Report: Randomised Controlled Trial of Dialectical Behaviour Therapy Interventions for Young People with Difficulties Regulating their Emotions

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Executive Summary

Background: There is a need for rigorous research on Dialectical Behaviour Therapy (DBT) for young people with emotion dysregulation (ED) and emerging Borderline Personality Disorder (BPD). This report describes a randomised controlled trial (RCT) conducted at Headspace Southport between May 2018 and July 2019. The RCT tested the outcomes of two different DBT interventions: a 16-week, intensive DBT program, and an 8-week DBT skills training group. We hypothesised that improvements would be greatest for participants in the 16-week DBT group, at the primary follow-up time-point of 16 weeks.

Methods/Design: This RCT employed a staggered, parallel-groups design. We aimed to recruit 120 participants (60 per condition), aged 16-25 years, who met criteria for ED and/or emerging BPD. Participants were randomised via a computer-generated sequence. Participants received DBT at headspace Southport, a youth mental health service in Gold Coast, Australia. Data was collected via online surveys at baseline, and follow-up points of 8, 16, and 24 weeks. Researchers assessing outcomes were blind to group assignment.

Results: Analyses were conducted to compare group outcomes on the primary variable of ability to regulate emotions, and secondary outcomes of suicidal ideation, coping skills, mindfulness, depression, anxiety, stress, functioning, and impulsivity. The main analysis was a 3 x 2 mixed-design Analysis of Variance (ANOVA). Both groups showed significant improvements over time with DBT, on almost all measured outcomes. Comparing DBT interventions (8-week skills program vs 16-week intensive program), there were two variables on which participants' outcomes differed based on group allocation. Participants in the 16-week program reported significantly greater quality of life, and lower suicidality risk, compared to participants in the 8-week program, at 16-week follow-up.

Discussion: This trial demonstrated the efficacy of DBT for improving treatment outcomes with young people, aged 16-25 years, displaying ED and BPD symptoms. The results suggested that participants in the 8-week program received similar benefits to participants in the 16-week program. However, there was some additional benefit of the 16-week program, for improving quality of life, and reducing suicidality risk. These findings have implications for the mental health industry, in terms of guiding best practice for other organisations using DBT with young people. This trial contributed valuable information to the DBT literature, by filling a knowledge gap on the efficacy of different DBT interventions with young people.

Trial Registration: This trial was registered (before recruitment of the first participant) on the Australian New Zealand Clinical Trials Registry: ACTRN12618001023246.

Keywords: Randomised controlled trial, Dialectical Behaviour Therapy, young people, Borderline Personality disorder, Emotion dysregulation.

Introduction

This report describes a research project conducted at Headspace Southport from May 2018 to July 2019. The project was funded by the Gold Coast Primary Health Network and conducted by the Lives Lived Well research team at the University of QLD. Lives Lived Well employed a Clinical Project Lead (Carlie Robertson) and a Clinical Research Assistant (Lily Davidson) to design and implement the intervention and to collect and analyse data. The research project was embedded in routine practice at headspace which included training and supervision of clinicians. This report includes results from three time points – baseline, 8 and 16 weeks. Data is continuing to be collected at 24 weeks post baseline for the final group and will be reported by approximately August 30, 2019.

Adolescence and emerging adulthood are high-risk periods for the development of psychiatric problems. Poor mental health during this time is predictive of ongoing challenges in adult life (Ibraheim, Kalpakci, & Sharp, 2017; Pepping, Duvenage, Cronin, & Lyons, 2016). During the transition to adulthood, young people can experience increased difficulties in flexibly responding to, and managing their emotions (Theurel & Gentaz, 2018). High levels of emotion dysregulation (ED) are also associated with increased anxiety (Folk, Zeman, Poon & Dallaire, 2014), depression (Perlman et al., 2012), conduct problems (Dadds *et al*., 2016), attentional deficits and hyperactivity (Shaw, Stringaris, Nigg & Leibenluft, 2014), and harmful alcohol and drug use (Korsgaard, Torgersen, Wentzel-Larsen & Ulberg, 2016; Langås, Malt & Opjordsmoen, 2012).

A core feature of Borderline Personality Disorder (BPD) is difficulty regulating emotions (Crowell, Beauchaine & Linehan, 2009; Glenn & Klonsky, 2009; Hughes, Crowell, Uyeji & Coan, 2012; Ibraheim, Kalpakci & Sharp, 2017). Suicidal (Greenfield *et al*., 2015) and self-injurious behaviours (Brickman et al., 2014) are commonly used by individuals with BPD to regulate their emotions. The incidence of suicide attempts among individuals with BPD is highest among those in their twenties, with a lifetime completion rate of 10% (Paris & Zweig-Frank, 2001).

Dialectical Behaviour Therapy (DBT) is a behavioural therapy model developed as treatment for parasuicidal (i.e. apparent attempt at suicide in which death is not the aim) women with BPD (Robins & Chapman, 2004; Swales, Heard & Williams, 2000). The term "dialectic" refers to the two opposing foci that characterise DBT: acceptance and change. The skills modules delivered in DBT generally focus on building acceptance-oriented skills such as distress tolerance, or change-oriented skills such as emotion regulation. A range of strategies are used including communication, validation, problem-solving, and case management (Rathus & Miller, 2002). Four modes of treatment are typically used in DBT and include group skills training, individual psychotherapy, telephone coaching between sessions (when required), and a therapist consultation team meeting (Robins & Chapman, 2004).

There is good evidence that DBT is an effective treatment for adults with suicidal tendencies and BPD. Extensive research on DBT in adult populations supports its efficacy in a range of therapeutic settings (Groves, Backer, Van den Bosch & Miller, 2011; Stoffers et al., 2012). Success of the therapy with adult populations has prompted its adaptation to youth populations. When compared to treatment as usual, there is evidence DBT results in

significant improvements for young people across a range of outcomes including: frequency of psychiatric hospitalisations (Rathus & Miller, 2002); treatment completion rates (Rathus & Miller, 2002); overall functioning (McDonell et al., 2010); use of psychotropic medications (McDonell et al., 2010; Pistorello et al., 2012); depression (Pistorello et al., 2012); suicidality (Pistorello et al., 2012); BPD symptoms (Pistorello et al., 2012); social adjustment (Pistorello et al., 2012); and non-suicidal self-injurious behaviour (McDonell et al., 2010; Pistorello et al., 2012; Santamarina et al., 2017). Despite these promising results, the body of DBT research on younger populations is limited and lacks methodological rigour, because most trials have been quasi-experimental.

The aim of this trial was to investigate the effectiveness of DBT for young people exhibiting ED and BPD symptoms. Given that there is limited quality evidence, it is important to fill current knowledge gaps on: the effectiveness of DBT for young people with ED and BPD symptoms, and on the intensity or format of DBT required to achieve positive outcomes. To achieve this, researchers on this trial conducted a randomised controlled trial (RCT) comparing two DBT interventions: an 8-week DBT skills training group and an intensive 16-week DBT program, incorporating 16-weeks of individual DBT therapy and DBT-skills training groups. We hypothesised that, while both groups would show improvements, these improvements would be greatest for participants in the 16-week DBT group, at the primary follow-up time-point of 16 weeks. If successful, this trial could have widespread, practical implications for the way practitioners use DBT with young people. Moreover, this trial has the potential to provide sound empirical support for the efficacy of DBT as an intervention for young people with BPD and/or ED and demonstrate the superiority of one DBT intervention (8-week DBT skills group or 16-week intensive DBT program).

Method

Design

This RCT employed a parallel groups, superiority design, comparing the effectiveness of two intervention arms: (i) an 8-week DBT skills training group and (ii) a 16-week intensive DBT program. This study protocol was approved by the Human Research Ethics Committee A at the University of Queensland (UQ) (#2018000419).

Participants

Participants were 106 young people (mean age = 20.5 years), consisting of 74.5% females, 21.7% males, and 3.8 % transgender and other gender participants (see Table 1, next page, for further demographic information). Participants were referred to the program by clinicians at Headspace Southport and other healthcare services in the Gold Coast region of QLD. To be eligible, participants had to be 16-25 years old, and displaying symptoms of emotion dysregulation (score > 40 on the Difficulties in Emotion Regulation Scale -16 Item version; DERS-16; Bjureberg et al., 2016) and/or emerging BPD (answer 'true' to 3 or more items on the International Personality Disorders Examination BPD subscale; IPDE; Loranger, Janca & Satorius, 1997). The following exclusion criteria applied: had received DBT before, was not fluent in English (spoken or written), had an unmodified hearing impairment, had a current serious medical problem or traumatic injury, was currently experiencing psychotic episodes, had a moderate to severe intellectual impairment, or was currently experiencing acute alcohol or drug withdrawal.

Materials

The following materials were required during the project: computer(s) with access to software subscriptions of Qualtrics, SPSS Statistics, and Microsoft Powerpoint (for creating online surveys, conducting data analysis, and creating group PowerPoints respectively), computer or smartphone access for participants to complete online surveys (all participants had their own), DBT booklets for participants (created from photocopies of "DBT Skills Training Handouts and Worksheets" [Linehan, 2014]), a copy of Marsha Linehan's "DBT Skills Training Manual" (Linehan, 2015) for clinicians to use, PowerPoints and 'prompt sheets' to assist group facilitators (written by the clinical project lead, based on Marsha Linehan's books), boxes with sensory stimuli (for participants in group sessions), one mobile phone for phone coaching, diary cards for 16-week program participants (see Appendix A), attendance record and fidelity checklists for group facilitators, roster for group facilitators, roster for phone coaching, training and certification for DBT facilitators (acquired through Peter King, trainer at the Australian DBT Institute). *Note.* There were eighteen DBT clinicians involved in facilitating this program.

Table 1. *Descriptive characteristics of the total sample and subsamples of participants in the DBT program.*

Variables	Total (*N* = 106)	8-Week Program (*N* = 54)	16-Week Program (*N* = 52)
Demographics			
Sex, *n* (%)			
Male	23 (21.7)	12 (23.1)	9 (17.6)
Female	79 (74.5)	37 (71.2)	41 (80.4)
Transgender	2 (1.9)	2 (3.8)	1 (2.0)
Other	2 (1.9)	1 (1.9)	
Age, *M (SD)*	20.6 (2.5)	20.9 (2.5)	20.3 (2.6)
Birth Country, *n* (%)			
Australia	89 (84.0)	44 (84.6)	43 (84.3)
Other	17 (16.0)	8 (15.4)	8 (15.7)
Indigenous Status			
Aboriginal	7 (6.7)	5 (9.6)	1 (2.0)
Aboriginal & Torres Strait Islander	1 (1.0)	0 (0)	1 (2.0)
Neither Aboriginal/Torres Strait Islander	97 (92.4)	47 (90.4)	49 (96.1)
Employment Status, *n* (%)			
Not Working	66 (62.9)	35 (67.3)	30 (58.8)
Casual/ Part time	31 (29.6)	13 (25.0)	17 (33.3)
Full time	8 (7.6)	4 (7.7)	4 (7.8)
Highest Education			
Secondary School Incomplete	28 (26.7)	15 (28.9)	13 (25.9)
Secondary School Complete	28 (26.7)	12 (23.1)	16 (31.4)
Certificate/Diploma	41 (39.1)	23 (44.2)	17 (33.4)
Bachelor Degree	8 (7.6)	2 (3.8)	5 (9.8)
Relationship Status, *n* (%)			
Not in a relationship	56 (56.6)	20 (38.5)	27 (52.9)
In a relationship	43 (43.4)	32 (61.5)	24 (47.1)
Student Status, *n* (%)			
Yes	39 (37.1)	17 (32.7)	21 (41.1)
No	66 (62.9)	35 (67.3)	30 (58.8)

Note. Table 1 continues over the page.

Family History Mental Health			
Yes	81 (77.9)	45 (86.5)	35 (68.6)
No	0 (0)	0 (0)	0 (0)
Unsure	23 (22.1)	7 (13.5)	16 (31.4)
Recent Mental Health Treatment			
Yes	75 (78.1)	27 (62.8)	35 (70.0)
No	21 (21.9)	16 (37.2)	15 (30.0)

Note. Recent Mental Health Treatment = Within past 2 months. Valid Percentages reported (percentages accounting for missing cases).

Procedure

Study setting. The study took place at Headspace Southport (Gold Coast, Queensland). Headspace is for youth mental health. The centre is run by Lives Lived Well, a not for profit organisation providing mental health and drug and alcohol services in QLD and NSW.

Recruitment. The DBT program was promoted to clinicians at Headspace Southport and other mental health organisations on the Gold Coast (e.g. Headspace Tweed Heads, Robina Hospital Child and Youth Mental Health Inpatient Unit; Gold Coast University Hospital Acute Care Team) via recruitment flyers, emails, and in-person. When young people were referred to the program (via phone or email), the clinical research assistant at Headspace called them to assess their eligibility (inclusion criteria above) and obtain their verbal consent to participate in the research project. The aim was to recruit 60 participants per condition (120 participants total) during the project. Based on practical limitations (referral numbers, clinician capacity and room availability) we recruited a final sample of 106 participants, across three treatment waves. Wave 1 treatment groups (*n* = 30) operated between May and August 2018. Wave 2 (*n* = 37) operated between September and December 2018. Wave 3 (*n* = 39) operated between January and May 2019.

Allocation to Interventions. Once participant numbers reached capacity (approximately two weeks before the first group session of each wave was due to begin), the recruited participants were randomly allocated to one of two DBT interventions: 8-weeks or 16-weeks of DBT. Allocation was done by a research assistant at the University of Queensland (UQ), using a computerised randomisation table. Participants were allocated on an approximately equal ratio. All outcome assessors and data analysts remained blind to participants' allocation until after all data analyses were complete, including all members of the LLW research team at UQ, and the research assistant at Headspace Southport.

Interventions. Participants were randomly assigned to one of the two interventions described below. The interventions were facilitated by a team of eighteen staff at headspace Southport who were trained and certified as DBT facilitators. The content for the DBT group skills sessions was written (in PowerPoint form) by a senior clinician at headspace, with several years' experience delivering DBT. Group content was based on materials the "DBT Skills Training Manual" [Linehan, 2015], written by DBT founder, Marsha Linehan. The content was adapted to suit 8-week and 16-week interventions (e.g. in the 16-week program, some topics were covered over two weeks, unlike the 8-week group). All participants received a booklet with handouts, extracted from the "Handouts and Worksheets" booklet that accompanies Linehan's manual. The certified DBT clinicians at headspace Southport used these resources to facilitate standardised groups. The facilitators of both programs worked on a roster system, wherein a team of 4-5 clinicians would rotate in and out as facilitator, providing breaks for facilitators some weeks.

> *Commitment Phase.* All participants received a preliminary phone call with the clinical research assistant (prior to being recruited), during which they discussed important information about the program, including: explanation of DBT, dates, time, location, barriers to attendance, and attendance expectations (in DBT, missing

three consecutive sessions results in discharge from the program; Linehan, 2014). Participants in the 16-week program received additional commitment work during the two weeks prior to DBT group sessions beginning. The 16-week participants received up to three contacts by their assigned DBT practitioner (phone or face-to-face), during which they completed a DBT commitment contract, which highlighted their goals, reasons for attending, barriers to attendance, and more (Linehan, 2014). Due to clinician capacity, participants in the 8-week program did not receive these commitment contacts (the 8-week DBT program did not include contact with an individual DBT practitioner).

8-Week DBT Group Skills Program. Participants in the 8-week group attended weekly, DBT group skills sessions for 8 consecutive weeks. Sessions were held on a mid-week afternoon, from 4:30-6:00pm (90 minutes) at Headspace, Southport. The group size was determined by the practical limitations mentioned above (e.g. referral numbers). The 8-week group sizes were as follows: Wave 1: 10 participants, Waves 2: 15 participants, and 3: 15 participants. Each of the 8 sessions covered one topic, including: Orientation, Mindfulness, Distress Tolerance (Part 1), Distress Tolerance (Part 2), Emotion Regulation (Part 1), Emotion Regulation (Part 2), Interpersonal Effectiveness, and Walking the middle path (See Table 2 on the next page for session topics).

16-Week Intensive DBT Program. Participants in the 16-week group attended one weekly DBT group skills session, and one weekly, individual DBT counselling session (with a DBT-trained clinician), for 16 consecutive weeks. Group sessions followed the same format as the 8-week program (described above). The groups covered the following 16 topics: Orientation, Mindfulness (Part 1), Walking the Middle Path (Parts 1-3), Mindfulness (Part 2), Distress Tolerance (Parts 1-3), Emotion Regulation (Parts 1-3), Mindfulness (Part 3), Interpersonal Effectiveness (Parts 1-3) (See Table 2, next page, for session topics). The 16-week group sizes were as follows: Wave 1: 10 participants, Wave 2: 12 participants, Wave 3: 12 participants. Participants in the 16-week program were assigned an individual DBT practitioner (one of the DBT group facilitators). Individual sessions were arranged between participants and their assigned DBT practitioner, to occur at Headspace Southport, at a suitable time each week (duration: 50 minutes). Individual practitioners tailored therapy to suit each participant, using Linehan's DBT-tools (e.g. handouts and diary cards) (Linehan, 2015). Facilitators also attended weekly, 90-minute DBT consults, during which they could seek advice from other clinicians. Participants in the 16-week group also had access to phone coaching for DBT-skills, 7-days per week (8am-8pm), for the 16-weeks of intervention.

Data Collection. Data was collected via online surveys that were created using Qualtrics and emailed to participants by the clinical research assistant at Headspace Southport. Participants were emailed a link to the baseline survey on the Friday before their first DBT group session. Participants also received surveys via email at the following timepoints: 8, 16 and 24 weeks from the baseline email (note: 24-week follow-up data is not available for analyses in this report, as it is still being collected). Responses were considered valid if

returned within 3 weeks. Participants received $30 reimbursement for completing each survey (via bank transfer from the LLW finance team), equating to a potential of $120 reimbursement per person.

Table 2. Session Topics Covered in 8-week DBT Program and 16-Week DBT Programs.

Group Session Number	8-Week Program	16-Week Program
1	Orientation	Orientation
2	Mindfulness	Mindfulness (3 States of Mind)
3	Walking the Middle Path	Walking the Middle Path (Dialectics)
4	Distress Tolerance Part 1	Walking the Middle Path (Validation)
5	Distress Tolerance Part 2	Walking the Middle Path (Behaviourism)
6	Emotion Regulation Part 1	Mindfulness (What Skills)
7	Emotion Regulation Part 2	Distress Tolerance Part 1
8	Interpersonal Effectiveness	Distress Tolerance Part 2
9	N/A	Distress Tolerance Part 3 (Reality Acceptance)
10	N/A	Emotion Regulation Part 1
11	N/A	Emotion Regulation Part 2
12	N/A	Emotion Regulation Part 3
13	N/A	Mindfulness (How Skills)
14	N/A	Interpersonal Effectiveness (FAST Skill)
15	N/A	Interpersonal Effectiveness (GIVE Skill)
16	N/A	Interpersonal Effectiveness (DEAR MAN Skill)

Note. N/A = Not Applicable.

Statistical Analyses

Assumptions Testing. Various tests were conducted to ensure compliance with the assumptions of a Mixed-Model Analysis of Variance (mixed ANOVA). These assumptions included: continuous dependent variable (DV), categorical independent variables (IVs), absence of outliers, normal distribution, homogeneity of variance, sphericity, and adequate sample size. In cases where the assumption of sphericity was violated, the *F*-value was corrected using the Greenhouse-Geisser. Skewed distributions of DVs were corrected with appropriate transformations when required. Outliers were removed when impacting significantly on skewness and/or the main outcome.

Preliminary Analyses. To identify any key differences between the two DBT interventions at baseline, characteristics from baseline surveys were compared using chi-square tests (categorical variables) and t-tests (continuous variables). All analyses were conducted on an intention-to-treat basis, using a *p*-value of <0.05 to indicate statistical significance.

Main Analysis. Data was analysed using a 3 x 2 mixed-design ANOVA, with a within-subjects factor of time (baseline, follow-up 1 at 8 weeks, follow-up 2 at 16 weeks) and a between-

subjects factor of type of treatment (8-week group or 16-week group). All randomised participants were included in intent-to treat analyses according to their group allocation.

Measures

The online surveys contained the following measures. Participants completed all questionnaires below at every time-point, unless otherwise stated.

Demographics

Participants reported the following demographics at baseline: age, gender, birth country, Aboriginal/Torres Strait Islander status, family history of mental illness (Yes/No/Unsure), highest level of education, student status, employment status, and relationship status (Yes/No).

Screening Measures

Borderline Personality Disorder Symptoms. Measured using the BPD subscale of the International Personality Disorder Examination (IPDE) (Loranger, Janca & Satorius, 1997): The IPDE is a semi-structured clinical interview designed as a standardised diagnostic tool for identifying mental health disorders. The IPDE BPD subscale uses a dichotomous (true/ false) scoring procedure to identify personality traits indicative of BPD. Note. This measure was used to determine eligibility only.

Primary Outcome

Emotion Regulation. Measured using the Difficulties in Emotion Regulation Scale – 16 Item Version (DERS-16) (Bjureberg et al., 2016). The DERS-16 is an abbreviated version of the original 36-item DERS (Gratz & Roemer, 2004). The DERS was designed to be a comprehensive measure of ED (and was also used to determine eligibility; see 'Method' section). The DERS taps into emotional dimensions of awareness of emotions, acceptance of emotions, ability to engage in goal directed behaviour when experiencing negative emotions and access to effective emotion regulation strategies. The DERS achieves this by using a five-point Likert scale ranging from 1 "Almost Never" to 5 "Almost Always". The final score of the DERS provides insight into how the respondent regulates their emotions, their awareness of their own emotional state and their ability to control their emotions.

Secondary Outcomes

Quality of Life. Measured using the Assessment of Quality of Life - 6 Dimensions (AQOL-6D) (Richardson, Peacock, Hawthorne, Iezzi, Elseworth, & Day, 2012). The AQOL-6D measures six dimensions related to quality of life, then provides a global 'utility' score. The dimensions measured are independent living, relationships, mental health, coping, pain and senses.

Coping Skills. Measured using the Coping Inventory for Stressful Scale (CISS) (Endler & Parker, 1990). The CISS has been designed to measure 3 different coping styles: task-

oriented coping, emotion-oriented coping, and avoidance-oriented coping . Respondents are asked to rate their coping styles on a five-point Likert scale ranging from “1: Not at All” to “5: Very Much”. The three coping styles reflect the different ways individuals handle stressful situations and provide insight into whether they react to stress well or poorly. In this study, we used the Emotion-Oriented coping (negative) and Task-Oriented coping (positive) subscales.

Suicidal Ideation. Measured using the Mini International Neuropsychiatric Interview (M.I.N.I.) Suicidality Screen (Sheehan et al., 1998). The M.I.N.I. suicidality screen is taken from the larger standardised Mini-International Neuropsychiatric Interview, which aims to assess whether the respondent has been suicidal, and the magnitude of their suicidality. The scale contains six items and uses dichotomous response selection (Yes/No).

Mindfulness. Measured using the Five Facet Mindfulness Questionnaire - Short Form (FFMQ-SF; Bohlmeijer et al., 2011). The FFMQ-SF is an abbreviated (24-item) version of the original 39-item FFMQ (Baer et al., 2006). The FFMQ-SF is highly reliable and valid measure of different aspects of Mindfulness. This is achieved by use of a five-point Likert scale that ranges from “1: Never or Very Rarely True” to “5: Very Often or Always True”. The five facets are observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.

Depression, Anxiety, Stress. Measured using the Depression Anxiety Stress Scale - 21 Item Version (DASS-21) (Henry & Crawford, 2005). The DASS-21 is an abbreviated version of the original, 42-item DASS (Lovibond et al., 1995). The DASS has been designed to measure the magnitude of three significant emotional states: depression, anxiety and stress. This is achieved by use of a four-point Likert scale that ranges from “0: Did not apply to me at all” to “3: Applied to me very much or most of the time”. The resulting score provides feedback about the respondents functioning over the past week and how each of these negative emotions has been affecting them.

Impulsivity. Measured using the Short UPPS-P Impulsive Behaviour Scale (S-UPPS-P; Cyders et al., 2014). This is achieved by using a four-point Likert scale that ranges from “1: Agree Strongly” to “4: Disagree Strongly”. The UPPS-P model of impulsivity proposes that impulsivity as a multi-faceted and multi-dimensional construct, comprising five impulsive personality traits: Negative Urgency, Lack of Perseverance, Lack of Premeditation, Sensation Seeking, and Positive Urgency.

Functioning. Measured using the Multidimensional Adolescent Functioning Scale (MAFS) (Wardenaar, Johanna, Wigman, et. al., 2013). The MAFS is a 23-item scale, designed to measure everyday functioning in adolescents. The MAFS includes three separate subscales that assess: family-related functioning, peer-related functioning and general functioning. The MAFS uses a four-point Likert scale that ranges from “1: Not at all/ Rarely” to “4: Always/ Almost always”.

Results

Preliminary Analyses

Tests in the preliminary stages of analysis highlighted the need to transform data for a few outcomes using recommended methods (see Tabachnick & Fidell, 2007) and remove some extreme outliers prior to final analyses. Variables with significant positive skew were correcting using a square root transformation (SQRT). These variables were: AQOL-6D Utility Score, FFMQ Non-react, SUPPS Lack of Perseverance, SUPPS Negative Urgency, SUPPS Sensation Seeking, and MAFS General Functioning. Variables with significant negative skew were correcting using a reflection of the square root transformation. These variables were: DASS-21 Depression, and CISS Emotion Oriented Coping. The following variables were corrected for normality by removing an extreme outlier (no transformation): FFMQ Observe, FFMQ Act Aware, and SUPPS Lack of Premeditation. For variables corrected using the reflection of the square root transformation (SQRTr), results must be interpreted with caution, as the direction of effects appears inversed (see Appendix B; analyses performed using variables with a SQRTr transformation are indicated by "*Reflection of Square Root Transformation performed").

Main Analyses

*Significant Main Effects***.** Data was analysed using a 3 x 2 mixed-design ANOVA, with a within-subjects factor of time (baseline, follow-up 1 at 8 weeks, follow-up 2 at 16 weeks) and a between-subjects factor of type of treatment (8-week or 16-week groups). Results revealed that any form of DBT treatment (8 or 16 weeks) had a significant effect (improvement) over time (95% confidence level) on the following outcome variables (see Appendix B for graphs of main effects, and Table 3 below for statistics relevant to all main effects).

- Ability to Regulate Emotions, $F(1.75, 138.51 = 41.278$, $p < 0.001$, $\eta p2 = .343$.
- Stress, $F(2, 152) = 8.168$, $p < 0.001$, $\eta p2 = .097$.
- Depression, $F(2, 154) = 8.488$, $p < 0.001$, $\eta p2 = .099$.
- Emotion-orientated coping, $F(2, 114) = 36.621$, $p < 0.001$, $\eta p2 = .391$.
- Task-orientated coping, $F(2, 158) = 7.439$, $p = .001$, $\eta p2 = .086$.
- Mindful observation skills, $F(2, 150) = 4.530$, $p = .012$, $\eta p2 = .057$.
- Non-reactance to inner experience, $F(1.72, 130.99) = 11.895$, $p < 0.001$, $\eta p2 = .135$.
- Non-judgement of inner experience., $F(2, 152) = 4.245$, $p = .016$, $\eta p2 = .053$.
- Ability to Describe, $F(1.85, 140.36) = 6.011$, $p = .004$, $\eta p2 = .073$.
- Lack of perseverance, $F(1.72, 92.59) = 6.899$, $p = .003$, $\eta p2 = .113$.
- Negative urgency, $F(2, 106) = 9.248$, $p < 0.001$, $\eta p2 = .148$.
- Positive urgency, $F(2, 110) = 3.963$, $p = .022$, $\eta p2 = .067$
- Sensation Seeking, $F(1.66, 91.08) = 4.83$, $p = .015$, $\eta p2 = .081$.
- Lack of premeditation, $F(2, 106) = 9.759$, $p < .001$, $\eta p2 = .155$.
- Family-related functioning, $F(2, 154) = 3.561$, $p = .031$, $\eta p2 = .044$.
- Peer-related functioning, $F(2, 154) = 14.908$, $p < .001$, $\eta p2 = .162$.
- Quality of Life, $F(2, 146) = 7.158$, $p = .001$, $\eta p2 = .089$.

Interaction Effects (Time by DBT Group). There was only one outcome on which clients who received the 16-week intensive treatment had significantly better outcomes at the primary follow-up time point (16-weeks), than clients who received the 8-week treatment. This variable was overall quality of life (AQOL-6D Utility score). For quality of life, there was a main effect of time, meaning participants in both groups reported significant improvement in quality of life over time with DBT treatment, *F(*2, 146) = 7.158, *p* = .001, *ηp2* = .089. There was also a significant interaction between time and DBT group, indicating that participants in the 16-week program showed significantly greater improvements in quality of life, than participants in the 8-week program, over time; *F(*2, 146) = 5.003, *p* = .008, *ηp2* =.064. Figure 1 (below) shows that both groups reported similar quality of life at 8-week follow-up, however the 16-week group continued to improve over time, while the 8-week group reported a slight decrease in quality of life between follow-ups at 8-weeks and 16-weeks follow-ups.

Changes in Quality of Life Over Time Receiving DBT Treatment

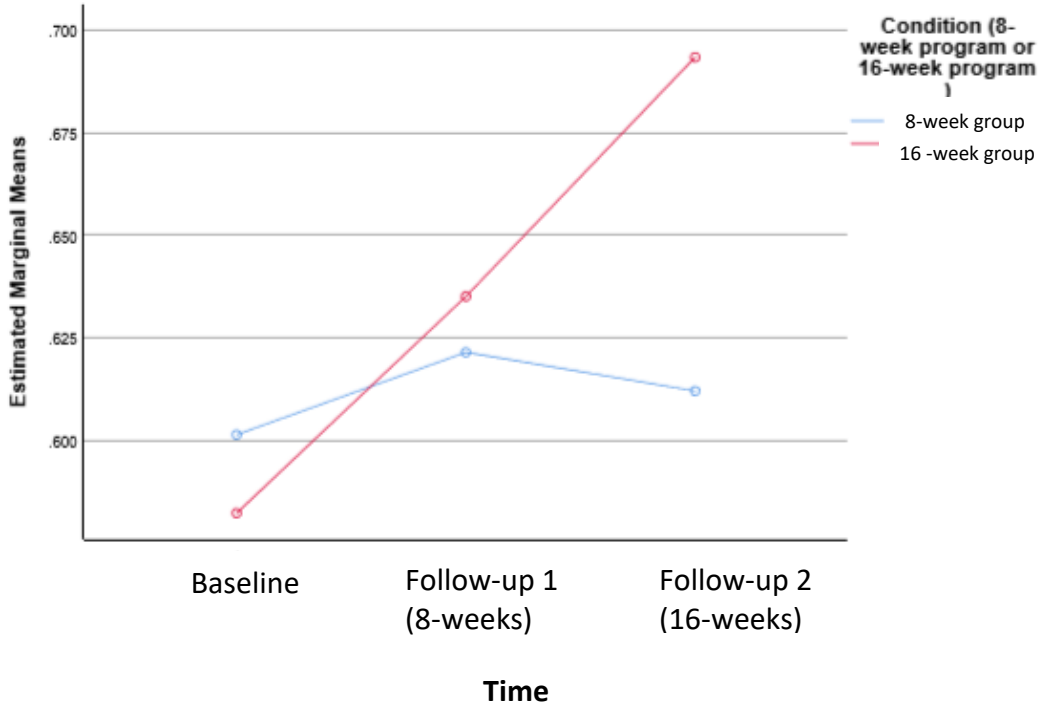


Figure 1. Comparing change in quality of life over time from baseline to 16-week follow-up, for the 8-week DBT program and 16-week DBT program subsamples.

Non-Significant Main Effects. Results also showed that DBT in any form (8-week or 16-week program) had no significant main effect on **anxiety**, *F*(2, 154) = 1.820, *p* = .166, ηp2 = .023; **ability to act with awareness**, *F*(2, 150) = 2.733, *p* = .068, ηp2 = .035; and **general functioning** *F*(2, 154) = 1.05, *p* = .352, ηp2 = .013. For each of these variables, there was also no significant interaction between time and DBT group, indicating no difference between the outcomes of DBT groups over time.

Non-Parametric Tests

For the suicidality variable, the data was non-normally distributed, and no transformations or removal of outliers could correct for normality. The sign test (non-parametric test) for non-normal distributions was used to test for individual differences in scores within each treatment group over time. Overall test results showed significant change from baseline (*M* = 13.19) to Follow-up 2 (*M* = 12.90) (Z = -2.12; *p* = .034). But when results were analysed by group, only the 16-week group showed significant improvement in suicidality risk over time. Results of the sign test for the 8-week group indicated that there were no significant differences between participants' MINI scores from baseline (*M* = 12.63) to follow-up one (*M* = 12.73) (*p* = .839) or baseline to follow-up two (*M* = 13.43) (*p* = .690). Significant differences in MINI scores were reported for the 16-week group from both baseline (*M* = 12.78) to follow-up one (*M* = 11.53) (Z = -2.28, *p* = .026); and baseline to follow-up two (*M* = 12.31) (Z = -2.30, *p* = .022).

Table 3. Main Effects of Mixed Model ANOVA Comparing Outcomes of DBT 8-week Group and 16-week Group.

Variables	***F***	**df**	**Sig.**	**Partial Eta^2**
DERS Total	41.28	1.75, 138.51	.00***	.343
DASS Stress	8.17	2, 152	.00***	.097
DASS Depression	.49	2, 1548	.00***	099
DASS Anxiety	1.82	2, 154	.166	.023
AQOL-6D Utility Score	7.16	2, 146	.001**	.089
CISS Emotion Oriented Coping	36.62	2, 114	.00***	.391
CISS Task Oriented Coping	7.44	2, 158	.001***	.086.
FFMQ Observe	4.53	2, 150	012*	.057
FFMQ Non-react	11.90	1.72, 130.99	.00***	.135
FFMQ Non-Judge	4.25	2, 152	.016*	.053
FFMQ Describe	6.01	1.85, 140.36	.004***	.073
FFMQ Act Aware	2.73	2, 150	068	.035
SUPPS-P Lack of Perseverance	6.90	1.72, 92.59	.003***	.113
SUPPS-P Negative Urgency	9.25	2, 106	.00***	.148
SUPPS-P Lack of Premeditation	9.76	2, 106	.00***	.155
SUPPS-P Positive Urgency	3.96	2, 110	.022*	.067
SUPPS-P Sensation Seeking	4.83	1.66, 91.08	.015*	.081
MAFS FAMILY	3.56	2, 154	.031*	.044
MAFS PEER	14.91	2, 154	.00***	.162
MAFS GENERAL	1.05	2, 154	.352	.013

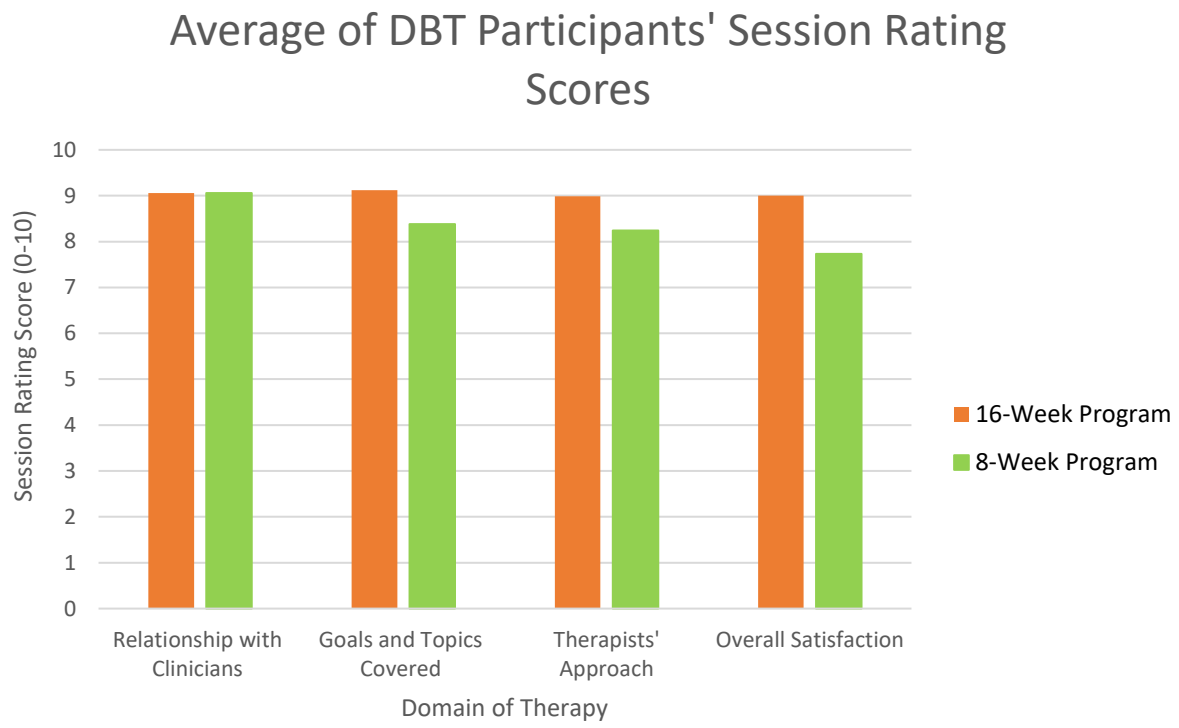
*Note. DERS-16 = Difficulties with Emotion Regulation Scale; DASS = Depression and Anxiety Scale; AQOL = Assessment of Quality of Life Six Dimensions; CISS = Coping in Stressful Situations; FFMQ = Five Face Mindfulness Questionnaire; SUPPS-P = Short Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency, Impulsive Behaviour Scale; MAFS = Multidimensional Assessment of Adolescent Functioning Scale; *p <.05 ** p <.01 ***p<.005.*

Client Satisfaction

We asked participants in Wave 3 (January-May 2019) to complete session rating scales (SRS; Duncan et al., 2003) after every group session. The session rating scale assesses participants' satisfaction with the session, on four domains: therapeutic relationship, goals and topics addressed, therapists' approach, and overall satisfaction.

Comparing Satisfaction Across Groups: 8-Weeks vs 16-Weeks DBT

Graph 1 (below) compares the average of SRS submitted weekly by participants in the 8-week DBT program and 16-week DBT program, on four domains of therapy. Ratings were slightly higher from participants in the 16-week program; however, the average satisfaction scores were high for participants in both interventions. *Note.* These scores were not tested for statistically significant differences between groups satisfaction scores.



Attendance Rates

Table 4, below, shows the attendance rates of participants in the DBT program, compared by treatment condition (8-week versus 16-week program) and Treatment Wave (1-3).

The overall attendance rate (across both DBT programs) was high, at 80.6%. Overall, attendance was higher in the 8-week program (55.85%), compared to the 16-week program (46.50%). The same pattern existed in every treatment wave, with higher attendance rates in the 8-week group, compared to the 16-week group (see Table 4 below).

Collapsing across treatment conditions, attendance was lowest in Wave 1 (43%), followed by Wave 3 (54.66%), and highest in Wave 2 (60.19%). The same pattern existed when comparing attendance rates in the 8-week group, and 16-week group, at each treatment wave; for both treatment groups, attendance was lowest in Wave 1, followed by Wave 3, and highest in Wave 2 (see Table 4 below).

Table 4. Attendance Rates of the Overall sample and subsamples of DBT Participants, Presented by Treatment Wave.

Attendance Rates	**Overall (*N* = 106)**	**8-Week Group (*n* = 52)**	**16-Week Group (*n* = 54)**	**% Difference by Condition**
All Waves Combined, *M (%)*	12.39 (80.60)	4.47 (55.85)	7.92 (46.50)	9.35%
Wave 1 Attendance, *M (%)*	5.47 (42.97)	3.70 (46.25)	6.35 (39.69)	5.56%
Wave 2 Attendance, *M (%)*	7.39 (60.19)	5.13 (64.13)	9.00 (56.25)	7.88%
Wave 3 Attendance, *M (%)*	5.68 (54.66)	4.38 (54.75)	8.73 (54.56)	0.19%

Note. M = Mean. % Difference by Condition = difference between attendance percentage for 8-week group and 16-week group

Qualitative Feedback from Clinicians and Participants

To obtain qualitative data, Headspace' clinical research assistant conducted a group interview with several DBT facilitators who worked on this project, and phone calls with 21 participants from DBT Wave 2. Facilitators and participants gave mostly positive feedback about the program. Participants who attended consistently reported feeling improvements on a broad range of outcomes, including mindfulness, interpersonal effectiveness, distress tolerance, and more. A common theme emerged around the duration of the program. Both facilitators and participants said that the 8-week program was too short to cover the content thoroughly; the program felt rushed compared to the 16-week group. Although the quantitative data showed no statistical difference in improvements between interventions, this feedback about the program duration was consistent, and could be considered for future programs (see 'Practical Implications' in 'Discussion' section, below).
Note. Qualitative feedback is not included in this report, because the voice-recordings have not been transcribed or thematically analysed. Ethics approval was obtained to conduct qualitative research with participants (UQ Human Research Ethics Committee A: #2018000419).

Discussion

The aim of this study was to investigate the efficacy of DBT for improving treatment outcomes in young people with emotion dysregulation and emerging BPD. The study also aimed to investigate the format and intensity of DBT required to achieve positive outcomes with this population. To achieve this, we conducted a RCT, comparing the outcomes of two DBT interventions: an 8-week DBT skills training group and an intensive 16-week DBT program, which incorporated DBT-skills training groups, and individual DBT therapy. We hypothesised that improvements would be greatest for participants in the intensive 16-week DBT program, at the primary follow-up time-point of 16 weeks.

Improvements Over Time

In line with hypotheses, results showed that participation in DBT, regardless of group allocation (8-week group or 16-week group), was related to improvements on a range of target outcomes. The outcomes included the primary outcome of ability to regulate emotions, and secondary outcomes of mindfulness, depression, stress, coping in stressful situations, impulsivity traits, functioning and suicidality risk. These results support and contribute new knowledge to the growing body of empirical evidence on the efficacy of DBT for improving treatment outcomes in adolescents and young adults (e.g. McDonell et al., 2010; Pistorello et al., 2012; Santamarina et al., 2017). Most past studies on DBT in younger populations lack methodological rigour (mostly quasi-experimental trials). The current study demonstrated positive outcomes of DBT, in the context of a RCT. Since the RCT is the most scientifically rigorous method for evaluating the effectiveness of interventions (Bondemark & Ruf, 2015), this study contributes valuable empirical evidence in support of DBT is an effective treatment for young people with ED and emerging BPD.

Contrary to hypothesises, participation in the DBT program (8-week or 16-week program) had no significant impact on anxiety, general functioning, and ability to act with awareness. One possible explanation for these unexpected results is decreased wellbeing following treatment. Research suggests that 5-10% of all patients experience adverse effects during the treatment period, because therapy can trigger distressing experiences (Lambert, 2013). It is possible that these non-significant results would differ at the 24-week follow-up, after possible adverse effects of treatment have subsided. Achieving a larger sample may also alter results, via increased statistical power. This is particularly true for 'ability to act with awareness', because it was very nearly significant (p = .052). While these results were unexpected, most main effects aligned with hypotheses, and supported the effectiveness of DBT for improving treatment outcomes in the current sample.

Comparing DBT Interventions: 8-weeks vs 16-weeks

Contrary to hypotheses, there were only two variables on which participants in the 16-week DBT program showed significantly greater improvement over time. These were quality of life, and suicidality risk. Participants in the 16-week program reported significantly greater quality of life than participants in the 8-week program, at 16-week follow-up. Participants in the 16-week program also reported significantly reduced suicidality risk from baseline to 8-

week and 16-week follow-ups, whereas participants in the 8-week program did not. This result is particularly noteworthy, because reducing suicidality is a major objective of DBT (Linehan, 2014), and suicide is high amongst young people with BPD (Paris & Zweig-Frank, 2001). Given that only the 16-week group showed reduced suicidality at 8-week follow-up, and the major difference between the interventions at that point was access to individual DBT sessions, it is likely that the additional treatment was related to reduced suicidality risk. While most outcomes in this study showed the two interventions to be equally effective, results for quality of life and suicidality risk, suggest that the 16-week, intensive DBT program may result in added benefits in these areas.

Program Attendance

Overall, the attendance rate of the total sample was high (80.6%). Attendance was excellent, compared to the average compliance rate for medical and psychosocial appointments worldwide (58%); according to a meta-analysis of RCTs on attendance at medical appointments (Macharia & Leonard, 1992). Attendance was highest in the 8-week group overall, and during every treatment wave (see Table 3 for attendance rates).

Practical Implications

Since almost all results showed that participants in both programs received equal treatment benefits, certain practical considerations may inform the future DBT programs at Headspace Southport. There are benefits to running the 8-week program, because it requires fewer resources. Specifically, the 8-week program requires fewer DBT practitioners, fewer clinical rooms, and allows more young people to access DBT (because numbers are not restricted by one-on-one DBT clinician availability, and the shorter program means faster turnover). Participants in the 8-week program also attended more consistently than participants in the 16-week program. These practical considerations favour a shorter, DBT skills program.

However, the intensive program resulted in significantly improved quality of life and suicidality risk. The suicidality outcome should be interpreted with caution, because the data was non-normally distributed, hence statistical analyses used for this variable were not as strong as for other measures. However, there was consistent feedback during the qualitative interviews, that also favoured the 16-week program. Participants in the 16-week program consistently reported that the individual sessions were important for learning to apply the DBT skills to their own life. Both clinicians and young people also consistently reported that the 8-week program felt too short to cover the content thoroughly. All factors considered, the most suitable program may require compromise between the 8-week program and 16-week programs. In future, the Headspace DBT program may resemble the 8-week DBT skills group (or slightly longer; e.g. 10-12 weeks), with access to some form of individual DBT coaching (e.g. a drop-in service, at designated times weekly, where participants can seek advice in a one-on-one setting). Results of the current study provide novel insight into the intensity and format of DBT required to achieve positive outcomes.

Note. The quantitative results should be weighed most heavily, since this is the most reliable information available. Qualitative data was not statistically analysed, although consistent themes emerged.

Strengths

The key strengths of this study are research design and generalisability of the sample. Most existing research on DBT with young people lacks methodological rigour (mostly quasi-experimental). The research design used in the current study (RCT) is the most scientifically rigorous method for evaluating the effectiveness of interventions (Bondemark & Ruf, 2015). By using a RCT design, this study increased reliability of the evidence for DBT as an effective intervention for young people with ED or emerging BPD. The current sample size (*N* = 106) was larger than many previous studies of DBT with young people (e.g. Ougrin et al., 2015), and it was a community sample (e.g. as opposed to a university sample). Further, the research was conducted by mental health professionals, in a 'real world' clinical setting, alongside their clinical responsibilities. These three factors increased the likelihood that results are reliable, and generalisable to 16-25-year-old Australians seeking treatment for ED and emerging BPD.

Limitations

The key limitations of this trial include use of self-report measures, inconsistency of commitment phase between treatment waves and treatment groups (8-week versus 16-week program), and lack of 24-week follow-up data. These limitations are discussed below.

1. Self-Report Measures: There are various shortcomings of self-reported, that relate to the reliability and validity of results (e.g. bias, ability of participants to introspect, etc.) (Stone, et al., 1999). However, in psychology studies, self-report measures are often the most effective measures available, because most relevant outcomes are intangible (e.g. mindfulness, depression). In the current study, all measures used were psychometrically validated, and participants were paid for completing each survey. Both these factors are likely to increase reliability of results.

2. Inconsistencies in Commitment Phase:

   Firstly, the commitment phase described in the 'Method' section was not implemented until the start of Wave 2. The commitment phase was added upon clinician's request (to increase retention rate, and to adhere to DBT protocols; Linehan, 2014). Increased emphasis on commitment may have improved attendance rates, across both groups, based on higher overall attendance in Waves 2 (60%) and 3 (55%), compared to Wave 1 (43%).

   Secondly, participants in the 8-week condition did not receive individualised commitment contacts, due to clinician capacity (see 'Method' section). However, it is unlikely that this inconsistency biased results, because attendance rates were consistently higher in the 8-week group, compared to the 16-week group (during every treatment wave). Furthermore, the 16-week group did not show greater improvements at follow-up than the 8-week group, so it is unlikely that the additional commitment contacts biased results.

3. Lack of 24-Week Follow-Up Data: The results in this report only reflect changes seen up to follow-up 2 (16-week follow-up). Unforeseeable delays (e.g. attaining ethics approval), prevented the project team from delivering results of the 24-week follow-up data by the report due date (July 15th). Follow-up 2 results will be available by approximately August 30th, 2019. Results in this report may differ when data analyses are completed, comparing baseline to follow-up 3 (24-week follow up).

These potential limitations are reported for transparency, however they should not detract from the fact this RCT is one of the most methodologically rigorous trials of DBT interventions for young people, to date.

Recommendations for Future Research

Future researchers should aim to improve on the limitations mentioned earlier. Specifically, future studies should ensure the commitment phase is consistent across treatment groups, and treatment waves. Future studies should aim to recruit a larger sample (e.g. original goal of *N* = 60 participants per condition), to increase statistical power. To achieve this, researchers need to ensure there are clearly defined project dates and milestones, and that enough resources have been allocated for that time period (e.g. trained DBT clinicians). As with any novel research, results from this study will require support from future RCTs, to demonstrate reliability of these results. The current research team should also re-evaluate the recommendations made in this report, after analysing the twenty-four-week follow-up data, to ensure recommendations are accurate.

Conclusion

The aim of this study was to investigate the efficacy of two different DBT interventions for improving treatment outcomes in YP with ED and emerging BPD, using a rigorous research method (RCT) conducted in a 'real world', clinical setting. The current study provided sound empirical support for DBT improving a range of outcomes in young people with ED and/or emerging BPD. The study also demonstrated that both DBT interventions provided similar benefits for participants, at 16-week follow-up, with some additional benefits of the 16-week DBT program, on quality of life and suicidality risk.

These results contribute valuable information to the scientific and clinical communities, about the efficacy of DBT for young people with ED and BPD, and the intensity and form of DBT required to achieve positive outcomes in this population. Considering the particularly high risk of suicide among people in their twenties with BPD and ED (Paris & Zweig-Frank, 2001), it is crucial that the scientific and clinical communities are aware of interventions that are effective for young people with BPD and ED. The results of this trial may inform the mainstreaming of such interventions, reducing preventable harm and loss of life among young people with ED or BPD.

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Appendix A. DBT Diary Card Template

Filled Out in Session YES NO

DBT Diary Card

Date:

Day & Date	Urges to...			Emotions						Actions				Skills
	Use (eg alcohol)	Suicide	S/H	Enjoyment	Sad	Shame	Anger	Fear	Guilt	DSH	Withdraw	Lying	Crying	DBT
	0-5	0-5	0-5	0-5	0-5	0-5	0-5	0-5	0-5	#	#	#	#	0-7
Mon														
Tues														
Wed														
Thurs														
Fri														
Sat														
Sun														

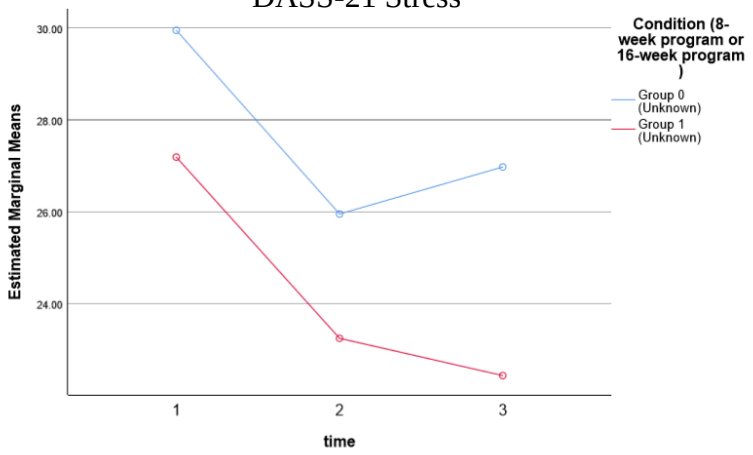
Homework Assigned and Results this week?	Used Skills (DBT Skills) 0 = Not thought about or used 1 = Thought about, not used, didn't want to 2 = Thought about, not used, wanted to 3 = Tried but couldn't use them	4 = Tried, could do them but they didn't help 5 = Tried, could use them, helped 6 = Didn't try, used them, didn't help 7 = Didn't try, used them, helped

Urges to:	Coming into Session (0-5)	After Session (0-5)	Belief I can Change or Regulate my:	Coming into Session (0-5)	After Session (0-5)
Quit Therapy			Emotions		
Suicide			Actions		
Self-Harm			Thoughts		

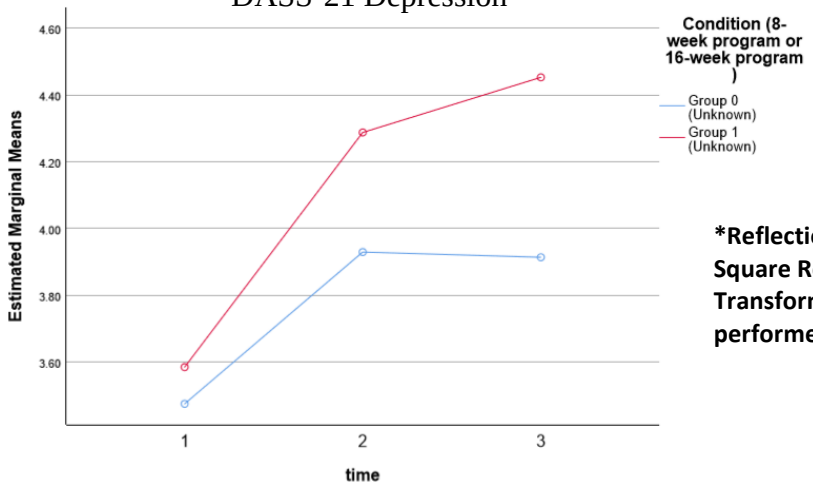
Appendix B. Graphs of Variables with Significant Main Effect of Time, Indicating Significant Impact of DBT on Treatment Over Time (Baseline, to Follow-Up 2).

KEY: RED LINE ---- = 16 WEEK GROUP; BLUE LINE ---- = 8 WEEK GROUP

DASS-21 Stress



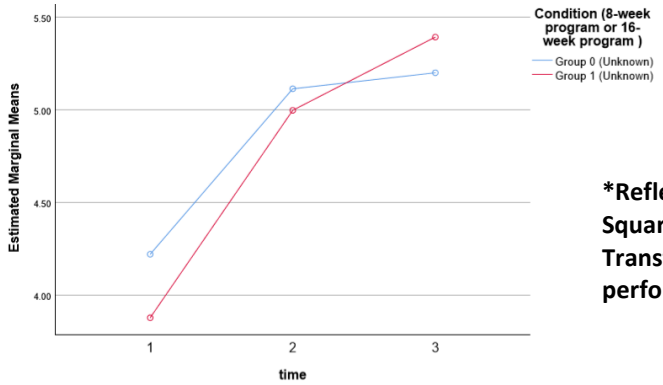
DASS-21 Depression



***Reflection of Square Root Transformation performed**

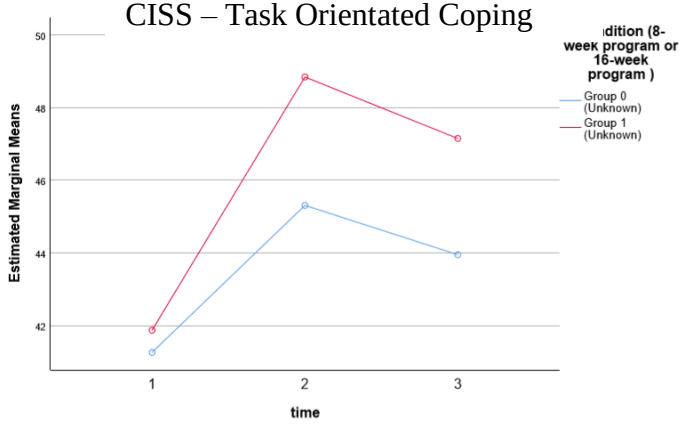
Profile Plots

CISS - Emotion Orientated Coping



***Reflection of Square Root Transformation performed**

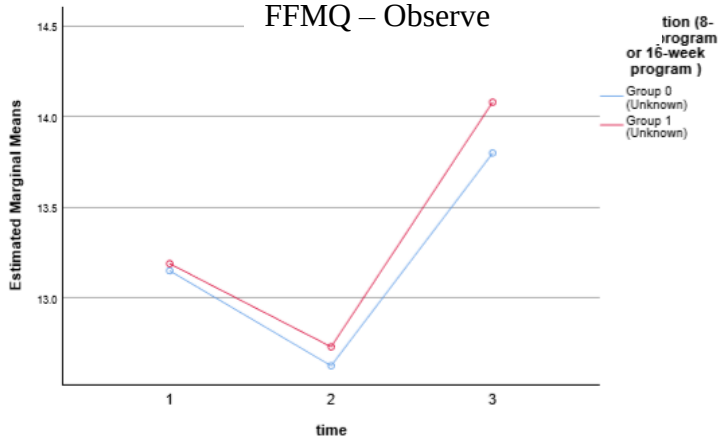
CISS – Task Orientated Coping



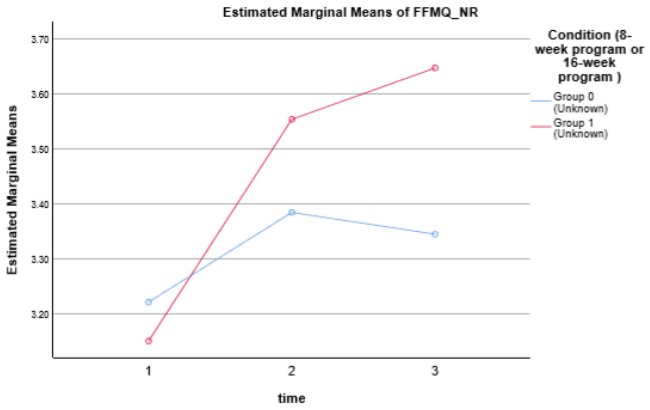
Lives Lived Well headspace Southport

KEY: RED LINE ---- = 16 WEEK GROUP; BLUE LINE ---- = 8 WEEK GROUP

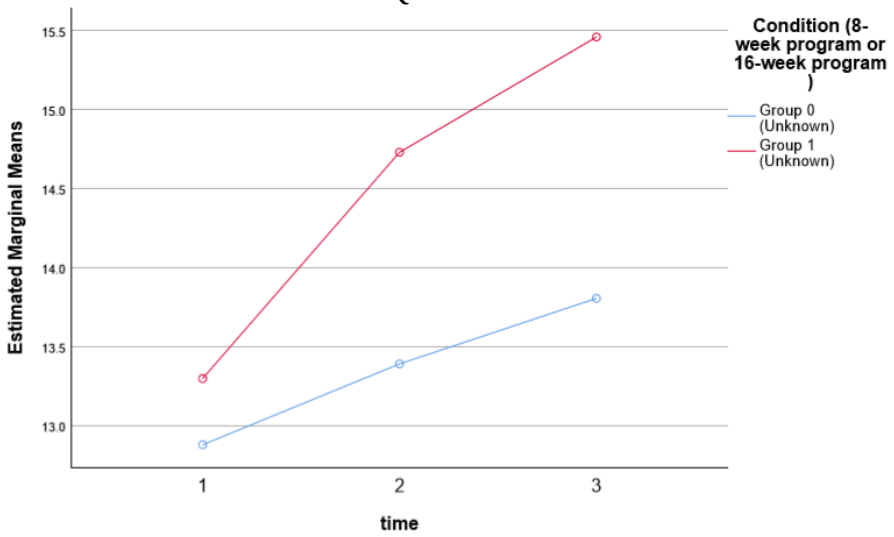
FFMQ – Observe



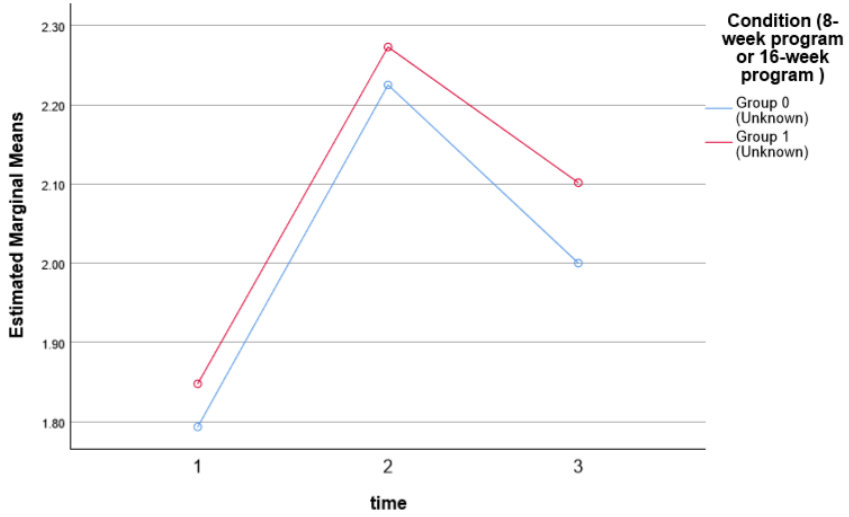
FFMQ – Non-React



FFMQ Describe



SUPPS Negative Urgency

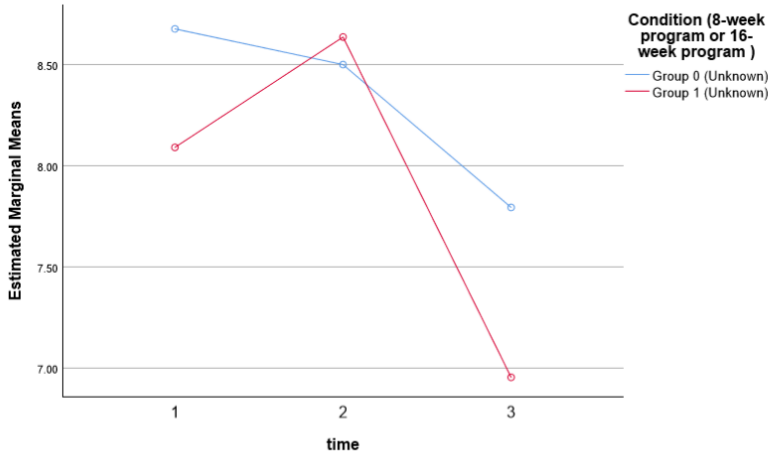


Lives Lived Well

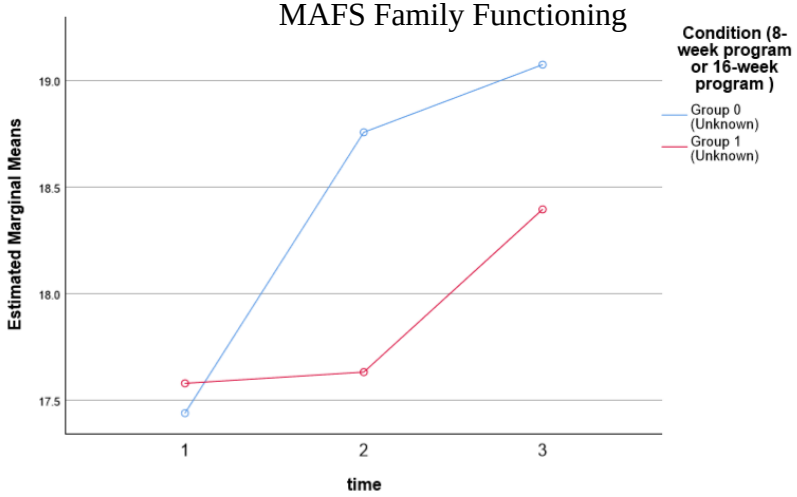
headspace
Southport

KEY: RED LINE ---- = 16 WEEK GROUP; BLUE LINE ---- = 8 WEEK GROUP

SUPPS Lack of Perseverance

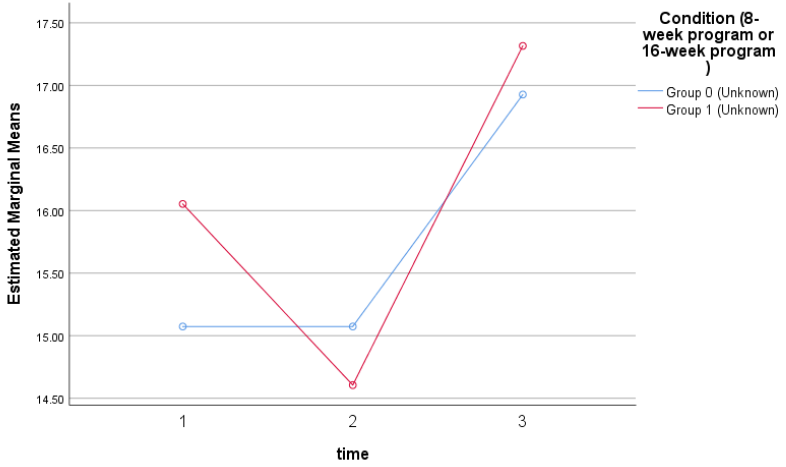


MAFS Family Functioning

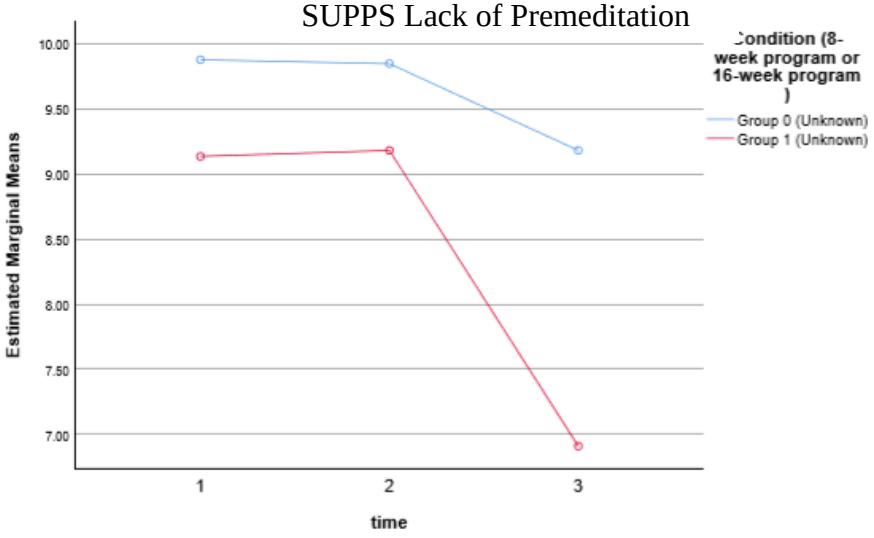


Profile Plots

MAFS Peer Functioning



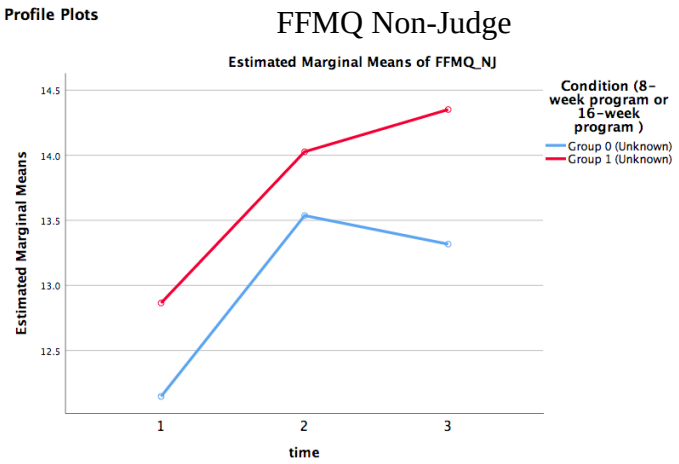
SUPPS Lack of Premeditation



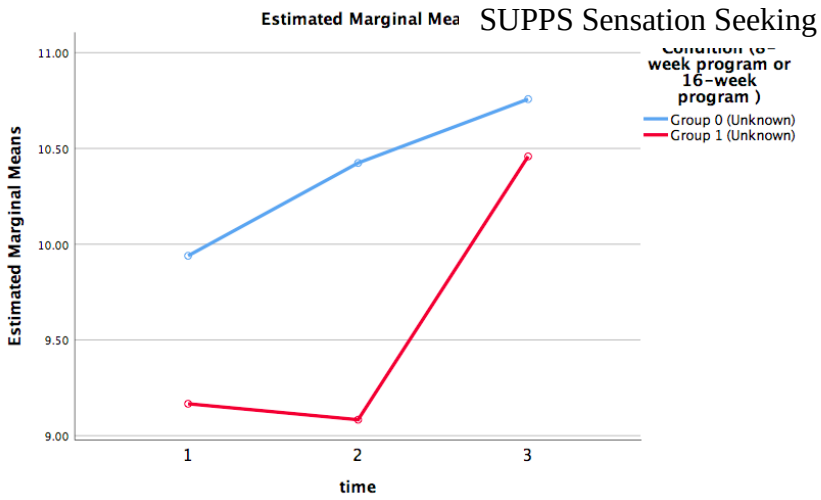
Lives Lived Well headspace Southport

KEY: RED LINE ---- = 16 WEEK GROUP; BLUE LINE ---- = 8 WEEK GROUP

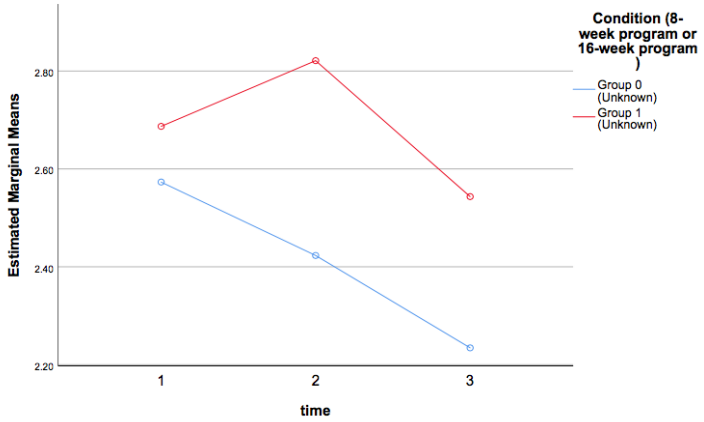
FFMQ Non-Judge



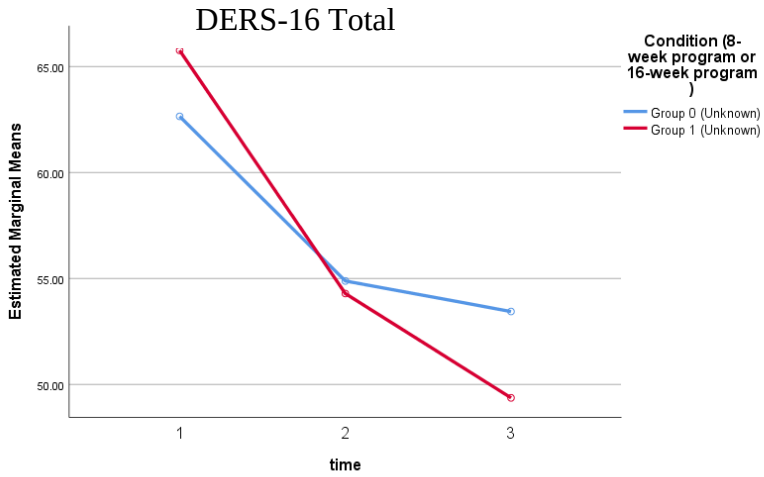
SUPPS Sensation Seeking



SUPPS Positive Urgency



DERS-16 Total



Lives Lived Well headspace Southport