their bipolar experiences (Lobban et

al., 2012).  I retained the initial part of the definition ("making the most of our lives") as it is

sufficiently flexible to accommodate the different meanings that 'managing' may hold for

people depending on how they want to "make the most" of their life.

Existing research into how people manage bipolar moods has traditionally focused

mostly on those who use medication.  There is a body of evidence exploring the use of

psychosocial interventions in supporting people to manage bipolar moods (Reinares et al.,

2014, Vieta, 2013) though the focus is on these interventions as an adjunctive therapy to

medication, and interventions frequently include components aiming to increase medication

adherence (Luty, 2006; Morris & Miklowitz, 2006).

Previous qualitative investigations have explored the variety of ways in which people manage bipolar moods when using medication, such as increasing their understanding of bipolar moods, attempting to recognise triggers and warning signs, and making lifestyle choices to promote mood stability (Russell & Browne, 2005; Mansell et al., 2010).  Murray et al. (2011) found similar strategies were used by people diagnosed with BD considered to be 'high functioning'.  The majority of Murray et al.'s sample used medication on an as-needed basis, with only a minority not taking any medication.  Current qualitative research therefore does not provide an understanding of the ways in which people manage bipolar moods when they do not use medication.

**Study Aims**

The lack of research into how people manage bipolar moods when they have chosen not to use medication is surprising given the significant number of people who make this decision at some point (Leclerc et al., 2013).  It may be that a more detailed understanding of the processes involved in managing bipolar moods without medication might indicate which factors help people when they make this choice, which factors might present difficulties, and how such difficulties can be overcome.  This study aims to provide a starting point in addressing this gap in the literature.

I employed a qualitative design for this study as this is appropriate for exploratory research focussing on subjective experiences and processes (Thompson & Harper, 2012).  I used grounded theory (GT) methods to guide sampling and analyse the data as this approach is concerned with developing theories about social and psychological processes, and is therefore congruent with the research question's focus on process .

The research question for this study is: "What are the processes by which people attempt to manage bipolar mood experiences without medication?". I chose to focus on processes, rather than on people's experiences more broadly, as examining processes entails

gaining an understanding of the mechanisms linking individual's experiences and beliefs to their subsequent decisions and behaviour, which I hope will lead to more clinically useful findings. The purpose of this study is not to suggest that people diagnosed with BD should be able to manage without medication, or that medication is inappropriate. Indeed, the increased rate of hospitalisation and suicide attempts following decisions to stop using medication (Colom et al., 2005) would suggest that there are some people diagnosed with BD for whom medication may be necessary in order to be able to manage their moods safely. However, such outcomes are not recorded in all cases where people stop using medication, and my aim is for this study to act as a starting point in understanding the processes which may operate when people diagnosed with BD feel they can manage without medication.

**Method**

**Design**

In contrast to traditional GT, which is rooted in a positivist epistemology (e.g. Glaser & Strauss, 1967), I employed Charmaz's (2006) constructivist approach. Unlike positivist GT, Charmaz's approach does not seek to establish or describe an objective 'truth' about phenomena. It instead seeks to understand how individuals construct their experiences within the context of "larger and, often, hidden positions, networks, situations, and relationships" (Charmaz, 2006, p.133). This stance seemed appropriate as the processes related to people's mood-management behaviours could be seen as linked to how they construct their mood experiences against the backdrop of experiences in relationships and their wider social context (BPS, 2010). Constructivist GT also stresses that researchers should reflect on how their own implicit assumptions and theories shape data collections and analysis. As previous literature in this area seems to be influenced by researchers' own views and values (i.e. focussing on concepts such as 'lack of insight' and seeing 'nonadherence' as inherently

problematic), an approach that requires researchers to make their own assumptions explicit seemed especially appropriate.

This stance required me to acknowledge my preconceptions about bipolar moods and psychological intervention from an early stage of the research process. I reflected on the impact of having had little clinical or research experience with people who experience bipolar moods, and sought to address this through discussions with supervisors and individuals diagnosed with BD. One such assumption I identified was that people would seek to address their elevated moods and bring them back to a 'normal' level. A further assumption I identified was that people who did not use medication for bipolar moods would have found the diagnosis of BD unhelpful and be sceptical of it as a construct. Discussions in supervision and with service users led me to recognise these assumptions and consider alternatives, enabling me to be open to aspects of participants' experiences I otherwise may not have been aware of.

**Participants**

I recruited and interviewed ten individuals diagnosed with BD. Five participants identified as male, five as female. In order to be eligible for the study, participants had to report having received a diagnosis of BD from a mental health professional, and as a result of this been offered medication for their moods, but subsequently to have chosen not to use it for a minimum of three months. These criteria were chosen to ensure that individuals had been offered medication specifically to manage bipolar moods, and that these moods had a significant effect on their life. The criterion of choosing not to use medication for a minimum of three months was chosen following consultation with service users, who identified from their experiences that three months would be the minimum length of time expected to begin adjusting to no longer using medication and begin to make any necessary changes as a result.

**Procedure**

Ethical approval was obtained from Lancaster University's ethics committee prior to recruitment. Participants were recruited through the following avenues:

- Through my attendance at service user groups run by the charity Bipolar UK to talk about the research;

- Advertising the project using profiles on the social networking sites Twitter and Facebook;

- An e-mail containing details of the study was sent to members of Spectrum Connect, a database of individuals interested in participating in mental health research held by a research centre in the North West. This database was chosen as many of its members are known to have a diagnosis of BD, reflecting its host institution's primary research interests.

**Consent.** When participants expressed an interest in the study at a support group, or responded to seeing the study advertised, they were supplied with a copy of the participant information sheet and consent form. Participants were asked to return the consent form if they wished to take part. Upon receiving the consent form I contacted participants on the telephone to collect background information that could be used to guide sampling (e.g. age, occupation, time since they had last taken medication, time since last mood episode).

**Sampling.** I interviewed the first four people who returned consent forms to me. Following this, participants were chosen for interviews on the basis of theoretical sampling (Draucker et al., 2007), whereby individuals are chosen for interviews on the basis of having had experiences which it is hoped will provide data to refine developing themes and categories. During this second phase of recruitment (interviews five to seven), the Structured Clinical Interview for DSM-IV (SCID; First et al., 1997) was used as a tool to guide theoretical sampling, as I identified that my data at that point was largely based on the

experiences of people who mostly experienced low rather than high moods.  The SCID was used at this point to identify a further three participants from the pool who predominantly experienced periods of elevated rather than low mood.

Strauss and Corbin (1998) suggest that data collection should continue until a point of 'theoretical saturation' is reached, whereby no new codes or elements of a model can be found within data.  This study instead aims for Dey's (1999) criteria of 'theoretical sufficiency', whereby data is collected until it is possible to construct a coherent model of the phenomenon under investigation.  This was because the concept of "theoretical saturation" can be interpreted as implying the development of a 'complete' theory corresponding to an objective reality.  This can be viewed as incompatible with a constructivist approach to GT, which emphasises the role of the researcher's own subjectivity in deciding if and when a theory is regarded as 'complete' (Charmaz, 2006).

**Use of the SCID.**  I used the SCID as a tool to gather background information about the bipolar experiences of all participants in the study.  The SCID was chosen for this purpose as it provides a detailed and structured framework for gathering such information.  SCID data was gathered primarily to provide background context as to participants' accounts of managing moods without medication.  As mentioned above, the SCID was also used to guide theoretical sampling during the second phase of recruitment.  At this stage I identified that in order to develop my model my next three participants should be individuals who predominantly experienced elevated moods, as my initial four participants tended to experience more periods of low mood.  I used the SCID for theoretical sampling purposes with Simon, Leanne, Kevin and Nicole, and on the basis of the information obtained chose to interview the former three participants.  Nicole was subsequently interviewed in the next stage of recruitment.  For these participants the SCID was completed over the telephone after

they had registered for the study. For all other participants, the SCID was completed over the telephone in the days leading up to the research interview.

       **Interviews.** Interviews were arranged with participants in locations of their choice. At the start of the research interview participants were asked to complete the Internal State Scale (ISS; Bauer et al., 1991). Participants were then interviewed according to a flexible topic guide (see Appendix C), developed in collaboration with supervisors and people with lived experience of bipolar moods. As recommended by Charmaz (2006) this interview schedule was adapted as data collection progressed in order to collect data that would refine developing themes and categories. Interviews lasted between 60 and 105 minutes.

**Analysis**

       I recorded, transcribed, and analysed interviews according to the grounded theory methods described by Charmaz (2006). This involved an initial coding process of going through transcripts line-by-line and assigning brief descriptive codes to items of data. As recommended by Charmaz, my initial codes took the form of gerunds (verbs ending in '-ing') wherever possible, in order to frame data in terms of actions and processes. I then undertook a process of focussed coding, whereby I used the most frequent or significant initial codes to categorise segments of data more broadly. I then analysed the relationships between these focussed codes and developed categories that I felt contributed towards an overall theoretical framework. I elevated categories that I considered to outline key overarching themes within the data to the status of 'concepts'. Throughout this process I kept memos detailing observations and reflections that I felt to be relevant to the research question. I used ideas from memos to develop categories and concepts from focussed codes. Observations from memos were also key in explicating the links between categories and concepts that led to me organising the data into a theoretical model. I also employed a constant comparative approach, in which new data was continually compared against codes that had already been

developed in order to find points of similarity and divergence within the data. This process also entailed me making comparisons between the developing theoretical model and raw data, in order to ensure the model was grounded in participants' accounts.

I discussed initial codes and focussed codes from a preliminary interview with supervisors. Following this I discussed the process of coding and analysis regularly with supervisors in order to ensure transparency and quality.

## Results

The mean age of participants in the study was 36 years (range= 29-50). The mean time 'off medication' amongst the nine people who had taken medication for their mood at some point was 38.8 months (range= 8 months-10 years). One person had been offered medication for their moods but never taken it. Two people had received diagnoses of 'manic depression' due to being diagnosed before the concept of BD was introduced. Demographic information relating to participants' age, received diagnosis, and length of time not using medication is displayed in Table 1. All names used in Table 1 and throughout this report are pseudonyms.

**Insert Table 1**

Data relating to participants' SCID and ISS scores is displayed in Table 2. No participant met SCID criteria for a current depressive, manic or hypomanic episode. Nine participants met SCID criteria for having experienced previous depressive episodes. The participant who did not (Hayley) had experienced many episodes of severe low mood, but these had not been of long-enough duration to meet the SCID's cut-off for a depressive episode. Nine participants met SCID criteria for having experienced a past manic episode, while one (Nicole) met criteria for a past hypomanic episode.

**Insert Table 2**

The model I developed from participants' interviews is presented diagrammatically in figure 1.  The model depicts a sequential process beginning with the decision not to use medication, leading to choices about how to act in response to changing mood states.  Throughout this, the concept of 'Ideas About Myself and My Moods' influenced the choices participants make.  This concept relates to how participants perceived themselves and their moods, and how their understanding of their moods affected their perception of themselves.  Rather than outlining this concept separately, I will discuss it with reference to key points where it influences other elements of the model.

<div align="center">**Insert Figure 1**</div>

**Deciding Whether to Use Medication**

The initial decision whether to stop using medication entailed what Liam described as a "cost-benefit analysis" (p.2).  Participants cited side-effects as a major concern, describing distress resulting from problems including weight gain, tremors, loss of libido, and lithium toxicity.  For Hayley, who had never used medication for bipolar moods, her concern with side-effects arose from others' stories and her negative experiences with medication prescribed for other problems.

At this point the theme 'Ideas About Myself and My Moods' is particularly influential.  Participants frequently described side-effects changing their view of themselves in ways they found undesirable:

> *Not only did it change my mind, my thoughts, my abilities, my passions, my personality and my spark, everything, it also changed me physically to the point of not recognising myself in the mirror, I wasn't me anymore, I was somebody else.* (Leanne, p.16).

Amongst other concerns, participants' cost-benefit analyses were often influenced by medication's perceived effectiveness.  For example, Lisa stated that when she used

medication "I still had an episode" (p.7), and concluded "what's the point in taking meds if you're still gonna have [an episode] probably?" (p. 8).

**Searching for Alternatives to Medication**

Having decided not to use medication, participants then searched for experiences that might help them develop ideas about how to live without medication.  These experiences ranged from consultations with nutritionists (Simon) through to participation in courses and psycho-education on bipolar moods (Leanne, Lisa, Nicole).  Participants seemed to search for such experiences wherever they could outside of the NHS, where they tended to report their options for finding new strategies were limited.  Liam talked about the benefits of participating in a research trial through which he accessed CBT specifically for bipolar moods, which he had found unavailable on the NHS.  Other participants described accessing courses through third sector organisations, or gaining ideas from others while attending service user support groups.  Four participants described paying for private therapy they had been unable to access on the NHS, which Hayley and Nicole described as being particularly helpful in developing new strategies for managing.  These experiences frequently gave participants practical suggestions that shaped their strategies for managing moods.  For Hayley, therapy helped her develop the strategy of avoiding certain triggers for low moods:

> *Going through the entire life experience and then having certain things pieced together and saying well that might have had something to do with why you think that and why you get triggers for that*[…] *I keep well away from my parents a lot of the time because they trigger me something rotten. I will now go over for a cup of coffee for about an hour and that's it.* (p.20)

Participants tended to seek out experiences where they might learn ideas that were congruent with their existing 'Ideas About Myself and My Moods'.  For example, Simon saw his bipolar moods as being largely precipitated by poor diet and exposure to chemicals whilst

working in a laboratory, and his choice to consult a nutritionist was guided by the idea he could reduce toxins in his body through diet.

**Trying to Keep Mood at a Preferred Level**

Participants attempted to make changes in their lives to keep their mood in a desired state, intending to stave off any potential undesired mood changes (examples of these strategies and others used by participants at different stages in the model are displayed in Table 3). These changes typically involved maintaining behaviours such as healthy eating, regular exercise, a consistent sleep pattern, and activities such as meditation and yoga. These activities were sometimes seen to stabilise mood through exerting a positive overall effect on wellbeing, which was believed to subsequently have a positive impact on mood.

In making these changes participants frequently attempted to plan activities in such a way as to try and reduce stress, which was seen as a trigger for unwanted moods:

*…I'm very aware that, erm, stress triggers both highs and lows within me, um… and that I really do need to balance different areas of my life, um, and not include as much emphasis on work or friends or whatever, and I need to keep all of these things running alongside one another, which is obviously a challenge.* (Katy, p.12)

Although participants attempted to maintain their mood in a desired state, participants differed as to which mood states they viewed as 'desirable'. This seemed to be influenced by 'Ideas About Myself and My Moods', specifically with regard to their views about whether bipolar moods positively impacted their ability to be the type of person they wanted to be. It was much more common within the sample for participants to view high moods positively- low moods were seen as an undesirable state. The extent to which participants consciously engaged in 'Trying to Keep Mood at a Preferred Level' seemed to be determined by the extent to which moods were perceived as a problem. For example Lisa, who rarely

experienced low mood and perceived her high moods positively, spoke about her attempts to spend more time engaging in calming activities, but went on to say:

> *...while I've been talking it sounds like it's been a really explicit plan but it's not necessarily been like that, and the occasions I've spoke of they are kind of like occasions, I don't think, I generally tend not to manage it that much because it's not that much of a problem.* (p.33)

This therefore seemed to be a strategy that Lisa engaged in, but only occasionally and perhaps not always consciously.

One specific factor was highlighted as a particular obstacle to implementing strategies at this point in the process: rewards from implementing strategies were often only seen over the longer term, and the strategies frequently required time, effort, and as Simon described it, "discipline" (p.30). This meant it could be tempting to stray from these strategies (such as healthy eating, no alcohol) in favour of more immediately rewarding behaviours, such as eating unhealthy foods or drinking alcohol with friends.

Some participants also identified finances as a barrier to being able to implement these strategies, and the strategies that are described in the rest of the model. For example, Simon stated:

> *Well really that's about the same time that we've been talking about[…] when I was making more effort with this nutritional programme, but I was spending a lot of money, you can't really be spending £60 an hour talking to someone for a bit of management if you see what I mean, you know. You can't afford it [laughs], and a nutritionist was the cheap side of things.* (p.37)

**Insert Table 3**

**Channeling Energy into Something Positive**

Participants used strategies with this intention when they felt their mood was high (due to previous strategies either not being implemented or not being 100% effective), but did not feel sufficiently concerned about the consequences of this to change their mood. Participants were more likely to use this type of strategy when high moods were evaluated as having a positive effect, as part of 'Ideas About Myself and My Moods'. Participants stated that when high in mood they would actively choose to take advantage of this by increasing exercise (Nicole), productivity (Leanne, Hayley), or take advantage of their increased creativity by spending more time engaging in creative pursuits:

> *Like if I'm quite high I can be very creative at night and I'll sit writing and doing stuff and it's like, there's a voice in me that's like you should have gone to bed, you know you're a human being you need to sleep, but part of me's fighting against it and won't.* (Nick, p.13)

However, as nick alludes to in the above quote, this course of action was identified as potentially making mood more elevated, leading to a risk that it could begin to have a destructive, rather than constructive, effect.

**Trying to Bring About a More Desired State**

These strategies were used when participants noticed their mood going higher or lower than desired, and subsequently acted with the intention of inducing a preferred cognitive, emotional, or physiological state. Leanne described this as

> *…altering the emotional state, so if you're feeling low anything that makes you feel good and if you're feeling high anything that'll calm you down, if you're paranoid anything that'll make you feel safe…* (p.25)

Andrew described how, when high, he was tempted to find stimuli that would speed up his enjoyable thought patterns, but also felt there was a need to break this in order to influence his mood:

*...when your own ideas are reaffirming what you already thought, then you've got to get out and into a place where that doesn't happen. You've got to get out of those loops if you like, and I see being high as you're in a loop that's self-affirming*[…] *so you've got to change the inputs*. (pp. 25-26).

Participants described a variety of other stimuli to bring their mood down to the level they desired when feeling high, ranging from a hot bath through to the use of oils.  Hayley described two of her strategies:

*I do have natural herbal thing called valerian root, or valerian mixed with various other things that I will take if I need to get a very deep sleep. Um, obviously there are some times where I think I need that very deep sleep because if I don't get it things are going to get quite bad.* (p. 13).

Some participants cited that the effect of using these strategies when low was to tackle what Kevin and Nicole termed "negative thoughts", which tended to centre around negative evaluations of the self or recurring feelings of isolation.  Subsequent strategies ranged from practical activities that would alleviate negative feelings, such as pampering or getting a haircut (Leanne) or looking at lists of forthcoming positive activities (Nick), through to strategies directly challenging thoughts, learnt through techniques such as meditation or cognitive therapy.

An additional set of difficulties also impacted on the intentions described in 'Doing Things to Keep My Mood at a Preferred Level', but are described here as they exerted the greatest impact at this point in the process.

**Enjoying being high.**  The enjoyment of being high in mood was described by participants as affecting their motivation to use strategies that might change their mood.  For example, Nick stated that:

*...there's a line where once it's crossed I'll just go with it and I'll want it to be higher,*

*so I'll kind of be then, I'll then switch from being sensible, like let's calm it down a bit*

*to like actually let's… I'll collect wood for my own bonfire.* (p. 27).

This obstacle was frequently reported by participants whose 'Ideas about Myself and My Moods' saw elevated mood as having a positive effect on productivity and creativity, or where elevated mood was seen as a valued part of the personality.

**Feeling demotivated if low.**  Feelings of low mood could alter participants' perceptions of themselves, such that they no longer wished to put strategies into place.  Katy described how her more negative views of herself when low might impact on her feeling able to implement intentions to organise time with friends:

[…]*there are times when I'm quite good at organising people and suggesting things*

*that we can do, but when I'm feeling down it feels like, mmm… It feels like I can't get*

*organised enough and… that I worry about whether other people want to spend time*

*with me.* (p.7).

**Trying to Evaluate How I Experience Things**

Throughout the process of managing without medication participants described efforts to evaluate their mood states, such as when 'Trying to Keep My Mood at a Preferred Level'. Evaluating mood states is emphasised at this specific stage of the model as it seemed to take on a particular significance here, with participants reporting actively attempting to determine whether bipolar moods were impacting on their motivation to implement strategies, and looked for indicators suggesting that moods might be affecting their perception.  This was sometimes done by using smartphone apps or internet 'mood trackers'.  Significant others played a key role at this stage, with participants frequently looking to them to point out the occurrence of these indicators- as Andrew stated: "my partner's a medical writer, so she kind of knows, she's sort of very good at spotting if I'm going a bit funny or what have you" (p.

3).  Awareness of the presence of these indicators sometimes helped participants make a conscious choice to use strategies to alter their affective state.  At this point participants either returned to the previous stage of the model and implemented strategies to change their mood, or they moved on to the next step and evaluated whether strategies had exerted the desired effect.

**Evaluating the Effects of Non-Medication Strategies**

This process is encapsulated by the three diamonds forming a decision-tree at the bottom of Figure 1. In much the same way that participants described undertaking a cost-benefit analysis around whether or not to stop taking medication, they also seemed to undergo this process regarding whether to carry on using specific non-medication strategies. Similar concerns were addressed as in the cost-benefit analysis relating to medication. Participants first of all evaluated whether strategies had achieved their aims.  If strategies had been successful, participants then evaluated whether the consequences of using a strategy cohered with their 'Ideas About Myself and My Moods'.  For example, Kevin stated in regards to the strategy of self-medicating with alcohol:

> *… ultimately I don't think that I could carry on long term and do what I want to do with my life, simply being depressed and relying on alcohol to get by, because for me that's not what I wanna do.* (p. 35).

If effective strategies were seen as congruent with participants' ideas about themselves and their moods they were utilised again, and participants returned to using the same strategies employed near the start of the process.  If strategies were incongruent with participants' ideas about themselves and their mood, they began to search for further inspiration about how to manage without medication.  At this stage of the model participants also compared the consequences of their non-medication strategies with the consequences of using medication, in light of their 'Ideas About Myself and My Mood':

*Since I'm off the medication I'm a much more stable person, I'm much calmer about everything, about the lows, about the highs, about normal life, everything is much more… I wanna say in control but it's not in control, but it just feels different to when I'm on the medication.* (Nicole, p.50).

This process also involved comparing the overall experience of life without medication to that of life with medication:

*…when you're on medication you often feel very beholden to the prescriber and the prescriber becomes a god, and you're very aware that you have to play to the prescriber because you're feeling so shitty and you actually want some help*[…] *When you're not on medication, you realise that you don't have that and it's actually very, very freeing.* (Liam, pp. 45-46).

Participants were faced with a different choice if they evaluated strategies as unsuccessful and their mood was still higher or lower than they might wish. At this point participants began to weigh up the possible consequences their mood might have on their life if left unaltered. If participants were worried about destructive consequences, they would return to the model's starting point of deciding whether or not to use medication. For example, Leanne stated "if I get close to[…] I'm gonna lose my child, I'm not being a good mum, I'm dangerous to me cos I'm being dumb or to others then I'll take the medication" (p. 16). Notably, Leanne had stated that following a previous manic episode her child had indeed been taken into care. As Leanne's quote indicates, her decision-making process considered how the consequences of not using medication might impact significant others, and how this in turn might impact her views of herself. Leanne was the participant who seemed most willing to use medication again for short periods if she had to (to the extent she kept spare medication at home in case it was needed). This may have been due to her experience of finding short-term courses of olanzapine effective in managing more difficult

periods of higher mood ("I know I can go to bed tonight and take olanzapine and tomorrow all of these symptoms will be gone", p. 21). Although this section of the model is based on less data than other elements, I would hypothesise that such relative willingness to use medication was associated with experiencing negative consequences of past mood episodes. This was articulated by Lisa when she stated:

> *...but like I say I've never being in hospital and maybe if I had been we'd be having a different conversation, but so far I've managed to sort of skate um... you know, on the top of the ice and it hasn't broke anything.* (p.5).

**Discontinuing daily tasks.** If strategies had not altered participants' moods and they were less worried about possible consequences, they described disengaging from daily tasks and taking "time out [to] just let myself get better" (Nick, p.28). This typically involved taking time off from work and other commitments, and waiting for the period of bipolar mood to run its course. Lisa described a point at which, if she had not implemented strategies or strategies had not worked, she felt her mood was no longer manageable and she would stop trying to influence her mood:

> *...once I've started sleeping 2 or 3 hours a night or even 1 or none, it's too late for management strategies it really is[...] I'm on it and I'm not going to back off, you know what I mean [laughs], even if they would work I have no desire whatsoever to do anything about it, I'm in it and I'm just gonna let it.* (p. 21).

Other participants stated that once their mood reached this point, they would need to turn to others for practical help, and would encounter difficulties when others were not around to provide this. For example, Simon described an occasion where a friend found and recalled cheques he had written during a manic episode, and stated:

> *that was one time when a friend, Clive, was really quite helpful, um... at the time when I was really going off my head and he just provided a grounding force and*

*stopped me getting into any real trouble, and generally it's been a lack of people like*

*that around that have, when I have had times when I've gone a bit off my head, I've*

*gone a bit out of control…* (p. 42)

Participants who allowed periods of elevated mood to reach this point tended to have 'Ideas about Myself and My Moods' which involved high moods being seen positively. Once mood had eventually returned to a more stable level, participants then re-engaged in some attempts to manage mood by reverting to strategies employed in 'Trying to Keep Mood at a Preferred Level'.

## Discussion

This paper is the first to explore the processes by which people manage bipolar moods without medication. Participants described undertaking an ongoing evaluative process while managing their moods, relating to issues such as whether or not to stop using medication, whether current ways of managing cohered with their views of themselves and their moods, the effectiveness of strategies for managing, and whether they would have to use medication again at some point in the future. Furthermore, participants' intentions when implementing strategies varied across time depending on their evaluations of their mood state and its consequences.

### Findings in the Context of Current Literature

**Literature on managing bipolar moods.** The results of the current study fit well with findings from studies that have investigated experiences of managing bipolar moods *with* medication. As in Mansell et al.'s (2010), Russell and Browne's (2005) and Murray et al.'s (2011) qualitative studies, participants cited the influence of others at key times when managing their mood, most frequently through loved ones pointing out when mood states may be becoming a problem. Congruent with previous findings, participants also cited the

importance of making lifestyle changes in order to reduce levels of stress and increase overall wellbeing.

Unlike the studies mentioned above, the current project enquired not just about participants' intentions but also their subsequent actions, and whether intentions were followed through.  None of the studies above explored this link between intention and action, and pursuing this line of enquiry in the present study highlighted important obstacles and challenges for those managing bipolar moods without medication.

**Models of health behaviour.**  The processes described by participants fit well with models of coping in the health literature.  Levanthal et al.'s (1984) Self Regulation Model (SRM), as applied to mental health research by Lobban et al. (2003) suggests that people's ways of managing in response to a health difficulty are influenced by their beliefs around personal identity, and about the nature, cause, and consequences of their difficulty.  The model presented here suggests such beliefs were highly pertinent for this sample, with participants frequently considering whether behaviours would help them move towards realising ideas that might be considered part of 'personal identity', such as who they wanted to be and how they might achieve their potential.  Consistent with the SRM, participants' behaviours also frequently cohered with their mood-related beliefs.  For example, participants who saw their elevated moods as having a positive effect on their life were more likely to reject strategies that were seen as leading their mood towards a less elevated state.

The model presented here also fits with Horne and Weinman's (1999) Necessity Concerns Framework (NCF).  The NCF expands on the SRM by suggesting that decisions whether or not to use medication will be influenced not just by an individual's perceptions of themselves and their health condition, but also by their perceptions of medication's necessity and effectiveness.  Consistent with other authors' findings (e.g. Clatworthy et al., 2009), participants' decisions whether or not to use medication seemed to fit within the NCF, as

concerns with these areas were frequently reported.  This study builds on this knowledge by suggesting that beliefs outlined in the SRM and NCF seemed pertinent to participants' decisions whether to use any strategy, not just medication.  For example, when deciding to use a strategy participants seemed to consider its possible consequences (or conversely, the consequences of not using it), and then interpret these consequences according to their beliefs about themselves and their moods.  Furthermore it would seem that components of the SRM relating to people's beliefs about their moods and their own ability to overcome health-related barriers (e.g. beliefs like "I am not disciplined enough to stick to my healthy eating", or "once I get too high I'll just want to make myself higher") may have had a particular impact on participants' reports of whether they implemented their intentions related to mood-management.

**Clinical Implications**

From the model presented, one might hypothesise that interventions might usefully seek to prepare individuals for challenges that arise as they negotiate this process.  For example, some participants stated that at times it was easy to forget about 'Trying to Keep Mood at a Preferred Level' due to the distal nature of any perceived benefits, and that they would instead pursue more immediate gratifications, such as eating unhealthy foods or drinking alcohol.  Similarly, when thinking about implementing strategies to 'Bring About a More Desired State' once mood had become high or low, participants described difficulties with such as feeling motivated to use strategies at times they were either enjoying being high or feeling demotivated due to low mood.  Cognitive models of social problem-solving may be clinically useful in supporting people to consider how they might wish to face such obstacles. Chang et al. (2004) suggest that individuals may acquire problem-solving skills that help them meet their goals through developing a "positive problem-orientation" (p.15): that is, through developing positive beliefs about one's own problem-solving efficacy, and seeing

problems as a challenge through which positive outcomes or learning can occur, rather than as a source of failure or fear.  Cheng et al. suggest that a positive problem-solving orientation leads to being able to more effectively learning to generate possible solutions in a rational and systematic manner. Such problem-solving interventions may help people identify and make plans for motivation-related difficulties that could negatively impact their ability to manage without medication.  Interventions at this stage might seek to address individual's problem-orientation (e.g. appraisals of one's ability to cope when confronted with tempting stimuli, or of the possible effects of mood on problem-solving ability) beliefs about problem-solving and support them to develop methods for systematically generating a range of responses to problems they might face, and evaluating these responses' potential consequences.

Findings from this study also point to the possible need for wider systemic change in services.  Current guidance from NICE (2006) and the APA (2002) emphasise the primary role of medication in managing bipolar moods.  Although the revised version of the NICE guideline released for consultation (NICE, 2014) places more emphasis on psychosocial interventions it is still largely devoted to considerations around medication.  Indeed, applying the NCF to this area of research has led some authors to suggest that psychosocial interventions should focus on addressing beliefs about medication that may lead to decisions not to use it (Chapman & Horne, 2013).  The findings of this study suggest some people who have chosen not to use medication will have already very carefully weighed up the costs and benefits associated with this choice, and that a professional stance that emphasises the importance of medication and attempts to promote adherence may therefore not be conducive to engaging such individuals in services.  This may have been reflected in the fact that no participants in this study cited NHS services as influential at the point of 'Searching for Alternative Ways of Managing'.  Instead of focussing on medication and promoting

adherence, services may need to emphasise a broader range of approaches in order to engage people who have decided not to use medication.  This may entail professionals taking a more open, collaborative stance that takes account of, and attempts to support, individual's complex decision-making processes, and accepting that some individuals may safely choose not to use medication.  This might make services more acceptable for people who manage bipolar moods without medication, and may promote engagement should they wish to make use of other interventions that are on offer that may be of help.

**Future Research**

Researchers could continue the lines of enquiry opened up in this paper by investigating which factors might predict being able to manage well without medication. Specifically, the present study suggests that the SRM and NCF may be useful frameworks for investigating whether beliefs about one's own self, moods and management strategies are associated with subsequent outcome (e.g. hospitalisation, or severity of unwanted moods). Furthermore, future researchers could also examine which demographic or mood-related features predict positive outcomes when managing bipolar moods without medication.  This could help inform conversations between service users and professionals about whether to use medication, the possible consequences of not doing so, and what difficulties may be likely to occur.  Further qualitative work might also address the issue of what people who do not use medication for bipolar moods would and would not find acceptable as elements of psychosocial interventions.

The findings of this study also suggest it may be useful to investigate the processes by which people who receive other psychiatric diagnoses might manage when they choose not to use medication.  A possible starting point may be to investigate such processes in people diagnosed with psychosis, another diagnosis where medication-based approaches have predominated but frequently not been accepted by service users (Morrison et al., 2012). and

where a psychosocial intervention aimed specifically at people who do not use medication has recently been evaluated (Morrison et al., 2014).  Understanding more about the processes by which people manage experiences associated with psychosis when not using medication may inform the development of future interventions for this group.

**Limitations**

This paper does not present a model generalizable to all people who manage bipolar moods without medication.  In line with a constructivist GT approach (Charmaz, 2006), the aim is instead to produce a model that represents how this study's participants construct the processes involved in managing without medication, in order to act as a starting point in the establishment of further knowledge about this under-researched area.

Some may question whether findings presented here are based on a group of individuals whose bipolar experiences are different to those of people who present at services requesting support.  This can be refuted to some extent using data from the SCID, which as well as guiding sampling also systematically collected information about participants' mood experiences.  All participants described a number of past mood experiences that are seen as clinically significant within the scoring guidelines of the SCID.  Furthermore, half of the sample reported that the impact of their mood experiences had at some point been severe enough to result in hospitalisation.

**Conclusion**

Existing research often suggests that non-adherence to medication among people diagnosed with BD is inherently problematic, and is the result of a lack of insight and/or inaccurate cognitions about medication.  In contrast, the findings of this study suggest that the decision to stop using medication may be based on well-founded concerns about the effects (and side-effects) of medication, and may be the result of a deliberate evaluative process rather than a 'lack of insight'.  Furthermore, once this decision was made, it would seem this

study's participants engaged in an ongoing decision-making process of evaluating the effects

of strategies and deciding whether other strategies are necessary, against pre-conceived views

of themselves, who they want to be, and beliefs about their moods.

**Highlights**

- There is currently little research about how people manage bipolar moods without

  medication

- This qualitative study uses grounded methods to explore this phenomenon

- Participants described making decisions based on evaluating mood-management

  techniques

- Current models of non-adherence may not capture the complexity of peoples'

  decision-making

- Understanding this complexity is important in building acceptable services for this

  group

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MANAGING BIPOLAR MOODS WITHOUT MEDICATION

**Table 1.  Participant Demographic Information.**

| Name | Age | Length of Time Since Last Took Medication | Psychiatric Diagnosis |
|------|-----|------------------|----------------------|
| Andrew | 43 | 1 year | Bipolar I |
| Hayley | 50 | Never used medication | Manic Depression |
| Katy | 31 | 8 months | Bipolar II |
| Kevin | 36 | 18 months | Bipolar I |
| Leanne | 31 | 9 months | Bipolar I |
| Liam | 32 | 6 months | Bipolar NOS |
| Lisa | 29 | 9 years | Bipolar I |
| Nick | 30 | 5 years | Bipolar I |
| Nicole | 37 | 8 months | Bipolar II |
| Simon | 42 | 10 years | Manic Depression |

**Table 2.  Summary of Participants' SCID and ISS Data[3] (maximum possible SCID scores given in brackets).**

| Participant | SCID Score | | | ISS Score | | |
|---|---|---|---|---|---|---|
| | **Past Depressive Episode Score (11)** | **Past Hypomanic Episode Score[4] (12)** | **Past Manic Episode Score (11)** | **Wellbeing Score** | **Activation Score** | **ISS Classification** |
| Andrew | 11 | 0 | 11 | 170 | 20 | Euthymic |
| Hayley | 5 | 0 | 10 | 250 | 340 | Manic/hypomanic |
| Katy | 9 | 0 | 5 | 70 | 170 | Mixed state |
| Kevin | 7 | 0 | 11 | 180 | 0 | Euthymic |
| Leanne | 11 | 0 | 11 | 260 | 250 | Manic/hypomanic |
| Liam | 11 | 0 | 9 | 240 | 150 | Euthymic |
| Lisa | 10 | 0 | 11 | 190 | 170 | Manic/hypomanic |
| Nick | 10 | 0 | 11 | 210 | 230 | Manic/hypomanic |
| Nicole | 11 | 12 | 0 | 210 | 70 | Euthymic |

[3] SCID scores reported here represent the number of items to which participants gave responses meeting SCID scoring criteria for clinical significance.
[4] Participants automatically scored 0 for 'past hypomanic episode' if they described past episodes of elevated mood meeting SCID criteria for a full manic episode.

| Simon | 10 | 0 | 11 | 140 | 280 | Manic/hypomanic |

**Table 3.  Examples of Strategies Used by Participants at Different Stages of the Model**

| Stage of Model | Strategies Used (and Who By) |
| --- | --- |
| Trying to keep mood at a preferred level | Doing more exercise (Kevin); Eating well (Kevin, Nicole, Simon); Being self-employed (Katy); Only having short contact with triggering family members (Hayley); Trying to avoid stress (Nick); Going to France at certain times of year (to mitigate changes in daylight) (Simon); Making time with partner (Katy) |
| Channelling energy into something positive | Focussing on a specific task or project (Liam); Making a to-do list and systematically working through it (Leanne); Spending more time on creative tasks and activities (Nick); Focus on being productive at work (Lisa); Archery (Hayley); Doing the garden (Hayley) |
| Trying to bring about a more desired state | Self-medicating with alcohol (Kevin; Liam); Pampering, make-up (Leanne); Changing perception of unpleasant thoughts (Nicole); Setting more work to do in the morning (Katy, Liam); Taking valerian root (Hayley); Taking vitamin E (Simon); Lighting scented oils (Leanne); Keeping usual bedtime routine (Katy); Going to a gallery (Andrew); Taking dog for walks (Nicole); Do a boring task (Lisa); Stopping and reflecting (Leanne); Spend time with someone soothing (Lisa) |

| Stage of Model | Strategies Used (and Who By) |
| --- | --- |
| Trying to evaluate how I experience things | Asking a friend's opinion about a situation (Liam); Using an online mood tracker (Katy); Compare my current mood to Winnie the Pooh characters (Leanne); Use an app to record my mood (Nick); Partner telling me when I'm too high (Andrew, Hayley, Leanne); Using meditation to observe feelings (Nicole) |
| Discontinuing daily tasks | Taking time off work (Nick); Letting myself stay high (Nick); Finding things to spend money on (Simon); Going to parties (Lisa); Going travelling with friends (Lisa) |
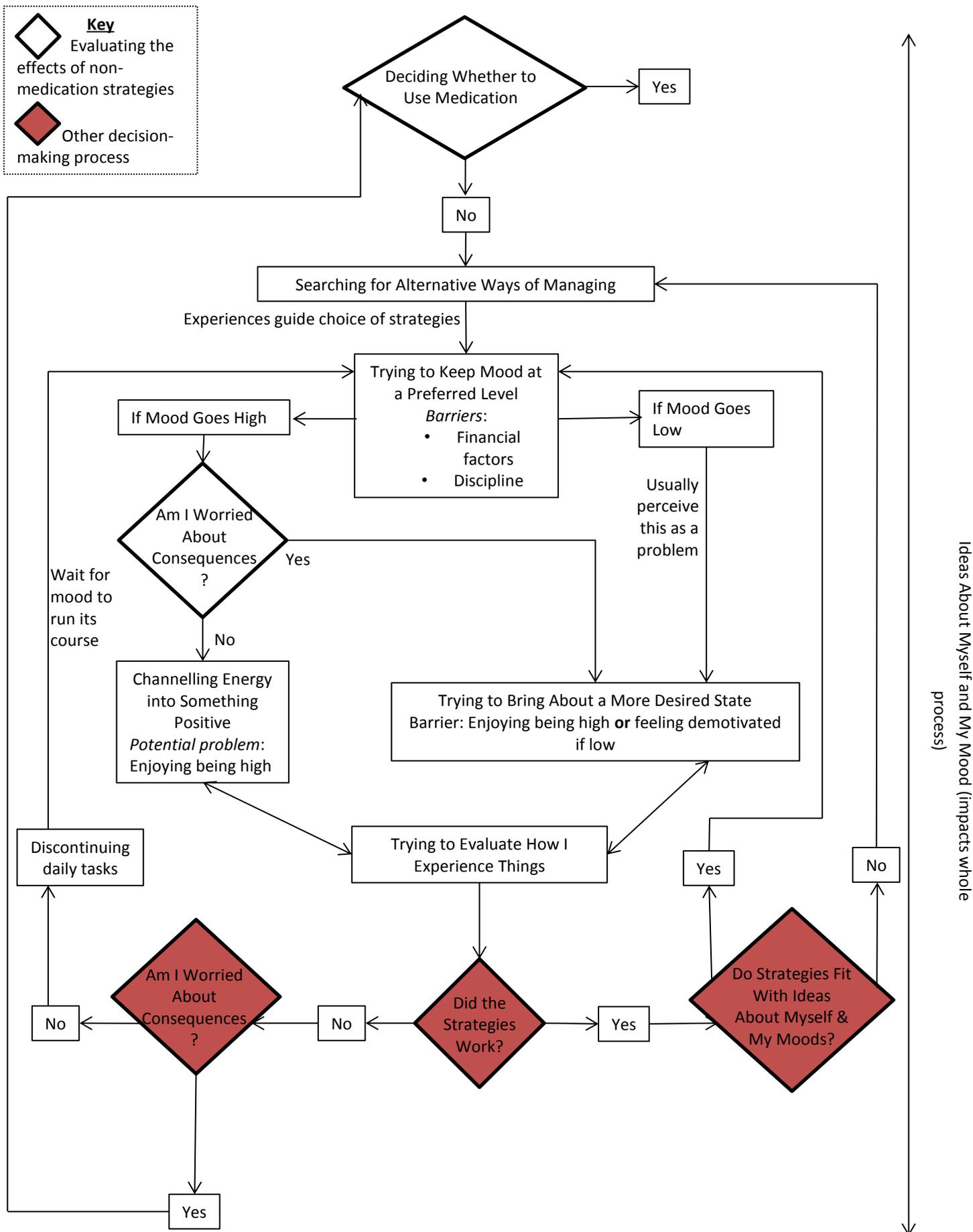
Figure 1: Diagrammatic Representation of Model

**Appendix C:**

**Sample Interview Topic Guide**

1. My name's Reed Cappleman and I'm doing this research as part of my training in clinical psychology.  I'm finding out about the experiences of people diagnosed with bipolar who don't take medication, hoping that this might tell us some things about the ways that people try and manage their moods when they don't use medication. I'll be recording what you say to me on this voice recorder if that's OK.  After the interview I'll type it all up, and then that typed-up version will be saved with a password on the uni's secure computer network.  I'll write up the results in my final report, and try and get the results published in journals, but any quotes I use from you won't use your name, and people won't be able to identify who you are. Have you got any questions you'd like to ask before we begin?

2. Is there a time you did take medication for bipolar mood? What happened?

3. I'm interested in understanding more about why you do not take medication for your bipolar experiences. Could you say a bit about this? (What, if anything influenced you? What was going on in your life around then?)

4. **How is your mood without the medication**? Do you have any periods where you feel low in mood? What kinds of things do you do? (Who, if anyone, helps? Ask same questions for highs)

5. Has there been a period of **time** when you didn't use medication and **things went well**? Can you tell me about it? What happened?

6. Can you tell me about a period of time you weren't using medication **and things didn't go so well**? What happened?

7. Have your **thoughts and feelings** about medication **changed at all** since you stopped taking it? If so, in what way?

8. What **lessons have you learned** from not using medication for your bipolar experiences?

9.  How would you **describe the person you are now**? How's that different to when you took medication? What helped you get to this point?

10. Looking back**, are there any other events** that stand out in your mind? Could you describe them? (In the domain of: relationships, work, things you do in your spare time.  How did this affect you? How did others respond? What did you do?)

11. **Who, if anyone, has been most helpfu**l when you've not been taking medication for your mood?  What did they do? Were any people unhelpful? What did they do?

12. Has not taking medication for your mood had an **effect on any other important areas** of your life? How so? Has this influenced your decision to carry on/stop taking medication?

13. If someone you were close to had a diagnosis of bipolar disorder and they were thinking of not taking medication- **what advice would you give** them? Why?

14. Have there been **any other important aspects** to not using medication to manage your bipolar experiences that we've not touched on so far? Or anything you'd like to say some more about?

15. Do you have any questions you'd like to ask me?

16. Thank the participant for their time, ascertain if they would be willing to participate in a follow-up interview if necessary.

**Appendix D:**

**Development of the Category "Channeling Energy into Something Positive"**

Presented below is an excerpt from Nicole's interview, detailing how the category "Channeling My Highs Into Something Positive" emerged

from her data.  Points in the interview where I am speaking are represented in itallics.

| Initial Codes | Data | Focussed Codes |
|---|---|---|
| High running its course<br><br>Trying to channel energy positively<br><br>Booking in different things with<br><br>friends;<br><br>Friends supporting me<br><br>Being in a club dancing<br><br>Being out til 4am<br><br>Ditching alcohol altogether<br><br>Ditching alcohol altogether<br><br>Feeling better all over | *Can I just jump back a bit to something you mentioned about um kind of, if your mood's higher you*<br><br>*might do different things, like you might go out walk the dog or you might go for a swim… what*<br><br>*would happen if you didn't do those things, I'm just wondering?*<br><br>Um… nothing really… the high would just run its course I guess, but I try to use the energy to use it<br><br>to channel it into positive things, because the temptation of course for me, the temptation is to ring<br><br>up all my friends and to book in different things so I'll go for lunch with one dinner with another,<br><br>but I don't eat when I book those things, it's just an excuse to get to see them.  And I rabbit on ten to<br><br>the dozen about rubbish, and you know they do support me they see it no, they recognise it, and then<br><br>I'll be like let's go dancing, and next thing you know I'm in a club somewhere on a Tuesday night<br><br>dancing til 4am, and that's not particularly, I don't drink alcohol anymore, I should put that in.<br><br>That's one of the big changes I made, I ditched alcohol altogether.  Because the highs with the<br><br>alcohol made me even higher, and the lows with the alcohol were too intense.  So since I've taken<br><br>the alcohol out and sorted out the diet I have felt better all over really.  So now I try to channel the | Channeling my highs into<br><br>something positive<br><br><br><br><br><br><br><br><br><br><br><br>Feeling better after giving<br><br>up alcohol<br><br>Channeling my highs into |

| | | |
|---|---|---|
| Channeling energy into positive things | energy of the high into positive things, rather than channel the energy into crazy fun which doesn't serve me any purpose.<br><br>*OK, so I was gonna ask about, cos you said that if you didn't do something like go for a walk or a swim you'd end up meeting friends, you could end up in a club til 4am on a tuesdy evening dancing [laughs]... I was going to ask about what it is that makes you think "that's not what I wannna do?"* | something positive |
| Not getting a longer term reward<br>Only having fleeting memories<br>Only having fleeting memories<br>Doing things better for my body<br>Being in a better place to manage<br>Putting myself first<br>Dancing in a more controlled manner | Well it just doesn't… there's no reward there longer term because longer term it should, once the high's over, all I've got is the fleeting memories of all the people that were my best mates in the club and I'm never going to see them again anyway, but at least if I've swum there's something that's better for my body you know, it's building physical strength and it's building the serotonin which puts me in a better place to manage if the low comes after the high, so I think it feels, that's what I was saying earlier, it's about putting myself first this time in a more positive way.  And don't get me wrong I still sometimes go and dance, but it's just in a more controlled manner [laughs]. | Channeling my highs into something positive |

The table below details selected focussed codes that make up the category "Channeling My Highs into Something Positive", selected initial codes from which these focussed codes were developed, which interviews these codes come from, and example quotes to illustrate the focussed codes.

| Focussed Code | Selected Initial Codes | Participant | Selected quotes |
| --- | --- | --- | --- |
| Funneling racing thoughts towards a focus | Racing mind is cause for concern; Needing to funnel racing thoughts into a focus; Not having a focus for racing thoughts could be dangerous | Liam | I think I'd be more concerned about it now if I thought that my mind was racing and stuff… because I'd think what am I going to do with that. So I need to have something to focus on and funnel it into. So I'd fear that if I didn't have any means to do that then I would end up back in, you know, back in the initial manic episode back in 2004. |
| Having to be occupied when high | Using exercise; Trying to find new things Having to be occupied when high; Cleaning house when high; Doing the garden Dong hobbies Doing vegetables | Hayley | […] the other things I use are exercise, um… trying to find new things to do… becoming occupied, especially if I'm going up high, I've got to be occupied, I can clean this house in about two seconds flat when I'm really high, you know, it's like whoosh, round like that, or I do the garden quite a lot, I've got a real thing going with my plant, so hobbies, I think anything you're into, I think hobbies, plants, I do vegetables and things at the end of the garden |
| Doing things you find good to do | Taking up archery Doing what you can manage People should go for it if it'll help | Hayley | |
| Feeling a thrill | Motorbike is thrilling Going for long distance is great | Hayley | |

| Focussed Code | Selected Initial Codes | Participant | Selected quotes |
|---|---|---|---|
| Being more productive when I'm high | Things occupying my mind<br>Getting things clocked off<br>Being high and productive is good<br>Having a productive day<br>Getting jobs done<br>Keeping it going when productive | Leanne | Well today, it is a nice sunny day and that automatically puts everybody in a better mood anyway. And then because it's been a productive day and we're getting jobs done and I finally got my fish tank filter cleaned and that kind of thing, it's just ended up quite productive and it's like alright well keep that going you've got an hour and a half this morning, get a few more jobs knocked up, go and visit your grandma, I've done a lot in the first two hours of getting the child out to school and sorted for the day… |
| Being creative when I'm high | Being creative at night when high<br>Sitting writing and doing stuff<br>Getting lots of ideas<br>Recording ideas when high | Nick | Like if I'm quite high I can be very creative at night and I'll sit writing and doing stuff and it's like, there's a voice in me that's like you should have gone to bed, you know you're a human being you need to sleep, but part of me's fighting against it and won't. And I think the high in me is like, ah a few hours is all you need you'll be fine, and sometimes I can go through short periods where I don't need very much sleep. |
| Allowing for spending when I'm high | Spending more money when high<br>Having a day when I buy lots of stuff | Nick | |

| Focussed Code | Selected Initial Codes | Participant | Selected quotes |
|---|---|---|---|
| Channeling my highs into something positive | Doing a big food shop when high<br>Enjoying my highs<br>Having productive highs<br>Having a sense of speed and clarity | Nicole | |
| Being absorbed in one thing | Thinking I can do this or that<br>Enjoying being productive<br>Producing something quick and impulsive<br>Doing something more time-consuming | Lisa | …cos you look at your garden and think oh I could do this I could do that, cos you enjoy it don't you, you enjoy being proactive or productive or creative. But it can be, sometimes like you know if you're doing something creative you can produce something dead quick and dead impulsive or you can do something much more time-consuming, I used to do mosaics cos you can just make yourself sit there, and you can do something beautiful for somebody but it's really quite time-consuming and fiddly, and you have to stay in the same place and you have to concentrate and it's quite absorbing… |

**The following is an excerpt from a memo written on 22/04/14 after my interview with Nicole, demonstrating how the memo-writing process influenced the development of the category "Channeling My Highs into Something Positive":**

It seems the concern for Nicole isn't so much "how do I stop the highs", but is more about "how am I going to act when I'm high, how am I going to channel the energy?". This seems to be quite different to the way that Katy talked about her high moods- she seemed to see them as something to pretty much avoid, at the expense of trying to achieve 'equilibrium' (due to her experience of her high moods de-railing her long-term plans?). It's perhaps closer to the sort of process that Nick describes, where he welcomes the creativity that his high moods bring. For Nick, high moods were synonymous with achievement, and had led to him getting prizes at work. For Nicole, she too seemed to link her high moods into achievement- with being hypomanic and writing a business plan that she was proud of, feeling like she might be becoming more independent and being ready to go back to work, realising her idea of herself as something capable.

For people like Nick and Nicole, who see their high moods as something that gets them closer to where they want to be, is there something about harnessing these moods perhaps? Using the energy, drive and creativity? Trying to enjoy the extra productivity, making the most of it? It seems there is- but this begs the question, what happens when people allow their high moods to carry on like this and they become higher and higher? What about when it starts to become destructive? Do they realise? Do other people try and stop it? Leanne seemed to relish the energy and productivity her high moods could bring, and she said her husband would rein her in if need be… What if it gets too late for this? Or what if no-one notices the high? Nick talks about getting to a point where he just has to let the mood take its course… Is this what happens if this enjoyable period is allowed to go too far?

**Appendix E:**

**Internal State Scale**

Name: _____          Date: _____

## INTERNAL STATE SCALE (v.2)

For each of the following statements, please blacken the circle on the line that best describes the way you have felt <u>over the past 24 hours</u>. While there may have been some change during that time, try to give a single summary rating for each item.

**Today my mood is changeable.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                           Very much so
Rarely                                            Much of the time

**Today I feel irritable.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                            Very much so
Rarely                                            Much of the time

**Today I feel like a capable person.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                            Very much so
Rarely                                            Much of the time

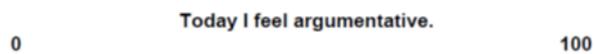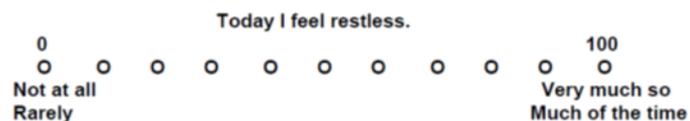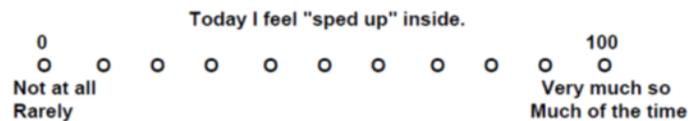**Today I feel like people are out to get me.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                            Very much so
Rarely                                            Much of the time

**Today I actually feel great inside.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                            Very much so
Rarely                                            Much of the time

**Today I feel impulsive.**

0                                                      100

O   O   O   O   O   O   O   O   O   O   O

Not at all                                            Very much so
Rarely                                            Much of the time

1

**Today I feel depressed.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
Not at all                                                              Very much so
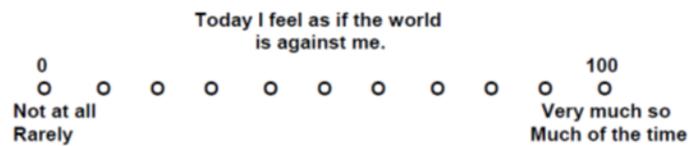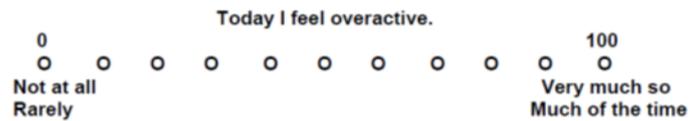Rarely                                                                  Much of the time

**Today my thoughts are going fast.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
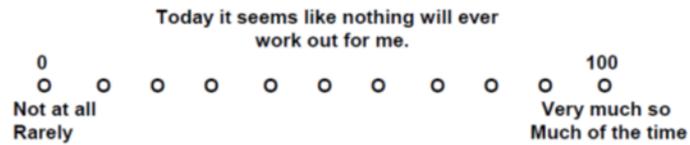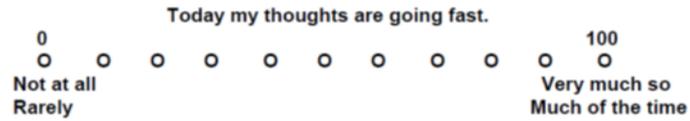Not at all                                                              Very much so
Rarely                                                                  Much of the time

**Today it seems like nothing will ever
work out for me.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
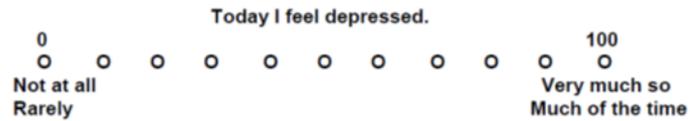Not at all                                                              Very much so
Rarely                                                                  Much of the time

**Today I feel overactive.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
Not at all                                                              Very much so
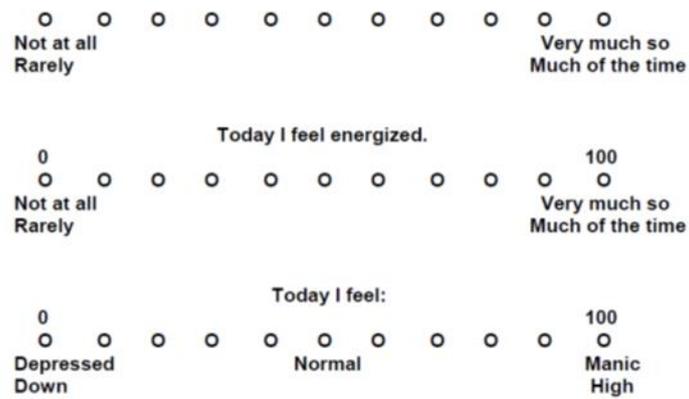Rarely                                                                  Much of the time

**Today I feel as if the world
is against me.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
Not at all                                                              Very much so
Rarely                                                                  Much of the time

**Today I feel "sped up" inside.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
Not at all                                                              Very much so
Rarely                                                                  Much of the time

**Today I feel restless.**

0                                                                                    100
O    O    O    O    O    O    O    O    O    O    O
Not at all                                                              Very much so
Rarely                                                                  Much of the time

**Today I feel argumentative.**

0                                                                                    100

2

```
   o    o    o    o    o    o    o    o    o    o    o
Not at all                                   Very much so
Rarely                                       Much of the time
```

Today I feel energized.
```
   0                                              100
   o    o    o    o    o    o    o    o    o    o    o
Not at all                                   Very much so
Rarely                                       Much of the time
```

Today I feel:
```
   0                                              100
   o    o    o    o    o    o    o    o    o    o
Depressed                Normal                  Manic
Down                                             High
```

from:

Bauer M, et al. Independent assessment of manic and depressive symptoms by self-rating. scale characteristics and implications for the study of mania. Arch Gen Psychiatry 1991; 48:807-12.

3

**Section Three: Critical Appraisal**

**Reflections on the Process of Conducting Research with People who Do Not Use**

**Medication for Bipolar Moods**

**Word Count: 3,549**

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In this paper I will reflect on methodological issues that occurred during the process of conducting a qualitative research project examining the processes by which people manage bipolar moods without medication (Cappleman, 2014). This project was the first to recruit a sample comprised entirely of people diagnosed with Bipolar Disorder (BD) who do not use medication. I will outline challenges that occurred during this process and suggest some possible ways of overcoming them, with the purpose of providing guidance for future researchers who wish to conduct future research with this group. I will focus on the process of recruitment, as this is the area that produced most challenges and where key decisions had to be made. As well as outlining these decisions and their outcome, I will also reflect on the process of recruitment more generally, and what I learnt about the key issues to consider when conducting research in this area through my interactions with service users. I will then use these learning points and reflections to outline suggestions for future researchers wishing to carry out research with people who manage bipolar moods without medication.

## Outline of the Cappleman (2014) Study

Decisions not to use medication among people with BD have frequently been attributed to individual lack of insight about the nature and severity of BD (e.g. Latalova, 2012), or inaccurate beliefs about medication (e.g. Clatworthy, Bowskill, Parham, Rank, Scott & Horne, 2009). This is reflected in the dominance of medication-based approaches to managing bipolar moods in current professional guidelines, for example those produced by the National Institute for Health and Clinical Excellence (NICE, 2006). Consequently, research efforts in this area have focussed on how adherence to medication may be improved (Clatworthy et al., 2009). The processes by which people manage bipolar moods without medication have not received any prior research attention prior to Cappleman's (2014) study, and consequently little has been known about the ways in which people attempt to manage their moods in this way after receiving a diagnosis of BD, or what obstacles they might face.

Cappleman (2014) concludes that participants seemed to repeatedly engage in decision-making processes as to whether or not to use specific management strategies, and that participants made these decisions with reference to their beliefs about themselves and their moods.  It would seem that future research with people who do not use medication for bipolar moods is warranted in order to ascertain which factors may predict better outcomes in people who manage bipolar moods without medication, in order to inform future interventions for this group.  The complexity of the processes described by these participants could not be accounted for in a traditional 'lack of insight' model, suggesting that clinicians may need to strive to understand more about the decision-making processes undertaken by some people with BD who do not use medication, in order to ensure services can be acceptable and accessible for such individuals.

**Key Decisions During the Recruitment Process**

One of the first decisions I had to make related to where I would find my sample. Previous studies investigating non-adherence to medication among people diagnosed with BD have recruited from health service settings (e.g. Clatworthy et al., 2007; Yen et al., 2005), but have tended to recruit mixed samples of people who do use medication, those who use medication intermittently, and those who state they have stopped using medication, with the latter group typically forming a small fraction of the sample.  These studies have tended not to report how long participants have stopped using medication, or only established non-adherence as occurring over short time-scales such as one week.  The extent to which previous researchers recruiting from psychiatric service settings have managed to recruit people who would consider themselves not to use medication in managing bipolar moods is therefore unclear, though it would seem likely the numbers of such people in samples have been low, despite recruitment being staged across one or more large university-hospital psychiatric departments.  Clinical services for people diagnosed with BD in the NHS tend to

emphasise the importance of using medication, reflecting the emphasis of the National Institute for Health and Clinical Excellence's (NICE) guidance (2006). This might indicate that recruiting within NHS settings for people who do not use medication to manage bipolar moods would be difficult, as the focus on medication within such settings could be seen as increasing the possibility that people who decide not to use it would also decide not to use services. Surprisingly little research has addressed this possibility, although some evidence suggests that 'accepting the need for medication' is associated with more frequent use of services after discharge from psychiatric hospital (Axelrod & Wetzler, 1989).

In order to aid me in my decision I consulted a service user researcher at a local mental health research centre. Through this consultation it became apparent that, in this individual's experience of facilitating service user support groups for people diagnosed with BD, many people diagnosed with BD who choose not to use medication are often very willing to talk about their experiences, but may be more likely to be in contact with service user organisations than health services. We also discussed the possibility that interacting with the growing community of mental health service users on online platforms such as Twitter may be a fruitful method of recruiting individuals who prefer not to use health services or attend service user groups. Furthermore, we also wondered whether recruiting from outside of NHS settings may remove any possibility of participants initially suspecting the research aim would be to gather data to inform future clinical interventions promoting adherence to medication, or worrying that information about their medication usage would be available to their NHS care team. I therefore decided that, rather than recruiting through NHS sites, I would focus my recruitment more widely on mental health organisations, local service user groups, and social networking sites.

Through my field supervisor I was also able to access a research database of individuals across the country who are willing to be contacted via e-mail with details of

mental health research projects they are invited to take part in. This proved to be an invaluable resource, providing four out of my final ten participants. However, in this paper I will concentrate the other methods of recruitment I pursued, as these produced more challenges on which to reflect.

**Engagement with Local Service User Networks .** From my conversation with this service user researcher, it was clear that local service user groups and organisations receive many requests for research, and that building positive relationships would be vital in order to secure collaboration. The first step in forming positive relationships with local service user groups was to consult with a local research advisory panel of mental health service users with an interest in providing advice and recommendations to researchers. This research advisory panel gave further suggestions as to networks and groups I could contact in the North West in order to further my recruitment. Through attending the panel's meetings, I also met leaders of service user support groups in the North West run by the charity Bipolar UK. This proved invaluable in building relationships that led to me attending these groups to talk to their members about the research.

It was also important that as part of this engagement process I offered something helpful to the service user group leaders and group members, rather than just using their time to talk about my research. I therefore suggested to groups that I could talk about the role of clinical psychologists, how the profession differs from others, and how a clinical psychologist might work with someone diagnosed with BD and/or their family members. This offer seemed to be well received by group leaders, who reported they had not had any previous guest speakers involved in clinical psychology, and this arrangement seemed to facilitate the process of being invited to groups to disseminate details of the study.

**Engagement with Social Networking.** Service users I consulted with suggested that social networking would be a valuable resource for widening my participant pool and for

making links with local service user organisations, who might be willing to disseminate details of the research.  Social networking sites such as Twitter and Facebook have greatly changed the way individuals communicate, potentially bringing positive opportunities to promote clinical psychology as a profession and to disseminate details of research projects to a wide audience (BPS, 2012).  Prior to this project I had maintained an occasional presence on the website Twitter, primarily 'tweeting' details of news relevant to clinical psychology or mental health.  However, I realised that were I to use Twitter in research recruitment I would need to develop a more active presence in order to facilitate engagement with its active online community of individuals blogging about mental health related issues, in order to increase my number of 'followers' in this community and therefore ensure details of the study contained in my posts would be seen (and hopefully 'retweeted') by a wider audience.  Notably, I found that organisations that had not replied to e-mails asking me to disseminate details of the study were much more willing to do so when contacted via social media.  I would hypothesise that social media was helpful here in adding a more 'human' face to such requests than it is possible to impart via an e-mail.  Even the limited space of a Twitter profile provides access to a photo, brief information about the individual, and some access to their online persona through the medium of their previous 'tweets'.

Although I received many requests for further information about the research from my 'tweets' carrying a link to the study's flyer, a much smaller proportion was followed up once individuals had received a full copy of the participant information sheet, detailing the steps involved in participation.  It could be possible that from reading a 'tweet' of 140 characters and a short flyer providing an outline of the project, some individuals had not expected participation to involve the 2 hour commitment of completing the Structured Interview for DSM-IV (SCID; First et al., 1997) and a research interview, and were put off by this.  This hypothesis might be supported by the fact that many people who contacted me after receiving

a study flyer following initial contact being made via a research database also chose not to participate when they had full details of what the study entailed. This experience suggests that there may be many people who do not use medication for bipolar moods who are open to the idea of participating in research, but who may be put off if time demands of doing so are felt to be excessive. It might also be hypothesised that such people may be willing to participate in quantitative studies involving the completion of brief questionnaires or scales.

Individuals who enquired about the project after viewing promotional materials via social networking or Spectrum Connect also expressed different concerns to those who I initially approached face-to-face. When attending Bipolar UK groups, it was possible to openly address issues relating to confidentiality and anonymity very early on during contact. By contrast, those who responded to seeing a flyer for the study often had concerns about such issues. Two potential participants who wished to discuss such concerns (and did not go on to form part of the final sample) emphasised that it would be detrimental to their career if their confidentiality around their diagnosis and choice not to use medication were to be broken. At this point I had to make it clear to participants that complete confidentiality could not be guaranteed, as ethical permissions I obtained to conduct the research made it clear that in the case of serious concerns about a participant or another individual, I would have to discuss this with my supervisors, and possibly contact a health professional involved in the person's care if this was felt to be warranted by the level of risk.

**Effectiveness of my recruitment strategy.** I aimed to interview up to 15 participants and interviewed ten. Had more time been available, I believe including more people would have been possible. Two people returned consent forms but were not interviewed, while in the final week of data collection I was contacted by a leader of a Bipolar UK support group some distance away who wished to take part and also knew of other people who attended his group who were eligible to do so. This contact occurred late in the study due to the group

leader having only just seen the study's flyer on the Facebook page of the International

Bipolar Foundation, after my request that they disseminate details of the project. This delay

possibly reflects the fact that long periods sometimes elapsed between organisations

receiving my request to disseminate the study details and then placing them on their social

networking profiles, and that there may have possibly been delays between organisations

promoting the research and the information then being seen by people eligible to take part.

Ultimately I do not feel the sample size is a significant limitation of the project as

within Charmaz's (2006) constructivist GT the aim is not to produce a generalizable theory,

but instead to represent how the study's participants construct the phenomena under

investigation. However, an extra stage of data collection may have provided opportunity to

elaborate or revise more tentative parts of the model (e.g. fear of the consequences of

uncontrolled moods leading to greater willingness to use medication in future). Future

researchers may wish to bear in mind that recruiting this specific sub-group of people

diagnosed with BD may be more time-intensive, and accommodate this within their

schedules.

**Reflections on the Process of Recruitment**

It quickly became apparent during the process of recruitment that attempting to recruit

people who do not use medication following a psychiatric diagnosis frequently entails

coming into contact with people who do use medication. For example, attending support

groups entails speaking to a mixed group of people who do and do not use medication (with

the former outnumbering the latter in my experience of conducting this study), whilst on

social networking sites people who do use medication for bipolar moods may contact

researchers to discuss the research and its purposes. This led to some discussions with

service users that prompted me to reflect on my own views on medication and medical

models of bipolar moods, and raised my awareness of issues that clinical psychologists who

wish to conduct research recruitment with people who do not use medication should be mindful of.

For example, when I disseminated details about the study at Bipolar UK support groups, I found I received a mixed, somewhat polarized reaction.  At one group (where the majority of members did use medication), I found that some people reacted to the study with alarm, believing I was advocating that no people should take medication for bipolar moods. Other individuals stated they were unsure whether I would find anything of value from the research, as they believed that any people who could manage bipolar moods without medication were likely to have been wrongly diagnosed, or highly unrepresentative of the vast majority of people diagnosed with BD.  By contrast, other individuals stated they felt the research was long overdue, that current systems place too much emphasis on medication and its monitoring, and that more needs to be done to highlight the damaging effects of medication.

On reflection, the process of recruiting for this study placed me in a position of seeing how recent debates in mental health relating to the place of psychiatric medication in society affect people with lived experience of psychological distress.  The advent of the 5$^{th}$ edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5; APA, 2013) has seen mainstream media sources publish a number of opinion pieces suggesting that psychiatric medication is widely over-prescribed, and that this reflects a wider process of ordinary human experience being over-medicalised (e.g. Fraser, 2013; Moncrieff, 2013).  Some people with lived experience of using psychiatric medications have responded by suggesting that such claims are highly stigmatising towards those who do choose to take medication (Whitehead, 2013), and that these claims fail to understand the nature and severity of the difficulties that lead many to see medication as a necessary part of their lives (Walker, 2013).

Following my initial experiences of receiving mixed reactions to the study when talking about it to service users during recruitment, I reflected on how some might interpret the research in light of these current debates, and that some might see me as advocating an 'anti-medication' stance. I further reflected on how some of my own attitudes may have impacted on how service users reacted to the research, and acknowledged that I indeed held negative views about medication based on a family member's past adverse experiences. Furthermore, I noticed my own implicit assumptions that there must be a way for people to manage their moods without medication, if given the correct input. I subsequently considered how these views might be devaluing of some service users' experiences, and might affect my engagement with some service users in unhelpful ways. This led to me considering issues such as the importance of personal choice in deciding whether to use medication or not, and acknowledging this may be a legitimate preferred option for many people.

Following my experience of recruiting for this study, I would recommend that clinical psychologists recruiting for similar projects in future need to be aware of such debates, and consider where they stand in relation to them. Such awareness might facilitate better service user engagement, which from my experience has been a vital part of the recruitment process, and may also impact on how service users we come into contact with see clinical psychology as a profession. Furthermore, I found that becoming aware of these debates during the process of recruitment and reflecting on my own stance led to me becoming more aware of my own assumptions that could impact on subsequent data gathering and analysis. Within constructivist GT, maintaining awareness of one's assumptions and preconceptions is seen as an integral part of the research process, so that one can attempt to 'work beyond' them when collecting and analysing data (Thornberg, 2012). A reflexive attitude towards one's own beliefs and preconceptions is also seen as a key component of other qualitative research

paradigms (Thompson & Harper, 2012).  Therefore, it may be that for qualitative researchers conducting studies with people who do not use medication after psychiatric diagnosis, recruitment is an important stage of the study in which to reflect on issues that come up in discussion with service users, and what these might reveal about one's own assumptions in relation to key areas such as medication and psychiatry.  Memo writing or keeping a reflective journal may be useful ways of doing this.

**Conclusions and Recommendations**

My experience with this study leads me to believe that clinical psychology research with people who do not use medication after receiving a psychiatric diagnosis is very much possible.  Furthermore, it would seem from the initial interest in the study on social networking websites such as Twitter that larger-scale quantitative research is feasible, particularly if it utilises relatively brief measures.  This may be especially pertinent with regards to the possibility of conducting future research that examines links between beliefs and subsequent outcome among people who manage bipolar moods without medication, as suggested by Cappleman (2014).  My experiences of recruiting for that project lead me to believe that such research might be possible, with social networking websites potentially playing an important role in this, so long as brief questionnaires and measures were used.

On the basis of my experiences in this study, I would also make the following recommendations for future researchers who wish to conduct research recruitment with people who do not use medication for bipolar moods:

- If possible, access existing databases of potential research participants.  It is likely this will entail having existing links with mental health research centres or academic institutions, possibly with members of these institutions involved from early on in the research as a key part of the research team.

- Build positive relationships with service user groups and organisations from the stage of planning the study.  As well as ensuring that the study's aims and its design are acceptable to service users, this could provide helpful advice about how best to approach other service user groups or organisations who could provide invaluable support and advertise the project to their members.  This may be especially important when trying to recruit this specific group of people who could be difficult to reach through traditional avenues such as NHS services.

- Consider how recruitment materials can clearly and succinctly communicate study protocols around confidentiality and anonymity, as these may be key concerns for some participants.

- Be aware that the issue of medication is a potentially emotive topic.  When publicising the research during recruitment, take time to reflect on your own stance, how this could influence the ways in which people perceive you and the research, and whether this is helpful.  Furthermore, the process of speaking to service user groups and organisations during recruitment may highlight one's own beliefs about the medical model that could impact subsequent data collection and analysis during qualitative research, and it is important to reflect on this.

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**Section Four: Ethics Materials**


**Materials Submitted to Division of Health Research Ethics Committee in Order to Gain**

**Ethical Permissions**


**Word Count: 4,528**


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Division of Health Research, Lancaster University

**RESEARCH ETHICS AT LANCASTER**

### Stage 1 Self-Assessment Form (Part A)  -  for Research Students

*(To be completed by the student together with the supervisor in all cases; send signed original to Research Support)*

Student name and email:     r.cappleman@lancaster.ac.uk

Supervisor name:      Dr Ian Smith                    Department:     DClinPsy

Title of project:      Managing Bipolar Mood Experiences Without the Use of Medication: A Qualitative Investigation.

Proposed funding source (if applicable):     N/A

1.   Please confirm that you have read the code of practice, 'Research Ethics at Lancaster: a code of practice' and are willing to abide by it in relation to the current proposal? **Yes**
       *If no, please provide explanation on separate page*

2.   Does your research project involve non-human vertebrates, cephalopods or decapod crustaceans? **No**     *If yes, have you contacted the Ethical Review Process Committee (ERP) via the University Secretary (Fiona Aiken)?*     **?**

3a.  Does your research project involve human participants i.e. including all types of interviews, questionnaires, focus groups, records relating to humans etc?  **Yes**
       *If yes, you must complete Part B unless your project is being reviewed by an ethics committee*

3b.  If the research involves human participants please confirm that portable devices (laptop, USB drive etc) will be encrypted where they are used for identifiable data **Yes**

3c.  If the research involves human participants, are any of the following relevant:

   **Yes**  The involvement of vulnerable participants or groups, such as children, people with a learning disability or cognitive impairment, or persons in a dependent relationship

   **Yes**  The sensitivity of the research topic e.g. the participants' sexual, political or legal behaviour, or their experience of violence, abuse or exploitation

   **No**  The gender, ethnicity, language or cultural status of the participants

   **No**  Deception, trickery or other procedures that may contravene participants' full and informed consent, without timely and appropriate debriefing, or activities that cause stress, humiliation, anxiety or the infliction of more than minimal pain

   **No**  Access to records of personal or other confidential information, including genetic or other biological information, concerning identifiable individuals, without their knowledge or consent

   **No**  The use of intrusive interventions, including the administration of drugs, or other treatments, excessive physical exertion, or techniques such as hypnotherapy, without the participants' knowledge or consent

   **No**  Any other potential areas of ethical concern? (Please give brief description)

4.   Are any of the following potential areas of ethical concern relevant to your research?

**No** Could the funding source be considered controversial?

**Yes** Does the research involve lone working or travel to areas where researchers may be at risk (eg countries that the FCO advises against travelling to)? If yes give details.

**No** Does the research involve the use of human cells or tissues other than those established in laboratory cultures?

**No** Does the research involve non-human vertebrates?
            *If yes, has the University Secretary signified her approval?*     ?

?  Any other potential areas of ethical concern? (Please give brief description)

> The project involves the researcher lone working in the process of completing interviews with participants. Relevant NHS policy and university guidance will be adhered to. See ethics application and research protocol for further information.

5.   Please select **ONE** appropriate option for this project, take any action indicated below and in all cases **submit the fully signed original self-assessment to RSO**.

☐   **(a) Low risk, no potential concerns identified**
The research does **NOT** involve human participants, response to all parts of Q.4 is 'NO'. No further action required once this signed form has been submitted to RSO

☐   **(b) Project will be reviewed by NHS ethics committee**
Part B/Stage 2 not usually required, liaise with RSO for further information. If Lancaster will be named as sponsor, contact RSO for details of the procedure

☐   **(c) Project will be reviewed by other external ethics committee**
Please contact RSO for details of the information to submit with this form

☒   **(d) Project routed to UREC via internal ethics committee**
SHM and Psychology only. Please follow specific guidance for your School or Department and submit this signed original self-assessment to RSO

☐   **(e) Potential ethical concerns, review by UREC required**
Potential ethical concerns requiring review by UREC, please contact RSO to register your intention to submit a Stage 2 form and to discuss timescales

☐   **(f) Potential ethical concerns but considered low risk, (a)-(e) above not ticked**
Research involves human participants and/or response to one or more parts of Q.4 is 'YES' but ethical risk is considered low. Provide further information by completing PART B and submitting with this signed original PART A to RSO

Student signature:        _____        Date:   _____

Supervisor signature:     _____        Date:   _____

Head of Department (or delegated representative)        Name:   _____

Signature:        _____        Date:   _____

*Research Support Office (RSO) ethics contact details: ethics@lancs.ac.uk or Debbie Knight ext 92605*

**Faculty of Health and Medicine Research Ethics Committee (FHMREC)**

**Lancaster University**

Application for Ethical Approval for Research

Instructions

1. Apply to the committee by submitting

   ✓ **The University's Stage 1 Self-Assessment Form (standard form or student form)** *and* **the Project Information & Ethics questionnaire.  These are available on the Research Support Office website:** LU Ethics

   ✓ **The completed FHMREC application form**

   ✓ **Your full research proposal (background, literature review, methodology/methods, ethical considerations)**

   ✓ **All accompanying research materials** such as, but not limited to,

      1) Advertising materials (posters, e-mails)
      2) Letters of invitation to participate
      3) Participant information sheets
      4) Consent forms
      5) Questionnaires, surveys, demographic sheets
      6) Interview schedules, interview question guides, focus group scripts
      7) Debriefing sheets, resource lists

2. **Submit all the materials electronically** as a **SINGLE** email attachment in PDF format. Instructions for creating such a document are available on the FHMREC website (http://www.lancs.ac.uk/shm/research/ethics/).

3. **Submit one underline collated and underline signed paper copy** of the full application materials. If the applicant is a student, the paper copy of the application form must be signed by the Academic Supervisor.

4. Committee meeting dates and application submission dates are listed on the research ethics committee website http://www.lancs.ac.uk/shm/research/ethics.   Applications must be submitted by the deadline stated on the website, to:

   **Diane Hopkins**
   **Faculty of Health & Medicine**
   **B03, Furness College**
   **Lancaster University, LA1 4YG**
   d.hopkins@lancaster.ac.uk

5. Attend the committee meeting on the day that the application is considered.

| |
|---|
| 1. Title of Project: Managing Bipolar Mood Experiences Without the Use of Medication: A Qualitative Investigation |
| 2.  If this is a student project, please indicate what type of project by ticking the relevant box:<br><br>☐ PG Diploma        ☐ Masters dissertation        ☐ MRes        ☐ MSc        ☐ DClinPsy SRP<br><br>☐ PhD Thesis     ☐ PhD Pall. Care/Pub. Hlth/Org. Hlth & Well Being     ☐ MD    ☒ DClinPsy Thesis<br><br>☐ Special Study Module (3rd year medical student) |
| 3.  Type of study<br><br>☒ Involves direct involvement by human subjects |

☐ Involves existing documents/data only.  Contact the Chair of FHMREC before continuing.

| **Applicant information** |
|---|
| 4. Name of applicant/researcher:<br><br>Reed Cappleman<br><br> |
| 5. Appointment/position held by applicant and Division within FHM Trainee Clinical Psychologist, Division of Health Research<br><br> |
| 6. Contact information for applicant:<br><br><br>E-mail: r.cappleman@lancaster.ac.uk  Telephone: 07888953026<br><br><br>Address: 40 Stanway Street, Stretford, Manchester, M32 0JL<br><br> |
| 7. Project supervisor(s), if different from applicant:<br><br><br>Name(s): Dr Ian Smith<br><br><br>E-mail(s): i.smith@lancaster.ac.uk _____<br><br> |
| 8. Appointment held by supervisor(s) and institution(s) where based (if applicable):<br><br><br>Lecturer in Research Methods & Senior Clinical Tutor, Division of Health Research<br><br> |
| 9. Names and appointments of all members of the research team (including degree where applicable)<br><br><br>Dr Fiona Lobban, Associate Director, Spectrum Centre for Mental Health Research<br><br> |

**The Project**

**NOTE:** In addition to completing this form you must submit a detailed research protocol and all supporting materials.

10. Summary of research protocol in lay terms (maximum length 150 words).

Bipolar experiences can negatively affect individuals' lives in a variety of ways.  Clinical guidance currently suggests pharmacological intervention as the first line of intervention, despite some research indicating that many people who experience bipolar mood states would prefer to manage them independently of medication. This project aims to understand the helpful factors and processes for those who manage their bipolar experiences without medication, as this might provide useful information for others wishing to do so. The project will aim to recruit up to 15 people who have undergone periods where they have not used medication to manage their bipolar experiences. Participants will be interviewed about their experiences and these interviews will be analysed using methods from grounded theory. The aim of this analysis will be to produce a model of the processes by which individuals develop strategies for managing their bipolar experiences without medication.

11. Anticipated project dates:

        Start date: 01/10/13    End date: 31/05/14

12. Please describe the sample of participants to be studied (including number, age, gender):

Up to 15 participants will be recruited for this study. As the study will use purposive sampling, demographic variables such as gender will only be used in sampling according to the need to construct as comprehensive a model as possible of the phenomena under investigation. Potential participants will be excluded if they are unable to speak English, as resource limitations will preclude the possibility of accessing interpreters.

Participants from 18 years of age and upwards who have been given a diagnosis of bipolar disorder by a mental health profession and been offered medication as a result will be eligible for inclusion in the study.  Participants younger than this will not be considered, as childhood bipolar disorder is characterised by diagnostic systems as its own specific entity, with a different presentation and affecting the individual in different ways to bipolar disorder in adulthood (Banaschewski, 2010).

Individuals will be considered for inclusion if they have not used any medications prescribed for the purpose of managing bipolar experiences for three consecutive months or more within the last year. However, it is likely that the purposive sampling may focus more on individuals who are currently not taking medication. In addition, individuals will only be eligible to participate if they are not currently taking medication with mood stabilising side-effects for another medical condition (e.g., epilepsy).

Individuals will also only be considered for inclusion if they are deemed to possess capacity to consent to research as outlined in the Mental Capacity Act (2005). This shall be established using guidelines published by the British Psychological Society (BPS, 2008). In the case of individuals lacking capacity, the person will not be considered for inclusion in the project due to the study's timescale resulting in insufficient time to identify an appropriate consultee to act in the best interests of those lacking capacity.

13. How will participants be recruited and from where? Be as specific as possible.

I shall recruit participants in the following ways:

- Attending service user groups for people with bipolar disorder to verbally give them information about the project. Initially I shall begin by contacting group leaders in the North West, though may look at other groups elsewhere in the country if necessary to find sufficient participants for the project. Group leaders shall be contacted through the relevant contact at Bipolar UK, the organisation which organises the groups, and give them information about the study. If group leaders invite me to attend, I shall ask if group members who meet inclusion criteria would like to participate, and if group members would like to pass on the study information to anybody else they know who might like to take part. People who might like to participate or who might know somebody else who does will be given a copy of the flyer and the participant information sheet;

- By contacting local organisations and charities that support people with bipolar disorder, and asking if they can distribute the participant information sheet to individuals who might meet inclusion criteria;

- By using 'Spectrum Connect', a database held by a local research centre, containing details of people with bipolar disorder interested in participating in research. I will contact people on the database using a letter and copies of the flyer and participant information sheet;

- Through information about the study being included in the National Service User Network's (NSUN) e-mail newsletter. The information shall include the following text alongside Lancaster University's logo: "Have you been given a diagnosis of bipolar disorder by a mental health professional? Have you ever had a period of managing your

mood without medication for three months or more? Would you be interested in talking to someone about your experiences of managing bipolar disorder without medication? If so then you may wish to participate in a research study being conducted at Lancaster University looking at how people with a diagnosis of bipolar disorder who prefer not to use medication manage their mood. It is hoped that this research will help professionals develop ideas about coping strategies which might be helpful for other people with bipolar disorder who don't want to use medication.  Participation will involve answering some questions over the phone, then meeting the researcher to fill in some questionnaires and complete an interview. If you think you might be interested in taking part and would like to find out more, please e-mail r.cappleman@lancaster.ac.uk."


- By using social media, specifically the websites Facebook and Twitter.  I shall e-mail Facebook groups for people with bipolar disorder asking if they could feature a 'wall post' giving details of my study.  On twitter I shall 'tweet' individuals who blog about issues related to bipolar disorder and service user involvement.  This tweet shall contain a link to a page containing an image of the project flyer.  The text of the tweet will request that the individual 'retweet' the message to their followers;

- By posting advertisements for the study on internet forums. The forum post shall be titled "Research Participants Required: Managing Bipolar Moods Without the Use of Medication". The forum post shall then contain the same text as included in the advertisement in NSUN's e-mail newsletter (see above).

  The forums I will be contacting in order to request permission to post details of the study are:
  www.healthyplace.com/forum/bipolar-disorder
  www.psychforums.com/bipolar
  http://www.sane.org.uk/what_we_do/support/supportforum/
  www.rethink.org/talk/forum
  www.bphope.com
  http://www.dailystrength.org/c/Bipolar-Disorder/support-group
  www.bipolarsupport.org
  http://forums.psychcentral.com/bipolar/
  http://www.uncommonforum.com/viewforum.php?f=19
  http://www.madinamerica.com/forums/forum/psychiatric-drugs/
  http://www.mentalhealthforum.net/forum/forum37.html
  http://www.theicarusproject.net/forums/

  Before posting on the forum I will e-mail the admin to ask permission to create a post detailing the study and my contact details.


- Through placing advertisements in local newspapers, and seeking to gain local news coverage about the project through local newspapers and radio.  The advertisement will utilise text from the project flyer to give brief details about the purpose of the study, who I aim to recruit, and a contact e-mail.  Individuals who contact me will then be sent a copy of the participant information sheet via e-mail. Any stories about the project in local media will include my contact details for people interested about the project to contact me.

- Through word of mouth: if individuals who I meet during the course of the study (e.g., service user research advisory groups, other professionals involved in research) expresses an interest in taking part, I will provide them with my contact details and ask

them to contact me so I can e-mail them a copy of the project flyer.  If people state they know somebody who might be interested in taking part, I will give my contact details to that person to pass on to the potentially interested third party, so they can contact me if they wish to do so.  It is hoped that the requirement that potentially interested parties contact me (rather than me taking their contact details and contacting them) reduces any potential elements of coercion that may occur during word-of-mouth recruitment.

The flyer that the individual sees at the start of the process (either through clicking a link on a website or through being sent it by me via e-mail) will include my e-mail address and project mobile phone number, so that individuals can contact me should they wish to participate or ask any further questions about the project.  When I am contacted I will answer any questions people may have, and send them a postal copy of the participant information sheet, consent form and an SAE.  I will then ask individuals to return the consent form in the envelope. Once I have the individual's signed consent form, I shall telephone them on the number provided in order to complete the screening process.  Potential participants will also be able to scan the form and return it via e-mail.

At the point of this telephone contact I will need to collect information about the person such as their age, gender, ethnicity, if they have been given specific diagnoses, and how long they have not been using medication to manage their bipolar disorder (or the duration of the longest continual period they stopped taking their medication for over the previous twelve months). I will also ask the person for contact details for a health professional whose care they are currently under (e.g. GP, care co-ordinator). If preliminary data analyses suggest the Structured Clinical Interview for DSM IV (SCID) (First, Gibbon, Spitzer, Williams & Benjamin, 1997) should also be used as an instrument to guide theoretical sampling (see paragraph below) I will discuss this with participants at this point, and ask when will be a convenient time to complete this over the telephone.

I will arrange to interview the first three people who wish to take part and are currently no longer using medication. Other people wishing to take part will be placed on a list of potential participants and will be selected for participation according to decisions about the varieties of person needing to be sampled in order for the model being developed to be the most comprehensive possible (known as theoretical sampling- see Charmaz, 2006).  For example, if a model is developed from preliminary analyses that only seems to account for the experiences of white British males, the next phase of sampling may focus on people who are female, are of a different ethnicity, or from a different cultural background.  As data analysis progresses, it may also be necessary for me to use the SCID as a tool to guide theoretical sampling. The SCID is a structured interview of people's experiences relating to mental health, and will provide qualitative information about individual's mood states and experiences that may be useful to guide sampling (e.g. if they experience agitation or have at any point had to stay in hospital because of their mood) depending on the model constructed from the first waves of interviews and data analysis.

Interviews shall be conducted face-to-face where possible. If this is impractical due to the participant's location, the participant will be offered the opportunity to be interviewed by

telephone or using skype. At the start of the Skype interview, participants will be informed that the internet is not secure and offered the option of withdrawing from the research. A Skype account will be created for the purposes of this study, and will not be used for any private purposes.

It is also possible that as the model derived from the data develops I might return to participants who have already been interviewed to seek further information to expand on the information they have already given.

14. What procedure is proposed for obtaining consent?

When participants contact me about the study they will have the opportunity to ask any questions they might have about the project.  Participants will then have as long as they want to decide whether to participate or not.

If an individual is interested in participating, I will send them a copy of the participant information sheet and consent form, along with an SAE.  Potential participants will be asked to return the signed consent form to me if they would like to participate.  When the consent form is returned with the person's signature, I will telephone them and collect demographic information.  If the data analysis so far necessitates the use of the SCID to guide theoretical sampling, I will at this point arrange with the participant a convenient time to complete the SCID over the phone.

If theoretical sampling indicates somebody is an appropriate individual to participate in a research interview, I will contact them by telephone to arrange when will be a convenient time and place to meet.  If the person has not already completed the SCID interview procedure over the phone, I will arrange with them a convenient time to do this prior to the research interview.  During the telephone call where I administer the SCID and at the start of the face-to-face meeting, I shall offer the participant the opportunity to ask any further questions they might have about the research.

In line with the Mental Capacity Act (2005), it will be assumed that potential participants have capacity to take part unless evidence suggests otherwise.  Upon meeting with participants I will be vigilant for any indicators that the person is experiencing a depressed or manic mood episode, which might impair their ability to give informed consent to participate in the research.  I will do this by asking about their wellbeing over recent days and looking for behavioural indicators that they might be experiencing such mood states.  If I have cause for concern about the person's capacity to consent, I will follow guidance set out by the British Psychological Society and attempt to ascertain the person's understanding of why the purpose of the research and what is expected of them if they wish to take part.  Potential participants being unable to answer these questions correctly would lead to me having cause for concern about their capacity and not carrying on the interview at that time.  In such instances individuals would be given the option for me to return to speak to them at another point in time.

15. What discomfort (including psychological), inconvenience or danger could be caused by participation in the project?  Please indicate plans to address these potential risks.

During the conduct of the interview there may be issues around potential participants lacking capacity to decide whether or not to participate in research due to fluctuations in their mood states.  The interviews will be conducted by a researcher who has received training in issues

relating to capacity and had experience of assessing capacity over the course of previous research and clinical work, and will be adhering to practice guidelines from the BPS (2008) for considering issues relating to capacity in research.

There may be a risk of participants becoming distressed during the interview whilst they are talking about their bipolar mood experiences.  If this occurs the researcher will enquire as to the participant's welfare. If necessary the participant will be given the choice of continuing, taking a break or terminating the interview.  I will keep the voice recorder running, but will be guided by the participant's wishes as to whether or not they would like to continue.  Participants will be given information about resources they can access should the study raise any distressing issues.  These resources will include information about how to access mental health support services, as well as information about charities and service user organisations such as Mind and Bipolar UK.  The next day I shall contact participants by telephone in order to ascertain that the participant has not been experiencing distress in the period following the interview.

It is possible that during the interviews participants will relay information that gives the researcher cause for concern as to their welfare or the welfare of others.  The participant information sheet shall explain that in such events the researcher will need to break confidentiality and speak to one or both of their supervisors to gain further direction. The researcher will have access to supervision from professionals at the Spectrum research centre, where the field supervisor is based, to discuss such issues (or other issues associated with participants' clinical needs) as they are identified.

There may also be a risk of participants' data being included in the project after they have changed their mind about participation and would like it to be withdrawn.  Participants will be free to ask to have their information withdrawn at any time, though this might not be possible once the data has been anonymised and analysed.  In order to safeguard against this risk, this information will be included on the participant information sheet and consent form, and verbally highlighted to the participant when they are given the consent form.

16.  What potential risks may exist for the researcher(s)?  Please indicate plans to address such risks (for example, details of a lone worker plan).

There may be a risk of harm or danger to the researcher, who will potentially be conducting interviews in unfamiliar locations which may include people's homes.  To ensure my safety I will adhere to the university's guidance and Lancashire Care's policy on lone working, ensuring that colleagues are aware of my exact whereabouts, when meetings should be finishing, and the registration of the car I have used to travel to the meeting.  I shall telephone the relevant colleague at the end of the meeting to confirm my safety.  If I do not contact the colleague by the agreed time, they will be under instruction to attempt to contact me, and then if they receive no answer to contact the police.  Participants will be informed that colleagues are aware of my whereabouts.

17.  Whilst we do not generally expect direct benefits to participants as a result of this research, please state here any that result from completion of the study.

There may be no direct benefit to participation in this study.  However, people may find it a

positive experience to participate in an interview where they are invited to reflect on the experience of managing their bipolar experiences and be listened to by an impartial researcher. Participants may also gain indirect benefit from the possibility that sharing these experiences might benefit other people with a diagnosis of bipolar disorder.

18. Details of any incentives/payments (including out-of-pocket expenses) made to participants:

Refund of cost of travel to and from interview location, when this is not the person's home. The limit of this shall be in line with that set out in the Lancaster DClinPsy's relevant policy.

19. Briefly describe your data collection and analysis methods, and the rationale for their use

A qualitative methodology has been chosen for this study, as this approach is well suited to research questions examining experience and processes (Thompson & Harper, 2012). Specifically, grounded theory methods will be used to analyse the data as they pay specific attention to how an understanding of the ways in which individuals construct their reality can be used to build an understanding of social and psychological processes (Charmaz, 2006). This specific method has been chosen as it is well suited to constructing models of processes associated with phenomena, especially those related to individual experience, and this is the aim of this study.

Data shall be analysed using the constructivist approach to grounded theory outlined by Charmaz (2006). This approach does not seek to produce a 'true' picture of the phenomenon under investigation that can be generalised to everybody. Instead it seeks to produce a theory or model that represents the experiences of the participants, and recognises that the research process is inevitably affected by the researchers' own experiences and history.

Field notes will be written as the interviews and analysis proceed, in order to capture ideas and reflections that might be relevant to later analysis. Typed transcripts shall then be 'line-by-line coded' (Charmaz, 2006). This is a process of initial coding which involves going through the transcript line-by-line and summarising the data by assigning it brief labels that describe its content. Throughout this process 'memos' shall be written to make notes of how codes might relate to one another, comparisons that can be made between different codes within and between interviews, and anything the researcher notices about their own ideas or preconceptions. This is then followed by 'focused coding', which entails using the most frequent or significant initial codes to categorise segments of data more broadly. Interviews from subsequent series of interviews are then coded in relation to these initial interviews. Following this a further advanced level of coding is applied that seeks to develop the existing

codes into a conceptual framework.

20.  Describe the involvement of users/service users in the design and conduct of your research. If you have not involved users/service users in developing your research protocol, please indicate this and provide a brief rationale/explanation.

Members of the Lancaster DClinPsy's Public Involvement Network were consulted during the process of developing the research idea and identifying possible practical issues relating to studying this topic area. The Spectrum Centre's Research Advisory Group (a group of service users offering advice relating to research) were later consulted on the feasibility of the idea once it was further developed, and provided input into the development of the inclusion and exclusion criteria and the recruitment process.

21. What plan is in place for the storage of data (electronic, digital, paper, etc.)?  Please ensure that your plans comply with the Data Protection Act 1998.

While the project is ongoing, electronic copies of data will be kept on the university's secure server. Any printed copies of transcripts will be kept in a locked cabinet at the home of the researcher.

After the study is completed and the final mark has been received, data shall be retained by the university for 10 years. This will include transcripts, coded data, and consent forms. Consent forms will be scanned and saved as a PDF.  The paper copies will then be shredded.

22. Will audio or video recording take place?        ☐ no        ☒audio        ☐video

If yes, what arrangements have been made for audio/video data storage? At what point in the research will tapes/digital recordings/files be destroyed?

All interviews will be audio recorded (if interviews take place via Skype they shall be recorded by placing a voice recorder within range of the computer speakers; if interviews are conducted over the telephone the phone will be set to loudspeaker and the voice recorder placed within range of the telephone speaker). Audio files will be transferred from the voice recorder onto on the university's secure server as soon as possible after interviews, as it will not be possible to encrypt files on the voice recorder.  Once the final mark for the project has been awarded and the research has been accepted for publication, audio files will be deleted. The DClinPsy programme's research administrator will be responsible for deleting the files at the end of this period.

23.  What are the plans for dissemination of findings from the research?

Participants will be sent a letter informing them of the study's findings.  I shall also offer to attend service user groups in the Greater Manchester area that have assisted in recruitment and

provide verbal feedback of the findings.  If possible, groups that were involved in recruitment and are further afield from the researcher's place of residence will also be offered verbal feedback, though this might be difficult due to time considerations.  If verbal feedback is not possible, group leaders shall be sent a letter detailing the project's findings.

The project shall be disseminated by its submission as part of a thesis. Following submission of the project in the thesis, it shall be edited into a condensed format and submitted to a relevant journal for publication.  The researcher will also attempt to identify relevant conferences at which to present the research, either through a powerpoint presentation or poster presentation.

24. What particular ethical problems, not previously noted on this application, do you think there are in the proposed study?

There are circumstances in this project in which confidentiality may be broken. These circumstances are those in which the researcher has serious concerns about the physical safety of the participant or another individual, e.g. if participants disclose plans to end their life, or plans to physically injure other individuals. These limits to confidentiality will be detailed on the participant information sheet.

Signatures:        Applicant: …………………………..………………….....................................

                   Date: …………………………………………...........................................

                   Project Supervisor* (if applicable): ………………………………….................

                   Date: ………………………………………….........................................

*I have reviewed this application, and discussed it with the applicant.  I confirm that the project methodology is appropriate.  I am happy for this application to proceed to ethical review.

**Appendix F:**

**Correspondence from Lancaster University's Division of Health Research's Ethics Committee**

LANCASTER
UNIVERSITY

Applicant: Reed Cappleman
Supervisor: Ian Smith
Department: DHR

09 August 2013

Dear Reed and Ian,

**Re: Managing Bipolar Mood Experiences**

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 University Research Ethics Committee (UREC), 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 (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 the Research Ethics Officer, Debbie Knight (01542 592605 ethics@lancaster.ac.uk) if you have any queries or require further information.

Yours sincerely,

*S.C. Taye*

Sarah Taylor
Secretary, University Research Ethics Committee

Cc Professor T McMillan (Chair, UREC); Professor Paul Bates (Chair, FHMREC)

Applicant: Reed Cappleman
Supervisor: Dr Ian Smith
Department: DHR

**LANCASTER**
**UNIVERSITY**

24 September 2013

Dear Reed and Ian,

**Re: Managing Bipolar Mood Experiences**

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

*To note, approval has been granted on condition that identifiable data (including recordings of participants' voices) will be deleted from the audio recorder as quickly as possible after the data has been transferred to the LU secure server.*

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 (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 the Research Ethics Officer, Debbie Knight (01542 592605 ethics@lancaster.ac.uk) if you have any queries or require further information.

Yours sincerely,

*S.C. Taylor*

Sarah Taylor
Secretary, University Research Ethics Committee

Cc Professor T McMillan (Chair, UREC); Professor Paul Bates (Chair, FHMREC)

**Appendix G:**

**Research Protocol Submitted to Ethics Committee**

**Managing Bipolar Mood Experiences Without the Use of Medication: A Qualitative**

**Investigation**

**Research Protocol: Version 1**

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**Dr Fiona Lobban, Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University**

**Dr Ian Smith, Doctorate in Clinical Psychology, Division of Health Research, Lancaster University**

**Introduction**

Bipolar disorder is a diagnosis included in the World Health Organisation's *International Classification of Diseases* (10th edition), also known as ICD-10 (WHO, 1992), and the American Psychiatric Association's *Diagnostic and Statistical Manual* (4th edition), also known as DSM-IV (APA, 2000). Both diagnostic systems conceptualise bipolar disorder's main features as periods of depression, mania or hypomania interspersed with periods of mood stability. Mania refers to periods of elevated mood accompanied by high levels of physical and mental energy, increases in goal-orientated behaviour, and increased engagement in pleasurable activities (APA, 2000). The individual may experience these periods as enjoyable, but they might also experience agitation or unusual experiences such as hearing voices, or engage in risky behaviour. Hypomania has similar characteristics to mania, but is categorised according to its shorter duration and an alteration in functioning in its more general sense (i.e. the changes may be positive and/or negative) (APA, 2000). Mansell and Pedley (2008) found that the most common problematic experience for those with bipolar disorder was dysphoria- feelings of anxiety, guilt and depression occurring during low mood episodes. Weissman et al. (1996) estimate the prevalence of bipolar disorder in the UK and US to be around 1-1.5% of the population. It is common for mood episodes to feature both low and elevated mood either simultaneously or in rapid alternation ('mixed episodes'), and individuals often experience less severe feelings of low mood between periods of elevated mood and depression (BPS, 2010).

Bipolar experiences can often negatively affect individuals' quality of life (Michalak, Yatham, Kolesar & Lam, 2006). Manic episodes may result in people feeling out of control of their moods (Mansell, Rigby, Tai, & Lowe, 2008), and the associated unusual experiences can be confusing and difficult for people to make sense of after they have occurred (Bonney & Stickley, 2008). Dysphoria during low mood episodes carries a risk of self harm and suicidal ideation (Mansell & Pedley, 2008), whilst one estimate suggests that between 10% and 15% of people who are admitted to hospital due to problems associated with bipolar disorder will die due to suicide (Hawton et al., 2005).

The National Institute for Clinical Excellence's guidelines for bipolar disorder suggest that medication should be the primary treatment for people with bipolar disorder, with other approaches (e.g., psychological therapies) being used in addition where necessary (NICE, 2006). However, medication used in the management of bipolar disorder tends to eliminate aspects of bipolar experiences that people may perceive as positive (Jamison, 1996), such as increased self-awareness, empathy, creativity and productivity (Parker, Paterson, Fletcher, Blanch & Graham, 2012). There is currently a lack of good quality data demonstrating the effectiveness of mood stabiliser medication in the longer term management of bipolar disorder (Smith, Cornelius, Warnock, Bell & Young, 2007), and the medications can have aversive side effects such as tremor, weight gain, diabetes and underactive thyroid (Berk & Berk, 2003). Questions remain as to whether such side effects exacerbate levels of distress and whether the long term use of medication may diminish individuals' overall functioning (Whitaker, 2010).

Perhaps due to some of these issues, Mansell, Powell, Pedley and Jones (2010) found that for some people with bipolar disorder, personal beliefs about 'recovery' are associated with the wish to manage bipolar mood experiences in the long term without using medication. However, the British Psychological Society's report *Understanding Bipolar Disorder* notes that despite these findings, people with bipolar disorder are rarely given a choice as to whether they wish to manage their mood with medication or rely solely on other approaches (BPS, 2010).

**The Present Study**

Although some people with bipolar disorder wish to be able to manage their mood experiences without medication (Mansell, Powell, Pedley, Thomas & Jones, 2010) there is an absence of research about the processes by which these people do manage and their experiences linked to this. There is also an absence of data as to how many people with bipolar disorder manage their experiences without using medication. Amongst people with psychosis, another mental health diagnosis which many professionals believe is best managed by long term medication use (Whitaker, 2010) it is estimated that around 40%-50% do not consistently use medication long-term (see

Morrison et al., 2011).  However, it is unknown how many of these might people might consider themselves to be 'managing' their experiences associated with psychosis.

Regardless of how many people with bipolar disorder manage their bipolar experiences without using medication, knowledge of their experiences and the ways in which they manage their mood may inform professionals' knowledge of effective ways in which individuals can respond to bipolar experiences.  This may support the development of interventions other than medication, improving the range of options they can offer service users.  This study therefore poses the following research question:

"What are the processes by which people with bipolar disorder who choose not to use medication manage their bipolar experiences?"

A qualitative methodology has been chosen for this study, as this approach is well suited to research questions examining experience and processes (Thompson & Harper, 2012).  Specifically, grounded theory methods will be used to analyse the data as they pay specific attention to how an understanding of the ways in which individuals construct their reality can be used to build an understanding of social and psychological processes (Charmaz, 2006).

**Method**

**Participants**

Up to 15 participants will be recruited for this study.  It is felt that this number represents a reasonable compromise between the need to complete the project within a fixed time span, and the requirement of studies using grounded theory methods to attempt to reach data 'sufficiency', whereby new data does not necessitate revising the categories and themes developed during the analysis (Dey, 1999).

Participants from 18 years of age and upwards who have been given a diagnosis of bipolar disorder by a mental health profession and been offered medication as a result will be eligible for inclusion in the study.  Participants younger than this will not be considered, as childhood bipolar disorder is characterised by diagnostic systems as its own specific entity, with a different presentation and affecting the individual in different ways to bipolar disorder in adulthood (Banaschewski, 2009).

Individuals will be considered for inclusion if they have not used any medications prescribed for the purpose of managing bipolar experiences for three consecutive months or more within the last year.  Three months was chosen as an appropriate cut-off point following consultation with an advisory panel of service users with bipolar disorder, who suggested that in their experience two months without medication would be long enough for the medications to cease having any mood stabilising effects.  It was then decided that an additional month without medication would be required, in order for participants to have had enough experience of living without its effects to be able to talk about it for the duration of an interview.  It was also decided that the period without medication would have to be within the last year in order to ensure that these experiences can be remembered clearly for the purpose of the interview.  In addition, individuals will only be eligible to participate if they are not currently taking medication with mood stabilising side-effects for another medical condition (e.g., epilepsy).

Individuals will also only be considered for inclusion if they are deemed to possess capacity to consent to research as outlined in the Mental Capacity Act (2005).  This shall be established using

guidelines published by the British Psychological Society (BPS, 2008). In the case of individuals lacking capacity, the person will not be considered for inclusion in the project due to the study's timescale resulting in insufficient time to identify an appropriate consultee to act in the best interests of those lacking capacity. Individuals who are deemed to currently be experiencing a clinically significant episode of elevated mood (as measured by the use of a screening instrument) will not be considered for the study.

**Design**

This study will take a qualitative approach. Recruitment shall proceed according to theoretical sampling (Charmaz, 2006), whereby participants are selected to take part in interviews if it is anticipated they will provide data that will allow the model built from the data so far to be extended. After recruitment and completing a structured clinical interview and mood questionnaire, participants will complete a semi-structured interview expected to last between one and two hours. Questions asked in interviews conducted later in the project will be informed by the findings of the analysis up to that point. Second interviews may be completed with some participants in order to facilitate a deeper analysis of points of interest. Interviews will be recorded, transcribed and then analysed using grounded theory methods (Charmaz, 2006). The quality of the analysis shall be ensured by keeping a rigorous audit trail of memos, initial codes, focused codes and advanced codes throughout. An initial interview, along with examples of data coding and analysis, will be checked by members of the research team in order to ensure that the main researcher's analysis is transparent and its methods are comprehendible to others.

**Materials**

At the recruitment stage I will require the use of a mobile phone, for potential participants to contact me. During the research interviews with participants, an interview schedule shall be used as a guide (see Appendix A). Interviews shall be recorded using a voice recorder, and then transcribed by the principal investigator using a transcription pedal.

Prior to completing a research interview participants will be asked to complete the Mood Disorder and Psychosis subsections of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID) (First, Gibbon, Spitzer, Williams & Benjamin, 1997). Depending on the model that is constructed as data collection and analysis proceeds, the SCID may be used as a tool to guide theoretical sampling, as it provides a structured method for gaining qualitative information about specific facets of individual's bipolar experiences (e.g. whether the individual experiences agitation, or if they have ever had to stay in hospital due to their mood). Any participants who do not complete the SCID as part of the sampling process will be asked to do so prior to their research interview, so that the SCID can be used to provide detailed information about the characteristics of the final sample. In either case, the SCID shall be completed over the telephone prior to any research interview taking place.

Participants will also be asked to complete the Internal State Scale (Bauer et al., 1991) (see Appendix B) at the beginning of their face-to-face interview, as this instrument will give a more in-depth picture of participants' mood state on the day of interview, allowing for a more accurate description of the sample in the project's write-up.

**Procedure**

I shall recruit participants in the following ways:

- Attending service user groups for people with bipolar disorder to verbally give them information about the project. Initially I shall begin by contacting group leaders in the North West, though may look at other groups elsewhere in the country if necessary to find sufficient participants for the project. Group leaders shall be contacted through the relevant contact at Bipolar UK, the organisation which organises the groups, and be given information about the project. If group leaders invite me to attend, I shall ask if group members who meet inclusion criteria would like to participate, and if group members would like to pass on the study information to anybody else they know who might like to take part. People who might like to

participate or who might know somebody else who does will be given a copy of the participant information sheet;

- By contacting local organisations and charities that support people with bipolar disorder, and asking if they can distribute the participant information sheet to individuals who might meet inclusion criteria;

- By using 'Spectrum Connect', a database held by a local research centre, containing details of people with bipolar disorder interested in participating in research. I will contact people on the database using a letter and a copy of the participant information sheet;

- Through information about the study being included in the National Survivor User Network's (NSUN) e-mail newsletter. The information will be a brief paragraph outlining the study's aims, inclusion criteria, and my contact e-mail. Potential participants who contact me will then be sent a copy of the participant information sheet via e-mail;

- By posting advertisements for the study on internet forums. The forum post shall be titled "Research Participants Required: Managing Bipolar Moods Without the Use of Medication". The forum post shall then contain the same text as included in the advertisement in NSUN's e-mail newsletter (see above).

  The forums I will be contacting in order to request permission to post details of the study are:

www.healthyplace.com/forum/bipolar-disorder

www.psychforums.com/bipolar

http://www.sane.org.uk/what_we_do/support/supportforum/

www.rethink.org/talk/forum

www.bphope.com

http://www.dailystrength.org/c/Bipolar-Disorder/support-group

www.bipolarsupport.org

http://forums.psychcentral.com/bipolar/

http://www.uncommonforum.com/viewforum.php?f=19

http://www.madinamerica.com/forums/forum/psychiatric-drugs/

http://www.mentalhealthforum.net/forum/forum37.html

http://www.theicarusproject.net/forums/

> Before posting on the forum I will e-mail the admin to ask permission to create a post detailing the study and my contact details.

- By using social media, specifically the websites Facebook and Twitter.  I shall e-mail Facebook groups for people with bipolar disorder asking if they could feature a 'wall post' giving details of my study.  On twitter I shall 'tweet' individuals who blog about issues related to bipolar disorder and service user involvement.  This tweet shall contain a link to a page showing details of the study and the participant information sheet.  The text of the tweet will request that the individual 'retweet' the message to their followers;

- Through placing advertisements in local newspapers.  The advertisement will contain brief details about the purpose of the study, who I aim to recruit, and a contact e-mail. Individuals who contact me will then be sent a copy of the participant information sheet via e-mail.  I will also attempt to place stories about the project in local print and radio media, detailing the study, its purpose and my contact details;

- Through word of mouth: if individuals who I meet during the course of the study (e.g., service user research advisory groups, other professionals involved in research) expresses an interest in taking part, I will provide them with my contact details and ask them to contact me so I can e-mail them a copy of the project flyer. If people state they know somebody who might be interested in taking part, I will give my contact details to that person to pass on to the potentially interested third party, so they can contact me if they wish to do so.  It is hoped that the requirement that potentially interested parties contact me (rather than me taking their contact details

and contacting them) reduces any potential elements of coercion that may occur during word-of-mouth recruitment.

Participants will also be sent a consent form and SAE along with the participant information sheet. The participant information sheet will include my e-mail address and project mobile phone number, so that individuals can contact me should they wish to ask any further questions about the project. When participants return their signed consent forms (either through the post or by scanning the signed consent form and sending it to me electronically), I will contact them on the telephone number provided. At this point I will collect information about the person such as their age, gender, ethnicity, if they have been given specific diagnoses, and how long they have not been using medication to manage their bipolar disorder (or the duration of the longest continual period they stopped taking their medication for over the previous twelve months). I shall also request details for a named health professional whose care they are under. If the SCID is being used as a tool to guide theoretical sampling I will then arrange to complete the SCID over the telephone at a time convenient to the participant.

At this point the individual will be thanked for the information they have given and informed that I will contact them if they are to be invited to a research interview (depending on how theoretical sampling progresses). If an individual is selected, I will telephone them to arrange a convenient time for them to meet me for a face-to-face interview. If they have not completed the SCID as part of the sampling process, I will also arrange with the person a convenient time before the face-to-face interview for me to complete the SCID with them over the telephone.

Initially I will arrange to meet the first three participants in the North West who are willing to take part, meet the inclusion criteria, and are currently not using medication to manage their bipolar experiences (as a sample mostly comprising of such individuals will be better suited to answer the research question). I will transcribe and analyse these interviews, and then proceed to employ theoretical sampling (Charmaz, 2006). This involves sampling in a way that aims to broaden categories of data and the theories for understanding participants' experiences that have been developed from the initial three interviews. Depending on the content of my analysis from my initial

three interviews, it may be necessary to target my subsequent sampling on the basis of characteristics such as participants' age, gender, or how long they have not been using medication. The characteristics I choose to focus on for my sampling will depend on the questions arising from the data analysis so far and the types of participant who might give interview data that will help to answer them and expand the model derived from the data. As described above, potential participants may be asked to complete the SCID procedure in a telephone interview if it is thought this will provide useful information to guide theoretical sampling. Throughout the recruitment process participants residing in the North West will be given priority, due to the time constraints imposed upon the project. All individuals invited to participate in the research interview will be asked to complete the SCID beforehand over the telephone, if they have not already done so as part of the sampling process. This is because the SCID is being used in order to gain clinical information about the final sample so it can be accurately described in the write-up.

I will arrange to meet participants for interviews in their homes or another location convenient to them. Participants will also be offered the opportunity to complete interviews via skype or telephone (depending on their personal choice) if this is more convenient. To ensure my safety I will adhere to Lancaster University guidance and Lancashire Care's policy on lone working, ensuring that colleagues are aware of my exact whereabouts, when meetings should be finishing, and the registration of the car I have used to travel to the meeting. I shall telephone the relevant colleague at the end of the meeting to confirm my safety. If I do not contact the colleague by the agreed time, they will be under instruction to contact the police. Participants will be informed that colleagues are aware of my whereabouts.

At this meeting I shall offer the participant the opportunity to ask any further questions they might have about the research, and then ask them to sign a consent form. If being interviewed via Skype, participants will be informed that the internet is not secure and offered the option of withdrawing from the research. A Skype account will be created for the purposes of this study, and will not be used for any private purposes. I will ask participants to complete the Internal State Scale (if doing the interview via skype or telephone I will read out the items to the person and ask

them to choose from the available responses), then use a voice recorder to record the subsequent interview, which is expected to last approximately an hour to two hours. The Internal State Scale is a measure of mood that gives an indication of an individual's mood state on a specific day, by asking them questions about their mood and asking them to respond using items on a Likert scale. It can be given to participants for them to fill in independently, or the researcher can read the questions to participants if they prefer (or if they are completing the interview via skype). Along with the SCID, the Internal State Scale is being used as a tool to gain descriptive information about the final sample. I will make it clear to participants that they are free to have a break from the procedure whenever they like. At the end of the procedure I will thank the participant for their time and ask if it would be possible to return to them later to ask them further questions if this is necessary.

The voice recording will then be transcribed onto word processing software. All names included in the transcript will be pseudonymised, including the names of participants. Both the audio recording and the word processed transcript shall be stored on Lancaster University's secure server. The audio recording will be erased by the DClinPsy programme's research administrator once I have received a mark for the project and the results have been written up for publication. The written transcript will be stored by the university for 10 years after submission then destroyed by the DClinPsy's research administrator, as per university regulations. As mentioned above, the data analytic process may require second interviews with some participants in order to expand on preliminary findings. Any second interviews will follow the same procedure as outlined above.

**Proposed Analysis**

Data shall be analysed using the constructivist approach to grounded theory outlined by Charmaz (2006). This approach does not seek to produce a 'true' picture of the phenomenon under investigation that can be generalised to everybody. Instead it seeks to produce a theory or model that represents the experiences of the participants, and recognises that the research process is inevitably affected by the researchers' own experiences and history.

Field notes will be written as the interviews and analysis proceed, in order to capture ideas and reflections that might be relevant to later analysis. Typed transcripts shall then be 'line-by-line coded' (Charmaz, 2006). This is a process of initial coding which involves going through the transcript line-by-line and summarising the data by assigning it brief labels that describe its content. Throughout this process 'memos' shall be written to make notes of how codes might relate to one another, comparisons that can be made between different codes within and between interviews, and anything the researcher notices about their own ideas or preconceptions. This is then followed by 'focused coding', which entails using the most frequent or significant initial codes to categorise segments of data more broadly. Interviews from subsequent series of interviews are then coded in relation to these initial interviews. Following this a further advanced level of coding is applied that seeks to develop the existing codes into a conceptual framework.

**Practical Issues**

The principal researcher will require training in the SCID in order to administer it with participants. This entails watching a training DVD (approximately 6 hours of footage) and practicing scoring the SCID using the case examples therein. The next stage of training entails watching another professional trained in the SCID administering the interview, and then being recorded administering the tool with a volunteer. This recording is then marked by an appropriate professional trained in the use of the tool. This training shall be accessed through the research centre to which one of the project's team is attached.

The cost of photocopying materials such as interview schedules and participant information sheets will be met by the Lancaster University Doctorate in Clinical Psychology. Travel expenses to interviews with participants shall be paid by the NHS trust that employs the interviewer.

**Ethical Issues**

During the conduct of the interview there may be issues around potential participants lacking capacity to decide whether or not to participate in research due to fluctuations in their mood states. The interviews will be conducted by a researcher who has received training in issues relating to

capacity and had experience of assessing capacity over the course of previous research and clinical work, and will be adhering to practice guidelines from the BPS (2008) for considering issues relating to capacity in research.

There may be a risk of participants becoming distressed during the interview whilst they are talking about their bipolar mood experiences. If this occurs the researcher will enquire as to the participant's welfare. If necessary the participant will be given the choice of continuing, taking a break or terminating the interview (although the tape recorder will be left running until the researcher leaves the interview location). Participants will be given information about resources they can access should the study raise any distressing issues. These resources will include information about how to access mental health support services, as well as information about charities and service user organisations such as Mind and Bipolar UK. The next day I shall contact participants by telephone in order to enquire as to their welfare in the period following the interview.

It is possible that during the interviews participants will relay information that gives the researcher cause for concern as to their welfare or the welfare of others- for example if the participant describes concrete plans to harm others or end their own life, and describes possessing the means to carry out this plan. The participant information sheet shall explain that in such events the researcher will need to break confidentiality and discuss this issue with one or both of their supervisors. Participants will be reminded of this at the start of interviews. The researcher will have access to supervision from professionals at the Spectrum research centre, where the field supervisor is based, to discuss such issues (or other issues associated with participants' clinical needs) as they are identified.

There is also a risk of harm or danger to the researcher, who will potentially be conducting interviews in unfamiliar locations which may include people's homes. The researcher shall ensure their safety by following Lancashire Care NHS Foundation Trust's lone worker policy at all times, for example by ensuring others are aware of their whereabouts and that they have made arrangements to contact others at set times in order to confirm their safety. This plan is also in keeping with Lancaster University guidance on lone working during field work.

**Dissemination**

Participants will be sent a letter informing them of the study's findings.  I shall also offer to attend service user groups in the Greater Manchester area that have assisted in recruitment and provide verbal feedback of the findings.  If possible groups that were involved in recruitment and are further afield from the researcher's place of residence will also be offered verbal feedback, though this may not be possible due to time and resource limitations.  If verbal feedback is not possible, group leaders shall be sent a letter detailing the project's findings.

Following submission of the project, it shall be edited into a condensed format and submitted to a relevant journal for publication.  The researcher will also attempt to identify relevant conferences at which to present the research, either through a powerpoint presentation or poster presentation.

**Proposed Timescale**

| Activity | Date |
|---|---|
| Submit ethics application | 26/06/13 |
| Data collection | Begin: 01/08/13<br>Finish by: April 2013 |
| Data analysis | Ongoing alongside data collection: to be completed by end of April |
| Submit thesis | Mid-May 2014 |
| Submit papers for publication | End of August '14 |

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**Appendix H:**

**Recruitment Flyer**

# Flyer for Research Study: Managing Bipolar Mood Experiences Without the Use of Medication

- Have you been given a diagnosis of bipolar disorder by a mental health professional?

- Have you been offered medication to try and help you manage bipolar moods?

- Over the last year, have you had a period of managing your mood without medication for three months or more?

- Would you be interested in talking to someone about your experiences of managing bipolar disorder without medication?

## *If so… I'd like to hear from you!*

I'm carrying out a research project looking at the experiences of people who manage their bipolar experiences without using medication. This could help other professionals develop ideas which might be helpful for other people diagnosed with bipolar disorder who don't want to use medication.

Taking part will involve answering some questions over the phone, then filling in a questionnaire and completing an interview face-to-face or via skype or telephone.

If you think you might be interested in taking part and would like to find out more, please e-mail me on r.cappleman@lancaster.ac.uk, or telephone me on (insert project mobile number here)

**Appendix I:**

**Participant Information Sheet**

**Participant Information Sheet**


*Managing Bipolar Mood Experiences Without the Use of Medication: A Qualitative Investigation*


My name is Reed Cappleman and I am conducting this research as a student the Doctoral training programme in Clinical Psychology at Lancaster University, Lancaster, United Kingdom.


**What is the study about?**

The purpose of this study is to find out more about how people diagnosed with bipolar disorder who choose not to take medication manage their bipolar mood experiences. It is hoped this will tell us more about the different factors that help people manage their bipolar moods without medication, and the processes behind this.


**Why have I been approached?**

You have been approached because the study requires information from people who have gone for a period of time without using medication to manage their bipolar mood experiences, either currently ongoing or in the past.


**Do I have to take part?**

No.  It's completely up to you to decide whether or not you take part.


**What will I be asked to do if I take part?**

If you decide you would like to take part, the next step is for you to complete the consent form I have sent you and return it to me in the enclosed Stamped Addressed Envelope.  I will then contact you by telephone to ask you to provide some information about yourself like your age, gender, ethnicity, if you have been given any mental health diagnoses, whether you currently use medication, and the longest period of time you have gone without using medication. I will also ask for contact details of a health professional you're involved with (like your GP).


You will then be placed on a list of people willing to take part in the study. Not all people on this list will be required to participate any further. This is because I will need to talk to a wide selection of people to make sure the study is of good quality. This means that

sometimes I might have to give preference to certain people according to characteristics like age, gender or how long they've not been using medication. If you are asked to participate in the next part of the study, the next step will be for you to complete a more in-depth assessment over the telephone. This assessment looks at how your mood may have affected your life over the years, and usually takes about an hour. Depending on your answers in this assessment, you may be asked to complete in the final part of the study, which involves meeting the researcher face-to-face to talk with them about your experiences.

The meeting can take place in your own home, or in a public location if you prefer. It will also be possible to complete the interview via skype or telephone At the start of the meeting you will be asked to sign a consent form, and complete another brief mood questionnaire. I will invite you to talk with me for around an hour about your experiences of managing bipolar mood experiences without medication. You will be free to take a break at any point during this process.

There is also a possibility that I might approach you at a later date to ask to speak to you again to get more information about some of the things you talked about when we met. This will be so I can make sure I'm getting as good an understanding as I can of people's experiences of managing their mood without medication. It will be completely up to you whether you want to speak to me again or not. Agreeing to take part in the first interview does not mean you are under any obligation to speak to me again if you do not wish to. If I approach you about another interview, it will be within six months of our first interview.

**What do I do if I want to take part?**

If you want to take part you can contact me on **07852 523 594** or e-mail me on r.cappleman@lancaster.ac.uk.

**What happens if I change my mind about taking part?**

You will be free to change your mind about participating at any point. You are also welcome to ask at any point after the interview has finished for your data to be withdrawn from the project. Although every effort will be made to do so, this may not be possible once the data has been anonymised and analysed, as at this point it may be difficult to tell which data belongs to who.

**Why do I need to fill out mood questionnaires and be asked questions about my mental health?**

This is so I can get an accurate picture of the types of person who are taking part in the study, and how their mood affects their life.

**Will my data be confidential?**

The information you provide is confidential. However, participants using Skype should be aware that the internet cannot be guaranteed to be a completely secure means of communication.

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- o Audio recordings will deleted after the project has received its final mark, and once the findings have been accepted for publication by an academic journal (whichever happens later)
- o Hard copies of questionnaires and consent forms will be kept in a locked cabinet.
- o The computer files containing transcribed interviews will be stored on Lancaster University's secure server.
- o At the end of the study, hard copies of questionnaires and consent forms will be kept securely in a locked cabinet for ten years. At the end of this period, they will be destroyed.
- o The typed version of your interview will be made anonymous by removing any identifying information including your name. Anonymised direct quotations from your interview may be used in the reports or publications from the study, so your name will not be attached to them.

There are some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and speak to my supervisors about this.  If possible, I will tell you if I have to do this.

**What will happen to the results?**

The results will be summarised and reported in a thesis, and may be submitted for publication in an academic or professional journal.  The results might also be presented at conferences.

**Are there any risks?**

There are no risks anticipated with participating in this study.  However, if you experience any distress following participation you are encouraged to inform the researcher and contact the resources provided at the end of this sheet.

**Are there any benefits to taking part?**

Although you may find participating interesting, there are no direct benefits in taking part.

**Who has reviewed the project?**

This study has been reviewed by the Faculty of Health and Medicine Research Ethics Committee, and approved by the University Research Ethics Committee at Lancaster University.

**Where can I obtain further information about the study if I need it?**

If you have any questions about the study, please contact the main researcher:

Reed Cappleman:      r.cappleman@lancaster.ac.uk, tel: 07852 523 594

**Complaints**

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Craig Murray    Tel: (01524) 592 970

Acting Research Director/Senior Lecturer in Research Methods

Email: c.murray@lancaster.ac.uk

Doctorate in Clinical Psychology

Division of Health Research

C16 Furness Building, Lancaster University

Lancaster

LA1 4YG

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Paul Bates Tel: (01524) 593718

Associate Dean for Research Email: p.bates@lancaster.ac.uk

Faculty of Health and Medicine

(Division of Biomedical and Life Sciences)

Lancaster University

Lancaster

LA1 4YD

Thank you for taking the time to read this information sheet.


**Resources in the event of distress**

You will be provided with resources you may find helpful when you meet the researcher for your interview. These will be for local support groups and charities which provide support for people with bipolar disorder.


Should you feel distressed after the interview, the researcher will be willing to talk to you about this and if necessary discuss how you might be able to access further support.  The researcher will also contact you by telephone the day after the interview, in order to see you have felt afterwards and if you feel you could do with any additional support.

**Appendix J:**

**Consent Form**

## Consent Form: "Managing Bipolar Mood Experiences Without the Use of Medication: A Qualitative Investigation"

We are asking if you would like to take part in a research project investigating how people diagnosed with bipolar disorder who choose not to use medication manage their mood. We hope this will help us learn about coping strategies other people might be able to use too.

Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator, Reed Cappleman. If you would like to participate in this study please sign this form and return it to me in the SAE provided.

**Please initial**

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study ☐

2. I confirm that I have had the opportunity to ask any questions and to have them answered. ☐

3. I consent to completing two assessments of my mood and the effect it has on my life. ☐

4. I understand that, depending on the type of people the researcher needs to interview and the outcome of the mood assessments, I may or may not be invited to participate in an interview. ☐

5. I understand that my interview will be audio recorded and then made into an anonymised written transcript. ☐

6. I understand that audio recordings will be kept until the research project has been examined and findings have been published. ☐

7. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

8. I understand that once my data have been anonymised and incorporated into themes it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication. ☐

9. I understand that the information from my interview will be pooled with other participants' responses, anonymised and may be published. ☐

10. I consent to information and quotations from my interview being used in reports, conferences and training events.

11. I understand that any information I give will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to myself or others, in which case the principal investigator may need to share this information with his research supervisor.

12. I consent to Lancaster University keeping written transcriptions of the interview for 10 years after the study has finished.

13. I consent to taking part in the above study (please sign below)

**Name of participant**                                          **Signature**

**Date**

**Participant's Contact Telephone Number:**

**Name of researcher**                                          **Signature**

**Date**