`FRAME-EX´ - FRAME Running for EXercise in children and young people with disabilities - a study protocol for a quasi-experimental single-arm trial

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Background

Children and young people with physical disabilities, including cerebral palsy (CP) and muscular dystrophy, are less physically active and socially engaged than their typically developing peers (1, 2). Reduced levels of daily physical activity (3), may contribute to poorer health, reduced fitness, and an increased risk of secondary musculoskeletal and cardiorespiratory impairments (4). These secondary complications can initiate or reinforce a negative cycle of further deconditioning, diminished participation, and reduced quality of life. Over time, such trajectories contribute to reduced life expectancy, with respiratory illness being the leading cause of death among individuals with severe physical disabilities (5, 6). Evidence suggests, that many of these adverse health trajectories may be preventable, or at least reversible, through regular participation in physical activity, which has consistently been associated with improved quality of life in children and adolescents with disabilities (7, 8). For children and young people with moderate to severe mobility limitations, opportunities for engaging in independent running or cycling are often inaccessible. This underscores the need for alternative, enjoyable, and developmentally appropriate modes of physical activity.

Frame Running, an adaptive sport developed in Denmark in 1991, offers such an opportunity. Using a three-wheeled frame equipped with a saddle and handlebars, but no pedals, athletes can walk or run using their feet while supported by the frame. Frame Running has gained substantial popularity among children and young people with CP, as it provides both recreational and competitive participation for individuals with considerable walking limitations (9).

Despite its growing use, Frame Running remains underexplored in the scientific literature. To date, only a limited number of published studies have examined this activity, with a subset focusing on health-related impacts and physiological outcomes. One previous intervention study, conducted without a control group, reported that a 12-week, research-initiated Frame Running program delivered twice weekly led to improvements in cardiorespiratory fitness and peripheral muscle function in children and young adults with CP (10). Additionally, a cross-sectional study (11) and a qualitative interview study (12) reported positive influences on psychosocial well-being and self-reported quality of life, respectively.

No study to date has evaluated the outcomes of Frame Running in pragmatic, real-world settings, where training occurs as part of everyday practice in community sports clubs. This limits the generalizability of existing findings, most of which stem from researcher-initiated interventions with protocol standardization. Currently, one multicenter randomized controlled trial (RCT)(13) and two feasibility studies are published (14, 15) both focusing primarily on cardiovascular fitness through more standardized, research-initiated interventions that are only partially individualized. Understanding how children and young people experience and respond to Frame Running in routine community sports environments is essential for informing future clinical recommendations, program implementation, and adaptive sports development.

Given these knowledge gaps, there is a clear need for studies that examine the impact of Frame Running under real-world conditions, with particular attention to functional ability, participation, and quality of life.

Aim and Research Objective

The overall aim of this project is to examine changes in functional ability, participation and quality of life following a pragmatic Frame Running intervention in children and young people with physical disabilities.

Research objective:

- Investigate changes in the primary outcome measure; functional ability using the Mobility domain of the Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT) (16), and a series of secondary outcome measures on mobility capacity, physical endurance, performance of everyday activities, and health-related quality of life in children and young people with physical disabilities,

Methods

Findings from the study will be reported according to the relevant EQUATOR checklists (17). This protocol is prepared in line with the SPIRIT checklist (18). The clinical intervention study will be registered in ClinicalTrials.gov, and any important protocol modifications will be documented in the registry and reported in subsequent publications.

Study design

The study employs a quasi-experimental single-arm design consisting of a 12-week low-intensity control period followed by a 12-week moderate-to-high intensity Frame Running intervention period. The design reflects careful consideration of ethical issues and participant well-being, particularly given the heterogeneity of functional ability among children and adolescents with physical disabilities. Although randomized controlled trials (RCTs) are conventionally regarded as the gold standard for causal inference, an RCT was deemed neither ethically nor practically feasible, as the required group homogeneity would likely exclude children with greater impairments, reduce equity in participation, and limit generalizability. Recruitment challenges within minority groups further support the use of a pragmatic, inclusive design.

To strengthen internal validity, a rolling inclusion procedure is applied to ensure that both control and intervention periods are represented across all seasons. Comparing differential change scores between the control and intervention periods (Δcontrol vs. Δintervention) helps mitigate potential maturation effects, seasonal variation, and learning effects associated with repeated testing.

The overall FRAME-EX project follows a mixed-methods approach, integrating quantitative and qualitative components to address the overarching aim. The conceptual framing is informed by the Medical Research Council (MRC) guidance on complex interventions (19), with emphasis on mechanisms of change and contextual influences. Although the overall FRAME-EX project includes an embedded qualitative component, the present study protocol focuses exclusively on the quantitative evaluation. Qualitative data will be collected as part of the broader project but are not analysed within the scope of this study.

Within the MRC framework, the current evaluation therefore concentrates on:

i. Refining the intervention theory and underlying assumptions informed by prior feasibility work
ii. Conducting the quantitative impact evaluation of functional outcomes
iii. Preparing for future implementation and dissemination based on accumulated evidence.

Setting

The study is conducted in collaboration with four Danish athletics clubs offering structured Frame Running training: Odense Atletik GF, Randers Freja Atletik, Kolding KFUM Atletik og Motion, and Parasport Frederiksberg. Training takes place on outdoor tracks and/or indoor facilities, providing year-round accessibility. Athletes typically train 1–2 times per week for approximately 60 minutes under the supervision of experienced coaches.

Training is guided by a standardized manual co-developed by Frame Running coaches, Frame Running sports consultants, and the research team, ensuring consistency across sites while remaining grounded in established club practices. The program is delivered by experienced coaches who have been introduced to the manual's structure and progression principles. Training quality and implementation are supported through ongoing dialogue and collaborative supervision between coaches, sports consultants, and the research team, thereby maintaining fidelity without imposing a researcher-driven or laboratory-controlled intervention model.

Participants are included once they have joined the club and provided informed consent. All data collection takes place on-site during regular training sessions to reduce participant burden and enhance ecological validity.

Participants

Eligible participants are children and young people aged 8–18 years with a diagnosis of CP or another condition causing physical disability. Participants may have some prior Frame Running experience, such as informal use or occasional training, but must not have taken part in structured, organized, or performance-oriented Frame Running training within the past 12 weeks. They must be able to propel the Frame Running bike forward independently and be able to understand and follow instructions related to Frame Running activities.

Exclusion criteria are: Severe visual and/or cognitive impairments that would compromise safe participation, and known medical conditions that could limit or contraindicate involvement in the study (e.g., significant cardiovascular or pulmonary disease).

Sample size

Sample size estimation is based on the primary outcome measure the PEDI-CAT Mobility domain. Following Shore et al.(20), the standard deviation for this outcome measure is assumed to be 7.7 points. For this study a clinically meaningful change is estimated as half of the difference between children classified in GMFCS levels III (58.1) and IV (49.9), corresponding to 4.1 points. Using a two-sided α of 0.05, 80% power, and the standard formula for detecting a mean difference in a continuous outcome, the required sample size is estimated to be 28 participants. To account for potential drop-out and maintain adequate statistical power, a minimum of 35 participants will be recruited.

Recruitment process

Participants are recruited through the four participating athletics clubs, schools and municipal paediatric rehabilitation services. Potential participants are identified when joining a club or by contacting the research team via a contact form on the project website. Written study information is provided by the principal investigator (TUP), followed by oral information before obtaining informed consent. Written informed consent is obtained from participants (if aged $\geq$ 14 years) and/or their legal guardians.

Recruitment follows a rolling inclusion procedure to balance seasonal variation and align with natural club enrolment. Recruitment will continue from March 2026 until at least 35 participants are included.

Intervention

The study consists of a controlled 24-week intervention period divided into a 12-week control period followed by a 12-week intervention period. Both periods use the newly developed Frame Running training manual (21), which categorizes exercises by intensity and difficulty: green exercises represent low intensity/low complexity, whereas yellow/red exercises indicate moderate to high intensity and greater complexity.

<u>Control period (12 weeks)</u>

During the control period, participants may engage in Frame Running familiarization activities. These activities are limited to a maximum of one session per week at the athletics club. Each session may last up to 60 minutes and focuses solely on becoming comfortable with the Frame Runner, including basic handling and introductory movement patterns performed exclusively at green (low-intensity) exercises. The purpose of this period is both to ensure sufficient familiarity with the equipment and the club environment, and to provide a low-intensity comparison phase against which changes observed during the subsequent higher-intensity intervention can be evaluated. No additional Frame Running training outside the scheduled weekly session is permitted.

Intervention period (12 weeks)

During the intervention period, participants complete two weekly training sessions at moderate to high intensity. At least one 60-minute session per week must take place at the athletics club under the supervision of an experienced coach. The second 60-minute weekly session may be completed at home.

Training follows the progression structure outlined in the exercise training manual, incorporating yellow and red exercises to achieve moderate-to-high physiological and technical challenge. Each session includes a structured warm-up, targeted technical skill development, endurance and speed intervals, and participation-oriented activities. Adjustments to intensity and activity selection are permitted within the manual's boundaries to accommodate functional ability and ensure safety.

Figure 1 provides a design overview.

Figure 1. Design overview

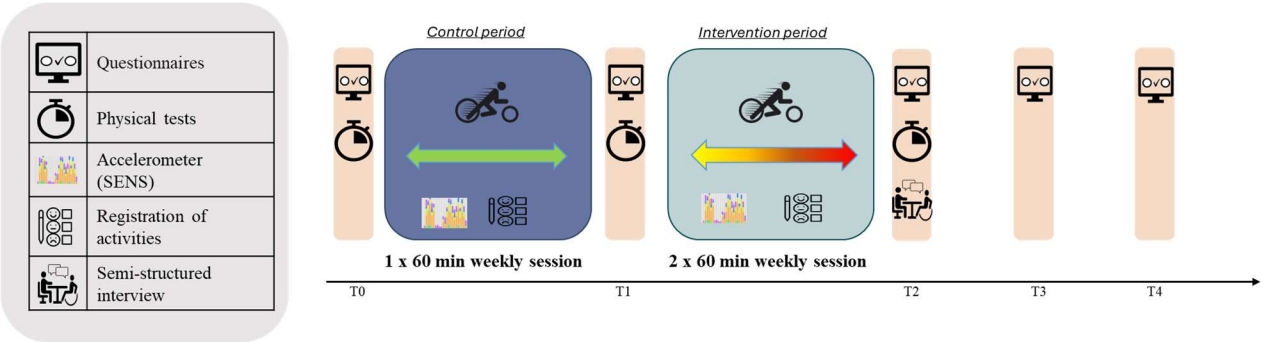

Figure 1. Overview of assessment time points: T0 = baseline before the control period; T1 = baseline before the intervention period; T2 = end-of-intervention follow-up; T3 = 6-month post-intervention follow-up; and T4 = 12-month post-intervention follow-up. Registration of activities includes both the participant-reported training diary and the coach-reported trainer log.

Data collection, outcomes and analysis

Quantitative data

Quantitative data will be collected through standardized questionnaires and physical performance tests. All quantitative outcomes will be assessed at three time points:

- Baseline prior to the control period (T0)
- Follow-up prior to the intervention period (T1)
- Follow-up at the end of the intervention period (T2)

In addition, all questionnaires will be administered at two extended follow-up time points:

- Six-month after T2 (T3)
- Twelve-month after T2 (T4)

This measurement schedule enables comparison of change during the low-intensity control period and during the moderate-to-high intensity intervention period, consistent with the quasi-experimental single arm trial design.

Primary outcome

The primary outcome is functional mobility assessed using the Mobility domain of the Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT). The PEDI-CAT is a digital assessment tool designed to evaluate functional performance in children across several domains, including daily activities, mobility, and social/cognitive functioning. In this study, only the PEDI-CAT Mobility domain is used as the primary outcome measure. It provides standardized scores based on age-referenced item response theory, ensuring sensitivity to clinically meaningful changes over time. The PEDI-CAT demonstrates excellent reliability, with test–retest intraclass correlation coefficients typically above 0.90 across domains, and strong internal consistency supported by Rasch modelling. Validity is well established, including good construct validity demonstrated through expected associations with functional classification levels (e.g., GMFCS), and discriminant validity showing clear differentiation across severity groups (16, 22).

Secondary outcomes

Secondary outcomes cover domains of physical performance, functional ability beyond mobility, participation, and health-related quality of life:

Physical performance tests

Standardized physical performance tests will be conducted by trained test personnel using uniform protocols to ensure consistency across sites. Tests are selected based on their feasibility for children with motor impairments and their relevance to functional gains expected from Frame Running. The physical test battery comprises three validated and widely used performance measures, supplemented by a study-specific Frame Running test developed to capture functional capacity in participants who have limited or no walking or standing ability:

- **6-Minute Frame Running Test (6MFRT):**
  An endurance test in which the child or young person covers as much distance as possible on a Frame Runner within six minutes. The test provides an indicator of aerobic capacity and functional endurance specifically during Frame Running (23, 24).

- **10-Meter Frame Running Sprint Test (10MFRST):**
  A newly developed short-distance sprint test in which the child or young person covers 10 meters as quickly as possible from a stationary start on a Frame Runner. The test is designed to evaluate functional components of speed, acceleration, and explosive mobility within frame-based running movements.

- **1-Minute Sit-to-Stand Test (1MSTS):**
  A strength and endurance test in which the child or young person performs as many sit-to-stand repetitions as possible within one minute. The test evaluates lower-limb power, muscular endurance, and functional strength relevant for daily activities (25, 26).

- **1-Minute Walk Test (1MWT):**
  A short endurance test measuring the distance a child or young person can walk in one minute. It offers a quick assessment of functional mobility and walking pace (27, 28).

Functional ability (PEDI-CAT secondary domains)

Functional ability beyond mobility will be assessed using the Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT) Daily Activities, Social/Cognitive, and Responsibility domains. These domains assess self-care and daily activities, social interaction and cognitive functioning, and independence in managing daily life tasks, respectively.

Participation

Participation will be assessed using the Children's Assessment of Participation and Enjoyment / Preference for Activities of Children (CAPE-PAC). The instrument evaluate how children participate in everyday activities, including diversity, intensity, context, and preference (29).

Health-related quality of life

Health-related quality of life will be measured using the Pediatric Quality of Life Inventory (PedsQL), a validated pediatric patient-reported outcome instrument covering physical, emotional, social, and school functioning (30).

Explorative outcomes

In addition to the primary and secondary outcomes, a few exploratory measures will be collected to provide supplementary insight into training intensity and psychosocial impact.

Psychosocial impact

The psychosocial impact of assistive devices is assessed using the Psychosocial Impact of Assistive Devices Scale (PIADS), which captures perceived competence, adaptability, and self-esteem. PIADS is administered alongside the other questionnaires to explore broader psychosocial effects of participating in Frame Running and using the Frame Runner (31).

Rating of Perceived Exertion—Pediatric Scale (RPE-P)

Perceived exertion will be assessed using a child-friendly visual version of BORG RPE (32) the Rating of Perceived Exertion—Pediatric Scale (RPE-P) (33) immediately before and after the 6-Minute Frame Running Test. This measure provides a subjective indicator of exertion and perceived effort, supporting interpretation of physiological responses and individual variation in intensity tolerance. RPE-P have demonstrated good validity in children and adolescents (33).

Intervention Exposure and Fidelity Measures

Training diary, trainer logs, and SENS accelerometer data are collected as intervention exposure and fidelity measures rather than outcomes. These measures provide essential information about training dose, adherence, and delivery quality, but are not included as study outcomes.

Training diary (participant-reported)

Following each training session, participants (with assistance from parents if needed) will complete a training diary documenting:

- date and duration of the session,
- whether training occurred at the club or at home,
- perceived intensity using the green/yellow/red intensity scale derived from the project's training manual.

The diary enables monitoring of adherence, training dose, and participant-reported intensity during both the control and intervention periods.

Training log (coach-reported)

After each training session, coaches complete a structured trainer log, which enables documentation of attendance, adherence to the training manual, training intensity, and any deviations or adverse events. These logs contribute to assessment of intervention fidelity, safety monitoring, and contextual interpretation of training exposure.

Physical activity measurement

Objective physical activity will be recorded using a SENS motion® (Copenhagen, Denmark) accelerometer. In addition, a heart-rate monitor will be used during physical performance tests to provide complementary information on physiological intensity. Together, the accelerometer and heart-rate data offer objective estimates of activity levels, movement patterns, and changes in habitual physical activity across study phases.

Data collection procedures

All physical performance tests are performed on-site in the athletics club environment, scheduled in connection with regular training sessions to minimize participant burden. Test personnel involved in physical testing will receive standardized training to ensure consistency across sites.

Questionnaire data are distributed digitally via secure mail (e-Boks) and monitored for completeness at each assessment time point via REDCap® (Research Electronic Data Capture, Vanderbilt University, USA). The participant training diary is completed electronically via the myCAP® mobile application (REDCap, Vanderbilt University, USA), which sends notifications to the parent/guardian prompting registration of training frequency, duration, location, and perceived intensity.

Coaches complete trainer logs after each session by scanning a QR code that provides direct access to a structured questionnaire in the SurveyXact platform (Ramboll, Denmark).

Objective physical activity is recorded using a thigh-worn - or alternatively shoe-worn - SENS motion® (Copenhagen, Denmark) accelerometer, fitted during test sessions and worn for three predefined two-week periods:

- the first two weeks of the control period (T0)
- the last week of the control period and first week of intervention period (T1)
- the last two week of the intervention period (T2)

During physical performance tests, heart-rate data are collected using arm-worn heart-rate monitor to complement the accelerometer data. Data are downloaded and checked for completeness upon return.

Table 1 provides an overview of all study outcomes, including their domains, instruments, and assessment time points.

Table 1. Overview of Outcome Measures

Outcome type	Outcome measure	Domain	Instrument / test	Time points
Primary	Functional ability	Mobility	PEDI-CAT	T0, T1, T2
Secondary	Physical performance	Endurance / mobility capacity / speed	6MFRT, 1MWT, 1MSTS, 10MFRST	T0, T1, T2
Secondary	Functional ability	Daily activities, social/cognitive, participation	PEDI-CAT	T0, T1, T2
Secondary	Participation	Activity diversity, intensity context	CAPE/PAC	T0, T1, T2
Secondary	Health-related quality of life	Physical, emotional, social, school functioning	PedsQL	T0, T1, T2
Exploratory	Psychosocial impact	Competence, adaptability, self-esteem	PIADS	T0, T1, T2

Exploratory	Perceived exertion	Subjective intensity	Rating of Perceived Exertion—Pediatric Scale (RPE-P)	T0, T1, T2
Exploratory	Long-term changes	Participation, QoL, functional ability	All questionnaire-based outcomes	T3, T4

Table 2 summarises the intervention exposure and fidelity measures collected to contextualise training dose and delivery.

Table 2. Overview of Exposure and Fidelity Measures

Measure type	Variable	Instrument	Time points
Participant-reported exposure	Frequency, duration, location, perceived intensity, enjoyment	Training Diary (myCAP® app, REDCap®)	After each session
Coach-reported fidelity	Attendance, manual adherence, intensity, safety	Trainer Log (SurveyXact)	After each session
Objective activity exposure	Habitual physical activity, movement intensity, heart rate	SENS motion® accelerometer + heart-rate monitor	T0, T1, T2

Planned statistical analysis

Descriptive statistics (means and standard deviations for continuous variables; frequencies and percentages for categorical variables) will be used to summarise participant characteristics at baseline. Between-timepoint comparisons for descriptive purposes will be explored using paired t-tests for continuous variables and chi-square tests for categorical variables.

Longitudinal changes across T0, T1 and T2 (between-periods change score - control period versus intervention period) will be analysed using a paired (subjects are their own controls) random-effects mixed linear models, enabling estimation of average change over time under the assumption of normally distributed residuals. Missing data will be handled using maximum likelihood estimation, which allows inclusion of participants with incomplete repeated-measures data. Analyses will be undertaken both per protocol and according to the intention-to-treat principle. For this study, intention-to-treat means that participants with partial follow-up or incomplete outcome data will remain included in the analysis through likelihood-based approaches. A per-protocol analysis will be

conducted including only participants who achieve at least 75% adherence to the prescribed training dose across the intervention period. Adherence will be calculated based on completed training sessions (club-based and home-based) relative to the prescribed number of sessions. Participants below this adherence threshold will be excluded from the per-protocol analysis but retained in the intention-to-treat analysis through likelihood-based approaches.

Long-term questionnaire data at T3 and T4 will be analysed descriptively and explored using extended mixed models where appropriate.

All statistical tests will use a significance level of $p = 0.05$ and 95% confidence intervals. Analyses will be performed using Stata 19 (StataCorp LP, College Station, TX, USA).

Training diary data and trainer logs will be analysed descriptively to characterise training exposure, adherence, session intensity, and intervention fidelity. Continuous variables (e.g., session duration) will be summarised using means and standard deviations or medians and interquartile ranges, while categorical variables (e.g., location, attendance, manual adherence) will be summarised using frequencies and percentages. These exploratory data will support contextual interpretation of dose–response patterns and fidelity across sites.

Accelerometer data (SENS) and accompanying heart-rate data are collected as exploratory outcome measures and will be analysed in a separate study; they are therefore not included in the present analysis plan.

Ethical considerations and data management

The study will follow the principals of the Declaration of Helsinki (34) and has been evaluated by the Regional Committee on Health Research Ethics (Region of Southern Denmark) (S-20232000 – 99) and Research Ethics Committee at the University of Southern Denmark (SDU-REC) (REC598), which has assessed it as not being subject to further notification/evaluation. The General Data Protection Regulation (GDPR) will be followed.

Children and their parents/guardians will be provided oral and written information about the respective study, and informed parental consent and child assent will be obtained by the project coordinator. Written information will be developed in a child version and a parent version.

A data management plan (DMP) has been developed, providing details on how data will be collected and managed throughout the project, as well as how they will be documented, stored, and archived after the project has been concluded.

All study data, including the final study dataset, will be treated confidentially, and access will be restricted to the research team. When reporting findings, no data will be traceable to individual participants.

Dissemination

Dissemination plans include peer-review publication of study results in national and international journals for publication irrespective of the outcome. In addition, results will be presented at scientific and non-scientific meetings and conferences with all relevant key stakeholders.

Discussion

This study protocol presents a quasi-experimental single-arm evaluation of a structured Frame Running intervention for children and young people with physical disabilities. The study addresses a gap in current evidence, as research on functional and participatory outcomes of adaptive sports remains limited, particularly for children with significant mobility limitations. By combining quantitative outcomes with qualitative observations and interviews, the study aims to generate a nuanced understanding of how Frame Running may support functional ability, participation, and quality of life.

The pragmatic nature of this design is central. Embedding the intervention within existing athletics clubs ensures ecological validity, supports feasibility, and mirrors how Frame Running is practiced in real-world community settings. The two-phase structure - with a low-intensity control period followed by a moderate-to-high intensity intervention - facilitates examination of change over time while balancing methodological rigor with ethical and practical considerations in this population. The rolling inclusion procedure further reduces the risks of seasonal bias. The study also benefits from a comprehensive outcome battery, long-term follow-ups (6 and 12 months), and detailed process measures capturing adherence, intensity, and fidelity.

A key strength of this study is the integration of multiple data sources - physical tests, standardized questionnaires, training diaries, and trainer logs - allowing for a multidimensional evaluation of the intervention. The structured training manual and coach supervision support fidelity, while the inclusion of children and young people with varying levels of mobility increases generalizability.

Also some limitations must be acknowledged. The lack of randomisation limits causal inference, and although the within-subject design and repeated measurements reduce inter-individual variability, residual confounding (e.g., maturation effects or unmeasured contextual factors) may persist. Reliance on self-reported training diaries introduces potential recall bias, though notifications aim to enhance completeness. Variation across clubs and coaches may influence delivery despite the standardized manual.

Despite these considerations, the study is expected to provide valuable evidence regarding the potential impacts, feasibility, and lived experiences associated with Frame Running. Findings may contribute to the development of scalable community-based adaptive sport programs and inform clinical and municipal practices regarding physical activity for children with physical disabilities.

Conclusion

In conclusion, this study protocol presents a robust and methodologically well-justified study designed to evaluate the benefits of a structured Frame Running intervention. The combination of quantitative and qualitative methods (embedded in this study but described elsewhere), long-term follow-up, and real-world setting enhances the study's potential to advance the evidence base for adaptive sports and to inform practice in paediatric rehabilitation, community sports clubs, and disability services. The findings are expected to contribute meaningful and actionable knowledge on how Frame Running may support functional ability, participation, and quality of life among children and young people with physical disabilities.

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