Protocol

A comparison of online and face-to-face Dialectical Behaviour Therapy: A parallel group randomized trial and pragmatic evaluation

Chief-Investigator:

Associate Professor Richard Lakeman Richard.lakeman@scu.edu.au (1)

Co-investigators:

Stacey Anderson stacey@searchlightpsychology.com.au (1, 4)
Professor Brenda Happell brenda.happell@scu.edu.au (1)
Professor John Hurley John.Hurley@scu.edu.au (1)
Dr Claudia Hererra claudia@dbtinstitute.com.au (2)
Dr Andrew Leggett Andrew.Leggett@health.nsw.gov.au (3)
Dr Peter King peter.king@scu.edu.au (1,2)
Dr Steve Provost Steve.Provost@scu.edu.au (1)
Dr Richard Tranter Richard.Tranter@health.nsw.gov.au (3)

(1) SCU, (2) Australian DBT Institute, (3) Mid North Coast Local Health Service District (LHD), (4) PhD student, Psychologist in private practice

Contents

This project will compare the outcomes of face-to-face provision of Dialectical Behaviour Therapy (DBT) with online delivery in a naturalistic setting. Consenting adults who have been assessed by the Australian DBT Institute and accepted into a high fidelity DBT programme will be allocated to either individual therapy and skills training online or face-to-face.

Registration

This trial will be registered prospectively at: The Open Registries Network and The Australian New Zealand Clinical Trial Registry.

Ethical Approval

This project was approved by the Southern Cross University Human Research Ethics Committee (#2022/033) on the 8/4/2022

Background

Dialectical Behavioural Therapy (DBT) is time and resource intensive therapeutic programme for the treatment of borderline personality disorder (BPD), related syndromes and increasingly for a range of problems believed to be underpinned by difficulties with emotional regulation. BPD is an enormously costly condition which effects an estimated 20% of psychiatric outpatients, and is associated with very high rates of morbidity and mortality (Beatson et al., 2010). DBT involves a staged and targeted programme, including weekly individual therapy, telephone coaching and skills training (traditionally taught didactically in 2-3 hour groups face-to-face) in cycles of 12-24 weeks (Linehan, 1993, 2015). COVID-19 social distancing restrictions abruptly curtailed the provision of face-to-face skills training (often considered the most important element of DBT programmes) in many parts of the world including in Australia (Lakeman & Crighton, 2021). DBT programmes eventually resumed in some places and services tried to adapt the face-to-face skills programmes (often with limited training, experience in the provision of online

therapy, or strategies to evaluate effectiveness) and resumed face-to-face programmes when able.

Prior to COVID-19 there were few examples of online skills training groups or online provision of DBT reported in the literature. This project team has completed a review of the available evidence (Lakeman et al., 2022, p. abstract):

> *Dialectical Behaviour Therapy (DBT) programmes, often the only available treatment for people diagnosed with borderline personality disorder were rapidly converted to online delivery during the COVID-19 pandemic. Limited research exists surrounding how the major elements of DBT are delivered in an online environment. This scoping review considered the operationalisation of online delivery of DBT and its effectiveness. EBSCO host databases were searched using free text. Of 127 papers, 11 studies from 2010- 2021 investigating online DBT for any clinical population were included in the review. A narrative synthesis of papers selected was undertaken. Seven articles reported results from five clinical trials (n=437). Most adaptations mirrored face-to-face programs although there was considerable variation in how therapy was facilitated. Attendance was reported to be greater online with comparable clinical improvements to face-to-face for those who remained in therapy. Additional challenges included managing risk, therapist preparedness and technology difficulties. Online delivery of DBT programmes is feasible and may be more accessible, acceptable and as safe and effective as face-to-face delivery. However, mirroring face-to-face delivery in an online environment may not be the most effective and efficient way to adapt DBT to online provision. Research is needed to identify areas which require further adaptation.*

This review found no examples of trials comparing the delivery of the standard programme face-to-face or via online methods. The few trials of online programmes were typically abridged or adapted versions of DBT for specific populations. Commentary and description of programme adaptations in response to COVID-19

typically involved attempting to mirror face-to-face delivery of the skills group and individual therapy online.

The project group then surveyed practitioners of a high fidelity DBT programme run by the DBT Institute of Australia. This organization had developed a platform to provide online DBT prior to COVID-19 (a world first it would seem, but not formally evaluated).

The project team undertook an SCU approved exploration of this programme (HREC: #2021/097: The experiences of therapists adapting to and delivering a high-fidelity dialectical behaviour therapy programme in an online environment). The following paper (presently under review) arose from this project:-

> *High fidelity dialectical behaviour therapy online: Learning from experienced practitioners*
>
> *Abstract*
>
> *Dialectical behaviour therapy (DBT) is an effective treatment for borderline personality disorder and other problems underpinned by difficulties with emotional regulation. The main components of DBT are skills training groups and individual therapy. The COVID-19 outbreak forced a rapid adaptation to online delivery, which largely mirrored face-to-face programmes using videoconferencing technology. This study aimed to elicit and describe the experiences and learning of therapists involved in providing high-fidelity DBT programmes via the Australian DBT Institute which established an online delivery platform called DBT Assist™ prior to the COVID-19 pandemic. Seven therapists were interviewed. Data were transcribed and analysed thematically. Delivering skills training online, either exclusively or in hybrid form (with face-to-face individual therapy), was acceptable and even preferable to therapists and clients. It was considered safe, the programme was associated with few non-completers, and it improved the accessibility of DBT to those who might otherwise not be able to engage in a face-to-face programme. Skills training*

utilised a 'flipped-learning' approach which improved the efficiency of online delivery. Other unique and helpful features of the online programme were described. The best outcomes associated with online DBT are likely to be achieved through careful adaptation to the online environment in accord with the principles of DBT rather than mirroring face-to-face processes. Further research is required to determine the efficacy of online therapy relative to face-to-face, and who might be best suited to different modes of delivery.

We believe we have established both the safety and efficacy of online DBT programmes and in particular the Australian DBT Institute's online programme. This next phase aims to establish whether it is as effective as face-to-face versions in a naturalistic environment in which people are usually offered face-to-face, online or a hybrid version of both. We do not seek to manipulate any condition of usual treatment, or capture any data that is not usually collected.

The CONSORT 2010 guidelines for reporting parallel group randomized trials will be used to structure this protocol and to report the results of this trial (Moher et al., 2010).

Objectives / hypothesis

The primary objective is to establish whether or not online provision of DBT is as effective as face-to-face provision of DBT in a naturalistic setting.

The hypothesis are:

- That both face-to-face and online modes of delivery will lead to a significant reductions in symptoms from baseline / referral to completion of the programme;
- That there will be no significant difference in outcomes between face-to-face and online delivery of DBT.

Qualitative interviews will be undertaken with a sample of participants to establish if the outcomes and targets of treatment as measured by routinely collected outcome measures are those which are most meaningful to both client and therapist. Additionally, these interviews will aim to explore what aspects of the programme in

the different modes of delivery are found to be most useful by DBT participants and to provide a narrative account of the process of change as previously undertaken by the project lead in a face-to-face only DBT programme (Lakeman & Emeleus, 2020; Lakeman et al., 2020).

Methods

Trial Design

A naturalistic (based on intention to treat) prospective parallel group randomized trial will form the framework for this trial.

Participants

Eligible participants will include all people over the age of 18 who have been referred to and assessed by the Australian DBT Institute and accepted into their DBT programme. Participants must be able to access either the Gold Coast or Melbourne clinics and available for face-to-face therapy if allocated. They must also have access to the internet and a private place to engage in online therapy.

The Australian DBT Institute is a private provider of DBT services in Australia. Clients can self-refer and fees are met privately or through private insurance schemes including the NDIS. The Australian DBT Institute also trains and credentials therapists and contracts therapists to provide individual therapy and to facilitate skills groups. The clients of non-contracted therapists can also participate in the facilitated skills groups either online or face-to-face.

In this trial only those clients who are referred to the Australian DBT Institute and who are referred to credentialed DBT therapists contracted by the Australian DBT Institute will be eligible to participate. This ensures that the clients receive the highest quality of service and that all elements of the DBT programme are provided. These elements include the regular participation of therapists in a consult group (a

form of clinical supervision) and that all participants receive a sufficient period of 'pre-commitment' preparation before commencing the programme. These elements are neglected in some programmes.

The Australian DBT Institute anticipates contracting 4 individual therapists who provide either face-to-face or online therapy to clients at Gold Coast or Melbourne clinics.

Recruitment

New referrals who are engaged in the 'precommitment' or 'foundational' stage of therapy will be offered an information sheet and invitation to participate in the trial by their individual therapist. For individual clients who are interested in participating in the trial, an appointment will be arranged with the Australian DBT Institute research officer and data manager to further discuss the trial and, if applicable, obtain consent to participate in the trial. A rebate of $600 will be offered to self-funded participants whichever mode of therapy delivery a person is allocated to. A token gift voucher will be provided to participants whose therapy is entirely funded by a third party such as the National Disability Insurance Scheme. These offers will be revealed only on inquiry or after consent in order to reduce this being an inducement to participate. It will be explained to participants that if they choose to participate **the only thing that will vary from usual care and treatment is the random allocation to either face-to-face or online provision only for one complete cycle of DBT.** They will receive therapy by the same nominated or recommended therapist and beyond some questions relating to their expectations and preferences will complete the same outcome measures as they would if they elect not to participate in the programme. They would however, share their anonymized data with the research team.

Participants will have the opportunity to discuss their interest, and concerns with the chief investigator or any other named investigator and 'opt in' by signing and returning a consent form to the research officer (this needs to occur before commencement of the first skills group). On the same consent form participants will also be invited to 'opt in' to participate in qualitative interviews with a member of the

research team.

The Australian DBT Institute Research officer will maintain a spreadsheet with the names and unique identifiers of participants and their group allocation shared with the principle investigator (these will be stored securely on password protected cloud servers). Outcome measures and routinely collected demographic information and other questions will only be shared to the research team for the purposes of analysis in de-identified form and linked with the assigned unique identifier.

Interventions

The standard DBT programme consists of individual therapy, skills training (undertaken in groups), the opportunity for out-of-session skills coaching if required and therapists who are supported by attendance at a weekly consultation group. The standard programme is described in detail by Linehan (Linehan, 1993; Linehan, 2015). The adaptations and enhancements to the standard programme by the Australian DBT Institute are detailed by the investigators in a paper presently under review.

The Australian DBT Institute's Executive Director, Dr. Peter King, developed the institute's trauma informed adaptation to the standard DBT (Linehan, 1993) to address the gap in trauma informed practice in DBT. In creating the Australian DBT Institute's preferred approach, Dr King was influenced by several factors including his research (King, 2017), a partnership with Behavioral Tech LLC (2003 – 2008), as well as providing clinical supervisions to mental health practitioners, delivery of therapeutic work and facilitation of professional development workshops in DBT and trauma informed approaches for over 15,000 health professionals since 2004. The Institute's comprehensive DBT program comprises of all modes of treatment identified standard DBT (Linehan, 1993): Individual Therapy (including commitment), DBT Skills Training, Phone Coaching and Consultation team with a trauma informed lens.

Trauma-informed Individual Therapy in DBT

Using the institute's trauma informed DBT programme, mental health practitioners utilise a phase-based framework rather than Linehan's stages of treatment originally developed for individuals with a diagnosis of borderline personality disorder in mind (Linehan, 1993). In the trauma informed DBT approach, the pre-treatment stage, in addition to the psychosocial assessment, orientation and commitment, there is specific assessment of trauma conducted by an intake clinician. Following this, there is a phase of stabilization conducted by an individual therapist, trained in the trauma informed DBT approach, in which patients are assisted to become aware of existing resources and to promote a sense of self-agency in participants that also includes feeling safe and contained. Furthermore, psychoeducation, neuroeducation and a learning style assessment are carried out so that individuals gain awareness and understanding of their presenting symptoms, triggers, somatic markers as well as ways of maintaining themselves in the regulated zone or 'window of tolerance' (Baldini et al., 2014) and preventing autonomic dysregulation with strategies such as 'applying the brakes' (Rothschild, 2017, p. 79) in distressful situations. Part of the stabilization phase is the weekly engagement in skills training in a group setting along with weekly individual sessions where participants learn how to integrate the new skills into their environments.

Trauma-informed DBT skills training.

In line with the institute's approach in individual sessions, skills training facilitators (primary facilitator and co-facilitator), trained in DBT-TI, ensure that key steps are included meeting client needs in a safe, collaborative, and empathetic manner, avoiding practices that may retraumatize individuals likely with histories of trauma. The institute has policies and procedures to keep providers' skills up to date through training and supervision so they can be responsive and adapt the environment to support clients' sense of physical and emotional safety. Facilitators and co-facilitators of the groups in which the skills are delivered have the awareness and anticipate that certain environmental stimuli within a training program may generate strong emotions and reactions in individuals who are sensitive to the environment (e.g., triggers such as visual or auditory stimuli, access to exits, seating

arrangements, etc). Hence, they implement strategies to help clients participate safely and cope with triggers that evoke painful experience.

The primary facilitator uses the first week of individual therapy to orientate the members on the guidelines to participate in groups, agreements and expectations, which is followed through and reinforced by facilitators during the introductory week of skills groups. Additionally, there are explanatory videos on how to navigate the platform, how to join zoom meetings for those who attend online, samples of skills and accompanying worksheets. Participants receive weekly emails notifying them that the content that will be covered in the session is available for them to review beforehand.

The four primary skill sets taught in DBT are mindfulness, distress tolerance, emotional regulation and interpersonal effectiveness. In this programme mindfulness is integrated throughout the programme. The four skill sets are taught in 3 modules of 9 weeks each (distress tolerance, emotion regulation and interpersonal effectiveness) following the Australian school calendar (4 intakes per year) as a strategy to allow participants to process content and prevent dropouts. Groups are not larger than 12 participants and not smaller than 6. The structure of the training presents mindfulness on the first two weeks of every module, although different emphasis depending on the skill to be learnt, followed by 6 weeks of content and one week of review and one of self-reflection and assessment tools.

The Australian DBT Institute skills training groups are scheduled to align with the Queensland school terms. They are 9 weeks in duration and scheduled as follows:

- 25/4/2022 - Module 1 (Mindfulness 2 weeks - Distress Tolerance - 6 weeks - 1 week review)
- 11/7/2022 - Module 2 (Mindfulness 2 weeks - Emotion Regulation - 6 weeks - 1 week review)
- 3/10/22 - Module 3 (Mindfulness 2 weeks - Interpersonal Effectiveness - 6 weeks - 1 week review)

Several face-to-face and online groups are run in any given week. Once allocated to a group, participants remain with that group until completion of that module. They remain with an allocated individual therapist for as long as they are enrolled in the DBT programme (which can be more than one four module cycle).

On consent and randomization to face-to-face or online the individual therapy will continue via the allocated mode and the person will be allocated to either an online or face-to-face group. All outcome measures, and questionnaires are completed online using the DBT Assist platform regardless of allocation.

Outcomes

Routinely measures of problems in the DBT programme include at baseline (pre-commitment) and at standard intervals (minimally at the end of the modules… 6 weeks) and at 3 months follow-up:

- The Depression Anxiety & Stress Scale 21 (DASS-21) (Lovibond & Lovibond, 1995)
- Difficulties in Emotion Regulation Scale (DERS-16) (Gratz & Roemer, 2004)
- The Borderline Symptom List (BSL-23) and supplementary behavioural questions (Kleindienst et al., 2020)
- The World Health Organization Brief Quality of Life Assessment (WHOQUOL-BREF) (The Whoqol Group., 1998)

These scales have all been validated and are routinely used in DBT programmes, in clinical practice more broadly, and in research studies. They broadly address the problems which people seeking DBT identify with. Thus, they are used to inform discussions between therapists and clients about progress and treatment targets. All, also have scores which have been validated to indicate the severity of symptoms, what counts as clinically significant change, and typical scores in clinical versus non clinical populations. It is hypothesized that both groups will demonstrate significant improvement from baseline to follow-up on global measures (i.e. reduction in mean

scores for each tool). Improvement on sub-scales will be explored as appropriate (e.g. reduction in ‘stress’, ‘anxiety’ and ‘depression’ on the DASS)-21.

Whilst these measures are those frequently used in DBT research reliance on these measures alone is problematic as DBT is programme which is highly targeted to the individual’s problems and individual therapy is highly focused on a treatment hierarchy commencing with life threatening behaviours, therapy interfering behaviours and then those which interfere with quality of life (Linehan, 1993; Linehan, 2015). Often the incidence of negotiated treatment targets (thoughts, feelings or behaviours) are recorded on bespoke diary cards quite unique to the individual. It is therefore proposed that individuals provide a brief statement about what their aspirations are at the beginning of treatment and a summary of what they have addressed and what is important to them at commencement and at the end of each skills module.

Brief interviews with a individuals or therapist-client dyads will also attempt to elicit what are personally meaningful outcomes for clients and how the DBT programme (regardless of mode of delivery) has been helpful.

Basic demographic information will be gathered on intake including: Age, Gender, Diagnosis (if conferred and by what kind of professional), history of hospitalization, place of residence, Aboriginal status, occupation, years of education, relationship status (and children), family history, previous psychotherapy.

The Depression Anxiety & Stress Scale (DASS-21)

The DASS-21 is a 21 item self-rating scale designed to measure symptomology as related to depression, anxiety and stress (Lovibond & Lovibond, 1995). A person is asked to indicate their agreement to statements along a 4-point Likert scale where 0=never and 3=Almost Always. The DASS-21 is a widely used instrument and has been proven to show good internal consistency and concurrent validity (Stats go here) (Antony et al., 1998). The DASS-21 has an excellent test-retest reliability (ICC = .99). The total sale has a high internal consistency (α = 0.90–0.95), good for

depression (0.91), and acceptable for anxiety (0.81) and stress (0.89) (Lovibond & Lovibond,1995).

DASS-21 Scoring	Depression	Anxiety	Stress
Normal	0-4	0-3	0-7
Mild	5-6	4-5	8-9
Moderate	7-10	6-7	10-12
Severe	11-13	8-9	13-16
Extremely Severe	14+	10+	17+

The Difficulties in Emotion Regulation Scale (DERS-16)

Difficulties in Emotion Regulation Scale -16 (Bjureberg et al., 2016) is a 16 item self-rated measure of five facets of emotion regulation: clarity, impulse, goals, non-acceptance and strategies. The DERS-16 is a short form of the longer DERS-36 (Gratz & Roemer, 2004). As for its longer version the factors contained within the DERS-16 are intended to broadly map across a functional model for emotion regulation in which awareness and understanding of emotions, acceptance of emotions, impulse control, and access to strategies perceived as helping to alleviate symptoms is posited (Gratz & Roemer, 2004). Items are scored along a 5 point Likert scale where 1=Almost Never and 5=Almost Always with higher scores indicating greater difficulty in emotion regulation. The DERS-16 has good internal consistency (α=0.93) and has been shown to predict clinical severity and treatment outcomes in treatment seeking adults with difficulties in emotion regulation (Hallion et al., 2018).

The Borderline Symptom List (BSL-23)

The BSL-23 is a self-reported scale addressing primarily thoughts and feelings which typically arise in those diagnosed with borderline personality disorder. The items on the BSL are scored on a five-point Likert scale (0-4). The mean scores can be used to classify the severity of symptoms. These mean scores are highly correlated to the number of symptoms elicited during a structured clinical interview as was as global measures of functioning (Kleindienst et al., 2022).

BSL-23 in the BPD calibration sample (BPD_CAL)		Values of external measures (BPD and HC samples) across the BSL-23 classes of severity		
Severity classification (BSL-23)	Range of BSL-23 mean scores	Number of BPD-symptoms (IPDE)	Global Severity Index (GSI, SCL-90-R)	Global Assessment of Functioning (GAF)
None or low	0–.28 rounded: [0, .3)	.19 ± .95	.11 ± .0.11	88.35 ± 10.5
Mild	.28–1.07 rounded: [.3, 1.1)	2.88 ± 2.76	.62 ± .3	67.79 ± 15.57
Moderate	1.07–1.87 rounded: [1.1, 1.9)	5.22 ± 2.04	1.17 ± .37	53.69 ± 9.55
High	1.87–2.67 rounded: [1.9, 2.7)	5.90 ± 1.75	1.62 ± .46	50.51 ± 9.61
Very high	2.67–3.47 rounded: [2.7, 3.5)	6.5 ± 1.73	1.99 ± .44	47.49 ± 8.5
Extremely high	3.47–4 rounded: [3.5, 4]	7.2 ± 1.23	2.76 ± 0.39	49.8 ± 10.71

Correction to: A proposed severity classification of borderline symptoms using the borderline symptom list (BSL-23) (Kleindienst et al., 2022)

The BSL-23 has been found to be sensitive to change after three months of a DBT programme with an effect size of d=0.47 (Bohus et al., 2009). Recovery (from BPD) is defined as a mean score of ≤ 0.72 and improvement or deterioration is defined as a change in score of ± 0.32 (Bohus et al., 2009).

The World Health Organization Brief Quality of Life Assessment (WHOQUOL-BREF)

The WHOQUOL-BREF (The Whoqol Group., 1998) is a routinely used self-reported measure of quality of life which has been found to have good internal consistency (Cronbach's alpha coefficients for the domain scores ranged from 0.66 to 0.84) in multiple culturally diverse settings. The interval between test and retest ranged from 2-8 weeks. Correlations between items at time points one and two were generally high, ranging from .68 for the Safety facet to .95 for Dependence on Medication.

Administration of outcome measures

Demographic information is collected routinely and stored on the clinical record held by the Australian DBT Institute. These data will be extracted by the Australian DBT Institute research officer after consent is received. A unique identifier will be created for each consenting participant to identify their unique data set and this will be annotated on the person's signed consent form.

All other measures are entered online via the DBT-Connect Platform. These data will be extracted one week after each collection point by the research officer and shared with the researcher in an excel spreadsheet.

All measures will be completed at baseline. The WHOQUOL-BREF will only be completed at baseline, after the final skills module and at three months follow-up. There is no theoretical reason to expect quality of life to improve until after completion of the programme as improving quality of life is the final treatment target in DBT.

All other measures (the DASS-21, BSL-23 and DERS-18) will be completed at the end of each completed skills module.

Sample Size

30 participants in each group will be sought (N=60).

Financial and practical factors limit this study to a sample size of 30 participants per group.

Randomization

It was noted in the previous phase of this project (in which therapists were interviewed about their experience of online DBT) that some therapists had personal preferences for face-to-face or online work and rated their competency in working via different modes differently. Therapists noted that clients too, sometimes preferred face-to-face or on-line modes. To control for this known potential confounding factor and other unknown potential confounds, consenting participants allocated to a therapist will be alternatively assigned to either face-to-face or online mode. This will ensure that roughly equal numbers of people will be assigned to each mode of delivery.

Participants will be allocated to a therapist as per usual protocols. Each therapist will have a finite capacity to see referred participants. Each therapist will have an equal number of allocations for online or face-to-face therapy. These allocations will be placed in an individual envelope and these envelopes shuffled. The research officer will open a randomly selected envelope (assigned to each therapist) to reveal the person's allocated mode of delivery after they have consented to participate.

Statistical Methods

Previous evidence suggests that it is reasonable to expect changes in the main variables (pre to post) to have a Cohen's d of not less than .5 (moderate sized effects). This results in power for the tests of repeated measures of approximately 75%. While this is slightly below optimal, clinical members of the team are confident that outcomes should be of clinical significance, which would result in much greater power. Any differences between the effectiveness of treatments will be assessed as the interaction component of a mixed-model ANOVA, which is the most powerful method for detecting such differences. It should be noted, however, that the team's expectation is that the online training will be at least as effective as the traditional approach, if not superior.

Qualitative Interviews

The purpose of these qualitative interviews are to provide a case series to illustrate in a more personal way how people progress in DBT, what outcomes are most meaningful and what is most helpful in achieving those outcomes.

The most closely matched client who consents to being interviewed (according to baseline measures) in the face-to-face therapy will be matched with an on-line allocated client (most closely matched) for each therapist.

These clients will be interviewed near commencement, approximately half-way through the programme, on completion and at 36 weeks (3 months follow-up). With their permission they will be interviewed with their therapist.

A minimum of 6 clients will be interviewed. Whilst the focus will largely be on the client's experience interviewing the therapist and client together acknowledges the importance of the therapeutic alliance between personal therapist and client (Bedics et al., 2015) and enables the therapist to work through any issues which might arise for the client in that conversation. Discussions about treatment goals and progress with DBT therapists is a usual practice and open discussion about the alliance which includes shared goals and understanding is considered so important that tools have been developed to facilitate such conversations at every session and across psychotherapeutic approaches (Duncan et al., 2003). Actual skill use has been found to be a predictor of symptom improvement and retention in therapy (Barnicot et al., 2016). Gauging which skills individuals have learned, used and found useful will provide a potentially rich insight into the process of therapy.

The interviewer will be an experienced DBT therapist (with no association with the Australian DBT Institute) and the and will address in a semi-structured way the following questions:

1. What the expectation and focus of treatment has been;
2. What elements of the process have been considered most helpful or challenging;
3. What have been the most personally significant outcomes for individuals;
4. What skills have been acquired and been found to be useful.

With full consent a sample of diary cards for the preceding DBT skills module will be examined and summarized for each person in the case series. Note diary cards address behavioural or psychological targets as negotiated between the therapist and client.

The qualitative data will be analyzed using inductive methods informed by grounded theory (Corbin & Strauss, 2014). Members of the team have utilized a similar method to describe the process of change in a naturalistic DBT programme (Lakeman & Emeleus, 2020).

Non-completers or those who elect to change modes

Participants will be informed of their absolute right to withdraw from the study, indeed to withdraw from therapy or elect to change modes of delivery if that mode is available to them. Drop-out rates in randomized controlled trials of DBT are on average around 28%, appear to be as likely in control groups as in those in active treatment, but few studies report reasons for non-completion (Dixon & Linardon, 2020). In some naturalistic community mental health settings dropout rates in DBT programmes are as high as 51.8% (Landes et al., 2016). Other programmes report very high retention and why this is remains largely unexplained and understanding why people don't complete programmes is considered a highly important research question (Barnicot et al., 2011)

In DBT a treatment dropout is typically defined as missing four consecutive appointments of any one treatment component (Linehan, 1993, 2015). The usual strategy is to offer the person the opportunity to resume at the beginning of a treatment module. Interviews with experienced therapists contracted to the Australian DBT Institute (paper under review) found that drop-outs were much rarer than in the reported literature. It was suggested that this was the case because of the personal investment clients make in the programme, sufficient time being given to the pre-commitment phase of therapy, and the opportunity to 'catch up' on skills groups using DBT-Connect if people are unable to attend face-to-face groups.

Whilst, it is not anticipated that there will be a significant number of people who drop out or switch modes, should a person wish to do so permission will be sought to interview the person about their reasons and to explore their baseline data with those who complete the programme.

The Australian DBT Institute is responsible for providing a high fidelity DBT programme of the highest quality and regardless of mode of delivery scrupulously attend to the programme elements such as safety planning, peer review via the consultation group and all programme elements recommended by Linehan (1993). Client's may or may not have involvement of other health professionals in their care and may require acute intervention of other services including emergency services. In DBT the therapist does not interfere, intervene, or intercede on behalf of the client responsibility of the DBT therapist to address and this is made clear to all participants from the outset. The individual is presumed to have the capacity to engage with other elements of the service system and DBT may assist them to do this more skillfully. This project does not interfere in any way with the usual and well established clinical governances processes, referral pathways or accountability processes established between client, therapist, the DBT Institute and other involved agencies. Some in this population may or may not be receiving medical or psychiatric care. However, no participant in this research might be considered highly dependent on DBT. DBT might reasonably be considered 'treatment' for some people. However, this 'treatment' primarily aims to empower and provide skills to the client and when a crisis occurs that may demand, require or involve other services, the DBT therapist does not become overly involved.

The only foreseeable risk of involvement in this research for participants above and beyond the potential risks associated with living with the problems associated with whatever motivated the individual to seek DBT or usual care, is that a person may be randomized to a mode of delivery they don't prefer, is inconvenient or isn't the 'best fit'. However, these issues are rarely clear from the outset of DBT and should these issues arise then in the first instance the person will discuss and attempt to address problems via a DBT framework with their individual therapist. If in consultation with the therapist-client and consult group an alternative mode of delivery is recommended (or indeed any other change e.g. to primary therapist) this will be honored. This research is naturalistic in the sense that apart from allocation to mode

of delivery all other processes are left to the discretion of the treating therapist and team.

A risk to the research process is a potential failure to recruit sufficient participants into the online arm of this study. The sample sizes were carefully considered to arrive at 30 in each arm and we have considerable confidence in recruiting sufficient numbers. However, should an inadequate sample be obtained we may seek to extend this project for a further cycle in 2023.

Project Plan (Condensed GANTT Chart)

TASK	START	END
Recruitment & Allocation		
Recruitment	30/03/2022	08/04/2022
Allocation to Condition	11/04/2022	12/04/2022
Therapy		
Commitment	28/03/2022	15/04/2022
Skills Group Module One	25/04/2022	24/06/2022
Skills Group Module Two	11/07/2022	09/09/2022
Skills Group Module Three	03/10/2022	02/12/2022
Data Collection (outcome measures)		
Baseline	11/04/2022	16/04/2022
Point One	27/06/2022	02/07/2022
Point Two	12/09/2022	17/09/2022
Point Three	05/12/2022	10/12/2022
3 months post completion	20/02/2023	25/02/2023
Qualitative Interviews		
Baseline	18/04/2022	02/05/2022
Middle	29/08/2022	12/09/2022
Completion	28/11/2022	12/12/2022
3 months post completion	20/02/2023	06/03/2023

DBT Online vs Face-2-Face Parallel Trial

Dr Richard Lakeman

Wed, 3/30/2022

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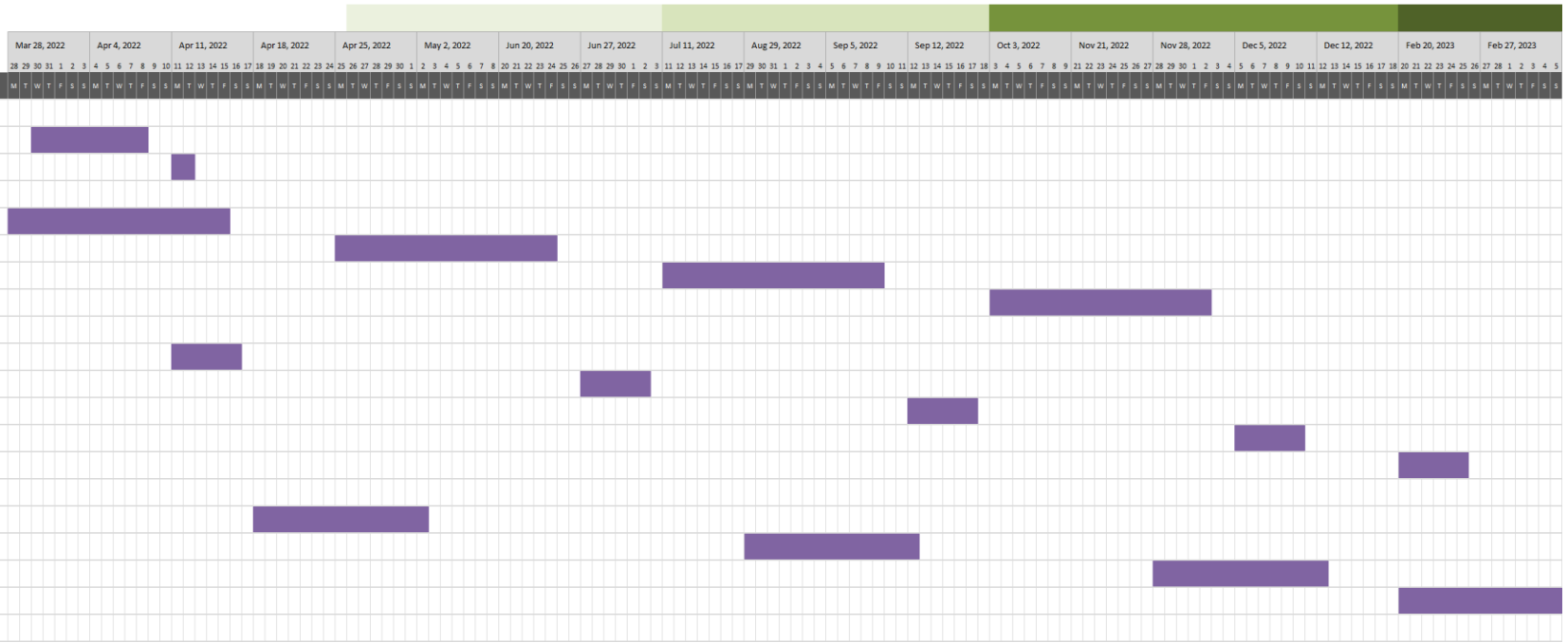
TASK	START	END
Recruitment & Allocation		
Recruitment	30/03/2022	08/04/2022
Allocation to Condition	11/04/2022	12/04/2022
Therapy		
Commitment	28/03/2022	15/04/2022
Skills Group Module One	25/04/2022	24/06/2022
Skills Group Module Two	11/07/2022	09/09/2022
Skills Group Module Three	03/10/2022	02/12/2022
Data Collection (outcome measures)		
Baseline	11/04/2022	16/04/2022
Point One	27/06/2022	02/07/2022
Point Two	12/09/2022	17/09/2022
Point Three	05/12/2022	10/12/2022
3 months post completion	20/02/2023	25/02/2023
Qualitative Interviews		
Baseline	18/04/2022	02/05/2022
Middle	29/08/2022	12/09/2022
Completion	28/11/2022	12/12/2022
3 months post completion	20/02/2023	06/03/2023



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