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Comparing the Effect of Internet-Delivered Self-Care Training and Play Therapy on the Quality of Life of Children with Type 1 diabetes in 2021 in Isfahan City- Randomized Clinical Trial

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Abstract

Objective: Type 1 diabetes mellitus (T1DM) is one of the most common chronic diseases in childhood, and its management is associated with many problems. The study aimed to compare the effect of group self-care training and patient child play (PCP) on quality of life (QoL) in children with type 1 diabetes in Isfahan, Iran.
Materials and Methods: This randomized trial was done from January 2020 to October 2021 in Endocrine and Metabolism research center of Isfahan University of medical sciences. Seventy- five children aged 8 to 11 years with T1DM who did not have a severe behavioral problem based on the child behavior checklist (CBCL) were simple randomly assigned to three groups: self-care training, play therapy, and control. The self-care group received ten education sessions via the Skyroom and the playgroup performed PCP for ten sessions. The control group did not receive any psychological intervention. All participants received routine diabetes medication. They completed a health-related QoL questionnaire for children (KIDSCREEN-52) before and after the intervention. Data were analyzed using SPSS-23 software and analysis of covariance.
Results: A significant difference between the mean scores of the post-test subscales of physical well-being (*P*= 0.003), psychological well-being (*P*= 0.003), moods and emotions (*P*= 0.02), self-perception (*P*= 0.002), self-autonomy (*P*= 0.002), parental relationships and family life (*P*= 0.001), social and peers support (*P*= 0.04), school environment (*P*= 0.003) and social acceptance (*P*= 0.001) in PCP group.
Conclusion: Self-care training and PCP are effective in increasing the QoL, and can be used as a complementary treatment in children with T1DM.
Keywords: Quality of life, Diabetes mellitus, Play therapy, Children

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Introduction

Type 1 diabetes mellitus (T1DM) is an autoimmune disease in which the immune cells react against the insulin-producing cells in the pancreas (1). It is one of the most common chronic diseases in childhood and adolescence (2) and accounts for 5 to 10% of all diagnoses of diabetes. The number of children with T1DM worldwide is approximately 542 thousand, with an incidence of 3- 5%. The average annual incidence of T1DM in Iran is increasing, and from 0.8 to 50 in one hundred thousand children or young adults are variable (3).

Managing and controlling diabetes in children is multidimensional and complex, which includes frequent monitoring of blood sugar, proper nutrition, regular physical activity, and regular insulin injections. Lack of control of diabetes in children leads to various complications such as hypoglycemia, hyperglycemia and ketoacidosis, growth retardation, and micro- and macrovascular diseases. Due to high care needs, diabetes has severe physical and psychological consequences for children and many family challenges. One of these challenges is that children do not follow the medical instructions and care needed to control their blood sugar (4).

On the other hand, children with T1DM have more psychological distress and risk of emotional, behavioral, and psychiatric disorders than others. In particular, the prevalence of depression, anxiety, and eating disorders in these children is high. They may be anxious in social interactions due to fear of high blood sugar and understanding their differences from peers (5).

These changes in children's personal, psychological and social life strongly affect their quality of life (QoL) (6).

QoL is defined as people perception of their position in life in the context of the culture and value systems in which they live and about their goals, expectations, standards, and concerns (7). Health-related QoL indicates how an illness or medical condition affects an individual physical, emotional, psychological, and underlying well-being (8). Childreninability to properly control diabetes causes wide-ranging changes in their lifestyle and severely affects their QoL (1).

In the treatments used for individual with diabetes, especially in children and adolescents, interventions for their psychological and self-management problems, have often been neglected. There are several psychological therapies for physical and mental self-care training, that one of the major components of them is psychoeducation (9) about illnesses and their emotional components, such as depression, anxiety, and substance use disorders, etc. The results of studies indicate the effect of psychoeducation and self-care training on the QoL of children with diabetes (10-12).

On the other hand, one of the types of interventions that are used to teach and develop skills such as self-care in children is play therapy (PT). Because children have less verbal and cognitive ability than adults to express their emotions, play is a means for them to deal with problems (13). The primary purpose of serious games (therapy) is to train, practice and promote self-care (14). PT effectively teaches self-care in a wide range of chronic diseases, including T1DM (15). Various studies have shown that PT has a positive effect on controlling blood sugar, reducing anxiety, reducing fear of insulin injections and improving quality of life in children with T1 diabetes (16,17).

In our study compared to previous studies, instead of using conventional approaches to play therapy, serious games and game boards have been used. The “patient child” play (PCP) set has been designed to increase self-control and emotional recognition skills in children six years and older. Also, its effectiveness in improving self-control and anger management in children was studied (18-21).

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In the present study, PCP was adapted to teach children with T1DM how to perform routine medical care and deal with psychological problems. Also, the self-care training protocol used in this study combined physical self-care skills with the psychological skills that these children need. So, this study aimed to compare the effect of internet-delivered self-care training and PCP on the QoL of children with T1DM.

Material and methods

This study is a randomized trial on children aged 8 to 11 years with T1DM who were referred to Isfahan diabetes center from June to March 2019. They received a diagnosis of T1DM based on the opinion of a pediatric endocrinologist, 75 children were selected based on purposive sampling and inclusion and exclusion criteria. After informed consent, participants were divided randomly into three groups groups equally: self-care training, PCP, and control (each group 25 children) by random allocation software in such a way that they were assigned by permuted block random allocation and each block included 6 participants.

In this study, assuming that the minimum detectable effect size for quality of life is delta = 0.9 (considering $\alpha = 0.05$ and $1-\beta = 0.8$) (22), the sample size in each group obtained at least 20 patients. Considering the possible dropout, 25 participants were assigned in each group. CONSORT Flow Diagram of the study has been shown in figure 1.

Inclusion criteria were the absence of severe behavioral and emotional problems in children based on the child behavior checklist (CBCL) -which was filled out by parents, not receiving further psychotherapy for the past six months, and completing the informed consent form by the child parents. Individuals with absence of more than two treatment sessions and hospitalization during the intervention were excluded.

Parents of all participants completed the HRQoL questionnaire for children (KIDSCREEN) online in the pre-test and post-test stages.

CBCL, with 113 questions, assesses the problems of children and adolescents aged 6 to 18 in 8 domains: anxiety/depression, isolation/ depression, somatic complaints, social problems, thought problems, attention problems, rule-breaking behaviors, and aggressive behavior. The school-age assessment forms are the CBCL/6-18, completed by parents or surrogates; the

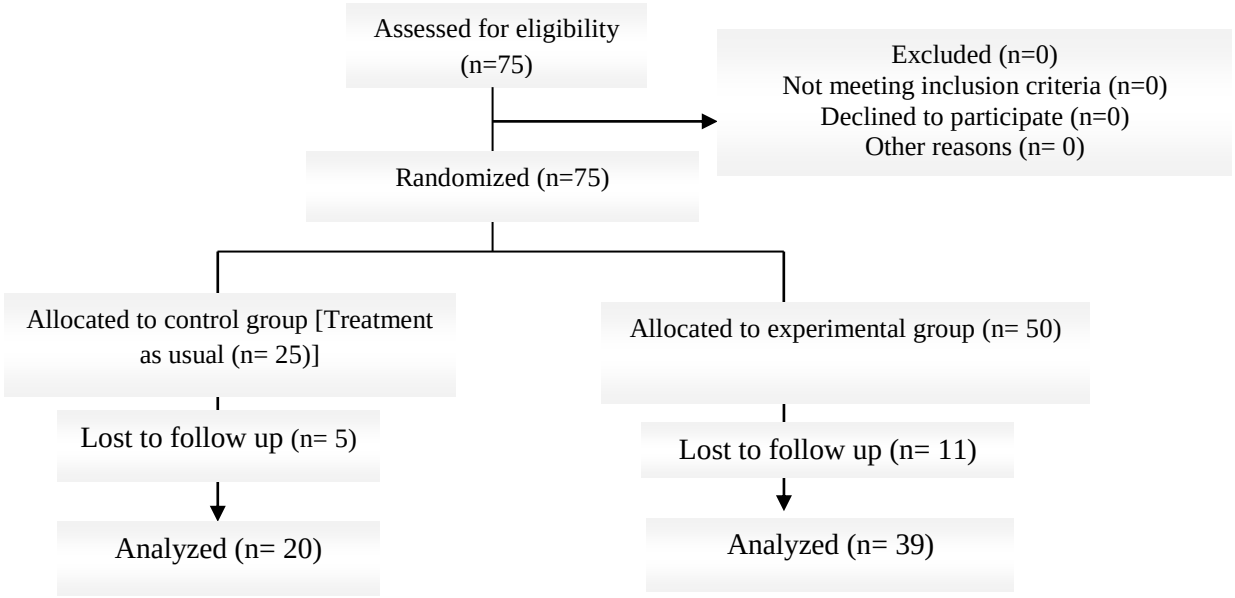

Figure 1. Consort flow diagram of the study

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teacher's report form (TRF/6-18), completed by teachers and other school staff; and the youth self-report (YSR/11-18), completed by children and adolescents. The overall validity coefficients of CBCL forms were reported to be 0.97 using Cronbach's alpha and 0.94 using retest validity. Content validity, criterion validity, and construct validity of these forms were reported to be favorable (23). The Persian version of this tool had suitable reliability (Cronbach's alpha 0.63 to 0.95 and the range of temporal stability coefficients 0.32 to 0.67) (24).

KIDSCREEN-52 is a self-assessment tool for assessing QoL of children and adolescents with chronic illness aged 8 to 18 and proxy scales are available for parents and other caregivers. As a result of their simultaneous development in 13 European countries, the KIDSCREEN instruments are truly cross-national HRQoL measures. Form 52 items of the KIDSCREEN consists of 10 dimensions, including physical well-being, psychological well-being, mood and emotions, self-perception, self-autonomy, parent relationship, family life, social support and peers, school environment, social acceptance, and financial resource. Each question receives a score of 1 to 5 for the frequency of a particular behavior or feeling (1= never, 2= rarely, 3= sometimes, 4= often, 5= always) or the severity of the attitude (1= not at all, 2= up to indicates 3= average, 4= very much, 5= infinite) over the past week. A higher score means a better QoL. The internal consistency reliability of the instrument was reported by Cronbach's alpha in all dimensions between 0.77 and 0.89. Also, its convergent validity was between 0.51 and 0.68 through correlation with the dimensions of the Munich QoL questionnaire. The reliability of this tool by retest method was strong on 551 Iranian students for all scales (alpha coefficients of all dimensions were higher than 0.70) (25).

The self-care training group received online training for 10 (2-hour) sessions online via the Skyroom platform. In each session, mothers and children participated, and the children shared their experiences. The training protocol taught by an educated health psychologist included training in the physical care required for diabetes (principles of proper nutrition, familiarity with different food groups, principles of physical activity and exercise, insulin injection, and blood sugar testing). For preparing the protocol have been used the educational resources of Gabric Diabetes Association (26) and handbook of diabetes (27) **.**It also included training of recognizing the emotions, problem-solving, relaxation, assertiveness skills, anger management, and identifying dysfunctional thoughts and beliefs about diabetes using the refrences such as “Archives of disease in childhood“ (28), CBT Toolbox for Children (29) and “Life skills education“ (30). The sessions were interactive and active learning, and the children were given exercises to do at home. The content of the ten sessions was as follows (Table 2).

The game used in the play therapy group

Table 2. The content of the ten sessions was as follows

Session 1: Recognizing and getting to know the coach and the kids, teaching emotion recognition, naming emotions (emotion cycle game)
Session 2: Grading the intensity of emotions, physical symptoms of emotions, and correct expression.
Session 3: Training in emotion management skills (anger, sadness, anxiety, and worry), training in proper breathing and training in relaxation skills.
Session 4: Teaching cognitive triangles, traps, and common misconceptions. Problem-solving skills training.
Session 5: Familiarity with diabetes in simple language, familiarity with feelings and emotions related to the experience of diabetes (fear of insulin injection, fear of rising and falling blood sugar, etc.), strategies to regulate specific emotions of diabetes.
Session 6: Principles of proper nutrition, nutritional communication, and emotion regulation.
Session 7: Principles of exercise and physical activity in diabetes control, exercise communication, and emotion regulation.
Session 8: Principles of proper sleep in diabetes control sleep communication, and diabetes control.
Session 9: Examining common thoughts and beliefs about diabetes and correcting them with children’s cooperation and using critical thinking.
Session 10: Summarizing and completing the course.

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PCP from Shadram's educational and therapeutic games company. This game is specially designed to help children who have problems with self-control for various reasons. In this game, children learn essential social skills such as taking turns, listening to others, following the game's rules, etc. PCP consists of two games, feeling alarm and Watchtower. The feeling alarm consists of 3 groups of cards: a) say no firmly- for saying no and assertiveness training; b) world of emotions- for identifying emotions in different situations; c) the magic trio- for training cognitive triangle thoughts, emotions, and behaviors based on CBT. The Watchtower game consists of 3 sets of cards named a) Prediction- for training self-control skills in different situations; b) my police- for training the importance of order, timing, physical and mental care of the body, relaxation training, etc.; c) magic of words for teaching recognition and correction dysfunctional thoughts and beliefs (31). The card's content was changed to suit for problems of children with diabetes. The playing group performed PCP for ten sessions. The play was posted for each child, and they were asked to play it with their parents twice a week for five weeks. The play has a guide that thoroughly explains how to do it. Furthermore, the researcher sent short videos to mothers about how to do different parts of the play. The control group received only routine diabetes interventions.

Statistical analysis

Data were analyzed using SPSS-23 software and multivariate analysis of covariance (MANCOVA) by modulating confounding variables (pre-test scores).

In 2019, before the start of the project's implementation stages, it first received the ethics code IR.MUI.MED.REC.1399.255 from the Research Ethics Committee of Isfahan University of Medical Sciences and the code IRCT20180909040974N3 from the Iranian Clinical Trial Registration Center.

Ethical considerations

The study was approved by the Research Ethics Committee of Isfahan University of Medical Sciences (No: IR.MUI.MED.REC. 1399.255) and the code IRCT 20180909040974N3 from the Iranian Clinical Trial Registration Center.

Results

At the beginning of the study، 75 children were selected based on inclusion and exclusion criteria. They were randomly assigned to three groups: self-care training, PCP, and control. 6 participants from the Selfcare training group were removed from the group due to the absence of more than 2 sessions. 5 participants of the PCP group were removed from the group due to non-cooperation in playing the game. 5 participants of the control group did not cooperate in completing the questionnaire.

Table 2 shows the demographic characteristics of the participants.

Table 3 shows the mean and standard deviation of the pre-test and post-test scores of children's QoL subscales in groups.

As it has been shown in Table 3, the average post-test scores of all subscales of KIDSCREEN-52 in the two experimental groups were more significant than the average scores of the control group. ($P< 0.05$)

The results of the Shapiro-Wilk test showed KIDSCREEN-52 subscles scores had a normal distribution ($P< 0.05$).

The observed F for Levin's test showed there were no significant differences between the variance scores of the subscales of physical

Table 2. Frequency distribution of age and sex of samples participating in the research

Group	Sex		*P*-value	Age				*P–value*
	Boy	Girl		8 years	9 years	10 years	11 years	
Selfcare training	7	12		6	4	3	6	
Pcp	8	12	0.61	5	4	4	7	0.7
Control	9	11		7	3	4	6	

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Table 3. The mean and standard deviation of the pre-test and post-test scores of children's QoL subscales in the two experimental groups and the control group

Dependent variable	Group	N	Pre-test		Post-test		*P–value*
			Mean	Standard deviation	Mean	Standard deviation	
Physical wellbeing	Self-care training	19	14.70	4.90	19.15	3.70	0.001
	PCP	20	15.05	4.79	19.20	4.04	0.003
	Control	20	15.10	5.28	15.25	14.12	0.544
Psychological wellbeing	Self-care training	19	19.55	6.27	24.30	4.35	0.564
	PCP	20	19.05	6.46	24.15	3.71	0.035
	Control	20	19.50	4.80	19.10	7.04	0.329
Mood and emotions	Self-care training	19	21.30	6.45	27.20	7.60	0.796
	PCP	20	21	6.31	27.50	7.09	0.449
	Control	20	21.40	6.36	21.75	8.09	0.329
Self- Perception	Self-care training	19	20.10	3.32	24.05	5.01	0.90
	PCP	20	19.70	5.28	24.45	4.40	0.590
	Control	20	20.25	3.30	19.85	3.31	0.456
self-autonomy	Self-care training	19	18.55	6.16	23.60	4.98	0.374
	PCP	20	18.70	2.95	23.25	5.27	0.793
	Control	20	18.40	3.48	18.65	4.10	0.652
Parent relationship and family life	Self-care training	19	19.25	5.50	23.40	3.66	0.048
	PCP	20	18.95	5.87	24.05	3.83	0.013
	Control	20	18.60	7.25	18.15	6.09	0.475
Social support and peers	Self-care training	19	14.75	5.83	18.65	6.27	0.307
	PCP	20	14.40	5.11	17.95	6.36	0.324
	Control	20	14.64	6.01	14.30	4.99	0.329
School environment	Self-care training	19	13.40	5.57	18.60	4.79	0.568
	PCP	20	13	2	18.40	6.15	0.295
	Control	20	13.80	6.17	13.65	5.70	0.423
Social acceptance	Self-care training	19	12.50	3.25	18.10	5.23	0.656
	PCP	20	12.95	2.52	18.85	4.35	0.762
	Control	20	12.55	2.18	12.60	4.19	0.745

well-being (*P*= 0.68), mood and emotions (*P*= 0.9), self-perception (*P*= 0.10), self-autonomy (*P*= 0.12), parental relationships and family life (*P*= 0.14), social and peers support (*P*= 0.74), and children's social acceptance (*P*= 0.54)**.** Therefore, the null hypothesis, i.e., the homogeneity of variances, is accepted, and the statistical method of multivariate analysis of covariance can be used to analyze the data obtained from the research.

The results of Pillai's trace (*P*= 0.005) and Hotelling's trace (*P*= 0.001) showed there was significant differences between the scores of dependent variables between PCP, self-care training and control groups. For pairewise comparing between 3 groups, LSD test was used (Table 4).

According to the results of Table 4, there were no siginficant differences in the subscale of KIDSCREEN-52 between the two experimental and control groups except the subscale of parent relationship and family life.

Discussion

Our study demonstrated that the experimental groups (self-care and PCP) had a significant improvement in QoL compared to the control group in the subscale of parent relationship and family life. One of the most significant challenges for parents with diabetes is that children do not follow medical instructions and diabetes-related care. Because in both the self-care training and PCP, children learned self-control and self-care skills, which led to better control of their blood sugar. So, increasing treatment adherence in children reduced their challenges with their parents. In addition, mother-child interactions increased thorough the study because children attended in self-care sessions with their parents and played PCP with them. Also, the mothers know more about their children’s emotions and feelings during the sessions and the play. As a result, the quality of the mother-child relationship has improved.

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Table 4. comparing the mean scores of KID-SCREEN52 subscales in the two experimental and control groups

Variables	Groups	Mean difference	Significance level
Physical wellbeing	Control- self-care	-1.783	0.055
	Control –PCP	-1.034	0.247
	Self-care -PCP	0.749	0.420
psychological wellbeing	Control- self-care	0.721	0.595
	Control –PCP	-0.407	0.757
	Self-care -PCP	-1.128	0.413
Mood and emotions	Control- self-care	0.868	0.574
	Control –PCP	-1.714	0.256
	Self-care -PCP	-2.582	0.103
Self-perception	Control- self-care	0.032	0.967
	Control –PCP	-0.400	0.594
Self-autonomy	Control- self-care	0.182	0.874
	Control –PCP	-0.532	0.634
	Self-care-PCP	-0.714	0.540
Parent relationship and family life	Control- self-care	1.849*	0.025
	Control –PCP	-0.038	0.961
	Self-care-PCP	-1.886*	0.024
Social support and peers	Control- self-care	0.144	0.822
	Control –PCP	-0.051	0.935
	Self-care-PCP	-0.195	0.764
School environment	Control- self-care	-0.081	0.950
	Control –PCP	-0.232	0.854
	Self-care-PCP	-0.150	0.909
Social acceptance	Control- self-care	-0.948	0.528
	Control –PCP	-1.307	0.372
	Self-care -PCP	-0.359	0.814

This has led to a significant improvement in the QoL in the parent relationship and family life.

The finding of the present study was consistent with the results of other studies, which have shown that self-care training is practical on the QoL of children and adolescents with diabetes.for example Larijani, Ardakani, in a research they conducted under the title of the effectiveness of an intervention based on information-motivational-behavioral skills model on the quality of life anxiety and depression of children with diabetes, showed that this type of intervention increases the quality of life of children with diabetes. Hadizadeh and Jafari, in a research they conducted on patients with type 1 diabetes, showed that training psychological techniques has a significant effect on improving the quality of life.

Also, this hypothesis was in line with other studies that investigated the effectiveness of self-care training on variables such as depression, social anxiety, promotion of self-management behaviors, blood sugar control in children with diabetes. (12,32,33).

Also, our findings consist of previous research that had shown the effect of PT on improving treatment adherence, QoL, and parent-child relationship in children with diabetes.for example Tarkhan and Hajari in their research, which was conducted under the title of the effectiveness of play therapy on quality of life and blood sugar control in children aged 7-14 with type 1 diabetes, showed that this model of play therapy is effective in improving the quality of life of children with diabetes (16,17,34) and specifically, a few research had shown the effect of PCP on children's problems such as aggression and self-control (18,19,20,21).

However, the present study indicated no significant differences between the two experimental and control groups in other subscales of the QoL. Our study was performed where children had less interaction with others, and their interactions were limited to the family due to Covid-19 specific restrictions. As a result, there were slight changes in subscales of QoL, such as social support and peers, school environment, social acceptance, etc., in the post-test.

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Finally, the present study showed that the PCP group had significantly higher mean scores in the subscale of a parent-child relationship than the self-training group in the post-test stage. The PCP seems to have components (such as increasing executive function and problem-solving) that help improve the parent-child relationship. One of the conditions of the present study was that children played PCP with their parents. Since the play of the present study was a kind of treatment for children, parents' attitude to the play differed from the usual daily games. It can increase the belief that play is an important developmental activity for children, beyond entertainment. These parents believe they can teach their children various skills, such as social skills or behavior regulation skills, via play so the parent-child relationship can improve (35).

One of the limitations of the present study was the difficulty in transferring educational concepts due to the virtual training situation. Also, the PCP was not held in the peer groups. It was sent to the participants, and the game was played at home with the cooperation of the parents. Although the researcher made sure that the child-parent does PCP at home as often as needed for the study by constantly calling the participating parents, these conditions can have different results than playing with other children.

Conclusions

Our study demonstrated that the experimental groups (self-care and PCP) had a significant improvement in QoL compared to the control group in the subscale of parent relationship and family life.

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Conflict of Interest

No potential conflict of interest was reported by the authors.

Authors' contributions

All authors have accepted responsibility for the entire content of this manuscript and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved and approved the version to be published.

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