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Research paper

BI-REAL: A 12-session DBT skills group intervention adapted for bipolar disorder – A feasibility randomised pilot trial

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ABSTRACT

International guidelines endorse psychological treatment for Bipolar Disorder (BD); however, the absence of a recognised gold-standard intervention requires further research. A Dialectical Behaviour Therapy (DBT) skills group intervention with 12 sessions was developed. This pilot randomised controlled trial (RCT) aims to evaluate the feasibility, acceptability, and outcomes variance of Bi-REAL – Respond Effectively, Assertively, and Live mindfully, tailored for individuals with BD, in preparation for a future RCT.

Methods: 52 participants (female = 62.7 %; mean age = 43.2 ± 11.1) with BD were randomised by blocks to either the experimental group (EG; $n = 26$; Bi-REAL + Treatment as Usual, TAU) receiving 12 weekly 90-minutes sessions, or the control group (CG; n = 26, TAU). Feasibility and acceptability were assessed with a multimethod approach (qualitative interviews, semi-structured clinical interviews and a battery of self-report questionnaires – candidate main outcomes Bipolar Recovery Questionnaire (BRQ) and brief Quality of Life for Bipolar Disorder (QoL.BD)). All participants were evaluated at baseline (T0), post-intervention (T1) and 3-month follow-up (T2).

Results: Acceptability was supported by participants' positive feedback and ratings of the sessions and programme overall, as well as the treatment attendance (86.25 % of sessions attended). The trial overall retention rate was 74.5 %, with CG having a higher dropout rate across the 3-timepoints (42.31 %). A significant Time × Group interaction effect was found for BRQ and QoL.BD favouring the intervention group ($p < .05$).

Limitations: The assessors were not blind at T1 (only at T2). Recruitment plan was impacted due to COVID-19 restrictions and replication is questionable. High attrition rates in the CG.

Conclusions: The acceptability of Bi-REAL was sustained, and subsequent feasibility testing will be necessary to establish whether the retention rates of the overall trial improve and if feasibility is confirmed, before progressing to a definitive trial.

1. Introduction

Bipolar disorder (BD) is a psychiatric disorder with early onset and a chronic course, featuring second place as a cause of disability-adjusted life-years (Krahn, 2011). This disorder presents sub-clinical symptoms even during euthymic periods (Léda-Rêgo et al., 2023; Pini et al., 2005; Wittchen et al., 2003), and its high comorbidity with anxiety and depressive symptoms, as well as other mental health disorders, contributes to the difficulties in its treatment (Angst and Cassano, 2005; GBD Mental Disorders, 2022).

People with BD tend to engage in mental processes that lead to excessive upregulation and downregulation of both positive and negative affect, even during euthymic phases (Dodd et al., 2019). Consequently, research shows that the use of maladaptive cognitive and

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emotion regulation strategies, such as rumination (Dodd et al., 2019) and self-criticism (Lowens, 2010), have a damaging impact on mood symptoms (Dodd et al., 2019; Miola et al., 2022). Despite notable progress in drug treatment, recovery rates for patients with BD remain relatively low (Geddes and Miklowitz, 2013). The treatment for BD has been mainly focused on decreasing the symptoms of manic, mixed, or depressive episodes and preventing their recurrence (Goodwin et al., 2016; Ratheesh et al., 2023). However, new paradigms that emphasise and prioritise recovery have given a new impetus to psychological interventions, with an increasing interest in improving functionality and personal recovery (Fico et al., 2022; Hancock and Perich, 2022).

In the last ten years, multiple global guidelines and considerations addressing the treatment of BD have been released (Butler et al., 2018; Evans, 2000; Goodwin et al., 2016; NICE, 2018; Ratheesh et al., 2023), and even though they consistently state adjunctive psychological treatment is essential and more efficacious than drug treatment alone, they also stress the poor quality of the current empirical evidence (Butler et al., 2018; Miklowitz, 2008a; Oud et al., 2016). The most empirically tested psychosocial interventions for BD include Cognitive-Behavioural Therapy (CBT) (Chiang et al., 2017), Family-Focused Therapy (FFT) (Fiorillo et al., 2015; Miklowitz, 2008b) or analogous forms of family psychoeducation (Colom and Vieta, 2006) and Interpersonal and Social Rhythm Therapy (IPSRT) (Inder et al., 2015; Swartz et al., 2012). While certain studies endorse its advantages, the results and methodological quality of these studies have been scrutinized by systematic reviews and meta-analyses, deeming many outcomes inconclusive due to a noted risk of bias (Butler et al., 2018; Oud et al., 2016; Salcedo et al., 2016).

A growing body of evidence supports Dialectical Behaviour Therapy (DBT) as a promising adjunctive treatment for people with BD. DBT emerged as a therapeutic approach specifically designed for individuals exhibiting pronounced suicidality, heightened emotional dysregulation, and consequentially manifesting severe maladaptive behaviours (Linehan, 1993). Nowadays, DBT is considered the most effective treatments for borderline personality disorder (BPD) (Stoffers-Winterling et al., 2022), and given the overlapping symptoms of the two disorders (e.g., emotion dysregulation, suicidality, impulsivity, interpersonal difficulties, and treatment non-adherence), it is reasonable to consider that it may be a good fit for BD. The biosocial model (Linehan and Wilks, 2015) claims the development of extreme emotional lability is based on characteristics of the child (e.g., baseline emotional sensitivity, impulsivity), in transaction with a social context that shapes and maintains the lability. Substantial research has reported on the biological vulnerability of BD, manifesting through discernible neuroanatomic alterations (Frey et al., 2013), neurotransmitters dysregulation (Lee et al., 2022), epigenetic factors (Vieta et al., 2018), dysregulation of the circadian rhythm (Muneer, 2016) and pervasive emotional dysregulation, contributing to a higher severity of the disorder (Becerra et al., 2013; Van Rheenen et al., 2015). Additionally, comparisons between patients with BD, BPD, and comorbid BD and BPD, maladaptive strategies used to regulate emotions were found across both groups and those comorbid for BD and BPD demonstrated a compounding effect of impulsivity and difficulty in accessing emotion regulation strategies (Bayes et al., 2016). Given the shared difficulties and vulnerabilities of BPD and BD (e.g., emotion dysregulation, suicidality, impulsivity, interpersonal difficulties, and treatment non-adherence), and the particularities of BD, such as mood symptoms and energy level variation, as well as the tendency to upregulate positive affect, and over-use downregulation strategies for both positive and negative affect (Koenders et al., 2020), it is reasonable to consider the training of DBT skills to address these difficulties. Furthermore, there is evidence of invalidating experiences being common in people with BD, with reports of high prevalence of childhood emotional abuse and neglect and elevated internal shame (Fowke et al., 2012).

Van Dijk et al. (2013) were the first to conduct a pilot study using a DBT based programme for adults with BD, showing preliminary improvements in mania symptoms and emotional dysregulation. Previously, Goldstein et al. (2007) had conducted a single-arm open trial for adolescents with BD, where they presented improvements in suicidality, non-suicidal self-injury (NSSI), emotional dysregulation, and depressive symptomatology, which were later supported by a pilot Randomised Controlled Trial (RCT) (Goldstein et al., 2015). Since then, a couple of single-arm and pilot studies have been conducted, and a recent systematic review has summarised their results (Jones et al., 2023). This systematic review shows encouraging results of the use of DBT skills training for BD, nevertheless, small sample sizes and the high risk of bias, resulted in insufficient evidence to affirm its efficacy and RCTs are still needed to confirm the promising preliminary data (Jones et al., 2023).

To the best of our knowledge, there's no previous Dialectical Behaviour Therapy skills training (DBT-ST) programme designed for individuals with BD in Portugal, and customised psychological interventions for this group remain scarce (Alves, 2022). Difficulties in accessing psychology services in the public sector results in treatment as usual (TAU) for BD in Portugal consisting almost exclusively of general psychiatric support. In the mental health field, it is recognised worldwide that there is a significant gap between the availability of evidence-based treatments for BD and their actual implementation rates. Factors such as limited access to mental health services, stigma, insufficient training of healthcare professionals, and challenges in engaging individuals with BD all contribute to this treatment gap (Henderson et al., 2013; Nestsiarovich et al., 2017). Approaches that can take advantage of the flexibility of online and digital tools and allied healthcare workers have been reported as the best way to tackle this need (Butler et al., 2018).

Considering the lack of definitive trials using DBT for BD (Jones et al., 2023), and recent developments and suggestions to enhance its efficacy for this client group (DiRocco et al., 2020), we decided to develop a pilot intervention that integrated and applied these developments. We developed *Bi-REAL – Respond Effectively and Live mindfully*, a 12-session online DBT-ST group programme adapted for BD.

This pilot study aims to lay the groundwork for a full-scale RCT. It intends to assess the feasibility and acceptability of Bi-REAL, an online DBT-ST group for BD (considering all its spectrum), in comparison to a control group (receiving TAU). This study also intends to assess the variance of the candidate measures regarding recovery and quality of life, with assessments at baseline, 3 and 6-months post-randomisation.

2. Methods

2.1. Trial design

A feasibility intervention study with a nested mixed methods evaluation was employed. This pilot followed a two arms parallel randomised controlled trial (pilot-RCT) design, in a 1:1 ratio to either the experimental group (EG: intervention arm: receiving Bi-REAL - 12 session DBT-ST plus TAU), or to a control group (CG) receiving Treatment as Usual (TAU) (control arm: receiving just TAU - psychiatric support every 3/6 month and occasionally unspecialised psychotherapy). There is hardly any information about TAU for BD in Portugal, thus, we describe the information collected to help inform future studies. The study comprised a multimethod approach including qualitative and quantitative methods and analysis, and outcome measures were administered at baseline (T0), post-intervention (T1–3 months after randomisation), and at 6 months follow-up (T2–3 months post-intervention). The detailed study protocol is in supplementary material 1. Some instruments listed in the protocol were not explored in the current study but will be used in a follow-up study regarding processes. This study complied with the ethical standards of the Declaration of Helsinki (1964) and its later amendments or comparable ethical standards and registered with ClinicalTrials.gov (NCT02637401).

2.2. Analytical methods

Data analyses were conducted using the Statistical Package for the Social Sciences (IBM SPSS, version 27.0). Descriptive statistics were computed for sociodemographic and clinical data, as well as for the study variables and Bi-REAL's acceptability and usefulness. Independent sample *t*-tests and Chi-square were used to compare intervention and control groups at baseline. Comparison analyses (*t-student* or chi-square tests) of the baseline information participants who completed follow-up assessments and those who dropped out of the study were also conducted, and Mann–Whitney U was used to assess non-parametric comparisons (e.g. completers vs non-completers). Cramer's V was used to measure the association between categorical variables (values close to zero are considered weak, and close to 1 strong). Outcomes variance and was assessed using statistical analyses following intention-to-treat (ITT) principles and recommendations from the CONSORT 2010 checklist for pilot trials (Eldridge et al., 2016). Accordingly, all participants who completed the baseline assessment were included in the analyses regardless of follow-up assessments.

Based on the stepped rules of thumb for pilot trials, for a 90 % powered trial and two-sided 5 % significance, it is recommended to have a pilot sample size per treatment arm of 25, for small (0.2) standardised effect sizes (Whitehead et al., 2016). According to similar studies recruiting in the UK (since none was found in Portugal), a 17 % attrition rate was found, thus we set a goal of 60 participants for randomisation, to account for a loss of approximately 10 and still have 25 per arm remaining.

Linear mixed models (LMMs) were performed to analyse the variance of the candidate outcome measures. LMMs is a statistical model particularly used for repeated, longitudinal measures and is a reliable procedure to handle missing data because this approach allows incomplete cases to be included in the analysis, and all available data are used to obtain parameter estimates, and the missing at-random assumption for these analysis was explored through Little's MCAR test ($\chi^2 = 72.352$, $p = .966$). In the LMMs model, we used the restricted maximum likelihood method and the compound symmetry covariance structure. Participants were included as a random effect. The time variable was coded as *time 1* (baseline – T0), *time 2* (post-intervention – T1) = 1 and *time 3* (3 months follow-up – T2) = 2. The group was coded as *intervention group* = 1 and *control group* = 0. Fixed effects were time, group, and *time* × *group* interaction. The model included psychological support as a covariant to control for its effect. Moreover, LMMs efficiently utilize available data, accommodating missing observations and unbalanced designs. They also address correlated errors in measurements taken over time or across related units, ensuring accurate estimation of standard errors. Importantly, insights gained from LMM analyses can inform future study designs by identifying sources of variability that impact sample size calculations. Thus, LMMs facilitates robust assessment of candidate measures' variance and informing decisions for future research.

2.3. Participants

Participant demographics and clinical variables can be seen in Table 1 by group. Briefly, 51 participants were included in the trial, between the ages of 22–65 (M = 42.61 years, SD = 10.24), 65.4 % were females, with 49 % having children and the majority with BD type I (64.7 %) or type II (33.3 %) with a mean age of onset of 24.43 (±7.69). Most participants (75 %) had been hospitalised an average of 2.1 times (ranging from 0 to 20 times). Regarding the usual care received, almost all the participants were undergoing psychiatric treatment (96 %), with quarterly psychiatric monitoring and were medicated with mood stabilisers (84.3 %) and antipsychotic medication (56.9 %), with 35.3 % receiving psychological support. Participants were recruited via clinician referrals, online and through flyers from outpatient mental health, and through Association for support of Depressive and Bipolar Patients (ADEB) newsletter and referrals. See Fig. 1 for participants flow Consort Chart.

Table 1
Sociodemographic and clinical characteristics of subjects by groups.

	Experimental group M(±SD) or %	Control group M(±SD) or %	All Participants M(±SD) or %	Comparison *t-test* or χ^2
Demographics	$n = 26$	$n = 25$	$N = 51$	p
Average age (years)	42.15 (8.85)	43.08 (11.67)	42.61 (10.24)	0.750
Gender				0.691
Female	65.4 %	60 %	62.7 %	–
Male	34.6 %	40 %	37.3 %	–
Marital status				0.884
Single	38.5 %	36 %	37.3 %	–
Married	23.1 %	32 %	27.5 %	–
Non-marital partnership	11.5 %	12 %	11.8 %	–
Divorced/ separated	26.9 %	20 %	23.5 %	–
With Children	42.3 %	56 %	49 %	0.328
Schooling years	16.27 (3.44)	15.68 (3.31)	15.98(3.36)	0.537
Employed|	73.1 %	60 %	66.7 %	0.322
Clinical characteristics				–
Age of onset	22.88 (7.33)	26.04 (7.86)	24.43(7.69)	0.145
Nr of hospital admissions	1.57 (2.38)	2.72 (4.53)	2.14(3.61)	0.263
Diagnosis				0.322
Bipolar I	73.1 %	56 %	64.7 %	–
Bipolar II	26.9 %	40 %	33.3 %	–
Other Specified BD	–	4 %	2 %	–
Treatment				
Psychiatric medication	100 %	88 %	94.1 %	0.069
Antidepressants	38.5 %	40 %	39.2 %	0.910
Antipsychotics	57.7 %	56 %	56.9 %	0.903
Anxiolytics	42.3 %	32 %	37.3 %	0.447
Mood Stabilisers	88.5 %	80 %	84.3 %	0.406
Psychotherapy	30.8 %	40 %	35.3 %	0.490

Note. M = mean; SD = standard deviation; p = significance level - differences between groups were calculated using the adequate test (*t*-test or χ^2 = Chi-square) for all the abovementioned variables; BD = bipolar disorder.

2.3.1. Inclusion criteria

Participants aged between 18 and 65 years old were required to meet Diagnostic criteria for Bipolar and related disorders according to DSM-5 (American Psychiatric Association, 2013), had two or more interferent mood episodes in the last 5 years, were fluent in Portuguese, had means to access the online group (i.e., internet access and zoom) and were euthymic at baseline.

2.3.2. Exclusion criteria

Participants were excluded if there was active suicide ideation at baseline; BD secondary to an organic cause; continuous illicit substance misuse resulting in uncertain primary diagnosis; high-risk pervasive disorders such as BPD; evidence of active self-harm. To control for the effect of the intervention, participants were informed they would be excluded for any alterations in medications <4 weeks prior to baseline. Participants receiving other individual psychotherapeutic support were included for ecological validity, as long as it was not a specialized approach to BD.

2.4. Procedure

The study was presented to all the healthcare professionals at the clinical sites (3 public hospitals in the centre of Portugal) and ADEB, and they were asked to refer patients. Patients were then invited to attend a

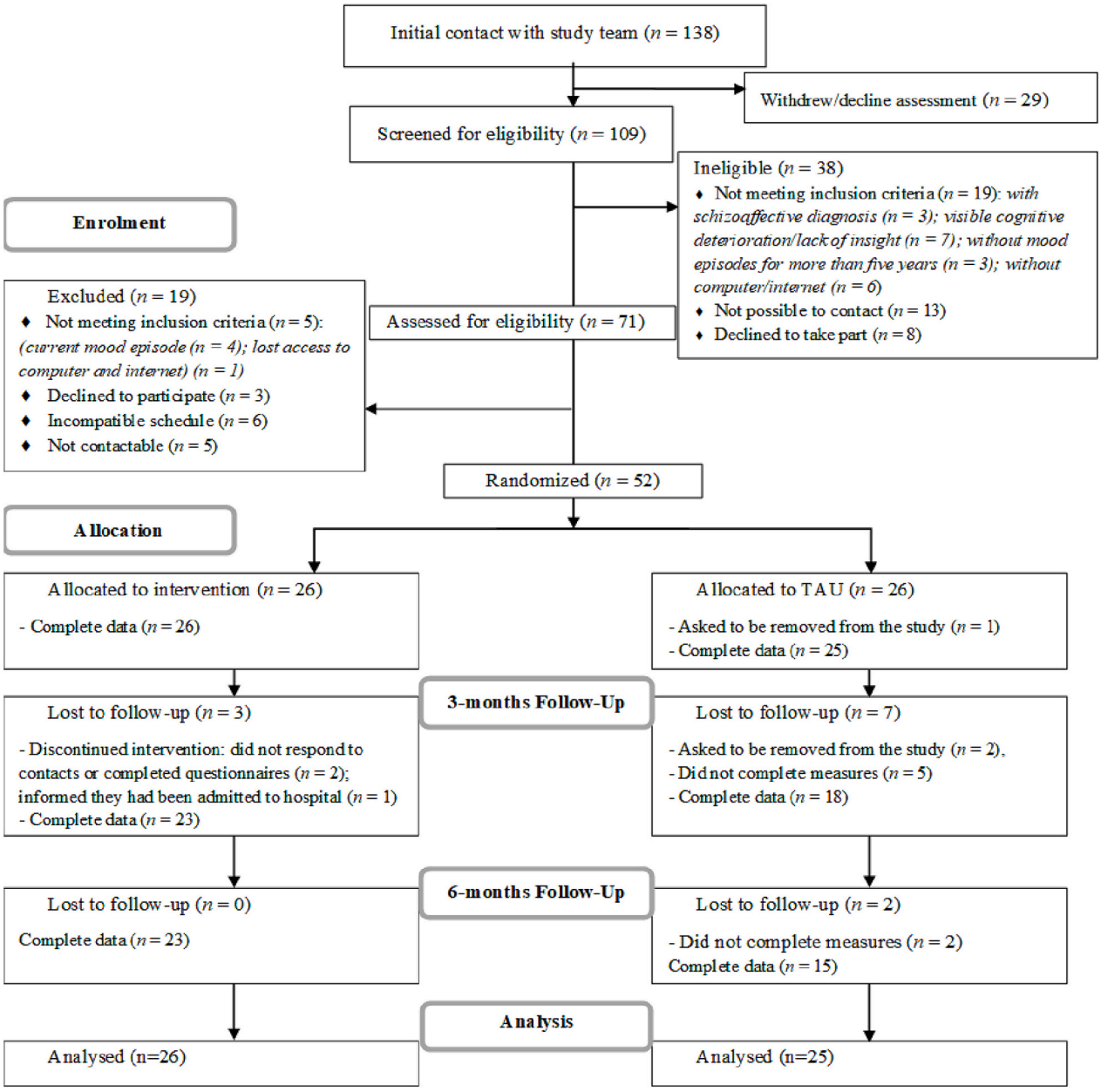


Fig. 1. Flow chart diagram of trial participants.

baseline eligibility assessment interview that could take place in person or online. There was a 6-month period of interruption of the in-person recruitment due to Covid-19 restrictions. Adjustments were made to the study protocol and re-submitted to ethics committees.

To ensure concealment, stratified block randomisation was performed by an external researcher before the start of each EG, using coded data. Participants were distributed equally by age and status of psychological support (undergoing vs not receiving) using the randomisation website (www.randomization.com). The post-intervention (T1) assessment was not blind to allocation due to the qualitative interview of the EG being done simultaneously with T1 assessment measures, and to the limited human resources. At 6-month follow-up, the participant allocation was blind to the interviewer. Approximately 138 participants were referred, 109 screened for eligibility, of which 71 met eligibility criteria (51.4 %). We screened participants by phone and in person, and all baseline assessments were via Zoom. Participants' medication was registered at each assessment moment and not standardised as is consistent with psychotherapy trials (medication type and dosage were decided on an individual basis by their psychiatrist); to minimise changes in medication effects, participants were informed that they had to be on the same medication for at least one month to enter the programme and should inform if it changed during its duration.

2.5. Intervention and control

The intervention arm received Bi-REAL (12 + 1 weekly sessions) plus TAU. Bi-REAL was developed based on the skills training component of standard DBT, with adjustments being made for BD. Each session had a duration of 90 min (with a 15-minute break in the middle), starting with a mindfulness exercise (5 min) followed by the homework review (40 min) and was delivered weekly via zoom. The content of the sessions was developed using the manualised skills of the standard treatment (Linehan, 2015), the DBT skills manual by Van Dijk (2009), and building up on the proposal of a recent study to enhance DBT for BD, with permission from the authors to adapt their handouts – CAMERAS (see Appendix 1 in DiRocco et al., 2020). Additionally, we consulted with a

team of researchers and clinicians who delivered DBT to people with mood instability and received consultation from experienced DBT therapists. Moreover, the duration was consistent with previous studies delivering DBT-ST adapted for people with BD (Eisner et al., 2017; Soler et al., 2009), with an additional pre-session. The complete outline of the programme can be seen in Table 2. Homework was set every session in order to provide opportunities to generalise the skills learned, along with supportive handouts. Most sessions had power point presentation and exercises to facilitate skills acquisition, and some had auxiliary videos. Participants were offered the possibility to have up to three individual sessions (of 45 min maximum) delivered via video call or telephone and could also message or email to ask for support in applying/understanding skills. Additionally, participants were offered an optional booster session 1.5 months after the end of the programme. Participants were expected to attend at least 60 % of the sessions (being the criteria to consider they completed the programme) and were informed that they would be out of the programme if they missed four consecutive sessions (i.e., DBT 4 miss rule).

Participants in TAU received their usual treatment from the national health system, which was mainly psychiatric routine monitoring every three months. Participants could also receive additional psychological support if it was not a BD-adapted intervention (assessed at baseline).

The intervention was delivered by three clinical psychologists (with two in each group - a leader and a co-leader, as defined in the DBT skills training manual; Linehan, 2015). Facilitators had a cognitive behavioural therapy (CBT) background and more than five years of clinical practice in addition to previous experience delivering group interventions for pilot trials. All therapists were trained in DBT (at least five days of intensive training) and received additional training about BD and Bi-REAL. The team delivering the intervention programme met fortnightly and received weekly supervision.

Table 2
Bi-REAL Session outline and targets.

Skills module	Session	Content and skills	Target problems/session focus
Pre-session	0	DBT Assumptions General and personal Goals, Biosocial Theory for Bipolar Disorder	DBT Assumptions, Group Rules and confidentiality
Mindfulness	1	Wise mind What Skills: Observe, Describe, Participate	Understand emotion mind, reason mind and wise mind. Introduction to Mindfulness
	2	How Skills: Non-judgmentally, One-Mindfully, Effectively	Attention Focus, notice thoughts. Not reacting to urges and impulsive behaviour
Emotion regulation	3	Understand, Identify and Label emotions	Perception and processing of emotions
	4	Check the Facts, Opposite action	Behaviour and Cognitive Change
	5	Problem Solving in practice	Skilfully make an action plan. Put emotions into action
	6	CAMARAS – managing highs and lows for depressive and hypo/manic symptoms	Knowing what to do when a mood change arises.
	7	ABC PLEASE Skills, Build Mastery Cope ahead	Managing vulnerability to emotions Anticipate reactions, plan
Distress tolerance	8	TIPP – Temperature, Intense exercise, Paced breathing and Progressive muscle relaxation Managing Extreme emotions	Managing extreme mood states, prevent impulsive reactions. Focusing attention
	9	Distract, Self-Soothe, Radical Acceptance	Capacity to tolerate difficult emotions
Interpersonal effectiveness	10	DEAR MAN (Describe, Express, Assert, Reinforce; Mindful, Appear Confident, Negotiate)	Managing situations that cue emotions
	11	GIVE FAST (Gentle, act Interested, Validate, Easy manner)	Relationship and Self-respect effectiveness
	12	Remember Validation What was learned, what to take home.	Review of the contents of the programme and intention to keep using the skills in everyday life.

2.6. Feasibility outcomes

The feasibility of the pilot trial was assessed regarding the number of potential participants identified and contacted, randomised, and data completion at all timepoints. Acceptability was evaluated by a qualitative interview post-intervention, written based on Hasson-Ohayon et al.' (2006). Additionally, participants from the EG answered questions about Bi-REAL's acceptance, utility and satisfaction at T1. Participants were asked to appraise how much the programme enhanced their mood regulation, their general opinion of the programme, facilitators, and suggestions for improvement. Additionally, acquisition and mood improvement/stability were assessed through an online Diary card, submitted before each session (consult complete protocol for further details); and acceptability of the programme was also assessed with *Group Session Rating Scale* (GSRS; Quirk et al., 2013), after each session. Participants were sent a link to rate the sessions anonymously to decrease social-desirability bias. This measure uses a four-item visual analogue scale designed to assess key dimensions from 0 to 40: relationships, goals and topics, approach or Method; and overall. Treatment adherence was measured through the number of sessions attended (pre-treatment session plus the 12 sessions of Bi-REAL. The boost session was not considered for attendance since it was optional.

Dropout rates were assessed regarding the EG, having been defined as not completing the measures at post-intervention assessments regardless of the number of sessions attended.

2.6.1. Outcome measures

A table with measures and assessment timings and more detailed information about the instruments used for assessment can be consulted in the protocol (supplementary material 1). The following instruments to confirm the diagnosis and assess the presence of mood episodes were rated by the researchers: *Clinical Interview for Bipolar Disorder* (CIBD; Azevedo et al., 2023b) – Clinical semi-structured interview for diagnosing Bipolar and Related disorders. It includes an empowerment scale towards bipolar symptomatology, which provides a global empowerment upwards score; *Young mania rating scale (YMRS)* (Young et al., 1978) – evaluates mania symptoms presence/severity; and *Hamilton Depression Rating Scale (HDRS)* (Hamilton, 1960) – evaluates depressive symptoms presence/severity. Euthymia was defined as scores <8 for both YMRS and HDRS.

The following self-report questionnaires were used to assess the variance of the candidate measures:

Bipolar Recovery Questionnaire (BRQ; Azevedo et al., 2023a; Jones et al., 2013), is a 36-item developed to measure personal recovery in people with BD.

Brief Quality of Life in Bipolar Disorder (Brief QoL.BD; Azevedo et al., 2023c; Michalak et al., 2010) measures quality of life in BD and has been designed for and validated with individuals with BD.

Furthermore, the following self-report measures were used to assess additional outcomes of interest:

Depression Anxiety and Stress Scale (DASS-21; Henry and Crawford, 2005; Pais-Ribeiro et al., 2004) – we used the anxiety and depression subscale, with 7 items each. The Portuguese version was reliable for

anxiety and depression with a Cronbach alpha of 0.83 and 0.85, respectively.

Difficulties in Emotion Regulation Questionnaire (DERS; Coutinho et al., 2010; Gratz and Roemer, 2004) is a 36-item instrument measuring difficulties in regulation emotions with 6 subscales. In this study, we only used the total score, which previously showed an excellent Cronbach's α of 0.93.

External and Internal Shame Scale (EISS; Ferreira et al., 2022) – has 8 items and assesses shame as a total and entails two subscales of external and internal shame. This scale showed good internal consistency (α = 0.89).

Ruminative Responses Scale (RRQ-10; Dinis et al., 2011) – is a 10-item scale that measures the individuals' tendency to ruminate, comprising two subscales with acceptable internal consistency: brooding (α = 0.74) and reflection (α = 0.75).

Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS; Castilho et al., 2015; Gilbert et al., 2004) is a 22-item self-report questionnaire with three factors: Inadequate Self, Hated Self and Reassured Self. Together the first two assess Self-criticism, which was used in this study, as well as the Self-Reassurance subscale.

3. Results

3.1. Trial feasibility outcomes

The recruitment plan included three public hospitals and online recruitment (allowing self-referral) and took place between December 2019 and January 2021, with follow-up ending in October 2021 (and after which the programme was offered to the control group). A flow diagram depicting the recruitment and retention outcomes is shown in Fig. 1. Initial contact was established with 138 individuals, and out of these, 109 underwent eligibility screening (79 %). A total of 71 potential participants were assessed for eligibility, of which 52 were randomised to CG or EG ($n = 26$). Our recruitment goal of 60 was not achieved (52/60), however the 25 per arm was preserved, as intended. After the randomisation and allocation to the groups, one participant from the CG (who was blind to the condition) contacted the team, asking to be withdrawn from the study for personal reasons and informing they did not want to continue to the following assessment timepoint.

The waiting time between first contact and the groups was a barrier, resulting in the attrition of individuals initially engaged during recruitment. Furthermore, the group running schedule was also a barrier, causing the loss of eligible participants who could not attend the proposed dates and times.

3.2. Baseline differences, trial retention and dropout reasons

The baseline demographics and clinical characteristics of the sample can be found in Table 1, and no mean differences were found between the CG and EG. The retention rate at post-intervention (T1) assessment was 80.39 %, with the control arm having significantly more loss to follow-up than the intervention [EG T2: $n = 23$ (T0 = 26), vs CG T1: $n = 15$ (T0 = 25); $\chi^2(2) = 6.27$, $p = .044$; Cramer's $V = 0.351$]. The overall retention from baseline to 6-months follow-up (T2) was 74.51 %. The overall retention from baseline to 6-months follow-up (T2) was 74.51 %, with an good retention of the EG (88.46 %) and a poor retention of the CG (57.69 %). Attrition rate considering people randomised to both groups ($N = 52$) was of 26.92 % ($n = 14$ lost at 6 month follow up), being higher than the reference value of 17 % from similar studies (Wright et al., 2021).

Differences between completers of the trial and dropouts were explored (participants who did not complete primary outcomes at follow-up) regarding baseline sociodemographic, clinical history and characteristics and no significant differences were found either in dropouts or non-completers vs completers, except for the variable schooling years, which was significantly lower in non-completers (Mann–Whitney U = 16.5, completers $n = 21$, non-completers $n = 5$, $p = .015$ two-tailed). Regarding the control groups dropouts, most people did not answer our questions regarding the reasons for dropout, but the ones who did ($n = 3$) mentioned a lack of time to book the follow-up interview, and one mentioned they had a distressing event in their life and did not want to carry on in the trial.

3.3. Bi-REAL feasibility and acceptability

A total of 26 participants were allocated to receive Bi-REAL, of which 23 (88.46 % retention) completed assessments at all timepoints, and 21 completed the programme (80.79 % completed intervention, attending ≥7 sessions), distributed across three groups (n ≈ 8). Participants attended a mean of 10.35 sessions (1 + 12 – including the pre-session), above the minimum established of 60 %.

Participants in the EG answered some questions in the post-intervention assessment, along with the other measures, to assess their acceptability of the programme and usefulness (detailed outcomes - supplementary material 2).

Satisfaction with the programme was high, considering all the participant selected 9 or 10, with a mean score of 9.48 (range = 1–10), and when asked how much they would recommend the programme to other people with BD, the mean rate was 9.96 out of 10.

The GSRS filled in after each session gathered a total of 200 answers (EG), achieving high means across the four dimensions (range = 0–40): Relationships (38.37 ± 3.05), Approach or Method (37.59 ± 4.81), Goals and Topics (37.29 ± 5.02) and Overall (37.31 ± 5.67). Most participants felt improvements, rating (0–4) between "3-better" or "4-much better", and considered the intervention useful scoring it "3-useful" to "4-very useful"(0–4), showing a good acceptability of the programme and suitability to their needs. Regarding the duration of the sessions, most participants considered it ideal (60.9 %), with some participants reporting they were a bit too long (30.4 %), and the remaining finding them short. Regarding the total number of sessions, most participants indicated they would have liked to have had more sessions (60.9 %), and 34.8 % considered the programme length ideal.

The qualitative interview with an independent researcher ($n = 23$) reported good acceptability from participants, with the main highlights being the relationship with the facilitators and other participants, namely meeting other people with BD and learning skills to deal with their emotions and thoughts. The provided materials and programme delivery were also highlighted as positive dimensions of Bi-REAL. An example statement from a participant is *"understanding my emotions better and being able to talk about them without feeling judged"*. A summary table with the qualitative analysis of the interviews can be found in supplementary material 3.

Non-completers described several reasons for not completing the intervention: one participant mentioned incompatibility with job demands (attended 4 sessions), and another participant expressed significant difficulty attending sessions due to social anxiety (attended 4 sessions). One participant self-admitted to hospital due to exacerbation of depressive symptoms and expressed intention to attend the programme another time when feeling more stable, stating that his worsening of symptoms was unrelated to the programme. Another participant dropped out for logistical constraints (e.g. computer malfunction), and one participant's information could not be retrieved (calls were not returned).

3.4. Candidate clinical outcomes

A *group x time* significant effect was found for Recovery for time 2 (β = −427.90; CI = [−654.10, −201.69], $p > 0.001$) and time 3 [β = −438.33 CI = [−675.54, −201.11], $p > 0.001$), with significant higher scores for EG. The same tendency was found for QoL.BD and DERS, and further outcomes measures variance can be found in Table 3. The trajectories of outcomes variance and standard error can be seen in Fig. 2

Table 3
Estimated marginal means and fixed effects for outcome measures.

Outcome measures	Group	Time 1 *M* (*SE*)	Time 2 *M* (*SE*)	Time 3 *M* (*SE*)	Effect	*B* (*SE*)	Confidence Interval 95 %	*p*
Recovery (BRQ)	*Intervention*	2290.30 (84.36)	2639.90 (87.30)	2523.47 (81.01)	Time 2	349.60 (76.12)	[198.01,501.194]	>0.001**
	Control	2317.98 (87.51)	2239.69 (96.34)	2112.82 (101.14)	Time 3	233.16 (77.84)	[78.18, 388.15]	0.004**
					Group	27.68 (121.48)	[−214.49, 269.85]	0.820
					Time 2 x Group	- 427.90 (113.62)	[−654.10, −201.69]	>0.001**
					Time 3 x Group	- 438.33 (119.17)	[−675.54, −201.11]	>0.001**
					PsychologicalSup	- 97.00 (83.90)	[−263.17, 69.17]	0.250
Quality of Life (QoL.BD)	*Intervention*	35.38 (1.58)	42.58 (1.65)	39.75 (1.72)	Time 2	7.20 (1.82)	[3.58, 10.82]	>0.001**
	Control	37.84 (1.60)	37.92 (1.90)	36.24 (1.99)	Time 3	4.37 (1.89)	[0.62, 8.13]	0.023*
					Group	2.46 (2.25)	[−2.00, 6.91]	0.277
					Time 2 x Group	−7.12 (2.73)	[−12.54, −1.68]	0.039*
					Time 3 x Group	- 5.96 (2.85)	[−11.62, −0.30]	0.039*
					PsychologicalSup	−2.50 (1.64)	[−5.77, 0.77]	0.132
Self-Reassurance (FSCSR_SR)	*Intervention*	13.71 (1.24)	16.89 (1.27)	16.39(1.30)	Time 2	3.18 (1.02)	[1.16, 5.21]	0.002**
	Control	15.03 (1.28)	15.32 (1.42)	13.50 (1.46)	Time 3	2.68 (1.06)	[0.57, 4.79]	0.014**
					Group	1.32 (1.78)	[−2.23, 4.87]	0.460
					Time 2 x Group	- 2.89 (1.54)	[−5.96, 0.18]	0.064
					Time 3 x Group	- 4.21 (1.61)	[−7.41, −1.00]	0.011**
					PsychologicalSup	−2.38 (1.18)	[−4.73, −0.04]	0.046*
Depressive Symptoms (HDRS)	*Intervention*	4.59 (0.72)	3.46 (0.77)	4.43 (0.78)	Time 2	−1.14 (0.98)	[−3.07, 0.80]	0.247
	Control	3.88 (0.73)	5.10 (0.90)	7.06 (0.93)	Time 3	- 0.16 (0.98)	[−2.11, 1.79]	0.871
					Group	- 0.71 (1.02)	[−2.74, 5.25]	0.486
					Time 2 x Group	2.35 (1.46)	[−0.54, 6.28]	0.110
					Time 3 x Group	3.34 (1.48)	[0.40, 2.14]	0.026*
					PsychologicalSup	0.19 (0.72)	[−1.25, 1.63]	0.798
Difficulties Regulating Emotions (DERS)	*Intervention*	90.95 (3.80)	71.92 (3.98)	74.94 (4.14)	Time 2	- 19.04 (4.35)	[−27.70, −10.37]	>0.001**
	Control	85.58 (3.92)	83.24 (4.58)	87.06 (4.81)	Time 3	- 16.02 (4.52)	[−25.21, −7.03]	0.001**
					Group	-5.37 (5.46)	[−16.21, 5.47]	0.328
					Time 2 x Group	16.70 (6.55)	[−31.90, −4.74]	0.013**
					Time 3 x Group	18.32 (6.83)	[−31.90, −4.74]	0.009**
					PsychologicalSup	13.30 (3.99)	[5.37, 21.22]	0.001**

Note. *M* = Mean; *SE* = Standard Error; *Psychologicalsup* = Psychological Support; *BRQ* = Bipolar Recovery Questionnaire; *HDRS* = Hamilton Depression Rating Scale; *YMRS* = Young Mania Rating Scale; *QoL.BD* = Quality of Life in Bipolar Disorder; *DERS* = Difficulties in Emotion Regulation Questionnaire; *FSCSR_SR* = Forms of Self-Criticising/Attacking & Self-Reassuring Scale - Self Reassurance.
* $p < .05$.
** $p < .01$.

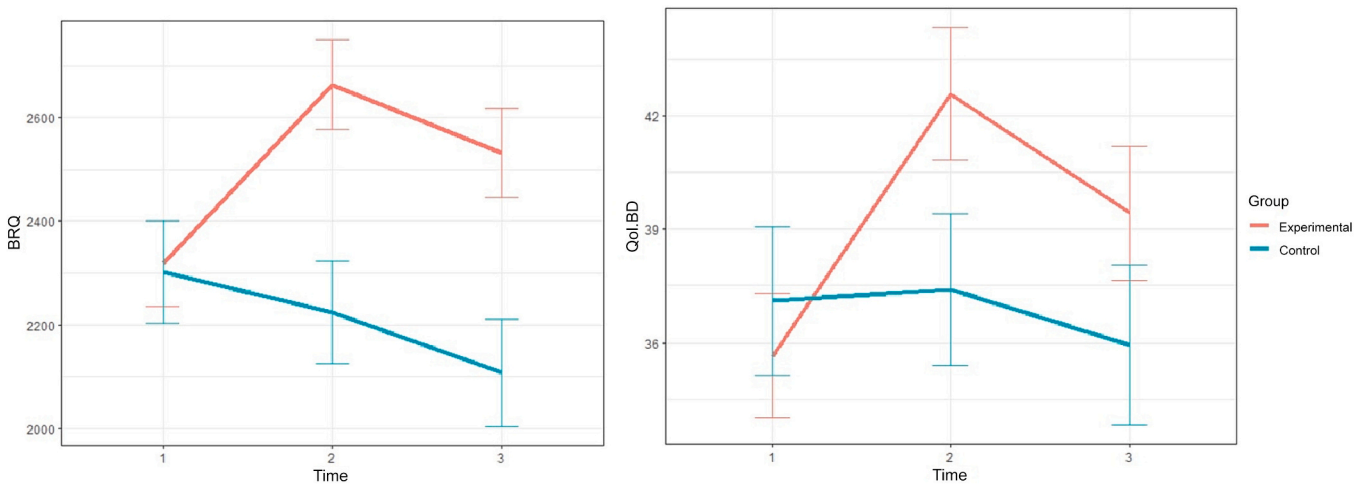


Fig. 2. Intervention and control group trajectories for the BRQ (Bipolar Recovery Questionnaire) and QoL.BD scores from time 1 (Baseline) to time 3 (3-month follow-up) (based on mean estimates and error bars from linear mixed models).

based on LMM's mean estimates and error. Additionally, significant *time x group* interactions were found in for DERS, self-reassurance, and depression. When looking at the pairwise comparisons between groups for depression (HDRS), there was a significant difference in T2 between EG and CG, with the last being significantly higher (mean difference EG-$CG_{T2} = 2.63$; $p = .033$). No significant differences or interactions were found for the other outcomes measures. Some differences between the EG and CG were seen in the pairwise comparison for empowerment (with significant differences within the EG, with improvements at T1 and T2). A summary of the pilot feasibility trial outcomes is presented in Table 4.

Table 4
Summary of feasibility aims findings.

Aim	Method of measurement	Outcome	Interpretation
Acceptability of the intervention to patients	i) Proportion of participants completing treatment (defined as attending at least 60 % of the 12 + 1 group therapy sessions); ii) Participant ratings of treatment satisfaction and recommendation. iii) Participants' rating of GSRS. iv) qualitative analysis of semi-structured interviews with participants at the end of therapy;	- 21(n = 26) 81 % completed treatment - All participants rated 9 or 10 their satisfaction and probability to recommend Bi-REAL (range 0–10) - Participants rated all sessions quite high, with a mean rating above 37 in all items (0–40) - Overall positive assessment with encouragement to do more sessions and offer the intervention broadly.	Positive outcomes support the programme's acceptability, with some suggestions to improve.
Feasibility of study procedures	i) Recruitment;	- Over 130 participants were referred over a 13-month period, with 71 assessed for eligibility,	Future feasibility RCT should be able to recruit at least 4 participants per month using the current referral strategy and recruitment plan
Candidate measures revealing significant change for this client group without safety concerns	i) Significant interaction time x group in candidate measures ii) Incidence of serious adverse reactions from trial involvement.	- Changes in measures with improvements in EG in comparison with CG - No serious adverse events resulting from the trial were recorded.	Consistent with the possibility to observe change in the candidate measures for this intervention.
Performance of candidate outcome measures	Variance of the outcome measures	BRQ and QoL-BD showed a significant change over time; DERS, HDRS and FSCSR_SR showed significant differences, and CIBD Empowerment differed between groups in T1 and T2. EISS, RRQ, YMRS and FSCSR_SC showed no significant differences.	Majority of measures appear sensitive to change; BRQ appropriate to be used as primary outcome measure. Unclear if the absence of change on mania measures is due to insensitivity or floor effects.

4. Discussion

The principal aim of this study was to evaluate the feasibility and acceptability of the Bi-REAL programme, a Dialectical Behaviour Therapy Skills Training (DBT-ST) intervention tailored for individuals with bipolar and related disorders. The acceptability objectives were clearly achieved, and most feasibility outcomes were achieved. Regarding feasibility objectives, the retention rate overall was 74.51 % of participants completing all the assessment points (T0, T1 and T2), with 88.46 % of the EG maintained and only 57.69 % of the control group retained at follow up. The broader picture where the recruitment plan is included is satisfactory, with 138 participants referenced, though only 55.07 % of those were eligible for the study which is something that needs to be accounted for when recruiting for a larger study. The disruption of the COVID-19 pandemic might have affected these numbers, because the dates of the beginning of the programme were postponed, and the first participants to be recruited in 2019, were only assessed and contacted considerably later, which might have affected the enrolment rates.

We aimed to recruit 60 participants, to account for attrition rates, having recruited 52 participants for randomisation. The attrition rate considering the entire duration of the study was higher than expected (26.92 %, versus reference value of 17 %). The dropout rate was significantly higher in the control group (42.31 % versus 11.54 %), and it is a concern that needs to be addressed for a future RCT. These differences can raise worries about outcome bias. However, Bell et al. (2013) also state that unequal dropout rates do not necessarily mean the results are biased. Considering the nature of the study, the most important message is to try to prevent such dropout rates in a future trial, thus offering an active control option with group sessions might be a good way to increase retention. Moreover, in the future an additional way to contact participants should be retrieved, to decrease the number of participants that we were not able to reach for follow up, as well as reinforcing the importance of participating in all time points.

Evidence for the acceptability of Bi-REAL was sustained by the different sources of information and collected data. The sessions' assessments (using GSRS) yielded highly positive evaluations of the overall programme, with very positive reviews of the interpersonal relationships, method and approach used, and its goals. The assessment of the programme also showed good satisfaction scores, perceived usefulness, and overall favourable feedback from participants, supporting the programme's suitability to their needs. The attendance rates of the experimental programme were superior to similar previous studies, with 80.77 % of participants completing the minimum number of sessions of the programme, in comparison with less than 60 % reported by Wright et al. (2021). The dropout from the treatment group was 19 %, significantly below the average rate of 31 % from internet-based treatments (Melville et al., 2010). Only one dropout mentioned reasons related to the intervention, describing feeling highly anxious within the group during homework review. On reflection, we consider that the specific period during which this trial was conducted (overlapping with the Covid-19 pandemic) might have benefited this study's high retention and attendance rates considering that people were confined to their homes, with fewer activities than usual, which some participants mentioned during the delivery of the programme. In contrast, the attrition might have been higher due to interruptions or the collection of data, and a delay between first contact and baseline assessment.

Qualitative interviews with participants (post-intervention) supported the programme's acceptability and provided invaluable insights into the aspects that resonated most effectively and areas of refinement. A recurrent suggestion from participants was to extend the number of sessions while maintaining the content. This alteration might help tackle some appointed challenges, particularly those related to dense content requiring additional time for proper comprehension and skill implementation. In a future definitive trial, this will be considered, as well as the simplification of some materials identified as "too dense" (further details in supplementary material 3).

Our study's additional contribution includes the characterisation of treatment as usual for BD in Portugal. Most of our participants were receiving quarterly routine psychiatric care. They were medicated with mood stabilisers (84.3 %) and antipsychotics (56.9 %). Only 35 % were undergoing psychological treatment, which is quite far from the numbers described by Vieta and Colom (2004), according to whom 85 % of patients with BD would usually receive psychological treatment, or what is recommended by international guidelines (NICE, 2018; Yatham et al., 2018).

In Portugal, the lack of human resources providing psychological intervention in the public sector is a significant barrier in accessing treatment. An evaluation of the Portuguese mental health plan carried

out in 2017 indicated that Portugal failed to achieve recommendations to enhance community-based care for serious mental illnesses such as BD, and to provide better access to care, mentioning financial reasons (Xavier et al., 2017). We believe an online programme like Bi-REAL can be easily accessible and follows the current trend of e-health interventions for severe mental health disorders that have received less attention (Bock et al., 2022; Hidalgo-Mazzei et al., 2015).

Despite the study's design not focusing on the efficacy of the treatment, the outcome measures revealed significant interactions between the attributed group and time, with the experimental group evidencing higher recovery and quality of life, and lower difficulties in regulating emotions. Therefore, BRQ presents a good candidate to be used as primary outcome in a definitive trial, and QoL.BD together with DERS will be used as secondary outcomes in a definitive RCT. Our study is in line with Wright et al. (2021), which also observed changes in recovery after a DBT-informed approach for people in the bipolar spectrum. Moreover, depressive symptoms were stable in the EG, while the CG worsened at the 6-month follow-up. This outcome is consistent with other DBT interventions for BD, which provided preliminary evidence in decreasing depressive symptoms recurrence (Valls et al., 2022; Van Dijk et al., 2013), nonetheless, being a pilot study with a TAU comparison group, it is underpowered and this effect could arguably result from a nocebo effect, on the group that did not received the treatment.

In addition, we found evidence of a decrease in the difficulties regulating emotions (DERS) in the intervention arm, consistent with other DBT-ST for BD (Eisner et al., 2017; Neacsiu et al., 2014) and changes in empowerment to deal with symptoms and self-reassurance, that should be further explored in a future study. Changes were not found regarding shame, emotional reactivity, rumination or self-criticism. The short length of the treatment might have contributed to the absence of changes in these processes.

4.1. Limitations, barriers and future research

While providing encouraging and valuable insights, the current study is not exempt from certain limitations. The lack of blinding of the participants regarding the condition they are allocated to is particularly challenging in psychology intervention studies, considering usually the participants know if they have been allocated to the treatment group. Nonetheless, to blind participants allocation and simultaneously maintain more participants in the control group, the introduction of an active control group with the same number of contact moments, could significantly improve the reliability of the study. Additionally, the assessors were not blind to treatment, which has been known to generate performance bias in the case of participants and detection bias for assessors (Juul et al., 2021). A more robust approach in a definitive trial should incorporate a blinding strategy covering all assessment moments, to decrease bias as much as possible.

Moreover, we encountered a substantial dropout rate within the control group, further compounded by our efforts to ascertain the reasons for attrition proving unsuccessful. This dual challenge significantly impacts our ability to draw conclusive insights from the study, as a portion of the data remains inaccessible. The absence of dropout reasons hampers our understanding of participant behaviour and introduces potential biases in the interpretation of study outcomes.

Another facet warranting attention is the attrition of potential participants due to access to technological resources. Some individuals were prevented from participating due to a lack of means to engage digitally, which had not been anticipated. In forthcoming definitive trials, proactive measures should be adopted, such as providing the necessary resources (i.e. tablets, computers) to access the groups for the duration of the trial (Bock et al., 2022; Hyland et al., 2022). Furthermore, diversifying schedules and offering multiple time slots would facilitate participant enrolment, bolstering the number of eligible participants and enhancing the possibility to achieve desired sample sizes for a robust RCT.

Another limitation that should make us look with caution at the recruitment plan and retention rates is the context of the COVID-19 pandemic, which might not be replicated in a full-scale RCT. In order to properly address the mentioned limitations and implement improvements to the design and to the therapy protocol, subsequent feasibility testing will be necessary to establish whether the retention rates of the overall trial improve, before progressing to a definitive trial of Bi-REAL.

5. Conclusion

In conclusion, the viability and feasibility of implementing a trial of this design among individuals with bipolar disorder are substantiated, underlining the practicality and acceptance of the proposed methodology, having identified areas for enhancement. Furthermore, the detected areas to improve retention, assessment bias and overall acceptability offer a strategic pathway to optimise the study before a definitive trial, contributing to its successful execution.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jad.2024.04.033.

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Ethics approval and consent to participate

This study was approved by the Faculty of Psychology and Educational Sciences Ethics Committee (Reference Number: 06/12/13/5.11) and the Ethics Committee of all the sites involved and went through the scrutiny of the Scientific Committee of ADEB. Data confidentiality and anonymity was assured, as well as clear instructions about the General Data Protection Regulation (GDPR).

CRediT authorship contribution statement

Julieta Azevedo: Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Michaela Swales:** Writing – review & editing, Supervision, Project administration, Conceptualization. **Diogo Carreiras:** Writing – review & editing, Methodology, Investigation, Data curation. **Raquel Guiomar:** Writing – review & editing, Visualization, Investigation, Formal analysis, Data curation. **António Macedo:** Writing – review & editing, Supervision, Conceptualization. **Paula Castilho:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization.

Declaration of Generative AI and AI-assisted technologies in the writing process

While preparing this work, the authors used Chat GPT 3.5 to improve language and readability. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the publication's content.

Declaration of competing interest

The authors have no conflict of interest to declare.

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