

A pilot Randomized Controlled Trial of Dialectical Behavior Therapy (DBT) for Craving and Cessation in Marijuana Use Disorder Patients: Feasibility, Acceptability, and Appropriateness

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Keywords: Dialectical behavior therapy, Marijuana, Feasibility, Craving, Lapse

DOI: <https://doi.org/10.21203/rs.3.rs-31085/v1>

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Abstract

Purpose: This study has investigated the feasibility and preliminary efficacy of DBT for Marijuana cessation and craving reduction as a pilot RCT.

Methods: sixty-one participants were randomly assigned to one of the DBT or psycho-education as active control-group with two-month follow-up. Patients completed measures at pre-interventions, post-interventions, and a two-month follow-up.

Results: feasibility in DBT is significantly higher than the control group. In the DBT group 29/30 (96% retention) and in control group 24/31 (77% retention) completed all sessions ($\chi^2= 4.95, p = 0.02$). Moreover, 29/30 (96%) in the DBT group and 20/31 (64.5%) in the control group completed the two-month follow-up ($\chi^2= 9.97, p = 0.002$). For the acceptability of the intervention, results showed 16.57 (agree) in DBT and 9.6 (neither agree nor disagree) in control groups for $p < 0.05$. For appropriateness, results showed 17.03 (completely agree) in DBT and 10.7 (neither agree nor disagree) in control-groups for $p < 0.05$. for craving, results confirmed that there is no significant difference between groups ($F = 3.52, p > 0.05$); however, in "emotionality," subscale DBT showed a significant reduction rather than the control group ($F = 19.94, p < 0.05$). For cessation rates, DBT was compared with the control group at the posttest (46% vs. 16%) and follow-up (40% vs. 9.5%), and results proved higher effectiveness in the DBT group for $p < 0.05$. Furthermore, among those who have lapsed, participation in the DBT group had fewer days than consume for $p < 0.05$.

Conclusions: DBT shows feasibility, acceptability, and promise in improving cessation rate in Marijuana use disorder and warrants further investigations.

Introduction

Marijuana is the most prevalent substance that has been reported to be a significant problem among adult substance abuse treatment seekers(1). Marijuana, as one of the unauthorized drugs, is accompanied by major physical, psychological, and social consequences(2). Studies have shown that regular and heavy Marijuana use patterns correlate with increasing the risk of mood disorder, anxiety, and psychotic episode; although the causality has not been demonstrated, these patterns can increase the course of mental health problems (3). Also, several medical problems such as respiratory system deficits, stroke, myocardial infarction, digestive tract cancers are associated with Marijuana use patterns, especially among those with Marijuana use disorder (MUD) (4, 5). In patients with MUD, approximately one in three Marijuana users have met criteria for MUD, and the proportion is increasingly growing(6). One of the most critical problems in substance use disorder treatment is craving, a factor known as the root cause of relapses and treatment failures (7). MUD patients report visual, tactile, and olfactory cues related to craving and compulsivity sensations (8).

So far, the Food and Drug Administration (FDA) in the United States has not approved any psychopharmacotherapy for MUD, and therefore psycho-social interventions have achieved special attention (9). The most widely used psychological treatment in SUD context is cognitive-behavioral therapy (CBT) (10). This psychotherapy is somewhat efficient in SUD, but most MUD patients do not achieve cessation and unmotivated to continue skill training, so relapse rates remain considerable (10, 11). One of the main reasons for this low rate is CBT limitations. First, CBT protocols do not focus on comorbid problems, whereas most people with SUD have at least one psychiatric or psychological problem. The second cognitive restructuring may not be useful for all SUD patients. In fact, some patients may be unable to restructure their dysfunctional cognitions and core beliefs despite receiving CBT (9–11).

Furthermore, emotion regulation deficits strongly associated with increased addictive behaviors such as SUD. With emotion regulation, peoples adjust their emotional experiences with distressing and unpleasant events. It is essential for the successful overcoming of environmental demands and personal welfare (12). On the behavioral levels, studies have found that Marijuana craving cues are strongly associated with deficits in the regulation of negative affect and emotions (12, 13). Also, in neural levels during the reappraisal of negative stimuli, MUD and regular user's patients have shown altered neural activity and functional connectivity. Moreover, Marijuana user is related to dysfunctions in amygdala and amygdala–dIPFC coupling activity (12). Together, these findings demonstrate that emotionally based psychotherapy is required to manage comorbid problems and eliminated CBT limitations.

One of the psychotherapies in the third waives behavior therapy cluster is dialectical behavior therapy (DBT). DBT has been described as the intervention of emotion regulation deficits by focusing on dangerous impulse in borderline personality disorder and SUD. DBT goals include improving and regulating emotions as a primary mechanism of change; in fact, this psychotherapy is a transdiagnostically treatment and suitable for comorbid problems. DBT skills training is made up of four modules: distress tolerance, interpersonal effectiveness, emotion regulation, and mindfulness. Overall, in the context of SUD, DBT teaches emotion regulation skills to decrease engagement in pathological emotion regulation strategies. It also interferes with the poor quality of life situations, reduces drug-seeking behavior, and helps patients to function adaptively by accepting unpleasant emotions such as craving (7, 11, 12).

Research literature shows the efficacy and effectiveness of DBT in various comorbid problems and diseases such as suicide (14), forensic psychiatric patients (15), and irritable bowel syndrome (16). Nevertheless, studies have shown contradictory results about the effectiveness of implementing DBT on various SUD populations (17, 18). Furthermore, these pieces of literature have recommended the use of the larger samples, more clear instruments for outcome variables, specific, and integrated protocols (19).

Additionally, based on our investigation, no DBT randomized clinical trial has been conducted about cessation (with or without comorbid problems) in MUD patients. In this regard, a DBT intervention to increase the cessation rate and craving among MUD patients has been developed in this study.

This pilot trial has investigated the feasibility and preliminary efficacy of DBT relative to a psycho-education condition that has been controlled for time duration and attention. Feasibility has been assessed via contentment and session completion rates. Preliminary efficacy has been evaluated via DBT impact on cessation rate, reduction consuming rates compared to the psycho-education condition. Although craving and acceptance of craving are not the primary goals of DBT, they have been compared in two interventions.

Methods

Trial design

This study has been developed based on a controlled randomized clinical trial, including the pretest, posttest, and two-month follow-up phase. The DBT has then been compared with a psycho-education treatment.

Sample Size

As the sampling method comprises snowball sampling and strict eligibility criteria, based on similar pieces of research, at least 20 participants have been determined for each group [11]. However, it has been attempted to achieve a greater sample size.

Selection Criteria

To be included in the study, participants had to (1) attend MUD psychiatric diagnosis, (2) be at least 18 years old, (3) not have any current or past history of major psychiatric disorders, (4) not be using any other SUD treatment, and (5) be willing to attend intervention and complete surveys (questionnaires and urine kit). Exclusion criteria include (1) unwillingness to continue the study, (2) the absence of more than two sessions, (3) starting secondary psychotherapy, and (4) determine the use of other substances (except alcohol, nicotine, and caffeine) during any stages of research. Participants included inclusion criteria who referred to the clinic affiliated with Kermanshah University of Medical Sciences.

Participations, Procedure, And Randomization

Due to the non-existence of any Cannabis Use Disorder Treatment Center in Iran, there is no specific place to select patients. Any other way, patients who are in drug treatment centers referred for treating other drugs use disorders; and comorbidity of drug use is among the exclusion criteria in this study that may lead to misleading results. Therefore, the families and acquaintances of those who referred to the drug treatment center were interviewed. At this stage, from date November 01, 2019, to November 5, 2019, out of relatives and families of drug users referring to drug treatment centers, 15 were diagnosed with MUD.

Then, using snowball sampling, after 15 days of investigation, 83 patients were diagnosed with MUD. Of the 83 MUD patients who were approached, 75 consented, eight declined to participate, and 14 were ineligible. The primary reasons for declining were anxiety of addiction stigma and time constraints. Most ineligible patients had multi illicit use disorders, so they did not meet the criteria for study entry. Therefore, 61 patients completed the baseline assessment and were included in the current analyses. These patients randomly assigned to each group with a random number table. From December 01, 2019, to March 20, 2020, interventions have been implemented. The follow-up phase started on March 21, 2020, and ended on May 20, 2020, (two-month follow-up). For control exclusion criteria before each session, a six-pack of six-drug kits for Methamphetamine, Amphetamine, Cannabis, Methadone, Benzodiazepines, and Morphine was administered to individuals through urine.

Blinding

Both groups were blind to the existence of another group of the research. However, patients were informed about participating in research and not about another group. One day after the end of treatment, the post-test was carried out by mental health technicians with a master's degree in psychology.

Outcomes Measures

Abstinence

to identify abstainers, a Marijuana urine test kit prepared by Kian Teb Company (officially licensed by National Medical Device Directorate IR. IRAN) was used.

Marijuana smoking

For patients who have lapsed during the post-test of follow-up, a self-report scale was designed. On this scale, patient checkmarks consumed days 30-days ago. The first thirty days after the last session was considered as the post-test smoking pattern, and the second-month follow-up was considered as follow-up Marijuana use pattern.

Craving

The short-form of the Marijuana Craving Questionnaire (MCQ) is a 12 items self-report questionnaire with the ten-items for assessment of subjective cannabis craving. This scale consists of 4 factors, including compulsivity, emotionality, expectancy, and purposefulness. According to how patients were thinking or feeling "right now," they placed checkmarks in the questionnaire, ranging from 1 or strongly disagree to 7 or strongly agree on this scale. Results showed that this questionnaire's internal consistency is suitable ($\alpha = 0.90$). This measure was administered following a 12-hour deprivation period. The typical onset of Marijuana craving and withdrawal symptoms is approximately observed within one day after cessation; thus, the questionnaire scores in the current paper can be conceptualized as an index of the propensity to

experience Marijuana craving following deprivation (20). In Iran's MUD patients, MCQ internal consistency was $\alpha = 0.87$. The details about MCQ psychometrics properties will be published as a separate study as soon as possible.

Acceptability

Acceptability of Intervention Measure (AIM) was employed to measure the acceptability of interventions. AIM measured on a 5-point Likert scale (from Completely Disagree with 1 point to Completely Agree with 5 points). The final score is calculated by mean points. This questionnaire developed by Weiner et al. (2017), and they reported Cronbach's $\alpha = 0.85$ for internal consistency (21).

Appropriateness

Intervention Appropriateness Measure (IAM) used for Appropriateness. The IAM consist of a four-item scale that measures perceived intervention appropriateness. Items are measured on a five-point Likert scale (Completely Disagree to Completely Agree), which calculates the mean score. Higher points mean participant feels this intervention is more appropriate for his/her. For this tool, Cronbach's $\alpha = 0.91$ and all Factor Loadings reported higher than 0.8 (21).

Intervention

Dialectical Behavior Therapy

DBT as a group intervention consisted of 16 sessions (meeting once a week for 90 minutes) with one psychotherapist and her co-therapist. The intervention protocol was an adaptation of DBT to SUD based on three basic manuals (11, 22, 23). The primary objective of the DBT is to reduce dysfunction in emotion regulation and craving via increasing cessation rates and improvement of skills. Table 1 shows DBT contents per session. This treatment implanted by a Ph.D. of clinical psychology that blinded about another group and the main goals of the research.

Table 1
DBT contents per session

| Cessation | contents |
|--|--|
| Pre-session | Explanation of dialectical behavioral therapy, principles, and goals. brief introduction of the content of each session. familiarity with participants. Giving people an intervention booklet to read at home. |
| 1st session (mindfulness1) | introduce the concept of mindfulness and three mental states (wise, reasonable, emotional) and their relations with substance use. |
| 2nd sessions (mindfulness 2) | Teaching two clusters of mindful skills. first, include viewing, participation, and description. Second include non-judgmental stance and inclusive self-consciousness. |
| 3rd session | summarizing the mindfulness sessions. Definition of addiction, common therapies of addiction, introduction, and teaching of dialectical avoidance technique, review of the positive and negative aspects of abstinence, explanation and Investigating the relapse and its cause, explaining the skill of the pure mind, the addicted mind, the types of behaviors related to the pure mentality and the addicted mentality, and the preparation of a list of supporters. |
| 4rd -5th sessions (Distress tolerance) | teaching distraction strategies with five skills include activities, comparisons, emotions, thoughts, contributing using away. through enjoyable activities, focusing on work or other topics, counting, leaving the situation, paying attention to daily tasks, distracting from thoughts and self-harm behaviors. teaching and training self-soothing with five senses. |
| 6th -7th sessions (Emotion regulation) | Definition of emotion, how emotions work, familiarity with emotion regulation skills. Emotion Identification Exercise, Emotion Registration Exercise. Identifying barriers to experiencing emotion in a healthy way and ways to overcome these barriers. Teaching creating short-term positive emotional experiences for experiencing positive emotional states. |
| 8th -10th sessions (Emotion regulation and distress tolerance in MUD context) | Explain the craving and its connection to the experience of emotions. Introducing methods for identifying values. importance committed action based on a list of important values in life. Develop new coping strategies in response to unpleasant emotions, sensations, and cognitions especially craving as multidimensional problem. teaching problem solving and behavior analysis. |

| Cessation | contents |
|----------------------------------|--|
| 11th session | Basic acceptance technique training. Living in the present moment techniques. |
| 12th -13th sessions | interpersonal effectiveness training. Participants learning assertiveness skills about substance users people. Other skills include Non-verbal communication, Verbal communication, Problem-solving, Decision-making and Listening skills. |
| 14 th – 16th sessions | Review sessions. Eliminate ambiguities. Exercise skills in the presence of other people. |

Psychoeducation

Psychoeducation is an updated and straightforward information about Marijuana dangers and its management addiction as well as craving pamphlet. It is also more ethical than without offering any intervention. A psychiatrist with five years of experience in addiction psychotherapy implemented this intervention. This intervention includes problem-solving skills, assertiveness, and craving management in eight sessions and is designed for eliminated common practical factors among psychotherapies to specify pure DBT effects.

Therapists And Treatment Adherence

For checking adherence, audios of sessions were recorded with the consent of all the participants. Then a DBT researcher and psychotherapist who was not involved in the treatment groups checked contents secession. Sessions were divided into 15-minute modules that were chosen for adherence checks randomly. Treatment stance and the occurrence and depth of DBT processes were appraised. Based on the treatment manual, the modules rated the adherence level as either adequate or not adequate. The majority (83%) was judged as having been conducted adequately.

Statistical Method

Demographic information was gathered and reported the frequency, mean, and standard deviation, and for outcomes, repeated measures ANOVA and chi-square tests were conducted by SPSS software version 26.

Results

Feasibility

In the psycho-education group, 24/31 and the DBT group, 29/30 completed all sessions (retention rate 77% in the control group vs. 96% DBT). Additionally, in the DBT group, 96% (29/30) completed the two-month follow-up, whereas, in the control group, 64.5% (20/31) completed follow-up (Fig. 1). The chi-square test was employed, and the association between group and retention was observed, $\chi^2 = 4.95$, $p = 0.02$ for post-treatment and, $\chi^2 = 9.97$, $p = 0.002$ in the follow-up phase. Consequently, retention rates in DBT were significantly higher than psycho-education in post-treatment and follow-up phases.

Acceptability And Appropriateness

For acceptability and appropriateness of intervention, patients completed the AIM and IAM scales in post-treatment phase. For acceptability, results showed 16.57 in DBT and 9.6 in psycho-education groups ($p < 0.05$). For appropriateness, results showed 17.03 in DBT and 10.7 in psycho-education groups ($p < 0.05$). As there are not any norms for these measures, these points were transferred to Likert-based scale questionnaires. For acceptability, results showed "agree" for the DBT group versus "neither agree nor disagree" for the psychoeducation group. For appropriateness, results showed "completely agree" for the DBT group versus "neither agree nor disagree" for the psychoeducation group.

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Participant Characteristics

Demographic variables in participants are presented in Table 2. Analyses reports showed that there was no significant difference between the two groups regarding these variables. It should be noted that since over 97% of the participants were male from the beginning, the results were reported only for men.

Table 2
Mean and standard deviation of demographic variables in the intervention and control groups at the test phases

| Variable | | Intervention group Mean (SD) | Control Group Mean (SD) | p-value |
|--|---|---------------------------------|----------------------------|--------------------------------|
| Educational Level ^s | Under diploma ^a | 2(6%) | 6(19%) | Educational Level ^s |
| | Diploma ^a | 14(46%) | 15(48%) | |
| | University student or graduate ^a | 14(46%) | 10(33%) | |
| Age | | 25.6(5.67) | 27.19(7.48) | Age |
| months of Using | | 19.53(5.9) | 17.48(6.03) | months of Using |
| Craving Total)) | Pre-test | 45.2(8.3) | 47.9(10.2) | Craving Total)) |
| | Post-test | 42.13(7.7) | 44.48(8.1) | |
| | Follow-up | 42.66(9.25) | 45.8(8.4) | |
| a: Data are expressed as N%. b: Independent t-test was used. c: The chi-square test was applied. | | | | |

Outcomes Efficacy

For craving, the hypothesis of equal covariance matrices was examined (Box's M = 3.63, P = 0.74). The results of this test suggested homogeneity in the covariance matrices. Mauchly's test of sphericity also showed the establishment of the sphericity assumption ($p = 0.42$ and Mauchly's W = 0.97).

The results of the intergroup test and intergroup relation are also presented in Table 3. According to Table 3, the effect levels for craving ($F = 3.52$, $p > 0.05$) suggest that there is no significant difference between groups. These results repeated in three subscales of craving include compulsivity, expectancy, and purposefulness. However, in emotionality, subscale results showed a significant reduction in DBT rather than psycho-education group 10.6 vs. 14.4 in the post-test and 10.43 vs. 13.26 in the follow-up phase ($F = 19.94$, $p < 0.05$).

Table 3

Repeated measures ANOVA for variables between the ACT group and control group in the pre-test, post-test, and follow-up

| Variable | | Source | Type III Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared | Observed Power ^a |
|-----------------------------------|-----------------------------------|----------------------------------|-------------------------|--------|-------------|--------|-------|---------------------|-----------------------------|
| craving | Tests of Within-Subjects Effects | factor 1 | 347.696 | 2 | 173.848 | 2.6 | 0.07 | 0.04 | 0.512 |
| | | factor 1 * group | 4.76 | 2 | 2.38 | 0.036 | 0.11 | 0.001 | 0.055 |
| | | Error(factor 1) | 7845.154 | 118 | 66.48 | | | | |
| | Tests of Between-Subjects Effects | group | 341.084 | 1 | 341.084 | 3.52 | 0.06 | 0.056 | 0.455 |
| | | Error | 5708.79 | 59 | 96.75 | | | | |
| | emotionality | Tests of Within-Subjects Effects | factor 1 | 257.33 | 2 | 128.65 | 11.69 | 0.00 | .165 |
| factor 1 * group | | | 74.70 | 2 | 37.35 | 0.37 | 0.03 | 0.05 | 0.63 |
| Error(factor 1) | | | 1297.81 | 118 | 10.99 | | | | |
| Tests of Between-Subjects Effects | | group | 283.89 | 1 | 283.89 | 19.94 | 0.00 | 0.25 | 0.9 |
| | | Error | 839.906 | 59 | 14.23 | | | | |

About cessation, the results indicated that in the post-test and follow-up, DBT had a higher rate of cessation than the control treatment (Table 4) ($p < 0.05$). It was also found among those who continued to use the drug, the number of monthly use days in the post-test and the follow-up periods (two months) was significantly lower in the intervention group rather than the control group.

Table 4
cessasstion and consumption between groups

| | | DBT | control | P value |
|---------------------------------|-----------|-------------|-------------|---------|
| Cessation ^b | post-test | 14(46%) | 5(16%) | 0.01 |
| | Follow-up | 12(40%) | 3(9.5%) | 0.006 |
| Number of days use ^c | post-test | 2.43 ± 1.8 | 7.5 ± 5.03 | 0.00 |
| | Follow-up | 3.44 ± 1.91 | 8.75 ± 3.27 | 0.00 |

b: The chi-square test was applied c: independent sample T-test

Discussion And Conclusion

This study examined the feasibility, acceptability, and preliminary efficacy of a 16-session DBT intervention for craving and cessation in MUD patients. This intervention showed strong evidence of feasibility. Moreover, acceptability and appropriateness rates of the DBT group were high and suitable. On the other hand, results showed that DBT is a promising intervention for Marijuana cessation in patents with MUD. Although this study is the first RCT of DBT on the MUD, the scientific literate about DBT on other addictive behavior shows similar results.

For example, Rezaei (2019) explored the efficacy of DBT for Methadone therapy patients. The result showed that DBT could reduce Methadone usage and improve emotion regulation (24). Moreover, another study showed that the implantation of DBT in alcohol-dependent patients improved alcohol-related behavior and emotional deficits, which is similar to the results of the present study (25). Nevertheless, in craving, the result showed there is not any significant difference between groups. About this finding, our result contradicts the majority of all pieces of research. For example, Rezaei. Z et al. found that DBT significantly improved craving among methadone users patients (11). This result also repeated in Rabinovitz. S paper (26). One of the main reasons for this contradiction is in the present study, DBD had greater improvement in the emotionality subscale of craving ($p < 0.5$). Since the most important structure of Marijuana craving is its emotional dimensions (3, 12), the lack of changes in other subscales has caused a non-significance in the craving as a whole scale. So the results of the present study of temptation are somewhat co-directional to the findings of previous studies.

On the behavioral levels, studies found that Marijuana craving cues were strongly associated with deficits in the regulation of negative affect and emotions (12, 13). Also, in neural levels during the reappraisal of negative stimuli, MUD and regular user's patients showed altered neural activity and functional connectivity. Furthermore, a Marijuana user was related to dysfunctions in the amygdala and amygdala-dIPFC coupling activity (12). Together, these findings demonstrate that emotion regulation problems and craving are prevalent in MUD patients, and they can interfere cessation process. DBT, as third-wave

behavior therapy, has strong emotional basics. This therapy encompasses three emotional goals, including understand emotions, reduce emotional vulnerability, and decrease emotional suffering. Patients understand unpleasant emotions are a normal part of life, and accepting their existence is more healthful rather than trying to avoid controlling them (11, 24). Overall, DBT is an emotion regulation that helps patients in teaching, understanding, labeling emotions, reducing emotional vulnerability, and decreasing emotional suffering. These skills help MUD patients to labeling emotions that related to craving. This improvement in emotional states can improve dysfunctions in the amygdala and amygdala–dlPFC coupling activity. In the same way, it improves emotional craving-related brain structures and so on, reduce impulsive behavior (e.g. lapse). Also, with the "distress tolerance" component of DBT, patients learn to stay with bad emotions so that they can accept unpleasant craving situations. Therefore, by increasing craving, they no longer consume Marijuana immediately. Similarly, with other DBT components, they learn reinforcement management and problem-solving skills that they can help MUD patients to reduce Marijuana consumption (20, 22, 24, 27, 28).

Despite these results, the present study also had some limitations. First, to evaluate the most effective components of treatment (such as mindfulness, distress tolerance), there were not groups receiving the third wave of other therapies (ACT or MBSR). This study had only a two-month follow-up period and could not follow the long-term evaluation due to the medical and hardware conditions of the study site. Next, it is recommended that in future research, the mediating and confounding variables to be examined in order to investigate the results of similar research in the present study. Other factors affecting relapse and recurrence could also be examined. Moreover, women can be used so that gender-related implications are determined.

Declarations

Ethics approval and consent to participate: Written informed consent (about participate in study) was obtained from all participants before the initiation of the research. The tools used in this study were all filled anonymously and an ID code was used. This project was assessed and approved by ethic committee of Kermanshah university of medical science (Ir.kums.rce.1398.1203). Moreover, this study is registered in the Thailand Registry of Clinical Trials (TCTR20200319007).

Consent for publication: during sampling individual session was held. We received consent for publication results from each participant.

Availability of data and material: Data of participants who consented to the public sharing of data are accessible from the first author upon reasonable demands.

Competing interests: The authors certify that they have no competing interests.

Funding: This study was a funded by the Deputy of Research of Kermanshah University of Medical Sciences, Iran.

Authors' contributions: The first author and corresponding author conceived of the presented idea. The first author with second author developed the protocol and performed the sampling. Second author. and fourth. The author verified the analytical methods. The corresponding author encouraged the first author to investigate This matter and supervised the results of the findings. all authors discussed the results and contributed to the final manuscript.

Acknowledgements: We would like to express our gratitude to the respected staff of the hospitals affiliated with Kermanshah University of Medical Sciences who have cooperated in the implementation of this study.

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Figures

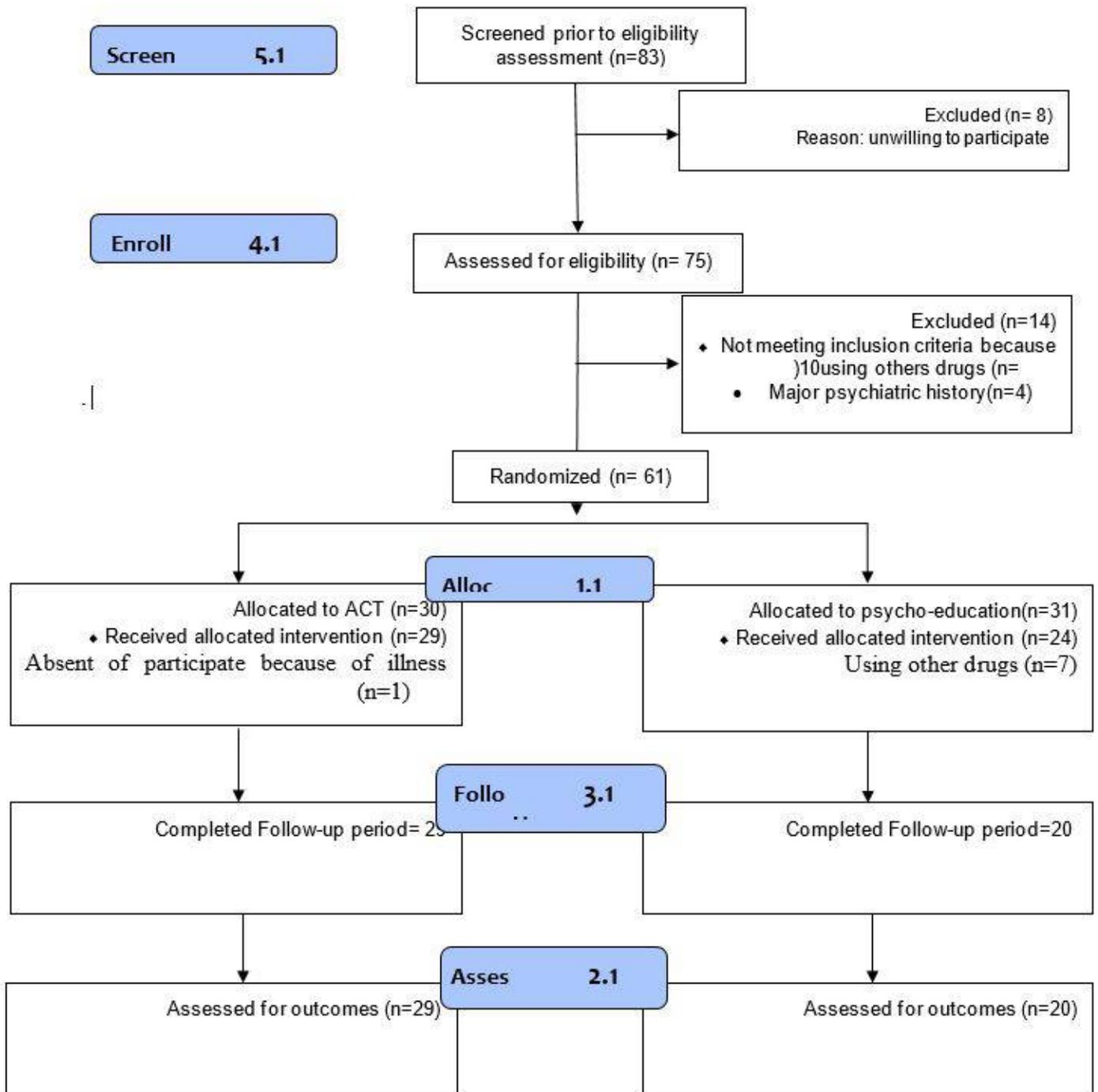


Figure 1

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