Full Title	**Bi-REAL - DBT Skills Online Group Intervention for Bipolar Disorder: a feasibility study**
Short Title/Acronym	Bi-REAL a DBT Skills intervention for BD: feasibility study
Document date:	**Version 1.4 - 31.12.2020**
National Clinical Trial:	NCT04797351 (Date registered: 15/03/2021)
Unique Protocol ID:	UPID: BD/130116/2017_Pilot
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Contents

1. GLOSSARY of Terms and Abbreviations

ABED	Associação de Apoio aos Doentes Depressivos e Bipolares
AR	Adverse Reaction
BD	Bipolar Disorders
BSD	Bipolar Spectrum Disorder
DBT	Dialectical Behaviour Therapy
FPCEUC	Faculty of Psychology and Educational Sciences – University of Coimbra
FMUC	Faculty of Medicine – University of Coimbra
HMDS	Hamilton Depression Scale
ICF	Informed Consent Form
Participant	An individual who takes part in a clinical trial
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
ST	Skills Training
UC	University of Coimbra
YMRS	Young Mania Rating Scale

2. SUMMARY/SYNOPSIS

Short Title	**BI-REAL: a 12-session DBT Skills Group Intervention adapted for Bipolar Disorder – a feasibility Randomized Pilot Trial**
Methodology	Feasibility study with a two-arm randomised parallel controlled trial design
Research Sites	*University of Coimbra - Center for Research in Neuropsychology and Cognitive and Behavioral Intervention (CINEICC)*
Objectives/Aims	To assess the feasibility and acceptability of a future definitive randomised controlled trial (RCT) evaluating the feasibility and acceptability of a Dialectical Behaviour Therapy Skills intervention for adults with bipolar and related disorders
Number of Participants/Patients	60
Main Inclusion Criteria	*Client group: individuals with a Diagnosis of Bipolar and Related Disorders:* *Inclusion criteria:* i) aged 18 or over ii) lifetime diagnosis of Bipolar Disorder (I,II, "other specified bipolar disorder") or Cyclothymic Disorder, according to DSM-V iii) mood instability (at least one complete mood episode in the last 5 years, and reported interference of sub-clinical mood symptoms) iv) Sufficient competency in Portuguese to be able to complete study measures without the need for translation. v) Having access to means to participate in the online group (i.e. access to a stable internet connection, having a functional camera and microphone on their computer, and zoom) Exclusion criteria: i) current high risk of suicide (measured through clinical interview) ii) Bipolar disorder secondary to an organic cause; iii) Diagnosis of substance dependence or continuous illicit substance misuse resulting in uncertain primary diagnosis;

	iv) Acute episode of mania, hypomania or major depressive episode (at baseline) or not euthymic. v) Other high-risk pervasive disorders such as Borderline Personality Disorder; persistent self-injury; *vi)* the person lacks capacity to consent to treatment, low insight *vii)* Receiving psychological specific treatment for BD
Statistical Methodology and Analysis (if applicable)	Quantitative analysis: descriptive, linear mixed models Qualitative analysis: qualitative interview and questionnaire assessing programmes utility, acceptability and satisfaction
Proposed Start Date	01.02.2020
Proposed End Date	31.08.2022
Study Duration	24 months from obtaining approvals to delivery of intervention programme to the experimental group, and assessment of all participants 6 month after randomisation; plus 6 months post data collection for production of a report.

3. SCIENTIFIC RATIONALE

Bipolar disorder (BD) is a serious mental disorder characterised by episodes of mania, hypomania, and depression, occurring with a typically cyclical course (Johnson, 2004). In addition to mood instability, BD has been associated with significant functional impairment, lower quality of life, and higher rates of suicide compared to the general population (Pompili et al., 2014). Despite advancements in pharmacological and non-pharmacological treatments, BD often involves recurring episodes and subclinical symptoms within episodes (Geddes & Miklowitz, 2013). Predicting the course and outcome of the disorder remains challenging. BD ranks as the sixth leading cause of disability-adjusted life years worldwide, imposing substantial costs on society, patients, and mental health services (Vos et al., 2020).

Even though the aetiology of BD is still unclear, it is considered multifactorial, involving a combination of genetic and environmental factors. While fewer studies have explored the role of psychosocial factors in the development and maintenance of BD, some risk factors have been identified. Negative

early experiences, family characteristics, and adverse life circumstances have been implicated. Research has also found higher levels of childhood abuse and current internalised shame in individuals with BD compared to control groups. Stressful life events may act as triggers for affective symptoms, and individuals with BD often face stigma, which can negatively impact their social and occupational functioning (Fowke et al., 2012). Pharmacological interventions prevail as the primary management tool in BD. However, most patients are not fully stabilised on drug therapies alone, and a large number of patients experience residual symptoms; thus, full functional recovery is uncommon (Geddes & Miklowitz, 2013; Roth & Fonagy, 2005). Hence, growing evidence and international guidelines support the need to use psychosocial interventions as adjuvant therapies to improve recovery in BD (C. Henry et al., 2011; Slade & Longden, 2015).

Our research adopts a recovery-based perspective, aiming to foster hope, understanding, and empowerment while striving for a meaningful and satisfying life, with less emphasis on clinical outcomes. Recovery in mental health encompasses more than the traditional clinical definition focused on symptom reduction, hospitalisation rates, and medication adherence. It emphasises achieving a better quality of life despite ongoing clinical symptoms (Jones et al., 2013).

Psychoeducation (PE) and Cognitive-Behavioral Therapy (CBT) are the most extensively studied psychosocial interventions for BD, with some evidence supporting their efficacy (Colom et al., 2009; NICE, 2014; Salcedo et al., 2016). However, there are also contradictory findings contesting their efficacy, and that is why there are still no consensual Gold standard psychosocial interventions in BD (Geddes & Miklowitz, 2013). A systematic review regarding empirically supported psychosocial interventions for BD suggested Dialectical Behavior Therapy (DBT) as a promising treatment for BD needs further research (Salcedo et al., 2016). Nonetheless, standard DBT and the available evidence of its efficacy mainly target key psychological and interpersonal processes hypothesised to contribute to negative emotion (e.g. anger, sadness) but does not address or help clients to manage high/hypomanic mood states present in BD, which demands an adaptation of the standard skills training to BD. We took that into consideration and the work of DiRocco et al. (2020), along with the DBT skills workbook that Van Djick (2009) developed for people with BD, and developed a 12-session skills intervention programme. A couple of studies have examined modified versions of DBT as an intervention for Bipolar Disorder for adolescents and adults, with preliminary encouraging results (Goldstein et al., 2014; Van Dijk et al., 2013; Wright et al., 2018). Even so, none has been fully powered randomised controlled trial or included individuals across the BSD, and there is no evidence, as far as we know, that any intervention programme with DBT for BD was conducted in Portugal. Thus, DBT seems to be a promising approach, given its components for emotion regulation, and has shown some

preliminary findings to reduce depressive and manic symptoms as well as to improve emotional dysregulation in BD groups (Goldstein et al., 2007; Van Dijk et al., 2013).

This study aims to investigate if our programme Bi-REAL (Respond Effectively and Live mindfully), a 12-session online DBT skills intervention for BD, is acceptable and feasible and if it shows preliminary improvements in selected variables connected to recovery and emotional regulation and other psychological processes, in a randomised controlled pilot trial.

4. TRIAL AIMS

1. To inform the recruitment and timeline of a future fully powered trial by establishing the number of participants identified, approached, consented, randomised and completed.
3. To refine future trial procedures by establishing the acceptability and experience of the trial process to participants, including randomisation and completion of outcome measures.
4. To determine the optimal primary outcome measure in a future trial by assessing the performance of selected candidate primary outcome measures with respect to the level of acceptability to participants (completion rates) and participant-perceived relevance and value, and based on some additional secondary measures that are thought to improve with DBT-ST.
5. To inform estimation of sample size for a future trial by measuring data completeness at follow-up (participant attrition).
7. To further assess the acceptability of the treatment via qualitative interviews and, based on input from trial participants and clinicians, to further refine and develop the treatment manual and the procedures for training trial therapists.

4.1 General aims

We will also evaluate whether the following criteria have been met prior to planning a future definitive trial:

1. Trial participation does not lead to serious negative consequences (unexpected adverse reactions) for our participants.
2. Any serious concerns about the acceptability and feasibility of the trial procedures can be rectified prior to a full trial.
3. Follow-up data at 3 months is available from at least 60% of participants.
4. At least 60% of patients complete treatment (attend at least 50% of possible sessions).

5. METHOD

5.1 Research Design

Our feasibility study is a two-arm randomised parallel controlled trial design: where we intend to have 60 participants that will be randomised on a 1:1 ratio to Treatment as Usual (TAU) [control arm] or Bi-REAL programme plus TAU (TAU + Bi-REAL) [intervention arm]. Outcome measures will be recorded at baseline and at post-intervention (3 months after baseline) and with a follow-up point at 3 months after treatment ends (6 months post-randomisation). See appendix 1 for more detail.

5.2 Inclusion Criteria

i) aged 18 or over
ii) lifetime diagnosis of Bipolar Disorder (I,II, "other specified bipolar disorder") or Cyclothymic Disorder, according to DSM-V (American Psychiatric Association, 2013)
iii) mood instability (at least one complete mood episode in the last 5 years, and reported interference of sub-clinical mood symptoms)
iv) Sufficient competency in Portuguese to be able to complete study measures without the need for translation.
v) Having access to means to participate in the online group (i.e. access to a stable internet connection, having a functional camera and microphone on their computer, and zoom)

5.3 Exclusion Criteria

viii) current high risk of suicide (measured through clinical interview)
ix) Bipolar disorder secondary to an organic cause;
x) Diagnosis of substance dependence or continuous illicit substance misuse resulting in uncertain primary diagnosis;
xi) Undergoing an acute episode of mania, hypomania or major depression (at baseline) or not euthymic (cut off YMRS > 8 and HMDS >8 used);
xii) Other high-risk pervasive disorders such as Borderline Personality Disorder, persistent self-injury;
xiii) The person lacks the capacity to consent to treatment, has low insight
xiv) Receiving psychological intervention tailor-made for BD (if the person is receiving psychological support, the person assessing them will register the recurrence and type of intervention and assess on a case-by-case basis if this treatment is concurrent)

Neither medication status nor the presence of other co-morbid psychiatric conditions (apart from the previously mentioned exclusion of BPD) will serve as exclusion criteria but will be recorded. Participants will not be denied access to routine care but will have changes to their support and treatment recorded.

The decision to include patients that are receiving some kind of psychological intervention, which is not adapted for BD was made in conscience, under the assumption that this skills training can be useful for people with BD even if they are undergoing psychological treatment that does not address these skills and can thus be useful to deliver parallelly to it. The usual complete DBT treatment also has DBT skills training plus individual therapy, with the addition of this being DBT based. Nevertheless,

it is common to have patients going to the skills groups and receiving parallel individual psychological support in other therapy, and it is seen as useful. By not changing the current conditions of the patients recruited, we are also respecting the ecological validity of the study.

5.4 Recruitment Sites

To establish the feasibility of the full RCT, we will deliver the Bi-REAL programme online with the collaboration and referral of three hospitals in the centre of Portugal: Centro Hospital e Universitário de Coimbra (CHUC), Centro Hospitalar de Leiria (CHL) and Centro Hospitalar do Oeste (CHL) and with the additional collaboration of a national association that supports people with bipolar diagnosis (ADEB[1]).

5.5 Treatment Arms

Bi-REAL was developed in consultation with other researchers and clinicians who delivered DBT to people with mood instability. Furthermore, the research team was composed of clinical psychologists and psychiatrists with expertise in DBT and dealing with BD patients. The programme was thus conceptualised respecting the five key principles of DBT: i) clearly structured treatment; ii) application of behavioural therapy; iii) emphasis on validation of emotional response; iv) dialectical stance, balancing acceptance and change; v) integration of mindfulness practice. The programme was thus organised in a pre-session to contextualise the skills training and its principles, where the bio-social model adjusted to BD was presented, and the assumptions and goals of treatments were explained. The 12 sessions were then conceptualised to follow the same structure as the treatment proposed in the skills training manual (Linehan, 2014); the four skills modules of DBT (i.e. mindfulness, interpersonal effectiveness, emotional regulation and distress tolerance), with more sessions being dedicated to emotion regulation (6/12), considering it necessary to dedicate more training and time to this topic. The sessions seek to include examples that people with BD can relate to and cover skills for observing events, thoughts, emotions and bipolar symptoms and skills to down-regulate high emotions and upregulate low/depressive symptoms. The component of interpersonal difficulties will also be covered in detail to help participants develop their skills in order to decrease possible triggering situations of bipolar mood swings. There is an effort to help participants to learn and generalise behaviours through teaching and practice. Homework provides opportunities to generalise these skills across real-world contexts and continue the use of skills beyond treatment end. Moreover, participants can have up to 3 individual sessions (of 30 minutes maximum) delivered online or by

[1] For more information https://www.adeb.pt/

telephone to help them generalise skills (a register will be kept with the number of sessions taken by each participant).

Real-life generalisation of skills was also supported by the facilitators within sessions via email (participants will be allowed to submit support with skills application and homework) or message for quick advice on skills use. Additionally, participants will be invited to attend a group booster session at 1,5 months post-intervention to help keep the skills present and generalise to their lives (see Appendix 2 for programme layout).

Each Bi-REAL group will be delivered by two clinical psychologists, a leader and a co-leader (as defined in the DBT skills training manual, Linehan 2014). Both therapists will have a CBT background, experience delivering group interventions, and intensive training (at least 5 days intensive training) in DBT. The leader will be the same across groups.

Our comparison arm will be receiving general psychiatric treatment, which in Portugal is considered the treatment as usual (even though it is not clearly described in the literature) and can be receiving psychotherapy, as long as it is not a specialized intervention for people with BD. There is no formal data to indicate the likely content of TAU for individuals with Bipolar Disorder in Portugal. Thus, we will record this in terms of the services received by each participant during the trial in order to characterise the TAU across services. The decision to keep people that are receiving other kind of individual therapy intends to keep the ecological validity of the study and characterize what is the treatment as usual. At the same time, since DBT full programme includes individual therapy and sees it as a mean to help generalize what is learned, it is not seen as concurrent but complementary. Also, since there is no gold-standard psychological treatment for this client group against which to benchmark a new treatment, we want to know what they are receiving and what can be helpful to add.

5.6 Study Recruitment Plan

Participants will be recruited via i) psychiatric services and specialist appointments for mood disorder and bipolar disorder; ii) ADEB (newsletter and sessions online to associates to raise interest); iii) online support groups for bipolar disorder vii) self-referral (adds online and distribution of flyers and posters in mental health services).

Researchers will be present at the hospitals and ADEBs facilities to recruit potential participants at advised moments (e.g. when they go for their routine appointment, at events for people with BD). Additionally, patients identified by their psychiatrists as a potential participant will be approached by clinicians at their routine appointments, who will briefly explain what the study consists of, and if

permission to contact is given, they will be approached by the research team via telephone/email (according to their mentioned preference).

People who self-refer will be contacted by the research team to discuss the study and then, if the participant wishes to proceed, they will need to sign a consent form and send it to the research team, after which they will the be assessed. For the complete study recruitment and procedure flow chart see Appendix 1.

5.7 Procedure

Participants which reveal interest in the study at the screening process will agree a suitable date and time with the researcher (either face-to-face or online) to do the following assessment. The screening interview will allow an explanation of the study details, addressing any queries, and address the suitability of the participant to the study. Individuals deemed ineligible at this stage will be informed accordingly. All participants will be thanked for their collaboration and will be reassured that what they choose to do will have no impact in the care they receive. Eligible participants will then coordinate a convenient date and time with the researcher for the baseline assessment appointment.

At baseline assessment (which can take place face to face or through videocall) the researcher will discuss the study information sheet and request the patient to read the consent form and sign (after asking any additional questions). If the participant needs more time to consider the study, the researcher will reschedule a second moment to allow for the appropriate time for them to consider their participation. In this baseline assessment the participant will undergo a semi-structured clinical-interview (Clinical Interview for Bipolar Disorder; Azevedo et al., nd), and the interviewer will also fill in two additional scales to monitor depressive and hypo/mania symptoms (Hamilton Depression Scale and Young Mania rating Scale, respectively). At this point, the researcher will also ask the necessary questions to understand if the person meets inclusion / exclusion criteria.

If the participant is eligible for the study, they will then complete the baseline self-report measures (see Appendix 3): measures assessed by the clinician will take place during the assessment (i.e. CIBD, YMRS and HMDS), and the self-report measure will be sent via link to be completed online. Participants in the experimental group will additionally fill in an adapted diary card and submit it once a week (between sessions), where they are asked to rate their emotions intensity and use of skills (see Appendix 4). Additionally, after each session participants will be asked to anonymously fill in the Group Session Rating Scale (GSRS; Duncan et al., 2003) which briefly assessed participants experience of the group regarding relationships in the group, goals and topics, approach/method, and overall cohesion.

Following randomisation (more details in that section) participants will be followed up by the research team at 3 and 6 months post baseline. At 3 month follow up (post-randomisation) blinding was not

conducted considering the need to conduct a qualitative interview of the intervention programme. Independent clinicians and researchers conducted these interviews, and the qualitative interview was anonymised so that participants could share their experience freely about the facilitators, programme and group. All the assessment moments are described in Appendix 1 and the assessment measures per moment in Appendix 3.

5.8 Randomisation Procedure

Following completion of the baseline assessment, eligible participants will be randomised on a 1:1 ratio (minimisation by age and psychological support status [undergoing psychotherapy versus not receiving psychological support]) to Treatment as Usual (TAU) [control arm] or Treatment as Usual plus Bi-REAL programme (TAU + BI-REAL) [intervention arm]. We will perform a stratified block randomization after participant has attended a baseline assessment and has consented to the trial, a member of the research team will enter a set of data on the randomisation website (www.randomization.com). Participants will receive an email informing them of the arm to which they have been allocated. For participants allocated to the intervention arm, they will be informed at the group starting date and time.

5.9 Data collection

5.9.1 Feasibility and acceptability of study and treatment:

- Feasibility will be assessed in terms of numbers of patients identified, approached, consented, randomised and completed over the active period of recruitment and treatment, as well as participant attrition from the trial and from treatment.
- To assess acceptability all participants will complete a questionnaire about their experience in the trial, at the end of the programme, and will be interviewed to express what was more and less useful in the programme, suggestions, and skills retention. The participants will also be asked at 6 month follow up what was retained and continues to be used in their daily life, to assess transferability of what was learned.

5.10 Measures

The following measures where used, to assess diagnosis, clinical symptoms and self report:

Diagnosis and mood episode/functionality/empowerment (completed at baseline and 3, 6 months post baseline):

- Clinical Interview for Bipolar Disorder (CIBD; Azevedo et al., nd) – Clinical semi-structured interview which allows for the diagnosis of Bipolar and Related disorders. It includes an

assessment of mood symptoms interference and empowerment towards bipolar symptomatology by the interviewee – outcomes considered will include empowerment and interference of mood symptoms

- Young Mania Rating Scale - observer rated, measures current mania symptoms
- Hamilton Depression Scale - observer rated, measures current depressive symptoms

5.10.1 Primary outcomes:

• BIPOLAR DISORDER RECOVERY QUESTIONNAIRE (Jones et al., 2013), a 36 item self-report measure that has been developed to measure personal recovery in people with Bipolar Disorder.

• BRIEF QUALITY OF LIFE IN BIPOLAR DISORDER SCALE(Michalak et al., 2010), a self-report measure of quality of life in bipolar disorder that has been specifically designed for and validated with individuals with the condition.

The additional measures selected for this study include secondary outcomes we believe might change due to the skills developed in the programme, and some hypothesised mechanisms of change, providing data on their performance and preliminary analysis of change. Hypothesised treatment targets include difficulties in regulating emotions, hyper/hypo activation, emotional acceptance, emotional awareness, self-reassurance, self-criticism (hated selfxxx(and shame.

5.10.2 Self-report measures of therapy process (completed at baseline, 3, and 6 months post baseline):

- Depression Anxiety and Stress Scale (DASS-21) (Henry & Crawford, 2005) – we will use the depression and anxiety subscales to assess the psychological distress.
- Multidimensional assessment of thymic states (MATHYS) (Henry et al., 2008) - is a visual analogic scale consisting of 20 items. These items corresponded to five quantitative dimensions: emotional reactivity (EM), thought/cognitive processes (CO), psychomotor function (MO), motivation (VO) and sensory perception (SE). These are them grouped and vary into three continuous: Hypo-reactivity/Hyper-reactivity (EM), Retardation/Acceleration (CO, MO), and Decrease/Increase (VO, SE). The range of scores is from 0-200 and it will vary between the continuous with zero corresponding to one end and 200 to the other, and values around 100 will correspond to stability.
- Distress Tolerance Scale (DTS) (Simons & Gaher, 2005) - is a 15 item self-report measure of emotional distress tolerance. Individuals select on a 1-5 likert scale (Strongly Disagree, Mildly

Disagree, Feel Neutral, Mildly Agree, Strongly Agree) about each of the statements about distress tolerance.

- Difficulties in Emotion Regulation Questionnaire (DERS) (Gratz & Roemer, 2004) - is an instrument measuring emotion regulation problems. The 36 items self-report scale asks respondents how they relate to their emotions in order to produce scores on the following subscales: Nonacceptance of emotional responses: tendency to have a negative secondary or non-accepting reaction to one's own distress; Difficulty engaging in goal-directed behaviour: difficulty in concentrating and/or accomplishing tasks when experiencing negative emotions; Impulse control difficulties: difficulty remaining in control of one's behaviour when experiencing negative emotions; Lack of emotional awareness: reflects a lack of awareness or inattention to emotional responses; Limited access to emotion regulation strategies: reflects the belief that there is little one can do to regulate oneself once upset; and Lack of emotional clarity: reflects the extent to which an individual knows and is clear about his or her emotions. This scale measures an integrative conceptualization of emotion regulation as involving not just the modulation of emotional arousal, but also the awareness, understanding, and acceptance of emotions, and the ability to act in desired ways regardless of emotional state.
- Philadelphia Mindfulness Scale (PHLMS) (Cardaciotto et al., 2008) – this scale has 20 items and measures two dimensions of mindfulness: Acceptance and Awareness (having 10 items per subscale, and providing separate scoring for the dimensions and not as a total). This self report scale asks people to assess how much they have experienced each of the described items over the past week, and participants rate from 0-Never, 1-Rarely, 2-Sometimes. 3- Often, to 4-Very often.
- External and Internal Shame Scale (EISS) (Ferreira et al., 2022) – assesses global shame experience, as well as its external and internal dimensions. This scale consists of eight items, generated to measure the four central domains of general feelings of shame, and present in both external and internal shame: inferiority/inadequacy, sense of exclusion, uselessness/emptiness and criticism/judgment. Each of the dimensions is composed of four items: external (e.g., "I feel that others see me as uninteresting") and internal dimensions (e.g., "I feel that I am different and inferior to the others"), to which the participants must answer using a 5-point scale (0 = "Never" to 4 = "Always"). Scores vary between 0 and 32 points, with higher values indicating higher levels of shame.
- Ruminative Responses Questionnaire (RRQ-10) (Treynor et al., 2003) – a 10-item scale that measures the individuals' tendency to ruminate when in a sad or depressed mood. This scale comprises two subscales: brooding (5 items) and reflection (5 items). To the statement "what

you generally do, not what you think you should do when feel down, sad or depressed" respondents are asked to rate each item on a 4 point scale (1 = "almost never" to 4 = "almost always"). Thus, scores may range between 10 and 40, with higher scores indicating higher levels of ruminative responses styles.

- Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS) - (Gilbert et al., 2004) is a 22-item self-report questionnaire in which participants are asked to rate how they typically think and react when things go wrong for them. To a first probe statement: "When things go wrong for me…" participants respond on a 5-point Likert scale (ranging from 0 = not at all like me to 4 = extremely like me). A scale has three factors: Inadequate Self (e.g. 'I think that I deserve my self-criticism'; 'I remember and dwell on my failings'); Hated Self (e.g. 'I stop caring about myself'; 'I do not like being me'); Reassured Self (e.g. 'I still like being me'; 'I can feel lovable and acceptable').

5.10.3 Measures completed session by session by participants in Bi-REAL + TAU condition.

- Online Version of Diary card submitted before each session (see Appendix 4);
- Group Session Rating Scale (GSRS; Duncan et al., 2003) participants are asked to fill in this assessment scale after each session in an anonymous way to decrease social-desirability bias; this measure uses a four-item visual analogue scale designed to assess key dimensions from 0 to 40: Relationship (0 – *"I did not feel heard, understood, respected, and/ or accepted by the leader and/ or the group"* to 40 - *"I felt heard understood, respected, and accepted by the leader and the group*"); Goals and Topics (0 – "*We did not work on or talk about what I wanted to work on and talk about"* to 40 - *"We worked on and talked about what I wanted to work on and talk about."*); Approach or Method (0 – "The leader and/ or the group's approach is not a good fit for me" to 40 – "The Leader and group's approach is a good fit for me."); and Overall (0 – "There was something missing in group today - I was not engaged" to 40 – "Overall today's group was right for me - I felt engaged").

5.10.4 Qualitative process evaluation

This feasibility study will focus upon understanding what might be seen as facilitators and barriers to implementation of the intervention to inform implementation of the intervention within a future definitive trial. Within these, we will consider seek to understand the *context* (how external factors influence the delivery and functioning of the interventions) and *implementation* (evaluation of the way in which the intervention is delivered, and the quality and quantity of the intervention delivered).

5.11 Criteria for Discontinuation

We will discontinue the treatment if the participant manifest they do not wish to continue with the intervention or study; the participant or facilitators (or researchers) believe that the intervention or trial participation will result in, or is likely to result in, a serious adverse reaction if continued; if the participant does not attend four consecutive group therapy sessions (they are made aware of this rule before starting).

5.12 End of Study Definition

The end of the study will be defined as after providing the programme to the control group, after their last 6 month follow up assessment which is part of our ethic responsibility.

6. STATISTICAL CONSIDERATIONS

6.1 Sample Size

60 participants (30 per group) will allow us to address the stated objectives of this feasibility trial. This represents recruitment to Bi-REAL at full capacity (10 per group), with equivalent numbers randomised to TAU. Previous studies with this population estimate an attrition rate of 17% (with respect to the primary end point at nine months post-randomisation. Our sample size of 48 will allow us to estimate this level of attrition for a future definitive trial with a precision of ±15% with 95% certainty.

6.2 Method of analysis

Given the feasibility objectives of this study, the initial focus of data analysis will be descriptive, regarding the enrolment data, attrition rates and treatment and study dropoust. We will also describe the acceptability of the programme though the report of the programme assessment questionnaire and interview, along with the scores of the GSRS. The number of people completing the intervention will be reported and it is defined as attending at least 65% of group sessions, which corresponds to 8 sessions approximately). We will also report on the number who complete the research outcome measures alongside means and standard deviations regarding the number, length and frequency (time between) of sessions. All protocol deviations, along with reasons and number of missing items on questionnaires will be reported.

To address the other primary outcome (i.e., recovery and QoL) and informing future sample size estimation) levels of completion and mean and standard deviations (or equivalent) for all outcomes for both study arms will be reported at baseline, three and six months follow up, as will participant

rankings of personal value and relevance of clinical outcome measures. Additionally we expect to do linear mixed models analysis to explore the time x group interaction in the variables in study.

6.3 Qualitative analysis

Qualitative interviews will be analysed using a framework approach, whereby data will be coded according to both theme and case, and then abstraction of themes and explanatory inferences will occur iteratively with codes, themes and inferences being quality checked by a second team members.

7. ETHICS

7.1 The intervention

Particular caution and attention must be taken when administering a new therapeutic intervention to monitor any potential negative reactions. Although psychological interventions generally have minimal harmful effects, there is still a slight risk involved. The skills training we developed is however based on a well-established treatment (DBT), and it has been adapted and used in BD, with no adverse reactions reported, and with good acceptability (Eisner et al., 2017; Goldstein et al., 2015; Van Dijk et al., 2013). Nevertheless, more robust studies are still needed, since most of these studies were pilots as well. Our programme seeks to follow the same principles, with some additional innovations, namely with specific skills to help upregulate and down regulate emotions in depressive/hypo/manic periods. If at any period a potential ethical issue arises from delivery of the treatment, the participants will be approached, and risk protocol will be put into place (according to the place where they are routinely followed). Information provided by participants as part of their treatment will be treated in confidence. Participants will be informed of the circumstances under which confidentiality may be broken and will be consulted with as far as possible if this should become necessary.

In addition, regarding the group session, a set of "ground rules" will be established at the pre-session, together with the facilitators. All group participants will be made aware that they should not divulge what is talked in the group, and at the same time they do not have to share any information in the group that they do not wish to. Due to the training approach and format of the group, which is not the same as a traditional therapeutic group, participants can discuss the material and exercises without having to share personal information if they do not wish to.

7.2 Use of randomisation

Participants will informed of the randomisation procedure and that they have a fifty-fifty chance to receive the treatment. Since we are aware of the ethical issue underlying the allocation to a control group, and the possible frustration/disappointment of the participants for not being allocated to the

intervention group, we also make sure they know the importance of the randomisation for a future definitive trial, and this ensures the two groups do not differ systematically in their baseline characteristics. The participants are also informed they will be offered the possibility to do the programme after they finish their 6 month follow up assessment, so they have the same possibility as the experimental group.

7.3 Informed consent

At the initial contact with the research team, the study will be discussed, and patients asked whether they wish to move to the next stage (receiving the full information sheet and arranging a telephone research screening interview, with specific consent, if appropriate). If the patient indicates at this point – or later - that they do not wish to take part they will not be contacted further by the research team, other than to invite them to take part in a brief survey to ascertain their reasons for not taking part. If at the baseline assessment the patient wishes to consent to participation at that point the researcher will take consent and then proceed to the research assessment; if the patient does not wish to participate their involvement will finish at this point, and reasons will be noted. If the patient wishes to take more time to consider the study, the research assessment appointment will be rescheduled to allow sufficient time for them to consider their participation. Participants judged not to have capacity due to severe symptom levels will be reassessed at a later point convenient to them and directed the necessary care in the meantime.

7.4. Participant and researcher Risk

Inherent in the nature of the population under scrutiny is the risk of suicide. We will follow good clinical practice in monitoring for suicide risk during all research assessments with service-user participants. Risk to/from self or others, if detected, will be responded to in accordance with the established protocols established in the hospitals or association the participants are followed. Participants will be informed of any circumstances under which confidentiality may be broken.

7.5 Data Protection

Information collected in clinical assessment will be stored according to standard practice and GDPR advice, stored in a way that allows them to be easily traced and located if required, while making sure the paper documents are stored in locked cabinets and access is restricted to the people in the research team that need access. This documents will be stored in the hosting research center – CINEICC, in the building 2 facilities of the Faculty of Psychology and Educational Sciences, University of Coimbra. Information held on computers will be stored in a password protected location with codes

replacing personal data when possible. Original research records will be retained for 5 years, after which they will be retained in electronic form and original records destroyed. The electronic records will be kept for 10 years after the end of the study.

8. RESEARCH GOVERNANCE

The study will be conducted in compliance with the principles of the Declaration of Helsinki and in accordance with all applicable regulatory requirements for a study with its specifications. The University of Coimbra and its scientific committee will monitor its progress, and relevant contacts are provided for participants to contact in case they have any concerns regarding the study. The same agreement has been made with the hospitals and organisation collaborating with the study.

8.1 Monitoring and adverse events

All serious adverse events that are trial or treatment related will be recorded and immediately reported to the responsible investigator, and measures to be taken will be discussed. Additionally, in line with other studies, we will screen for adverse events that are not trial or treatment related and active withdrawals from treatment. We will also monitor if the participant changed their medication. Participants will be asked at their follow-up assessments if any adverse events happened since the beginning of their participation, or since the last assessment (in the 6 month follow up).

9. FINANCE AND FUNDING

This study is funded by the Portuguese Foundation of Science and Technology (or: *Fundação para a Ciência e Tecnologia - FCT),* with the attribution of an individual doctoral scholarship (funder reference number: SFRH/BD/130116/2017).

10. CHANGES TO THE INITIAL PROJECT

Changes to the assessment procedures were done due to the pandemic Covid-19, which had implications in the recruitment strategies and the timings initially projected. This project proposal was adjusted and resubmitted to the ethics committee involved in the study and approved.

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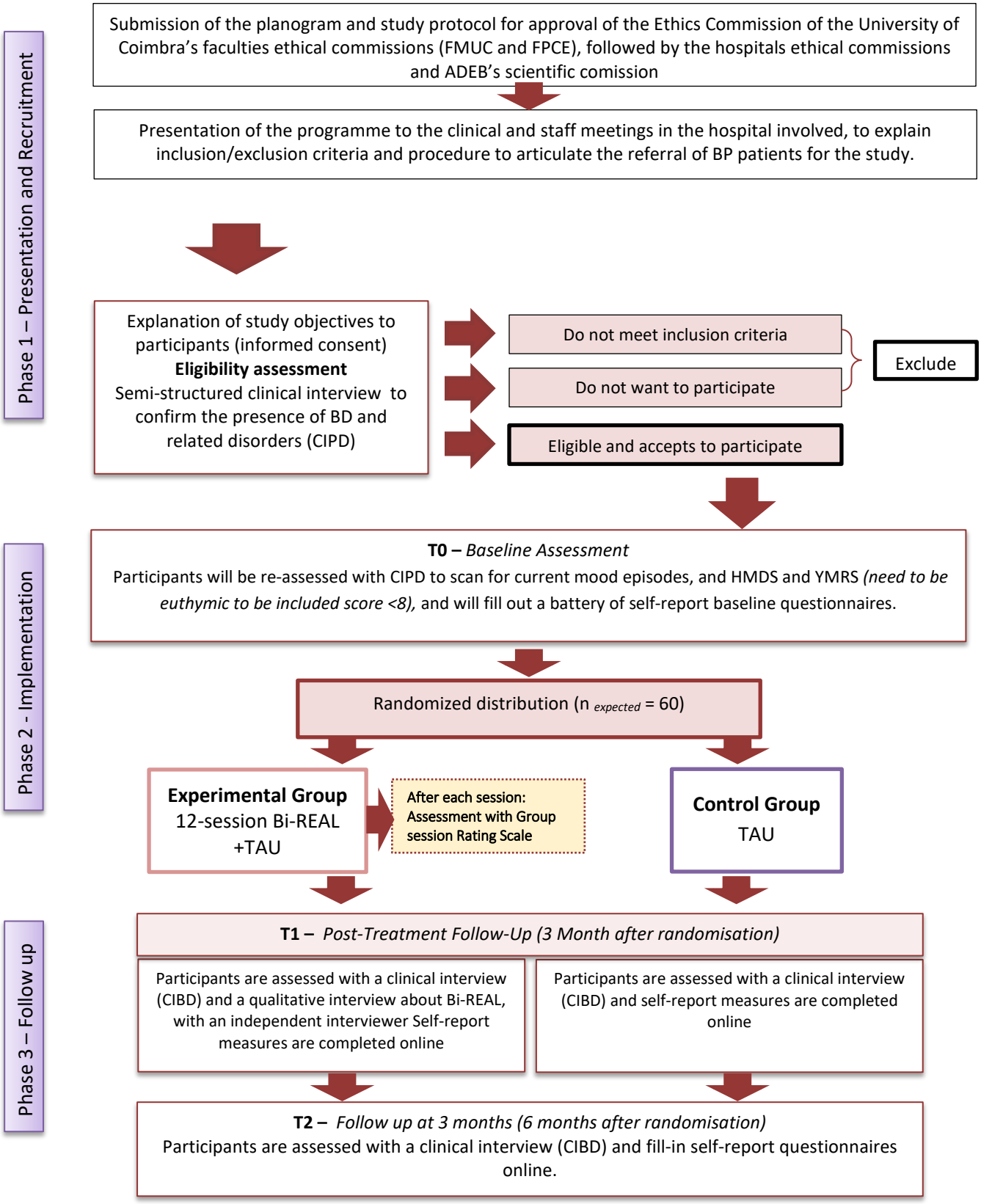
Appendix 1 - Study Procedure: Application phases, randomised distribution of participants and assessment moments



Appendix 2 : Bi-REAL: 12-Session DBt-ST programme for Bipolar Disorder Layout

MODULE	SESSION	CONTENT AND SKILLS	TARGET PROBLEMS / 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 the difference between 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 behavior
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	Skilfully make an action plan. Put emotions into action
	6	CAMARAS – managing highs and lows	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, 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	Validation Review what was learned, what to take home.	Review of the program and intention to continue training skills.

Appendix 3: Timing of Measures Completed by Participants

Table 1 - Schedule of participants' assessment

	Pre-intervention		**During Intervention**[2]	**Post-intervention**	
	Screening	*Baseline*	*Each session*	*Post-treatment*	*3 months follow-up*
Clinical Interview for Bipolar Disorder (CIBD)	✓	✓		✓	✓
Demographics (e.g**.** Age, education, employment)		✓			
Clinical History *(e.**g.**, family history of mood disorder, age of onset, number of affective episodes, hospitalisation)*		✓			
Hamilton Rating Scale for Depression (HMDS)		✓		✓	✓
Young Mania Rating Scale (YMRS)		✓		✓	✓
Quality of Life in Bipolar Disorder (QOL-BD)		✓		✓	✓
Bipolar Recovery Questionnaire (BRQ)		✓		✓	✓
Multidimensional assessment of thymic states (MATHYS)		✓		✓	✓
Distress Tolerance Scale (DTS)		✓		✓	✓
Depression Anxiety and Stress Scale (DASS-21)		✓		✓	✓
Difficulties in Emotion Regulation Questionnaire (DERS)		✓		✓	✓
Philadelphia Mindfulness Scale (PHLMS)		✓		✓	✓
External and Internal Shame Scale (EISS)		✓		✓	✓
Rumination-Reflexion Questionnaire (RRQ-10)		✓		✓	✓
Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS)		✓		✓	✓
The group session rating scale (GSRS)[2]			✓		
Bi-REAL Diary card[2] (Appendix 4)			✓		

[2] Only for the Experimental Group

Appendix 4: Diary card (1/2)

Diary Card

Week overall assessment	Mood	Sleep	Adherence to medication *Did you take your medication as prescribed?*		
	-5 to +5	Mean number of hours daily:	Yes	No	Only part of it
Week 1					

Mood Scale:

-5 = Extremely depressed/ the more depressed I have ever been | 0 **= Stable Mood** (neither depressive nor hypo/maniac) **5 =** Extremely hipo/maniac (the most maniac I have ever been)

Instructions: Mark the days where you used the following skills

Mindfulness	1. Wise Mind	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	2. Observe	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	3. Describe	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	4. Participate	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	5. Non-judgemental	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	6. One mindfully	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	7. Effectively	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
Emotional Regulation	8. Identify and name emotions	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	9. Check the Facts	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	10. Opposite Action	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	11. Problem Solving	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	12. Accumulate Positives	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	13. Build Mastery	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	14. Cope ahead	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	15. CAMERAS	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
Distress Tolerance	16. STOP	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	17. TIPP	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	18. ACCEPTS	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	19. Self-Soothing	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	20. Redirect the mind	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	21. Open hand, half smile	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	22. Radical Acceptance	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
Interpersonal Effectiveness	23. DEAR MAN	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	24. GIVE FAST	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun
	25. Interpersonal Validation	Monday	Tuesday	Wednes.	Thurs	Friday	Sat	Sun

Appendix 4: Diary card (2/2)

Register emotions and skills frequence during the week:

0 = Not at all	1 = A little bit	2 = Somehow	3 = A bit strong	4 = very strong	5 = Extremely strong

Anger	Fear	Joy	Nervous/ Anxiety	Sadness	Shame/ Guilt	Use of the skill and their effect
0-5	0-5	0-5	0-5	0-5	0-5	0-7

Rating scale anchors for mood:
1 = Severely depressed (the most depressed I get) 5 = Stable mood (not depressed, not hypo/manic)
10 = Severely hypo/manic (the most hypo/manic I get)

***Used Skills**

0 = Not thought about or used	4 = Tried, could use them, but they didn't help
1 = Thought about, not used, didn't want to	5 = Tried, could use them, helped
2 = Thought about, not used, wanted to	6 = Didn't try, used them, didn't help
3 = Tried but couldn't use them	7 = Didn't try, used them, helped

Connecting with the personal goals stablished:

Regarding the behaviour you want to decrease, how would you say you manage to do that this week:

I did not have this behaviour at all	***1***	***2***	***3***	***4***	***5***	*I did it every time I felt like doing it*

Regarding the behaviour you want to increase, how would you say you manage to do that this week:

I did not have this behaviour at all	***1***	***2***	***3***	***4***	***5***	*I did it every time I planned to do it*