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Web-based early intervention for children with motor difficulties aged 3–8 years old using multimodal rehabilitation (WECARE): protocol of a patient-centred pragmatic randomised trial of paediatric telerehabilitation to support families

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ABSTRACT

Introduction Mild motor difficulties in children are underdiagnosed despite being highly prevalent, leaving such children often underserved and at higher risk for secondary consequences such as cardiovascular disease and anxiety. Evidence suggests that early patient-oriented interventions, coaching parents and providing children with early stimulation should be provided, even in the absence of a diagnosis. Such interventions may be effectively delivered via telerehabilitation.

Methods and analysis A family-centred, pragmatic randomised controlled trial will be carried out to evaluate the real-world effectiveness of a Web-based Early intervention for Children using multimodAl REhabilitation (WECARE). Families of children with motor difficulties, 3–8 years of age, living in Quebec, Canada, and receiving no public rehabilitation services (n=118) will be asked to determine up to 12 performance goals, evaluated using the Canadian Occupational Performance Measure (COPM, the primary outcome). Families will be randomised to receive either usual care or the WECARE intervention. The WECARE intervention will be delivered for 1 year via a web-based platform. Families will have access to videoconferences with an assigned rehabilitation therapist using a collaborative coaching approach, a private chat function, a forum open to all intervention arm participants and online resources pertaining to child development. Participants will be asked to re-evaluate the child's COPM performance goals every 3 months up to 1 year post allocation. The COPM results will be analysed using a mixed Poisson regression model. Secondary outcomes include measures of the child's functional ability, parental knowledge and skills and health-related quality of life, as well as qualitative outcomes pertaining to parental satisfaction and service delivery trajectories. Investigators and quantitative data analysts will be blinded to group allocation.

Ethics and dissemination The CIUSSS de l'Estrie—CHUS ethics committee approved this trial (2020-3429). Study results will be communicated via peer-reviewed journal publications, conference presentations and stakeholder-specific knowledge transfer activities.

Trial registration number NCT04254302.

Strengths and limitations of this study

- The Web-based Early intervention for Children using multimodAl REhabilitation (WECARE) Study evaluates an innovative telerehabilitation intervention based on a multimodal web platform offering one-on-one therapist videoconferencing sessions, a private chat function, an online forum and online resources.
- This is the first randomised controlled trial where the families of children with mild motor difficulties are offered a telerehabilitation intervention.
- The WECARE Study takes a pragmatic and patient-centred approach, comparing the intervention results with usual care in a real-world setting with patient-centred goals as the primary outcome.
- WECARE aligns itself with current scientific evidence and new international paediatric rehabilitation recommendations for early intervention services to be non-categorical (ie, independent of the diagnosis), interdisciplinary, patient-centred and aimed at fostering childhood development and family empowerment.
- Results are based primarily on parents' perceptions and not on objective motor performance measures, which may limit study conclusions.

INTRODUCTION

Motor difficulties affect 400 000–800 000 Canadian children,[1 2] half of whom do not have timely access to rehabilitation services

to support their development.[3] Motor difficulties are defined as having fine and/or gross motor skills below expectations for the child's age.[4] Early interventions and rehabilitation are effective for improving children's health, development and functioning.[5–7] However, only children with severe motor difficulties have access to these services, while children with so-called mild disabilities rarely receive timely services, facing waiting periods of up to 2 years.[8 9] Children who experience these 'mild' disabilities, such as developmental coordination disorder (DCD; 5%–6% prevalence), are not only underserved but also often underdiagnosed,[10 11] further limiting access to services.[12]

Children with motor difficulties are at higher risk of cardiovascular disease, obesity, lower self-efficacy, social isolation, depression and anxiety.[8–15] Motor difficulties and their secondary consequences also impact the children's family, who often report a lower sense of well-being and higher levels of stress,[16 17] an increased economic burden due to frequent medical consultations and care requirements[17–22] and 'shopping for diagnoses and services' to gain access to specialised services.[18 19] New evidence suggests that early prediagnosis patient-oriented interventions aimed at coaching parents and providing children with early stimulation should be provided even in the absence of a diagnosis.[12 20–22] Healthcare systems have been relatively slow to adopt new evidence on how to best organise services. Numerous systematic reviews have documented the effectiveness of early intervention on childhood development.[12 23 24] These reviews and many editorials highlight the importance of stimulating children[25 26] and providing parental guidance to optimise development, functioning, health and well-being.[27 28]

Parental guidance to stimulate the child's development can be provided through telerehabilitation, defined as providing rehabilitation services at distance.[29] Telerehabilitation can increase access to services and flexibility of care.[30 31] A pilot study conducted by our team confirmed the relevance and feasibility of conducting a trial to evaluate web-based, early rehabilitation services for children with mild motor difficulties.[32 33] A systematic review exclusively examining paediatric telerehabilitation identified the same key approaches: child developmental stimulation and parental guidance.[29] This systematic review confirmed that telerehabilitation interventions were effective for a broad range of childhood outcomes, including motor functioning, and suggested that multimodal technological approaches might be most effective. Results from a pilot study suggest that a web-based rehabilitation intervention is relevant for children with mild motor disabilities and is perceived to be particularly helpful in the early stages, when initial concerns arise about motor development.[32 33] These findings illustrated the need to develop a more comprehensive family-centred multimodal online intervention to support families of children with motor disabilities, the Web-based Early intervention for Children using multimodAl REhabilitation (WECARE) intervention. Children aged 3–8 years old are a key group, as so-called 'mild' motor difficulties often become apparent after the age of three and during the first years of school, when motor expectations increase.

Research questions and objectives

Can a multimodal early online rehabilitation improve the motor performance of 3–8 year-old children with motor difficulties in comparison with usual care? The overarching goal of this family-centred, mixed-method, randomised, innovative pragmatic trial is to evaluate the effectiveness of the WECARE intervention for children aged 3–8 years with motor difficulties living in Quebec (Canada). The primary objective is to evaluate, in comparison with usual care, the effectiveness of the WECARE Programme for improving the child's performance on parent-identified motor targets.

Secondary objectives are as follows:

1. To evaluate the effect of the intervention on children's functional abilities, parental knowledge and skills and the children and parents' health-related quality of life (HRQoL).
2. To explore factors influencing the implementation of the intervention within the current service delivery context.
3. To compare the service delivery trajectories and costs across trial arms.

The primary hypothesis is that children in the experimental arm will perform better on motor performance outcomes than children in the usual care arm. Secondary hypotheses are that children in the experimental arm will display higher functional abilities, and their families will report greater knowledge and skills and and greater HRQoL, will use less public and private healthcare services and will incur fewer out-of-pocket and system-level expenses after the 1-year intervention period.

METHODS AND ANALYSIS

Design

A family-centred innovative pragmatic, parallel-group, allocation-concealed, superiority randomised controlled trial assessing real-world effectiveness of the WECARE intervention will be offered to families of children with motor difficulties living in Quebec, Canada, and receiving no public rehabilitation services. The parent or legal guardian of the child will be the primary respondent, but the entire family will have access to the WECARE intervention. A mixed-method parallel design[34] will be used to concurrently collect quantitative and qualitative data.

This trial was designed according to the latest guidelines on pragmatic randomised controlled trials,[35 36] using the gold standard Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (https://www.spirit-statement.org/) and the TElehealth in CHronic Disease (TECH) conceptual framework. The TECH model[37] is a reference for structuring the design and evaluation of telehealth programmes to ensure interventions are acceptable to patients and delivered in a

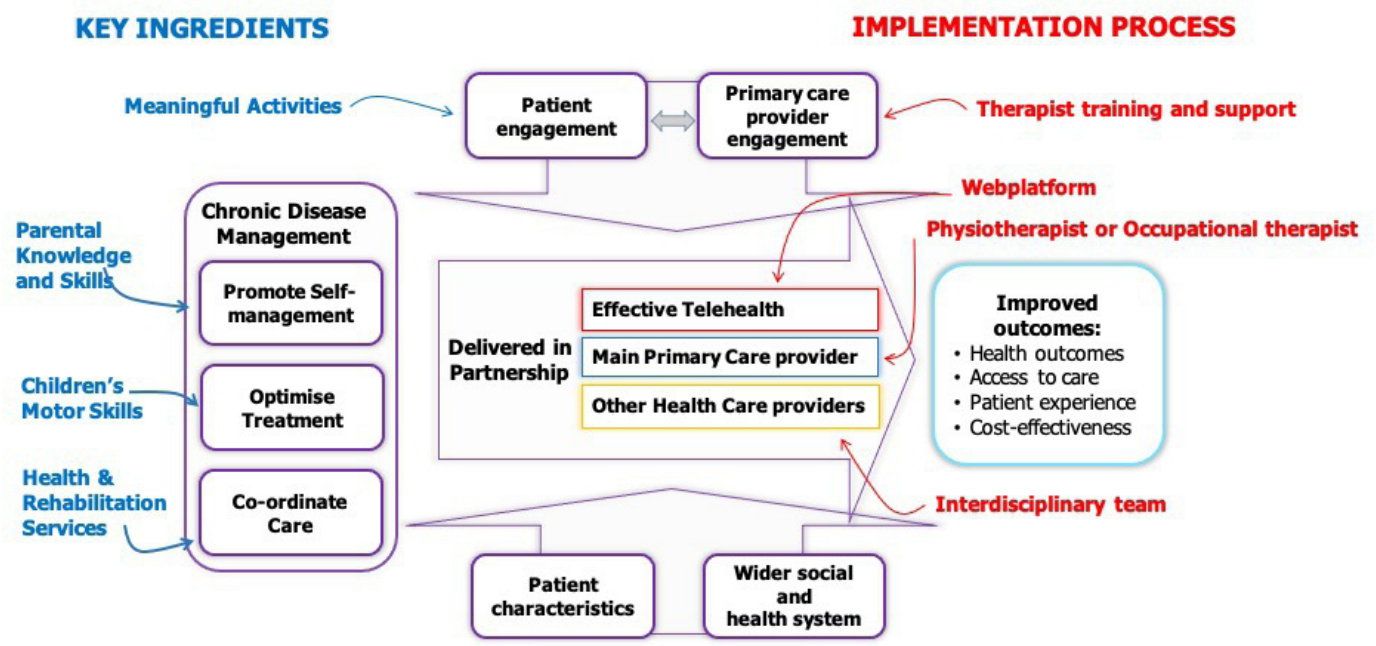

Figure 1 Illustration of how the Web-based Early intervention for Children using multimodAl REhabilitation (WECARE) intervention fits within the TElehealth in CHronic Disease (TECH) model. The key active ingredients of the WECARE intervention are embedded into the patient engagement (ie, meaningful activity) and chronic management best practices (ie, parental knowledge and skills, children's motor skills and access to rehabilitation) of the TECH model and how the implementation processes build on therapist engagement (ie, training and support) and effective service delivery (ie, effective web platform, a primary therapist and an interdisciplinary team) to achieve the desired outcomes. Key ingredients are defined as the factors contributing directly to the expected outcomes, which are, in our case, known modifiable factors influencing children's motor development. A multimodal approach with various activities to deliver the key ingredients will be used. The implementation processes are defined as the mechanisms used to implement the intervention and activities into a real-world setting.

cost-effective manner. Figure 1 presents how the WECARE intervention fits within the TECH model, including its key active intervention ingredients.

Intervention

Control arm

Participants randomised into the control arm will receive usual care as per the service delivery models available in their region. Usual care may include referral for services, general recommendations or references to online content deemed appropriate by a healthcare professional or no services at all. As this is a pragmatic trial, no attempt will be made to standardise practices in the control arm.

Experimental arm

The WECARE intervention was developed based on lessons learnt in a previous pilot study,[32 33] a systematic review of telerehabilitation interventions[29] and a consultation of parents, clinicians and other stakeholders who may take part in such an intervention. It provides families of children with motor difficulties with access to rehabilitation therapists for 1 year. This duration was selected to reflect the sometimes seasonal aspect of motor difficulties, to capture whether changes in motor performance would occur without the WECARE intervention (eg, as the child ages or on access to services associated with long wait times) and to aid in the analysis of economic outcomes. The primary therapist will be an occupational therapist or a physiotherapist (herein 'therapist') working according to a transdisciplinary model.[38 39] Therapists will use a collaborative coaching approach[40 41] to support the family in helping the child achieve meaningful motor outcomes based on intervention objectives selected by the primary respondent. The active ingredients of the WECARE intervention will be delivered via a multimodal web-based platform, using a flexible approach, which is structured at first but adaptable and needs-based throughout:

Thirty-minute videoconference appointments with the therapist to help increase parental knowledge and skills in problem-solving for the child's motor performance issues, provide recommendations to support the child's motor development and assess and intervene online directly with the child, if needed; semimonthly appointments will be offered during the first 3 months and then on a participant-identified needs basis until the end of the intervention period.

Always available online resources with flexible access based on participant needs:

- A chat function where participants can privately contact the therapist to discuss concerns about the child's motor development.
- A forum open to all participants in the experimental arm where interparticipant and participant-therapist communication is fostered and participants

are encouraged to ask questions and share their experiences.
- Static online information via links to relevant websites and other online child development resources.

The therapists may also act as case managers to connect families with community-based services available in their region. All therapists receive a 1-day training prior to their involvement in the study. They participate in weekly 30-minute transdisciplinary meetings to discuss ongoing cases with fellow therapists and monthly 60-minute mentoring and review meetings with the principal investigator.

Sample size

The analysis of the primary study outcome will be conducted using a mixed Poisson regression model that will estimate the difference in the attainment of clinically relevant performance goals between study arms (see the Primary outcome section). Extensive Monte Carlo simulations were conducted to determine the statistical power needed to detect differences in success rates between study groups. The chosen mixed Poisson model approach allows for a robust estimation of statistical power as important variance parameters (ie, within-arm SD) are implicitly determined by the expected success rates in the study arms. To enable a conservative sample size estimation, a relatively high baseline (control arm) success rate was assumed as well as a moderate number of predefined targets per study individual: the expected number of targets set at T0 per individual ranges from 1 to 12, conservatively assuming a uniform distribution. A further conservative assumption was made that up to 25% of the defined targets may be achieved under control conditions and that heterogeneity in success rates across covariates may explain up to 10% of the total variation of the observed successes. Based on these cautious assumptions and a total of 100 000 Monte Carlo simulations, it is expected that a sample size of 100 individuals (50 per arm) is sufficient to detect clinically relevant differences of ≥15 percentage points in the success rate, that is, an increase from 25% to 40% (relative increase: 1.6) with more than 80% power. A retention rate of 85% was used, given the loss to follow-up rate reported for web-based interventions,[42] the follow-up rate found in the feasibility trial[32] and the new adherence strategies included in this trial. This results in a targeted study sample of 59 participants per study arm, for a total of 118 participants.

Study sample and recruitment

Participants will be referred to the project by a health or education professional. They may also be self-referred (ie, will be recruited independently from any professional referral, via recruitment campaigns). Recruitment materials will contain a link to the online eligibility questionnaire, which the families will be invited to complete, should they, healthcare professionals or educators suspect that the child has motor difficulties. Selection bias will be minimised by working with a wide range of community, educational and healthcare partners and by using traditional recruitment methods (eg, email campaigns and print/digital media) and social media to ensure that recruitment activities reach the broadest possible population.

Inclusion/exclusion criteria

Participants will be the parent or legal guardian of a child:
1. Aged 3–8 years old.
2. With or at risk of motor difficulties, as confirmed via the DCD Questionnaire (DCDQ) or Little DCDQ.
3. With at least one motor-related intervention objective prior to allocation, as confirmed via the Canadian Occupational Performance Measure (COPM).
4. Living in the province of Quebec, Canada.
5. With functional communication skills in French.

Participants will be excluded if they are receiving public physiotherapy or occupational therapy services for their motor difficulties at time of study enrolment. Eligibility criteria are inclusive and are not limited to children with an existing diagnosis related to motor difficulties so as to increase generalisability of the findings[36] as they relate to all children with mild motor difficulties who do not have access to public rehabilitation services at time of recruitment.

Eligibility process

The eligibility questionnaire will give introductory information about the study, confirm geographical and age-based eligibility and ask the parent to complete an online version of the DCDQ or the Little DCDQ, two validated questionnaires identifying subtle motor difficulties for children aged 3–4 and 5–8, respectively.[43 44] Eligible participants will be asked to consent online (please refer to the online supplemental file 1 to view the informed consent form) to participate in the full study; those who do so will be contacted by a member of the research team to schedule an online interview with a research assistant (T0 assessment). During this interview, the research assistant will confirm informed consent and eligibility criteria, including the meaningfulness and relevance of the child's motor difficulties via the COPM,[45] as detailed below. On confirming their full eligibility, participants will be randomised into the experimental or control arm and will be granted access to the full intervention as appropriate.

Allocation and blinding

The family will be the unit of randomisation. A web-based randomisation service (REDCap) will allocate participants to either usual care or the WECARE intervention (1:1). To ensure equal distribution of participants between arms, permutated blocks of variable size will be generated. No stratification or minimisation strategies will be used.

Participants will set their motor performance goals prior to allocation to avoid the influence of the allocation arm on goals selection. Once allocation has occurred,

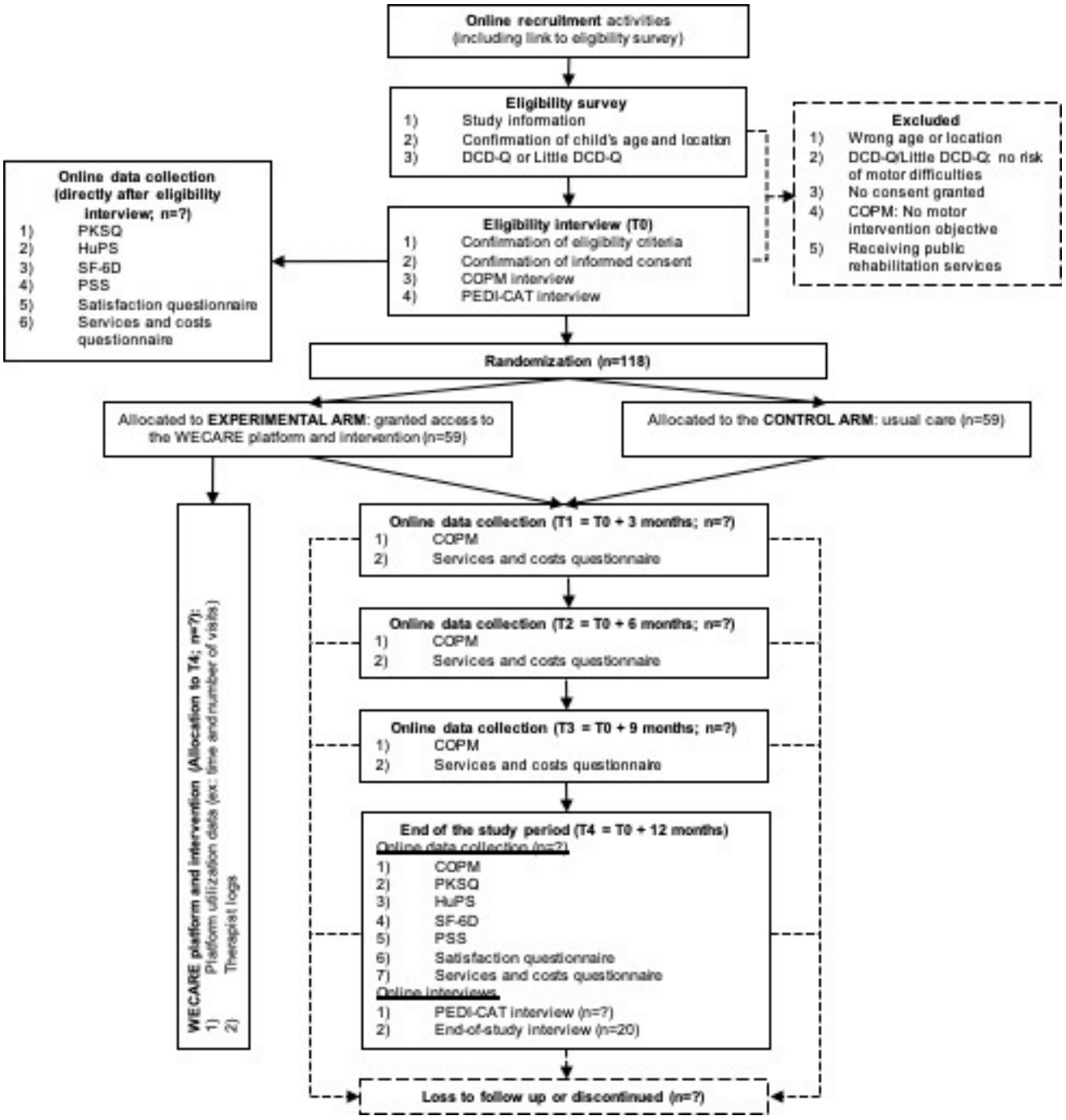

Figure 2 Patient timeline, eligibility process and data collection for the Web-based Early intervention for Children using multimodAl REhabilitation (WECARE) Study. COPM, Canadian Occupational Performance Measure; (Little) DCDQ, (Little) Developmental Coordination Disorder Questionnaire; HuPS, Health-Related Quality of Life Utility Measure for Preschool Children; PEDI-CAT, Paediatric Evaluation of Disability Inventory—Computer Adaptive Test; PKSQ, Parental Knowledge and Skills Questionnaire; PSS, Parental Stress Scale; SF-6D, short-form six dimensions.

the participant, the study coordinator and the therapists will be aware of participant allocation. Investigators and quantitative data analysts will be blinded to group allocation; no unblinding procedures are expected.

Outcomes and data collection

The participant timeline is presented in figure 2, including the screening, eligibility and data collection processes.

Primary outcome

The child's performance on motor goals and the parent's satisfaction with their child's performance, as well as the importance of the goals, will be collected with the COPM. The COPM uses a structured interview to identify intervention goals. Ten-point Visual Analogue Scales (VAS) are used to identify the importance, present performance and satisfaction with performance for

each selected goal. Higher scores indicate higher importance, better performance and higher satisfaction with the child's performance.[46] An increase of more than two points on the 10-point VAS is considered as a meaningful clinical difference[47] and will be used as an indication of the attainment of the child's motor performance goal. The COPM does not require any physical or hands-on materials,[45] which is consistent with an online trial. The COPM is a clinical and research tool[48] providing information about the impact of the intervention on activities and participation.[47] It is the best tool available to measure changes in a child's performance for child-specific items not easily assessed with other standardised instruments.[46] Its validity, reliability and sensitivity to change have been extensively studied.[48] A published paediatric adaptation of the COPM will be used in this trial.[47] The paediatric adaptation of the COPM has been validated with parents of children between 2 and 8 years old.[46 47] It showed good construct and criterion validity and inter-rater agreement.[46] A French version of the COPM has been used with parents[49] and to evaluate web-based interventions for children with disabilities.[50]

Primary outcome data collection

At T0, a research assistant will conduct an online interview where participants will be asked to identify up to 12 motor performance-related goals and will be asked to rate each goal on the performance, satisfaction and importance COPM scales. They will then be asked to select up to three primary goals to inform the intervention for the following 3-month period. This will ensure identification of all goals before participants are aware of their allocation arm. Every 3 months, participants will self-complete online the three COPM scales for each goal, select their main goals for the next 3-month period and identify new goals if applicable. For participants in the experimental arm, therapists will be informed of these goals. For the primary analysis, only the attainment of goals identified at T0 will be considered, based on performance scores. For the initial goals attained, secondary analyses will document the magnitude of change (ie, using raw VAS performance score) and the time to achieve goals (ie, months elapsed to achieve a 2-point or more increase), as well as the changes in importance and satisfaction scores, between arms.

Secondary outcomes instruments and data collection

All secondary outcome measures are validated and have previously been used with children with motor difficulties, use continuous data, are sensitive to change and are available in French. All secondary outcome measures can be completed and submitted online by the participants, with the exception of the Paediatric Evaluation of Disability Inventory—Computer Adaptive Test (PEDI-CAT), which requires an online interview with a research assistant. Secondary outcome measures will only be collected at T0 and T4.

Changes in children's functional abilities will be evaluated with the mobility and self-care subscales of the PEDI-CAT.[51] The PEDI-CAT is a parent-reported adaptative questionnaire for parents of children and youth aged 0–20 years.[51] Each question is selected by the computer algorithm based on the child's socio-demographic data and answers to previous questions, up to a maximum of 15 for each domain.[51] The number of items needed to establish the child's score may vary according to the stopping rules of the algorithm.[51] For each question, parents indicate their child's ability to participate in a presented activity (eg, putting on socks) on a 4-point scale ranging from 'unable=can't do, doesn't know how or is too young' to 'easy=does with no help, extra time, or effort, or child's skills are past this level'.[52] Subscale scores are expressed as T-scores. Content validity analysis confirmed each domain is unidimensional.[52] All domains of the PEDI-CAT have excellent test–retest reliability.[53]

Changes in the parent's knowledge and skills about motor difficulties will be evaluated via the French version of the Parental Knowledge and Skills Questionnaire (PKSQ).[54] The PKSQ has been validated for parents of children with DCD aged 0–18 years old.[54] An adapted version of the PKSQ will be used to remove the focus from DCD and ensure its relevance for all motor difficulties. The adapted PKSQ includes two out of the three constructs of the original version of the PKSQ. The adapted version includes 14 questions about parental understanding of motor difficulties and their perception of their capacity to manage their child's motor difficulties. Questions are scored by the parent on a 7-point Likert Scale ranging from 'not at all' to 'to a very great extent'.[54]

Parents will rate children's HRQoL with the Health-Related Quality of Life Utility Measure for Preschool Children (HuPS) tool, an HRQoL tool for children aged 2–5 years.[55] The HuPS includes 12 questions about the child's abilities rated on 3-point to 5-point scales (eg, seeing, speaking, using hand and fingers and self-care). Intrarater and inter-rater reliability is good.[55]

Changes in the parent's HRQoL will be measured with the short-form six dimensions (SF-6D).[56] The SF-6D is a tool measuring health utility in adults and includes items on physical and social functioning, role limitations, pain, mental health and vitality. Total scores range from −0.574 to 1 (worse possible health to perfect health). The minimally important differences for SF-6D range from 0.011 to 0.097, with a mean of 0.041.[56] This tool has previously been used to describe HRQoL among parents of children with disabilities.[57]

Parental stress will be measured with the Parental Stress Scale (PSS), consisting of 18 questions about parental feelings and experience.[58] Each statement is scored on a 5-point Likert Scale (1=strongly agree to 5=strongly disagree). Higher scores indicate lower parental stress. The PSS has a good concurrent validity and test–retest reliability.[58]

Satisfaction, service delivery trajectories, health economics and platform utilisation measures

Satisfaction with the intervention will be evaluated via questionnaires adapted from Dunst, Trivette and Hamby[59]; open-ended questions; and interview guides. The use of public rehabilitation services during the study will be documented for participants in both arms, as this reflects how this intervention would be rolled out in real life (ie, WECARE may be offered before face-to-face publicly funded interventions but might overlap with them). Service delivery trajectories as well as system-level and out-of-pocket costs will be documented every 3 months via a questionnaire about services received in the last 3 months (ie, public or private healthcare and school-based services). The use of the platform by participants in the experimental arm will be assessed in terms of the number of visits and the time spent on the WECARE platform overall and in each subsection (ie, videoconferencing, private chat, forum and resources), as well as the number of chat messages sent to the therapist, the number of new threads or posts created on the forum and the number of resources consulted.

Data analysis

Analyses will be conducted according to the intention-to-treat principle. The primary outcome will be analysed using a mixed Poisson regression model, as the dependent variable consists of count data and observations are independent, to determine if families in the experimental arm attained more clinically meaningful goals than the families in the control arm. However, as a Poisson model assumes that mean and variance are identical, in the case where overdispersion would be observed, a negative-binomial regression model will be used.[60 61] The model will include, as offset variable, the number of individually defined targets and the following covariates: the severity of the child's motor difficulties (dichotomised as 'mild difficulties' or 'low functioning' based on PEDI-CAT T0 scores), as well as child and familial characteristics, that is, sex, age and income. Data will be reported as the exponentiated values of the coefficients of the mixed Poisson regression along with 95% CIs.

The effects of the WECARE intervention will also be examined within the following participant subgroups: severity of motor difficulties and child/participant sex. The effect of the following intervention-specific covariates will also be explored: intervention dosage (exposure to the different WECARE modes of service, ie, time spent on information, forums and chat and virtual appointments) and date of inclusion in the intervention (categorised by month).

Linear mixed-effect models will be used to compare secondary outcomes, expressed as continuous pre–post intervention scores. Participants will be treated as random effect, and an autocorrelation structure will be considered on repeated measures made on the same participant. The integration of quantitative and qualitative data will be conducted following an explanatory approach[34] to provide a deeper understanding of the intervention effects according to variability in participant characteristics and the interactions with implementation processes.

Satisfaction, service delivery trajectories, health economics and platform utilisation measures

Information pertaining to satisfaction collected via questionnaires and interviews, including user acceptability of the WECARE intervention, will be analysed, respectively, with descriptive statistics and a mixed inductive–deductive qualitative approach of content analysis,[62] building on the models used to conduct the interviews.[37] The economic analysis will be based on incremental cost-effectiveness ratios,[63] using a 1.5% annual discount rate, and sensitivity analyses with discount rates of 0% and 3%.[64] Non-parametric analyses with 5000 bootstrap replications[65 66] will be performed to estimate the CI, while cost-effectiveness acceptability curves will compare on a probabilistic basis the cost-effectiveness thresholds for different costs per unit gain.[67 68] Service delivery trajectories and platform utilisation measures, including the occurrence of technical issues, will be analysed with descriptive statistics. No interim analyses are planned for this study.

Adherence

All participants will be contacted every 3 months to encourage study adherence, coinciding with key data collection time points. For participants in the experimental arm, regular appointments with the therapist, every 2 weeks for the first 3 months, will foster additional adherence to the WECARE intervention. Furthermore, a notification system tied to a personal email will inform the participant of relevant content added to the WECARE platform, including new videoconferencing appointments and new communications sent by the therapist via the private chat function. To optimise adherence among participants in the control arm and to thank them for participating in the study, a 3-month access to the online forum and the resources section of the platform will be granted following the 1-year data collection period.

Patient involvement

Three patient partners (MJF, KT and CW) aided in the design of the WECARE intervention and of trial procedures, participated in the recruitment process and will contribute to knowledge translation activities.

ETHICS AND DISSEMINATION

No specific risk was reported in a recently conducted systematic review of telerehabilitation studies.[29] Exercises or manipulations that may be undertaken as part of the intervention will target common daily activities and will be performed under parental supervision. Minor accidents (eg, falls during balance exercises) will be documented in a therapist logbook. Should therapists detect severe health conditions (eg, muscular dystrophy) or signs of

distress (eg, suicidal ideation), they are instructed to refer to a physician or local resources identified by the research team. Adverse events will be reported, within 24 hours, to the executive committee (CC, MM, M-CB and JB). The executive committee will convene monthly to oversee all aspects of trial management. Given the digital nature of the intervention and data collection, the security of study data, be it for transit or storage, was at the forefront during the development of the web and data collection platforms. All data collection is undertaken via REDCap, a secured data collection platform hosted on University of Sherbrooke servers. The WECARE platform was developed with reputable partners (National Research Council of Canada) and is hosted on secure servers at the University of Sherbrooke. Due to the overall safety profile of this trial, no data and safety monitoring board was convened, and no interim analysis or stopping guidelines are expected. Evidence suggests that health inequity risks exist where wealthier families might benefit more from web-based interventions.[51] Should eligible families have no internet access at home, the research team will work with community resources to provide participants with internet access. Such challenges will be documented to inform future trials.

The WECARE trial was registered at ClinicalTrials.gov and was approved by the ethics committee of the CIUSSS de l'Estrie—CHUS (identifier: 2020-3429). The ethics committee will be informed of any deviation from the protocol. No deviation will be applied until the amended protocol has been approved by the ethics committee. The executive committee will oversee the intrastudy and external data sharing process on a case by case basis; deidentified participant data as well as additional study documentation could be made available on reasonable request. Publications of study findings will be done via peer-reviewed journals and conference presentations, as well as stakeholder-specific knowledge transfer activities. Substantive contributions will be recognised in the authorship of these publications, as determined by the executive committee.

PROJECT STATUS

Recruitment began in March 2020 and ended in October 2020. Data collection is expected to end in October 2021, with the project closing in April 2022.

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