



SCHOOL OF PSYCHOLOGY- DOCTORATE IN CLINICAL PSYCHOLOGY

MAJOR RESEARCH PROJECT

LITERATURE REVIEW: Physical Activity and Mood in Bipolar Disorder: A Systematic Review

EMPIRICAL PAPER: Association Between Physical Activity and Mood in Bipolar Disorder

Submitted by Helena Blowers, to the University of Exeter
as a thesis for the degree of Doctor of Clinical Psychology, April 2016

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Signature:

Author's Declaration

The literature review was completed independently by the author. In terms of the empirical work, participants recruited between September 2015 and January 2016 were collected jointly by the author and another DClinPsy trainee, Hannah Moakes. Her project utilised additional measures for the project titled "Dominance Motivation, Goal Pursuit and Mania in Bipolar Disorder". The author screened around two thirds of potential recruits to the study. Monitoring of participant diary completion and data entry were shared equally between the author and the other trainee. All other aspects of the study were completed by the author including data analysis, and write up.

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SCHOOL OF PSYCHOLOGY
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LITERATURE REVIEW

Physical Activity and Mood in Bipolar Disorder: A Systematic Review

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Abstract

Background: Bipolar disorder is associated with a higher rate of physical health problems and lower levels of physical activity than other clinical and general populations. Despite the potential benefits of physical activity to people with bipolar disorder, little research has been published around this and no recent review of this topic is available. Due to the clinical utility of summarising the available research evidence on this topic, this review aimed to answer the question “Is physical activity associated with manic and depressive symptoms in people with bipolar disorder?”.

Methods: Seven electronic databases were searched using a range of search terms to reflect physical activity and bipolar disorder variables.

Results: Ten studies were identified that reported associations between physical activity and mood symptoms of bipolar disorder. There were inconsistent findings on the relationship between physical activity and mood, in particular with relation to manic symptoms, with reports of physical activity being both helpful and harmful to manic symptoms. Findings were more consistent with regards to the association between physical activity and depressive symptoms, with most showing that higher levels of physical activity are associated with lower depressive symptoms.

Limitations: Many studies had small sample sizes and very few manipulated physical activity and included a control group. Measures and diagnosis method were heterogeneous. Four studies lacked a direct measure of manic symptoms.

Conclusions: Results showed inconsistent findings with regards to the relationship between physical activity and mood symptoms and further research is needed to inform any guidelines developed for this client group.

Keywords: Bipolar disorder, physical activity, manic symptoms, depressive symptoms.

Introduction

Bipolar disorder (BD) is a relapsing and remitting mental health condition which typically involves periods or episodes of low or depressed mood, alternating with periods of hypomania or mania, in which an individual has irritable or elevated mood (American Psychiatric Association, 2013). This is in conjunction with an increase in goal-directed activities, without considering the potential risks associated with pursuing those activities, decreased need for sleep, pressure to keep talking, subjective experience of racing thoughts, increased psychomotor activation, grandiosity and distractibility (American Psychiatric Association, 2013). BD is associated with impairment in both social and personal functioning (National Collaborating Centre for Mental Health, 2014) and a higher rate of physical health problems (Carney & Jones, 2006), such as obesity (Fagiolini et al., 2002), cardiovascular disease and diabetes (Gomes et al., 2013; Kilbourne et al., 2004).

Physical activity (PA) has well-known physical health benefits, reducing the risk of various illnesses such as cardiovascular disease, type 2 diabetes and stroke, in addition to helping to maintain a healthy weight and build muscle strength, making everyday tasks easier to perform (World Health Organization [WHO], 2010). Looking at the physical health benefits alone shows the potential benefits of PA for people with bipolar disorder, who have a higher risk of developing these physical health problems (National Collaborating Centre for Mental Health, 2014). PA has also been shown to contribute to emotional wellbeing, with numerous studies showing PA to be associated with enhanced affect and mood in the general population (Biddle & Mutrie, 2001).

The benefits of PA for depression have also been well documented (Biddle & Mutrie, 2001; Cooney et al., 2013; Harris, Cronkite, & Moos, 2006; Rethorst, Wipfli, & Landers, 2009; Robertson, Robertson, Jepson, & Maxwell, 2012), and PA is

recommended as one possible intervention for subthreshold depressive symptoms or mild to moderate depression in NICE (2009) guidelines for unipolar depression.

Several psychological and physiological mechanisms have been proposed as explanations for the benefits of PA for depression, one of which is the monoamine hypothesis. This hypothesis posits that engaging in PA leads to an increase in the availability of neurotransmitters that are diminished in depression, such as dopamine, norepinephrine and serotonin (Craft & Perna, 2004).

Despite the documented benefits of PA, little research has been published around the potential benefits of PA for people with BD, who have been found to be less physically active than other clinical and general populations (Elmslie, Mann, Silverstone, Williams, & Romans, 2001; Gomes et al., 2013; Janney et al., 2014; Kilbourne et al., 2007; Vancampfort et al., 2015).

A systematic review by Wright and colleagues (Wright, Everson-Hock, & Taylor, 2009) looked at the potential benefits and risks from PA for people with BD, and identified only six studies that had investigated this topic. The newly updated NICE guidelines for BD (National Collaborating Centre for Mental Health, 2014) recommend that people with the disorder, particularly those on long-term medication, are offered a combined PA and healthy eating programme to help with weight reduction/management, however the potential impact on mood symptoms of BD (i.e., mania and depression) is not mentioned. This is a change from the previous NICE (2006) guidelines for BD, which noted the potential for exercise to be both harmful and helpful for manic symptoms, as it may arouse the physiological system, increase energy and exacerbate manic symptoms, and potentially increase strain on the cardiovascular system. It was noted that there was no research evidence to support either helpful or unhelpful consequences of exercise.

An explanation for the potential for PA to be harmful for manic symptoms could come from the effects of PA on the Behavioural Activation System (BAS). The BAS regulates cognitive and affective processes that support goal-driven behaviour and reward responsiveness. A dysregulation in BAS has been linked to manic and depressive symptoms in BD (Alloy & Abramson, 2010; Johnson, Edge, Holmes, & Carver, 2012), and the BAS dysregulation theory proposes that individuals with BD have a BAS that is overly sensitive to goal oriented cues, which then results in large fluctuations in activation and deactivation in the BAS (Depue & Iacono, 1989; Depue, Krauss & Spont, 1987). When applied to PA, in particular high intensity PA, perceived success or feelings of satisfaction during engagement in PA could increase confidence, energy and optimism in people with BD, which could then increase energy and effort expended, leading to a further increase in manic symptoms (Lowenstein, Wright, Taylor, & Moberly, 2015).

Research has also shown that structure and routine in daily life are important in improving symptoms of BD. Disruption in circadian rhythm, such as sleep and social rhythm (Lee, Son, & Geum, 2013) has been found to be associated with BD, in that markers of circadian rhythms are disrupted, both in affective episodes and during euthymic periods (McKenna, Drummond, & Eyer, 2014; Jones, 2001; Jones, Hare, & Evershed, 2005). PA has been found to have benefits for sleep in healthy individuals (Driver & Taylor, 2000), and has been used effectively to treat insomnia (Reid et al., 2010). A recent study on sleep and PA in individuals with BD (McGlinchey, Gershon, Eidelman, Kaplan, & Harvey, 2014) found that, for participants who had reported high levels of sleep disturbances, engaging in PA during the day was associated with less sleep disturbance the following night. The potential for PA to entrain more regular circadian rhythms could help to balance mood in individuals with BD.

Due to the potential clinical utility of summarising the available research evidence on PA and BD, and the fact that no recent literature reviews were found in this topic area, this review will identify and assess studies examining association between physical activity and mood symptoms in people with bipolar disorder, to answer the question “Is physical activity associated with manic and depressive symptoms in people with bipolar disorder?”

Method

The Preferred Reporting Items for Systematic reviews and Meta Analyses (PRISMA) guidelines (Liberati et al., 2009) were used to structure this review.

Inclusion Criteria

Types of studies. Articles were included if they were qualitative or quantitative studies investigating the relationship between any form of PA and symptoms of mania and/or depression in individuals with BD. Designs included prospective, retrospective, correlational, cross-sectional and experimental studies.

Types of participants. Participants of all ages were included in the review. Participants in the studies were identified as having BD, defined as bipolar I disorder, bipolar II disorder, cyclothymia or bipolar disorder not otherwise specified. This could be determined by a clinician, through a standard diagnostic interview or through self-report, either through self-reported diagnosis or reaching a cut-off score on a measure of BD. Participants with or without medication were included. Studies were not excluded due to participants' medical comorbidities.

Types of outcome measures. Studies measuring or enquiring about mood symptoms associated with PA or exercise among people with BD were included. Outcome measures included measures of mood symptoms (depressive and/or manic symptoms), either measured via interview or through self-reports, and measures of PA in terms of duration, intensity and/or frequency, also either through objective

measures or through self-reports. Qualitative studies were included if they involved research questions that included PA as a variable within a sample of people with BD or identified themes involving PA generated from a sample of people with BD.

Exclusion criteria

Types of studies. Papers not written in English were excluded. Review and theoretical papers were also excluded. Additionally, “grey” literature, such as conference abstracts, was excluded.

Types of participants. Studies using a heterogeneous sample in terms of psychiatric diagnosis, i.e. including individuals with diagnoses other than BD, and that did not report associations with PA separately by diagnosis were excluded. Articles were also excluded if they only included non- or subclinical populations.

Information Sources

The following electronic databases were searched from the beginning of the databases until January 2016: The Cochrane Library, PubMed, CINAHL, Embase, PsycARTICLES, psycINFO and SPORTDiscus. Reference lists of the articles retrieved and review articles (Wright, Everson-Hock, & Taylor, 2009; Vancampfort et al., 2013) were also examined for possible relevant studies.

Search

Titles and abstracts were searched to identify papers reporting on the relationship between any form of PA and symptoms of mania and/or depression in individuals with BD, using (* for truncated search terms): (physical activity OR exercise OR sport OR strength training OR resistance training OR endurance training OR weight training OR weight lifting OR run* OR walk* OR jog* OR swim* OR yoga OR pilates OR gym class OR exercise class OR fitness class OR fitness OR exercise therapy OR tai chi OR aerobic exercise) AND (bipolar disorder OR bipolar illness OR bipolar depression OR bipolar I OR bipolar II OR mania OR hypomania OR manic

OR hypomanic OR cyclothymia OR cyclothymic OR hyperthymia OR hyperthymic
OR psychotic mania OR affective psychosis OR bipolar manic disorder)

Study Selection

Initial screening of titles and abstracts was performed by the principal researcher to assess if articles met the eligibility criteria, based on type of study, participants and outcome measures. After these characteristics were extracted from the abstracts, articles that met all of the aforementioned inclusion and exclusion criteria were read in full and assessed again for eligibility. The Quality Assessment Tool for Quantitative Studies (Effective Public Health Practice Project, 2009; Appendix A and B) was used to evaluate the quality of articles found, assessing (A) selection bias, (B) study design, (C) confounders, (D) blinding, (E) data collection methods and (F) withdrawal and drop-outs. The tool was developed for use in public health, providing a standardised way of looking at quality of studies. No studies were excluded from the review on the basis of quality but the tool was used to evaluate the weight of evidence when conducting the narrative synthesis, and ratings are reported in Table 1. Additionally, the Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Review of Interventions (Hannes, 2001; Appendix C) was used to aid critical appraisal of the qualitative studies included in this review, looking at credibility, transferability, dependability and confirmability. This equates to internal validity, external validity or generalisability, reliability and objectivity in quantitative research. This informed ratings of qualitative studies, such that they could be assessed within the framework of the Quality Assessment Tool for Quantitative Studies, to allow a consistent evaluation across studies.

Data Extraction

Data from the full text articles were extracted using the population, interventions, comparisons and outcomes (PICO; O'Connor, Green & Higgins, 2011)

method. The author used a paper version data extraction form (Appendix D).

Summaries for the studies are presented in Table 1. Data were extracted from each included study on: (a) sample and diagnosis of BD, (b) the design of the research and type of intervention when applicable, (c) type of outcome measure, such as changes in mood symptoms, (d) the main findings from the study.

Results

Study Selection

The screening and selection of studies is displayed in Figure 1. A total of 1105 citations resulted from the search across databases. After removal of duplicates and screening of abstracts and titles, 21 studies were extracted for assessment of eligibility. A further six studies were identified from reference lists of the papers extracted. Seventeen studies were found to violate eligibility criteria, resulting in ten papers for review.

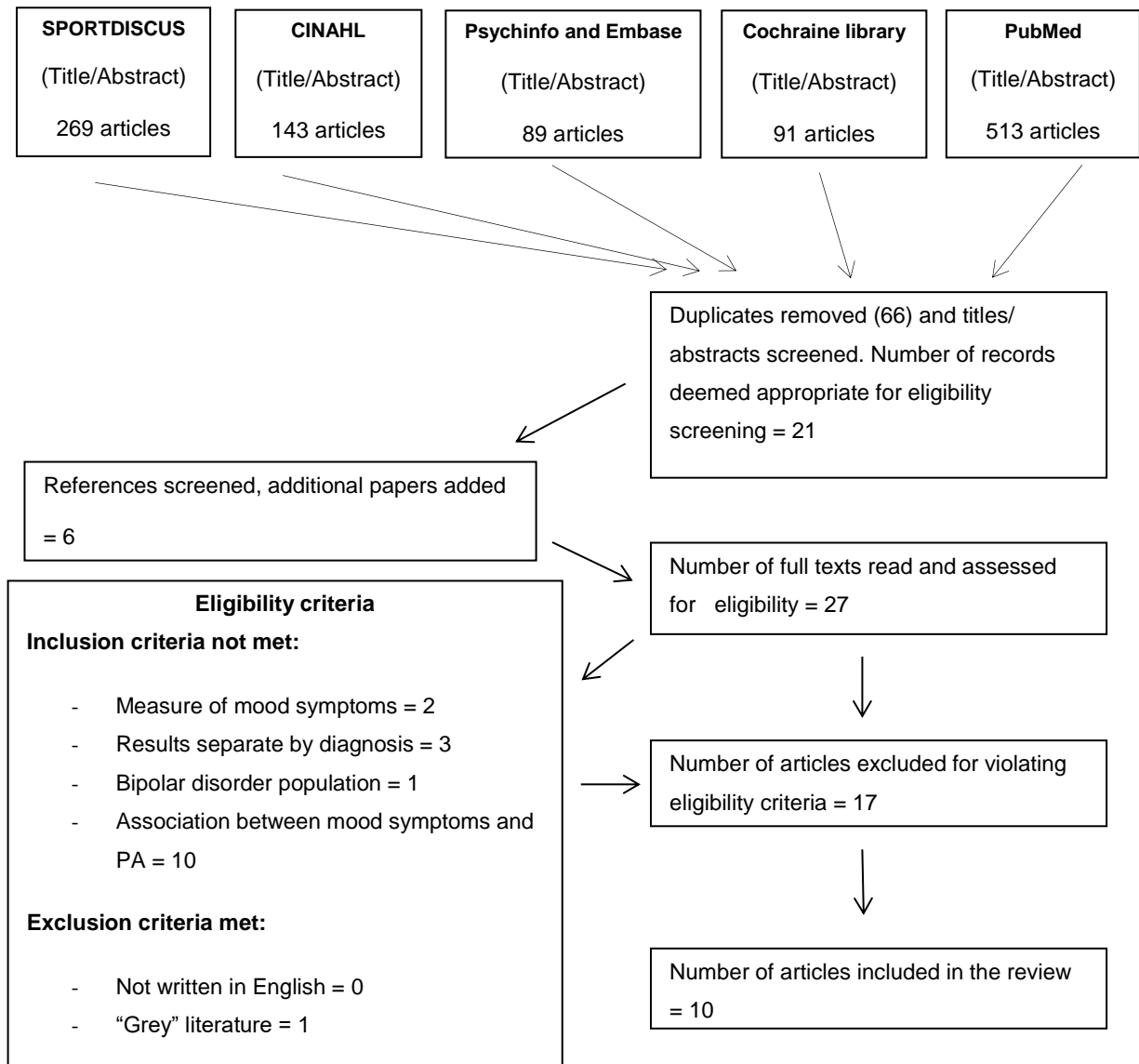


Figure 1. Search strategy and process of identification, screening, eligibility and inclusion for review.

Study Characteristics

Table 1 shows the characteristics of the 10 studies included in this review.

Table 1

Studies included in the review, including design, measures, relevant findings and evaluation.

Author	Design and Aim	Sample	Mood and physical activity measures	Main findings relating to mood and physical activity, with effect sizes.	Evaluation	Quality ratings
<u>Quantitative findings</u>						
<u>Cross-sectional studies</u>						
Jewell et al. (2015)	Case control. Comparing levels of PA in adolescents with and without diagnosis of BD.	86 participants with diagnosis of BD and control group of 50 participants without diagnosis. BD group: 29% male, mean age 16.2. Control group: 21% male, mean age 16.0.	K-SADS-PL for diagnosis, 12-item K-SADS DRS and extended 13-item K-SADS MRS, 17 item WAVE-PA subscale.	Adolescents with BD less likely to meet recommended vigorous PA ($p = .005$). Effect sizes: Cohen's $d = -.31$ for depression scores and $.22$ for mania scores.	Strengths: First study to examine PA in adolescents with BD. Limitations: Mood symptoms and PA measured for association were not in the same reference week (mood symptoms for the most severe week in the previous month). Control group only group matched and only for age and gender. Not able to examine directionality. Generalisability may be an issue as participants were recruited from the same tertiary centre. The WAVE screener has not been validated.	A- Moderate B- Moderate C- Moderate D- Weak E- Moderate F- N/A Overall: Moderate

Sylvia et al. (2013a)	Cross-sectional study looking at association between exercise and course of bipolar illness, and socioeconomic factors.	287 participants with diagnosis of BD. 41.3 % male, mean age 38.9.	Q-LES-Q. Blinded raters measured severity of BD symptoms with CGI-BP and the BISS. LIFE-RIFT.	Greater severity of depression associated with less frequent exercise. Effect sizes: $\beta = -.018$ for BISS depression score and $\beta = -.024$ for CGI-BP depression score. Depression in the past year associated with less frequent exercise when controlling for current depression symptoms. Effect size: not reported. Greater manic symptoms associated with more frequent exercise. Effect size: $\beta = .027$ for BISS mania score and $\beta = .178$ for CGI-BP mania score. Manic symptoms in the past year associated with more exercise when controlling for current manic symptoms. Effect size: not reported.	Strengths: Blinded raters to evaluate severity of BD symptoms. Large sample size. Analyses examining percentage of last year spent manic/hypomanic or depressed for controlled for current mood state.	A- Strong B- Moderate C- N/A D- Strong E- Strong F- Strong Overall: Strong
<u>Longitudinal studies</u>						
Ng, Dodd & Berk (2007)	Retrospective cohort study, A-B design. Examining the therapeutic effects of PA in BD.	Inpatients with BD diagnosis in a private psychiatric unit. 49 total participants, 14 in a walking group (intervention) and 35 non-participants in	Clinician rated CGI-S and CGI-I and self-reported 21-item version of the DASS).	CSI-S and CSI-I: no significant difference between groups at time 2. DASS: significant difference between groups at time 2 on total DASS (Cohen's $d = .82, p = .005$) and on subscales: depression ($d = .57, p = .048$), anxiety ($d = .92, p = .002$), stress ($d = .76, p = .01$).	Strengths: Naturalistic intervention. First study to examine therapeutic effects of PA in BD using mood measures. Limitations: Recall and selection biases, no randomisation or	A- Moderate B- Moderate C- Moderate D- Moderate E- Strong F- Not applicable Overall: Strong

walking group.
 Walking group: 6 males, mean age 43.6.
 Non-participant group: 9 males, mean age 43.9.

control for confounding variables, and BD sub-type not identified.
 Only indirect measure of manic symptoms.
 Exclusion of participants who did not attend regularly.

Uncontrolled pre-post design studies

Hays et al. (2008)	Uncontrolled pre-post design, examining serum DHEAS levels before and after acute bout of exercise, and the impact of exercise on perceptions of well-being.	26 outpatients with a diagnosis of BD, 18-65 years of age, mean 42. 13 male participants.	PAR-Q, 7-point Likert scale of well-being (severely depressed to excessively happy).	Significant increase in reports of well-being from pre-to post intervention. A subject who began his exercise bout as "excessively happy" had both a decrease in DHEAS and normalisation in perceptions of well-being. 10 participants reported no change in perceptions of wellbeing after exercise. Fourteen of the subjects reported that exercise improved global wellbeing by one to two points on the 7 point scale and one subject reported improvement of 3 points. In contrast, one subject reported a decrease in global wellbeing after exercise. This single subject reported that his wellbeing changed from between moderately happy (6) and excessively happy or manic (7) to mildly	Strengths: Activity manipulated Limitations: Only used an unvalidated 7-point Likert scale as a mood measure. No exercise history was established. No control group.	A- Moderate B- Moderate C- N/A D- Moderate E- Weak F- Strong Overall: Moderate
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happy (5). This subject was one of the eight participants whose DHEAS decreased after the exercise bout.

Sylvia, Nierenberg, Stange, Peckham & Deckersbach (2011)	Uncontrolled pre-post design, developing an integrated psychosocial treatment to reduce medical burden in individuals with BD. Intervention: nutrition/weight loss, exercise and wellness treatment.	10 total participants, with BD diagnosis. 4 participants in group 1 (first part of intervention), 1 male, mean age 60. 6 participants in group 2 (second part of intervention), 4 males, mean age 50.2.	M.I.N.I CGI-BP, MADRS, YMRS, PAR-Q, PWBS, LIFE-RIFT, Quality of Life Self-Assessment, Exercise Questionnaire.	For group 2: Increased PA (non-significant, $p = .20$), Effect size: $r = .36$. Significant reduction in depressive symptoms ($p = .01$), Effect size: $r = .42$. Non-significant reduction of manic symptoms (YMRS: $p = .35$, Effect size $r = .29$; CGI-BP: $p = .14$, Effect size: $r = .32$)	Strengths: Validated exercise and diet interventions in addition to CBT. Limitations: Lack of finalised treatment manual, more than just exercise as part of the intervention and therefore confounded, lack of measures of treatment integrity, standardised assessment of acceptability, lack of a blinded independent rater, very small groups so not enough power to detect meaningful clinical differences. Also perhaps not representative of typical population with BD, 90% were college educated and 60% currently employed. No control group.	A- Moderate B- Moderate C- Moderate D- Weak E- Strong F- Strong Overall: Moderate
Sylvia, Salcedo, Bernstein, Baek, Nierenberg & Deckersbach	Uncontrolled pre-post design. To test whether a consolidated treatment	5 participants with BD, overweight or obese (BMI over 25).	PAR-Q, MADRS YMRS, CGI-BP, LIFE-RIFT.	Participants' exercise more than tripled over the 20 weeks. Depressive symptoms and overall functioning improved. Manic symptoms increased (although not significantly).	Strengths: Validated exercise and diet interventions in addition to CBT. Limitations: Open trial, no control	A- Moderate B- Moderate C- Moderate D- Weak E- Strong F- Strong Overall: Moderate

ch (2013)	<p>(NEW-Tx) is feasible and helpful for people with BD. Intervention: 20 week individual CBT-based treatment with three modules, one of which was “exercise emphasises increasing weekly physical activity”.</p>	<p>Effect sizes: Overall CGI decrease: $d = .67$</p> <p>Depression symptoms decrease: MADRS: $d = .26$ CGI-depr: $d = .62$</p> <p>Manic symptoms increase: YMRS: $d = .59$ CGI-mania: $d = .53$</p>	<p>group. Other components may contaminate exercise findings. Very small sample size with volunteers, indicating motivation for intervention.</p>
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Experimental studies

Edenfield (2007)	<p>Experimental design, 2 treatment phases with four treatment orders, combined series cross over and interaction, (A/B/A/C/A versus A/C/A/B/A) and interaction</p>	<p>8 participants with BD diagnosis. Ages 26-55, mean age 37.38</p>	<p>SCID for diagnosis. MDQ, PAR-Q. ASRM and BDI-II at days 7 and 14 of each intervention phase, and at 1, 3 and 6 month follow-up. Also SRLE. The brief COPE.). POMS. Plus daily self-monitoring form for 43 days, recording mood and stress, daily</p>	<p>Increased PA in all conditions. Descriptive statistics indicated that depressive symptoms were lower and decrease or no change in manic symptoms post intervention. Effect sizes: Not reported</p>	<p>Strengths: Single-case design with cross over and interaction and validated measures. Experience sampling providing objective measures through pedometers.</p> <p>Limitations: Limited generalisability due to small number of participants. Contamination between conditions. Possible hyper-compliance</p>	<p>A- Weak B- Strong C- Moderate D- Unknown E- Strong F- Strong</p> <p>Overall: Moderate</p>
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(A/B/A/B/A versus A/C/A/C/A), with A = Assessment, B = Exercise prescription (8 sessions of 30 minutes walking over 2 weeks), C = Standard behavioural activation (8 sessions of 30 min of sedentary activity for 2 weeks). Exploring the utility of incorporating exercise into treatment protocols for people with BD.

exercise including prescribed activities and pedometer

and therefore confounded results.

Qualitative studies

Suto, Murray, Hale, Amari & Michalak (2010)

Cross-sectional qualitative design, looking at self-management

32 participants with BD diagnosis, 12 male, mean age 41.1

M.I.N.I. for screening to confirm diagnosis and MSIF. YMRS and HAM-D 29. Q-LES-Q and SAS.

Six major themes of wellness strategies were identified, one of which included exercise (theme 1: sleep, rest, exercise and diet), with exercise being reported as a popular wellness strategy. Participants reported

Strengths: Rigorous strategies to minimise bias, including the use of qualitative software, internal consistency meetings and member checking where 11

A- Weak
B- Moderate
C- N/A
D- Moderate
E- Strong
F- N/A

Overall:

	strategies used by high functioning people with BD.			a wide range of activities they found helpful, included walking, exercise routines, yoga, tai chi, dance, swimming and snowboarding.	participants were asked to comment on the derived themes to see if it reflected their perspectives. Both qualitative and quantitative measures used.	Moderate
				Effect sizes: Not applicable.	Limitations: No comparison to "non-high functioning" individuals with BD. Possible confirmation bias from participants and researchers with regards to themes.	
Uebelacker , Weinstock & Kraines (2014)	Cross-sectional, online survey	86 participants with diagnosis of BD or manic depression who practiced yoga. 11 males, mean age 33.	MDQ, Questionnaire about yoga practice, why, how long, frequency and 4 yes/no questions about the impact on BD symptoms. Also included open ended questions about the impact of yoga on life and BD symptoms.	Participants reported both positive and negative effects. Positive effects included distraction from negative thoughts and alleviation of worries. Negative effects included that when manic yoga could increase energy and agitation. . Effect sizes: Not applicable.	Strengths: Quite a large sample for a qualitative study. Limitations: No structured interview used to confirm BD diagnosis. Only used MDQ as a screening tool and un-validated questionnaire.	A- Weak B- Moderate C- N/A D- Weak E- Weak F- Strong Overall: Weak
Wright, Armstrong, Taylor & Dean	Cross-sectional qualitative study	25 participants with diagnosis of BD, ages 24-71, mean 51.	SCID-BD for diagnosis. PAR, Semi-structured interview about	Three main themes: Regulating exercise for mood regulation, exercise as a double-edged sword and	Strengths: Transcripts read by two researchers prior and agreed on coding. Third	A- Moderate B- Moderate C- Moderate D- Moderate

(2012)	exploring experiences of exercise in people with BD.	10 male participants.	impact of exercise on mood.	bringing structure to chaos. Effect sizes: not applicable.	researcher cross-referenced with original accounts.	E- Moderate F- Strong Overall: Strong
					<p>Limitations: Mood was not measured with a scale, just anecdotally, and the affective state of participants at the time of the interview was not explored. Interviews conducted over the phone, possibly limiting engagement/rapport.</p>	

Notes. BD = bipolar disorder; PA = physical activity; M.I.N.I. = Mini International Neuropsychiatric Interview; MSIF = Multidimensional Scale of Independent Functioning; YMRS = Young Mania Rating Scale; HAM-D 29 = Hamilton Depression Rating Scale; Q-LES-Q = The Quality of Life Enjoyment and Satisfaction Questionnaire; SAS = Social Adjustment Scale; MDQ = Mood Disorder Questionnaire; SCID-BD = The Structural Clinical Interview for DSM-IV bipolar disorder; PAR = Seven day Physical Activity Recall; K-SADS-PL = Schedule for Affective Disorders and Schizophrenia for School- Aged Children, Present and Lifetime version; DRS = Depression Rating Scale; MRS = Mania Rating Scale; WAVE = Quick Weight, Activity & Excess screener; CGI-BP = Clinical Global Impression Scale for Bipolar Disorder; BISS = Bipolar Inventory of Symptoms Scale; LIFE-RIFT = The Range of Impaired Functioning Tool for overall functioning and life satisfaction; CGI-S = Clinical Global Impression Severity; CGI-I = Clinical Global Impression Improvement; DASS = Depression Anxiety Stress Scales; PAR-Q = Physical Activity Readiness Questionnaire; DHEAS = Dehydroepiandrosterone Sulphate; MADRS = Montgomery Asberg Depression Rating Scale; PWBS = Psychological Well-being Scale; SRLE = Survey of Recent Life Events; COPE = looks at adaptive and problematic coping reactions; POMS = Profile of Mood States.

Participants. The included studies involved 664 participants, 579 with BD and 85 without a BD diagnosis. To confirm BD diagnosis, seven studies used a diagnostic interview, one study used a questionnaire, one study used a referral from a psychiatrist and one study analysed hospital discharges using the International Statistical Classification of Diseases and Related Health Problems (ICD-10; WHO, 1992) diagnostic criteria. Sample sizes ranged from 5 to 287.

Interventions. One study involved a walking group. Another study involved participants engaging in an acute bout of exercise and three studies involved prescribed exercise. The other five studies did not involve PA interventions, but examined covariation of mood and PA in individuals with BD.

Comparisons. One study included a non-clinical control group. Of the studies that manipulated exercise, one involved a clinical (BD) group which did not receive the intervention being studied. The other study involved four treatment orders, with one quarter of participants not receiving a PA intervention.

Outcome measures. Only one study used a validated questionnaire to examine PA levels, the Seven Day Physical Activity Recall (PAR; Blair et al., 1985), and only one study used an objective measure of PA (a pedometer). There was not much consistency between the studies in terms of mood measures and overall there were 20 different mood/quality of life measures used across the studies.

Critical Evaluation

Quantitative studies

Four out of the seven quantitative studies identified for this review reported a significant association between engaging in PA and lower depressive symptoms, with effect sizes ranging from small to large (Ng, Dodd & Berk, 2007; Sylvia et al., 2011, 2013a, 2013b). One study reported a significant increase in reports of well-

being (Hayes et al., 2008) following an exercise intervention and one study reported descriptive statistics showing lower depressive symptoms following an exercise intervention (Edenfield, 2007). Results are more conflicting with regards to manic symptoms, with any associations identified not reaching a statistically significant level, with the exception of Sylvia and colleagues' (2013a) study, which found that greater manic symptoms were associated with higher PA levels.

Cross-sectional studies. Two cross-sectional studies were identified. Jewell et al. (2015) compared levels of PA in adolescents with and without a BD diagnosis. Participants were all recruited from this same tertiary centre, thus limiting the generalisability of the findings. Mood symptoms were measured during the most severe week of the previous month, however there was no measure of mood in the week PA was measured, limiting the reliability of any potential associations found between PA and mood. Within-group analysis of the BD group showed no significant difference in depression or mania scores between those that engaged in fewer total days of PA across the week than those engaging in higher levels of PA. However, the sample size was not adequately powered to detect small effect sizes.

Sylvia and colleagues' (2013a) study on people with BD enrolled in the Comparative Effectiveness of a Second Generation Antipsychotic Mood Stabilizer and a Classic Mood Stabilizer for bipolar disorder (CHOICE) study (Nierenberg et al., 2014) found that greater severity of current depressive symptoms was associated with less frequent exercise, and depression experienced in the past year was also associated with less frequent exercise when controlling for current depressive symptoms. Conversely, greater manic symptoms were found to be associated with more frequent exercise, and manic symptoms experienced in the past year were associated with more frequent exercise when controlling for current manic

symptoms. Frequency of PA was obtained through self-report, but no standardised measure was used for this, limiting the internal validity of this study.

Longitudinal studies. One longitudinal study was identified, a retrospective cohort study by Ng, Dodd and Berk (2007), examining the therapeutic effects of a walking group for inpatients with BD. Non-participants formed a control-group. Participants in the walking group reported significantly lower scores on all subscales of the Depression Anxiety Stress Scale (DASS; Lovibond & Lovibond, 1995) at discharge than non-participants. Participants determined the intensity of the walking themselves, which limits the internal validity of the study. The authors excluded participants who were non-regular attendees to the walking group, but they lacked a clear criterion for this, increasing selection bias and limiting the external validity of the study.

Uncontrolled pre-post design studies. Hays and colleagues (2008; Hays, 2007) studied the effects of an acute bout of exercise (20 minutes walking at 70% maximum heart rate) on dehydroepiandrosterone sulphate (DHEAS) and perceptions of well-being in 26 outpatients with BD diagnosis in the USA and found a significant increase in self-reported well-being after the PA intervention. This study used an unvalidated 7-point Likert scale to measure mood, ranging from severely depressed to excessively happy (manic), with neutral (not depressed or manic) in the middle. This limits the generalisability of these findings. Furthermore, no exercise history was established for participants, which could be a confounding factor on the results found. No control group was used which further limits the internal validity of this study.

Sylvia, Nierenberg, Stange, Peckham and Deckersback (2011) developed an integrated psychosocial treatment for people with BD, which involved three treatment

modules: Exercise, Nutrition/weight loss and Wellness Treatment (NEW Tx). The goal was to engage participants in moderate intensity exercise five days per week for 30 minutes each day. This study involved two intervention groups implemented at different times. No significant changes were found for mood measures for the first group. Participants in the second group showed a significant reduction in depressive symptoms following the intervention but no significant change was found in manic symptoms. No causal inference can be drawn however, as there was no control group. Furthermore, the intervention included more than just PA, which means there could be several confounding factors influencing the conclusions drawn from this study.

Sylvia and colleagues (2013b) later studied the NEW Tx treatment for overweight individuals with a diagnosis of BD and found that depressive symptoms and overall functioning improved for the participants, however no significant change was found for manic symptoms. Due to the lack of control group, no causal inference can be drawn. Furthermore, this study was an open trial, contributing to selection bias of people already motivated to make changes to their PA levels.

Experimental studies. One experimental study was identified. Edenfield (2007) used a combined series crossover design with two interventions: exercise prescription of 30 minutes of walking over four days during a single week, with a total of eight PA sessions across two weeks of intervention, and standard behavioural activation of a sedentary activity. The objective of this study was to examine the effects of using PA in treatment protocols for people with BD. Participants were all sedentary at the start of the study, and people who engaged in 30 minutes of PA, three times a week were excluded from participating. All participants reported engaging in the prescribed level of PA following the study across all conditions, even

those who had been prescribed the sedentary activity, potentially confounding the results. Regardless, descriptive statistics indicated a similar decrease in depression symptoms, regardless of treatment order, for all participants. Furthermore, descriptive statistics indicated that manic symptom scores remained similar or lower than baseline for all participants throughout the study. The small sample size of eight participants further limits the generalisability of this study.

Qualitative studies

Two out of the three qualitative studies identified for this review reported the potential for PA to be both helpful and harmful for manic symptoms, depending on mood state at the time and the intensity of PA engaged in (Uebelacker et al., 2014; Wright et al., 2012). This does not reflect the findings in the quantitative studies identified, where only one study reported increased manic symptoms with increased PA.

Suto, Murray, Hale, Amari and Michalak (2010) looked at self-management strategies used by a sample of 32 high functioning people with BD. Participants reported a range of PA they found helpful for their BD symptoms, including walking, exercise routines, yoga, tai chi, dance, swimming and snowboarding. The interviews conducted were semi-structured and participants chose whether to be interviewed individually or as part of a group. This could have meant different participants and researchers focusing on different questions or elaborating on different issues, limiting the generalisability of findings.

Uebelacker, Weinston and Kraines (2014) examined self-reported risks and benefits of yoga amongst individuals with BD. The authors used the Mood Disorder Questionnaire (MDQ; Hirschfield et al., 2000) to screen for BD, but no other measure was used to confirm diagnosis of BD, which limits the generalisability of the findings

onto the wider BD population. Participants reported both positive and negative effects of yoga on their BD symptoms. Positive effects included alleviation of worries, distraction from negative thoughts and slowing of thoughts. Negative effects included intensifying frustration, increased lethargy, increased agitation as a result of energetic breathing and a heated room having the potential to contribute to a move from hypomania to mania. The authors only used qualitative measures and yes/no questions to enquire about the impact of yoga on BD symptoms, further limiting the generalisability of the results from this study.

Wright, Armstrong, Taylor and Dean's (2012) study on the relationship between PA and BD identified three main themes through interpretative phenomenological analysis: *regulating exercise for mood regulation*, *bringing structure to chaos* and *exercise as a double edged sword*, with participants reporting the potential of PA to be both helpful and harmful, potentially relaxing but also increasing hypomania/mania. Participants spoke about the interaction between type of PA and mood state, such that for manic symptoms it is more helpful to engage in calming PA. The researchers used Interpretive Phenomenological Analysis (IPA), and although steps were taken to minimise bias, such as dual coding and cross referencing of themes, it is still possible that themes reported in the study were biased to some extent by the researchers' expectancies and interpretation of participants' accounts.

Discussion

This review has highlighted that there is still only a limited body of literature investigating the associations of physical activity with mood in individuals with bipolar disorder, however six out of the ten studies reviewed were published in the last five years, indicating an increasing interest in this subject. The research question: "Is

physical activity associated with manic and depressive symptoms in people with bipolar disorder?" is still unresolved, with the studies reviewed providing inconsistent findings on the relationship between physical activity and mood symptoms in people with bipolar disorder.

Based on the behavioural activation system theory, it was expected that the studies reviewed would find an association between higher levels of physical activity and an increase in manic symptoms for people with bipolar disorder, due to the potential increase in reward striving, confidence, optimism and energy during engagement in physical activity. However, only one study (Sylvia et al., 2013a) found this association. Furthermore, this study also found that greater depressive symptoms were associated with low physical activity levels. These associations were also suggested in two of the qualitative studies (Suto et al., 2010; Wright et al., 2012, where participants reported physical activity as being both helpful and not helpful for bipolar disorder symptoms. However, this has not been tested through randomised experimental manipulation and only includes participants' subjective reports, therefore no causal inference can be drawn. Additionally, none of the studies reviewed included any measures of the behavioural activation system (e.g. BIS/BAS scales; Carver & White, 1994), or constructs relating to this, such as reward, confidence, energy and optimism. Thus it is not clear whether physical activity is associated with these psychological mechanisms that are theoretically governed by the behavioural activation system and therefore limited conclusions can be drawn from this review with regards to the relevance of the behavioural activation system to the association between physical activity and bipolar symptoms.

With the exception of two of the qualitative studies (Uebelacker et al., 2014; Wright et al., 2012) where participants reported physical activity to be beneficial for

their sleep, none of the studies reviewed reported on the association between physical activity and people's circadian rhythms, despite there being evidence that physical activity can help with sleep disturbance associated with bipolar disorder (McGlinchey et al., 2014). Therefore, on balance, this review found that insufficient tests of the circadian rhythms hypothesis have been carried out to date. However, future studies could investigate this by examining the regularity of people's physical activity engagement, with regards to time of day and gaps between instances of physical activity. Furthermore, people's sleep patterns could be investigated to provide further information on the potential association between circadian rhythms, physical activity and mood symptoms.

Although findings from the studies reviewed are inconsistent in terms of the association between physical activity and manic symptoms, there have been more consistent findings with regards to association between physical activity and depression symptoms. Overall, there appears to be a negative relationship between physical activity and depressive symptoms (Edenfield, 2007; Hays et al., 2008; Ng, Dodd, & Berk, 2007; Sylvia et al., 2011; Sylvia et al., 2013b; Wright et al., 2012).

A limitation of the studies reviewed is the inconsistency in measures used, with only one of the studies using a validated physical activity measure. Furthermore, there was a wide variety of mood measures used. This makes comparisons between studies difficult and limits the generalisability of findings. A further limitation of the studies reviewed is the lack of discrimination between different intensities and duration of physical activity and how this may be a factor in the relationship between physical activity and mood. Participants in two of the qualitative studies (Uebelacker et al., 2014; Wright et al., 2012) reported the potential for physical activity to be both helpful and harmful for manic symptoms, depending on mood state at the time and

the intensity of physical activity engaged in, i.e., that engaging in calming (low intensity) physical activity is helpful to manic symptoms. Furthermore, there may be a neurobiological reason why vigorous intensity physical activity may increase manic symptoms more than low or moderate intensity PA, due to elevation in the noradrenergic system (Alsuwaidan & McIntyre, 2009), which is already dysregulated in people with BD (Newberg, Catapano, Zarate, & Manji, 2008). Due to the potential clinical implications of people engaging in vigorous physical activity when vulnerable to a manic episode, this needs to be investigated further.

An additional limitation is the lack of a direct manic symptom measure in four of the studies. The small total number of studies, with five of the studies having fewer than 30 participants, also limits the conclusions that could be drawn. Furthermore, the small sample sizes make it unlikely that there was sufficient statistical power to detect moderate to large effect sizes if they existed in the population. That being said, Sylvia and colleagues (2013b) found medium effect sizes for increase in manic symptoms and small to medium effect sizes for decrease in depression symptoms in their study of five participants. Finally, due to the cross-sectional nature of most of the studies reviewed, the longer-term relationship between physical activity engagement and mood remains unclear, and causality cannot be inferred. This is important to consider for future research, in order to inform any guidelines developed for this client group.

Conclusions

This review does not provide adequate evidence that physical activity is associated with manic and depressive symptoms in individuals with bipolar disorder. Associations are inconsistent across the studies included in the review, and it is impossible to draw any conclusions about causations as no adequately powered

randomised controlled studies were identified. Furthermore, this review found insufficient support for either the behavioural activation system theory or the circadian rhythm theory for bipolar disorder, although it should be noted that this was partly because the studies reviewed were not designed as a test of these theories. Future research could examine longitudinal associations using repeated measures within individuals, allowing a more accurate observation of the association between individual changes in mood and engagement in physical activity. This should be done through structured, validated and reliable measures of mood and physical activity, looking at both manic and depressive symptoms and different intensities and durations of physical activity.

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Appendices

Appendix A – The Quality Assessment Tool for Quantitative Studies

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1. Very likely
- 2. Somewhat likely
- 3. Not likely
- 4. Can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1. 80 - 100% agreement
- 2. 60 – 79% agreement
- 3. less than 60% agreement
- 4. Not applicable
- 5. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

- 1. Randomized controlled trial
- 2. Controlled clinical trial
- 3. Cohort analytic (two group pre + post)
- 4. Case-control
- 5. Cohort (one group pre + post (before and after))

- 6. Interrupted time series
- 7. Other specify _____
- 8. Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

- 1. Yes
- 2. No
- 3. Can't tell

The following are examples of confounders:

- 1. Race
- 2. Sex
- 3. Marital status/family
- 4. Age
- 5. SES (income or class)
- 6. Education
- 7. Health status
- 8. Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

- 1. 80 – 100% (most)
- 2. 60 – 79% (some)

- 3. Less than 60% (few or none)
- 4. Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

- 1. Yes
- 2. No
- 3. Can't tell

(Q2) Were the study participants aware of the research question?

- 1. Yes
- 2. No
- 3. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

- 1. Yes
- 2. No
- 3. Can't tell

(Q2) Were data collection tools shown to be reliable?

- 1. Yes
- 2. No
- 3. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

- 1. Yes
- 2. No
- 3. Can't tell
- 4. Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1. 80 -100%
2. 60 - 79%
3. less than 60%
4. Can't tell
5. Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3
Not applicable			

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1. 80 -100%
2. 60 - 79%
3. less than 60%
4. Can't tell

(Q2) Was the consistency of the intervention measured?

1. Yes
2. No
3. Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

1. Yes
2. No
3. Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1. Yes
2. No
3. Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

- 1. Yes
- 2. No
- 3. Can't tell

GLOBAL RATING

COMPONENT RATINGS

A	SELECTION BIAS	STRONG	MODERATE	WEAK
		1	2	3
B	STUDY DESIGN	STRONG	MODERATE	WEAK
		1	2	3
C	CONFOUNDERS	STRONG	MODERATE	WEAK
		1	2	3
D	BLINDING	STRONG	MODERATE	WEAK
		1	2	3
E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK
		1	2	3
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK
		1	2	3
				Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

- 1 STRONG (no WEAK ratings)
- 2 MODERATE (one WEAK rating)
- 3 WEAK (two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

- 1 Oversight
- 2 Differences in interpretation of criteria
- 3 Differences in interpretation of study

Final decision of both reviewers (circle one):

- 1 STRONG**
- 2 MODERATE**
- 3 WEAK**

Appendix B – The Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

- Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.
- Score NO, if no mention of randomization is made.

Was the method of randomization described?

- Score YES, if the authors describe any method used to generate a random allocation sequence.
- Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
- If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

- Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which

intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

- Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.
- If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)

An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)

An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study

A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after))

The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series

A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score YES if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score NO if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least

80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A)SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) and there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); and there is 60 - 79% participation (Q2 is 2).

'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); or there is less than 60% participation (Q2 is 3) or selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); or (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) and (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) and (Q2 is 3) or control of confounders was not described (Q1 is 3) and (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); and the study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); or the study participants are not aware of the research question (Q2 is 2); or blinding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); and the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); and the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); and the data collection tools have not been shown to be reliable (Q2 is 2) or reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) or both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) OR Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix C- Critical appraisal of qualitative research

Chapter 4 – Critical appraisal of qualitative research

This chapter should be cited as: Hannes K. Chapter 4: Critical appraisal of qualitative research. In: Noyes J, Booth A, Hannes K, Harden A, Harris J, Lewin S, Lockwood C (editors), *Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions*. Version 1 (updated August 2011). Cochrane Collaboration Qualitative Methods Group, 2011. Available from URL <http://cqrmg.cochrane.org/supplemental-handbook-guidance>

Key points

- Critical appraisal of qualitative studies is an essential step within a Cochrane Intervention review that incorporates qualitative evidence.
- The overarching goal of critical appraisal in the context of including qualitative research in a Cochrane Intervention Review is to assess whether the studies actually address questions under meaning, process and context in relation to the intervention and outcomes under review.
- Review teams should use a critical appraisal instrument that is underpinned by a multi-dimensional concept of quality in research and hence includes items to assess quality according to several domains including quality of reporting, methodological rigour and conceptual depth and breadth.
- Critical appraisal involves (i) filtering against minimum criteria, involving adequacy of reporting detail on the data sampling, -collection and-analysis, (ii) technical rigour of the study elements indicating methodological soundness and (iii) paradigmatic sufficiency, referring to researchers' responsiveness to data and theoretical consistency.
- When choosing an appraisal instrument a Review teams should consider the available expertise in qualitative research within the team and should ensure that the critical appraisal instrument they choose is appropriate given the review question and the type of studies to be included.
- Reviewers need to clarify how the outcome of their critical appraisal exercise is used with respect to the presentation of their findings. The inclusion of a sensitivity analysis is recommended to evaluate the magnitude of methodological flaws or the extent to which it has a small rather than a big impact on the findings and conclusions.

Introduction

Considerable debate exists on whether or not concepts such as validity and reliability apply to qualitative research and if so how they could be assessed. Some researchers have stated that qualitative research should establish validity, reliability and objectivity. Others plead for an adjustment of these concepts to better fit the qualitative research design. As a consequence, critical appraisal instruments might differ in the criteria they list to complete a critical appraisal exercise. Some researchers consider appraisal instruments a tool that can be utilized as part of the exploration and interpretation process in qualitative research (Popay et al, 1998; Spencer, 2003). Edwards et al (2002) describes the use of a “signal to noise” approach, where a balance is sought between the methodological flaws of a study and the relevance of insights and findings it adds to the overall synthesis. Other researchers do not acknowledge the value of critical appraisal of qualitative research, stating that it stifles creativity (Dixon-Woods, 2004). While recognising that all these views have some basis for consideration certain approaches succeed in positioning the qualitative research enterprise as one that can produce a valid, reliable and objective contribution to evidence synthesis. It is these that may therefore have more potential to be generally accepted within the context of producing Cochrane Intervention Reviews. The Cochrane Collaboration recommends a specific tool for assessing the risk of bias in each included study in an intervention review, a process that is facilitated through the use of appraisal instruments addressing the specific features of the study design and focusing on the extent to which results of included studies should be believed. This suggest that in assessing the methodological quality of qualitative studies the core criterion to be evaluated is researcher bias. Believability in this context refers to the ability and efforts of the researcher to make his or her influence and assumptions clear and to provide accurate information on the extent to which the findings of a research report hold true. However, it is the actual audit trail provided by researchers that allows for an in-depth evaluation of a study. Most existing appraisal instruments use broader criteria that account for reporting issues as well. We suggest that these issues should be part of the appraisal exercise. Currently, there are four possibilities to make use of qualitative research in the context of Cochrane Intervention reviews:

1. The use of qualitative research to define and refine review questions a Cochrane Review (**informing reviews**).
2. The use of qualitative research identified whilst looking for evidence of effectiveness (**enhancing reviews**).
3. The use of findings derived from a specific search for qualitative evidence that addresses questions related to an effectiveness review (**extending reviews**).
4. Conducting a qualitative evidence synthesis to address questions other than effectiveness (**supplementing reviews**).

The latter use (Supplementing) is beyond the scope of current Cochrane Collaboration policy (Noyes et al, 2008). Stand alone qualitative reviews that supplement Cochrane Intervention reviews need to be conducted and published outside of the Cochrane context.

Critical appraisal applies to all of the above possibilities.

Reviewers should bear in mind that narratives used in reports of quantitative research cannot be considered qualitative findings if they do not use a qualitative method of datacollection and –analysis. Therefore, critical appraisal based on instruments developed to assess qualitative studies is not applicable to reports that do not meet the criteria of being a ‘qualitative study’..

This chapter breaks down in four sections. **Section 1** addresses translated versions of core criteria such as validity, reliability, generalisability and objectivity of qualitative studies. **Section 2** presents an overview of different stages involved in quality assessment. **Section 3** guides the researcher through some of the instruments and frameworks developed to facilitate critical appraisal and **section 4** formulates suggestions on how the outcome of an appraisal of qualitative studies can be used or reported in a systematic review.

Section 1: Core criteria for quality assessment

Critical appraisal is “the process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a decision” (Hill & Spittlehouse, 2003). Instruments developed to support quality appraisal usually share some basic criteria for the assessment of qualitative research. These include the need for research to have been conducted ethically, the consideration of relevance to inform practice or policy, the use of appropriate and rigorous methods and the clarity and coherence of reporting (Cohen & Crabtree, 2008). Other criteria are contested, such as the importance of addressing reliability, validity, and objectivity, strongly related to researcher bias. Qualitative research as a scientific process needs to be “rigorous” and “trustworthy” to be considered as a valuable component of Cochrane systematic review. Therefore an evaluation using such criteria is essential. Nevertheless we should acknowledge that the meaning assigned to these words may differ in the context of qualitative and quantitative research designs (Spencer et al, 2003).

Does translation of terminology compromise critical appraisal?

The concepts used in table 1 are based on Lincoln and Guba's (1985) translation of criteria to evaluate the trustworthiness of findings. Acknowledging the difference in terminology does not obviate the rationale or process for critical appraisal. There might be good congruence between the intent of meanings relevant to key aspects of establishing study criteria, as demonstrated in table 1.

Table 1: Criteria to critically appraise findings from qualitative research

Aspect	Qualitative Term	Quantitative Term
Truth value	Credibility	Internal Validity
Applicability	Transferability	External Validity or generalisability
Consistency	Dependability	Reliability
Neutrality	Confirmability	Objectivity

This scheme outlines some of the core elements to be considered in an assessment of the quality of qualitative research. However, the concept of confirmability might not be applicable to approaches inspired by phenomenology or critical paradigms in which the researcher's experience becomes part of the data (Morse, 2002). The

choice of critical appraisal instruments should preferably be inspired by those offering a multi-dimensional concept of quality in research. Apart from methodological rigour, that would also include quality of reporting and conceptual depth and breadth.

What indications are we looking for in an original research paper?

There are a variety of evaluation techniques that authors might have included in their original reports, that facilitate assessment by a reviewer and that are applicable to a broad range of different approaches in qualitative research. However, it should be stated that some of the techniques listed only apply for a specified set of qualitative research designs.

- **Assessing Credibility**: *Credibility* evaluates whether or not the representation of data fits the views of the participants studied, whether the findings hold true.
Evaluation techniques include: having outside auditors or participants validate findings (member checks), peer debriefing, attention to negative cases, independent analysis of data by more than one researcher, verbatim quotes, persistent observation etc.
- **Assessing Transferability**: *Transferability* evaluates whether research findings are transferable to other specific settings.
Evaluation techniques include: providing details of the study participants to enable readers to evaluate for which target groups the study provides valuable information, providing contextual background information, demographics, the provision of thick description about both the sending and the receiving context etc.

- **Assessing Dependability:** *Dependability* evaluates whether the process of research is logical, traceable and clearly documented, particularly on the methods chosen and the decisions made by the researchers. Evaluation techniques include: peer review, debriefing, audit trails, triangulation in the context of the use of different methodological approaches to look at the topic of research, reflexivity to keep a self-critical account of the research process, calculation of inter-rater agreements etc.
- **Assessing Confirmability:** *Confirmability* evaluates the extent to which findings are qualitatively confirmable through the analysis being grounded in the data and through examination of the audit trail. Evaluation techniques include: assessing the effects of the researcher during all steps of the research process, reflexivity, providing background information on the researcher's background, education, perspective, school of thought etc.

The criteria listed might generate an understanding of what the basic methodological standard is a qualitative study should be able to reach. However, a study may still be judged to have followed the appropriate procedures for a particular approach, yet may suffer from poor interpretation and offer little insight into the phenomenon at hand. Consequently, another study may be flawed in terms of transparency of methodological procedures and yet offer a compelling, vivid and insightful narrative, grounded in the data (Dixon-Woods et al, 2004). Defining fatal flaws and balancing assessment against the weight of a message remains a difficult exercise in the assessment of qualitative studies. As in quantitative research, fatal flaws may depend on the specific design or method chosen (Booth, 2001). This issue needs further research.

Section 2: Stages in the appraisal of qualitative research

Debates in the field of quality assessment of qualitative research designs are centred around a more theoretical approach to evaluating the quality of studies versus an evaluation of the technical adequacy of a research design. How far criteria-based, technical approaches offer significant advantages over expert intuitive judgement in assessing the quality of qualitative research is being challenged by recent evidence indicating that checklist-style approaches may be no better at promoting agreement between reviewers (Dixon-Woods, 2007). However, these appraisal instruments might succeed better in giving a clear explanation as to why certain papers have been excluded. Given the fact that few studies are completely free from methodological flaws, both approaches can probably complement each other.

Is the use of a critical appraisal instruments sufficient in assessing the quality of qualitative studies enhancing Cochrane intervention reviews?

Three different stages can be identified in a quality assessment exercise: filtering, technical appraisal and theoretical appraisal. The first stage links to the inclusion criteria of study types that should be considered to enhance or extent Cochrane Reviews and requires no specific expertise. The required expertise for the next two stages ranges from a basic understanding of qualitative criteria to be able to critically appraise studies to a more advanced level of theoretical knowledge on certain approaches used.

- **Stage 1: Filtering:**
Within the specific context of enhancing or extending Cochrane Reviews, and viewing critical appraisal as a technical and paradigmatic exercise, it is worth considering limiting the type of qualitative studies to be included in a systematic review. We suggest restricting included qualitative research reports to empirical studies with a description of the sampling strategy, data collection procedures and the type of data-analysis considered. This should include the methodology chosen and the methods or research techniques opted for, which facilitates the systematic use of critical appraisal as well as a more paradigmatic appraisal process. Descriptive papers, editorials or opinion papers would generally be excluded.
- **Stage 2: Technical appraisal:**
Critical appraisal instruments should be considered a technical tool to assist in the appraisal of qualitative studies, looking for indications in the methods or discussion section that add to the level of methodological soundness of the study. This judgement determines the extent to which the reviewers may have confidence in the researcher's competence in being able to conduct research that follows established norms (Morse, 2002) and is a minimum requirement for critical assessment of qualitative studies. Criteria include but are not limited to the appropriateness of the research design to meet the aims of the research, rigour of data-collection and analysis, well-conducted and accurate sampling strategy, clear statements of findings, accurate representation of participants' voices, outline of the researchers' potential influences, background, assumptions, justifications of the conclusion or whether or not it

flows from the data, value and transferability of the research project etc. For this type of appraisal one needs to have a general understanding of qualitative criteria. Involving a researcher with a qualitative background is generally recommended.

- **Stage 3: Theoretical appraisal:**

In addition to assessing the fulfillment of technical criteria we suggest a subsequent, paradigmatic approach to judgment, with a focus on the research paradigm used in relation to the findings presented. Although some critical appraisal instruments integrate criteria related to theoretical frameworks or paradigms most of them are pragmatic. These do little to identify the quality of the decisions made, the rationale behind them or the responsiveness or sensibility of the researcher to the data. Therefore, a consideration of other criteria should be considered. This would e.g. include an evaluation of methodological coherence or congruity between paradigms that guide the research project and the methodology and methods chosen, an active analytic stance and theoretical position, investigator responsiveness and openness and verification, which refers to systematically checking and confirming the fit between data gathered and the conceptual work of analysis and interpretation (Morse et al, 2002). For this type of overall judgment a more in-depth understanding of approaches to qualitative research is necessary. It is therefore recommended that a researcher with experience of qualitative research -who can guide others through the critical appraisal process- is invited. Experienced methodologists may have valuable insights into potential

biases that are not at first apparent. It should be mentioned though that the need for a paradigmatic input might depend on the type of synthesis chosen.

The Cochrane Qualitative Research Methods group recommends stage 3 whenever the instrument chosen for stage 2 does not cover for a paradigmatic approach to judgment. Other considerations include involving people with content expertise for the evaluation exercise. They are believed to give more consistent assessments, which is in line with what the Cochrane Collaboration suggests for the assessment of risk of bias in trials (Oxman et al, 1993).

Section 3: A selection of instruments for quality assessment

A range of appraisal instruments and frameworks is available for use in the assessment of the quality of qualitative research. Some are generic, being applicable to almost all qualitative research designs; others have specifically been developed for use with certain methods or techniques. The instruments also vary with regard to the criteria that they use to guide the critical appraisal process. Some address paradigmatic aspects related to qualitative research, others tend to focus on the quality of reporting more than theoretical underpinnings. Nearly all of them address credibility to some extent. The list with examples presented below is not exclusive with many instruments still in development or yet to be validated and others not yet commonly used in practice. It draws on the findings of a review of published qualitative evidence syntheses (Dixon-Woods et al, 2007) and the ongoing update of it. Reviewers need to decide for themselves which instrument appears to be most appropriate in the context of their review and use this judgement to

determine their choice. Researchers with a quantitative background also need to consider an input from a researcher familiar with qualitative research, even when an appraisal instrument suitable for novices in the field is opted for.

Which instruments or frameworks are out there?

- **Checklists embedded in a software program to guide qualitative evidence synthesis:**
Some evidence synthesis organisations have developed and incorporated a checklist in the software they make available to assist reviewers with the synthesis of qualitative findings. Typically, potential reviewers need to register to be able to use it. However, the instruments are also available outside the software program on the websites of both organisations¹.

Examples:

QARI software developed by the Joanna Briggs Institute, Australia

URL: <http://www.joannabriggs.edu.au/services/sumari.php>

¹ URL: http://www.joannabriggs.edu.au/cqrmg/tools_3.html. A detailed guide on how to conduct a QARI supported Systematic Review, including a detailed explanation of the 10 critical appraisal criteria, can be found on the JBI-website: http://www.joannabriggs.edu.au/pdf/sumari_user_guide.pdf
URL for instrument on process evaluation: <http://eppi.ioe.ac.uk/cms/default.aspx?tabid=2370&language=en-US>. Tools exist which help to assess quality along three dimensions: quality of reporting, sufficiency of strategies for increasing methodological rigour, and the extent to which study methods and findings are appropriate to answer the review question (For an example, see Harden et al 2009 study).

Used by: Pearson A, Porritt KA, Doran D, Vincent L, Craig D, Tucker D, Long L, Henstridge V. A comprehensive systematic review of evidence on the structure, process, characteristics and composition of a nursing team that fosters a healthy environment. *International Journal of Evidence-Based Healthcare* 2006; 4(2): 118-59.

Rhodes LG et al. Patient subjective experience and satisfaction during the perioperative period in the day surgery setting: a systematic review. *Int J Nurs Pract* 2006; 12(4): 178-92.

EPPI-reviewer developed by the EPPI Centre, United Kingdom

URL: <http://epi.ioe.ac.uk/eppireviewer/login.aspx>

Used by: Bradley P, Nordheim L, De La Harpa D, Innvaer S & Thompson C. A systematic review of qualitative literature on educational interventions for evidence-based practice. *Learning in Health & Social Care* 2005; 4(2):89-109.

Harden A, Brunton G, Fletcher A, Oakley A. Teenage pregnancy and social disadvantage: a systematic review integrating trials and qualitative studies. *British Medical Journal* Oct 2009.

- **Other online available appraisal instruments:**
Most of the instruments in this selection are easily accessible and clearly define what is meant by each individual criterion listed. As such, they may be particularly useful if reviewers with little experience of qualitative research are required to complete an assessment.

Examples:**Critical Appraisal Skills Programme (CASP):**

http://www.phru.nhs.uk/Doc_Links/Qualitative%20Appraisal%20Tool.pdf

Used by: Kane GA et al. Parenting programmes: a systematic review and synthesis of qualitative research. Child Care Health and Development 2007; 33(6): 784-793.

Modified versions of CASP, used by:

Campbell R, Pound P, Pope C, Britten N, Pill R, Morgan M, Donovan J. Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. Social Science and Medicine 2003; 56: 671-84.

Malpass A, Shaw A, Sharp D, Walter F, Feder G, Ridd M, Kessler D. 'Medication career' or "Moral career"? The two sides of managing antidepressants: A meta-ethnography of patients' experience of antidepressants. Soc Sci Med. 2009; 68(1):154-68.

Quality Framework UK Cabinet Office

http://www.gsr.gov.uk/downloads/evaluating_policy/a_quality_framework.pdf

Used by: MacEachen E et al. Systematic review of the qualitative literature on return to work after injury. Scandinavian Journal of Work Environment & Health 2006; 32(4): 257-269.

Evaluation Tool for Qualitative Studies

<http://www.fhsc.salford.ac.uk/hcprdu/tools/qualitative.htm>

Used by: McInnes RJ & Chambers JA. Supporting breastfeeding mothers: qualitative synthesis. *Journal of Advanced Nursing* 2008; 62(4): 407-427.

- **Checklists developed by academics and commonly used in published qualitative evidence syntheses:** Such checklists have been selected and utilised by other researchers in the specific context of an evidence synthesis.

Examples:

The Blaxter (1996) criteria for the evaluation of qualitative research papers, used by:

Gately C et al. Integration of devices into long-term condition management: a synthesis of qualitative studies. *Chronic Illn* 2008; 4(2): 135-48.

Khan N et al. Guided self-help in primary care mental health - Meta-synthesis of qualitative studies of patient experience. *British Journal of Psychiatry* 2007; 191: 206-211.

The Burns' (1989) standard for qualitative research, used by:

Barroso J, Powell Cope GM. Meta-synthesis of qualitative research on living with HIV infection. *Qualitative Health Research* 2000; 10: 340-53.

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Section 4: Integrating outcomes of critical appraisal in a systematic review.

In a 'best case' scenario a qualitative synthesis or primary study will achieve a positive assessment or score for each of the criteria against which it has been assessed according to the critical appraisal instrument used. However, this will most likely not be the case for the majority of studies and researchers need to be aware of the fact that the assessment or score might depend on the instrument that has been used, which increases the value of involving a researcher with a qualitative background in the appraisal process. For studies that fail to report sufficient

information or it is clear that the study is weak when matched against a certain criterion e.g. because of a methodological flaw a decision needs to be made whether to include the study or not.

How to use and report the critical appraisal outcome?

- To include or exclude a study: In this particular case, only high quality studies are included. The potential risk is that valuable insights are excluded from the synthesis. Studies rated as “low quality” because of methodological flaws or lack of reporting may nevertheless generate new insights, grounded in the data, while methodological sound studies may suffer from poor interpretation of data, leading to an insufficient insight into the phenomenon under study (Dixon-Woods, 2007).² This approach was used by Carlsen et al (2007), who excluded 5 out of 17 studies following quality appraisal.

Potential format of presentation:

Study/Criterion*	Study 1	Study 2	Study 3	Study 4	Study 5
Crit 1	X	/	/	x	/
Crit 2	X	x	/	x	x
Crit 3	X	x	X	x	x

² The loss of potential valuable studies is less likely if one would opt for a critical appraisal instrument which assesses conceptual depth and breadth of findings as well as methodological rigour. Currently, there is no guidance on how these two aspects might be balanced out. Sensitivity analyses could be considered.

Crit 4	X	?	/	x	x
Crit 5	X	x	X	?	x
Quality rating H/L**	H	Judge!***	L	H	Judge!
Comments		Motivate****	Motivate		Motivate

*Authors may choose to give more weight to certain criteria and use this in their final judgment.

** H/L= High/Low

*** For studies that are clearly on the verge between in- and exclusion researchers a judgement on whether to include or exclude should be made and discussed with potential co-reviewers.

**** Authors should include a motivation for in- or exclusion, particularly for those cases where judgments are being made.

- To give more weight to studies that scored high on quality: In this particular case, all valuable insights remain included. However, it might be complex to report on the findings of the synthesis given the 'subgroups' of studies. One strategy to cope with the issue of weighing studies is to report the findings of differently rated studies in separate sections. However, this has an impact on the potential richness of the presented synthesis, especially in those approaches generating new theory based on all of the relevant and illuminating findings. No fixed parameters currently exist to determine the weight of qualitative studies. Reviewers choosing this approach need to evaluate which methodological flaws have a substantial impact on the findings presented. The key issue to consider is the extent to which the quality of reporting and choices made by the authors is acceptable in terms of inclusion of the evidence in the Cochrane review which it aims to enhance.

Potential format of presentation:

Study/ Criterion*	Study 1 Subgroup 1	Study 2 Subgr. 1/2	Study 3 Subgr. 2	Study 4 Subgr. 1	Study 5 Subgr. 1/2
Crit 1	X	/	/	x	/
Crit 2	X	x	/	x	x
Crit 3	X	x	x	x	x
Crit 4	X	?	/	x	x
Crit 5	X	x	x	?	x
Qual. rating H/L	H	Judge!	L	H	Judge!
Comments		Motivate	Motivate		Motivate

Both approaches could benefit from a sensitivity analysis evaluating what happens to the findings of a study when low or high quality studies are removed. Thomas et al (2004) conducted such a sensitivity analysis and found that the findings of three studies rated as low quality did not contradict those from studies of a higher quality. This was confirmed by Noyes' and Popays' (2007) study on directly observed therapy and tuberculosis. The synthesis would have come to the same conclusions

with or without their inclusion. It indicates that there might be little to gain from including lower quality studies in a synthesis (Harden, 2008).

- To describe what has been observed without excluding any studies: In this particular case, all potential valuable insights remain included, because the worth of individual studies might only become recognisable at the point of synthesis rather than in the phase of appraisal. In this approach, the responsibility for evaluating the quality of the studies is devolved to the reader from the researcher.

The Cochrane Qualitative Research Methods Group sees value in all of these approaches. However, in line with current Cochrane policy, when conducting a Cochrane Intervention review and integrating qualitative evidence we recommend the two first approaches emphasizing the methodological soundness of studies rather than their contribution to science in general. The decision lies with the review team. Regardless of the approach eventually chosen for the quality assessment stage of the review there is a need to preserve the transparency of the method through careful documentation of decisions made. The convention of using at least two researchers for the quality assessment process is a useful legacy from quantitative-based review processes; not so much for inter-rater consistency purposes but, at the very least, to open up the data to a broader range of possible interpretations.

Conclusion

Quality assessment of qualitative research studies remains a contested area. While considerable widespread debate continues around the feasibility and utility of critical appraisal it is nevertheless possible to make recommendations within the specific context of informing, enhancing and extending a Cochrane Review. Balancing assessment against the weight of a message is a difficult exercise. In assessing the quality of an original study reviewers should focus on quality of reporting, methodological rigour and conceptual depth and bread of studies. Review Teams should deliberately seek indications that demonstrate rigour truth-and trustworthiness in the studies **(section 1)**. Filtering, technical appraisal and theoretical appraisal are the three main stages in a critical appraisal exercise. Review teams need to make sure that they have the necessary expertise on board to be able to complete each phase of the critical appraisal exercise **(section 2)**. In choosing an assessment instrument review teams need to consider the appropriateness of their choice in the context of their review and be aware of the fact that whether or not a study meets the standard might depend on the instrument used **(section 3)**. Review teams can opt to use the outcome of their critical appraisal to in- or exclude studies, to give high quality studies more weight or to inform themselves without excluding any. Regardless of the approach eventually chosen there is a need to preserve the transparency of the method through careful documentation of decisions made. The use of at least two researchers to complete the critical appraisal process is recommended **(section 4)**.

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Appendix D- Data extraction form

Reference Number

Title

Author(s)

Source

Date: Vol.: Part: Pages:

Objective

Target group

Setting

Population

Study population

Sampling method

Power Calculation?

Entry and exclusion criteria

Representative of sample

Size of intervention and control groups

Comparability of intervention and control groups

Description of Intervention

Experimental intervention (including timescale and any aspects of complexity)

Control (including timescale and any aspects of complexity)

Outcomes: Measures and Instruments

Timing of measures

Nature of measures

Baseline

Instruments used

Were instruments validated?

Length of follow up

Study Design

Results

Means and SDs of primary outcomes by group

Means and SDs of primary outcomes by group

Attrition (D/O) from study and from intervention and control groups

What statistical tests were used?

Conclusions

Author's conclusions

Reviewer's commentary

Generalisability of findings

Other comments



SCHOOL OF PSYCHOLOGY

DOCTORATE IN CLINICAL PSYCHOLOGY

EMPIRICAL PAPER

Association Between Physical Activity and Mood in Bipolar Disorder

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Primary Research Supervisor: **Dr Kim Wright**

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Target Journal: Journal of Affective Disorders

Word Count: 7947 words (excluding abstract, table of contents,
list of figures, references, footnotes, appendices)

**Submitted in partial fulfilment of requirements for the Doctorate Degree in
Clinical Psychology, University of Exeter**

Abstract

Background: Despite the published evidence for the benefits of physical activity on mood in the general population and in people with mental illness, there is a lack of research into the associations between physical activity and mood in people with bipolar disorder. The current study therefore aimed to investigate the relationship between symptoms of mania and depression and different intensities, regularity, and total duration of physical activity per day and across the week.

Methods: People with a diagnosis of bipolar disorder ($N = 29$) completed daily diaries on physical activity and manic and depressive symptoms over 14 days. Analysis included multilevel modelling, t -tests and correlation analysis.

Results: No association was found between manic symptoms and physical activity, either at the within- or the between-person level. An association was found at the within-person level between higher duration of physical activity and lower depression symptoms, however no association was found at the between-person level.

Limitations: The small sample size was adequate only to detect large-sized effects for between-person hypotheses. Participants were highly active and may not be representative of the wider BD population. Physical activity levels were assessed via self-report.

Conclusions: The relationship between physical activity and manic symptoms in BD remains inconclusive, but a significant within-person association indicates that physical activity may reduce depressive symptoms in the short term. Given previous research on physical activity and manic symptoms, people with BD and professionals working with them may need to remain cautious, modifying any PA engagement depending on mood state.

Keywords: Bipolar disorder, physical activity, manic symptoms, depressive symptoms.

Introduction

Bipolar disorder (BD) is a remitting, typically chronic and relapsing mental health disorder (American Psychiatric Association, 2013), associated with difficulties in social and personal functioning (National Collaborating Centre for Mental Health, 2014) and higher rates of physical health problems (Carney & Jones, 2006), such as diabetes, cardiovascular disease (Kilbourne et al., 2004) and obesity (Fagiolini et al., 2002). Long-term treatment for BD is mainly pharmacological, and the side effects of the medications used further contribute to the already higher risk of obesity and cardiovascular risk (National Collaborating Centre for Mental Health, 2014).

Physical activity (PA), which is defined by the World Health Organization ([WHO], 2015) as any bodily movement that is produced by skeletal muscles requiring expenditure of energy, including activities partaken in as part of travel, recreation, work, play or household chores, is well known to have physical health benefits (WHO, 2010) and is becoming increasingly recognised as being beneficial for emotional wellbeing (Biddle & Mutrie, 2001). PA is also recognised as being beneficial for mental illness such as depression (Biddle & Mutrie, 2001; Cooney et al., 2013; Harris, Cronkite, & Moos, 2006; Rethorst, Wipfli, & Landers, 2009; Robertson, Robertson, Jepson, & Maxwell, 2012) and is recommended as one possible intervention for subthreshold depressive symptoms or mild to moderate depression in NICE (2009) guidelines. People with BD have been found to be less physically active than other clinical and general populations (Elmslie, Mann, Silverstone, Williams, & Romans, 2001; Gomes et al., 2013; Janney et al., 2014; Kilbourne et al., 2007; Vancampfort et al., 2015).

Despite the published evidence for the benefits of PA on mood in the general population as well as in people with mental illness such as depression, there is still a

lack of research on the associations between PA and mood in people with BD, with the latest NICE guidelines (National Collaborating Centre for Mental Health, 2014) mostly focusing on weight reduction or management rather than the potential impact on mood symptoms. The previous NICE (2006) guidelines advised caution when recommending PA for individuals with BD, drawing on the depression literature for the potential for PA to be helpful for depressive symptoms, but highlighting the potential for PA to be either helpful or harmful for manic symptoms.

Indeed, an inconsistent relationship between different mood states in BD and PA was highlighted in Wright and colleagues' (Wright, Armstrong, Taylor, & Dean, 2012) qualitative study of exercise amongst individuals with BD, where participants reported that PA could be both helpful and harmful, depending on mood state at the time and the type of PA they were engaging in. In particular, participants expressed that when they were experiencing symptoms of mania it was helpful to engage in more calming PA. The accounts in this study indicated that when people start to experience manic symptoms and are not regulating their PA levels, this can increase the intensity or duration of the PA, which can then exacerbate manic symptoms further. This complicated relationship was further reported in Uebelacker, Weinston and Kraines' (2014) qualitative study on yoga and BD, where participants reported both positive and negative effects of yoga on their depressive and manic symptoms, in particular if breathing was too energetic/rapid or if the temperature of the room was too hot, this could increase agitation and other manic symptoms.

One theory that could explain the anecdotal accounts of PA potentially being harmful for manic symptoms is the Behavioural Activation System (BAS) dysregulation theory (Depue & Iacono, 1989; Depue, Krauss & Spont, 1987). The BAS regulates goal directed behaviour and appetitive motivation to obtain rewards

and according to the BAS dysregulation theory, individuals with BD have excessive increase in and sustained BAS activity when they encounter reward incentives or perceive goal success relating to important life events, which then leads to manic/hypomanic symptoms. This is hypothesised to be in part mediated by increases in reward striving behaviour. Conversely, if individuals with BD perceive a definite failure in a task, this would lead to an excessive decrease in BAS activity (Alloy & Abramson, 2010; Johnson, Edge, Holmes, & Carver, 2012; Nusslock, Abramson, Harmon-Jones, Alloy & Hogan, 2007), and experiences of depressive symptoms, in particular low motivation, anhedonia, hopelessness and psychomotor retardation (Alloy, Nusslock & Boland 2015). PA could trigger the approach system which would be protective against depression symptoms, however individuals with BD engaging in high intensity PA could perceive excessive goal success or feelings of satisfaction which can then increase reward striving behaviour, energy and effort expanded, leading to a further increase in manic symptoms (Lowenstein, Wright, Taylor, & Moberly, 2015).

At the neurobiological level of explanations for why certain intensities or timing of PA with respect to mood states may increase or induce manic episodes, by impacting the noradrenergic system, which, among other neurobiological systems, has been shown to be dysregulated in BD (Newberg, Catapano, Zarate, & Manji, 2008). Acute PA can elevate norepinephrine, which could induce manic episodes or increase manic symptoms if it is too elevated (Alsuwaidan & McIntyre, 2009), with vigorous intensity PA potentially elevating it more than lower intensity PA.

In general, studies that have looked at the relationship between PA and mood in BD have looked at cross-sectional associations and lacked specific information about the features of PA that might make it more or less beneficial with respect to

particular mood states, such as total duration or intensity of PA. The relationship found in these studies between PA and different mood states has been inconsistent, with one study reporting that higher levels of PA are associated with more manic symptoms (Sylvia et al., 2013a) at the within-person level, whilst others have reported that higher levels of PA are associated with less manic symptoms at the within-person (Hays et al., 2008; Sylvia, Nierenberg, Stange, Pechkam, & Deckersback, 2011) and between-person level (Edenfield, 2007; Jewell et al., 2015). These studies had several limitations, including a lack of robust measures of manic symptoms, small sample sizes and lack of control groups to control for confounding variables such as baseline PA levels and co-morbid mental and physical health problems. Furthermore, there has been a lack of blinding to treatment and blinding of assessors in these studies and a lack of longitudinal data.

Findings have been more consistent with regards to the relationship between PA and depression symptoms in people with BD, with studies reporting both within- and between-person associations between fewer depressive symptoms and engaging in PA (Edenfield, 2007; Hays et al., 2008; Ng, Dodd, & Berk, 2007; Sylvia et al., 2011; Sylvia et al., 2013b; Wright et al., 2012) or between lower PA levels and more depressive symptoms (Sylvia et al., 2013a). However, it is important to note that none of these studies can reliably demonstrate causality, and more robust experimental studies are needed to further support this relationship.

The national guidelines for PA in adults (Department of Health [DOH], 2011) recommend at least 150 minutes a week of moderate intensity PA, such as fast walking or cycling, in bouts of 10 minutes or more, with suggestions that people do 30 minutes per day, five days a week. Alternatively, people are said to gain the same benefits from 75 minutes of vigorous activity, such as running or tennis, spread

across the week, or by engaging in a mixture of moderate to vigorous activity which equates to 150 minutes of moderate activity. Furthermore, the guidelines suggest that people engage in activity that improves muscle strength (e.g., carrying heavy loads or exercising with weights) on at least two days a week, although it appears that this can be included within the 150/75 minutes recommended.

Recent advice on PA for people with affective disorders (Stanton, Happell, Hayman, & Reaburn, 2014) recommends that people with BD should be encouraged to engage in low to moderate, or self-selected intensity of PA for 30-40 minutes, three to four times per week, which is similar to the national guidelines for PA, whilst considering the potential that PA may exacerbate manic symptoms. It is of interest that Stanton and colleagues recommend low to moderate or self-selected intensity rather than vigorous intensity PA, and this might reflect findings from studies that suggest a potential for energetic PA to be unhelpful in terms of manic symptoms (Uebelacker et al., 2014; Wright et al., 2012).

The guidelines for PA encourage people to spread activity over the week and engage in regular PA from week to week, maintaining a regular level of exercise rather than in bursts separated by periods of inactivity. This could be important to consider for people with BD, as disruption to circadian rhythm, such as sleep and social rhythm (Lee, Son, & Geum, 2013), has been found to be associated with BD. Markers of circadian rhythms are disrupted, both in affective episodes and during euthymic periods (Jones, 2001; Jones, Hare, & Evershed, 2005; McKenna, Drummond, & Eyler, 2014). Research has suggested that manic/hypomanic and depressive episodes in people with BD may be explained by the social zeitgeber theory (Ehlers, Frank, & Kupfer, 1988), which proposes that if zeitgebers (external cues, such as PA and meals, which determine circadian rhythms) are disturbed, this

will derail biological and social rhythms and trigger affective symptoms (Grandin, Alloy, & Abramson, 2006), suggesting that routine and regularity in day to day life (and therefore also in PA engagement) could be important for people with BD.

Given the above limitations to the existing literature, in particular with regards to lack of longitudinal data and lack of focus on different types of PA, the aim of this research project was to investigate the relationship between PA and mood in people with BD using diary methodology, which allows a prospective investigation of this relationship, within and between individuals. Of particular interest was the relationship between symptoms of mania and depression and different intensities of PA, regularity of PA, and the total duration of PA per day and across the week.

Hypotheses

Primary hypotheses.

1. Based on previous findings (Edenfield, 2007; Hays et al., 2008; Jewell et al., 2015; Sylvia et al., 2011; Wright et al., 2012) there will be an association between total duration of low to moderate intensity PA during any given 24 hour period and symptom scores for mania on that day, such that greater time spent in low to moderate intensity PA will be associated with lower manic symptom score on that day. This relationship was also expected at the between-person level, such that people who have higher mean levels of low to moderate intensity PA would have lower mean levels of manic symptoms across the diary period.
2. Controlling for mean duration of low to moderate PA per day over the two weeks, regularity of low to moderate PA across the two weeks will be correlated with mean manic symptom score across the two weeks, in that the

more regularly people engage in PA across the two weeks, the lower their manic symptom scores will be.

- a. Furthermore, it is expected that the between-person association between total duration of low to moderate PA and average daily mania is moderated by regularity of low to moderate PA, in that mania symptoms will be lowest in those who have the highest level of PA and engage in PA more regularly.
3. Based on previous findings (Uebelacker et al., 2014; Wright et al., 2012) there will be an association between total duration of vigorous PA during any given 24 hour period and symptom scores for mania on that day, controlling for duration of low to moderate PA, such that greater time spent in vigorous PA will be associated with higher manic symptom score. This relationship was also expected at the between-person level, such that people who have higher mean levels of vigorous intensity PA would have higher mean levels of manic symptoms across the diary period.

Secondary hypotheses.

4. Based on the evidence base for PA and depression, there will be a negative association between total duration of PA engaged in during any given 24 hour period and depression score across this period, such that greater duration of PA will be associated with lower depression scores. This relationship was also expected at the between-person level.
5. Controlling for mean duration of PA per day over the two weeks, regularity of any type of PA across the two weeks will be correlated with mean depression symptom score across the two weeks, in that the more regularly people

engage in PA across the two weeks, the lower their depression symptom scores will be.

- a. Furthermore, it is expected that the association between total duration of PA and average daily depression is moderated by regularity of PA, such that depression symptoms will be lowest in those who have the highest level of PA and engage in PA more regularly.

Methods

Design

A longitudinal design was employed, using daily diaries, over 14 days, to explore within- and between participant associations between variables. A diary design was used rather than experience sampling methods due to recruitment being countrywide and the author being unable to meet with participants in person to explain and ensure correct usage of an experience sampling device, coupled with the cost and risk of sending such equipment. The predictor variables were intensity, duration and regularity of PA. The outcome variables were symptom levels of depression and symptom levels of mania.

Power analyses

A priori power analysis was conducted to determine the number of participants needed for the study. The required sample size of 30 participants was based on the within-person hypotheses, which was of greatest interest in the diary design (see Appendix A for details).

Participants

The sample consisted of 29 individuals aged 18 years and over (65.5% female [$n = 19$]; age $M = 45.0$ years, range = 29-71, $SD = 10.9$) with a diagnosis of BD (Bipolar I: $n = 26$, Bipolar II: $n = 3$). To maximise the chances of recruiting an

adequate number of participants, the sample, recruitment efforts and data collection were shared with another DClinPsy trainee. Ethical approval was given from the National Research Ethics Service (NRES; Appendix B), then ratified by the School of Psychology Ethics Committee (Appendix C). Informed written consent was sought from all participants and it was made clear that they had the right to withdraw from the study at any time.

The participants were recruited via Spectrum Connect (a voluntary group connecting researchers, service users and health care providers), Bipolar UK, the AccEPT service (a local research clinic), databases of potential participants held by the Mood Disorders Centre (MDC) at Exeter University and advertisement in the community. Figure 1 shows the flow of participants into the study. An inclusion criteria was a diagnosis of BD (bipolar I, bipolar II, cyclothymia or BD not otherwise specified). Potential participants were excluded if they were not already actively engaging in at least one instance of 10 minutes of low, moderate or vigorous intensity PA per week. Potential participants were also excluded if they met DSM-IV criteria for a depressed or a manic episode in the last month¹, due to the ethical implications of adding burden on people when acutely unwell. Additionally, the study aimed to look at relationships between mood and PA within individuals, and if mood is stably high or low, this would limit statistical power to look at that relationship. However, there was an option for participants to contact the researcher if their symptoms improved, if they still wished to participate in the study. The screening interview was then conducted again to ensure readiness to participate.

Furthermore, individuals who had current substance dependence or who were actively suicidal were excluded from the study². This was due to ethical reasons, and the possible confounding of the effects of substances on PA levels and mood

symptoms. Additionally, exclusion of non-English speaking individuals was necessary as the diaries and measures were in English³.

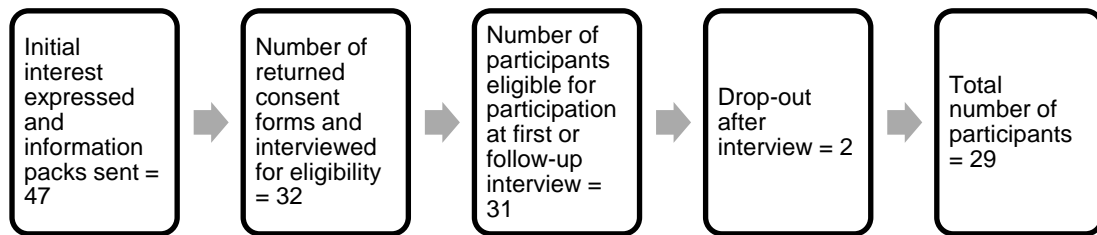


Figure 1. Flowchart of participant flow into the study.

Measures

The Structured Clinical Interview for DSM-IV- (SCID; First, Spitzer, Gibbon, & Williams, 2002). The SCID was administered at baseline to confirm BD diagnosis according to DSM-IV criteria. The SCID is a commonly used measure for lifetime and current BD diagnosis, and can distinguish between different types of BD. The SCID has been found to have good reliability (Lobbestael, Leurgans, & Arntz, 2011). Module A, Mood Episodes, was used to screen for current manic or depressive episode (as per exclusion criteria) and to confirm BD diagnosis based on past manic episode, or past major depressive episode and hypomanic episode. Modules B and C (Psychotic Symptoms) and Module E (Substance Use Disorders) were also administered for exclusion criteria. The interview was conducted via telephone and audio-recorded. Risk was managed using the risk assessment protocol for the MDC at University of Exeter (Appendix D). A subsample of seven SCID interviews were double-rated by a blind second rater, with perfect agreement upon diagnosis (BD I or II, as none of the participants met criteria for cyclothymia or BD not otherwise specified) and exclusion criteria.

The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001; Appendix E). This was used to measure depressive symptoms at baseline,

middle and end of the daily diary period. The PHQ-9 is a widely used scale for measuring, screening and monitoring the severity of depression. The PHQ-9 asks about depressed mood over the last two weeks, but to improve temporal precision it was adapted to ask about the last week for the measurement occasion at the mid-point and end of the diaries. The diagnostic validity and reliability of the PHQ-9 has been well established (Kroenke et al., 2001) and had high internal reliability at all measurement points of the current study, Cronbach's $\alpha = .85-.92$.

The Internal State Scale (ISS; Bauer et al., 1991; Appendix F). The ISS was designed as a simple self-report measure of mood state, and is ideal for use in daily diaries to track mood symptoms in BD, as it asks to rate mood over the preceding 24 hours. The ISS was administered at baseline and in the daily diaries. For the present study, the activation (mania) and depression subscales were used for analysis. The ISS has been found to be a valid discriminator of mood states in BD (Bauer, Vojta, Kinosian, Altshuler, & Glick, 2000; Cooke, Kruger, & Shugar, 1996) and there was high internal reliability in the current study for the activation subscale at baseline, Cronbach's $\alpha = .90$, and for the daily diaries, Cronbach's $\alpha = .87$. At baseline, the depression scale had good reliability, Cronbach's $\alpha = .78$, but excellent reliability for the daily diaries, Cronbach's $\alpha = .92$.

The Altman Self-Rating Mania Scale (ASRM; Altman, Hedeker, Peterson & Davis, 1997; Appendix G). The ASRM is a brief self-report measure, with five items that relate to how the individual has been feeling for the past week, assessing the presence and severity of manic symptoms. The ASRM is used in both clinical and research settings and has shown good reliability and validity (Altman, Hedeker, Peterson, & Davis, 2001). The ASRM was administered at baseline and at the end of week one and two, showing an internal reliability of Cronbach's $\alpha = .73-.74$.

Godin Leisure-Time Exercise Questionnaire (GLTEQ, Godin & Shephard, 1985, 1997; Appendix H). The GLTEQ was used to establish a baseline of participants' habitual PA levels. The GLTEQ asks the individual to report the frequency of strenuous, moderate and mild exercise he/she engages in during a typical week. It can be used to obtain a baseline of total days per week for which the individual engages in each type of PA. The GLTEQ has been reported to have good reliability and moderate validity (Godin & Shephard, 1997).

The International Physical Activity Questionnaire (IPAQ) long form (The IPAQ Group, 2002; Appendix I). The IPAQ was used to establish PA engaged in over the last seven days before starting the diary. The IPAQ is an international measure frequently used in research, with validity and reliability shown across 12 countries (Craig et al., 2003). The IPAQ assesses PA undertaken in four different domains: leisure time, work-related, domestic and transport-related PA, and allows for classification of participants' activity levels as low, moderate or high using algorithms involving Metabolic Equivalent of Task (MET) minutes (energy requirements for different intensities of activity). The IPAQ short form (Appendix J) was adapted for daily monitoring of PA levels as part of the diary by asking participants about their exercise levels over the preceding 24 hours.

Development of materials. A patient advisory group was consulted (see Appendix K for details).

Procedure

An information sheet (Appendix L) was sent out to the relevant organisations to distribute, with contact details to express interest to participate in the study. Interested participants phoned or e-mailed the researcher and were sent an information sheet (Appendix M) outlining the aims of the research project and what

involvement in the project would entail, as well as a consent form (Appendix N) to return prior to screening interview.

Once consent forms were received by the author, participants were contacted at an agreed time to complete the DSM-IV SCID interview over the phone. Once the interview was completed and participants were deemed to meet inclusion criteria, they were given participant identification numbers, to ensure anonymity of online data. Links to online baseline measures were then sent to participants to complete prior to commencement of daily diaries. Participants were also sent links to each day of the online diaries, with dates corresponding to each link. Prompts were given by email when needed to remind participants to complete their daily diaries. Two participants expressed a wish to complete the measures on paper, and therefore measures were sent to them in the post following their SCID interviews. They then returned their measures in the post after each week.

Once a participant completed his/her two weeks of diary input, a letter was sent out to thank him/her for participating in the study with an online shopping voucher and confirmation that a summary letter would be sent out once data had been analysed, if they expressed a wish to receive this.

Data Screening

All variables for analysis met parametric assumptions of normality and homoscedasticity as determined via histograms, scatterplots and the Kolmogorov-Smirnov test. All variables were screened for univariate outliers by calculating standardised scores (z-scores), with outliers identified as scores more extreme than $\pm 3.29 \times SD$ (See appendix O for further details).

Analysis Strategy

For hypotheses 1-5, multilevel modelling was used for data analysis as it allowed an examination of associations between PA and bipolar symptoms at a within-person level, whilst allowing for non-independence of days within person. Within-person (daily) variables (i.e., symptoms of mania and depression and intensity and duration of PA on a given day), were centred around their respective person-means, to provide truer estimates of within-person associations without between-person “contamination”, whereas individual difference variables (i.e., mean symptoms of mania and depression across days, mean duration of PA across days and mean number of days between instances of PA) were grand-mean-centred (Enders & Tofighi, 2007). The researcher then re-entered mean levels of daily variables to model between-person variance, separate from within-person variance.

Results

Table 1 shows demographic and baseline variables for participants in the study. Of the 29 participants, 19 were female and 10 male. A total of 27 participants were on medication to manage their BD whilst two were not on any medication. No participant was excluded from the analysis as all participants completed at least 10 out of 14 days of diary inputs (in line with power calculations for sample size). All participants completed all baseline measures. In total, 393 diary entries were completed, with only 13 missed days across 6 participants. The other 23 participants completed all daily diary entries. Table 2 shows correlations among between-person variables and Table 3 shows correlations between- and within-person variables.

Table 1

Demographic and baseline variables with means and standard deviations, in addition to clinical status.

Variable	Mean	SD	Clinical / PA status
Age	45	10.85	
BD subtype			Bipolar I: 26 Bipolar II: 3
Baseline measures:			
<u>Mood</u>			
ISS Mania	96.90	113.17	Over clinical threshold=7
ASRM	3.34	3.10	Over clinical threshold=9
PHQ-9	8.66	5.86	<5 (no depression)=7 5-9 (mild)=12 10-14 (moderate)=4 15-19 (moderately severe)=4 >20 (severe)=2
ISS Depression	32.76	42.00	
<u>PA</u>			
MET minutes of low intensity PA ^a	1548.10	1374.54	
Days involving low intensity PA across week ^b	6.03	3.10	
MET minutes of moderate intensity PA ^a	1420.00	1728.4 3	
Days involving moderate intensity PA across week	3.66	3.27	
MET minutes of Vigorous intensity PA ^a	1525.79	2821.50	
Days involving vigorous intensity PA across week	1.93	2.70	
MET minutes of Total PA ^a	4493.90	4116.54	
Level of PA week before baseline ^c (number of people meeting each category)			Low: 5 Moderate: 13 ^d High: 11 ^d
Days per week of PA typical week	5.55	2.01	

Notes. ^a As measured in Metabolic Equivalent of Task (MET) minutes (energy requirements for different intensities of activity, see appendix P). ^b Number of days when any PA of that type was present. ^c As defined by the IPAQ (appendix P). ^d Meet criteria for minimum recommended amount of PA using categories stated in DOH guidelines.

Table 2

Correlations among between-person variables at baseline, middle and end of study.

	Baseline																Mid		Post	
	ISS M	ASRM	PHQ -9	ISS D	IPAQ Low PA min	IPAQ low PA days	IPAQ mod PA min	IPAQ mod PA days	IPAQ vig PA min	IPAQ vig PA days	IPAQ total PA	GLT days low	GLT days mod	GLT days vig	GLT total days	PHQ -9	ASRM	PHQ -9	ASRM	
ISS Mania	-																			
ASRM	.47*	-																		
PHQ-9	.36	.17	-																	
ISS D	-.07	-.25	.59**	-																
IPAQ low PA min	-.14	.02	-.13	-.08	-															
IPAQ low PA days	-.05	.04	-.17	-.19	.68***	-														
IPAQ mod PA minutes	.12	.03	.03	-.04	.46*	.34	-													
IPAQ mod PA days	.12	-.02	-.09	-.24	.18	.26	.80***	-												
IPAQ vig PA min	.22	.18	.13	-.24	-.05	.02	.24	.37*	-											
IPAQ vig PA days	.19	.27	.18	-.28	-.14	-.17	.16	.33	.83***	-										
IPAQ total PA	.19	.15	.06	-.21	.49**	.39*	.74***	.65***	.77***	.59***	-									
GLT days of low	.01	.30	.05	-.02	.24	.46*	.08	.10	.02	-.04	.13	-								
GLT days of mod	.12	.21	-.04	-.34	.08	.16	.21	.27	-.08	.01	.06	.24	-							
GLT days of vig	.08	-.09	.11	-.11	-.09	.05	.22	.38*	.81***	.70***	.62***	-.21	-.12	-						
GLT total days	.12	.14	.04	-.22	.30	.59***	.36	.41*	.14	.08	.35	.71**	.44*	.06	-					
PHQ-9	.01	.14	.78**	.77**	-.37	-.40*	-.25	-.40*	-.07	-.07	-.28	-.05	-.00	-.00	-.17	-				
ASRM	.16	.34	-.02	-.26	-.18	.08	.04	.08	.29	.13	.15	.19	-.13	.14	.18	-.20	-			
PHQ-9	.32	-.12	.79**	.56**	-.10	-.26	-.14	-.28	-.10	.05	-.02	-.14	.08	-.08	-.08	.80**	-.20	-		
ASRM	.36	.44*	.09	-.06	-.14	-.03	.12	.15	-.13	.00	-.09	.11	.13	-.09	.14	-.11	.55**	-.17	-	

Notes. ISS M = internal state scale mania subscale; ISS D = internal state scale depression subscale; PA = physical activity low to mod = total minutes of low to moderate intensity PA, Vig PA = total minutes of vigorous intensity PA; Total PA = total minutes of any PA; ASRM = Altman self- rating mania scale; PHQ-9 = the patient health questionnaire; IPAQ = international physical activity questionnaire; min = metabolic equivalent of task (MET) minutes GLT = Godin leisure-time exercise questionnaire; low = low intensity physical activity. * $p < .05$. ** $p < .01$. *** $p < .001$

Table 3

Correlations between baseline variables and daily measures.

		Baseline											Mid			Post			Daily						
		ISS M	ASRM	PHQ-9	ISS D	IPAQ low PA min	IPAQ low PA days	IPAQ mod PA min	IPAQ mod PA days	IPAQ vig PA min	IPAQ vig PA days	IPAQ Total PA	GLT days low	GLT days mod	GLT days vig	GLT Total days	PH Q-9	ASRM	PHQ-9	ASR M	ISS M	ISS D	Low to mod PA	Vig PA	total PA
		Daily	ISS M	.59**	.16	.16	.03	.08	.04	-.06	-.14	.06	-.12	.05	-.02	-.23	-.09	.05	.04	.31	.29	.33	-	.07	.09
ISS D	.25		-.21	.68**	.60**	.13	-.06	-.04	-.18	-.03	-.13	.01	-.15	-.26	-.01	-.12	.63**	-.22	.85**	-.09	.68**	-	-.09	-.09	-.12*
Low to mod PA	-.16		-.12	-.25	-.19	.42*	.18	.56**	.42*	.14	.13	.47*	-.21	.23	.04	.04	-	.03	-.21	-.09	-.32	-.15	-	.09	.93**
Vig PA	-.10		-.31	-.21	-.12	-.05	-.21	.03	.14	.31	.42*	.21	-.52**	-.13	.60**	-.34	-.15	-.19	-.15	-.08	-.32	-.13	.10	-	.31**
	Total PA	-.17	-.17	-.28	-.20	.39*	.14	.54**	.43*	.19	.19	.49**	-.29	.20	.14	-.12	-	.00	-.23	-.10	-.40	-.14	.96**	.15	-

Notes. Within-person associations in bold; ISS M = internal state scale mania subscale; ISS D = internal state scale depression subscale; PA = physical activity low to mod = total minutes of low to moderate intensity PA, Vig PA = total minutes of vigorous intensity PA; Total PA = total minutes of any PA; ASRM = Altman self-rating mania scale; PHQ-9 = the patient health questionnaire; IPAQ = international physical activity questionnaire; min = metabolic equivalent of task (MET) minutes GLT = Godin leisure-time exercise questionnaire; low = low intensity physical activity. * $p < .05$. ** $p < .01$. *** $p < .001$

Hypothesis 1-3: Predicting manic symptoms from PA intensity and regularity.

To test Hypotheses 1 and 3, a two-level random intercepts multi-level model was constructed, with days nested within persons, predicting log-transformed daily mania scores from the amount of log-transformed daily low to moderate intensity PA and vigorous PA. Analysis of an empty model with no predictors revealed that the proportion of variability within people (ICC) was .69. In other words, 69% of the total variability in daily mania scores was between people, and 31% was between days and within people.

When log daily low to moderate PA and log daily vigorous PA were simultaneously entered into the model, these variables were not found to be significant predictors of manic symptoms over the diary period at the within person level (low to moderate PA: $B = .07$, $SE(B) = .04$, $z = 1.71$, $p = .08$; vigorous PA: $B = .01$, $SE(B) = .05$, $z = .11$, $p = .91$). To investigate the between-person association, mean log low to moderate PA and mean vigorous PA were entered into the model simultaneously, but were not found to be significant predictors of mean daily manic symptoms (low to moderate PA: $B = -.38$, $SE(B) = .42$, $z = -.90$, $p = .37$; vigorous PA: $B = -.11$, $SE(B) = .24$, $z = -.46$, $p = .65$). As vigorous PA was neither a significant predictor of daily manic symptoms at the within-person nor the between-person level, it was dropped from the model. After dropping vigorous PA from the model, the between-person coefficient for low to moderate PA remained non-significant, $B = -.42$, $SE(B) = .41$, $z = -1.04$, $p = .30$, as did the within-person coefficient, $B = .07$, $SE(B) = .04$, $z = 1.71$, $p = .08$. Thus, no support emerged for Hypotheses 1 and 3: neither low to moderate PA nor vigorous PA were significantly associated with manic symptoms.

To investigate whether the regularity of PA (i.e., the standard deviation of the number of days between each instance of low to moderate PA) was associated with average daily manic symptom level, regularity of PA was added to the model as a person-level predictor. Failing to support Hypothesis 2, regularity of low to moderate PA was not significantly associated with mean levels of daily manic symptoms after controlling for mean level of low to moderate PA ($B = -.06$, $SE(B) = .20$, $z = -.30$, $p = .76$). Failing to support Hypothesis 2a, when entered in a final step, the interaction between regularity of low to moderate PA and mean level of low to moderate PA across the week was not a significant predictor of mean levels of daily manic symptoms ($B = 1.11$, $SE(B) = 1.07$, $z = 1.04$, $p = .30$).

No statistically significant association was therefore found between total duration of either low to moderate PA or vigorous PA on any given day and symptom scores for mania on that day. There was also no association between these variables at the between-person level. Furthermore, regularity of low to moderate PA did not predict mean manic symptoms and did not moderate the relationship between mean low to moderate PA and mean manic symptoms.

Hypothesis 4 and 5: Predicting depressive symptoms from total PA duration and regularity.

To test Hypothesis 4 and 5, a two-level random intercepts multi-level model was constructed, with days nested within persons, predicting log daily depression scores. Analysis of an empty model with no predictors revealed that the proportion of variability within people (ICC) was .58. In other words, 58% of the total variability in depression scores was between people, and 42% was between days and within people.

Supporting Hypothesis 4, when log-transformed total daily duration of PA was entered into the model, it was found to be a significant negative predictor of daily depressive symptoms at the within-person level ($B = -.10$, $SE(B) = 0.04$, $z = -2.24$, $p = .03$). To investigate the between-person association, mean log-transformed total PA was added to the model, but this was not a significant predictor of mean levels of depressive symptoms ($B = -.14$, $SE(B) = .37$, $z = -.38$, $p = .70$).

To investigate whether the average depressive symptom levels depend on the regularity of PA (i.e., the standard deviation of the number of days between each instance of PA), regularity was added to the model as a person-level predictor. Failing to support Hypothesis 5, regularity of PA across the week was not significantly associated with mean levels of daily depression symptoms ($B = .30$, $SE(B) = .24$, $z = 1.28$, $p = .20$), controlling for total duration of PA. Failing to support Hypothesis 5a, when entered in a final step, the interaction between regularity of PA and mean level of PA across the week was not a significant predictor of mean levels of daily depression symptoms ($B = .22$, $SE(B) = .88$, $z = .25$, $p = .80$).

In summary, there was a significant within-person association between the amount of PA engaged in during any given 24 hour period and depressive symptoms; the more PA (of all kinds) that a person engaged in, the lower their depression score on that day. However, the equivalent association was not found at the between-person level.

Exploratory Analysis

Exploratory analyses were performed to look at whether participants who met national PA guidelines reported lower depression and/or mania scores over the diary period. However, neither mania symptom scores nor depression

symptoms scores were significantly lower in participants who met national PA guidelines ($n = 14$ in week one, $n = 12$ in week two), compared to those who did not ($n = 15$ in week one, $n = 17$ in week two), in either week of the study (see table 4).

Table 4

Mean manic and depressive symptoms by meeting national guidelines.

	Manic symptoms				Depression symptoms			
	Met guidelines	Didn't meet guidelines	<i>t</i>	<i>p</i>	Met guidelines	Didn't meet guidelines	<i>t</i>	<i>p</i>
	M (SD)	M (SD)			M (SD)	M (SD)		
Week 1	65.20 (67.50)	87.43 (61.59)	-.93	.36	28.27 (24.92)	52.10 (43.71)	-1.79	.09
Week 2	51.43 (71.19)	84.87 (62.19)	1.34	.19	26.07 (24.44)	54.79 (50.95)	-1.81	.08

Note. Manic and depression symptoms as measured daily on the ISS activation and depression subscale.

Additionally, exploratory analysis was performed to investigate whether participants' habitual PA was correlated with mean daily depression and manic scores, however, habitual PA was neither significantly correlated with mean daily depression scores ($r = -.17$, $p = .37$), nor with mean daily manic symptoms ($r = -.22$, $p = .26$), across the two weeks of the diary phase.

Discussion

To the author's knowledge this is the first study to investigate the daily relationship between manic and depressive symptoms and intensity and duration of physical activity for people with a diagnosis of bipolar disorder. Contrary to our hypotheses, no significant association was found between total

duration of low to moderate or vigorous physical activity and manic symptom scores, either at the within- or the between-person level. This was inconsistent with previous studies that have reported higher levels of physical activity being associated with less manic symptoms (Edenfield, 2007; Hays et al., 2008; Jewell et al., 2015; Sylvia et al., 2011) and some studies reporting associations between physical activity and more manic symptoms (Sylvie et al., 2013a), in addition to the two qualitative studies (Uebelacker et al., 2014 ; Wright et al., 2012) that found physical activity could be both helpful and harmful for manic symptoms.

The null findings are also inconsistent with what would be predicted by the behavioural activation system theory, i.e., that vigorous activity would trigger an excess or sustained activity in the system (Johnson et al., 2000; Nusslock et al., 2007) and therefore be associated with hypomanic/manic symptoms. One possible explanation is that physical activity does not act as a trigger of the behavioural activation system in this client group. However, the study found an association between physical activity and depression on the within-person level, and therefore physical activity could have triggered a relatively mild activation of the behavioural activation system, with antidepressant consequences (Alloy, Nusslock, & Boland, 2015). There is a possibility that there was not much of a goal striving component to the physical activity participants engaged in, but if there had been, it might have triggered hyperactivation of the behavioural activation system and therefore manic symptoms. It is important to note however that the current study is limited as a test of the behavioural activation system theory and therefore any assumptions made about this are speculative.

As previously stated, supporting the hypothesis of association between physical activity and depression, a significant association was found at the

within-person level between greater duration of physical activity over a 24 hour period and lower depression scores on that day. This supports the literature on the association between physical activity and depression (e.g. Biddle & Mutrie, 2001), and adds to previous findings within bipolar disorder samples (Edenfield, 2007; Hays et al., 2008; Ng et al., 2007; Sylvia et al., 2011; Sylvia et al., 2013a; Sylvia et al., 2013b; Wright et al., 2012). On a psychological level, it has been suggested that mechanisms for the association between physical activity and depression may be coping self-efficacy, the individual's belief that they can complete a task with the desired outcome (Craft, 2005) and distraction (Stathopoulou & Powers, 2006). On a neurobiological level, it has been suggested this association could be due to the possible homeostatic effect of physical activity on neurobiological dysfunction in bipolar disorder, such as monoamine neurotransmitter systems (including serotonin), in that physical activity increases extracellular serotonin which positively impacts mood (Alsuwaidan & McIntyre, 2009). It is important to note however that the results from the current study show association, and therefore cannot be interpreted as evidence that physical activity reduces depression symptoms. Indeed, it is possible that this represents reverse causality, i.e., that people engage in more physical activity on days when they feel less depressed. Furthermore, a third variable explanation may be possible, such as social activities being correlated with more physical activity and less depressive symptoms, which could generate a negative correlation between physical activity and depression. No support was found at the between-person level for this hypothesis, nor for the hypothesis that the association between total duration of physical activity and daily depression would be moderated by regularity of physical activity. It is important to highlight that statistical power is much higher for the within-person

analysis in this study than the between-person analysis, due to the small sample size but high number of data points for each participant. The coefficients are in the same direction and of similar magnitude for between- and within-person associations, which suggest that it is likely to be a statistical power issue, and so the null between-person findings may represent a Type II error. Alternatively, this could reflect an adaptation effect such that the association between physical activity and lower depressive symptoms is not apparent at the aggregate level even if emerging at the day to day level. It could be that benefits of physical activity on depression become relatively more marginal as people engage in more activity, restricting the size of the between-person relationship between physical activity and depression in this population. This could be further explored in future research, but would require a larger sample size than in the current study.

Exploration of the relationship between physical activity in accordance with national guidelines and mean levels of both manic and depressive symptoms over that week showed that people who met the guidelines reported lower manic and depressive symptoms during that week, but this did not reach significance. Additionally, no significant correlations were found between daily mania and depression scores across the diary period and participant's habitual levels of physical activity. A limitation to these analyses is the small sample size, which meant that statistical power was adequate only to detect large-sized effects.

This study has several other limitations. The majority of recruitment was through Spectrum connect, a voluntary group of participants, limiting the variability in participants and limiting generalisability. Additionally, the way the study was advertised may have biased the type of individuals expressing an

interest in the study, i.e., those who were already interested in physical activity as a way of managing their bipolar disorder symptoms, as well as the minimum requirement of 10 minutes of physical activity per week as advertised in the entry criteria. This is highlighted in the fact that at baseline, 24 out of 29 participants (83%) reported meeting the minimum recommended weekly amount of physical activity in the week preceding the baseline measures, and at a habitual level in terms of days per week in any given week, as measured by the GLTEQ. This is a substantially higher proportion than at a national level, with the British Heart Foundation (2015) reporting that 67% of adult men and 55% of adult women in England meet the recommendations for weekly physical activity. As discussed previously in this paper, studies of people with bipolar disorder have shown that this population has lower levels of physical activity than non-clinical populations and other clinical populations (Gomes et al., 2013; Janney et al., 2014; Kilbourne et al., 2007; Vancampfort et al., 2015), therefore this sample may not be representative of the wider bipolar disorder population. As a result, this study may not represent the true association in the wider bipolar disorder population.

It was not possible to examine any cumulative effect of being physically active over a longer time period on manic or depressive symptoms in this study, but the fact that the majority of participants were meeting the national guidelines for minimum amount of physical activity means that there was not much variability between people's activity levels, which may have contributed to the lack of support for between-person hypotheses. Additionally, there is a potential for intensive observation to have influenced participants' levels of physical activity during the study, in that they may have engaged in more physical activity than usual due to knowing their activity levels were being examined.

Moreover, participants were relatively active and their preconceptions about the relationship between physical activity and mood may have influenced the results. Another limitation was the self-reported nature of this study, with participants self-reporting their physical activity engagement, without an objective measure of the intensity and duration of physical activity. A review by Sallis and Saelens (2000) showed that self-reports of physical activity do not accurately reflect the absolute amount of physical activity people engage in, such that people tend to overestimate the amount of exercise they do, particularly with regards to vigorous activity. The fact that the current study did not use objective measures of physical activity further limits the findings presented. The diary was completed several hours after the physical activity engagement so it is likely to be biased by error in recall or current mood state in terms of how participants reported their physical activity. Future studies could consider using a pedometer or an app on a smartphone in addition to self-reports in order to complete a more accurate analysis of the relationship between different intensities and total time of physical activity on mood symptoms.

A further limitation of this study was the lack of specificity of which type of physical activity participants were engaging in. This would have allowed for a more thorough analysis of the specific features of physical activity that might make it more or less beneficial with respect to particular mood states, beyond the intensity and duration of physical activity. In particular, this would have allowed for exploration of the potential impact of the rhythmicity of physical activity. In Wright and colleagues' study (2012), rhythmic physical activity was reported to be favoured over physical activity that did not permit a repetitive, regular rhythm. Rhythmic physical activity such as walking, swimming, rowing,

cycling and running provides a predictable repetitiveness and structure, which participants in the study reported to have a calming effect during episodes of hypomania or mania. Future research could explore this anecdotal effect using quantitative measures.

The analysis around regularity of physical activity was limited due to a lack of measures of time of day when participants had engaged in physical activity, with days between activities calculated, but no analysis of variability in terms of time of day was possible. The lack of timing information resulted in a coarse measure of regularity. It has been suggested that physical activity can mediate circadian phase shifts in the general population (Edwards, Reilly & Waterhouse, 2009) and markers of circadian rhythms have been found to be disrupted for people with bipolar disorder (Jones et al., 2005; Jones, 2001, McKenna et al., 2014). Therefore, future research could expand on this by examining variability of both time of day and time or days between physical activity occurrences, as well as other factors (zeitgebers) related to social and biological rhythm, such as sleep and meals, to examine whether regularity of physical activity can be helpful to maintain regularity in these rhythms.

As well as the above limitations, there were also a number of strengths to this study. First, the longitudinal design allowed a more accurate observation of mood and engagement in physical activity than existing literature, which has predominantly looked at cross-sectional associations. Second, the study utilised structured, validated and reliable measures of mood and physical activity. Third, the author separated different intensities of physical activity to investigate if manic symptoms were differentially associated with these, as has been suggested in previous studies. Fourth, the use of the SCID interview provided rigorous assessment of BD diagnosis.

Conclusions

The findings from this study do not provide support for the hypothesis that different amounts and intensities of physical activity are associated with manic symptoms in people with bipolar disorder. Furthermore, the findings do not support an association between vigorous physical activity and manic symptoms as expected from the behavioural activation system theory. The only significant result was the association between depressive symptoms and total amount of physical activity at the within-person level, in that participants reported lower depressive symptoms on days they engaged in physical activity than on days they did not engage in physical activity. Considering the limitations highlighted, further research is warranted, particularly using objective measures of physical activity, distinguishing further between the different types of physical activity and following mood symptoms and levels of physical activity over a longer period of time.

The results from this study should be interpreted in the context of the limitations outlined, and this study cannot provide recommendations with regards to physical activity interventions for people with bipolar disorder. However, from a clinical perspective, participants in this study did report fewer depressive symptoms on days they engaged in physical activity, and the physical health benefits of physical activity are undisputed. It is worth noting that although people did not report significantly more manic symptoms on days they engaged in vigorous physical activity in the current study, due to previous research reporting inconsistent findings with regards to this, people with bipolar disorder and professionals working with them may need to remain cautious and modify any physical activity engagement depending on mood state at the time.

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Appendices

Appendix A – Power Analysis Calculations

For the within-person components of hypotheses 1, 3 and 4, the critical factor was the number of days (Bolger, Davis, & Rafaeli, 2003). When estimating the number of participants needed for recruitment, the premise was that people would complete a mean of at least 10 out of 14 days. Assuming 40 people would be recruited and that 10 people would not complete the study, this would provide data for 300 days. To calculate the effective sample size, a correction was made for the nesting of days within persons, depending on the intra-class correlation (ICC) for outcome variables, which was estimated at .30. From this, the design effect was calculated (Kish, 1965) to be 3.7 [$= 1+(x-1)*ICC$], where x = mean number of days per person (i.e., 10), with the effective sample size being $300/3.7 = 81$. Using the statistical package G*Power (Faul, Erdfelder, Buchner, & Lang, 2009), it was found that this effective sample size of 81 (from 30 completing participants) would provide .80 power to detect a medium sized effect ($r = .30$) for within-person daily diary associations, so 40 participants were recruited.

Power calculations for the between-person components of hypotheses 1, 3 and 4, based on a medium sized between-person correlation ($r = .30$), revealed that power of .80 for alpha = .05 would require 81 participants. This was based on the absence of comparable research, and the fact that under these circumstances it is reasonable to look for a medium-sized effect (Cohen, 1992). Power calculations for the between-person hypotheses 2, 2a, 5 and 5a, based on the hypothesised predictor explaining a medium sized $f^2 = .15$ (i.e., 15% of the unexplained variance in the outcome), revealed that power of .80 would require 55 participants.

Power calculations were also done for the exploratory analysis using G*Power. The effect size used for these hypotheses was based on the available literature on the effects of PA on depression (Rethorst et al., 2009), due to lack of studies including effect sizes for samples of people with BD. Rethorst and colleagues found that $g = -0.80$, so the formula $r = d / (\sqrt{d^2 + 4})$ in which d is approximately equal to g , was used. For 80% power, with an effect size of $r = .37$, alpha of .05, 52 participants would be required to test these hypotheses. Due to difficulties in recruiting such a high number of participants in the time available for this study and the strength of the diary method for examining within-person relationships, the between-person hypotheses were exploratory, with an expectation that they may be underpowered.

Appendix B – NHS Ethics Documentation**Health Research Authority**

NRES Committee South West - Frenchay

Level 3, Block B

Whitefriars

Levens Mead,

Bristol BS1 2NT

Email: nrescommittee.southwest-frenchay@nhs.net

Telephone: 0117 342 1335

Fax: 0117 342 0445

27 May 2015

Mrs Helena Blowers
32 Hallett Road
Castle Cary
Somerset
BA7 7LG

Dear Mrs Blowers

Study title : Relationship between physical activity, goal pursuit and mood in Bipolar disorder
REC reference: 15/SW/0069
IRAS project ID: 170945

Thank you for your response. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 15 May 2015

Documents received

The documents received were as follows:

Document	Version	Date
Participant information sheet (PIS) [Participant information sheet for BD group]	1.2	19 May 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Copies of advertisement materials for research participants	1	
Copies of advertisement materials for research participants (controls)	1	
Covering letter on headed paper		
Covering letter on headed paper	1.0	28 April 2015
Evidence of Sponsor Insurance or Indemnity (non NHS Sponsors only)		08 August 2015
GP/consultant information sheets or letters [Information for CMHT]	1.1	21 April 2015
GP/consultant information sheets or letters [Information sheet for GP]	1.0	20 April 2015

Interview schedules or topic guides for participants		
Ins. Cert.		01 August 2014
IRAS Checklist XML [Checklist_26022015]		26 February 2015
IRAS Checklist XML [Checklist_06032015]		06 March 2015
IRAS Checklist XML [Checklist_06032015]		06 March 2015
IRAS Checklist XML [Checklist_26042015]		26 April 2015
IRAS Checklist XML [Checklist_29042015]		29 April 2015
Letter from funder		
Letter from sponsor		23 February 2015
Letter from statistician (undated)		
Letters of Invitation to participant (Poster)	1	23 December 2014
Letters of Invitation to participant (covering letter)		undated
Letters of Invitation to participant	1.0	03 January 2015
Participant consent form [Consent form BD group]	1.1	21 April 2015
Participant consent form [Consent form control group]	1.0	21 April 2015
Participant Information sheet (PIS) [Control group Information sheet]	1.1	20 April 2015
Participant Information sheet (PIS) [Participant Information sheet for BD group]	1.2	19 May 2015
REC Application Form [REC_Form_26022015]		26 February 2015
Referee's report or other scientific critique report (for HB)		27 October 2014
Referee's report or other scientific critique report (for HM)		27 October 2014
Research protocol or project proposal	n/a	undated
Summary CV for Chief Investigator (CI) Helena Blowers		
Summary CV for student (HM)		
Summary CV for supervisor (student research)		
Summary, synopsis or diagram (flowchart) of protocol in non technical language	1	06 January 2015
Validated questionnaire (BIS/BAS)		
Validated questionnaire – Daily diary measures	1	6 January 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/8/W/0069	Please quote this number on all correspondence
-------------	--

Yours sincerely



Naazneen Nathoo
REC Manager

Copy to: Mrs Gail Seymour

Appendix C – University of Exeter Ethics Documentation

apache@exeter.ac.uk

on behalf of

Ethics Approval System <D.M.Salway@exeter.ac.uk>

Reply all

To:

Blowers, Helena;

02/06/2015

Inbox

Ethical Approval system

Your application (2015/929) entitled Physical activity, goals, and mood in bipolar disorder has been accepted

Please visit <http://www.exeter.ac.uk/staff/ethicalapproval/>

Please click on the link above and select the relevant application from the list

Appendix D – Risk Assessment Protocol for the Mood Disorder Centre**MOOD DISORDERS CENTRE****PROTOCOL FOR ASSESSING AND REPORTING RISK**

The following principles and procedures govern risk assessment and reporting in the Mood Disorders Centre (MDC). The MDC does not manage risk.

General principles

MDC clinical academic faculty are responsible for risk assessment in their research programmes. This includes ensuring that staff, students and interns working with them receive adequate induction and training prior to participant contact in which risk could be disclosed and ongoing supervision during their research work.

Many of the research projects in the MDC will include supplementary and more detailed protocols for risk assessment.

The AccePT Clinic has its own risk protocol.

General procedures

Background training materials are available on the shared directory. All staff should attend training in the use of this protocol as soon as is reasonably possible and attend training normally at least annually. If they undertake any work where risk may be an issue prior to receiving formal training, it is the PI's responsibility to ensure that they have reviewed all the materials and have received bespoke training.

Whenever any significant risk is identified a risk assessment should be completed and (counter-) signed by the responsible member of staff. If at all possible this should be done at the time of the assessment, or as soon afterwards as possible. This record should be kept on file in line with the Centre's or study's data storage procedures.

Any significant, but not imminent risk should be reported to the person's GP and, if appropriate, other health care professionals, as soon as is reasonably possible.

For research outside of the local area, PIs / supervisors should familiarise themselves with the local providers' risk procedures, and researchers should hold the relevant contact details needed in the case of immediate risk.

When clinical academic staff are away from the Centre they should ensure appropriate cover is arranged for any risk issues that might arise in their absence.

When conducting telephone interviews in which risk may be disclosed, the interviewer should establish the telephone number and location of the participant at the start of the call, and clarify the boundaries of confidentiality (as per trial / clinic protocol).

Exeter emergency contact numbers

- Crisis Resolution Home Treatment Team (East and Mid Devon) 07968 845048

Please note, this number is to make an urgent referral to the Crisis Team and should not be given out to participants / clients / members of the public under any circumstances. The participant's / client's GP can also make an urgent referral to the Crisis Team and should be the first port of call.

- Exeter Accident and Emergency Department
This is located at the Royal Devon and Exeter Hospital (Wonford), Barrack Road, Exeter, EX2 5DW
- Student Health Services – The Streatham Campus Student Health Centre is located in Reed Mews and is run solely for students. Phone: 01392 676606 (Streatham) or, 01392 211511 (St Luke's)

If you need a doctor urgently out of Student Health Centre opening hours, phone the Devon Doctors on Call Patient line: 0845 6710 270

Exploring Risk in Research Interviews

THOUGHTS

"I see that you've said / you mentioned that..... These are thoughts / feelings that people suffering from depression often have, but it's important to make sure you are receiving the right kind of support. So I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

- | | | |
|---|---|----------|
| 1 | Do you know how you would kill yourself?
If yes – details | Yes / No |
|---|---|----------|

2 Have you made any actual plans to end your life? Yes / No
 If **yes** – details

ACTIONS

3 Have you made any actual preparations to kill yourself? Yes / No
 If **yes** – details

4 Have you ever attempted suicide in the past? Yes / No
 If **yes** – details

PREVENTION

5 Is there anything stopping you killing or harming yourself at the moment? Yes / No
 If **yes** – details

6 Do you feel that there is any immediate danger that you will harm or kill yourself? Yes / No

Details:

FOLLOW-UP FROM PREVIOUS CONTACT

7 **If Action B was enacted at previous assessment and level B risk is identified at current assessment:** Last time we met I suggested that you spoke to your GP about these thoughts, and I also wrote to your GP about this. Have you been able to speak with your GP about these thoughts since we last met? Yes / No

See risk table overleaf for appropriate actions

Researcher Risk Protocol To be used following any indication of risk from questionnaire items, responses to interview questions or any other sources. Look at answers from the sheet to determine the level of risk, A B or C:

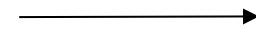
Actions by Researcher

Tell Participant

All answers 'no' apart from Q5 'yes':



A



I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings (as per trial protocol).

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6



B1

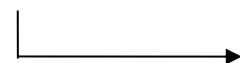


Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings. (as per trial protocol).

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 **and** 'no' to Q7

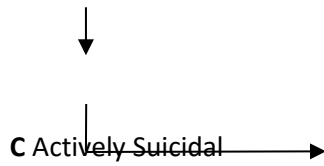


B2



I think it's important that your GP knows how difficult things are for you right now. I will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings. (as per trial protocol). N.B: telephone call to GP to be followed up by letter. The letter should include the statement "the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan."

Scoring 'no' to Q5 or 'yes' to Q6



I am very concerned about your safety at this moment, I am not a clinician but I would like you to talk to one right now. I am going to make some telephone calls now to your GP Care Co-ordinator / Crisis Management team/the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.

Action to take in the case of immediate risk:

Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up**. Follow your trial's chain of supervisory clinical contact in order to involve supervisory clinician right away. Then either yourself or the supervisory clinician* should follow the chain of contact below:

1. **GP / out of hours GP; if not**
2. **Crisis team; if not**
3. **Call ambulance; if this does not result in ambulance attending** 4. **Clinician accompanies to A&E (by taxi rather than private car)**

**Individual projects should determine in advance whether clinician or researcher (with clinician support) enacts steps 1-4*

Risk Report

Patient name: _____

DOB: _____

*Suicide risk information:**Include whether the participant has reported any of the following:*

- *History of previous suicide attempts*
- *Current suicidal ideation*
- *Relevant inventory scores (e.g., BDI item 9)*
- *Suicide plans / preparations*
- *Protective factors*
- *Regular contact with GP?*

Date reported: ___/___/___

Additional notes / actions taken:

*As part of the MDC risk protocol, suicide risk is **managed** by the patient's GP.*

Date action taken: ___/___/___

Researcher / assessor: _____ Signed: _____ Date:
___/___/___

Supervisor: _____ Signed: _____ Date:
___/___/___

Appendix E – The Patient Health Questionnaire (PHQ-9)

PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things				
Feeling down, depressed, or hopeless				
Trouble falling or staying asleep, or sleeping too much				
Feeling tired or having little energy				
Poor appetite or overeating				
Feeling bad about yourself — or that you are a failure or have let yourself or your family down				
Trouble concentrating on things, such as reading the newspaper or watching television				
Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual				
Thoughts that you would be better off dead or of hurting yourself in some way				

If you checked off any problems, how difficult have those problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
 Somewhat difficult
 Very difficult
 Extremely difficult

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

0 100
Not at all Very much so
Rarely Much of the time
Today my thoughts are going fast.

0 100
Not at all Very much so
Rarely Much of the time
Today it seems like nothing will ever
work out for me.

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

0 100
Not at all Very much so
Rarely Much of the time
Today I feel as if the world
is against me.

0 100
Not at all Very much so
Rarely Much of the time
Today I feel "sped up" inside.

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

0 100
Today I feel argumentative.

2

Not at all Very much so
Rarely Much of the time

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

0 100
Depressed Normal Manic
Down High
Today I feel:

Appendix G – The Altman Self-Rating Mania Scale (ASRM)**Instructions:**

1. There are 5 statements groups on this questionnaire: read each group of statements carefully.
2. Choose the one statement in each group that best describes the way you have been feeling for the past week.
3. Check the box next to the number/statement selected.
4. Please note: The word "occasionally" when used here means once or twice; "often" means several times or more and "frequently" means most of the time.

Question 1

- 0 I do not feel happier or more cheerful than usual.
- 1 I occasionally feel happier or more cheerful than usual.
- 2 I often feel happier or more cheerful than usual.
- 3 I feel happier or more cheerful than usual most of the time.
- 4 I feel happier or more cheerful than usual all of the time.

Question 2

- 0 I do not feel more self-confident than usual.
- 1 I occasionally feel more self-confident than usual.
- 2 I often feel more self-confident than usual.
- 3 I feel more self-confident than usual.
- 4 I feel extremely self-confident all of the time.

Question 3

- 0 I do not need less sleep than usual.
- 1 I occasionally need less sleep than usual.
- 2 I often need less sleep than usual.
- 3 I frequently need less sleep than usual.
- 4 I can go all day and night without any sleep and still not feel tired.

Question 4

- 0 I do not talk more than usual
- 1 I occasionally talk more than usual.
- 2 I often talk more than usual.
- 3 I frequently talk more than usual.
- 4 I talk constantly and cannot be interrupted

Question 5

- 0 I have not been more active (either socially, sexually, at work, home or school) than usual.
- 1 I have occasionally been more active than usual.
- 2 I have often been more active than usual
- 3 I have frequently been more active than usual.
- 4 I am constantly active or on the go all the time. *Permission for use granted by EG Altman, MD*

Appendix H – Godin Leisure-Time Exercise Questionnaire (GLTEQ)

Godin Leisure-Time Exercise Questionnaire

1. During a typical 7-Day period (a week), how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
<p>a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)</p>	_____
<p>b) MODERATE EXERCISE (NOT EXHAUSTING) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)</p>	_____
<p>c) MILD EXERCISE (MINIMAL EFFORT) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)</p>	_____

2. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. <input type="checkbox"/>	2. <input type="checkbox"/>	3. <input type="checkbox"/>

Appendix I – The International Physical Activity Questionnaire (IPAQ)**INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE
(October 2002)****LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT****FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)**

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

Yes

No →

Skip to PART 2: TRANSPORTATION

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ **days per week**

No vigorous job-related physical activity →

Skip to question 4

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ **hours per day**

_____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

_____ **days per week**

No moderate job-related physical activity →

Skip to question 6

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

No job-related walking



Skip to PART 2: TRANSPORTATION

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

No traveling in a motor vehicle



Skip to question 10

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

No bicycling from place to place



Skip to question 12

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
 _____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

No walking from place to place



***Skip to PART 3:
 HOUSEWORK, HOUSE
 MAINTENANCE, AND
 CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
 _____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

No vigorous activity in garden or yard



Skip to question 16

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
 _____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

No moderate activity in garden or yard



Skip to question 18

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
 _____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

No moderate activity inside home



**Skip to PART 4:
 RECREATION, SPORT
 AND LEISURE-TIME
 PHYSICAL ACTIVITY**

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
 _____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

No walking in leisure time



Skip to question 22

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
 _____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

No vigorous activity in leisure time



Skip to question 24

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

No moderate activity in leisure time



**Skip to PART 5: TIME
SPENT SITTING**

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ **hours per day**
_____ **minutes per day**

This is the end of the questionnaire, thank you for participating.

Appendix J – The IPAQ Short Form**INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE**

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active **today**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 24 hours**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 24 hours**, did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **Yes**

No vigorous physical activities → **Skip to question 3**

2. How much time did you spend doing **vigorous** physical activities in the **last 24 hours**?

_____ **hours**

_____ **minutes**

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 24 hours**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 24 hours**, did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **Yes**

No moderate physical activities → **Skip to question 5**

4. How much time did you spend doing **moderate** activities in the **last 24 hours**?

_____ **hours**
_____ **minutes**

5. Don't know/Not sure

Think about the time you spent **walking** in the **last 24 hours**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 24 hours**, did you **walk** for at least 10 minutes at a time?

_____ **Yes**

No walking → **Skip to question 7**

6. How much time did you spend **walking** in the **last 24 hours**?

_____ **hours**
_____ **minutes**

Don't know/Not sure

The last question is about the time you spent **sitting** during the **last 24 hours**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

6. During the **last 24 hours**, how much time did you spend **sitting**?

_____ **hours**
_____ **minutes**

Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix K – Development of Materials

In order to develop the online diaries in a user-friendly way and to minimise burden placed on participants, two members of the Lived Experience Group (LEG), a patient advisory group, in Exeter were consulted. This involved the members considering the feasibility of filling in the proposed measures once per day and the most appropriate order for the measures. One of the LEG members then met the researcher to discuss their thoughts around this and to consult on the information sheet, consent form and advertisement for recruitment.

Appendix L – Information Sheets for Organisations**Study of Bipolar disorder, physical activity and goal pursuit****Information Sheet**

Our names are Helena Blowers and Hannah Moakes and we are Trainee Clinical Psychologists. We are doing a study exploring two separate aspects of Bipolar disorder i) the relationship between physical activity and mood, and ii) the pursuit of goals and mania. We are also interested in how these two areas (physical activity and goal pursuit) relate to each other. Both of these studies could influence the development of interventions for individuals with Bipolar disorder.

We would like to ask your help with regards to recruitment, by putting up this advertisement where you see your clients. Additionally, if you have clients who you feel would be interested in taking part in the study, we would be grateful if you could pass on the participant information sheet to them.

Aims of study

This study aims to look at the physical activity levels of individuals with Bipolar disorder, and how this may affect their symptoms of mania and depression. It also aims to look at the goals set by individuals with Bipolar disorder and how goal pursuit relates to symptoms of mania.

What is involved?

Participants will be taking part in an initial interview that will be conducted over the phone, which asks about current and previous Bipolar symptoms. This interview will take approximately 1 hour, but timing of the interview would be agreed with the participant beforehand. The initial interview will be audio recorded to enable researchers to listen to it again for accuracy of the researcher. The recordings will be stored in a password protected computer and only accessible to the researchers. The recordings will not be used for any other research projects in the future.

Following the telephone interview, we will confirm whether or not participants are eligible to take part in the study. If they are eligible to take part, we would send them a link to questionnaires that would be filled in anonymously. Alternatively, for participants who do not have access to the internet, we can send the questionnaires in the post with a prepaid envelope to return them to us. Participants will also be asked to identify two goals that they plan to work towards during the duration of the study. We estimate these questionnaires should take approximately 30 minutes to complete, but could take longer.

Once this has been completed participants would be filling in daily diaries, at the end of each day, for two weeks. This will be done online, or for participants who don't have access to the internet this can be done on paper. At the end of week one and end of week two participants will be asked to complete two additional short questionnaires.

The diaries should take approximately 12- 15 minutes to complete each day, but could take longer. This will ask about the physical activity/exercise participants have done that day, rate their mood, feelings in general to life events and report on goal progress.

Are there any risks?

Taking part in these studies will require participants to commit to fill in the daily diaries each evening for two weeks. Additionally, they will need to participate in the phone interview, where they may be asked questions that they find difficult or upsetting. They will however be given the opportunity to discuss this with the researchers, and will be encouraged to contact their GP or care co-ordinator if they find any of the tasks upsetting. We will notify participants' GP of their participation in this study. This is to ensure that they receive the best possible care and support if their symptoms worsen during the course of the study.

Contact for further information

The research workers on this study are Helena Blowers and Hannah Moakes. They can be contacted on :

Mood Disorders Centre
School of Psychology
University of Exeter
Exeter EX4 4QG
01392 264645 / ha285@exeter.ac.uk ; hm349@exeter.ac.uk

If you have any further questions please feel free to talk to Kim Wright or Nick Moberly, the supervisors on this project:

Dr. Kim Wright
Clinical Psychologist
Mood Disorders Centre
School of Psychology
University of Exeter
Exeter EX4 4QG
01392 265227
K.A.Wright@exeter.ac.uk

Dr Nick Moberly
Mood Disorders Centre
School of Psychology
University of Exeter
Exeter EX4 4QG
01392724656
N.J.Moberly@exeter.ac.uk

We would like to thank you for taking the time to read this information sheet.

Sincerely

Helena Blowers & Hannah Moakes

Appendix M – Participant Information Sheet**Study of Bipolar disorder, physical activity and goal pursuit****Participant Information Sheet**

Our names are Helena Blowers and Hannah Moakes and we are Trainee Clinical Psychologists. We are doing a study exploring two separate aspects of Bipolar disorder i) the relationship between physical activity and mood, and ii) the relationship between the pursuit of goals and mania. We are also interested in how physical activity and goal pursuit relate to each other. Both of these studies could influence the development of interventions for individuals with Bipolar disorder.

We would like to invite you take part in this study, but before you decide whether or not you would like to participate, please read this information sheet carefully. Please feel free to contact us, at the contact details given below, if you have any further questions after reading this information sheet.

Aims of study

This study aims to look at the physical activity levels of individuals with Bipolar disorder, and how this may be associated with their symptoms of mania and depression. It also aims to look at the goals set by individuals with Bipolar disorder and how goal pursuit relates to symptoms of mania.

What is involved?

Should you wish to participate, you will be taking part in an initial interview that will be conducted over the phone, which asks about your current and previous Bipolar symptoms. This interview will take approximately 1 hour of your time, but timing of the interview would be agreed with you beforehand. The initial interview will be audio recorded to enable researchers to listen to it again to ensure accuracy of the researcher. The recordings will be stored in a password protected computer and only accessible to the researchers. The recordings will not be used for any other research projects in the future.

Following the interview, we would inform you whether or not you are eligible to take part in the study. If you are eligible for this study, this is not a clinical diagnosis of Bipolar disorder, and if you wish, you can consult your GP for further advice. If you decide to take part we will then send you a link to questionnaires that you would fill in anonymously. Alternatively, if you do not have access to the internet, we can send you the questionnaires in the post with a prepaid envelope to return them to us. We estimate these questionnaires should take approximately 30 minutes to complete, but could take longer.

Also, you will be asked to identify two goals that you plan to work towards during the duration of the study. You will be asked to identify one achievement goal and one social influence goal. Along with this information sheet you will find some examples of

goals that might help you to generate your own personal goals. There is also a goal setting form that you will be asked to complete if you decide to participate in the study.

Once these have been completed you would be filling in daily diaries, at the end of each day, for two weeks. This will be done online, or for participants who don't have access to the internet this can be done on paper. At the end of week one and end of week two you will be asked to complete two additional questionnaires.

The diaries should take approximately 12- 15 minutes to complete each day, but may take longer. You will be asked about the physical activity/exercise you have done that day, rate your mood, feelings in general to life events and report on goal progress.

All your personal details will be kept confidential and stored in a secure place, and when the results from the study are written up, it will not include your name or any other identifiable information, just information about the range of participants in the studies, such as average age, gender and the results of questionnaires and diaries.

Why am I being asked to take part?

You have been invited to take part in this study because you are someone who has been diagnosed with Bipolar Disorder, or someone who thinks that this diagnosis may fit with your experiences.

Do I have to take part?

It is completely up to you whether or not you take part. If you decide you would like to take part, please contact us via the below details and we will send you a Consent form for you to fill in and return without cost. We will also arrange a time to ring you to complete the phone interview and send you a link to the questionnaires. If you decide to take part, you will still be able to end your participation at any time, without having to give a reason.

Are there any risks?

Taking part in these studies will require you to commit to fill in the daily diaries each evening for two weeks. Additionally, you will need to participate in the phone interview, where you will be asked questions that you may find difficult or upsetting. You will however be given the opportunity to discuss this with the researchers, and we will encourage you to contact your GP or care co-ordinator if you find any of the tasks upsetting.

Are there any benefits?

By taking part in these studies you would be helping us build the evidence base for Bipolar disorder research and possibly contributing to interventions being developed in the future. As a thank you for your time, we will send you a gift voucher following your completion in the study.

Where will the results be shown?

The researchers aim to publish the work in an academic journal and to report the findings at an academic conference. We will also give all participants who request one a summary of the results of the research, and will give this summary to the

organisations who assisted with advertising our study. Your identity will not be revealed in any report or publication. Generally our research is reported on the University of Exeter Mood Disorders Centre website at: <http://www.centres.ex.ac.uk/mood>.

Will my taking part in this study be kept confidential?

We will notify your GP of your participation in this study. This is to ensure that he / she is aware of what this will involve for you and can take this into account if you have contact with one another during or after the study. We will also inform Spectrum that you are taking part, to ensure they can respond to any queries that may arise from you.

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that is collected from the interview will have your name and address removed so that you cannot be recognised from it. We may include quotations from interviews within reports of the findings. However these will be anonymous and it will not be possible to identify from whom they came. Confidentiality will be broken only in exceptional circumstances, for example if it is felt by the researcher that you or someone else may be at immediate risk. In such circumstances it may be necessary for us to inform another person(s), for example your GP, but as far as possible we will do this in discussion with you.

Contact for further information

If you would like any independent advice about participating in research you can contact Folk.us at www.projects.ex.ac.uk/folk.uk/, PALS the local Patient Advice and Liaison Service, or INVOLVE at www.invo.org.uk/.

[If at any time during the study you wish to make a complaint then you can contact PALS, or Dr Tim Kurz, at T.R.Kurz@exeter.ac.uk \(Psychology Research Ethics Committee, University of Exeter\).](#)

The research workers on this study are Helena Blowers and Hannah Moakes. They can be contacted on :

Mood Disorders Centre
School of Psychology
University of Exeter
Exeter EX4 4QG
01392 264645 / ha285@exeter.ac.uk ; hm349@exeter.ac.uk

If you have any further questions please feel free to talk to Kim Wright or Nick Moberly, the supervisors on this project:

Dr. Kim Wright
Clinical Psychologist
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01392 265227
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Dr Nick Moberly
Mood Disorders Centre
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01392724656
N.J.Moberly@exeter.ac.uk

We would like to thank you for taking the time to read this information sheet.

Sincerely

Helena Blowers & Hannah Moakes

Appendix N – Consent Form

Centre Number:

Study Number:

CONSENT FORM

Title of Project: Physical Activity, Goals and Mood in Bipolar Disorder

Name of Researcher:

Please initial all

boxes

1	I confirm that I have read and understand the information sheet dated 19.5.15 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<input type="checkbox"/>
2	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.	<input type="checkbox"/>
3	I understand that data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>
4	I agree to provide my contact details and GPs details in order to allow researchers to notify my GP of my participation and respond appropriately in the unlikely event of an immediate risk to me or to someone else.	<input type="checkbox"/>

In addition you may indicate your preference below with respect to two further items, by initialling the box if you agree to the item

5	I agree to my interview to be audio-taped for research and data analysis purposes	<input type="checkbox"/>
6	I would like to be sent information about the results of the research when they are available	<input type="checkbox"/>

Name of Participant

Date

Signature

Name of Person taking consent.

Date

Signature

Appendix O – Data Screening

All variables were analysed for parametric assumptions of normality and homoscedasticity using histograms and the Kolmogorov-Smirnov test of normality. All variables were screened for univariate outliers by calculating standardised scores (z-scores), with outliers identified as scores more extreme than $\pm 3.29 \times SD$. These procedures identified that one participant was a significant outlier due to the amount of habitual vigorous PA reported at baseline; however this had been established at interview to be due to the participant's occupation. Therefore the participant's results were included in the analysis; however the amount of vigorous PA was reduced to equal $3.29 SD$ to reduce the influence of this person's data in the analyses. Furthermore, as recommended in scoring guidelines for the IPAQ (see appendix P), to normalise the usually skewed distribution of levels of activity, the scores of participants who had reported over 180 minutes in each level of activity over the week (low, moderate or vigorous) were reduced to 180 minutes per activity when calculating baseline PA levels.

The distributions of daily mania and depression scores were significantly skewed and to correct this, participants' manic and depression scores were \log_{10} transformed. This also removed all outliers. Furthermore, the distribution of daily amount and mean amount of all intensities of PA was significantly skewed; therefore they were also \log_{10} transformed. Following this and given that in terms of within-person analysis the study was adequately powered, histograms of residuals after analyses indicated that assumptions of normality met requirements for parametric testing.

Appendix P – Relevant Guidelines for Data Processing and Analysis of the IPAQ

4.1 Continuous Variables

Data collected with IPAQ can be reported as a continuous measure. One measure of the volume of activity can be computed by weighting each type of activity by its energy requirements defined in METs to yield a score in MET–minutes. METs are multiples of the resting metabolic rate and a MET-minute is computed by multiplying the MET score of an activity by the minutes performed. MET-minute scores are equivalent to kilocalories for a 60 kilogram person. Kilocalories may be computed from MET-minutes using the following equation: MET-min x (weight in kilograms/60 kilograms). MET-minutes/day or MET-minutes/week can be presented although the latter is more frequently used and is thus suggested. Details for the computation for summary variables from IPAQ short and long forms are detailed below. As there are no established thresholds for presenting METminutes, the IPAQ Research Committee propose that these data are reported as comparisons of median values and interquartile ranges for different populations.

4.2 Categorical Variable: Rationale for Cut Point Values

There are three levels of physical activity proposed to classify populations:

1. Low
2. Moderate
3. High

The algorithms for the short and long forms are defined in more detail in Sections 5.3 and 6.3, respectively. Rules for data cleaning and processing prior to computing the algorithms appear in Section 7.

Regular participation is a key concept included in current public health guidelines for physical activity. Therefore, both the total volume and the number of days/sessions are included in the IPAQ analysis algorithms. The criteria for these levels have been set taking into account that IPAQ asks questions in all domains of daily life, resulting in higher median MET-minutes estimates than would have been estimated from leisure-time participation alone. The criteria for these three levels are shown below. Given that measures such as IPAQ assess total physical activity in all domains, the “leisure time physical activity” based public health recommendation of 30 minutes on most days will be achieved by most adults in a population. Although widely accepted as a goal, in absolute terms 30 minutes of moderate-intensity activity is low and broadly equivalent to the background or basal levels of activity adult individuals would accumulate in a day. Therefore a new, higher cutpoint is needed to describe the levels of physical activity associated with health benefits for measures such as IPAQ, which report on a broad range of domains of physical activity.

‘High’

This category was developed to describe higher levels of participation. Although it is known that greater health benefits are associated with increased levels of activity there is no consensus on the exact amount of activity for maximal benefit. In the absence of any established criteria, the IPAQ Research Committee proposes a measure which equates to approximately at least one hour per day or more, of at least moderate-intensity activity above the basal level of physical activity. Considering that basal activity may be considered to be equivalent to approximately 5000 steps per day, it is proposed that “high active” category be considered as those who move at least 12,500 steps per day, or

the equivalent in moderate and vigorous activities. This represents at least an hour more moderate-intensity activity over and above the basal level of activity, or half an hour of vigorous-intensity activity over and above basal levels daily. These calculations were based on emerging results of pedometers studies.

This category provides a higher threshold of measures of total physical activity and is a useful mechanism to distinguish variation in population groups. Also it could be used to set population targets for health-enhancing physical activity when multidomain instruments, such as IPAQ are used.

'Moderate'

This category is defined as doing some activity, more than the low active category. It is proposed that it is a level of activity equivalent to "half an hour of at least moderate-intensity PA on most days", the former leisure time-based physical activity population health recommendation.

'Low' This category is simply defined as not meeting any of the criteria for either of the previous categories.

5. Protocol for IPAQ Short Form

5.1 Continuous Scores

Median values and interquartile ranges can be computed for walking (W), moderate intensity activities (M), vigorous-intensity activities (V) and a combined total physical activity score. All continuous scores are expressed in MET-minutes/week as defined below.

5.2 MET Values and Formula for Computation of MET-minutes/week

The selected MET values were derived from work undertaken during the IPAQ Reliability Study undertaken in 2000-2001³. Using the Ainsworth et al. Compendium (*Med Sci Sports Med* 2000) an average MET score was derived for each type of activity. For example; all types of walking were included and an average MET value for walking was created. The same procedure was undertaken for moderate-intensity activities and vigorous-intensity activities. The following values continue to be used for the analysis of IPAQ data: Walking = 3.3 METs, Moderate PA = 4.0 METs and Vigorous PA = 8.0 METs. Using these values, four continuous scores are defined:

Walking MET-minutes/week = 3.3 * walking minutes * walking days

Moderate MET-minutes/week = 4.0 * moderate-intensity activity minutes * moderate days

Vigorous MET-minutes/week = 8.0 * vigorous-intensity activity minutes * vigorous-intensity days

Total physical activity MET-minutes/week = sum of Walking + Moderate + Vigorous

METminutes/

week scores.

5.3 Categorical Score

Category 1 Low

This is the lowest level of physical activity. Those individuals who not meet criteria for Categories 2 or 3 are considered to have a 'low' physical activity level.

Category 2 Moderate

The pattern of activity to be classified as 'moderate' is either of the following criteria:

a) 3 or more days of vigorous-intensity activity of at least 20 minutes per day

OR

b) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day

OR

c) 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum Total physical activity of at least 600 MET-minutes/week.

Individuals meeting at least one of the above criteria would be defined as accumulating a minimum level of activity and therefore be classified as 'moderate'. See Section 7.5 for information about combining days across categories.

Category 3 High

A separate category labelled 'high' can be computed to describe higher levels of participation.

The two criteria for classification as 'high' are:

a) vigorous-intensity activity on at least 3 days achieving a minimum Total physical activity of at least 1500 MET-minutes/week

OR

b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes/week.

See Section 7.5 for information about combining days across categories.

5.4 Sitting Question in IPAQ Short Form

The IPAQ sitting question is an additional indicator variable of time spent in sedentary activity and is not included as part of any summary score of physical activity. Data on sitting should be reported as median values and interquartile ranges.

To-date there are few data on sedentary (sitting) behaviours and no well-accepted

thresholds for data presented as categorical levels.

6.2 MET Values and Formula for Computation of MET-minutes

Total Physical Activity Scores

An overall total physical activity MET-minutes/week score can be computed as:

Total physical activity MET-minutes/week = sum of Total (Walking + Moderate + Vigorous) METminutes/week scores.

6.3 Categorical Score

As noted earlier, regular participation is a key concept included in current public health guidelines for physical activity. Therefore, both the total volume and the number of day/sessions are included in the IPAQ analysis algorithms. There are three levels of physical activity proposed to classify populations – 'low', 'moderate', and 'high'. The criteria for these levels are the same as for the IPAQ short [described earlier in Section 4.2]

Category 1 Low

This is the lowest level of physical activity. Those individuals who not meet criteria for Categories 2 or 3 are considered 'low'.

Category 2 Moderate

The pattern of activity to be classified as 'moderate' is either of the following criteria:

d) 3 or more days of vigorous-intensity activity of at least 20 minutes per day

OR

e) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day

OR

f) 5 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 600 MET-minutes/week.

Individuals meeting at least one of the above criteria would be defined as accumulating a moderate level of activity. See Section 7.5 for information about combining days across categories.

Category 3 High

A separate category labelled 'high' can be computed to describe higher levels of participation. The two criteria for classification as 'high' are:

a) vigorous-intensity activity on at least 3 days achieving a minimum Total physical activity of at least 1500 MET-minutes/week

OR

b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes/week.

See Section 7.5 for information about combining days across categories.

7. Data Processing Rules

In addition to a standardized approach to computing categorical and continuous measures of physical activity, it is necessary to undertake standard methods for the cleaning and treatment of IPAQ datasets. The use of different approaches and rules would introduce variability and reduce the comparability of data.

There are no established rules for data cleaning and processing on physical activity. Thus, to allow more accurate comparisons across studies IPAQ Research Committee has established and recommends the following guidelines:

7.1 Data Cleaning

I. Any responses to duration (time) provided in the hours and minutes response option should be converted from hours and minutes into minutes.

II. To ensure that responses in 'minutes' were not entered in the 'hours' column by mistake during self-completion or during data entry process, values of '15', '30', '45', '60' and '90' in the 'hours' column should be converted to '15', '30', '45', '60' and '90' minutes, respectively, in the minutes column.

III. In some cases duration (time) will be reported as weekly (not daily) e.g., VWHRS, VWMINS. These data should be converted into an average daily time by dividing by 7. IV. If 'don't know' or 'refused' or data are missing for time or days then that case is removed from analysis.

Note: Both the number of days *and* daily time are required for the creation of categorical and continuous summary variables

7.2 Maximum Values for Excluding Outliers

This rule is to exclude data which are unreasonably high; these data are to be considered outliers and thus are excluded from analysis. All cases in which the sum total of all Walking, Moderate and Vigorous time variables is greater than 960 minutes (16 hours) should be excluded from the analysis. This assumes that on average an individual of 8 hours per day is spent sleeping. The 'days' variables can take the range 0-7 days, or 8, 9 (don't know or refused); values greater than 9 should not be allowed and those cases excluded from analysis.

7.3 Minimum Values for Duration of Activity

Only values of 10 or more minutes of activity should be included in the calculation of summary scores. The rationale being that the scientific evidence indicates that episodes or bouts of at least 10 minutes are required to achieve health benefits. Responses of less than 10 minutes [and their associated days] should be re-coded to 'zero'.

7.4 Truncation of Data Rules

This rule attempts to normalize the distribution of levels of activity which are usually skewed in national or large population data sets.

In IPAQ short - it is recommended that all Walking, Moderate and Vigorous time variables exceeding '3 hours' or '180 minutes' are truncated (that is re-coded) to be equal to '180 minutes' in a new variable. This rule permits a maximum of 21 hours of activity in a week to be reported for each category (3 hours * 7 days). In IPAQ long – the truncation process is more complicated, but to be consistent with the approach for IPAQ short requires that the variables total Walking, total Moderate intensity and total Vigorous-intensity activity are calculated and then, for each of these summed behaviours, the total value should be truncated to 3 hours (180 minutes). When analysing the data as categorical variable or presenting median and interquartile ranges of the MET-minute scores, the application of the truncation rule will not affect the results. This rule does have the important effect of preventing misclassification in the 'high' category. For example, an individual who reports walking for 10 minutes on 6 days and 12 hours of moderate activity on one day could be coded as 'high' because this pattern meets the '7 day' and "3000 MET-min" criteria for 'high'. However, this uncommon pattern of activity is unlikely to yield the health benefits that the 'high' category is intended to represent.

7.5 Calculating MET-minute/week Scores

Data processing rules 7.2, 7.3, and 7.4 deals first with excluding outlier data, then secondly, with recoding minimum values and then finally dealing with high values. These rules will ensure that highly active people remain classified as 'high', while decreasing the chances that less active individuals are misclassified and coded as 'high'.

Using the resulting variables, convert time and days to MET-minute/week scores [see above Sections 5.2 and 6.2; METS x days x daily time].

Appendix Q – Dissemination Statement

The results of this study will be disseminated to interested parties through feedback, journal publication and presentation.

Dissemination to participants.

As stated on the participant information sheet participants will be informed of the results of the study if they wished to receive this. The NHS research ethics committee and RD&E Research and Development team will be sent a summary of the findings of the study and will be informed that the study is now complete.

Journal Publication

It is expected that the study will be submitted for publication with the Journal of Affective Disorders (Impact factor 3.383).

Presentation

On 13th June 2016, my research findings will be presented to an academic audience, for peer review, as part of the Doctorate in Clinical Psychology at the University of Exeter.

Appendix R – Guidelines for Authors. Journal of Affective Disorders

JOURNAL OF AFFECTIVE DISORDERS

Official Journal of the International Society for Affective Disorders

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