PSIY-511-15: Adapting and Evaluating Dialectical Behaviour Group Therapy for Adults with Dual Diagnosis (Intellectual Disabilities with Psychiatric Disorder)

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Study Protocol & Statistical Analysis

Present study

The present study is a pilot community-based, double blind, randomized controlled trial of an adapted DBT skills group and program for individuals with Intellectual and Developmental Disabilities (IDD) and psychiatric illness. The purpose of this study was to clinically evaluate and empirically determine the feasibility and effectiveness of delivering an adapted DBT community-based skills group to adults with intellectual disability and transdiagnoses. Dykstra and Charlton's work, *Dialectical Behavior Therapy Skills Training: Adapted for Special Populations* (DBT-SP; written in 2004 and revised in 2008; Dykstra & Charlton, 2008, Charlton & Dystra, 2011), was the basis from which the adapted DBT manual and program (i.e. aDBT-ID) was used in the present study. As part of a community based DBT program, in addition to the manualized skills group, other components included mental health treatment i.e. psychiatric medication and consultation, individual therapy, crisis services, caregiver coaching and team consultation for both the researchers and clinicians.

Methods

Participants

A community based sample of 19 adults with mild to moderate IDD and transdiagnoses i.e. co-morbid psychiatric disorders participated in the present study. Inclusion criteria were: age 18-65 years old, administratively confirmed diagnosis of mild to moderate IDD, co-morbid psychiatric diagnoses and history of emotional and behavioural concerns and lead agency commitment i.e. allocated caregiver to attend all sessions. Exclusion criteria included a diagnosis of autism spectrum disorder or acute psychosis interfering with daily functioning.

The group participants comprised of 9 males and 10 females; ages ranging from 22 to 34 with one 52 year old. All were referred with confirmed diagnoses of mild (16) to moderate (3) IDD established by their administrative eligibility for support services i.e. DSM-V criteria for IDD. All lived in either residential treatment homes (3), group homes (5), host family home (2) or independent living either alone (4) with a roommate (2), with their parents (2) or a spouse (1).

Co-morbid psychiatric diagnoses upon referral (not mutually exclusive) included Personality Disorders (BPD 10, Mixed PD 2), Mood Disorders (Depression 2, Anxiety 8, Bi-Polar 3, OCD 2), Psychotic Disorders (2), Childhood Disorders (ADHD/ADD 7), Trauma Disorders (PTSD 4), Substance Abuse Disorder (1), Sexually Problematic Behaviour/Pedophilia (2), Acquired Brain Injury (1), Seizure Disorder (2) and Speech and Language Disorder (1). All participants were identified as having significant problems with emotional dysregulation and chronic interpersonal difficulties with family, friends and caregivers. In addition, the majority

were experiencing behavioural difficulties with anger that impacted their daily functioning. All participants had a medication regime including a range of psychotropic medications for behavioural control and mental health stability (e.g. anti-psychotics, anti-depressants, anti-anxiety, mood stabilizers) and treatments for associated physical health conditions (anti-convulsants, diabetes medication).

Clinical services outside of the group included psychiatric medication oversight for all participants except four who had family physicians prescribing. All participants had regular therapy or treatment interventions with either assigned social workers, psychologists, behaviour therapists, nurse or addiction counsellors. Also, participants had a variety of tertiary care team involvement including specialization in either dual diagnosis, mental health crisis, assertive community treatment and 24 hour access to mental health crisis lines. Some participants had regular legal oversight from either court diversion workers or probation officers.

A total of 22 caregivers participated in the group trial, with n=14 completing assessments. Caregiver participants were comprised of both men and women from a range of developmental and mental health agencies. Majority were front line staff or direct support workers (14) apart from two behaviour therapists, two social workers and two family members. One participant had two workers attend due to his need for supervision. Most of the caregivers had known the clients for less than three years (15), with three knowing their clients between 3-10 years and one for over 10 years. The amount of client contact ranged from 1-3 days a week (8) to 3-7 days a week (7) to bi-weekly or monthly (4). The duration of each contact ranged from intermittent daily contact (9), to 2-3 hours contact (6) to one-to-one counselling (4). The latter proportions likely influenced by living situation (e.g. group homes, host family and independent living) and type of contact (e.g. direct support hours, consultation services or therapy sessions.)

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Procedure

Following ethical approval, clients and caregivers were recruited through partnering developmental and mental health agencies that provide support services to persons with IDD, and through expression of previous interest by affiliated mental health professionals. Additionally, information letters were distributed to agencies who had expressed an interest in available treatment services. All referred respondents were then screened for eligibility based on inclusion and exclusion criteria using administrative data and informant interview. Once eligible participants were identified and consent obtained, they were asked to invite their preferred caregiver to attend the group with them. Subsequently, caregivers were either given or sent a letter of information and consent form for attendance. Written consent was confirmed at pre-assessment; with consent for participant involvement including the use of a multi-modality approach of both written text and verbal discourse.

Participants and caregivers were then de-identified and randomly assigned utilizing a relevant software (Randomizer.org; or "Research Randomizer") with the researcher blind to group identities. Randomization occurred once a dozen participants were recruited and then again prior to the second group to accommodate rolling recruitment. Participants were initially allocated to either the treatment group or waitlist control group for one of the three sequential groups. All participants attended their assigned group except for one who requested an earlier group due to travel limitations and one replacement for the last group following client attrition.

Measures

Participation in the aDBT-ID trial was initiated by recruitment letters and by convenience sampling through partnering agencies. Referrals were initially screened for eligibility criteria e.g. level of ID and ASD, and availability of both client and caregiver for the trial and time commitment required for group randomization and attendance. Upon referral and consent by both client and caregiver, an interview was conducted by a research assistant (independent from the research team and blind to the group allocation) who confirmed eligibility and obtained written consent. The interview was completed prior to randomization to one of the three groups, and one month prior to group commencement. The interview included a demo-graphic questionnaire which included information on age, gender, locality, living arrangements, affiliated agency, caregiver role and experience, diagnoses, medications, and existing clinical services and supports.

After the questionnaire, a two part assessment involving an interview and psychometric measures was conducted. The interview conducted with clients to identify insight into their own emotional and behavioural difficulties, and their motivation to gain coping skills with these difficulties. Caregivers were also interviewed about their perspectives of the client's overall profile and need for treatment. The second part included a battery of both psychometric and observational measures to gather baseline measures of client emotional regulation, anger control and psychopathology. Standardized measures included the Difficulties in Emotional Regulation Scale (Gratz & Roemner, 2004), Novaco Anger Scale: Provocation Inventory (Novaco, 2003), and Reiss Scale of Dual Diagnosis (Reiss, 1990), respectively. The caregiver interview aimed to identify what they perceived the presenting problems to be, the effect of the issue(s), how they addressed the issue with the participant, and coping strategies currently utilized. The matched caregiver pre-assessment measures included the Emotion Regulation Checklist (Cicchetti & Shields, 1997; adapted with written permission by Cicchetti, 2016), Novaco Anger Scale: Provocation Inventory (Novaco, 2003) and Reiss Scale of Dual Diagnosis (Reiss, 1990). Measures were completed in relation to caregiver perspectives of clients' profiles of emotional regulation, anger control and mental health difficulties. The psychometric measures noted above all have robust validity indices as noted in their respective manuals.

Following group treatment, interviews and post assessments were conducted by independent research assistants, with both participants and caregivers, within approximately four weeks of group completion. In addition to re-administered assessments to measure potential change, the post-interview included an update and feedback questionnaire that focused on their qualitative experiences participating in the group, what they learned, whether they believed the skills presented would benefit their daily lives, coping strategies that they were currently utilizing, and feedback regarding suggested changes to the group. They were also asked about any significant changes in their circumstances since their group attendance (e.g. residential moves, hospitalizations, or legal charges) to illustrate possible contributory attrition factors if applicable. Also administered was an adapted multiple choice questionnaire, the Global Impression of Change: aDBT-ID. The measure was adapted from the Patients Global Impression of Change Scale (Hurst & Bolten, 2004) and then reviewed with the research team for face validity. The questionnaire identified the initial presenting problems and then measured both client and caregiver perspectives of overall change following the group, and for each respective module; with five responses ranging from no change to significant change. Accordingly, the interviews with the caregivers matched the clients' post assessment with the psychometric measures, feedback interview and GIC questionnaire.

Statistical Analysis

Outcomes for the group were evaluated using both quantitative and qualitative measures in order to identify any group treatment changes; but also to assess the experiences by both clients and caregivers in the treatment process and their views on participation in community-based research. Given the small sample group and attempts at research rigour, quantitative measures were analysed utilizing an 'intent to treat' paradigm such that all participants who started the group were included in analysis. Using a mixed method ANOVA within SPSS v24, group differences, within and between, were assessed using non-parametric analysis due to group composition i.e. Wilcoxon signed-rank and Man-Whitney U tests, respectively.

Qualitative measures were evaluated using thematic analysis (Braun & Clarke, 2006) for both client and caregiver interviews to identify and illustrate thematic patterns through an iterative process of data immersion, category generation and theme identification followed by inter-rater verification.

Post-assessment data was unable to be obtained for one participant and one caregiver, and as such both qualitative and quantitate components were conducted with a sample size of N=18.