How Counseling Based on Acceptance and Commitment Therapy and Supported with Motivational Interviewing Affects Levels of Functional Recovery in Patients Diagnosed with Schizophrenia: A Quasi-Experimental Study

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Abstract

This study aimed to determine how counseling based on acceptance and commitment therapy (ACT) and supported with motivational interviewing (MIs) affected functional recovery in individuals diagnosed with schizophrenia (IDSs). A quasi-experimental design was used. The participants of this study were 87 individuals diagnosed with schizophrenia (36 in the experimental group and 51 in the control group). The experimental group received counseling based on ACT and supported with MIs. The data were collected between September 2018 and May 2019 using a Descriptive Information Form and the Functional Remission of General Schizophrenia Scale (FROGS). The participants in the experimental group were given a group counseling program of 8 sessions at community mental health centers in downtown Malatya, Turkey. The results revealed a statistically significant difference in the mean scores on FROGS between those in the IDS experimental group and those in the control group. The scores increased on both groups.

Introduction

Individuals diagnosed with schizophrenia (IDSs) have problems in daily activities, social functioning and occupational functioning besides cognitive deficits, and they cannot return to pre-disease functional levels even during clinical remission (Lahera et al., 2018; Ohi et al., 2019). Schizophrenia affects approximately 1% of the general population worldwide (Perälä, Suvisaari, Saarni, & et al., 2007). The global prevalence of schizophrenia increased from 13.1 million in 1996 to 20.9 million in 2016 (Charlson et al., 2018). Schizophrenia is one of the top 15 leading causes of disability worldwide (Vos et al., 2017). It may be stated that there is a tremendous literature on antipsychotic medication treatment used in treatment of this disorder that affects especially positive symptoms of the disease, preventing frequent hospitalizations and providing mild to moderate cognitive improvements (Cooper, Laxhman, Crellin, Moncrieff, & Priebe, 2019; Désaméricq et al., 2014; Haddad, Brain, & Scott, 2014; Husa et al., 2017). However, use of these medications may be financially and socially costly due to many undesirable side effects (De Picker, Morrens, Chance, & Boche, 2017). The World Health Organization estimates that the direct cost of treatment for schizophrenia accounts for 7 to 12% of the gross national product in developed countries (Chong et al., 2016). In Turkey, which is a developing country, the total cost of schizophrenia treatment was calculated as USD 616 million (Yıldız & Cerit, 2006). Some of the social problems that antipsychotic treatment can cause include that, due to the side effects of these drugs (e.g., tardive dyskinesia), they may be evaluated to cause obvious and involuntary movements in various extremities and increase stigma, as well as causing socially undesirable conditions such as weight gain and obesity (Sajatovic & Jenkins, 2007).

Schizophrenia management is evolving into a more comprehensive model based on functional recovery. Although there is no standard definition of functional recovery in schizophrenia, researchers suggest that functional recovery will occur not only by remission of symptoms, but also by achieving greater autonomy to manage one's own life (Lahera et al., 2018; Silva & Restrepo, 2019). Decreasing symptoms and relapse rates in schizophrenia contribute to improving general life functions, but this is not sufficient to achieve functional recovery. The concept of functional recovery goes beyond clinical remission and encompasses many aspects of an individual's life. Therefore, functional recovery and social integration are among important therapeutic goals in schizophrenia (Coşkun & Şahin Altun, 2018; Silvana et al., 2014). If the aim is functional recovery, which now has a very important place in treatment of schizophrenia, then it is essential to implement new therapeutic approaches and combinations. Therefore, today, it is recommended to employ a combination of pharmacological and psychosocial approaches in treatment of schizophrenia. Group counseling, which is one of the psychosocial approaches for IDSs, may be structured as a group activity. Group

counseling based on various approaches of therapy may ensure shorter periods of hospitalization, reduce relapse and increase IDS insight and functionality (Orfanos & Priebe, 2017; Yıldız, 2020).

This study provides a new perspective on the impact of acceptance and commitment therapy (ACT)-based and motivational interviewing (MI)-supported consulting, which is promising for the functional recovery of IDSs. Although both therapies advocate different treatment philosophies and models, they actually achieved significant results in some areas that will constitute the content of functional recovery in IDSs. For example, MI contributes to functional recovery by providing treatment motivation and cognitive rehabilitation mostly in IDSs (Ertem & Duman, 2019; Fiszdon, Kurtz, Choi, Bell, & Martino, 2016), while ACT seems to contribute to functional recovery by decreasing the rate of hallucination-related distress, anxiety, depression and hospitalization (Ridenour, Hamm, & Czaja, 2019; Yıldız, 2020). For this reason, there may be psychosocial approaches that produce pragmatic results in supporting functional recovery by acting jointly with ACT and MI. Given that both therapy approaches have a potential for functional recovery and have not yet been tested not only in IDSs, but in other populations, it has been wondered whether the combination of ACT and MI would be useful for providing integrative care. Considering that more research is needed to develop effective treatments that not only alleviate distress but also support functional recovery for IDSs, every step that appears to be taken seems very important. This study came to life with the idea that the already evidence-based and new emerging combinations for schizophrenia should offer a range of treatment options.

Background

In recent years, early studies in treatment of psychotic disorders through a third generation Cognitive Behavioral Therapy (CBT), namely the ACT, have provided promising results (Alicia, Tania, David, & Isabelle, 2018; Gaudiano et al., 2015; Ghouchani et al., 2018; Thomas et al., 2014). According to the ACT model, the source of the problem is the individual's association with unwanted emotions, thoughts and personal experiences, as well as their efforts to change, suppress, eliminate or control them. The ACT model argues that the individual can have a meaningful and enriched life only through the acceptance of the presence of symptoms (unwanted emotions, thoughts, feelings or personal experiences, etc.) and differentiating them from self. ACT suggests that, if the individual is too busy fighting emotions, avoiding painful memories or trying to replace negative thoughts with positive ones, they become incapable of meeting the essential needs in their lives. As a result, they turn into a strict and inefficient "*problem-solver*" (Davies & Nagi, 2017; Harris, 2019). The ACT model attempts to break this vicious cycle by attaining two main objectives based on six fundamental principles. The first objective is to deal effectively with painful feelings and thoughts, and the second is to lead a rich, fulfilled and meaningful life in line with personal values. Based on the acceptance

and awareness approaches, the ACT model helps change the relationship between disturbing thoughts, unpleasant feelings, painful memories or hurtful experiences to open up space in the life of the individual. Reducing symptoms (thoughts, memories, feelings, bodily sensations, etc.) or changing their content is never a goal of ACT (Davies & Nagi, 2017).

Recent meta-analyses suggested that ACT is at least as effective as the more traditional forms of CBT and provides desirable results in terms of creating acute and long-term effects on symptoms (Öst, 2008; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009). ACT is currently listed as an empirically supported psychotherapy by the Society of Clinical Psychology in a number of psychiatric conditions including psychosis (Society of Clinical Psychology, 2018). In a randomized controlled study, Shawyer *et al.* tested the efficacy of ACT in psychosis and found that ACT provided positive results even in persistent psychosis (Shawyer et al., 2017). In a recent meta-analysis which examined the effects of third-generation therapies including ACT in treatment of psychotic group disorders, current therapies were reported to provide significant improvements in patient functionality (Louise, Fitzpatrick, Strauss, Rossell, & Thomas, 2018). According to the results of a recent systematic review on the effects of the ACT model in individuals with psychotic disorders, ACT was found to be a transdiagnostic approach with pragmatic outcomes in psychotic disorders such as schizophrenia (Yıldız, 2020).

In recent years, MI came into use as a psychosocial approach to increase intrinsic motivation for change and strengthen commitment by discovering and solving ambivalence (Miller & Rollnick, 2012). Schizophrenia frequently causes a significant and permanent decrease in motivation levels, such that it prevents the individual from getting involved in psychosocial rehabilitation and may directly cut back the effectiveness of these treatments (Fiszdon et al., 2016; Medalia & Saperstein, 2011). Resistance in the therapy process, which is directly related to a decrease in motivation levels, is usually caused by uncertainties about the change or indecisiveness towards the goals required by the treatment. At this point, there is a need to develop supportive methods to break resistance to therapy, which is almost inevitable. MI is a client-oriented and guiding treatment technique. This helps improve client motivation, compromise and understanding for therapy, and it becomes possible to resolve confusion (Miller & Rollnick, 2012). In therapies such as ACT, clients may often resist the tasks or mindfulness exercises required for effective therapy (Yıldız, 2020). In the MI process, the client's complaints are listed together with these resistors and may be handled by identifying the automatic thoughts that come to mind during these complaints and understanding the resilience of the client at a common point (Miller & Rollnick, 2012). Considering that MIs focus on ambivalence related to change, the technique may promise a reinforcement of the existing effective treatments, including the agreed-upon CBT approaches (Miller & Rollnick, 2012). Furthermore, considering that

MI may be particularly useful to enhance the efficacy and effectiveness of existing treatments, rather than changing them (Westra, Constantino, & Antony, 2016), a combined practice of MI and ACT appears as a pragmatic and effective approach.

From an integrative perspective, ACT seems to share some concepts and ideas with MI. For example, both therapy approaches emphasize an egalitarian client-therapist relationship, the individual's experience of contributing to the change process, importance of understanding the values of the individual to advocate a life in line with them, as well as adapting interventions according to the individual and not avoiding openly facing the individual (Bricker & Tollison, 2011). Therefore, MI and ACT are highly likely to complement each other. Moreover, both therapeutic approaches conform to the philosophy of psychiatric nursing with their focus on therapeutic communication, based on the idea that each individual is valuable, has the potential for change, and there is meaning in all behavior (Fiszdon et al., 2016; Harris, 2019; Hayes, Strosahl, & Wilson, 2011; Miller & Rollnick, 2012; Yıldız, 2020). Therefore, both therapies may be administered by psychiatric nurses to overcome lack of motivation, which is one of the major obstacles in treatment of IDSs. On the other hand, the review of the national and international literature returned no studies using ACT and MIs together. This shows the importance of testing both therapeutic approaches together for IDSs. It is assumed that psychiatric nurses can achieve positive results in psychosocial treatment of IDSs in group therapies integrating both approaches of therapy. Defining and testing this combination may definitely be a significant contribution to IDSs and the literature in this field.

Aims

This study was conducted to determine how counseling based on ACT and supported with MIs affected the levels of functional recovery in IDSs.

Hypothesis of study

H_1: Counseling of IDSs with ACT supported with MIs will improve levels of functional recovery.

Methods

Design

A quasi-experimental design with a control group, pretest and posttest was used in this study. This design includes collecting data before and after the implementation of an intervention from experimental group participants and control group participants. The reporting rigor was demonstrated using the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) checklist (See Supplementary File 1).

Participants

The participants were IDSs receiving treatment at two community mental health centers (Göztepe and Yeşilyurt CMHCs) in the city of Malatya and at the CMHC of the city of Elazığ. The experimental and control groups were selected from CMHCs located at two different provinces via the simple random sampling method in order to prevent the IDSs from influencing each other. However, these three CMHCs were identical in terms of their working methods, the facilities they offered, their healthcare staff and the patient population they served. The control group was selected from the Elazığ CMHC, and the experimental group was from the Malatya (Göztepe and Yeşilyurt) CMHCs.

The following conditions were selected as the inclusion criteria for IDSs participating in this study: (1) diagnosis of schizophrenia according to the DSM-5 criteria; (2) 18 to 65 years of age; (3) openness to communication and cooperation; (4) in remission (except for exacerbation). Individuals were excluded if: (1) diagnosis of dementia and/or other organic disorders; (2) current use of alcohol or psychoactive substances and (3) mental retardation established with hospital records.

Sample Size

In this study, the software "G. Power-3.1.9.2" was used, and the required sample size was calculated in a 95% confidence level. The pretest and posttest results were aimed to be examined to evaluate the effectiveness of a counseling program based on ACT and supported with MI on individual improvement. The effect size obtained from previous studies was found to be 0.93 (Gumley et al., 2017), and with 0.90 theoretical power, the minimum required sample size was calculated as 52 (26 experiments, 26 controls). Nevertheless, considering potential dropouts, 52 participants were planned to be assigned to each of the experimental and control groups. Before starting the data collection phase of the study, the first researcher (EY) interviewed all the IDSs regularly attending these three centers about their participation in the study. However, 6 individuals from the experimental group registered at the Göztepe CMHC quit on the grounds of secondary illness, difficulties with transport, moving house, parents' illness or old-age. 10 individuals from the experimental group at the Yeşilyurt CMHC had to be hospitalized due to sudden exacerbation of their condition, and 1 person in the control group at the Elazığ CMHC left the study without giving any reason. Therefore, the study was conducted with a total of 87 individuals diagnosed with schizophrenia, out of which 36 were the experimental group, and 51 constituted the control group (Figure 1).

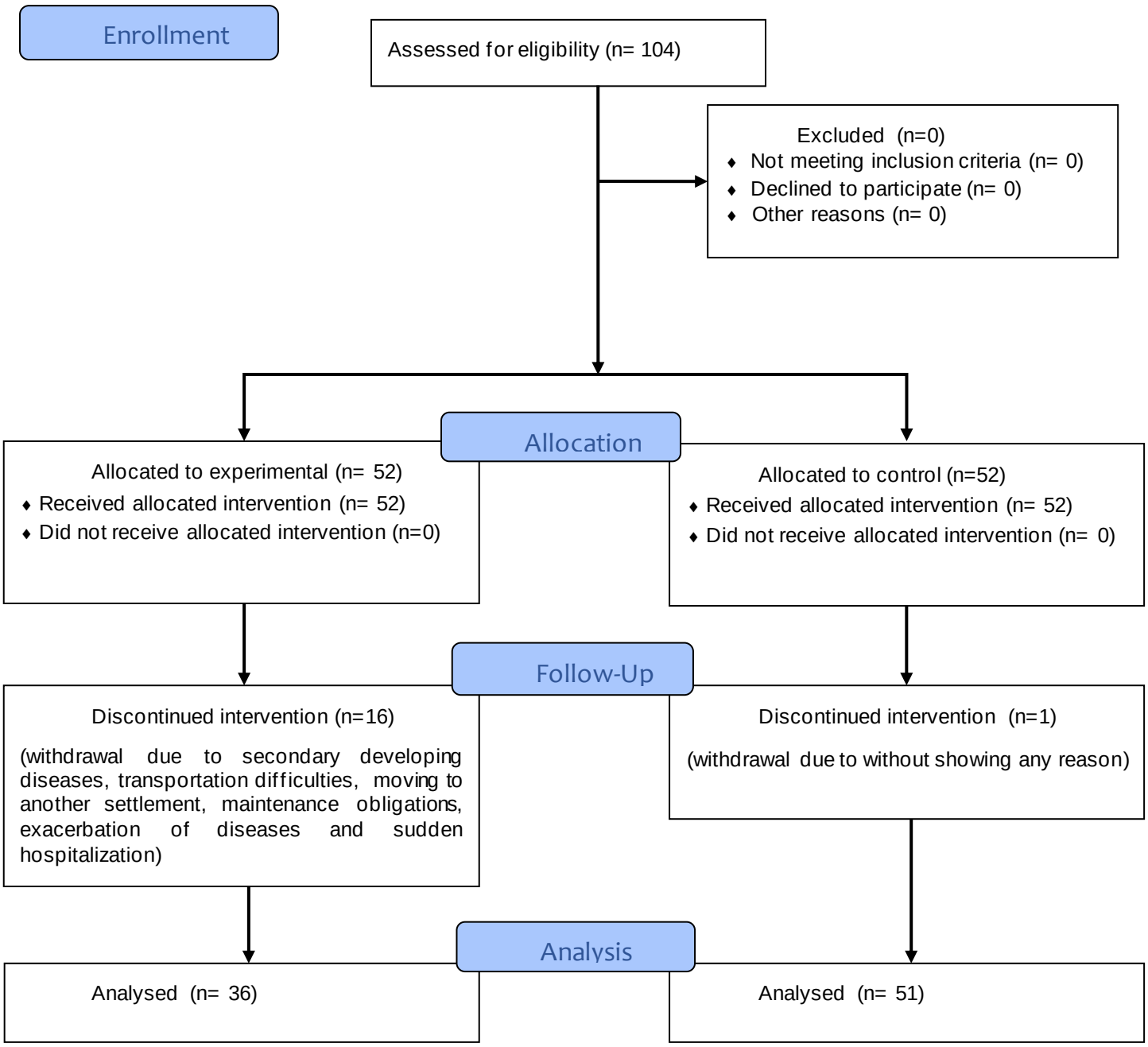


Figure 1. Flow Diagram

Psychiatric Nursing Initiative

The therapist (EY) is an experienced psychiatric nurse with a doctoral degree in psychiatric nursing and had completed basic training programs for ACT and MI before starting group counseling. In the study, the files of the IDSs registered with the CMHCs of the cities of Malatya and Elazığ were examined and evaluated in terms of compliance with the study criteria. Since the psychiatric nursing initiative applied to the experimental and control groups contained differences in itself, this section was examined under two separate titles, "Psychiatric Nursing Initiative in the Experimental Group" and "Psychiatric Nursing Initiative in the Control Group".

Psychiatric Nursing Initiative in the Experimental Group

ACT-based group counseling sessions supported with MI were held with the experimental group. There was a total of 8 sessions, and each lasted approximately 70 minutes. The group sessions were held once a week under the leadership of the researcher at the CMHCs in Malatya.

Procedures for Data Collection. After the individuals who met the criteria were informed about the study, they were invited to a CMHC for a preparatory session. In this session, the purpose and importance of working with IDSs and the content and duration of the group counseling program were explained, and the participants were inquired about their expectations. After the preparatory session, the date and time were set for the first session with the IDSs, and the process was started. This session focused mainly on getting acquainted and developing a therapeutic alliance.

Treatment Motivation (Sessions 1 and 2): As one of the therapies to be used in this study, MI involved examining, analyzing and resolving the ambivalence experienced by IDSs in terms of compliance with therapy and treatment, as well as strengthening commitment to change and trust. The researcher intentionally adhered to the guiding principle to achieve this goal. Particularly at the early stages of group counseling with MIs, the focus was on increasing the motivation of the IDS to change in the desired direction. However, the MI process was also included in the other sessions where necessary and maintained as a recourse when issues emerged related to the motivation of the IDSs. Consequently, it was made easier to participate in the treatment process for those who were reluctant to change or ambivalent (Fiszdon et al., 2016; Medalia & Saperstein, 2011; Miller & Rollnick, 2012; Westra et al., 2016).

Acceptance and commitment, functionality (Sessions 3-8): In Session 3, group counseling was started based on ACT. The goal at the core of these sessions was to increase the functional recovery level of the individual. Group counseling continued until Session 8. In order to establish an effective bond with the individuals, during these sessions, we emphasized that we were "on the same ship" with the IDSs. The researcher was particularly alert about any "*potential tendency to have the*

upper hand" in their relationship with the IDSs. In order to achieve this, the "*Metaphor of the Two Mountains*" was shared in Session 3. At the beginning of this session (Session 3), "*10 Breathing Exercises*" were performed to capture the moment (self-exercise). Many ACT protocols contain a significant amount of psychoeducation. This was achieved by the researcher through exercises based on experience, as well as metaphors, rather than in a didactic fashion. In the group counseling session, the metaphors were determined with consideration to the group circumstances so that they could 1) provide an intensive flow of information in a short period of time, 2) be acceptable to all, thus adopted easily, and 3) improve individuals' tendency to remember. In the intervention, the metaphors of struggling in the swamp, rope pulling against monsters, the lie detector and the leaves in the stream were the main components of the ACT-based group counseling process (Harris, 2019). The researcher sought answers for two key questions in order to quickly conceptualize any problems related to the IDSs from an ACT point of view. These questions were: "(1) *Toward what values does the individual want to advance?*" and "(2) *What are the obstacles in the path of the individual?*" The sessions were structured around the following steps: (a) self-exercise (breathing exercise); (b) review of the previous session; (c) basic interventions, and (d) homework.

Six basic therapeutic processes followed in the ACT sessions included being present at the moment ("here and now"), defusing ("follow your thoughts"), acceptance ("be open"), contextual self ("pure awareness"), values ("know what matters") and value-driven actions ("do what needs to be done"). These techniques helped develop an approach to improve psychological flexibility and increase functionality. Furthermore, awareness exercises such as body and breathing, body screening, awareness movement and three-minute breathing techniques were used during the group counseling program, especially at the beginning of each session. Another technique used was cognitive defusing (techniques to increase psychological distance from thoughts) (Harris, 2019; Hayes et al., 2011; Yıldız, 2020). The aim of using all these techniques was to help the patients pay attention to the present moment, be able to observe their own lives, bodies, emotions and thoughts internally, act without judgment and rush, accept themselves as they were, discover their physical and mental limitations, develop skills to identify and recognize the symptoms, progress, treatment and life effects of their condition, and finally, improve their coping skills. This experiential work aimed to increase the motivation and functional recovery of the IDSs. Detailed information about the content of the group counseling program provided to the experimental group is given in Table 1.

Table 1. Content of the Group Counseling Program Based on Acceptance and Commitment Therapy and Supported with Motivational Interviews

Sessions	Theme	Objectives	Agenda	Exercise and Homework
Procedures for Data Collection		1. Ensuring Patient Participation in the Group Counseling Program Based on Acceptance and Commitment Therapy and Supported with Motivational Interviews 2. Explaining the study aim, the content and timetable of the program 3. Finding out patient expectations from the program	None	None
1	Exploring Ambivalence	1. Evaluate, analyze, and resolve patient ambivalence in treatment compliance. 2. Collect pre-test data.	A. Declare the agenda (Basic question: "What are we going to discuss today?") B. Apply the pre-test. C. Assess patient resistance to change. D. Understand symptoms and identify the factors hindering treatment. E. Apply significance and reliability-qualification criteria. F. 1 minute of silence and close.	None
2	Improving and Maintaining Motivation	1. Reinforce change and commitment in terms of patients' compliance with treatment and increase motivation.	A. Summarize the previous session and explain the agenda. B. Ask questions to trigger change ("If you change, how much do you think you can?" "Imagine you keep living as you do today without any change. Where do you see yourself in 10 years?" "What makes you worry about your situation?" "What would make you stop doing these things?")	None

			C. Use questions that can accelerate change (“If you decide to do it, which way do you prefer?” “What are the pros?” “What do you want to do?”) D. Use the significance criteria. E. Reveal the balance of decision-making. F. Ask questions about the future (“What do you think will happen when you change?” “Where do you see yourself in 10 years?” “If you don't change, what do you think will happen in the future?”) G. Reveal goals and values. H. 1 minute of silence and close.	
3	Defusion	1. Seeing the true nature of patients’ thoughts: help them realize that they are neither more nor less than words and pictures. 2. Respond to the functionality of thoughts, not their literal meanings (in other words, evaluating to what extent thoughts work, rather than to what extent they are true). 3. Allow thoughts flow in and out without trying to hold on to them. 4. Critical thinking on why defusion is needed with patients. 5. Improving the functional recovery levels of patients.	A. Summarize the previous session and explain the agenda. B. The “10 Breaths” exercise C. Help patients be aware of their own thoughts (“What is your mind telling right now?” “What does your thinking side say about this?” “Are you aware of what you are thinking right now?” “Be aware of what your mind is doing right now.”) D. Ask patients if their thoughts work (“How does this thought help you? Does it make it easier for you to cope with when you hold on to that thought?” “If you did what the thought tells you to, would your life be more meaningful and peaceful or would it become stuck and painful?”) E. Ask patients if they realize it when they associate and dissociate with their thoughts	✓ I'll ask you to try some exercises, if you like: ✓ Until the next session, first of all I would like to know how your thoughts hunt you, how do they entrap you? Under what circumstances does this repeat? What does it say? I need you to realize it whenever you are entrapped by your thoughts and say, “Oops! I got caught again.” ✓ When you are stressed, worried, or notice a thought that is ‘hot’ for you, do the “Leaves in the Stream” or the “Metaphor of the Old Story-teller” exercise.

			("How much influence does that thought have on you right at this moment?" "Do you realize how the thought has captivated you?") F. Ensure that the thought is realized without getting carried away with its content. G. Allow thoughts flow in and out without trying to hold on to them. H. "Leaves in the Stream" or the metaphor of the "Old Story-teller" exercise I. 1 minute of silence and close.	✓ Finally, whenever you realize that your thoughts are trying to entrap you, let them do their job, but don't let yourself into them, don't get into the thoughts.
4	Acceptance	1. Allow patients to experience their own thoughts and feelings regardless of whether they are pleasant or painful. 2. Make room for patients' thoughts and feelings and make them stop fighting these. 3. Allow patients to express themselves in their natural flow of emotions and thoughts. 4. Critical thinking on why acceptance is needed with patients. 5. Improving the functional recovery levels of patients.	A. Summarize the previous session and explain the agenda. B. The "Anchor" exercise C. Discussion of exercises and homework D. Establish an open, non-defensive, and in-depth therapeutic relationship with undesired personal experiences ("Let it be there." "Be open and make room for it." "Let it remain where it is." "Stop fighting it." "Make peace with it." "Let it be there.") E. Advocate acceptance in as much as it allows us to act in accordance with our own values rather than acceptance of each emotion and thought. F. Share the wisdom that, "If it does not enable us to engage in behaviors that make sense and enrich our lives, there is no point in making room for our painful experiences."	✓ Practice making room for your feelings as we did today until the next session. ✓ When you find yourself struggling with your feelings, just go through this exercise once. ✓ Finally, be aware of the times you are struggling with your feelings over the next week, and the times you are open to them, making room for them.

			G. Emphasize that change almost always causes anxiety and that we may have difficulty in accomplishing change if we do not want to make room for it. H. Exercise with "Walking in the Swamp Metaphor." I. Exercise with "Monsters in the Ship Metaphor." J. 1 minute of silence and close.	
5	Here and Now	1. Explain exactly what is happening by raising conscious awareness of the patient's immediate experiences, bringing together important information about changing or maintaining behavior. 2. Being spiritually present, securing consciousness, awareness, and flexible attention. 3. Provide flexible attention directed at the external material world together with the inner psychological world. 4. Increase functionality through critical thinking and discussion with patients on why it is necessary to be present.	A. Summarize the previous session and explain the agenda. B. The "10 Breaths" exercise C. Discussion of exercises and homework D. Use the "Time Machine Metaphor" to explain the idea of the present. E. The "Hands and Self" exercise F. 1 minute of silence and close.	✓ Daily breathing exercises of ten to twenty minutes at home or outside (while washing the dishes, driving, in the shower, when listening to music, walking, lying down, etc.) until the next session. ✓ Whenever you have an opportunity during the day (for example, during TV commercials, when grocery shopping, waiting at the traffic lights) inhale deeply and slowly for five to ten minutes. ✓ Whenever you feel isolated, start losing concentration, go crazy, or step into a stressful environment, apply the short focusing techniques.
6	Contextual-Observant Self	1. Ensure that patients are connected to a sense of awareness that is independent of thoughts and feelings and provides a safe and stable viewpoint for observing and accepting them.	A. Summarize the previous session and explain the agenda. B. The "10 Breaths" exercise C. Discussion of exercises and homework	✓ As the "10 Breaths" exercise continues, give this instruction: "As you do these exercises, from time to time be mindful of who notices them."

		2. Guide individuals to stop escaping from their suffering and create 'a space' within where their suffering cannot hurt no matter how great it is. 3. Increase functionality through critical thinking and discussion with patients on why the observant self is necessary.	D. Present the "Sky and Weather Metaphor." E. Present the "Chess Board Metaphor." F. "Follow Your Thinking" experiential exercise G. 1 minute of silence and close.	✓ In the same, when doing other exercises, they should be done for the self who observes them.
7	Values and Value-Oriented Actions	1. Improving the functional recovery levels of patients. 2. Clarify patients' values, evaluate them, and help patients reinforce their connection with these values. 3. Ensure that patients use their values as a guide for their behavior. 4. Transform patient values into ongoing and progressive forms of action. 5. Critical thinking and discussion with patients on why value-oriented action is needed with a view to increase functionality.	A. Summarize the previous session and explain the agenda. B. The "10 Breaths" exercise C. Share the "Two Mountains Metaphor" with the patients. D. Introduction to the values (difference between values and objectives). E. Share the "Two Children in the Car Metaphor" with the patients. F. Share the "Compass Metaphor" with the patients. G. The "Anchor" exercise H. Use *DARE* to overcome life obstacles in accordance with the values. ***D:*** *(Defusion)* ***A:*** *(Acceptance of discomfort)* ***R:*** *(Realistic goals)* ***E:*** *(Embracing values)* I. 1 minute of silence and close.	✓ Firstly, perform the breathing exercise. ✓ Do the following two exercises until the next session: (a) Notice the moments when you act on your own values. (b) What does it look like when you do this and what does it change?

8	Conclusion	1. Evaluate the Group Counseling Program based on Acceptance and Commitment Therapy and supported with Motivational Interviews. 2. Collect post-test data. 3. Ensure that the patients continue daily with the exercise techniques they learned in the Group Counseling Program based on Acceptance and Commitment Therapy and supported with Motivational Interviews.	A. Declare the agenda. B. Let patients evaluate the Group Counseling Program based on Acceptance and Commitment Therapy and supported with Motivational Interviews. C. The "10 Breaths" exercise D. Discuss with the patients how they will continue daily with the exercise techniques they learned in the Group Counseling Program based on Acceptance and Commitment Therapy and supported with Motivational Interviews. E. Collect post-test data. F. 1 minute of silence and close.	None

Psychiatric Nursing Initiative in the Control Group

In this study, there was no initiative on the control group until the study was completed. The individuals in the control group continued to receive only standard treatments, such as drug treatment and routine practices at the CMHC. After the study, those in the control group could receive the same program applied to the experimental group if they were so inclined.

Instruments

Descriptive Information Form. The Descriptive Information Form was developed by the researcher and consisted of 11 questions on socio-demographic characteristics such as age, sex, marital status, number of children, co-habitants, education, work, economic status, duration of illness, number of hospitalizations in the last year and duration of medication, as well as the course of treatment.

Functional Remission of General Schizophrenia Scale (FROGS). The Functional Remission of General Schizophrenia Scale (FROGS) was developed by Llorca *et al.* (Llorca et al., 2009). It was adapted to Turkish in the same year by Emiroğlu *et al.* It is a 5-point Likert-type scale consisting of 19 items. The reasons why FROGS was preferred for the purpose of this study may be listed as follows: (1) The results of the analysis obtained from the original version of the scale (Cronbach's Alpha = 0.90, CFI = 0.897, RMSEA = 0.075) were on acceptable levels, (2) the internal consistency coefficients obtained from the Turkish version, item analysis procedures and reliability coefficients between the interviewers; for validity studies, factor analysis needs to be within acceptable limits of the construct validity and criterion validity calculations, and (3) the scale is frequently used to evaluate functional recovery in IDSs. It has 4 subscales as activities of daily living, health and treatment, social functioning and occupational functioning. The minimum total score that is possible in the scale is 19 points, and the maximum is 95 points. Each item is rated from 1 to 5, and the total score is obtained by adding the scores in all items. A review of the evaluation of functional recovery levels showed that a score below 58 points is considered low, scores in the range of 59-66 are moderate, and a score of 66 and above is considered high for IDSs. Moreover, the higher the total score, the higher the functional recovery level. The Cronbach's Alpha internal consistency coefficient in the reliability study of the Turkish version was found to be 0.89 (Emiroğlu, Karadayı, Aydemir, & Üçok, 2009). In this study, the Cronbach's Alpha coefficient of the scale was found to be 0.89, as well.

Data Collection

The data were collected by the first researcher (EY) in a special room at the CMHCs by reading out the questions and recording answers in the forms in a time of 15 to 20 minutes on average. The plan of the research was announced to the participants ahead of time. Moreover, the first researcher explained to the participants the study's goals and procedures. Only the patients who agreed to participate in this study were selected as participants. The pretest and posttest forms (Descriptive Information Form and FROGS) were applied in the experimental and control groups between September 2018 and May 2019. In this period, the individuals in the experimental and control groups continued to receive standard treatments such as medication and other routine practices of the CMHCs.

For this study, ethical approval was obtained from the Scientific Research and Publication Ethics Committee of the Inönü University with the resolution number 2018/13-30. Furthermore, written permission was obtained from the concerned institutions to conduct the Malatya and Elazığ CMHC legs of the study. After the last test was administered to the experimental and control groups, group counseling was offered to the individuals in the control group upon their wishes.

Data Analysis

The statistical analysis of the quantitative data was performed with the SPSS (the Statistical Package for the Social Sciences) 25 software package. Compliance with normal distribution, Shapiro-Wilks and Kolmogorov-Smirnov tests, histogram, P-P graph, Q-Q graph, skewness and kurtosis were evaluated. As a result of the analyses, the data found to be of normal distribution were presented as "mean (standard deviation)." The significance level was accepted as $p<0.05$. The effect sizes of the study were interpreted according to the general rule of Cohen (Cohen's d) and calculated according to the group mean values. All effect sizes were based on pre- and post-intervention change scores. The assessment of the effect sizes was as follows: 0.20 to 0.49 was considered small, 0.50 to 0.79 was moderate, and 0.8 and above indicated a large effect size (Cohen, 1988).

Results

Table 2. Comparison of control variables of experimental and control groups.

Control Variables	Control Group (n=51)		Experimental Group (n=36)		X^2	p
	n	%	n	%		
Age						
22-39 years	13	25.5	12	33.3		
40-48 years	22	43.1	13	36.1	0.715	0.699*
49 and over	16	31.4	11	30.6		
Gender						
Female	9	17.6	12	33.3	2.836	0.092*
Male	42	82.4	24	66.7		
Marital status						
Married	11	21.6	8	22.2	0.005	0.942*
Single	40	78.4	28	77.8		
Presence of children						
Yes	13	25.5	7	19.4	0.436	0.509*
No	38	74.5	29	80.6		
People living with						
Alone	8	15.7	5	13.9	2.198	0.333*
Family	28	54.9	25	69.4		
With a relative	15	29.4	6	16.7		
Education status						
Primary school	9	17.6	6	16.7		
Secondary school	20	39.2	13	36.1	0.144	0.931*
High school	22	43.2	17	47.2		
Working status						
Employed	3	5.9	1	2.8	0.464	0.639**
Unemployed	48	94.1	35	97.2		
How to perceive the economic situation						
Low	15	29.4	8	22.2	.561	0.454*
Middle	36	70.6	28	77.8		

Disease duration (years)						
1-11	12	23.5	10	27.8	0.852	0.653*
12-19	22	43.2	12	33.3		
20 and over	17	33.3	14	38.9		
Number of hospitalization in the last year						
None	26	51.0	21	58.3	1.110	0.574*
1 and 2 times	10	19.6	8	22.2		
3 and over	15	29.4	7	19.4		
Drug usage period (years)						
1-7	13	25.5	4	12.5	2.116	0.347*
8-18	23	45.1	16	50.0		
19 and over	15	29.4	12	37.5		

* Chi-square test was used.

** Fisher's Exact Test was used.

Between the experimental and control groups, no statistically significant differences ($p>0.05$) were found in terms of identifying characteristics such as age, sex, marital status, number of children, co-habitants, education, work, perception on own economic status, duration of illness, number of hospitalizations in the last year and duration of medication, and both groups were found to be similar (Table 2).

Table 3. Comparison of FROGS total and subscale pre-test and post-test mean scores of individuals with schizophrenia in the control groups.

Control Group	Pre-test (n=51) Mean (SD)	Post-test (n=51) Mean (SD)	Test	p*
Social Functioning	10.80 (2.22)	12.07 (1.78)	t = -10.15	**p= 0.001**
Health and Treatment	7.60 (1.87)	8.52 (1.75)	t = -24.23	**p= 0.001**
Activities of Daily Living	11.92 (2.17)	12.76 (2.14)	t = -16.39	**p= 0.001**
Occupational Functioning	5.01 (2.24)	5.33 (1.92)	t = -4.78	**p= 0.001**
FROGS Total	35.35 (6.58)	38.70 (5.72)	t = -18.73	**p= 0.001**

* t-Test in dependent groups.

The comparisons of the pretest and posttest mean scores of the total and subscale scores of the control group are presented in Table 3. An analysis of the FROGS dimension pretest and posttest mean scores of the control group showed an increase in the posttest score in comparison to the pretest score, and the difference between the pretest and posttest mean scores was statistically significant (p: 0.001). Similarly, the mean total pretest score was found to increase from 35.35±6.58 to 38.70±5.72, and the difference between the pretest and posttest mean scores was statistically significant (p: 0.001) (Table 3).

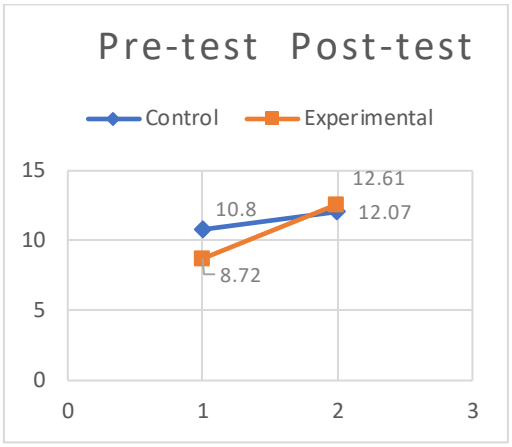
Table 4. Comparison of FROGS total and subscale pre-test and post-test mean scores of individuals with schizophrenia in the experimental groups.

Experimental Group	Pre-test (n=36) Mean (SD)	Post-test (n=36) Mean (SD)	Test	p*
Social Functioning	8.72 (2.30)	12.61 (2.69)	t = -9.49	**p= 0.001**
Health and Treatment	5.91 (1.53)	10.05 (2.75)	t = -8.74	**p= 0.001**
Activities of Daily Living	10.41 (1.94)	17.33 (2.11)	t = -38.46	**p= 0.001**
Occupational Functioning	3.75 (1.02)	5.86 (0.76)	t = -31.79	**p= 0.001**
FROGS Total	28.80 (5.57)	45.86 (6.48)	t = -21.76	**p= 0.001**

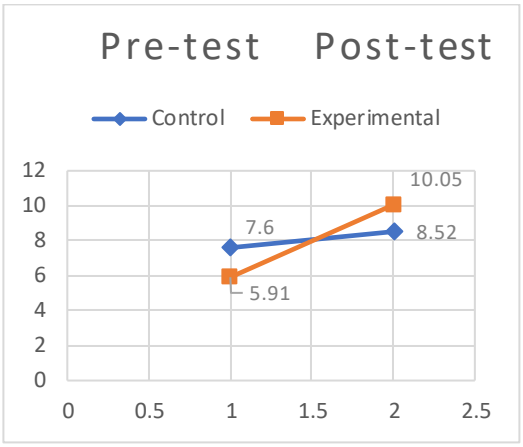
* t-Test in dependent groups.

The comparison of the pretest and posttest mean scores of FROGS total and subscale scores of the individuals in the experimental group is presented in Table 4. An analysis of the FROGS dimension pretest and posttest mean scores of the individuals in the experimental group showed an increase in the posttest score in comparison to the pretest score, and the difference between the pretest posttest mean scores was found to be statistically significant (p: 0.001). A similar situation was observed in the total FROGS score. The mean total pretest score of FROGS increased from 28.80±5.57 to 45.86±6.48, and the difference between pretest and posttest mean scores was statistically significant (p: 0.001) (Table 4) (Figure 2).

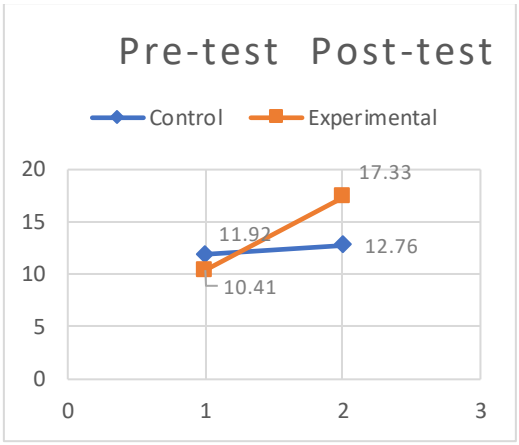
Social Functioning



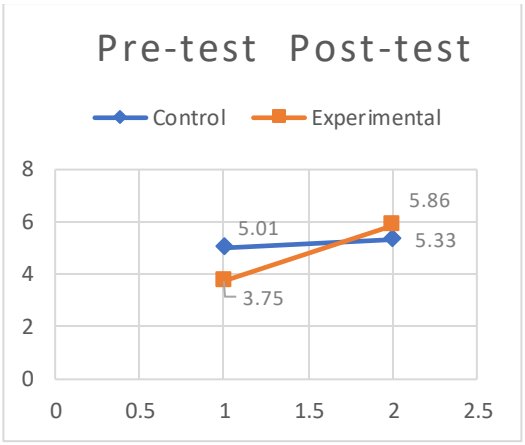
Health and Treatment



Activities of Daily Living



Occupational Functioning



FROGS Total

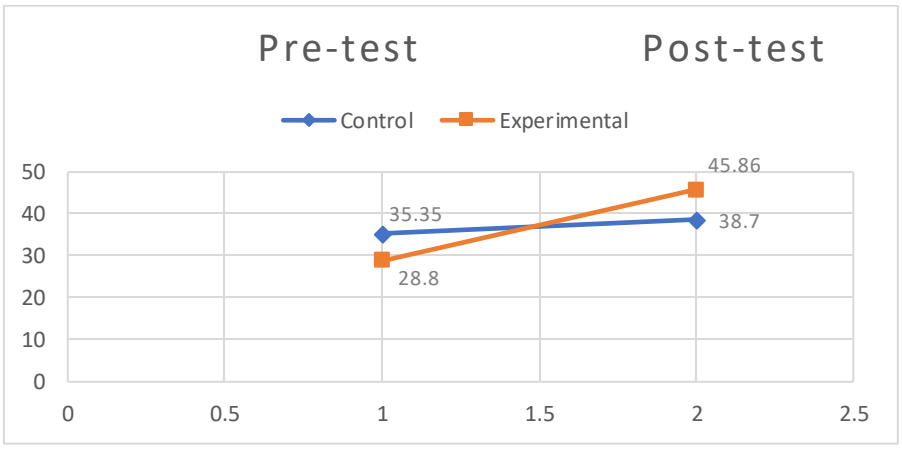


Figure 2. The distribution charts of the individuals in the experiment and control group, the pre-test and the post-test, the FROGS subscale and the total score averages

Table 5. Comparison of FROGS total and subscale pretest and posttest mean scores of individuals with schizophrenia in the experimental and control groups.

FROGS and Sub-Dimensions	Implementation Times of the Scale	Control Group (n=51)		Experimental Group (n=36)		Test	P*
		Mean (SD)	Cohen's d**	Mean (SD)	Cohen's d**		
Social Functioning	Pre-test	10.80 (2.22)	0.63	8.72 (2.30)	1.55	t = 4.23	**p= 0.001**
	Post-test	12.07 (1.78)		12.61 (2.69)		t = -1.03	p= 0.305
Health and Treatment	Pre-test	7.60 (1.87)	0.50	5.91 (1.53)	1.86	t = 4.45	**p= 0.001**
	Post-test	8.52 (1.75)		10.05 (2.75)		t = -2.92	**p= 0.005**
Activities of Daily Living	Pre-test	11.92 (2.17)	0.38	10.41 (1.94)	3.41	t = 3.32	**p= 0.001**
	Post-test	12.76 (2.14)		17.33 (2.11)		t = -9.85	**p= 0.001**
Occupational Functioning	Pre-test	5.01 (2.24)	0.15	3.75 (1.02)	2.34	t = 3.54	**p= 0.001**
	Post-test	5.33 (1.92)		5.86 (0.76)		t = -1.77	p= 0.081
FROGS Total	Pre-test	35.35 (6.58)	0.54	28.80 (5.57)	2.82	t = 4.86	**p= 0.001**
	Post-test	38.70 (5.72)		45.86 (6.48)		t = -5.43	**p= 0.001**

* t-Test in independent groups.

** The effects were evaluated according to Cohen's general rule and calculated according to group averages. All effect sizes are based on pre-treatment change points. The evaluation is as follows: small effect from 0.20 to 0.49, moderate effect from 0.50 to 0.79, and large effect from 0.8 and above.

The comparison of the pretest and posttest FROGS total and subscale scores of the IDSs in the experimental and control groups included in this study is presented in Table 5. Generally speaking, it was found that the difference between the mean pretest total and subscale scores of the individuals in the experimental and control groups was statistically significant (p: 0.001). When the mean scores of the posttest were examined according to the total scale and subscales of FROGS, it was found that the difference between the mean scores of the individuals in the experimental and control groups was statistically significant (p: 0.001), except in the "Social Functioning" and "Occupational Functioning" subscales (Table 5).

A review of the effect sizes of the experimental and control groups according to the FROGS subscales showed that, in the "Social Functioning" dimension, the experimental group had a large effect size (*Cohen d*: 1.55), and the control group had a moderate effect size (*Cohen d*: 0.63). While the experimental group had a large effect size (*Cohen d*: 1.86) in the "Health and Treatment" dimension, the control group had a moderate effect size (*Cohen d*: 0.50) in the same dimension. In the "Activities of Daily Living" dimension, the experimental group had a large effect size (*Cohen d*:

3.41), and the control group had a small effect size (*Cohen d*: 0.38). In the "Occupational Functioning" dimension, the effect size of the experimental group was large (*Cohen d*: 2.34), while that of the control group was small (*Cohen d*: 0.15). As for the FROGS total score, while the experimental group had a large effect size (*Cohen d*: 2.82), the effect size of the control group was moderate (*Cohen d*: 0.54) (Table 5).

Discussion

This study was conducted with a view of responding to the current uncertainties regarding the functional recovery of IDSs who need a long-term treatment and care but suffer from inequalities in healthcare services and adverse life events. In line with the above, this study was conducted to determine how a counseling program based on ACT and supported with MIs affected the levels of functional recovery in IDSs. This experimental model study focused on the functional recovery levels of the individuals by integrating ACT and MI in IDSs with a different perspective, and therefore, it is to be considered a unique and pioneering piece of research on levels of functional recovery. Within the framework of the main hypothesis of this study, ACT and MI seem to be a promising combination in terms of increasing functional recovery levels for IDSs. Clinically, the combination of ACT and MI may be a pragmatic approach to functional recovery in schizophrenia for psychiatric nurses and other clinicians. On the other hand, since there are no studies on the combination of the two main components of this study, ACT and MI, the discussion section is structured by the findings of studies from the field literature using similar psychosocial approaches.

In this study, the mean total pretest scores of FROGS were found to be 28.80±5.57 in the experimental group and 35.35±6.58 in the control group. Based on this finding, it may be stated that the functional recovery levels of the individuals in the control group in the pretest were slightly higher than those of the experimental group. This situation may be explained by the fact that the CMHC with the control group was put into service relatively earlier than the two CMHCs with the experimental group, and their practices were more stable. It was determined that the difference between the mean total pretest scores of the individuals in the experimental and control groups was statistically significant ($p<0.05$). Moreover, it was found that the functional recovery levels of the individuals in the control and experimental groups were low in the pretest results. Low-level functional recovery in IDSs is not a new finding. Indeed, similar studies in the literature showed that functional recovery in IDSs is low (Çapar & Kavak, 2019; Leucht et al., 2012). In the background, complex dynamics such as unpredictable and fluctuating treatment process, cognitive functions, affect, motor activity and movements, physical functions, social relations and occupational functions may account for low functional recovery.

According to the posttest data of the study, there was an increase in the functional recovery levels of the individuals in the experimental group in comparison to the control group, and this was statistically significant ($p<0.05$). This finding from the study does not seem surprising at first glance, since no intervention was applied to the control group, while a combination of ACT and MI was applied to the experimental group. However, given the pioneering nature of the available data, it may be argued that the combination of interventions used in this study provides the basis for future experimental studies and presents important data for various treatment comparisons (e.g. psychosocial and / or pharmacological approaches) that are likely to be applied. Similarly, the posttest data showed that the functional recovery levels of the individuals in the experimental group increased significantly compared to the pretest measurements ($p<0.05$). This statistically significant increase in the experimental group showed a large effect size on overall functionality (*Cohen d*: 2.82). According to this finding, it may be argued that the level of functional recovery of the IDSs in the experimental group increased as the intervention was a highly effective approach. Since there has been no study on the combination of ACT and MI used in this study, it is not possible to make a direct comparison in the literature. However, according to a limited number of studies examining the effects of ACT on psychotic disorders, it was found that ACT had promising results in schizophrenia. The findings of a Canadian study showed that ACT could be beneficial to individuals with psychotic symptoms of childhood trauma (general symptom severity, anxiety symptoms and acceptance of emotional regulatory abilities) (Spidel, Lecomte, Kealy, & Daigneault, 2018). In a study conducted in Iran, it was concluded that ACT improved overall health and reduced aggression in psychotic methamphetamine addicts (Ghouchani et al., 2018). Emphasis on the use of ACT as a promising therapy in treatment of depression in psychotic disorders appears to be a common outcome of two studies (Gumley et al., 2017; White et al., 2011). It was found that ACT provided a subjective benefit in psychotic disorders (Shawyer et al., 2017), and it had positive effects on treatment satisfaction and recovery expectations (Gaudiano et al., 2015). In the context of psychotic disorders, the fact that ACT is easier and less costly than other therapies appears as an interesting finding (Thomas et al., 2014). In one study, it was reported that ACT reduced the discomfort associated with frequent hallucinations encountered in psychotic disorders, and it was accepted as a positive symptom (Gaudiano & Herbert, 2006). However, in another study, no significant difference was reported in improving hallucinations (Shawyer et al., 2012). According to the findings of a study (2002) consisting of only 4 ACT sessions, ACT reduced psychotic symptoms by 50% (Bach & Hayes, 2002). Studies have reported that MI, another intervention branch integrated in this study, focuses rather on clinical recovery in schizophrenia. Even though it is not possible to talk about a common conclusion for all these studies (Chien, Mui, Gray, & Cheung, 2016; Chien, Mui, Cheung, & Gray, 2015; Ertem & Duman, 2019; Kreyenbuhl, Record, & Palmer-Bacon, 2016; Vanderwaal, 2015), some randomized controlled

studies found that MI improved treatment compliance and reduced psychotic symptoms and hospitalizations in IDSs (Chien et al., 2016; Chien et al., 2015; Ertem & Duman, 2019). Given the fact that clinical recovery in IDSs is an important stage in functional recovery (Lahera et al., 2018), the significance of MI is certainly understood much better. The results of this study suggested that the combination of ACT and MI is effective in increasing levels of functional recovery.

A review of the literature on supporting functional recovery in schizophrenia emphasized the insufficient evidence and the need for further studies on functional recovery. Psychosocial intervention studies are found to be mostly on the psychoeducation of the patient, family psychoeducation, social skills training and cognitive therapies. In a recent systematic review, it was proposed that these psycho-social rehabilitation interventions should be considered as evidence-based practices in schizophrenia and become an important part of the standard treatment of the condition (Morin & Franck, 2017). According to the findings of a study, which investigated the effects of awareness-based psycho-social skills training (PST) to promote insight and functional recovery in schizophrenia, awareness-based PST was found to be effective in increasing the insight and functional recovery levels of individuals (Yılmaz & Okanlı, 2018). In an experimental study investigating the effects of PST and metacognitive training on social and cognitive functioning in schizophrenia without using a control group, statistically significant results were obtained in the areas of psychopathology and social and cognitive functioning in both the PST and metacognitive training groups (Yıldız et al., 2018). In a similar study conducted in Australia, PST was provided to IDSs, and it was found to improve social functioning and interpersonal relations (Wauchope, Terlich, & Lee, 2016). A similar study in Spain found that social skills training applied to IDSs reduced negative symptoms and increased functional recovery during the 6-month follow-up (Rus-Calafell, Gutiérrez-Maldonado, Ortega-Bravo, Ribas-Sabaté, & Caqueo-Urízar, 2013). The findings of a study which aimed at supporting and evaluating functional recovery in IDSs were published in 2018. Using the Delphi technique, the study obtained the views of 53 experts. As a result, 92.3% of these experts agreed that psycho-social interventions are necessary to achieve functional recovery. Among all proposed interventions, a combination of various therapies (including social skills training, family therapy, cognitive therapies, social cognitive training and occupational programs) were listed as the most useful approaches to achieve functional recovery (Lahera et al., 2018). In this respect, it may be stated that the current literature supports the findings and methodology of this study. Furthermore, considering that the concepts and ideas adopted in ACT, and as another intervention component of this study, MI, are parallel, it may be argued that this combination is the first step in eliminating uncertainties about implementation by psychiatric nurses and other clinicians.

In the FROGS subscales of ACT-based and MI-supported group counseling, it was found that the scores in the activities of daily living dimension including compliance with biological rhythms such as regulation of sleep and nutrition, administrative and financial management, personal hygiene, coping with stress and anger control items increased more than those in the other subscales. In fact, the dimension of activities of daily living displayed a large effect size (*Cohen d*: 3.41) in the experimental group. According to this finding, it is possible to argue that the activities of daily living of the IDSs in the experimental group improved, and the intervention proved to be an effective approach. This suggests that, as a result, the ACT-based group counseling supported with MI increases motivation, awareness and psychological resilience and reduces cognitive and experiential avoidance, as well as further supporting the individual's ability to take behavioral steps that are consistent with their core values (Hayes et al., 2011). Although it is not possible to compare the intervention combination used in this study to other therapies, the large effect sizes obtained from the combination of ACT and MI in the context of functional recovery revealed the pragmatic aspect of the intervention.

According to the posttest data, the functional recovery levels of the individuals in the control group increased on a statistically significant level ($p<0.05$) in comparison to their pretest measurements. This statistically significant increase in the control group created a moderate effect size on overall functionality (*Cohen d*: 0.54). This finding suggested that routine interventions such as psycho-social services, home health services, follow-up and treatments within the framework of the community-based mental health model support functional outcomes at the CMHC settings.

In this study, it was found that the ACT-based and MI-supported intervention increased the functional recovery levels in the experimental group. This result confirmed the study's hypothesis that "Counseling based on acceptance and commitment therapy and supported with motivational interviewing increases the levels of functional recovery in IDSs."

Limitations and Directions for the Future

Some limitations of this study should be mentioned. First of all, the quasi-experimental design did not allow a random distribution of the participants to the experimental and control groups, thus limited the generalizability of the results. Therefore, randomized controlled trials with a strong experimental design may be advised. Secondly, no follow-up measurements were made after the completion of the counseling program, and no assessment could be made on the long-term effects of a counseling program based on ACT and supported with MIs. As a matter of fact, given the importance of the positive results of this study in terms of IDSs, future studies may carry out a longer follow-up evaluation of a counseling program based on ACT and supported with MIs (e.g. 6 months).

Thirdly, a counseling program based on ACT and supported with MIs was compared to the usual treatment in line with institutional policies and did not control some specific factors (e.g., symptoms of IDSs, pharmacological agents used by individuals in the experimental and control groups) and non-specific factors related to intervention (e.g., clinician's time and attention). Future studies may compare intervention groups with effective treatment methods (e.g., CBT, web-based programs) to ACT-based and MI-supported counseling.

Conclusion

In conclusion, it was found that counseling based on ACT and supported with the MI technique proved effective in improving functional recovery in IDSs in comparison to the control group. Moreover, the difference between the pretest and posttest subscale and total mean scores of the IDSs was found to be statistically significant. Therefore, it is possible to argue that counseling based on ACT and supported with MIs is effective in improving functional recovery in IDSs.

Relevance for Clinical Practice

Based on the findings of the study, it is advisable to apply ACT-based and MI-supported counseling programs at CMHCs and clinics in combination with a routine (pharmacotherapy) treatment. It may be beneficial for psychiatric nurses working with IDSs at CMHCs and psychiatry clinics to take an active role in planning and implementing psycho-social interventions. Furthermore, these psychiatric nurses are advised to receive ACT and MI trainings to implement psycho-social interventions based on ACT and MI. ACT and MI are recommended to be used in psychiatric nursing care provided to IDSs and studies to be conducted to increase functional recovery levels.

Conflict of Interest

The author(s) declare no potential conflicts of interest with respect to the research, authorship and publication of this article.

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Supplementary File 1

TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported? ✓	Pg #
Title and Abstract				
Title and Abstract	1	Information on how unit were allocated to interventions	✓	1-2
		Structured abstract recommended	✓	1-2
		Information on target population or study sample	✓	1-2
Introduction				
Background	2	Scientific background and explanation of rationale	✓	3
		Theories used in designing behavioral interventions	✓	4-6
Methods				
Participants	3	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	6-7
		Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	7-10
		Recruitment setting	✓	6-7
		Settings and locations where the data were collected	✓	10
Interventions	4	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	7-9
		○ Content: what was given?	✓	Tab.1
		○ Delivery method: how was the content given?	✓	Tab.1
		○ Unit of delivery: how were the subjects grouped during delivery?	✓	7-9
		○ Deliverer: who delivered the intervention?	✓	7-9
		○ Setting: where was the intervention delivered?	✓	7-9
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	7-9
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	7-9
		○ Activities to increase compliance or adherence (e.g., incentives)	✓	7-9
Objectives	5	Specific objectives and hypotheses	✓	6
Outcomes	6	Clearly defined primary and secondary outcome measures		NA
		Methods used to collect data and any methods used to enhance the quality of measurements	✓	9-10
		Information on validated instruments such as psychometric and biometric properties	✓	9-10
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	✓	6
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✓	7
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	✓	7
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	✓	7

TREND Statement Checklist

Blinding (masking)	9	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.		NA
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	✓	6-7 NA
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis Methods for imputing missing data, if used Statistical software or programs used	✓	10 NA NA NA
Results				
Participant flow	12	Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) ○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study ○ Assignment: the numbers of participants assigned to a study condition ○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention ○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition ○ Analysis: the number of participants included in or excluded from the main analysis, by study condition Description of protocol deviations from study as planned, along with reasons	✓ ✓ ✓ ✓ ✓ ✓	Fig.1 Fig.1 Fig.1 Fig.1 Fig.1 Fig.1 NA
Recruitment	13	Dates defining the periods of recruitment and follow-up	✓	10
Baseline Data	14	study condition Baseline characteristics for each study condition relevant to specific disease prevention research Baseline comparisons of those lost to follow-up and those retained, overall and by study condition Comparison between study population at baseline and target population of interest	✓ ✓	10 10 10 10
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	✓	10

TREND Statement Checklist

Numbers analyzed	16	Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✓	11
		Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	✓	NA
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✓	11-12
		Inclusion of null and negative findings	✓	11-12
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	✓	11-12
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	✓	11-12
Adverse events	19	Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	✓	11-12
DISCUSSION				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✓	12-15
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✓	12-15
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✓	12-15
		Discussion of research, programmatic, or policy implications	✓	12-15
Generalizability	21	Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	✓	16
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	✓	16

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: http://www.cdc.gov/trendstatement/