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Effect of Family-Professional Collaboration on Children with Cerebral Palsy Performance, and Caregivers' Quality of Life and Burden: A Randomized Control Trial.

Submitted in partial fulfilment of the requirement for the master's degree in the Department of Rehabilitation Health Sciences at the College of Applied Medical Sciences, King Saud University.

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

﴿وقل ربي زدني علما ﴾

سورة طه: آية (١١٤)

ABSTRACT

Background: Family–professional collaboration is important to enhance the outcomes for children with cerebral palsy (CP) and their caregivers. Implementing the "Family–professional collaboration" involves ~~a~~ four-step process: mutually agreed-upon goals, shared planning, shared implementation, and shared evaluation.

***Aims*:** to examine the effect of the training program of the "family-professional collaboration for physical therapists; on the performance of children with CP and consider their caregivers' quality of life and burden.

***Methods*:** A randomized, single-blinded control study involved 28 physical therapists and 44 pairs of children with cerebral palsy and their caregivers assigned randomly into (the experimental group consisted of 12 physical therapists and 21 children and their caregivers) and (the control group consisted of 16 physical therapists and 23 children and their caregivers). The children received intensive physical therapy sessions for six weeks (5 sessions/week) and each session lasted 45- 60 minutes. The Physical therapists in the experimental group received two online training sessions 3 hours each); the first session included a training on data collection procedures and the application of the outcome measures; and the second session included training on the application of the family-professional collaboration and how to treat the children accordingly. Physical therapists in the control group received the first session training only. Outcome measures included: Goal Attainment Scaling (GAS) to measure the children's performance towards attaining their intervention goals, the World Health Organization Quality of Life Brief (WHOQOL- Brief) to examine the caregivers' quality of life, and the Zarit Burden Interview (ZBI) to evaluate the caregivers' burden.

Results: All Children showed improvement on the GAS change rate ($p = 0.002$), and the effect size was ($\eta p^2 = 0.20$) small, with no significant differences between groups ($p < 0.44$), and the effect size was ($\eta p^2 = 0.02$) with trivial effect size. Nevertheless, the children in the experimental group showed higher performance in the last assessment than the control group. In contrast, the control group's performance increased in the first assessment and decreased in the last assessment. There were no main effects of time and group or interaction of time × group reported on WHOQOL-brief domains and no main effect of time on ZBI, but there was the main effect between groups ($p = 0.03$), $\eta p^2 = 0.11$ in favour of the experimental group.

Conclusion: Family professional collaboration is an important practice to be applied during the session of the intervention for children with CP to improve goals attainment and reduce their caregivers' burden.

Keywords: Family-professional collaboration, partnerships, children's performance, quality of life, burden, caregivers, physical therapists.

Dedication

This thesis is dedicated to:

My parents, brothers and sisters.

All children with disabilities and their families. You may face difficult times, but the love and support you have for one another will make the difference.

Acknowledgments

First of all, I would like to thank almighty God, the most gracious and the most merciful, for his blessing given to me during my study and completing this thesis.

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I would like to extend my thanks to all the participants of this study, including the children, their families and the physical therapists who made themselves available despite their busy schedules. Huge thanks go to all those in charge of the pediatric units in SBAHC.

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Finally, I strongly believe that this study will have huge benefits to anyone interested in reading this final project.

Thank you...

Sarah Alotaibi

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III. Abbreviations

COPM	Canadian Occupational Performance Measure
CP	Cerebral Palsy
CWDA	Children with disabilities association
FCC	Family Centred Care
GAS	Goal Attainment Scaling
GMFCS	Gross Motor Function Classification System
GMFM	Gross Motor Functional Measure
ICF-CY	International Classification of Functioning, Disability and Health for Children and Youth
KSU	King Saud University
OPHI-II	Occupational Performance History Interview-II
PEDI	Pediatric Evaluation of Disability Inventory
Q	World Health Organization Quality of Life- Brief items
WHOQOL-100	World Health Organization Quality of Life
WHOQOL-Brief	World Health Organization Quality of Life- Brief
QOL	Quality of Life
RCT	Randomized Control Trial
SBAHC	Sultan Bin Abdulaziz Humanitarian City
WHO	World Health Organization
ZBI	Zarit Burden Interview

Chapter 1. Introduction

1.1 Introduction

Family-professional collaboration is recognized as a critical element in family-centred care (FCC) and acknowledged in pediatric rehabilitation as the best practice for children with disabilities. It has a positive effect on the children's and their families' outcomes (1).

Family–professional collaboration has been suggested as important for determining goals, planning, and applying interventions that meet the priorities and needs of the family (2-4). It advocates reciprocal respect and confidence, sharing of information and skills, open communication, engagement in decision-making, and methods that integrate family beliefs, priorities, and needs into intervention (5-7).

Family–professional collaboration is identified by two complementary elements: the first element is a relational practice like displaying respect and empathy and effective listening; the second element is participatory practice, such as the family engagement in the intervention procedure by integrating family requirements and preferences into the intervention (5, 8, 9).

The concept of family–professional collaboration provides chances for children to achieve therapeutic goals in association with their activities through everyday routines and is assumed to encourage learning (10, 11). Moreover, collaborative goal-setting and intervention has been found to enhance child development, functional tasks performance, psychological adjustment and goal accomplishment (12-16). Furthermore, it has a positive influence on caregivers' emotional well-being and quality of life (QOL), levels of stress and burden, their satisfaction with healthcare services, sense of competency, and participation in the intervention process (14, 17-22).

Although the participatory practices have been found to be more highly associated with positive results than relational practices, the professionals carry out the participatory practices less frequently than relational practices, which means not only using trusting relationships with families, but also using certain practices that make the balance of power equal so that families become the final decision-makers and factors of change (8, 23, 24). The collaboration process with families to investigate their requirements and concerns was considered by families and professionals as an area for improvement (8, 17).

In 2014, An and Palisano created a training model to enhance this practice by physical therapists; the model of Family–Professional Collaboration encompasses four strategies to facilitate interaction between family and professionals. Those strategies are: 1) mutually agreed-upon goals, 2) shared planning, 3) shared implementation, and 4) shared evaluation of child and family outcomes (25). This model has been used to manage children with physical disability in many conditions but not children with cerebral palsy (CP) (1).

Cerebral palsy (CP) is one of the most widespread motor disabilities of childhood, and is described as a group of non-progressive disorders that happen in the developing fetal or infant brain and lead to posture and movement problems (26, 27). Physical therapists have an essential role in the management of children with CP, along with their families. The aims of physical therapy management are to facilitate the participation needs of the child with CP and reduce the physical impairments. Physical therapy assists children with CP in reaching their maximum potential of functional independence and increasing their fitness level. Moreover, they enhance the QOL of the children and their families by reducing the effect of physical impairments (28, 29). In addition, the family plays a crucial role in long-term caregiving for an individual with an illness or disability such as CP (30). The term ‘family’ is used to comprise the patient, caregiver and other family members (30). Further, the description of the caregiver is varies, but generally is the person who gives help to the patient (31).

Therefore, the current study aims to examine the effectiveness of family-professional collaboration training programs for physical therapists on the performance of children with CP, and the QOL and the burden on their caregivers.

1.2 Operational Definitions

Family-professional collaboration: mutual respect and confidence, sharing of information and skills, open communication, engagement in decision-making, and methods that integrate family beliefs, priorities, and needs into intervention (5-7).

Professional: health care providers. In this study, the health care provider is the physical therapist.

Child performance: means children's progression towards attaining their interventional goals.

Relational practices: means a practice that consists of those interpersonal behaviours like warmth, empathy, active listening, authenticity and seeing parents in a positive light (32, 33).

Participatory practices: means a practice that is more action-oriented and involves control and methods of sharing. The therapists share all of the information with families, encourage parents to make their own decisions, encourage families to use their existing knowledge and capabilities, and aid families to gain new skills (32, 33).

Family-professional collaborative model (4 strategies): the model involves four strategies for the collaborative intervention process:1) Mutually agreed-upon goals, 2) Shared planning, 3) Shared implementation, and 4) Shared evaluation of child and family outcomes.

Cerebral palsy (CP): "describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to nonprogressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour; by epilepsy, and by secondary musculoskeletal problems" (26).

Quality of Life (QoL): is defined by WHO as "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (34).

Burden: is defined as "a multidimensional response to physical, psychological, emotional, social and financial stressors usually associated with the experience of caring" (35).

1.3 Research Questions

1- Does the training program of the family-professional collaboration for physical therapists affect the performance of children with CP towards attaining their intervention goals?

2- Does the training program of family-professional collaboration for physical therapists affect the caregivers’ QOL?
3- Does the training program of family-professional collaboration for physical therapists affect the caregivers’ burden?

1.4 Objectives of the study

1. To examine the effect of the training program of family-professional collaboration for physical therapists on the performance of children with CP towards attaining their intervention goals.
2. To examine the effect of the training program of family-professional collaboration on the QOL of caregivers of children with CP.
3. To examine the effect of the training program of family-professional collaboration on the burden of caregivers of children with CP.

1.5 Hypotheses

Null hypotheses:

1. The training program of family-professional collaboration for physical therapists does not affect the performance of children with CP towards attaining their intervention goals.
2. The training program of family-professional collaboration for physical therapists has no effect on the QOL of caregivers of children with CP.
3. The training program of family-professional collaboration for physical therapists has no effect on the burden of caregivers of children with CP.

1.6 Significance of the study

Family-professional collaboration has a vital role in setting meaningful goals for children and their families and implementing the intervention within the family conditions as it is identified, based on the family’s needs and priorities. It provides a great probability of improving children’s goals accomplishment and caregiver well-being, the feeling of competency, and more engagement in intervention. However, delivering services tailored to the children and their caregiver’s needs is challenging for professionals. This area needs more investigation to increase knowledge about the collaborative intervention and its implication on the outcomes of different children’s conditions and their caregivers. Such as, the outcomes of the children with CP and their caregivers because they suffered from postural and movement impairments that require long-term care from their caregivers.

This research is important because it examines the training program for physical therapists on the collaborative intervention (four-steps process) that is designed to fit the children and their family’s needs, preferences, and routines.

Furthermore, this research might enhance the use of the procedures and strategies of the family- professional collaboration (four-step process) for optimizing the children performance and their caregiver’s QOL and burden. The findings of this research could increase the awareness of physical therapists regarding the importance of the collaborative intervention process and its reflection on children's performance and the QOL and burden of their caregivers.

In addition, the obtained knowledge could assist organizations in improving the services quality assurance program and improving professional practice for those who treat children with CP in rehabilitation settings. Also, it facilitates further research to improve the collaborative intervention process.

CHAPTER II

LITERATURE REVIEW

Chapter 2. Literature Review

This chapter aims to define and explore the key concepts related to this study. It begins with introducing the core ideas around family-professional collaboration and the component of the four-step process to implement the collaborative model in physical therapy sessions in pediatric rehabilitation. It will then outline the critical interpretation of different studies on collaborative intervention and children's performance, and caregivers' QOL and burden, with a rationale for the relevance of this study.

2.1 Family-professional collaboration

The service delivery models for children with disabilities and their families have highlighted the family contribution to rehabilitation (25, 36-38). Family engagement in the process of the intervention and making the services fit the child and family requirements and priorities are challenging parts of family–professional collaboration (39-42). The researchers reported that professionals look to develop collaborative relationships and produce collaborative relationships with families by giving families information and skills associated with interventions, and they reduce parents' concerns and requirements (43-45).

Therapists reported that they spend a lot of time revising home instructions and explaining the handling and positioning methods to the family, whereas they spend less time concentrating on other needs of the child and the concerns and needs of the family (25, 44). Together, families and professionals suggested that professionals are effectively providing certain information linked to the health condition of the child, and that the collaboration process with families to meet their needs and concerns is an element that needs to be improved (39-41). Even though professionals indicated the significance of providing knowledge, including involving family members in decision-making, assisting families to obtain services, and considering individuals as unique while services were provided, these ideas are not constantly reflected in how the services are delivered (41). This discrepancy revealed the deficiency of knowledge of collaborative intervention processes. Many literatures reinforce the effectiveness of family–professional collaboration. However, there is inadequate research on methods and strategies that encourage collaboration (e.g., how therapists and families mutually agreed on the goals and identified roles and responsibilities when planning and implementing the intervention). Moreover, The researchers found physical therapists believed in collaborative goals setting with parents (86%) and children (66%) to a great extent whereas (69%) of physical therapists stated applying collaborative goals setting with parents to a great extent in comparison to (39%) with children (46).

An and Palisano (2014) have developed a family–professional collaboration model for pediatric rehabilitation (25). This model consolidates the philosophy of FCC and adds to the abilities and strengths of the family (6, 33, 47). It consists of three fundamental principles: (1) family identified needs; parents of children with disabilities have strengthened the importance of taking into account families in the wider context of their lives and delivering services that fit the family's unique requirements; (2) shared responsibility: in a collaborative approach, professionals have information and skills related to health conditions, development of the child, and intervention processes and families who are the best authorities on their children's personalities, interests, strengths, and challenges. Professionals and families discuss choices, share ideas, opinions, decision-making, and the responsibility to select and implement interventions. Sharing responsibility leads to optimizing the family's desired goals achievement; and (3) family empowerment: engaging parents in providing collaborative service is assumed to increase their feeling of control and worthiness (25).

The Family–Professional Collaboration model includes a four-step process. Step 1(mutually agreed upon goals), the collaborative process, starts with discussing the family’s requirements correlated to child development, preferences, and everyday routines. This discussion results in mutual agreement on intervention goals. Step 2 (hared planning), the intervention planned by family and professionals. The mission of the family and professional is agreed, and interventions are integrated into the family's everyday routines. Step 3 (shared implementation), family and professionals participate in implementing the intervention that involves the shared application of the intervention. While the intervention process is individualized, engaging the family is necessary for the implementation and progression of the intervention plan and for constructing the capability of both family and professional to encounter the family's known needs. Step 4 (shared evaluation child and family outcomes), evaluation of child and family outcomes. The evaluation process of the individualized outcomes is carried out from the family and professional perspectives. Also, they discuss the changes, successes, and challenges and therefore define whether or not the goals were accomplished (25). The distinctive characteristic of the collaborative intervention process is the implementation of strategies that ease family–therapist interaction involving *the client-centred interview process of the Canadian Occupational Performance Measure (COPM)* (by exploring the child’s interests and needs, identifying family priorities, and rating the child’s current performance), *visualizing a preferred future* (by determining a specific, observable goal), *scaling questions* (by rating a preferred future, identifying the process towards the preferred future) and *family routine and activity matrix* (by identifying activities to practise, identifying possible times to implement the activities and identifying roles of family members and therapists (48). The strategies and examples of questions implemented by the therapist to foster collaboration are summarized in (Appendix 7). Family–professional collaboration is a continuous process and all the four-step processes of collaboration are iterative and cyclic, as shown in (Figure1).

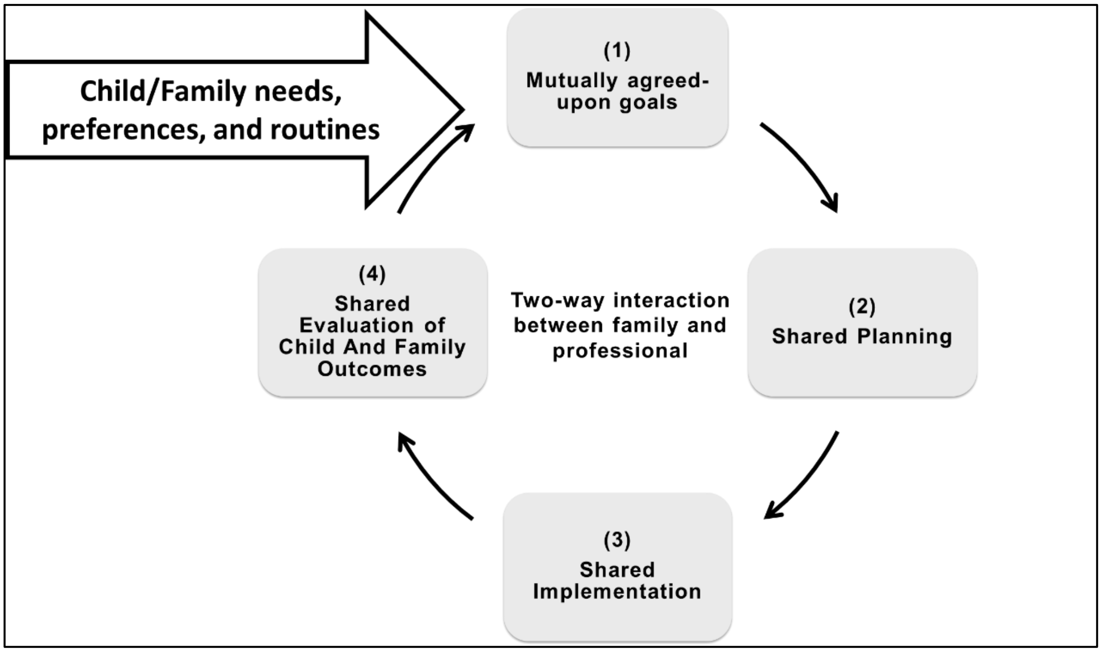

Figure 1: Model of the family–professional collaboration: a four-step process of collaborative service delivery.
Reproduced from An and Palisano (25).

2.2 Family-professional collaboration and children's performance

Utilizing the collaborative approach in interventions means the development and the application of treatment taking into consideration the child and family-identified goals for children with disabilities. It has shown improvement in the child's development, and the performance of functional tasks and goals achievements (11-13, 15, 16). The COPM and Goal Attainment Scale (GAS) are two common examples of individualized tools for goals setting that have been successfully used in pediatric rehabilitation (11, 13, 25, 49-53). These tools are flexible, consistent and provide accommodation for various individualized objectives of children and their families. Regarding GAS administration, there is no specific qualification or accreditation required. However, some training is recommended because the nature of GAS needs high-level communication and problem-solving skills by professionals. GAS has advantages over the COPM because it is free and more flexible. These properties make GAS a suitable outcome measure if the rehabilitation program or the study objectives relate to family-directed goals. Additionally, GAS might be helpful if the study requires unique goals, which can be hard to assess with a more standardized tool (54).

The collaboration process suggests allowing children to perform and achieve intervention goals through everyday activities (10, 11). In a randomized trial, children who underwent task-oriented strength training and functional tasks practice showed significant improvement in gross motor activities compared to children who went through an intervention focused on normalization and facilitation of movement patterns (55). Additionally, one randomized trial conducted by therapists concentrated on altering the motor skills that the child requires to perform the function within their usual living environment founded on the child or parent-specified goals. This method was more effective in attaining self-care and motor outcomes than the therapeutic method that concentrated on the quality of movement (45). Also, a study conducted by Lowing et al

(2009). found significant advancements after goal-directed, activity-focused therapy compared to activity-focused therapy in self-care, motor capacity, and mobility (56).

Furthermore, a two-case report examined the acceptability and feasibility of the family–professional collaboration model (four-step process) developed by An et al (2016). The interaction of mother–therapist was described by mutual sharing of knowledge and open communication in a supportive manner. In addition, the two mothers and two therapists reported that the therapists involved the mothers in the intervention process and suited the interventions to family and child needs (57). Subsequently, the same researchers conducted a randomized control trial (RCT) that included children with different physical disabilities (diagnoses: CP, arthrogryposis multiple congenita, Down's syndrome, Prader-Willi syndrome, moyamoya disease, and developmental delay), their families and physical therapists. The therapists treated the children either in the clinics or in their homes for six weeks (one intervention session per week); they found child performance and satisfaction on the (COPM) and the Family Empowerment Scale improved in the two groups ($p<0.05$), but no differences between groups ($p>0.05$). Nevertheless, the effect size for change in child performance ($d= 0.73$) and satisfaction of the parent ($d=1.08$) on the (COPM) favoured the experimental group subjected to the collaborative intervention (1). The current study examined the effects of the same collaborative intervention process including only children with CP and conducted in one rehabilitation setting for all children.

Further, RCT was conducted by occupational therapists who applied the five-step Occupational Therapy Home Program (OTHP) process. These steps are: 1- establish a collaborative relationship, 2- identified mutual family-child goals, 3- determine activity or intervention suitable to goals, 4- support parents by telephone or home visit and 5- evaluate outcomes. The study included children with CP aged 4-12 years and all Gross Motor Function Classification System (GMFCS) levels distributed into three groups: 8 weeks OTHP, 4 weeks OTHP, and no OTHP therapy. They found both groups with OTHP more effective and the children met their interventional goals better than with no OTHP (58).

Additionally, the study compared a child-focused approach, a context-focused approach, and a regular care approach. The study involved children with CP aged between 18 and 47 months and all GMFCS levels. The two approaches began with setting goals and selecting the treatment plan. Initially, therapists made a needs analysis of the strengths and weaknesses of each child and their environment. Secondly, therapists in a child-focused approach utilized the body function and structure domain of the International Classification of Functioning, Disability and Health for Children and Youth ICF-CY as a starting point.

In contrast, therapists in a context-focused approach utilized the environmental factors of the ICF-CY as a starting point. The therapists in child-focused and context-focused approaches received one-day training on the goals setting and intervention process. The results indicated that all approaches were significant without differences between them in self-care and mobility abilities after six months (59).

Moreover, Pollock et al.'s study (2013) included children with CP aged 1- 5 years and GMFCS levels between I-V, and used the context of CP children who received the context-focused intervention. The problems prioritized by their families by completing the COPM established the foundation of the activity goals for the intervention. The researchers found the children had significant positive changes regarding parent-identified activity goals using the COPM (60). The next part of this chapter will discuss family professional collaboration and caregivers' outcomes (QOL and burden).

2.3 Family-professional collaboration, caregivers' quality of life and burden

As has been illustrated in the literature, family–professional collaboration is deemed to be one of the most significant supports those services offer to the families (7, 61-63). Moreover, Summers et al. (2007) reported that collaboration becomes a mediator for the QOL experienced by the families (64). In countries like Australia, the United States and Turkey, the sufficiency of the supports which met the family needs (provision endorsement meets the families' actual needs) and the family–professional collaboration has an impact on caregivers QOL (61, 64-66). Furthermore, in Spain, the results showed that the degree of satisfaction of caregivers with the support was a good predictor of QOL (67). The ratings of collaboration quality were considered a vital factor interceding this effect, which is consistent with Summers et al.'s (2007) result.

Accordingly, the level of support adequacy and the family–professional collaboration becomes essential in evaluating the efficacy of the services (67). The caregivers' QOL is inversely proportional to caregivers' levels of burden, as parents of children with chronic illness have low levels of QOL associated with high levels of caregiving burden (68, 69).

Apparently, when service is based upon the needs and preferences of the family, and when the family obtains sufficient and well-timed information while the collaborative partnership with health professionals is encouraged, the family may encounter less burden accompanying their caregiver’s role; hence, an expected positive impact in QOL is to be noticed (19-21). Therefore, the collaboration process was recommended in pediatric oncology services to lower the caregivers' burden level (70).

Regarding the literature, a study was conducted by experienced occupational therapists who received training on providing treatment based on client-centred occupational therapy guidelines for patients with dementia. The intervention comprised ten, one-hour sessions for five weeks and concentrated on both patients and their caregivers. The first four sessions included diagnostics and goal identifying. Also, both patients and informal caregivers learned to select and prioritize activities that they wanted to improve. For this, the occupational therapist utilized three client-centred narrative interview instruments: first, the Occupational Performance History Interview-II (OPHI-II) directed at the patient; second, the ethnographic interview for the caregiver; and third, the COPM for both patient and caregiver. In the other six sessions, patients were educated to enhance the compensatory and environmental strategies to increase their daily activities performance. Their caregivers were trained in cognitive and behavioural interventions for adequate supervision, problem-solving, and coping strategies. These strategies improved QOL for both patients and their caregivers more than those who did not receive it (71).

furthermore, one clinical trial was conducted in the psychiatric field to address the influence of using the collaborative care model on the care burden of the families of patients with mental disorders. The study involved caregivers such as father, mother, sister, brother, spouse, child, son and daughter-in-law. The model implemented in the intervention group consisted of motivation, preparation, engagement, and evaluation phases which clinical psychologists and nursing staff delivered for 11 weeks. The researchers found that the intervention group had a significant reduction in the level of care burden compared to the control group, after applying the collaborative care model (72).

Moreover, in RCT a single-blinded study aimed to examine the effect of collaborative dementia care on the burden level of caregivers of patients with dementia. The study involved spouse, domestic partner, daughter, son, sibling, other family members, hired caregivers and friends. The intervention was delivered through telephone and internet by a trained care team who offered education, support and care coordination with team specialists like an advanced practice nurse, social worker, and pharmacist for 12 months, adjusted according to the patient and their caregivers' needs. The trained care team responded to the needs of the caregivers firstly, screened for common problems, and gave personal support and standardized education. This decreased caregivers' depression and burden levels (73). In the physical therapy field, the effect of the collaboration process on the caregiver burden and QOL of children with CP remains unknown.

2.4 Population of interest: Cerebral palsy

CP is defined as a group of permanent neurodevelopment disorders of movement and posture that start in early childhood and continue throughout life (74). The prevalence of CP worldwide is 2.11 per 1000 live births and in Saudi Arabia is 2.34 per 1000 live births (75, 76). Children with CP are usually diagnosed before the age of three (77). This condition is attributed to malformations or brain damage to the child's developing brain through their fetal life or during a short period after birth. The damage is nonprogressive, but it persists throughout the life span, and remains with the children and their caregivers for the rest of their lives (74, 78, 79).

The aetiology and types of CP and the severity of impairments differ between children and depend on the extent of brain damage (77, 80). Traditionally, children with CP are classified according to the type of motor impairments or distribution of involvement. Often, the GMFCS is used to classify the functional level of children with CP (81).

Generally, CP is usually associated with disturbances of sensation, perception, cognition, communication, behaviour, epilepsy, and secondary musculoskeletal problems (78, 79). In parallel, parents of children with CP also encounter difficulties when assisting their children with struggles in their daily lives as they play an essential caregiving role. They need to be alert to their children's needs and physically present(28) .

Contemporary evidence in rehabilitation services for children with CP draws attention to essential concepts. Highlighted is the family-centred service that promotes collaborative decision-making between the therapist, child and family, and expresses respect for the unique situation of each family (10, 82). Further, meaningful therapy goals help the child successfully complete their functional activities (52).

2.5 Conclusion

This chapter included the definition of the key terms and the literature review that showed the gaps in the evidence. The effect of the collaborative intervention was studied widely in some healthcare specialties like nursing and psychology. However, only a few studies examined the effect of collaborative intervention on children's performance in physical therapy. The limitation of these studies was the inadequate sample sizes used to detect the significance level, including different pediatric conditions that may affect the accuracy of the results of changes in the children's performance. Most of the studies incorporated other professional specialties like physical therapists and occupational therapists. In particular, there were limitations in studies that implemented the approach on children with CP; there was variability in participant characteristics such as the involvement of all GMFCS, and most of these studies included young children and were applied in the various clinical settings.

Generally, there is a lack of evidence investigating the effect of collaboration on caregivers' QOL and burden. To the best of my knowledge, no previous study has been conducted in physical therapy field on the caregivers' QOL and burden. Therefore, this study is the first RCT to investigate these caregivers' outcomes. Further, this study has the potential to give physical therapists a framework by which to implement the strategies of the collaborative intervention process and observe its effects on outcomes for children with CP and their caregivers. The following chapter will discuss the methodology employed in this study and give a detailed description of the participants, the setting, and the data collection and analysis process.

CHAPTER III

METHODOLOGY

Chapter 3. Methodology

This chapter illustrates the research methodology used to answer the research questions. The study design, research instruments, and data collection methods are outlined, including sample size and sampling, description and recruitment of participants, protocol of physical therapists' training program, procedures of the data collection process and detailed data analysis plan.

3.1 Research design

The study was an experimental, randomized control trial. A single-blinded design with two parallel groups was used. The physical therapists were randomly assigned to either experimental or control groups as presented in (Figure 2). The physical therapists in the experimental group have treated children using the collaborative intervention process. The physical therapists in the control group have used the routine intervention process. According to their therapist groups, the eligible children and their caregivers were allocated randomly to these two groups referred to in Chapter 4 (Figure 2).

3.2 Participants

The recruitment took place in periods between December 2020 to November 2021. The enrolment of participants in this study was conducted in two stages: first, the physical therapists' recruitment, then second, the children and their caregivers' recruitment. Out of 135 screened children, only 54 children with CP accompanying their caregivers and 36 physical therapists were recruited voluntarily from rehabilitation centres in Riyadh city (Sultan Bin Abdulaziz Humanitarian City (SBAHC) and the

Children with Disabilities Association (CWDA)). The recruitment of the therapists and children with their caregivers followed the following criteria:

3.3 Recruitment and eligibility criteria of the physical therapists

Physical therapists were recruited by sending participation invitations via email. After that, the principal investigator answered the physical therapists' questions by phone or email and selected the training time for the physical therapists who met the inclusion criteria and signed to participate in the study. The inclusion criteria for physical therapists were therapists with at least one year of working experience in the physical therapy field and who could communicate with the child's caregiver using the Arabic language. In addition, the experimental group physical therapists were required to rate their level of confidence in their ability to implement the collaborative strategies 4-5 out of 5 after receiving the training; otherwise, they were excluded from the study. All physical therapists have rated their confidence ≥ 4.

3.4 Recruitment and eligibility criteria of the children and their caregivers

The total number of children with CP and their caregivers signed to participate in the study was 54, who all met the study criteria. They were recruited conveniently from intensive rehabilitation programs. On the admission date, the principal investigator met the child with his/her caregiver to explain the study process and answer their questions to make the participation informed. The eligibility of the children and their caregivers followed the following criteria: ***Inclusion Criteria were*** children with CP, children aged between 2 to 12 years, Gross Motor Function Classification System (GMFCS) level (I, II, and III), and children who attended the physical therapy sessions accompanied by their caregivers (parents, relatives who take care of the child). ***The Exclusion Criteria were*** children who underwent recent surgery or after Botulinum toxin injection treatment, Children with other conditions which could affect the session processes, like an uncontrolled seizure disorder or discontinued physical therapy intervention of the child.

3.5 Sample size calculation

The sample size was computed using the *Power Sample Size and Calculation Program* (version 3.1.6). Based on a previous study report, the calculation to test the differences between two independent groups' means using a two-tailed test was used the child's performance as medium effect size (d= 0.7), with a significance of (0.05), a power level of (0.80).

The result required 34 pairs of participants (children with CP and their caregivers) divided equally between each study group. For the possibility of participants' drop-out, 20% was added to the sample calculation, resulting in 44 participants (experimental group= 22 and control group= 22).

Additionally, an extra 10 participants were added because the data was collected during the COVID-19 pandemic with a higher possibility of drop-out. The final sample was 54 pairs of children and their caregivers. According to the literature, each physical therapist treated 1 or 2 children as a maximum ratio (1). In each group, at least 26 physical therapists were recruited (13 per group)

3.6 Ethical considerations and consent

Before the commencement of this study, ethics approval was obtained from the Institutional Review Board (IRB) at King Saud University (KSU) (No. E-20-4777) (Appendix 1.1), College of Medicine, SBAHC (No.36-2020-IRB) (Appendix 1.2) and CWDA (Appendix 1.3).

All participating physical therapists signed the electronic informed consent form prior to the study starting (Appendix 2.1). Moreover, the caregivers signed the consent form for themselves and their children through the hardcopy form (Appendix 2.2), according to the convention of the IRB. Furthermore, permission was gained to use the Arabic version of ZBI by emailing the publisher.

3.7 Blindness

The study is single-blinded as the participating children and their caregivers were blinded to the study groups (experimental or control group). The principal investigator explained the study information to the children and their caregivers without informing them about which group they were assigned to.

3.8 Randomization and sampling method

The physical therapists and children with their caregivers were recruited in the study conveniently. First, the principal investigator created a list of the physical therapists' names who agreed to participate in the study. Then, the physical therapists were randomly assigned to the study groups using a simple random sampling method (the name of the therapist who was located in an odd number was assigned to the experimental group and the name of the therapist located in an even number was assigned to the control group).

The in-charge therapists were responsible for distributing to physical therapists the eligible pairs of children with CP and their caregivers. The allocation of the participants was based on the physical therapists who treated the child belonging to a particular study group. Therefore, the child was considered in the experimental group if he/she was treated by the therapist who received a training program on the collaborative intervention process (4 strategies), and the child was considered in the control group if treated by the therapist who received no instruction related to the collaboration model (treated using the routine therapy process). Moreover, the details of both study groups were concealed from the in-charge therapists who randomly distributed the children to either an experimental or control group.

3.9 Intervention

3.9.1 Training program for physical therapists

The training protocol was based on the An and Palisano (2014) program with some modifications to fit the current study's purpose and conditions (25). It comprised two instructional training sessions for six hours (3 hours/ session).

The objectives of the first training session were to:1- clarify the purposes of the study and ethical considerations, 2- briefly explain the research instruments (GAS, WHOQOL-Brief, ZBI), and 3- give instructions on the types of goals that would be written for intervention, demonstrate the GAS rating procedures and caregivers' rating of the importance and difficulty of the goal, and writing examples with the physical therapists (Appendix 7).

The objectives of the second training session were to explain the procedure for the collaborative intervention process and provide an example for this practice. physical therapists were given summary material for the collaborative model, and they had time to review it before and during the study conduction. Detailed descriptions of the therapists' training program and implementation of the strategies are described in (Appendix 7).

3.9.2 Implementation of the training program

The program was conducted using online training sessions via ZOOM. The training was provided in subgroups or individualized training sessions for the physical therapists in the experimental and control groups, to suit their availability. The intervention part in this study (family-professional collaboration (four-step process) training) conducted as detailed below:

Specific Strategies and Procedures to Implement the Family-professional Collaboration (four-Step Process):

Step 1 Mutually agreed-upon goals

The aim of Step 1 is to determine mutually agreed-upon goals that are specific, measurable, and achievable within a defined period of time. Mutually agreed-upon goals prepare a base for shared planning and decision-making. The therapist will facilitate conversation to get to know a child's interests, previous experiences, challenges, and family preferences and priorities. To involve the family in goal setting, we will use the client-centred interview process used for the Canadian Occupational Performance Measure (COPM) and ''visualizing a preferred future''.

1. ***The COPM*** is a client-centred outcome measure whose interactive interview process is appropriated for family– professional collaboration.
2. ***The visualizing a preferred future*** is a key strategy of solution-focused conversation. The purpose of this strategy is to enable the family to orient toward positive changes in the immediate future and to determine what will be changed when the intervention plan is successful.

Step 2 Shared planning

The aim of Step 2 is to develop an intervention plan that meets the child and family needs. The therapist facilitates shared planning and integrates intervention into family daily routines by using **‘‘scaling questions’’** and the **‘‘family routine and activity matrix’’.**

1- The use of ***scaling questions*** is aimed at helping the family in estimating meaningful progress towards the accomplishment of a goal, and identifying where or how to start.
2- ***The Family Routine and Activity Matrix*** offers a structure for identifying how to embed interventions into daily family routines.

Step 3 Shared implementation

The parent and therapist continue to work together while applying the intervention and adjust the intervention plan if needed.

Step 4 Shared evaluation of child and family outcomes

The parent and the therapist determine whether the intervention is effective or not, and goals are attained. Self-reporting and individualized outcome measures are recommended. In our study we will use the Goal Attainment Scaling (GAS) system to determine if the goal is reached.

Table 1 Strategies and examples of questions by physical therapists to foster collaboration.

Key strategies	Example questions
Step 1. Mutually agreed-upon goals.	
Client-cantered interview process [a]:	
– Exploring child's interests and needs	''What does your child/family like to do?'' ''What are some activities that your child would like to do?'' ''Has your child tried the activity?'' (In response to a desired activity) ''Is there a particularly difficult part of this activity for your child?''
– Identifying family priorities	''I would like you to imagine a scale 0 to 3. '0' represents being not at all important, '1' a little important, '2'moderately important and '3' represents being very important. How important is it to your family for (child's name) to be able to do this activity?''
– Rating child's current performance	''On a scale of 0 to 3, where '0' means your child does not find it at all difficult to do the activity very well, '1' a little difficult, '2'moderately difficult and '3' represents being very difficult for your child to do the activity at all, where would you say your child is today?'' ''Can you describe how your child does the activity?''
Visualizing a preferred future:	
– Determining a specific, observable goal for the immediate future	the immediate future ''In 2 months (upon completion of intervention), when you see your child performing the activity, what might make you say, 'Wow, something is different, he is doing well!''
Step 2. Shared planning	
Scaling questions:	
– Rating a preferred future	''On the same scale of 0 to 3 that you used to rate your child's current performance of the activity, where would you say your child will be in 2 months when the intervention is successfully completed?''
– Identifying process towards the preferred future	[if a parent rated 1 as child's current performance and 2 as performance upon completion of intervention] ''What would be the differences between 1 and 2?'' ''What do you suppose is needed to move your child from 2 to 3?'' ''How can I help?''
Family routine and activity matrix:	
– Identifying activities to practise	''What do you think needs to occur for your child to achieve (the goal)?'' ''Is there anything you and/or your child are doing at this time?'' ''How are things going?''
– Identifying possible times to implement the activities	''Can you tell me about a typical day routine for your family?'' ''Are there especially good times for your child and family to work on this activity?'' ''Are there especially bad times when it would be very difficult for your child and family to practise this activity?''
– Identifying roles of family members and therapists	''Who will be responsible for carrying out this activity with your child at (a specific time)?'' ''How will you/your family support your child while carrying out the activity?'' ''Is there anything your family needs to carry out the activities?'' ''How can I support your child and family?''
Step 3: Shared implementation	
Family's reflection on intervention	''How have things gone since our last sessions?'' Follow-up questions depending on response: ''What did you/your child like the best?'' ''What was difficult?'' ''Were there any changes in your child's performance?'' ''Do you have questions or concerns about your family carrying out (the activities) as we planned?'' ''How do you think we should change the plan?''
Step 4. Shared evaluation	
Family evaluation	''On a scale of 0 to 3, where '0' is not at all difficult to do the activity (very good performance) and '3' represents being very difficult for your child to do the activity at all, where would you say your child is today?'' ''Can you describe your child's current performance of (the activity)?''
Guiding to a new goal	''We can continue to work on this activity for better performance or determine a new goal. Which one do you prefer?''

Interview questions adapted from the Canadian Occupational Performance Measure (COPM) and Goals attainment Scale (GAS).

Adapted from: An and Palisano (25)

3.9.3 Evaluation of physical therapists

Physical therapists in the experimental group rated their confidence level to implement the four strategies for the collaboration model using a five-point Likert scale (5=greatly confident, 4= fairly confident, 3=moderately confident 2=somewhat confident, and 1=not at all confident). If the therapist rated the confidence level ≤ 3, they received further individual demonstration sessions for identified difficulties to ensure their ability to apply the collaborative model and they evaluated their confidence level again if still same they excluded from the study. The defined inclusion criteria for the confidence level of the physical therapists were ratings of 4 or 5 for the collaborative model and no physical therapists were excluded for this reason.

3.10 Procedures and data collection process

The training program for physical therapists was completed before the recruitment of children. The physical therapists in the experimental group received two instructional training sessions and procedural fidelity was ensured through several strategies. The physical therapists were asked to rate their confidence by executing four strategies for collaborative intervention with children by the end of the second training session. physical therapists with confidence levels ≤3 received an additional individualized training session. Consequently, they evaluated their confidence level (if the confidence level remained ≤ 3, they were excluded from the study). The physical therapists were also asked to practise collaborative strategies with the children who were under treatment at that time and report any difficulties they faced to the principal investigator for further clarification. Further, the physical therapists in the experimental group have been asked to keep the information regarding the family collaboration model confidentially and not share it with physical therapists in the control group. All participating physical therapists in experimental and control groups were licensed as physical therapist practitioners, and they received the same training on GAS. physical therapists in the control group did not receive training on the collaborative intervention process, they only received the first training session.

The pairs of children and their caregivers were assigned to the physical therapists after the caregiver completed the demographic information sheet, the first assessment of the WHOQOL-Brief and ZBI questionnaires.

The participating physical therapists treated children according to their groups. The children received the therapeutic session as below (Table 2):

Table 2 Details of the physical therapy session

Session 1	Perform assessment and determine the intervention goal.
Session 2	Planning the intervention and starting implementation of the intervention.
Session 14 or 15	Re-assessment for child performance towards achieving the intervention goals using GAS (first assessment).
Other Sessions	Implementation of the intervention
Last session 30	Children’s final evaluation for GAS, and caregivers completing the WHOQOL and ZBI (last assessment).

The intervention goals for children were restricted to everyday or leisure activities at home and community based on the two domains of the International Classification of Functioning, disability, and health for Child and Youth version (ICF-CY), which are activity limited and participation restricted. After the goals were identified, the therapist asked the caregiver to rate the importance and the difficulty level for each goal according to GAS. In children's revaluation for GAS, the physical therapists in the experimental group performed the revaluation according to the collaborative model in contrast to the therapist in the control group performing the revaluation in their normal way of practice. The principal investigator was responsible for obtaining the pre-and post-intervention evaluation for WHOQOL-brief and ZBI for children's caregivers.

3.11 Outcome measures

3.11.1 Demographic information

1- Physical therapists' information:

The physical therapists filled out the demographic information after signing the consent form using an electronic form which consisted of; name, nationality, age, contacts information, level of education, number of clinical experiences in physical therapy generally and in the pediatric field and the working place.

2- Children's and their caregiver's demographic information

The caregivers filled out the Sociodemographic sheet; the information included information for the child and the caregivers and the child's family (Appendix 7). Also, the physical therapists filled the Clinical Characteristics Sheet for the children (Appendix 7).

3.11.2 Goals Attainments Scale

GAS is an outcome measure that enables goals to be suited to the unique requirements of each patient and quantifies meaningful change, clinically using a standardized scoring procedure which is as well allows the comparison of goal achievement across groups and individuals (83). The usability of GAS as an outcome measure in rehabilitation research or treatments for disabled people, such as pediatric rehabilitation is increasing. GAS showed good inter-rater reliability when written by physical therapists (κ = 0.73) and good content validity as long as the person who wrote the goals had adequate experience (84, 85). Furthermore, it displayed excellent sensitivity to change, as has been verified in different contexts and populations (86-90). GAS consists of a 5-point Likert scale where (-2) is the lowest score at the baseline level, (-1) mean progression toward the goals but not reached (0) representing the expected level after the intervention (+1) showed better level than expected (+2) is the highest score which means the best possible level (Appendix 5) (91).

GAS is analysed by transforming the goal achievement rating to the T-Score, a standardized measure with a mean of (50) and a standard deviation of (10). Consequently, if the goals were met, the T-score was 50; exceeding goal expectations resulted in a T-score higher than 50 and failing to achieve goals resulted in a T-score of less than 50 (92, 93). In This study, the outcome scores of the goals were converted using a computerized program that calculates the baseline score, the T-Score (achieved score), and the change score through an available spreadsheet calculator (94).

3.11.3 World health organization quality of life- Brief

The WHOQOL-BREF is a self-report questionnaire used in the current study to assess the QOL of the caregivers. The questionnaire is a short version of WHOQOL-100 that focused on measuring the respondents' perception for two weeks preceding the administration (95, 96). It consists of twenty-six items to measure the four domains of QOL that are identified by WHO; physical health (7 items which are: Q 3, 4, 10, 15, 16, 17and 18), psychological health (6 items which are: Q 5, 6, 7, 11, 19, and 26), social relationships (3 items which are: Q 20, 21, and 22), and environment (8 items which are:

Q 8, 9, 12, 13, 14, 23, 24, and 25); and the first two items are concerned with the general perception of QOL(Q1) and health satisfaction (Q2). These items scored on a five-point Likert scale ranging from (1) mean strongly agree to (5) mean strongly disagree; the overall QOL calculated by responses mean scores of each subscale (97). Previous studies identified that the cut-off point was ≥60 points for adequate levels. The closer grade to 100 revealed higher QOL and 0 is the lowest QOL (98). The questionnaire computed by transforming the row scores on the four domains to 0-100 to align with WHOQOL-100 (99).

The translation of the Arabic version showed good validity and reliability, where the Test-retest reliability for the full questionnaire was (0.093) using the intraclass correlation coefficient (ICC). Also, the examination of Internal consistency using Cronbach's Alpha was ≥0.70 for the full questionnaire. Of the 24 items that formed the domains, 21 met the item internal consistency requirement of correlations ≥0.4 with the equivalent domain, whereas 16 met the item distinctive validity criterion with greater correlations of their equivalent domain than with other domains. Domain scores differentiated significantly between well and unwell groups. Moreover, the internal consistency (IC) of WHOQOL-brief in children with chronic illness was α-C = 0.84. this version has been used in the current study (97)(Appendix 3).

3.11.4 Zarit Burden Interview-short version

The Zarit Burden Interview (ZBI) is one of the common tools used to measure caregiver burden (100). The short version of the ZBI consists of 12 items scales that enable the clinician and researcher to assess the caregiver burden quickly without affecting the validity. These items are rated on a 5-point Likert scale from (0) which represents never to (4) almost always. The total score ranged from 0 to 48, where a higher score demonstrates more sense of burden (101). A score 17 or more was known as a high burden level. The Arabic translation of the short version was published by Bachner, Y. G.(101). exploratory factor analysis supported that short version has a two-factor structure similar to the original ZBI scale (personal strain and role strain) (101, 102). Both factors represented sufficient internal consistency (ά= 0.89 and ά=0.77,) respectively (102). The concurrent validity of the Arabic language version found a significant negative association with caregiver well-being and associating positively with depression and emotional exhaustion. The Arabic version is useful tool for measuring the caregiving burden (Appendix 4) (101).

3.11.5 Gross Motor Function Classification System

GMFCS is used as an international language to categorize and provide standardized descriptions of gross motor function levels of children with CP (103, 104). GMFCS involves five levels that illustrate the typical performance of children at home and the community, rather than the optimal capacity detected through motor testing at the clinic (105, 106). It is a valid and reliable classification tool and useful for children with CP up to 18 years (105-110). In this study, GMFCS was used to determine the inclusion criteria for children. (Appendix 6).

3.12 Data analysis

Data analyses were processed using IBM SPSS Statistics for Windows, version 28 (IBM Corp., Armonk, N.Y., USA). The Shapiro-Wilk test was utilized to examine the normality of the data for continuous variables. The descriptive statistics were presented as mean and standard deviations if the data were normally distributed or as median and (1st - 3rd quartiles) if the data were non-normally distributed. Frequency and percentage were used to present the categorical data. The comparison between the experimental and control groups at the baseline level was computed using the independent sample t-test for normally distributed data, the Mann-Whitney test for non-normally distributed data and the chi-square or Fisher exact test (if the number of observations was less than 5) for categorical data. Mixed analysis of variance (ANOVA) was used to analyse the effect of physical therapists training on the collaborative model on the group (experimental, control), time (first assessment and last assessment), and group-by-time interaction for all dependent variables (GAS changed rate, WHOQOL-brief domains and ZBI). The effect size was interpreted depending on the guidelines proposed by Cohen (1988), that the effect size considered as < 0.1 = trivial effect, 0.1 - 0.3 = small effect, 0.3 - 0.5 = moderate effect and > 0.5 = large difference effect (111).

CHAPTER VI

RESULTS

Chapter 4. Results

This chapter will present a summary and analysis of the results and outline the study's outcomes in relation to the study objectives.

Results

The Shapiro-Wilk Test showed that data were normally distributed ($P > 0.05$) except for children's age and physical therapists' experience ($P < 0.05$). Generally, 36 physical therapists and 54 pairs composed of children with their caregivers were enrolled in this study. Forty-four pairs (21 in the experimental group and 23 in the control groups) and 28 physical therapists were included in the final data analysis. The reasons for the exclusion of the participants are outlined in (Figure 2)

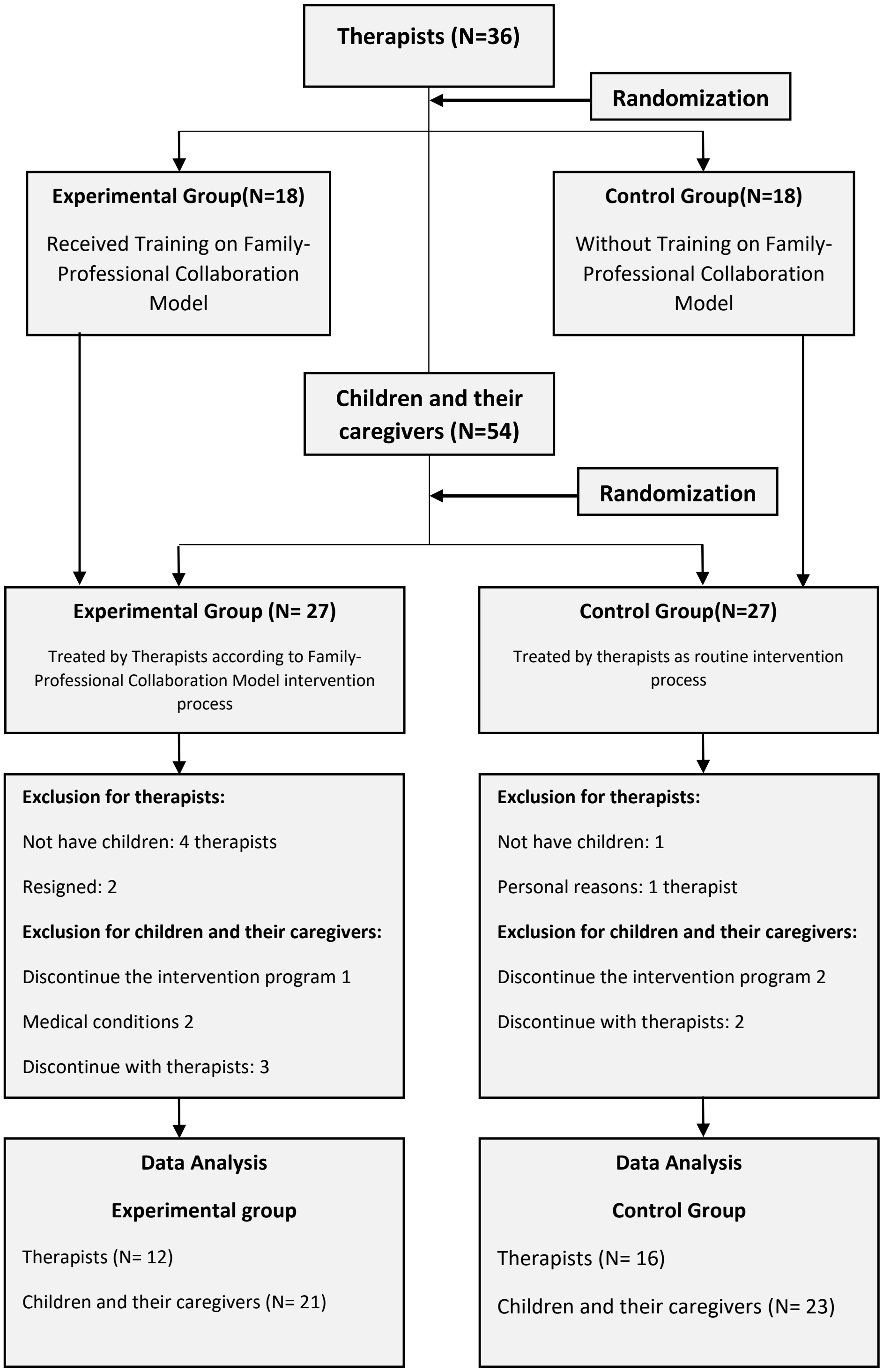

Figure 2 Chart of participants flow and distribution into study groups.

4.1 Participant's characteristics and the baseline comparison between groups

Table 3 Demographic and clinical characteristics of the participant

Characteristics	Experimental group N= 21	Control group N= 23	Comparison at baseline
Children			
Age (years)	6 (4-8)	6 (3-9)	U = 227, *p* = 0.73
Gender:			
Boys	16 (76.2%)	11(47.8%)	X^2= 3.72, *P*=0.054
Girls	5 (23.8%)	12(52.2%)	
GMFCS levels:			
Classification (I)	0 (0%)	1(4.3%)	Fisher exact test, *P*=0.49
classification (II)	6 (28.6%)	5(21.7%)	
classification (III)	15(71.4%)	17(73.9%)	
Caregivers			
Number	21	23	-
Age (Years)	35.90 ±7.20	34.04 ±6.78	t(42) = 0.063, *p* = 0.38
caregivers' Education:			
Secondary or lower	7(33.4%)	10 (43.5)	X^2= 8.30, *P*= 0.307
Bachelor's Degree or higher	14(66.6)	13 (56.5%)	
Working status:			
Full time	10 (50%)	6 (27.3%)	X^2= 2.295, *P*= 0.13
House	10 (50%)	16 (72.7%)	
Financial level:			
<3000	1(4.8%)	2(8.7%)	Fisher exact test, *P*=0.98
3000-6000	6 (28.6%)	6 (26.1%)	
6001-9000	5 (23.8%)	7 (30.4%)	
9001-12000	4 (19.0%)	4 (17.4%)	
>12000	5 (23.8%)	4 (17.4%)	
QOLWHO- brief Domains:			
Physical health	65.90 ±16.720	70.83 ±16.322	t(42) = -.771 *P*= 0.445
Psychological health	65.00±17.544	66.61 ±17.466	t(42)= -.161,*P* = 0.87
Social relationships	67.75 ± 19.177	79.35± 19.915	t(42)= -1.869,*P*= .069
Environment	62.65 ± 17.098	67.57 ± 12.591	t(42)= -.897, *P* = 0 .375
ZBI	16.2 ±7.25	10.26 ± 6.38	t(42) = 2.396, *P*= .021*

Data are represented as mean ± SD unless otherwise stated. Data represented as median (1st –3rd quartiles) for children age, frequency and percentage for (Gender, GMFCS, caregiver's education, working status and financial level). %= percent, U= Mann-Whitney, X^2=chi-square, t= independent simple t-test, GMFCS= Gross Motor Function Classification System, QOLWHO- brief= world health organization quality of life brief, ZBI= Zierat Burden interview. Significant difference P<0.05.

The 28 physical therapists with a median experience of 4.5 (3-16.5) years were included in the analysis. 16 physical therapists in the control group were 3 (18.8%) male, 13 (81.3%) female and 12 physical therapists in the experimental group were 5(41.7%) male and 7(58.3%) female.

The data of 44 Children with CP aged between 2 to 12 years old with a median of 6 years (3.25 - 8.75) were computed. The children's GMFCS levels were 1(2.3%) classification (I), 11(25%) classification (II) and 32(72.7%) classification (III). All Children were accompanied by their caregivers, where mothers represented 34 (77.3%) and other relatives10 (22.7 %). The other participants' characteristics are detailed in (Table 3).

At baseline, the Mann-Whitney test indicated that there were no significant differences between physical therapist experience in the experimental group median of 5.00 (2.25 - 17.75) and in the control group median of 4.00 (3 - 13.75), (U= 84, *P*= 0.599). Moreover, there were no significant differences between the children's age in the experimental group median 6 (4 - 8) years and the control group median 6 (3 - 9) years, (U = 227, p = 0.73).

Additionally, the comparison between the two groups for (CP classification, children's gender and caregiver's education, work status, and income are detailed in (Table 3). Based on the independent t-test, there were no significant differences between the groups in the (WHOQOL- brief domains) for the caregivers (Table 3). However, the levels of caregivers' burden were significantly higher in the experimental group at the first assessment (P= .021) (Table 3).

4.2 Effect family professional collaboration

To study the main effect and interaction of the physical therapists training to apply the collaborative model on the dependent variables (changed in GAS rate, WHOQOL-brief domains and ZBI), data were analysed using a mixed analysis of variance (ANOVA) considering the within-subjects factor of Time (first assessment and last assessment) and a between-subject factor of Groups (control and experimental).

Levene's test indicated homogeneity of variances between the groups and equal covariances according to Box’s M test ($P>0.05$).

4.2.1 Effect of family professional collaboration on children's performance

There was a main effect of time on GAS changed rate F (1,42) = 10.76, $p = 0.002$, $\eta p^2 = 0.20$ which is considered a small effect, but there was no main effect of Group, F (1, 42) =0.94, $p < 0.44$, $\eta p^2 = 0.02$ which is reflected trivial effect. Both groups showed improvement in GAS change rate with no significant differences between them. However, an interaction between time and group were presented on GAS changed rate, F (1, 42) = 4.53, $p = 0.04$, $\eta p^2 = 0.10$ small effect (Figure 3). Most of the improvements for the control group happened during the first weeks of physical therapy intervention. The children showed a higher GAS change rate during the first assessment (19.11, SE 1.48) and the rate of change was decreased during the last assessment (11.08, SE 1.44). While the experimental group revealed no significant differences in the rate of GAS changes between the first and last assessment (14.49, SE 1.55; 12.78, SE 1.51) respectively. Moreover, the experimental group showed greater changes than the control group in the last assessment. However, the change did not reach the significance level.

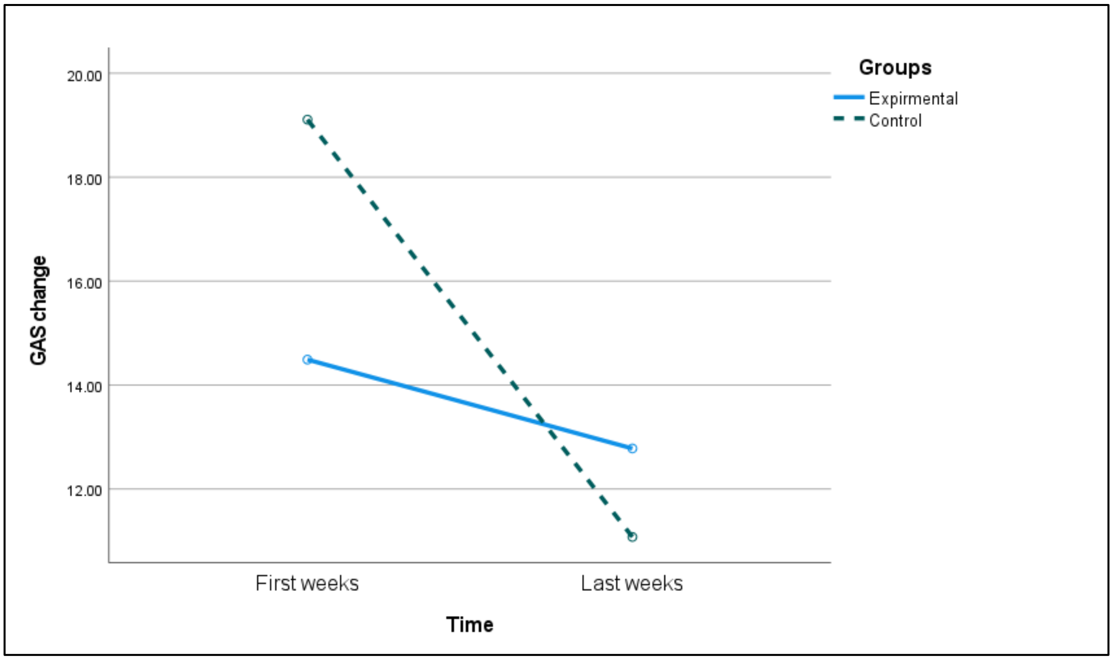

Figure 3 Interaction between time × group for GAS (first assessment and last assessment)

4.2.2 Effect family professional collaboration on caregivers' quality of life and burden

There were no main effects or interaction of time or group reported on quality-of-life domains (Table 4). Furthermore, There were no main effect of time on Burden F (1,42) = 0.87, *p* = 0.36, $\eta p^2 = 0.02$ but there was a main effect of Groups F(1,42) = 5.06, *p* = 0.03, $\eta p^2 = 0.11$. The burden was decreased for the experimental group from 15.43± 1.56 (SE) in the first assessment to 13.38 ± 1.51 (SE) in the last assessment after applying the collaborative model, but the control group had a slightly lower result in the last assessment (9.74, SE 1.44) rather than first assessment (10.26, SE 1.49). Although there was a mean difference between experimental and control at baseline (mean differences 4.62 SE 2.14 *p*= 0.04) in the favoured to control group, the differences decreased after the intervention (mean differences 1.70 SE 2.09, *P*=0.42), the effect size for experimental was moderate effect (0.31) and for control was small effect (0.12). there was no interaction, F (1,42) = 2.46, *p* = 0.12, $\eta p^2 = 0.06$ (Table 4).

Table 4 Result of the effect of the family- professional collaboration on caregivers' Quality of life (WHOQOL-Brief) (within-subjects effect, between-subjects effect and time Group interaction)

	Within-subjects effect			Between subject effect			Interaction		
WHOQOL- brief domains:	**F**	**P**	**ηp2**	**F**	**P**	**ηp2**	**F**	**P**	**ηp2**
Physical health	.559	.459	.013	.606	.441	.014	.019	.892	.000
psychological health	1.778	.190	.041	.455	.504	.011	.635	.430	.015
social relationships	.000	.999	.000	3.071	.087	.068	1.089	.303	.025
Environmental	.007	.344	.021	.965	.331	.022	.007	.934	.000

F=magnitude of effect, ηp^2= Partial eta square (Effect size). significance level <0.05.

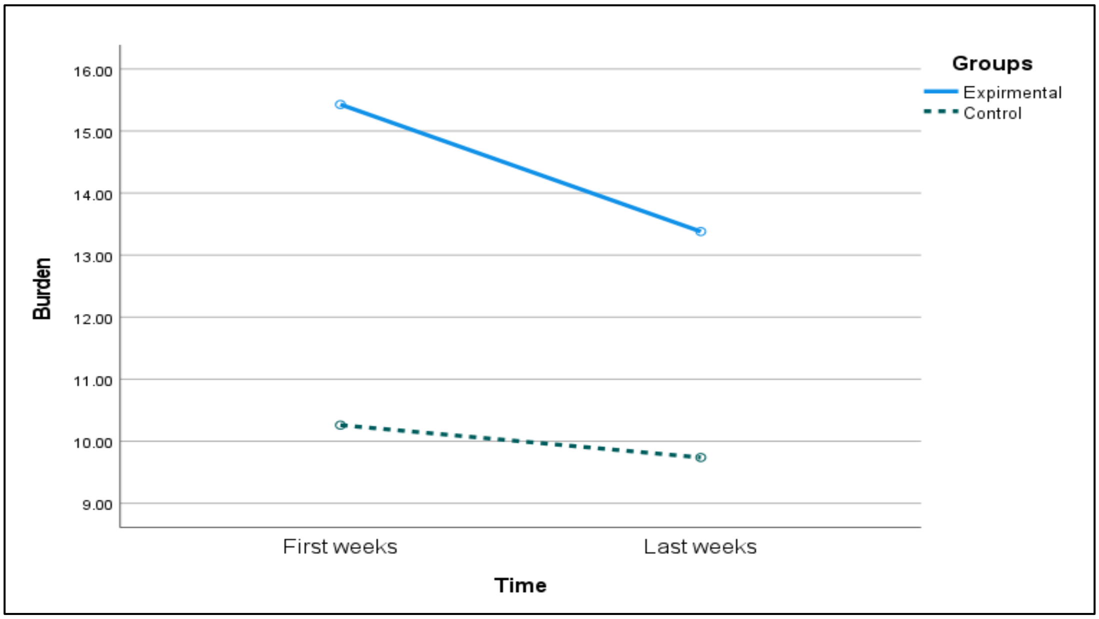

Figure 4 . Interaction between time × group for ZBI (first assessment and last assessment)

CHAPTER V

DISCUSSION

Chapter 5. Discussion

This chapter will address the implications and limitations of the study's results with specific reference to the research questions and the issues discussed in the literature review.

5.1 Discussion

The objectives of this study were to examine the effect of the training program of family-professional collaboration (four-step process) for physical therapists on; the performance of children with CP toward attaining their goals. In addition, it effects on their caregivers' QOL and the burden.

The main findings of this study revealed that children in experimental and control groups showed better performance towards their intervention goals with no differences between groups. However, the experimental groups had greater changes in GAS than the control group in the last assessment but didn't reach significance. In addition, the QOL domains for the caregivers didn't show statistically significant levels within each group and between the two groups. In contrast, the caregivers' burden was significantly different between groups favoured for the experimental group after the intervention.

The therapists' experience plays an important factor in establishing a good relationship and effective communication with the patients, which is reflected in the outcome; as stated, older and more experienced therapists showed effective behaviour that focused on patients' emotions, and were amiable (112, 113). The experience of the pediatric physical therapists who participated in this study ranged from one year to twenty years and showed no statistically significant differences between the study groups (experimental vs control group) (P= 0.599).

The current study's findings showed that physical therapists training to apply the collaborative intervention process had the main effect of time on children's performance in all study groups where the GAS change rate was (p = 0.002) with a small effect of size in favour of the experimental group. Children in both experimental and control groups showed improvement after physical therapy without significant differences between the groups. Nevertheless, an interaction between time and group was presented on GAS changed rate (p =0.04) with a moderate effect size.

These results were consistent with An et al.'s study (2017) that applied the same collaborative four strategies of the current study. The researchers found the children's performance increased in the experimental and control group (p<0.05), but there was no difference between the groups and the effect size of children's performance which changed scores was the medium effect (0.73) in favour of the experimental group when the achievement was measured by COMP.

In addition, in Pollock et al.'s study (2013), the children with CP who were treated by therapists trained to provide context-focused therapy showed significant positive changes on COPM when the intervention goals were identified by their parent. Kruijsen-Terpstra et al's study (2015), showed all three study groups (child focused, context-focused, and regular care approaches) with training delivered by trained physical and occupational therapists had significantly improved, but there was no difference between the groups when measured by COPM and GAS (59, 60). These studies varied in the intensity and duration of intervention for the children and their ages, and included all GMFCS levels in Pollock et al. (2013) and Kruijsen-Terpstra et al.'s study (2015), and children with the different pediatric conditions in the sample of An et al.'s study (2017).

Interestingly in this trial, the control group showed a higher GAS change rate during the first assessment through the first weeks of physical therapy intervention, but the rate of change decreased during the last assessment through the last weeks of physical therapy intervention. In contrast, the experimental group showed no significant differences in the GAS change rate between the first and last assessments during physical therapy sessions. Similarly, the study conducted on children with CP to provide OTHP for the goals selected by the child and family revealed that the four weeks group therapy showed higher performance on both COPM and GAS scores than eight weeks groups without differences between the two groups at eight weeks, and even though results did not reach the significance level (114).

Likewise, eight weeks of occupational therapy home program for children with CP which implemented a collaborative process (5 steps process) yielded statistically significant differences in children's performance and rating of their parent’s satisfaction compared with the control group (no OTHP). In the 4 weeks OTHP group, parents did not terminate the program after 4 weeks, as the parents reported the program as helpful and persisted for 8 weeks. Findings demonstrated statistically significant differences compared with the control group (no OTHP) and there was no difference according to COPM and GAS measurement at baseline, after 4 weeks and 8 weeks between intervention groups (4 weeks and 8 weeks OTHP) (13).

The reasons for the variation are unclear but could be attributed to the commitment and motivation of the children and their families being better for short programs rather than long interventions. Meanwhile, the physical therapists in the control group during the first weeks of the intervention were focused on the children’s treatment. In contrast, the physical therapists in the experimental group were directing the sessions to tailor the child and caregivers’ needs and preferences and actively engaging the caregivers in the treatment of the child by mutually agreeing the interventional goals, discussing the treatment plan, determining the roles during the intervention and motivating the caregivers to share their observations and adjust the interventional plan accordingly. Consequently, it resulted in maintaining the improvement for children in the experimental group throughout the physical therapy intervention period. The supportive evidence indicated that involving the family in goal settings and measuring the change may have benefits for their perception of the performance of their child and the (11, 56).

In addition, the study in the psychological field stated the same results as the current study. Both groups, the experimental group (which received the Memory and Aging Program intervention) and the control group (no intervention), showed improvement in GAS scores toward their goals when identified in a collaborative manner using an interview with trained graduate students with the supervision of a psychologist (83).

Considering the factors which could influence the children's performance towards attaining their intervention goals, this trial included children aged two to twelve years. Pollock et al.'s study (2013) reported that age was only the factor related to the COPM change score as the parent of younger children (lower than 3 years) reported more change. Moreover, studies indicated the same results when measuring the children's changes by the Pediatric Evaluation of Disability Inventory (PEDI) (12, 115). Another study showed a fast rate of change in motor growth curves for young children with CP measured by the Gross Motor Functional Measure (GMFM) (109).

Children with GMFCS levels I to III enrolled in this study to eliminate any differences in performance change rate. The previous study indicated that GMFCS levels were not statistically significant in the group with high COPM change scores and were not associated with change scores. However, the sample size for each level was very small to detect the differences and the GMFCS level was considered clinically important in the achievement of the goals (60). In addition, the age of the children and their GMFCS level were not statistically significant between the groups at the beginning of the current study.

Regarding the goals factors, the intervention goals in the present study were unified to address the activities' limitation and participation restriction domains of ICF. Also, using GAS to measure the total score of change for all goals helped eliminate the differences in achievement scores for each child's identified goals. The authors in a previous randomized trial found minor differences in some goal characteristics which do not serve to conclude that the nature of the intervention goals for children with CP could explain differences in children's performance levels and satisfaction according to their parents' rating on the COPM. This is because children in both groups with the high and low change had a combination of simple and complex goals over various ICF domains (complex goals means involving three or more activities and the simple goals means involving one or two activities) (60). In the present study, each goal involved only a single dimension of change.

Moreover, the studies mostly found that the children have faster and a larger option of change in their performance when focusing on the task and environmental factors than those who needed some learning or practice throughout the period of time (53, 60, 116). The growing evidence showed that the intervention that targeted the impairment of body function and structure made minor changes and may not enhance the performance of the activity goals measured via COPM (49, 60, 117-123).

On the other hand, the outcomes of the caregivers in this study revealed no main effects of the intervention on the caregivers' WHOQOL-brief domains for the first and last assessments or between the experimental and control groups. Additionally, there was no significant effect of the intervention between the first and last assessment on caregivers' burden that was measured by ZBI (*p* = 0.36). Interestingly, there was a positive main effect between groups in the last assessment of ZBI (*p* = 0.03) favoured to experimental group. The effect of the collaborative intervention on the caregivers' QOL and burden has not been addressed before in the physical therapy field and this distinguishes the present study.

Likely, the study that addressed the effect of Collaborative Dementia Care, but the therapy was conducted using telephone and the internet on the caregivers' well-being. The researchers found that the caregivers' burden and depression decreased significantly for the experimental group within 6 months and 12 months compared to the control group, and self-efficacy was increased for the experimental group which showed mostly satisfaction with the intervention (73).

In agreement, Haghgoo et al.'s study (2018), showed that the level of burden for the caregivers of patients with mental disorders reduced significantly in the experimental group who received the collaborative care model after 11 sessions of therapy, compared to caregivers in the control group who received the usual intervention (72).

On the contrary, in the RCT study, older patients with dementia and their informal caregivers showed a significant improvement in QOL and their health status compared to the control group, after applying client-centred occupational therapy guidelines utilized for patients with dementia. The first four sessions were for diagnosis, selecting goals and prioritizing the activities using three different types of client-centred interview instruments: OPHI-II, the ethnographic interview and the COPM) (71).

The caregivers of children with CP have a higher burden level and lower QOL than caregivers of healthy children (124). The previous studies reported that QOL and the burden of the caregivers are associated with the severity of the neurological impairment of CP; the burden increased with a higher level of neurological impairments which leads to deterioration in their QOL (125, 126). In addition, Davis et al. found that children's age correlates significantly with caregivers' burden, where caring for the older children increased the burden on their caregivers (127).

Furthermore, the education level was found to be associated with all QOL domains of caregivers of children with CP Thus, caregivers with a high level of education have improved coping strategies to face the difficulties. Implementing some training programs for caring for their children effectively reduces the burden of care (125, 128, 129). In addition, it found the working status has a significant relationship with the QOL; the working caregivers obtained higher scores of QOL than non-working caregivers. It seems that having good financial resources reduces the stressors and burden and improves physical and psychological wellbeing (82, 125).

The current study showed no difference between the groups at baseline for the WHOQOL-brief domains. In contrast, the first assessment of ZBI was significantly higher in the experimental group (*P*= .021). It could be because the participants were assigned randomly to study groups. Additionally, a previous study indicated that the burden of the caregivers of children with CP has a positive linear relationship with severity levels of anxiety and depression (129). The researchers considered depression as a significant predictor of burden, while anxiety was not determined as a predictor of burden as related to unanticipated life experience (130-133). This study was conducted during the COVID-19 pandemic which may impact the burden and QOL of the caregivers. The noticeable differences in burden between the control and experimental groups may be linked to factors that were not measured in this study.

Unlike the previous studies, the present study focused on one condition (CP), the setting of physical therapy intervention was similar for all the children, and the children in both groups were lived inhouse in the rehabilitation centre for the intensive treatment. Further, it included only the physical therapists to deliver the service to the children and their caregivers. Despite the importance of the study’s findings, the present study has some limitations that should be considered.

5.2 Study limitations

1. The study was implemented during the COVID-19 pandemic which may affect the caregivers' QOL and burden.
2. The pandemic limited the children's treatment period, which for a lengthy period prevented the researchers from collecting the data.
3. The study didn’t measure the caregivers' anxiety and depression levels, which could affect the QOL and burden and cause the differences in burden between the study groups at baseline.
4. The therapists in the control group weren’t blinded to the study objectives which may affect their interactions with the children and their caregivers during the sessions.
5. The study was a single-blinded design.
6. The study only evaluated the short-term effect of the intervention.
7. The study involved the various relationships of the caregivers to the children (mothers, fathers, sisters, and aunt), which might affect the QOL and burden.

5.3 Recommendations

1. Conducting a randomized control study with a double-blinded design is recommended.
2. Further studies are needed with a larger and matched sample.
3. Studies conducted to apply the collaborative model to different conditions and different rehabilitation settings.
4. Studies to address the effects of the collaborative model’s different children’s and their caregivers’ outcomes.
5. Studies with longer intervention duration and follow-up after intervention are needed.

6. A study to consider the assessment of anxiety and depression of the caregivers at baseline.
7. A study that unifies the assessment of the children by one assessor.
8. A study involving an equal number of children for each therapist, to avoid the learning effect.

5.4 Implications for Practice and Education

Based on this study's findings, the physical therapists in experimental group were capable of applying the family professional collaborative model, which enabled them to overcome the challenges of engaging caregivers in the intervention process for their children. Thus, results have been reflected in continued attainments of the intervention goals throughout the therapeutic period and provided the caregivers with the needed support that decreased their burden. This suggests the need for training programs for pre- and post-graduation education on collaborative strategies with caregivers to support their needs and priorities in the interventions. Furthermore, the results indicated the quality of the service and established measurement of the children and their caregivers' outcomes. Finally, results will raise healthcare providers' awareness about the importance of delivering collaborative intervention, and provide insight for further research.

5.5 Conclusion

This study showed that means of GAS rating changes increased after the intervention for the children but did not reach the significance level between the experimental and control groups. Nevertheless, the experimental group has a higher GAS change in the last assessment, contrary to the control group which has a higher GAS change in the first assessment. Furthermore, the QOL showed no significant improvement for the caregivers. However, the burden decreased significantly for the experimental group compared to the control group. The training program for therapists effectively improved the children with CP and their caregivers' outcomes, and future research is recommended in this area.

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V. Appendix

Appendix 1: Institutional Review Board

Appendix 1. 1: King Saud Unversity

Kingdom of Saudi Arabia
King Saud University (34)
P.O. Box 7805 Riyadh 11472
Tel: +966 11 467 00 11
Fax: +966 11 467 19 92
http://medicalcity.ksu.edu.sa

المملكة العربية السعودية
جامعة الملك سعود (٣٤)
ص.ب ٧٨٠٥ الرياض ١١٤٧٢
هاتف +٩٦٦١١٤٦٧٠٠١١
فاكس +٩٦٦١١٤٦٧١٩٩٢

جامعة الملك سعود
King Saud University
المدينة الطبية الجامعية

03.05.2020 (10.09.1441)
Ref. No. 20/0329/IRB

To: **Ms. Sarah Laffai Al-Otaibi**
Master Student
Department of Rehabilitation Health Sciences – Physical Therapy
King Saud University College of Applied Medical Sciences
Email: Sarah-otaibi@hotmail.com, 438202987@student.ksu.edu.sa
Principal Investigator

Cc: Dr. Maha F. Al-Gabbani – malgabbani@ksu.edu.sa
Supervisor

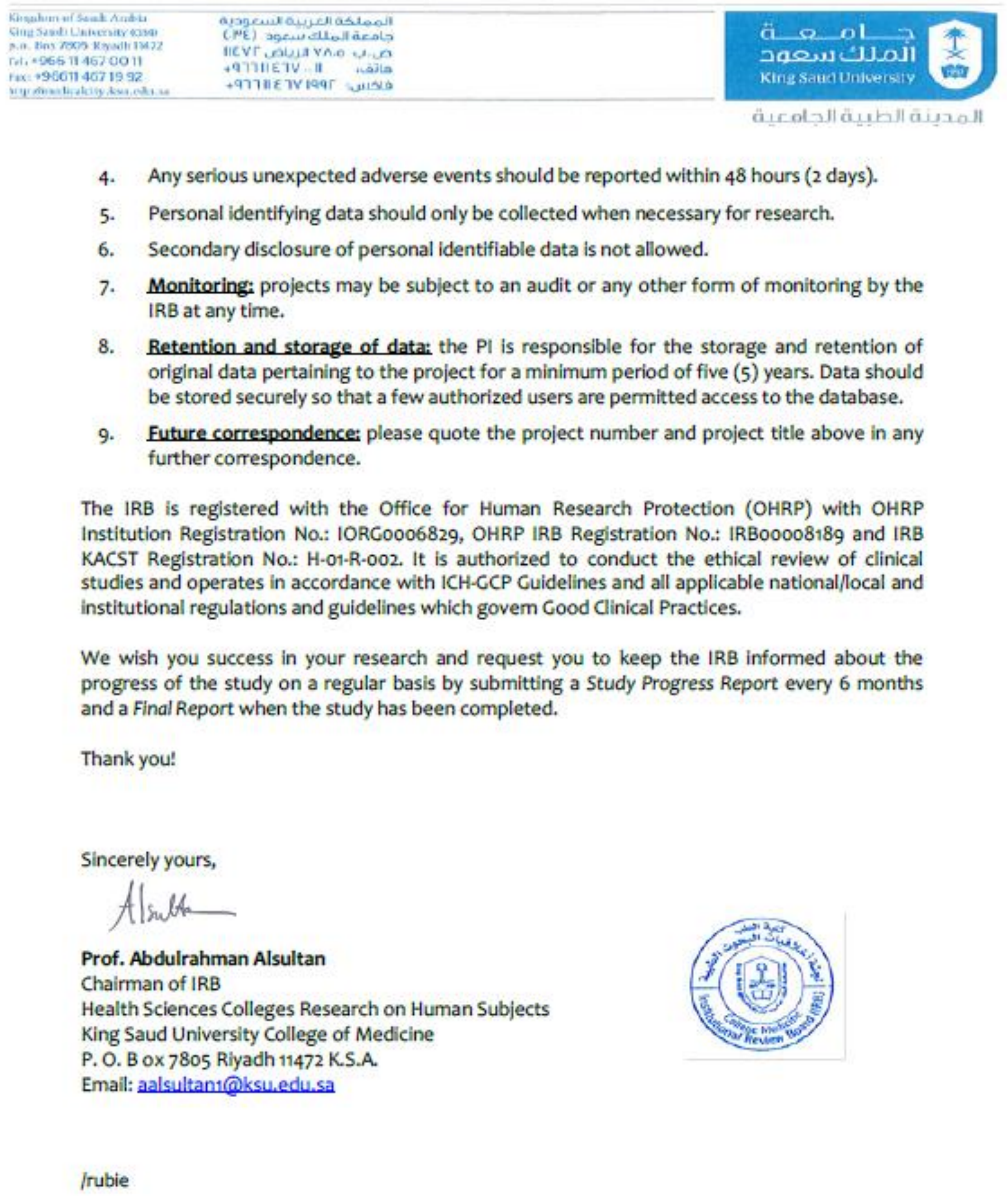
Subject: **IRB Approval on Research Project No. E-20-4777**
Study Title: "Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child Performance and Caregivers Quality of Life and Burden: Randomized Control Trial"
Type of Review: Full-Board
Date of Approval: 21 April 2020
Date of Expiry: 21 April 2021

Dear Ms. Sarah Laffai Al-Otaibi,

Thank you for your response to the comments of the Board regarding the above-mentioned research project which was initially reviewed and discussed in the IRB Meeting 07 (Academic Year 1440-1441) held on 23 March 2020 (28 Rajab 1441). The revised proposal submitted in response to the comments of the board and the clarifications provided are satisfactory. Therefore, the project is now **approved**. You are granted permission to conduct this study as approved by the IRB.

Please be informed that in conducting this study, you as the principal investigator, are required to abide by the rules and regulations of the Government of Saudi Arabia, the KSUMC IRB policies and procedures and the ICH-GCP Guidelines. This approval shall remain valid until the expiry date noted above assuming timely and acceptable responses from the IRB's periodic requests for surveillance and monitoring information, with the following terms and conditions:

1. **Modifications to Research/ Amendments to the approved project:** any modifications to the research (including changes to the informed consent document(s) must receive IRB approval prior to implementation of the changes. Substantial variations may require new submission.
2. **Annual Reports:** continued approval of this project is dependent on the submission of annual reports. If you wish to have your protocol approved for continuation, please submit a completed request for reapproval of an approved protocol form (KSU-IRB 017E) at least 30 days before the expiry date. Failure to receive approval for continuation before the expiration date will result in automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and can never be reported or published as research data.
3. All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible.



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المملكة العربية السعودية
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فاكس +٩٦٦١١٤٦٧١٩٩٢

جامعة الملك سعود
King Saud University
المدينة الطبية الجامعية

4. Any serious unexpected adverse events should be reported within 48 hours (2 days).
5. Personal identifying data should only be collected when necessary for research.
6. Secondary disclosure of personal identifiable data is not allowed.
7. **Monitoring:** projects may be subject to an audit or any other form of monitoring by the IRB at any time.
8. **Retention and storage of data:** the PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years. Data should be stored securely so that a few authorized users are permitted access to the database.
9. **Future correspondence:** please quote the project number and project title above in any further correspondence.

The IRB is registered with the Office for Human Research Protection (OHRP) with OHRP Institution Registration No.: IORG0006829, OHRP IRB Registration No.: IRB00008189 and IRB KACST Registration No.: H-01-R-002. It is authorized to conduct the ethical review of clinical studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

We wish you success in your research and request you to keep the IRB informed about the progress of the study on a regular basis by submitting a *Study Progress Report* every 6 months and a *Final Report* when the study has been completed.

Thank you!

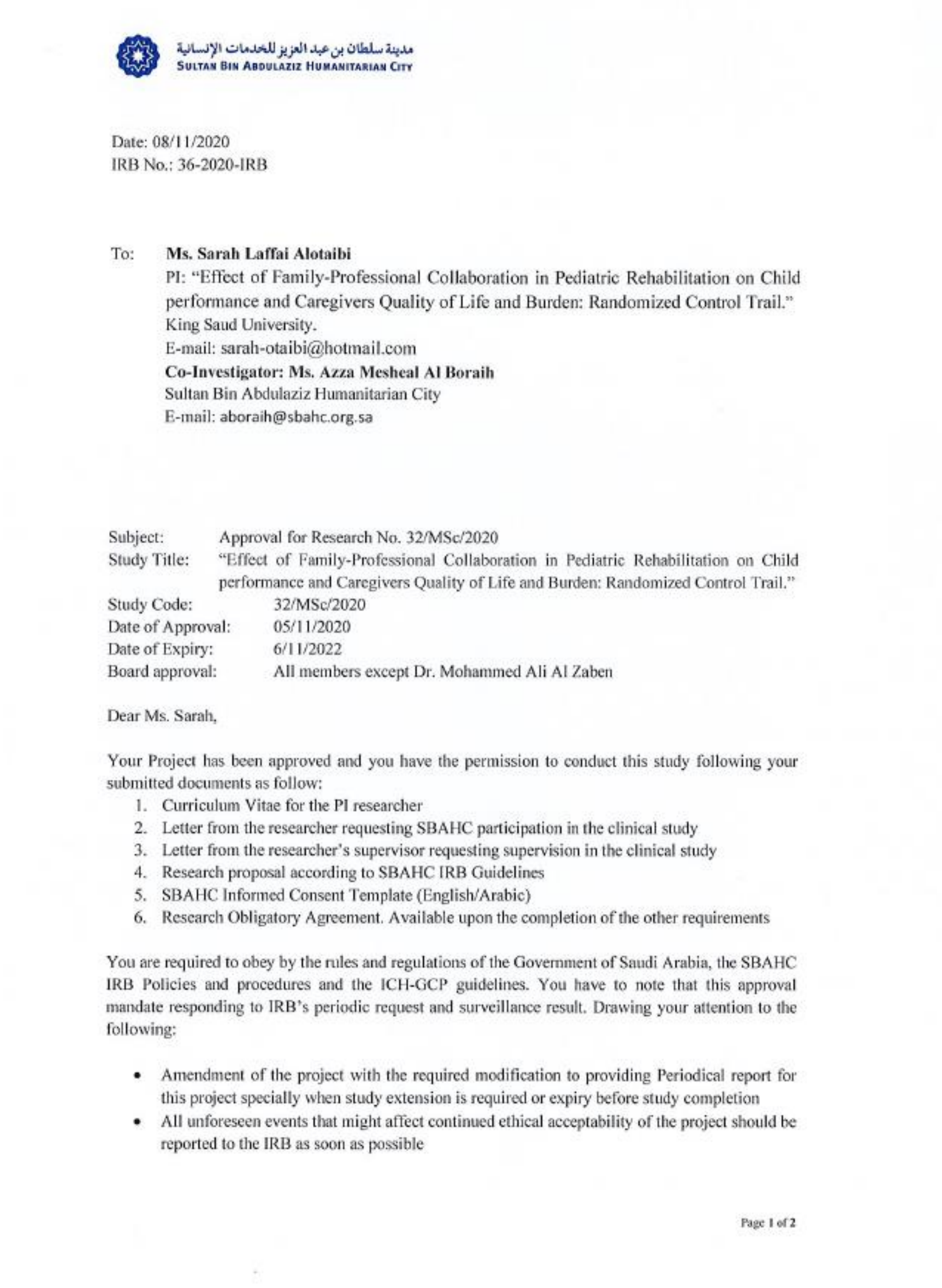
Sincerely yours,

Alsultan

Prof. Abdulrahman Alsultan
Chairman of IRB
Health Sciences Colleges Research on Human Subjects
King Saud University College of Medicine
P. O. B ox 7805 Riyadh 11472 K.S.A.
Email: aalsultan1@ksu.edu.sa

/rubie

Appendix 1. 2: Sultan Bin AbdulAziz Humanitarian City



مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY

Date: 08/11/2020
IRB No.: 36-2020-IRB

To: **Ms. Sarah Laffai Alotaibi**
PI: "Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child performance and Caregivers Quality of Life and Burden: Randomized Control Trail."
King Saud University.
E-mail: sarah-otaibi@hotmail.com
Co-Investigator: Ms. Azza Mesheal Al Boraih
Sultan Bin Abdulaziz Humanitarian City
E-mail: aboraih@sbahc.org.sa

Subject: Approval for Research No. 32/MSc/2020
Study Title: "Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child performance and Caregivers Quality of Life and Burden: Randomized Control Trail."
Study Code: 32/MSc/2020
Date of Approval: 05/11/2020
Date of Expiry: 6/11/2022
Board approval: All members except Dr. Mohammed Ali Al Zaben

Dear Ms. Sarah,

Your Project has been approved and you have the permission to conduct this study following your submitted documents as follow:

1. Curriculum Vitae for the PI researcher
2. Letter from the researcher requesting SBAHC participation in the clinical study
3. Letter from the researcher's supervisor requesting supervision in the clinical study
4. Research proposal according to SBAHC IRB Guidelines
5. SBAHC Informed Consent Template (English/Arabic)
6. Research Obligatory Agreement. Available upon the completion of the other requirements

You are required to obey by the rules and regulations of the Government of Saudi Arabia, the SBAHC IRB Policies and procedures and the ICH-GCP guidelines. You have to note that this approval mandate responding to IRB's periodic request and surveillance result. Drawing your attention to the following:

- Amendment of the project with the required modification to providing Periodical report for this project specially when study extension is required or expiry before study completion
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible

- Any serious unexpected adverse events should be reported within 48 hours (2 days)
- Personal identifying data should only be collected when necessary for research.
- Secondary disclosure of personal identifiable data is not allowed.
- Monitoring: projects may be subject to an audit by the IRB at any time.
- The PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- Data should be stored securely so that a few authorized users are permitted access to the database.

The IRB registered with the IRB KACST Registration No. H-01-R-090. It is authorized to conduct the ethical review of clinic studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

For Future Correspondence, please quote the project number and project title above and you are requested to keep IRB informed about your study progress and submit project progress report every six (6) months. A final report should be provided upon completion of the study.

Wish you a success in your research project.

Yours sincerely,

Prof. Khalid Al-Rubeaan
Chairman-IRB
Sultan Bin Abdulaziz Humanitarian City

Appendix 1. 3: Children with Disability Asscociation

جمعية
الأطفال
ذوي الإعاقة
Children with Disability Association
مركز الملك فهد بن عبد العزيز

سعادة الدكتورة/ فهده بنت عبدالعزيز آل الشيخ الموقرة

وكيلة كلية العلوم الطبية التطبيقية

السلام عليكم ورحمة الله وبركاته

بعد التحية،،،

إشارة إلى الخطاب المرسل لجمعية الأطفال ذوي الإعاقة المتضمن طلب الموافقة للطالبة/ سارة لفاي العتيبي. تفيدكم انه لا مانع لدينا من إجراء البحث المتعلق برسالة الماجستير في مراكز الجمعية بعنوان (تأثير التعاون بين العائلة والاخصائي أثناء تأهيل الطفل على أداء الأطفال لوجود الحياة والعبء على مقدم الرعاية لهم تجربة عشوائية محكمة)

علماً أنه لابد من استكمال الآتي:

1-ارسال طريقة البحث والاستبانة.

2- خطاب موافقة الأخصائية والاهل للمشاركة في البحث.

3- حضور الأخصائية بنفسها او من ينوب عنها لعمل المقابلات واكمال الدراسة.

4- الإشارة الى الجمعية الأطفال ذوي الإعاقة في بحثها.

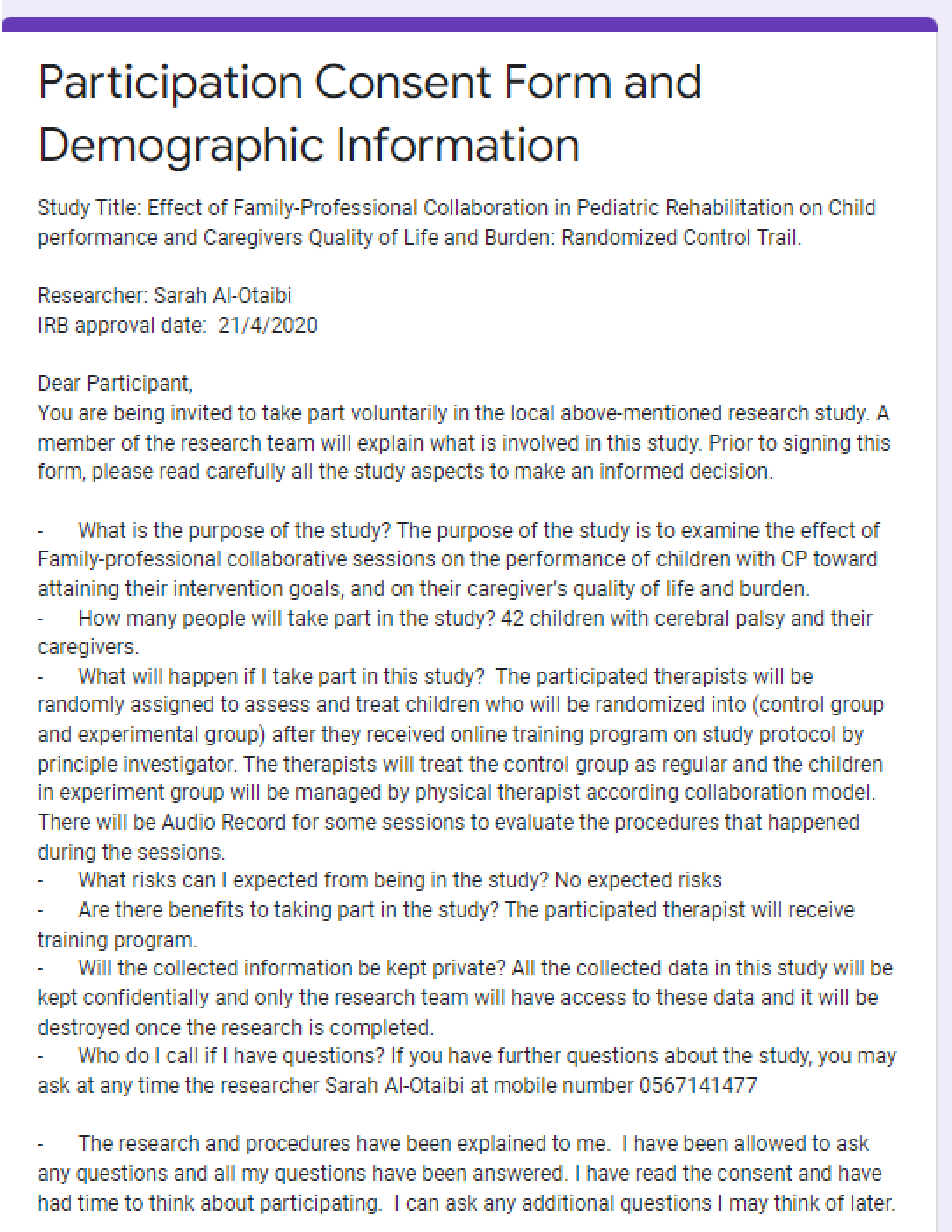
ولسعادتكم خالص الشكروالتقدير

مدير مركز الملك فهد – بجمعية الأطفال ذوي الإعاقة

أ/ مها بنت حامد دردير

Appendix 2: Consent forms

Appendix 2. 1: Physical Therapists consent



Participation Consent Form and Demographic Information

Study Title: Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child performance and Caregivers Quality of Life and Burden: Randomized Control Trail.

Researcher: Sarah Al-Otaibi
IRB approval date: 21/4/2020

Dear Participant,
You are being invited to take part voluntarily in the local above-mentioned research study. A member of the research team will explain what is involved in this study. Prior to signing this form, please read carefully all the study aspects to make an informed decision.

- What is the purpose of the study? The purpose of the study is to examine the effect of Family-professional collaborative sessions on the performance of children with CP toward attaining their intervention goals, and on their caregiver's quality of life and burden.
- How many people will take part in the study? 42 children with cerebral palsy and their caregivers.
- What will happen if I take part in this study? The participated therapists will be randomly assigned to assess and treat children who will be randomized into (control group and experimental group) after they received online training program on study protocol by principle investigator. The therapists will treat the control group as regular and the children in experiment group will be managed by physical therapist according collaboration model. There will be Audio Record for some sessions to evaluate the procedures that happened during the sessions.
- What risks can I expected from being in the study? No expected risks
- Are there benefits to taking part in the study? The participated therapist will receive training program.
- Will the collected information be kept private? All the collected data in this study will be kept confidentially and only the research team will have access to these data and it will be destroyed once the research is completed.
- Who do I call if I have questions? If you have further questions about the study, you may ask at any time the researcher Sarah Al-Otaibi at mobile number 0567141477

- The research and procedures have been explained to me. I have been allowed to ask any questions and all my questions have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later.

Appendix 2. 2: Children and their caregivers consents

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY

INFORMED CONSENT FOR MEDICAL & CLINICAL STUDIES

الموافقة المستنيرة للمعلومات الطبية والدراسات السريرية

For REC use only:
Full Board [ ]
Expedited [ ]
Proposal No. ______

SECTION A:

STUDY INFORMATION

Study Title:	Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child performance and Caregivers Quality of Life and Burden: Randomized Control Trail.
Protocol Number/Study Code:	
Principal Investigator:	Sarah Alotaibi
Principal Investigator Address:	Riyadh, Saudi Arabia
Telephone:	0567141477
Email:	Sarah-otaibi@hotmail.com
Sponsor	Nil

القسم أ:

معلومات عن الدراسة

عنوان الدراسة:	**تأثير التعاون بين العائلة والاخصائي اثناء تأهيل الأطفال على أداء الاطفال وجودة الحياة والعبء على مقدم الرعاية لهم : تجربة عشوائية محكمة**
رقم البروتوكول/ رمز الدراسة:	
الباحث المسؤول:	ساره لفاي العتيبي
عنوان الباحث المسؤول:	الرياض ، المملكة العربية السعودية
الهاتف:	0567141477
البريد الإلكتروني:	Sarah-otaibi@hotmail.com
الممول:	لا يوجد

INTRODUCTION

Dear Participant,

You are invited to take part in a clinical research study. To help you decide, you should understand the study and what it will involve for you. To make an informed decision to take part you should know the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

You can leave the study at any time without giving a reason if you do not wish to provide one. It will not affect your regular medical care. Before your participation in the study can be confirmed, you have to complete initial tests for the study doctor.

It cannot be promised that the study will help you but in the future the information we get from this study may help improve the future treatment of people with the same condition.

Once you have decided that you want to take part, you (or legally acceptable representative) will be asked to sign the informed consent form. You will be given a copy of the signed form to keep, and the original will stay at the study center.

مقدمة

عزيزي المشارك،

أنت مدعو للمشاركة في دراسة بحثية سريرية، ولكن ينبغي عليك فهم الدراسة وماستتضمنه لمساعدتك على اتخاذ القرار. يجب عليك معرفة الغرض من الدراسة والإجراءات والفوائد والمخاطر والعوامل المقلقة والإجراءات المتخذة وذلك لاتخاذ قرار مستنير للمشاركة، وتسمى هذه العملية "موافقة مستنيرة".
نرجو تخصيص وقت لقراءة المعلومات التالية بعناية ومناقشتها مع الآخرين، ويمكنك سؤال طبيب الدراسة في حالة عدم وضوح أي أمر أو رغبت بالحصول على معلومات إضافية.

يمكنك الانسحاب من الدراسة في أي وقت بدون إبداء سبب إن لم يكن لديك الرغبة في التبرير، فذلك لن يؤثر على الرعاية الطبية العادية التي تتلقاها، كما يجب عليك إكمال الاختبارات الأولية لطبيب الدراسة قبل التأكيد على مشاركتك.

لا نعدك بأن الدراسة ستساعدك، ولكن قد تساعد المعلومات المستمدة من هذه الدراسة في تحسين العلاج في المستقبل للأشخاص المصابين بنفس الحالة.

بمجرد أن تقرر بأنك ترغب بالمشاركة، سيطلب منك (أو من ممثلك المعترف به قانونيا) التوقيع على نموذج الموافقة المستنيرة، وسيتم تسليمك نسخة من النموذج الموقع لتحتفظ به وستكون النسخة الأصلية محفوظة في مركز الدراسة.

SECTION B:

1. **What is the purpose of the study?**
   The purpose of the study is to examine the effect of Family-professional collaborative sessions on the performance of children with CP toward attaining their intervention goals, and on their caregiver's quality of life and burden.
2. **How many people will take part in the study?**
   42 participants
3. **Study location?**
   Sultan Bin Abdulaziz Humanitarian City
4. **What will happen if I take part in this study?**
   The physical therapist will assess and treat the participated child, and some sessions will be recorded to Study the procedures that were followed during sessions
5. **What is expected of me during the study?**

القسم ب:

1. ماالغرض من الدراسة؟
   يهدف البحث لدراسة تاثير التعاون بين الاهل والاخصائي على أداء الأطفال المصابين بالشلل الدماغي و وجودة حياة والعبء على مقدم الرعاية لهم
2. كم عدد الأشخاص الذين سيشاركون في الدراسة؟
   42 مشارك
3. موقع الدراسة؟
   مدينة الأمير سلطان بن عبدالعزيز للخدمات الإنسانية
4. ماذا سيحدث إذا شاركت في هذه الدراسة؟
   سيقوم اخصائي العلاج الطبيعي التقييم والعلاج للطفل المشارك وسيكون هناك تسجيل صوتي للجلسة لدراسة الإجراءات التي اتبعت خلالها لاحقا.
5. ماالمتوقع مني خلال الدراسة؟

SBAHC 1477 – RSC (07/20) NP
IRB Form 005 – E&A

Appendix 3: World Health Organization Quality of Life- Brief

Appendix E: WHOQOL-BREF

يرجى قراءة كل سؤال و تقيم ما تشعر به ووضع دائرة حول الرقم الذي يعطي أفضل إجابة بالنسبة لك

		سيئة للغاية	سيئة	لا بأس	جيدة	جيدة جدا
(G1)1	كيف تقيم نوعية حياتك	1	2	3	4	5

		غير راض على الاطلاق	غير راض	لا راض ولا غير راض	راض	راض تماما
(G4)2	ما مدى رضاك عن صحتك	1	2	3	4	5

الأسئلة التالية تستفسر عن مدى تعرضك لأشياء معينة خلال الأسبوعين الماضيين

		لا يوجد	قليلا	بدرجة متوسطة	كثير جدا	بدرجة بالغة
(F1.4) 3	إلى أي حد تشعر بأن الألم الجسدي يمنعك من القيام بالأعمال التي تريدها ؟	1	2	3	4	5
(F11.3)4	الى أي مدى أنت بحاجة للعلاج الطبي لتتمكن من القيام بأعمالك اليومية ؟	1	2	3	4	5
(F4.1)5	إلي أي مدى تستمتع بالحياة ؟	1	2	3	4	5
(F24.2)6	إلي أي مدى تشعر بأن حياتك ذات معنى ؟	1	2	3	4	5
(F5.3)7	الى أي مدى أنت قادر على التركيز ؟	1	2	3	4	5
(F16.1)8	الى أي مدى تشعر بالأمان في حياتك اليومية ؟	1	2	3	4	5
(F22.1)9	إلى أي حد تعتبر أن البيئة المحيطة بك صحية ؟	1	2	3	4	5

الأسئلة التالية تستفسر عن مدى قدرتك على إتمام أمور معينة خلال الأسبوعين الماضيين

		لا يوجد	قليلا	بدرجة متوسطة	كثير جدا	بدرجة بالغة
(F2.1)10	هل لديك طاقة كافيه لمزاولة الحياة اليومية؟	1	2	3	4	5
(F7.1)11	هل أنت قادر على قبول مظهرك الخارجي؟	1	2	3	4	5
(F18.1)12	هل لديك من المال ما يكفي لتلبية احتياجاتك؟	1	2	3	4	5
(F20.1)13	ما مدى توفر المعلومات التي تحتاجها في حياتك اليومية ؟	1	2	3	4	5
(F21.1)14	إلي أي مدى لديك الفرصة لممارسة الأنشطة الترفيهية؟	1	2	3	4	5

		سيئة للغاية	سيئة	لا بأس	جيدة	جيدة جدا
(F9.1)15	الى أي مدى أنت قادر على التنقل بسهولة؟	1	2	3	4	5

الأسئلة التالية تطلب منك أن تعبر عن مدى رضاك نحو جوانب مختلفة من حياتك خلال الأسبوعين الماضيين

		غير راض على الاطلاق	غير راض	لا راض ولا غير راض	راض	راض تماما
(F3.3)16	كم أنت راض عن نومك ؟	1	2	3	4	5
(F10.3)17	إلي أي مدى أنت راض عن قدرتك على القيام بنشاطاتك اليومية ؟	1	2	3	4	5
(F12.4)18	كم أنت راض عن قدراتك على العمل ؟	1	2	3	4	5
(F6.3)19	كم أنت راض عن نفسك ؟	1	2	3	4	5
(F13.3)20	كم أنت راض عن علاقاتك الشخصية ؟	1	2	3	4	5
(F15.3)21	كم أنت راض عن حياتك الجنسية ؟	1	2	3	4	5
(F14.4)22	كم أنت راض عن الدعم أو المساعدة من الأصدقاء ؟	1	2	3	4	5
(F17.3)23	كم أنت راض عن الأوضاع في مكان سكنك؟	1	2	3	4	5
(F19.3)24	كم أنت راض عن الخدمات الصحية المتوفرة لك ؟	1	2	3	4	5
(F23.3)25	كم أنت راض عن وسائل المواصلات التي تستخدمها ؟	1	2	3	4	5

الأسئلة التالية تشير إلي كم من المرات شعرت أو تعرضت فيها لأشياء معينة خلال الأسبوعين الماضيين

		أبدا	نادرا	غالبا	غالبا جدا	دائما
(F8.1)26	كم من المرات كانت لديك مشاعر سلبية مثل المزاج السيء، اليأس، القلق، الاكتئاب؟	1	2	3	4	5

هل قام أحدهم بمساعدتك لتعبئة هذه الاستمارة؟ (رجاءً قم بوضع دائرة: نعم أو لا)	نعم	لا

كم إستغرق من الوقت لتعبئة هذه الاستمارة؟ ....

شكرا لك

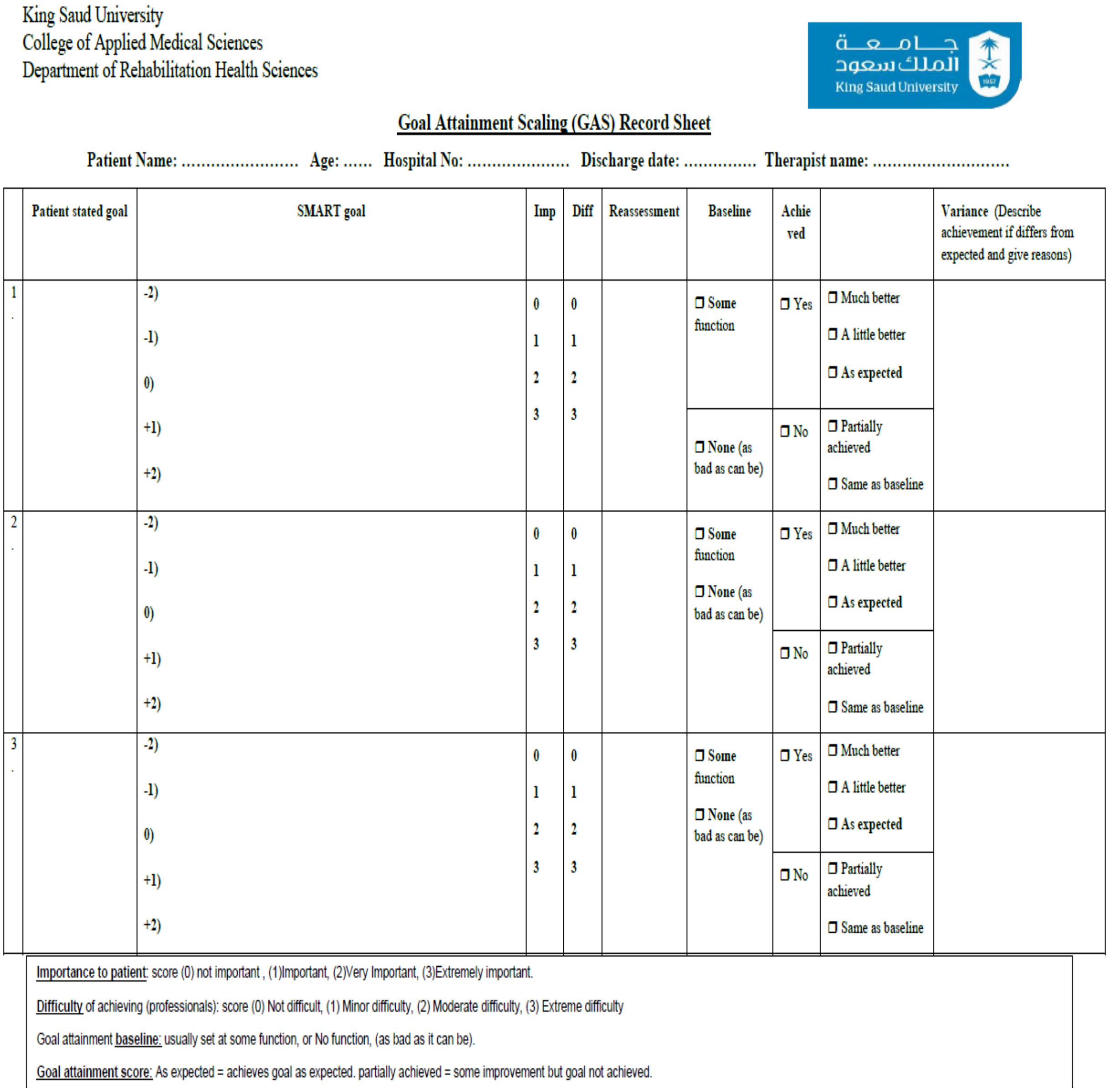
Appendix 4: Zarit Burden Interview

The abridged Arabic version of the Zarit Burden Interview (ZBI-A)

لأسئلة هذه هي بخصوص علاقتك مع قريبك الذي تعتني به. لكل سؤال يوجد خمس امكانيات أجوبه تبدأ من0 – بالمرة لا وحتى 4– تقريبا دائما. اشر إلى الإجابة الأكثر ملاءمة لإحساسك.

	0 بالمرة لا	1 لأوقات متباعدة	2 في بعض الأحيان	3 في أوقات متقاربة	4 تقريبا دائماً
هل تشعر انه بسبب الوقت الذي تقضيه مع قريبك ليس لديك وقت كافي لنفسك؟	0	1	2	3	4
هل تشعر بالصراع والضغط بين القلق على قريبك وبين واجبات اخرى مثل عملك أو عائلتك؟	0	1	2	3	4
هل تشعر انك غاضب عند تواجدك بجوار قريبك؟	0	1	2	3	4
هل تشعر ان قريبك يؤثر على علاقاتك مع ابناء العائلة الاخرين بطريقه سلبيه؟	0	1	2	3	4
هل تشعر بالتوتر بجوار قريبك؟	0	1	2	3	4
هل تشعر ان صحتك تضررت بعد مشاركتك في عناية قريبك؟	0	1	2	3	4
هل تشعر انه ليس لك خصوصيات بقدر كاف بسبب قريبك؟	0	1	2	3	4
هل تشعر ان حياتك الاجتماعية تضررت بسبب قريبك؟	0	1	2	3	4
هل تشعر انك فقدت السيطرة على حياتك منذ مرض قريبك؟	0	1	2	3	4
هل تشعر بعدم الثقة بخصوص العلاج الصحيح لقريبك؟	0	1	2	3	4
هل تشعر انك بحاجه لأن تفعل أكثر من اجل قريبك؟	0	1	2	3	4
هل تشعر انك كنت تستطيع ان تهتم بقريبك بصوره افضل؟	0	1	2	3	4

Appendix 5: Goals Attainment Scale



King Saud University
College of Applied Medical Sciences
Department of Rehabilitation Health Sciences

Goal Attainment Scaling (GAS) Record Sheet

Patient Name: …………………… **Age:** …… **Hospital No:** ………………… **Discharge date:** …………… **Therapist name:** ………………………

	Patient stated goal	SMART goal	Imp	Diff	Reassessment	Baseline	Achieved		Variance (Describe achievement if differs from expected and give reasons)
1.		-2) -1) 0) +1) +2)	0 1 2 3	0 1 2 3		☐ Some function	☐ Yes	☐ Much better ☐ A little better ☐ As expected	
						☐ None (as bad as can be)	☐ No	☐ Partially achieved ☐ Same as baseline	
2.		-2) -1) 0) +1) +2)	0 1 2 3	0 1 2 3		☐ Some function ☐ None (as bad as can be)	☐ Yes	☐ Much better ☐ A little better ☐ As expected	
							☐ No	☐ Partially achieved ☐ Same as baseline	
3.		-2) -1) 0) +1) +2)	0 1 2 3	0 1 2 3		☐ Some function ☐ None (as bad as can be)	☐ Yes	☐ Much better ☐ A little better ☐ As expected	
							☐ No	☐ Partially achieved ☐ Same as baseline	

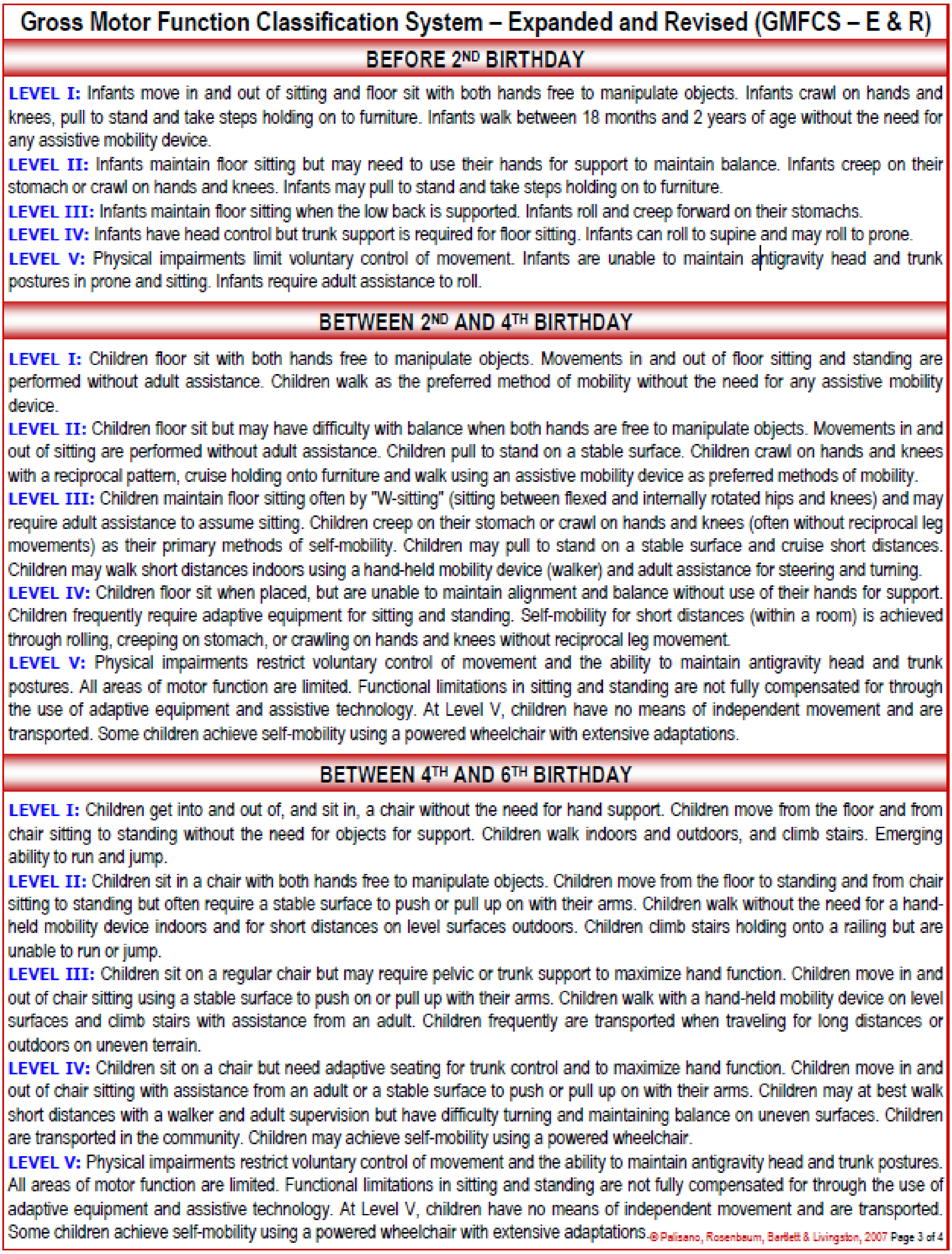
Importance to patient: score (0) not important , (1)Important, (2)Very Important, (3)Extremely important.

Difficulty of achieving (professionals): score (0) Not difficult, (1) Minor difficulty, (2) Moderate difficulty, (3) Extreme difficulty

Goal attainment baseline: usually set at some function, or No function, (as bad as it can be).

Goal attainment score: As expected = achieves goal as expected. partially achieved = some improvement but goal not achieved.

Appendix 6: Gross Motor Function Classification System



Gross Motor Function Classification System – Expanded and Revised (GMFCS – E & R)

BEFORE 2ND BIRTHDAY

LEVEL I: Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk between 18 months and 2 years of age without the need for any assistive mobility device.

LEVEL II: Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees. Infants may pull to stand and take steps holding on to furniture.

LEVEL III: Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs.

LEVEL IV: Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.

LEVEL V: Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.

BETWEEN 2ND AND 4TH BIRTHDAY

LEVEL I: Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.

LEVEL II: Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.

LEVEL III: Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.

LEVEL IV: Children floor sit when placed, but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.

LEVEL V: Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.

BETWEEN 4TH AND 6TH BIRTHDAY

LEVEL I: Children get into and out of, and sit in, a chair without the need for hand support. Children move from the floor and from chair sitting to standing without the need for objects for support. Children walk indoors and outdoors, and climb stairs. Emerging ability to run and jump.

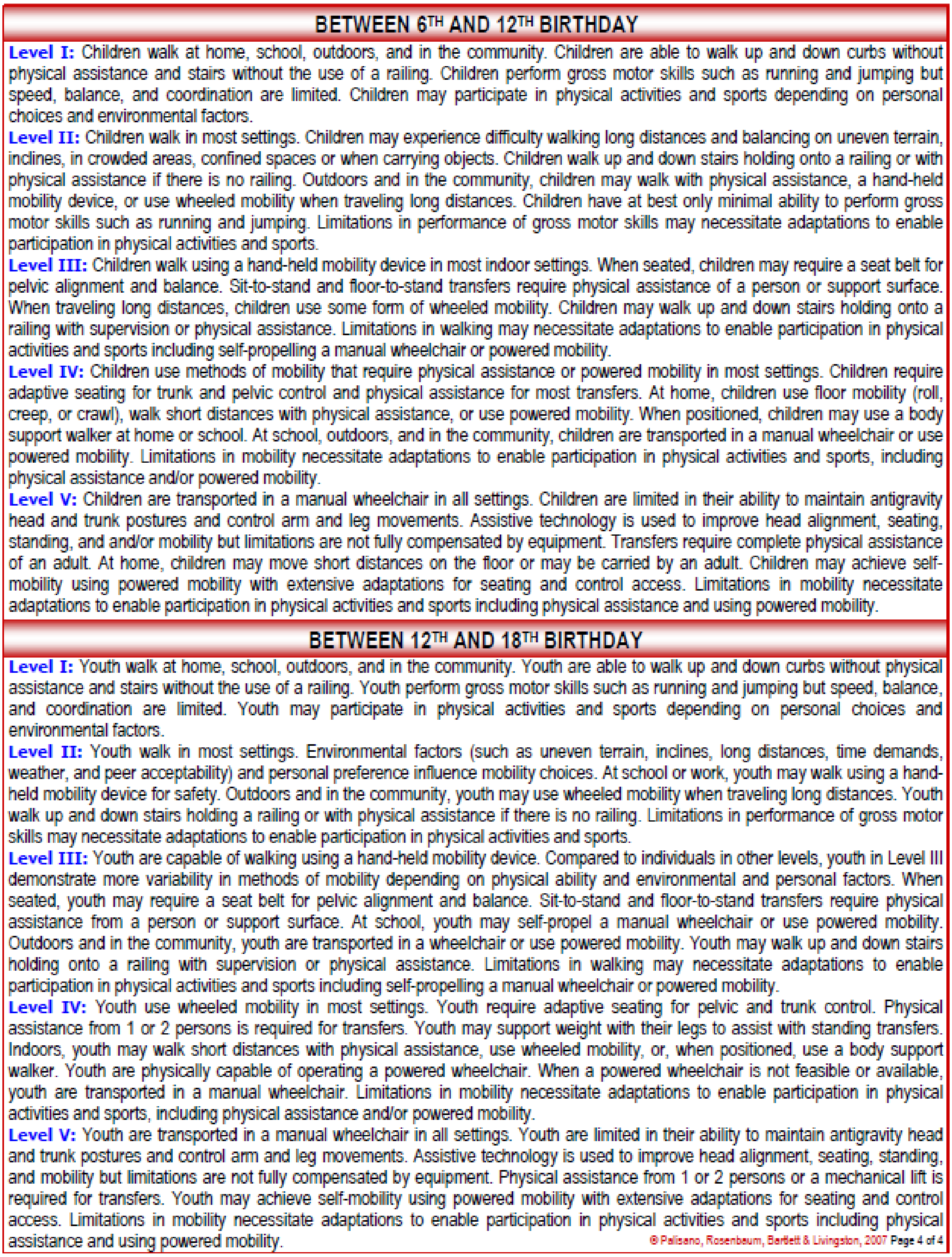
LEVEL II: Children sit in a chair with both hands free to manipulate objects. Children move from the floor to standing and from chair sitting to standing but often require a stable surface to push or pull up on with their arms. Children walk without the need for a hand-held mobility device indoors and for short distances on level surfaces outdoors. Children climb stairs holding onto a railing but are unable to run or jump.

LEVEL III: Children sit on a regular chair but may require pelvic or trunk support to maximize hand function. Children move in and out of chair sitting using a stable surface to push on or pull up with their arms. Children walk with a hand-held mobility device on level surfaces and climb stairs with assistance from an adult. Children frequently are transported when traveling for long distances or outdoors on uneven terrain.

LEVEL IV: Children sit on a chair but need adaptive seating for trunk control and to maximize hand function. Children move in and out of chair sitting with assistance from an adult or a stable surface to push or pull up on with their arms. Children may at best walk short distances with a walker and adult supervision but have difficulty turning and maintaining balance on uneven surfaces. Children are transported in the community. Children may achieve self-mobility using a powered wheelchair.

LEVEL V: Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.

Page 3 of 4



BETWEEN 6TH AND 12TH BIRTHDAY

Level I: Children walk at home, school, outdoors, and in the community. Children are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Children may participate in physical activities and sports depending on personal choices and environmental factors.

Level II: Children walk in most settings. Children may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas, confined spaces or when carrying objects. Children walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Outdoors and in the community, children may walk with physical assistance, a hand-held mobility device, or use wheeled mobility when traveling long distances. Children have at best only minimal ability to perform gross motor skills such as running and jumping. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

Level III: Children walk using a hand-held mobility device in most indoor settings. When seated, children may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance of a person or support surface. When traveling long distances, children use some form of wheeled mobility. Children may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

Level IV: Children use methods of mobility that require physical assistance or powered mobility in most settings. Children require adaptive seating for trunk and pelvic control and physical assistance for most transfers. At home, children use floor mobility (roll, creep, or crawl), walk short distances with physical assistance, or use powered mobility. When positioned, children may use a body support walker at home or school. At school, outdoors, and in the community, children are transported in a manual wheelchair or use powered mobility. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

Level V: Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and and/or mobility but limitations are not fully compensated by equipment. Transfers require complete physical assistance of an adult. At home, children may move short distances on the floor or may be carried by an adult. Children may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

BETWEEN 12TH AND 18TH BIRTHDAY

Level I: Youth walk at home, school, outdoors, and in the community. Youth are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Youth perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Youth may participate in physical activities and sports depending on personal choices and environmental factors.

Level II: Youth walk in most settings. Environmental factors (such as uneven terrain, inclines, long distances, time demands, weather, and peer acceptability) and personal preference influence mobility choices. At school or work, youth may walk using a hand-held mobility device for safety. Outdoors and in the community, youth may use wheeled mobility when traveling long distances. Youth walk up and down stairs holding a railing or with physical assistance if there is no railing. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

Level III: Youth are capable of walking using a hand-held mobility device. Compared to individuals in other levels, youth in Level III demonstrate more variability in methods of mobility depending on physical ability and environmental and personal factors. When seated, youth may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance from a person or support surface. At school, youth may self-propel a manual wheelchair or use powered mobility. Outdoors and in the community, youth are transported in a wheelchair or use powered mobility. Youth may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

Level IV: Youth use wheeled mobility in most settings. Youth require adaptive seating for pelvic and trunk control. Physical assistance from 1 or 2 persons is required for transfers. Youth may support weight with their legs to assist with standing transfers. Indoors, youth may walk short distances with physical assistance, use wheeled mobility, or, when positioned, use a body support walker. Youth are physically capable of operating a powered wheelchair. When a powered wheelchair is not feasible or available, youth are transported in a manual wheelchair. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

Level V: Youth are transported in a manual wheelchair in all settings. Youth are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and mobility but limitations are not fully compensated by equipment. Physical assistance from 1 or 2 persons or a mechanical lift is required for transfers. Youth may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

Appendix 7: Physical Therapists Training Program

Physical Therapists Training Program Booklet

Edited by:

Sarah Alotaibi

Reviewed by:

Dr.Maha Algabbani

Training Protocol

Preparation of physical therapists:

Learning material	Training booklet, Presentation.
Required time for training	**Control group:** First session: 3 hours **Experimental group:** First session: 3 hours Second session: 3 hours
Location	Online (Zoom)

Part 1

Preparation of physical Therapists (experimental group and control group):

Learning objectives:

1. Explain the study and ethical issues.
2. Recognize the instrumentation that will be used in the research.
3. Understand GAS scale method in writing intervention goals and using its scoring system.
4. Know the study procedures and the therapist’s role.

Outcomes:

By the end of this program the therapist will be able to:

1. Identify study requirements (participant inclusion criteria) and follow the study’s ethics.
2. Write and score the intervention goals using GAS scale.
3. Apply the study procedure to participants.

Overview of Study and Ethical Issues

Title: The Effect of Family-Professional Collaboration on Children with Cerebral Palsy's Performance, and Caregivers' Quality of Life and Burden: a Randomized Control Trial.

Ethical consideration:

1. The study was approved by the institutional review board in the College of Medicine at King Saud University, Sultan Bin Abdulaziz Humanitarian City, Children with Disabilities Association. All participants must sign the consent form, and the investigator will answer their questions.

Purpose of Study:

This study aimed to examine the effect of family-professional collaborative sessions on the performance of children with CP toward attaining their intervention goals, and on the caregiver's quality of life and burden level.

Study sample: 54 participants (children accompanied by caregivers) in both groups.

Inclusion criteria:

Children:

1. Children with CP.
2. Aged from 2 to 12 years.
3. GMFCS level (I, II and III).
4. Children's treatment should be in combination with their caregivers (parent, or relatives who take care of child).

Physical therapist:

Physical therapist with at least 1 years' experience and able to communicate well with child's caregiver in Arabic.

Exclusion criteria:

Children:

1. Children who underwent recent surgery, or after Botulinum toxin injection treatment.

2. Children who have other conditions that could affect the session process, like an uncontrolled seizure disorder.

Research instrumentation:

1. **Goal Attainment Scale (GAS): filled by physical therapists**

GAS is a technique of scoring the extent to which a child’s individual goals are attained during intervention.

In fact, each child has their own individualized goals that rated on a standardized level which allows statistical analysis. Every goal is rated on a five-point Likert scale, as shown below:

+2	the highest score which means the best possible level (greatly exceed the expected outcome)
+1	showed better level than expected (slightly exceed the expected outcome)
0	representing the expected level after the intervention (expected outcome)
-1	mean progression toward the goals but not reached (less than expected outcome)
-2	The child's performance at baseline (much less than expected outcome)

Table 3: GAS scoring System

The participating physical therapists must adhere to the following criteria for scale development:

A. The physical therapists should be set the intervention goals with the children and their caregivers. These should be based on their request for help and requirements, and should describe the main aim of therapy for each discipline in terms of the activity and participation domains of the ICF child and youth version (ICF-CY).
    1. **Activity:** is the execution of a task or action by an individual.
    2. **Participation:** is involvement in a life situation.
    3. **Activity limitations**: are difficulties an individual may have in executing activities.
    4. **Participation restrictions:** are problems an individual may experience in involvement in life situations.

B. The five levels of the Goal Attainment Scaling scales should be specific, measurable, achievable, realistic/relevant and time-related (SMART).

C. Scales should be constructed ordinally with incremental steps of equal intervals. To ensure ordinality, each Goal Attainment Scaling scale should reflect a single dimension of change.

D. The goals should be weighted according to the importance and difficulties as in the table below:

importance	**Codes**	**difficulties**	**Codes**
Not important	0	Not difficult	0
Important	1	Minor difficulty	1
Very Important	2	Mod difficulty	2
Extremely important	3	Extreme difficulty	3

Table 4: GAS weighting and codes

The **GAS scoring system** is shown below:

<table>
<tr><th colspan="4">GAS scoring system</th></tr>
<tr><td rowspan="5">At Outcome:
Was the goal achieved?</td><td rowspan="3">Yes</td><td>Much better</td><td>(+2)</td></tr>
<tr><td>A little better</td><td>(+1)</td></tr>
<tr><td>As expected</td><td>0</td></tr>
<tr><td rowspan="2">No</td><td>Partially achieved</td><td>(-1)</td></tr>
<tr><td>No change (same baseline)</td><td>(-2)</td></tr>
</table>

Goal Attainment Scaling (GAS) Record Sheet

Patient Name: …………………… Age: …… Hospital No: ………………… Discharge date: …………… Therapist name: ……………………….

	Patient stated goal	**SMART goal**	**Imp**	**Diff**	**Baseline**	**Achieved**		**Variance (**Describe achievement if differs from expected and give reasons)
1.		**-2)** **-1)** **0)** **+1)** **+2)**	**0** **1** **2** **3**	**0** **1** **2** **3**	☐ **Some** function ☐ **None** (as bad as can be)	☐ Yes	☐ Much better ☐ A little better ☐ **As expected**	
						☐ No	☐ Partially achieved ☐ Same as baseline	
2.		**-2)** **-1)** **0)** **+1)** **+2)**	**0** **1** **2** **3**	**0** **1** **2** **3**	☐ **Some** function ☐ **None** (as bad as can be)	☐ Yes	☐ Much better ☐ A little better ☐ **As expected**	
						☐ No	☐ Partially achieved ☐ Same as baseline	
3.		**-2)** **-1)** **0)** **+1)** **+2)**	**0** **1** **2** **3**	**0** **1** **2** **3**	☐ **Some** function ☐ **None** (as bad as can be)	☐ Yes	☐ Much better ☐ A little better ☐ **As expected**	
						☐ No	☐ Partially achieved ☐ Same as baseline	

Importance to patient: score not important, Important, Very Important, Extremely important.

Difficulty of achieving (professionals): score Not difficult, Minor difficulty, Moderate difficulty, Extreme difficulty

Goal attainment **baseline**: usually set at some function, or No function, (as bad as it can be).

Goal attainment score: As expected = achieves goal as expected. partially achieved = some improvement but goal not achieved.

same as baseline = no change, a little better = achieved more than the goal, Much better – over achieved goal

The goal for intervention will be restricted to everyday or leisure activities at home and in the community (activity and participation parts in International Classification of Functioning, Disability and Health (ICF). For example, if a child's current therapy goal is walking independently 5 meters indoors or taking 10 steps at home or in the therapy room, walking in a controlled environment will not be a goal. Activity or participation related to walking, however, can be a goal. For example, a goal for activity and participation for the child might be walking using a walker to travel with a parent from the family's home to a convenience store located on the next street.

Example:

The child's main goal:	Walking around at home more easily, including the staircase. Observable target behaviour: walking down 10 steps of the stairs
score	**Goals**
-2	Walks down the stairs without alternating steps with one hand on the stair rail and the other held by a carer
-1	Walks down the stairs without alternating steps and holding the stair rail only, while supervised by a carer
0	Walks down the stairs with alternating steps, with one hand on the stair rail and the other held by a carer
+1	Walks down the stairs with alternating steps and holding the stair rail only, while supervised by a carer
+2	Walks down the stairs unaided, with alternating steps, holding the stair rail and not supervised by a carer

2. **World Health Organization Quality of Life -Brief (WHOQOL-Brief): the questionnaire will be handed to caregivers**

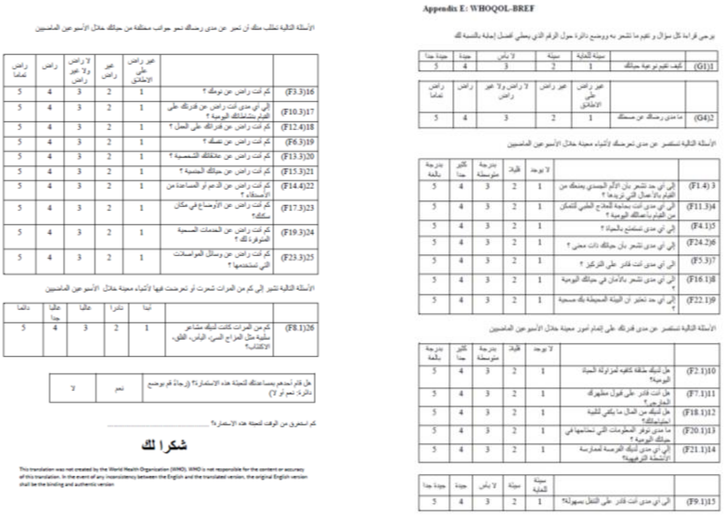


Figure 3: world health organization quality of life -brief (WHOQOL-Brief)

3. Zarit Burden Interview-short version (ZBI):

The Zarit Burden Interview (ZBI) will be used to measure caregiver burden. The short version of the ZBI consists of 12 items scales. These items are rated on a 5-point Likert scale from 0 which represent never to 4 which represent almost always. The higher score demonstrating more sense of burden.

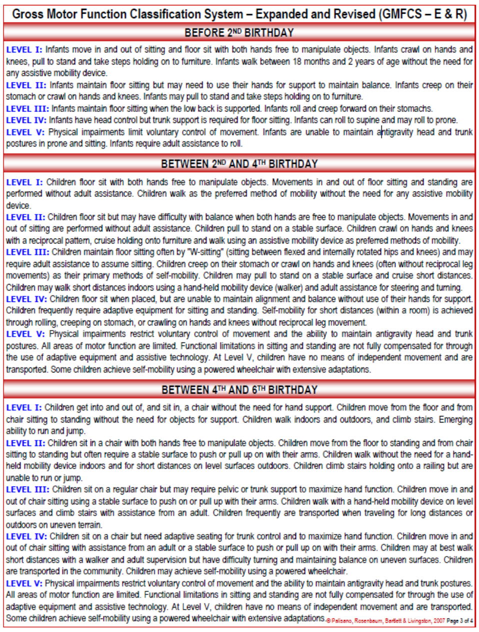
The abridged Arabic version of the Zarit Burden Interview (ZBI-A)

لأسئلة هذه هي بخصوص علاقتك مع قريبك الذي تعتني به. لكل سؤال يوجد خمس امكانيات أجوبه تبدأ من0 – بالمرة لا وحتى 4– تقريبا دائما. اشر إلى الإجابة الأكثر ملاءمة لإحساسك.

	0 بالمرة لا	1 لأوقات متباعدة	2 في بعض الأحيان	3 في أوقات متقاربة	4 تقريبا دائماً
هل تشعر انه بسبب الوقت الذي تقضيه مع قريبك ليس لديك وقت كافي لنفسك؟	0	1	2	3	4
هل تشعر بالصراع والضغط بين القلق على قريبك وبين واجبات اخرى مثل عملك أو عائلتك؟	0	1	2	3	4
هل تشعر انك غاضب عند تواجدك بجوار قريبك؟	0	1	2	3	4
هل تشعر ان قريبك يؤثر على علاقاتك مع ابناء العائلة الاخرين بطريقه سلبيه؟	0	1	2	3	4
هل تشعر بالتوتر بجوار قريبك؟	0	1	2	3	4
هل تشعر ان صحتك تضررت بعد مشاركتك في عناية قريبك؟	0	1	2	3	4
هل تشعر انه ليس لك خصوصيات بقدر كافٍ بسبب قريبك؟	0	1	2	3	4
هل تشعر ان حياتك الاجتماعية تضررت بسبب قريبك؟	0	1	2	3	4
هل تشعر انك فقدت السيطرة على حياتك منذ مرض قريبك؟	0	1	2	3	4
هل تشعر بعدم الثقة بخصوص العلاج الصحيح لقريبك؟	0	1	2	3	4
هل تشعر انك بحاجه لأن تفعل أكثر من اجل قريبك؟	0	1	2	3	4
هل تشعر انك كنت تستطيع ان تهتم بقريبك بصوره افضل؟	0	1	2	3	4

Figure 4: Zarit Burden Interview (ZBI)

4. Gross Motor function classification systems (GMFCS) – Attached to appendix.



Gross Motor Function Classification System – Expanded and Revised (GMFCS – E & R)

BEFORE 2ND BIRTHDAY

LEVEL I: Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk between 18 months and 2 years of age without the need for any assistive mobility device.

LEVEL II: Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees. Infants may pull to stand and take steps holding on to furniture.

LEVEL III: Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs.

LEVEL IV: Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.

LEVEL V: Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.

BETWEEN 2ND AND 4TH BIRTHDAY

LEVEL I: Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.

LEVEL II: Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.

LEVEL III: Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.

LEVEL IV: Children floor sit when placed, but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.

LEVEL V: Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.

BETWEEN 4TH AND 6TH BIRTHDAY

LEVEL I: Children get into and out of, and sit in, a chair without the need for hand support. Children move from the floor and from chair sitting to standing without the need for objects for support. Children walk indoors and outdoors, and climb stairs. Emerging ability to run and jump.

LEVEL II: Children sit in a chair with both hands free to manipulate objects. Children move from the floor to standing and from chair sitting to standing but often require a stable surface to push or pull up on with their arms. Children walk without the need for a hand-held mobility device indoors and for short distances on level surfaces outdoors. Children climb stairs holding onto a railing but are unable to run or jump.

LEVEL III: Children sit on a regular chair but may require pelvic or trunk support to maximize hand function. Children move in and out of chair sitting using a stable surface to push on or pull up with their arms. Children walk with a hand-held mobility device on level surfaces and climb stairs with assistance from an adult. Children frequently are transported when traveling for long distances or outdoors on uneven terrain.

LEVEL IV: Children sit on a chair but need adaptive seating for trunk control and to maximize hand function. Children move in and out of chair sitting with assistance from an adult or a stable surface to push or pull up on with their arms. Children may at best walk short distances with a walker and adult supervision but have difficulty turning and maintaining balance on uneven surfaces. Children are transported in the community. Children may achieve self-mobility using a powered wheelchair.

LEVEL V: Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.

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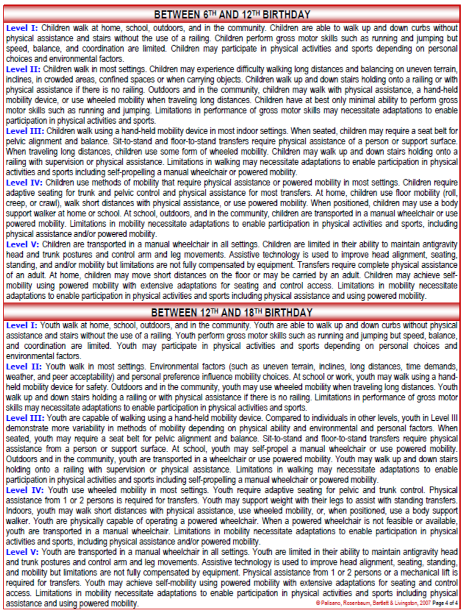

BETWEEN 6TH AND 12TH BIRTHDAY

Level I: Children walk at home, school, outdoors, and in the community. Children are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Children may participate in physical activities and sports depending on personal choices and environmental factors.

Level II: Children walk in most settings. Children may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas, confined spaces or when carrying objects. Children walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Outdoors and in the community, children may walk with physical assistance, a hand-held mobility device, or use wheeled mobility when traveling long distances. Children have at best only minimal ability to perform gross motor skills such as running and jumping. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

Level III: Children walk using a hand-held mobility device in most indoor settings. When seated, children may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance of a person or support surface. When traveling long distances, children use some form of wheeled mobility. Children may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

Level IV: Children use methods of mobility that require physical assistance or powered mobility in most settings. Children require adaptive seating for trunk and pelvic control and physical assistance for most transfers. At home, children use floor mobility (roll, creep, or crawl), walk short distances with physical assistance, or use powered mobility. When positioned, children may use a body support walker at home or school. At school, outdoors, and in the community, children are transported in a manual wheelchair or use powered mobility. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

Level V: Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and and/or mobility but limitations are not fully compensated by equipment. Transfers require complete physical assistance of an adult. At home, children may move short distances on the floor or may be carried by an adult. Children may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

BETWEEN 12TH AND 18TH BIRTHDAY

Level I: Youth walk at home, school, outdoors, and in the community. Youth are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Youth perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Youth may participate in physical activities and sports depending on personal choices and environmental factors.

Level II: Youth walk in most settings. Environmental factors (such as uneven terrain, inclines, long distances, time demands, weather, and peer acceptability) and personal preference influence mobility choices. At school or work, youth may walk using a hand-held mobility device for safety. Outdoors and in the community, youth may use wheeled mobility when traveling long distances. Youth walk up and down stairs holding a railing or with physical assistance if there is no railing. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

Level III: Youth are capable of walking using a hand-held mobility device. Compared to individuals in other levels, youth in Level III demonstrate more variability in methods of mobility depending on physical ability and environmental and personal factors. When seated, youth may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance from a person or support surface. At school, youth may self-propel a manual wheelchair or use powered mobility. Outdoors and in the community, youth are transported in a wheelchair or use powered mobility. Youth may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

Level IV: Youth use wheeled mobility in most settings. Youth require adaptive seating for pelvic and trunk control. Physical assistance from 1 or 2 persons is required for transfers. Youth may support weight with their legs to assist with standing transfers. Indoors, youth may walk short distances with physical assistance, use wheeled mobility, or, when positioned, use a body support walker. Youth are physically capable of operating a powered wheelchair. When a powered wheelchair is not feasible or available, youth are transported in a manual wheelchair. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

Level V: Youth are transported in a manual wheelchair in all settings. Youth are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and mobility but limitations are not fully compensated by equipment. Physical assistance from 1 or 2 persons or a mechanical lift is required for transfers. Youth may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

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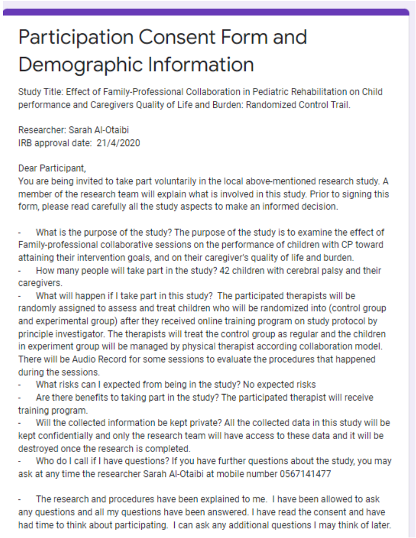
The physical therapists will provide the Motor classification for each child according to GMFCS. **only children with level I to level I included in this study**

5. Demographic data forms:

A. Children and caregivers' form: filled by caregivers and physical therapists

B. Physical therapists form:



Participation Consent Form and Demographic Information

Study Title: Effect of Family-Professional Collaboration in Pediatric Rehabilitation on Child performance and Caregivers Quality of Life and Burden: Randomized Control Trail.

Researcher: Sarah Al-Otaibi
IRB approval date: 21/4/2020

Dear Participant,
You are being invited to take part voluntarily in the local above-mentioned research study. A member of the research team will explain what is involved in this study. Prior to signing this form, please read carefully all the study aspects to make an informed decision.

- What is the purpose of the study? The purpose of the study is to examine the effect of Family-professional collaborative sessions on the performance of children with CP toward attaining their intervention goals, and on their caregiver's quality of life and burden.
- How many people will take part in the study? 42 children with cerebral palsy and their caregivers.
- What will happen if I take part in this study? The participated therapists will be randomly assigned to assess and treat children who will be randomized into (control group and experimental group) after they received online training program on study protocol by principle investigator. The therapists will treat the control group as regular and the children in experiment group will be managed by physical therapist according collaboration model. There will be Audio Record for some sessions to evaluate the procedures that happened during the sessions.
- What risks can I expected from being in the study? No expected risks
- Are there benefits to taking part in the study? The participated therapist will receive training program.
- Will the collected information be kept private? All the collected data in this study will be kept confidentially and only the research team will have access to these data and it will be destroyed once the research is completed.
- Who do I call if I have questions? If you have further questions about the study, you may ask at any time the researcher Sarah Al-Otaibi at mobile number 0567141477

- The research and procedures have been explained to me. I have been allowed to ask any questions and all my questions have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later.

Protocol of Data Collection

All children in both groups will have physical therapy sessions 5 times per week for 6 weeks. Each session will be for at least 45 minutes.

On admission day all participants' caregivers will sign the consent form, and complete the children and caregivers' demographic form, WHOQOL- Brief and ZBI Questionnaires

In the first session, the children will receive assessments and the goals will be determined using GAS.

In the second session, the children and their caregivers in both groups will receive the intervention plan and start intervention if possible.

Other sessions (3- 30) will be for implementing the intervention.

During mid intervention (14 or 15 session), the therapist will re-evaluate the children's performance by GAS.

In the last session, a final evaluation of GAS, ZBI, and WHOQOL-Brief questionnaire.

When physical therapists are treating children in the experimental group, they will interact with the caregivers and provide intervention using the collaborative strategies as described in the therapist training program. When the physical therapists are treating children in the comparison group, they will be asked to provide intervention as they normally do.

Physical therapists' role:

All participating physical therapists in the study will sign the consent form and fill in the therapist demographic sheet prior to their enrolment.

All the physical therapists will be responsible for:

1. Filling in the patient status section in the child demographic sheet.
2. Assessing children and providing the intervention.
3. For physical therapists in the experimental group, interacting with the children's caregivers and providing intervention using the collaborative strategies, whereas physical therapists in the comparison group will provide the intervention as they usually do.

Part 2

Preparation of physical therapists (experimental group):

Learning objectives:

1. To understand the concept of collaboration and its importance in the rehabilitation process.
2. To recognize the basic parts of the collaborative intervention process.
3. To understand the family-professional collaborative model.

Outcomes:

By the end of this program the therapist will be able to:

1. Integrate the concept of collaboration into the rehabilitation process.
2. Apply the family -professional collaborative model.

Family-professional collaboration:

Family-professional collaboration is defined as a mutually supportive interaction through which knowledge and skills are shared, mutual understandings occur, and shared decision are made. The collaborative process is characterized by mutual respect and trust, sharing information, open communication, shared decision-making, and processes that incorporate family beliefs, needs, and preferences into the intervention.

Family-professional collaboration involves both:

1- Relational practice (e. g. being respectful, active listening)
2- Participatory practice (e.g., family involvement in decision-making and intervention planning) components.

Family-Professional Collaborative Model: (Intervention Protocol)

<u>Description of the Model</u>

The model is innovative as it offers specific strategies and procedures to facilitate collaborative interaction between families and professionals in setting meaningful intervention goals to the family, providing ways to achieve these goals, and evaluating individualized outcomes.

Specific Strategies and Procedures to Implement the Collaborative 4 Step Process:

Step 1 Mutually agreed-upon goals

The aim of Step 1 is to determine mutually agreed-upon goals that are specific, measurable, and achievable within a defined period of time. Mutually agreed-upon goals prepare a base for shared planning and decision-making. The therapist will facilitate conversation to get to know a child's interests, previous experiences, challenges, and family preferences and priorities. To involve the family in goal setting, we will use the **client-centred interview process used for the Canadian Occupational Performance Measure (COPM)** and ''**visualizing a preferred future''.**

3. ***The COPM*** is a client-centred outcome measure whose interactive interview process is appropriated for family– professional collaboration.
4. ***The visualizing a preferred future*** is a key strategy of solution-focused conversation. The purpose of this strategy is to enable the family to orient toward positive changes in the immediate future and to determine what will be changed when the intervention plan is successful.

Step 2 Shared planning

The aim of Step 2 is to develop an intervention plan that meets the child and family needs. The therapist facilitates shared planning and integrates intervention into family daily routines by using **''scaling questions''** and the **''family routine and activity matrix''.**

3- The use of ***scaling questions*** is aimed at helping the family in estimating meaningful progress towards the accomplishment of a goal, and identifying where or how to start.

4- ***The Family Routine and Activity Matrix*** offers a structure for identifying how to embed interventions into daily family routines.

Step 3 Shared implementation

The parent and therapist continue to work together while applying the intervention and adjust the intervention plan if needed.

Step 4 Shared evaluation of child and family outcomes

The parent and the therapist determine whether the intervention is effective or not, and goals are attained. Self-reporting and individualized outcome measures are recommended. In our study we will use the Goal Attainment Scaling (GAS) system to determine if the goal is reached.

Key strategies	Example questions
Step 1. Mutually agreed-upon goals. ***Client-cantered interview process [a]:***	
– Exploring child’s interests and needs	‘‘What does your child/family like to do?’’ ‘‘What are some activities that your child would like to do?’’ ‘‘Has your child tried the activity?’’ (In response to a desired activity) ‘‘Is there a particularly difficult part of this activity for your child?’’
– Identifying family priorities	‘‘I would like you to imagine a scale 0 to 3. ‘0’ represents being not at all important, ‘1’ a little important, ‘2’moderately important and ‘3’ represents being very important. How important is it to your family for (child’s name) to be able to do this activity?’’
– Rating child’s current performance	‘‘On a scale of 0 to 3, where ‘0’ means your child does not find it at all difficult to do the activity very well, ‘1’ a little difficult, ‘2’moderately difficult and ‘3’ represents being very difficult for your child to do the activity at all, where would you say your child is today?’’ ‘‘Can you describe how your child does the activity?’’
Visualizing a preferred future:	
– Determining a specific, observable goal for the immediate future	the immediate future ‘‘In 2 months (upon completion of intervention), when you see your child performing the activity, what might make you say, ‘Wow, something is different, he is doing well!’’
Step 2. Shared planning ***Scaling questions:***	
– Rating a preferred future	‘‘On the same scale of 0 to 3 that you used to rate your child’s current performance of the activity, where would you say your child will be in 2 months when the intervention is successfully completed?’’
– Identifying process towards the preferred future	[if a parent rated 1 as child’s current performance and 2 as performance upon completion of intervention] ‘‘What would be the differences between 1 and 2?’’ ‘‘What do you suppose is needed to move your child from 2 to 3?’’ ‘‘How can I help?’’
Family routine and activity matrix:	
– Identifying activities to practise	‘‘What do you think needs to occur for your child to achieve (the goal)?’’ ‘‘Is there anything you and/or your child are doing at this time?’’ ‘‘How are things going?’’
– Identifying possible times to implement the activities	‘‘Can you tell me about a typical day routine for your family?’’ ‘‘Are there especially good times for your child and family to work on this activity?’’ ‘‘Are there especially bad times when it would be very difficult for your child and family to practise this activity?’’
– Identifying roles of family members and therapists	‘‘Who will be responsible for carrying out this activity with your child at (a specific time)?’’ ‘‘How will you/your family support your child while carrying out the activity?’’ ‘‘Is there anything your family needs to carry out the activities?’’ ‘‘How can I support your child and family?’’
Step 3: Shared implementation	
Family’s reflection on intervention	‘‘How have things gone since our last sessions?’’

	Follow-up questions depending on response: ‘‘What did you/your child like the best?’’ ‘‘What was difficult?’’
	‘‘Were there any changes in your child’s performance?’’
	‘‘Do you have questions or concerns about your family carrying out (the activities) as we planned?’’
	‘‘How do you think we should change the plan?’’
Step 4. Shared evaluation	
Family evaluation	‘‘On a scale of 0 to 3, where ‘0’ is not at all difficult to do the activity (very good performance) and ‘3’ represents being very difficult for your child to do the activity at all, where would you say your child is today?’’
	‘‘Can you describe your child’s current performance of (the activity)?’’
Guiding to a new goal	‘‘We can continue to work on this activity for better performance or determine a new goal. Which one do you prefer?’’

Table 1: Strategies and examples of questions by therapists to foster collaboration.

[a] Interview questions adapted from the Canadian Occupational Performance Measure (COPM) and Goals attainment Scale (GAS). Adapted from: An and Palisano (25)

الملخص والمستخلص العربي

الملخص

الخلفية: تعاون العائلة والأخصائي أمر بالغ الأهمية لزيادة نتائج الأطفال المصابين بالشلل الدماغي ومقدمي الرعاية لهم. وتتضمن عملية تنفيذ التعاون بين العائلة والأخصائيين أربع خطوات: الأهداف المتفق عليها بشكل متبادل، والتخطيط المشترك، والتنفيذ المشترك، والتقييم المشترك.

الأهداف: دراسة تأثير البرنامج التدريبي للتعاون بين العائلة والأخصائيين في مجال العلاج الطبيعي على أداء الأطفال المصابين بالشلل الدماغي نحو تحقيق أهدافهم العلاجية، وكذلك تأثير البرنامج على جودة حياة مقدمي الرعاية لهم، وعلى عبءهم.

الطريقة: دراسة عشوائية ضابطة، ضمت ثمانية وعشرين أخصائي علاج طبيعي، وأربعة وأربعين طفلاً مصابًا بالشلل الدماغي، ومقدمي الرعاية لهم. تم تقسيم المشاركين بشكل عشوائي إلى مجموعتين كالتالي (المجموعة التجريبية وتتضمن 12 أخصائي علاج طبيعي و 21 طفلا مع مقدمي الرعاية لهم) و (المجموعة الضابطة وتتضمن 16 أخصائي علاج طبيعي و 23 طفلا مع مقدمي الرعايه لهم). تلقى الأطفال المشاركين جلسات علاج طبيعي مكثفة لمدة 6 أسابيع (5 جلسات / أسبوع) حيث استمرت كل جلسة لمدة 45- 60 دقيقة. تلقى اخصائيي العلاج الطبيعي في المجموعة التجريبية جلستين تدريبيتين عبر الإنترنت مدة كل منهما(3 ساعات) ؛ تضمنت الجلسة الأولى تدريبًا على إجراءات جمع البيانات وتطبيق المقاييس المستخدمة في الدراسة. أما الجلسة الثانية فقد تضمنت تدريباً على تطبيق التعاون بين العائلة والاخصائي وكيفية علاج الأطفال على هذا الأساس. كما تلقى اخصائيي العلاج الطبيعي في المجموعة الضابطة الجلسة الأولى للتدريب فقط. ثم تم قياس النتائج بمقياس تحقيق الهدف (GAS) لقياس أداء الأطفال نحو تحقيق أهدافهم العلاجية، وملخص جودة الحياة لمنظمة الصحة العالمية (WHOQO-Brief) لقياس جودة حياة مقدم الرعاية، ومقابلة عبء زاريت (ZBI) لتقييم عبء مقدم الرعاية.

النتائج: أظهرجميع الأطفال في المجموعتين التجريبية والضابطة تحسناً في معدل تغير GAS($p = 0.002$)، وكان حجم التأثير ($\eta p^2 = 0.20$) وهوتأثير صغير، مع عدم وجود فروق ذات دلالة إحصائية بين المجموعات ($p > 0.44$)، وكان حجم التأثير ($\eta p^2 = 0.02$) وهوتأثير بسيط. ومع ذلك ، أظهر الأطفال في المجموعة التجريبية أداءً أفضل في التقييم الاخير من المجموعة الضابطة حيث استمروا في التقدم نحو الأهداف العلاجية خلال فترة التدخل.

في المقابل ، ارتفع أداء المجموعة الضابطة في التقييم الأول وانخفض في التقييم الاخير.ولم تكن هناك تأثيرات أو تفاعل رئيسي للوقت أو المجموعة على مجالات جودة الحياة، ولم يكن هناك تأثير رئيسي للوقت على العبء لمقدمي الرعاية، ولكن كان هناك تأثير رئيسي بين المجموعات (p = 0.03)، $\eta p^2 = 0.11$ بالتفضيل للمجموعة التجريبية.

الخلاصة: يعد التعاون بين الأخصائين والعائلة ممارسة مهمة يجب تطبيقها أثناء جلسات العلاجية للأطفال المصابين بالشلل الدماغي لتحسين تحقيق الأهداف وتقليل عبء مقدمي الرعاية لهم.

المستخلص العلمي

خلفية البحث: تم اقتراح تعاون العائلة والأخصائيين في إعادة تأهيل الأطفال باعتباره أمرًا بالغ الأهمية لتحديد الأهداف والتخطيط وتنفيذ التدخل العلاجي الذي يلبي احتياجات وأولويات عائلة الطفل. إن تحديد هدف والعلاج التعاوني لهما آثار إيجابية على تحسين نمو الأطفال وأدائهم للمهام الوظيفية وتحقيق الأهداف. أيضًا ، يرتبط ارتباطًا إيجابيًا بالتحسن في الصحة العاطفية للوالدين ، ومستويات التوتر ، ورضاهم عن خدمات الرعاية الصحية ، والشعور بالكفاءة ، والمشاركة في العلاج. تتضمن عملية تنفيذ التعاون بين العائلة والأخصائيين من أربع خطوات: الأهداف المتفق عليها بشكل متبادل ، والتخطيط المشترك ، والتنفيذ المشترك ، والتقييم المشترك.

الأهداف: دراسة تأثير البرنامج التدريبي لتعاون العائلة وأخصائيين العلاج الطبيعي على: 1- أداء الأطفال المصابين بالشلل الدماغي نحو تحقيق أهدافهم العلاجية ، 2- جودة حياة مقدمي الرعاية لهم ، 3- العبء على مقددمي الرعاية لهم. .

منهجية البحث: دراسة عشوائية ضابطة، ضمت ثمانية وعشرين أخصائي علاج طبيعي، وأربعة وأربعين طفلاً مصابًا بالشلل الدماغي، ومقدمي الرعاية لهم. تم تقسيم المشاركين بشكل عشوائي إلى مجموعتين كالتالي (المجموعة التجريبية وتتضمن 12 أخصائي علاج طبيعي و 21 طفلا مع مقدمي الرعاية لهم) و (المجموعة الضابطة وتتضمن 16 أخصائي علاج طبيعي و 23 طفلا مع مقدمي الرعايه لهم). تلقى الأطفال المشاركين جلسات علاج طبيعي مكثفة لمدة 6 أسابيع (5 جلسات / أسبوع) حيث استمرت كل جلسة لمدة 45- 60 دقيقة. تلقى اخصائيي العلاج الطبيعي في المجموعة التجريبية جلستين تدريبيتين عبر الإنترنت مدة كل منهما(3 ساعات) ؛ تضمنت الجلسة الأولى تدريبًا على إجراءات جمع البيانات وتطبيق المقاييس المستخدمة في الدراسة. أما الجلسة الثانية فقد تضمنت تدريباً على تطبيق التعاون بين العائلة والاخصائي وكيفية علاج الأطفال على هذا الأساس. كما تلقى اخصائيي العلاج الطبيعي في المجموعة الضابطة الجلسة الأولى للتدريب فقط. ثم تم قياس النتائج بمقياس تحقيق الهدف (GAS)

لقياس أداء الأطفال نحو تحقيق أهدافهم العلاجية، وملخص جودة الحياة لمنظمة الصحة العالمية (WHOQO-Brief) لقياس جودة حياة مقدم الرعاية، ومقابلة عبء زاريت (ZBI) لتقييم عبء مقدم الرعاية.

النتائج:

1. أظهر الأطفال تحسناً نحو تحقيق أهدافهم بعد تدخل العلاج الطبيعي في كلا المجموعتين. على معدل تغير الأهداف (GAS) ($p = 0.002$) ، وكان حجم التأثير ($\eta p2 = 0.20$) وهو تأثير صغير ، مع عدم وجود فروق ذات دلالة إحصائية بين المجموعات ($p <0.44$) وكان حجم التأثير ($\eta p2 = 0.02$) وهو تأثير ضئيل.

2. لا توجد فروق ذات دلالة إحصائية بين المجموعة الضابطة والتجربية، ولكن كان هناك تفاعل بين عوامل الوقت والمجموعة في معدل تغير الأهداف (GAS) ($P = 0.04$) وحجم التأثير الصغير ($\eta p2 = 0.10$).

3. حدثت معظم التحسينات للمجموعة الضابطة خلال الأسابيع الأولى من تدخل العلاج الطبيعي حيث أظهر الأطفال معدل تغير أعلى في GAS) (أثناء التقييم الأول (19.11 ، SE 1.48) ، وانخفض معدل التغيير أثناء التقييم الاخير (11.08 ، SE 1.44). بينما أظهرت المجموعة التجريبية عدم وجود فروق ذات دلالة إحصائية في معدل تغيرات الغاز بين التقييم الأول والاخير (14.49 ، SE 1.55، 12.78 ، SE 1.51) على التوالي. كما أظهرت المجموعة التجريبية تغيرات أعلى من المجموعة الضابطة في التقييم الاخير، إلا أن التغيير لم يصل إلى مستوى الدلالة.

4. لم تكن هناك آثار أو تفاعلات رئيسية للوقت أو المجموعة في مجالات جودة الحياة لمقدمي الرعاية.

5. لم يكن هناك تأثير رئيسي للوقت على العبء ($p = 0.36$) وحجم التأثير ($\eta p2 = 0.02$) ولكن كان هناك تأثير رئيسي للمجموعات ($p = 0.03$) ، وحجم التأثير ($\eta p2 = 0.11$).

6. انخفض العبء بعد تطبيق النموذج التعاوني لمقدمي الرعاية في المجموعة التجريبية أكثر من مقدمي الرعاية في المجموعة الضابطة.

الخلاصة: ظهر تحسن الأطفال في المجموعات التجريبية والضابطة على تغييرفي الأهداف GAS (مع عدم وجود فرق بين المجموعات على الرغم من أن المجموعة التجريبية لديها تحسن كبير في التقييم الاخير أكثر من المجموعة الضابطة. لا توجد فروق ذات دلالة إحصائية بين المجموعات لمقدمي الرعاية QOL ، ولكن كانت هناك فروق ذات دلالة إحصائية بين المجموعات في العبء للمجموعة التجريبية. تؤيد هذه الدراسة قيمة التعاون بين العائلة والأخصائيين لتحسين نتائج الأطفال ومقدمي الرعاية لهم، وتوصى بالبحث المستقبلي في هذا النطاق

تأثير التعاون بين العائلة والأخصائي على أداء الأطفال المصابين بالشلل الدماغي، وجودة الحياة والعبء على مقدم الرعاية لهم: تجربة عشوائية محكمة.

أعدتها الطالبة

ساره بنت لفاي بن مفرح العتيبي

بكالوريوس علاج طبيعي

نوقشت الرسالة بتاريخ 1443/11/7 ه- الموافق 2022/06/06 م

وتمت إجازتها

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