The Effectiveness of Play Therapy-Based Physiotherapy Programs versus Conventional Programs in Treatment Adherence and Gross Motor Function in Children with Cerebral Palsy GMFCS Level III-IV: A Randomised Controlled Trial Protocol

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1. Title

The effectiveness of play therapy-based physiotherapy programs versus conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV: a Randomized Controlled Trial protocol.

2. Summary

Background: Children with cerebral palsy (CP) frequently struggle with gross motor function, which can interfere with their daily activities and quality of life. Although physiotherapy is an important intervention for improving gross motor function in children with cerebral palsy, adherence to treatment remains a challenge. Physiotherapy programs based on play therapy have been proposed as a new alternative approach to improving treatment adherence and gross motor function in children with cerebral palsy. The aim of this research protocol is to compare the efficacy of play therapy-based physiotherapy programs compared to traditional physiotherapy programs in improving treatment adherence and gross motor function in children with CP GMFCS level III-IV.

Methods: This study will be a randomized controlled trial with a sample size of 64 children aged 4-12 with CP GMFCS level III-IV. Participants will be randomly assigned to receive either a play therapy-based physiotherapy or conventional physiotherapy program 45 minutes twice a week for a period of 16 weeks. Treatment adherence will be measured using a combination of physiotherapy session attendance rates, an adherence logbook and the Goal Attaindance Scale (GAS). Gross motor function will be assessed using the Gross Motor Function Measure (GMFM-88) and Quality of life will be measured using the CPQoL-Child, all this will be measured at baseline, 5 weeks, 10 weeks and 16 weeks of intervention and a follow-up at 24 weeks will be done. Data will be analysed using descriptive statistics, independent t-tests, ANCOVA and correlations.

Key words: infantile cerebral palsy, play-therapy, treatment adherence, gross motor function, quality of life and physiotherapy.

3. Título

La eficacia de los programas de fisioterapia basados en la terapia de juego frente a los programas de fisioterapia convencionales para mejorar la adherencia al tratamiento y la función motora gruesa en niños con parálisis cerebral GMFCS nivel III-IV: un protocolo de investigación para un ensayo controlado aleatorizado.

4. Resumen

Antecedentes: Los niños con parálisis cerebral (PC) suelen tener alterada la función motora gruesa, lo que puede interferir con sus actividades diarias y su calidad de vida. Aunque la fisioterapia es una intervención importante para mejorar la función motora gruesa en niños con CP, la adherencia al tratamiento sigue siendo un desafío. Los programas de fisioterapia basados en la terapia de juego se han propuesto como una nueva alternativa para mejorar la adherencia al tratamiento y la función motora gruesa en niños con parálisis cerebral. El objetivo de este protocolo es comprobar la eficacia de los programas de fisioterapia basados en la terapia de juego en comparación con los programas de fisioterapia convencionales para mejorar la adherencia al tratamiento y la función motora gruesa en niños con PC GMFCS nivel III-IV.

Métodos: Este estudio será un ensayo controlado aleatorizado con un tamaño de muestra de 64 niños de 4 a 12 años con PC GMFCS nivel III-IV. Los participantes serán asignados al azar para recibir fisioterapia basada en terapia de juego o fisioterapia convencional 45 minutos dos veces por semana durante un período de 16 semanas. La adherencia al tratamiento se medirá mediante una combinación de tasas de asistencia a las sesiones de fisioterapia, un libro de registro propio y la escala de logro de objetivos (GAS). La función motora gruesa se evaluará mediante el Gross Motor Function Measure (GMFM-88) y la Calidad de vida se medirá mediante el CPQoL-Child, todo esto se medirá al inicio, a las 5 semanas, 10 semanas y 16 semanas de intervención y un se hará seguimiento a las 24 semanas. Los datos se analizarán mediante estadística descriptiva, pruebas t independientes, ANCOVA y correlaciones.

Palabras clave: parálisis cerebral infantil, terapia de juego, adherencia al tratamiento, función motora gruesa, calidad de vida y fisioterapia

5. Background

The term Cerebral Palsy (CP) is a chronic non-degenerative condition of the developing brain which has no cure, few disease-modifying interventions and lots of comorbidities (1–3). Is the most common cause of physical disability in childhood, decreasing quality of life (QoL), and is characterised by a variety of movement and postural disorders, causing activity limitation (4,5).

Multiple etiologies of cerebral palsy affects 2-3 out of every 1,000 live births (1). This interference can happen during the perinatal period including the time during pregnancy (82%), the time of birth (10%), and the first two years of life (8%) (4). Genetic variations, congenital abnormalities, preterm birth, kernicterus, intrauterine growth restriction and infection, hypoxic ischaemia, cerebrovascular insults and accidental and non-accidental brain injury, are known as risk factors that can be combined to cause CP pathways (2,4).

Cerebral palsy is generally diagnosed clinically by identifying and classifying defining features based on movement disorders in the earliest at 6 months (corrected for prematurity), but it is usually confirmed the second year of life when the signs are consistent and neuroimaging (MRI) is available to confirm brain injury (2,4).

The cerebral palsy related movement and tone disorders are very heterogenous and it ca be classified topographically with the terms hemiplegia (20-30%), diplegia (55-70%) and quadriplegia (10-15%) and by its motor type divided into four categories (2,4,6):

- Spastic (80%): The damage is originated in the brain and tracks controlling movement. There's a velocity-dependent increased tone (stiff muscles), which is not necessarily continuous, hyperreflexia and upper motor neuron signs.
- Dyskinetic (15%): The damage is originated in the subcortical structure. We can see uncontrolled, repetitive, and involuntary movements that might be stereotyped with a fluctuating muscle tone.

It can be dystonic, characterised by hypertonia and hypokinesia causing stiff movements; or choreoathetoid, characterised by hypotonia and hyperkinesia causing quick and uncontrolled jerky and twisting movements.

- Ataxic (4%): The damage is originated in the cerebellum. There's a loss of the coordination of muscles, of accuracy of movement and unspecific hypotonia. The movement is characterised by atypical force, rhythm, and control of it.
- Mixed pattern (1%): There's no predomination of atypical tone or movement disorder and the most frequent mixed type is a combination of spastic and athetoid patterns.

We can see that this classification doesn't have into account activity and participation limitations as CP must relate to the International Classification of Functioning, Disability and Health (ICF) framework for disability (7). That's why an instrument like the Gross Motor Function Classification System (GMFCS) it's a better tool of classification. This is an age-dependent classification system which describes 5 groups of CP depending on their level of mobility (2,4), without having into account the type of CP, and determines which equipment or mobility aids may the child need in the future in order to provide a prognosis (8). Level 1 denotes minimal disability whereas level 5 denotes complete dependence. Also, there are other functional classification systems that include manual ability, sitting stability, communication skills and eat and drink ability (8).

The principle symptoms of CP are movement disorders caused by spasticity and/or dystonies, resulting in musculoskeletal secondary problems such as hip pain or displacement, weak gross motor ability, hand dysfunction and/or equinus deformity ending up in mobility limitations (2, 4). Moreover, patients with CP may also experience complications not related to movement including intellectual disability (50%), pressure ulcers, incontinence (25%), sleeping, behavioural or emotional disorders (20-25%), vision, hearing and communicating impairments (25%), scoliosis, hydrocephalus, epilepsy (35-62%), cardio-respiratory status or endocrine insufficiency that decrease life expectancy and play as a handicap in the treatment (2,4).

Moreover, there is evidence that socioeconomic status, ethnicity, and gender can influence the incidence (9-13), severity (11) and type of CP (9) as well as affecting their quality of life. Some research attributed this to restricted access to healthcare during pregnancy and childbirth, environmental toxins, and greater rates of premature birth and low birth weight. Three of these research (10, 11, 13) determine that understanding better population groups will improve outcomes over the life course of children with CP and their treatment adherence, but that further investigations might be required to identify how socioeconomic status and ethnicity may influence, and this should be transferred also to planning physiotherapy programs.

The treatments for CP varies depending on the specific symptoms and should be multidisciplinary, but in general is focused on movement disorders and musculoskeletal deformities where physicians and surgical specialist commonly use intramuscular onabotulinumtoxinA, oral or intrathecal muscle relaxants, selective dorsal rhizotomy and hip preventive surgeries, which have to be combined with physiotherapy to obtain maximum benefits (2,4). Nevertheless, before deciding which treatment use is important to discuss expectations with the families to facilitate a tailored multidisciplinary treatment plan based on the patient's individual needs and achievable goals (4).

However, the main treatment is physiotherapy as a way of symptoms management as soon as CP is diagnosed. This intervention will be used especially during childhood and adolescence, to treat movement and balance problems, but also throughout their entire lives. An international practice guideline of improving motor function in CP and published in 2022 (3) determines that there are different modalities and approaches including: massage, weight-bearing, electrical stimulation, treadmill use, stretching, strengthening, endurance training, constraint-induced movement therapy, hippotherapy, virtual reality and biofeedback. Although physiotherapy is the main treatment, there is minimal data supporting on one modality over another due to the difficulty on studying this population (3,4,6).

Children with CP often need intensive and ongoing physical therapy to control their symptoms, improve motor skills, and maintain quality of life. That's why treatment adherence can be a significant challenge in this population, leading to

suboptimal patient outcomes and increasing healthcare costs. Therefore, exploring new interventions that improves treatment adherence and motor function in children with CP is an important research goal.

What it's surprising is that knowing that we are treating children, there's no treatment that includes playing as an intervention. Play is children's natural environment through which they communicate, explore and develop motor skills and social interaction (14). According to some studies (14–17), play therapy is an intervention based on play and its benefits are: increasing the level of oxytocin, enhancing well-being and trust, reinforcing the therapeutic relationship and activating mirror neurons (15); all that providing neuroplasticity and creating new neuronal pathways that helps in improving altered skills like gross motor function is (15). Based on this theory and the fact that physiotherapy programs in children with CP are long lasting and can be boring, exhausting and demotivating, physiotherapy sessions should be more effective and enjoyable if they focused on both the physical and emotional needs of children through play (14,16).

It exists different types of play therapies, but the two most common types of therapeutic play are directed therapeutic play and non-directed therapeutic play. In the directed type, the therapist directs the play and its objectives, determining the theme and content of the play process as well as the activity in which the child will participate (14,16). In the non-directed type, the environment and materials are still selected by the therapist with the same purpose as before, but now is the child who decides the rest of the activity making it spontaneous (14,16). The choice of which type use should be individualized so the physiotherapist who works with the child should plan therapy sessions around his or her motivations and limitations (16).

Having this into account, play therapy-based physiotherapy programs are a relatively new approach to treating children with CP. These programs aim to increase treatment adherence by using play and games to make physiotherapy sessions more enjoyable and engaging for children. While some studies (16-18) have suggested that play therapy-based interventions can improve gross motor function and treatment adherence in children with CP, the evidence base is limited and inconclusive as their methodologies aren't consistent.

A study from 2012 (17) that investigated the efficacy of play therapy combined with conventional therapy in improving hand function ability in children with spastic diplegic cerebral palsy, concluded that the interventional group showed better outcomes than the group not doing the session based on play therapy. In addition, an integrative review from 2018 (18) studied the use of play therapy in motor rehabilitation in CP. Most of the studies included in this review used computer games and video games and concluded that incorporating play-based activities into the treatment of children with cerebral palsy, when used correctly, is important to encourage motor skill improvement and benefit the therapeutic relationship, making therapy more dynamic and effective.

There's also a thesis from 2016 (16), on which I've based my hypothesis, which determined that play could serve as a mediator and an appropriate developmental approach for children with chronic health conditions (as CP is) who attend physiotherapy sessions in order to achieve physical and emotional changes. Also, this thesis concluded saying that "although the information presented was not sufficient to draw conclusion, it could serve as a first step for new researchers to study it" (16).

So, having into account the most commons signs of CP, the role of physiotherapy in its treatment, the duration of the treatment, the benefits of play therapy and the poor evidence that exists about it; the aim of this study is to investigate whether play therapy-based physiotherapy programs are more effective than conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV. This study will use a randomized controlled trial design to compare the effectiveness of play therapy-based physiotherapy programs and conventional physiotherapy programs in a sample of children with CP.

This study's findings will have important implications for clinical practice, as they may inform the development of more effective and engaging physiotherapy interventions for children with CP, potentially leading to improved treatment adherence and better gross motor function outcomes which may increase consequently QoL. All in all, I'm sure this protocol of investigation is the first step of something that has been highly requested in the recent years.

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7. Research Question and Hypothesis

7.1. Research Question

Are play therapy-based physiotherapy programs more effective than conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV?

7.2. Hypothesis

Play therapy-based physiotherapy programs are more effective than conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV.

8. General and Specific Objectives

8.1. General Objective

To compare the effectiveness of play therapy-based physiotherapy programs versus conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV over a 24-week period.

8.2. Specific Objectives

I. To compare treatment adherence among children receiving game-based physiotherapy and those receiving conventional physiotherapy.
II. To evaluate improvements in gross motor function among children receiving game-based physiotherapy and those receiving conventional physiotherapy.
III. To compare quality of life between children receiving game-based physiotherapy and those receiving conventional physiotherapy.
IV. To identify potential factors that may influence quality of life, treatment adherence, and improvements in gross motor function in both treatment groups.

9. Methodology

9.1. Design

This study will be a randomized controlled trial (RCT) comparing the effectiveness of play therapy-based physiotherapy programs with conventional physiotherapy programs in improving treatment adherence and gross motor function in children with CP GMFCS level III-IV. Owing to the nature of the intervention, this is a prospective study and participants and physiotherapists will not be able to be blinded to group allocation. However, to minimise the risk of bias, outcome assessors will be blinded to group allocation.

9.2. Participants, Recruitment and Criteria of Selection

9.2.1. Participants

The participants of this research will be children with CP GMFCS level III-IV, aged 4 to 12 years and receiving physiotherapy services.

For the sample size (Annex I), help will be requested from a statistician, and it will depend on factors such as the expected effect size based on previous studies or clinical knowledge, the level of statistical power desired and the level of significance. For example, knowing that similar studies have a sample size of 30, which is always their limitation, a medium effect size is expected, a power of 80% is desired and 0.5 is considered as the level of significance, a sample size of around 64 participants (32 in each group) might be appropriate. However, this sample size might need to be adjusted based on the recruitment rate, dropout rate, and effect size observed during the study.

9.2.2. Recruitment

Participants will be recruited from rehabilitation centres or special education schools which treat children with cerebral palsy GMFCS level III-IV. Potential participants will be screened and chosen based on the inclusion and exclusion criteria. Those who match the inclusion criteria will be invited to participate in the study and an initial screening (Annex II) will be organized in the same centre where they receive their regular treatment. The research purpose, methodology,

risks and benefits and their rights as study participants, will be explained by a call and, if the parents required, it will be explained face to face. The informed consent will be obtained from the parents or legal guardians before starting the baseline assessment.

To ensure diversity in the sample and be able to identify potential factors in the statistical analysis, efforts will be made to recruit participants from a range of socio-economic backgrounds and ethnicities. All the process will be conducted ethically, respectfully and sensitively to the needs of the group being investigated.

Moreover, the study team should take the appropriate steps to guarantee that all possible participants have equitable access to the study and that the recruitment procedure respects potential participants' and their families' privacy and autonomy.

9.2.3. Field of Research

The intervention will take place at a centre, or a special education school specialised in neuropediatric rehabilitation, where they will have all of the required equipment and space for the intervention sessions, which will be led by qualified physiotherapists with experience treating children with cerebral palsy. Some potential places could be ASPACE or CEE l'Arboç because they are specialised in treating children with these characteristics, have enough space to conduct the interventions (explained in section 12. Necessary Resources) and, as I've done my internship there, it would be easier to arrive at an agreement with them.

9.2.4. Selection Criteria

The inclusive and exclusive criteria are designed to ensure that every participant is representative of the target population and has similar levels of impairments and functional limitations.

The inclusion criteria will be:

- Children diagnosed with cerebral palsy by a paediatric neurologist.
- Aged between 4 and 12 years.

- Classified as level III-IV on the GMFCS (A).
    - Children with level III GMFCS walk with assistive mobility devices as they have limitations walking outdoors and in the community.
    - Children with level IV GMFCS have self-mobility with limitations as children are transported or use power mobility outdoors and in the community.
- Regularly receiving physiotherapy at a rehabilitation centre.
- Able to follow instructions and participate in play-based therapy sessions.
- Parental or guardian inform consent signature.

On the other hand, the exclusion criteria will be:

- Children with other neurological or genetic disorders.
- Children with severe cognitive, communication or comorbidities impairments that would interfere with the assessment of outcomes.
- Any contraindications to physical activity or play-based therapy as assessed by a physician.
- Children who are currently participating in other clinical research which might confuse the study's findings.

9.2.5. Randomization

Participants will be randomly assigned to either the experimental group (play therapy-based physiotherapy program) or the control group (conventional physiotherapy program). However, to guarantee group balance, randomization might be stratified by age, gender and GMFCS level. In addition, allocation concealment will be applied to reduce the risk of bias for the outcome assessors.

To do the stratified randomization, first participants will be categorized by the level of GMFCS (III or IV). Then, they will be divided into two subgroups according to age (4-7 years and 8-12 years) and inside these subgroups they will be divided by gender (male and female). Within each stratum, participants will be randomly allocated to either group using a computer-generated randomization list created by an independent statistician who will not be involved in the study.

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9.3. Intervention

The intervention will consist of two groups: a play therapy-based physiotherapy group (experimental group) and a conventional physiotherapy group (control group).

The play therapy-based physiotherapy group will receive 45 minutes sessions of play therapy-based physiotherapy twice a week for 16 weeks (32 sessions in total). The play therapy-based physiotherapy sessions will be conducted by a trained and licensed physiotherapist and will be planned incorporating playing activities such as ball games, obstacle courses, music, sensory toys, and pretend play combined with standard physiotherapy exercises (Annex III). All that, based on the child's interests and abilities, with the aim of engaging the child in a pleasant and enjoyable activity that simultaneously enhances gross motor function. Moreover, the physiotherapist will offer feedback and positive reinforcement throughout play therapy sessions to encourage adherence. The therapist will also give advice and assistance to the child as needed to ensure that they can do each exercise safely and efficiently and the family will receive home recommendations based on play to assist their worries and questions.

The conventional physiotherapy group will receive 45 minutes sessions of conventional physiotherapy twice a week for 16 weeks (32 sessions in total). The conventional physiotherapy sessions will also be conducted by a trained and licensed physiotherapist and will include standard physiotherapy exercises following the international clinical practice guideline from 2022 of Jackman M, et al (3). These sessions will be planned for each child's needs and goals, for improving gross motor function and increasing treatment adherence. Moreover, the physiotherapist will offer feedback and positive reinforcement throughout sessions to encourage adherence. The therapist will also give assistance as needed to ensure that they can do each exercise safely and efficiently and the family will receive home recommendations based on their worries and questions.

Both groups will get their respective treatments at the same location, and the study team will rigorously monitor adherence to the intervention program. The study team will also gather information on any adverse events or problems that may occur throughout the intervention.

9.4. Outcome Measures

In this research protocol de dependent variables will be treatment adherence and gross motor function as primary outcome measures and quality of life as a secondary measure, while de independent variable is the type of physiotherapy program received either the play therapy-based physiotherapy program or the conventional physiotherapy program.

9.4.1. Treatment Adherence

Treatment adherence will be measured as a primary outcome and refers to the extent to which a patient follows or complies with the recommended or prescribed treatment plan and it's a process in which the appropriate treatment is decided after a proper discussion with the patient and its family to establish its goals and motivations (B). Having into account this definition, treatment adherence will be measured using objective and subjective measures noted in a logbook by the physiotherapist after each session (Annex IV). In this logbook it will be measured the percentage of completed physiotherapy sessions out of the total number of sessions scheduled, the percentage of exercises done in each session, how the child felt while doing each exercise and if parents/carers have followed the recommendations given. The maximum punctuation is 12 and the minimum is 1 point. The physiotherapist will not know which punctuation receive each option in order to reduce the risk of bias.

In addition, the Goal Attainment Scale (GAS) will be used as a method to measure if the goals determined before starting the intervention has been achieved or not (B), which is highly related to treatment adherence. This goal setting will be done based on parents or guardians and children's needs and motivations, which will be commented with the physiotherapist so that he or she can plan a tailored physiotherapy program. Moreover, all the goals will follow the SMART criteria to try to be as much objective and measurable as possible.

B. Cusick A, et al. A comparison of goal attainment scaling and the Canadian Occupational Performance Measure for paediatric rehabilitation research. Pediatr Rehabil. 2006 Jun;9(2):149-57.

9.4.2. Gross Motor Function

The gross motor function will be also measured as a primary outcome and refers to the ability to coordinate and control movements using the large muscles in the body to perform physical activities, such as crawling, walking, jumping, running, and climbing (C). It will be measured using the Gross Motor Function Measure – 88 items (GMFM-88) (C), a standardized observational measure developed to evaluate changes in gross motor function over time in children with cerebral palsy. It consists of 88 items that are rated on a 4-point scale from 0 (cannot perform) to 3 (performs well) and is divided into five dimensions: A (lying and rolling), B (sitting), C (crawling and kneeling), D (standing) and E (walking, running and jumping). Also, you can evaluate the child using devices or orthoses, which is why I chose this instrument over the GMFM-66 items.

9.4.3. Quality of Life

The quality of life will be measured as a secondary outcome being the person's or parents' total perception of well-being including physical, psychological, and social aspects of life (D). It will be measured with the Cerebral Palsy Quality of Life Questionnaire for child (CP QoL-Child) (D), which is a specific questionnaire designed to measure the health-related quality of life (HRQoL) of children with cerebral palsy consisting of 66 items divided in 6 different domains of quality of life based on the ICF: social well-being, functioning, participation and physical health, emotional well-being, access to services, and pain and impact of disability. It can be completed by parents or caregivers (4-12 years) as well as by older children (9-12 years) on their own, in the last case it consists of 53 items as it doesn't ask about parents or caregivers QoL. Each item is scored on a 5-point Likert scale ranging from "never" to "always" or "not at all" to "very much".

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9.5. Data Collection

Many steps will be applied during the study to guarantee the security and confidentiality of participants' data. To begin, all data obtained will be kept totally secret and only authorized members of the study team will have access to it. To do the allocation concealment, a statistician will generate the randomization list by given to participants a unique identification number, which will be used to assign them to one or another group.

For the outcome measure assessment different procedures will be conducted. The GAS, the GMFM-88 and the CP QoL-Child will be done at baseline, after 5, 10 and 16 weeks and at the follow-up assessment at 24 weeks. In the baseline the GAS will be used as a way for the physiotherapist to plan the intervention and in the mid-term assessments the goals achievement will be measured, all this by the physiotherapist. The GMFM-88 will be assessed by the outcome assessor and the CP QoL-Child will be done by parents or caregivers who will give the questionnaire to the research assistants for them to score it and save it.

On the other hand, the logbook will be completed by the physiotherapist after each participant session and at the end of the 16 weeks intervention will be given to the research assistants to do the data collection and after that, the analysis.

All paper-based data will be stored in locked cabinets in a secure research facility and electronic data will be kept on a password-protected computer and will be stored and managed from Microsoft One Drive cloud, which contains a double security system. Exclusively authorized people will be able to access to the data.

Only de-identified data will be shared in any publications or presentations emerging from the study to protect the privacy and confidentiality of participants. Without express written authorization, participants' personal data will not be shared with anybody outside of the study team.

Once all the study is finished, the obtained data may be maintained for a limited time, as needed by institutional guidelines, before being securely deleted to prevent unauthorized access or use. Overall, the research team is committed to maintaining the greatest levels of privacy and confidentiality to protect the safety and well-being of all study participants.

9.6. Data Analysis

All data collected from the assessments, questionnaires and the logbook will be analysed using appropriate statistical methods with the help of an expert statistician to achieve the aims of this research protocol. The statistical analyses will be conducted using a statistical software package such as JASP and the statistical significance will be set at p-value <0.05 and CI (Confidence Interval) 95%. When p-value < 0,05, the null hypothesis (Ho) will be rejected meaning that the results are statistically significant. The Ho is: There is no significant difference between the effectiveness of play therapy-based physiotherapy programs and conventional physiotherapy programs in improving treatment adherence and gross motor function in children with cerebral palsy GMFCS level III-IV.

After collecting all data, it will be placed into a spreadsheet for basic data cleaning and categorization (Annex V). Descriptive statistics (e.g., mean, median, standard deviation, range…) will be calculated to summarize quantitative variables such as age, attendance rate, treatment adherence logbook, GAS score, GMFM-88 score and CP QOL-Child score, while frequency distributions and percentages will be used to summarize categorical variables such as gender, GMFCS level (III or IV), socio-economic status, ethnicity, and type of intervention. All that describes the participants' demographic and baseline characteristics, as well as analyses the distribution of the variables of interest.

Statistical analysis will be done to test the hypothesis using appropriate methodologies based on the data distribution and characteristics. For quantitative variables, t-tests or ANOVA may be used to compare means between the two groups (play therapy-based physiotherapy versus conventional physiotherapy). However, for categorical variables, chi-square or Fisher's exact test might be used, but in this study, it may not be necessary as the hypothesis doesn't include categorical variables.

Moreover, linear regression analysis may be used to investigate the association between treatment adherence and gross motor function while to identify predictors of treatment adherence, gross motor function and quality of life, including age, gender, GMFCS level, social-economic status, ethnicity, and treatment group so potential confounding variables will be controlled for in the

regression model. In addition, for identifying predictors of treatment adherence each part of the logbook will be analysed in this same way.

Lastly, the findings will be presented concisely and understandably, using tables and graphics and conclusions will be formed based on the statistical significance.

9.7. Study limitations

Some potential limitations of the study might include sample size as it may be too small to make generalizable results to a larger population of children with cerebral palsy and the study will only cover children with GMFCS levels III-IV of a specific range of age. So further studies may require a larger sample size.

Secondly, the study may not capture the long-term effects of the interventions, as the follow-up period is relatively short.

Thirdly, owing to the nature of the intervention, participants and physiotherapists will not be able to be blinded to group allocation. This means that there is a risk of bias in the study, as participants and physiotherapists may behave differently or have different expectations based on their group assignment. However, to minimize this risk, outcome assessors will be blinded to group allocation. This means that the assessors who are measuring the outcome of gross motor function will not know which group each participant belongs to so this can help reduce bias in the assessment of outcomes. On the other hand, treatment adherence is partly subjective, and the physiotherapist can be biased. That's why we will provide specific explanation of how to complete the logbook to try to be as much objective as possible.

Fourthly, there can also be external confounding factors such as medication usage, family support or comorbidities, which could influence treatment results. These confounding factors might be avoided or had into account by registering them.

Finally, the use of self-reported quality of life measure completed by parents, guardians, or the participants themselves limits the study. While this measure can give useful information on the child's quality of life, there is a risk of biases, and the subjective nature of the measure may limit the findings' generalisation. Another objective measure of quality of life, might be used in future research.

10. Ethical Considerations

The study will strictly follow ethical guidelines to protect the rights and welfare of the participants. Before the beginning of the study, all subjects will have to provide informed consent signed. Before the informed consent (IC), a full verbal explanation will be done where all questions will be answered. The informed consent (Annex VI) will include a full explanation of the study's aims, methods, possible risks, and benefits, as well as the confidentiality safeguards that will be put in place. Participants will have the option to withdraw from the research at any moment with no consequences.

The privacy, anonymity and confidentiality of the participants will be rigorously protected. All personal and medical information will be kept strictly secret and only authorized professionals involved in the study will have access to it. Instead of using their names, participants' identities will be secured by providing them unique identification numbers.

Data collected during the study will be analysed and reported in a way that protects the privacy and confidentiality of the participants. Participants and parents or guardians will be able to know the results of the study at any moment.

All potential risks or damage to participants will be minimized. The research therapies are considered to be safe and are widely used in clinical practice. Throughout the study, adverse events will be observed and recorded, and appropriate actions will be taken to manage and report them as needed.

The research will be carried out in accordance with the relevant laws and regulations, as well as ethical guidelines such as the Declaration of Helsinki and Good Clinical Practice. Prior to the start of the study, a corresponding Institutional Review Board (IRB) or an independent ethical committee will examine and approve the study protocol.

11. Workplan

I will use a work plan in the form of a table chronogram (Table 1) to successfully plan and execute this research project. Each task, its timing, and the person responsible will be specified in the table which is separated into the phases of the project. This will make it easier to track progress and guarantee that all components of the project are completed on time. This will be used to increase efficiency and guarantee that the study is done within the timeframe specified while keeping a high level of quality.

The work plan is divided into 4 phases:

- Phase I → During this phase, the project proposal and the research design will be developed. The resources needed for the study will be identified and potential foundation will be looked for. It will end with the approval from the ethical committee and the recruitment of the research team.
- Phase II → During this phase, the recruitment and initial screening will be done. The intervention and the assessment will be carried out and will end with the follow-up assessment.
- Phase III → The analysis and interpretation of the results will be done and the final report will be written.
- Phase IV → Is the last part of the project and it's not time-defined because depending on when the project is finished it will be longer or shorter, but the aim of this phase is to ensure that the study findings are disseminated.

This work plan is just a prediction of how it should be conducted but is subjected to changes based on factors such as recruitment rate, dropout rate and effect size observed during the study. Moreover, there are several people that will be in charge of different tasks, that's why in the Table 2 you can find the description of the role and responsibilities of each member.

Role	Responsibilities
Principal Researcher (PR)	• Develop the research question and design the research protocol • Obtain funding if necessary

	• Supervise research execution and ensure that ethical requirements are followed • Supervise research team and delegate tasks • Analyse study data and interpret results • Write and publish the final report and do the dissemination
Research Assistants (RAs)	• Assist the principal researcher with administrative tasks and help tracking study progress • Recruit participants and obtain informed consent • Collect and manage data • Assist with interpretation of results and dissemination of findings
Statistician (ST)	• Assists with sample size calculation and randomization • Helps in developing the data analysis plan • Conducts statistical analyses • Assists in the interpretation of statistical findings
Outcome Assessors (OAs)	• They will be physiotherapists trained for ensuring that the measures are administrated consistently across all participants • They will not know the participant allocation • Administer and score assessments for gross motor function measure.
Physiotherapists (PTs)	• They will be trained on the study protocol and will follow it rigorously • Deliver physiotherapy interventions • Monitor participant progress and adjust interventions as needed • Give parents recommendations • Assess treatment adherence logbook and GAS • Document intervention delivery

Table 2: Roles and responsibilities of research team members.

Tasks	Responsible	Month 0				Month 1				Month 2				Month 3				Month 4				Month 5			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
PHASE I: PLANNING AND PREPARATION OF THE PROJECT																									
Research Question + Hypothesis + Objectives	PR																								
Literature Review + Write Background	PR																								
Study Design + Creation of the protocol	PR																								
Ethics Approval	PR																								
Find Funding Sources	PR																								
Recruitment of the Research Team	PR																								

Tasks	Responsible	Month 4				Month 5				Month 6				Month 7				Month 8				Month 9				Month 10				Month 11				Month 12				Month 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
PHASE II: PARTICIPANT RECRUITMENT, INTERVENTION AND ASSESSTMENT																																									
Recruitment + Screening + IC	RAs + PR																																								
Randomization	PR + ST																																								
Baseline Assesstment (week 0)	OAs + RAs																																								
Mid-term Assesstment I (week 5)	OAs + RAs																																								
Mid-term Assesstment II (week 10)	OAs + RAs																																								
End-Intervention Assesstment (week 16)	OAs + RAs																																								
Follow-up Assesstment (week 24)	OAs + RAs																																								
Treatment Adherence Assesstment	PTs + RAs																																								
Intervention (16 weeks)	PTs																																								

Tasks	Responsible	Month 13				Month 14				Month 15				Month 16			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
PHASE III: DATA ANALYSIS AND REPORT																	
Data cleaning + Analysis	PR + ST																
Interpretetion of Results	PR + RAs																
Final Report	PR																
PHASE IV: DISSEMINATION OF RESULTS	PR + RAs																

Table 1: Work plan chronogram. PR: Principal Researcher, RAs: Research Assistants, ST: Statistician, OAs: Outcome Assessors and PTs: Physiotherapists

12. Necessary Resources

12.1. Type of Resources

Many resources will be necessary to ensure the success of this project. There are three types of resources: human resources, material resources, which can be fungible or inventoriable, and other resources. The principal researcher, research assistants, a statistician, outcome assessors, physiotherapists and participants are among the human resources (Table 3). Material resources (Table 4) include equipment for doing the intervention, the data administration and the statistical analysis, such as questionnaires, physiotherapy material, computers and software. Lastly, other resources (Table 5) include the fees and miscellaneous. The needed resources for this project are mentioned in the tables below (Tables 3-5), along with their quantity, availability and estimated cost. These tables are designed to serve as a guide to ensure that all necessary resources are accounted for and that their budget is properly allocated being subjected to changes if needed.

Human Resources					
Role	**Quantity**	**Salary (€/month)**	**nº Month**	**Estimated Cost**	**Availability**
Principal Research	1	750	16	12.000,00 €	Myself
Research Assistant	2	600	10	12.000,00 €	Need to hire
Statistician	1	700	1	700,00 €	Need to hire
Physiotherapist	4	1.200	4	19.200,00 €	Need to hire
Outcome Assessor	2	600	1	1.200,00 €	Need to hire
Participant	60	-	-	-	Need to recruit
Total Cost				**45.100,00 €**	

Table 3: Human Resources description and estimated budget

Material Resources				
Resource	**Description**	**Type**	**Estimated Cost**	**Availability**
Play-Therapy equipment	Different size and texture balls, sensory toys, adaptative toys, music equipment...	Inventoriable	500,00 €	Need to pruchase
Physiotherapy equipment	Positioning equipment, balance boards, different size roller, tunnels...	Inventoriable	- €	Available in the centre
Physiotherapy consumables	Gloves, alcohol wipes, massage cream, disposable paper towels...	Fungible	- €	Available in the centre
Office supplies	Paper, ink, pencils, pens...	Fungible	200,00 €	Need to pruchase
IT Equipment	3 laptops	Inventoriable	- €	
Data collection	Logbooks, GMFM App+ , GAS sheet	Fungible	1.000,00 €	Need to pruchase
Data storage	OneDrive	Inventoriable	495,00 €	Need to pruchase
Data management	JASP Software	Inventoriable	Free	Need to pruchase
Total Cost			**1.700,00 €**	

Table 4: Material Resources description and estimated budget

Other Resources		
Resource	**Description**	**Estimated Cost**
Ethical aproval fees	Charged by an IRB for review of research proposals	1.000,00 €
Insurance fees	To protect against any accidents or injuries that may occur during the study	500,00 €
Publication fees	For publishing papers, posters, or other materials related to the project	1.500,00 €
Miscellanious	Travel expenses, equipment maintenance and repairs, communication expenses...	1.000,00 €
Total Cost		**4.000,00 €**

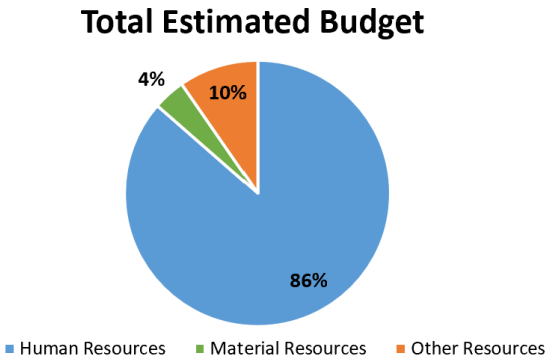
Table 5: Other Resources description and estimated budget

Table 6 shows the final cost estimation and offers an extensive overview of the budget for each type of resource. The budget for the project, as shown graphically in Graphic 1, mainly goes to managing and carrying out the study, including paying the researcher and research assistants their salaries. Since those working in these roles may be PhD students or research interns, universities or research institutions may in certain cases cover these costs. The last option would be recruiting volunteers.

Each physiotherapist will be responsible for conducting two sessions per week with 16 children, with each session lasting for a range of one hour (45 minutes for the session itself and 15 minutes for completing the logbook and registering the session). As a result, the physiotherapists will work for a total of 32 hours per week, and their monthly salary will be 1200€.

Total Estimated Budget	
Resource	**Total Estimated Cost**
Human Resources	44.800,00 €
Material Resources	2.033,00 €
Other Resources	5.000,00 €
Total Cost	**51.833,00 €**

Table 6: Total Estimated Budget



Graphic 1: Total Estimated Budget

12.2. Foundation

Finding appropriate funding sources can be a difficult task, but financial support is an essential aspect of research. The potential foundations listed in this section describe how my research project might be funded.

There are two ways that may be used to control the project's potentially large budget. First, looking into the foundation options (Table 7) might be taken into consideration. On the other hand, in order to lower the cost of the research study, it is also possible to apply for a pre-doctoral internship, which not only offers financial help but also improves research abilities (Table 8).

Foundation Name	Focus Area	Deadline	Grant Amount
La Marató de TV3	Biomedical research in Catalonia related to specific topics	Every March	Up to 400.000€
Fundación "La Caixa"	Supports research in healthcare	Every March	Up to 50.000€
Fundación Maphre	Biomedical research of specific topics	Every October	Up to 30.000€
Col·legi de Fisioterapeutes de Catalunya	Physiotherapy research of specific topics	Every September	Up to 6.000€

Table 7: Foundations for Research Funding

Institution Name	Description	Duration	Salary
Fundación "La Caixa"	Provides funding for pre-doctoral research in any university of Europe	3 years	40.000€
Fundació Universitària del Bages (FUB) - Campus Manresa	Provides funding for the doctoral thesis in their research department	3 years	18.000€
Universitat de Vic – Universitat Central de Catalunya	Provides funding for the doctoral thesis in their research department	3 years	17.500€

Table 8: Pre-doctoral Internships in Physiotherapy in Barcelona

13. Applicability and Usefulness of the Results

The applicability and usefulness of this project's outcomes are important for multiple reasons. To begin, cerebral palsy is a chronic disorder that impairs children's ability to move, perform daily tasks and participate in life. Physiotherapy is a significant part of cerebral palsy treatment since it tries to enhance function and minimize secondary complications. When compared to conventional physiotherapy, the use of play-based physiotherapy has been suggested as a potentially more successful strategy to engage children in therapy and promote treatment adherence while improving gross motor function. So, the results of this randomized controlled study will aid in determining if the hypothesis is correct. That's why if the study reveals that is more successful, it might have significant implications for the development of new interventions and treatment protocols for children with CP, which is the main goal of this project.

Furthermore, the identification of potential factors that may influence treatment outcomes is also valuable for improving treatment approaches in the future. By identifying these potential factors, physiotherapists can develop more tailored treatment plans considering the unique needs and circumstances of each patient. All in all, this can help to improve treatment outcomes and ensure that they receive the most effective and tailored physiotherapy program. For example, if this study shows that children from poor socioeconomic status or an specific ethnic group respond better to play therapy-based physiotherapy program or vice versa, physiotherapist may adapt treatment techniques to these specific populations to be more tailored and equitable.

Lastly, in case that the hypothesis is found to be wrong, the methodology of the study, including the inclusion and exclusion criteria and the use of stratified randomization, will add to the domain of cerebral palsy research and serve as a model for future studies as well as the study's emphasis on incorporating individuals from a variety of socioeconomic situations and ethnicities will assist to guarantee that the findings are applicable to a broad range of children with cerebral palsy. Moreover, the study's attention on ethical issues, such as getting informed consent and providing fair access to the study, will contribute to the general ethical standards and best practices in this field.

14. Dissemination Plan

In this section I will show you the steps that will be conducted to do the dissemination of the project and its results. The purpose of this is to outline the strategies and activities that will be used to disseminate the findings of the research project to ensure that the results of this study reach relevant stakeholders, such as healthcare professionals, parents/caregivers of children with cerebral palsy, and other researchers in the field of paediatric rehabilitation.

Firstly, once the study is finished and the final report is written, I will submit it to a peer-reviewed journal in the field of paediatric rehabilitation, physiotherapy, and cerebral palsy. This will enable to disseminate the findings to a broader audience of healthcare professionals and researchers, and to contribute to the knowledge base on this topic. Also, this ensures that the project is evaluated and criticised by other experts in the field, increasing its visibility and credibility.

Journal	Description	Impact Factor (IF)	Q level
Developmental Medicine & Child Neurology	Publishes high-quality multidisciplinary research and is highly respected and well-regarded	4.864	Q1
BMC Pediatrics	It's an open access journal and publishes research on all aspects of paediatrics. It has a strong reputation	2.567	Q2
Journal of Neurologic Physical Therapy	Dissemination linked to neurologic physical therapy. Excellent quality maintained by a rigorous, double-blind peer-review procedure	4.741	Q1
Physical and Occupational Therapy in Pediatrics	Provides important information to physiotherapist and occupational therapists in the developmental and physical rehabilitation of new-borns, children, and teenagers	2.297	Q2

Table 9: List of the journals, their description, Impact factor and Q level.

In the previous table (Table 9), we can see a list of the journals to which I would submit the project report, their order, and the reason for their selection, all this information is extracted from Scimago Journal & Country Rank (E). I would start with the first option (Developmental Medicine & Child Neurology), and in case of rejection, I would make the necessary corrections suggested by the first journal and then submit it to the second option. I would continue this process until one of these journals accepts the project. If none of these journals accepts it, I would look for other similar journals of lesser importance.

Simultaneously, a poster will be created to present it at national and international conferences and congresses related to paediatric rehabilitation, physiotherapy, and cerebral palsy (Table 10). This will allow reaching a wide audience of healthcare professionals and researchers, and to receive feedback and engage in discussions about the implications of the findings.

Congress	Description	Periodicity
World Physiotherapy Congress	brings together physiotherapists from around the world to share knowledge, research and ideas on a variety of topics related to physiotherapy.	Each two years
European Academy of Childhood Disability Conference	This international conference brings together healthcare professionals, researchers, and families to share knowledge and best practices related to childhood disability	Annually
Congrès Internacional de Fisioteràpia	Is a congress focused on physiotherapy that takes place in Barcelona and the aim is shearing knowledge and best practices related to physiotherapy	Each two years

Table 10: List of the congresses, their description and periodicity.

E. Scimago Journal & Country Rank [Internet]. Scimagojr.com. [cited 5 of April 2023]. Available in: https://www.scimagojr.com/

Finally, a webinar could be conducted to share the results of the study with parents/caregivers of children with cerebral palsy, CP rehabilitation centres, and other interested parties. The objective is to disseminate the findings directly to the people who are most affected by this condition as a way of recommendation and to engage in a dialogue about the implications of the research for their daily lives.

15. Annexes

15.1. Annex I: Calculation of the Sample Size

For calculating the sample size the following formula have been used (F, G):

$$\boldsymbol{n} = \frac{2\mathbf{SD}^2(\boldsymbol{Z_{\alpha/2}} + \boldsymbol{Z_{\beta}})^2}{\boldsymbol{d}^2}$$

Where:

- **n** = sample size
- **Zα/2** = the Z-score for the desired level of significance so for 95% confidence level α=0.05, Zα/2 = 0.05/2 = 0.025. This from Z table is **1.96**.
- **Zβ** = the Z-score for the desired statistical power so for 80% power where β is 0.20, Zβ = **0.8416** from the Z table.
- **SD** = the estimated standard deviation of the outcome variable based on other studies is **2.43** (18).
- **d** = the effect size (difference in means divided by the pooled standard deviation) taking into account the previous study (18) it will be **1.2**.

Having into account all this, the sample size should be:

$$\boldsymbol{n} = \frac{2\mathbf{SD}^2(\boldsymbol{Z_{\alpha/2}}+\boldsymbol{Z_{\beta}})^2}{\boldsymbol{d}^2};\ \boldsymbol{n} = \frac{2\text{x}\mathbf{2.43}^2(\mathbf{1.96}+\mathbf{0.8416})^2}{\mathbf{1.2}^2};\ \boldsymbol{n} = 64.37\ \approx \mathbf{64}\ \text{participants}$$

Sample size = 64 participants.

Remember that this sample size may need to be adjusted by a statistician based on factors such as recruitment rate and expected dropout rate.

F: Charan J, Biswas T. How to calculate sample size for different study designs in medical research? Indian J Psychol Med. 2013 Apr;35(2):121-6.
G. Kadam P, Bhalerao S. Sample size calculation. Int J Ayurveda Res. 2010 Jan;1(1):55-7.

15.2. Annex II: Initial Screening Form

Participant ID:

Date of screening:

Personal Information:

- Name:
- Date of birth:
- Age:
- Gender:
- Ethnicity:
- Address:
- City:
- State:
- Zip code:
- Phone number:
- Email address:

Medical Information:

- Diagnosis of cerebral palsy: Yes or No
- GMFCS level: III or IV
- Other medical conditions that may impact their ability to participate in the study (e.g., uncontrolled seizures, cardiac conditions, respiratory conditions):
- Current medications:
- History of surgery related to cerebral palsy:
- History of seizures:
- Allergies:
- Medical devices or equipment currently used:
- Cognitive or communication impairments that may impact their ability to follow instruction:

Social and Demographic Information:

- Parent/guardian name:
- Relationship to participant:
- Occupation:
- Education level:
- Family socio-economic status:
- Primary language spoken at home:
- Other languages spoken:
- Access to transportation:

Physiotherapy History

- Where does he/she do physiotherapy?
- How often?
- How is it? What does he/she do?
- What's the duration of each session?
- How's the adherence? Does he/she cry or laugh during the session?
- Do you get recommendations?

Other

- Is the participant able to attend physiotherapy sessions twice a week for 16 weeks? Yes or No
- Has the participant been involved in any other clinical research studies in the past 3 months? Yes or No
- Any other relevant information:

15.3. Annex III: Play Therapy Activities and Games

Photo of the Activity	Description
	With this activity, we aim to encourage our child to keep his or her head upright, thus improving his or her head control, while also offering them an entertaining game.
	With this activity, we aim to encourage our child to maintain trunk control while attempting to score a ball into a hoop on the ground.
	In this activity, we encourage the child's standing with support at a table or shelf where there is a toy that motivates him or her to stand up (with or without help).
	In this activity, we promote the child's sitting position with greater or lesser support surface, while also encouraging dorsal stretching by attempting to reach a motivating toy.
	In this activity, we encourage the extension of the back will trying to play. Also, we gain back strength as our child needs to keep the attention in height.

	In this activity, we encourage the pelvis stability on knees position and to keep the back straight we play with the child in his shoulders' plane.
	In this activity we encourage our child to gain standing stability while playing with a toy that motivates him or her to stand up (with or without help), which is in a table or shelf.
	In this activity, we encourage the child's sitting position with greater or lesser support surface, while promoting rotation as he or she needs to pass objects from one side to the other.
	In this activity, we can construct an obstacle course out of cones, beanbags, hula hoops, and other things that will test the child's mobility. It's useful to strengthen gross motor function and to encourage the kid to crawl, roll, or walk around the obstacles. They can use their devices or orthoses if necessary.

Other play therapy activities

- **Sensory Play:** We can use sensory play to activate the senses and encourage mobility in your child. Finger painting, sand play, water play, and playdough are some examples.

- **Animal Walks:** We can make the child imitate various animal motions, such as cat crawls, crab walks, and bunny hops. This aids in the improvement of balance, coordination and muscle strength.
- **Balloon Games:** We can use balloons to play activities that improve hand-eye coordination, spatial awareness, and upper body strength. For example, we can play balloon volleyball, where the child needs to maintain the balloon in the air and pass it to the physiotherapist.
- **Ball Games:** We can use a soft ball or beach ball to play catch or soccer. This can aid in the development of hand-eye coordination, upper-body strength, and gross motor abilities.
- **Musical chairs:** We can play the game of musical chairs, encouraging him or her to walk or crawl around the chairs and sit down when the music stops. This can aid in the improvement of mobility, balance, and coordination.
- **Simon Says:** We can play Simon Says with the child, giving him or her directions like "Simon says touch your toes" or "Simon says crawl under the bridge." This game can help to improve the listening abilities, the ability to follow directions, and the general motor coordination.

We may remember that these are just some proposals and that each activity should be adapted to the patient needs and interests.

15.4. Annex IV: Logbook

Patient nº	
Data	
Session nº	

Assistance	☐ Yes	0p
	☐ No	1p
Time of session done	☐ 0-15 minutes	1p
	☐ 15-30 minutes	2p
	☐ 30-45 minutes	3p

Exercises	**1**	**2**	**3**	**4**	
Task completion	☐ Not done	☐ Not done	☐ Not done	☐ Not done	0p
	☐ Initaties	☐ Initaties	☐ Initaties	☐ Initaties	1p
	☐ Partially complet	☐ Partially complet	☐ Partially complet	☐ Partially complet	2p
	☐ Completes	☐ Completes	☐ Completes	☐ Completes	3p
Did you help him/her?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	1p
	☐ No	☐ No	☐ No	☐ No	0p
Did he/she laugh?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	1p
	☐ No	☐ No	☐ No	☐ No	0p
Did he/she cry?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	0p
	☐ No	☐ No	☐ No	☐ No	1p
Did he/she get mad?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	0p
	☐ No	☐ No	☐ No	☐ No	1p

Did the parents follow the recommendations?	☐ Yes	1p
	☐ No	0p

TOTAL SCORE	__ / 12

This is the logbook that will be used during the treatment adherence measurement, but the physiotherapist will not have the punctuation in order to not bias him or her.

15.5. Annex V: Categorization of the Variables

Variable	Typology	Method of Analysis	Statistical Test
Age	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
Attendance rate	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
Treatment Adherence Logbook	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
GAS Score	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
GMFM-88	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
CP QOL-Child	Quantitative Continuous	Descriptive Statistics	Mean, median, standard deviation, range
Gender	Categorical Nominal	Descriptive Statistics	Frequency distributions, percentages
Ethnicity	Categorical Nominal	Descriptive Statistics	Frequency distributions, percentages
Type of Intervention	Categorical Nominal	Descriptive Statistics	Frequency distributions, percentages
GMFCS Level	Categorical Ordinal	Descriptive Statistics	Frequency distributions, percentages
Socio-economic Status	Categorical Ordinal	Descriptive Statistics	Frequency distributions, percentages

15.6. Annex VI: Information Sheet and Informed Consent

Title of the Study: Investigating the Effectiveness of Play-based Interventions on Treatment Adherence and Gross Motor Function in Children with Cerebral Palsy GMFCS level III-IV.

Responsible Researcher: Marta Ferrón Carbonell

Place where the Study will be conducted: XXXXXXXXX

1. Introduction

Your child has been invited to participate in a research study. However, before you, as the legal representative of your child, agree to his/her participation in this study, please carefully read this form and ask any questions that arise to ensure that you understand the study procedures, risks, and benefits, so that you can make a **voluntary** decision about whether you wish for your child to participate in the study or not. Once you have understood the study and if you wish for your child to participate, you will be asked to sign this informed consent form, of which you will receive a signed and dated copy.

This study has been approved by the XXXXXX Ethics Committee.

2. Main objective of the study and justification

Cerebral palsy is a neurological disorder that affects children's mobility and coordination and has a significant influence on their quality of life. While physiotherapy can help children with cerebral palsy improve their gross motor function, it can also be monotonous and tiresome for them. There is a need to investigate alternative physiotherapy treatments that are engaging and enjoyable for children while simultaneously improving their gross motor performance. Play-based therapies have been proposed as a possible strategy to attaining these objectives, but more research is required to determine their effectiveness. The purpose of this study is to fill a gap in the literature and provide evidence-based recommendations for the use of play-based treatments in children with cerebral palsy to improve treatment adherence and gross motor function.

3. Participants

The participants of this study it's voluntary and will be children diagnosed with cerebral palsy (CP) aged 4 to 12 years old who are classified as level III or IV on the Gross Motor Function Classification System (GMFCS) and who match the inclusion and exclusion criteria.

The inclusion criteria are the following:

- Children diagnosed with cerebral palsy by a paediatric neurologist.
- Aged between 4 and 12 years.
- Classified as level III-IV on the GMFCS.
- Regularly receiving physiotherapy at the rehabilitation centre.
- Able to follow instructions and participate in play-based therapy sessions.
- Parental or guardian inform consent signature.

4. Study procedures

If you agree to participate in this study, you will be randomly assigned to either the experimental group (play therapy-based physiotherapy program) or the control group (conventional physiotherapy program), both done in a reserved place to maintain your child privacy.

The play therapy-based physiotherapy group will receive 45 minutes sessions of play therapy-based physiotherapy two times a week for 16 weeks (32 sessions in total). These sessions will include play-based activities such as ball games, obstacle courses, music, sensory toys and pretend play combined with standard physiotherapy exercises, all based on your child motivations and your family needs.

The conventional physiotherapy group will receive 45 minutes sessions of conventional physiotherapy two times a week for 16 weeks (32 sessions in total). These sessions will include exercises and activities aimed at improving strength, range of motion, coordination, and balance based on your child motivations and your family needs.

All sessions will be led by trained and licensed physiotherapists with experience treating children with cerebral palsy and you will continue to receive your regular

physiotherapy services in addition to participating in the study. Participants and physiotherapists will not be able to be blinded to group allocation. However, to minimize the risk of bias, outcome assessors will be blinded to group allocation.

5. Risks and Benefits

There are no known risks associated with participating in this study beyond those potential associated with regular physiotherapy treatment such as temporary muscle soreness, fatigue, and discomfort during the physiotherapy sessions. There's no contraindication associate it to the study and it must be considered that there may be a therapeutic indeterminacy.

However, you may benefit from participating in this study by potentially improving your child's treatment adherence and gross motor function, which could lead to better overall health and well-being improving both you and your child quality of life. Moreover, the study results may also contribute to the development of more effective treatment programs for children with cerebral palsy.

6. Compensation

There will be no compensation provided for participation in this study.

7. Confidentiality and Data Collection

All the information collected in this study will be kept strictly confidential and will only be accessed by the study team. Your data will be coded with a unique identification number to ensure your anonymity and only the responsible researcher will have access to them. When the research results are published or presented at scientific conferences, no information that could reveal their identity will be included, and after 5 years of publication, it will be deleted.

All this mechanism will be conducted to ensure the confidentiality of the processed data and their protection in accordance with General Data Protection Regulation (GDPR) (EU) 2016/679 on the protection of individuals regarding the processing of personal data and on the free movement of such data and other applicable data protection laws.

8. Voluntary Participation

Participation in this study is entirely voluntary. You have the right to refuse to participate or to withdraw totally or partially from the study at any time without penalty, you may do so by notifying the research team and not being necessary stating the reason or cause. Your refusal or withdrawal will not affect your child's access to his/her regular physiotherapy services.

9. Contact Information

If you have any questions or concerns about this study, you may contact Marta Ferrón Carbonell by phone +34 65XXXXX66 or by email address XXXXXXX. If you have any questions or concerns about your rights as a research participant, you may contact [insert name and contact information of institutional review board or ethics committee].

10. Rights of the Participant and Informed Consent

As a legal representative of my child, I have read, understood, and discussed the above information with the responsible investigator, and my questions have been satisfactorily answered. My child's participation is voluntary, and we may withdraw at any time without cause or responsibility. I have the right to know the results and if any doubts arise during the investigation, I can contact the responsible investigator.

By signing below, I confirm that I have been informed and understood that the data obtained in the study may be published or disseminated for scientific purposes. I also agree that my child participates in this research study and I will receive a signed and dated copy of this consent.

Parent or guardian's signature (if participant is a minor): _____

Date: _____

11. Letter of Revocation

Title of the Study: Investigating the Effectiveness of Play-based Interventions on Treatment Adherence and Gross Motor Function in Children with Cerebral Palsy GMFCS level III-IV.

Responsible Researcher: Marta Ferrón Carbonell

Place where the Study will be conducted: XXXXXXXXX.

Name of the participant: _____

Through this letter, I wish to inform my decision to withdraw my child from this research protocol for the following reasons: (this section is optional and can be left blank if desired).

_____

_____

_____

_____.

If you wish, you may request that all information obtained be provided to you and, unless you communicate otherwise, the information will be deleted.

Signature of the parent/guardian (if participant is a minor) _____

Date _____