A randomized controlled trial of the Korean version of the Program for the Education and Enrichment of Relational Skills for Young Adults (PEERS®-YA-K) with autism spectrum disorder

ClinicalTrials.gov identifier: NCT03310775

Study protocol and statistical analysis plan

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Recruitment of participants

The participants were recruited from the Child and Adolescent Psychiatric Clinic at Seoul National University Bundang Hospital, through advertisements at the Smile Together Foundation (a local advocacy institute of ASD), a community of child and adolescent psychiatrists, an internet group of families of youth with ASD, and a website for Seongnam Child and Adolescent Psychiatry Mental Health Care Center. Inclusion criteria for young adults included: (1) between 18 and 35 years of age, (2) graduated from high school or expected to graduate by the time the intervention starts, (3) experiencing social difficulties as recognized by young adults and/or social coaches, (4) previously diagnosed with or possibly having a diagnosis of ASD, (5) verbally fluent, (6) full scale intelligence quotient (FSIQ) ≥ 70 by standardized intelligence test, and (7) substantially motivated to participate to intervention. Exclusion criteria included: (1) history of major mental illness (e.g., schizophrenia, bipolar disorder, psychosis, and risk of self-mutilation), (2) significant physical disabilities including visual and/or hearing impairments, (3) clinically significant neurological or physical disease that would preclude participation in group-based social activities, and (4) difficulties for parents to understand and cooperate with the intervention.

The study was approved by IRB of Seoul National University Bundang Hospital (IRB no. B-1611/371-303). Written informed consent was completed by all young adults and social coaches who participated in the present study.

Screening and randomization process

Participants were screened for eligibility by telephone interview using the Phone Screening Interview in the PEERS®-YA treatment manual. Motivation, social problems related to friendships, willingness to follow the rules in the group, comorbidities, and inclusion and exclusion criteria were discussed during the telephone interview.

Diagnosis of ASD was confirmed for screened individuals by two board-certified child psychiatrists based on diagnostic criteria of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders. The Autism Diagnostic Observation Schedule (ADOS; Lord et al. 2008) and the Autism Diagnostic Interview-Revised (ADI-R; Lord et al. 1994) were used for supporting diagnostic procedures and administered and scored by a special educator trained and certified for these instruments (GYB). IQ was assessed using the Korean Wechsler Adult Intelligence Scale-IV (K-WAIS-IV; Hwang et al. 2012) and assessment of adaptive functioning was conducted using the Korean version of the Vineland Adaptive Behavior Scale-II (K-VABS-II; Volkmar 2013, Hwang, Kim & Hong 2014). Subjects meeting eligibility criteria were randomly assigned to a treatment group (TG) or waitlist control group (CG) using randomized block design. We divided each group into two separate treatment groups of approximately 9–10 young adults.

Subjects

Forty-eight young adults ranging from 18 to 35 years old and their social coaches were recruited for the RCT. Ten participants were excluded during the randomization procedure; six were not adequately motivated, one did not meet the diagnosis of ASD, one had difficulty understanding self-report scales, one had a problem with school, and one had to fulfill a military commitment. A total of 38 participants were screened, but one participant refused to be randomized to the CG. As a result, 37 participants were randomized; 19 were assigned to TG and 18 to CG.

Treatment intervention

The PEERS®-YA consisted of 16 weekly 90-minute sessions. Social coaches and the young adults were given concurrent sessions in separate rooms and each session was led by

five trained treatment leaders. One of the trained treatment leaders (HJY) was a PEERS® Certified Provider for both PEERS® for Adolescents and PEERS®-YA, and another group leader was certified for PEERS® for Adolescents (JHK). Both received 20 hours of comprehensive training through the UCLA PEERS® Clinic by the program developer for each program. The social coach group leaders were board-certified child psychiatrists and special educators with specialty training in the treatment of ASD and group therapy; the young adult group leaders were licensed clinical psychologists and graduate-level trainees in clinical psychology. The behavioral coaches were clinical psychology trainees and psychology graduate students with experience working with children and adolescents with ASD and other developmental disorders. All members of the treatment team were trained and supervised by PEERS® Certified Providers for the duration of the intervention.

The treatment leaders translated the Korean version of the PEERS®-YA Treatment Manual together and had regular meetings (once every week for four months) until the translation was completed. In addition to the treatment sessions, the Social Coaching Handouts and the appendices of the original PEERS®-YA Treatment Manual were translated into Korean, including the Planned Absence Sheet, Phone Roster, In-group Call Assignment log, and Homework Compliance Sheets, the latter of which was used to rate treatment adherence.

After the translation was completed, the PEERS®-YA Certified Provider conducted a 24-hour training workshop on the implementation of the treatment sessions. As part of this training, treatment leaders observed each session of the treatment conducted in Korean by the PEERS®-YA Certified Provider and then established reliability with the treatment protocol before conducting sessions with participants.

The behavioral coaches, who provided support to the group leaders, were fully trained and supervised by a young adult group leader in all content and intervention processes, and attended weekly case conference meetings. Behavioral coaches conducted role-play

demonstrations of targeted skills, provided social coaching with performance feedback during behavioral rehearsal exercises, and monitored treatment fidelity and homework compliance throughout the sessions.

The didactic lessons focused on the social skills necessary for developing and maintaining friendships, romantic relationships, and managing peer conflict and rejection. The lessons included conversational skills, electronic forms of communication, developing friendship networks and finding sources of friends, appropriate use of humor, peer entry and exiting strategies, organizing and having successful get-togethers with friends, handling teasing and chronic bullying in the school or workplace, managing peer pressure, conflict resolution, strategies related to dating etiquette, showing romantic interest, asking someone on a date, going on dates, and general dating guidelines. The detailed processes and characteristics of the PEERS®-YA intervention are described by Laugeson (2017).

Within the young adult group, each session included a homework review and didactic lesson including a role-play demonstration of targeted behaviors. Appropriate and inappropriate examples of social etiquette were demonstrated by the behavioral coaches. Didactic lessons were followed by behavioral rehearsal exercises in which young adults practiced the appropriate newly learned skills while receiving performance feedback from the treatment team.

Within the social coach group, homework was reviewed and discussed for two-thirds of the session and homework compliance and quality were recorded. During the review, specific instructions on how to provide assistance and social coaching to the young adults outside of the treatment setting were provided. After homework review and discussion, the social coaches received didactic instruction regarding the targeted social skill being highlighted in the young adult group. Social Coaching Handouts were also distributed, which provided an outline of the rules and steps of the lesson, as well as a summary of upcoming homework

assignments.

The last ten minutes of every 90-minute group included a reunification between young adults and social coaches in which the rules and steps of the targeted skills were highlighted, and homework assignments were given to young adults and social coaches. Research staff monitored treatment fidelity directly from the treatment manual in every session in order to maintain the integrity of the program and ensure that all material was covered.

Measures

Every participant and their social coach in the TG completed outcome measures prior to the start (test 1) and after the completion of the intervention (test 2). Participants and social coaches in the CG completed outcome measures upon entering the study (test 1), prior to the start of treatment (test 2), and after the completion of the treatment (test 3). Four months after completing the program, both groups completed outcome measures to evaluate the maintenance of the treatment effects (TG: test 3; CG: test 4). Assessment schedules for both groups are shown in Figure 1. Social skills training was prohibited for the CG during the waiting period, but medication and general follow-up visits for counseling were allowed.

Primary measures

1. *Autism Diagnostic Observation Schedule, second edition (ADOS-2 Module 4; Lord et al. 2012)*

The ADOS-2 is a standardized test designed to diagnose individuals with ASD by observing their communication and social behaviors during semi-structured play and/or an interview. The ADOS-2 is composed of four modules. Each module is selected according to the expressed language level and chronological age of participants and requires 35 to 40 minutes to administer. The current study used ADOS-2 module 4. Module 4 of the ADOS-2 is

used to diagnose adolescents and adults who are verbally fluent. It is scored on five domains: language and communication, reciprocal social interaction, imagination, stereotyped behaviors, restricted interests, and other abnormal behaviors. In this study, raters on ADOS-2 examined participants blinded to the group of participants and also for pre-treatment or post-treatment.

2. *Test of Young Adult Social Skills Knowledge (TYASSK; Laugeson 2017)*

The TYASSK is 30-item criterion-based measure developed for use with the PEERS®-YA intervention. The TYASSK is used to evaluate the change in young adults' knowledge of specific social skills taught during the intervention period, with two items derived from each of the lessons. The TYASSK is based on the Test of Adolescent Social Skills Knowledge. The test requires approximately 5 minutes to complete and includes buzzwords related to the didactic lessons. Young adults who participated in this study were asked to select the most fitting of the two possible answers. Scores range from 0 to 30, with higher scores reflecting more knowledge of social skills. The English version of the TYASSK was translated into Korean with the author's permission, and then back-translated into English by a bilingual translator unrelated to this study.

3. *Korean Version of the Social Skills Rating System (K-SSRS; Elliott & Gresham 1991, Moon 2003)*

The SSRS is a multi-rater feedback questionnaire (teacher, parents, and student forms) to assess social skills, problematic behaviors and academic competence (in the Teacher report form) and it consists of three forms for: pre-school, elementary, and secondary students. The SSRS for secondary students, originally developed for adolescents, has been proven to be appropriate for use in evaluating the social skills of adults with high functioning ASD. It was modified for college students (K-SSRS: college level) and its reliability and utility were

verified by Moon (2003). The K-SSRS consists of 27 items which are rated on a Likert scale from 1 (“not at all”) to 7 (“almost always”).

4. *Social Responsiveness Scale-2 (SRS-2; Constantino & Gruber 2012)*

The SRS-2 is a 65-item scale used to screen children at risk for ASD and consists of measures regarding the child’s social interactions, communication, and stereotyped behaviors. Individual items are rated on a Likert scale from 1 (“not at all”) to 4 (“almost always”) to measure the severity of ASD symptoms as they occur in natural social settings. The SRS-2 consists of four forms: preschool (ages 2.5-4.5 years), school-age (ages 4-18 years), adult (ages 19 years and older), and an adult self-report. The individual is classified as being at a high risk of ASD when the score is greater than 75. In this study, we used the adult form reported by the caregiver and the self-report form.

Secondary measure

1. *Korean version of the Vineland Adaptive Behavior Scale, second edition (K-VABS; Volkmar 2013, Hwang, Kim, & Hong 2014)*

The K-VABS is an interviewed survey and measures adaptive behaviors of individuals such as personal and social skills, used for everyday living from birth to age 90. These are based on the reports of primary caregivers and teachers. The K-VABS contains 5 domains each with 2-3 subdomains. The main domains are: Communication, Daily Living Skills, Socialization, Motor Skills, and Maladaptive Behavior (optional). Behaviors are rated on a 0 (a skill that is not used by the individual) – 2 (a skill used most of the time) rating scale. The current study used only the communication, daily living skills, and socialization domains.

2. *Beck Depression Inventory (BDI; Beck, Steer, & Garbin 1988, Han et al 1986)*

The BDI is a 21-question, self-report inventory, rated from 0 to 3 in terms of intensity. The items are used to assess the intensity of 21 depression-related symptoms and attitudes such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, fatigue, weight loss, and lack of interest in sex. The current study used the BDI-II published in 1996 which was designed for individuals ages 13 and over. The maximum score of the BDI is 63 points, with a suggested interpretation of: minimal range = 0–13, mild depression = 14–19, moderate depression = 20–28, and severe depression = 29–63.

Statistical analyses

Baseline characteristics were compared between the TG and DTG with independent samples t-tests for continuous variables and Fisher's Exact Test for categorical variables. Changes in outcomes between baseline and post-intervention were examined with paired t-tests and also the maintenance of treatment effects in both groups. Post-intervention follow-up measurements were analyzed using repeated measures analysis of variance (ANOVA) comparing both between-group and between-time differences in outcomes with groups by a measured time point interaction. The significance of difference was interpreted with treatment x time interaction from the analysis, and the treatment effect size was assessed with Cohen's d for the interaction (Morris, 2008). All statistical analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA) and statistical significance was defined as $p < 0.05$.