Effectiveness of interventions using a smartphone cognitive behavior therapy application for children with mental health disorders: A single-arm uncontrolled study

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Abstract

Background: ince the coronavirus disease 2019 pandemic, the prevalence of mental health disorders among children in Japan has increased rapidly, and mental healthcare for children is an increasingly important part of pediatric healthcare delivery. We previously developed a smartphone-based self-monitoring application to deliver cognitive behavioral therapy (CBT app), implemented it in healthy children, and reported its effectiveness for health promotion.

Objective: This study sought to examine the effectiveness of the CBT app in children with mental health disorders.

Methods: The participants were 115 children with mental health disorders (e.g., school refusal, orthostatic hypotension, eating disorders, or developmental disorders, among others) aged 12–18 years. The CBT app-based program comprised 1 week of psychoeducation followed by 1 week of self-monitoring. After reading story-like scenarios, participants created a self-monitoring sheet with five panels: events, thoughts, feelings, body responses, and actions. All participants received regular mental healthcare from physicians in addition to the app-based program. Several psychometric scales, including the Patient Health Questionnaire for Adolescents, Questionnaire for Triage and Assessment with 30 items (QTA30), Depression Self-Rating Scale for Children, Pediatric Quality of Life Inventory (PedsQL), and Rosenberg Self-Esteem Scale, were completed at the beginning of the intervention and 2 and 6 months thereafter. Participants were divided into four groups on the basis of the presence or absence of depressive symptoms [Dep (+)/Dep (-)] and completion or non-completion of the CBT app-based program [App (+)/App (-)]. The primary and secondary outcomes were the improvements in the QTA30 total scores and the scores on the other psychometric scales, respectively. A paired-samples t-test was used for statistical analysis. The Medical Ethics Committee of Fukuoka University Faculty of Medicine (approval number: U22-05-002) approved the study design.

Results: There were 48, 18, 18, and 7 participants in the Dep (+) App (+), Dep (+) App (-), Dep (-) App (+), and Dep (-) App (-)

groups, respectively. Twenty-four participants dropped out. In the depressed participants, the QTA30 and PedsQL scores improved significantly at 6 months regardless of completion or non-completion of the CBT app-based program. However, among the non-depressed participants, the scores only showed significant improvements in those who completed the app-based program. There were no significant changes in the scores on the other scales in any group. There was a significant positive correlation between Patient Health Questionnaire for Adolescents scores and the number of self-monitoring sheets completed.

Conclusions: The CBT app was useful for improving QTA30 and PedsQL scores of children with mental health disorders. However, a higher-intensity CBT program is necessary for more severely depressed children. Clinical Trial: University Hospital Medical Information Network Clinical Trials Registry (registration number: 000046775).

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[Abstract]

Background: Since the coronavirus disease 2019 pandemic, the prevalence of mental health disorders among children in Japan has increased rapidly, and mental healthcare for children is an increasingly important part of pediatric healthcare delivery. We previously developed a smartphone-based self-monitoring application to deliver cognitive behavioral therapy (CBT app), implemented it in healthy children, and reported its effectiveness for health promotion.

Objectives: This study sought to examine the effectiveness of the CBT app in children with mental health disorders.

Methods: The participants were 115 children with mental health disorders (e.g., school refusal, orthostatic hypotension, eating disorders, or developmental disorders, among others) aged 12–18 years. The CBT app-based program comprised 1 week of psychoeducation followed by 1 week of self-monitoring. After reading story-like scenarios, participants created a self-monitoring sheet with five panels: events, thoughts, feelings, body responses, and actions. All participants received regular mental healthcare from physicians in addition to the app-based program. Several psychometric scales, including the Patient Health Questionnaire for Adolescents, Questionnaire for Triage and Assessment with 30 items (QTA30), Depression Self-Rating Scale for Children, Pediatric Quality of Life Inventory (PedsQL), and Rosenberg Self-Esteem Scale, were completed at the beginning of the intervention and 2 and 6 months thereafter. Participants were divided into four groups on the basis of the presence or absence of depressive symptoms [Dep (+)/Dep (-)] and completion or non-completion of the CBT app-based program [App (+)/App (-)]. The primary and secondary outcomes were the improvements in the QTA30 total scores and the scores on the other psychometric scales, respectively. A paired-samples t-test was used for statistical analysis. The Medical Ethics Committee of Fukuoka University Faculty of Medicine (approval number: U22-05-002) approved the study design.

Results: There were 48, 18, 18, and 7 participants in the Dep (+) App (+), Dep (+) App (-), Dep (-) App (+), and Dep (-) App (-) groups, respectively. Twenty-four participants dropped out. In the depressed participants, the QTA30 and PedsQL scores improved significantly at 6 months regardless of completion or non-completion of the CBT app-based program. However, among the non-depressed participants, the scores only showed significant improvements in those who completed the app-based program. There were no significant changes in the scores on the other scales in any group. There was a significant positive correlation between Patient Health Questionnaire for Adolescents scores and the number of self-monitoring sheets completed.

Conclusions: The CBT app was useful for improving QTA30 and PedsQL scores of children with mental health disorders. However, a higher-intensity CBT program is necessary for more severely depressed children.

Trial Registration: University Hospital Medical Information Network Clinical Trials Registry (registration number: 000046775).

Keywords: smartphone, cognitive behavioral therapy, app, adolescent

[Introduction]

Since the coronavirus disease 2019 (COVID-19) pandemic, the prevalence of mental health disorders among children has increased rapidly, and mental healthcare for children is an increasingly important part of pediatric healthcare delivery [1,2]. Especially in Japan, the number of children with school refusal, which was increasing even before the COVID-19 pandemic, is rapidly rising, and the “hikikomori” (severe social withdrawal) phenomenon may become more common in the post-pandemic era [3]. In addition, it has been reported that COVID-19 has led to an increase in the number of children worldwide with depression, eating disorders, and sleep disorders [4-7]. Disability-adjusted life years of Japanese adolescents indicated that mental health disorders accounted for approximately 20% of the burden of disease [8]. Therefore, it is important to establish a system for the treatment of these children's mental health disorders.

Cognitive behavioral therapy (CBT) is one of the most effective means of treating mental health disorders in children. CBT, which focuses on improving the emotional state by changing thinking and behavior patterns, has been applied to a range of mental health disorders including depression, anxiety disorders, insomnia, and eating disorders [9-11]. In a study applying CBT in children with school refusal, improvements in school attendance, depression, and anxiety were reported [12]. However, the use of CBT treatments for mental health disorders in children and adolescents is often limited, where adolescents frequently refuse face-to-face psychotherapy because of embarrassment or time constraints. In recent years, mental health research has increased on CBT treatment provided via the Internet and smartphones as an alternative to face-to-face CBT treatment [13-17], and the effectiveness of such treatment is reportedly no different from that of face-to-face CBT [18,19].

We previously developed a smartphone-based self-monitoring application to deliver CBT (CBT app), implemented it in 217 healthy children, and reported its effectiveness for health promotion [20]. The CBT app was highly effective in terms of providing users with self-monitoring skills and reducing depressive symptoms. This study sought to examine the effectiveness of the CBT app in children with mental health disorders including school refusal, eating disorders, and developmental disorders, among others. The primary outcome of this intervention is the improvement in the Questionnaire for Triage and Assessment with 30 items (QTA30) score after implementation of the CBT app, and the secondary outcomes is the improvement in the scores on other psychometric scales.

[Methods]

Study Design

We conducted a prospective single-arm clinical trial involving 115 children with mental health disorders aged 11–18 years (mean age, 14.9 years). The trial was registered in the University Hospital Medical Information Network Clinical Trials Registry (registration number: 000046775). Participants were enrolled from six collaborating institutions, and there were 49 and 66 male and female participants, respectively. The primary diagnoses were school refusal (n = 54), orthostatic dysregulation (n = 15), eating disorders (n = 13), developmental disorders (n = 10), irritable bowel syndrome (n = 5), sleep disorders (n = 5), somatoform disorders (n = 4), obsessive-compulsive disorder (n = 3), and other mental health disorders (n = 6). Participants who were receiving medication did not change their medications during the study period. Participants were divided into four groups on the basis of the presence or absence of depressive symptoms [Dep (+) /Dep (-)] and completion or non-completion of the CBT app-based program [App (+)/App (-)] (Figure 1). Depression symptoms were evaluated using the 9-item Patient Health Questionnaire for Adolescents (PHQ-9A), and program completion was verified on the basis of server records.

Ethics Approval

The design of this study and the procedures for obtaining informed consent were approved by the Medical Ethics Committee of Fukuoka University Faculty of Medicine (approval number: U22-05-

002).

Procedure

The study inclusion criteria were as follows: (1) aged 11–18 years, (2) first visit to a collaborating institution within 6 months, (3) approval for concurrent psychiatric treatment by the attending physician, and (4) access to a smartphone or Wi-Fi network. After the participants and parents signed the informed consent form, the CBT app was installed on their smartphones. While using the CBT app at home, participants visited the hospital at 1–2-month intervals to receive psychological counseling for their primary illnesses from their physicians. The observation period was 6 months, and psychometric scales were assessed at the beginning of the intervention and 2 and 6 months thereafter.

CBT App

A smartphone-based CBT app, named Mugimaru, was developed. The program based on the app was described in detail previously [20]. Briefly, the program comprised 1 week of psychoeducation followed by 1 week of self-monitoring. Mugimaru presents story-like scenarios to provide psychoeducation, so that adolescents can easily understand the rationale of the CBT and are motivated to continue using the app. The story featured an adolescent boy, an adolescent girl, and a cat (Mugimaru). In the story, the boy and girl have troubles in their relationships with friends and concerns about their future. Mugimaru teaches them how feelings, thoughts, and actions mutually affect each other. Similarly, they learn that their feelings are associated with their thoughts and actions. The story consisted of 10 scenarios, and participants could browse 1–2 scenarios each day. After reading one scenario, a new scenario could be read on the following day. The ending of the story was available 1 week after the participants had read the rest of the story. During the intervention period, participants completed several self-monitoring sheets comprising five panels: events, thoughts, feelings, body responses, and actions. The participants inputted their thoughts, feelings, body responses, and actions in association with daily events. In another window, the adolescents could input comments or advice for a friend who had experienced the same event. This input was used by adolescents to practice cognitive reappraisal and problem solving. Figure 2 shows screenshots of the smartphone CBT app. By repeatedly creating self-monitoring sheets, the adolescents could monitor their own experiences develop solutions, and make necessary changes. The shortest time in which Mugimaru can be completed is 2 weeks. All of the data were stored in the main server, and the participants were informed in advance that only the principal investigator could view the data.

Psychometric Scales

The following four psychometric scales were used for outcome assessment.

1) QTA30

The QTA30, a psychosomatic evaluation scale for pediatric populations created by the Japanese Society of Psychosomatic Pediatrics [21], is a standardized tool for triage and assessment of pediatric patients with mental health disorders that takes Japanese cultural and social factors into account. The QTA30 comprises four scales: physical symptoms, depression symptoms, sense of self-efficacy, and anxiety symptoms. Higher scores on all scales correlate with poorer mental health. A total score of ≥ 37 points is considered to indicate poor mental health.

2) Depression Self-Rating Scale for Children (DSRS-C)

The DSRS-C is an 18-item self-report questionnaire that measures depressive symptoms [22]. Participants are asked to select one of three response options for each item: “most of the time” (score = 2), “sometimes” (score = 1), or “never” (score = 0). The maximum score is 36, and higher scores indicate stronger depressive tendencies. The Japanese version of the DSRS-C has good reliability

and validity [23]. The cutoff score for possible depression on the Japanese version is 16 points.

3) Pediatric Quality of Life Inventory (PedsQL)

The PedsQL is a brief measure of adolescents' health-related quality of life [24]. The 23 items are distributed among four generic core scales: physical functioning, emotional functioning, social functioning, and school functioning. Items are scored as 0 ("never"), 1 ("almost never"), 2 ("sometimes"), 3 ("often"), or 4 ("almost always"). The total scale score is calculated as the mean score of all the items transformed to a 0–100 scale. Higher scores indicate better health-related quality of life. The Japanese version of the PedsQL has good reliability and validity [25].

4) Rosenberg Self-Esteem Scale (RSES)

The RSES is the most widely recognized and used measure of global positive and negative attitudes toward the self [26]. It comprises 10 items, and responses are provided via a 4-point Likert scale (4, "strongly agree"; 3, "agree"; 2, "disagree"; 1, "strongly disagree"). Negatively worded items are reverse scored, and total scores range from 10 to 40. Higher scores reflect greater levels of self-esteem. The Japanese version of the RSES has good reliability and validity [27].

Data Analysis

As stated previously, the primary outcome of this study is the improvement in QTA30 scores after completion of the CBT app-based program, and the secondary outcome is the improvement in the scores on the DSRS-C, PedsQL, and RSES. A paired-samples t-test was used for statistical analysis. We also evaluated the correlations between the number of self-monitoring sheets completed by participants and their psychometric scale scores.

[Results]

In total, 115 children with mental health disorders participated in this study. According to the PHQ-9A data, 79 of the children were depressive (PHQ-9A score ≥ 5), and 36 were non-depressive (PHQ-9A score < 5) (Figure 1). Although 91 participants completed the 6-month outcome measurements, 24 dropped out (13 depressive and 11 non-depressive participants) before the 6-month measurements. Of the 91 participants who completed the 6-month outcome measurements, 66 also completed the CBT app-based program (48 depressive and 18 non-depressive participants); of the remaining 25 participants, 18 were depressive and 7 were non-depressive. The 91 participants who completed the 6-month outcome measurements were divided into four groups on the basis of the presence or absence of depressive symptoms (indicated by the PHQ-9A score) and completion or non-completion of the CBT app-based program [Dep (+) APP (+), Dep (+) APP (-), Dep (-) APP (+), and Dep (-) APP (-) groups]. The pre-intervention scores on each psychological scale are shown in Table 1.

1. Outcomes at 2 and 6 months (Figure 3)

QTA30: In the depressive participants, the QTA30 scores at 6 months improved significantly regardless of the completion [Dep (+) App (+)] or non-completion [Dep (+) App (-)] of the CBT app-based program. In the non-depressive participants, the QTA30 score at 2 months improved significantly only among those who completed the program [Dep (-) App (+)].

DSRS-C: Regardless of the completion or non-completion of the CBT app-based program or the presence or absence of depressive symptoms, the DSRS-C scores did not improve significantly at 2 or 6 months.

PedsQL: In the depressive participants, the PedsQL scores at 6 months improved significantly regardless of the completion [Dep (+) App (+)] or non-completion [Dep (+) App (-)] of the CBT app-

based program. In the non-depressive participants, the PedsQL scores at 2 and 6 months improved significantly only among those who completed program [Dep (-) App (+)].

RSES: Regardless of the completion or non-completion of the CBT app-based program or the presence or absence of depressive symptom, the RSES scores did not improve significantly at 2 or 6 months.

2. Comparison of Psychometric Scale Scores Between the App Completion and Non-completion Groups (Table 1)

The PHQ-9A scores showed a trend toward being higher among the participants who did not complete the CBT app-based program compared with the scores among those who completed it, and the scores were significantly higher among the depressed than among non-depressed participants. The scores on the other psychometric scales showed no group differences.

3. Correlation Between the Number of Monitoring Sheets Completed and Baseline Psychometric Scale Scores (Figure 4)

There was a significant positive correlation between the PHQ-9A score at baseline and the number of monitoring sheets completed.

Discussion

This single-arm clinical trial demonstrated the limited efficacy of our CBT app-based program in terms of improving the scores on some psychometric scales of children with mental health disorders. In children with non-depressive symptoms, significant improvements in the QTA30 total scores and PedsQL scores were seen over a 2-month follow-up period. In children with depressive symptoms, the QTA30 total scores and PedsQL scores were significantly improved at the 6-month follow-up, but this was not related to completion of the CBT app-based program. The results should be interpreted with caution because of the single-arm study design and because psychological counselling was also provided.

As alluded to above, improvements in the QTA30 and PedsQL scores at the 2-month follow-up were seen in children with non-depressive symptoms, albeit only among those who completed the CBT app-based program. No such improvement was seen in those with depressive symptoms at the 2-month timepoint. Although the CBT app has potential as an easily accessible, low-intensity intervention, it might not be sufficiently effective for children with depressive symptoms. Skar et al. [28] analyzed the factors associated with nonresponse among children receiving CBT and identified higher baseline stress and older age as significant predictors; they also identified high intensity of the CBT intervention as key to prevent nonresponse. Nevertheless, the usefulness of app-based low-intensity CBT has also been noted. A meta-analysis of 66 randomized controlled trials of app-supported smartphone interventions for mental health problems found no significant difference in effectiveness versus active face-to-face interventions, showing the potential of apps to serve as cost-effective, easily accessible, low-intensity interventions for those who cannot receive standard high-intensity psychological treatment [29]. Adding standard CBT after low-intensity CBT was also reportedly effective in improving anxiety disorders in children [30,31]. The present CBT app consisted of two modules (psychoeducation and self-monitoring); additional modules including cognitive restructuring and behavioral activation are necessary to increase the effectiveness of the CBT app for children with more severe depression.

Another notable finding of this study was long-term (i.e., at the 6-month follow-up) improvements in QTA30 and PedsQL scores in children with depressive symptoms. However, the improvements were seen in both the program completion and non-completion groups; as a medical examination was also performed and psychosocial counseling was provided in conjunction with the CBT app, it was

not possible to partial out the effects of the CBT app when analyzing the changes in the QTA30 and PedsQL scores in children with depressive symptoms. In general, smartphone and internet-based CBT apps are of low intensity, and their effects do not persist for a long time [32]; this likely explains why many intervention studies have 3-month outcome assessment periods [33]. In practice, it is difficult to provide treatment for mental health disorders using an app alone, i.e., without also providing psychosocial counseling, so intervention studies comparing groups receiving psychosocial counseling with and without an app-based intervention are necessary to precisely determine the effects of apps.

One of the goals of this study was to learn about the differences in clinical characteristics between the CBT app-based program completion and non-completion groups. In general, the non-completion rate for smartphone- and web-based CBT is between 10% and 30% [34-36]. Predictors of discontinuation of CBT app use include worse physical health, lower education level, cognitive deficits, and less positive expectations of the outcome [34,37,38]. More severe pretreatment symptoms, comorbidities, lack of social support, and parental conflict are also associated with nonresponse to CBT [34,39-42]. In our study, 24 participants (20.9%) dropped out and another 25 (21.7%) discontinued the CBT app-based program. Among the latter cases, the PHQ-9A scores showed a trend toward being higher in those who did not complete the program compared with the scores among those who completed it, and the scores were significantly higher among the depressed versus non-depressed participants. Furthermore, given that the participants with higher PHQ-9A scores completed more monitoring sheets, it appears that, although individuals with more severe depressive symptoms may be more likely to use a CBT app initially, that may also be more likely to give up. A stepped-care approach, which begins with lower-intensity internet-delivered CBT and then proceeds to more intensive treatments with face-to-face therapist involvement, could be effective for those who might otherwise show a poor response [30,31].

A few limitations of this study need to be addressed. First, this was a single-arm clinical trial with depressed and non-depressed groups; a control group not using the app derived from the same population would be needed to precisely determine the effects of our CBT app. Second, the inclusion of participants with many disorders, such as school refusal, eating disorders, and developmental disorders, among others, may have led to variability in the results; conducting an intervention study including a population with a single disorder may have increased the reproducibility of the results. Third, 45 of the 115 participants dropped out of the study or discontinued their app use. There was a greater tendency toward dropout or discontinuation of the app among participants without depressive symptoms, and it is necessary to devise ways to encourage them to continue using the program.

Our CBT app-based program was useful for improving the health and quality of life of children with mental health disorders classified as non-depressive. The program also seemed to be useful for children with depressive symptoms, although the importance of regular psychosocial counseling is undeniable. A higher-intensity CBT program is necessary for more severely depressed children.

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Conflicts of Interest
None declared.

Authors’ Contributions

SN, AO, RS, RI, KK, and CH were the lead researchers in the six collaborating institutions and participated in the design of the study. SN compiled the manuscript. RO, TI, TK2, NM, CT, CF, YS, and MM recruited and examined participants and provided psychological counseling. MH, AK, MI, and TK1 designed the CBT app. TK3 conducted the statistical analyses. All authors read and approved the manuscript. TK1, TK2, and TK3 correspond to Takashi Katayama, Tasuku Kitajima, and Tatsuki Kakuma, respectively.

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Abbreviations
CBT; cognitive behavioral therapy
app; application
PHQ9A; Patient Health Questionnaire for Adolescents
QTA30; Questionnaire for Triage and Assessment with 30 items

PedsQL; Pediatric Quality of Life Inventory
DSRS-C; Depression Self-Rating Scale for Children
RSES; Rosenberg Self-Esteem Scale

Figure Legends

Figure 1
Participant flow chart.

Figure 2
Screenshots of the smartphone cognitive behavior therapy application.

Figure 3
Changes in psychometric scores in the four groups during the follow-up period.
*significant change in score (pre- vs. post-intervention; $P < 0.05$).
QTA30, Questionnaire for Triage and Assessment with 30 items; DSRS-C, Depression Self-Rating Scale for Children; PedsQL, Pediatric Quality of Life Inventory; RSES, Rosenberg Self-Esteem Scale.

Figure 4
Correlation between the number of self-monitoring sheet participants completed and the Patient Health Questionnaire for Adolescents score.

Table1. The pre-intervention values for each psychometric scale in the 4 groups.

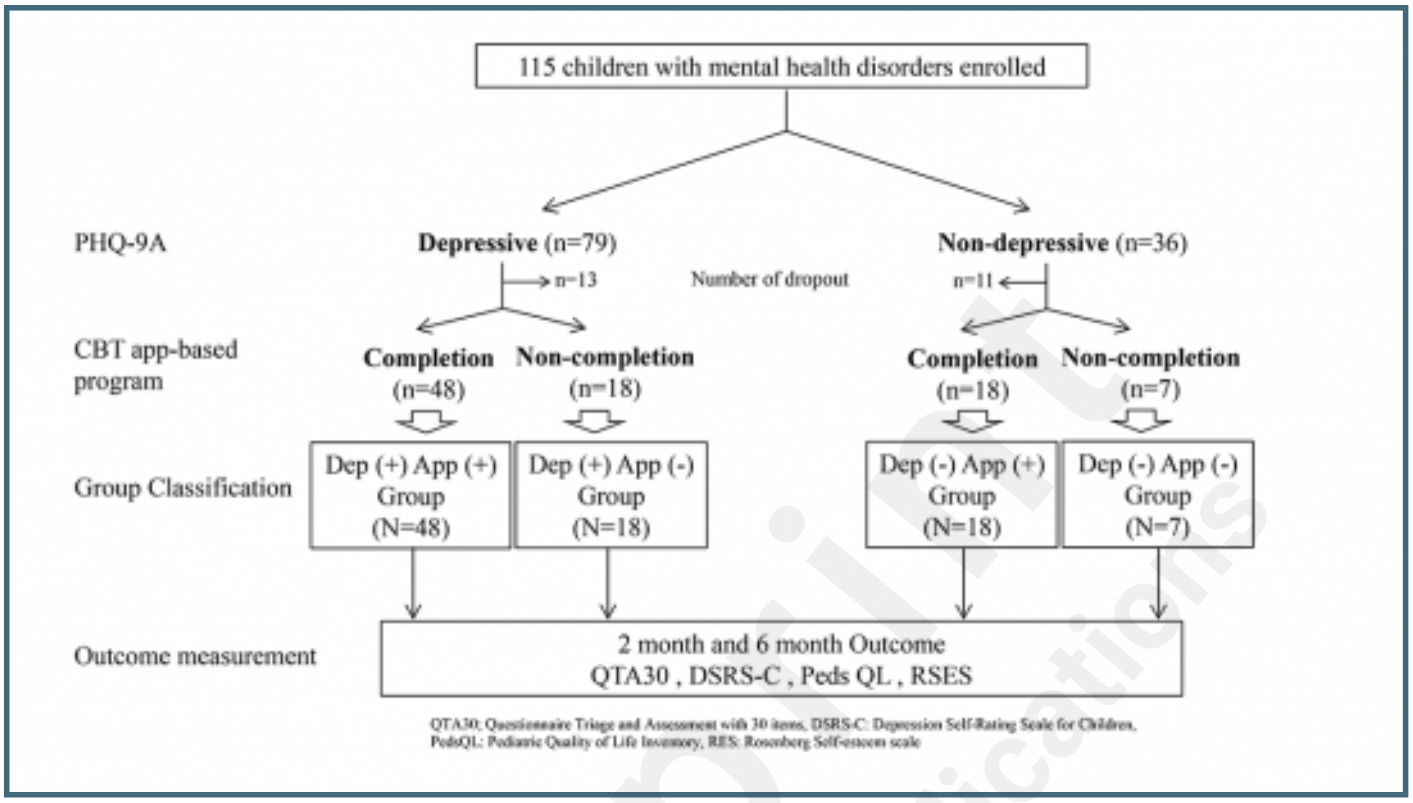
	Depressive			Non-depressive		
	App completion (n=48)	App non-completion (n=18)	p value	App completion (n=18)	App non-completion (n=7)	p value
PHQ9A	10.94 ± 5.02	13.33 ± 4.51	0.071	1.72 ± 1.56	3.29 ± 0.95	0.007
QTA30-total	54.83 ± 14.19	55.61 ± 12.35	0.828	27.94 ± 12.13	25.43 ± 6.02	0.499
DSRS-C	18.77 ± 5.33	17.83 ± 5.53	0.541	10.17 ± 3.24	11.57 ± 6.32	0.592
PedsQL	64.22 ± 17.53	67.81 ± 13.01	0.371	84.96 ± 8.42	78.57 ± 12.13	0.235
RSE	20.85 ± 4.31	21.50 ± 4.83	0.623	27.94 ± 3.90	26.57 ± 5.97	0.588

PHQ9A; Patient Health Questionnaire-9, QTA30; Questionnaire Triage and Assessment with 30 items, DSRS-C: Depression Self-Rating Scale for Children, PedsQL: Pediatric Quality of Life Inventory, RES: Rosenberg Self-esteem scale

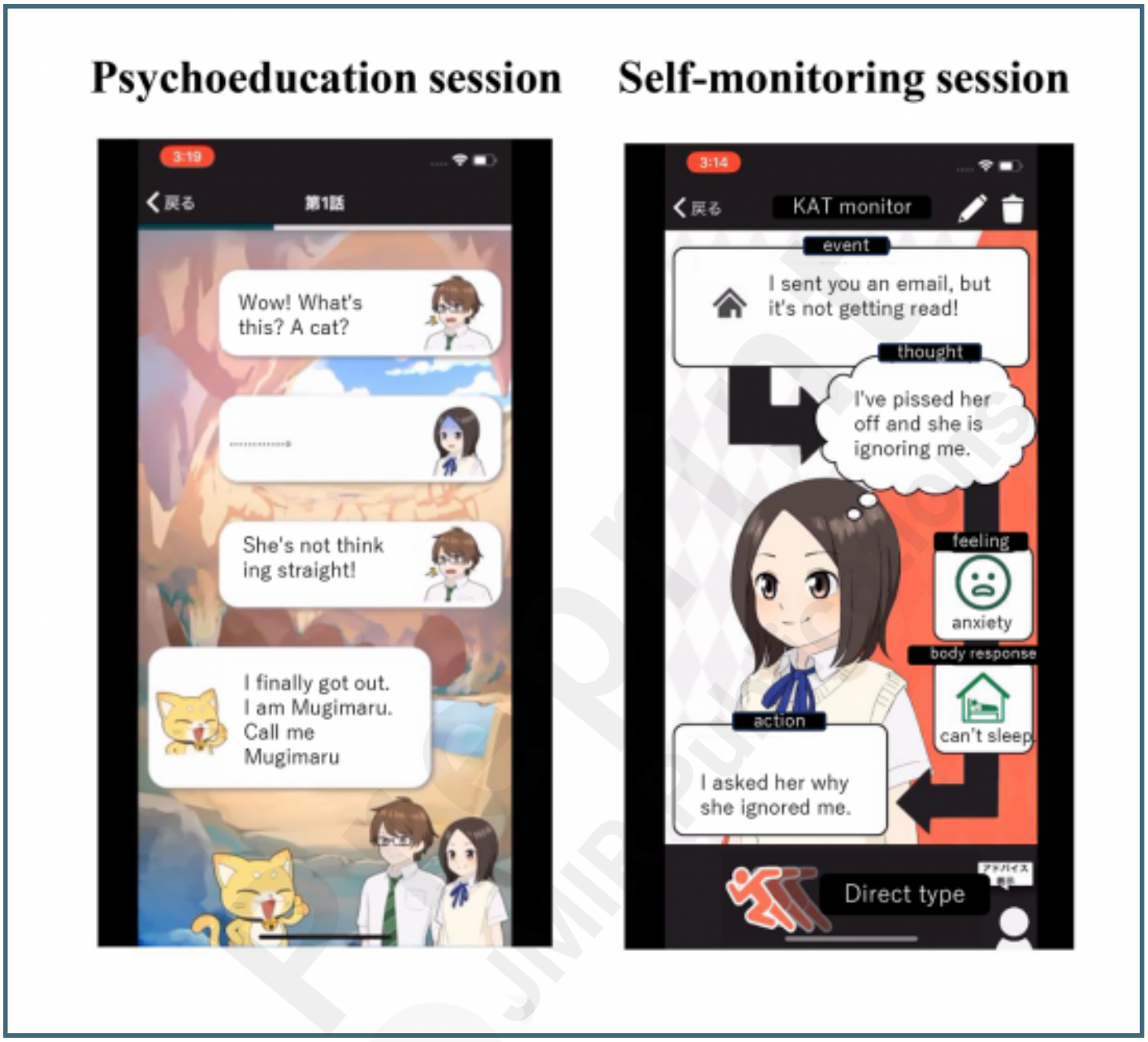
Supplementary Files

Figures

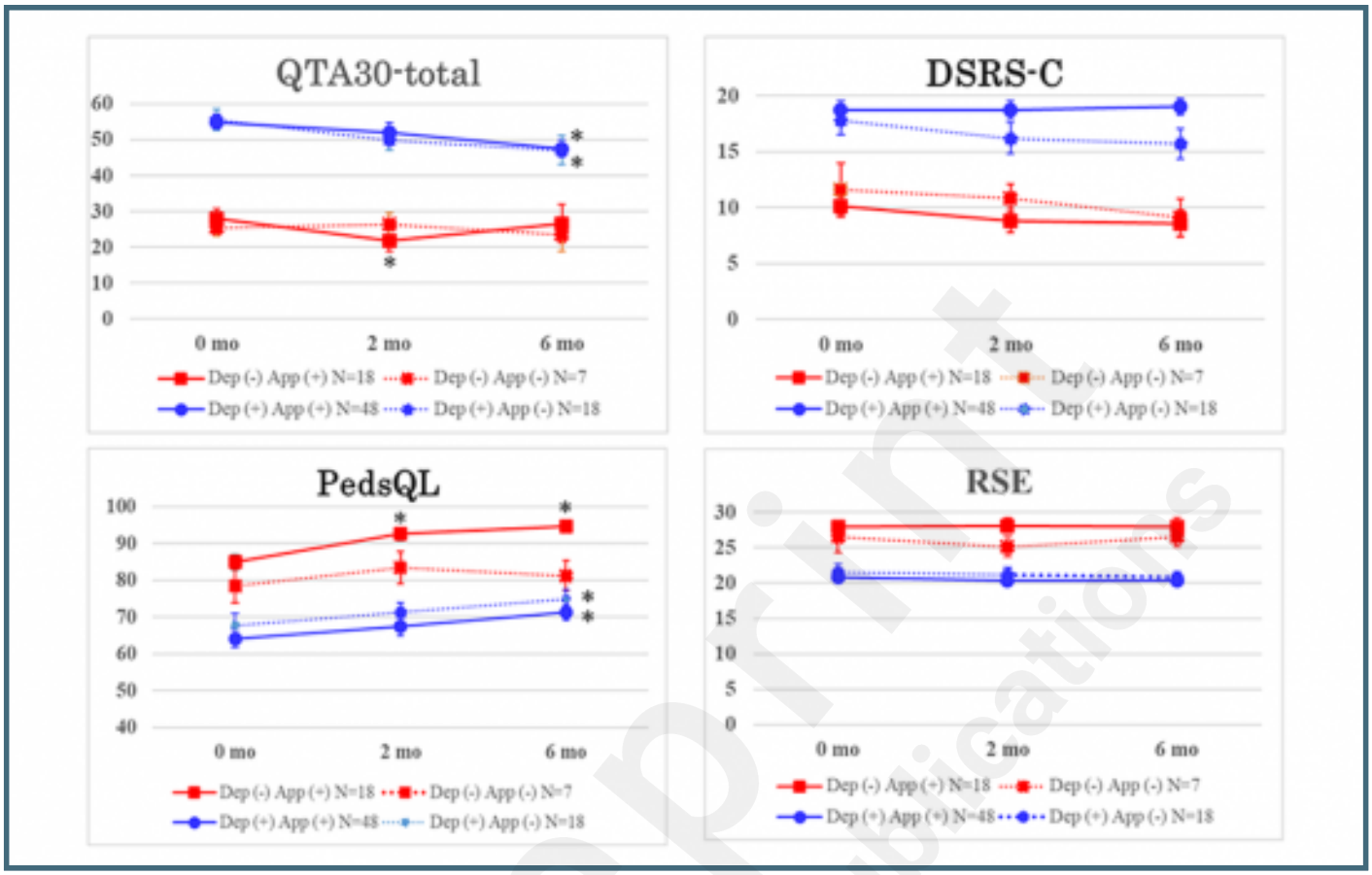
Participant flow chart.



Screenshots of the smartphone cognitive behavior therapy application.



Changes in psychometric scores in the four groups during the follow-up period.



Correlation between the number of self-monitoring sheet participants completed and the Patient Health Questionnaire for Adolescents score.